Review Article

Access this article online
Quick Response Code:

Website: www.jorthodsci.org
DOI: 10.4103/jos.jos_13_24

Skeletal and dental effects of skeletally anchored forsus fatigue resistant devices during class II malocclusion treatment: A meta-analysis and systematic review

Osama Eissa, Samira Diar-Bakirly[1], Humam Saltaji[2] and Tarek El-Bialy[2]

Abstract

OBJECTIVE: To evaluate and compare the skeletal and dental treatment effects of Class II malocclusion cases using skeletally anchored Forsus (miniscrew-anchored FRD or miniplate-anchored FRD), with conventional Forsus FRD.

MATERIALS AND METHODS: Unrestricted electronic search of six databases and additional manual searches were performed up to July 2023. Randomized controlled trials having one treatment arm with skeletal anchored Forsus FRD in treatment of Class II malocclusion and another matched treatment group treated with conventional Forsus FRD were included in this review. Risk of bias assessment was performed using Cochrane's Risk of Bias Tool. No restrictions were set concerning treatment duration, or the cephalometric analysis used. Skeletal and dentoalveolar outcomes data were extracted by two authors independently.

RESULTS: Three studies using miniscrews as means of skeletal anchorage were evaluated and qualified for the final review and meta-analysis. Three other studies using miniplates were considered in the systematic review but were not qualified for a meta-analysis. The data gathered from the miniscrews anchored FRD papers included a total of 93 Class II patients (46 treated with miniscrew-anchored Forsus FRD, 47 treated with conventional Forsus FRD). The meta-analysis showed a statistically significant reduction in the SNA angle in favor of miniscrew-anchored Forsus FRD (mean difference: −0.26, CI: −0.50 to −0.02), a nonsignificant difference in the SNB (mean difference: 0.17, CI: -0.06 to 0.39), a statistically significant increase in the SN–MP angle in favor of miniscrew-anchored Forsus FRD (mean difference: 0.53, CI: 0.06–1.00)—a statistically significant reduction in the L1-MP angle in favor of miniscrew-anchored Forsus FRD (mean difference: −2.12, CI: −4.96 to −2.12). Data from miniplate-anchored FRD included 31 Class II patients treated with mini plate anchored FRD. Although meta-analysis was not applicable to these studies, lower incisor inclination was observed to be less.

CONCLUSIONS: Based on the existing evidence, the use of skeletal anchorage could not enhance forward mandibular growth. However, miniscrew-anchored Forsus FRD could minimize mandibular incisor protrusion while miniplates could even retract the mandibular incisor position with a headgear effect on the maxilla.

Keywords:

Class II malocclusion, Forsus FRD, meta-analysis, miniplate, miniscrew, systematic review

Department of Orthodontics, Faculty of Dentistry, Tanta University, Egypt, [1]Clinical Director, Global Education Dental Training Center, Dubai, UAE, [2]Department of Dentistry and Dental Hygiene, Division of Orthodontics, School of Dentistry, University of Alberta, Canada

Address for correspondence:
Dr. Osama Eissa, Department of Orthodontics, Faculty of Dentistry, Tanta University, Egypt.
E-mail: osama.ea.eissa@gmail.com

Submitted: 30-Jan-2024
Revised: 17-Jun-2024
Accepted: 14-Aug-2024
Published: 25-Nov-2024

How to cite this article: Eissa O, Diar-Bakirly S, Saltaji H, El-Bialy T. Skeletal and dental effects of skeletally anchored forsus fatigue resistant devices during Class II malocclusion treatment: A meta-analysis and systematic review. J Orthodont Sci 2024;13:54.

Introduction

Class II malocclusion is considered one of the most common orthodontic problems encountered in daily orthodontic practice. McNamara[1] in 1981 concluded that mandibular skeletal retrusion was the most common skeletal characteristic of the Class II malocclusion cases whereas only a small percentage of the cases in his study showed maxillary skeletal protrusion. Various treatment protocols have been applied for the correction of Class II malocclusion. Extraoral traction, maxillary molar distalization appliances, functional jaw orthopedic appliances, and Class II intermaxillary elastic mechanics can be used for the treatment of some mild to moderate Class II malocclusions.[1]

In orthodontic practice, patient cooperation during treatment has been a concern in the past few decades and several studies have addressed this phenomenon as one of the key factors for the success of any orthodontic treatment.[2-4] Because of this, noncompliance-based treatment approaches have also been investigated for Class II malocclusion management. Fixed Class II appliances (FCIIA) have the advantage of not depending upon patient cooperation, and they can also be used concurrently with brackets. Numerous types of fixed Class II appliances are now available for treatment of Class II malocclusion. These fixed appliances have the disadvantage of producing significant dentoalveolar side effects that limit the amount of concomitant skeletal correction.[5] A recently published systematic review assessing the treatment effects of FCIIAs concluded that these appliances were effective in the correction of Class II malocclusion mainly through dentoalveolar rather than skeletal effects.[6] Several studies have recently focused on eliminating or minimizing these undesirable dentoalveolar effects.[7-9]

The most used methods of skeletal anchorage include miniscrews[9] and miniplates.[10] Miniscrews anchored fixed functional appliances have been recently used to minimize dentoalveolar effects and promote skeletal changes. There are controversies in the literature regarding the effects of using miniscrews or miniplates in conjunction with fixed functional appliances which may be due to different treatment methodologies, study designs, type of skeletal anchorage used, or even due to the type of the appliance itself. A recent systematic review and meta-analysis evaluating the skeletally anchored Forsus FRD for correction of Class II malocclusions suggested that employing skeletal anchorage with Forsus FRD did not demonstrate superior skeletal effects; however, it effectively mitigated the proclination of the lower incisors.[11] The results of this systematic review should be interpreted with great caution as they were based on the amalgamation of outcomes from both miniplates and miniscrews anchored Forsus FRD. This blending of distinct anchorage methods introduces a potential source of heterogeneity in the results, as miniplates and miniscrews may impart divergent biomechanical forces and treatment responses. The inclusion of these different anchorage techniques may compromise the accuracy and reliability of the conclusions drawn from the meta-analysis. In contrast, our proposed research takes a deliberate and focused approach by analyzing the outcomes of studies on miniscrew-anchored Forsus Fatigue Resistant Device individually. This separation of results from those involving miniplate-anchored devices is a strategic decision aimed at fostering a more consistent and comparable methodology with the intention is to enhance the clarity of outcome interpretation within our study. The consideration of separate anchorage types in our research design aims to enhance the internal validity and scientific rigor of the study, enabling a more nuanced understanding of the skeletal and dentoalveolar effects of Forsus Fatigue Resistant Device in Class II malocclusions.

Thus, a systematic review evaluating the skeletal and dental effects of skeletally anchored FRD, taking into consideration and separating miniscrews from miniplates anchored FRD, is certainly needed to provide clinicians with the highest level of evidence.

Materials and Methods

Protocol registration

The protocol of this review has been registered in the PROSPERO database (CRD42017075460). This systematic review followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement.

Information sources and search

Six electronic databases were systematically and unrestrictedly surveyed from inception up to July 2023 including (1) Medline, (2) Cochrane Central Register of Controlled Trials, (3) Embase, (4) Lilacs, (5) Scopus, and (6) Web of Science. The search strategy had no restrictions concerning language or publication year. The bibliographies of the included trials and relevant reviews were also manually searched in the main orthodontic journals. A partial Grey literature search was also assessed through proper registers and databases including conference abstracts, and unpublished or unidentified studies. After the removal of all duplicates, articles were screened based on title and abstract. When titles and abstracts were insufficient to decide, the full text of the article was also screened. When necessary, authors were contacted for complementary data or clarifications. The search was performed by two investigators (O.E and S.D.B.). Disagreements among studies to be included were resolved by discussion between these two authors until a final consensus was reached.

Eligibility criteria

The selection criteria that were applied for the inclusion of articles in the review are shown in Table 1. A study was considered eligible when it reported on one treatment arm the use of a Forsus FRD with miniscrew anchorage or miniplate and other treatment arms with conventional Forsus FRD.

After the removal of all duplicates, articles were screened based on title and abstract. When titles and abstracts were insufficient to decide, the full text of the article was also screened.

Data collection process and data items

Data were extracted independently by two investigators (O.E and S.D.B). The collected data included: sample size, characteristics of patients, mean age, intervention, treatment duration, and skeletal and dental outcomes [Table 2]. Disagreements about extracted data were resolved by discussion between authors till a final consensus was reached.

Outcome

The primary outcomes were the mandibular forward growth and lower incisors' inclination and position. Secondary outcomes included the treatment effects of the appliance on maxillary growth, apical base relationship, vertical skeletal effects, and soft tissue changes.

Risk of bias assessment in individual studies

The Cochrane Risk of Bias Tool was used to analyze the risk of bias in each RCT study included, with the following criteria for assessment: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective outcomes reporting, and other sources of bias [Table 3]. The overall risk of bias was judged as high, low or unclear for randomized studies. Non-randomized controlled clinical trials were appraised using the criteria listed in the methodological index for nonrandomized studies (MINORS).[3]

Risk of bias assessment between studies

A summary of the certainty of conclusions and strength of the evidence was analyzed using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) approach. The quality of evidence was assessed as high, moderate, low, or very low for all outcomes.

Summary measures

We considered all outcome measurements that the investigators used to evaluate the skeletal and dentoalveolar treatment effects as primary outcomes. This includes measurement of maxillary forward (SNA, angle between anterior cranial base and A point), mandibular forward (SNB), and vertical changes as well as anteroposterior maxilla–mandibular relationship. Dentoalveolar measurements of inclination and anteroposterior positioning of maxillary and mandibular incisors were also considered.

Data synthesis

Data retrieved from articles using miniplate-anchored Forsus appliances was not eligible for a quantitative analysis. Data retrieved from articles using miniscrew-anchored Forsus FRD were pooled to provide an estimate of the effectiveness of the

Table 1: Eligibility criteria used for the study selection

Category	Inclusion Criteria	Exclusion Criteria
Participants	Growing adolescents with a Class II malocclusion due to mandibular deficiency	Patients with craniofacial syndromes and/or cleft lip palate Patients with temporomandibular joint disorders Animal studies
Intervention	Miniscrew- or miniplate-anchored Forsus FRD	Patients with Class II malocclusion treated with fixed functional appliances other than Forsus FRD, headgear, extractions, Class II elastics, orthognathic surgery, distalization, or removable functional appliances
Comparison	Conventional Forsus FRD	
Outcomes	Studies providing skeletal and dentoalveolar cephalometric measurements	Electromyographic evaluation Cost–benefit analysis Patients' acceptance
Study design	Randomized controlled clinical trials Prospective Controlled clinical trials	Retrospective clinical trials Abstracts Case reports Case-control Observational studies Cohort studies Letters to the Editor Narrative reviews Systematic reviews and meta-analyses. Laboratory studies.

Table 2: Summary of the collected data in this systematic review

Study	Sample size		Characteristics of Patients	Mean Age (years)		Intervention	Treatment Duration (months)		Outcomes		
	FMS	FRD		FMS	FRD		FMS	FRD	Measures	FMS	FRD
Eissa *et al.*[14]	15 10 F 5 M	14 8F 6M	1. Skeletal Class II malocclusion with mandibular retrognathia (ANB: 4.5 º; SNB, 76 º) 2. Normal vertical growth pattern (SN-MP angle in 25º–-35 º range 3. Minimal or no crowding in the mandibular arch (0–5 mm), 4. No extracted or missing permanent teeth (third molars excluded) 5. Undergoing circumpubertal phase of skeletal development (CVMI 2–4) 6. No medical history or systemic disease that could affect normal growth of the body or jaws.	12.5±1.12	12.7±1.0	In FRD group, Forsus were installed. In FMS group, miniscrews were inserted between lower 3 and 4 , and a piece of 0.016×0.016 SS wire was inserted between miniscrew head and vertical slot in lower Damon canine bracket.	6.42±1.04	6.06±0.76	SNA SNB ANB SN–MP ANS–ME L1–NB mm L1–NB º U1–NA mm U1–NA º Overjet	–0.79±0.5 0.5 0.17±0.59 –0.97±0.64 0.67±1.31 1.45±1.17 1.29±1.069 4.7±4.04 –2.56±1.368 –8.1±4.47 –5.55±1.45	–0.51±0.057 0.15±0.48 –0.7±0.62 0.52±1.52 1.1±1.43 1.5±0.97 6±2.96 –1.98±2.06 –6.88±4.15 –4.47±1.59
Elkordy *et al.*[15]	15 F	16 F	-Females 11–14 y of age -Skeletal Angle Class II division 1 malocclusion with a deficient mandible (SNB # 76u) -Horizontal or neutral growth pattern (MMP # 30u) -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	13.07±1.14	13.25±1.12	In Group I, conventional Forsus FRD were installed. In experimental group II, miniscrews were inserted between lower 3 and 4 , and a piece of 0.019×0.25 SS wire was inserted between miniscrew head and bonded to labial surface of canine	5.34±1.29	4.86±1.32	SNA SNB ANB SN–MP ANS–ME L1–NB mm L1–FPº U1–FP mm U1-FPº	–0.26±0.45 0.69±0.41 –0.52±0.44 0.62±0.72 1.06±0.88 0.87±0.62 5.26±2.71 –3.76±1.28 –11.17±3.51	–0.08±0.6 0.35±0.48 –0.32±0.52 –0.09±1.13 0.12±1.18 2.22±0.7 9.05±2.91 –2.32±1.33 –9.15±3.01
Aslan *et al.*[9]	16 5M 11F	17 10M 7F	-at least half Class II molar relationship, -horizontal or normal growth pattern, -minimum (up to 3 mm) or no crowding, -no extracted or missing permanent teeth (third molars were excluded), -active growth period.	13.68±1.09	14.64±1.56	In FRD group, Forsus were installed. In FMS group, miniscrews were inserted between lower 3 and 4 , and a piece of 0.018×0.25 SS wire was inserted between miniscrew head and the vertical slot in the lower canine bracket.	6.5±1.97	5.5±1.80	SNA SNB ANB SN–MP ANS–ME L1–VRL mm L1–MP º U1–VRLmm U1–HRL º Overjet	–0.49±1.01 –0.17±1 –0.31±1.19 0.71±1.27 1.81±1.54 1.09±1.76 3.61±5.07 –3.16±1.9 –8.94±5.7 –4.28±2.15	–0.08±0.5 –0.03±0.8 –0.11±0.88 0.21±1.14 1.18±2.25 2.34±1.68 9.29±3.81 –1.79±1.9 –2.68±4.43 –4.08±2.02

Contd...

Table 2: Contd...

Study	Sample size		Characteristics of Patients	Mean Age (years)		Intervention	Treatment Duration (months)		Outcomes		
	FMS	FRD		FMS	FRD		FMS	FRD	Measures	FMS	FRD
Unal *et al.*[7]	None	117 111F 66M	-Skeletal and dental Class II with ANB>4o -Overjet>5o -Normal or low angle growth pattern -Permanent dentition with no extraction or hypodontia -Minimum crowding		12.6±1.23 years	First phase: leveling and alignment until 19×25 SS archwire was inserted with TPA Second phase: two miniplates placed bilateral at the symphysis of the mandible and adjusted by miniscrews. 3–4 weeks after surgery, Forsus appliance selected and adjusted without levelling the mandibular arch.		7.2 Months	SNA SNB ANB SN–MP ANS–ME L1–VRL mm L1–MP º U1–VRLmm U1–HRL º Overjet		NA
ElKordy *et al.*[16]	16	16	- Skeletal Class II with deficient mandible and a horizontal or neutral growth pattern - Class II div 1 incisor relation with increased overjet (>5mm) - Mandibular incisor crowding less than 3 mm	12.06±0.79	12.5±0.9	- Passive TPA was soldered to the permanent first molars - 0.022 brackets bonded to both arches in the FRD group and only to the upper arch in the FMP group. Leveling and alignment until 19×25 SS wires, cinched back.			SNA SNB ANB SN–MP L1–VRL mm L1–MP º U1–VRLmm U1–HRL º Overjet	–0.79±0.96 0.97±1.06 –1.62±1.37 2.06±1.44 1.15±1.52 –1.49±4.7 1.09±1.33 –3.77±0.98	0.05±0.85 0.22±0.66 –0.28±0.53 0.15±1.27 –1.76±0.64 9.18±2.42 0.45±1.18 –2.51±0.99
Turkkahraman *et al.*[10]	15 2 F 13 M	15 8 F 7 M	- Class II molar relationship - Convex profile characterized by mandibular deficiency - Minimum 7mm overjet minimum crowding in the upper and lower arch	12.77±1.24	13.2±0.82	- 0.018 preadjusted roth brackets. - All maxillary and mandibular teeth including second molars were bonded in the Forsus only group. Only the maxillary teeth were bonded and ligated in the miniplate group. - 2 miniplates were bent and fixed using 9mm screws in the lowest hole and 7 mm screws at the top of the plate.			SNA SNB ANB SN–MP ANS–ME L1–MP º U1–PP Overjet	–0.45±0.79 0.52±1.08 –1.20±1.00 1.06±1.56 3.76±2.15 –2.86±4.83 –13.66±5.88 –4.80±2.07	–0.96±0.82 0.44±0.67 –1.41±0.60 –0.08±0.86 3.77±4.55 13.37±5.01 –10.15±5.04 –8.40±2.12

Table 3: The Cochrane Collaboration's tool for assessing risk of bias

Article	Random Sequence Generation	Allocation Concealment	Blinding of Participants and Personnel	Blinding of Outcome Assessment	Incomplete Outcome data	Selective Reporting	Other Bias
Elkordy *et al*.[15]	Low	Low	Unclear	Low	Low	Low	Unclear
Eissa *et al*.[14]	Low	Low	Low	Low	Low	Low	Unclear
Elkordy *et al*.[16]	Low	Low	Unclear	Low	Low	Low	Unclear
Aslan *et al*.[9]	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear

miniscrew-anchored FRD using a fixed-effects model, given that there were three trials eligible for quantitative analysis and considering the expected statistical homogeneity.[12] Fixed-effects models are preferred when no significant differences are expected between patients and evaluation methods. For all outcomes, the mean difference with standard deviation and 95% confidence intervals were calculated. Clinical heterogeneity was examined by assessing the characteristics of the selected trials, including similarity between interventions, patients, phase of treatment in which intervention was applied, and outcome measures. We planned to evaluate publication bias if at least 10 studies were to be included in a meta-analysis, using a funnel plot by visually assessing the extent of funnel plot asymmetry.[13] Statistical heterogeneity across the studies was tested using the I^2 statistic, with a guide for interpretation as follows: 0%–30%, not important; 30%–50%, moderate heterogeneity; 50%–100%, considerable heterogeneity. The pooled effect estimate was considered significant if *P* was <0.05. A meta-analysis software (The Cochrane Collaboration's software Review Manager, RevMan) was used to perform data analyses.

Results

Study selection

One hundred thirty- five articles were initially identified through electronic search, and three articles were obtained through manual search [Figure 1]. Seventy-four articles remained after the exclusion of duplicates, and a total of 11 articles were included based on the title abstract screening. For the miniscrews skeletal anchored FRD assessment, three articles,[9,14,15] having one treatment arm with miniscrew-anchored Forsus FRD and the other treatment arm with conventional Forsus FRD were included in the systematic review. These studies were designated as RCTs and were included in the meta-analysis. Whereas for the miniplate-anchored FRD assessment, initially 7 studies were identified using miniplate in at least one group, only 3 studies met the inclusion criteria and thus were included in the systematic review.[7,10,16] Two of these studies have compared the miniplate group to no treatment and conventional Forsus.[10,16] Whereas one of them didn't have a control group rendering the data not suitable for meta-analysis.[7]

Study characteristics

Miniscrew-anchored Forsus FRD: The three selected studies were RCTS, evaluating the skeletal and dental treatment effects of Forsus FRD indirectly anchored with miniscrews and comparing them with matched groups treated with conventional Forsus FRD. For the whole study, patients' selection criteria were similar regarding the patients' stage of skeletal growth, skeletal Class II malocclusion due to mandibular retrognathia, and normal or horizontal mandibular growth. Sample sizes ranged from 14 to 17 patients per study group, the treatment was performed during circumpubertal stages of skeletal development (age ranged from 12.5 to 14.6 years), and the duration of functional appliance treatment ranged from 4.8 to 6.5 months. All studies reported skeletal and dental treatment effects such as maxillary and mandibular anteroposterior changes, apical base relationships as well as maxillary and mandibular incisors inclination.

Miniplate-anchored Forsus FRD The three selected studies evaluated the treatment effects of miniplate-anchored Forsus FRD on the maxilla, mandible, overjet, and mandibular incisors and included one RCT. The sample size ranged from 15 to 17 per study group (age ranged from 11.27 to 14.02 years). All studies reported skeletal and dental treatment effects such as maxillary and mandibular anteroposterior changes, apical base relationships as well as maxillary and mandibular incisors inclination.

Risk of bias within studies

Assessment of the risk of bias of RCTs using the Cochrane tool is presented in Table 3 and Figure 2 with the following criteria for assessment: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective outcomes reporting, and other sources of bias. All the miniscrews included studies were all RCTs; one of them was considered to have an unclear risk of bias, whereas the other two studies presented a low risk of bias. In the miniplate studies, only one was RCT and the other two were nonrandomized clinical trials. MINORS tool to assess the risk of bias of those studies was used in Table 4. An unbiased assessment of the endpoints was not justified in the studies.

Risk of bias within studies

Because only three studies of the miniscrew-anchored Forsus FRD were included in this meta-analysis,

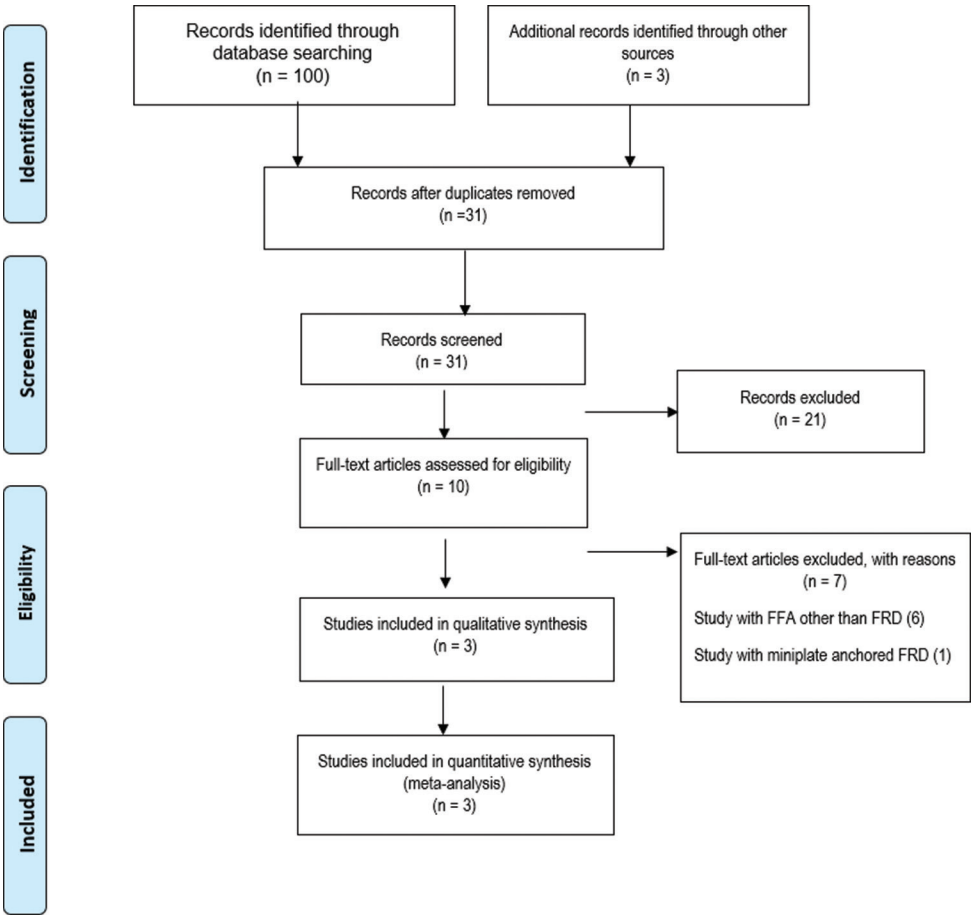

Figure 1: PRISMA flow chart for study selection process

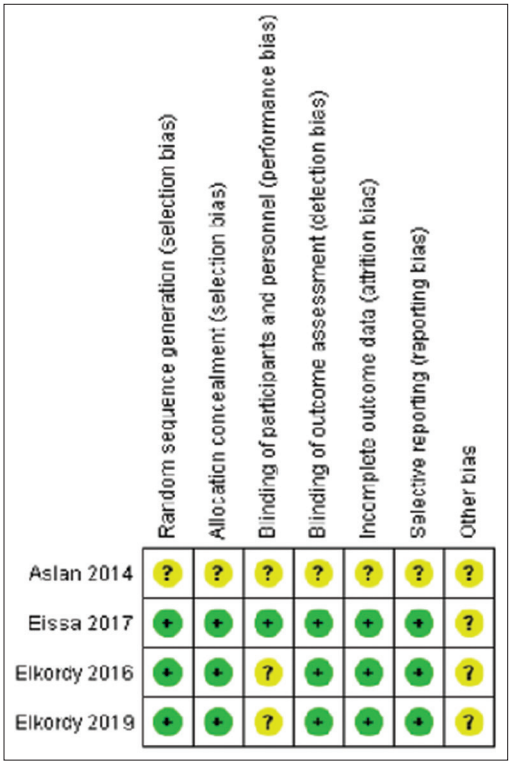

Figure 2: Risk of Bias Assessment

publication bias was not considered. Based on the GRADE recommendations, the body of evidence reporting the main outcomes ranged from moderate to high due to high I^2 values reported for outcomes measuring lower incisors' position. Consequently, the results of this analysis can be relied on to conclude clinical recommendations [Table 5].

Results of individual studies

In all three miniscrew-anchored Forsus RCTS, patients were treated with a non-extraction approach. Forsus FRD was selected and inserted into the patient's mouth following the manufacturer's instruction; the maxillary end of FRD was inserted into headgear tubes of the maxillary molars using EZ2 module clips. Pushrod was inserted onto mandibular archwire distal to canine brackets. For miniscrew-anchored Forsus FRD groups, miniscrews were inserted bilaterally between the mandibular canine and first premolar root area at the level of the mucogingival junction. A segment of stainless-steel wire was inserted between the mandibular canine and the hole in miniscrew neck to establish an indirect anchorage. Treatment effects were assessed using lateral cephalograms in two studies[4,5] and CBCTs in one study. Two studies evaluated the skeletal, dental,

and soft tissue treatment effects, whereas only one study evaluated the skeletal and dental treatment effects.

In all the miniplate studies, only the upper arch was bonded, and the teeth were figure-8 ligated. After leveling and alignment, and after reaching steel wires, an archwire size 0.016x0.022 stainless steel and larger dimensions, the miniplates were surgically fixed using surgical screws. All patients were observed at 4 weeks intervals, the miniplates were removed after attaining a Class I molar relationship. The success rate of the miniplates was reported to be 91% in two studies[7,10] and a failure rate of 13.3% in one study.[16] Skeletal and dentoalveolar changes between controls and miniplate-anchored FRD were reported in 2 studies,[10,16] whereas Unal *et al*.[7] reported the mean change before and after the use of FRD.

Table 4: The revised and validated version of MINORS for non-randomized studie

	Turkkahraman *et al*.[10]	Unal *et al*.[7]
1. A clearly stated aim:	2	2
2. Inclusion of consecutive patients	2	1
3. Prospective collection of data	2	2
4. Endpoints appropriate to the aim of the study	2	2
5. Unbiased assessment of the study endpoint	0	0
6. Follow-up period appropriate to the aim of the study	2	2
7. Loss to follow up less than 5%	1	2
8. Prospective calculation of the study size	2	2
9. An adequate control group	2	0
10. Contemporary groups	2	1
11. Baseline equivalence of groups	2	0
12. Adequate statistical analyses	2	2
Total	21	16

The items are scored 0 (not reported), 1 (reported but inadequate) or 2 (reported and adequate). The global ideal score being 16 for non-comparative studies and 24 for comparative studies

Effects of interventions

Three randomized clinical trials analyzing 93 patients and comparing miniscrew-anchored Forsus FRD versus conventional Forsus FRD were combined in a meta-analysis [Figures 3-11].

Anteroposterior skeletal measurements

The analysis showed a statistically significant reduction in the SNA angle [Figure 3] in favor of miniscrew-anchored Forsus FRD (mean difference, –0.26; $P = 0.03$; fixed-effects 95% CI, –0.50 to – 0.02; $I^2 = 0\%$; $T^2 = 0.47$). A nonsignificant difference in the SNB [Figure 4] was found between the two interventions (mean difference, 0.17; $P = 0.15$; fixed-effects 95% CI, –0.06 to 0.39; $I^2 = 25\%$; $T^2 = 2.65$). The ANB angle [Figure 5] showed a non-significant difference between the two interventions (mean difference, –0.22; $P = 0.09$; fixed-effects 95% CI, –0.48 to 0.03; $I^2 = 0\%$; $T^2 = 0.06$).

Vert-ical skeletal measurements

Our analysis showed a statistically significant increase in the SN-MP angle [Figure 6] in favor of miniscrew-anchored Forsus FRD (mean difference, 0.53; $P = 0.03$; fixed-effects 95% CI, 0.06–1.00; $I^2 = 0\%$; $T^2 = 0.80$). For the ANS-Me measurement, a statistically significant increase [Figure 7] was found in favor of miniscrew-anchored Forsus

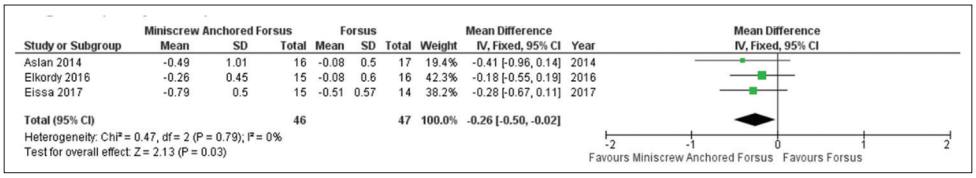

Figure 3: SNA Angle

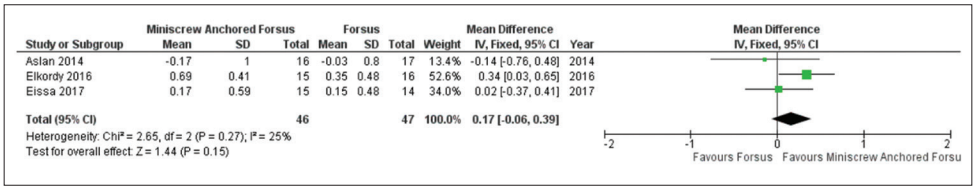

Figure 4: SNB Angle

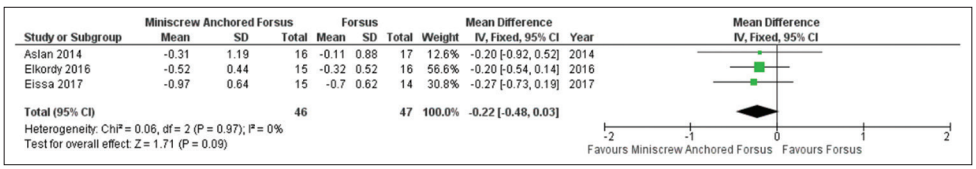

Figure 5: ANB

FRD (mean difference, 0.71; $P = 0.009$; fixed-effects 95% CI, 0.18–1.24; $I^2 = 0\%$; $T^2 = 0.94$).

Dental measurements

The results showed a statistically significant reduction in the L1–MP angle [Figure 8] in the miniscrew-anchored Forsus FRD-treated patients (mean difference, –2.12; $P < 0.0001$; fixed-effects 95% CI, –4.96 to – 2.12; $I^2 = 53\%$; $T^2 = 4.29$). For the L1–NB measurement, a statistically significant reduction [Figure 9] was found in favor of miniscrew-anchored Forsus FRD (mean difference, –1.05; $P < 0.0001$; fixed-effects 95% CI, –1.42 to –0.68; $I^2 = 70\%$; $T^2 = 6.63$). The overjet [Figure 10] showed a nonsignificant difference between the two interventions (mean difference, –0.75; $P = 0.09$; fixed-effects 95% CI, –1.62 to 0.13; $I^2 = 0\%$; $T^2 = 0.91$).

Soft tissue measurements

The L lip-E [Figure 11] plane showed a non-significant difference between the two interventions (mean difference, –0.78; $P = 0.13$; fixed-effects 95% CI, –1.62 to 0.13; $I^2 = 2\%$; $T^2 = 1.02$).

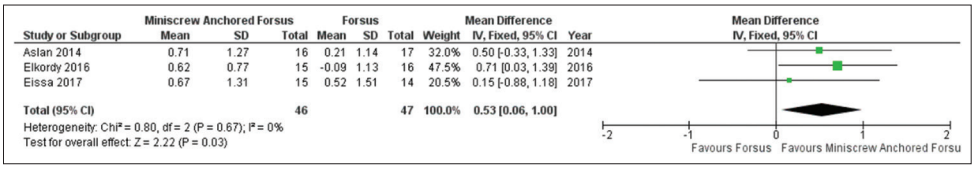

Figure 6: SN-MP Angle

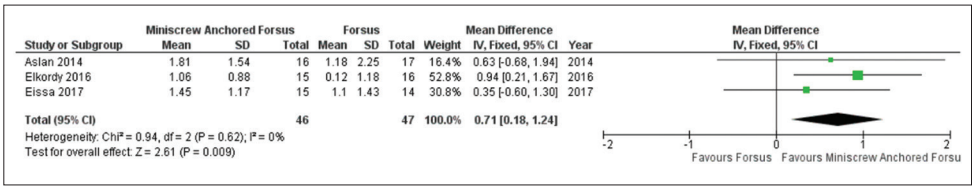

Figure 7: Lower anterior facial height (ANS-Me mm)

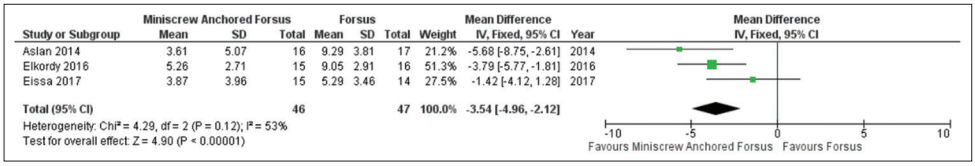

Figure 8: Lower incisor inclination (L1-MP Angle)

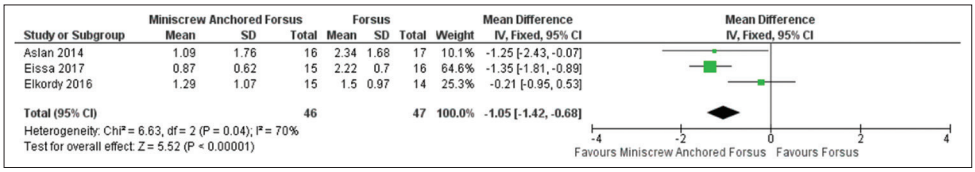

Figure 9: Lower incisor AP position (L1-NB mm)

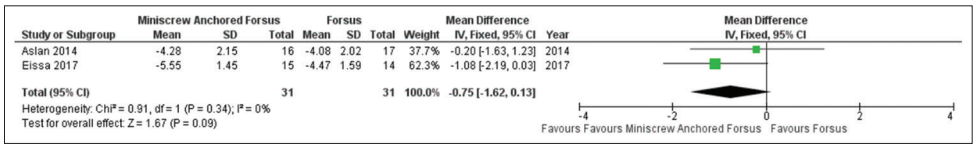

Figure 10: Overjet (mm)

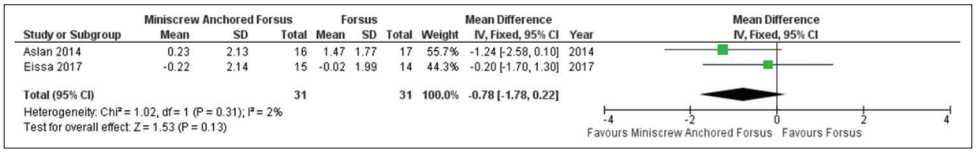

Figure 11: Lower lip to E plane

Table 5: GRADE summary of findings table for the main outcomes of the systematic review

Question: The use of miniscrew-anchored Forsus FRD compared to conventional Forsus FRD in Class II malocclusion

Patient or population: Skeletal Class II malocclusion with mandiblular deficiency

Intervention: Use of miniscrew-anvhored Forsus FRD

Comparison: Use conventional Forsus FRD

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	The use of miniscrew-anchored Forsus FRD	Conventional Forsus FRD	Relative (95% CI)	Absolute (95% CI)		
SNA												
3	Randomised trials	Not serious	Not serious	Not serious	Not serious	None	46	47	-	MD 0.26 lower (0.5 lower to 0.02 lower)	⊕⊕⊕⊕ High	Important
SNB												
3	Randomised trials	Not serious	Not serious	Not serious	Not serious	None	46	47	-	MD 0.17 higher (0.06 lower to 0.39 higher)	⊕⊕⊕⊕ High	Important
ANB												
3	Randomised trials	Not serious	Not serious	Not serious	Not serious	None	46	47	-	MD 0.22 lower (0.48 lower to 0.03 higher)	⊕⊕⊕⊕ High	Important
SN-MP												
3	Randomised trials	Not serious	Not serious	Not serious	Not serious	None	46	47	-	MD 0.53 higher (0.06 higher to 1 higher)	⊕⊕⊕⊕ High	Important
ANS-Me												
3	Randomised trials	Not serious	Not serious	Not serious	Not serious	None	46	47	-	MD 0.71 higher (0.18 higher to 1.24 higher)	⊕⊕⊕⊕ High	Important
L1-MP												
3	Randomised trials	Not serious	Serious	Not serious	Not serious	None	46	47	-	MD 3.54 lower (4.96 lower to 2.12 lower)	⊕⊕⊕◯ Moderate	Important
L1-NB (mm)												
3	Randomised trials	Not serious	Serious	Not serious	Not serious	None	46	47	-	MD 1.05 lower (1.42 lower to 0.68 lower)	⊕⊕⊕◯ Moderate	Important
Overjet												
2	Randomised trials	Not serious	Not serious	Not serious	Not serious	None	31	31	-	MD 0.75 lower (1.62 lower to 0.13 higher)	⊕⊕⊕⊕ High	Important
L lip-E plane												
2	Randomised trials	Not serious	Not serious	Not serious	Not serious	None	31	31	-	MD 0.78 lower (1.78 lower to 0.22 higher)	⊕⊕⊕⊕ High	Important

CI: Confidence interval; MD: Mean difference

Discussion

Summary of evidence

In this review, randomized clinical trials were selected to evaluate the skeletal and dental treatment effects of miniscrew-anchored Forsus FRD. The meta-analysis showed a significant decrease in SNA angle in favor of miniscrew-anchored FRD, which could be attributed to the headgear effect of the appliance due to the posteriorly directed forces on the maxilla, which could restrict maxillary forward growth. In addition to the headgear effect on the maxilla, miniplate studies reported significant retroclination of the upper incisors as well.

In the miniscrew studies, the duration of functional appliance treatment ranged from 4.8 to 6.5 months which may be not enough for mandibular growth to take place. This could explain the non-significant increase in SNB angle in all selected studies. This finding was consistent with those of other fixed functional appliances studies which reported little or no effect on mandibular growth.[5,17-19] However, a significant increase in the mandibular length had been noted in the miniplate studies, possibly because of the result of adaptation in condylar growth.[10,16] Observation for ANB angle changes indicated that the use of miniscrews as a means of skeletal anchorage could not achieve additional skeletal treatment effects. Meanwhile, in the miniplate studies, changes reported in the maxilla and mandible led to improvement in skeletal relations, consequently resulting in a significant decrease in the ANB angle[7,10,16] The vertical skeletal treatment effects, included changes in SN–MP angle and lower anterior facial height (ANS–Me), showed a statistically significant increase in favor of miniscrew-anchored Forsus FRD. A plausible explanation of this skeletal treatment effect may be attributed to the downward and forward direction of the forces applied by the appliance that could result in an enhanced vertical condylar growth and consequently, an increase in the lower facial height.[10] Similarly, SN–MP angle and lower anterior facial height (ANS-Me), showed a statistically significant increase in miniplate-anchored Forsus studies as well. In this case, the point of force application is believed to be the reason behind this effect since it is more anterior to the mandibular center of resistance.[16]

The effect of the appliance on lower incisors' inclination and position was reported in changes in L1-MP angle and L1-NB measurement. The results showed a statistically significant reduction in both measurements in favor of miniscrew-anchored Forsus FRD which indicates that miniscrews could minimize mandibular incisors protrusion. In the conventional Forsus FRD, the appliance resulted in a significant mandibular incisors protrusion which led to early correction of the overjet and consequently limited skeletal correction of the malocclusion. It was suggested that the adjunctive use of miniscrews with Forsus FRD should be significantly favored over the conventional FRD. GRADE assessment tool results show that there is high-quality evidence to support that conclusion. Noteworthy is the effect reported by miniplate-anchored Forsus studies, where the lower incisors inclination was not only controlled but rather significant retroclination was observed. This effect of miniplate-anchored Forsus is desirable and demanded in situations where mandibular incisors are proclined with diastema to start with.

Limitation

The result of this systematic review should be interpreted with caution due to the limited number of eligible studies included in the meta-analysis. Additionally, one study has an unclear risk of bias. Another limitation to the present study was a failure to blind the patients and the clinicians which represented a common risk of bias. However, complete blinding in such clinical trials cannot be achieved in real clinical scenarios. Finally, pooling results from a CBCT study with two other studies using lateral cephalograms might be problematic. However, in the present study, similar measurements were used to assess the same outcomes, and the reliability of combining both data was reasonable, which precluded the calculation of standardized mean difference.

Conclusions

Based on the existing evidence, the following can be concluded regarding the effectiveness of the use of miniscrews as a means of anchorage with Forsus FRD

- Miniscrew-anchored, miniplate-anchored and conventional Forsus FRD could effectively correct Class II malocclusion mainly through dentoalveolar changes.
- The use of miniscrews as a means of anchorage with Forsus FRD could not enhance forward mandibular growth which could be attributed to the short treatment duration of FRD which may be not enough for mandibular growth to take place. Nevertheless, the use of miniplates as a means of anchorage would lead to a better mandibular positional change in addition to a considerable increase in mandibular length.
- Miniscrew-anchored Forsus FRD has a headgear effect on the maxilla; meanwhile, miniplate-anchored Forsus FRD cause retroclination of maxillary incisors as well.
- Miniscrew-anchored Forsus FRD could minimize mandibular incisors inclination whereas miniplate-anchored Forsus FRD could cause their retroclination.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

References

1. McNamara JA. Components of Class II malocclusion in children 8–10 years of age. Angle Orthod 1981;51:177-202.
2. Bos A, Hoogstraten J, Prahl-Andersen B. On the use of personality characteristics in predicting compliance in orthodontic practice. Am J Orthod Dentofacial Orthop 2003;123:568-70.
3. Story RI. Psychological issues in orthodontic practice. Am J Orthod Dentofacial Orthop 1966;52:584-98.
4. El-Mangoury NH. Orthodontic cooperation. Am J Orthod 1981;80:604-22.
5. Jones G, Buschang PH, Kim KB, Oliver DR. Class II non-extraction patients treated with the Forsus Fatigue Resistant Device versus intermaxillary elastics. Angle Orthod 2008;78:332-8.
6. Koretsi V, Zymperdikas VF, Papageorgiou SN, Papadopoulos MA. Treatment effects of removable functional appliances in patients with Class II malocclusion: A systematic review and meta-analysis. Eur J Orthod 2015;37:418-34.
7. Unal T, Celikoglu M, Candirli C. Evaluation of the effects of skeletal anchoraged Forsus FRD using miniplates inserted on mandibular symphysis: A new approach for the treatment of Class II malocclusion. Angle Orthod 2015;85:413-9.
8. Celikoglu M, Buyuk SK, Ekizer A, Unal T. Treatment effects of skeletally anchored Forsus FRD EZ and Herbst appliances: A retrospective clinical study. Angle Orthod 2016;86:306-14.
9. Aslan BI, Kucukkaraca E, Turkoz C, Dincer M. Treatment effects of the Forsus Fatigue Resistant Device used with miniscrew anchorage. Angle Orthod 2014;84:76-87.
10. Turkkahraman H, Eliacik SK, Findik Y. Effects of miniplate anchored and conventional Forsus Fatigue Resistant Devices in the treatment of Class II malocclusion. Angle Orthod 2016;86:1026-32.
11. Arvind *P* TR, Jain RK. Skeletally anchored forsus fatigue resistant device for correction of Class II malocclusions-A systematic review and meta-analysis. Orthod Craniofac Res 2021;24:52-61.
12. Higgins JPT, Thomas J, Chandler J, Cumpston M, Li T, Page MJ, Welch VA. Cochrane Handbook for Systematic Reviews of Interventions. John Wiley and Sons; 2019.
13. Sterne JA, Egger M. Funnel plots for detecting bias in meta-analysis: Guidelines on choice of axis. J Clin Epidemiol 2001;54:1046-55.
14. Eissa O, El-Shennawy M, Gaballah S, El-Meehy G, El Bialy T. Treatment outcomes of Class II malocclusion cases treated with miniscrew-anchored Forsus Fatigue Resistant Device: A randomized controlled trial. Angle Orthod 2017;87:824-33.
15. Elkordy SA, Abouelezz AM, Fayed MMS, Attia KH, Ishaq RAR, Mostafa YA. Three-dimensional effects of the mini-implant-anchored Forsus Fatigue Resistant Device: A randomized controlled trial. Angle Orthod 2016;86:292-305.
16. Elkordy SA, Abouelezz AM, Fayed M, Aboulfotouh MH, Mostafa YA. Evaluation of the miniplate-anchored Forsus Fatigue Resistant Device in skeletal Class II growing subjects: A randomized controlled trial. Angle Orthod 2019;89:391-403.
17. Cacciatore G, Ghislanzoni LTH, Alvetro L, Giuntini V, Franchi L. Treatment and posttreatment effects induced by the Forsus appliance: A controlled clinical study. Angle Orthod 2014;84:1010-7.
18. Oztoprak MO, Nalbantgil D, Uyanlar A, Arun T. A cephalometric comparative study of Class II correction with Sabbagh Universal Spring (SUS (2)) and Forsus FRD appliances. Eur J Dent 2012;6:302-10.
19. Franchi L, Alvetro L, Giuntini V, Masucci C, Defraia E, Baccetti T. Effectiveness of comprehensive fixed appliance treatment used with the Forsus Fatigue Resistant Device in Class II patients. Angle Orthod 2011;81:678-83.