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

Jie Xiang, Yuanyuan Yin, Ziqi Gan, Sangbeom Shim and Lixing Zhao
State Key Laboratory of Oral Diseases, National Clinical Research Center for Oral Diseases, Department of Orthodontics, West China Hospital of Stomatology, Sichuan University, Chengdu, China

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.

(Aust Orthod J 2021; 37: 50 - 61. DOI: 10.21307/aoj-2021-005)

Received for publication: April 2020
Accepted: September 2020

Jie Xiang: Xiangkeane11@163.com; Yuanyuan Yin: 1042520312@qq.com; Ziqi Gan: 415777437@qq.com; Sangbeom Shim: 496509309@qq.com; Lixing Zhao: Zhaolixing1228@hotmail.com

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. Rather than maxillary protrusion, mandibular retrusion is reported to be the dominating etiological 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. 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.

As a widely used orthodontic device, fixed functional appliances (FFA) have been employed for mandibular advancement since 1905. Different from removable functional appliances, FFA may be applied simultaneously with fixed appliances and make treatment effects less reliant on compliance. 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. The appliance is attached bilaterally from a headgear tube on the maxillary molar to the arch wire distal to mandibular canine. Through a coaxial spring and pushrod incorporated in the FFRD, continuous orthopaedic forces are applied to correct mild mandibular retrusion. 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. 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.

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. 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. 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 malocclusion patients in active growth; (2) Intervention and controlled protocol: comprehensive orthodontic treatments using a FFRD with and without TADs (miniscrews, mini-implants or miniplates);

| 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
the treatment procedure details were not specifically described in the publication of Gandedkar et al., 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 were evaluated as low risk while the other two were deemed an unclear risk of bias. The study of Aslan et al. 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. 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.
| 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, dentoalveolar, 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, dentoalveolar |
| 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, dentoalveolar, 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, dentoalveolar, 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 wires engaged) T2: After an edge-to-edge incisor relationship was achieved or 10 months | Skeletal, dentoalveolar |
| Gandedekar 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: Pretreatment T1: Class I molar relationship achievement (After removal of FFRD) T2: One-year post-treatment | Skeletal, dentoalveolar, 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.
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 studies24-28 and Ar-Pog was used in one study.25 Furthermore, Go-Pog was also mostly used in the study of Gandedkar et al.28 except for Co-Gn. Three RCTs23-25 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 RCTs23-25 employing miniscrews and one CCT28 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 miniscrew-anchored group compared with the conventional group (L1/MP change: 3.61 ± 5.07 versus 9.29 ± 3.81 °, P < 0.001). Turkkahraman et al.27 reported that significant L1 retroclination was

---

**Table V.**

| Study        | Co-Gn | Ar-Pog | Go-Pog | MP/SN | GoMe/FH |
|--------------|-------|--------|--------|-------|---------|
| Aslan 2014   | +     | +      | ?      | ?     | +       |
| Eissa 2017   | +     | +      | +      | ?     | +       |
| Elkordy 2016 | +     | +      | +      | +     | +       |
| Elkordy 2019 | +     | +      | +      | +     | +       |

**Figure 2.** Risk of bias summary for RCTs.
### Table III. Intervention details of included studies.

| Study ID          | Brackets       | Bonding protocol                        | TAD clinical protocol                                                                 | Pushrods insertion sites                      | 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 0.018*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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{23,24,27} For measuring the change in sagittal position of the lower lip, Aslan et al.\textsuperscript{23} used Lbinf-VRL and Eissa et al.\textsuperscript{24} used Li-E as indicators, both of which did not identify a statistically significant difference. However, Turkkahraman et al.\textsuperscript{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

| 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 |
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.\textsuperscript{34} Since anchorage loss is a principal factor limiting the skeletal effects of FFRD, future studies should be designed to investigate whether minipiles 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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{23,25-28} Noticeably, the mechanism of proclination reduction was heterogeneous between minipiles and miniscrews. Employed as direct anchorage, the minipiles provided immediate attachment sites for the pushrods of the FFRD and consequently saved the mandibular incisors from directly receiving the forward force.\textsuperscript{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.\textsuperscript{23} 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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{38,39} Factors, such as lip thickness, labial tension and soft tissue compensation may also affect lip position.\textsuperscript{40-42}

**Strengths and limitations**

To date, no systematic review focusing 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.\textsuperscript{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\textsuperscript{23,25} were included in the present study since no applicable data were recognised elsewhere.\textsuperscript{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.\textsuperscript{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
None declared.

Funding
No funding was received.

Registration
Registration was not performed.

Corresponding author
Lixing Zhao
State Key Laboratory of Oral Diseases
National Clinical Research Center for Oral Diseases
Department of Orthodontics
West China Hospital of Stomatology
No. 14, Section 3, South Renmin Road
Chengdu 610041
China
Email: Zhaolixing1228@hotmail.com.

References
1. Joshi N, Hamdan AM, Fakhouri WD. Skeletal malocclusion: a developmental disorder with a life-long morbidity. J Clin Med Res 2014;6:399-408.
2. El Hajj N, Basil-Nassif N, Tsauk A, Moshanna-Fattal C, Bouserhal JP. Maxillary and mandibular contribution to the establishment of class II malocclusion in an adult Lebanese population. Int Orthod 2017;15:677-97.
3. McNamara JA, Jr. Components of class II malocclusion in children 8-10 years of age. Angle Orthod 1981;51:177-202.
4. Ghislazoni LT, Baccetti T, Toll D, Defraia E, McNamara JA Jr., Franchi L. Treatment timing of MARA and fixed appliance therapy of Class II malocclusion. Eur J Orthod 2013;35:394-400.
5. Pancherz H. Treatment of class II malocclusions by jumping the bite with the Herbst appliance. A cephalometric investigation. Am J Orthod 1979;76:423-42.
6. Pancherz H, Malmgren O, Hägg U, Omblus J, Hansen K. Class II correction in Herbst and Bass therapy. Eur J Orthod 1989;11:17-30.
7. O’Brien K, Wright J, Comooy F, Sanjie Y, Mandal N, Chadwick S et al. Effectiveness of treatment for Class II malocclusion with the Herbst or twin-block appliances: a randomized, controlled trial. Am J Orthod Dentofacial Orthop 2003;124:128-37.
8. Heining N, Güz G. Clinical application and effects of the Forsus spring. A study of a new Herbst hybrid. J Orofac Orthop 2001;62:436-50.
9. 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.
10. Arora V, Sharma R, Chowdhary S. Comparative evaluation of treatment effects between two fixed functional appliances for correction of Class II malocclusion: A single-center, randomized controlled trial. Angle Orthod 2018;88:259-66.
11. Adusumilli SP, Sudhakar P, Mummidi B, Varma DP, Arora S, Radhika A et al. Biomechanical and clinical considerations in correcting skeletal class II malocclusion with Forsus ™. J Contemp Dent Pract 2012;13:918-24.
12. Linjawi AI, Abbasy MA. Dentoskeletal effects of the forsus ™ fatigue resistance device in the treatment of class II malocclusion: A systematic review and meta-analysis. J Orthod Sci 2018;7:3.
13. Cacciatore G, Alvetro L, Defraia E, Ghislazoni LT, Franchi L. Active-treatment effects of the Forsus fatigue resistant device during comprehensive Class II correction in growing patients. Korean J Orthod 2014;44:136-42.
14. 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.
15. Giuntini V, Vangelisti A, Masucci C, Defraia E, McNamara JA Jr., Franchi L. Treatment effects produced by the Twin-block appliance vs the Forsus Fatigue Resistant Device in growing Class II patients. Angle Orthod 2015;85:784-9.
16. Unal T, Celikoglu M, Candirli C. Evaluation of the effects of skeletal anchored Forsus FRD using miniplates inserted on mandibular symphysis: A new approach for the treatment of Class II malocclusion. Angle Orthod 2013;85:413-9.
17. 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.
18. Patil HA, Kerudi VV, Rudagi BM, Sharan JS, Tekale PD. Severe skeletal Class II Division I malocclusion in postpubertal girl treated using Forsus with miniscrew anchorage. J Orthod Sci 2017;6:147-51.
19. Cumpton M, Li T, Page MJ, Chandler J, Welch VA, Higgins JP et al. Updated guidance for trusted systematic reviews: a new edition of the Cochrane Handbook for Systematic Reviews of Interventions. Cochrane Database Syst Rev 2019;10:Ed000142.
TAD-ANCHORED FFRD: A SYSTEMATIC REVIEW

20. Moher D, Liberati A, Tetzlaff J, Altman DG, PRISMA Group. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. BMJ (Clinical research ed) 2009;339:b2535.
21. Stang A. Critical evaluation of the Newcastle-Ottawa scale for the assessment of the quality of nonrandomized studies in meta-analyses. Eur J Epidemiol 2010;25:603-5.
22. Balshem H, Helfand M, Schünemann HJ, Oxman AD, Kunz R, Brozek J et al. GRADE guidelines: 3. Rating the quality of evidence. J Clin Epidemiol 2011;64:401-6.
23. 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.
24. Eissa O, El-Shennawy M, Gaballah S, El-Mehy 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.
25. Elkordy SA, Abouelezz AM, Fayed MM, Mostafa YA. Three-dimensional effects of the mini-implant-anchored Forsus Fatigue Resistant Device: A randomized controlled trial. Angle Orthod 2016;86:292-305.
26. Elkordy SA, Abouelezz AM, Fayed MM, 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.
27. Turkkahraman H, Elicik SK, Fındık Y. Effects of miniscrew and conventional Forsus Fatigue Resistant Devices in the treatment of Class II malocclusion. Angle Orthod 2016;86:1026-32.
28. Gandedkar NH, Shrikantaiah S, Patil AK, Baser MA, Chng CK, Ganeshkar SV et al. Influence of conventional and skeletal anchorage system supported fixed functional appliance on maxillo-mandibular complex and temporomandibular joint: A preliminary comparative cone beam computed tomography study. Int Orthod 2019;17:256-68.
29. El-Sheikh MM, Godfrey K, Manosudprasit M, Viwattanatipa N. Force-deflection characteristics of the fatigue-resistant device spring: an in vitro study. World J Orthod 2007;8:30-6.
30. Phan KL, Bendeus M, Hägg U, Hansen K, Rabie AB. Comparison of the headgear activator and Herbst appliance—effects and post-treatment changes. Eur J Orthod 2006;28:594-604.
31. Kinzinger G, Gülßen N, Yildizhan F, Hermanns-Sachweh B, Diedrich P. Anchorage efficacy of palatally-inserted miniscrows in molar distalization with a periodontally/miniscREW-anchored distal jet. J Orofac Orthop 2008;69:110-20.
32. El-Beialy AR, El-Beialy AR, Abou-El-Ezz AM, Attia KH, El-Bialy AM, Mostafa YA. Loss of anchorage of miniscrows: a 3-dimensional assessment. Am J Orthod Dentofacial Orthop 2009;136:700-7.
33. Liu EJ, Pai BC, Lin JC. Do miniscrows remain stationary under orthodontic forces? Am J Orthod Dentofacial Orthop 2004;126:42-7.
34. Kim S, Herrling S, Wang IC, Alcalde R, Mak V, Fu I et al. A comparison of miniplates and teeth for orthodontic anchorage. Am J Orthod Dentofacial Orthop 2008;133:189.e1-9.
35. Aras A, Ada E, Saracoğlu H, Gezer NS, Aras I. Comparison of treatments with the Forsus fatigue resistant device in relation to skeletal maturity: a cephalometric and magnetic resonance imaging study. Am J Orthod Dentofacial Orthop 2011;140:616-25.
36. Ozturmak MO, Balshem H, Saltaji H, Flores-Mir C, Preston B, Tabbaa S. Patient experiences with the Forsus Fatigue Resistant Device. Angle Orthod 2013;83:437-46.
37. Cornelis MA, Scheffler NR, Nyssen-Behets C, De Clerck HJ, Tulloch JF. Patients’ and orthodontists’ perceptions of miniplates used for temporary skeletal anchorage: a prospective study. Am J Orthod Dentofacial Orthop 2008;133:18-24.