Original Article

Three-dimensional effects of the mini-implant–anchored Forsus Fatigue Resistant Device: *A randomized controlled trial*

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ABSTRACT

Objective: To detect three-dimensionally the effects of using mini-implant anchorage with the Forsus Fatigue Resistant Device (FFRD).

Materials and Methods: The sample comprised 43 skeletal Class II females with deficient mandibles. They were randomly allocated into three groups: 16 patients (13.25 ± 1.12 years) received FFRD alone (Forsus group), 15 subjects (13.07 ± 1.41 years) received FFRD and mini-implants (FMI group), and 12 subjects (12.71 ± 1.44 years) were in the untreated control group. Three-dimensional analyses of cone beam computed tomographic images were completed, and the data were statistically analyzed.

Results: Class I relationship and overjet correction were achieved in 88% of the cases. None of the two treatment groups showed significant mandibular skeletal effects. In the FMI group, significant headgear effect, decrease in maxillary width, and increase in the lower facial height were noted. In the FMI group, retroclination of maxillary incisors and distalization of maxillary molars were significantly higher. Proclination and intrusion of mandibular incisors were significantly greater in the Forsus group.

Conclusions: FFRD resulted in Class II correction mainly through dentoalveolar effects and with minimal skeletal effects. Utilization of mini-implant anchorage effectively reduced the unfavorable proclination and intrusion of mandibular incisors but did not produce additional skeletal effects. (*Angle Orthod.* 2016;86:292–305.)

KEY WORDS: Forsus Fatigue Resistant Device; Mini-implants; Class II malocclusion; Fixed functional; Anchorage

INTRODUCTION

Class II malocclusion is considered one of the most encountered problems in the orthodontic practice.[1] Its prevalence was recently found to be between 15% and 30% in different populations.[2–5] Mandibular deficiency was proven to be the most dominant component of this malocclusion.[6,7]

Treatment during the period of active growth depends mainly on redirection of mandibular growth, which can be achieved with a number of removable functional appliances. These appliances, however, have major limiting factors, including their dependence on patient compliance.[8]

The Herbst appliance was introduced in 1905 as a compliance-free Class II corrector; interest in this appliance was renewed by Pancherz in 1979.[9] The Forsus Fatigue Resistant Device (FFRD) was introduced by Vogt in 2006.[10] The author claimed

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that the FFRD was successful in the treatment of Class II division 1 malocclusion. However, the treatment effects were mainly dentoalveolar.[1,11–16]

Few studies and case reports have suggested the use of mini-implant anchorage in conjunction with fixed functional appliances to reduce the mandibular incisor proclination that compromised the skeletal effects.[17–20] A recent trial[21] was performed to test the efficiency of added mini-implant anchorage to FFRD using lateral cephalograms. However, conventional cephalograms present three-dimensional (3D) objects as two-dimensional (2D) images and are mainly based on excellent superimposition of the left and right sides, which is rarely accurate. The uncertainties in locating anatomical landmarks due to the deficiency of well-defined outlines and shadows are major drawbacks of 2D analysis.[22]

The aim of this clinical trial was to detect the 3D dental and skeletal changes associated with the use of indirect mini-implant anchorage with FFRD and to test the efficiency of this type of anchorage in obtaining skeletal rather than dentoalveolar effects.

MATERIALS AND METHODS

Subjects

The study method was approved by the Faculty of Dentistry Ethical Committee, Cairo University. Sample size calculation was done using G power software (Universität Düsseldorf, Düsseldorf, Germany), with an alpha value of .05 and a power of 80% based on the study by Weschler and Pancherz[23] and revealed the need for 12 subjects per group. The patients and parents were informed about the nature of the study and informed consent forms were signed. The patients' eligibility criteria are shown in Table 1.

A computer-generated random list was created (https://www.random.org/), and allocation concealment was achieved with opaque sealed envelopes. The patients were randomly allocated into three groups: 16 patients were treated with FFRD (3M Unitek, Monrovia, Calif) (Forsus group), with a mean age of 13.25 $\pm$ 1.12 years; 15 patients received FFRD and lower mini-implants (FMI group), with mean age of 13.07 $\pm$ 1.41 years; and 15 untreated Class II subjects (12.71 $\pm$ 1.44 years) served as a control group.

Patient Attrition

None of the treatment groups' patients discontinued the trial. Two of the control patients wanted to start treatment immediately, and the third couldn't be reached after 3 months. Thus, 12 subjects completed the observation period, and 31 subjects continued the clinical trial.

Methods

The 0.022-inch slot 3M MBT brackets were bonded to maxillary and mandibular arches, and a passive transpalatal arch was cemented to the maxillary first molars. Brackets of the mandibular canines and first premolars were bonded with exaggerated bracket tip to allow root divergence. Levelling and alignment proceeded until treatment reached a phase including 0.019 $\times$ 0.025-inch stainless-steel archwires. Wires were cinched distal to the maxillary and mandibular first molars. Periapical radiographs were taken for middle phalanges of the middle fingers of left hands of the patients at this stage to detect the MP3 stage of skeletal maturation according to Rajagopal[24] (Figure 1). Cone beam computed tomographic (CBCT) images were obtained with an i-CAT CBCT unit (Imaging Sciences International, Hatfield, Pa). The first image (T1) was obtained immediately before insertion of FFRD and mini-implants in the two treatment groups.

In the FMI group mini-implants (1.6 $\times$ 10 mm; 3M Unitek) were inserted under local anesthesia between the mandibular canines and first premolars according to AlSamak et al.,[25] and 0.019 $\times$ 0.025-inch stainless-steel wire segments were used for fixation of the

Table 1. Eligibility Criteria of Patients Included in the Study

Inclusion Criteria	Exclusion Criteria
• Females 11–14 y of age • Skeletal Angle Class II division 1 malocclusion with a deficient mandible (SNB $\leq$ 76°) • Horizontal or neutral growth pattern (MMP $\leq$ 30°) • Increased overjet (minimum 5 mm) with Class II canine relationship (minimum of half unit) • Erupted full set of permanent teeth with mandibular arch crowding less than 3 mm • At the time of insertion of the FFRD, the patients had to be in the MP3 G or MP3 H stage according to Rajagopal[24]	• Systemic disease • Any signs or symptoms of temporomandibular dysfunction • Extracted or missing permanent tooth/teeth • Facial asymmetry • Parafunctional habits • Severe proclination or crowding that requires extractions in the lower arch

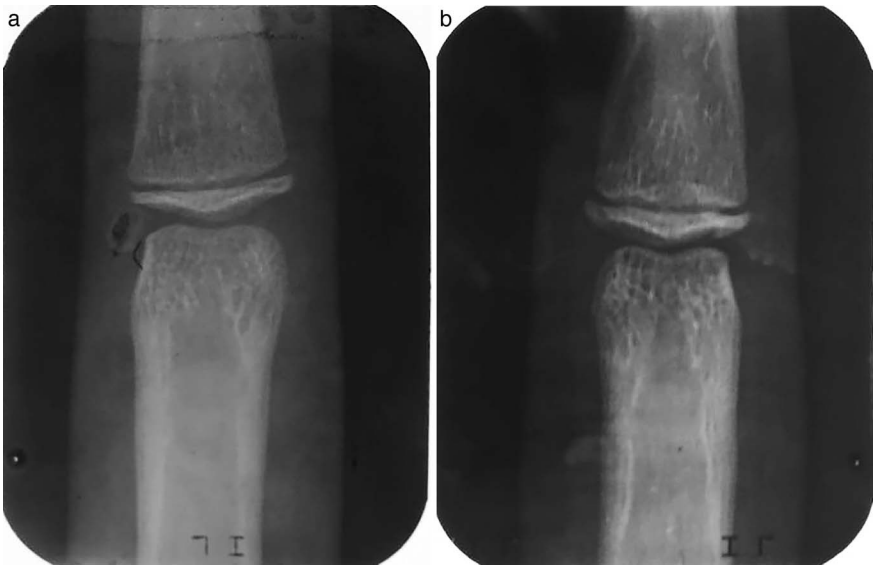

Figure 1. Periapical radiographs showing MP3 stages G (a) and H (b).

mini-implants to the mandibular arch and were bonded to the labial surface of the mandibular canines (Figure 2).

In both groups, selection of the proper size of the FFRD was done according to the manufacturer's instructions. The pushrods of the appliance were inserted onto the mandibular archwires distal to the mandibular canines (Figure 3).

Follow up visits occurred every 3–4 weeks, and at these visits, the mini-implants and wire segments were checked for stability and the appliance was checked for activation. Split crimps were used for appliance activation, according to the manufacturer's instructions. Treatment was continued until overcorrection to an edge-to-edge incisor relationship was reached. The appliances and mini-implants were then removed and the second set of CBCT images (T2) was obtained.

Figure 2. The fixation wire used in the study.

The control group subjects were sent for uptake of the first CBCT image (T1) after inclusion in the study and random allocation. The observation period was 6.25 $\pm$ 1.06 months. The control subjects were then sent for uptake of the second images (T2), which were considered their pretreatment records. Orthodontic treatment was then performed on all patients in the control group.

CBCT Imaging and 3D Analysis

The analysis was done using Invivo Anatomage version 5.2 (Anatomage, San Jose, Calif). The assessors were blinded during the analysis. The analysis included skeletal and dental measurements (Figure 4; Table 2). The measurements were performed by the same observer twice and by another observer.

Statistical Analysis

Analysis was performed with Statistical Package for the Social Sciences (SPSS) version 22.0 (SPSS Inc, Chicago, Ill) for Windows. Data were explored for normality using the Kolmogorov-Smirnov test. Concordance correlation coefficients (CCCs) were calculated to detect the intra- and interexaminer reliability of the used measurements. Paired *t*-tests were performed to detect the changes within each group. A one-way analysis of variance (ANOVA) test was used for comparing the mean changes among the three groups. Multiple-comparison Bonferroni tests were performed

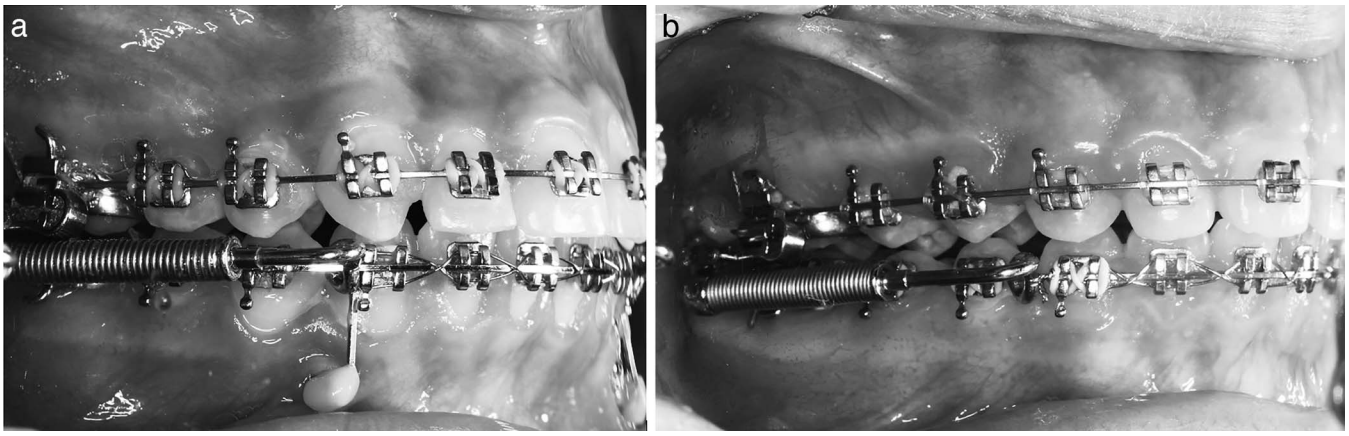

Figure 3. Forsus Fatigue Resistant Device (FFRD) inserted in the FFRD and mini-implants (FMI) group (a) and Forsus group (b).

for the statistically significant ANOVA variables ($P < .05$) for pairwise comparisons among groups.

RESULTS

Clinical Results

The FFRD was able to correct the Class II relationship to a dental Class I relationship (molar and canines) in 88% of the cases in a mean time of 5.34 $\pm$ 1.29 and 4.86 $\pm$ 1.32 months in the FMI and Forsus groups, respectively. There was a clinically significant improvement of the overbite, overjet, and soft tissue profile (Figures 5 and 6).

Statistical Results of CBCT Analysis

Normality tests showed the data to be normally distributed. The CCC values ranged from good to excellent (0.721–0.974) in terms of intra- and interobserver agreement of the selected measurements at 95% confidence limits.

There were no statistically significant differences among the mean ages of the three groups. The control group observation period showed a statistically significant longer duration than the Forsus group (Table 3).

Skeletal Changes (Tables 4 and 5)

Most of the vertical skeletal measurements did not change significantly with treatment in both groups. The lower facial height and MP/SN increased significantly only in the FMI group. SNA decreased significantly only in the FMI group. SNB, B-FP, and right and left effective mandibular lengths increased significantly in the three groups. The ANB and A-B

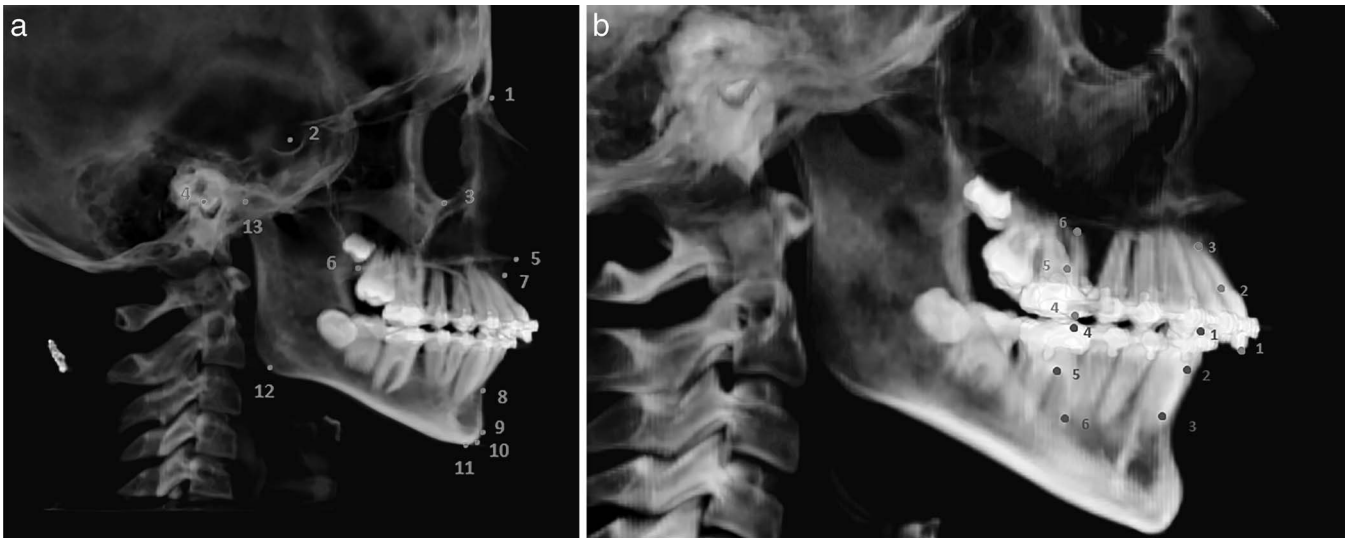

Figure 4. (a) Skeletal landmarks used in the study: 1, Nasion; 2, Sella Turcica; 3, Orbitale; 4, Porion; 5, Anterior nasal spine; 6, Posterior nasal spine; 7, A point; 8, B point; 9, Pogonion; 10, Gnathion; 11, Menton; 12, Gonion; and 13, Condylion. (b) 1, Incisal tip of crown of maxillary/mandibular incisor; 2, Midroot of maxillary/mandibular incisor; 3, Root apex of maxillary/mandibular incisor; 4, Mesiobuccal cusp of maxillary/mandibular first molars; 5, Furcation point of maxillary/mandibular first molars; and 6, Mesiobuccal root apex of maxillary/mandibular first molars.

Table 2. Definitions of the Included Measurements in the Study

Measurement	Definition
MMP	The three-dimensional (3D) angle between the palatal line and the mandibular plane; maxillary-mandibular plane angle
MP/SN	The 3D angle between the line S-N and the mandibular plane
Y axis angle	The 3D angle between y-axis and Frankfurt horizontal plane
Facial height ratio	The ratio of lower to total facial height
Jaraback ratio	The ratio between posterior to anterior facial height
Lower facial height	The distance between the anterior nasal spine (ANS) and the Menton (Me)
SNA	The angle between the points S,N and A
A-FP	The linear distance between the A point and the frontal plane
Effective maximum length	The linear distance between the Condylion and A points
SNB	The angle between the points S,N and B
B-FP	The linear distance between the B point and the frontal plane
Right effective mandibular length	The linear distance between the right Condylion and the Gnathion points
Left effective mandibular length	The linear distance between the left Condylion and the Gnathion points
ANB	The angle between three landmarks: A, N, and B
AB difference	The distance between projections from points A and B on the frontal plane
Maxillary width	The linear distance between the right and left maxillary points
Mandibular width	The liner distance between the right and left Gonion points
U1 AP position	The horizontal distance between the incisal edges of the upper central incisors and the frontal plane, as viewed from the sagittal view
U1 vertical position	The linear distance from the midroot of the upper incisors to the FHP, as viewed from the sagittal view
U1 inclination	The angle formed between the frontal plane and the upper right and left central incisor long axes, as viewed from the sagittal view
UR6 C. AP position	The linear distance between the mesio-buccal cusp tip of UR6 and the vertical plane, as viewed from the sagittal view
UR6 R. AP position	The linear distance between the mesio-buccal root apex of upper right first molar and the vertical plane, as viewed from the sagittal view
UL6 C. AP position	The linear distance between the mesio-buccal cusp tip of upper left first molar and the vertical plane, as viewed from the sagittal view
UL6 R. AP position	The linear distance between the mesio-buccal root apex of upper left first molar and the vertical plane, as viewed from the sagittal view
UR6 vertical position	The linear distance between the furcation area of the upper right first molar to the FHP, as viewed from the sagittal view
UL6 vertical position	The linear distance between the furcation area of the upper left first molar to the FHP, as viewed from the sagittal view
L1 inclination	The angle formed between the frontal plane and the lower incisors long axes, as viewed from the sagittal view
L1 AP position	The horizontal distance between the incisal edges of the lower incisors and the frontal plane, as viewed from the sagittal view
L1 to NB line	The horizontal distance between the incisal edges of the lower incisors and the NB line, as viewed from the sagittal view
L1 vertical position	The linear distance from the midroot of the lower incisors to the mandibular plane, as viewed from the sagittal view
LR6 vertical position	The linear distance from the furcation points of the lower right first molar to the mandibular plane, as viewed from the sagittal view
LL6 vertical position	The linear distance from the furcation points of the lower left first molar to the mandibular plane, as viewed from the sagittal view
LR6 AP position Cr	The linear distance between the mesio-buccal cusp tip of lower right first molar and the vertical plane, as viewed from the sagittal view
LL6 AP position Cr	The linear distance between the mesio-buccal cusp tip of lower left first molar and the vertical plane, as viewed from the sagittal view
LR6 AP position R	The linear distance between the mesio-buccal root apex of lower right first molar and the vertical plane, as viewed from the sagittal view
LL6 AP position R	The linear distance between the mesio-buccal root apex of lower left first molar and LL6 and the vertical plane, as viewed from the sagittal view

difference decreased significantly in all groups. As for the transverse plane, maxillary and mandibular widths did not show statistically significant differences.

Upon comparing the three groups, the FMI group showed statistically significant maxillary retrusion (A-FP decreased by -0.33 ± 0.63 mm) and significant reduction in the maxillary width (-0.68 ± 1.35 mm).

Figure 5. Intraoral and extraoral photos of a Forsus group patient before and after treatment.

Table 3. Comparison of Mean Ages and Duration of the Three Study Groups (One-Way Analysis of Variance [ANOVA] and Multiple Bonferroni Method Tests)[a]

	Study Group	Mean	SD	*P*-Value	*P* (Control-FMI)	*P* (Control-Forsus)	*P* (FMI-Forsus)
Age	Control	12.71	1.44	.345	NS	NS	NS
	FMI	13.07	1.41				
	Forsus	13.45	1.12				
Duration	Control	6.25	1.06	.019*	.198	.016*	.856
	FMI	5.34	1.29				
	Forsus	4.86	1.32				

[a] FMI indicates the group receiving Forsus Fatigue Resistant Device (FFRD) and mini-implants; Forsus, the group receiving only FFRD; NS, not significant.

* Significant at $P \leq .05$.

Dentoalveolar Changes (Tables 6 and 7)

Statistically significant retroclination of the maxillary incisors was evident in the FMI and Forsus groups as compared to the control group ($-11.17^\circ \pm 3.51^\circ$ and $-9.15^\circ \pm 3.01^\circ$). The maxillary incisors were significantly extruded in the FMI group only.

The maxillary first molars significantly moved mesially in the control group in contrast to the FMI and Forsus groups, in which they significantly moved distally. The maxillary first molars showed significant extrusion in the control group and significant intrusion in the FMI and Forsus groups.

The mandibular incisors were significantly proclined ($5.26^\circ \pm 2.71^\circ$ and $9.05^\circ \pm 2.91^\circ$ in the FMI and Forsus groups, respectively) and intruded in the treatment groups, as compared with the control group. In the Forsus group the mandibular incisors moved significantly forward more than in the other two groups (0.66 ± 1.42 mm, 0.81 ± 1.49 mm, and 2.55 ± 0.88 mm in the control, FMI, and Forsus groups, respectively).

The mandibular first molars were significantly extruded and moved in a mesial direction in the three groups. The mesialization was shown to be most significant in the Forsus group.

DISCUSSION

The subjects included in the study were Class II division 1 females, with the exclusion of Class II division 2, which was proven to be a separate entity that differs from Class II division 1.[26] A previous trial[21] included male and female subjects, who have different growth patterns and rates,[27] having Class II division 1 and 2 occlusions, which might have led to questionable results.

To overcome the drawback of unreliable chronological age as an indicator of skeletal maturation stage,[28] the MP3 staging method was used according to Rajagopal,[24] and only the MP3 G and H stage patients were included. An untreated control group was included in order to compare the results of the fixed functional phase in the FMI and Forsus groups with the effect of the normal growth, as was previously recommended.[29,30] Previous noncontrolled trials[16,31] mentioned that they could not assess whether the skeletal changes were due to growth or treatment.

The vertical changes showed that the FMI group had a significant increase in the MP/SN angle, which cannot be considered clinically significant (MP/SN increased by $0.68^\circ \pm 0.77^\circ$). However, both Forsus and FMI groups showed a statistically significant intrusion for the maxillary first molars, which was greater in the FMI group (1.3 mm and 1.78 mm, respectively). The molar intrusion was also evident in previous studies[12] but was not reported in others.[21,32] This was coupled with the significant mandibular molar extrusion that was reported in both treatment groups (more in the FMI group). It could be considered that the intrusive effect on the maxillary molars was compensated for by the extrusion of the mandibular ones. The remaining factor was the more significant maxillary molar distalization in the FMI group due to the redistribution of forces to the maxilla after the addition of mini-implants (mean of 2.5 mm) that was proven in the literature to cause more bite opening.[33]

As for the antero-posterior skeletal changes, there was a significant reduction of the SNA and ANB angles together with a significant increase in SNB and effective mandibular length in both treatment groups. The occurrence of the same findings in the control group negated the effect of appliances as a driver for these skeletal changes. These results were in agreement with those of other studies[1,15,16,21] and in disagreement with the findings of Jones et al.,[32] who reported 4.4 mm of mesial mandibular movement, which could be attributable to their use of the Pitchfork analysis that was previously proven to be inaccurate.[34] The one significant skeletal effect over the control group was the headgear effect produced by the FFRD in both treatment groups.

The mean of distal movement of the maxillary molars and distalization of the anterior dentition were significantly greater in the FMI group. Retroclination of maxillary incisors was significant enough to cause a subsequent lock of occlusion that prohibited the creation of a Class I canine relationship in 12% of the cases.

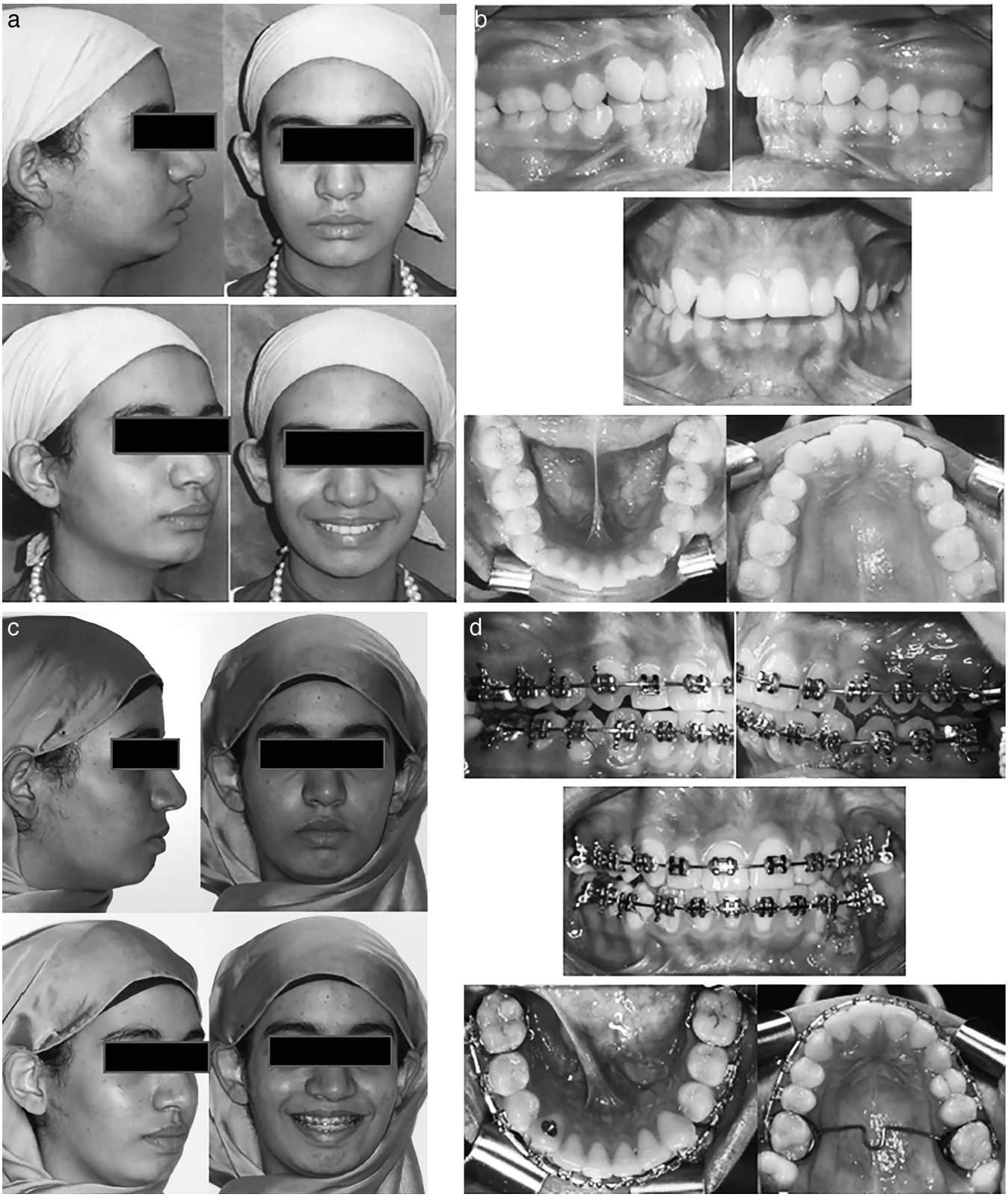

Figure 6. Intraoral and extraoral photos of Forsus Fatigue Resistant Device and mini-implants (FMI) group patient before and after treatment.

Table 4. Mean Values of Parameters at the Beginning (T1) and End (T2) and the Mean Difference (T2-T1) of the Skeletal Measurements in the Three Study Groups[a]

Measurement	Time of Measurement	Control, N = 12			FMI, N = 15			Forsus, N = 16		
		Mean	SD	*P*-Value	Mean	SD	*P*-Value	Mean	SD	*P*-Value
MMP	T1	30.10	3.57	.117	29.07	5.42	.539	25.50	6.31	.587
	T2	29.29	3.84		29.35	4.92		25.66	6.96	
	T2–T1	−0.81	1.65		0.28	1.73		0.16	1.14	
MP/SN	T1	37.69	4.79	.356	39.72	5.96	.008**	35.85	6.24	.75
	T2	37.39	5.36		40.34	6.20		35.76	6.51	
	T2–T1	−0.30	1.08		0.62	0.77		−0.09	1.13	
Y axis angle	T1	60.18	2.56	.239	60.19	3.92	.608	59.40	3.30	.332
	T2	59.81	2.59		60.30	4.06		59.12	3.61	
	T2–T1	−0.37	1.03		0.11	0.83		−0.28	1.13	
Facial height ratio	T1	0.58	0.02	.491	0.56	0.02	.138	0.57	0.03	.773
	T2	0.58	0.02		0.56	0.02		0.57	0.03	
	T2–T1	0.00	0.01		0.00	0.01		0.00	0.01	
Jaraback ratio	T1	0.62	0.03	.838	0.60	0.05	.61	0.63	0.05	.83
	T2	0.62	0.04		0.60	0.04		0.63	0.06	
	T2–T1	0.00	0.01		0.00	0.01		0.00	0.01	
Lower facial height	T1	61.33	4.87	.158	60.86	3.86	.000**	60.02	4.80	.68
	T2	61.85	4.61		61.92	3.84		60.14	5.24	
	T2–T1	0.53	1.20		1.06	0.88		0.12	1.18	
SNA	T1	81.50	3.03	.465	80.07	3.60	.039*	83.22	2.15	.61
	T2	81.57	3.10		79.81	3.57		83.15	2.07	
	T2–T1	0.08	0.34		−0.26	0.45		−0.08	0.60	
A-FP	T1	1.88	2.58	.132	1.68	3.44	.06	2.58	2.65	.357
	T2	2.13	2.56		1.35	3.42		2.45	2.76	
	T2–T1	0.25	0.53		−0.33	0.63		−0.12	0.51	
Effective maximum length	T1	80.89	3.73	.38	83.04	4.34	.21	83.75	3.07	.267
	T2	81.23	4.48		83.37	4.40		84.00	3.30	
	T2–T1	0.34	1.30		0.33	0.98		0.25	0.87	
SNB	T1	74.23	2.70	.045*	72.98	3.47	.000**	75.85	2.30	.011*
	T2	74.67	2.50		73.68	3.29		76.20	2.18	
	T2–T1	0.43	0.66		0.69	0.41		0.35	0.48	
B-FP	T1	−7.97	4.02	.009**	−8.31	5.63	.002**	−7.44	4.49	.000**
	T2	−6.82	3.95		−7.63	5.44		−6.45	4.21	
	T2–T1	1.15	1.26		0.68	0.71		0.99	0.72	
Right effective mandibular length	T1	99.03	4.76	.000**	101.12	4.53	.000**	101.4	4.72	.003**
	T2	99.86	4.61		102.30	4.16		102.3	4.45	
	T2–T1	0.83	0.50		1.18**	0.90		0.86	0.98	
Left effective mandibular length	T1	98.86	4.74	.000**	102.15	4.68	.000**	102.1	5.36	.000**
	T2	100.1	4.86		103.51	4.67		103.2	5.20	
	T2–T1	1.14	0.66		1.36	1.12		1.01	0.74	
ANB	T1	7.18	0.84	.023*	6.89	1.64	.000**	7.32	1.88	.026*
	T2	6.62	1.05		6.37	1.81		7.00	2.01	
	T2–T1	−0.56	0.74		−0.52	0.44		−0.32	0.52	
AB difference	T1	9.85	1.78	.011*	10.16	3.12	.001**	9.82	2.87	.000**
	T2	8.89	1.72		9.37	3.17		9.17	3.04	
	T2–T1	−0.96	1.10		−0.79	0.76		−0.65	0.59	
Maxillary width	T1	56.03	3.04	.159	58.59	3.18	.071	58.60	2.09	.137
	T2	56.50	3.39		57.92	2.81		58.90	2.15	
	T2–T1	0.46	1.06		−0.68	1.35		0.31	0.79	
Mandibular width	T1	79.54	5.26	.408	83.87	5.13	.442	84.03	4.60	.063
	T2	79.94	4.58		84.06	5.08		84.50	4.61	
	T2–T1	0.40	1.60		0.19	0.93		0.47	0.94	

[a] FMI indicates the group receiving Forsus Fatigue Resistant Device (FFRD) and mini-implants; Forsus, the group receiving only FFRD.
* Significant at $P \leq 0.05$; ** Highly significant at $P < .01$; Paired *t*-tests.

These findings were in agreement with those of Aslan et al.[21] Another study[32] reported mesial movement of the maxillary molars with the FFRD. Cacciatore et al.[16] reported 0.7 mm of distal movement of the maxillary molars after FFRD therapy.

Regarding the mandibular incisor changes, the introduction of mini-implants with rigid attachment to the mandibular canines in the current study resulted in remarkable favorable changes in limiting the proclination of the mandibular incisors. It was

Table 5. Comparison of the Mean Differences (T2-T1) for the Skeletal Measurements Among the Three Study Groups (One-Way Analysis of Variance [ANOVA] and Multiple Bonferroni Method Tests)[a]

Measurement	Study Group	Mean Difference T2–T1	SD	*P*-Value	*P* (Control-FMI)	*P* (Control-Forsus)	*P* (FMI-Forsus)
MMP	Control	−0.81	1.65	.145	NS	NS	NS
	FMI	0.28	1.73				
	Forsus	0.16	1.14				
MP/SN	Control	−0.30	1.08	.051	NS	NS	NS
	FMI	0.62	0.77				
	Forsus	−0.09	1.13				
Y axis angle	Control	−0.37	1.03	.403	NS	NS	NS
	FMI	0.11	0.83				
	Forsus	−0.28	1.13				
Facial height ratio	Control	0.00	0.01	.260	NS	NS	NS
	FMI	0.00	0.01				
	Forsus	0.00	0.01				
Jaraback ratio	Control	0.00	0.01	.858	NS	NS	NS
	FMI	0.00	0.01				
	Forsus	0.00	0.01				
Lower facial height	Control	0.53	1.20	.040*	.499	.429	.037*
	FMI	1.06	0.88				
	Forsus	0.12	1.18				
SNA	Control	0.08	0.34	.207	NS	NS	NS
	FMI	−0.26	0.45				
	Forsus	−0.08	0.60				
A-FP	Control	0.25	0.53	.035*	.031*	.276	.884
	FMI	−0.33	0.63				
	Forsus	−0.12	0.51				
Effective maximum length	Control	0.34	1.30	.965	NS	NS	NS
	FMI	0.33	0.98				
	Forsus	0.25	0.87				
SNB	Control	0.43	0.66	.171	NS	NS	NS
	FMI	0.69	0.41				
	Forsus	0.35	0.48				
B-FP	Control	1.15	1.26	.383	NS	NS	NS
	FMI	0.68	0.71				
	Forsus	0.99	0.72				
Right effective mandibular length	Control	0.83	0.50	.474	NS	NS	NS
	FMI	1.18	0.90				
	Forsus	0.86	0.98				
Left effective mandibular length	Control	1.20	0.66	.542	NS	NS	NS
	FMI	1.36	1.12				
	Forsus	1.01	0.74				
ANB	Control	−0.56	0.74	.460	NS	NS	NS
	FMI	−0.52	0.44				
	Forsus	−0.32	0.52				
AB difference	Control	−0.96	1.10	.621	NS	NS	NS
	FMI	−0.79	0.76				
	Forsus	−0.65	0.59				
Maxillary width	Control	0.46	1.06	.015*	.029*	1.0	.046*
	FMI	−0.68	1.35				
	Forsus	0.31	0.79				
Mandibular width	Control	0.40	1.60	.786	NS	NS	NS
	FMI	0.19	0.93				
	Forsus	0.47	0.94				

[a] FMI indicates the group receiving Forsus Fatigue Resistant Device (FFRD) and mini-implants; Forsus, the group receiving only FFRD; NS, not significant.

* Significant at $P \leq .05$.

confirmed by the change in their antero-posterior position (0.81 mm in the FMI group and 2.55 mm in the Forsus group). These results were in agreement with those of Aslan et al.,[21] who reported more limited proclination of mandibular incisors (3.6° ± 5.07° and 9.3° ± 3.8° in the FMI and Forsus groups, respectively). Both treatment groups showed significant intrusion of the mandibular incisors, which was

Table 6. Mean Values of Parameters at the Beginning (T1) and End (T2) and the Mean Difference (T2-T1) of the Dento-Alveolar Measurements in the Three Study Groups[a]

		Control, N = 12			FMI, N = 15			Forsus, N = 16		
Measurement	Time of Measurement	Mean	SD	*P*-Value	Mean	SD	*P*-Value	Mean	SD	*P*-Value
U1 AP position	T1	8.25	3.51	.065	6.67	3.65	.000**	8.04	3.43	.000**
	T2	8.96	3.20		3.00	4.29		5.72	3.59	
	T2–T1	0.71	1.20		−3.67	1.28		−2.32	1.33	
U1 vertical position	T1	37.61	3.11	.966	39.20	3.75	.009**	40.16	2.71	.168
	T2	37.58	2.70		39.94	3.84		40.59	3.13	
	T2–T1	−0.02	1.86		0.73	0.94		0.43	1.19	
U1 inclination	T1	27.71	3.78	.139	25.00	7.56	.000**	25.63	4.53	.000**
	T2	28.60	3.47		13.83	7.70		16.48	4.50	
	T2–T1	0.89	1.94		−11.17	3.51		−9.15	3.01	
UR6 C. AP position	T1	38.40	3.11	.000**	40.56	6.09	.000**	42.65	3.77	.000**
	T2	39.92	2.99		38.14	6.31		41.18	4.33	
	T2–T1	1.52	0.86		−2.41	1.40		−1.47	1.17	
UR6 R. AP position	T1	41.53	2.93	.052	40.86	5.00	.228	42.68	3.13	.745
	T2	42.10	2.89		41.18	5.21		42.78	3.59	
	T2–T1	0.58	0.92		0.33	1.00		0.09	1.13	
UL6 C. AP position	T1	38.84	3.12	.000**	40.20	5.77	.000**	42.42	3.65	.000**
	T2	40.17	2.97		37.60	5.80		40.92	3.85	
	T2–T1	1.33	0.90		−2.60	1.31		−1.50	1.10	
UL6 R. AP position	T1	41.26	2.74	.006**	40.37	5.11	.119	42.29	2.93	.004**
	T2	41.89	2.52		40.75	4.93		42.99	2.96	
	T2–T1	0.63	0.64		0.38	0.88		0.70	0.82	
UR6 vertical position	T1	31.63	2.90	.026*	33.11	2.88	.000**	34.15	3.00	.000**
	T2	32.50	2.36		31.44	2.82		32.85	3.05	
	T2–T1	0.86	1.16		−1.68	0.72		−1.30	0.71	
UL6 vertical position	T1	32.23	2.41	.036*	32.70	3.35	.000**	33.94	2.69	.000**
	T2	32.85	1.99		30.90	2.91		32.73	3.00	
	T2–T1	0.62	0.89		−1.79	1.05		−1.21	0.74	
L1 inclination	T1	37.99	7.62	.942	38.15	7.89	.000**	36.24	7.18	.000**
	T2	38.02	8.10		43.41	8.85		45.29	5.85	
	T2–T1	0.03	1.35		5.26	2.71		9.05	2.91	
L1 AP position	T1	1.46	2.89	.136	0.43	4.17	.054	1.54	3.56	.000**
	T2	2.11	2.72		1.24	3.97		4.09	3.71	
	T2–T1	0.66	1.42		0.81	1.49		2.55*	0.88	
L1 to NB line	T1	8.32	1.65	.395	7.85	1.84	.000**	8.11	2.23	.000**
	T2	8.41	1.68		8.71	1.97		10.33	2.54	
	T2–T1	0.09	0.35		0.87	0.62		2.22	0.70	
L1 vertical position	T1	27.83	3.33	.884	26.97	2.06	.000**	27.01	1.99	.000**
	T2	27.78	2.77		26.04	1.59		25.35	1.86	
	T2–T1	−0.05	1.09		−0.93	0.78		−1.66	0.71	
LR6 vertical position	T1	17.56	1.79	.012*	16.34	2.53	.000**	16.71	2.42	.000**
	T2	17.95	1.69		18.09	2.30		18.08	2.57	
	T2–T1	0.38	0.44		1.75**	0.61		1.37	0.56	
LL6 vertical position	T1	16.95	2.37	.006**	16.40	1.82	.000**	16.62	2.22	.000**
	T2	17.51	2.32		17.85	1.84		17.78	2.33	
	T2–T1	0.56	0.58		1.45**	0.57		1.16	0.89	
LR6 AP position Cr	T1	37.74	3.51	.019*	38.59	6.05	.003**	40.76	5.35	.039*
	T2	39.09	3.69		40.34	5.79		42.85	4.01	
	T2–T1	1.34	1.70		1.74**	1.90		2.08	3.70	
LR6 AP position R	T1	3.35	35.78	.016*	31.80	7.27	.003**	33.29	5.23	.103
	T2	3.28	36.79		33.15	6.73		34.09	5.50	
	T2–T1	1.61	3.64		1.35**	1.45		0.80	1.85	
LL6 AP position C	T1	38.70	3.44	.07	37.95	5.60	.000**	40.00	3.25	.000**
	T2	39.57	3.52		39.27	4.91		42.76	3.47	
	T2–T1	0.87	1.51		1.33**	1.02		2.76	1.28	
LL6 AP position R	T1	30.96	3.71	.155	31.35	6.54	.114	33.49	4.20	.031*
	T2	31.93	3.54		32.08	6.25		34.35	4.43	
	T2–T1	0.97	2.20		0.73	1.67		0.86	1.45	

[a] FMI indicates the group receiving Forsus Fatigue Resistant Device (FFRD) and mini-implants; Forsus, the group receiving only FFRD.
* Significant at $P \leq .05$; ** Highly significant at $P < .01$; Paired *t*-tests.

Table 7. Comparison of the Mean Differences (T2-T1) for the Dento-Alveolar Measurements Among the Three Study Groups (One-Way Analysis of Variance [ANOVA] and Multiple Bonferroni Method Tests)[a]

Measurement	Study Group	Mean Difference T2–T1	SD	*P*-Value	*P* (Control-FMI)	*P* (Control-Forsus)	*P* (FMI-Forsus)
U1 AP position	Control	0.71	1.20	.000**	.000**	.000**	.016*
	FMI	−3.67	1.28				
	Forsus	−2.32	1.33				
U1 vertical position	Control	−0.02	1.86	.352	NS	NS	NS
	FMI	0.73	0.95				
	Forsus	0.43	1.19				
U1 inclination	Control	0.89	1.94	.000**	.000**	.000**	.195
	FMI	−11.17	3.51				
	Forsus	−9.15	3.02				
UR6 C. AP position	Control	1.52	0.86	.000**	.000**	.000**	.097
	FMI	−2.41	1.40				
	Forsus	−1.47	1.17				
UR6 R. AP position	Control	0.58	0.92	.477	NS	NS	NS
	FMI	0.33	1.00				
	Forsus	0.09	1.13				
UL6 C. AP position	Control	1.33	0.90	.000**	.000**	.000**	.029*
	FMI	−2.60	1.31				
	Forsus	−1.50	1.10				
UL6 R. AP position	Control	0.63	0.64	.517	NS	NS	NS
	FMI	0.38	0.88				
	Forsus	0.70	0.82				
UR6 vertical position	Control	0.86	1.16	.000**	.000**	.000**	.696
	FMI	−1.68	0.72				
	Forsus	−1.30	0.71				
UL6 vertical position	Control	0.62	0.89	.000**	.000**	.000**	.237
	FMI	−1.79	1.05				
	Forsus	−1.21	0.74				
L1 inclination	Control	0.03	1.35	.000**	.000**	.000**	.000**
	FMI	5.26	2.71				
	Forsus	9.05	2.91				
L1 AP position	Control	0.66	1.42	.000**	1.000	.001**	.001**
	FMI	0.81	1.49				
	Forsus	2.55	0.88				
L1 to NB line	Control	0.09	0.35	.000**	.005**	.000**	.000**
	FMI	0.87	0.62				
	Forsus	2.22	0.70				
L1 vertical position	Control	−0.05	1.09	.000**	.034*	.000**	.064
	FMI	−0.93	0.78				
	Forsus	−1.66	0.71				
LR6 vertical position	Control	0.38	0.44	.000**	.000**	.000**	.186
	FMI	1.75	0.61				
	Forsus	1.37	0.56				
LL6 vertical position	Control	0.56	0.58	.008**	.007**	.093	.777
	FMI	1.45	0.57				
	Forsus	1.16	0.89				
LR6 AP position Cr	Control	1.34	1.70	.770	NS	NS	NS
	FMI	1.74	1.90				
	Forsus	2.08	3.70				
LL6 AP position Cr	Control	0.62	1.25	.000**	.399	.000**	.005**
	FMI	1.33	1.02				
	Forsus	2.76	1.28				
LR6 AP position R	Control	1.32	1.61	.592	NS	NS	NS
	FMI	1.35	1.45				
	Forsus	0.80	1.85				
LL6 AP position R	Control	0.97	2.20	.938	NS	NS	NS
	FMI	0.73	1.67				
	Forsus	0.86	1.45				

[a] FMI indicates the group receiving Forsus Fatigue Resistant Device (FFRD) and mini-implants; Forsus, the group receiving only FFRD; NS, not significant.

* Significant at $P \leq .05$; ** Highly significant at $P < .01$.

less in the FMI group (0.93 mm) than in the Forsus group (1.61 mm).

In the current study, the pushrod was inserted distal to the mandibular canines and led to 9.3° of proclination of mandibular incisors in the Forsus group. However, Cacciatore et al.[16] placed the pushrod distal to the mandibular first premolars, which resulted in a mean of 5° of mandibular incisor proclination. This may give rise to the question of whether the distal placement of the pushrod could have resulted in reduction of the unwanted mandibular incisor mesial movement; this question requires further studies.

As for the mandibular first molars, significant mesialization was only reported for the Forsus group, versus the other two groups (mean of 2.76 mm), which could be explained by the significantly greater mandibular incisor proclination, which in turn created more space for the mandibular molars to tip mesially.

The incorporation of mini-implants with FFRD reduced the mandibular incisor proclination but could not lead to additional increase in the mandibular growth. It led to significant restriction of maxillary growth and distalization of the maxillary dentition. This might shed light on the indications of this modality in patients with mild to moderate dento-alveolar maxillary excess.

CONCLUSIONS

- FFRD was successful in treatment of Class II division 1 malocclusion through dentoalveolar changes and minimal significant skeletal changes.
- The use of mini-implants with FFRD could not produce significant additional sagittal skeletal effects.
- The incorporation of mini-implants with FFRD decreased the mandibular dentoalveolar side effects and increased the distalizing effects of the appliance on the maxillary arch.

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