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"VERTICAL EFFECTS OF FUNCTIONAL APPLIANCE THERAPY IN GROWING PATIENTS WITH SKELETAL CLASS II MALOCCLUSION –A SYSTEMATIC REVIEW AND META-ANALYSIS"

Dentistry

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ABSTRACT

Aim: To evaluate the effectiveness of functional appliance therapy in the vertical dimension in growing patients with skeletal class II malocclusion **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 CRD42023480848. A thorough search of databases was conducted till December 2023 to identify studies evaluating the effectiveness of functional appliance therapy in the vertical dimension 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 5.4.1. 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:** Five studies met the eligibility criteria and underwent qualitative synthesis, with five studies in meta-analysis. Upon quality assessment, the studies demonstrated a low risk of bias, ensuring a comprehensive evaluation of the evidence base. Outcomes like lower anterior facial height and total anterior facial height were assessed quantitatively. Pooled estimate through SMD favored the functional appliance group over the control or other modality group ($p>0.05$). The funnel plot did not reveal the presence of any heterogeneity indicating the absence of publication bias. **Conclusion:** The treatment effects of FAs on the skeletal tissues in patients with Class II malocclusion were probably of clinical importance. The treatment of Class II malocclusion with FAs was associated with stimulation of mandibular growth and significant dentoalveolar and soft tissue changes. Along with the sagittal changes, functional appliances also bring about vertical changes. Under the limitations of the number of available studies and total samples for this systematic review, the following conclusions could be made: 1. Functional appliances bring about a significant increase in lower anterior facial height (ANS- Me) of individuals with skeletal class II malocclusion 2. Total anterior facial height (N-Me) shows a significant increase in growing individuals with skeletal class II malocclusion

KEYWORDS

Growing patients, skeletal class II malocclusion, mandibular retrognathism, removable functional appliance, fixed functional appliance, lower anterior facial height, total anterior facial height, systematic review

INTRODUCTION:

Several orthodontic patients are seen with class II dentofacial deformities. Among children within the age range of 6 to 15 years, the occurrence of skeletal class II malocclusions is at 37%. **Mc Namara** reported mandibular retrusion as the most common characteristic of Class II malocclusion.[1] In growing patients, two-phase treatment of Class II skeletal malocclusions, which includes growth modification with functional appliances followed by orthodontic treatment with fixed appliances, has been advocated as an appropriate treatment approach.[2,3] The primary objectives of growth modification in all orthodontic treatment approaches are to correct skeletal discrepancy and enhance facial aesthetics.[4] Successful correction of Class II Division 1 malocclusion can be achieved by generating a combination of dental and skeletal effects using both removable and fixed functional appliances.[5] Functional appliances produce varying effects depending on their design, which has led to a variety of studies comparing different types of functional appliances.[6] The favorable treatment outcomes of functional appliances based on mandibular growth, attributed either as a mandibular length augmentation or effective condyle growth.[7,8,9,10] Furthermore, some researchers have supported a restriction effect on the maxilla.[11,12,13,14,15] Several studies utilizing functional appliances have observed skeletal changes in the anteroposterior dimension and increase in vertical facial height in the short term.[16,17,18]

The Twin-block (TB) appliance can lead to undesirable treatment effects, including mandibular incisor proclination, an increase in vertical facial dimension (which is harmful in high-angle patients), clockwise rotation of the maxillary plane, and a limited increase in mandibular growth that may not be maintained in the long term..[19,20,21,22] **McDonagh et al** reported an increase in the anterior facial height and that the soft tissue changes tended to reflect the changes seen in the hard tissues. A significant portion of the clinical data on the effects of functional appliance therapy has been derived from the analysis of pre- and post-treatment results of selectively successful cases. Previous researchers have often failed to include an untreated control group in their study design, while others have used patients of varying ages, unsuccessful cases, or those undergoing alternative forms of orthodontic treatment.[23]

While the sagittal effects of functional appliances have been studied in the dental literature, the vertical effects have not been compared. Therefore, this systematic review and meta-analysis aim to assess the changes in the vertical dimension resulting from using various functional appliances.

Aim:

The current systematic review aims to evaluate the effectiveness of functional appliance therapy in the vertical dimension in growing patients with skeletal class II malocclusion

Methodology:

Protocol And Registration

This systematic review was conducted and performed according to the preferred reporting items for systematic review and meta-analysis (PRISMA) statement[29] After searching for previously registered similar studies, the Review protocol of this Systematic review was registered on November 20,2023 with the National Institute of Health Research database and registered in Prospective Registration of Systematic Review (PROSPERO)- CRD42023480848.

Information Sources And Search

A comprehensive electronic search was conducted up until December 2023, covering studies published over the past 33 years (1990 to 2023) using the following databases: PubMed, Google Scholar, and EBSCOhost to retrieve English-language articles. Searches in clinical trial databases, cross-referencing, and grey literature were carried out using Google Scholar, Greylist, and Open Grey.

A manual search was also performed in various journals, including orthodontic journals such as the American Journal of Orthodontics and Dentofacial Orthopedics, Angle Orthodontist, European Journal of Orthodontics, Journal of Orthodontics, Orthodontics, Journal of Oral Biology and Craniofacial Research, and Journal of Craniofacial Research.

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

In addition to the electronic search, a hand search was performed, and the reference lists of selected articles were reviewed. The reference lists of identified studies and relevant reviews were also examined for any additional studies.

Study Selection And Eligibility Criteria:

The review question aimed to assess the effectiveness of functional appliance therapy in the vertical dimension for growing patients with skeletal Class II malocclusion. Inclusion and exclusion criteria were established prior (Table 1). After removing duplicates, articles were screened based on title, abstract, and full text. If the decision based on the title and abstract was inconclusive, the full-text article was obtained. In cases where an identical study was published in multiple languages, the English version was considered.

Table 1. Eligibility Criteria Used For The Study Selection.

Category	Inclusion Criteria	Exclusion Criteria
Participant Characteristics	Studies on human patients with skeletal class II malocclusion with the retruded mandible of age between 10 to 15 yrs of any gender.	1) Patients with craniofacial syndromes and/or cleft lip palate 2) Patients with temporomandibular joint disorders
Intervention	The intervention involves using Removable functional appliance or Fixed functional appliance for treating skeletal class II malocclusion with mandibular retrusion.	Patient with skeletal class II malocclusion treated with methods other than removable or fixed functional appliances.
Comparator/Control	Untreated patients with Skeletal class II malocclusion with mandibular retrusion.	
Outcome	1) Evaluation of lower anterior facial height with removable or fixed functional appliances. 2) Evaluation of total anterior facial height with removable or fixed functional appliances.	Any other outcome reported
Study Design	1) Randomized controlled trials 2) Prospective controlled clinical trials 3) Studies carried out in the time period of 1990 to December 2023 4) Studies carried out in any country 5)Full articles in English	1) Animal Studies 2) Unsupported opinion of experts 3) Replies to the author/editor 4) Interviews 5) Commentaries 6)Books/conferences/ abstracts 7) Summaries 8) Cross-sectional surveys 9) Case series 10) Case reports or reports of cases 11) Case–control observational studies 12) Cohort studies 13) Retrospective clinical trials 14) Narrative reviews 15) Systematic reviews 16) Meta-analyses 17) Non -English articles

Screening Process

The search and screening process, following the predefined protocol, was carried out by two reviewers. The selection of articles occurred in two phases. In phase one, both reviewers examined the titles and abstracts of all articles, excluding those that did not meet the inclusion criteria. In phase two, the full articles were independently reviewed and assessed by the same reviewers. Any disagreements were resolved through discussion, and if a consensus could not be reached, a third reviewer was involved to make the final decision. The final selection of articles was made through mutual agreement among all three authors.

Quality Assessment Of Included Studies

The methodological quality of the included studies was assessed using the Cochrane Collaboration Risk of Bias (ROB)-2 tool. This tool covers various domains such as random sequence generation (selection bias), allocation concealment (selection bias), blinding of personnel and equipment (performance bias), blinding of outcome assessment (detection bias), incomplete outcome data (attrition bias), selective reporting (reporting bias), and other potential biases, evaluated through signaling questions in Review Manager (RevMan) 5.4.1 software. The overall risk for each study was categorized as low, moderate, or high based on these domains and criteria. A study was considered to have a low overall risk only if all domains were rated as low risk. A high overall risk was assigned if one or more domains were rated as high risk. Studies were assigned a moderate risk assessment if one or more domains were rated as 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-squared $\leq 24\%$), otherwise a random effects model (Der Simonian- Laird method) was used.[33] All statistical analyses were performed using RevMan 5.4.1 (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 treatment effect estimates across different trials was assessed using Cochran's test for heterogeneity and the I^2 statistic, which indicates the percentage of total variation across studies attributed to heterogeneity rather than chance. Heterogeneity was considered statistically significant if $p < 0.1$. According to the Cochrane Handbook, I^2 values can be interpreted as follows: (1) 0 to 40% suggests low heterogeneity, (2) 30% to 60% indicates moderate heterogeneity, (3) 50% to 90% suggests substantial heterogeneity, and (4) 75% to 100% represents considerable heterogeneity.[30]

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.[31]

Data Collection Process And Data Items

After removing duplicates, the reference lists of the included studies were screened, resulting in the exclusion of 116 studies. The full-text articles were then assessed for eligibility, and those that did not meet the inclusion criteria were excluded. Six studies met the eligibility criteria and were included in the qualitative synthesis. These six studies were also included in the meta-analysis. The flowchart illustrating the identification, inclusion, and exclusion of studies is

shown in Figure 1 below.

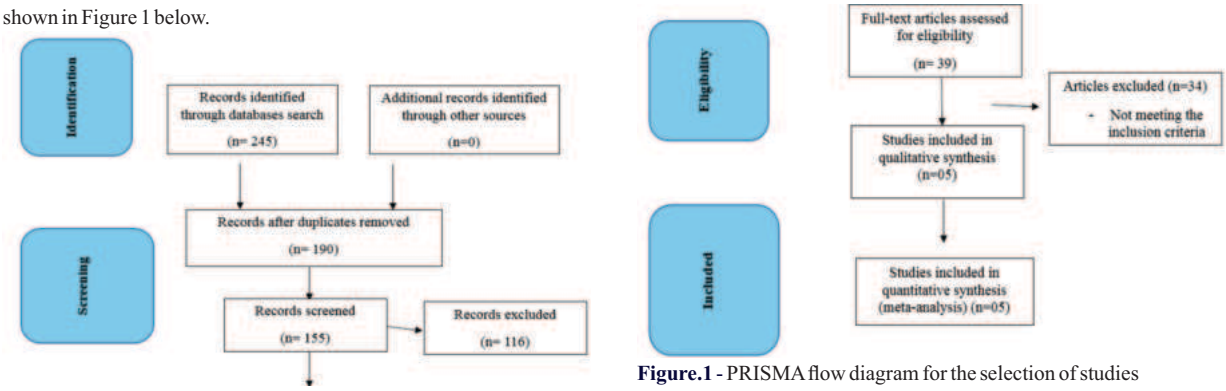

Figure.1 - PRISMA flow diagram for the selection of studies

Table 2 – Demographic data of the five studies included in the current systematic review

Study	Design	Setting	Characteristics of patient	Intervention	No of patients	Age in Years (Mean)	Materials/ Measures	Assessment of results	Conflict of Interest
Colin Nelson (1993)[24]	Randomized controlled trial	Dunedin, New Zealand	Angles Class II division 1 malocclusion with mandibular retrognathia.	Gp 1 -Frankel function regulator Gp 2- Harvold activator Gp 3- Untreated control group	Gp 1: 13 Gp 2: 12 Gp 3: 17	Gp 1: 11.70 Gp 2: 11.70 Gp 3: 11.53	Investigation was carried out on lateral cephalograms obtained just before insertion of Frankel function regulator appliance and activator appliance	Skeletal changes: Total anterior facial height, lower anterior facial height increment in the Frankel function regulator group and Harvold activator group	Not stated
David O Morris (1998)[25]	Prospective clinical study	The Royal London Hospital, UK	Skeletal Angle Class II division 1 malocclusion with a deficient mandible	Gp 1 -Bass appliance Gp 2 -Bionatar appliance Gp 3- Twin block appliance Gp4- Untreated control group	Gp 1: 13 Gp 2: 18 Gp 3: 16 Gp 4: 20	Gp 1: 12.5 Gp 2: 11.8 Gp 3: 11.5 Gp 4: 11.2	Lateral cephalometry and 3D Analysis were done before and immediately after treatment.	Skeletal Changes: Total anterior facial height, lower anterior facial height increment in bass, bionatar and twin block appliance group	Not stated
Heather M. Illing et al (1998)[26]	Randomized controlled Trial	The Royal London Hospital, UK	Skeletal class II malocclusion with Mandibular retrognathia	Gp 1 -Bass appliance Gp 2 -Bionatar appliance Gp 3- Twin block appliance Gp4- Untreated control group	Gp 1: 13 Gp 2: 18 Gp 3: 16 Gp 4: 20	Gp 1: 12.5 Gp 2: 11.8 Gp 3: 11.5 Gp 4: 11.2	Lateral cephalometric radiographs were taken immediately before (T1) and after removal of the bass, bionatar and twin block appliance (T2) to compare treatment outcome	Skeletal Measurements: Total anterior facial height, lower anterior facial height increment in bass, bionatar and twin block appliance group	Not stated
Asli Baysal et al (2014)[27]	Prospective clinical trial	Izmir Katip Celebi University, Turkey	Skeletal Angles Class II malocclusion with a deficient mandible	Gp 1: Herbst Gp 2: Twin Block Gp 3: Untreated control group	Gp 1: 20 Gp 2: 20 Gp 3: 20	Gp1: 12.74 GP 2: 13.0 Gp 3: 12.17	Lateral cephalometric radiographs were taken immediately before (T1) and after removal of the herbst and twin block appliance (T2) to compare treatment outcomes	Skeletal changes: Total anterior facial height, lower anterior facial height increment in herbst and twin block appliance group	Not stated
Seniz Karacay et al (2006)[28]	Prospective clinical trial	Gulhane Military Medical Academy.	Skeletal Angles Class II malocclusion with a deficient mandible	Gp 1: Forsus Gp 2: Jasper Gp 3: Untreated control group	Gp 1: 16 Gp 2: 16 Gp 3: 16	Gp1: 13.6 GP 2: 14.0 Gp 3: 13.8	Lateral cephalometric radiographs were taken immediately before (T1) and after removal of the Forsus and jasper jumper appliance (T2) to compare treatment outcomes	Skeletal changes: Total anterior facial height, lower anterior facial height increment in Forsus and Jasper Jumper appliance group	Not stated

Assessment of methodological Quality of included studies

All the included studies were largely comparable in methodological quality. All the included studies has low risk of bias with all the respected domains. The highest risk of bias was seen for incomplete outcome data and selective reporting.

Domains of blinding of random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment have 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

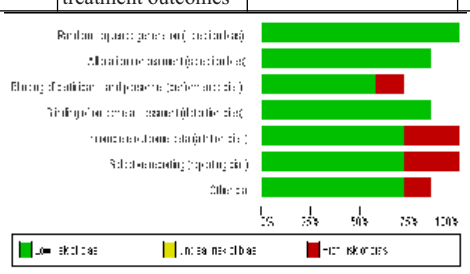

Figure 2: Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

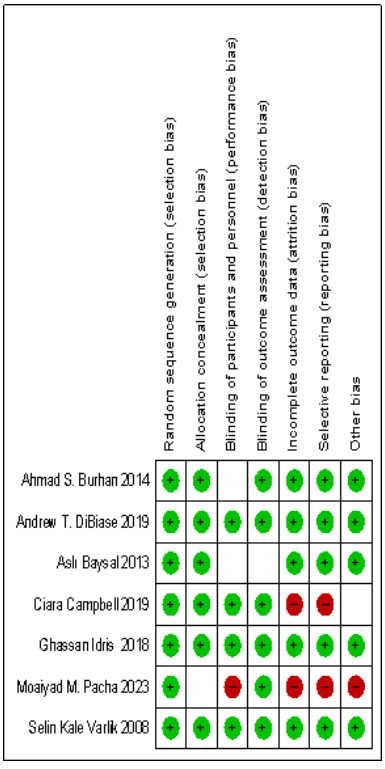

Figure 3: Risk Of Bias Summary: review authors' judgements about each risk of bias item for each included study

RESULT:

Study Selection

The search strategy resulted in 245 articles. A total of 116 records were excluded on the basis of screening of title and abstract. The full texts of 39 articles were obtained and assessed for eligibility. Respecting all selection phases based on the eligibility criteria, 5 articles qualified for final analysis. Figure 1 displays the different steps of the selection process entered in the PRISMA flow chart.

Study Characteristics

All the studies took place in a university setting. Growing patients with skeletal class II malocclusion with mandibular retrognathy were included with a mean age of 13.07 years. Patients were divided into two groups (Treated with removable functional appliance or fixed functional appliance and Untreated control group). Studies provided hard and soft tissue cephalometric outcomes based on lateral cephalometric analysis. All articles included in this review had a low risk of bias (Figure 2).

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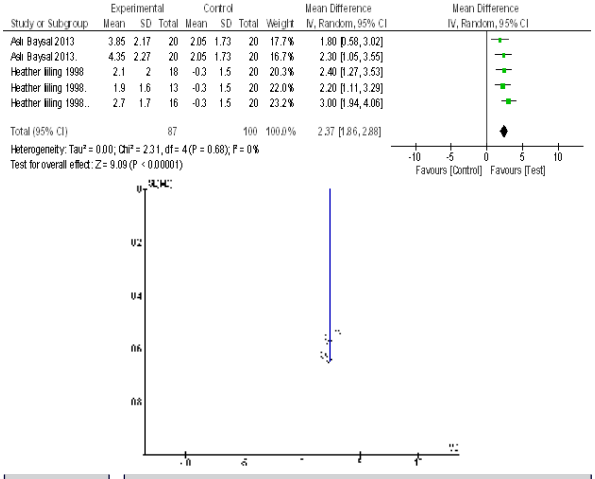

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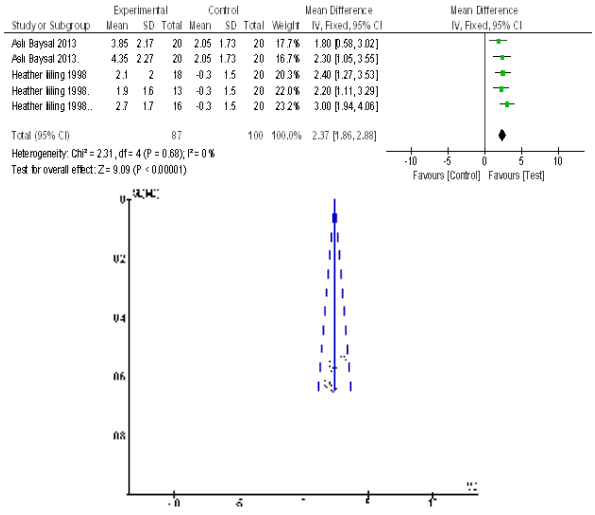

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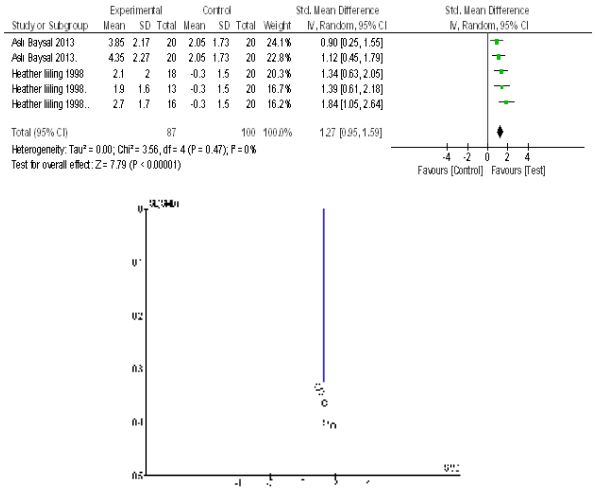

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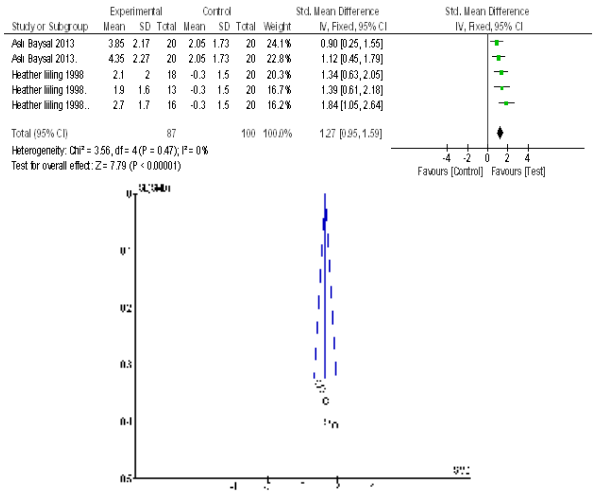

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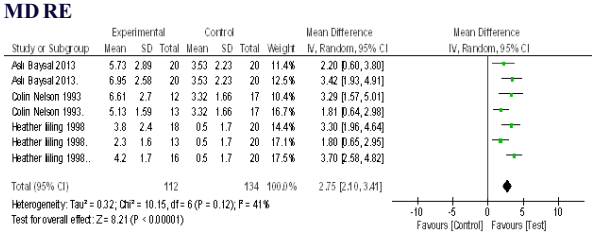

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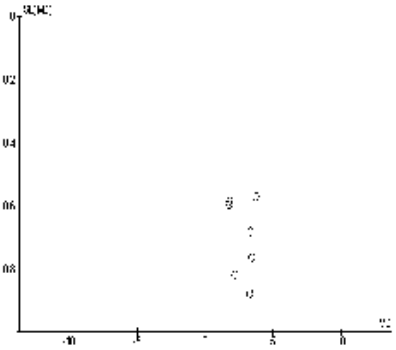

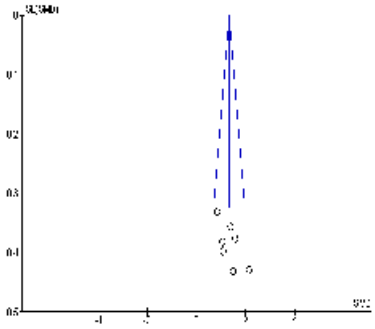

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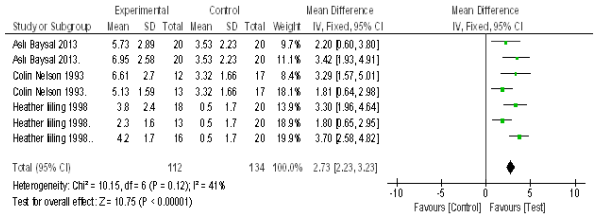

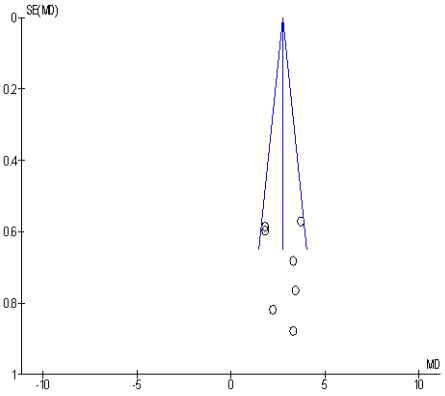

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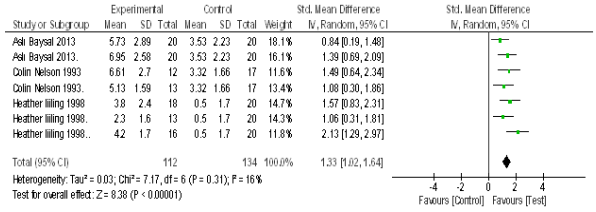

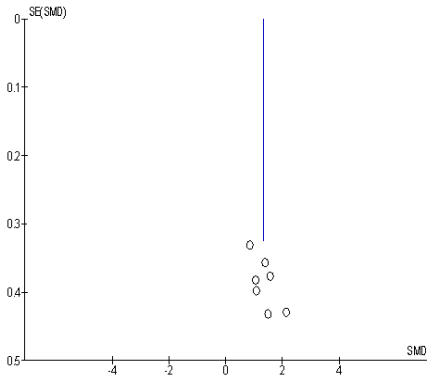

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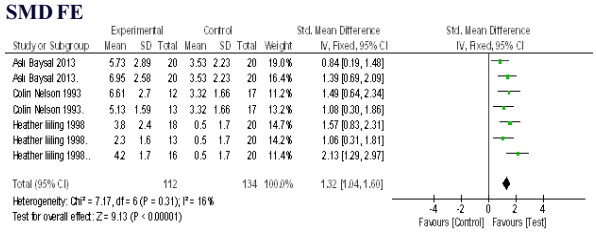

DISCUSSION:

Summary Of Evidence

This systematic review involved data from 187 Class II patients. These included 249 treated patients with functional appliances (FA) and 122 untreated patients. The studies were conducted from 2 randomized controlled trials (RCTs) and 3 prospective clinical trials (Pcct). The skeletal and dental changes assessed by radiographic methods in treating Class II malocclusion were reviewed for removable and fixed functional appliances.

In the **1993** study by **Colin Nelson et al**., it was found that total anterior facial height increased by 5.13 mm (SD = 1.59 mm) after using the Frankel appliance, and by 6.61 mm (SD = 2.70 mm) after applying the activator, compared to the control group, which showed an increase of only 3.32 mm (SD = 1.66 mm). Both appliance groups demonstrated a notable increase in anterior face height (N-Me). Similar changes were observed in other studies at the onset of functional appliance treatment, such as those by Chang et al. Furthermore, the increase in N-Me was significantly correlated with a rise in molar height in both appliance groups.

In a **2008** study by **Selin Kale Varlik**, the mean difference in lower anterior facial height changes was reported as 1.7 mm (SD = 1.8 mm) for the Bass appliance, 2.0 mm (SD = 2.6 mm) for the Bionator appliance, and 2.2 mm (SD = 2.0 mm) for the Twin Block appliance. In comparison, the control group had a mean difference of -0.5 mm (SD = 2.3 mm). The study also found the mean difference in total anterior facial height changes to be 1.9 mm (SD = 1.8 mm) for the Bass appliance, 4.0 mm (SD = 2.4 mm) for the Bionator appliance, and 4.5 mm (SD = 1.9 mm) for the Twin Block appliance. The control group showed a mean difference of 0.6 mm (SD = 2.4 mm

The control group showed a slight reduction in lower anterior facial height, with a mean decrease of 0.3 mm and a standard deviation of 1.5 mm. In contrast, the treatment groups demonstrated significantly greater increases, with the most notable clinical changes observed. The Twin Block group had the largest increase, with a mean difference of 2.7 mm and a standard deviation of 1.7 mm. This was followed by the Bionator group, which had a mean difference of 2.1 mm and a standard deviation of 2.0 mm, and the Bass group, showing a mean difference of 1.9 mm and a standard deviation of 1.6 mm. Clark (1995) reported a significant increase in total vertical face height with Twin Block therapy, with increases of 6.29 mm in males and 4.93 mm in females over 12 months. Cura et al. (1996) observed an increase in total face height with Bass therapy, reporting a mean difference of 3.4 mm and a standard deviation of 2.1 mm, while the Activator group showed a mean difference of 4.6 mm and a standard deviation of 1.8 mm, as noted in a **1998** study by **Heather Illing et al**.

Seniz Karacay et al., **2005** reported the mean difference in total anterior facial height between the Forsus appliance and the control group was 5.03 mm, with a standard deviation of 0.34 mm. For the Jasper Jumper, the mean difference compared to the control group was 4.47 mm, with a standard deviation of 0.34 mm. Additionally, the mean difference in lower anterior facial height between the Forsus appliance and the control group was 4.87 mm (SD = 0.29 mm), while for the Jasper Jumper, the mean difference was 5.00 mm (SD = 0.29 mm) compared to the control group.

An increase in both lower anterior and posterior face heights is consistently observed following Twin Block (TB) therapy. Toth and McNamara (1999) documented a 3.0 mm increase in anterior face height, while Lund and Sandler (1998) reported a 2.6 mm increase in total anterior face height compared to control groups. Mills and

McCulloch (1998) also noted significant increases relative to controls, with a 3.8 mm increase in total anterior face height. When evaluating the increase in lower anterior face height during TB treatment, it is important to consider the impact of acrylic contouring. Additionally, Pancherz (1982) reported a 1.8 mm increase in lower anterior face height with a banded Herbst design.

In a **2013** study by **Asli Baysal et al**., the mean difference in total anterior face height with the Herbst appliance was 6.95 mm, with a standard deviation of 2.58 mm. The Twin Block appliance showed a mean difference of 5.73 mm (SD = 2.89 mm), while the control group had a mean difference of 3.53 mm (SD = 2.23 mm). For lower anterior face height, the Herbst appliance resulted in a mean difference of 4.35 mm (SD = 2.27 mm), while the Twin Block appliance showed a mean difference of 3.85 mm (SD = 2.17 mm). In contrast, the control group exhibited a mean difference of 2.05 mm (SD = 1.73 mm).

An increase in the vertical dimension will likely be noticeable to a layperson. Therefore, it is important to assess changes in both the sagittal and vertical dimensions. This systematic review and meta-analysis also demonstrate a significant increase in both lower anterior facial height and total anterior facial height.

CONCLUSION

According to the existing evidence, the treatment effects of functional appliances were associated with stimulation of mandibular growth and with more pronounced dentoalveolar and soft tissue changes. Along with the sagittal changes functional appliances bring about vertical changes.

Under the limitations of the number of available studies and total samples for this systematic review, the following conclusions could be made:

1. Functional appliances bring about significant changes in lower anterior facial height (ANS- Me) of individuals with skeletal class II malocclusion
2. Total anterior facial height (N-Me) change was statistically significant in growing individuals with skeletal class II malocclusion
3. Patient and appliance-related factors might influence the outcome of functional appliance treatment

Limitations:

- Based on limited evidence functional appliances are effective in increasing total face height as well as lower anterior face height in children; however there remains insufficient evidence. Further well-designed randomized controlled trials are required to assess changes in vertical dimensions with functional appliances.

Future Scope:

- Three-dimensional quantification of the soft tissue changes is required to overcome current limitations in our understanding of the soft tissue changes obtained after the use of the Functional appliance in Class II division 1 malocclusion patients.

Abbrevations:

FAs: Functional appliances
RFAs: Removable functional appliances
FFAs: Fixed functional appliances
RCTs: Randomized controlled trials
PRISMA: Preferred reporting items for systematic review and meta-analysis
ROB: Risk of bias
MD: Mean deviation
SMD: Standard mean difference
TB: Twin block
Gp 1: Group 1
Gp 2: Group 2
Gp 3: Group 3
Gp 4: Group 4
T1: Before appliance delivery
T2: After appliance delivery

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Disclosure Of Interest:

The authors declare that they have no competing interests.
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Equal participation of all the authors.

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