



## **SKELETAL, DENTAL AND SOFT TISSUE EFFECTS OF FIXED FUNCTIONAL APPLIANCES IN CLASS II MALOCCLUSION: A SYSTEMATIC REVIEW AND META ANALYSIS**

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## **1. Introduction**

Class II malocclusion is a frequent condition and affects 25-30% of the general population. The etiology of skeletal class II malocclusion can be attributed to various factors, and hence accurate diagnosis is critical for selection of corresponding treatment options. Among all the factors, mandibular retrognathism is considered to be the most common causative factor for development of skeletal class II malocclusion [1]. Numerous treatment approaches involving removable and/or fixed appliances with/without extractions have been reported during the last century.

The various treatment options for Class II correction apart from myofunctional/FFAs include orthopedic appliances like headgears, camouflage line of treatment by extractions of premolars, distalization of the maxillary arch or the surgical correction of the underlying skeletal discrepancy when growth has completed [2]. FFAs are the most commonly used appliance to correct skeletal discrepancy in a growing stage, but still its enhancement effect on mandibular growth has been questionable [3].

Fixed functional appliance (FFA) was introduced first in dentistry by Dr Emil Herbst of Germany at the 5th International Dental Congress in Berlin in 1909 although many were sceptical about the stability of end results. Pancherz in 1979 [4] reintroduce Herbst appliance into modern orthodontics and made fixed functional appliances a popular choice for clinician to treat non-compliant skeletal class II malocclusions. Herbst appliance has morphed into many derivatives in the last 40 years, which use the same bite-jumping-mechanism but differ in appliance and/or anchorage design. All these fixed functional appliances correct the skeletal Class II malocclusion by the combined effects of skeletal and dental changes, including the advancement of mandible, restrict the growth of maxilla, proclination of the lower anterior, and retroclination of the maxillary anterior.

McNamara et al [5] showed a favourable treatment outcomes based on mandibular growth, based on mandibular length augmentation or effective condyle growth, however Cozza et al [6] disputed the magnitude of these effects. Furthermore, Covell [7] et al posits the restricting effect on the maxilla

which are questioned by others. Moreover, Kucukkeleş [8] corroborated that the dentoalveolar changes produced by functional treatment outweigh the skeletal changes attained.

An important distinction between removable and fixed functional, is the need for patient compliance, which has a strong influence on the treatment outcome. Hence, it is essential to evaluate those two types of functional appliances separately so as to investigate their clinical effectiveness. Previously published systematic reviews on the subject presented methodological limitations. The current systematic review provides an holistic view on treatment effects of fixed functional appliances.

### **AIM**

This study aimed to review and analyse current evidence from randomized controlled trials (RCTs) and prospective controlled clinical trials (pCCTs) by means of lateral cephalometric radiographs. The skeletal, dental, and soft tissue effectiveness of FFAs for the treatment of patients with Class II malocclusion in comparison with untreated individuals.

## **2. Materials And Methodology**

### **Protocol and registration:**

The protocol for the present systematic review was constructed according to the Cochrane Handbook for Systematic Reviews of Interventions 5.1.0. The systematic review is registered in PROSPERO (CRD42022381722). The systematic review is reported on the basis of the PRISMA statement.

### **Search strategy :**

The articles were sought and selected through a thorough literature survey from the following databases: (a) The Cochrane Library, (b) PubMed (c) SCOPUS, (d) Scientific Electronic Library Online, and (e) EMBASE (f) MEDLINE. Two blinded authors were assigned the responsibility of performing the eligibility assessment as well as data-collection processes of the articles. In the case of occasional conflicts, a thorough discussion was carried out on each article until reaching a conclusion. MESH terms and the respective keywords were used properly to fit each database ( table 1).The

search strategy included no limitations concerning language, publication year, or status. The reference lists of the included trials

and relevant reviews were manually searched as well.

TABLE 1

Electronic database	Search strategy used	Hits
<p><b>EMBASE</b> Searched via embase biomedical answers(&lt;1966 – week 1, august 2022) <a href="http://www.embase.com/search/advanced">http://www.embase.com/search/advanced</a></p>	<p>(maxill* AND (excess* OR prognath*)) OR (mandib* AND (deficien* OR retrognath* OR reposition* OR enhanc* OR advanc*)) OR functional OR orthopaedic* OR orthopedic* OR 'growth'/exp OR herbst OR 'magnetic telescopic device' OR 'ventral telescope' OR 'mandibular advancing repositioning splint' OR 'mandibular corrector appliance' OR 'biopedic appliance' OR 'ritto appliance' OR 'mandibular protraction appliance' OR 'mandibular anterior repositioning appliance' OR 'mara' OR 'functional mandibular advancer' OR 'jasper jumper' OR 'scandee tubular jumper' OR 'flex developer' OR 'adjustable bite corrector' OR 'bite fixer' OR 'forsus nitinol flat spring' OR 'forsus device' OR 'forsus appliance' OR 'twin force bite corrector' OR 'eureka spring' OR 'sabbagh spring' OR activator OR bionator OR 'bimler appliance' OR 'fraenkel appliance' OR 'frankel appliance' OR 'bass appliance' OR 'harvold appliance' OR 'andresen appliance' OR 'teuscher appliance' OR 'stoeckli appliance' OR 'stockli appliance' OR biobloc OR 'bite jumper' OR 'bite jumping' OR 'sii appliance' OR 'twin block' AND ('class ii malocclusion' OR class AND ii AND div* OR class AND ii OR ('class ii' AND orthodont*)) AND ('clinical trial'/exp OR 'comparative study'/exp OR 'controlled clinical trial'/exp OR 'double blind procedure'/exp OR 'prospective study'/exp OR 'randomized controlled trial'/exp) AND 'malocclusion'/exp</p>	598
<p><b>Scopus</b> Searched on October 10, 2022 <a href="http://www.scopus.com/search/form.url?display=advanced&amp;clear=t&amp;origin=searchbasic&amp;txGid=1lk b0B3HcbSzUk8cVtIzKL_%3a3">http://www.scopus.com/search/form.url?display=advanced&amp;clear=t&amp;origin=searchbasic&amp;txGid=1lk b0B3HcbSzUk8cVtIzKL_%3a3</a></p>	<p>(Herbst OR "Magnetic telescopic device" OR "Ventral telescope" OR "Mandibular advancing repositioning splint" OR "Mandibular corrector appliance" OR "Biopedic appliance" OR "Ritto appliance" OR "Mandibular</p>	1824

	<p>protraction appliance" OR "Mandibular anterior repositioning appliance" OR "MARA" OR "Functional mandibular advancer" OR "Jasper jumper" OR "Scandee tubular jumper" OR "Flex developer" OR "Adjustable bite corrector" OR "Bite fixer" OR "Forsus nitinol flat spring" OR "Forsus device" OR "Forsus appliance" OR "Twin force bite corrector" OR "Eureka spring" OR "Sabbagh spring" OR Activator OR Bionator OR "Bimler appliance" OR "Fraenkel appliance" OR "Frankel appliance" OR "Bass appliance" OR "Harvold appliance" OR "Andresen appliance" OR "Teuscher appliance" OR "Stoeckli appliance" OR "Stockli appliance" OR Biobloc OR "Bite jumper" OR "Bite jumping" OR "SII appliance" OR "Twin block") AND ("class ii malocclusion" OR class ii div* OR class ii/ OR ("class ii" AND orthodont*)) AND (functional OR orthopaedic* OR orthopedic* OR growth) AND (LIMITTO(SUBJAREA, "DENT") OR LIMITTO(SUBJAREA, "MULT"))</p>	
<p><b>MEDLINE</b> Searched via PubMed (1950 - week 1, august2022) <a href="http://www.ncbi.nlm.nih.gov/pubmed/advanced">http://www.ncbi.nlm.nih.gov/pubmed/advanced</a></p>	<p>(((((maxill* AND (excess* OR prognath*)) OR (mandib* AND (deficien* OR retrognath* OR reposition* OR enhanc* OR advanc*)) OR functional OR orthopaedic* OR orthopedic* OR growth)) OR (Herbst OR "Magnetic telescopic device" OR "Ventral telescope" OR "Mandibular advancing repositioning splint" OR "Mandibular corrector appliance" OR "Biopedic appliance" OR "Ritto appliance" OR "Mandibular protraction appliance" OR "Mandibular anterior repositioning appliance" OR "MARA" OR "Functional mandibular advancer" OR "Jasper jumper" OR "Scandee tubular jumper" OR "Flex developer" OR "Adjustable bite corrector" OR "Bite fixer" OR "Forsus nitinol flat spring" OR "Forsus device" OR "Forsus appliance" OR "Twin force bite corrector" OR "Eureka spring" OR "Sabbagh spring" OR Activator OR Bionator OR "Bimler appliance" OR "Fraenkel appliance" OR "Frankel</p>	<p>1564</p>

	<p>appliance" OR "Bass appliance" OR "Harvold appliance" OR "Andresen appliance" OR "Teuscher appliance" OR "Stoeckli appliance" OR "Stockli appliance" OR Biobloc OR "Bite jumper" OR "BiteNo limitations jumping" OR "SII appliance" OR "Twin block")) AND ("class ii malocclusion" OR class ii div* OR class ii/* OR ("class ii" AND orthodont*))) AND ((randomized controlled trial[pt] OR controlled clinical trial[pt] OR randomized controlled trials[mh] OR random allocation[mh] OR double-blind method[mh] OR single-blind method[mh] OR clinical trial[pt] OR clinical trials[mh]) OR ("clinical trial"[tw] OR ((singl*[tw] OR doubl*[tw] OR trebl*[tw] OR tripl*[tw]) AND (mask*[tw] OR blind*[tw])) OR (placebos[mh] OR placebo*[tw] OR random*[tw] OR research design[mh:noexp] OR comparative study OR evaluation studies OR follow-up studies[mh] OR prospective studies[mh] OR control*[tw] OR prospectiv*[tw] OR volunteer*[tw]))</p>	
<p><b>Cochrane Database of Systematic Reviews</b> Searched via The Cochrane Library on October 10, 20122 <a href="http://onlinelibrary.wiley.com/o/cochrane/cochrane_search_fs.html?newSearch=true">http://onlinelibrary.wiley.com/o/cochrane/cochrane_search_fs.html?newSearch=true</a></p>	<p>(maxill* AND (excess* OR prognath*)) OR (mandib* AND (deficien* OR retrognath* OR reposition* OR enhanc* OR advanc*)) OR functional OR orthopaedic* OR orthopedic* OR growth OR (Herbst OR "Magnetic telescopic device" OR "Ventral telescope" OR "Mandibular advancing repositioning splint" OR "Mandibular corrector appliance" OR "Biopedic appliance" OR "Ritto appliance" OR "Mandibular protraction appliance" OR "Mandibular anterior repositioning appliance" OR "MARA" OR "Functional mandibular advancer" OR "Jasper jumper" OR "Scandee tubular jumper" OR "Flex developer" OR "Adjustable bite corrector" OR "Bite fixer" OR "Forsus nitinol flat spring" OR "Forsus device" OR "Forsus appliance" OR "Twin force bite corrector" OR</p>	<p>658</p>

	<p>"Eureka spring" OR "Sabbagh spring" OR Activator OR Bionator OR "Bimler appliance" OR "Fraenkel appliance" OR "Frankel appliance" OR "Bass appliance" OR "Harvold appliance" OR "Andresen appliance" OR "Teuscher appliance" OR "Stoekli appliance" OR "Stockli appliance" OR Biobloc OR "Bite jumper" OR "Bite jumping" OR "SII appliance" OR "Twin block") AND ("class ii malocclusion" OR class ii div* OR class ii/ OR ("class ii" AND orthodont*))</p>	
<p><b>Cochrane Central Register of Controlled Trials</b> Searched via The Cochrane Library on October 10, 2022 <a href="http://onlinelibrary.wiley.com/o/cochrane/cochrane_search_fs.html?newSearch=true">http://onlinelibrary.wiley.com/o/cochrane/cochrane_search_fs.html?newSearch=true</a></p>	<p>(maxill* AND (excess* OR prognath*)) OR (mandib* AND (deficien* OR retrognath* OR reposition* OR enhanc* OR advanc*)) OR functional OR orthopaedic* OR orthopedic* OR growth OR (Herbst OR "Magnetic telescopic device" OR "Ventral telescope" OR "Mandibular advancing repositioning splint" OR "Mandibular corrector appliance" OR "Biopedic appliance" OR "Ritto appliance" OR "Mandibular protraction appliance" OR "Mandibular anterior repositioning appliance" OR "MARA" OR "Functional mandibular advancer" OR "Jasper jumper" OR "Scandee tubular jumper" OR "Flex developer" OR "Adjustable bite corrector" OR "Bite fixer" OR "Forsus nitinol flat spring" OR "Forsus device" OR "Forsus appliance" OR "Twin force bite corrector" OR "Eureka spring" OR "Sabbagh spring" OR Activator OR Bionator OR "Bimler appliance" OR "Fraenkel appliance" OR "Frankel appliance" OR "Bass appliance" OR "Harvold appliance" OR "Andresen appliance" OR "Teuscher appliance" OR "Stoekli appliance" OR "Stockli appliance" OR Biobloc OR "Bite jumper" OR "Bite jumping" OR "SII appliance" OR "Twin block") AND ("class ii malocclusion" OR class ii div* OR class ii/ OR ("class ii" AND orthodont*))</p>	<p>1256</p>
<p><b>Web of Science</b> Searched on October 10, 2022 <a href="http://apps.webofknowledge.com/WOS_GeneralS">http://apps.webofknowledge.com/WOS_GeneralS</a></p>	<p>TS=(maxill* AND (excess* OR prognath*)) OR TS=(mandib* AND (deficien* OR retrognath* OR</p>	<p>1685</p>

<p>earch_input.do?last_prod=WOS&amp;SID=PIG3aMpj DambMDFjp3e&amp;product=WOS&amp;highlighted_tab =WOS&amp;search_mode=GeneralSearch</p>	<p>reposition* OR enhanc* OR advanc*)) OR TS=(functional) OR TS=(orthopaedic*) OR TS=(orthopedic*) OR TS=(growth) OR TS=("Mandibular anterior repositioning appliance") OR TS=("Mandibular protraction appliance") OR TS=("Ritto appliance") OR TS=("Biopedic appliance") OR TS=("Mandibular corrector appliance") OR TS=("Mandibular advancing repositioning splint") OR TS=("Ventral telescope") OR TS=("Magnetic telescopic device") OR TS=(Herbst) OR TS=("Fraenkel appliance") OR TS=("Bimler appliance") OR TS=(Bionator) OR TS=(Activator) OR TS=("Sabbagh spring") OR TS=("Eureka spring") OR TS=("Twin force bite corrector") OR TS=("Forsus appliance") OR TS=("Forsus device") OR TS=("Forsus nitinol flat spring") OR TS=("Bite fixer") OR TS=("Adjustable bite corrector") OR TS=("Flex developer") OR TS=("Scandee tubular jumper") OR TS=("Jasper jumper") OR TS=("Functional mandibular advancer") OR TS=("MARA") OR TS=("Twin block") OR TS=("SII appliance") OR TS=("Bite jumping") OR TS=("Bite jumper") OR TS=(Biobloc) OR TS=("Stockli appliance") OR TS=("Stoekli appliance") OR TS=("Teuscher appliance") OR TS=("Andresen appliance") OR TS=("Harvold appliance") OR TS=("Bass appliance") OR TS=("Frankel appliance") AND (TS=("class ii malocclusion") OR TS=(class ii div*) OR TS=(class ii/) OR TS=("class ii" AND orthodont*))</p>	
<p><b>LILACS database</b> Searched on October 10, 2022 <a href="http://bases.bireme.br/cgi-bin/wxislind.exe/iah/online/?IsisScript=iah/iah.xis&amp;base=LILACS&amp;lang=i">http://bases.bireme.br/cgi-bin/ wxislind.exe/iah/online/?IsisScript=iah/iah.xis &amp;base=LILACS&amp;lang=i</a></p>	<p>orthodont\$ or angle class ii and functional</p>	<p>425</p>

PICO:

1. Patient, Population, or Problem: Class II postpubertal cases/ late adolescent/adult cases
2. Intervention, Prognostic Factor, or Exposure: Treatment done by fixed functional appliances (no limitation to the types of appliances used)
3. Comparison or Intervention: Compare Class II malocclusion treated with fixed functional appliance (experimental group) with Untreated group with class II malocclusion.(control group)
4. Outcome: Changes brought about in skeletal, dental, and soft-tissue cephalometric parameters after treatment of the experimental and control group

### **Eligibility Criteria And Study Selection**

The eligibility criteria were pre-determined (table 2). A study was considered eligible when

it reported on at least one treatment arm with a FFA and simultaneously all of the inclusion and none of the exclusion criteria were fulfilled. In order to investigate only the effects of FFAs, data concerning any previous or subsequent phases with fixed appliances were not included, since fixed appliances are likely to alter the effects caused by functional treatment. After the elimination of duplicates, the decision for the selection was made by taking into consideration the title, abstract, and, when it was considered necessary, the full text of the respective articles. When the same trial was published in various languages, the English version was preferred. Finally, articles including at least one treatment arm with FFAs were selected. Figure 1 depicts the article exclusion and selection process.

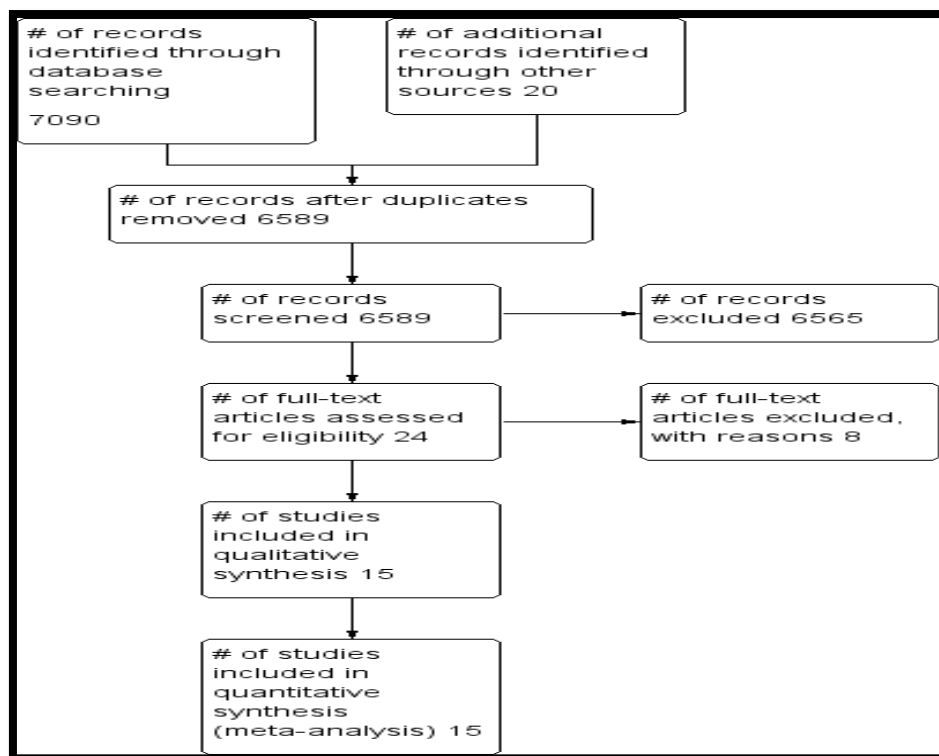
TABLE 2:

CATEGORY	INCLUSION	EXCLUSION
Participant characteristic	Studies on human patients with class II malocclusion of any gender and age	Patients with craniofacial syndromes and/or cleft lip palate Patients with temporomandibular joint disorders Animal studies
Intervention	Orthodontic treatment with fixed functional appliances	Patients with class ii malocclusion treated with extractions, Class ii elastics, orthognathic surgery, or removable Functional appliances
Comparison	Untreated patients with class ii malocclusion matched for age and gender	Studies without an untreated class ii control group
Outcome	Studies providing angular and linear skeletal, dentoalveolar and soft tissue cephalometric measurements from lateral cephalometric analysis	Electromyographic evaluation Evaluation employing 3d imaging techniques Cost-benefit analysis
Study design	Randomized controlled clinical trails Prospective and retrospective controlled clinical trial	Unsupported opinion of expert Editor' s choices Replies to the author/editor Interviews Commentaries Books'/conferences' abstracts Summaries Cross-sectional surveys Case series without a control



		Case reports Case-control studies	observational studies
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Figure 1:



### Statistical Analysis:

The data thus obtained were subjected to statistical analysis using the forest plot. Descriptive statistical test like the standard mean difference on the 95% confidence interval was done using the RevMan5 software.  $X^2$ -based  $Q$ -statistic method and  $i^2$  index were used to detect and assess the heterogeneity.

### Assessment of Risk of Bias in Individual Studies and Across Studies:

Heterogeneity was evaluated using the  $x^2$ -based  $Q$ -statistic method and  $i^2$  inde. The  $\chi^2$  was also

calculated for the same. Risk of bias for individual studies was appraised (independently by 2 authors) following pre-established characteristics, along with the scores that were allocated to the individual retrieved articles mentioned in Table 3 . The quality of the studies, with a maximum possible score of 17, was considered as follows:

1. Low: final score  $\leq 7$
2. Medium: final score  $>7$  and  $\leq 10$
3. Medium/high: final score  $>10$  and  $\leq 14$
4. High: final score  $>14$ .

TABLE 3:

PRE ESTABLISED CHARACTERISTICS		SCORE
1. Adequacy of sample selection description based on age and sex across the groups	Full: 2 points; partial: 1 point	2

2. Study design for the inclusion of the treated group	Prospective: 1 point; retrospective or not declared: 0 point	1
3. Description of the Class II (full, skeletal, and/or dental parameters;	Full: 2 points; partial: 1 point	2
4. Distribution of the different maturational stages among the investigated subjects	Full: 2 points; partial: 1 point	1
5. Adequacy of treatment description based on 3 criteria: (a) orthodontic appliance, (b) mandibular advancement or information when the functional treatment was stopped, and (c) length of the functional treatments (irrespective of the comprehensive multibracket appliance therapy when performed)	Full: 2 points; partial: 1 point	2
6. Incomplete outcome data (cephalometric magnification, success rate)	No: 1 point; yes: 0 point	1
7. Withdrawals declared or derivable	Yes: 1 point; no: 0 point	1
8. Description of the method error analysis (overall [random and systematic] errors; only systematic error; no)	Overall: 2 points, systematic: 1 point; no: 0 point	2
9. Blinding for measurements	Yes: 1 point; no: 0 point	0

10. Adequacy of statistics based on the comparisons of the intragroup changes over time among/between groups (yes, when parametric or nonparametric tests used where appropriate; no, when parametric tests used when nonparametric tests would be more appropriate, multiple comparisons with uncorrected <i>P</i> values, statistical analysis only partially described)	Yes: 2 points, no: 1 Point	2
11. Prior estimation of sample size or a posteriori power analysis	Yes: 1 point, no: 0 point	1
<b>TOTAL</b>		<b>15</b>

Calculations were performed by using the Comprehensive Meta-Analysis software (RevMan5). For each individual study, the RevMan5 software given by Cochrane allowed us to evaluate the risk bias in 6 domains (Figure 2). The evaluated fields are as follows: sequence generation (selection bias), allocation

concealment (selection bias), blinding of participants and personnel (performance bias), blinding of outcome assessors (detection bias), incomplete outcome data addressed (attrition bias), selective outcome reporting (reporting bias), and other bias.

FIGURE 2:

Bias	Authors' judgement
Random sequence generation (selection bias)	Low risk
Allocation concealment (selection bias)	Low risk
Blinding of participants and personnel (performance bias)	High risk
Blinding of outcome assessment (detection bias)	High risk
Incomplete outcome data (attrition bias)	Low risk
Selective reporting (reporting bias)	Low risk
Other bias	Low risk

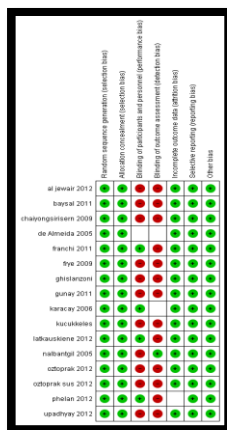
The overall risk of bias of the included trials was assessed according to the following: low risk of bias: if all fields were evaluated as at low

risk of bias (bias improbable to change the results critically); unclear risk of bias: if at least 1 or more fields were assessed as at unclear risk

of bias (bias carries some doubt about the results); and high risk of bias: if at least 1 or more fields were evaluated as at high risk of bias (bias critically affects the results)

(excluded from the primary analysis). This risk bias is displayed in Figure 3 with color coding (green: low risk; yellow: unclear risk; and red: high risk).

FIGURE 3:



After a thorough evaluation and discussion, the studies shown in Table 4 were selected for meta-analysis.

TABLE 4:

AUTHOR	YEAR	DESIGN	SAMPLE SIZE	TREATMENT	AUTHOR CONCLUSION
Nalbantgil <sup>9</sup>	2005	Prospective clinical trial	N = 23 C = 15	Skeletal, dental, and soft-tissue changes in late adolescent patients treated with Jasper Jumper	There were no significant changes in the vertical skeletal parameters. Overbite and overjet were reduced, and the soft tissue profile improved significantly. Jasper Jumper corrected Class II discrepancies mostly through dentoalveolar changes.
de Almeida <sup>10</sup>	2005	Prospective clinical trial	N: 30 C: 30	Herbst (modified)	modest, but statistically significant increase in mandibular length. This increase was less than

					that observed in adolescent Herbst patients in other studies
Karacay <sup>11</sup>	2006	Prospective clinical trial	N: 16 N: 16 C: 16	Gp1: Forsus nitinol flat spring; Gp2: Jasper jumper	Both the appliances cause significant incisor and molar movements, and these dentoalveolar changes are more effective than the skeletal changes in attaining Class I molar relationship
Kucukkeles <sup>8</sup>		Retrospective	N= 25 C= 15	Jasper Jumper appliance	Most of the correction was achieved by dentoalveolar changes, with not much alteration in the vertical dimension
Chaiyongsirisern <sup>12</sup>	2009	Prospective clinical trial	N = 16 C = 15	Adult patients treated with cast splint Herbst appliance with stepwise advancement followed by fixed appliance	The Herbst appliance with stepwise advancement is an available option for correcting borderline skeletal Class II malocclusion in adult patients.
Frye <sup>13</sup>	2009	Prospective clinical trial	N = 20 C = 19	Treated a skeletal Class II malocclusion with 2 fixed functional orthodontic appliances, the Herbst appliance and the functional mandibular advancer	A significant reduction of the overjet was achieved. No significant sagittal effects in terms of mandibular advancement. However, there was an inhibiting effect on the maxilla, which counteracted the natural growth process.

Gunay <sup>14</sup>	2011	Prospective clinical trial	N = 15 C = 12	Patients treated with ForsusTM FRD (3M Unitek Cor, Monrovia, CA, USA)	The ForsusTM FRD corrected the Class II discrepancies through dentoalveolar changes. The maxillary incisor crowns retroclined and mandibular incisor crowns tipped forward. The occlusal plane rotated in a clockwise manner. Skeletally no vertical or sagittal changes were noted.
Baysal <sup>15</sup>	2011	RCT	N: 20 C: 20	Cast splint Herbst (ME)	The effects of Herbst treatment on the soft tissue changed the soft tissue profile.
Franchi <sup>16</sup>	2011	Retrospective	N= 32 C= 26	ForsusFRD appliance	The effects on the mandible were mainly at the dentoalveolar level, with a large amount of mesial movement of the lower incisors and first molars.
Latkauskiene <sup>17</sup>	2012	Prospective clinical trial	N: 40 C: 18	Stainless steel crown Herbst	The occlusal correction of Class II growing patients who presented stable Class I one year after cHerbst treatment was achieved primarily due to the dentoalveolar changes and only limited skeletal change

Oztoprak <sup>18</sup>	2012	Prospective clinical trial	N = 20 C = 19	Forsus™ FRD (3M Unitek Cor, Monrovia, CA, USA) a semirigid 3-piece telescoping spring was used for Class II correction	No statistically significant vertical and sagittal skeletal effect on the maxilla and the mandible were present. The changes that took place were achieved by only dentoalveolar changes.
Phelan <sup>19</sup>	2012	Prospective clinical trial	N: 31 C: 30	Sydney magnoglide	The compliance-free Sydney Magnoglide is an effective functional appliance for Class II correction, both in the short term and after fixed appliance therapy.
Upadhyay <sup>20</sup>	2012	Prospective clinical trial	N = 18 C = 15	Subjects were treated using a nonextraction method with FFA	Did not affect the skeletal discrepancy. There were significant differences in the dental and soft tissue treatment effects between the groups. The lower incisors showed significant flaring in the FFA group.
Al jewair <sup>21</sup>	2012	Retrospective	N= 30 C= 40	MARA	MARA affect the skeletal and dentoalveolar craniofacial complex and is effective in normalizing the Class II malocclusion to Class I in patients treated during the

					skeletal growthspurt
Oztoprak sus <sup>22</sup>	2012	Prospective clinical trial	N = 20 C = 19	SUS2 (Dentaurum, Ispringen, Germany) used for Class II correction	No statistically significant vertical and sagittal skeletal effect on the maxilla and the mandible were present. The changes that took place were achieved by only dentoalveolar changes.

### 3. Results

The changes brought about by the FFA was evaluated broadly in the following 3 categories:

1. Skeletal
2. Dental
3. Soft tissue.

The skeletal changes were evaluated based on the changes brought about in the following cephalometric parameters:

1. Sella-Nasion-Point A (SNA) angle
2. Sella-Nasion-Point B (SNB) angle
3. Point A-Nasion-Point B (ANB) angle
4. Sella-Nasion-mandibular plane (SN-MP) angle

The dental changes were evaluated based on the changes

brought about in the following cephalometric parameters:

1. Incisor mandibular plane angle (IMPA)
2. Overjet
3. Overbite

The soft-tissue changes were evaluated based on the

changes brought about in the following cephalometric parameters:

1. H angle
2. Nasolabial angle

Following are respective forest plots with their respective tables of data



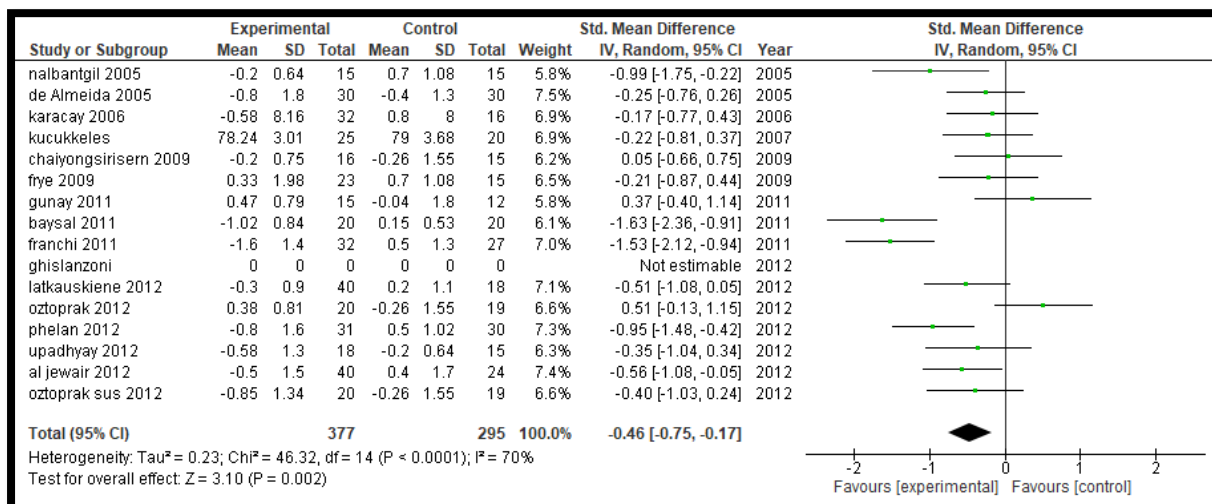


FIGURE 4: forest plot for SNA

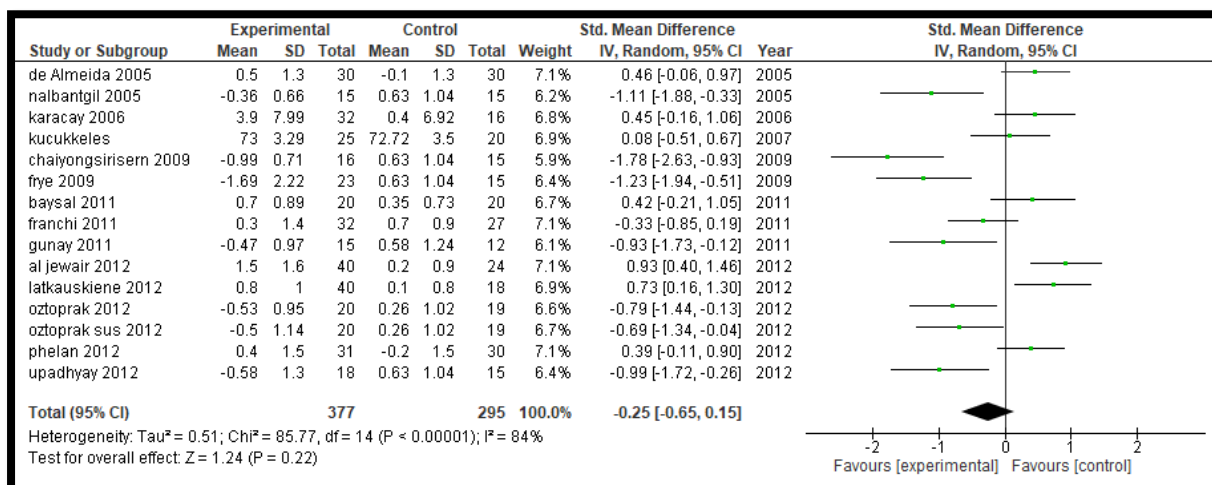


FIGURE 5: forest plot SNB

FIGURE 6: forest plot for ANB

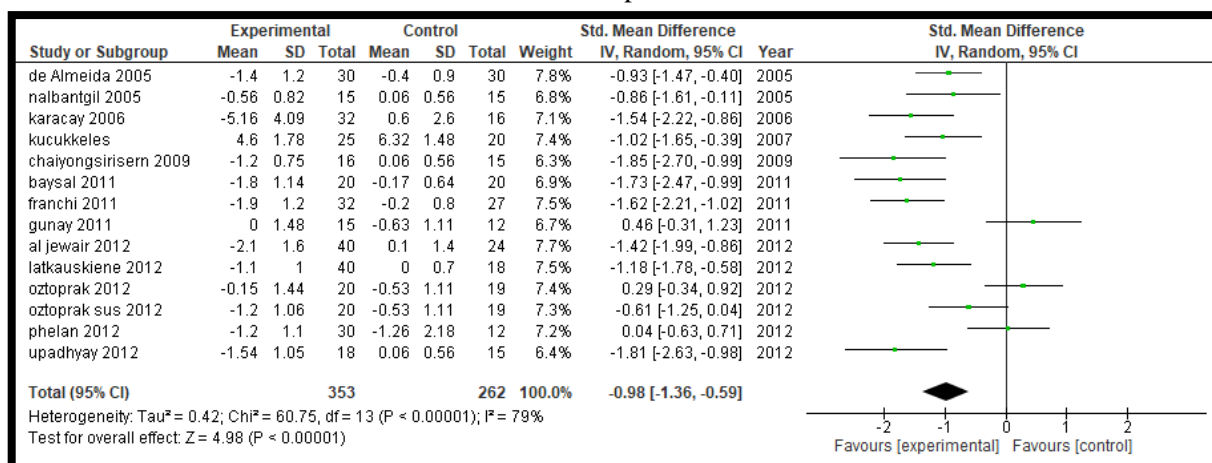


FIGURE 7: forest plot for SN MP

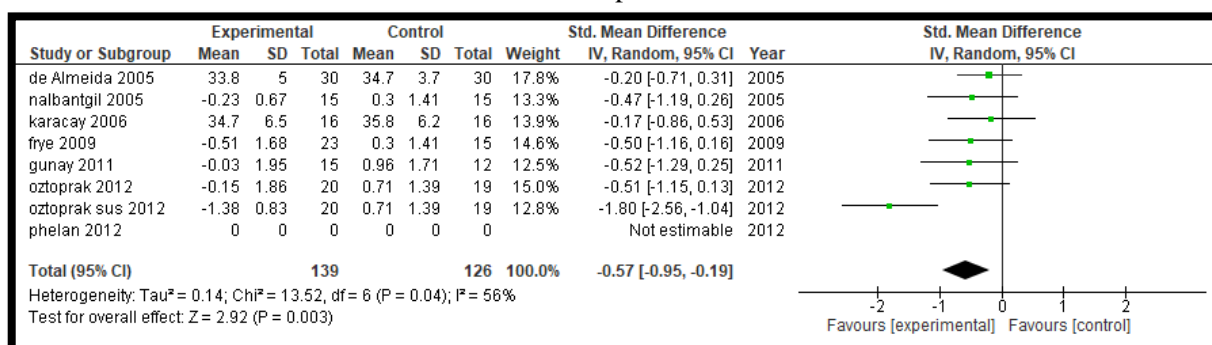


FIGURE 8: forest plot for IMPA

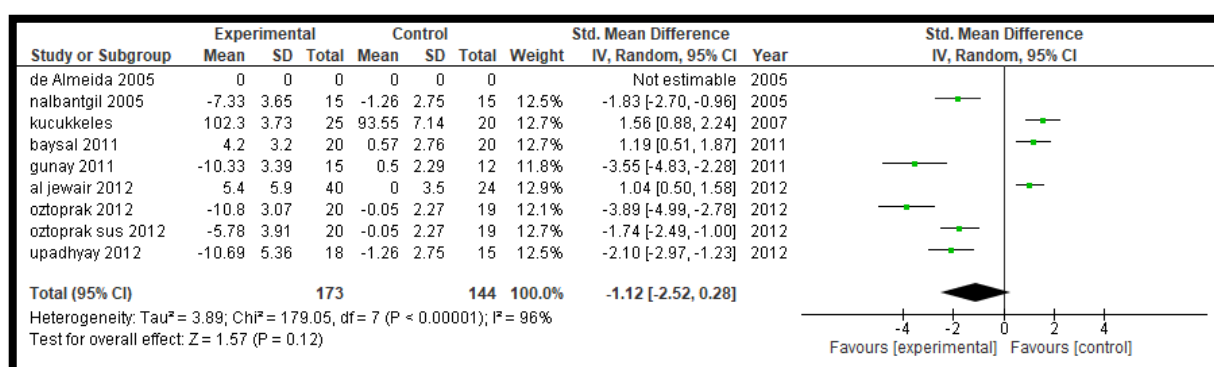


FIGURE 9: forest plot for OVERJET

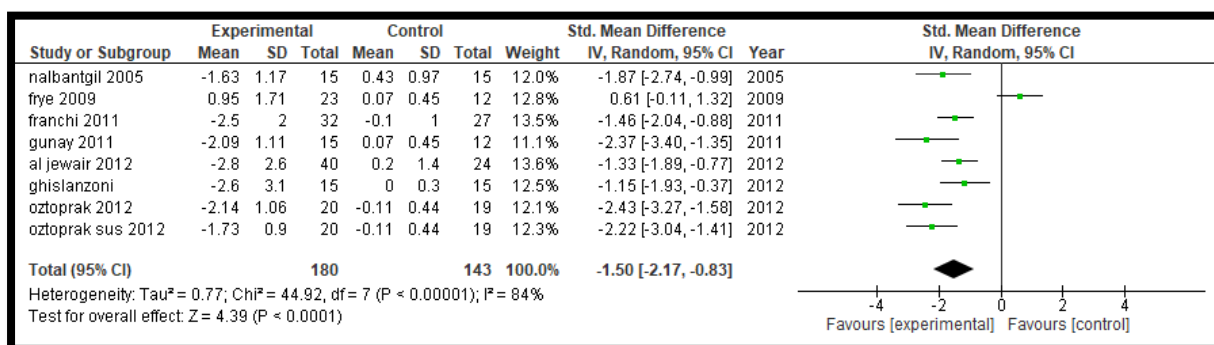
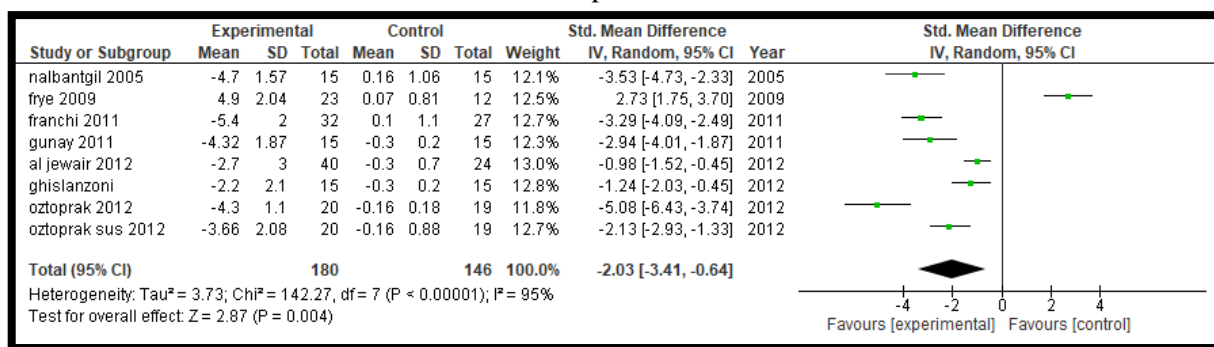


FIGURE 10. Forest plot for OVERBITE

FIGURE 11: forest plot for H ANGLE

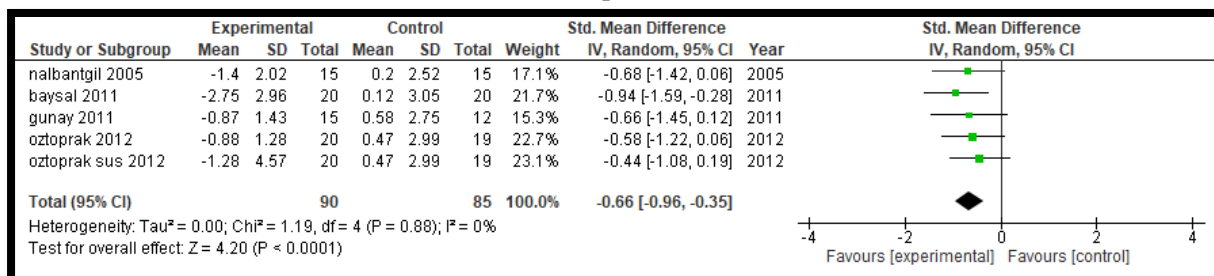
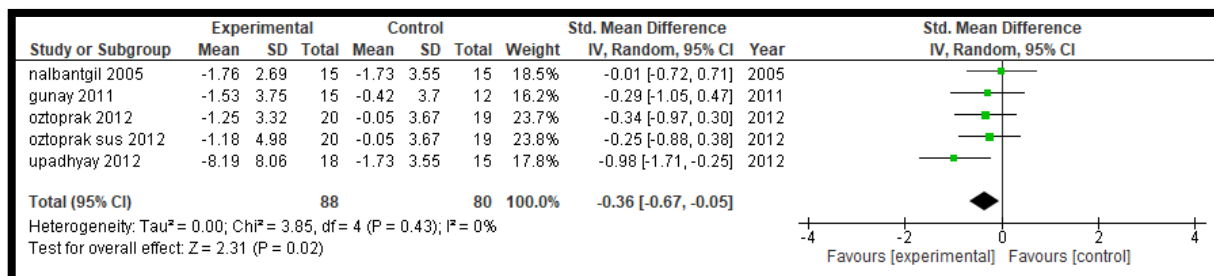


FIGURE 12: forest plot for NASOLABIAL ANGLE



Data extracted from forest plot 1:

Data extracted from forest plot 2:

SNB	EXPERIMENTAL			CONTROL		
STUDIES	MEAN	SD	TOTAL	MEAN 2	SD	TOTAL 2

SNA	EXPERIMENTAL			CONTROL		
STUDIES	MEAN	SD	TOTAL	MEAN 2	SD	TOTAL 2
upadhyay 2012	-0.58	1.3	18	-0.2	0.64	15
phelan 2012	-0.8	1.6	31	0.5	1.02	30
oztoprak sus 2012	-0.85	1.34	20	-0.26	1.55	19
oztoprak 2012	0.38	0.81	20	-0.26	1.55	19
nalbantgil 2005	-0.2	1.8	15	0.7	1.08	15
latkauskiene 2012	-0.3	0.9	40	0.2	1.1	18
karacay 2006	-0.58	8.16	32	0.8	8	16
gunay 2011	0.47	0.79	15	-0.04	1.8	12
frye 2009	0.33	1.98	23	0.7	1.08	15
franchi 2011	-1.6	1.4	32	0.5	1.3	27
de Almeida 2005	-0.8	1.8	30	-0.4	1.3	30
chaiyongsirisern 2009	-0.2	0.75	16	-0.26	1.55	15
baysal 2011	-1.02	0.84	20	0.15	0.53	20
al jewair 2012	-0.5	1.5	40	0.4	1.7	24
Total (95% CI)			352			275
al jewair 2012	1.5	1.6	40	0.2	0.9	24
baysal 2011	0.7	0.89	20	0.35	0.73	20
chaiyongsirisern 2009	-0.99	0.71	16	0.63	1.04	15
de Almeida 2005	0.5	1.3	30	-0.1	1.3	30
franchi 2011	0.3	1.4	32	0.7	0.9	27
frye 2009	-1.69	2.22	23	0.63	1.04	15
gunay 2011	-0.47	0.97	15	0.58	1.24	12
karacay 2006	3.9	7.99	32	0.4	6.92	16
latkauskiene 2012	0.8	1	40	0.1	0.8	18
nalbantgil 2005	-0.36	0.66	15	0.63	1.04	15
oztoprak 2012	-0.53	0.95	20	0.26	1.02	19
oztoprak sus 2012	-0.5	1.14	20	0.26	1.02	19
phelan 2012	0.4	1.5	31	-0.2	1.5	30
upadhyay 2012	-0.58	1.3	18	0.63	1.04	15
Total (95% CI)			352			275

Data extracted from forest plot 3:

ANB	EXPERIMENTAL			CONTROL		
STUDIES	MEAN	SD	TOTAL	MEAN 2	SD	TOTAL 2
de Almeida 2005	-1.4	1.2	30	-0.4	0.9	30
nalbantgil 2005	-0.56	0.82	15	0.06	0.56	15
karacay 2006	-5.16	4.09	32	0.6	2.6	16
chaiyongsirisern 2009	-1.2	0.75	16	0.06	0.56	15
baysal 2011	-1.8	1.14	20	-0.17	0.64	20
franchi 2011	-1.9	1.2	32	-0.2	0.8	27
gunay 2011	0	1.48	15	-0.63	1.11	12
al jewair 2012	-2.1	1.6	40	0.1	1.4	24

latkauskiene 2012	-1.1	1	40	0	0.7	18
oztoprak 2012	-0.15	1.44	20	-0.53	1.11	19
oztoprak sus 2012	-1.2	1.06	20	-0.53	1.11	19
phelan 2012	-1.2	1.1	30	-1.26	2.18	12
upadhyay 2012	-1.54	1.05	18	0.06	0.56	15
Total (95% CI)			328			242

Data extracted from forest plot 4:

SN - MP	EXPERIMENTAL			CONTROL		
STUDIES	MEAN	SD	TOTAL	MEAN 2	SD	TOTAL 2
de Almeida 2005	0.1	21	30	-0.3	1.7	30
nalbantgil 2005	-0.23	0.67	15	0.3	1.41	15
karacay 2006	34.7	6.5	16	35.8	6.2	16
frye 2009	-0.51	1.68	23	0.3	1.41	15
gunay 2011	-0.03	1.95	15	0.96	1.71	12
oztoprak 2012	-0.15	1.86	20	0.71	1.39	19
oztoprak sus 2012	-1.38	0.83	20	0.71	1.39	19
phelan 2012	-1	1	31	0.3	1.1	30
Total (95% CI)			170			156

Data extracted from forest plot 5:

IMPA	EXPERIMENTAL			CONTROL		
STUDIES	MEAN	SD	TOTAL	MEAN 2	SD	TOTAL 2
de Almeida 2005	5	6.1	30	1	2.9	30
nalbantgil 2005	-7.33	3.65	15	-1.26	2.75	15
baysal 2011	4.2	3.2	20	0.57	2.76	20
gunay 2011	-10.33	3.39	15	0.5	2.29	12
al jewair 2012	5.4	5.9	40	0	3.5	24
oztoprak 2012	-10.8	3.07	20	-0.05	2.27	19
oztoprak sus 2012	-5.78	3.91	20	-0.05	2.27	19
upadhyay 2012	-10.69	5.36	18	-1.26	2.75	15
Total (95% CI)			178			154

Data extracted from forest plot 6:

OVERJET	EXPERIMENTAL			CONTROL		
STUDIES	MEAN	SD	TOTAL	MEAN 2	SD	TOTAL 2
nalbantgil 2005	-4.7	1.57	15	0.16	1.06	15
frye 2009	4.9	2.04	23	0.07	0.81	12
franchi 2011	-5.4	2	32	0.1	1.1	27
gunay 2011	-4.32	1.87	15	-0.3	0.2	15
al jewair 2012	-2.7	3	40	-0.3	0.7	24
ghislanzoni	-2.2	2.1	15	-0.3	0.2	15
oztoprak 2012	-4.3	1.1	20	-0.16	0.18	19
oztoprak sus 2012	-3.66	2.08	20	-0.16	0.88	19
Total (95% CI)			180			146

Data extracted from forest plot 7:

OVERBITE	EXPERIMENTAL			CONTROL		
STUDIES	MEAN	SD	TOTAL	MEAN 2	SD	TOTAL 2
nalbantgil 2005	-1.63	1.17	15	0.43	0.97	15
frye 2009	0.95	1.71	23	0.07	0.45	12
franchi 2011	-2.5	2	32	-0.1	1	27
gunay 2011	-2.09	1.11	15	0.07	0.45	12
al jewair 2012	-2.8	2.6	40	0.2	1.4	24
ghislanzoni	-2.6	3.1	15	0	0.3	15
oztoprak 2012	-2.14	1.06	20	-0.11	0.44	19
oztoprak sus 2012	-1.73	0.9	20	-0.11	0.44	19
Total (95% CI)			180			143

Data extracted from forest plot 8:

H ANGLE	EXPERIMENTAL			CONTROL		
STUDIES	MEAN	SD	TOTAL	MEAN 2	SD	TOTAL 2
nalbantgil 2005	-1.4	2.02	15	0.2	2.52	15
baysal 2011	-2.75	2.96	20	0.12	3.05	20
gunay 2011	-0.87	1.43	15	0.58	2.75	12
oztoprak 2012	-0.88	1.28	20	0.47	2.99	19
oztoprak sus 2012	-1.28	4.57	20	0.47	2.99	19
Total (95% CI)			90			85

Data extracted from forest plot 9:

NASOLABIAL ANGLE	EXPERIMENTAL			CONTROL		
STUDIES	MEAN	SD	TOTAL	MEAN 2	SD	TOTAL 2
upadhyay 2012	-8.19	8.06	18	-1.73	3.55	15
oztoprak sus 2012	-1.18	4.98	20	-0.05	3.67	19
oztoprak 2012	-1.25	3.32	20	-0.05	3.67	19
nalbantgil 2005	-1.76	2.69	15	-1.73	3.55	15
gunay 2011	-1.53	3.75	15	-0.42	3.7	12
Total (95% CI)			88			80

#### 4. Discussion

This meta-analysis included data from 627 subjects (352 Class II patients and 275 untreated individuals/controls) from 15 RCTs and CCTs, which assessed linear as well as angular cephalometric changes induced by Class II treatment with FFAs. This meta-analysis was conducted considering specific parameters to evaluate the changes brought about by the FFA.

##### SNA:

The forest plot of SNA (Figure 4) depicted its pooled result, that is, the diamond in the experimental side, hence stating the intervention does support the FFA therapy. Indicating there is significant changes caused to the position of maxilla because of FFA. Panigrahi et al.[23] described a restraining effect on the downward and forward growth on the maxilla was demonstrate. Nalbantgil et al. [9] and others [24] [25] reported this to be the only skeletal effect that took place during Jasper Jumper therapy. A posterosuperior displacement of the maxillary jaw base (telescopic mechanism) was demonstrated in

the present study. This is a result of a posterosuperiorly directed force on the maxillary jaw base.

#### SNB:

The forest plot of SNA (Figure 5) depicted its pooled result, that is, the diamond in the experimental side, hence stating the intervention does support the FFA therapy. Stucki and Ingervall [26] and Covell [7] demonstrated an increase in mandibular length. The greatest displacement, correlated with the chin improvement shown by various cephalometric and clinical studies. The anterior condylar displacement seen in the present study was also reported by Pancherz [4] who reported posterior rotation of the mandible. This could account for the increased vertical dimension seen during Herbst treatment [5]. All dentoalveolar structures experience tensile stresses, except for the anterior nasal spine and the maxillary posterior teeth. Moreover, maximum tensile stress and von Mises stresses occurred in the condylar neck and head [23]. Hence, the evident changes in the mandible positioning.

#### ANB:

The results from the random-effects meta-analyses indicated that FFAs had a statistically significant contribution in the improvement of skeletal Class II relationship. This improvement was accomplished with equal contributions from mandibular growth augmentation and restriction of maxillary growth. However, the skeletal contribution in the sagittal plane to the correction of Class II malocclusion can be considered clinically small in concordance with previous studies [5, 16,17].

#### SN-MP

There were significant changes seen with respect to SN-MP (Figures 7). The studies included showed an increase in this angle along with some mandibular advancement, which in turn resulted in reduced skeletal as well as soft-tissue convexity.

#### IMPA

The results from the random-effects meta-analyse shows a significant increase in the IMPA as the appliance tends to cause flaring of the lower Incisor. This flaring should cause the

inter incisal angle to close, that is, reduce, but posttreatment retroclined upper incisor causes the overall interincisal angle to increase. Panigrahi et al [23] reported proclination of the mandibular incisors as the most pronounced dental side effect. Several cephalometric studies have supported this finding, although there were variations in the extent of this effect [4] [6].

#### Overjet and overbite:

The forest plot of overjet and overbite (Figure 9 -10) depicted its pooled result, that is, the diamond in the experimental side, hence stating reduction in overbite and overjet. These overjet and overbite corrections are due to both forward positioning of mandible and inclination of upper and lower incisors (Figures 11 and 12). The study by Nalbantgil et al [9] and others [14] [16] found mesial tipping was seen in relation to lower molars, whereas upper molar displayed distal tipping and intrusion. A clockwise rotation seemed to be produced in both the jaws caused due to the dentoalveolar effect [4].

#### **Nasolabial Angle:**

A significant amount of soft-tissue improvement was seen to favour the profile. A statistically significant increase in the nasolabial angle was observed. Such changes overall helped in the reduction of facial Convexity.

#### H angle:

In response to the dentoalveolar changes produced by the FFAs, a decrease is observed in the Holdaway angle.

## **5. Conclusion**

1. Fixed functional treatment is effective in treating Class II malocclusion with skeletal effects when performed during the pubertal growth phase.
2. Both mandibular elongation and maxillary growth restraint are seen.
3. Skeletal effects alone would not account for the whole Class II correction, with dentoalveolar effects always present, even in patients treated during puberty.
4. There were significant dental changes that were concluded from changes in the IMPA, overjet,

5. overbite, on the completion of the fixed functional therapy.

6. There were substantial changes in the soft-tissue profile of the patient, that is, in the H angle and nasolabial angle.

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