



Evaluation Of Treatment Effects Of Fixed Functional Appliances In Skeletal Class II Growing Patients Through A Systematic Review And Meta- Analysis

Sushma Sonawane¹, Sameer Narkhede², Karthick Shetty³, Priyanka C Mishra^{4*}, Vignesh Kadam⁵, Rakesh A Singh⁶

¹Professor & Guide, Department of Orthodontics & Dentofacial Orthopedics, DY Patil University School Of Dentistry, Nerul, Navi Mumbai Email id: sushma.sonawane@dypatil.edu

²HOD & Professor, Department of Orthodontics & Dentofacial Orthopaedics, DY Patil University School Of Dentistry, Nerul, Navi Mumbai Email id: sameer.narkhede@dypatil.edu

³Professor & Guide, Department of Orthodontics & Dentofacial Orthopaedics, DY Patil University School Of Dentistry, Nerul, Navi Mumbai Email id: karthick.shetty@dypatil.edu

^{4*}Postgraduate Student, Department of Orthodontics & Dentofacial Orthopedics, DY Patil University School Of Dentistry, Nerul, Navi Mumbai Email id: drpriyankkacmishra@gmail.com

⁵Lecturer, Department of Orthodontics & Dentofacial Orthopedics, DY

Patil University School Of Dentistry, Nerul, Navi Mumbai Email id: Vighaneshkadam99@gmail.com

⁶Professor & Guide, Department of Orthodontics & Dentofacial Orthopedics, DY Patil University School Of Dentistry, Nerul, Navi Mumbai Email id: rakeshkumar.singh@dypatil.edu

ABSTRACT

Aim: Evaluation of treatment effects of Fixed Functional Appliances in Skeletal Class II growing patients through Systematic Review and Meta- Analysis.

Methods: The review adhered to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines and was registered in PROSPERO with the registration number CRD42025633579. A thorough search of databases was conducted till Dec 2023 to identify studies evaluating the effectiveness of fixed functional appliance therapy in growing patients with skeletal class II malocclusion. Quality assessment was performed using the Cochrane risk of bias (ROB) -2 tool for randomized controlled trials (RCTs), evaluating each study's domains through Review Manager(RevMan) software version 5.3. The standardized mean difference (SMD) served as the summary statistic measure, employing a random-effect model with a significance threshold set at $p < 0.05$.

Results: Seven studies met the eligibility criteria and underwent qualitative synthesis, with eight studies in meta-analysis. Upon quality assessment, the studies demonstrated a range of moderate to low risk of bias, ensuring a comprehensive evaluation of the evidence base. Outcomes like overjet, overbite, nasolabial angle, interincisal angle, lip strain, changes in SNA0, SNB0, ANB0, wits appraisal, lower face height, U1-SN plane and occlusal plane were assessed quantitatively. Pooled estimate through SMD favoured the fixed appliance therapy group over control or other's modality group ($p > 0.05$). Funnel plot did not reveal the presence of any heterogeneity indicating absence of publication bias.

Conclusion: The treatment effects of FFAs on the skeletal tissues in patients with Class II malocclusion were probably of clinical importance. The treatment of Class II malocclusion with FFAs was associated with stimulation of mandibular growth and with more pronounced dentoalveolar and soft tissue changes. Patient- and appliance-related factors seem to influence the treatment outcomes, yet complementary research is required to thoroughly investigate the respective effects. The long-term effects of FFAs could not be properly assessed because of insufficient number of relative trials at present.

KEYWORDS: Adolescent, Child, Dentoalveolar Changes, Functional Appliance, Systematic Review.

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INTRODUCTION

An orthodontic treatment is considered successful when objective treatment goals and subjective patient desires are met. Subjects with Class II malocclusions are referred to orthodontists mainly for aesthetic improvement.¹ In these patients, increased overjet and unfavourable profile may lead to negative feelings of self-image and self-esteem. Thus, the treatment plan of these malocclusions should ideally be directed towards to solve the dentoskeletal disharmony in order to obtain a favourable facial aesthetics.²

Various treatment options and appliances are used for the viable treatment of Class II malocclusions, such as removable and fixed functional appliances, extraoral appliances, extraction therapy, and orthognathic surgery. Among these treatment alternatives the success of the functional therapy is mainly related to the co-operation of the patients.

These appliances produce sagittally and vertically intrusive forces as well as expansion in the transverse direction. They also typically demonstrate mesial movement of the mandibular molars, tipping of the mandibular incisors, and variable effects associated with mandibular growth.¹⁴ The major drawback with these appliances is the tendency to breakage that can occur both in the appliance itself and in the support system.

Functional appliance therapy is a commonly used treatment protocol for growing Class II patients. There appears to be a consensus that removable functional appliance therapy leads to improvement on facial appearance in Class II patients.³

Class II malocclusion is one of the most prevalent orthodontic conditions throughout the world, and typically, these deformities are treated by using functional appliances.⁴ At the beginning of the 20th century, extraoral forces were applied to the maxilla with headgear for the correction of Class II malocclusion. This therapeutic method was a reflection of the belief that prevailed during that era that the majority of skeletal Class II malocclusions are caused by the protrusion of the maxilla.⁵

However, subsequent studies indicated that the incidence of Class II division 1 malocclusion resulting from the protrusion of the maxilla does not exceed 20% of the total cases of Class II malocclusion, and the majority of these cases are significantly caused by mandibular retrusion, which prompted many researchers to use functional appliances that stimulate the growth of the mandible for the treatment of skeletal Class II malocclusion.⁶

Many researchers have developed various functional appliances, such as the Monoblock developed by Robin, the Activator developed by Andresen, the bionator developed by Balters, and the Function Regulator developed by Frankel.⁷

Despite the wealth of studies in the literature investigating the mechanism and treatment effects of various functional appliances, the vast majority has intended to concentrate on the measurable skeletal and dental changes induced and have ignored the effects of patient's vertical dimensions.⁸

Much of the clinical data available on the effects of functional appliance therapy has come from analysis of pre and post treatment results on biased successful cases.⁹

Going through evidences, till date no study has provided a comprehensive, qualitative and quantitative analysis on the effectiveness of fixed functional appliance therapy in various dimensions in growing patients with skeletal class II malocclusion. Therefore, we updated our research for related articles and conducted a systematic review with the aim to compare and

evaluate the effectiveness of fixed functional appliance therapy in vertical and sagittal dimension evaluating these as changes in skeletal, dental and soft tissues parameters in growing patients with skeletal class II malocclusion compared to placebo/ conventional or to an untreated control group through a meta-analysis.

METHODOLOGY

Protocol development

This review was conducted and performed in according to the preferred reporting items for systematic review and meta-analysis (PRISMA) statement¹⁸ and registered in Prospective Registration of Systematic Review (PROSPERO)- CRD42025633579
Study design

The review question was to assess the effectiveness of fixed functional appliance therapy in growing patients with skeletal class II malocclusion. The following focused research question in the Participants (P), Intervention (I), Comparison and Outcome (O) format was proposed "What is the effectiveness of fixed functional appliance therapy in growing patients with skeletal class II malocclusion?"

The PICO criteria were as follows:

P (population) – Patients with skeletal class II malocclusion.

I (intervention) - Fixed functional appliance, implant supported functional appliance.

C (comparator) – Compared to a placebo/ conventional or to an untreated control group.

O (outcome) – Effects of fixed functional appliances.

S (study design) – Comparative study, prospective study, clinical trials, cohort studies, longitudinal studies, randomised control trials.

Eligibility Criteria: Studies were selected based on following eligibility criteria's:

a) Inclusion Criteria: following were the inclusion criteria

1) Articles published in English language.

2) Articles from open access journals.

3) Articles published between 1990 to December 2023 and having sufficient data on effect of fixed functional appliance therapy on vertical and sagittal dimension changes in young adolescents with class II division 1 malocclusion compared to placebo or to a control mode of treatment.

4) Studies reporting results in terms of overjet, overbite, nasolabial angle, interincisal angle, lip strain, changes in SNA0, SNB0, ANB0, wits appraisal, lower face height, U1-SN plane and occlusal plane.

5) Clinical studies, cohort studies, longitudinal studies, comparative studies, randomised control trials will be included.

- 6) Articles reporting the study outcomes in terms of mean and standard deviation.
 - 7) Articles with skeletal class II malocclusion in growing children.
 - 8) Studies with individuals having overjet more than 5mm, mandibular retrognathism, minimal crowding in dental arches & presence of bilateral class II molar & canine relationship
- b) Exclusion Criteria: following were the exclusion criteria
- 1) Reviews, abstracts, letter to editor, editorials, animal studies and in vitro studies will be excluded
 - 2) Articles not reporting study outcomes in terms of mean and standard deviation.
 - 3) previous history of orthodontic treatment.
 - 4) Presence of systemic disease.
 - 5) Severe facial asymmetry.

Screening Process

The search and screening, according to previously established protocol were conducted by two authors. A two-phase selection of articles was conducted. In phase one, two reviewers reviewed titles and abstracts of all articles. Articles that did meet inclusion criteria were excluded. In phase-two, selected full articles were independently reviewed and screened by same reviewers. Any disagreement was resolved by discussion. When mutual agreement between two reviewers was not reached, a third reviewer was involved to make final decision. The final selection was based on consensus among all three authors. The corresponding authors of study were contacted via email where further information was required.

Search Strategy

A comprehensive electronic search was performed till December 2023 for the studies published within the last 33 years (from 1990 to 2023) using the following databases: PubMed, google scholar and EBSCOhost to retrieve articles in the English language. The searches in the clinical trials database, cross-referencing and grey literature were conducted using Google Scholar, Greylist, and OpenGrey.

A manual search of journals, including the orthodontic journals were hand searched: American Journal of Orthodontics and Dentofacial Orthopedics, Angle Orthodontist, European Journal of Orthodontics, Journal of Orthodontics, and Orthodontics, journal of oral biology and craniofacial research and journal of Craniofacial Research was also performed.

Appropriate key words and Medical Subject Heading (MeSH) terms were selected and combined with Boolean operators like AND. The relevant data was searched using the following keywords and their combinations: “skeletal malocclusion” (MeSH term) AND “fixed appliance” (MeSH term); “orthodontics” (MeSH term) AND “vertical dimension” (MeSH term); “overbite” (MeSH term) AND “overjet” (MeSH term) AND malocclusions (MeSH term); “class II molar & canine relationship” (MeSH term) AND “maxilla and mandible” (MeSH term) AND “comparative study” AND “longitudinal study” AND “prospective study” (MeSH term); “randomized controlled trials” (MeSH term).

In addition to the electronic search, a hand search was also made, and reference lists of the selected articles were screened. The reference lists of identified studies and relevant reviews on the subject were also scanned for possible additional studies.

Quality assessment of included studies

The methodological quality among included studies was executed by using Cochrane collaboration risk of bias (ROB) -2 tool.¹⁹ The tool has various domains like random sequence generation (selection bias), allocation concealment (selection bias), blinding of personnel and equipments (performance bias), blinding of outcome assessment (detection bias), incomplete outcome data (attrition bias), selective reporting (reporting bias) and other biases through their signalling questions in Review Manager (RevMan) 5.3 software. The overall risk for individual studies was assessed as low, moderate or high risk based on domains and criteria. The study was assessed to have a low overall risk only if all domains were found to have low risk. High overall risk was assessed if one or more of the six domains were found to be at high risk. A moderate risk assessment was provided to studies when one or more domains were found to be uncertain, with none at high risk.

Statistical analysis

The standardized mean difference (SDM) with 95% CI was calculated for continuous outcomes. A fixed effects model (Mantel-Haenszel method) was used if there was no heterogeneity ($p > 0.05$ or $I^2 \leq 24\%$), otherwise a random effects model (Der Simonian- Laird method) was used.²⁰ All statistical analyses were performed using the RevMan 5.3 (Cochrane Collaboration, Software Update, Oxford, UK). The significance level was kept at $p < 0.05$.

Assessment of heterogeneity

The significance of any discrepancies in the estimates of the treatment effects of the different trials was assessed by means of Cochran's test for heterogeneity and the I^2 statistics, which describes the percentage of the total variation across studies that is due to heterogeneity rather than chance. Heterogeneity was considered statistically significant if $P < 0.1$. A rough guide to the interpretation of I^2 given in the Cochrane handbook is as follows: (1) from 0 to 40%, the heterogeneity might not be important;

(2) from 30% to 60%, it may represent moderate heterogeneity; (3) from 50% to 90%, it may represent substantial heterogeneity; (4) from 75% to 100%, there is considerable heterogeneity.²¹

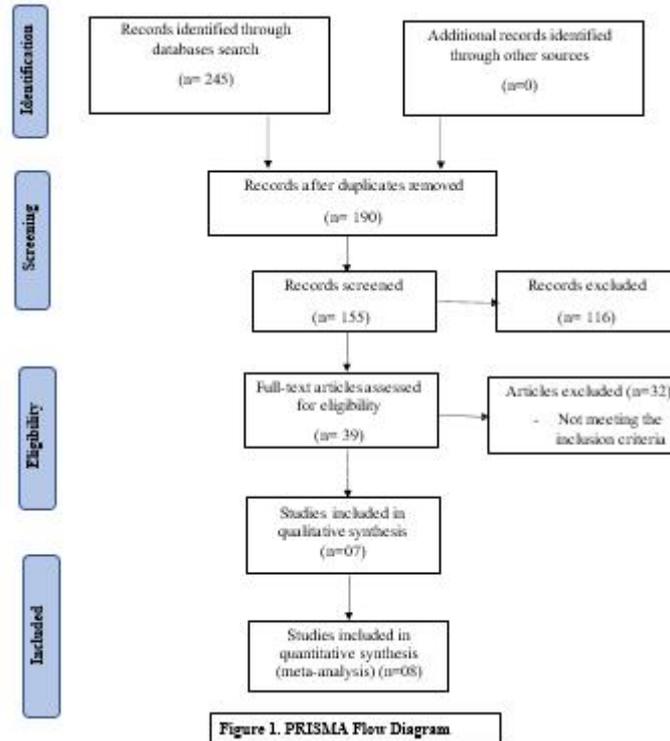
Investigation of publication bias

To test for the presence of publication bias, the relative symmetry of the individual study estimates was assessed around the overall estimates using Begg’s funnel plot. A funnel plot (plot of the effect size versus standard error) was drawn. Asymmetry of the funnel plot may indicate publication bias and other biases related to sample size, although asymmetry may also represent a true relationship between trial size and effect size.²²

RESULTS

Study Selection

After duplicates removal, reference list of included studies was screened. Of which 116 studies were excluded. After this full text articles were assessed for eligibility and articles that did not meet inclusion criteria were excluded. Seven studies fulfilled eligibility criteria and were included in qualitative synthesis. Of which six studies were included in meta – analysis. A flowchart of identification, inclusion and exclusion of studies is shown in Figure 1 below.



Assessment of methodological Quality of included studies

All the included studies were largely comparable in methodological quality. All the included studies had moderate to high risk of bias with all the respected domains. The highest risk of bias was seen for random sequence generation, allocation concealment, blinding of participants and personnel and selective reporting. Domains of blinding of outcome assessment, incomplete outcome data and other bias were given the lowest risk of bias by included studies. Risk of bias of included studies through Cochrane risk of bias (ROB)-2 tool is depicted in Figure 2 and 3 as shown below

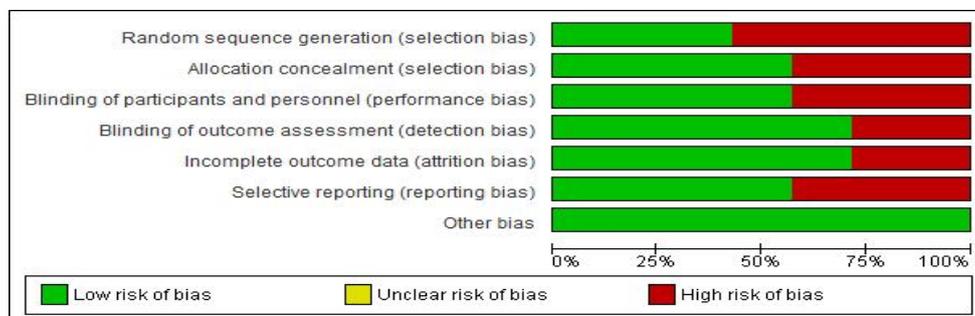


Figure 2: showing risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

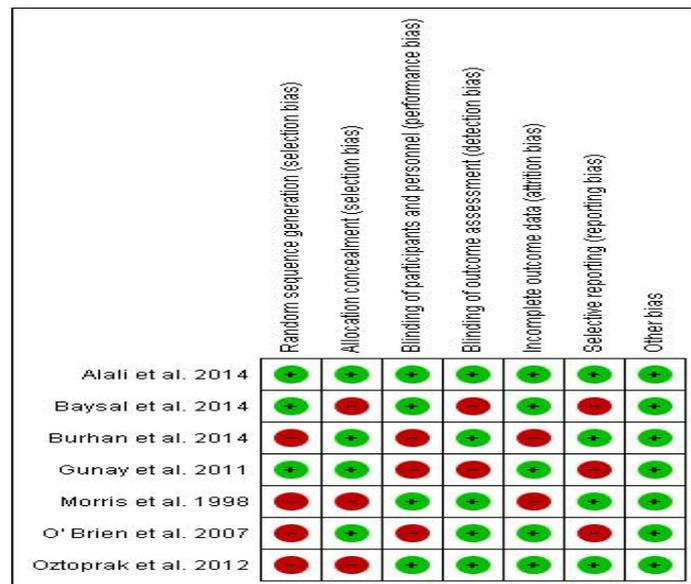


Figure 3: showing risk of bias summary: review authors' judgements about each risk of bias item for each included study.

Table 1: Table of characteristics of studies selected

S. no	Author, Year	Study Design	Objective	Sample Size	Type of Fixed Functional Appliance, Control Type	Duration of Treatment	Outcome	Conclusion
1.	David O. Morris et al, 1998	A prospective clinical study	To quantitatively evaluate and compare facial soft tissue profile changes produced by three functional appliances versus natural growth, using cephalometry and 3D laser facial scanning, while assessing the reliability of laser scanning for longitudinal soft tissue analysis.	47	Bass, Bionator and Twin Block appliances	9 months	Upper lip position remained stable despite the significant overjet reduction attained in the three appliance groups. Lower lip protrusion (up to 3.8 mm), lower lip length (up to 4.0 mm), and soft tissue lower and total face height increased significantly in all appliance groups by varying	The Twin Block appliance group (male and female) achieved greater changes in their facial soft tissues in comparison with the other two functional appliances.

Evaluation Of Treatment Effects Of Fixed Functional Appliances In Skeletal Class II Growing Patients Through A Systematic Review And Meta- Analysis

							amounts.	
2.	Kevin O'Brien et al, 2009	A multi-centre, RCT	To assess the effectiveness of early Twin-block therapy in managing Class II Division 1 malocclusion .	174 aged 8 to 10 yrs	Twin-block appliance	10 years	No differences found.	Twin-block treatment has no advantages over conventional treatment.
3.	Esen Ali Gunay et al, 2011	A prospective study	To assess short-term dentoalveolar and soft tissue changes in late adolescents treated with the Forsus™ FRD.	Test group - 27, mean age - 15 years 0.5-month, control group - 12, mean age -14 years 1 month	Forsus™ FRD and control group	Forsus™ FRD till treatment ends and control group for 6 months	Mandibular incisors proclined and intruded, maxillary incisors retroclined and extruded, with clockwise occlusal rotation, reduced overbite and overjet, and slight soft tissue improvement .	In late-adolescent patients Forsus™ FRD corrected Class II discrepancies through maxillary and mandibular dentoalveolar changes.
4.	Mehmet Oguz Oztoprak , 2012	A cephalometric comparative study	To compare dentofacial changes induced by SUS ² and Forsus FRD in late adolescents with Class II malocclusion against an untreated control group.	59, test 1 -15 years 3 months ± 1 year 2 months, test 2 - 15 years 1 month ± 1 year, control -14 years 9 months ± 1 year 3 months in the control group.	SUS ² , Forsus FRD, control group.	5-month 5 day ± 2-month 3 day for SUS ² , Forsus FRD 5-month 6 day ± 1 month 6-day, 6-month 1 day ± 1 month 5 day for control group	The effects were dentoalveolar and no significant vertical and sagittal skeletal effect.	Lower incisor proclination was more prominent with the Forsus FRD.
5.	Asli Baysal et al, 2013	RCT	To compare soft tissue profile changes following Twin Block and Herbst therapy.	60, test 1 - 20, mean age= 12.74 ± 1.43 years, test 2 - 20, mean age = 13.0 ± 1.32 years), control group - 20, mean age of 12.17 ± 1.47 years	Twin block, Herbst appliance, control group	15.81 ± 5.96 months Herbst appliance and 16.20 ± 7.54 months twin block appliance , for control group it was 15.58 ±	Soft tissue convexity, H angle, and mentolabial angle decreased in both groups, with greater mandibular soft tissue advancement observed in the Twin Block group than in the Herbst group.	Twin Block therapy resulted in greater advancement of mandibular soft tissues than Herbst and control groups.

						3.13 months.		
6.	Osama H. Alali, 2014	A prospective controlled evaluation	To assess the net dentofacial effects of the fixed lingual mandibular growth modifier (FLMGM).	38, FLMGM (n = 21, mean age 5 13.2 years), no treatment (n = 17, mean age 5 12.5 years).	Fixed lingual mandibular growth modifier (FLMGM) and control group.	8 months.	FLMGM treatment did not affect maxillary growth but increased mandibular length by 2.3 mm, advanced the chin by 1.6 mm, caused 4.0° upper incisor retroclination , with negligible vertical skeletal changes.	FLMGM was effective in treating growing Class II/1 patients and produced favourable dentofacial effects.
7.	Ahmad S. Burhan et al, 2014	Parallel-group, Randomized controlled trial	To compare the dentoalveolar and skeletal changes resulting from treatment using two popular functional appliances: the Bite-Jumping Appliance (BJA) and the Twin-Block Appliance (TBA).	44, 22 The Bite-Jumping Appliance (BJA), 22 Twin-Block Appliance (TBA). Aged 10.2–13.5 years.	Bite-Jumping Appliance (BJA), Twin-Block Appliance (TBA).	12 months	SNB increased significantly; lower incisors proclined and upper incisors retruded. BJA caused clockwise mandibular rotation with a 2.14° rise in SN:MP and a 1.78% decrease in Jarabak ratio, while TBA increased the Jarabak ratio by 1.26%, showing significant intergroup differences.	Each of the two appliances is recommended for the functional treatment of skeletal Class II malocclusion resulting from the retrusion of the mandible. The BJA is recommended when clockwise rotation is desired, whereas the TBA is recommended to inhibit vertical development.

Synthesis of Result

The meta-analysis was conducted with standardized mean difference (SMD) as summary statistic measure for assessing the effectiveness of fixed appliance therapy on vertical dimensions in terms of overbite, nasolabial angle, interincisal angle and lip strength as shown below in figure 4 – 13.

1. Overjet

Six studies containing data on 295 patients, of which (n=149) patients were evaluated fixed appliance therapy and (n=146) patients were evaluated by control modality for the evaluation in terms of overjet.

As shown in Figure 4. the Std. Mean Difference is 0.75 (-0.08 – 1.57) and the pooled estimates favours fixed appliance therapy group but this difference is not statistically significant (p>0.05).

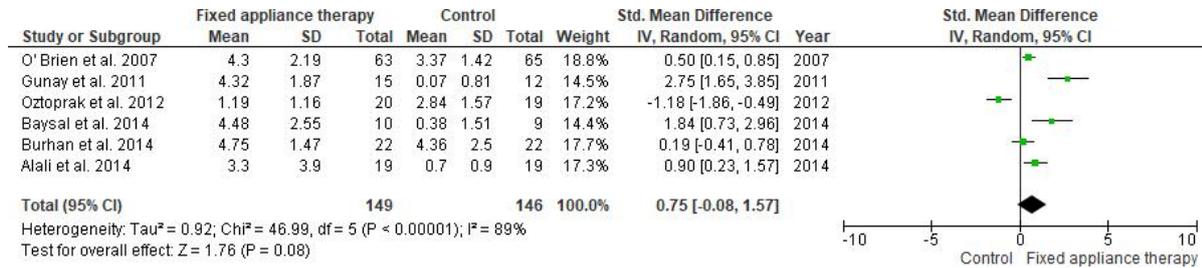


Fig 4: Comparison between fixed appliance therapy and control group for overjet

The funnel plot did not show significant asymmetry, indicating absence of publication bias as shown in Figure 5.

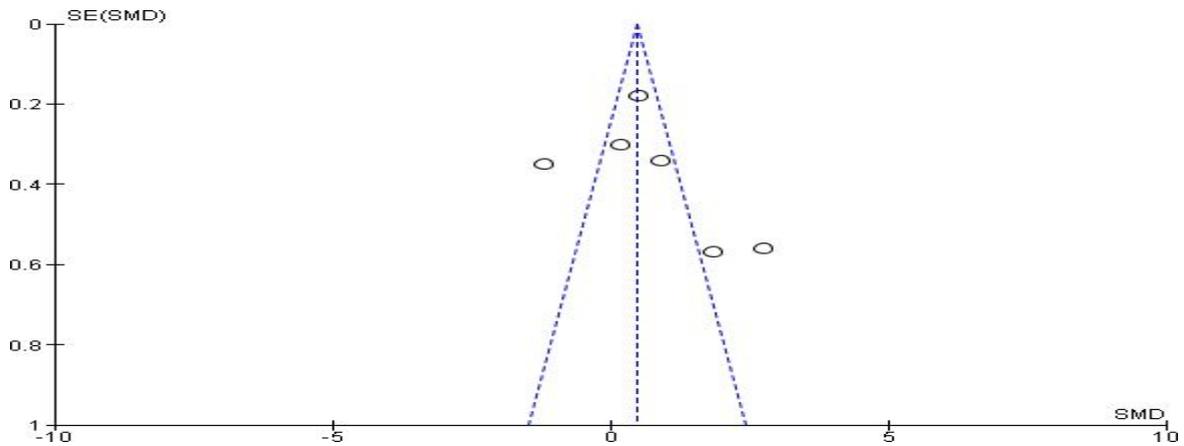


Figure 5: Showing demonstration of publication bias through Begg's Funnel plot with 95% confidence intervals

2. Overbite

Six studies containing data on 129 patients, of which (n=67) patients were evaluated fixed appliance therapy and (n=62) patients were evaluated by control modality for the evaluation in terms of overbite.

As shown in Figure 6. the Std. Mean Difference is 0.52 (-1.18 – 2.23) and the pooled estimates favours fixed appliance therapy group but this difference is not statistically significant (p>0.05).

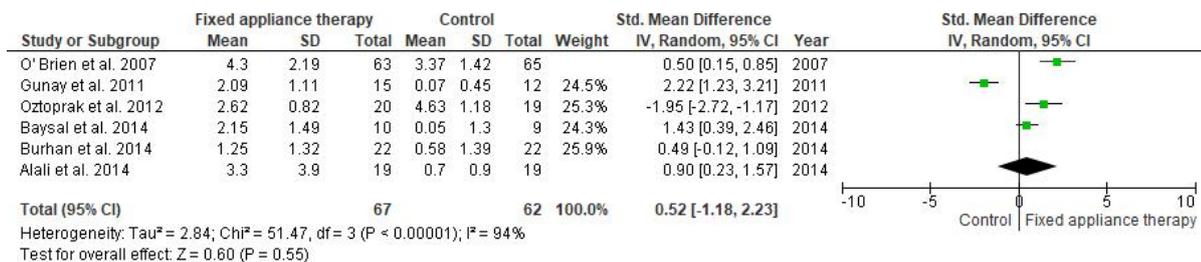


Fig 6: Comparison between fixed appliance therapy and control for overbite

The funnel plot did not show significant asymmetry, indicating absence of publication bias as shown in Figure 7.

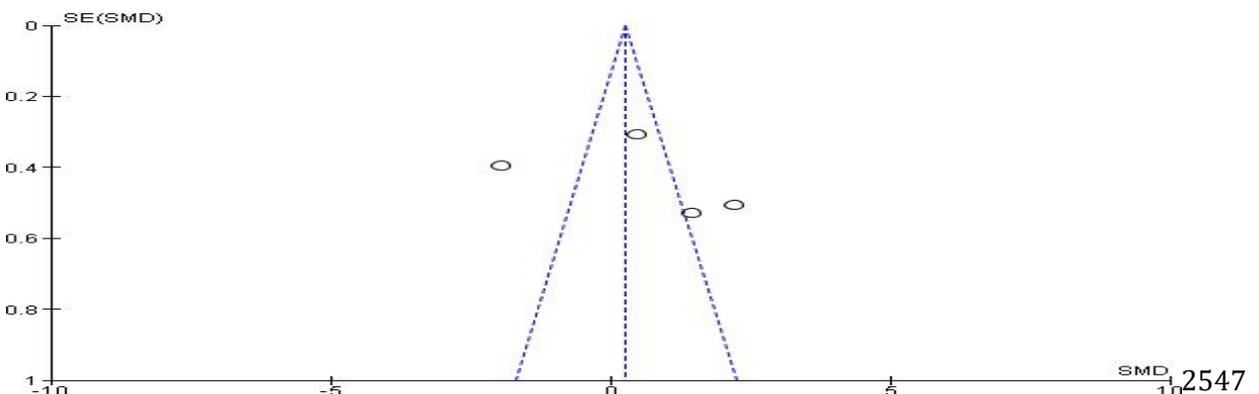


Figure 7: Showing demonstration of publication bias through Begg’s Funnel plot with 95% confidence intervals

3. Nasolabial angle

Six studies containing data on 100 patients, of which (n=52) patients were evaluated fixed appliance therapy and (n=48) patients were evaluated by control modality for the evaluation in terms of nasolabial angle.

As shown in Figure 8. the Std. Mean Difference is 0.20 (-0.20 – 0.59) and the pooled estimates favours fixed appliance therapy group but this difference is not statistically significant (p>0.05).

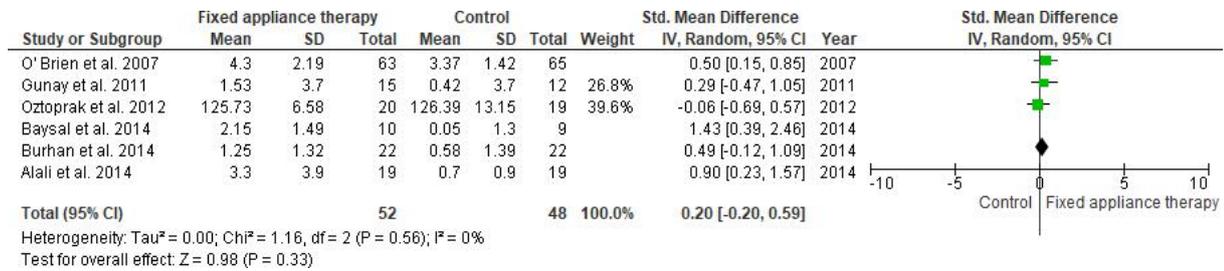


Fig 8: Comparison between fixed appliance therapy and control for nasolabial angle

The funnel plot did not show significant asymmetry, indicating absence of publication bias as shown in Figure 9.

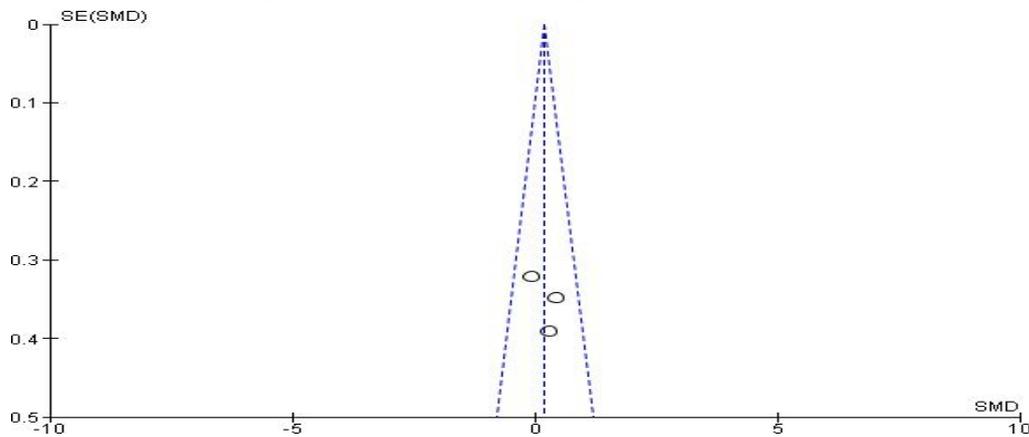


Figure 9: Showing demonstration of publication bias through Begg’s Funnel plot with 95% confidence intervals

4. Interincisal angle

Six studies containing data on 66 patients, of which (n=35) patients were evaluated fixed appliance therapy and (n=31) patients were evaluated by control modality for the evaluation in terms of interincisal angle.

As shown in Figure 10. the Std. Mean Difference is -0.17 (-2.62 – 2.29) and the pooled estimates favours fixed appliance therapy group but this difference is not statistically significant (p>0.05).

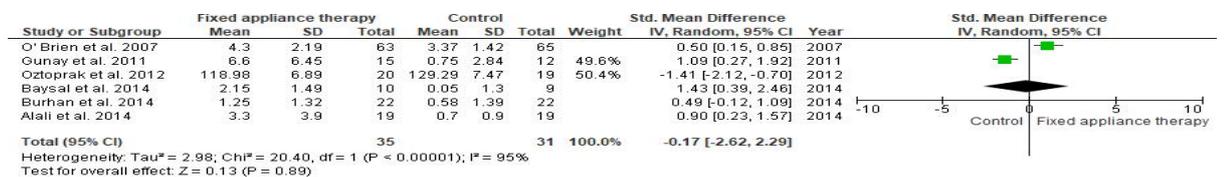


Fig 10: Comparison between fixed appliance therapy and control for interincisal angle

The funnel plot did not show significant asymmetry, indicating absence of publication bias as shown in Figure 11.

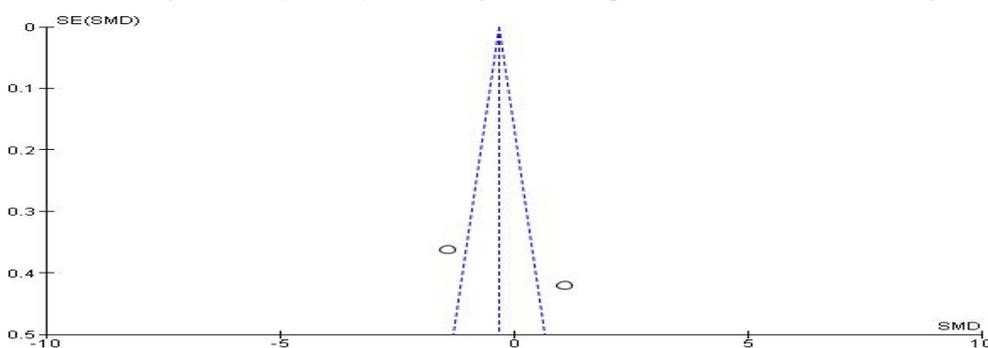


Figure 11: Showing demonstration of publication bias through Begg’s Funnel plot with 95% confidence intervals

5. Lip strain

Six studies containing data on 66 patients, of which (n=35) patients were evaluated fixed appliance therapy and (n=31) patients were evaluated by control modality for the evaluation in terms of lip strain.

As shown in Figure 12. the Std. Mean Difference is 0.47 (-0.69 – 1.62) and the pooled estimates favours fixed appliance therapy group but this difference is not statistically significant (p>0.05).

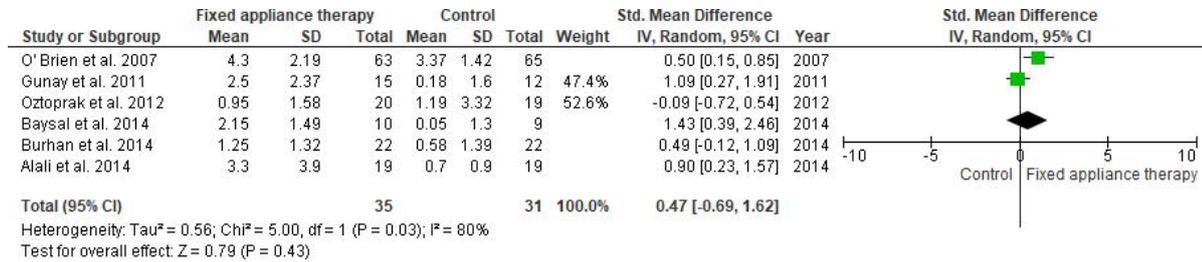


Fig 12: Comparison between fixed appliance therapy and control for lip strain

The funnel plot did not show significant asymmetry, indicating absence of publication bias as shown in Figure 13.

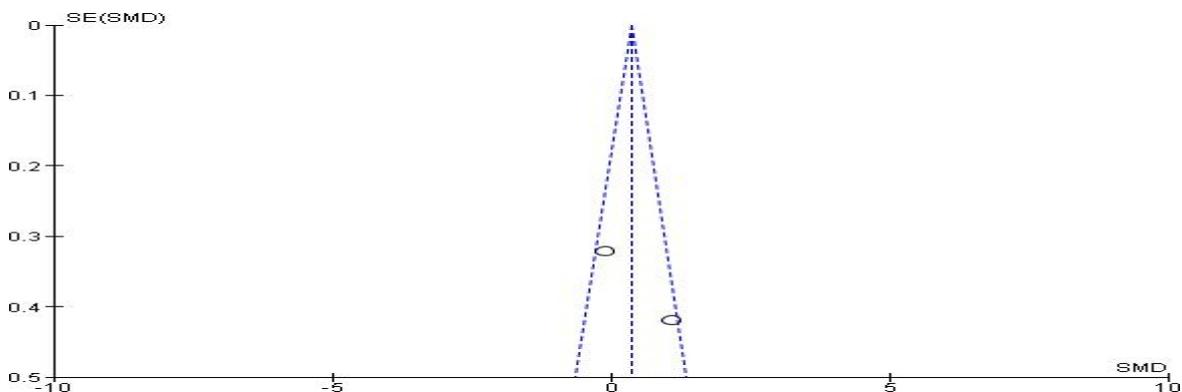


Figure 13: Showing demonstration of publication bias through Begg’s Funnel plot with 95% confidence intervals

6. Change in SNA0

Four studies [23,24] containing data on 164 patients, of which (n=96) patients were evaluated by fixed appliance therapy and (n=68) patients by conventional modality for SNA0 measurement.

As shown in Figure 14. the standard mean deviation SMD = -0.72 (-1.75 – 0.31) and the pooled estimates favours fixed appliance therapy group but this difference is not statistically significant (p>0.05).

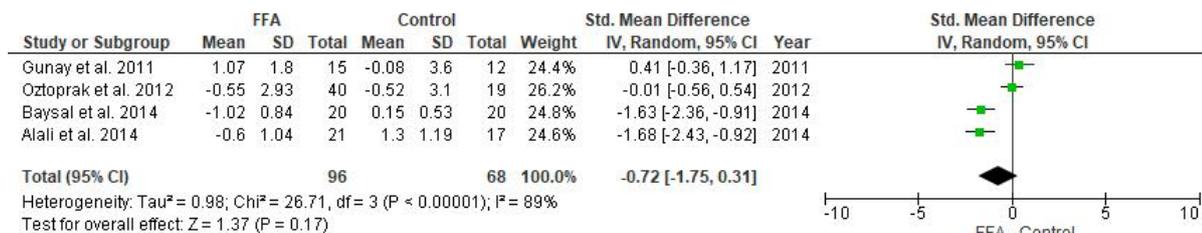


Figure 14: Comparison between Fixed appliance therapy and control modality for SNA0

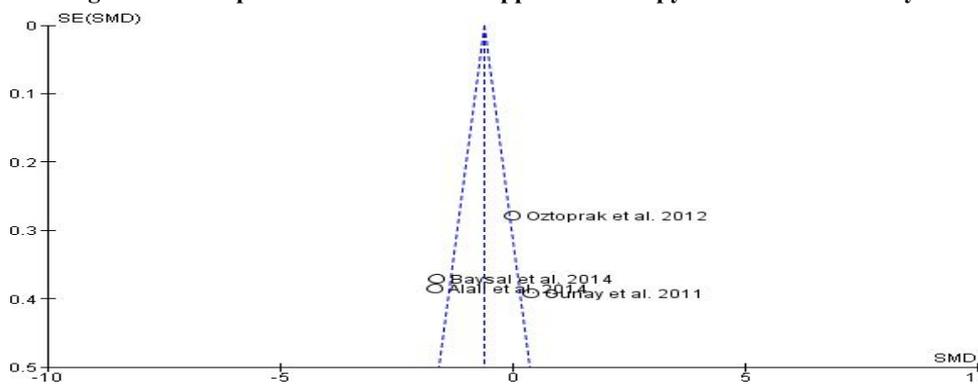


Figure 15: Showing absence of publication bias

7. Change in SNB0

Four studies containing data on 162 patients, of which (n=96) patients were evaluated by fixed appliance therapy (n=68) patients by control modality for SNB0 measurement.

As shown in Figure 16. the standard mean deviation SMD = 0.64 (-0.13– 1.41) and the pooled estimates favours control group but this difference is not statistically significant (p>0.05).

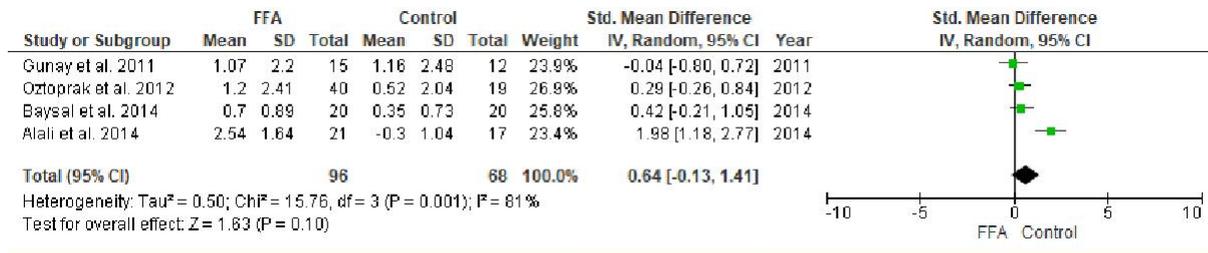


Figure 16: Comparison between Fixed appliance therapy and control modality for SNB0

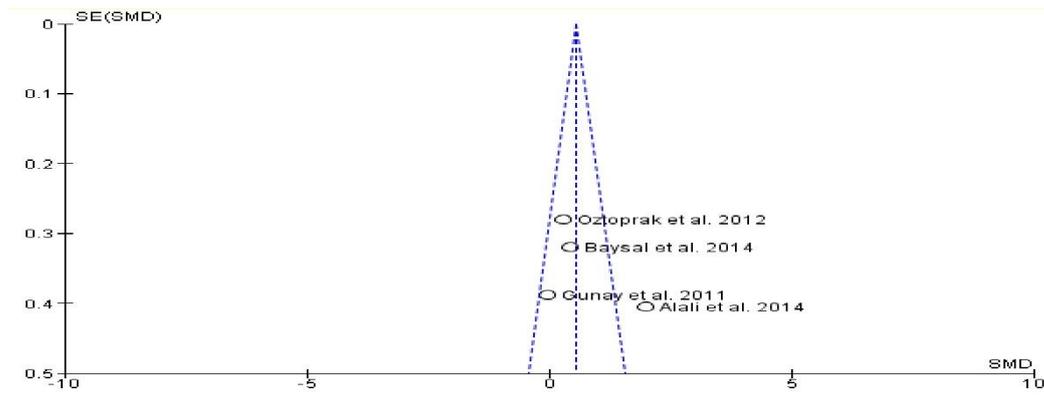


Figure 17: Showing absence of publication bias

8. Change in ANB0

Four studies containing data on 164 patients, of which (n=96) patients were evaluated by fixed appliance therapy and (n=64) patients by conventional modality for ANB0 measurement.

As shown in Figure 18. the standard mean deviation SMD = -1.00 (-2.42 – 0.43) and the pooled estimates favours fixed appliance therapy group but this difference is not statistically significant (p>0.05).

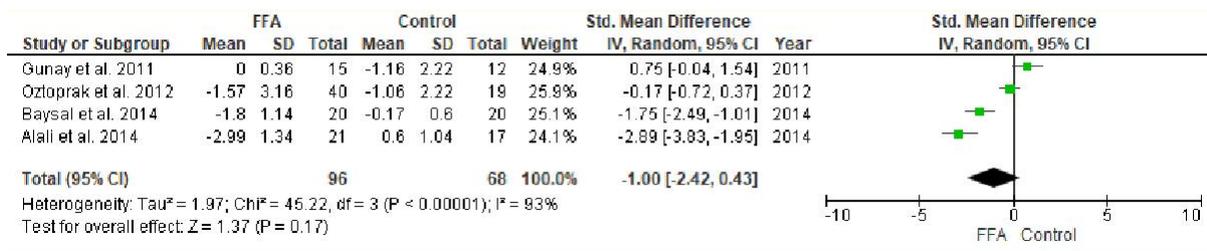


Figure 18: Comparison between Fixed appliance therapy and control modality for ANB0

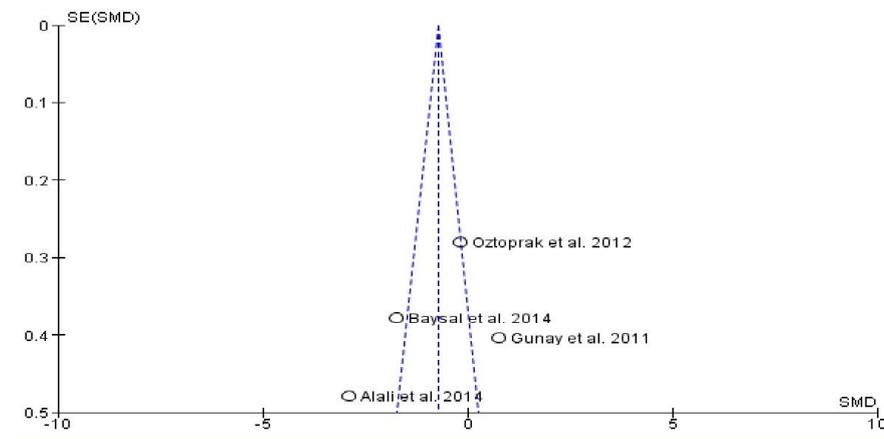


Figure 19: Showing absence of publication bias

9. Wit's appraisal/value

Two studies^{23,25} evaluating the effect of orthodontic approaches on wits value, pre- and post- operatively. As shown in Figure.20 the SMD is 1.24 (-4.11 – 6.60) and the pooled estimate signifies that on an average a difference of 1.24 was seen post-operatively and was statistically significant. ($p > 0.05$).

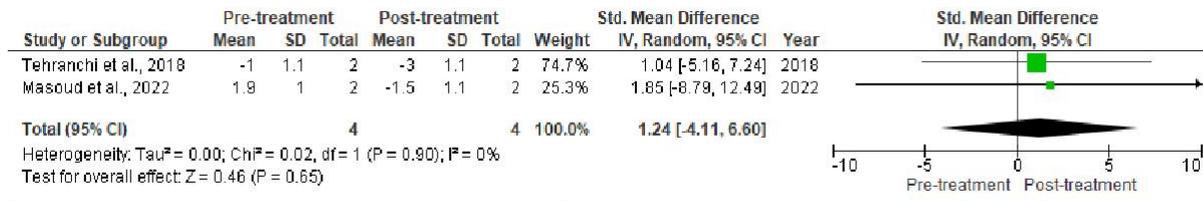


Figure 20: Pre- and post-operative comparison for wits value

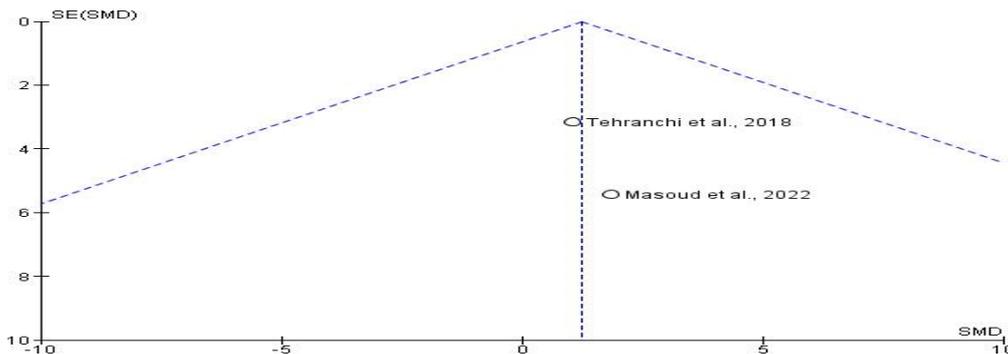


Figure 21: Showing Begg's Funnel plot with 95% confidence intervals demonstrating an absence of publication bias.

10. Interincisal angle

Two studies^{24,25} evaluating the effect of orthodontic approaches on interincisal angle, pre- and post-operatively. As shown in Figure 22. the SMD is -0.06 (-1.92 – 1.81) and the pooled estimate signifies that on an average a difference of -0.06 was seen post-operatively and was statistically significant ($p > 0.05$).

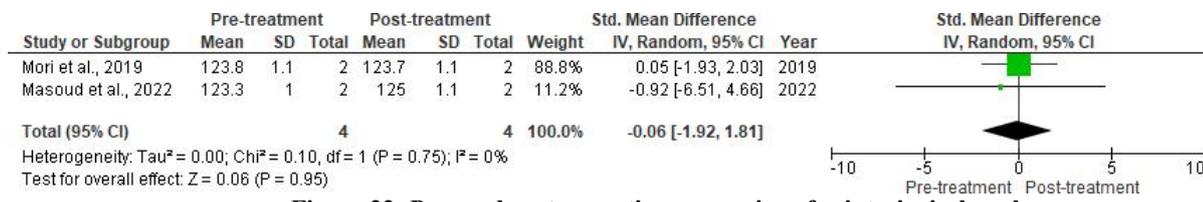


Figure 22: Pre- and post-operative comparison for interincisal angle

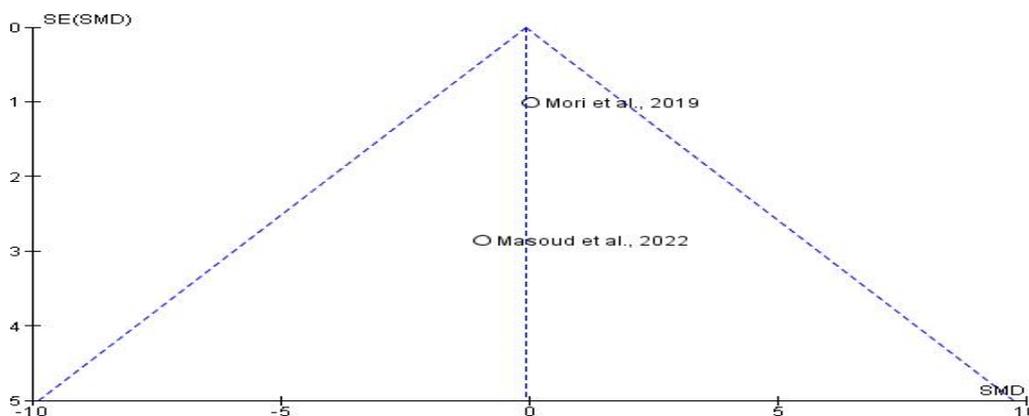


Figure 23: Showing Begg's Funnel plot with 95% confidence intervals demonstrating an absence of publication bias.

11. (ANS – Me) – lower face height

Two studies^{23,25} evaluating the effect of orthodontic approaches on lower face height (ANS - Me), pre- and post-operatively. As shown in Figure 24. the SMD is 0.05 (-2.33 – 2.43) and the pooled estimate signifies that on an average a difference of 0.05 was seen post-operatively and was statistically significant ($p > 0.05$).

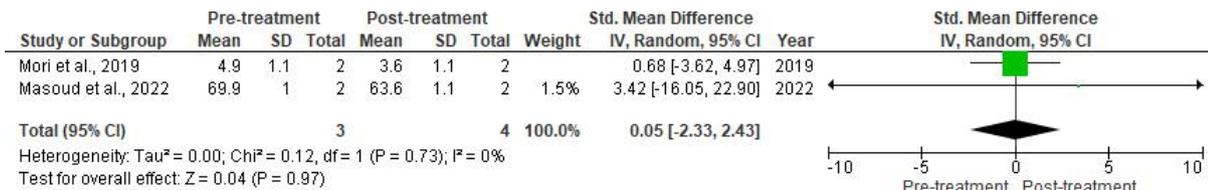


Figure 24: Pre- and post-operative comparison for lower face height (ANS -Me)

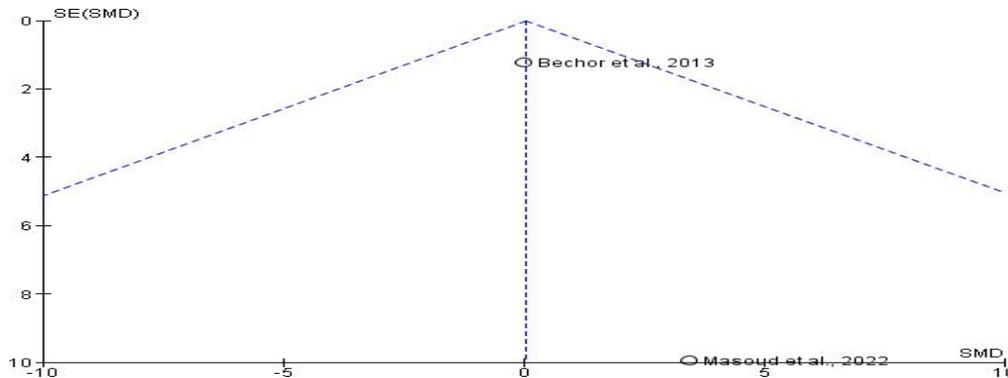


Figure 25: Showing Begg’s Funnel plot with 95% confidence intervals demonstrating an absence of publication bias.

12. Occlusal plane angle

Two studies^{22,25} evaluating the effect of orthodontic approaches on occlusal plane, pre- and post-operatively. As shown in Figure 26. the MD is -0.37 (-1.93 – 1.20) and the pooled estimate signifies that on an average a difference of -0.37 was seen post-operatively and was statistically significant. (p>0.05).

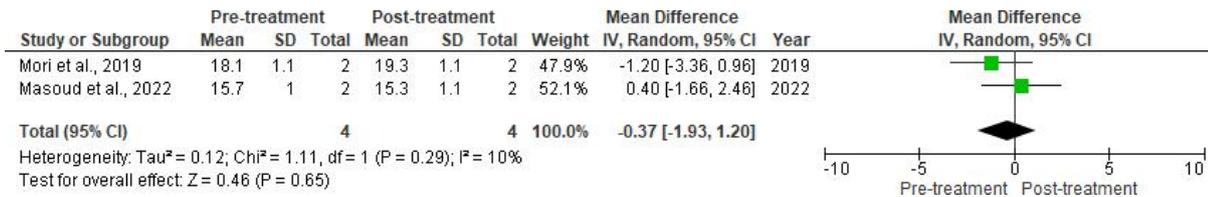


Figure 26: Pre- and post-operative comparison for occlusal plane

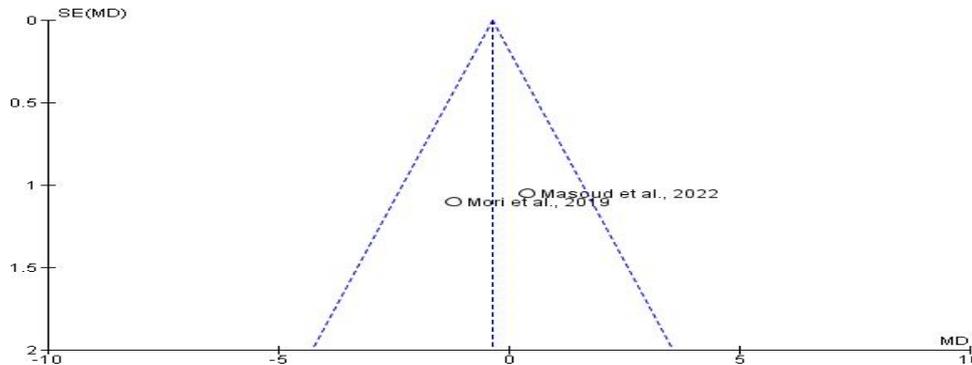


Figure 27: Showing Begg’s Funnel plot with 95% confidence intervals demonstrating an absence of publication bias.

13. U1 – SN plane

Three studies^{22,23,25} evaluating the effect of orthodontic approaches on U1-SN plane, pre- and post-operatively. As shown in Figure 28. the MD is -0.53 (-3.06 – 2.01) and the pooled estimate signifies that on an average a difference of -0.53 was seen post-operatively is not statistically significant. (p>0.05).

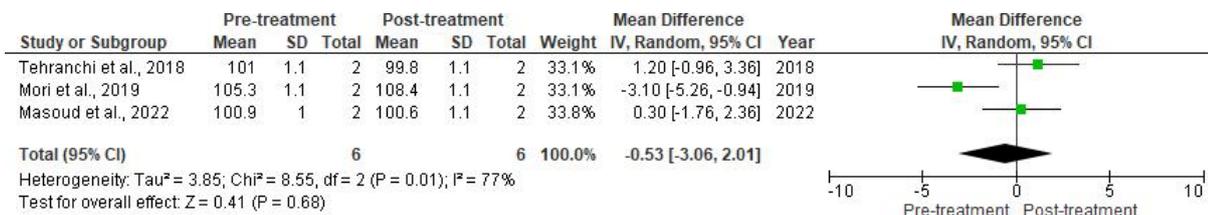


Figure 28: Pre- and post-operative comparison for U1-SN plane

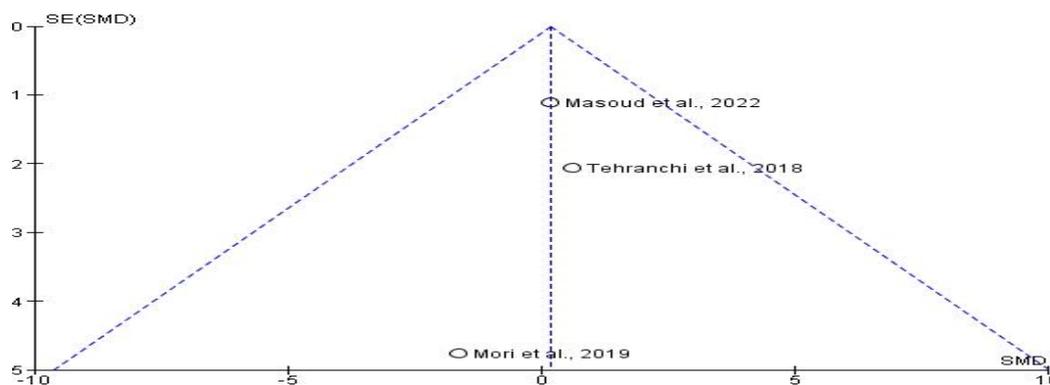


Figure 29: showing Begg's Funnel plot with 95% confidence intervals demonstrating an absence of publication bias.

DISCUSSION

Class II malocclusion is a frequent condition and a rather common reason for patients seeking orthodontic treatment.^{1,2} The development of Class II malocclusion could be attributed to several factors; hence, accurate diagnosis is important for the selection of the corresponding treatment plan. Among these factors, mandibular retrognathism is considered a dominant one.³ In this respect, mandibular advancement through the use of functional appliances is considered as a popular treatment approach in growing individuals.

Class II malocclusion is one of the most prevalent orthodontic conditions throughout the world, and typically, these deformities are treated by using functional appliances. At the beginning of the 20th century, extraoral forces were applied to the maxilla with headgear for the correction of Class II malocclusion. This therapeutic method was a reflection of the belief that prevailed during that era that the majority of skeletal Class II malocclusions are caused by the protrusion of the maxilla.³ However, subsequent studies indicated that the incidence of Class II division 1 malocclusion resulting from the protrusion of the maxilla does not exceed 20% of the total cases of Class II malocclusion, and the majority of these cases are significantly caused by mandibular retrusion, which prompted many researchers to use functional appliances that stimulate the growth of the mandible for the treatment of skeletal Class II malocclusion.⁴

Various treatment options and appliances are used for the viable treatment of Class II malocclusions, such as removable and fixed functional appliances, extraoral appliances, extraction therapy, and orthognathic surgery.⁶ Among these treatment alternatives the success of the functional therapy is mainly related to the cooperation of the patients. These appliances produce sagittally and vertically intrusive forces as well as expansion in the transverse direction. They also typically demonstrate mesial movement of the mandibular molars, tipping of the mandibular incisors, and variable effects associated with mandibular growth.⁷

The adherence to PRISMA guidelines, thorough literature search, and rigorous methodology, including Cochrane risk of bias assessment, underscored the credibility of these systematic reviews. With high overall study quality and minimal bias across the included studies, the evidence base supporting therapeutic recommendations for optimizing functional appliance therapy is robust and actionable.

However, there were also some limitations. Even after an unlimited search and eligibility criteria, there were very few studies with qualitative synthesis and quantitative synthesis. Only seven studies were included in the final assessment. More randomized controlled trials, prospective or follow-up studies with greater sample size and larger follow up period are needed to evaluate the effect of different type of functional appliances on the tooth movement.

A limitation of this research is a lack of an untreated control group, which means that the resulting changes can't be attributed to the treatment only, but also to ordinary growth. However, the resulting differences between the two groups can be attributed to the appliance differences, which fulfil the aim of the current research.

A systematic review is a transparent and repeatable procedure for identifying, selecting and critically assessing published or unpublished data to address a well-defined research question. Meta-analyses, a statistical analysis that incorporates numerical data from related studies, are frequently paired with systematic reviews. The best evidence is generally regarded as systematic reviews and meta-analyses. However, the calibre of the included studies has an impact on how strong the evidence is. In the present review, sufficient studies with a brief observation period and a known risk of bias were included. As a result, the presently available evidence is sufficient to make therapeutic recommendations in response to the current systematic review's focus question.

The strengths of the present review include the predefined protocol, the thorough and unrestricted literature search, and the strict methodology that was carefully followed during every stage of it following specific and detailed guidelines. In addition, the included studies enabled adequately powered meta-analyses for many important treatment outcomes, for which the required

meta-analysis sample size was fulfilled almost exclusively. Since a random-effects model was used for data synthesis, the results of the present study provide the average of the FFA effects across the included studies. Heterogeneity was explained in most cases by the predefined sub-group analyses, while sensitivity analyses indicated that the results were fairly robust. In addition, data from studies were considered as adequate to perform a subgroup analysis in order to minimize multiple testing. Although most of the included trials took place at university settings, their findings could possibly be generalized to the average patient due to their broad inclusion criteria. Finally, the vast majority of the included trials (89 %) were prospective cohort comparative studies, which represent more 'realistic' situations in matters of the daily clinical practice, compared to RCTs, and thus possibly strengthening the applicability of the outcomes.

Nevertheless, although no serious methodological limitations were found in the included original studies, their quality could have been better. Moreover, none of the included studies provided results concerning the number and the experience of the respective clinicians, which could introduce proficiency bias. Unfortunately, treatment results concerning the long-term effects of FFAs were not reported in the selected studies, precluding an assessment of the results' stability in current evaluation. Finally, the limited number of the eligible studies prevented the investigation of all the originally planned patient- and appliance-related factors in this review while reporting biases could not be formally assessed.

CONCLUSION

According to existing evidence, the following conclusions can be drawn on the short-term effectiveness of FFAs:

The treatment of Class II malocclusion with FFAs was associated with stimulation of mandibular growth and with more pronounced dentoalveolar and soft tissue changes with regards to improvement in parameters like wits appraisal, lower face height, U1-SN plane and occlusal plane. Patient- and appliance-related factors seem to influence the treatment outcomes, yet complementary research is required to thoroughly investigate the respective effects.

FUTURE RECOMMENDATIONS

Treatment of Class II malocclusion with fixed functional appliance seems to be not as effective as believed in matters of skeletal correction. Additional studies are required for a thorough assessment of the skeletal, dental, and soft tissue outcomes of fixed functional appliance in the long term. The provision of detailed data from these studies regarding patients' characteristics (gender, growth pattern, and skeletal maturation), particular features of the used functional appliance (the exact appliance design and possible incorporation of additional elements), as well as the followed retention scheme should be considered. Finally, in order to enable also the assessment of linear variables, the magnification factor of the lateral cephalometric radiographs should be reported in each of the respective trials.

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