

Use of Direct Miniplate Anchorage in Conjunction with the Forsus Fatigue Resistant Device in Class II Growing Females: A Randomized Controlled Trial.

Sherif A. Elkordy¹, Amr M. Abouelezz², Mona M.S. Fayed³,
Mai H. Aboufotouh⁴, Yehya A. Mostafa⁵

ABSTRACT:

Objective: The current randomized clinical trial aimed to evaluate the use of direct miniplates anchorage in conjunction with the Forsus Fatigue Resistant Device (FFRD) in treatment of skeletal Class II malocclusion.

Material and Methods: 48 Class II females were randomly allocated to either the conventional Forsus (FFRD) group (16 patients, mean age 12.1±0.9 years) Forsus with miniplates (FMP) group (16 patients, mean age 12.5±0.9 years), or untreated control group (16 subjects, mean age 12.1±0.9 years). After the leveling and alignment stage, miniplates were inserted in the mandibular symphysis in the FMP group. FFRD was inserted directly on the miniplates in the FMP and onto the lower wire in the FFRD group. The appliance was removed after reaching an edge to edge incisor relationship.

Results: The effective mandibular length significantly increased in the FMP group only (4.05±0.78). No significant differences were found in the maxillary dimensions. The upper incisors retroclined in the FFRD and FMP groups with no difference between them. The lower incisors showed a significant proclination in the FFRD group (9.17±2.42) and non-significant retroclination in the FMP group. Soft tissue parameters were improved in both treatment groups.

Conclusion: The use of miniplates with the FFRD was successful in increasing the effective mandibular length in Class II malocclusion subjects in the short term. The unfavorable proclination of the lower incisors was evident with the conventional FFRD but was successfully eliminated with the miniplates anchorage.

1- BDS., MSc., MRCS(Ed), PhD. Lecturer, Department of Orthodontics and Dentofacial Orthopedics, Faculty of Dentistry, Cairo University, Cairo, Egypt.

2- BDS, MSc, PhD. Professor, Department of Orthodontics and Dentofacial Orthopedics, Faculty of Dentistry, Cairo University, Cairo, Egypt.

3- BDS., MSc., PhD., Dr.Med.Dent. Professor of Orthodontics Department of Orthodontics and Dentofacial Orthopedics Faculty of Dentistry, Cairo University, Cairo, Egypt.

4- BDS., MSc., PhD. Lecturer, Department of Orthodontics and Dentofacial Orthopedics, Faculty of Dentistry, Cairo University, Cairo, Egypt.

5- BDS, FDSRCS(Ed), MSc, PhD. Professor, Department of Orthodontics and Dentofacial Orthopedics, Faculty of Dentistry, Cairo University, Cairo, Egypt.

Corresponding Author:

Sherif A. Elkordy, BDS., MSc., Associate lecturer, Department of Orthodontics and Dentofacial Orthopedics, Faculty of Oral and Dental Medicine, Cairo University, Cairo, Egypt.

E-mail: sherif.kordi@hotmail.com

Registration: This trial was registered at *ClinicalTrials.gov* with an identifier number: NCT02475785.

Clinical Relevance: The current trial proved the efficiency of the use of miniplates anchorage with FFRD in enhancement the skeletal outcomes of Class II treatment. The technique is advocated for use in Class II subjects having pre-treatment proclined lower incisors.

INTRODUCTION

Scientific background and explanation of rationale:

Mandibular retrusion was reported to be the most common characteristic of Skeletal Class II malocclusion^{1,2}. Class II profile attractiveness was previously investigated in the literature. It was found that patients, laypersons, orthodontists and oral surgeons, rated subjects with Class II profiles as non-attractive^{3,4}. Fixed functional appliances (FFA) are considered an attractive alternative over removable functional appliances (RFA) for treatment of Class II malocclusion in growing children; where the factor of patient cooperation is controlled^{5,6}. The Forsus Fatigue Resistant Device (FFRD)⁷, (3M Unitek Corp, Monrovia, Calif), is a semi-rigid FFA that was reported to be efficient and well-accepted by the patients⁸.

Recently, systematic reviews⁹⁻¹¹ concluded that the skeletal effects of RFAs and FFAs could be considered of negligible clinical importance. This could be attributed to the anchorage loss accompanied by these appliances that could compromise the skeletal correction^{12,13}. Several attempts were proposed to counteract the unwanted dento-alveolar side effects of FFAs including the use of skeletal anchorage. Studies¹³⁻¹⁶ proved that miniscrew anchorage reduced the lower incisors proclination but

were not able to achieve significant skeletal mandibular effects.

Titanium miniplates were introduced for the use in orthodontics in 1999 for open bite correction¹⁷. They were proven to be well accepted by patients and providers and became popular in various applications¹⁸⁻²¹. Recently, they were used for the direct loading of FFRD for correction of skeletal Class II malocclusion but the available studies were either retrospective²², non-controlled²³ or non-randomized^{24,25}.

Cone Beam Computed Tomography (CBCT) has an advantage of improved visualization over the conventional two dimensional (2D) imaging techniques²⁶. Shortcomings of 2D radiographic techniques were thoroughly mentioned in the literature²⁷. Errors in landmark identification, visualization and the superimposition of bilateral structures in the 2D cephalograms could compromise the accuracy of their use in research studies. Thus, CBCT was chosen as a radiographic imaging tool to evaluate the treatment effects.

Specific objectives or hypotheses:

This study aimed to compare the dental and skeletal effects of the use of FFRD alone or in conjunction with direct miniplates anchorage in treatment of skeletal Class II malocclusion as compared to an untreated Skeletal Class II control group. The tested null hypothesis was that the use of direct miniplates anchorage with FFRD would have no additional skeletal effects.

MATERIAL AND METHODS

Trial design and any changes after trial commencement

This was a parallel-group, randomized, controlled trial with a 1:1:1 allocation ratio. The trial was registered at *ClinicalTrials.gov* with an identifier number: NCT02475785.

Participants, eligibility criteria, and settings:

The participants were recruited at the Faculty of Dentistry, Cairo University outpatient orthodontic clinic. The study was self-funded by the authors who were part of the University staff. All the study participants were informed about the procedures and multiple radiation exposures. The sample comprised 48 female subjects. The inclusion criteria for the participants were as follows:

- Chronologically; the patients were 10-13 years of age.
- Skeletally, the patients had to be in the cervical maturational stage 3 as detected by the lateral cephalometric radiograph.
- Skeletal Angle Class II malocclusion with a deficient mandible. ($SNB \leq 76^\circ$) and a horizontal or neutral growth pattern. ($MP/SN \leq 39^\circ$)
- Class II division 1 incisor relation.
- Increased over jet (min 5 mm)
- Class II canine relationship. (minimum of half unit)
- Mandibular arch crowding less than 3 mm..

Interventions

The following steps were performed for each patient in the miniplates (FMP) and the FFRD alone groups;

A Trans palatal Arch (TPA) was placed in the upper arch together with bonding of 0.022" slot 3M MBT prescription brackets (3M Unitek Corp, Monrovia, Calif) were to upper and lower arches in the FFRD group and to the upper arch only in the FMP group. Leveling and alignment progressed until reaching 0.019X0.025-inch stainless steel wires with cinching back of the maxillary and mandibular wires. The patients were then referred for the uptake of a Cone Beam Computed Tomography (CBCT) scan which was considered as (T1). CBCT scanning was performed with the next generation i-CAT CBCT unit (Imaging Sciences

International, Hatfield, PA, USA) according to the manufacture instructions.

In the miniplates (FMP) group, the surgical procedures were performed under local anaesthesia. A single horizontal incision was made in the alveolar mucosa and the underlying muscle (immediately below the mucogingival line) down to the level of bone from the lower canine region on one side to that of the other side using blade no. 15. Two long Y shaped mini plates (Stryker, Leibinger, GmbH & Co. KG, Freiburg, Germany) were adapted to fit the contour of the underlying bone and adjusted to have their terminal parts at the lower canine regions bilaterally (**Fig. 1**). Drilling was done using compatible sized drills mounted on low-speed air motor under copious saline irrigation. The mini plates were fixed by three mini screws (with diameter of 2 mm) made of titanium. The most occlusal screw was 8 mm while the gingival screws were 10 mm in length. The flap was closed by making a continuous suture with lock using resorbable (4/0) sutures leaving the extensions of the plates perforating the attached gingiva near the mucogingival junction. Postoperative instructions and medications were prescribed to the patients, ice packs and soft diet were advised. Sutures were removed 7-10 days after the surgery.



Figure 1: Inserted Y shaped miniplates in the mandibular symphysis as used in the study.

In both treatment groups, selection of the proper size of the FFRD was done according to the manufacturer instructions and following the protocol used by Franchi et al.²⁸ The EZ module clip was inserted in the extraoral tubes of the upper first molars from the mesial to the distal sides and the pushrods were inserted onto the lower wires distal to the lower canines in the FFRD group and into the miniplates head in the miniplates group (**Fig. 2a and b**). Follow up visits were every 4 weeks; where the miniplates were checked for stability and the appliance was checked for activation. In case of need for activation, split crimps were used for this purpose according to the manufacturer instructions. The FFRD was planned to be removed either after 10 months from the start of the trial or after reaching an edge to edge incisor relationship, whichever occurs first. The miniplates were scheduled for removal afterwards.

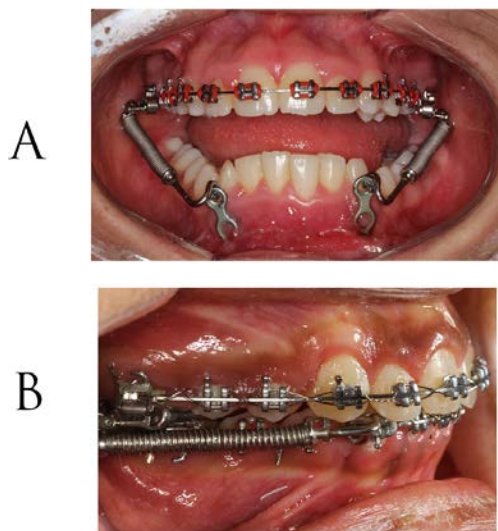


Figure 2: A: FFRD insertion in the FMP group. B: FFRD insertion in the FFRD group.

The observation period for the control group subjects was 7.26 ± 1.74 months and the second CBCT image (T2) was considered as their pre-treatment records to start orthodontic treatment.

Outcomes, primary and secondary and any changes after trial commencement:

The primary outcome of this study was the correction of the skeletal Class II profile convexity. This outcome was detected through measurement of the mean change in the effective mandibular length and position from baseline.

Secondary outcomes included:

- The maxillary skeletal effects.
- The dento-alveolar side effects of the appliance therapy that were detected through changes in the inclination and position of incisors and the molars.
- The soft tissue changes after treatment.

The outcomes were measured through analysis of CBCT images by two individuals who were not involved in the trial. The analysis was done using Invivo Anatomage version 5.2 (Anatomage, San Jose, CA, USA). The used landmarks are shown in (**Fig. 3 a-c**) and the included measurements are listed in **Table1**. The measurements were done by the same observer twice and by another observer.

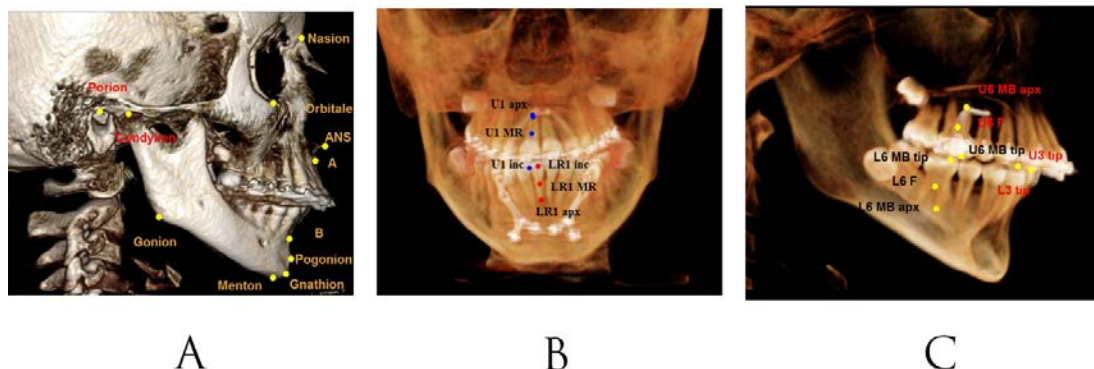


Figure 3: A: The skeletal landmarks used in the CBCT analysis. B and C: The dental landmarks used in the study.

Table 1: Definitions of the included measurements in the study

| Measurement | Definition |
|----------------------|--|
| MP/SN | The angle between the line S-N and the mandibular plane |
| SNA | The angle between the points S,N and A |
| Co-A | The linear distance between the Condylion and A points indicating the effective maxillary length. |
| SNB | The angle between the points S,N and B |
| Co-Gn | The linear distance between the Condylion and the Gnathion points indicating the effective mandibular length. |
| ANB | The angle between three landmarks: A, N, B |
| U1 to A Pog | The horizontal distance between the incisal edges of the upper central incisors and the A Pogonion line as viewed from the sagittal view |
| U1 Vertical Position | The linear distance from the mid-root of the upper incisors to the FHP as viewed from the sagittal view |
| U1/PP | The angle formed between the palatal plane and the upper central incisors long axes as viewed from the sagittal view |
| UR6 AP Position | The linear distance between the mesio-buccal cusp tip of U6 and the vertical plane as viewed from the sagittal view |
| U6 Vertical Position | The linear distance between the furcation area of the upper first molar to the FHP as viewed from the sagittal view |
| L1/MP | The angle formed between the mandibular plane and the lower incisors long axes as viewed from the sagittal view |
| L1 to A Pog | The horizontal distance between the incisal edges of the lower incisors and the A Pogonion line as viewed from the sagittal view |
| L1 Vertical Position | The linear distance from the mid-root of the lower incisors to the mandibular plane viewed from the sagittal view |
| L6 Vertical Position | The linear distance from the furcation points of the lower first molars to the Mandibular Plane as viewed from the sagittal view |
| L6 AP Position | The linear distance between the mesio-buccal cusp tip of lower left first molar and the vertical plane as viewed from the sagittal view |
| Angle of convexity | The angle between soft tissue Nasion, Subnasale, and soft tissue Pogonion |
| Naso-labial angle | The angle between Columella constructed point, Subnasale, and Labralis superior |
| Upper lip to E line | The horizontal distance between the Labrale superior and the E line. |
| Lower to E line | The horizontal distance between the Labrale inferior and the E line |

Sample size calculation:

The sample size calculation was based on a study by Manni et al.²⁹ who compared the use of Herbst appliance with and without mini screw anchorage and reported a significant increase in the Herbst mini screw group over their control group. The mean change in the mandibular length in the treatment and control

groups were 4.6 ± 2.43 mm and 0.9 ± 2.09 mm respectively. Thus, the mean difference was 3.7 with a standard deviation of 2.26. Because three groups were compared, Bonferroni adjustment was used as alpha level/number of comparisons = $0.05/3 = 0.0167$ to adjust for multiple comparisons. Power and Sample size calculation (PS) software (Department of

biostatistics Vanderbilt University) was used for sample size calculation. When the power was set at 90%, the allocation ratio was 1:1:1 and the Type I error probability (alpha) was set as 0.0167, eleven subjects were needed per group. To account for patient loss to follow up (attrition), a sample size of 48 patients was selected and divided into three groups, sixteen each.

Interim analyses and stopping guidelines:

In the FMP group, in case of increased miniplates mobility, the load was discontinued for about two weeks and resumed afterwards. In case of persistent mobility or breakage, the miniplates were replaced before continuing treatment.

Randomization (random number generation, allocation concealment and implementation of the random sequence):

A computer random sequence table was generated using the random number generator at “random.org” by a person who was not involved in the clinical trial (SB). To insure 1:1:1 allocation ratio, the randomization was made in blocks. Allocation Concealment was achieved through opaque well sealed envelopes. Patient data were written on the envelope before opening it. SB was responsible for opening the envelopes and implementation of the randomization process. All the study contributors had no access to the random list until the end of the trial.

Blinding:

Due to the nature of the study, the operator and patients could not be blinded. The outcome assessors (those who made the CBCT analysis) and the statistician were totally blinded from the nature of the clinical trial.

Statistical Analysis (primary and secondary outcomes, subgroup analyses)

Statistical analysis was performed with IBM SPSS (SPSS, Inc., IBM Corporation, NY,

USA) Statistics Version 20 for Windows. All bilateral variables were measured for the right and left sides but for the sake of simplification, averages were then taken and were statistically analyzed. Data were explored for normality using Kolmogorov-Smirnov and Shapiro-Wilk tests. Concordance Correlation Coefficients (CCC) were calculated with the 95% confidence limits to detect the intra and inter examiner reliability of all the selected measurements in the study. Paired t test was performed to compare between the pre-and post-treatment and/or observation CBCT measurements within the FMP, FFRD and control groups. One-way ANOVA was used for comparison of the baseline data and the mean changes between the three groups. This was followed by Bonferroni method for multiple comparison of the significant ANOVA variables. To account for different treatment/observation durations between the three groups, data of the mean changes were annualized.

RESULTS

Patient flow (include flow diagram early stopping and time periods):

Forty-eight patients were randomly allocated into three groups; sixteen patients were treated with the FFRD alone (FFRD group) with mean age 12.5 ± 0.9 years, sixteen patients had FFRD treatment in conjunction with lower miniplates (FMP group) with mean of 12.1 ± 0.9 years of age and sixteen patients served as an untreated control group with mean age of 12.1 ± 0.9 . The flow of patients through the study is shown in **Fig. 4**. Patient recruitment took place at the outpatient clinic of the department of Orthodontics, University. Recruitment was done by SK until reaching the target sample size. The recruitment started in Jan 2015 and ended in Dec 2015.

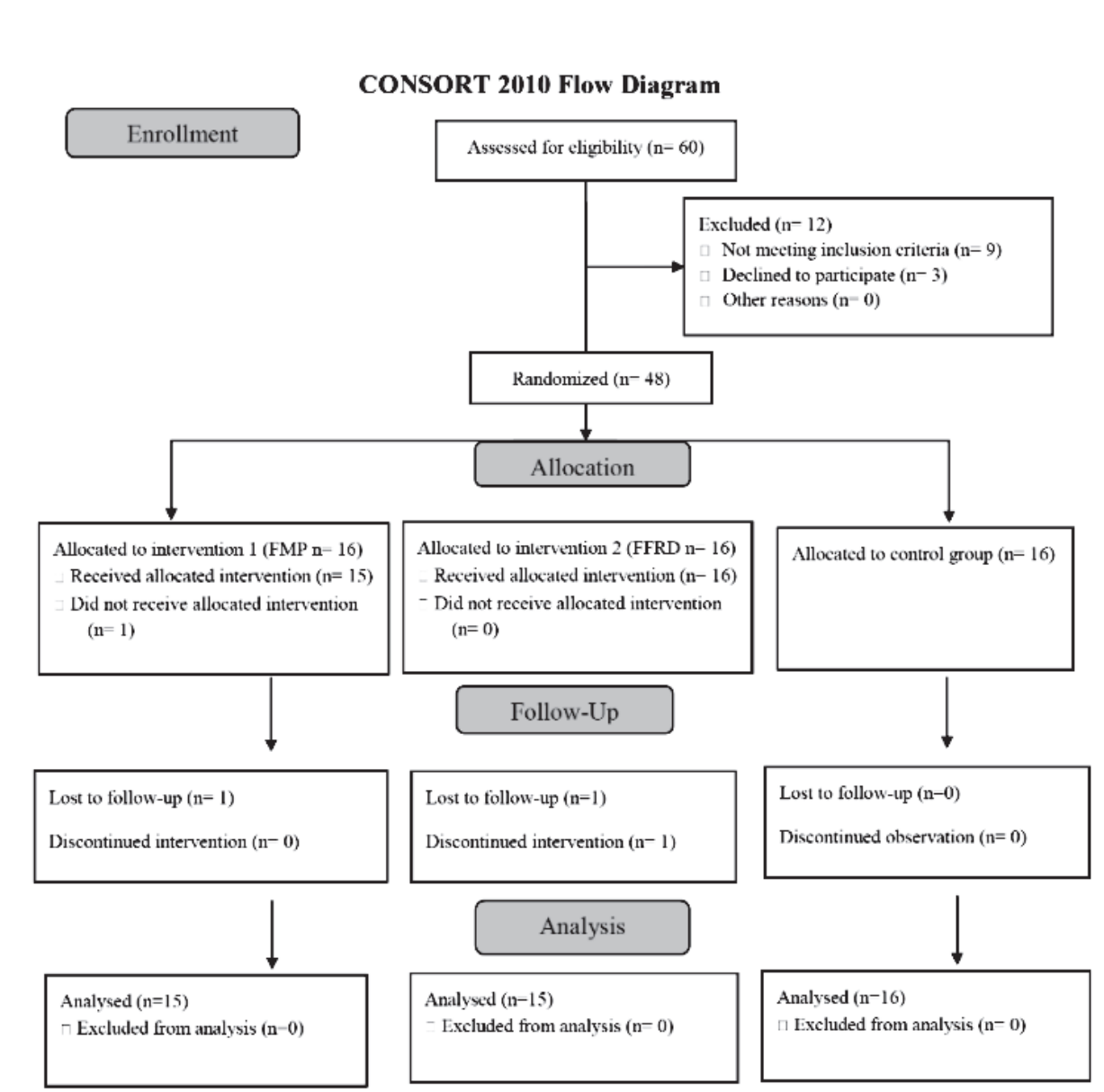


Figure 4: CONSORT 2010 flow diagram

Losses and exclusions after randomization, together with reasons:

Two patients were lost to follow up after randomization; one from the FMP group (before the miniplates insertion), and the other was from the FFRD group. The number of the analyzed subjects was fifteen in these groups. No dropouts were reported in the control group.

Follow up period: The mean follow-up period of the FMP, FFRD and control

groups were (in months) 9.42 ± 0.98 , 6.23 ± 1.61 and 7.26 ± 1.74 respectively, $P < 0.001$. Multiple comparison testing showed significant difference between FMP and FFRD, mean difference 3.2; 95% CI: 2.25-4.12, and between FMP and control group, mean difference 2.17; 95% CI: 1.17-3.14 (Table 2). An example of a patient in the FFRD and the FMP groups are presented in (Fig.5 and 6) respectively.



Figure 5: Photographs for a patient in the FFRD group; before treatment. and after the FFRD removal.



Figure 6: Extra and intra oral photographs for a patient in the FMP group; A: before treatment. B: after the FFRD removal.

Table 2: Comparison between the mean age and duration of treatment/ observation between the study groups. (One-Way Analysis of Variance [ANOVA] and Multiple Bonferroni Method Tests)

| Parameter | Study group | Mean | SD | 95% Confidence Interval for Mean | | F | P Value | P (FMP-FFRD) | P (FMP-Control) | P (FFRD-Control) |
|--------------------------|-------------|-------|---------|----------------------------------|-------------|-----------------|---------|--------------|-----------------|------------------|
| | | | | Lower Bound | Upper Bound | | | | | |
| Age | FMP | 12.06 | 0.79 | 11.60 | 12.51 | 1.44 | 0.25 | NS | NS | NS |
| | FFRD | 12.54 | 0.90 | 12.06 | 13.02 | | | | | |
| | Control | 12.13 | 0.86 | 11.67 | 12.58 | | | | | |
| Duration | FMP | 9.42 | 0.98 | 8.85 | 9.99 | 17.41 | <0.001* | <0.001* | <0.001* | NS |
| | FFRD | 6.23 | 1.61 | 5.37 | 7.08 | | | | | |
| | Control | 7.26 | 1.74 | 6.33 | 8.19 | | | | | |
| Multiple Benferroni test | | | | | | Mean Difference | | Std. Error | | P Value |
| Duration | | FMP | FFRD | 3.20 | | 0.55 | | <0.001* | | |
| | | FMP | Control | 2.17 | | 0.55 | | <0.001* | | |
| | | FFRD | Control | -1.03 | | 0.53 | | 0.1759 | | |

NS, non-significant; FMP, Forsus and miniplates group; FFRD, Forsus alone group; SD: standard deviation; Std Error, standard error

*: significant when $P < 0.05$.

Numbers analyzed for each outcome, estimation and precision, subgroup analyses:

Regarding the error analysis for the selected measurements in the study, the results of the CCC values ranged between 0.725–0.995 indicating good to excellent agreement. (Table 3)

The primary analysis was planned to be an intention-to-treat analysis to involve all patients who were to be randomly assigned. The attrition rate was 6.25% in the FMP and FFRD groups, and thus only fifteen subjects were included in the final analysis for these groups. Unlikely, no dropouts were encountered in the control group. Data for the changes within each group and for the comparison of the changes between the groups are presented in tables 4 and 5 respectively.

Skeletal Changes:

Starting with the mandibular dimensions, significant differences were reported between them in the effective mandibular length and SNB. Pair wise comparisons showed

a significant increase in these variables in the FMP as compared to the FFRD and control groups. The effective mandibular length increased in the FMP group (4.05 ± 0.78 , 95% CI: 3.60–4.50 mm). After data annualization, the effective mandibular length was still significantly increased in the FMP over the FFRD and control groups.

On the other hand, the effective maxillary length showed no significant difference between the groups. The SNA showed a significant difference between the control and FMP groups (difference of means 1.09, SE 0.33, $P=0.006$). As for ANB angle, it showed a significant decrease in the FMP group only as compared to the FFRD and control groups (-1.62 ± 1.37 ; 95% CI -2.41 – -0.83) indicating the improvement of the skeletal Class II relationship.

In the vertical plane, there was a significant increase in the MP/SN (2.06 ± 1.44 ; 95% CI 1.23–2.89) indicating a clockwise mandibular rotation in the FMP group as compared with other groups.

Table 3: Concordance Correlation Coefficients (CCC) for the intra-observer and inter-observer reliability of the measurements used in the study

| Measurement | Intra observer reliability scores | | | Inter observer reliability scores | | |
|----------------------|-----------------------------------|-----------------------|-------|-----------------------------------|-----------------------|-------|
| | CCC | 95% confidence limits | | CCC | 95% confidence limits | |
| SNA | 0.993 | 0.978 | 0.998 | 0.990 | 0.968 | 0.997 |
| SNB | 0.990 | 0.969 | 0.997 | 0.984 | 0.950 | 0.995 |
| ANB | 0.995 | 0.985 | 0.998 | 0.979 | 0.937 | 0.993 |
| Co-A | 0.993 | 0.978 | 0.998 | 0.963 | 0.896 | 0.987 |
| Co-Gn | 0.991 | 0.972 | 0.997 | 0.994 | 0.982 | 0.998 |
| MP/SN | 0.987 | 0.960 | 0.996 | 0.987 | 0.961 | 0.996 |
| U6 vertical position | 0.931 | 0.815 | 0.975 | 0.940 | 0.835 | 0.979 |
| U6 AP position | 0.975 | 0.932 | 0.991 | 0.974 | 0.920 | 0.992 |
| U1/PP | 0.997 | 0.990 | 0.999 | 0.988 | 0.962 | 0.996 |
| U1 Vertical position | 0.887 | 0.684 | 0.963 | 0.895 | 0.701 | 0.966 |
| U1 to A Pog | 0.990 | 0.968 | 0.997 | 0.972 | 0.915 | 0.991 |
| L1/ MP | 0.973 | 0.918 | 0.991 | 0.957 | 0.892 | 0.983 |
| L1 APog | 0.987 | 0.959 | 0.996 | 0.990 | 0.974 | 0.996 |
| L1 vert | 0.990 | 0.970 | 0.996 | 0.752 | 0.650 | 0.862 |
| L6 AP position | 0.968 | 0.911 | 0.988 | 0.974 | 0.922 | 0.991 |
| L6 vert | 0.982 | 0.946 | 0.994 | 0.921 | 0.778 | 0.973 |
| Angle of convexity | 0.979 | 0.939 | 0.993 | 0.981 | 0.940 | 0.994 |
| upper lip E line | 0.959 | 0.876 | 0.987 | 0.963 | 0.889 | 0.988 |
| lower lip E line | 0.983 | 0.948 | 0.995 | 0.982 | 0.943 | 0.994 |
| Naso-labial angle | 0.984 | 0.958 | 0.994 | 0.985 | 0.954 | 0.995 |

Table 4: Mean Values of Parameters at the Beginning (Pre) and End (Post) and the Mean Difference (Post-Pre) of the Skeletal, dental and soft tissue measurements in the Three Study Groups; Paired t test

| Measurement | Time point | Control | | | FMP | | | FFRD | | |
|-------------|------------|---------|------|-------------------|--------|------|-------------------|--------|------|-------------------|
| | | Mean | SD | P value | Mean | SD | P value | Mean | SD | P value |
| SNA | Pre | 83.07 | 3.02 | 0.20 | 81.23 | 3.75 | 0.009* | 83.06 | 2.14 | 0.81 |
| | Post | 83.36 | 3.12 | | 80.44 | 3.28 | | 83.01 | 2.23 | |
| | Post - Pre | 0.30 | 0.88 | | -0.79 | 0.96 | | -0.05 | 0.85 | |
| Co-A | Pre | 80.93 | 4.16 | 0.01* | 82.00 | 4.41 | 0.01* | 83.92 | 3.32 | 0.62 |
| | Post | 82.13 | 3.99 | | 83.13 | 4.60 | | 84.04 | 3.36 | |
| | Post - Pre | 1.20 | 1.74 | | 1.13 | 1.48 | | 0.12 | 0.99 | |
| SNB | Pre | 75.53 | 2.32 | 0.80 | 72.75 | 2.73 | 0.005* | 75.77 | 2.34 | 0.197 |
| | Post | 75.46 | 2.63 | | 73.72 | 2.57 | | 75.99 | 2.29 | |
| | Post - Pre | -0.07 | 1.05 | | 0.97 | 1.06 | | 0.22 | 0.66 | |
| Co-Gn | Pre | 106.73 | 3.78 | <0.001* | 107.68 | 4.11 | <0.001* | 103.86 | 6.74 | <0.001* |
| | Post | 107.83 | 3.88 | | 111.73 | 4.37 | | 104.73 | 6.52 | |
| | Post - Pre | 1.11 | 0.74 | | 4.05 | 0.78 | | 0.86 | 0.79 | |
| ANB | Pre | 7.61 | 1.44 | 0.79 | 8.45 | 1.90 | <0.001* | 7.30 | 1.44 | 0.053 |
| | Post | 7.66 | 1.23 | | 6.83 | 1.55 | | 7.02 | 1.53 | |
| | Post - Pre | 0.06 | 0.80 | | -1.62 | 1.37 | | -0.28 | 0.53 | |

| | | | | | | | | | | |
|--------------------|------------|--------|-------|-------------------|--------|-------|-------------------|--------|-------|-------------------|
| MP/SN | Pre | 36.58 | 4.32 | 0.36 | 41.35 | 6.92 | <0.001* | 36.12 | 6.32 | 0.65 |
| | Post | 36.27 | 4.34 | | 43.42 | 6.82 | | 36.27 | 6.74 | |
| | Post - Pre | -0.31 | 1.32 | | 2.06 | 1.44 | | 0.15 | 1.27 | |
| UI/PP | Pre | 116.91 | 7.29 | 0.014* | 113.03 | 7.02 | <0.001* | 115.81 | 4.05 | <0.001* |
| | Post | 118.26 | 6.90 | | 103.00 | 7.22 | | 106.84 | 5.30 | |
| | Post - Pre | 1.35 | 1.96 | | -10.03 | 4.39 | | -8.98 | 2.55 | |
| UI to A Pog | Pre | 10.64 | 1.64 | 0.07* | 9.24 | 1.89 | <0.001* | 9.38 | 2.08 | <0.001* |
| | Post | 11.00 | 1.52 | | 5.47 | 1.66 | | 6.87 | 1.80 | |
| | Post - Pre | 0.36 | 0.74 | | -3.77 | 0.98 | | -2.51 | 0.99 | |
| UI Vertposition | Pre | 36.04 | 3.25 | 0.03* | 39.59 | 3.14 | 0.009* | 40.28 | 2.70 | 0.145 |
| | Post | 36.86 | 3.12 | | 40.67 | 3.24 | | 40.73 | 3.15 | |
| | Post - Pre | 0.81 | 1.31 | | 1.09 | 1.33 | | 0.45 | 1.18 | |
| U6 AP position | Pre | 39.52 | 2.61 | <0.001* | 38.64 | 3.22 | <0.001* | 42.56 | 4.21 | <0.001* |
| | Post | 40.70 | 2.68 | | 36.87 | 3.79 | | 41.04 | 4.66 | |
| | Post - Pre | 1.18 | 0.90 | | -1.77 | 1.02 | | -1.53 | 1.07 | |
| U6 vert | Pre | 30.16 | 2.36 | <0.001* | 32.68 | 2.49 | 0.011* | 34.35 | 2.80 | <0.001* |
| | Post | 31.40 | 2.63 | | 31.60 | 2.67 | | 33.14 | 3.11 | |
| | Post - Pre | 1.24 | 0.86 | | -1.09 | 1.38 | | -1.21 | 0.77 | |
| L6 AP position | Pre | 39.36 | 3.08 | 0.036* | 36.93 | 4.21 | <0.001* | 40.36 | 4.20 | <0.001* |
| | Post | 40.12 | 2.96 | | 39.00 | 4.23 | | 43.19 | 4.56 | |
| | Post - Pre | 0.76 | 1.31 | | 2.08 | 1.26 | | 2.83 | 1.31 | |
| L6 vert | Pre | 16.23 | 2.35 | 0.004* | 17.41 | 2.00 | <0.001 | 17.09 | 1.55 | <0.001* |
| | Post | 16.73 | 2.17 | | 20.16 | 2.00 | | 18.35 | 1.61 | |
| | Post - Pre | 0.50 | 0.58 | | 2.75 | 0.78 | | 1.26 | 0.52 | |
| L1/MP | Pre | 100.78 | 7.08 | 0.15 | 99.30 | 5.39 | 0.258 | 99.81 | 8.17 | <0.001* |
| | Post | 101.47 | 7.75 | | 97.81 | 5.51 | | 108.99 | 6.63 | |
| | Post - Pre | 0.69 | 1.81 | | -1.49 | 4.70 | | 9.18 | 2.42 | |
| L1 A Pog | Pre | 2.20 | 1.48 | 0.56 | 2.13 | 1.80 | 0.16 | 2.13 | 1.87 | <0.001* |
| | Post | 2.31 | 1.44 | | 2.74 | 2.31 | | 5.09 | 1.80 | |
| | Post - Pre | 0.11 | 0.74 | | 0.61 | 1.54 | | 2.96 | 0.95 | |
| L1 vert | Pre | 26.87 | 2.39 | <0.001* | 28.59 | 2.96 | 0.014* | 27.41 | 1.83 | <0.001* |
| | Post | 27.22 | 2.34 | | 29.74 | 3.16 | | 25.65 | 1.81 | |
| | Post - Pre | 0.35 | 0.27 | | 1.15 | 1.52 | | -1.76 | 0.64 | |
| Angle of convexity | Pre | 157.19 | 5.29 | 0.25 | 155.47 | 5.17 | <0.001* | 155.62 | 3.42 | 0.009* |
| | Post | 156.65 | 5.34 | | 159.12 | 5.16 | | 157.11 | 3.93 | |
| | Post - Pre | -0.55 | 1.81 | | 3.65 | 2.37 | | 1.50 | 2.00 | |
| Nasolabial angle | Pre | 103.99 | 11.67 | 0.01* | 110.34 | 10.04 | 0.28 | 107.23 | 10.71 | 0.17 |
| | Post | 101.05 | 12.53 | | 112.21 | 10.81 | | 109.71 | 9.19 | |
| | Post - Pre | -2.95 | 4.08 | | 1.87 | 6.21 | | 2.48 | 6.79 | |
| Upper lip E line | Pre | 0.09 | 1.85 | 0.28 | 0.73 | 1.74 | <0.001* | -0.50 | 2.15 | 0.012* |
| | Post | -0.28 | 1.97 | | -1.91 | 1.80 | | -1.45 | 2.05 | |
| | Post - Pre | -0.37 | 1.30 | | -2.63 | 1.29 | | -0.96 | 1.33 | |
| Lower lip E line | Pre | 1.26 | 1.84 | 0.82 | 1.71 | 2.18 | 0.84 | 0.96 | 2.26 | 0.007* |
| | Post | 1.33 | 1.63 | | 1.61 | 2.21 | | 1.92 | 2.36 | |
| | Post - Pre | 0.07 | 1.14 | | -0.10 | 1.75 | | 0.95 | 1.21 | |

FMP, Forsus and miniplates group; FFRD, Forsus alone group; SD: standard deviation

*: significant when P< 0.05.

Table 5: Comparison of the Mean Differences (T2-T1) for the skeletal, dental and soft tissue measurements among the three study groups (One-Way Analysis of Variance [ANOVA] and Multiple Bonferroni Method Tests.

| Measurement | Study group | Mean | SD | 95% Confidence Interval for Mean | | Actual Study data | | | | | Annualized Data | | | |
|----------------------|-------------|--------|------|----------------------------------|-------------|-------------------|---------|-------------------|------------------|--------------|-----------------|-------------------|------------------|---------------|
| | | | | Lower Bound | Upper Bound | F | P-Value | P (Control -FFRD) | P (Control -FMP) | P (FFRD-FMP) | P- Value | P (Control -FFRD) | P (Control -FMP) | P (FFRD -FMP) |
| SNA | Control | 0.30 | 0.88 | -0.18 | 0.77 | 5.62 | 0.007* | NS | 0.05* | NS | 0.057 | NS | NS | NS |
| | FFRD | -0.05 | 0.85 | -0.51 | 0.40 | | | | | | | | | |
| | FMP | -0.79 | 0.96 | -1.35 | -0.23 | | | | | | | | | |
| Co-A | Control | 1.20 | 1.74 | 0.27 | 2.12 | 2.75 | 0.075* | NS | NS | NS | 0.167 | NS | NS | NS |
| | FFRD | 0.12 | 0.99 | -0.40 | 0.65 | | | | | | | | | |
| | FMP | 1.13 | 1.48 | 0.27 | 1.99 | | | | | | | | | |
| SNB | Control | -0.07 | 1.05 | -0.63 | 0.49 | 4.84 | 0.013* | NS | 0.01* | NS | 0.04* | NS | 0.04* | NS |
| | FFRD | 0.22 | 0.66 | -0.13 | 0.57 | | | | | | | | | |
| | FMP | 0.97 | 1.06 | 0.36 | 1.59 | | | | | | | | | |
| Co-Gn | Control | 1.11 | 0.74 | 0.71 | 1.50 | 77.96 | <0.001* | NS | <0.001* | <0.001* | <0.001* | NS | <0.001* | <0.001* |
| | FFRD | 0.86 | 0.79 | 0.44 | 1.29 | | | | | | | | | |
| | FMP | 4.05 | 0.78 | 3.60 | 4.50 | | | | | | | | | |
| ANB | Control | 0.06 | 0.80 | -0.37 | 0.48 | 13.06 | <0.001* | NS | <0.001* | <0.001* | <0.001* | NS | <0.001* | 0.01* |
| | FFRD | -0.28 | 0.53 | -0.56 | 0.00 | | | | | | | | | |
| | FMP | -1.62 | 1.37 | -2.41 | -0.83 | | | | | | | | | |
| MP/SN | Control | -0.31 | 1.32 | -1.01 | 0.39 | 12.94 | <0.001* | NS | <0.001* | <0.001* | 0.002* | NS | 0.002* | 0.03* |
| | FFRD | 0.15 | 1.27 | -0.53 | 0.82 | | | | | | | | | |
| | FMP | 2.06 | 1.44 | 1.23 | 2.89 | | | | | | | | | |
| U1/PP | Control | 1.35 | 1.96 | 0.31 | 2.39 | 65.17 | <0.001* | <0.001* | <0.001* | NS | <0.001* | <0.001* | <0.001* | 0.03* |
| | FFRD | -8.98 | 2.55 | -10.34 | -7.62 | | | | | | | | | |
| | FMP | -10.03 | 4.39 | -12.57 | -7.49 | | | | | | | | | |
| U1 to A Pog | Control | 0.36 | 0.74 | -0.03 | 0.76 | 82.72 | <0.001* | <0.001* | <0.001* | 0.001* | <0.001* | <0.001* | <0.001* | NS |
| | FFRD | -2.51 | 0.99 | -3.04 | -1.98 | | | | | | | | | |
| | FMP | -3.77 | 0.98 | -4.34 | -3.21 | | | | | | | | | |
| U1 Vertical position | Control | 0.81 | 1.31 | 0.11 | 1.51 | 0.94 | 0.397 | NS | NS | NS | NS | NS | NS | NS |
| | FFRD | 0.45 | 1.18 | -0.18 | 1.08 | | | | | | | | | |
| | FMP | 1.09 | 1.33 | 0.32 | 1.85 | | | | | | | | | |

| | | | | | | | | | | | | | | |
|-----------------------------|---------|-------|------|-------|-------|--------------|-------------------|-------------------|-------------------|-------------------|-------------------|-------------------|-------------------|-------------------|
| L1/MP | Control | 0.69 | 1.81 | -0.28 | 1.66 | 49.56 | <0.001* | <0.001* | NS | <0.001* | <0.001* | <0.001* | NS | <0.001* |
| | FFRD | 9.17 | 2.42 | 7.89 | 10.46 | | | | | | | | | |
| | FMP | -1.49 | 4.70 | -4.20 | 1.23 | | | | | | | | | |
| L1 A Pog | Control | 0.11 | 0.74 | -0.28 | 0.50 | 29.99 | <0.001* | <0.001* | NS | <0.001* | <0.001* | <0.001* | NS | <0.001* |
| | FFRD | 2.96 | 0.95 | 2.45 | 3.47 | | | | | | | | | |
| | FMP | 0.61 | 1.54 | -0.28 | 1.50 | | | | | | | | | |
| L1 Vertical position | Control | 0.35 | 0.27 | 0.20 | 0.49 | 39.69 | <0.001* | <0.001* | NS | <0.001* | <0.001* | <0.001* | NS | <0.001* |
| | FFRD | -1.76 | 0.64 | -2.09 | -1.42 | | | | | | | | | |
| | FMP | 1.14 | 1.52 | 0.27 | 2.02 | | | | | | | | | |
| U6 AP position | Control | 1.18 | 0.90 | 0.70 | 1.66 | 41.90 | <0.001* | <0.001* | <0.001* | NS | <0.001* | <0.001* | <0.001* | NS |
| | FFRD | -1.52 | 1.07 | -2.09 | -0.96 | | | | | | | | | |
| | FMP | -1.76 | 1.02 | -2.35 | -1.18 | | | | | | | | | |
| U6 Vertical position | Control | 1.24 | 0.85 | 0.78 | 1.69 | 28.86 | <0.001* | <0.001* | <0.001* | NS | <0.001* | <0.001* | <0.001* | NS |
| | FFRD | -1.21 | 0.77 | -1.62 | -0.80 | | | | | | | | | |
| | FMP | -1.08 | 1.38 | -1.88 | -0.29 | | | | | | | | | |
| L6 AP position | Control | 0.76 | 1.31 | 0.06 | 1.46 | 10.44 | <0.001* | <0.001* | <0.001* | NS | <0.001* | <0.001* | NS | 0.002* |
| | FFRD | 2.83 | 1.31 | 2.13 | 3.53 | | | | | | | | | |
| | FMP | 2.07 | 1.26 | 1.34 | 2.80 | | | | | | | | | |
| L6 Vertical position | Control | 0.50 | 0.58 | 0.19 | 0.81 | 49.02 | <0.001* | 0.004* | <0.001* | <0.001* | <0.001* | <0.001* | <0.001* | NS |
| | FFRD | 1.26 | 0.52 | 0.98 | 1.54 | | | | | | | | | |
| | FMP | 2.75 | 0.78 | 2.30 | 3.19 | | | | | | | | | |
| Angle of convexity | Control | -0.55 | 1.81 | -1.51 | 0.42 | 15.49 | <0.001* | 0.02* | <0.001* | 0.02* | <0.001* | 0.007* | <0.001* | NS |
| | FFRD | 1.50 | 2.00 | 0.43 | 2.56 | | | | | | | | | |
| | FMP | 3.65 | 2.37 | 2.28 | 5.02 | | | | | | | | | |
| Nasolabial angle | Control | -2.95 | 4.08 | -5.12 | -0.77 | 4.15 | 0.023* | 0.034* | NS | NS | 0.03* | 0.03* | NS | NS |
| | FFRD | 2.48 | 6.79 | -1.14 | 6.09 | | | | | | | | | |
| | FMP | 1.87 | 6.21 | -1.72 | 5.45 | | | | | | | | | |
| upper lip E line | Control | -0.37 | 1.30 | -1.06 | 0.33 | 11.92 | <0.001* | NS | <0.001* | 0.003* | 0.004* | NS | 0.002* | NS |
| | FFRD | -0.96 | 1.33 | -1.67 | -0.25 | | | | | | | | | |
| | FMP | -2.63 | 1.29 | -3.38 | -1.89 | | | | | | | | | |
| lower lip E line | Control | 0.07 | 1.14 | -0.54 | 0.67 | 2.62 | 0.0842 | NS | NS | NS | 0.059 | NS | NS | NS |
| | FFRD | 0.95 | 1.21 | 0.31 | 1.60 | | | | | | | | | |
| | FMP | -0.10 | 1.75 | -1.10 | 0.91 | | | | | | | | | |

NS, non-significant; FMP, Forsus and miniplates group; FFRD, Forsus alone group; SD: standard deviation;

*: significant when P< 0.05.

Dental Changes:

The upper incisors were significantly retroclined in the FFRD (-8.98 ± 2.55 , 95% CI -10.34 -7.62) and the FMP (-10.03 ± 4.39 ; 95% CI -12.57 -7.49) as compared to the control but with no significance between the FFRD and FMP groups. No significant difference was found in the upper incisors vertical position between the three groups.

The results for the lower incisors showed a significant proclination in the FFRD group (9.17 ± 2.42 ; 95% CI 7.89 – 10.46) and non-significant retroclination in the FMP group (-1.49 ± 4.70 ; 95% CI -4.20 -1.23). The lower incisors were also significantly advanced relative to the A-Pogonion line in the FFRD as compared with the other groups. The FMP and the control groups showed no significant difference in the lower incisors position. The FFRD group also showed significant lower incisors intrusion (-1.76 ± 0.64 ; 95% CI -2.09 -1.42) in contrast to the FMP that showed significant extrusion (1.14 ± 1.52 ; 95% CI 0.27-2.02) as compared with the control group.

The upper molars were significantly distalized and intruded in the FFRD and FMP groups as compared with the control. The amount of distal and apical molar movements was not significantly different between the FFRD and FMP groups. The mandibular molars were mesialized and extruded in all the groups but with variable values. The maximum mesialization was found in the FFRD group (2.83 ± 1.31 ; 95% CI 2.13-3.53), while the maximum extrusion was found in the FMP (2.75 ± 0.78 ; 95% CI 2.30- 3.19).

Soft tissue changes

The angle of convexity was improved in the FFRD and FMP groups as compared with the control group. The multiple comparison

tests showed its significant increase in the FMP as compared with the FFRD groups. This difference was not significant after comparison of the annualized data between the FFRD and FMP groups. The naso-labial angle change was only significant when compared between the FFRD and control groups (Difference of means 5.42, SE 2.05, $P=0.03$). The lower lip position did not differ significantly between all the groups. On the other hand, the upper lip was retracted relative to the E line in the FMP more than FFRD groups.

Harms:

The post-surgical pain and swelling were reported by all patients and were addressed by pain killers and anti-inflammatory drugs. Other adverse effects found in the study included excessive miniplate mobility which was considered as a sign of failure and was reported in 3 out of the 30 miniplates (10%). In failure cases, the loading was discontinued and new miniplates were inserted instead of the failed ones.

DISCUSSION

Undesirable tooth movements and anchorage loss complicate the treatment outcomes of Fixed functional appliances (FFA) and could hinder the skeletal correction.^{12,13,30} Skeletal anchorage was suggested to be used to overcome the dento-alveolar side effects of the appliance therapy^{13,16,22,23,25}.

Gender restriction of the current study sample to females was adopted because of the reported variations in the growth timing, pattern and rate between males and females^{31,32}. The validity of combination of the skeletal outcomes of growing subjects of both genders is thus questionable. Skeletal age is preferred to overcome the inaccuracy of the chronological age as an indicator of the growth

stage³³ and that was the reason for using the cervical vertebral maturation method for detection of the patients' skeletal age. Inclusion of an untreated control group having Skeletal Class II malocclusion was based on previous recommendations^{34,35}. Older non controlled trials mentioned that they could not assess whether the skeletal changes were due to growth effects or actual treatment changes^{36,37}. Historical control data were not available in our population due to lack of growth studies. Moreover, the validity of comparing skeletal changes of contemporary subjects with historical controls is questionable. Secular trends in human growth had been previously reported and showed a tendency of change in maturation timing and duration through the decades³⁸.

Titanium miniplates were used for directly anchoring the FFRD and the mandibular arches were not bonded in accordance with previous studies^{22,23,25} to apply load directly to the mandibular base. Y shaped miniplates were used as recommended by Huang et al.³⁹, who proved that the Y and T shaped miniplates produced the least amount of bone stresses when used for orthodontic anchorage.

Main findings in the context of the existing evidence, interpretation:

The primary outcome of the current study was to investigate the change in the Class II subjects' profiles mainly through the mandibular skeletal changes. The mandibular length (Co-Gn) was chosen as an indicator of the mandibular skeletal changes as recommended by McNamara⁴⁰. The normal growth yielded a modest increase in the mandibular length in the control that was not significantly different from the FFRD group. Miniplates anchored FFRD showed an increase of 4.05 mm in the Co-Gn which was almost triple the changes in the rest of the groups. Annualizing the data did not change this fact, so the difference was not due to the duration

discrepancy between the groups. It could be due to the direct application of the orthopedic force on the bone that transmitted a downward and forward force vector to the condyles. The FFRD group results are in agreement with the most recent systematic reviews that mentioned that FFAs could not induce skeletal changes^{41,42}. The inclusion of the control group was the reason for the discrepancy between our results and those of Turk kahraman et al.²⁵ who mentioned that the FFRD alone and FFRD miniplates were able to induce lengthening of the mandible.

Clockwise mandibular rotation was shown to be significantly higher in the FMP group in accordance with previous studies^{22,23,25}. The mentioned posterior rotation of the mandible could have masked the increase in the SNB which is only an indicator of mandibular positional change rather than a change of its size⁴³. Increased mandibular rotation could be explained by the direct application of the force on the mandibular symphysis at the canine position that is more anterior to the center of resistance of the mandible (between lower premolars) as compared with the FFRD group.

The maxillary skeletal changes showed no significant difference between all the groups and in accordance with previous studies^{22,23,25}. The skeletal relation as detected from the ANB angle showed an improvement of the skeletal Class II in the FMP group only. However, the magnitude of change (1.6 degrees) might be not clinically significant. Previous studies showed no significant difference in the ANB angle change between the FFA and the FFA with miniplates anchorage^{22,25}.

Regarding the dento-alveolar changes, our FFRD group results confirmed previous findings that FFRD suffered from a large amount of proclination of the lower incisors^{28,37} that did not give a chance for the mandible to surpass its normal growth amount. In the current study, 1.5° retroclination of the lower

incisors occurred in the FMP group which was in accordance with previous studies evaluating the same technique^{22,23,25} and is considered favorable to occur in Class II malocclusion subjects⁴⁴. The upper incisors were significantly retroclined in the FFRD and FMP groups as compared with the controls. The non-significant difference in upper incisor retroclination between the FFRD and FFRD with miniplates was consistent with Turk kahraman et al.²⁵.

In contrast to the control group, the upper molars were intruded and distally displaced in both treatment groups because of the force system of the FFRD appliance. As for the mandibular molars, mesialization and extrusion were evident in the three study groups. Upon comparison, the amount of mesialization was highest in FFRD (2.8 mm) followed by FMP (2 mm) then the controls (0.76 mm). as for the molar extrusion, the FMP showed almost double the amount of molar extrusion (2.75 mm) as compared with the FFRD group. This could be compensatory to the previously mentioned clockwise mandibular rotation that occurred only in the miniplates group. This alerts the importance of controlling the vertical dimension during the miniplates anchored FFRD therapy.

Improvement of the facial convexity, naso-labial angle and upper lip position were evident in the FFRD and FMP as compared with the control group. Flattening of the convex profile was higher in the FMP group due to the evident mandibular advancement in this group. The naso-labial angle was increased and the upper lip was retracted in the FMP and FFRD groups owing to the retraction of the upper incisors. Lower lip changes were not significantly different between the treatment groups. A great deal of variability was obvious in the soft tissue measurements and this confirmed that the relation between the soft and hard tissue response to orthodontic treatment is very complicated and cannot be predicted⁴⁵.

Results of the current parallel randomized trial showed that the miniplate anchored FFRD yielded favorable skeletal effects over the conventional FFRD and untreated controls and was successful in elimination of the unwanted the mandibular anchorage loss.

Limitations:

The investigated technique had several limitations. A minimum of two surgical procedures were needed for the miniplates insertion and removal. An additional surgery for re-insertion would be needed in case of miniplate failure. An additional cost is also an important disadvantage. The potential advantages of this technique should be weighed against its possible risks, side-effects and financial burden. Engagement of this modality as an integral part of the treatment planning for Class II growing patients still needs further investigation. One more limitation was the different experimental periods between the FFRD and FMP groups; which was managed by annualizing the data to confirm that the difference was not caused by variable treatment duration.

CONCLUSIONS

- The use of the miniplates in conjunction with the FFRD was successful in inducing a significant increase in the effective mandibular length in the short term.
- A clockwise rotation of the mandible was evident in the miniplates anchored FFRD that could have reduced the apparent sagittal correction.
- In contrast to the conventional FFRD, miniplates anchored FFRD showed retroclination of the lower incisors and no mandibular anchorage loss.

Author's contributions: The clinical procedures were performed by S. Elkordy and were supervised by all the authors. All authors contributed to data analysis and interpretation,

while the manuscript was prepared and revised by S. Elkordy and M. Fayed. All authors gave final approval and agreed to be accountable for all aspects of the work.

Compliance with ethical standards:

Conflict of interest: The authors declare that they have no conflict of interest.

Funding:

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Ethical approval: All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. The study protocol was accepted and approved by the Ethical Committee, Faculty of Dentistry, Cairo University, Egypt.

Informed consent: Informed consent was obtained from all individual participants included in the study. Additional informed consent was obtained from all individual participants for whom identifying information is included in this article.

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