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TREATMENT EFFECTS OF SPLINT-SUPPORTED FORSUS FATIGUE RESISTANT DEVICE WITH AND WITHOUT MINISCREW ANCHORAGE IN SKELETAL CLASS II GROWING PATIENTS, A RANDOMIZED CONTROLLED TRIAL

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ABSTRACT

Objectives: To assess the use of bimaxillary splint-supported Forsus Fatigue Resistant Device (FFRD) with and without miniscrew anchorage in treatment of skeletal Class II growing patients.

Materials and Methods: The sample comprised 26 skeletal Class II female patients. They were randomly distributed into two groups: 13 patients (11.87 ± 0.94 years) received splint-supported Forsus without miniscrews (SSF group) and 13 patients (12.02 ± 1.03 years) received splint-supported Forsus with miniscrews (SSFM group). Three-dimensional CBCT analysis was done, and the obtained data were statistically evaluated.

Results: Both groups showed significant skeletal headgear effect with reduction of SNA angle (-0.88° ± 0.51° and -1.15° ± 0.56°) in SSF and SSFM groups respectively. Lower incisors showed significant less proclination (5.1°±2.23°) and protrusion (0.8 mm ± 0.55 mm) in the SSFM group.

Conclusions: The splint-supported Forsus FRD was effective in treatment of skeletal Class II malocclusion with dentoalveolar changes and maxillary skeletal headgear effect. The use of miniscrews with the splints resulted in less lower incisors proclination.

KEYWORDS: Class II, Splint-supported, Forsus, growing, miniscrews

INTRODUCTION

Class II malocclusion contemplates one of the most frequently faced orthodontic problems [1] and it represents 20.6% of the Egyptian population at the age range between 11 and 14 years [2]. McNamara stated that mandibular retrusion or retrognathism was the most common characteristic of skeletal Class II malocclusion [3].

Forsus Fatigue Resistant Device (FFRD) (3M Unitek, Monrovia, Calif) is considered one of the

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most commonly used fixed functional appliances in the treatment of Class II malocclusion with a combination of skeletal (mainly maxillary restriction) and dentoalveolar effects [4,5]. Conventionally, the use of Forsus FRD necessitates full leveling & alignment of the arches before its use for the correction of Class II which could waste some important treatment time especially for patients with slight growth remaining.

The first intermaxillary splint-supported Forsus was the Crossbow (Xbow) appliance that allowed for immediate initiation of Class II treatment [6]. A recent study examined the effects of Forsus supported on newly designed intermaxillary splints and compared it to the conventional Forsus FRD. Splint-supported Forsus was found to be equally successful as the conventional Forsus FRD in correction of Class II malocclusion [7]. However, like other fixed functional appliances [4-9], it induced significant proclination of the mandibular incisors, limiting the skeletal effects of the appliance. Several studies have evaluated the effects of using skeletal anchorage with conventional FFRD aiming to decrease the mandibular incisors proclination during treatment [10-14].

The aim of this prospective clinical trial was to evaluate & compare the skeletal, dentoalveolar and soft tissue effects associated with the use of bimaxillary splint-supported FFRD in treatment of skeletal Class II growing patients with & without indirect miniscrew anchorage.

MATERIALS AND METHODS

This prospective randomized clinical study contained two-arm, parallel groups with a 1:1 allocation. Computer software was used to calculate the sample size based on the study by Aslan et al.[10], who compared the dentofacial effects of conventional FFRD used with and without miniscrew anchorage. When the power was set at 90%, the required sample size was found to be 11 subjects in each group. A random list was generated on (https://www.random.org/), and allocation was concealed using opaque sealed envelopes.

The participants in the two groups were recruited from the outpatient clinic of the Orthodontic Department, Faculty of Dentistry, XXXXXXX University following the same inclusion criteria (Table 1) (Figure 1 and Figure 2). Data from 13 subjects were used in each group.

TABLE (1): Eligibility Criteria of Patients included in the Study

Inclusion Criteria	Exclusion Criteria
• Females 11–14 y of age • Cervical vertebrae maturation stage 3 as detected by the lateral cephalometric radiograph • Skeletal Class II malocclusion with a deficient mandible (SNB ≤76 °) • Horizontal or Normal growth pattern (MMP ≤ 30°) • Increased overjet (minimum 5 mm) • Class II canine relationship (minimum of half unit) • Mandibular arch crowding less than 3 mm	• Systemic diseases • Extracted or congenitally missing permanent tooth/teeth • Facial asymmetry • Severe proclination or crowding requiring extractions

For every patient, full arch splints were constructed for both arches. The splints were made using 0.9 mm stainless-steel wires fitted along the labial and lingual surfaces extending between the first molars and soldered to the molar bands. Supplementary 0.7 mm stainless steel wires were adapted across the occlusal embrasures between the canine & first premolar on each side and were soldered to the labial and lingual main splint wires. For the SSFM group, the mandibular splint was modified by extending the occlusal wire labially in a gingival direction to form a hook. The wire framework was covered by clear acrylic resin extending 1-2 mm to the wires in an inciso-gingival direction and adapted to the tooth surfaces in the anterior region labially and lingually (Figure 3).

In both groups, the suitable size of the Forsus FRD was chosen using the manufacturer's instructions. The pushrods were attached onto the mandibular splint distal to the end of the acrylic framework at the canine region. In the SSFM group, the miniscrews were inserted in the same visit after mounting of the FFRD. The miniscrews employed in the study (Perfect Anchor, HUBIT Co., Ltd, Gyeonggi-do, Korea) were standard-type tapered titanium miniscrew (1.6 mm in diameter and 10 mm in length). Miniscrews were inserted at the inter-radicular space between the second premolar and first molar bilaterally at the level of the mucogingival junction in the mandible. Miniscrews were then ligated to the hooks of the mandibular splint with elastomeric chains (Memory Chain; American Orthodontics, Sheboygan, WI) applying an active force of 200 gm per side (Figure 3).

Follow-up visits were done every 4-6 weeks for every patient. During the visits, appliance activation was done when necessary and elastomeric modules for the SSFM group patients were changed.

CBCT scans were obtained for each patient in the two treatment groups with an I-CAT CBCT unit (Imaging Sciences International, Hatfield, Pa) immediately prior to the insertion of FFRD and was marked as (T1). Treatment in both groups was continued until bilateral Class I canine relationship. Afterwards, the appliances were removed and another post-treatment CBCT scans (T2) were acquired.

A standardized 3D Analysis of the CBCT scans was done using the Invivo Anatomage software version 5.2 (San Jose, CA, USA) (Table 2). The measurements were performed twice by the same observer and by different observer to identify the measurements errors and the observers were blinded.

Fig. (1): Pre-treatment photographs for a patient in the SSF group

Fig. (2): Pre-treatment photographs for a patient in the SSFM group

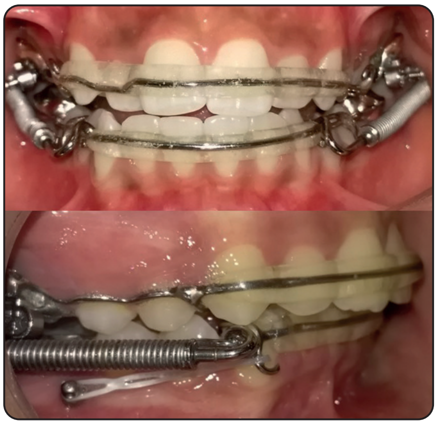

Fig. (3): Intraoral photographs of appliances used in SSF group and SSFM group

TABLE (2): Definitions of the Measurements Included 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/SN	The angle formed between the SN 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
U1 vertical position	The linear distance between the mid root of the upper central incisor to the FHP, 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

Statistical Analysis

The statistical analysis was performed by IBM SPSS Statistics Version 20 for Windows. Data were presented as mean, Standard Deviation (SD) for the preoperative and postoperative measurements as well as the mean differences between these measurements. Shapiro-Wilk test showed that the data was normally distributed. A paired t-test was used to compare the pretreatment and posttreatment measurements in the groups. Concordance correlation coefficient (CCC) was also made to identify the intra-observer and inter-observer measurements' reliability in the study.

RESULTS

Baseline Data and Treatment Duration

At baseline, chronological ages of subjects in both groups were compared, and the results showed good matching between the two groups (Table 3).

The mean treatment durations for the SSF and SSFM groups were 6.27 ± 1.02 and 7.66 ± 0.89 months, respectively, with a significant difference between the two groups (Table 4).

Measurement Error

The CCC values were in the range of 0.713 to 0.999, indicating good to excellent agreement (Table 5).

TABLE (3): Comparison Between the Mean Ages of the Study Groups (Paired t-Test) *

Group	Mean	SD	95% Confidence Interval Lower	95% Confidence Interval Upper	Mean Difference	P Value	P
SSF	11.87	0.94	-1.10	0.80	-0.153	0.738	NS
SSFM	12.02	1.03					

NS indicates nonsignificant; SSF: Splint-supported Forsus, SSFM: Splint-supported Forsus with miniscrew, SD: Standard deviation *Significant when P< .05

TABLE (4): Comparison Between the Mean treatment durations of the Study Groups (Paired t-Test)

Group	Mean	SD	95% Confidence Interval Lower	95% Confidence Interval Upper	Mean Difference	P Value	P
SSF	6.27	1.02	-2.32	-0.46	-1.392	0.00576**	S
SSFM	7.66	0.89					

S indicates significant; SSF: Splint-supported Forsus, SSFM: Splint-supported Forsus with miniscrew, SD: Standard deviation *Significant when P< .05

TABLE (5): Concordance Correlation Coefficients (CCCs) for the Intra-observer and Interobserver Reliability of the Measurements Used in the Study

Measurement	Intra-observer			Inter-observer		
	CCC	95% Confidence Interval		CCC	95% Confidence interval	
		Lower Bound	Upper Bound		Lower Bound	Upper Bound
SNA	0.941	0.723	0.996	0.974	0.755	0.998
SNB	0.919	0.609	0.995	0.968	0.733	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 Max. length	0.999	0.982	1	0.925	0.747	0.995
Effective Mand. Length	0.995	0.928	1	0.997	0.949	1
P line/MP (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/SN	0.965	0.57	0.998	0.758	0.36	0.982
U1- A Pog line	0.998	0.964	1	0.758	0.36	0.982
U1 Vertical position	0.978	0.926	1	0.99	0.954	0.999
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 vert. position	0.94	0.356	0.996	0.977	0.931	0.992
L6 vert. 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

Skeletal measurements (Tables 6, 7 and 8)

The SNA angle showed significant reduction (-0.88° ± 0.51° and -1.15° ± 0.56°) as well as posterior movement of the maxilla (-0.52 ± 0.33 mm and -0.6 ± 0.24 mm) in SSF and SSFM treatment groups, respectively. No significant differences were noted in both groups regarding the SNB, mandibular length or B-FP measurements. There was significant reduction in ANB angle in both groups (-1.36° ± 0.87° in SSF group and -1.56° + 0.74° in SSFM group). There was significant increase in MP/SN angle (0.94°± 0.23° and 1.17° ± 0.44°) for the SSF & SSFM groups respectively.

Dental and soft tissue measurements (Tables 6, 7 and 8)

The maxillary incisors in the SSF group showed significantly more retroclination than in the SSFM group as revealed by the U1/SN angle (-8.59°± 3.34° and -6.98° ± 1.55° respectively). The maxillary incisors also demonstrated a significant backward displacement relative to the A-Pog plane (-1.75 ± 0.65 mm and -1.53 ± 0.44 mm) in SSF and SSFM groups respectively with no significant difference between the two groups.

The AP position and inclination of the mandibular incisors in the SSFM group demonstrated significantly less protrusion (0.8 mm ± 0.55 mm) and proclination (5.1°±2.23°) than in the SSF group (1.40 ± 0.65 mm and 7.06°± 3.34°) with less amount of intrusion during treatment. The maxillary molars displayed a highly significant amount of distalization within SSF and SSFM groups (-1.56 ± 1.43 mm and -1.27 ± 1.33 mm, respectively) and intrusion. The mandibular molars showed a highly significant mesialization in the SSF and SSFM groups (2.99 mm ± 1.3 mm and 2.23 mm ± 1.24 mm, respectively) with significant extrusion.

Favorable soft tissue changes were noticed in both treatment groups including reduced facial convexity and flattening of the mento-labial sulcus (Figure 4 and Figure 5).

TABLE (6): Mean Values of Measurements at T1 and T2 and the Mean Difference (T2-T1) of the Skeletal, Dental and Soft Tissue Measurements in the SSF group; Paired t-Test *

Measurement	T1		T2		Mean diff.	SD	P value
	Mean	SD	Mean	SD			
SNA	82.99	2.52	82.11	2.28	-0.88	0.51	<.001*
SNB	76.61	2.21	76.41	2.13	-0.2	0.13	0.03
ANB	6.38	1.26	5.02	1.02	-1.36	0.87	<.005*
A-FP	5.86	2.29	6.38	2.24	0.52	0.33	<.001*
B-FP	3.87	2.04	2.90	1.37	-0.97	1.94	0.674
Effective Max. length	96.51	2.09	96.66	2.30	0.15	0.12	0.055
Effective Mand. length	114.1	4.06	114.31	3.90	0.30	0.20	0.063
MMP	32.10	7.50	32.65	7.86	0.55	0.58	<.001*
Gonial angle	128.22	8.02	128.62	9.19	0.40	1.78	0.66
MP/SN	34.31	4.80	35.25	4.95	0.94	0.15	<.001*
U1/SN	104.83	6.97	96.24	7.01	-8.59	3.34	<.001*
U1-APog	11.45	2.18	9.7	1.56	-1.75	0.65	<.001*
U1 vertical position	33.54	1.67	34.62	2.51	1.08	1.07	<.005*
U6 AP position	41.84	3.57	40.28	2.28	-1.56	1.43	<.002*
U6 vertical position	32.25	2.20	31.16	2.42	-1.09	0.71	<.001*
L1/MP	101.40	5.11	108.64	5.71	7.06	3.34	<.001*
L1-APog	3.82	2.06	5.32	1.67	1.4	0.65	<.001*

L1 vertical position	26.06	2.57	24.18	2.49	-1.88	0.80	<.001*
L6 AP position	41.75	5.86	44.73	4.04	2.99	1.3	<.001*
L6 vertical position	18.69	1.89	19.54	1.91	0.85	0.12	<.001*
Angle of Facial convexity	155.16	3.41	156.46	3.59	1.3	2.44	<.001*
Nasolabial angle	104.22	11.6	107.00	11.48	2.79	4.37	<.001*
Mentolabial sulcus	107.81	12.5	122.46	13.70	14.65	7.32	<.001*

SSF: Splint-supported Forsus, SSFM: Splint-supported Forsus with miniscrew, SD: Standard deviation

Significant when P< .05

TABLE (7): Mean Values of Measurements at T1 and T2 and the Mean Difference (T2-T1) of the Skeletal, Dental and Soft Tissue Measurements in the SSFM group; Paired t-Test *

Measurement	T1		T2		Mean diff.	SD	P value
	Mean	SD	Mean	SD			
SNA	83.73	1.99	82.58	1.84	-1.15	0.56	<.001*
SNB	77.55	2.23	77.21	2.00	-0.34	0.74	0.2
ANB	6.06	1.26	4.5	1.53	-1.56	0.74	<.005*
A-FP	4.54	1.53	5.14	1.34	0.6	0.24	<.001*
B-FP	4.01	2.21	3.84	1.81	-0.17	0.74	0.5
Effective Max. length	96.05	2.55	96.47	2.19	0.42	0.89	0.066
Effective Mand. length	112.87	4.03	113.52	3.31	0.65	1.05	0.076
MMP	30.25	4.98	31.09	5.35	0.83	1.08	<.005*
Gonial angle	129.78	7.09	129.73	7.38	-0.04	1.10	0.72
MP/SN	32.75	3.83	33.92	3.80	1.17	0.44	<.005*
U1/SN	105.61	6.00	98.63	5.41	-6.98	1.55	<.001*
U1-APog	11.60	2.02	10.07	1.47	-1.53	0.44	<.001*
U1 vertical position	34.00	1.41	35.29	1.67	1.29	0.53	<.001*
U6 AP position	42.28	2.68	41.02	2.08	-1.27	1.33	<.002*
U6 vertical position	32.36	2.21	31.57	1.86	-0.79	1.19	<.001*
L1/MP	100.72	4.22	105.83	4.30	5.10	2.23	<.001*
L1-APog	4.58	1.71	5.38	1.63	0.80	0.55	<.001*
L1 vertical position	25.75	1.99	24.65	2.04	-1.10	0.81	<.001*
L6 AP position	42.76	4.28	44.99	3.81	2.23	1.24	<.001*
L6 vertical position	18.91	1.63	20.49	3.14	1.58	2.18	<.001*
Angle of Facial convexity	156.26	3.41	158.16	3.59	1.9	1.44	<.005*
Nasolabial angle	106.85	10.14	109.22	9.13	2.37	1.01	<.002*
Mentolabial sulcus	105.63	17.18	118.79	15.95	13.16	2.72	<.001*

SSF: Splint-supported Forsus, SSFM: Splint-supported Forsus with miniscrew, SD: Standard deviation

Significant when P< .05

TABLE (8): Comparison of Mean Differences (T2-T1) for the Skeletal, Dental and Soft Tissue Measurements Between the Two groups; Paired t-Test *

Measurement	SSF		SSFM		Mean diff.	SD	P value
	Mean	SD	Mean	SD			
SNA	-0.88	0.51	-1.15	0.56	-0.27	0.05	0.81
SNB	-0.2	0.13	-0.34	0.34	-0.14	0.24	0.211
ANB	-1.36	0.87	-1.56	0.74	- 0.2	0.13	0.32
A-FP	0.52	0.33	0.6	0.24	0.08	0.37	0.223
B-FP	-0.97	1.94	-0.17	0.74	-0.80	0.69	0.534
Effective Max. length	0.15	0.12	0.42	0.89	0.27	0.37	0.533
Effective Mand. length	0.30	0.20	0.65	1.05	0.35	0.41	0.287
MMP	0.55	0.58	0.83	1.08	0.28	0.39	0.477
Gonial angle	0.40	1.78	-0.04	1.10	0.36	0.69	0.525
MP/SN	0.94	0.15	1.17	0.44	0.23	0.30	0.447
U1/SN	-8.59	3.34	-6.98	1.55	-1.61	1.14	<.005*
U1-APog	-1.75	0.65	-1.53	0.44	-0.22	0.45	0.635
U1 vertical position	1.08	1.07	1.29	0.53	-0.21	0.40	0.613
U6 AP position	-1.56	1.43	-1.27	1.33	-0.29	0.66	0.502
U6 vertical position	-1.09	0.71	-0.79	1.19	-0.30	0.44	0.17618
L1/MP	7.06	3.34	5.10	2.23	1.96	0.39	<.001*
L1-APog	1.4	0.65	0.80	0.55	0.65	0.30	<.005*
L1 vertical position	-1.88	0.80	-1.10	0.81	-0.78	0.37	<.005*
L6 AP position	2.99	1.3	2.23	1.24	0.76	0.78	0. 34891
L6 vertical position	0.85	0.12	1.58	2.18	-0.73	0.69	0.30592
Angle of Facial convexity	1.3	2.44	1.9	1.44	0.25	0.25	0.7600
Nasolabial angle	2.79	4.37	2.37	1.01	1.31	2.30	0.4570
Mentolabial sulcus	14.65	7.32	13.16	2.72	1.47	4.79	0.76310

SSF: Splint-supported Forsus, SSFM: Splint-supported Forsus with miniscrew, SD: Standard deviation

Significant when P< .05

Fig. (4): Post-treatment photographs for a patient in the SSF group

Fig. (5): Post-treatment photographs for a patient in the SSFM group

DISCUSSION

The use of Forsus FRD was found to be effective in treatment of the skeletal Class II malocclusion through a combination of skeletal and dentoalveolar effects [15,16] in addition to being acceptable by the patients [17]. Forsus FRD also allows easy and quick insertion by the clinician with high durability in the demanding oral environment [10] in contrast to the Herbst appliance which usually causes a higher degree of complications [18]. However, the need for full alignment and leveling of the dental arches before initiation Class II correction could result in significant delay that may compromise the skeletal effects of the appliance [19]. Also, it was noted that the amount of mandibular incisor proclination during fixed functional therapy was larger in patients treated in the post-pubertal stage [20].

Splint-supported FFRD was first introduced in literature under the name of Xbow appliance that uses the Forsus spring mounted on bimaxillary splints as a phase I appliance for correction of Class II malocclusion in the late mixed or early permanent dentition [6]. When compared to the conventional Forsus appliance connected to the arch wire and multibracket system, the Xbow corrector displayed an average reduction of around 6 months of the overall treatment duration [21].

In a recent study by Elkordy et al. the treatment effects of a newly designed splint-supported FFRD (same design used in this study) was compared to the conventional FFRD and a control group. It was found that the splint-supported Forsus was equally effective to the conventional FFRD in treatment of skeletal Class II malocclusion in growing patients with more skeletal effects in the form of significant headgear effect [7]. However, noticeable lower incisors proclination was evident in both groups.

The mean age of the patients in the SSF group was 11.87 ±0.94 years and in the SSFM group was 12.02 ± 1.03 years. When compared to other studies that evaluated the FFRD with miniscrew anchorage, the mean ages were similar to the study of Eissa et al. [12] but somewhat lower than the studies by Aslan et al.[10] and Elkordy et al.[11].

Regarding the mean treatment duration, significant difference was evident between the study groups with the SSFM group having longer treatment duration of 7.66 ± 0.89 months when compared to SSF group of 6.27 ±1.02 months. This longer duration can be attributed to the increased anchorage in the lower arch by the miniscrews thus, minimizing the lower incisor movement and therefore, a longer duration was required to produce the dentoalveolar effects.

Although the inclusion of an untreated control group of Class II patients would have been very beneficial to the study to account for the changes that occurred due to growth during the treatment duration, a decision was made not to include an untreated group. The main reason for this decision was the ethical concern of leaving patients untreated during a very critical growth phase keeping in mind that the main idea behind the current research was the earliest correction of Class II malocclusion in late growing patients.

The anteroposterior skeletal changes in both treatment groups showed significant skeletal changes with no difference between the two groups. Significant reduction of the SNA angle in both groups was noted. Similar findings were reported by Elkordy et al. [7] in their splint-supported Forsus group. The amount of maxillary retrusion (headgear effect) in this study was higher than previous studies that reported the same effect; Eissa et al. reported significant decrease in SNA angle by 0.51° and 0.79° in Forsus only group and Forsus/miniscrew group respectively [12]. Whereas Elkordy et al [11], and Aslan et al [10] revealed a decrease in SNA angle only in the Forsus/mini-screw group by 0.26° and 0.49° respectively. However, studies by Gunay et al. [22] and Oztoprak et al. [8] reported no skeletal effects of Forsus FRD on the maxilla. The higher maxillary skeletal effects reported in this study could have resulted from the earlier correction of the Class II malocclusion by the splint-supported Forsus.

In both study groups, no significant changes were noted in all the mandibular measurements. These results agree with many previous studies that recorded no significant stimulation of mandibular growth, nor significant mandibular advancement in patients treated with conventional FFRD [16,22,23], miniscrew-supported FFRD [10,11,12] or splint-supported FFRD [6,24]. Similar findings were obtained by recent systematic reviews which mentioned that Forsus FRD could not induce mandibular skeletal changes [25,26]. Significant decrease in ANB angle was seen in both groups. This change in ANB angle can be attributed to the reduction in SNA angle.

Regarding the anterior dental measurements, the maxillary incisors showed significant retroclination and retrusion in both treatment groups. These results were concurrent with Elkordy et al.[7] and Manni et al.[27] but contradicting with Aslan et al.[10], and Eissa et al.[12] who reported significant more upper incisors retroclination in the FRD/miniscrew group than the FFRD group with no mini-screw anchorage. This difference could be explained by variation in the miniscrew insertion position and the attachment method between the miniscrew and the lower arch.

The lower incisors demonstrated significantly less proclination and protrusion in the SSFM group in comparison to SSF group. This was consistent with Elkordy et al. [11] who reported an average of 9.05° in FFRD only group and 5.26° in FFRD/mini-screw group and Aslan et al. [10] who reported limited proclination of 3.6 ° in FFRD/mini-screw group and 9.3° in FFRD only group. This indicates that the use of miniscrew anchorage in the lower arch with Forsus FRD was successful in minimizing the mandibular dentoalveolar side effects. However, a study by Eissa et al.[12] concluded that the implementation of miniscrew anchorage with Forsus device did not limit the proclination of the lower incisors. This contradiction may be accredited to the smaller size of wire segment (0.016 X 0.016-inch stainless steel wire) used in their study for connecting the miniscrew to the mandibular arch, in comparison to Elkordy et al. [11] who used 0.019 X 0.025-inch stainless steel wire segment, and Aslan et al. [10] where a 0.018 X 0.025-inch stainless steel wire was used.

Regarding the soft tissue measurements, no statistically significant differences were noted between the study groups. Both groups demonstrated favorable changes in soft tissue parameters towards a better soft tissue profile. Widening of the nasolabial and mentolabial angles was significant in both groups and augmented the improvement in the patients' soft tissue profile following treatment. This was consistent with previous studies [7, 8, 13,16] and could be related to the forces acting on the maxillary arch in a distal direction.

LIMITATIONS

Absence of a control group of untreated Class II patients to account for changes due to growth during the treatment period.

CONCLUSIONS

- The use of splint-supported Forsus FRD was successful in treating patients with Class II malocclusion through a combination of skeletal (significant headgear effect) and dentoalveolar effects (retroclination of maxillary incisors and proclination of mandibular incisors). This protocol can be used in patients with limited amount of growth available or patients uncompliant with removable functional appliance.
- The addition of miniscrews to augment the anchorage in the mandibular arch resulted in less mandibular incisor proclination and protrusion.
- The soft tissue profile showed significant improvement by the FFRD treatment in most of the patients in both treatment groups.

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