Original Article

Evaluation of the splint-supported Forsus Fatigue Resistant Device in skeletal Class II growing subjects

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ABSTRACT

Objectives: To evaluate the use of the Forsus Fatigue Resistant Device (FFRD), supported with bimaxillary splints, in treatment of skeletal Class II malocclusion.

Materials and Methods: Data from 46 skeletal Class II females who received either conventional Forsus alone (FFRD group) (15 patients, 12.54 ± 0.90 years), FFRD and bimaxillary splints (splint-FFRD group) (15 patients, 12.29 ± 0.82 years), or were untreated controls (16 subjects, 12.1 ± 0.9 years) were retrieved from previous clinical trials. FFRD was inserted onto the mandibular archwire in the FFRD group after leveling and alignment with multibracket appliances. In the splint-FFRD group, Forsus was inserted between fixed maxillary and mandibular splints. Treatment continued until reaching an edge-to-edge incisor relationship.

Results: Both treatment groups failed to induce significant mandibular skeletal effects compared to the normal growth exhibited by untreated controls. The splint-FFRD group showed significant reduction of SNA (–0.88° ± 0.51°) and ANB (–1.36° ± 0.87°). The mandibular incisors showed significant proclination in the FFRD (9.17° ± 2.42°) and splint-FFRD groups (7.06° ± 3.34°).

Conclusions: The newly proposed splint-supported FFRD was equally effective as the conventional FFRD in treatment of Class II malocclusion with dento-alveolar changes and additional maxillary restricting effect. It has an additional advantage of immediate initiation of the Class II correction. (*Angle Orthod.* 2021;91:9–21.)

KEY WORDS: Class II; Forsus; Fixed functional appliance; Growing; Splint

INTRODUCTION

Mandibular deficiency was reported[1] as the most dominant component of skeletal Class II malocclusion. This emphasized the importance of Class II correctors that can achieve the desired mandibular growth enhancement in growing subjects. Fixed functional appliances (FFAs) have been recommended over removable ones because they provide full-time forces and overcome the compliance problem. The skeletal effects of FFAs are debatable, and recent evidence[2,3] supports that they were of negligible clinical importance. However, greater skeletal effects and less dento-alveolar compensation could be achieved when treatment started at the pubertal growth spurt.[4]

The Forsus Fatigue Resistant Device (FFRD) (3M Unitek, Monrovia, Calif) is an example of a hybrid FFA[5] that has been proven to be well accepted by patients.[6] However, it requires complete leveling and alignment of both arches prior to its insertion, which results in the waste of valuable time, especially in patients with a minimal amount of growth remaining.

Splint-mounted fixed Class II correctors were first introduced in 1988 through the splint type Herbst as a way to control lower incisor proclination and begin the FFA phase before placement of multibracket appliances.[7,8] Later, the Crossbow (X-Bow) appliance was introduced for Class II treatment in the late mixed or early permanent dentition.[9] The appliance incorporated

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Table 1. Eligibility Criteria of Patients Included in the Study

Inclusion Criteria	Exclusion Criteria
• Females 11–14 y of age • Skeletally, the patients had to be in the cervical maturational stage 3, as detected by the lateral cephalometric radiograph • Skeletal Class II malocclusion with a deficient mandible (SNB ≤ 76°) • Horizontal or neutral growth pattern (MMP ≤ 30°) • Increased overjet (minimum 5 mm) • Class II canine relationship (minimum of half unit) and Class II division 1 incisor relationship • Mandibular arch crowding less than 3 mm	• Systemic disease • Signs or symptoms temporomandibular disorders • Extracted or congenitally missing permanent tooth/teeth • Facial asymmetry • Severe proclination or crowding that requires extractions in the lower arch

a Forsus spring that was mounted on a maxillary hyrax expander with mandibular buccal and lingual bows that were inserted, without the need for fixed appliances but that did not have extensions to contact the upper incisors. This device showed a shorter treatment time, by an average of 6–10 months, when compared to the conventional FFRD.[10]

This study compared the skeletal and dental effects of a bimaxillary splint-supported FFRD (splint-FFRD) with matched groups of growing subjects who were treated with conventional FFRD and untreated Class II controls. The design of this appliance was devised to allow use of FFRD before insertion of fixed appliances and to simultaneously control the incisors through the bimaxillary splints.

MATERIALS AND METHODS

The sample was drawn retrospectively from two previous controlled trials,[11,12] the samples for which followed the same eligibility criteria (Table 1). Both trials were approved by the ethical committees at the Faculty of Dentistry, Cairo University, and the Faculty of Dentistry, Ain Shams University, in Egypt. G power software (Universität, Düsseldorf, Germany) was used in the two primary studies to calculate the sample size based on the study by Manni et al.,[13] 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 11 subjects per group.

For the conventional FFRD group, data from 15 female subjects were included; subjects had a mean age of 12.54 ± 0.90 years. 3M MBT brackets (0.022-inch slot) were bonded to both dental arches, and a passive transpalatal arch was cemented to the maxillary first molars. Levelling and alignment were performed until reaching 0.019 × 0.025-inch stainless-steel archwires, which were bent back distal to the first molars.

For the splint-FFRD group, data from 15 female subjects were included; subjects had a mean age of 12.29 ± 0.82 years. For every arch, a full splint was constructed from 0.9-mm stainless-steel wires that were adapted along the labial and lingual surfaces of the teeth from the first molar of one side to the other side and were soldered to bands that were cemented to the first molars. Additional 0.7-mm stainless-steel wires ran across the occlusal embrasure between the premolars on each side and were soldered to the labial and lingual wires. Clear acrylic resin was added over the framework extending 2 mm incisal and gingival to the wires and adapted to the labial and lingual tooth surfaces from canine to canine.

Cone-beam computed tomographic (CBCT) images were obtained with an i-CAT CBCT unit (Imaging Sciences International, Hatfield, Pa) immediately before insertion of the FFRD (T1) in the two treatment groups.

In both treatment groups, the proper size of the FFRD was selected following the manufacturer's instructions. The pushrods were inserted onto the archwires distal to the mandibular canines in the FFRD group and onto the mandibular splint distal to the end of the acrylic framework at the canine area in the splint-FFRD group (Figures 1 and 2).

Follow-up visits were scheduled every 4–6 weeks, and appliance activation was performed when needed. Treatment was continued until overcorrection to an edge-to-edge incisor relationship was reached in both groups. The appliances were then removed, and

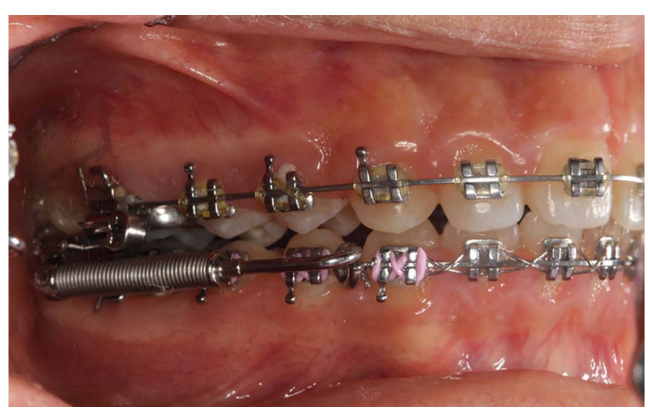

Figure 1. FFRD insertion in the FFRD group.

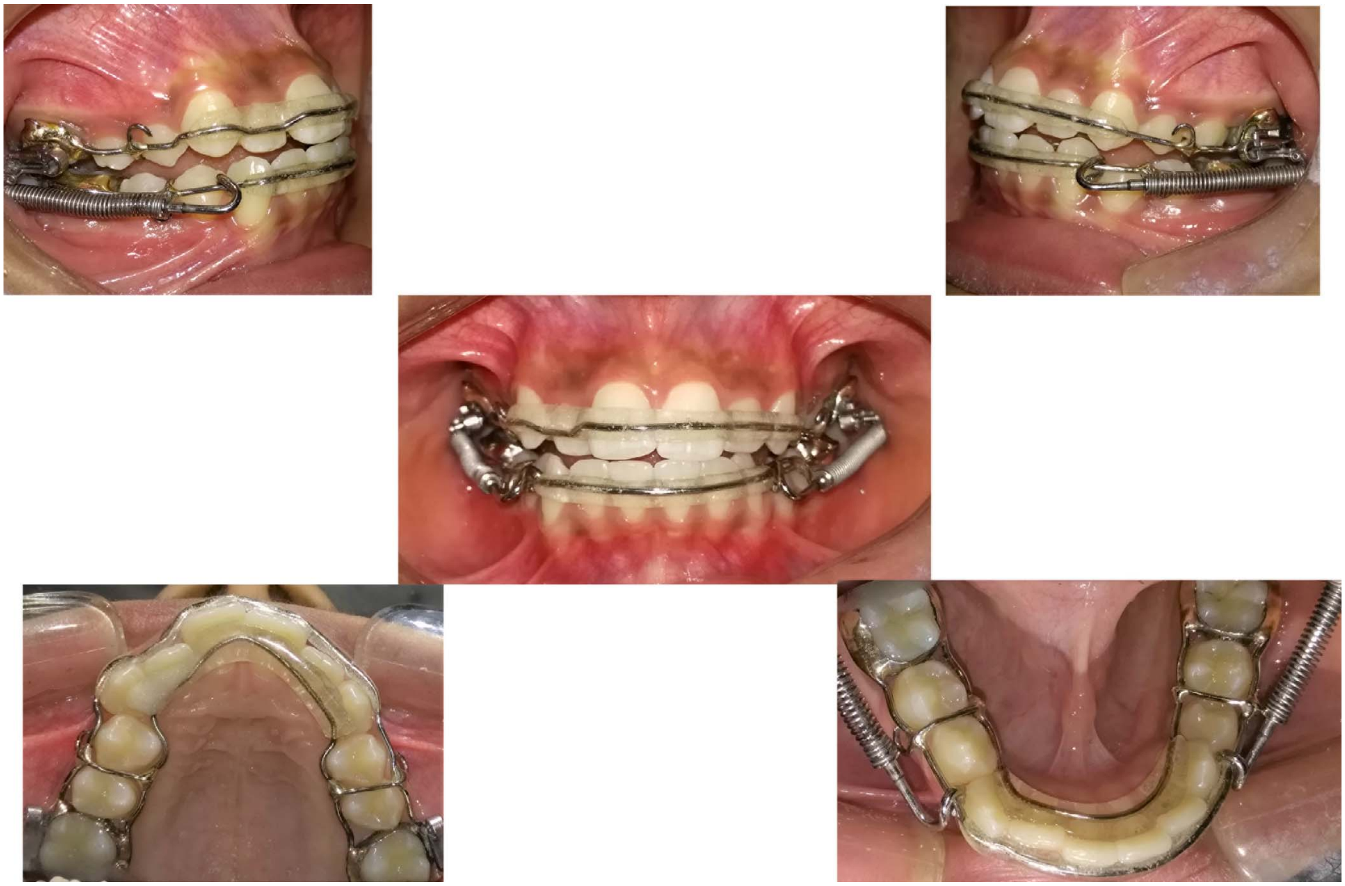

Figure 2. Intraoral views of the splint-FFRD appliance.

posttreatment (T2) CBCT images were obtained, followed by placement of a multibracket appliance in the splint-FFRD group.

The control group included 16 female subjects with a mean age of 12.13 $\pm$ 0.86 years who had T1 and T2 CBCT images, with an observation period of 7.26 $\pm$ 1.74 months. Their T2 CBCT was considered their initial record to start orthodontic treatment.

Analysis of the CBCT images was done using Invivo Anatomage version 5.2 (Anatomage, San Jose, Calif) (Table 2). The assessors were blinded during the analysis, which was performed by the same observer twice and by another observer to detect the measurement error.

Statistical Analysis

Statistical analysis was performed with SPSS (SPSS Inc, IBM Corporation, Armonk, NY) version 20 for Windows. All bilateral variables were measured for both sides and then the averages were statistically analyzed. Concordance correlation coefficients (CCCs) were calculated to detect the intra- and interexaminer reliability of the measurements.

Descriptive statistics reported the mean and standard deviation (SD) of the demographic information for the three groups. Data were explored for normality using Kolmogorov- Smirnov and Shapiro-Wilk tests, which revealed their normal distribution. A 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 the multiple-comparison Bonferroni test for the significant ANOVA variables.

RESULTS

Clinical Results

The FFRD was able to transform the Class II relationship to a dental Class I relationship in all cases, and patients in both treatment groups showed improvement in the extraoral and intraoral features. Clinical examples of one patient each from the FFRD and splint-FFRD groups are presented in Figures 3 and 4 and Figures 5 and 6, respectively.

Table 2. Definitions of the Included Measurements in the Study

Measurement	Definition
SNA	The angle between the points S, N, and A
SNB	The angle between the points S, N, and B
ANB	The angle between three landmarks: A, N, and B
A-FP	The linear distance between the A point and the frontal plane
B-FP	The linear distance between the B point and the frontal plane
Effective maxillary length (Co-A)	The linear distance between the condylion and A points indicating the effective maxillary length
Effective mandibular length (Co-Gn)	The linear distance between the condylion and the gnathion points indicating the effective mandibular length
MMP	The angle between the palatal plane ANS-PNS and the mandibular plane
Gonial angle	The angle between the points Co, Go, and Me
MP/SN	The angle between the line S-N and the mandibular plane
U1/PP	The angle formed between the palatal plane and the upper central incisors long axes, as viewed from the sagittal view
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
UR6 AP position	The linear distance between the mesio-buccal cusp tip of U6 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 midroot of the lower central incisors to the mandibular plane, viewed from the sagittal view
L6 AP position	The linear distance between the mesio-buccal cusp tip of lower left first molar and the vertical plane, as 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
Naso-labial angle	The angle between subnasale and labralis superior tangent to the columella
Angle of convexity	The angle between soft tissue nasion, subnasale, and soft tissue pogonion
Mento-labial sulcus	The angle between labrale inferior, sulcus inferior, and soft tissue pogonion

Baseline Data and Measurement Error

Baseline characteristics, including age, cervical vertebral maturation (CVM) stage, and dental and skeletal measurements, were compared, and the results showed close matching of the groups (Tables 3 through 5). Regarding the measurement error, the CCC values ranged from 0.724 to 0.999, indicating good to excellent agreement (Table 6).

Follow-Up

The mean follow-up periods for the FFRD, splint-FFRD, and control groups were 6.23 ± 1.61, 5.85 ± 0.68, and 7.26 ± 1.74 months, respectively, with a significant difference between the control and splint-FFRD groups (Table 4).

Skeletal Changes (Tables 7 and 8)

A significant decrease in the SNA angle (–0.88° ± 0.51°) and backward movement of the maxilla (–0.52 ± 0.33 mm) were found in the splint-FFRD group only. No significant differences were reported among all groups regarding the mandibular length, SNB, and B-FP measurements. The ANB angle was significantly reduced only in the splint-FFRD group (–1.36° ± 0.87°) when compared to the other groups.

The gonial angle was significantly decreased in the control group (–0.89° ± 0.76°) as compared to both treatment groups. No significant difference was found in the MMP angle between the study groups. The MP/SN change was only different between the splint-FFRD (0.71° ± 0.39°) and the control (–0.31° ± 1.32°) group.

Dental and Soft Tissue Changes (Tables 7 and 8)

The maxillary incisors were significantly retroclined in the FFRD (–8.98° ± 2.55°) and splint-FFRD (–8.59° ± 3.34°) groups, with no difference between them. 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 mm), both of which were greater than in the splint-FFRD group (7.06° ± 3.34° and 1.40 ± 0.65 mm, respectively); however, the differences were not statistically significant. The mandibular incisors were significantly intruded in both treatment groups.

Figure 3. Extra- and intraoral photographs for a patient in the FFRD group before treatment.

Maxillary molars were significantly distalized and intruded in the FFRD and splint-FFRD groups in contrast to the controls. The mandibular molars were mesialized and extruded in all groups, with a significantly higher extrusion in the FFRD group (1.26 $\pm$ 0.52 mm).

Both treatment groups showed favorable significant soft tissue changes when compared to the controls, including a reduced facial convexity and nasolabial angle and flattening of the mento-labial sulcus.

DISCUSSION

Treatment of skeletal Class II subjects was previously reported[4] to be more effective when achieved around the pubertal growth spurt. Upon using FFRD for Class II malocclusion treatment, levelling and alignment of both arches are required before starting the Class II correction. This considerable delay can result in missing the ideal time for performing treatment in patients who reach their pubertal period earlier than in those having a full set of permanent teeth.

The X-bow appliance was introduced in the literature,[9] in which the following was described: a Forsus spring was attached to the maxillary molar bands, and the position of the pushrods was controlled by Gurin locks on a mandibular labial wire. The device used in the current study had several modifications compared to the X-bow: it incorporated labial and lingual acrylic to splint both dental arches during the Forsus phase. Full splinting of the maxillary arch was used instead of premolar/molar splinting with the X-bow appliance. Additionally, in the mandibular arch, occlusal embrasure cross wires connecting the labial and lingual wires at the premolar region provided better splinting than did the first premolar occlusal rests in the X-bow appliance. Finally, the X-bow included a maxillary expansion device that was absent in the appliance used in the current study. This approach was supported by recent evidence[14] that concluded that the need for maxillary expansion to improve the sagittal dimension of Class II has not yet been proven.

Patient gender in this study was restricted to females to avoid the inaccuracy due to combining data from

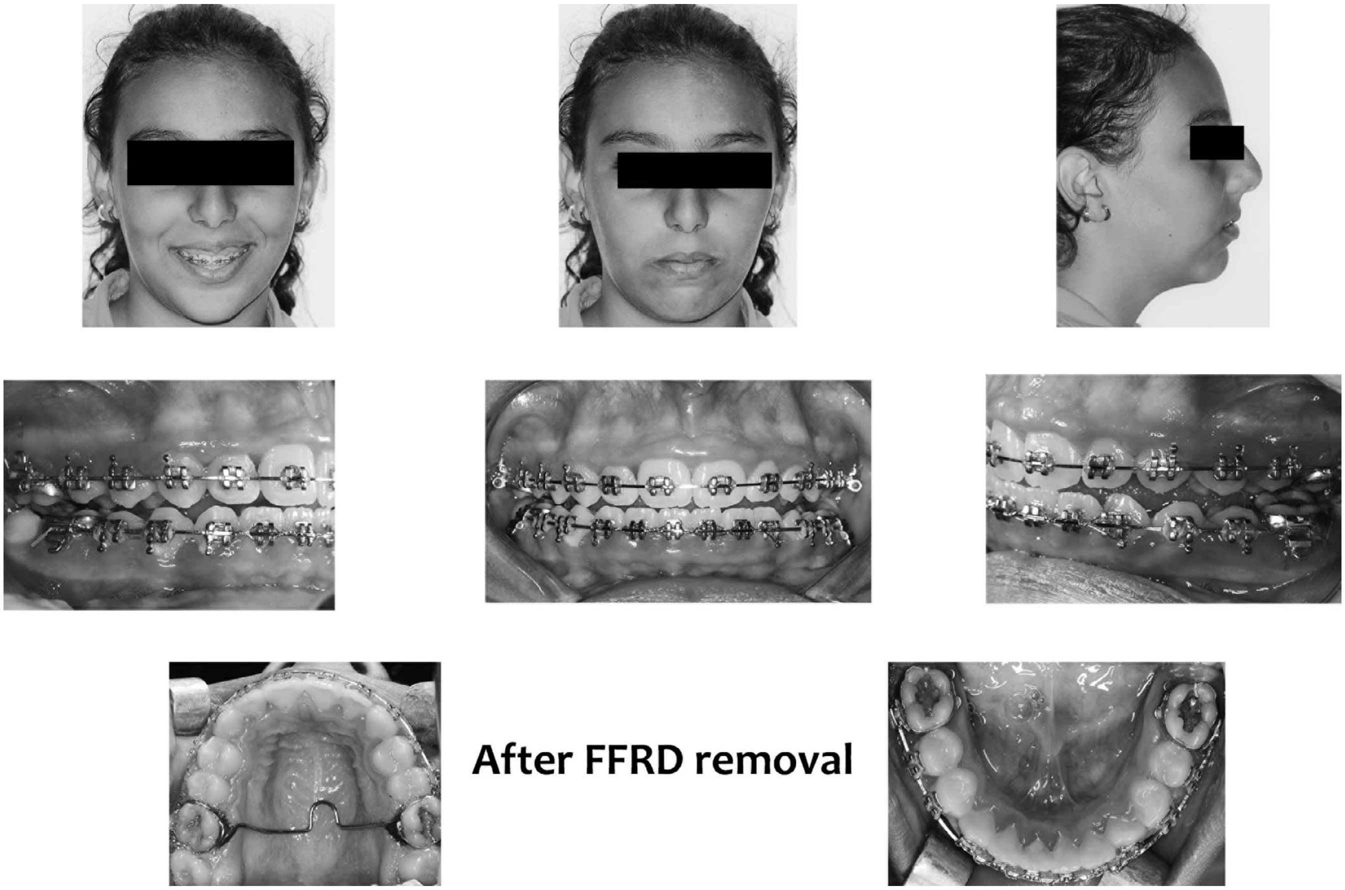

Figure 4. Extra- and intraoral photographs for a patient in the FFRD group after FFRD removal.

males and females who have different growth rates, timing, and patterns.[15] In order to test the splint-FFRD effectiveness, comparison was made to a group of patients who were treated with conventional FFRD in addition to a group of untreated controls, as previously recommended,[16] to separate the treatment effects from normal growth changes. The CVM was used to determine the maturational stage of the patients in addition to the chronological age, which was proven[17] to be inaccurate as a sole determinant of growth status. Matching of the three study groups was confirmed by the lack of significant differences among them at baseline with regard to the relevant features.

Upon comparing the treatment effects, in general there were no major differences between the conventional FFRD and the splint-FFRD groups regarding the dental and skeletal effects. Skeletally, both treatment groups showed a modest increase in the mandibular length that was not significantly surpassing the normal growth that occurred in the untreated controls. This was in agreement with previous evidence[2,3,18] that FFRD and its modifications were incapable of increasing the mandibular dimensions in growing subjects. The mandibular position, as indicated by the SNB and B point positions, was not significantly changed. Previous studies[9,19] evaluating the effect of the X-bow were in agreement with the current study in showing that minimal mandibular growth was induced by the appliance.

However, the results of the maxillary changes were different. The splint-FFRD group showed significant reduction in SNA and posterior displacement of A point compared with the other groups, indicating a more pronounced headgear effect. Additionally, ANB was significantly reduced only in the splint-FFRD group (by $-1.36° \pm 0.87°$), indicating improvement of the Class II relationship. The restricting effect on the maxilla exhibited by the splint-FFRD group was consistent with reports[9] on the X-bow appliance. This could reflect that the splint offered a more rigid connection between the maxillary dental arch and the FFRD spring than that provided by fixed appliances. This allowed transmission of distal forces to the maxillary alveolus, resulting in its backward positioning, which is an advantage in maxillary dento-alveolar protrusion cases. However, the size of the effect was small and needs to be confirmed with further research.

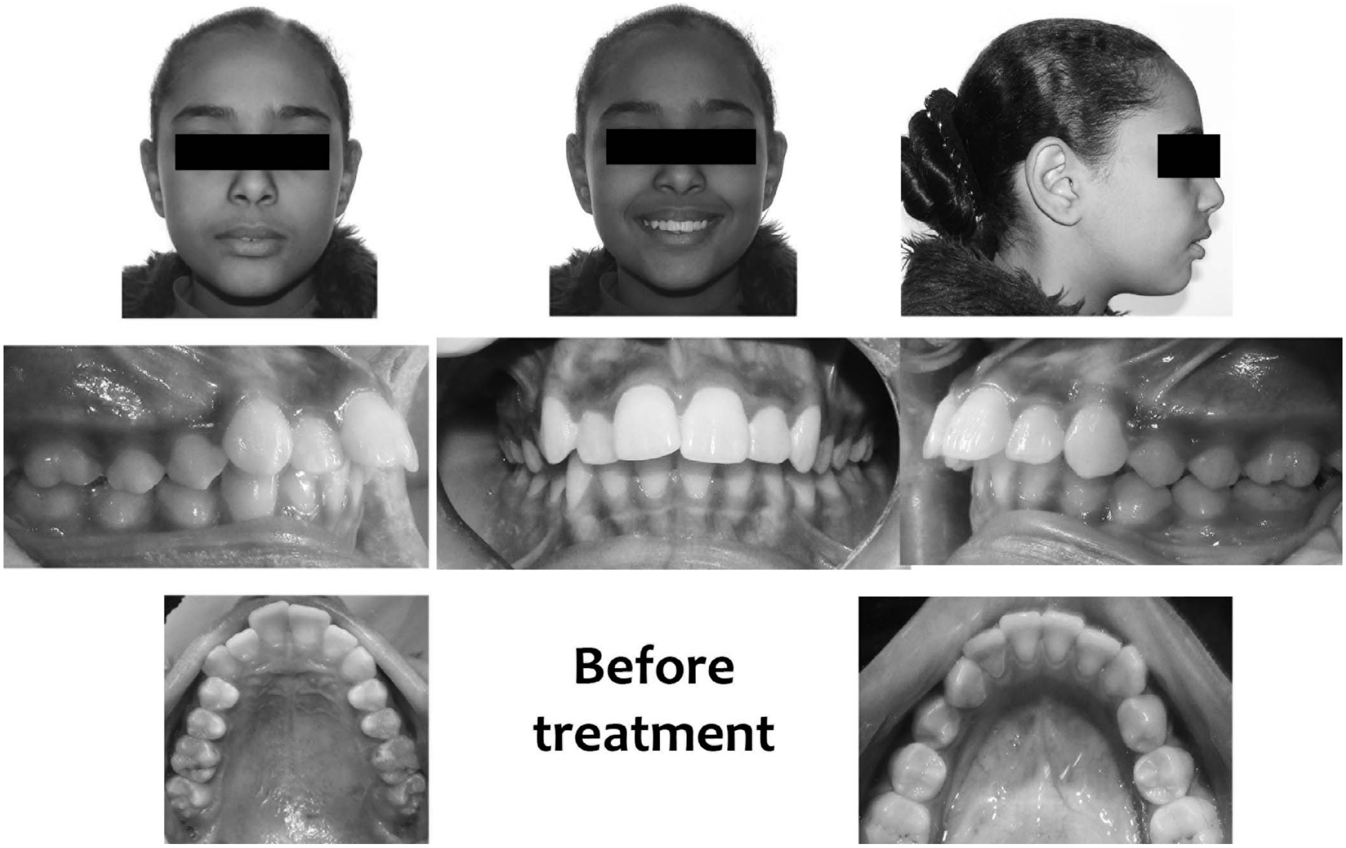

Figure 5. Extra- and intraoral photographs for a patient in the splint-FFRD group before treatment.

Retroclination of the maxillary incisors was evident in both treatment groups, with no difference between them. Flores-Mir et al.[9] documented retroclination of the upper incisors of 3.5° ± 5.3°, while Ehsani et al.[19] and Miller et al.[10] reported proclination of 1.62° ± 8.3° and 6.7° ± 9.6°, respectively, with the X-bow appliance. The reported variability in the direction of the effect with large SDs reflects the X-bow's poor control over the upper incisors. On the contrary, the current study showed upper incisor retroclination of 8.59° ± 3.3°, which confirmed the efficiency of the maxillary framework of the splint-FFRD group to control the upper incisors during the functional phase. These results should be interpreted with caution, however, because the previous X-bow studies[9,10,19] obtained their T2 record after fixed appliance removal, unlike the current study, in which T2 records were obtained immediately after FFA removal.

Regarding lower incisor proclination, despite showing no significant differences, the mean changes were 7.06° ± 3.3° and 9.18° ± 2.4° for the splint-FFRD and the FFRD groups, respectively. This demonstrated that the acrylic and wire frameworks offered somewhat greater control over the lower incisors than did the multibracket appliance. The mean values of incisor proclination in the splint-FFRD group were less than that induced by the X-bow appliance (9.6° ± 5.9°) in some reports[19] and higher than in other reports (4.8° ± 8.34°).[9] Similarly, forward movement of the lower incisors to the A-pogonion line was 1.40 ± 0.65 and 2.96 ± 0.95 mm for the splint-FFRD and FFRD groups, respectively.

The amount of mandibular molar extrusion was significantly lower in the splint-FFRD group than in the FFRD group, which can be attributed to the occlusal cross wires present at the premolar region in the former group and reflected better vertical control over the lower posterior teeth. On the other hand, skeletally, there was no significant difference in the change in the mandibular plane inclination between the treatment groups.

The current study compared a modified splint-supported FFRD to a conventional FFRD combined with fixed appliances. Unliked the conventional technique, the splint-supported appliance can allow the prompt initiation of the functional phase. This is beneficial to Class II subjects who present at the end of their pubertal spurt or during the mixed dentition stage, especially in settings where appliances such as the Herbst and X-bow, which can be immediately

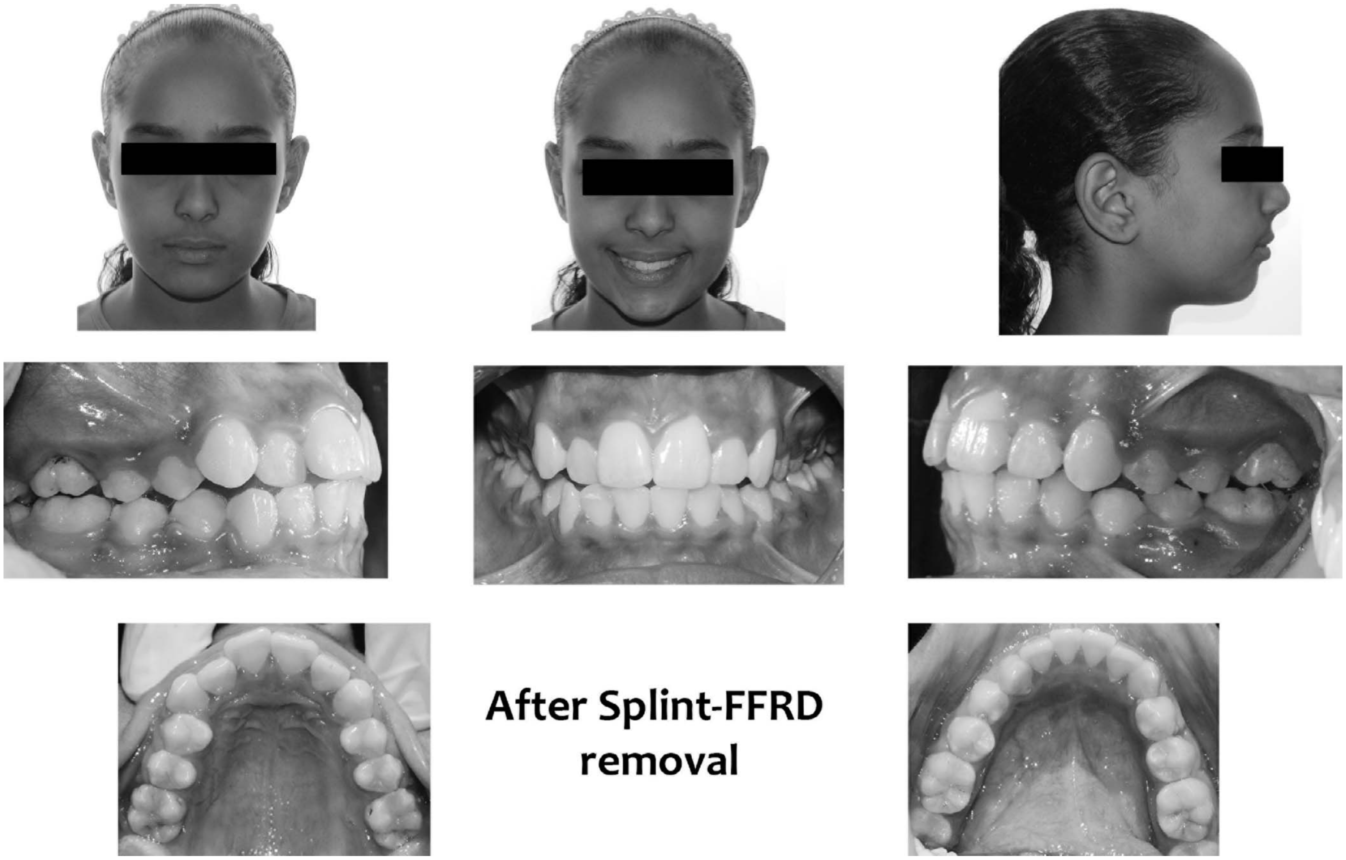

Figure 6. Extra- and intraoral photographs for a patient in the splint-FFRD treatment group after splint-FFRD removal.

inserted, are not available. In addition, using the splint-FFRD can help with reduction of the duration of wearing full multibracket appliances, and achieving an earlier improvement of the convex profile may have a positive impact on patients' self-esteem.[20] Keeping in mind these advantages and the lack of significant differences compared to the conventional FFRD, this appliance may be used as an option for treatment of Class II adolescents in the future.

Limitations

The current study had several limitations that should be considered when interpreting the results. Data were collected from two separate clinical trials, so the subjects in this comparison were not randomized, and selection bias cannot be ruled out. Different confounders were controlled by matching the groups at baseline; however, the inherent nature of cohort studies imposes further confounders. Restriction of the gender to females helped in validation of the comparison but limited the generalizability of the results. Different aspects of patient acceptance of the appliance require further investigation, including its esthetic appearance, size, and interference with function. Likewise, cost effectiveness needs to be analyzed on an individual patient basis before suggesting such treatment in clinical practice. The current study detected the changes during the FFA phase only, where T1 and T2 were immediately before and after the appliance installation and removal, respectively, so the dental relapse that may occur after the appliance was discontinued was not taken into consideration. Well-designed randomized controlled trials with long follow-up periods are needed to prove the effectiveness of the splint-FFRD and to investigate the stability of the treatment changes.

CONCLUSIONS

- FFRD was successful in the treatment of Class II malocclusion through dento-alveolar changes and minimal skeletal changes.
- The splint-supported FFRD was equally effective as the conventional FFRD, with no significant difference in the treatment effects, except for a modest maxillary headgear effect.
- The splint-supported FFRD can be an alternative used for patients during the late mixed dentition and those presenting during the pubertal peak.

Table 3. Comparison of the Baseline Characteristics Between the Study Groups (One-Way Analysis of Variance [ANOVA] Test)[a]

Variable	Study Group	Mean	SD	95% Confidence Interval for Mean		F	*P*-Value
				Lower Bound	Upper Bound		
SNA	Control	83.07	3.02	81.46	84.68	0.18	.839
	Splint-FFRD	82.62	1.78	81.64	83.61		
	FFRD	83.06	2.14	81.92	84.20		
SNB	Control	75.53	2.32	74.29	76.76	0.06	.945
	Splint-FFRD	75.60	1.32	74.87	76.33		
	FFRD	75.77	2.34	74.52	77.01		
ANB	Control	7.61	1.44	6.84	8.37	0.64	.534
	Splint-FFRD	7.02	1.49	6.20	7.84		
	FFRD	7.30	1.44	6.53	8.06		
A-FP	Control	2.86	2.16	1.71	4.02	0.19	.828
	Splint-FFRD	3.21	1.32	2.48	3.94		
	FFRD	2.73	2.86	1.21	4.26		
B-FP	Control	−6.43	2.97	−8.02	−4.85	0.11	.895
	Splint-FFRD	−6.60	1.81	−7.60	−5.60		
	FFRD	−6.96	4.36	−9.29	−4.64		
Effective maxillary length	Control	80.93	4.16	78.72	83.15	3.00	.059
	Splint-FFRD	82.34	2.65	80.87	83.80		
	FFRD	83.92	3.32	82.15	85.69		
Effective mandibular length	Control	106.73	3.78	104.72	108.74	3.01	.061
	Splint-FFRD	102.61	2.99	100.95	104.26		
	FFRD	103.87	6.74	100.28	107.46		
MMP	Control	28.45	4.75	25.92	30.98	0.90	.417
	Splint-FFRD	26.92	4.98	24.16	29.68		
	FFRD	25.93	6.21	22.62	29.24		
MP/SN	Control	36.58	4.32	34.28	38.88	1.45	.245
	Splint-FFRD	33.69	4.17	31.38	35.99		
	FFRD	36.12	6.32	32.75	39.49		
Gonial angle	Control	124.59	3.60	122.67	126.51	0.11	.894
	Splint-FFRD	125.58	4.79	122.92	128.23		
	FFRD	124.92	8.15	120.58	129.27		
U1/PP	Control	116.91	7.29	113.02	120.79	0.41	.665
	Splint-FFRD	115.26	3.02	113.58	116.93		
	FFRD	115.81	4.05	113.66	117.97		
U1 to A Pog	Control	10.64	1.64	9.76	11.52	5.36	.008*
	Splint-FFRD	11.63	2.02	10.51	12.75		
	FFRD	9.38	2.08	8.27	10.49		
L1/MP	Control	100.78	7.08	97.01	104.55	0.21	.809
	Splint-FFRD	101.43	5.14	98.58	104.27		
	FFRD	99.81	8.17	95.46	104.17		
L1 A Pog	Control	2.20	1.48	1.41	2.98	0.08	.922
	Splint-FFRD	2.33	0.77	1.91	2.76		
	FFRD	2.13	1.87	1.13	3.12		
L1 vertical position	Control	26.87	2.39	25.59	28.14	1.88	.165
	Splint-FFRD	25.87	2.43	24.53	27.22		
	FFRD	27.41	1.83	26.43	28.38		
Angle of convexity	Control	157.19	5.29	154.37	160.01	0.61	.548
	Splint-FFRD	156.50	3.00	154.84	158.16		
	FFRD	155.62	3.42	153.79	157.44		

[a] FFRD indicates Forsus alone group; SD, standard deviation.
* Significant when *P*-value is $<.05$.

Table 4. Comparison Between the Mean Age and Duration of Treatment/Observation Between the Study Groups (One-Way Analysis of Variance [ANOVA] and Multiple Bonferroni Method Tests)[a]

Parameter	Study Group	Mean	SD	95% Confidence Interval for Mean		F	*P*-Value	*P* (Control-FFRD)	*P* (Control—Splint-FFRD)	*P* (Splint-FFRD—FFRD)
				Lower Bound	Upper Bound					
Age	FFRD	12.54	0.90	12.06	13.02	0.93	.402	NS	NS	NS
	Splint-FFRD	12.29	0.82	11.83	12.74					
	Control	12.13	0.86	11.67	12.58					
Duration	FFRD	6.23	1.61	5.37	7.08	4.01	.025	NS	.03*	NS
	Splint-FFRD	5.85	0.68	5.48	6.23					
	Control	7.26	1.74	6.33	8.19					

[a] NS indicates nonsignificant; FFRD, Forsus alone group; amd SD, standard deviation.
* Significant when $P < .05$.

Table 5. Skeletal Maturational Stage for the Subjects in the Study Groups (Chi-Square Test)[a]

	CVM Stage 3	CVM Stage 4	Row Totals	Chi-Square	*P*-Value
FFRD	8 (8.15) [0.00]	7 (6.85) [0.00]	15	0.79	.673
Splint-FFRD	7 (8.15) [0.16]	8 (6.85) [0.19]	15		
Control	10 (8.70) [0.20]	6 (7.30) [0.23]	16		
Column Totals	25	21	46		

[a] The table shows the observed cell totals (the expected cell totals) and [the Chi-square statistics] for each cell; CVM indicates cervical vertebral maturation.

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

Measurement	Intraobserver			Interobserver		
	CCC	95% Confidence Interval Lower Bound	95% Confidence Interval Upper Bound	CCC	95% Confidence Interval Lower Bound	95% Confidence Interval Upper Bound
SNA	0.941	0.363	0.996	0.974	0.667	0.998
SNB	0.919	0.609	0.995	0.968	0.6	0.998
ANB	0.986	0.801	0.999	0.999	0.985	1
A-FP	0.999	0.987	1	0.996	0.946	0.997
B-FP	0.998	0.986	1	0.99	0.854	0.999
Effective maxillary length	0.999	0.982	1	0.925	0.747	0.995
Effective mandibular length	0.995	0.928	1	0.997	0.949	1
MMP	0.989	0.844	0.999	0.99	0.854	0.999
MP/SN	0.724	0.425	0.979	0.925	0.247	0.995
Gonial angle	0.874	0.879	0.991	0.949	0.428	0.998
U1/PP	0.965	0.57	0.998	0.758	0.36	0.982
U1-A Pog	0.998	0.964	1	0.758	0.36	0.982
U6 Vertical position	0.997	0.949	1	0.978	0.417	0.997
U6 AP position	0.953	0.458	0.997	0.988	0.414	0.997
L1/MP	0.914	0.183	0.994	0.979	0.937	0.993
L1 A Pog line	0.993	0.902	1	0.993	0.979	0.998
L1 vertical position	0.94	0.356	0.996	0.977	0.931	0.992
L6 vertical position	0.989	0.839	0.999	0.980	0.950	0.992
L6 AP position	0.974	0.667	0.998	0.950	0.853	0.984
Angle of facial convexity	0.979	0.939	0.993	0.981	0.940	0.994
Nasolabial angle	0.984	0.958	0.994	0.985	0.954	0.995
Mentolabial sulcus	0.993	0.978	0.997	0.972	0.918	0.990

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; Paired *t*-Test[a]

Measurement	Time Point	Control			FFRD			Splint-FFRD		
		Mean	SD	*P*-Value	Mean	SD	*P*-Value	Mean	SD	*P*-Value
SNA	Pre	83.07	3.02	.20	83.06	2.14	.81	82.62	1.78	<.001*
	Post	83.36	3.12		83.01	2.23		81.74	1.87	
	Post-Pre	0.30	0.88		−0.05	0.85		−0.88	0.51	
SNB	Pre	75.53	2.32	.80	75.77	2.34	.197	75.60	1.32	.002*
	Post	75.46	2.63		75.99	2.29		75.95	1.22	
	Post-Pre	−0.07	1.05		0.22	0.66		0.35	0.35	
ANB	Pre	7.61	1.44	.79	7.30	1.44	.053	7.02	1.49	<.001*
	Post	7.66	1.23		7.02	1.53		5.66	1.60	
	Post-Pre	0.06	0.80		−0.28	0.53		−1.36	0.87	
A-FP	Pre	2.86	2.16	.43	2.73	2.86	.925	3.21	1.32	<.001*
	Post	3.02	1.77		2.71	2.93		2.69	1.28	
	Post-Pre	0.16	0.78		−0.02	0.86		−0.52	0.33	
B- FP	Pre	−6.43	2.97	.79	−6.96	4.36	.43	−6.60	1.81	<.001*
	Post	−6.36	2.84		−6.64	4.61		−5.73	1.99	
	Post-Pre	0.07	1.03		0.33	1.62		0.88	0.70	
Effective maxillary length	Pre	80.93	4.16	.01*	83.92	3.32	.62	82.34	2.65	<.001*
	Post	82.13	3.99		84.04	3.36		82.97	2.71	
	Post-Pre	1.20	1.74		0.12	0.99		0.64	0.36	
Effective mandibular length	Pre	106.73	3.78	<.001*	103.86	6.74	<.001*	102.61	2.99	<.001*
	Post	107.83	3.88		104.73	6.52		104.31	2.84	
	Post-Pre	1.11	0.74		0.86	0.79		1.71	0.58	
MMP	Pre	28.45	4.75	.677	25.93	6.21	.736	26.92	4.98	.009*
	Post	28.33	4.39		26.02	6.91		27.45	5.31	
	Post-Pre	−0.12	1.15		0.10	1.14		0.53	0.67	
MP/SN	Pre	36.58	4.32	.36	36.12	6.32	.65	33.69	4.17	<.001*
	Post	36.27	4.34		36.27	6.74		34.40	4.32	
	Post-Pre	−0.31	1.32		0.15	1.27		0.71	0.39	
Gonial angle	Pre	124.59	3.60	<.001*	124.92	8.15	.53	125.58	4.79	.291
	Post	123.71	3.67		124.78	8.26		125.84	5.33	
	Post-Pre	−0.88	0.76		−0.14	0.89		0.27	0.95	
U1/PP	Pre	116.91	7.29	.014*	115.81	4.05	<.001*	115.26	3.02	<.001*
	Post	118.26	6.90		106.84	5.30		106.67	2.80	
	Post-Pre	1.35	1.96		−8.98	2.55		−8.59	3.34	
U1 to A Pog	Pre	10.64	1.64	.07*	9.38	2.08	<.001*	11.63	2.02	<.001*
	Post	11.00	1.52		6.87	1.80		8.99	1.93	
	Post-Pre	0.36	0.74		−2.51	0.99		−2.64	0.81	
U6 AP position	Pre	39.52	2.61	<.001*	42.56	4.21	<.001*	41.43	2.63	<.001*
	Post	40.70	2.68		41.04	4.66		40.22	2.52	
	Post - Pre	1.18	0.90		−1.53	1.07		−1.21	0.71	
U6 vertical position	Pre	30.16	2.36	<.001*	34.35	2.80	<.001*	32.29	2.30	<.001*
	Post	31.40	2.63		33.14	3.11		31.23	2.37	
	Post-Pre	1.24	0.86		−1.21	0.77		−1.06	0.90	
L1/MP	Pre	100.78	7.08	.15	99.81	8.17	<.001*	101.43	5.14	<.001*
	Post	101.47	7.75		108.99	6.63		108.48	5.06	
	Post-Pre	0.69	1.81		9.18	2.42		7.06	3.34	
L1 A Pog	Pre	2.20	1.48	.56	2.13	1.87	<.001*	2.33	0.77	<.001*
	Post	2.31	1.44		5.09	1.80		3.73	0.94	
	Post-Pre	0.11	0.74		2.96	0.95		1.40	0.65	
L1 vertical position	Pre	26.87	2.39	<.001*	27.41	1.83	<.001*	25.87	2.43	<.001*
	Post	27.22	2.34		25.65	1.81		24.15	2.42	
	Post-Pre	0.35	0.27		−1.76	0.64		−1.72	0.76	
L6 AP position	Pre	39.36	3.08	.036*	40.36	4.20	<.001*	39.45	3.19	<.001*
	Post	40.12	2.96		43.19	4.56		41.75	2.45	
	Post-Pre	0.76	1.31		2.83	1.31		2.30	1.87	
L6 vertical position	Pre	16.23	2.35	.004*	17.09	1.55	<.001*	18.67	1.84	<.001*
	Post	16.73	2.17		18.35	1.61		19.49	1.92	
	Post-Pre	0.50	0.58		1.26	0.52		0.82	0.25	
Angle of convexity	Pre	157.19	5.29	.245	155.62	3.42	.009*	156.50	3.00	<.001*
	Post	156.65	5.34		157.11	3.93		157.46	3.39	
	Post-Pre	−0.55	1.81		1.50	2.00		0.96	0.73	
Nasolabial angle	Pre	103.99	11.67	.011*	107.23	10.71	.166	104.73	11.43	.095
	Post	101.05	12.53		109.71	9.19		106.95	11.25	
	Post-Pre	−2.95	4.08		2.48	6.79		2.21	4.78	
Mentolabial sulcus	Pre	99.36	14.74	.067	104.81	13.17	.002*	106.43	8.59	<.001*
	Post	96.52	13.64		120.23	17.59		119.58	10.05	
	Post-Pre	-2.84	5.75		15.43	16.10		13.15	3.28	

[a] FFRD indicates Forsus alone group; SD, standard deviation.
* Significant when $P < .05$.

Table 8. Comparison of the Mean Differences (T2-T1) for the Skeletal and Dental 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	95% Confidence Interval for Mean Lower Bound	95% Confidence Interval for Mean Upper Bound	F	*P*-Value	Multiple Bonferroni Method Tests *P* (Control/Splint-FFRD)	*P* (Control/FFRD)	*P* (Splint-FFRD/FFRD)
SNA	Control	0.30	0.88	−0.18	0.77	9.35	<.001*	<.001*	NS	.014*
	Splint-FFRD	−0.88	0.51	−1.16	−0.59					
	FFRD	−0.05	0.85	−0.51	0.40					
SNB	Control	−0.07	1.05	−0.63	0.49	1.26	.293	NS	NS	NS
	Splint-FFRD	0.35	0.35	0.15	0.54					
	FFRD	0.22	0.66	−0.13	0.57					
ANB	Control	0.06	0.80	−0.37	0.48	15.21	<.001*	<.001*	NS	<.001*
	Splint-FFRD	−1.36	0.87	−1.84	−0.88					
	FFRD	−0.28	0.53	−0.56	0.00					
A-FP	Control	0.16	0.78	−0.25	0.57	3.81	.029*	.032*	NS	NS
	Splint-FFRD	−0.52	0.33	−0.70	−0.33					
	FFRD	−0.02	0.86	−0.48	0.44					
B- FP	Control	0.07	1.03	−0.48	0.62	1.85	.169	NS	NS	NS
	Splint-FFRD	0.88	0.70	0.49	1.27					
	FFRD	0.33	1.62	−0.53	1.19					
Effective maxillary length	Control	1.20	1.74	0.27	2.12	3.26	.048*	NS	.043*	NS
	Splint-FFRD	0.64	0.36	0.43	0.84					
	FFRD	0.12	0.99	−0.40	0.65					
Effective mandibular length	Control	1.10	0.74	0.71	1.50	5.72	.06	NS	NS	NS
	Splint-FFRD	1.71	0.58	1.38	2.03					
	FFRD	0.86	0.79	0.44	1.28					
MMP	Control	−0.12	1.15	−0.74	0.49	1.64	.205	NS	NS	NS
	Splint-FFRD	0.53	0.67	0.16	0.91					
	FFRD	0.10	1.14	−0.51	0.70					
MP/SN	Control	−0.31	1.32	−1.01	0.39	3.41	.042*	.037*	NS	NS
	Splint-FFRD	0.71	0.39	0.49	0.92					
	FFRD	0.15	1.27	−0.53	0.82					
Gonial angle	Control	−0.89	0.76	−1.29	−0.48	7.12	.002*	.002*	.047*	NS
	Splint-FFRD	0.27	0.95	−0.26	0.79					
	FFRD	−0.14	0.89	−0.61	0.33					
U1/PP	Control	1.35	1.96	0.31	2.39	76.89	<.001*	<.001*	<.001*	NS
	Splint-FFRD	−8.59	3.34	−10.44	−6.74					
	FFRD	−8.98	2.55	−10.34	−7.62					
U1 to A Pog	Control	0.36	0.74	−0.03	0.76	61.93	<.001*	<.001*	<.001*	NS
	Splint-FFRD	−2.64	0.81	−3.09	−2.19					
	FFRD	−2.51	0.99	−3.04	−1.98					
U6 AP position	Control	1.18	0.90	0.70	1.66	42.16	<.001*	<.001*	<.001*	NS
	Splint-FFRD	−1.21	0.71	−1.60	−0.81					
	FFRD	−1.53	1.07	−2.09	−0.96					
U6 vertical position	Control	1.24	0.86	0.78	1.69	42.05	<.001*	<.001*	<.001*	NS
	Splint-FFRD	−1.06	0.90	−1.56	−0.56					
	FFRD	−1.21	0.77	−1.62	−0.80					
L1/MP	Control	0.69	1.81	−0.28	1.66	46.63	<.001*	<.001*	<.001*	NS
	Splint-FFRD	7.06	3.34	5.20	8.91					
	FFRD	9.18	2.42	7.89	10.47					
L1 A Pog	Control	0.11	0.74	−0.28	0.51	51.55	<.001*	<.001*	<.001*	NS
	Splint-FFRD	1.40	0.65	1.03	1.76					
	FFRD	2.96	0.95	2.46	3.47					
L1 vertical position	Control	0.35	0.27	0.20	0.49	66.04	<.001*	<.001*	<.001*	NS
	Splint-FFRD	−1.72	0.76	−2.14	−1.30					
	FFRD	−1.76	0.64	−2.10	−1.42					
L6 AP position	Control	0.76	1.31	0.06	1.46	8.08	.001*	.021*	.001*	NS
	Splint-FFRD	2.30	1.87	1.26	3.33					
	FFRD	2.83	1.31	2.13	3.53					
L6 vertical position	Control	0.50	0.58	0.19	0.81	10.25	<.001*	NS	<.001*	.041*
	Splint-FFRD	0.82	0.25	0.68	0.96					
	FFRD	1.26	0.52	0.98	1.54					
Angle of convexity	Control	−0.55	1.81	−1.51	0.42	6.75	.003*	.040*	.003*	NS
	Splint-FFRD	0.96	0.73	0.56	1.36					
	FFRD	1.50	2.00	0.43	2.56					

Table 8. Continued

Measurement	Study Group	Mean Difference (T2-T1)	SD	95% Confidence Interval for Mean		F	P-Value	Multiple Bonferroni Method Tests		
				Lower Bound	Upper Bound			P (Control/Splint-FFRD)	P (Control/FFRD)	P (Splint-FFRD/FFRD)
Nasolabial angle	Control	−2.95	4.08	−5.12	−0.77	5.17	.01*	.031*	.019*	NS
	Splint-FFRD	2.21	4.78	−0.44	4.86					
	FFRD	2.48	6.79	−1.14	6.09					
Mentolabial sulcus	Control	−2.84	5.75	−5.91	0.22	15.29	<.001*	<.001*	<.001*	NS
	Splint-FFRD	13.15	3.28	11.34	14.97					
	FFRD	15.43	16.10	6.85	24.00					

[a] NS indicates nonsignificant; FFRD, Forsus alone group; and SD, standard deviation.
* Significant when $P < .05$.

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