Mandibular effects of temporary anchorage devices in Class II patients treated with Forsus Fatigue Resistant Devices: A systematic review

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Objective: To determine whether temporary anchorage devices (TADs) could enhance the mandibular effects of Forsus Fatigue Resistant Devices (FFRD) in growing patients presenting with a Class II malocclusion.
Materials and methods: Without language restriction, electronic and manual searches were conducted through databases and relevant journals until the 20th February, 2020. Studies comparing the therapeutic effects in Class II patients treated with TAD-anchored FFRD and patients receiving conventional FFRD were considered eligible. Two reviewers independently conducted the study inclusion, data extraction and risk of bias assessment following Cochrane guidelines. The outcomes were qualitatively synthesised and the level of evidence was evaluated using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) tool.
Results: Six studies meeting the selection criteria were identified. All except one reported that a greater reduction in the proclination of the mandibular incisors was achieved in TAD-anchored groups compared with the conventionally-treated groups. Controversial results were found in the skeletal and soft tissue descriptions of positional change. The evidence quality varied from very low to moderate.
Conclusion: Moderate-quality evidence suggests that TADs are beneficial in reducing the proclination of the mandibular incisors caused by FFRD in Class II patients. Controversies related to the effects on mandibular growth and soft tissue positional change remain. There is a trend that miniplates may enhance the mandibular skeletal effects of FFRD better than miniscrews but further investigation is indicated.
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Introduction

An Angle Class II malocclusion is a common maxillofacial deformity whose prevalence is estimated to range from 7.9% to 42.86% (20.9% on average) in different populations.[1] Rather than maxillary protrusion, mandibular retrusion is reported to be the dominating aetiological factor of a Class II malocclusion and, as a result, there is a significant impact on a patient's appearance as well as oral function.[2,3] It has been suggested that orthodontic treatments are efficient for most patients during their growth spurt, especially by stimulating mandibular growth by forward positioning of the mandible.[4]

As a widely used orthodontic device, fixed functional appliances (FFA) have been employed for mandibular advancement since 1905.[5,6] Different from removable functional appliances, FFA may be applied simultaneously with fixed appliances and make treatment effects less reliant on compliance.[7] Initially introduced as a hybrid FFA in 2001, the Forsus Fatigue Resistant Device (FFRD) (3M Unitek Corp, CA, USA) is a three-piece, semi-rigid telescoping system that overcomes the breakage problems associated with other devices.[8,9] The appliance is attached bilaterally from a headgear tube on the maxillary molar to the arch wire distal to mandibular canine.[10] Through a coaxial spring and pushrod incorporated in the FFRD, continuous orthopaedic forces are applied to correct mild mandibular retrusion.[11] Despite the confirmation of several benefits of a FFRD by previous investigations, an anchorage loss problem associated with mandibular incisor proclination remains unsolved, which affects the skeletal correction of the Class II malocclusion.[12] To minimise this shortcoming, multiple protocols have been adopted, which include adding negative torque to the anterior region of an arch wire, using rectangular arch wires of greater size or ligating mandibular teeth in a figure-8 pattern. However, no clinical modification has been shown to be totally effective.[13,14]

For their remarkable stability in anchorage enhancement, temporary anchorage devices (TADs) have recently been used as a support for FFRD. Several publications have demonstrated that the proclination of the mandibular incisors are efficiently diminished by the assistance of TADs and, consequently, the skeletal effects of FFRD are reinforced in Class II patients.[15-18] However, controversies still remain, making a critical systematic review necessary. Therefore, the primary objective of the present study was to evaluate if TADs could enhance the mandibular skeletal, dento-alveolar and soft tissue effects of a FFRD in growing patients presenting with a Class II malocclusion. It was expected that this information might be helpful when deciding whether to use TADs for specific purposes in appropriate patients.

Materials and methods

The present systematic review was conducted according to the Cochrane Handbook for Systematic Reviews of Interventions and reported following the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) checklist.[19,20] Two reviewers independently performed the literature search, study inclusion, data extraction and risk of bias assessment. Any dispute was discussed with a third counsellor.

Search strategy

An electronic search, without language restriction, was undertaken on the 20th February, 2020 in the following databases: PubMed, Embase, Cochrane Central Register of Controlled Trials (CENTRAL), System for Information on Grey Literature in Europe (SIGLE), ProQuest, Scopus, Web of Science. Details about the search method are presented in Table I. A complementary manual search was performed in relevant journals, including *The Angle Orthodontist*, the *American Journal of Orthodontics and Dentofacial Orthopedics*, the *Korean Journal of Orthodontics*, the *European Journal of Orthodontics* and the *Journal of Orthodontics*.

Eligibility criteria

Trials meeting the following criteria were determined as eligible: (1) Participants: Angle Class II maloc-clusion patients in active growth; (2) Intervention and controlled protocol: comprehensive orthodontic treatments using a FFRD with and without TADs (miniscrews, mini-implants or miniplates);

Table I. Search strategies for electronic database.

Step	PubMed	Embase, Scopus, WOS	CENTRAL, SIGLE, ProQuest
1	Fatigue Resistant Device* OR FRD OR Forsus	Fatigue Resistant Device* OR FRD OR Forsus	Forsus
2	Orthodontic Anchorage Procedures [MESH] OR miniscrew OR miniplate OR anchor* OR mini-implant* OR implant* OR TAD OR skeletal anchor*	Miniscrew OR miniplate OR anchor* OR mini-implant* OR implant* OR TAD OR skeletal anchor*	
3	1 AND 2	1 AND 2	

(3) Outcomes: orthodontically induced skeletal, dento-alveolar and/or soft tissue changes; (4) Study design: randomised controlled trials (RCT) or prospective clinical controlled trials (CCT).

Data extraction

After eligibility screening and inclusion, a customised form was employed for data extraction. Relevant information was collected, including the first author name, publication time, study design, participants' characteristics, grouping detail, surgical procedure, treatment protocol, measurement modality, sample loss and outcomes. The study authors were contacted for confirmation whenever necessary.

Risk of bias assessment

The bias risk of included RCTs was evaluated using Cochrane Collaboration's Risk of Bias tool, with the following seven domains taken into consideration: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting and other bias. For each domain, the risk of bias was judged as high, unclear, or low. Overall, the included RCTs were categorised as low risk (if all domains were assessed as low risk), unclear risk (if domains assessed as unclear risk ≥1), or high risk (if domains assessed as high risk ≥1).[19]

In addition, the evaluation of non-RCTs was conducted using the Newcastle-Ottawa Scale, identifying high quality choices with a 'star' based on three items: selection (four stars at most), comparability (two stars at most) and outcome (three stars at most). Generally, a non-RCT would be categorised as high quality for seven to eight stars, fair quality for five to six stars or poor quality for fewer stars.[21]

Data synthesis

The clinical heterogeneity and the statistical heterogeneity were considered across the studies. A meta-analysis was planned when clinical and statistical homogeneity were sufficient, otherwise the results would be summarised qualitatively. Review Manager 5.3 (Nordic Cochrane Centre, Cochrane Collaboration, Copenhagen, Denmark) was employed for the conduction of the meta-analysis. Outcomes, including data changes of angle, length and distance, were statistically pooled as continuous variables and adopted as effect measurements. A P value of 0.05 was considered as the threshold for statistical significance.

Quality of evidence

The overall quality of evidence was evaluated according to the risk of bias, inconsistency, indirectness, imprecision and other considered factors across the included studies, following the Grading of Recommendations Assessment, Development and Evaluation (GRADE) guidance.[22]

Results

Study selection

The electronic database search initially yielded 762 articles, with no additional studies identified through the manual search. After the removal of duplicates, titles and abstracts of 588 papers were subsequently screened. Of these, full texts of the remaining 15 studies were obtained and evaluated according to the eligibility criteria. Finally, six studies qualified for inclusion. Details are presented in Figure 1.

Study characteristics

Of the six included studies, four[23-26] were regarded as RCTs and the other two[27,28] were CCTs. In total, 161 circumpubertal patients undergoing comprehensive orthodontic treatment were involved, of which 85 participants were treated with a TAD-anchored FFRD and 86 subjects received conventional FFRD. Five studies[24-28] only assessed patients presenting with a Class II division 1 malocclusion, while the study of Aslan et al.[23] recruited seven division 2 patients (three in a TAD-anchored group and four in a conventional group) as well as 26 division 1 patients. The average treatment duration of the trials ranged from 4.86 to 10.45 months. Miniscrews were the predominant TAD device employed in three RCTs as indirect anchorage and miniplates were used in one RCT and two CCTs as direct anchorage. A CBCT and lateral cephalogram were used to measure the outcomes in three studies. For the outcomes measured, skeletal and dento-alveolar changes were reported in all six studies, while soft tissue changes were only reported in three.[23,24,27] General information and the intervention details related to the research are summarised in Table II and Table III. In addition, since some of

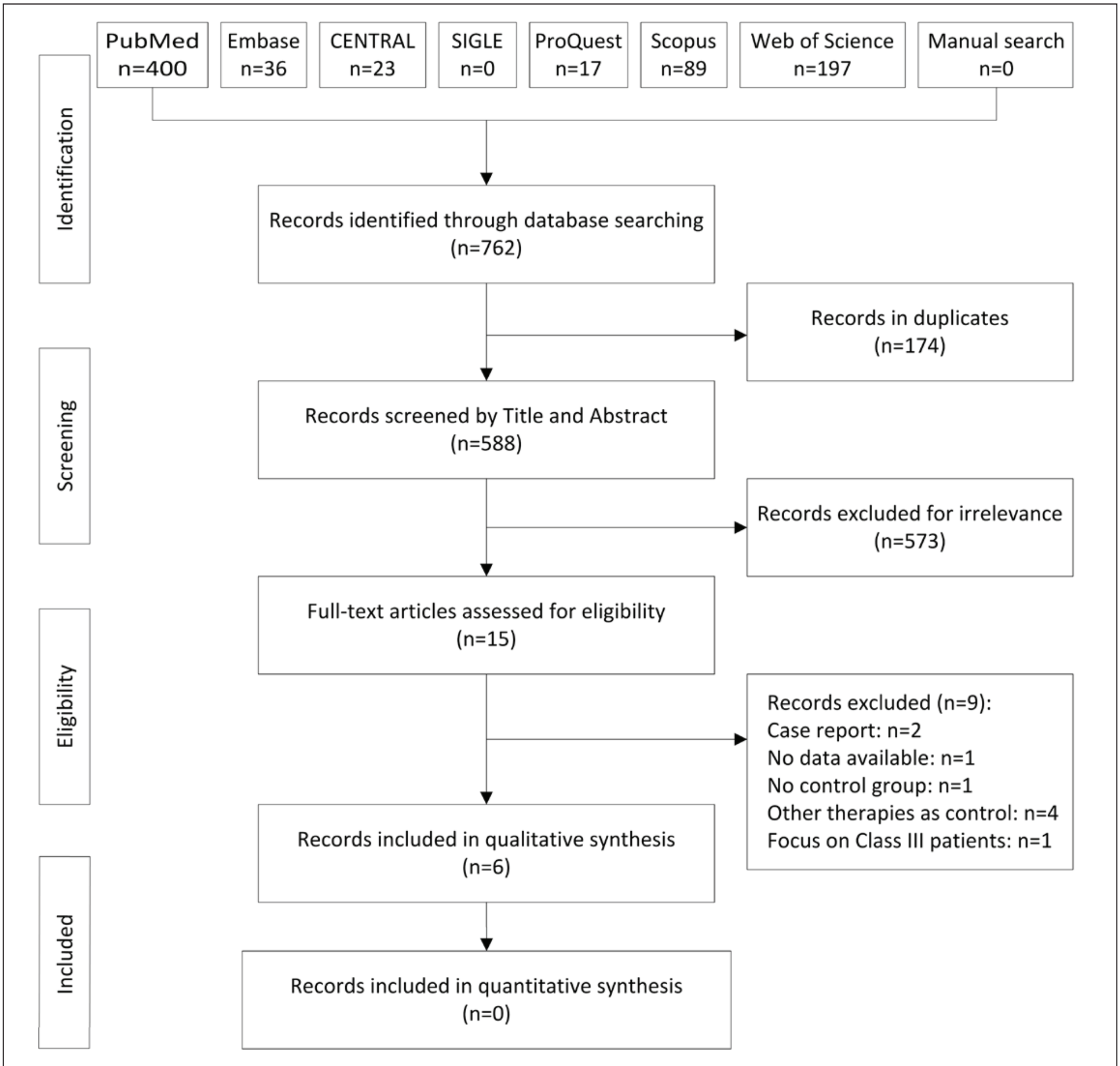

Figure 1. PRISMA flow diagram of study inclusion.

the treatment procedure details were not specifically described in the publication of Gandedkar et al.,[28] confirmation was sought from the researchers but a response was not available.

Risk of bias assessment

The risk of bias assessment for RCTs is presented in Figure 2. Of the four RCTs, two studies[25,26] were evaluated as low risk while the other two[23,24] were deemed an unclear risk of bias. The study of Aslan et al.[23] was assessed as an unclear risk in the domain of selection bias and detection bias, since the specific methods of random sequence generation, allocation concealment and blinding of outcome assessment could not be determined. Meanwhile, the study by Eissa et al.[24] was assessed to have an attrition bias because one sample was lost in the conventional group even though detailed information was reported. Although blinding of participants and personnel in the trials was impossible since the TADs were obviously identified during treatment, the deficiency may not impact the therapeutic outcomes because the surgical and orthodontic procedures were strictly performed

Table II. General information about included studies.

Study ID	Study design	Patients characteristics	Grouping	Intervention protocol	Sample loss	Measurement modality	Outcomes reported
Aslan et al., 2014 (23)	RCT	n=33, M15:F18 Angle Class II (26 division 1, 7 division 2)	E: n=16, M5:F11, age:13.68±1.09y C: n=17, M10:F7, age:14.64±1.56y	E: FFRD+Miniscrew C: FFRD	None	Lateral Cephalogram *T1: Before FFRD insertion (16*22 stainless-steel wires engaged)* *T2: After Class I molar relationship was achieved*	Skeletal, dento-alveolar, soft tissue
Elkordy et al., 2016 (25)	RCT	n=31, M0:F31 Angle Class II division 1	E: n=15, M0:F15, age:13.07±1.41y C: n=16, M0:F16, age:13.45±1.12y	E: FFRD+Mini-implant C: FFRD	None	CBCT *T1: Before FFRD insertion (19*25 stainless-steel wires engaged)* *T2: After an edge-to-edge incisor relationship was achieved*	Skeletal, dento-alveolar
Turkkahraman et al., 2016 (27)	CCT	n=30, M20:F10 Angle Class II division 1	E: n=15, M13:F2, age:12.77±1.24y C: n=15, M7:F8, age:13.26±0.82y	E: FFRD+Miniplate C: FFRD	None	Lateral Cephalogram *T1: Before FFRD insertion (16*22 stainless-steel wires engaged)* *T2: Class I molar relationship and overjet elimination achievement*	Skeletal, dento-alveolar, soft tissue
Eissa et al.,2017 (24)	RCT	n=30, M11:F19 Angle Class II division 1*	E: n=15, M5:F10, age:12.53±1.12y C: n=15, M6:F9, age:12.76±1.00y*	E: FFRD+Miniscrew C: FFRD	1 sample lost in the FFRD group	Lateral Cephalogram *T1: Before FFRD insertion (19*25 stainless-steel wires engaged)* *T2: Class I or overcorrected Class I canine and molar relationship achievement*	Skeletal, dento-alveolar, soft tissue
Elkordy et al.,2019 (26)	RCT	n=32, M0:F32 (allocated, 30 analysed) Angle Class II division 1	E: n=16, M0:F16, age:12.5±0.9y C: n=16, M0:F16, age:12.1±0.9y	E: FFRD+Miniplate C: FFRD	Both groups have 1 sample lost	CBCT *T1: Before FFRD insertion (19*25 stainless-steel wire engaged)* *T2: After an edge-to-edge incisor relationship was achieved or 10 months*	Skeletal, dento-alveolar
Gandedkar et al.,2019 (28)	CCT	n=16, M0:F16 Angle Class II division 1	E: n=8, M0:F8, age: 12.96±0.38y C: n=8, M0:F8, age: 13.11±0.38y	E: FFRD+Miniplate C: FFRD	None	CBCT *T0: Pre-treatment* *T1: Class I molar relationship achievement (After removal of FFRD)* *T2: One-year post-treatment*	Skeletal, dento-alveola, TMJ

E indicates TAD-anchored FFRD group; C indicates conventional FFRD group; M indicates Male patients; F indicates Female patients.

*15 patients were recruited but 14 patients were analysed because one sample discontinued the treatment in the conventional FFRD group.

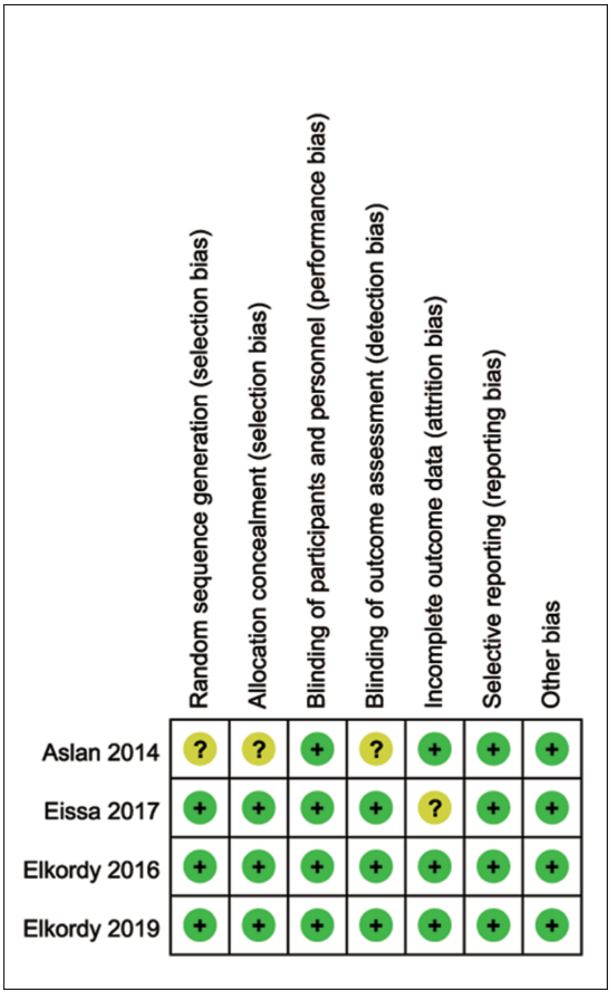

Figure 2. Risk of bias summary for RCTs.

as developed in all trials. Therefore, the performance bias in enrolled studies was judged as low by the reviewers.[19]

The risk of bias assessment for CCTs is summarised in Table IV. Eight stars were assigned to the study by Turkkahraman et al.,[27] which was assessed as high quality. Six stars were given to the study by Gandedkar et al.;[28] however, the study was assessed as poor quality by reviewers because of the lack of key information.

Effects of interventions

Meta-analyses could not be justified due to the great clinical heterogeneity across the included trials. Therefore, the outcomes of skeletal, dento-alveolar and soft tissue changes were systematically summarised instead. The definitions of cephalometric values are presented in Table V.

Mandibular skeletal effects

All the included studies reported mandibular skeletal changes. In reporting mandibular length, three common cephalometric values were used for measurement. Co-Gn was used in five studies[24-28] and Ar-Pog was used in one study.[23] Furthermore, Go-Pog was also mostly used in the study of Gandedkar et al.[28] except for Co-Gn. Three RCTs[23-25] using miniscrews found no significant difference between TAD-anchored and conventional groups. Similar findings were reported in the CCT of Turkkahraman et al.,[27] which indicated that the increase achieved in the miniplate-anchored group was not statistically significant. Conversely, Elkordy et al.[26] showed that more mandibular growth occurred with the assistance of a miniplate (Co-Gn change: 4.05 ± 0.78 versus 0.86 ± 0.79 mm, $P < 0.001$), which was consistent with the results of Gandedkar et al. (Co-Gn change: 5.5 ± 1.06 versus 3.12 ± 0.64, $P < 0.001$; Go-Pog change: 2.75 ± 1.1 versus 1.31 ± 0.37, $P = 0.011$).[28]

Mandibular rotation was measured by MP/SN in the six studies. In addition, GoMe/FH was also used by Gandedkar et al.[28] Three RCTs[23-25] employing miniscrews and one CCT[28] employing miniplates reported no statistically significant difference between groups. In contrast, two studies employing miniplates showed contrary results. Elkordy et al.[26] carried out a high-quality RCT and suggested that more backward rotation of the mandible was achieved in the TAD-anchored group compared with the conventional group (MP/SN change: 2.06 ± 1.44 versus 0.15 ± 1.27 °, $P < 0.001$), in agreement with the findings of Turkkahraman et al. (MP/SN change: 1.06 ± 1.56 versus -0.08 ± 0.86°, $P = 0.019$).[27]

Lower incisors inclination

Three cephalometric values, L1/MP, L1/NB and L1/FP were respectively used to measure the inclination change of the lower incisors in the enrolled studies.

Five studies, including three trials using miniplates and two trials employing miniscrews, demonstrated statistically significant intergroup differences.[23,25-28] Aslan et al.[23] reported that a significantly smaller increase in the proclination of lower incisors was found in the miniscew-anchored group compared with the conventional group (L1/MP change: 3.61 ± 5.07 versus 9.29 ± 3.81°, $P < 0.001$). Turkkahrman et al.[27] reported that significant L1 retroclination was

Table III. Intervention details of included studies.

Study ID	Brackets	Bonding protocol	TAD clinical protocol	Pushrod insertion site	Additional control
Aslan et al., 2014 (23)	Roth Slot size: 0.018-inch	E: Both arches (0.018*0.018-inch vertical slot brackets were bonded on lower canines) C: Both arches	Indirect anchorage *One 1.5*8mm miniscrew(Spider, Fla) was inserted between lower canine and first premolar on each side;* *The miniscrew was connected to the vertical slot of lower canine by a 0.018*0.025 SS wire segment.*	E: Mandibular archwires distal to canines C: Mandibular archwires distal to canines	Not mentioned
Elkordy et al., 2016 (25)	MBT (3M) Slot size: 0.022-inch	E: Both arches C: Both arches	Indirect anchorage *One 1.6*10 mm mini-implant (3M Unitek) was inserted between lower canine and first premolar on each side;* *The mini-implant was connected to the labial surface of lower canine by a 0.019*0.025 SS wire segment.*	E: Mandibular archwires distal to canines C: Mandibular archwires distal to canines	TPA: Cemented to upper first molars
Turkkahraman et al., 2016 (27)	Roth Slot size: 0.018-inch	E: Maxilla only C: Both arches	Direct anchorage Biforous miniplate was fixed on the *mandible with head perforating at the canine region*	E: The miniplate heads C: Mandibular archwires distal to canines	Not mentioned
Eissa et al., 2017 (24)	MBT (Ormco) Slot size: 0.022-inch	E: Both arches (Damon 3MX brackets with 0.018*0.018-inch vertical slot were bonded on lower canines) C: Both arches	Indirect anchorage *One 1.6*10 mm miniscrew (MCT, Korea) was inserted between lower canine and first premolar on each side;* *The miniscrew was connected to the vertical slot of lower canine by a 0.016*0.016 SS wire segment.*	E: Mandibular archwires distal to canines C: Mandibular archwires distal to canines	TPA: Cemented to upper first molars
Elkordy et al.,2019 (26)	MBT (3M) Slot size: 0.022-inch	E: Maxilla only C: Both arches	Direct anchorage *Two Y shaped miniplate (Stryker, Germany) were fixed on the mandibular region between lower canines with head perforating at the canine region;*	E: The miniplate heads C: Mandibular archwires distal to canines	TPA: Cemented to upper first molars
Gandedkar et al., 2019 (28)	Not specific* Slot size: 0.022-inch	E: Both arches C: Both arches	Direct anchorage *Two triangular miniplate (S.K. Surgical, India) were fixed in the anterior region of mandible with head perforating at the canine region*****	E: The miniplate heads C: Mandibular archwires distal to canines***	TPA: Cemented to upper first molars

E indicates TAD-anchored FFRD group; C indicates conventional FFRD group

*The type and brand of brackets were not specifically mentioned. Based on the pictures provided, the brackets used in the experimental group might be conventional brackets while those used in the controlled group might be SmartClip (3M) self-ligated brackets.

** Head perforating region was not specifically mentioned. Based on the pictures provided, it might perforate at the canine region.

*** The detailed site was not specifically mentioned. Based on the pictures provided, it might be distal to canine.

Table IV. Risk of bias assessment for CCTs following Newcastle-Ottawa Scale.

	Selection (maximum 4 stars)	Comparability (maximum 2 stars)	Outcome (maximum 3 stars)	Total score (maximum 9 stars)
Turkkahraman et al., 2016 (27)	4	1	3	8
Gandedkar et al., 2019 (28)	3	1	2	6

evident in the miniplate-anchored group compared with the L1 proclination of conventional group (L1/MP change: -2.86 ± 4.83 versus 13.37 ± 5.01°, $P < 0.001$). Elkordy et al.[26] shared the same findings in their report (L1/MP change: -1.49 ± 4.70 versus 9.17 ± 2.42°, $P < 0.001$). Gandedkar et al.[28] measured L1 inclination via L1/MP and L1/NB simultaneously, and the results of both values revealed a significant difference between the groups (L1/MP change: 0.75 ± 0.53 versus 4.75 ± 1.16°, $P < 0.001$; L1/NB change: 0.12 ± 0.23 versus 4.00 ± 0.88°, $P < 0.001$). Elkordy et al.[25] evaluated L1 inclination via L1/FP, and suggested that a miniscrew helped in limiting the proclination of mandibular incisors (L1/FP: 5.26 ± 2.71 versus 9.05 ± 2.91°, $P < 0.001$).

On the contrary, the unclear-risk RCT conducted by Eissa et al.[24] exhibited no intergroup significant difference despite the reduced proclination observed in the miniscrew-anchored group (L1/NB change: 4.7 ± 4.047 versus 6.00 ± 2.96°, $P = 0.546$).

Soft tissue position change

Three studies reported soft tissue outcomes evaluated by different cephalometric values.[23,24,27] For measuring the change in sagittal position of the lower lip, Aslan et al.[23] used Lbinf-VRL and Eissa et al.[24] used Li-E as indicators, both of which did not identify a statistically significant difference. However, Turkkahraman et al.[27] employed Li-S and suggested that the increase of lower lip protrusion was significantly less in the TAD-anchored group compared with the conventional group (Li-S change: -0.80 ± 2.07 versus 1.82 ± 1.47 mm, $P < 0.001$).

Quality of evidence

Results of GRADE assessment for the overall quality of available evidence are summarised in Table VI. The evidence quality of skeletal outcomes, including mandibular length and mandibular rotation, was assessed as moderate. The quality of evidence associated with lower incisor inclination was also moderate, whereas very low quality was identified for soft tissue positional change.

Discussion

Summary of evidence

The aim of conducting the present systematic review was to determine whether TADs could enhance the skeletal, dento-alveolar and soft tissue effects of a FFRD on the mandible in growing Class II patients. In all, six studies were included in the review. The results were not quantitatively but, rather, qualitatively synthesised due to the great clinical heterogeneity, such as the variance in the bracket bonding protocol, the TAD clinical protocol, the evaluation indicators

Table V. Definition of cephalometric values.

Cephalometric value	Definition
Mandibular skeletal measurement	
Co-Gn	The linear distance between Condylion point and Gnathion point
Ar-Pog	The linear distance between Articulare point and Pogonion point
Go-Pog	The linear distance between Gonion point and Pogonion point
MP/SN	The angle formed between mandibular plane and line S-N
GoMe/FH	The angle formed between line Go-Me and Frankfort plane
Lower incisors inclination	
L1/MP	The angle formed between the L1 long axis and the mandibular plane
L1/NB	The angle formed between the L1 long axis and line N-B
L1/FP	The angle formed between the L1 long axis and the frontal plane
Soft tissue position measurement	
Lbinf-VRL	The distance from lower lip to a self-defined vertical reference line
Li-E	The distance from lower lip to E line
Li-S	The distance from lower lip to S line

Table VI. GRADE assessment for quality of available evidence.

Quality assessment						Patients(n)		Relative effect (95% CI)	Quality
Studies	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	C*	E*		
Mandibular length									
6	Not Serious	Serious	Not serious	Not serious	None	86	85	Not pooled	⊕⊕⊕○ Moderate
Mandibular rotation									
6	Not Serious	Serious	Not serious	Not serious	None	86	85	Not pooled	⊕⊕⊕○ Moderate
Lower incisors inclination									
6	Not Serious	Serious	Not serious	Not serious	None	86	85	Not pooled	⊕⊕⊕○ Moderate
Soft tissue position change									
3	Serious	Serious	Not serious	Serious**	None	47	46	Not pooled	⊕○○○ Very low

*E indicates TAD-anchored FFRD group; C indicates conventional FFRD group

**Different cephalometric values consisting of self-defined reference landmarks/lines were used

and criteria for ending treatment. Moderate-quality evidence was acquired for the change of skeletal outcomes and lower incisor proclination, whereas very low-quality evidence was found for soft tissue change.

As a typical symptom of Class II patients, mandibular deficiency has been widely discussed in previous studies, which have demonstrated that fixed functional appliances, such as a FFRD, might be beneficial.[5-9] Considering that forces generated from a FFRD may be transmitted more to the mandible by anchorage enhancement, it was hypothesised that TADs may help in enhancing the mandibular skeletal effects of FFRD.[16-18,26,28,29] However, controversial results were found in the available studies. Three RCTs using miniscrews reported no significant difference between groups in relation to mandibular length change.[23-25] In the miniplate studies, Turkkahraman et al. conducted a high-quality CCT and showed that the increase in mandibular length was not significantly different.[27] While Elkordy et al. carried out a low-risk RCT, which reported that a significant increase of 4.05 mm was attained in the miniplate-anchored group. This was ascribed to the forward and downward force transmitted to the condyle and generated by the immediate application of an orthopaedic force on the mandible.[26] Nevertheless, the conclusion should be interpreted cautiously since the evaluation was merely conducted over a short period of time and long-term follow-up was required to exclude the effect of temporary growth acceleration. A similar suggestion resulted from the study of Phan et al., which found mandibular growth was still significant seven months after Herbst appliance treatment.[30] Interestingly, Gandedkar et al. reported that the increase was significant, not only upon the removal of the FFRD, but also at a one-year post-treatment review. However, the study was assessed to be of poor quality.[28]

A significant increase in mandibular backward rotation was achieved by TADs and reported by two low-risk studies employing miniplates. However, this finding was not found in three studies employing miniscrews. An additional poor-quality study employing miniplates showed no significant difference, but it should be noted that there is still uncertainty related to the effects between miniplates and miniscrews. The difference may be due to a greater vertical component of force that could be generated in the miniplate-anchored groups since their attachment site for FFRD pushrods was lower than miniscrew-anchored groups. Moreover, the stability of different TADs should also be taken into consideration. As reported by previous studies, forward movement of 0.4 mm and tipping of 2.65 ± 6.23° affected miniscrews during orthodontic loading, indicating that they were not absolutely stationary.[31-33] However, Kim et al. showed no miniplate movement by using bone markers as a reference in superimposition, suggesting that miniplates were more stable. It should be further noted that the miniplate heads in some subjects were bent buccolingually, which might also cause anchorage loss.[34] Since anchorage loss is a principal factor limiting the skeletal effects of FFRD, future studies should be designed to investigate whether miniplates might promote mandibular growth better than miniscrews during FFRD treatment.

A further possible factor that might diminish the skeletal effects is proclination of mandibular incisors.[15,35,36] To manage this common side-effect of a FFRD, research has advocated procedures that counteract lower incisors proclination should be applied during treatment. These clinical techniques might involve the addition of a negative torque to the anterior arch wire or using rectangular arch wires of greater size.[13,14] However, none have proved to be effective, which promoted the use of TADs. Within the current literature, five studies reported that TADs successfully minimised the proclination of mandibular incisors.[23,25-28] Noticeably, the mechanism of proclination reduction was heterogenous between miniplates and miniscrews. Employed as direct anchorage, the miniplates provided immediate attachment sites for the pushrods of the FFRD and consequently saved the mandibular incisors from directly receiving the forward force.[26-28] By comparison, miniscrews did not support the pushrods directly but served as indirect anchorage. Elkordy et al. used segments of 0.019 × 0.025-inch stainless-steel wire to enhance the anchorage of lower incisors by bonding one end to a miniscrew and the other end to the labial surface of the mandibular canine.[25] Similarly, Aslan et al. fixed a 0.018 × 0.025-inch stainless-steel wire segment between the miniscrew slot and vertical slot (0.018 × 0.018-inch) of the canine bracket.[23] In these trials, the mandibular incisors still directly received the forward force of the pushrods, while the rigid connection to the miniscrews provided resistance. Eissa et al. shared the same protocol as Aslan et al. but no significant difference was reported, and the researchers attributed this inconsistency to the size discrepancy between the segment (0.016 × 0.016-inch) and the vertical slot of canine bracket (0.018 × 0.018-inch), which might provide additional play allowing unwanted proclination.[24] Therefore, it is legitimate to extrapolate that TADs are superior in alleviating the proclination of mandibular incisors during FFRD application.

Three studies evaluated soft tissue positional change but only one reported that the protrusion of the lower lip was significantly reduced by the assistance of TADs.[27] Although research has concluded that lip position can be correlated with incisal repositioning, no significant difference was found in the reduction of lower lip protrusion despite minimal mandibular incisor proclination reported in two studies.[23,24,37] The factors affecting lip position are multiple, thus the effects of lower incisor position should not be determined in a simplistic way.[38,39] Factors, such as lip thickness, labial tension and soft tissue compensation may also affect lip position.[40-42]

Strengths and limitations

To date, no systematic review focussing on the effects of TADs as an aid to a FFRD has been previously published. In addition to the skeletal, dento-alveolar and soft tissue effects, details about the TADs application protocol (direct versus indirect anchorage) from the included studies were also summarised systematically, which may be useful for clinicians when performing relevant procedures. Elkordy et al.[43] implemented a meta-analysis of Class II patients to verify the effect of TADs during treatment employing fixed functional appliances, in which three publications were noted. However, only two[23,25] were included in the present study since no applicable data were recognised elsewhere.[44] Furthermore, other fixed functional appliances (Herbst, Twin Force bite corrector and Easy-fit Jumper) recruited in the previous meta-analysis were excluded in the present review to reduce the impact of appliance variation on the authenticity of the evidence. Finally, it is justified to synthesise the results qualitatively instead of quantitatively due to the significant clinical heterogeneity.

Although the present study was conducted following standard procedures, several limitations were apparent. Additional high-quality RCTs are needed for a more reliable conclusion since only four RCTs and two CCTs were eligible for inclusion in the present review despite searching the literature without language restriction. Moreover, the effects were not quantitatively measured, requiring future studies to minimise the clinical heterogeneity by developing a suitable standard for treatment process and evaluation. Recommendations regarding the necessity of using TADs in Class II cases treated using a FFRD could not be provided. It would be indispensable to take other aspects into comprehensive consideration, such as patient acceptance, side effects, disease burden and health-economic problems. Unfortunately, little evidence is available at present.[44-46]

Conclusion

Notwithstanding the limitations, the following conclusions are supported:

1. Moderate-quality evidence suggests that TADs are beneficial in alleviating the proclination of mandibular incisors caused by a FFRD in Class II patients.
2. Controversies remain regarding the effects of TADs on mandibular growth and soft tissue positional change.
3. It seems that miniplates reinforce the mandibular skeletal effects of FFRD better than miniscrews, but the evidence is weak.

For future research, high-quality RCTs following a standard treatment procedure and evaluation method are needed. The outcomes of long-term follow-up reports are also required. It would also be valuable to compare direct and indirect anchorage. Additionally, future studies would ideally have the adverse effects, financial cost and participants' acceptance clarified to provide more comprehensive recommendations for patients and clinicians.

Conflict of interest

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