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Systematic Review

Mandibular Advancement and Skeletal Anchorage in Class II Malocclusion Patients: A Systematic Review with Meta-Analysis

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Abstract: (1) Objectives: The purpose of this review was to compare the effects of combining skeletal anchorage and Class II devices, both from an overall perspective and individually for each type of appliance, considering as main outcomes the vertical dimensions and the inclination of the mandibular and maxillary incisors. (2) Materials and Methods: A search without time restrictions was performed up to February 2024 in PubMed, PubMed Central, Scopus, and Medline for randomized controlled trials, as well as prospective and retrospective cohort studies, considering Class II patients treated with and without skeletal anchorage. The effect measure used for the meta-analytic evaluation was the standardized mean difference (SMD). The SMD calculation was obtained by subtracting the mean values of T1–T0 for each individual treatment and then calculating the SMD between the treatments involved. The meta-analysis was performed using the standardized mean difference of the mean difference of the T1–T0 change in the outcome between the different treatments evaluated as the effect size. (3) Results: A total of 1217 documents were initially retrieved. According to the PRISMA protocol, 18 studies comparing different skeletal anchorage protocols (upper/lower miniscrews and miniplates), combined with four appliances (Herbst, Forsus, Carriere Motion, and elastics), were included in the analysis. No significant difference in skeletal divergence was found between groups from an overall point of view (SMD: 0.19 (−0.48 to 0.83) according to the random-effects model). A statistically significant reduction in IMPA° was found in patients treated with temporary anchorage devices (TADs) (SMD of 5.58 (3.40 to 7.75)), except for the elastics group (SMD: 3.76 (−0.91 to 8.43)). The effect on the upper incisors' inclination appeared to be strictly dependent on the type of anchorage (TADs in one or both of the arches). Some limitations must be considered when interpreting the results: the small number of studies included and the heterogeneity among them are among the limitations, and the temporal disparity among some studies; the ages of the patients were not always comparable; and, finally, the clinical relevance of the effects of TADs is sometimes questionable. (4) Conclusions: The vertical dimension seems not to be significantly affected by skeletal anchorage; instead, the proclination of mandibular incisors is generally reduced when TADs are used. Skeletal anchorage might be useful if lingual tipping of the upper incisors is required; however, it is influenced by the anchorage protocol.

Keywords: functional appliances; Class II; TADs; vertical dimension

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Citation: Gotti, E.; Doldo, T.; Castellana, F.; Cozzani, M.; Manni, A.; Gastaldi, G.; Boggio, A. Mandibular Advancement and Skeletal Anchorage in Class II Malocclusion Patients: A Systematic Review with Meta-Analysis. *Oral* **2024**, *4*, 417–440. https://doi.org/10.3390/oral4030034

Academic Editor: Giuseppina Campisi

Received: 12 July 2024
Revised: 13 September 2024
Accepted: 14 September 2024
Published: 19 September 2024

1. Introduction

One of the most frequent problems routinely diagnosed by any orthodontist is Class II malocclusion, affecting approximately one-third of the worldwide population [1], with a prevalence of 15% to 30% among different populations [2]. In 1890, this condition was defined by Edward H. The angle as the molar relationship where the mesiobuccal cusp of the maxillary first molar occludes to the buccal groove of the mandibular first molar [3]. The dental classification was then updated through the years, also taking into consideration soft tissue and skeletal problems [4]. In this view, Class II malocclusion can be a result of a retrognathic mandible, prognathic maxilla, or a combination of both, but mandibular retrusion is considered to be the most frequent cause [5,6]. Moreover, this represents a great concern for patients and clinicians, and early treatment with functional appliances is encouraged, as untreated Class II malocclusion may need future orthognathic correction in about 17.5–45.5% of treated orthognathic patients [7–10].

Therefore, when dealing with Class II patients, the ideal treatment should promote a forward mandibular movement, correcting the relationship between skeletal bases. Different therapies have been adopted by clinicians to achieve this goal and are included as a whole under the "functional jaw orthopedics" family, meaning all those orthodontic appliances that change the position of the mandible [1]. Although their efficacy has been proven through experimental and clinical trials [11,12], inevitable dentoalveolar side effects, such as maxillary incisors' retroclination and mandibular incisors' proclination [13], come along with the skeletal outcomes, reducing the space for proper mandibular advancement [14].

In order to reduce these complications, a proposed strategy was the association of conventional orthodontic treatment options with skeletal anchorage [15].

Recently, temporary anchorage devices (TADs) have been used together with fixed functional appliances (FFAs) [16–18] and other mandibular advancement protocols, such as Class II elastics [19–21] and Carriere Motion appliances [22]. Over the years, the number of systematic reviews directed to specific appliances in association with TADs has been increasing in the literature [16–18,23–25], but the results of these studies are controversial, with some of them reporting the significant advancement of the mandible and good anchorage control when skeletal anchorage was adopted [17,18], while others showed similar dentoskeletal changes to those obtained with conventional appliances [16,25].

The rationale for this apparent inconsistency may lie in the effectiveness of the devices used, so the purpose of this review was to compare the effects of skeletal anchorage combined with functional devices from an overall perspective and, in particular, individually for each type of device, since the majority of the literature is based on the general association of functional appliances and TADs.

Another reason for the discrepancy could lie in the control of the vertical dimension: it is well-known that a good control of the occlusal plane enables a reduction in the clockwise rotation of the mandible, improving the sagittal projection of the pogonion.

Therefore, two main outcomes are assessed in this review, and both may be controlled using TADs: firstly, the vertical dimension, reflected in the amount of mandibular rotation produced after treatment, and, secondly, the position of the mandibular incisors, which must always be governed in order to preserve the space necessary for the mandible to protrude.

2. Materials and Methods

2.1. Information Sources and Search Strategy

This study was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement [26]. The protocol has been registered in the PROSPERO database (registration number: CRD42024526446).

Two co-authors performed an independent blind search using the following databases: PubMed, PubMed Central (PMC), Scopus, and Medline. No restriction was made on the language or on the date of publication, and the electronic search was carried on until February 2024. Moreover, the references of the articles included were manually scored by the authors, and, afterwards, a supplemental hand search was also implemented.

Furthermore, through the use of the huge archive of preprints (https://arxiv.org/) in the study selection phase and of the database (http://www.opengrey.eu/, accessed on

10 February 2024), the authors were able to take into consideration the gray literature to access several abstracts from major conferences and other unreviewed material.

2.2. Key Words and Eligibility Criteria

The following keywords were used to search the literature: ("temporary anchorage devices (TADs)" or "mini-screws" or "mini-implants" or "mini-plates" or "skeletal anchorage") and ("fixed functional appliances" or "herbst" or "bionator" or "forsus" or "sander" or "carriere" or "Class II elastics" or "twin block") and ("Class II" or "Skeletal Class II" or "Class II malocclusion"). It is possible to find the search strategy below, in Table 1.

Table 1. The search strategy used in the US National Library of Medicine (PubMed) and Medical Literature Analysis and Retrieval System Online (MEDLINE) and adapted to the other sources, according to selected descriptors.

Strategy		Descriptors Used
#1	Population	(Class II malocclusion [tiab]) OR (skeletal Class II [tiab]) OR (growing patients [tiab])
#2	Intervention/Exposure	(skeletal ancorage [tiab]) OR (TADs [tiab]) OR (mini-implants [tiab]) OR (miniscrews [tiab]) OR (miniplates [tiab])
#3	Comparator	(no treatment [tiab]) OR (conventional therapy [tiab]) OR (Functional appliance [tiab]) OR (Mandibular propulsor[tiab])
#4	Outcomes	(skeletal divergence [tiab]) OR (IMPA [tiab]) OR (Is/PP [tiab]) OR (Is/SN [tiab]) OR (Overjet [tiab])
#5	Exclusion keywords	(Review [tiab]) OR (systematic review [tiab]) OR (narrative review [tiab]) OR (meta-analysis [tiab]) OR (editorial [tiab]) OR (letter [tiab]) OR (commentary [tiab]) OR (perspective [tiab]) OR (book [tiab])
#6	Search strategy	#1 AND #2 AND #3 AND #4 NOT #5

The studies included needed to be randomized clinical trials or either prospective or retrospective controlled clinical trials. Case reports, preliminary studies, descriptive studies, narrative reviews, and opinion articles were excluded from this selection.

Additionally, the comparison necessarily involved a test group of Class II malocclusion patients treated with appliance for mandibular propulsion associated with skeletal anchorage and a control group of individuals (either untreated, treated with the same appliance without TADs, or treated with another functional device).

The PICO question and the inclusion criteria are described in the following table (Table 2).

Table 2. PICO question.

Participants	Class II malocclusion patients who were treated with fixed functional appliances or Class II elastics (Inclusion criteria: Class II molar relationship, skeletal Class II malocclusion (ANB > 4), permanent or late mixed dentition. Exclusion: poor oral hygiene, bad habits, syndromes, and systemic disease)
Intervention	Skeletal anchorage in association with orthodontic treatment for mandibular advancement
Comparison	Conventional orthodontic treatment for mandibular advancement or no treatment
Outcome	Skeletal and dentoalveolar effects measured on cephalometric radiograph (no restriction on type of parameters collected in the analysis)

2.3. Data Items

After the first screening process, the following information was extracted from the studies considered: study method (location; design; funding; records type); sample size, age, gender, cervical vertebrae maturation, and characteristics of the participants; type and duration of interventions; and outcomes and main findings.

2.4. Risk of Bias

Two co-authors (AB and EG) independently assessed the methodological quality of the eligible RCTs utilizing the revised Cochrane risk-of-bias tool for randomized trials (RoB-2), which consists of five main domains, including bias arising from the randomization process, bias due to deviations from the intended interventions, bias due to missing outcome data, bias in the outcome measures, and bias related to the selection of reported results. The final judgments and the overall risk of bias were defined as "low" or "high" risk of bias or expressed as "some concerns" [27]. A third reviewer (FC) independently checked this assessment.

In order to assess the quality of nonrandomized case–control studies, the New Ottawa Scale was adopted.

2.5. Outcomes

The primary outcomes were the skeletal divergence (expressed in degrees and measured on cephalometric analysis either as SN/GoMe° or SN/GoGN°) and the inclination of the mandibular incisors relative to the mandibular plane (IMPA°°, IIGoMe°, or IIGoGN°).

The parameters evaluated as secondary outcomes were the inclination of the maxillary incisors relative to the palatal plane (IS/PP°) and relative to the line from Nasion to Sella (IS/SN°).

Finally, the authors assessed the changes in overjet among the various studies.

2.6. Meta-Analysis

The meta-analysis was performed using the standardized mean difference of the mean difference of the T1–T0 change in outcome between the different treatments evaluated as effect size. Standardized mean difference assessment was calculated by subtracting the measurement in controls from the measurement in cases. Calculation of mean change and the respective standard deviation (SD) was performed in the manner described by Cochrane collaboration procedures [28]. If SD of mean change values were not available, they were calculated based on 95%CI; otherwise, this measure was estimated from the standard deviations of the two assessment times by the following formula—SD Change = SD2 baseline + SD2 final − (2 × 0.7 × SD baseline × SD final)—adopting a correlation coefficient of 0.7 [29].

Multiple subgroup meta-analyses were performed to assess different effects according to four types of treatment (Herbst, elastics, Carriere, and Forsus, respectively). The I2 statistic and *p*-value was used to analyze heterogeneity among studies. A *p*-value < 0.1 or I2 > 50 will be considered as meaningful heterogeneity between studies. The common or random effects model was applied for all analyses according to heterogeneity. To assess publication bias, Egger's regression test was conducted and five funnel plots were built for each analyzed outcome (Supplementary Material—Table S1 and Figures S1–S5).

Moreover, sensitivity analysis can be also found in Supplementary Material section (Figures S6–S16).

All analyses were performed with RStudio 2023.03.1 software using meta package by a senior biostatistician.

3. Results

3.1. Study Designs

A total of 1217 documents were extracted from the four databases previously indicated. After the removal of duplicates, the screening process started and 54 studies remained to be assessed for eligibility. A careful full-text analysis performed by the operators brought the exclusion of 38 papers, due to the fact that they were case reports (14), narrative articles, or pilot studies (4); in the event that different outcomes were evaluated, such as pharyngeal space, acceptance by the patients, or success rate (4); or if a control group was not present (2). Inter alia, one study [30] reported the comparison between the control group and two test groups (both with skeletal anchorage) and met the required inclusion and exclusion criteria; thus, it was considered twice in the evaluation of the differences between the two test methods and the control one.

Eventually, the last 19 studies (involving a total of 600 patients) met the inclusion criteria. Figure 1 illustrates the PRISMA flowchart.

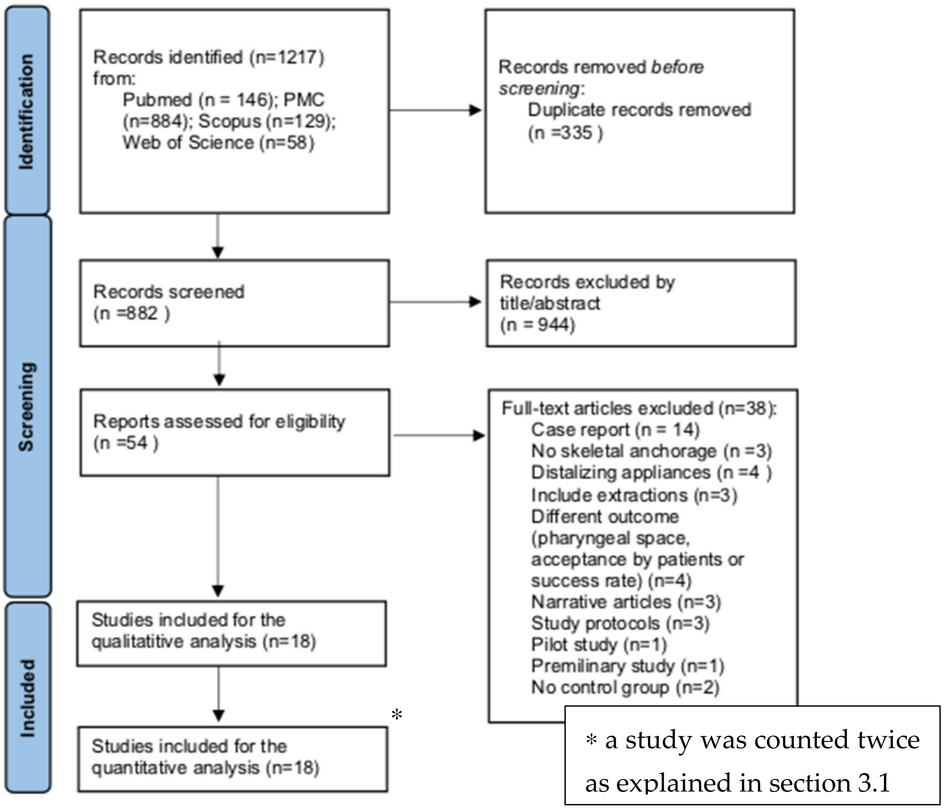

Figure 1. Flowchart of study selection process.

3.2. Characteristics of the Interventions

Among the 19 selected studies, the type of interventions submitted to the patients were mainly four: Herbst appliance [30–33], Forsus appliance [34–41], Class II elastics [19–21], and Carriere Motion appliance [22], all in association with skeletal anchorage. Afterwards, the different anchorage devices were adopted: mandibular miniscrews, maxillary and mandibular miniscrews, mandibular miniplates, and maxillary and mandibular miniplates. All the details can be found in Table 3, collecting the characteristics of the included studies.

Table 3. Characteristics of the studies.

Author and Year of Study	Method	Inclusion Criteria	Number of Patients	Sex and Mean Age	Skeletal Maturation	Appliance Type	Mean Time of Treatment	Outcomes	Main Findings
Manni et al., 2014 [33]	Study design: Retrospective cohort study Radiographic imaging: Lateral cephalograms Location: Not reported Funding source: Not reported	Bilateral Class II division 1, ≥1/2 cusp width. Permanent or late mixed dentition. No poor oral hygiene and motivation, no tooth agenesis or premature loss of permanent teeth, presence of second molars, no transverse or vertical discrepancies, and incomplete available records.	28 Test group: 14 Control: 14	Test: 6 males and 8 females; mean age 12.36 ± 1.5 years Control: 6 males and 8 females; mean age 12.28 v 1.0 ± years	Not reported	Test: acrylic splint miniscrew Herbst, miniscrews ligated with elastic chain Control: acrylic splint Herbst, no miniscrews	Test group: 8.1 ± 1.7 months Control 7.8 ± 1.1	Dental and skeletal effects	The association of Herbst appliance with miniscrews led to no mandibular incisor proclination, with a greater mandibular skeletal effect.
Manni et al., 2016 [30]	Study design: Retrospective study Radiographic imaging: Lateral cephalograms Location: Not reported Funding source: Not reported	Bilateral angle Class II division 1 malocclusion, ≥1/2 cusp width. Permanent or late mixed dentition. No poor oral hygiene and motivation, no tooth agenesis or premature loss of permanent teeth, no transverse or vertical discrepancies, and incomplete records.	60 Group 1: 20 Group 2: 20 Group 3: 20	Group 1: 11 boys and 9 girls, mean age 11.3 years Group 2: 10 boys and 10 girls, mean age 11.9 years Group 3: 11 boys and 9 girls, mean age 11.6 years	Not reported	Group 1: acrylic splint Herbst no miniscrews Group 2: acrylic splint miniscrew Herbst anchored with TADs and elastic chains Group 3: acrylic splint miniscrew Herbst anchored with TADs and metallic ligatures	Group 1: 7.4 months Group 2: 7.5 months Group 3: 7.4 months	Dental and skeletal effects	Both groups with skeletal anchorage exhibited reduced incisor proclination; in the group with miniscrews ligated with elastic chains, the orthopedic effect was increased compared to the metallic ligatures group.

Table 3. *Cont.*

Author and Year of Study	Method	Inclusion Criteria	Number of Patients	Sex and Mean Age	Skeletal Maturation	Appliance Type	Mean Time of Treatment	Outcomes	Main Findings
Fouda et al., 2022 [22]	Study design: RCT Radiographic imaging: CBCT Location: Cairo University, Egypt Funding source: Not reported	Postpubertal female patients, Class II div1 with at least an end-on Class II molar relationship bilaterally. Well-aligned posterior maxillary segments from the canine to maxillary second molar. Full permanent dentition, including second molars. No systemic conditions, no bad habits, no dental anomalies, and no previous orthodontic treatment.	24 Test group: 12 Control: 12	Postpubertal female patients Test gp: mean age 18 years Control: mean age 17.8 years	Not reported	Carriere Motion appliance was bonded in both groups Test group: miniscrews as anchorage Control: Essix appliance as anchorage Class II elastics from maxillary canine to the mandibular second molar bilaterally (first month ¼-inch heavy; then, 3/16-inch), 24 h per day	Test group: 6.1 ± 3 Control: 7.5 ± 3.7 months	Amount of anchorage loss in lower arch; Amount and type of distalization; Treatment duration.	Less anchorage loss in mandibular incisors were observed in the miniscrew group.

Table 3. *Cont.*

Author and Year of Study	Method	Inclusion Criteria	Number of Patients	Sex and Mean Age	Skeletal Maturation	Appliance Type	Mean Time of Treatment	Outcomes	Main Findings
Al-Dumaini et al., 2017 [19]	Study design: Prospective study Radiographic imaging: Lateral cephalograms Location: Damascus University, Syria Funding source: Not reported	10–13 yo Skeletal Class II div1 (ANB $\geq$ 5)/Deficient mandible with a normal or protruded maxilla. Convex facial profile. Average or vertical pattern of growth. Buccal segment relationship, greater than or equal to ½ Class II molar and canine relationships. Overjet $\geq$ 5 mm. No previous orthodontic treatment; no TMDs. No history of trauma, surgery in craniofacial area, chronic medication, and systemic disease.	52 Test group: 28 Control: 24	Test group: 14 boys and 14 girls, mean age 11.83 Control: 11 boys and 13 girls, mean age 11.75 years	Before pubertal growth spurt	Test: After 0.017, 3 0.025-in stainless steel archwires were placed in both arches, 4 miniplates were fixed bilaterally, 2 in the maxillary anterior areas and 2 in the mandibular posterior areas, and used for skeletal treatment with elastics. Control: untreated	Initial alignment and leveling phase: 7 months average Functional phase: 9 months average	Maxillary skeletal, mandibular skeletal, horizontal and vertical intermaxillary relationships, and dental variables.	Compared to control group, the patients treated with miniplates-based anchorage showed increased mandibular length together with a forward movement of the mandible. Besides the effects on mandible, the use of miniplates also allowed maxillary changes (reduction in length and posterior repositioning).

Table 3. *Cont.*

Author and Year of Study	Method	Inclusion Criteria	Number of Patients	Sex and Mean Age	Skeletal Maturation	Appliance Type	Mean Time of Treatment	Outcomes	Main Findings
Ozbilek et al., 2017 [21]	Study design: Prospective study Radiographic imaging: Lateral cephalograms Location: Antalya Education and Research Hospital, Turkey Funding source: Not reported	Full Class II molar relationship, a minimum of 5 mm overjet. Horizontal or normal growth pattern. Minimal crowding. No extracted or missing permanent teeth. No previous orthodontic treatment	12 Test group: 6 Control: 6	Test group: 12.9 ± 1.5 years, 3 boys and 3 girls Control: 12.3 ± 1.6 years, 3 boys and 3 girls	Active growth period	Test: 2 miniplates placed bilaterally at ramus of mandible and 2 miniplates at aperture piriformis area of maxilla. Miniplates adjusted and fixed by 3 miniscrews. Class II elastics of 500 gf were used bilaterally between miniplates Control: monobloc appliance	Test group: 0.86 ± 0.05 years Control: 0.65 ± 0.09 years	Skeletal, dentoalveolar, and soft tissue effects	No dentoalveolar effects were observed using miniplate anchorage. In addition, desirable skeletal outcomes were achieved through the use of skeletally anchored Class II elastics.
El-Dawlatly et al., 2021 [20]	Study design: RCT Radiographic imaging: Lateral cephalograms Location: Cairo University, Egypt Funding source: Self-funded by the authors	Mild to moderate Class II malocclusion. No caries, no missing teeth, and no periodontal disease. Adequate OH.	28 Test group: 14 Control: 14	Adolescent female patients Test group: mean age 15.66 ± 2 years Control: 15.1 ± 2.2 years	Not reported	Test group: Class II elastics combined with mini-implants Control: Class II elastics	Test group: 14.75 ± 1.8 months Control: 15.12 ± 1.67 months	1 ry outcome: lower incisors' inclination scores 2 ry: pre and post, skeletal and dental changes in control and test groups	No skeletal effects observed through the use of mini-implants + Class II elastics; instead, they obtained mainly dental effects and did not prevent lower incisor proclination. In the skeletal group, the Class II malocclusion was camouflaged with a distalization of the upper incisors

Table 3. *Cont.*

Author and Year of Study	Method	Inclusion Criteria	Number of Patients	Sex and Mean Age	Skeletal Maturation	Appliance Type	Mean Time of Treatment	Outcomes	Main Findings
Celikoglu et al., 2016 [34]	Study design: Retrospective study Radiographic imaging: Lateral cephalograms Location: Akdeniz University, Turkey Funding source: Not reported	Skeletal and dental Class II malocclusion due to mandibular retrusion (SNB < 78, ANB > 4). Overjet > 5 mm. Normal or low-angle growth pattern (SN-MP < 38). Permanent dentition, and no extraction or hypodontia. No clinical signs or symptoms of TMD.	32 Test group: 32 Control: 32	Test group: 10 females and 6 males; mean age 13.20 ± 1.33 years) Control: 9 females and 7 males; mean age 13.56 ± 1.27 years	Not reported	Test group: Forsus FRD EZ appliance with miniplate anchorage inserted in the mandibular symphyses Control: cast-type Herbst I appliance	Test group: 7.27 ± 0.84 months Control: 7.73 ± 1.27 months	Skeletal, dentoalveolar, and soft tissue effects	Both groups corrected the skeletal Class II malocclusion; in addition, the skeletally anchored Forsus showed no protrusion of mandibular incisors.
Ince-Bingol et al., 2021 [35]	Study design: Retrospective study Radiographic imaging: Lateral cephalograms Location: Baskent University, Turkey Funding source: Not reported	Skeletal Class II malocclusion due to mandibular deficiency (ANB > 4, SNB < 78, wits > 1). Angle Class II molar relationship. Normal growth pattern. Overjet 6 mm or more. Minor crowding or spacing. No congenital absence or loss of permanent teeth. No previous orthodontic treatment. No craniofacial syndrome. Good-quality lateral cephalograms.	38 Test group: 19 Activator group: 19 Control group: 19	Test group: 8 girls and 11 boys, mean age 13.03 ± 0.69 years Activator group: 7 girls and 12 boys, mean age 12.68 ± 0.73 years Control: 9 girls and 10 boys, mean age 12.95 ± 0.73 years	Pubertal peak growth stage (CS3-4)	Test group: miniplate anchored Forsus Fatigue-Resistant Device (MAF) Activator group: activator appliance attached to maxilla with a labial bow and Adams clasps Control group: untreated	Test group: 10.6 months Activator: 12 months Control: 12.4 months	Skeletal, dental, and soft tissue relationships	Both treatments successfully treated the Class II malocclusion, but the activator created greater mandibular changes than MAF due to the retroclination of maxillary incisors that it promoted.

Table 3. *Cont.*

Author and Year of Study	Method	Inclusion Criteria	Number of Patients	Sex and Mean Age	Skeletal Maturation	Appliance Type	Mean Time of Treatment	Outcomes	Main Findings
Manni et al., 2012 [32]	Study design: RCT Radiographic imaging: Lateral cephalograms Location: Not reported Founding source: Not reported	Bilateral Class II molar relationships equal or more than half a cusp, permanent or late mixed dentition	50; Test: 25 Control: 25	27 males and 23 females Mean age: 11.8 ± 1.7 years	Not reported	Test group: Herbst with miniscrew, linked by a metallic or elastic ligature to metallic buttons bonded to lower canines on each side Control gp: Herbst with no miniscrews	Test: 7.6 months Control: 7.5 months	Skeletal and dentoalveolar changes; failure of TADs	Lower mandibular incisor proclination was observed in the group of patients treated with Herbst with miniscrews.
Aslan et al., 2014 [36]	Study design: RCT Radiographic imaging: Lateral cephalograms Location: Gazi University, Turkey Funding source: Not reported	At least half Class II molar relationship, horizontal or normal growth pattern, minimum or no crowding, absence of extracted or missing permanent teeth (third molars were excluded), and active growth period.	48; Test: 16 Control: 17 Untreated: 15	Total: 22 males and 26 females Test: 13.68 ± 1.09 years Control: 14.64 ± 1.56 Untreated: 14.13 ± 1.5 years old	CVM 2-3	Test group: FFRD with miniscrew, mandibular canines bonded with 0.018 × 0.018-inch vertical slot brackets for attachment to miniscrew. An indirect anchorage was established by using a 0.018 × 0.025 ss between the vertical slot of the mandibular canine bracket and the miniscrew slot. Control group: FFRD Untreated group	Test: 6.5 ± 1.97 months Control: 5.5 ± 1.8 Untreated: 5.6 ± 1.29	Skeletal and dentoalveolar changes; failure of TADs	Miniscrew-anchored FFRD reduced the unfavorable labial tipping of lower incisors. Molar correction and overjet correction was totally dentoalveolar.

Table 3. *Cont.*

Author and Year of Study	Method	Inclusion Criteria	Number of Patients	Sex and Mean Age	Skeletal Maturation	Appliance Type	Mean Time of Treatment	Outcomes	Main Findings
Bremen et al., 2015 [42]	Study design: Prospective cohort study Radiographic imaging: Lateral cephalograms Location: University of Homburg/Saar, Germany Funding source: Not reported	Only minor crowding or well-aligned arches with a bilateral Class II molar occlusion of at least 1/2 cusp. No patient with a great excess or lack of space.	24; Test group: 12 Control: 12	14 males and 10 females Test group: 12 ± 1.6 years Control: 12.9 ± 1.2	Pubertal peak	Test group: Herbst appliance on 0.019″ × 0.025″ stainless steel archwires with cinch back and anchorage reinforcement from molar hook to Herbst axle plus active laceback (4N) between mandibular Herbst axle and MI inserted between lower second premolar and first molar Control: Herbst	Test group: 4.6 ± 0.4 Control: 4.7 ± 0.8 months	Lower incisor inclination	Skeletal anchorage showed less lower incisor proclination. No statistically significant differences in overjet reduction, incisor protrusion and intrusion, and occlusal plane inclination.
Turkkahraman et al., 2016 [37]	Study design: Prospective study Radiographic imaging: Lateral cephalograms Location: Suleyman Demirel University, Turkey Funding source: University grant	Permanent dentition and in active growth stages, Angle Class II molar relationship, convex profile with mandibular deficiency, at least 7 mm overjet, minimum crowding, no previous orthodontic treatment, and no systemic disease or craniofacial anomaly	30; Test group: 15 Control: 15	Total: 20 males and 10 females Test group: 12.77 ± 1.24 years Control: 13.26 ± 0.28	Not reported	Test group: FFRD attached to the headgear tubes of the maxillary molar bands and to the long arms of the miniplates (direct anchorage) Control: FFRD on reaching 0.019 × 0.025 ss	Test group: 9.4 ± 2.25 months Control: 9.46 ± 0.81	Skeletal, dentoalveolar, and soft tissue changes; failure of TADs	Both groups achieved growth of mandible and suppression of maxillary growth. In miniplate-anchored group, lower incisors' retrusion was obtained; on the contrary, in the conventional forsus group, lower incisor protrusion was observed. In the test group, there was no dentoalveolar side effect on mandibular teeth.

Table 3. *Cont.*

Author and Year of Study	Method	Inclusion Criteria	Number of Patients	Sex and Mean Age	Skeletal Maturation	Appliance Type	Mean Time of Treatment	Outcomes	Main Findings
Elkordy et al., 2016 [39]	Study design: RCT Radiographic imaging: CBCT Images Location: Cairo University, Egypt Funding source: Self	Females, 11–14 yo, skeletal Class II division 1 with a mandibular deficiency, horizontal or neutral growth pattern, overjet $\geq$ 5 mm, Class II canine relationship, erupted full set of permanent teeth with mandibular arch crowding $\leq$ 3 mm, no systemic disease, and signs of TMD or severe proclination of lower incisors	43; Test: 15 Control: 16 Untreated: 12	All females Test: 13.25 $\pm$ 1.12 years Control: 13.07 $\pm$ 1.41 Untreated: 12.71 $\pm$ 1.44	MP3	Test gp: FFRD on reaching 0.019 $\times$ 0.025 ss with mini-implant, bonded to the labial surface of the mandibular canines (indirect anchorage) Control gp: FFRD Untreated	Test gp: 5.34 $\pm/-$ 1.9 Control: 4.86 $\pm$ 1.32 Untreated: 6.25 $\pm$ 1.06 months	Skeletal and dentoalveolar changes	FFRD with mini-implants reduced the unfavorable proclination and intrusion of lower incisors; it did not produce additional skeletal effects.
Eissa et al., 2017 [40]	Study design: RCT Radiographic imaging: Lateral cephalograms Location: Tanta University, Egypt Funding source: Not Reported	Normal vertical growth pattern, skeletal Class II malocclusion with mandibular retrognathia, minimal or no crowding in the mandibular arch, no extracted or missing permanent teeth (third molars were excluded), and no medical history or systemic disease	38; Test group: 15 Control: 14 Untreated: 9	14 males and 24 females Test: 12.82 $\pm$ 0.9 Control: 12.76 $\pm$ 1.0 Untreated: 12.82 $\pm$ 0.9	Cervical vertebral stages 2–4	Test group: FFRD on reaching 0.019 $\times$ 0.025 ss with miniscrews, 0.016 $\times$ 0.016 ss archwire between the vertical slot of mandibular canine bracket and the miniscrew (indirect anchorage) Control: FFRD on reaching 0.019 $\times$ 0.025 ss Untreated group	Test group: 6.42 $\pm$ 1.04 months Control: 6.06 $\pm$ 0.76 Untreated: 6	Skeletal, dentoalveolar, and soft tissue changes; failure of TADs	Mini-screws anchored FFRD did not enhance mandibular growth nor prevent labial tipping of the lower incisors. The correction was mainly dentoalveolar.

Table 3. *Cont.*

Author and Year of Study	Method	Inclusion Criteria	Number of Patients	Sex and Mean Age	Skeletal Maturation	Appliance Type	Mean Time of Treatment	Outcomes	Main Findings
Elkordy et al., 2019 [38]	Study design: RCT Radiographic imaging: CBCT Images Location: Cairo University, Egypt Funding source: Self	10–13 yo, skeletal Class II division 1 with mandibular deficiency, horizontal or neutral growth pattern, overjet ≥ 5 mm, Class II division 1 incisor relation, Class II canine relationship, mandibular arch crowding < 3 mm and no systemic disease, extraction or missing teeth	48; Test group: 16 Control:16 Untreated: 16	All females Test: 12.5 ± 0.9 years Control: 12.1 ± 0.9 Untreated: 12.1 ± 0.9	CVM 3–4	Test gp: FFRD on reaching 0.019 × 0.025 ss with miniplate (direct anchorage) Control: FFRD on reaching 0.019 × 0.025 ss	Test: 9.42 ± 0.98 months Control: 6.23 ± 1.61 Untreated: 7.26 ± 1.74	Skeletal and dentoalveolar changes; failure of TADs	FFRD with miniplates increased the mandibular length in short term. Moreover, there was elimination of mandibular incisor proclination.
Manni et al., 2019 [43]	Study design: Prospective cohort study Radiographic imaging: Lateral cephalograms Location: not reported Funding source: Not reported	Skeletal Class II (ANB ≥ 4°), overjet ≥ 4 mm, bilateral Class II molar relationships ≥ half a cusp	26; Test group: 13 Control:13	Total: 13 males and 23 females Test: 12.8 ± 1.5 years Control: 12.2 ± 1.3	CVM 3	Test group: Herbst, upper and lower miniscrews; lower ligated with elastic chains to metallic buttons bonded; upper screws loaded with elastic chains ligated to the first molars. Control: Herbst only	Test: 10.0 ± 0.8 Control: 10.8 ± 2.1	Skeletal and dentoalveolar effects	Increased orthopedic effect as a result of Herbst treatment reinforced with 2 miniscrews in upper and 2 in lower arch.

Table 3. *Cont.*

Author and Year of Study	Method	Inclusion Criteria	Number of Patients	Sex and Mean Age	Skeletal Maturation	Appliance Type	Mean Time of Treatment	Outcomes	Main Findings
Gandedkar et al., 2019 [44]	Study design: Prospective study Radiographic imaging: CBCT Images Location: India Funding source: Not reported	Females, 12–16 yo, skeletal Class II division 1 and bilateral angle's Class II molar relationship, anterior overjet of ≥6 mm and 100% deep bite, minimal or no crowding or spacing, and non-extraction treatment plan	16; Test group: 8 Control: 8	All females Test group: 12.96 ± 0.38 years Control: 13.11 ± 0.38	Circumpubertal phase (15% pre, 70% pubertal, 15% post) (CVM method)	Test group: FFRD hooked on miniplates (direct anchorage) Control: FFRD on reaching 0.021 × 0.025 ss	Test: 10.45 ± 0.6 months Control: 7.59 ± 0.32	Skeletal, dentoalveolar and TMJ changes	The reinforcement with skeletal anchorage brought favorable changes to maxil-lomandibular complex and TMJ with non-significant relapse in comparison with conventional fixed functional appliances 1 year after treatment.
Kochar et al., 2021 [41]	Study design: RCT Radiographic imaging: Lateral cephalograms Location: Not reported Funding source: Not reported	Skeletal Class II malocclusion, mandibular retrognathism, angle Class II division 1 malocclusion, positive visualized treatment objective, overjet over 6 mm, average or horizontal growth pattern, and minimal crowding (<3 mm) in both arches	32 Test group: 16 Control: 16	Test: 8 boys and 8 girls, mean age 12.37 ± 1.09 years Control: 9 boys and 7 girls, mean age 12.06 ± 1.34 years	CVM 3	Test group: bimaxillary skeletal anchorage-supported fixed functional appliance (Forsus) Control: no treatment	7.44 ± 1.06 months	Skeletal and dental changes	Significant skeletal changes were obtained treating patients with bimaxillary skeletal anchorage-supported fixed appliance: retrusion and restricted posterior vertical growth in maxilla and increased length in mandible.

3.3. Quality Assessment

Among the nine included RCTs, three studies [20,32,40] were considered to have a low risk of bias; five study showed a moderate risk of bias, due to deviations from the intended interventions [22,36,38,39,41] (Figure 2). Then, a high risk of bias was attributed to the last RCT due to the randomization process, since it was made clear by the authors that randomizing the patients was not feasible [30].

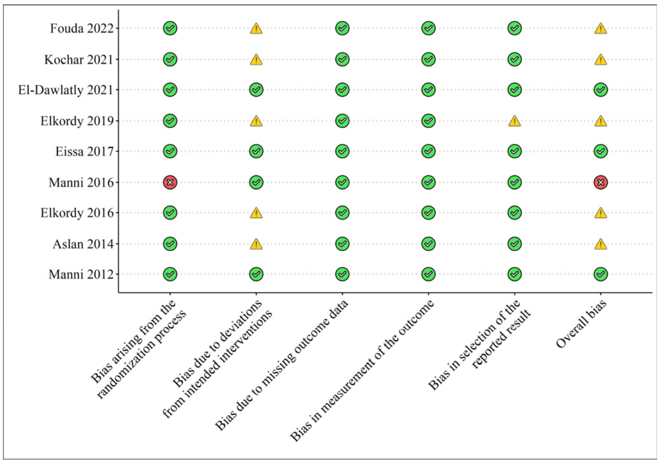

Figure 2. The revised Cochrane risk-of-bias tool for randomized trials (RoB-2).

With regard to the CCTs, all the included studies were considered to be of low quality (Figure 3).

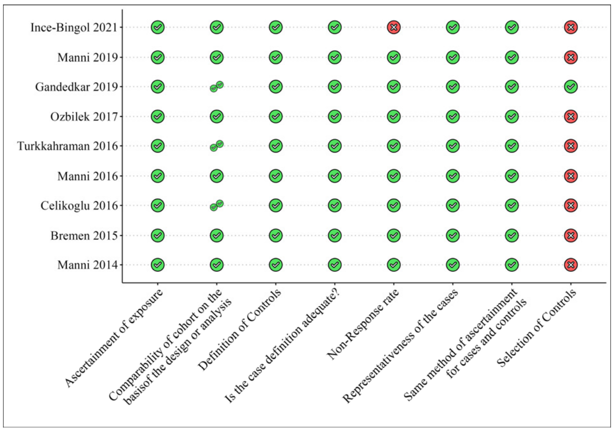

Figure 3. The New Ottawa Scale.

3.4. Meta-Analysis Results

All the included studies, with the exception of two [22,42], reported the skeletal divergence as a skeletal effect. The three dentoalveolar effects (upper and lower incisors' inclination and overjet) evaluated in this analysis were reported in all included studies: 15 studies reported the overjet (mm) [19,21,22,30–37,40–42,44]; 16 studies reported the inclination of mandibular incisors relative to the mandibular plane [19–22,30–38,41,42,44]; 4 studies reported the inclination of maxillary incisors relative to the palatal plane IS/PP° [21,31,37,38]; and 4 studies reported the inclination of the maxillary incisors relative to the anterior cranial base IS/SN° [19,34,35,44]. Due to the high heterogeneity among the included studies, a random effects model was adopted to highlight any significant statistical difference between groups.

3.4.1. Changes in Vertical Skeletal Dimension (SN/GoMe° or SN/GoGn°)

The meta-analysis results showed no statistically significant difference in the skeletal divergence using TADs in comparison to conventional therapy, although, in the skeletally anchored group, it was possible to appreciate an overall decrease in the parameter (SMD: 0.19 (−0.48 to 0.83)), Figure 4. A subgroup analysis by device type showed a statistically significant difference between the use of Herbst in combination with TADs and other procedures. The addition of skeletal anchorage resulted in a decrease in skeletal divergence in all studies focusing on Herbst (SMD: 1.44 (0.59 to 1.30)).

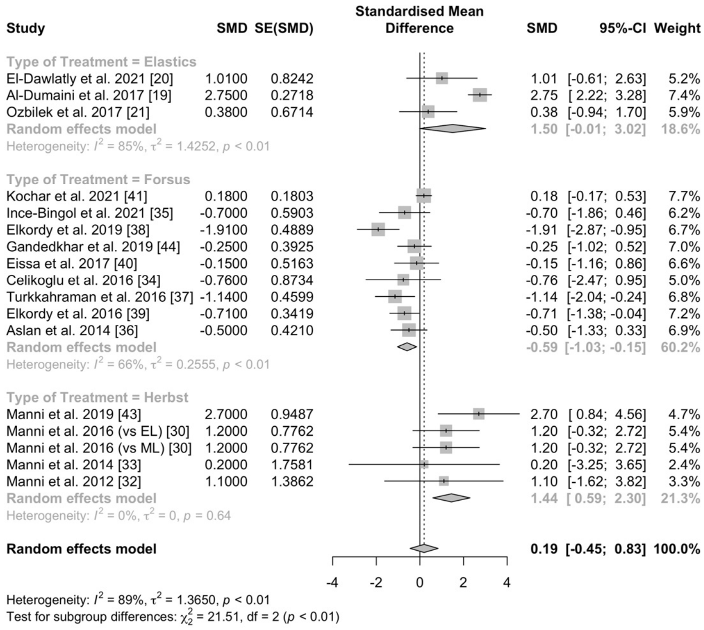

Figure 4. Changes in vertical skeletal dimension forest plot.

In the elastic subgroup, a not statistically significant reduction in the parameter was found according to the random effects model (SMD: −1.50 (−0.01 to 3.02)) while the skeletal divergence standardized mean difference proves to be statistically significantly different in the Forsus subgroup according to the random effects model (SMD: −0.59 (−1.03 to −0.15)).

3.4.2. Dentoalveolar Effects

- Overjet (mm)

A not significant overall standardized mean difference in overjet was observed between the control and case groups (SMD: 0.20 (−1.14 to 1.53), Figure 5). A subgroup analysis showed no statistically significant differences in SMD for the analyzed protocols. The observed changes in SMD were positive for the Herbst, elastics, Carriere groups, and negative for the Forsus group. The values were, respectively, SMD: 0.60 (−0.25 to 1.44), SMD: 2.61 (−0.48 to 5.69), SMD: 0.05 (−0.97 to 1.07), and SMD: −0.83 (−3.51 to 1.85), according to the random effects model.

- Inclination of mandibular incisors relative to mandibular plane (IMPA°, Ii/GoMe°, or Ii/GoGn°)

The overall random effects model showed a statistically significant reduction in mandibular incisor inclination concerning the patients treated with TADs with an SMD of 5.58 (3.40 to 7.75) (Figure 6).

In particular, the combination of Herbst, Forsus, and Carriere with skeletal anchorage was found to be effective in reducing the angular measurement (respectively, SMD: 5.13 (3.53 to 6.72), SMD: 7.24 (2.64 to 11.83), and SMD: 4.44 (1.85 to 7.03), according to the random effects model). The reduction was not statistically significant when Class II elastics and skeletal anchorage were used (SMD: 3.76 (−0.91 to 8.43)).

- IS/PP°

The effect on the inclination of the maxillary incisors relative to the palatal plane was not as statistically significant as the overall effect (SMD: −1.55 (−6.43 to 3.33)) (Figure 7).

A statistically significant reduction on the upper incisor inclination was found for the Forsus group with skeletal anchorage (SMD: 1.79 (−0.42 to 4.01) for the random effects model).

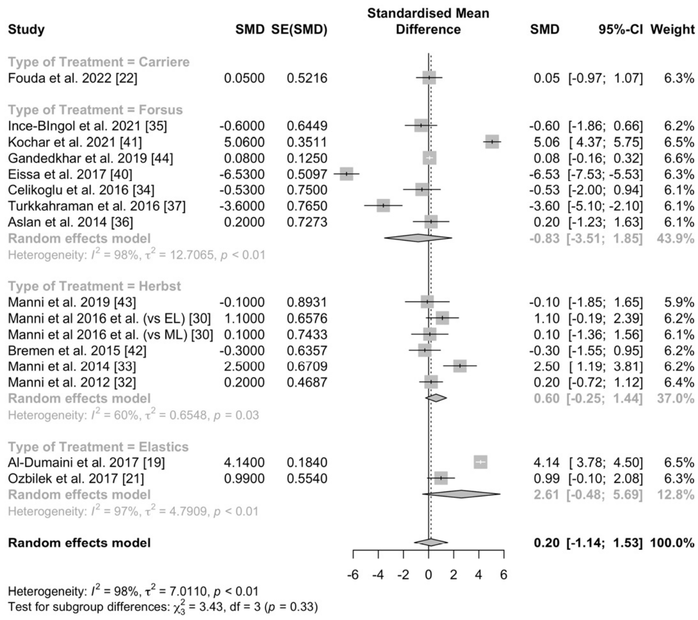

Figure 5. Overjet (mm) forest plot.

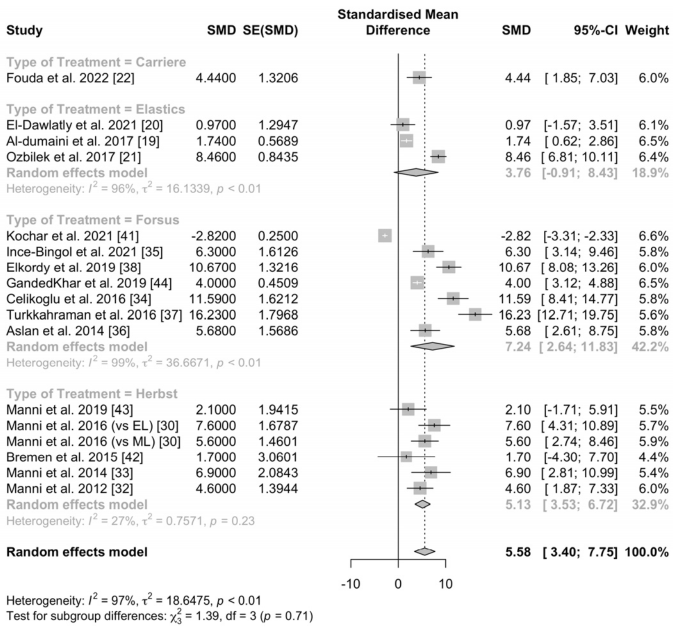

Figure 6. IMPA° forest plot.

- IS/SN°

A statistically significant reduction in the maxillary incisors' inclination with respect to the Sella–Nasion line after therapy with TADs was found (SMD: 4.79 (0.53 to 9.05)) (Figure 8). The difference was statistically significant in the subgroup analysis as well, with a decrease in the angle both for Forsus and for Class II elastics when associated with skeletal anchorage (SMD: 6.14 (0.76 to 11.52) and SMD: 1.55 (1.03 to 2.07), according to the random effects model, respectively).

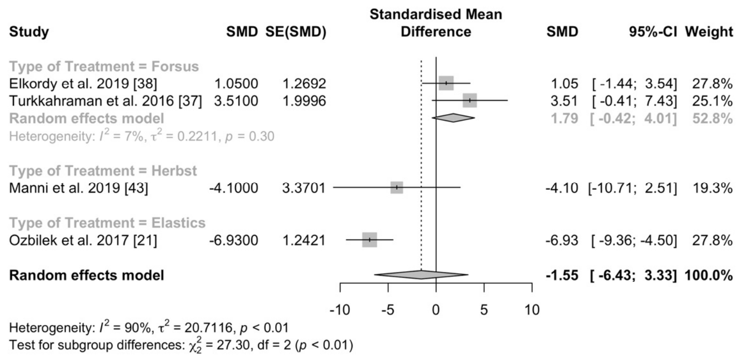

Figure 7. IS/PP° forest plot.

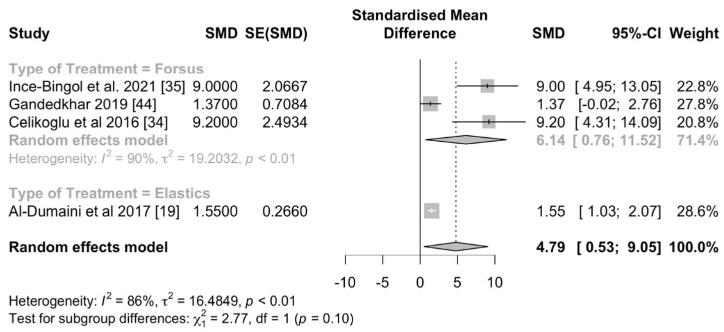

Figure 8. IS/SN° forest plot.

4. Discussion

The aim of functional treatment in patients with skeletal Class II and mandibular retrusion is to increase the projection of the chin, reduce the convexity, and improve the aesthetics of the profile. Despite the skeletal benefits, undesired dental effects (lingual tipping of the upper incisors, labial flaring of the lower ones, distal movement of the upper arch, and mesialization of the lower one), caused by anchorage loss, could reduce the amount of mandibular advancement [14,45]. Therefore, skeletal anchorage has been combined with functional appliances to minimize these common side effects [18,25]. However, the results of the studies on this topic were controversial, with some of them reporting favorable outcomes associated with skeletal anchorage [32,33], while others showed no differences compared to conventional treatment [36,39]. The rationale for this apparent inconsistency may lie in the effectiveness of the devices used; thus, the purpose of this review was to compare the effects of skeletal anchorage combined with different Class II devices, from an overall perspective and individually for each type of appliance.

Eighteen controlled and clinical trials were selected based on inclusion/exclusion criteria. Different anchorage devices (mandibular miniscrews, maxillary and mandibular miniscrews, mandibular miniplates, and maxillary and mandibular miniplates), combined with four appliances (Herbst, Forsus, Carriere Motion, and Class II elastics) were analyzed and compared to conventional devices with dental anchorage.

The primary outcome was to assess the control of the vertical dimension: it is a well-known fact that a good control of the occlusal plane enables us to reduce the clockwise rotation of the mandible, improving the sagittal projection of the Pog. TADs may be useful for this purpose, especially in hyperdivergent patients [46]. However, the meta-analysis results showed no statistically significant difference in the skeletal divergence using TADs compared to conventional therapy; this was in accordance with the conclusion of Muley [17,47] who evaluated only fixed functional appliances. An overall decrease in skeletal divergence was observed in the present study (0.19° of difference between the skeletally anchored and the control group, considering the random effects model); the subgroup analysis, categorized by type of appliance, revealed a statistically significant difference in mandibular rotation using Herbst in combination with TADs, compared with traditional dental anchorage: the addition of skeletal anchorage allowed a mean decrease in skeletal divergence of 1.44° in studies focused on this appliance. The reason for this could lie in the proper control of the occlusal plane, due to the presence of the acrylic splint and the TADs used in all the considered studies by Manni. Differently from other Class II appliances, the presence of the splint limits the extrusion of lower molars, while the TADs reduce the relative intrusion of the lower incisors: the overall result could be a reduction in the typical clockwise rotation of the occlusal plane.

Although a slight decrease in the parameter (1.50° of counterclockwise rotation) was reported also in the elastics group, the difference was not statistically significant, probably due to the presence of a high variability in both the applied protocol and the control group: Al-dumaini [19] compares Class II elastics on four miniplates vs. untreated patients; El-dawlatly [20] compares elastics with indirect anchorage (mandibular TADs linked to the arch with a metallic ligature) vs. conventional Class II elastic protocol; and Ozbilek [17,21] compares Class II elastics on four miniplates vs. monobloc appliance. Moreover, with this protocol, patient compliance is required and can influence the outcome of the analysis.

Differently from other devices, the skeletal divergence was increased in a statistically significant way (0.59° of difference between skeletally anchored and conventional group) when the Forsus appliance was combined with TADs, in consonance with the findings by Arvind [23], regardless of the type of anchorage (direct or indirect).

Considering the inclination of the lower incisors, the meta-analysis results showed that, compared to conventional therapy, the patients treated with TADs exhibit a statistically significant decrease in the flaring of the lower incisors (difference of 5.58° between skeletal and conventional anchorage, considering a random effects model), confirming the promising role of the skeletal anchorage in limiting the undesired mesialization of the lower arch, as reported by Huang [17] and Sherif [16]. In particular, the combination of Herbst, Forsus, and Carriere was found to be statistically significantly effective in reducing the angular measurement (IMPA°) when compared with conventional appliances (−5.16°, −7.24°, and −4.44°, respectively), while the reduction was not statistically significant when Class II elastics were used. The only group showing a low heterogeneity (27%) was the Herbst group, giving these data a greater predictability. The achievement of such results could lie in the presence of the acrylic splint and elastic ligatures, used in most of the studies by Manni, rather than stainless steel ligatures, connecting the lower arch with TADs. Indeed, TADs do not provide an absolute anchorage: when subjected to a force, they tend to slide or tilt slightly towards the direction of traction [48] and a ligature wire could not completely prevent the migration of anchored teeth; on the contrary, elastic chains, due to their elasticity, may produce a constant balancing traction directed towards the opposite side. Indeed, in the study by Bremen [42], where the lower anchorage is represented by a 19 × 25 ss arch with a metal ligature connected to the lower TADs, less control in the lower incisal position was observed (−1.70° of reduction in IMPA°, when compared with conventional anchorage). In the Class II elastic group, a great variability in the results was observed, possibly again due to the different protocols. The study by Ozbilek [21] showed a greater reduction in IMPA° since a direct anchorage on miniplates was applied, without the involvement of the lower arch. On the contrary, in the study by El-Dawlatly [20], when indirect anchorage (metal ligature linking lower miniscrews to the arch) was used, less control in the lower incisor position was observed. A similar condition with great variability was observed in the Forsus group: when direct anchorage onto miniplates was used [34,35,37,38], a better control on lower incisors is generally observed. On the contrary, when a lower multi-brackets appliance is simultaneously applied in combination with direct skeletal anchorage on miniplates, as in the study of Kochar [41] and Gandedkar [44], an increased labial tipping of the lower incisors is observed, probably because of the engagement of the arch during the arch alignment stages.

Regarding the Carriere appliance, the presence of skeletal anchorage confirmed the better control of the incisal position. Despite limitations due to the absence of a large number of works (only one study by Fouda [22] was considered), this conclusion confirmed the reduced sagittal control provided by a lower vacuum-formed retainer in the lower arch [49–51].

The inclination of the upper incisors was analyzed in two ways: relative to the palatal plane (PP) and to the anterior cranial base (SN). In the first case, a slight proclination of the maxillary incisors relative to the palatal plane was registered, although it was not as statistically significant in the meta-analysis as the overall effect (SMD: −1.55 (−6.43 to 3.33)). The subgroup analysis showed a difference between the Forsus group, in which a reduction in the upper incisor inclination was found (1.76° considering the common effects model) when skeletal anchorage was applied and the Herbst and elastics groups. In the latter two cases, although with the presence of a single article in both, a higher incisor inclination was registered (4.10° in the Herbst group and 6.93° in the elastic group).

When the inclination of the upper incisors was measured relative to the anterior cranial base (SN), a greater palatal tipping in the maxillary incisors was found after therapy in association with TADs (4.79° considering the random effects model). The difference was statistically significant in the subgroup analysis as well, with a decrease in the angle both for Forsus and for Class II elastics when associated with skeletal anchorage (SMD: 6.14 (0.76 to 11.52 and SMD: 1.55 (1.03 to 2.07), respectively). This contrast may be explained considering the kind and biomechanics of the anchorage system. In Class II treatment, the applied forces tend to mesialize the lower arch and distalize the upper one; however, when skeletal anchorage is set in the mandibular arch to prevent the mesialization of the lower incisors (as happened in most of the studies included in the present review), most of the forces could be transferred to the upper molars' arch, resulting in increased upper distalization, observable in both the molar and incisor position. Indeed, the only cases in which a lower decrease in the upper incisors' inclination has been recorded are those in which a skeletal anchorage was also applied in the upper arch [21,31].

5. Limitations

The achieved results must be interpreted with caution due to five main limitations.

First of all, the number of the included studies should be considered, being relatively small and thus making the eventual statistical significance less reliable.

Second, the statistical analysis was further impaired by the huge heterogenicity of the included studies. Therefore, the authors have admitted the adoption of a random effects model for data synthesis, in order to highlight any statistically significant difference (see Section 3.4). In particular, the highest diversification was found in the control groups chosen by the included studies: ideally, they should have been composed of samples of patients treated with the same appliance adopted in the test group with the absence of TADs as the only exception; instead, some studies used untreated patients as the control [19,35,41] or patients treated with different appliances and no skeletal anchorage [21,34]. In addition, the gap among the included studies was evident also in the different variables that were investigated in each of them: the missing uniformity limited the investigation of some of the outcomes that the authors originally intended to examine.

The third limitation was the timing, and the temporal disparity has a significant impact when dealing with samples of patients: not all the time were the windows comparable to each other, since the functional therapy was not always the only one considered. For example, some studies [41,42] lacked the intermediate X-ray and took the T1 lateral cephalogram at the end of fixed appliance therapy and not at the end of functional treatment.

Fourth, the age of the patients was not exactly comparable among the included studies, with only some of them reporting the cervical maturation stages.

Finally, the fifth limitation is related to the questionable clinical relevance of the effects brought about by the combination of TADs with functional appliances: indeed, even though there are statistical significant differences between the interventions, some of these changes have little importance from the clinical point of view.

Therefore, all limitations considered, further well-designed, high-quality studies, as RCTs, following strict inclusion and exclusion criteria, are needed to give superior significance to the conclusions reached in this systematic review.

6. Conclusions

Considering the available evidence and the highlighted limitations, the combination of TADs and functional appliances produces the following effects on the vertical dimension and on the position of the mandibular and maxillary incisors:

- In Class II malocclusion therapy, the vertical dimension is not significantly affected by the aid of skeletal anchorage: the control on the skeletal divergence obtained by TADs may be acceptable, but not clinically significant.
- Regarding the sagittal control of mandibular incisors, the role of TADs may be substantial: however, it has been shown that the result is strictly dependent on the kind of anchorage and treatment protocol.
- Regarding the sagittal control of maxillary incisors, skeletal anchorage might be useful also in the maxilla, especially when lingual tipping of the upper incisors should be reduced.

Supplementary Materials: The following supporting information can be downloaded at: https://www.mdpi.com/article/10.3390/oral4030034/s1, Table S1: Egger's regression test; Figure S1: Funnel plot skeletal divergence; Figure S2: Funnel plot overjet; Figure S3: Funnel plot IMPA°; Figure S4: Funnel plot IS/PP°; Figure S5: Funnel plot IS/SN°; Figure S6: Sensitivity analysis for skeletal divergence (elastics); Figure S7: Sensitivity analysis for skeletal divergence (Forsus); Figure S8: Sensitivity analysis for skeletal divergence (Herbst); Figure S9: Sensitivity analysis for overjet (Herbst); Figure S10: Sensitivity analysis for overjet (Elastics); Figure S11: Sensitivity analysis for overjet (Forsus); Figure S12: Sensitivity analysis for IMPA° (Forsus); Figure S13: Sensitivity analysis for IMPA° (Herbst)); Figure S14: Sensitivity analysis for IMPA° (Elastics); Figure S15: Sensitivity analysis for IS/PP° (Forsus); Figure S16: Sensitivity analysis for IS/SN°.

Author Contributions: E.G.: conceptualization, methodology, investigation, writing—original draft, and visualization. A.B.: conceptualization, resources, data curation, and writing—review and editing. F.C.: application of statistical, mathematical, computational, or other formal techniques to analyze or synthesize study data. T.D., G.G., A.M. and M.C.: conceptualization, validation, supervision, and project administration. All authors have read and agreed to the published version of the manuscript.

Funding: This research received no external funding.

Institutional Review Board Statement: Not applicable.

Informed Consent Statement: Not applicable.

Conflicts of Interest: The authors declare no conflicts of interest.

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