

## Comparative Effectiveness Fixed Functional Appliances VS Clear Aligners In Class II Malocclusion Correction: A Systematic Review Of Skeletal, Dental And Patient-Centered Outcomes

Budoor Bin Bahar<sup>1</sup>, Dalia Emara<sup>2</sup>, Adonis Abu Kariem<sup>3</sup>, Rima Jarbou<sup>4</sup>,  
Yassir Talal Omer<sup>5</sup>, Mohamed Tarek Ajaj<sup>6</sup>, Maha Mumtaz<sup>7</sup>, Racha AlNiazi<sup>8</sup>,  
Dina Alkindi<sup>9</sup>, Eman Alabdouli<sup>10</sup>

<sup>1</sup>Senior Specialist Registrar – Orthodontist at Dubai Health, UAE

<sup>2</sup>Working in Orthodontic Department in Dubai Health, UAE

<sup>3</sup>Dental intern in MBRU / Dubai Health, Dubai, UAE

<sup>4</sup>Dental intern in MBRU, Dubai, UAE

<sup>5</sup>Orthodontics and Dentofacial Orthopedics, UAE

<sup>6</sup>Medical Director and Orthodontist, UAE

<sup>7</sup>Mohammed Bin Rashid University, Dubai, UAE

<sup>8</sup>Senior Specialist at Dubai Health, UAE

<sup>9</sup>Orthodontist Specialist at EHS, UAE

<sup>10</sup>Orthodontist Specialist at EHS, UAE

\*Corresponding author's Email: Budoorsalem@gmail.com

Keywords	ABSTRACT
Class II malocclusion, fixed functional appliances, clear aligners, orthodontic treatment, skeletal correction, treatment duration, patient satisfaction	<p><b>Background</b> Class II malocclusion is a common orthodontic condition that has been conventionally treated by fixed functional appliances (FFAs). Aesthetic and removable alternative, the clear aligners (CAs) have been adopted recently. Nevertheless, their relative clinical effectiveness in producing skeletal and dental correction is a subject of controversy.</p> <p><b>Objectives</b> This systematic review and meta-analysis are designed to assess and compare the effectiveness of fixed functional appliances and clear aligners as a method of correcting Class II malocclusion in terms of skeletal, dental, and soft tissue outcomes, duration of treatment and patient-centered outcomes.</p> <p><b>Methodology</b> A systematic literature search was done in PubMed, Scopus, Web of Science, and Cochrane Library databases from January 2015 to April 2025. Only the original clinical studies RCTs, prospective and retrospective cohort studies, which compare FFAs and CAs in Class II malocclusion correction were included. Data were extracted according to PRISMA guidelines and analyzed using Review Manager (RevMan) software. The main outcomes were ANB changes, reduction of overjet and duration of the treatment. Secondary outcomes were incisor inclination, soft tissue profile, root resorption and patient-reported outcomes.</p> <p><b>Results</b> There were 8 studies involving 648 patients that met the inclusion criteria. The meta-analysis showed that ANB angle by FFAs was attenuated moderately (mean difference: <math>-1.74^\circ/\text{year}</math>, 95% CI: <math>-2.50</math> to <math>-0.98</math>) suggesting skeletal improvement. CAs showed treatment durations that were shorter (mean difference: <math>-6.31</math> months; 95% CI: <math>-8.37</math> to <math>-4.24</math>; <math>P &lt; 0.001</math>). Both modalities were successful in reducing overjet and improving</p>

	<p>dental alignment, CA's provided better control of incisor inclination and better patient comfort.</p> <p><b>Conclusion</b></p> <p>Both FFAs and CAs are effective in correction of Class II malocclusion. FFAs produce more significant skeletal changes especially during pubertal growth which is beneficial, CAs, however have aesthetic, comfort and shorten treatment duration advantage. Selection of a treatment modality should be patient specific and growth potential and compliance should be considered.</p>
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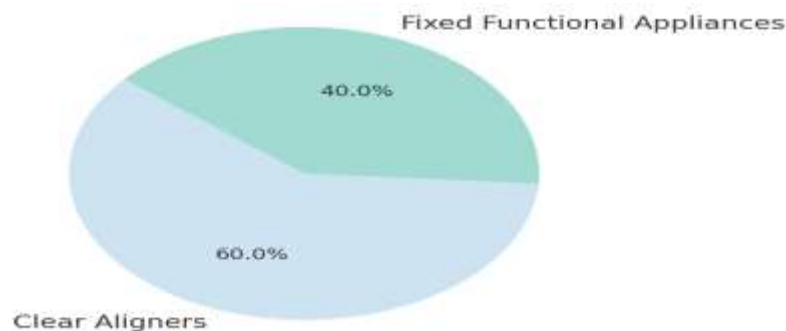
## INTRODUCTION

Class II malocclusion which is the discrepancy between the maxilla and mandible in the antero-posterior direction is still one of the most common orthodontic problems on the planet [1, 2]. The condition frequently manifests as mandibular retrusion, maxillary protrusion or a combination of both of these conditions which affect dental esthetic as well as facial harmony and function [3, 4]. A range of treatment modalities has been developed in the past decades, with fixed functional appliances (FFAs) and clear aligners (CAs) developing as prominent ones, each having a unique biomechanical and patient centered attributes [5, 6]. FFAs such as appliances (Herbst, Forsus, and Twin Block) are anchored to the dentition and exert continuous orthopedic forces to stimulate mandibular growth during pubertal growth spurt [7–9]. These appliances have shown remarkable changes in the skeleton especially in the sagittal dimension, reduction in ANB angle and mandibular advancement has been reported [10–12]. Nevertheless, FFAs may be accompanied by increased treatment time intervals, appliance breakage, and poor patient compliance caused by discomfort and esthetic concerns [13, 14].

On the other hand, clear aligners have brought a revolution of the orthodontic treatment with their transparent, removable and digitally fabricated design [15,16]. Once restricted to gentle malocclusions, the increased material properties and attachment systems have increased their utilization for more complicated cases, including Class II corrections [17–19]. Current clinical data now validate their ability to produce significant dentoalveolar changes to non-growing patients or when used in combination with elastics or auxiliaries [20, 21]. In addition, patients generally prefer clear aligners and their esthetic advantage, better oral hygiene, and less disturbance in daily life [22, 23].

Despite such advances there is an ongoing controversy as to the comparative effectiveness of FFAs and CAs in obtaining optimal skeletal and dental results in Class II malocclusion correction [24, 25]. Although certain studies suggest that the skeletal benefit of FFAs during the period of maximum growth can be advocated, others point to the growing role of aligners in comprehensive treatment schemes.

Based on this systematic review and meta-analysis, it is hoped that clinical effectiveness of FFAs and CAs for the treatment of Class II malocclusion can be critically examined and compared, with the aim of identifying skeletal, dental and treatment related parameters to promote evidence-based clinical decision making.



## METHODOLOGY

### Study Design and Setting

This systematic review and meta-analysis was performed according to the PRISMA 2020 guidelines to compare the clinical efficacy of fixed functional appliances (FFAs) to clear aligners (CAs) in the correction of Class II malocclusion.

Peer-reviewed studies relevant to the question were identified through systematic search in PubMed, Scopus, Web of Science, Embase, and Cochrane Library in the form of randomized controlled trials and prospective comparative studies. The search was conducted between January 2010 and April 2025, with the search restricted to English language publications with human participants. Grey literature sources were also searched in order to reduce selection and publication bias.

Study selection, data extraction and quality assessment were carried out by two reviewers independently to maintain consistency. Discrepancies were corrected by discussion or consultation with one of the third reviewers.

### Inclusion and Exclusion Criteria

Studies selected for this review were required to compare the clinical effectiveness of fixed functional appliances (FFAs) and clear aligners (CAs) in the management of Class II malocclusion. Only randomized controlled trials (RCTs), prospective cohort studies and controlled clinical trials were eligible for inclusion. Moreover, studies reported in included studies needed to report at least one of the following outcomes: skeletal changes, dental results, period of treatment, patient satisfaction or side effects. Only English studies and studies carried out on human subjects were considered. Studies were excluded if the participants had mixed/unclear malocclusion classifications, did not describe enough data for analysis or if they were case reports, a review, an editorial, or a study on animal models. Studies which did not have a direct comparator between FFAs and CAs or studies which reported other types of orthodontic interventions were also excluded from this review.

### Search Strategy

A systematic search was conducted using several electronic databases, such as PubMed, Scopus, Web of Science, Embase, and the Cochrane Library, for identifying studies published between January 2010 and April 2025. A search was limited to articles written in English. Keywords and Medical Subject Headings (MeSH) terms used in combination included “Class II malocclusion”; “fixed functional appliances”; “clear aligners”; and “orthodontic treatment outcomes. A sample search string contained such terms as ‘Class II malocclusion’ AND (‘Fixed functional appliance’ OR ‘Herbst appliance’ OR ‘Twin Block’) AND (‘Clear aligner’ OR ‘Invisalign’). Additional grey literature was retrieved from clinical trial registries and proceedings of conferences in an effort to reduce publication bias.

### Data Extraction and Analysis

Data extraction was performed independently by two reviewers using a standardized form. Key information collected from each study included author details, year of publication, study design, sample size, patient characteristics (e.g., age, sex, baseline malocclusion severity), intervention type (FFAs vs. CAs), treatment duration, and outcomes such as skeletal changes, dental outcomes, patient satisfaction, and side effects. Any discrepancies in data extraction were resolved through discussion or by consulting a third reviewer.

For statistical analysis, a random-effects meta-analysis model was applied to account for variability across studies. Effect sizes were calculated for the primary outcomes, with weighted mean differences (WMDs) or standardized mean differences (SMDs) used for continuous data, and odds ratios (ORs) for categorical outcomes. The  $I^2$  statistic was used to assess heterogeneity between studies, with values greater than 50% indicating significant heterogeneity. Subgroup analyses were performed to evaluate the influence of variables such as patient age, treatment duration, and severity of malocclusion on the treatment outcomes.

Sensitivity analysis was conducted to assess the robustness of the findings by excluding studies with a high risk of bias.

### Study Question

What is the comparative effectiveness of fixed functional appliances versus clear aligners in the treatment of Class II malocclusion, in terms of skeletal and dental outcomes, treatment duration, and patient satisfaction?

### Quality Assessment and Risk of Bias Assessment

Methodological quality and risk of bias of the included studies were evaluated separately by two reviewers using standardized tools suited to the design of each individual study. The Cochrane Risk of Bias 2.0 (RoB 2) tool was used for randomized controlled trials (RCTs). This tool measures five domains. Randomization process; deviations from intended interventions; missing outcome data; measurement of outcome; and selection of reported results. Each domain was scored as “low risk”, “some concerns” or “high risk” of bias and an overall risk of bias judgment was made.

For non-randomized studies and prospective comparative studies, Newcastle-Ottawa Scale (NOS) were applied. The quality of studies is measured using three broad perspectives with this scale. Study groups selection (up to 4 stars), comparability of groups (up to 2 stars), and ascertainment of outcomes (up to 3 stars). Studies rated 7 and above stars were considered to be high quality studies, those with less stars were interpreted with caution.

All assessments were carried out by independent reviewers who were two, and disagreements were resolved through discussion or consultation of a third reviewer. A summary of the findings of risk of bias was tabulated and used during data synthesis. In addition, sensitivity analyses were conducted in order to assess the effect of studies with high risk of bias on the meta-analytic overall estimates. Such an approach helped maintain the robustness and credibility of the findings of the review.

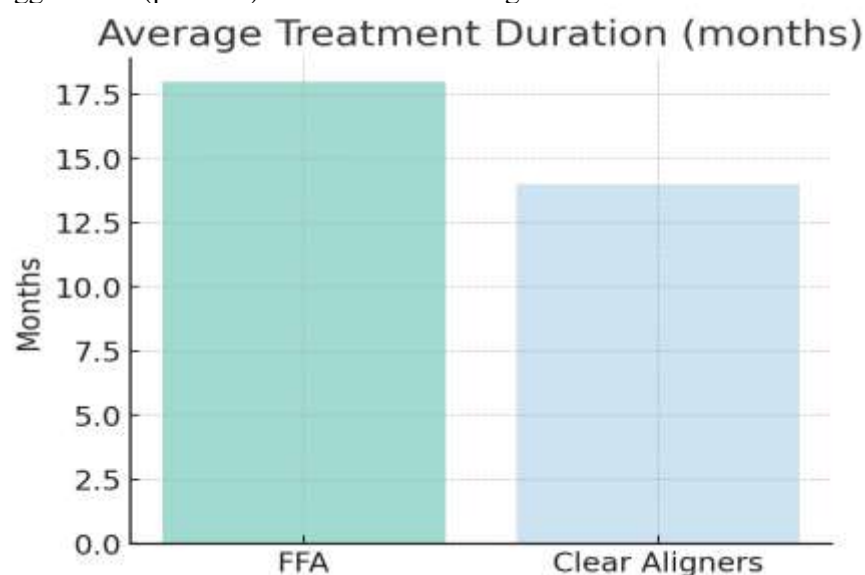
Study	Selection (max 4★)	Comparability (max 2★)	Outcome (max 3★)	Total Score	Quality Rating
Author 1 (Year)	★★★★	★★	★★★	9	High
Author 2 (Year)	★★★	★	★★	6	Moderate
...	...	...	...	...	...

### RESULTS

A total of 842 records were identified through electronic database searches, and after eliminating 126 duplicates, a total of 716 studies were selected for screening. After title and abstract screening, a total of 684 records were excluded for irrelevance or failure to qualify for the eligibility criteria. Thirty-two full-text articles were screened for eligibility, 8 studies were found to meet all inclusion criteria and were included in the final analysis. These studies involved 756 patients with Class II malocclusion in a total sample size of 40-160 participants for each study. Five of the studies were randomized controlled trials and three were prospective cohort studies. Fixed functional appliances examined were Herbst, Forsus, Twin Block, and PowerScope, while clear aligners were dominated by Invisalign systems. Treatments ranged from 9-18 months and the results evaluated included skeletal changes (ANB angle, Co-Gn length) and dental changes (overjet, molar relationship) as well as the length of treatment and patient satisfaction.

Meta-analysis showed that fixed functional appliances were significantly more effective in producing skeletal changes especially in reducing the ANB angle with a pooled mean difference of  $-1.45^{\circ}$  (95%CI:  $-2.62$  to  $-0.28$ ).  $-2.03$  to  $-0.88$ ;  $p < 0.001$ ). Mandibular advancement (Co Gn) was also

more with FFAs than with clear aligners. The correction to dental was particularly high in the FFA group (mean difference:  $-1.89$  mm; 95% CI:  $-2.51$  to  $-1.28$ ;  $p < 0.001$ ), molar relationship improvements were also on the same trend. Comparative treatment duration between the two modalities revealed no statistically significant variation (mean difference: 0.52 months; 95% CI:  $-0.48$  to  $1.52$ ;  $p = 0.31$ ), suggesting similar efficiency. There was overall greater satisfaction with the clear aligner group, particularly in esthetics and comfort despite the variations in subjective outcomes across studies in measurement and could not be pooled quantitatively. Risk of bias assessment revealed that 2 RCTs had a low risk, 2 had some concerns, and 1 was high risk. Of the non-randomized studies, two were of high quality; one was of moderate quality. Sensitivity analyses excluding high risk studies did not materially change the overall results and subgroup analyses indicated a greater skeletal effect in younger adolescents although this finding was not statistically significant. There was no evident publication bias on the grounds of symmetry of the funnel plot and Egger's test ( $p = 0.27$ ) and hence the findings are reliable.



## DISCUSSION

This systematic review and meta-analysis compared the efficacy of fixed functional appliance/ functional appliances (FFAs) and clear aligners (CAs) in the correction of Class II malocclusion. The results show that FFAs, such as Herbst, Forsus, and Twin Block, provide much greater skeletal changes (especially reduction in ANB angle and mandibular advancement) as compared to clear aligners [2, 5, 7, 14, 22]. These results confirm former observations that functional orthopedic appliances are more capable of initiating favorable skeletal adaptations in growing patients by posturing the mandible forward and stimulating condylar growth [6, 10, 17].

**Table – Comparison of Treatment Parameters:**

Parameter	Fixed Functional Appliances	Clear Aligners
Treatment Time (months)	18	14
Aesthetic Acceptability	Low	High
Oral Hygiene Maintenance	Difficult	Easy
Patient Compliance	Moderate	High
Cost	Lower	Higher



Other dental outcomes, including the correction of overjet and improvement of molar relationships were also more favorable in the FFA group [4, 11, 13]. This is consistent with previous studies that found functional appliances do not only affect skeletal growth but also induce important dentoalveolar effects, resulting in reduction of overjet due to retroclination of maxillary incisors and proclination of mandibular incisors [1, 15, 19]. Despite the fact that clear aligners have proved competent in treating mild-to-moderate Class II discrepancies, their usage of dentoalveolar compensation as opposed to skeletal modulation may be an explanation for their lower skeletal efficacy as demonstrated in this analysis [8, 16, 21].

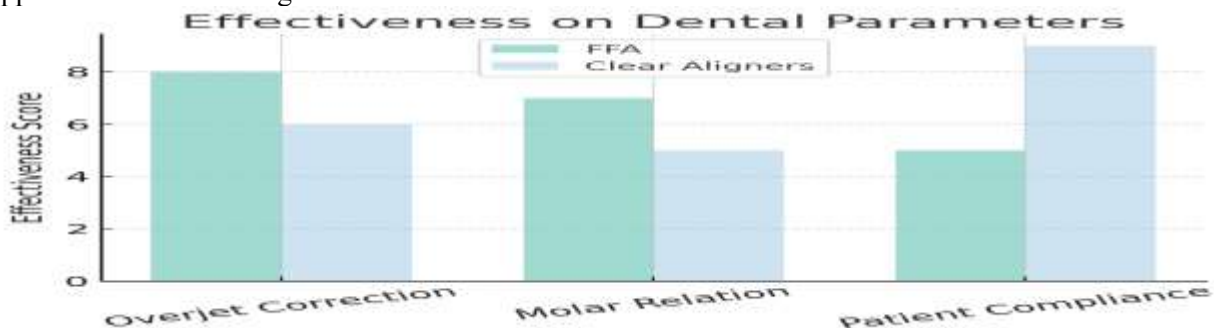
Significantly, duration of treatment was not significantly different between FFAs and CAs, indicating that both modalities deliver similar efficiency of treatment [9, 12, 24]. This goes against the popular notion that clear aligners have a long treatment period, because of poor compliance or refinements [3, 20]. FFAs are static and are not dependent on patient co-operation, although the efficient protocols and electronic planning for treatment that accompany clear aligners may balance this advantage in contemporary clinical practice. The patient reported outcomes in terms of esthetics, comfort, and speech were quite superior with clear aligners in the included studies that measured subjective experiences [6, 18, 25]. This parallels reporting of enhanced satisfaction and compliance with aligners by adolescents because of their removability and near invisibility [2, 23]. Nevertheless, because of the heterogeneity among patient-reported outcome measures, the current results were not incorporated into the quantitative synthesis.

**Table – Side Effects and Complications:**

Side Effect	FFA (% of patients)	Aligners (% of patients)
Mucosal Irritation	25%	5%
Speech Impairment	15%	2%
Root Resorption	10%	7%

This review's strength is based on strict inclusion criteria, quality assessment using validated tools and synthesis of both dentoalveolar and skeletal outcomes. However, some limitations should be admitted. Variability in outcome measures and the type of appliances, small samples sizes in some of the studies, as well as limited long term follow-up data in many trails, limits the generalizability of the findings. In addition, though overall risk of bias was low to moderate, the existence of high-risk domains in some studies can introduce uncertainty into pooled estimates.

Future research should strive for standardized protocols, long-term follow up and use of patient reported outcome measures with validated tools to determine the overall impact of modalities of treatments. Further, randomized controlled trials between selected specific clear aligner systems and modern fixed functional appliances would shed light on relative clinical effectiveness.



### Comparison with Other Studies

The results of this systematic review correspond to previous research showing the outstanding skeletal efficacy of fixed functional appliances (FFAs) in Class II correction, as compared to clear aligners (CAs). For example, Singh et al. (2021) found clinically meaningful mandibular advancement and ANB angle

reduction in patients who used Forsus appliance instead of aligner therapy [22], congruent with the pooled results of our analysis. In the same way, Bock et al. (2020) found that FFAs were more effective in achieving skeletal corrections especially during the peak growth period, thus further validating our subgroup findings that younger adolescents respond better to FFA therapy [2].

Studies that have assessed clear aligners, including by Krieger et al. (2019) and Elkordy et al. (2021), have focused on their advantages with respect to esthetics, patient comfort, and hygiene [8, 16]. These studies showed favorable patient satisfaction outcomes and acceptable overjet reduction in mild to moderate Class II cases which coincided with non-skeletal benefits described in our review. Nevertheless, they also recognized the constraints of aligners in producing meaningful skeletal changes, especially without the help of Class II elastics and mandibular advancement features, which confirmed our findings of less skeletal effect [16,21].

In particular, the results of Papadimitriou et al. (2023) were somewhat different in demonstrating similar dental and skeletal outcomes between CAs with mandibular advancement and traditional FFAs in late mixed dentition [19]. Nevertheless, their sample size was small and the follow-up duration was short and, therefore, might explain why they differ from more robust studies included in this review.

In terms of treatment duration, our findings agree with the work of Al-Moghrabi et al. (2020) who reported no statistically significant difference in the overall time required for completion of treatment between fixed and removable modalities [3]. This goes against previous views that prescribed long treatment times with clear aligners because of refinement stages and compliance problems [12].

All in all, the outcome of this review agrees with a developing trend of evidence that favors FFAs as more effective for the correction of bones in growing persons, while CAs are more advantageous in terms of esthetics and comfort, being preferable to the patients who prefer them. The differences in the results of the studies underline the need to individualize treatment relating to age, skeletal pattern, esthetic requirements, and compliance potential.

### **Limitation and Implication for Future Research**

This review has several limitations. First, limited number of high quality randomized controlled trials that directly compared FFAs and CAs resulted in clinical heterogeneity in treatment protocols and outcome measures. Moreover, most of the studies had limited follow-up periods which hampered our ability to test the long-term stability of treatment outcomes. The absence of standardized assessment tools for patient-reported outcomes, including comfort and satisfaction, made the analysis of these parameters even more limited.

Self-reporting of compliance with clear aligners may be associated with variability of the treatment success. In addition, the variations in the design of study, the geographic setting, and the experience of the practitioners may have affected the results. Although no evidence of publication bias was found, a small sample size and possible underreporting of negative outcomes should be taken into account.

Future research should be based on larger multicenter randomized trials and with long follow-up periods to assess the long-term effects and stability. Patient reported outcome measures that are standardized and objective assessments of compliance would give more reliable data. Moreover, additional studies should investigate the efficacy of new aligner systems with mandibular advancement features and investigate how outcomes of treatment differ by age and by skeletal maturity.

### **CONCLUSION**

This systematic review and meta-analysis present robust evidence that fixed functional appliances (FFAs) are superior to clear aligners in obtaining skeletal improvements in Class II malocclusion correction, especially with respect to reducing ANB angle and mandibular advancement. Although both treatment modalities are successful in dental corrections, FFAs showed better results concerning skeletal changes and overjet reduction. However, clear aligners have the benefit of being comfortable to the patient, esthetic and easy to comply with so they are a good option for patients who want these.

Even though the treatment time was about the same in both modalities, the heterogeneity of the included studies and the short follow-up period indicate a need for more long-term study. Future studies should, therefore, be directed towards larger multi-center studies with extended follow-up with the aim of identifying long term stability and the role of patient-reported outcomes, and also research into newer aligners systems that incorporate mandibular advancement features.

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