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Three dimensional evaluation of skeletal effects of two non-compliance appliances in the treatment of growing skeletal class iii patients

(A RANDOMIZED CONTROLLED CLINICAL TRIAL)

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ABSTRACT:

Background: This study evaluated three-dimensionally the skeletal effects of two different intraoral force application systems for treating skeletally growing ClassIII patients(RCT).

Methods: Thirty-three patients were recruited for this study and randomly allocated between three groups: GroupI(n=11)patients treated with CS2000(CSgroup/pulling force) GroupII(n=11)patients treated with reversed Forsus Fatigue Resistant(RFgroup/pushing force) and GroupIII(n=11)untreated control group(negative control). CBCT image was taken before treatment(T0) and after gaining a 2mm overjet or after an observation period of six months(T1). Skeletal measurements were assessed and compared between the two groups. Within group comparisons were done using Wilcoxon Sign Rank test.

Results: Sagittally in RF group, OLp-Apt increased by3.60mm, OLp- Bpt decreased by-2.50mm and OLp-Pg decreased as well by-2.00mm(P<0.0001). While in CSgroup, OLp-Apt increased by3.10mm, OLp-Bpt decreased by-1.10mm and OLp-Pg decreased as well by-1.00mm(P<0.0001). Wits appraisal increased by5.00mm and5.50mm in RF and CS group accordingly after treatment(P<0.0001). There was an increase in OLs-Apt in both treatment groups by3.80mm in RFgroup and 5.00mm in CSgroup(P<0.0001). Vertically there was a statistical significant difference between two groups.

ANS-Me decreased in RFgroup by-0.70mm and increased in CSgroup by2.00 mm. Both treatment groups demonstrated an increase in the SNA angle(2.6° in RF group and2.5° in CSgroup)(P<0.0001), a decrease in the SNB angle-1.00° in RFgroup and-2.00° in CSgroup(P<0.0001), hence increase ANB angle.

Conclusions: CS2000 spring and reversed Forsus Fatigue Resistance device both promoted forward maxillary advancement in an average of 5months. Both appliances gave close effects to bone anchored maxillary protraction devices and functional appliances, removing compliance factor out of the equation.

Key words: Skeletal changes, CBCT, growing skeletal Class III, CS 2000® appliance, Reversed Forsus Fatigue Resistant device.

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BACKGROUND

Orthodontic treatment of Class III malocclusions with skeletal and dentoalveolar imbalances, represents an endless problem among orthodontists.[1-5] This difficulty starts from their meticulous diagnosis and treatment planning till reaching satisfactory results and finallystability.[1, 6]

Class III malocclusions constitute 11.38% of the Egyptian population.[7] Their etiology is comprised of genetic, ethnic, environmental, and habitual factors.[8] They can be of dental or skeletal origin.[9, 10] Ellis and McNamara found that a combination of maxilla retrusion and mandibular protrusion is the most common skeletal relationship (30%) found in class III patients, followed by maxillary retrusion 19.5% and mandibular protrusion 19.1%.[11]

Untreated growing skeletal Class III malocclusion usually worsens over time as mentioned by Baccetti et al. and Wolfe et al.[12, 13] Unfortunately, most of the real mandibular prognathism will be treated later by orthognathic surgery. Nevertheless, 30-40% of the skeletal Class III has maxillary deficiency, which can be early corrected improving the skeletal and dentoalveolar relationships, avoiding surgery.[1, 14, 15]

Generally, appliances to correct growing skeletal Class III have been used to modify the skeletal pattern by enhancing the growth of the maxilla and restricting or redirecting the growth of the mandible.[16] Earlier, extra oral appliances like chin cup[17, 18] and facemask[19, 20] were used for orthopedic correction. They proved to be effective but need high patient compliance to wear.[21]

Later, intra oral appliances like Frankel functional regulator III appliance,[16, 22] reverse twin- block appliance[23] tandem or modified tandem appliance,[24] and class III splints[25, 26] were used to overcome patient compliance due to the minimal extra oral appearance. However, these appliances are challenging to wear, facing the same problem of compliance.[27] Other intraoral fixed appliances like 2x 4 fixed appliances[28] improved patients' compliance givingbetter and faster results.

Successively,[29-31] miniscrews and miniplates have been used in the orthopedic management of class III patients. Unfortunately, miniscrews had complications like injury to adjacent root, potential damage to tooth buds and fracture of the miniscrew itself.[32] Additionally, miniplates requires two invasive flap surgeries: one for insertion and another for removal,[30] pain, swelling, and speech difficulty occurring after both surgeries.[33, 34]

The CS-2000® (DynaFlex, St. Ann, Missouri.) is an inter-arch spring loaded module that has a pair of closed coil-springs bilaterally, and can be used with the same vector as Class III elastics.[35] Since the CS-2000® appliance is fixed inside the mouth, the springs act continuously, unlike elastics. This will have the benefit of permitting faster resolution of the malocclusion not relying on patients' compliance.[35]

Reversing the Forsus fatigue-resistant device (3M Unitek cooporation) will alter the known effect of the device when used in

correcting class II malocclusions. It was presented reversed by Elsheikh et al.[36] as method of Class III correction on a typodont. Recently in a randomized controlled trial, Eissa et al.[29] used the RF appliance anchored on miniscrews to evaluate the skeletal, dental, and soft tissue changes in the treatment of growing skeletal Class III malocclusion. The malocclusion was corrected by increase in maxillary forward growth, as well as mesial movement of the maxillary dentition.

The null hypothesis of this study is that there is no significant skeletal difference between the effect of the RF appliance and CS appliance in treating growing skeletal Class III malocclusions when compared to each other and to untreated control group.

METHODS

Subjects and methods

The study was a three armed randomized controlled clinical trial, parallel design. It was setup and recorded according to the CONSORT guidelines[37] The PICO question was: Did treating growing skeletal Class III patients (Patient P) using different force application systems: pulling force using CS 2000® appliance and pushing force using Reversed Forsus fatigue-resistant device (Intervention I) as compared to a negative control (Comparison C), had any change on the skeletal measurements(Outcome O)?

Participants, eligibility criteria, Study Setting and location

This study was registered in the clinicaltrial.gov (NCT04825951) in 01/04/2019. The study was conducted following the guidelines of "Declaration of Helsinki" after taking the approval of institutional review board at the Faculty of Dentistry, Alexandria University protocol record 070320212.[38] The recruitment of participants was conducted in the Department of Orthodontics, Faculty of Dentistry, Alexandria University, Egypt. The patients were examined and screened, taking into consideration the following eligibility criteria.

Inclusion criteria : age ranged from 8 years to 11 years, cervical vertebrae maturation index (CVMI 2 and 3) identified on the lateral cephalometric radiograph,[29, 39] angle Class III molar relation.[29] Skeletal class III ANB ranged (-4) – (0), Wits appraisal ranged (0) – (-5),[27] ,reversed over jet (-6) - (-1), good oral hygiene and healthy periodontal condition[40], normal vertical growth pattern (SN/MP angle 28˚–38˚)[41]

Exclusion criteria were: patients with a discrepancy between centric relation and maximum intercuspation,[42] patients who underwent previous orthodontic treatment,[25, 43] patients receiving drug therapy that may affect orthodontic tooth movement,[17] and had congenitally missing teeth or extracted teeth,[43] and finally patients with history of systemic disease or craniofacial syndromes and presence of clefts.[43, 44]

Pre-intervention preparation

First, a complete thorough explanation regarding the study procedures to both the participants and their parents in each group, and accordingly, an informed consent was obtained from each enrolled subject parents'. All enrolled subjects were prepared for

receiving appliances and starting intervention by recording medical and dental history. In addition to routine orthodontic records (intra-oral and extra-oral photographs, lateral cephalometric x-ray, panoramic x-ray and dental models), CBCTs were obtained. Patients were asked to undergo full mouth scaling and polishing, followed by proper oral hygiene instructions (using tooth brush, dental floss, and interdental brush). Before intervention, the patients were randomly allocated to one of the three groups: Group I: patients treated with CS2000 appliance, Group II: patients treated with reversed Forsus Fatigue Resistant device and Group III: untreated control group (negative controls).

Intervention

Group I: patients treated with CS2000 appliance (DynaFlex, St. Ann, Missouri)[45] For the maxillary arch, bands were selected (Ormco cooporation) to the upper two first permanent molars for a Nance appliance fabrication (Fig. 1.a). For the mandibular arch, bands were selected to lower first permanent molars and first premolars or stainless steel crown selection for first deciduous molar for the fabrication of a lower lingual arch of 0.9 mm thickness. The band of the premolar or the stainless steel crown had an attached bracket (Fig. 1.b). The CS spring was connected from the upper first permanent molar bands to the lower first premolar bands or stainless steel crowns (Fig. 1.c). The CS spring length (7mm/10 mm) was chosen according to the length measured between the lower premolar (or deciduous first molar) and the upper first permanent molar (Fig. 2).

The patients were observed every month. During follow up visits, activation of the spring was done. The force was calculated to be 150 gm/side in the first month. When the pivot teeth are coupled with the 300 grams from both sides, they are reinforced and served as the anchorage teeth. The force was increased to 250 gm/side in the following period.

Group II: patients treated with reversed Forsus Fatigue Resistant device EZ2 model (3M Unitek cooporation)[29] For the maxillary arch, bands were selected (Ormco cooporation) to the upper two first permanent molars and first premolars or stainless steel crown selection for first deciduous molar for a Nance appliance fabrication. The band of the premolar or the stainless steel crown had an attached bracket (Fig. 3.a). For the mandibular arch, bands were selected to lower first permanent molars for lingual arch fabrication of a 0.9mm thickness. The molar had a head gear tube (Fig. 3.b) the reversed Forsus fatigue resistant appliance was connected from upper first premolar bands or stainless steel crown to the lower first permanent molar bands (Fig. 3.c). The reversed Forsus fatigue resistant push rod length (23mm/ 25mm) was chosen according to the length measured between the upper first premolar (or deciduous first molar) and the lower first permanent molar with a measurement gauge (Fig. 4).

Patients were observed every month. During follow-up visits, if the spring module was compressed more than 2.5 mm under the stop on the push rod, reactivation was performed by adding a crimp onto the push rod to provide an additional 1.5 mm of activation.

The force was calculated at both times to be 150 gm/side in the first month, then increased to be to 250gm/side in the following period.

Group III: Control group of untreated skeletally growing class III patients was recruited to account for the possible effects of growth in the treatment groups. This group matched the treated groups in malocclusion, stages of skeletal maturation, and mean observation period. Those patients were treated after the period of the study.[29]

Post Intervention follow up

Photographs were taken every month to observe the progress. The lingual arches and Nance appliances were removed every month, cleaned and cemented properly. Alginate impressions, photographs and CBCTs were taken after gaining a positive overjet of 2 mm overcorrection or a 6 months period if positive overjet was not gained till that time. In both treated groups patients who achieved 2 mm overjet were left extra two weeks to settle occlusion. The patient from treated groups, who reached a 2 mm overjet, was left 2 weeks for the settling of occlusion and bite closure. CBCT images were acquired with X800 cone beam 3D imaging system (Morita 3DX; J Morita Mfg corp, Kyoto, Japan). The scan was done with field of view (FOV) 150mm X H 150 mm. The volume were reconstructed with 0.160 mm isometric voxel size. The tube voltage was 90 kVp and 8 mA, Exposure time was 20 seconds. The image was analyzed using OnDemand3D™ software (Cybermed Inc.) CBCT analyzing software. All of the scans were acquired with the patient sitting upright with the Frankfort horizontal plane parallel to the floor, in centric occlusion. The patient's head position was adjusted with the help of two laser beams, one parallel to the floor, coinciding with the Frankfort horizontal plane, and one vertical beam passing through the patient's facial midline. The patients were asked not to swallow or move their heads or tongues during exposure to prevent any distortion occurring. Coding of the CBCTs and collecting the data was done. Any drop out patient was replaced by another allocated to the same group and under taken the same procedures.

Cephalometric evaluation

All skeletal changes were analyzed using ProPlan CMF version 3.0 software (Materialise Europe, World Headquarters, Leuven, Belgium). After importing the DICOM files in the software, thresholding was performed to identify the bone (minimum 266 - maximum 3071) and remove artifacts and segmentation of the skull. All measurements were performed by the same examiner who was blinded to the type of treatment protocols (B.A). The cephalometric readings described by Bjork[46] and Pancherz[47] were used to analyze the baseline readings of the patients recruited. First reference planes were determined and allocated on the axial, coronal and sagittal views on CBCT (Fig.5a and Fig. 5b) and Table 1 and points are described in Table 2. The linear sagittal skeletal measurements (Fig. 6 a. and Fig. 6b) and Table 3, the linear vertical skeletal readings (Fig. 7 a. and Fig7b.) and Table 4, and Angular skeletal readings (Fig. 8 a and Fig 8 b) and Table 5. were calculated and analyzed.

Retention of the cases

If the patient had full dentition after correcting the anterior cross bite, fixed orthodontic treatment was done starting the case with a 2mm positive overjet. Those patients who were still in mixed dentition received class III splints and were instructed to wear them at night only (Fig 9). Finally, patients who had shallow bites by the end of the study period, habit breaking appliance used to avoid the development of any secondary habit. When the bite deepened, Class III splints were done only for night wear.

Sample size calculation

The sample size was estimated prospectively prior Sample size was estimated based on assuming 5% alpha error and 80% study power. Vanlaecken et al.,[45] and Eissa et al.,[29] respectively, reported mean 2.66 degrees change in skeletal pattern using CS appliance and 1.810 degrees change using Reversed Forsus appliance in treating class III malocclusion. Based on comparing the two means and using SD of 0.595,[29] sample size was calculated to be 11 patients per group. Total sample size will be 33 patients. Sample size was based on Rosner's method[48] calculated by Gpower 3.0.10.[49]

Randomization and patient allocation

Subjects complying with the inclusion criteria were randomly assigned using a computer-generated list to one of the three groups (CS appliance or RF appliance or control group). Allocation was performed by using permuted block technique, where allocation ratio was intended to be equal.[50] Only the supervisor was aware of the allocation group. Patients was randomly allocated to one of the three groups Group I (n=11) patients treated with CS2000 appliance (pulling force) Group II (n=11) patients treated with reversed Forsus Fatigue Resistant device (pushing force) and Group III (n=11) control group (negative control). This was fully illustrated in the flow chart in (Fig. 10).

Allocation concealment[51]

The list of allocation was generated prospectively using random allocation software. Each allocation was represented by a code (the serial of the participant in the study) and either of the group name. The allocation was sealed in sequentially numbered opaque envelopes by an assistant and the set of envelopes were given to the senior supervisor. When enrolling a new participant for intervention, the supervisor supplied the designated envelopeto the orthodontist.

Blinding

Participants and statistician were blinded (double blind) to the intervention group. After data collection was completed, the randomization code was broken to reveal the allocation group. The operator was blinded during recording of the measurements. To avoid bias, all CBCT scans were unidentified before assessment, achieving a simple blinding.

Statistical Analysis

Normality was checked using Shapiro Wilk test, box plots and descriptives. Variables was presented using Mean, Standard deviation and Median values. Comparison between groups at T0 and T1 for all variables was

performed using One Way ANOVA followed by Tukey's test with Bonferroni correction. Paired t test was applied for intragroup comparisons (between T0 and T1). Differences between T1 – T0 was assessed using Kruskal Wallis followed by post hoc test with Bonferroni correction. Significance level was set at P value of 0.05. All tests were two tailed. Data were analyzed using SPSS for windows version 23. Intraclass correlation coefficient was used to for reliability assessment Table 6.

Method error

The error in locating and measuring the changes of the landmarks by one examiner were measured on the cephalograms of 11 randomly selected subjects at the beginning of the study (B.A). All skeletal and dental changes in CBCTs were recorded twice independently on two separate occasions with a 2-week interval. Another examiner (T.Y) measured the skeletal and dental measurements independently. For all the cephalometric variables, differences between the independent repeated measurements of each individual before/after treatment were recorded. Also, differences between independent repeated measurements of the two examiners were noted.

RESULTS

Participant flow

All groups presented similar initial demographic and skeletal characteristics in Table 7. All groups presented similar initial age, sex distribution and skeletal maturation. Thirty three subjects were selected and agreed to participate in this trial with a mean age of 10.18 (±0.75years). The final sample in the Reversed Forsus group comprised 11 patients (7 female, 4 male). The CS 2000 group comprised also of 11 patients (7 female, 4 male). A control group of eleven patients was recruited group that matched the treated groups in malocclusion, stages of skeletal maturation, and mean observation period which was the six month period designed for the study. The gender distribution was 1.5:1 (F:M) in all groups.

Treatment time

Treatment time was illustrated in Table 7.The mean treatment time elapsed was 3.59 (±0.54) months in RF group and the mean treatment time was 5.55 (±0.52) months in CS 2000 group. Therefore, the treatment time of RF appliance was significantly lower than the comparative treatment group. The observation period of the controls was six month period.

Sagittal measurements

Table 8 showed the skeletal sagittal changes between treatment groups and untreated control group between T0- T1. Both groups showed an increase on OLp- Apt and decrease in OLp- Bpt and OLp- Pg. In RF group, the OLp- Apt increased by 3.60 mm, the OLp- Bpt decreased by -2.50mm and OLp- Pg decreased as well by -2.00 mm ($P < 0.0001$). While in CS group, the OLp- Apt increased by 3.10 mm, the OLp- Bpt decreased by -1.10 mm and OLp- Pg decreased as well by -1.00 mm ($P < 0.0001$). Upon comparing the treatment groups, the previously sagittal skeletal readings showed insignificant difference, significance was only found when compared to controls. Moreover, there was insignificant difference regarding the OLp-Co when 3 groups were compared to each other. Furthermore there was

an increase in the Wits appraisal that was insignificant between treatment groups and significant when comparing with the control group. The Wits appraisal different was there was 5.00 mm and 5.50 mm in the RF and CS group accordingly after treatment. ($P < 0.0001$).

Vertical measurements

Table 9 shows the vertical skeletal changes between study groups from T0- T1. There was an increase in OLp- Apt in both treatment groups by 3.80 mm in RF group and 5.00 mm in CS group ($P < 0.0001$). This increase wasn't significant between the treated groups, however it was significant when compared with the controls. For ANS- Me, there was a decrease in the RF group by -0.70 mm and increase by 2.00 mm in the CS group, hence the statistical significant different between treatment groups ($P < 0.0001$).

Angular measurements

Table 10 demonstrated the skeletal changes between the study groups comparing pre and post treatment changes. Both treatment groups demonstrated an increase in the SNA angle, decrease in the SNB angle and increase in ANB between T0- T1. Considering treatment groups comparison between T0- T1, no statistical difference was observed. Significance was only found when both treatment groups were compared solely with the untreated control group. The decrease of SNB angle between T0- T1 between treatment groups was -1.00° in RF group and -2.00 ° in CS spring group ($P < 0.0001$). The increase of SNA angle between T0- T1 between treatment groups was similar in both treatment groups. The SNA increased by -1.00° in RF group and -2.00 ° in CS spring group ($P < 0.0001$).Additionally, no statistical significant difference was found in the increase of ANB angle by 4.00° and 4.40° in RF group and CS group respectively between T0- T1. Also, there was a statistical significant difference between T0- T1 in three of the skeletal readings. First, the palatal plane angle significant increase of 3.40 ° in the RF group and significant decrease of -1.50 ° in the CS group. Second, mandibular plane angle statistical significant decrease of –7.30 ° in RF group and increase of 1.20 ° in CS group. Third and final, the occlusal plane significant decrease of -6.60 ° in RF group and increase of 1.80 ° in CS group ($P < 0.0001$).

Harms

Some technical failures occurred in the design of the appliances that needed some modifications. In the RF appliance group failures were: tube separation from the band, lingual placement of the lingual arch and malfunction of the Forsus spring itself. While in the CS appliance group failures were: band fracture, band separation from the lingual arch, lingual placement of the lingual arch and malfunction of the CS spring. Tubes separation from the lower bands failure was observed in RF group only, as it was seen in four patients comprising 23.5%. These patients were recalled for redoing of the lingual arch with new set of bands. This was done also for patients who confronted band separation from the lingual arch and band fracture which occurred in the CS appliance group in 5 patients (26.3%) and 2 patients (10.5%) respectively. Also, redoing the lingual arch was done because it was distalized and it was

hindering the tongue movement, as mentioned by 6 patients (35.3%) in RF group and 7 patients (36.8%). Finally, the appliances' spring malfunction themselves, had an exchange of this part till the aim of the study was reached. This occurred in two patients in each group.

DISCUSSION

The present study was exempted to evaluate skeletal effects three dimensionally after using two force applications: pulling force using CS appliance and a pushing force using RF appliance, compared to a control group in a short observational period of six months. The main idea of these two appliances is to cancel the patient compliance factor out of the equation. Upon reviewing and revising literature, that's the first study to examine skeletal changes three dimensionally after using different force directions.

The mean treatment duration for RF was 3.59 (0.54) months and 5.55 months (0.52) for CS, which was less than that in Moore's study[52] which elapsed 6.96 months. The longer treatment time could be attributed to the time of the RME followed by traction mechanics. In the current study, expansion wasn't included to examine purely the skeletal effects of both force application systems. In another study by Azabibi et al,[53] class III elastics used between hooks on the maxillary molar expander and an anterior point on vaccum appliance in the lower arch, the treatment elapsed was 4.34 months which was in close resemblance to the time taken for the current study since expansion was simultaneously done with the maxillary protraction.

The present study was a randomized controlled clinical trial. Thirty three patients were recruited and randomly allocated between three groups: Group I (n=11) patients treated with CS2000 appliance (CS group/ pulling force) Group II (n=11) patients treated with reversed Forsus Fatigue Resistant device (RF group/ pushing force) and Group III (n=11) untreated control group (negative control) with matched malocclusion and skeletal maturation, to exclude for the possible effects of growth in the treatment groups.[29]

All groups had similar baseline characteristics. The gender ratio in the three groups was nearly 1.5:1 with the female ratio more than the male ratio. Usually, young females are the most seen category applying for orthodontic treatment because of their higher aesthetic demands.[54] Mean age of the patients included in this study was 10.18 (±0.75years). Cha et al. and Merwin et al.[55, 56] recommended FM therapy should be started before the age of 8 years because of the lack of interdigitation of the circummaxillary suture at this early age, favoring the maxillary orthopedic response. Unfortunately, patient's compliance and oral hygiene maintenance are questionable, favoring the choice of an older group.

The force applied in both appliances was 150 gm/side in the first month, then increased to be to 250gm/side in the following period till the end of the observation period. This force protocol was similarly done by De Clerk et al[57] who proposed that a favorable maxillary response can be obtained with moderate continuous traction rather than heavy interrupted forces during the day. Also

Vanlaecken et al.,[45] performed a study where the same force was applied with a CS appliance giving positive effects in correcting the malocclusion.

Upon comparing and contrasting the two devices with the control group, having growth factor excluded, it was found that these two devices played a role in maxillary advancement that could be compared to that using bone anchored maxillary protraction in a short observation period of six months.[57]

Sagittal measurements

The sagittal skeletal changes were insignificant between two treatment groups and significant when compared to untreated controls. In the RF appliance group, patients showed 3.6mm maxillary anterior positioning, along with -2.5mm mandibular posterior positioning of chin and -2.0 mm posterior positing of the chin. This could be as a result of the pushing force on the maxilla in the RF group reciprocating the backward positing of the mandible, creating a positive overjet in the treatment group. Baik et al.[58] showed a similar backward movement of the mandibular base by 2.5 mm with the use of removable FRIII appliance. The changes in the current study were more than the results achieved by Eissa et al.,[29] who stated that the effect was only concised to the alveolar bone not the skeletal base. The Wits measurements were found to improve by 5.0 mm. This change can be partially attributed to the rotation of the occlusal plane rotation, where its inclination decreased in the treatment group. These results had a close resemblance to those achieved by the protraction facemask,[59] but more than the 2.7 mm reported using the FRIII appliance,[58] the 2.4 mm by the Bionator III appliance,[60] and 1.8 mm by tandam traction appliance,[61] which are considered as functional appliances to treat skeletally growing Class III patients.

Similarly, CS group accomplished 3.10mm maxillary anterior positioning, and -1.10mm and -1.00 mm mandibular and chin posterior positioning respectively. This could be a result of the inter-arch spring-loaded module acting like the class III elastics pulling the mandible in a more backwards position. Additionally, there was an increase in the Wits appraisal by 5.5 mm. The maxillary anterior positioning was increased by 4 mm in the study by Declerk, where the maxillary protraction was done on four miniplates.[30] This could be attributed to the force of application of the elastics applied in the other study. Baccetti found 3.1-mm-forward movements of A point in young patients treated using protraction facemasks.[62] This could be attributed to the rapid maxillary expansion with the maxillary protraction, giving more functional results.

Vanlaecken et al.,[45] using the CS appliance, found that the maxilla (A point) was found to move forward by 0.8 mm over a period of 1.3 years. Loiu[63, 64] reported a 5.8-mm-forward movement of the maxilla in 3 months using a maxillary expansion and constriction protocol in conjunction with protraction facemask. This is because the expansion protocol allows loosening of the maxillary sutures and the protraction spring acts on the sutures 24 h per day.

Vertical measurements

In the RF group, the lower anterior facial height decreased significantly by 3.80mm, which was reflected as increase in the over bite by 0.2 mm. While in the CS group, the lower anterior facial height increased significantly by 5.00mm than the untreated control group by 0.3mm and caused shallowing in the overbite by -0.5 mm. Vanlaecken et al.,[45] found that the mandibular base moved posteriorly by 2.8 mm partially due to a downward and backward rotation of the mandible as evidenced by a 4.2-mm increase in lower facial height (ANS- Me) and an increase in the mandibular plane angle of 1.6°.[62] Bacetti et al. [62]also reported a rotation of the mandible and a 2.5-mm restriction in mandibular protrusion with protraction facemask. A 2.5 mm posterior movement of the mandibular base and a 2.9-mm increase in the lower facial height was also reported by Ngan and associates.[59]

Angular measurements

In the current study, the CS group showed an increase in anteroposterior position of the maxilla (SNA) 2.6 ° and a decrease in the anteroposterior mandibular position (SNB) -1.00°. This might be a possible effect of the pulling force of the CS spring in a Class III vector on the mandible, reciprocating this force with an opposite one on the maxilla, leading to maxillary advancement. Subsequently, there was a significant increase in the ANB angle and the Wits appraisal. These findings were more than those found by Vanlaecken et al. using the same appliance,[45] where SNA increased by 1.9° during treatment, while SNB remained the same, ANB increased by 2.6°, and those found by DeClerck et al.,[57] study where the SNA increased by 2.23°, SNB decreased by 0.97°, and the average Wits correction was 5.49 mm.

The RF group showed an increase in anteroposterior position of the maxilla and a decrease in the anteroposterior mandibular position. This might be a possible effect of the pushing force of the appliance on the mandible, reciprocating this force with an opposite one on the maxilla, leading to maxillary forward growth redirecting. Similarly, these results were more than that of Eissa et al.,[29] where the RF was miniscrews supported, hence older patient group.

The CS group experienced a significant decrease in the palatal plane causing anti clock wise rotation of the maxilla, and significant increase in the mandibular and occlusal plane angles causing clock wise rotation of the mandible, reflected by the shallowing of the bite. The rotation of the mandibular and palatal planes of about 1°, compared with the control sample, was negligible.

In the RF group, there was a significant increase in the palatal plane angle denoting maxillary clockwise rotation in a forward and downward position. In the same treatment group, there was a significant decrease in both the occlusal plane angle and the mandibular plane angle indicating the anti-clockwise rotation of the mandible causing deepening of the bite. This finding was in accordance to the findings in Eissa et al.,[29] where there was a significant counterclockwise rotation of the occlusal plane. This rotation could be explained by the vertical force component of the device, which tends to intrude the maxillary incisors

and mandibular molars.[36, 65] In conclusion counterclockwise rotation of the occlusal plane could alter the anteroposterior relationship between the maxilla and the mandible.

Since the study was short term to investigate the effects of the two force applications for treating skeletal class III patients, a longer period of observation might be needed as a future recommendation to study success, stability and efficacy of treatment.

CONCLUSIONS

The null hypothesis was rejected.

Based on the results of the current study, it can be concluded that:

1. The CS 2000 spring and the reversed Forsus Fatigue Resistance device both promoted forward maxillary advancement in an average of 5 months.

2. Both treatment groups showed similar significant changes in the skeletal measurements in the direction of improving the skeletal class III discrepancy.

3. Both appliances gave close effects to bone anchored maxillary protraction devices and functional appliances, removing the compliance factor out of the equation.

Declarations:

Ethics approval and consent to participate

This study was conducted following the guidelines of "Declaration of Helsinki" after taking the approval of institutional review board at the Faculty of Dentistry, Alexandria University (IRB:00010556–IORG:0008839). All the patients and their parents or guardians were informed about the nature of the study, in addition to the risks and benefits of enrollment in the study. A signed informed consent was obtained from the patients' parents or guardians before the onset of the study. Privacy and confidentiality of participants will be assured.

Clinical termination will occur if allergic reaction occurred, patient disappearance for any reason like travelling, developing uncontrolled bad oral hygiene.

Consent for publication

Written informed consents were signed by patients whose were recruited according to the inclusion criteria for the purpose of publication.

Competing interests

The authors declare that they have no competing interest.

Availability of data and materials

The datasets used/ or analyzed during the current study are available from the corresponding author on reasonable request.

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REFERENCES

1. McNamara JA, Jr. Early intervention in the transverse dimension: is it worth the effort? Am J Orthod Dentofacial Orthop 2002;121:572-4.

2. Clark WJ. The twin block technique. A functional orthopedic appliance system. Am

JOrthod Dentofacial Orthop 1988;93:1-18.

3. McNamara Jr JA, Brudon WL. Orthodontic and Orthopedic Treatment in the Mixed Dentition. 3rd ed. Ann Arbor, Mich: Needham Press; 1993.

4. Proffit W, Fields H, Larson B, Sarver D. Contemporary Orthodontics 6th ed. St. Louis:Mosby; 2018.

5. Rakosi T, Graber T. Orthodontic and Dentofacial Orthopedic Treatment, Stuttgart: Thieme New York; 2010.

6. Graber LW, Vanarsdall RL, Vig KVL, Huang GJ. Orthodontics: Current principles and techniques. 6th ed. Saint Louis: Elsiever; 2017.

7. El-Mangoury NH, Mostafa YA. Epidemiologic panorama of dental occlusion. Angle Orthod 1990;60:207-14.

8. Azamian Z, Shirban F. Treatment Options for Class III Malocclusion in Growing Patients with Emphasis on Maxillary Protraction. Scientifica (Cairo) 2016;2016:8105163.

9. Jaradat M. An overview of Class III malocclusion (prevalence, etiology and management). J Adv Med Med Res 2018;25:1-13.

10. Guyer EC, Ellis EE, 3rd, McNamara JA, Jr., Behrents RG. Components of class III malocclusion in juveniles and adolescents. Angle Orthod 1986;56:7-30.

11. Ellis E, 3rd, McNamara JA, Jr. Components of adult Class III malocclusion. J Oral Maxillofac Surg 1984;42:295-305.

12. Baccetti T, Franchi L, McNamara JA. Growth in the Untreated Class III Subject. SeminOrthod 2007;13:130-42.

13. Wolfe SM, Araujo E, Behrents RG, Buschang PH. Craniofacial growth of Class III subjects six to sixteen years of age. Angle Orthod 2011;81:211-6.

14. Smyth RSD, Ryan FS. Early treatment of class III malocclusion with facemask. Evid Based Dent 2017;18:107-8.

15. Ngan P. Early timely treatment of Class III malocclusion. Semin Orthod 2005;11:140-5.

16. Loh MK, Kerr WJ. The Function Regulator III: effects and indications for use. Br J Orthod 1985;12:153-7.

17. Sugawara J, Asano T, Endo N, Mitani H. Long-term effects of chincap therapy on skeletal profile in mandibular prognathism. Am J Orthod Dentofacial Orthop 1990;98:127-33.

18. El Mehy G. Effect of chin cup therapy on the craniocervical angulation. Egypt Orthod J 2007;32:21-9.

19. Ngan P, Yiu C, Hu A, Hägg U, Wei SH, Gunel E. Cephalometric and occlusal changes following maxillary expansion and protraction. Eur J Orthod 1998;20:237-54.

20. Ngan P, Wilmes B, Drescher D, Martin C, Weaver B, Gunel E. Comparison of two maxillary protraction protocols: tooth-borne versus bone-anchored protraction facemask treatment. Prog Orthod 2015;16:26.

21. Sarangal H, Namdev R, Garg S, Saini N, Singhal P. Treatment Modalities for Early Management of Class III Skeletal Malocclusion: A Case Series. Contemp Clin Dent 2020;11:91-6.

22. Fränkel R. Maxillary retrusion in Class 3 and treatment with the function corrector 3. Rep Congr Eur Orthod Soc 1970:249-59.

23. Kidner G, DiBiase A, DiBiase D. Class III Twin Blocks: a case series. J Orthod 2003;30:197-201.

24. Abdelnaby YL, Hafez AM, Dae'r AA-k. Evaluation of modified tandem appliance in management of cases with maxillary retrusion. Egypt Orthod J 2009;36:101-17.

25. El-Masry E, Abdallah E, Mowafy M. Evaluation of the skeletal, dental and soft tissue effects of class III splints (clinical study). Egypt Orthod J 2013;43:1-25.

26. El Harouni N. Skeletal, dental and soft tissue changes following the treatment of class III malocclusion using the class III splint. Egypt Orthod J 2008;34:1-14.

27. Zere E, Chaudhari PK, Sharan J, Dhingra K, Tiwari N. Developing Class III malocclusions: challenges and solutions. Clin Cosmet Investig Dent 2018;10:99-116.

28. Hägg U, Tse A, Bendeus M, Rabie AB. A follow-up study of early treatment of pseudo Class III malocclusion. Angle Orthod 2004;74:465-72.

29. Eissa O, ElShennawy M, Gaballah S, ElMehy G, El-Bialy T. Treatment of Class III malocclusion using miniscrew-anchored inverted Forsus FRD: Controlled clinical trial. Angle Orthod 2018;88:692-701.

30. De Clerck H, Cevidanes L, Baccetti T. Dentofacial effects of bone-anchored maxillary protraction: a controlled study of consecutively treated Class III patients. Am J Orthod Dentofacial Orthop 2010;138:577-81.

31. Eid H, Elsayed W. The effects of combined skeletal anchor plates and removable TMA traction springs in growing patients with maxillary deficiency. Egypt Orthod J 2012;42:75-93.

32. Moon CH. Pros and Cons of Miniscrews and Miniplates for Orthodontic Treatment. In: Park JH (eds) Temporary Anchorage Devices in Clinical Orthodontics. Hoboke, NJ: Wiley Blackwell; 2020; pp.731-8.

33. Lam R, Goonewardene MS, Allan BP, Sugawara J. Success rates of a skeletal anchorage system in orthodontics: A retrospective analysis. Angle Orthod 2018;88:27-34.

34. Sugawara J. Temporary skeletal anchorage devices: the case for miniplates. Am J Orthod Dentofacial Orthop 2014;145:559-65.

35. Lombardo L, Carlucci A, Cervinara F, Siciliani G. A new, no-compliance class II correction strategy using nickel-titanium coil-springs. J World Fed Orthod 2015;4:40-9.

36. Elsheikh M, Manosudprasit M, Godfrey K, Viwattanatipa N. An inverted Forsuse for class III treatment: a pilot typodont study. Kerala Dent J 2003;6:19-24.

37. Moher D, Hopewell S, Schulz KF, Montori V, Gøtzsche PC, Devereaux PJ, et al. CONSORT 2010 explanation and elaboration: updated guidelines for reporting parallel group randomised trials. Int J Surg 2012;10:28-55.

38. World Medical Association

Declaration of Helsinki. Ethical principles for medical research involving human subjects. Bull World Health Organ 2001;79:373-4.

39. Baccetti T, Franchi L, McNamara Jr JA. The cervical vertebral maturation (CVM) method for the assessment of optimal treatment timing in dentofacial orthopedics. Semin Orthod 2005;11:119-29.

40. Loe H, Silness J. Periodontal disease in pregnancy. I. prevalence and severity. Acta Odontol Scand 1963;21:533-51.

41. Bishara SE, Abdalla EM, Hoppens BJ. Cephalometric comparisons of dentofacial parameters between Egyptian and North American adolescents. Am J Orthod Dentofacial Orthop 1990;97:413-21.

42. Menéndez-Díaz I, Muriel J, Cobo JL, Álvarez C, Cobo T. Early treatment of Class III malocclusion with facemask therapy. Clin Exp Dent Res 2018;4:279-83.

43. Auconi P, Scazzocchio M, Cozza P, McNamara JA, Jr., Franchi L. Prediction of Class III treatment outcomes through orthodontic data mining. Eur J Orthod 2015;37:257-67.

44. Souki BQ, Nieri M, Pavoni C, Pavan Barros HM, Junqueira Pereira T, Giuntini V, et al. Development and validation of a prediction model for long-term unsuccess of early treatment of Class III malocclusion. Eur J Orthod 2020;42:200-5.

45. Vanlaecken R, Williams MO, Razmus T, Gunel E, Martin C, Ngan P. Class III correction using an inter-arch spring-loaded module. Prog Orthod 2014;15:32.

46. Bjork A. The face in profile: an anthropological X-ray investigation on Swedish children and conscripts. Lund: Berlingska Boktrycheriet 1947:40–58.

47. Pancherz H. Vertical dentofacial changes during Herbst appliance treatment. A cephalometric investigation. Swed Dent J Suppl 1982;15:189-96.

48. Rosner B. Fundamentals of biostatistics. 8th ed. Boston, MA: Cengage Learning; 2015.

49. Universität Düsseldorf. G*Power. 2019. Available at: http://www.gpower.hhu.de/.

50. Saghaei M. Random allocation software for parallel group randomized trials. BMC Med Res Methodol 2004;4:26.

51. Clark L, Fairhurst C, Torgerson DJ. Allocation concealment in randomised controlled trials: are we getting better? Bmj 2016;355:i5663.

52. Moore KN. Cephalometric effects of Class III treatment: A comparison of ORTA™ and protraction facemask. Master of Science thesis. University of Illinois at Chicago; 2012.

53. Alzabibi BA, Burhan AS, Hajeer MY, Nawaya FR. Short-term effects of the orthodontic removable traction appliance in the treatment of skeletal Class III malocclusion: A randomized controlled trial. Dent Med Probl 2021;58:163-72.

54. Lagorsse A, Gebeile-Chauty S. [Does gender make a difference in orthodontics? A literature review]. Orthod Fr 2018;89:157-68.

55. Cha KS. Skeletal changes of maxillary

protraction in patients exhibiting skeletal class III malocclusion: a comparison of three skeletal maturation groups. Angle Orthod 2003;73:26-35.

56. Merwin D, Ngan P, Hagg U, Yiu C, Wei SH. Timing for effective application of anteriorly directed orthopedic force to the maxilla. Am J Orthod Dentofacial Orthop 1997;112:292-9.

57. De Clerck HJ, Cornelis MA, Cevidanes LH, Heymann GC, Tulloch CJ. Orthopedic traction of the maxilla with miniplates: a new perspective for treatment of midface deficiency. J Oral Maxillofac Surg 2009;67:2123-9.

58. Baik HS, Jee SH, Lee KJ, Oh TK. Treatment effects of Fränkel functional regulator III in children with class III malocclusions. Am J Orthod Dentofacial Orthop 2004;125:294-301.

59. Ngan P, Hägg U, Yiu C, Merwin D, Wei SH. Treatment response to maxillary expansion and protraction. Eur J Orthod 1996;18:151-68.

60. Garattini G, Levrini L, Crozzoli P, Levrini A. Skeletal and dental modifications produced by the Bionator III appliance. Am J Orthod Dentofacial Orthop 1998;114:40-4.

61. Atalay Z, Tortop T. Dentofacial effects of a modified tandem traction bow appliance. Eur J Orthod 2010;32:655-61.

62. Baccetti T, Franchi L, McNamara JA, Jr. Treatment and posttreatment craniofacial changes after rapid maxillary expansion and facemask therapy. Am J Orthod Dentofacial Orthop 2000;118:404-13.

63. Liou EJ. Effective maxillary orthopedic protraction for growing Class III patients: a clinical application simulates distraction osteogenesis. Prog Orthod 2005;6:154-71.

64. Liou EJ. Toothborne orthopedic maxillary protraction in Class III patients. J Clin Orthod 2005;39:68-75.

65. Carriére L. Nonsurgical Correction of Severe Skeletal Class III Malocclusion. J Clin Orthod 2016;50:216-30.

Figure titles:

Fig. (1):(a) Upper Nance. (b) Lingual arch with lower premolar band. (c)CS loaded.

Fig. (2):(a) Right. (b) Frontal. (c) Left.

Fig. (3): (a) Upper Nance with premolar bands. (b) Lingual arch. (c) Reversed Forsus FRD loaded.

Fig. (4): (a) RF. (b) Right. (c) Frontal. (d) left.

Fig. (5): (a)Sagittal view showing reference planes. (b) Frontal view showing sagittal plane

Fig. (6): (a) Sagittal view showing skeletal readings. (b) illustration showing linear sagittal skeletal readings

Fig. (7): (a) Sagittal view showing vertical measurements. (b) illustration of linear vertical skeletal measurements

Fig. (8): (a)Sagittal view showing angular skeletal measurements. (b) illustration of angular skeletal measurements

Fig 9(a): Side view of the class III splint used in the study

Fig 9(b): Occlusal view showing upper

component of the class III splint with posterior hooks to receive class III elastics.

Fig 9 (c): Occlusal view showing lower component of the class III splint with anterior hooks to receive class III elastics.

Fig 9 (d): Frontal view showing Class III splint in patient's mouth.

Fig 9 (e): Side view showing class III splint on patient's right side.

Fig 9 (f): Side view showing class III splint on patient's left side.

Fig. (10): Research design flow chart based on CONSORT statement guidelines.

Table (1): Reference planes.

Table (2): Definition of reference points.Table (3): Sagittal skeletal readings.

Table (4): Vertical skeletal measurements.Table (5): Angular skeletal measurements.

Table (6): Interexaminer reliability regrading all outcomes. Table (7):Demographic characteristics of the study sample.

Table (8): Sagittal skeletal measurements among the study groups. Table (9): Vertical skeletal measurements among the study groups. Table (10): Angular skeletal measurements among the study groups.

Table Legends:

List of abbreviations:

RCT	Randomized control trial
CBCT	Cone beam computed tomography
RF	Reversed forsus fatigue resistant
CS	CS 2000 spring
FM	Face mask therapy
RPE	Rapid palatal expansion
FR III	Frankel functional regulator III appliance
DICOM	(digital imaging and communication in medicine)

Table (1): Reference planes.

Symbol	Name	Definition
HRP	Horizontal referenceplane	Defined by 3 landmarks: right orbitale, left orbitale andporion
MSP	Midsagittal plane	Plane through sella and nasion perpendicular to HRP
SN	Sella-Nasion plane	Plane joining nasion and sella perpendicular to MSP
OL	Occlusal plane	Plane joining the maxillary incisal edge with superiousmesial cusp tip
OLp	Occlusal plane perpendicular	Plane produced by dropping a perpendicular line from sellato the occlusal plane perpendicular to the MSP
OLs	Occlusal plane sella	Plane parallel to OL passing through sella perpendicular tothe MSP
NL	Maxillary plane	Plane joining anterior nasal spine and posterior nasal spine perpendicular to the MSP
ML	Mandibular plane	Plane joining menton and left and right gonion

Table (2): Definition of reference points.

Symbol	Name	Definition
Co	Condylion	The most supero- posterior point on thecurvature of the condylar head
Pg	Pogonion	The most prominent point on the chin
ANS	Anterior nasal spine	The apex of the spina nasalis anterior
A point	Subspinal	The deepest point in the concavity of theanterior maxilla between the ANS and alveolar crest
PNS	Posterior nasal spine	The most posterior point on the contour of thepalate in the midsagittal plane
Me	Menton	The deepest point of the mandibularsymphysis
Go	Gonion	The lowest point of the bony contour of theangle of the mandible
S	Sella	The center of Sella turcica
N	Nasion	The most anterior point of the nasofrontalsuture
B point	Supramental	The innermost point on the contour of the mandible between the incisor and alveolarbone

Table (3): Sagittal skeletal and dental readings.

Variables	Definition
OLp- A pt.	Position of maxillary base
OLp- B pt.	Position of mandibular base (symphysis)
OLp- Pg	Position of mandibular base (chin)
OLp- Co	Position of condyle
Wits appraisal	Position of the maxillary base relative to the mandibular base

Table (4): Vertical measurements.

Variables	Definition
OLs- A pt.	Maxillary vertical position
ANS- Me	Lower facial height

Table (5): Angular measurements.

Variables	Definition
SNA	Maxillary base relative to SN
SNB	Mandibular base relative to SN
ANB	Skeletal relation
SN- NL	Palatal plane angle
SNL- ML	Mandibular plane angle
SN- OL	Occlusal plane angle

Table (6): Interexaminer reliability regrading all outcomes.

Outcomes	ICC	95% CI	P value
SNA	1.00	0.99 -1.00	**<0.0001***
SNB	0.99	0.96 – 0.99	**<0.0001***
ANB	0.99	0.98 – 0.99	**<0.0001***
Wits appraisal	0.98	0.94 – 0.99	**<0.0001***
SNL – NL	0.99	0.99 – 0.99	**<0.0001***
SNL – ML	0.99	0.98 – 0.99	**<0.0001***
SNL - OL	0.90	0.66 – 0.97	**<0.0001***
OLpA	0.99	0.98 – 0.99	**<0.0001***
OLpB	0.99	0.99 – 0.99	**<0.0001***
OLpg	0.99	0.97 – 0.99	**<0.0001***
OLp Co	0.99	0.98 – 0.99	**<0.0001***
OLs A	0.99	0.99 – 1.00	**<0.0001***
ANS Me	0.99	0.98 – 9.99	**<0.0001***

Table (7): Demographic variables and treatment time of the study groups.

		Reverse Forsus (n=11)	CS spring (n=11)	Control (n=11)	Test (P value)
Age: Mean (SD)		10.05 (0.85)	9.73 (0.65)	9.55 (0.82)	1.165 (0.326)
Gender: n (%)	Males	4 (36.4%)	4 (36.4%)	5 (45.5%)	0.254 (0.881)
	Females	7 (63.6%)	7 (63.6%)	6 (54.4%)	
CVM: n (%)	2	7 (63.6%)	6 (54.5%)	7 (63.6%)	0.254 (0.881)
	3	4 (36.4%)	5 (45.5%)	4 (36.4%)	
Treatment time: Mean (SD)		3.59 (0.54)	5.55 (0.52)	-	**8.635 (<0.0001*)**

*Statistically significant at p value≤0.05

Table (8): Sagittal skeletal measurements among the study groups.

			Reverse Forsus (n=11)	CS spring (n=11)	Control (n=11)	Test (*P* value)
OLp-A pt	T0	Mean (SD)	60.36 (3.44)	59.03 (6.05)	58.65 (3.20)	2.963 (0.227)
		Median	62.00	58.50	57.20	
		Min - Max	53.40 – 63.80	50.40 – 73.00	54.30 – 64.80	
	T1	Mean (SD)	63.75 (3.51)	61.96 (5.96)	57.69 (3.03)	**10.478 (0.005*)**
		Median	64.40[a]	62.10[ab]	56.30[b]	
		Min - Max	59.40 – 68.40	53.0 – 76.30	53.90 – 63.20	
	Difference	Mean (SD)	3.38 (1.90)	2.94 (1.06)	-0.96 (0.50)	**21.515 (<0.0001*)**
		Median	3.60[a]	3.10[a]	-0.90[b]	
		Min - Max	0.70 – 6.20	1.30 – 4.20	-1.60 – -0.10	
	Test (*P* value)		**2.937 (0.003*)**	**2.937 (0.003*)**	**2.937 (0.003*)**	
OLp-B pt	T0	Mean (SD)	62.98 (3.67)	60.77 (6.53)	61.24 (3.16)	2.061 (0.357)
		Median	63.80	61.30	61.20	
		Min - Max	55.80 – 67.0	52.00 – 76.00	57.00 – 66.10	
	T1	Mean (SD)	60.12 (4.49)	59.72 (6.04)	62.35 (2.95)	2.546 (0.280)
		Median	62.00	60.20	62.30	
		Min - Max	54.00 – 64.80	50.90 – 73.50	58.90 – 67.00	
	Difference	Mean (SD)	-2.86 (1.51)	-1.05 (1.32)	1.11 (0.40)	**22.024 (<0.0001*)**
		Median	-2.50[a]	-1.10[a]	1.00[b]	
		Min - Max	-5.50 – -1.30	-2.50 – 2.50	0.50 – 2.00	
	Test (*P* value)		**2.943 (0.003*)**	**2.002 (0.045*)**	**2.941 (0.003*)**	
OLp-Pg	T0	Mean (SD)	61.86 (4.35)	60.95 (6.77)	59.81 (2.88)	1.872 (0.392)
		Median	64.40	61.80	60.00	
		Min - Max	54.10 – 65.90	52.10 – 76.80	56.40 – 65.20	
	T1	Mean (SD)	60.98 (6.15)	60.05 (6.19)	61.53 (3.06)	1.104 (0.576)
		Median	63.10	61.40	61.60	
		Min - Max	53.00 – 69.50	51.10 – 74.10	58.20 – 66.90	
	Difference	Mean (SD)	-0.88 (3.24)	-0.90 (1.29)	1.72 (0.87)	**10.078 (0.006*)**
		Median	-2.00[a]	-1.00[a]	1.70[b]	
		Min - Max	-5.70 – 4.70	-2.70 – -1.90	0.70 – 3.40	
	Test (*P* value)		0.935 (0.350)	1.897 (0.058)	**2.937 (0.003*)**	
OLp-Co	T0	Mean (SD)	5.37 (2.31)	7.68 (0.79)	2.23 (1.07)	**20.878 (<0.0001*)**
		Median	5.45[a]	7.70[a]	1.85[b]	
		Min - Max	1.05 – 8.15	6.45 – 9.50	0.80 – 3.85	
	T1	Mean (SD)	4.87 (2.45)	7.80 (0.92)	2.20 (0.98)	**20.677 (<0.0001*)**
		Median	5.50[a]	7.75[b]	1.75[a]	
		Min - Max	1.10 – 8.50	6.50 – 9.50	1.05 – 3.75	
	Difference	Mean (SD)	-0.50 (1.08)	0.13 (0.61)	-0.04 (0.20)	2.150 (0.341)
		Median	-0.05	0.05 (0.60)	-0.10	
		Min - Max	-2.65 – 0.40	-0.95 – 1.40	-0.35 – 0.30	
	Test (*P* value)		1.117 (0.264)	0.711 (0.477)	0.679 (0.497)	

*Statistically significant at p value≤0.05

[abc] Different letter denote significant differences between groups.

Table (9): Vertical skeletal measurements among the study groups.

			Reverse Forsus (n=11)	CS spring (n=11)	Control (n=11)	Test (*P* value)
OLs-A pt	T0	Mean (SD)	32.15 (6.69)	30.45 (4.80)	30.45 (3.59)	0.065 (0.968)
		Median	31.40	32.50	29.60	
		Min - Max	25.30 – 45.80	22.50 – 35.40	25.10 – 35.90	
	T1	Mean (SD)	37.04 (6.71)	34.95 (5.63)	30.78 (3.27)	**7.019 (0.030*)**
		Median	36.60[a]	35.70[ab]	29.80[b]	
		Min - Max	25.90 – 47.30	24.60 – 41.50	26.20 – 35.20	
	Difference	Mean (SD)	4.89 (2.91)	4.50 (3.44)	0.33 (0.69)	**19.525 (<0.0001 *)**
		Median	5.00[a]	3.80[a]	0.30[b]	
		Min - Max	0.60 – 8.30	1.10 – 10.60	-0.80 – 1.10	
	Test (*P* value)		**2.937 (0.003*)**	**2.938 (0.003*)**	1.432 (0.152)	
ANS-Me	T0	Mean (SD)	62.85 (5.78)	58.69 (3.99)	58.90 (3.99)	4.107 (0.128)
		Median	64.80	59.00	59.60	
		Min - Max	55.40 – 72.30	54.10 - 64.40	53.80 - 65.00	
	T1	Mean (SD)	61.80 (6.39)	60.15 (4.25)	59.30 (4.12)	1.419 (0.492)
		Median	64.10	60.00	60.20	
		Min - Max	52.10 - 71.10	54.00 – 66.60	53.80 – 65.60	
	Difference	Mean (SD)	-1.05 (1.52)	1.45 (1.36)	0.40 (0.24)	**13.367 (0.001*)**
		Median	-0.70[a]	2.00[b]	0.40[ab]	
		Min - Max	-3.30 – 0.80	-1.40 – 3.00	0.00 – 0.80	
	Test (*P* value)		1.786 (0.074)	**2.402 (0.016*)**	**2.812 (0.005*)**	

Table (10): Angular skeletal measurements among the study groups.

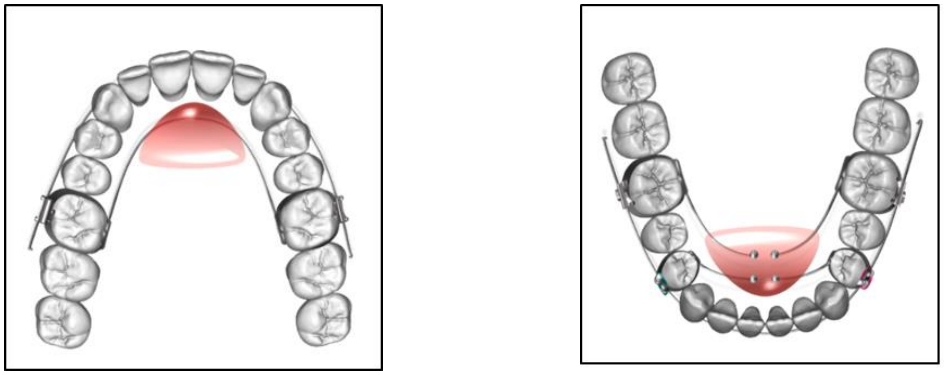
			Reverse Forsus (n=11)	CS spring (n=11)	Control (n=11)	Test (*P* value)
SNA	T0	Mean (SD)	81.10 (3.53)	79.76 (5.36)	78.99 (3.07)	3.814 (0.149)
		Median	82.00	80.30	79.20	
		Min - Max	72.40 – 86.50	71.00 – 86.20	73.90 – 86.00	
	T1	Mean (SD)	83.68 (3.25)	82.47 (4.72)	78.99 (3.07)	**8.335 (0.015*)**
		Median	84.00[a]	83.10[ab]	79.20[b]	
		Min - Max	76.00 – 89.10	74.80 – 88.70	73.90 – 86.00	
	Difference	Mean (SD)	2.58 (0.95)	2.71 (1.03)	0.00 (0.08)	**21.759 (<0.0001*)**
		Median	2.60[a]	2.50[a]	0.00[b]	
		Min - Max	1.20 – 3.70	0.80 – 4.00	-0.20 – 0.10	
	Test (*P* value)		**2.937 (0.003*)**	**2.936 (0.003*)**	0.000 (1.00)	
SNB	T0	Mean (SD)	82.63 (3.71)	82.95 (4.68)	81.85 (2.46)	1.405 (0.495)
		Median	83.30	82.40	82.20	
		Min - Max	74.00 – 88.90	75.00 – 88.00	78.00 – 86.50	
	T1	Mean (SD)	81.54 (2.69)	81.06 (4.93)	82.12 (2.48)	0.259

			Reverse Forsus (n=11)	CS spring (n=11)	Control (n=11)	Test (*P* value)
		Median	81.90	81.20	82.40	(0.879)
		Min - Max	73.30 – 86.70	73.00 – 87.00	78.20 – 86.50	
	Difference	Mean (SD)	-1.09 (1.31)	-1.89 (0.65)	0.26 (0.25)	**16.697 (<0.0001*)**
		Median	-1.00[a]	-2.00[a]	0.20[b]	
		Min - Max	-2.80 – 1.20	-2.90 - -1.00	0.00 – 0.80	
	Test (*P* value)		**2.049 (0.040*)**	**2.938 (0.003*)**	**2.527 (0.012*)**	
ANB	T0	Mean (SD)	-1.52 (0.71)	-3.10 (0.99)	-2.94 (1.39)	12.050 **(0.002*)**
		Median	-1.30[a]	-2.80[b]	-2.70[b]	
		Min - Max	-2.90 - -0.70	-4.90 - -1.80	-5.40 - -0.50	
	T1	Mean (SD)	2.17 (1.05)	1.50 (0.91)	-3.05 (1.33)	**22.749 (<0.0001*)**
		Median	2.40[a]	1.70[a]	-2.90[b]	
		Min - Max	0.20 – 3.60	0.40 – 3.60	-5.20 - -0.50	
	Difference	Mean (SD)	3.69 (1.14)	4.60 (1.08)	-0.11 (0.20)	**22.457 (<0.0001*)**
		Median	4.00[a]	4.40[a]	0.00[b]	
		Min - Max	1.40 – 5.30	3.50 – 6.60	-0.40 – 0.20	
	Test (*P* value)		**2.938 (0.003*)**	**2.937 (0.003*)**	1.791 (0.073)	
Wits appraisal	T0	Mean (SD)	-6.0 (0.0)	-5.0 (0.8)	-5.7 (0.6)	1.018 (0.601)
		Median	-6.0	-5.0	-6.0	
		Min - Max	-6.0 - -6.0	-6.0 - -4.0	-6.0 - -5.0	
	T1	Mean (SD)	-0.70 (0.5)	0.3 (1.0)	-5.7 (0.6)	21.062 **(<0.0001*)**
		Median	-1.0[ab]	0.5[b]	-6.0[a]	
		Min - Max	-1.0 – 0.0	-1.0 – 1.0	-6.0 - -5.0	
	Difference	Mean (SD)	5.25 (0.50)	5.25 (1.71)	0.0 (0.0)	20.874 **(<0.0001*)**
		Median	5.00 [a]	5.50 [a]	0.0 [b]	
		Min - Max	3.00 – 7.000	3.00 – 7.00	0.0 - 0.0	
	Test (*P* value)		**2.938 (0.003*)**	**1.890 (0.059*)**	0.000 (1.00)	1.826 (0.068)
SNL-NL	T0	Mean (SD)	9.43 (3.07)	9.80 (3.10)	14.25 (2.79)	**12.446 (0.002*)**
		Median	10.20	11.50	15.70	
		Min - Max	5.00 – 15.20	3.50 – 12.50	8.50 -17.50	
	T1	Mean (SD)	12.86 (2.90)[a]	8.72 (3.01)[b]	14.29 (2.73)[a]	**13.823 (<0.0001*)**
		Median	13.20[a]	10.10[b]	15.90[a]	
		Min - Max	8.90 – 18.60	1.90 – 11.90	8.50 – 16.90	
	Difference	Mean (SD)	3.44 (2.00)	-1.08 (1.61)	0.04 (0.29)	22.892 **(<0.0001*)**
		Median	3.40[a]	-1.50[b]	0.00[b]	

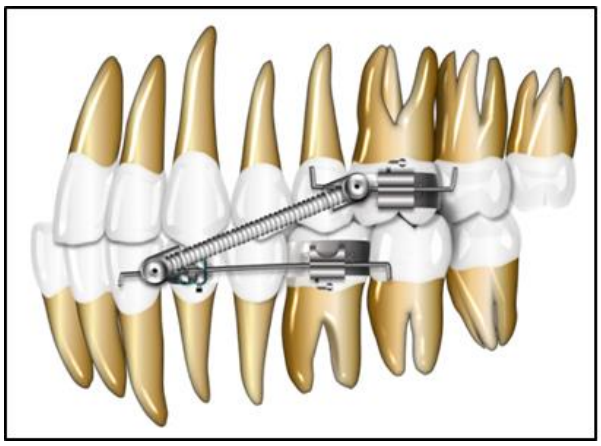
			Reverse Forsus (n=11)	CS spring (n=11)	Control (n=11)	Test (*P* value)
		Min - Max	0.10 – 6.50	-3.20 – 3.20	-0.60 – 0.60	
	Test (*P* value)		**2.937 (0.003*)**	**2.002 (0.045*)**	0.597 (0.551)	
SNL-ML	T0	Mean (SD)	35.60 (3.37)	33.3 (2.61)	34.03 (3.33)	2.776 (0.250)
		Median	36.30	32.50	34.80	
		Min - Max	29.70 – 39.90	30.60 – 38.80	28.80 – 38.10	
	T1	Mean (SD)	28.48 (4.09)	35.89 (3.32)	34.03 (3.33)	**14.058 (<0.0001*)**
		Median	27.90[a]	34.10[b]	34.80[b]	
		Min - Max	20.10 – 35.00	31.80 – 40.10	28.80 – 38.10	
	Difference	Mean (SD)	-7.12 (4.44)	2.59 (2.92)	0	**29.670 (<0.0001*)**
		Median	-7.30[a]	1.20[b]	0[c]	
		Min - Max	-17.50 - -2.60	0.40 – 7.10	0	
	Test (*P* value)		**2.936 (0.003*)**	**2.965 (0.003*)**	0.00 (1.00)	
SNL-OL	T0	Mean (SD)	21.85 (4.76)	16.67 (3.72)	19.16 (3.84)	**7.081 (0.029*)**
		Median	20.00[ac]	15.80[b]	18.70[bc]	
		Min - Max	16.30 – 28.90	9.00 – 22.50	13.10 – 25.30	
	T1	Mean (SD)	16.58 (4.96)	19.68 (3.27)	19.16 (3.84)	1.819 (0.180)
		Median	15.40	18.90	18.70	
		Min - Max	11.00 – 26.20	16.20 – 24.30	13.10 – 25.30	
	Difference	Mean (SD)	-5.26 (3.45)	3.01 (3.14)	0	**27.133 (<0.0001*)**
		Median	-6.60[a]	1.80[b]	0[b]	
		Min - Max	-10.30 - -0.20	-0.10 – 9.70	0	
	Test (*P* value)		**2.938 (0.003*)**	**2.847 (0.004*)**	0.00 (1.00)	

*Statistically significant at p value≤0.05

[abc] Different letter denote significant differences between groups.

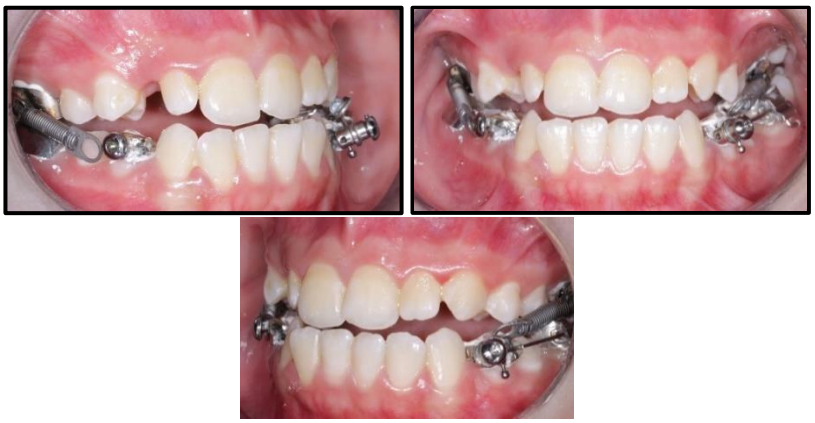


(a) (b)



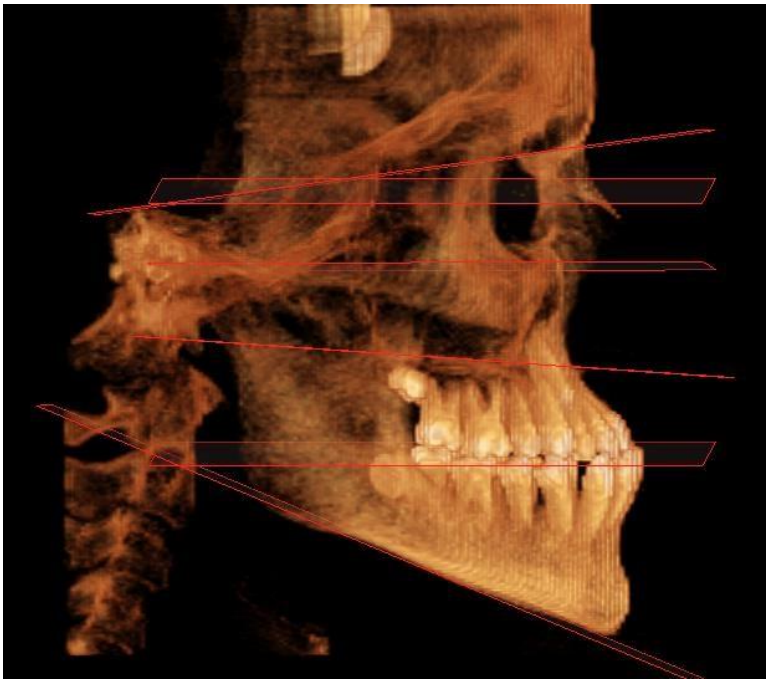
(c)

Fig. (1): (a) Upper Nance. (b) Lingual arch with lower premolar band. (c)CS loaded.

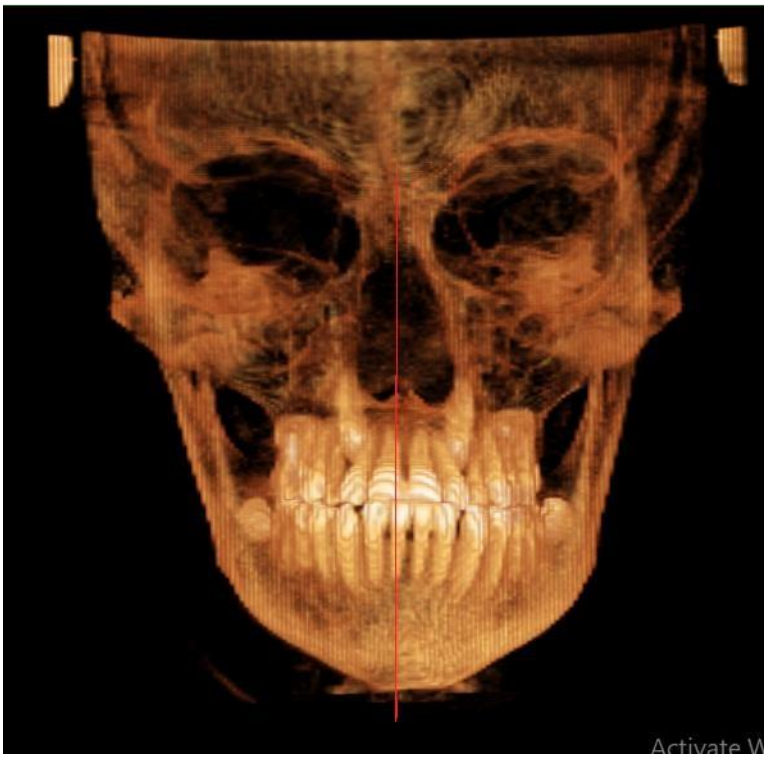


(a) (b) (c)

Fig. (2): (a) Right. (b) Frontal. (c) Left.

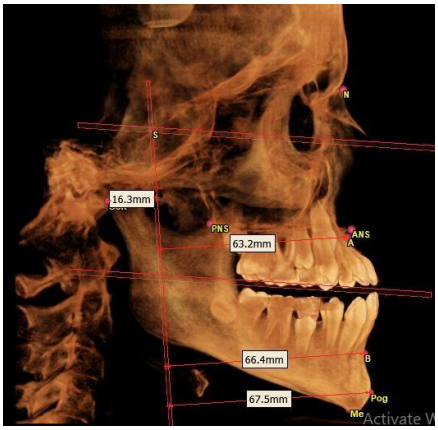


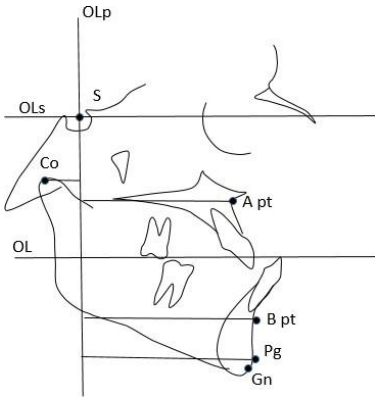
(a)



(b)

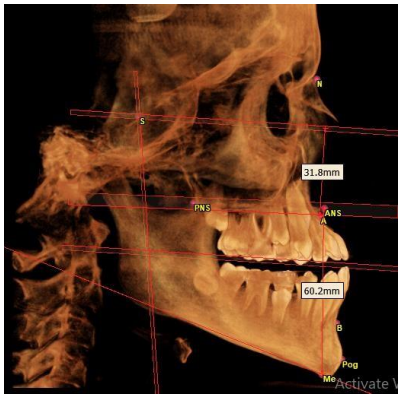
Fig.(5): (a) Sagittal view showing reference planes. (b) Frontal view showing sagittal plane.

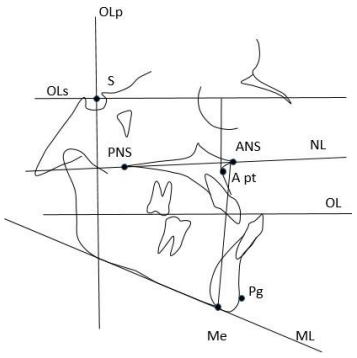




(a) (b)

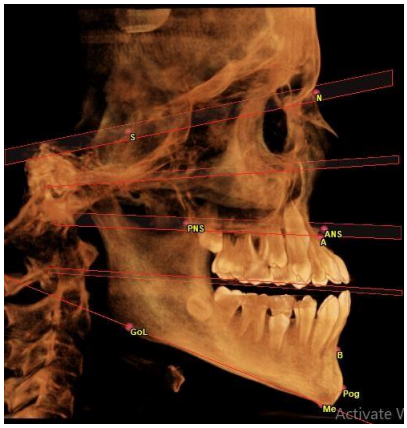
Fig. (6): (a) sagittal view showing skeletal readings. (b) illustration showing linear sagittal skeletal readings

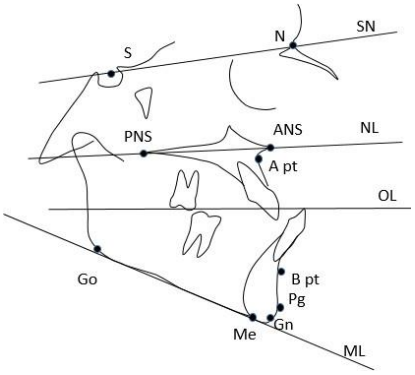




(a) (b)

Fig. (7): (a) Sagittal view showing vertical measurements. (b) illustration of linear vertical skeletal measurements





(a) (b)

Fig. (8): (a) Sagittal view showing angular measurements. (b) illustration of angular skeletal measurements

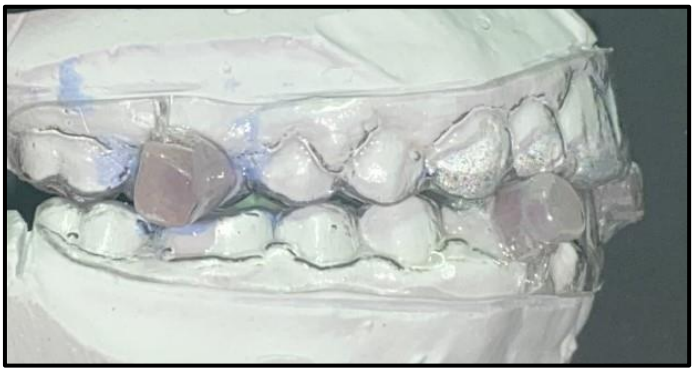


Fig 9(a): Side view of the class III splint used in the study

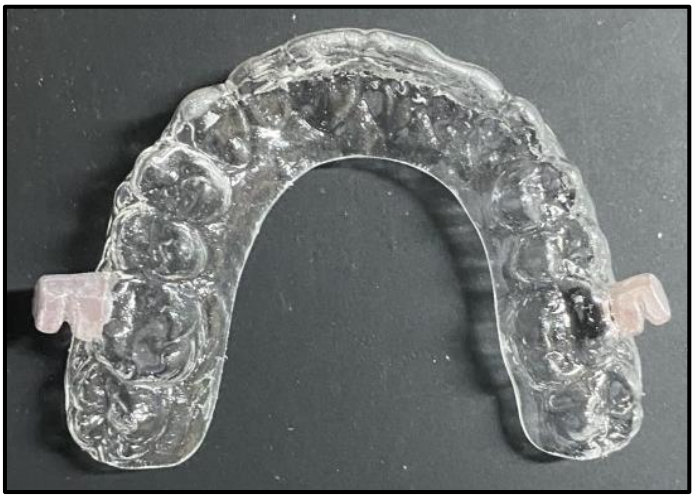


Fig 9(b): Occlusal view showing upper component of the class III splint with posterior hooks to receive class III elastics.

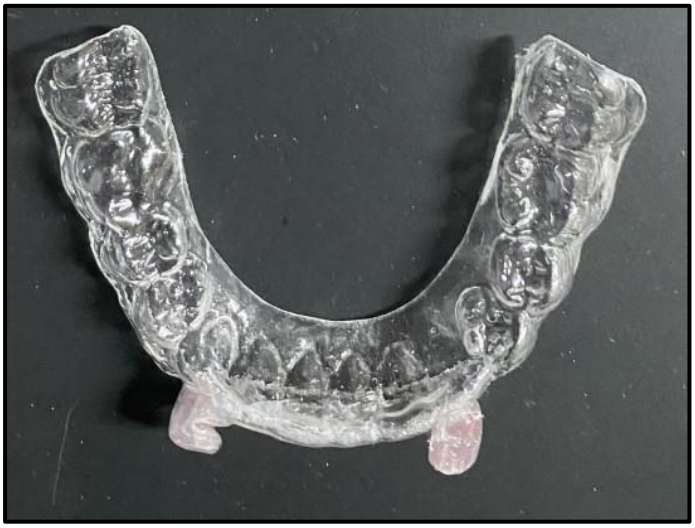


Fig 9(c): Occlusal view showing lower component of the class III splint with anterior hooks to receive class III elastics.

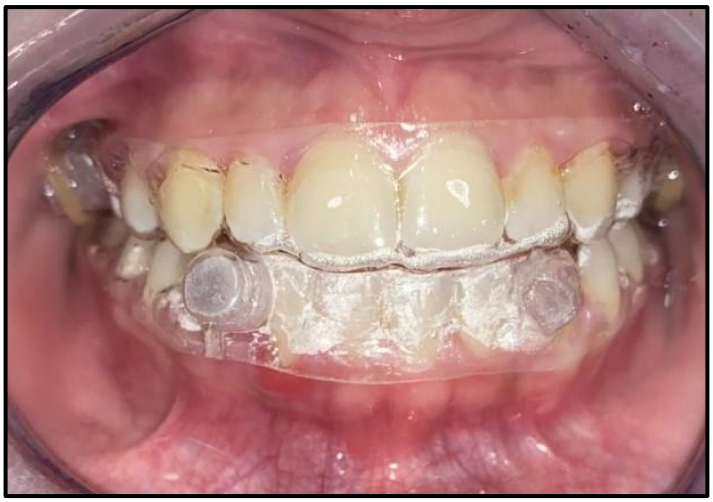


Fig 9 (d): Frontal view showing Class III splint in patient's mouth.

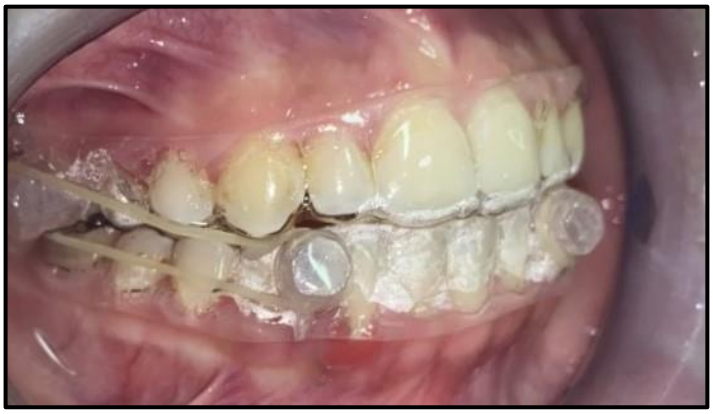


Fig 9 (e): Side view showing class III splint on patient's right side.

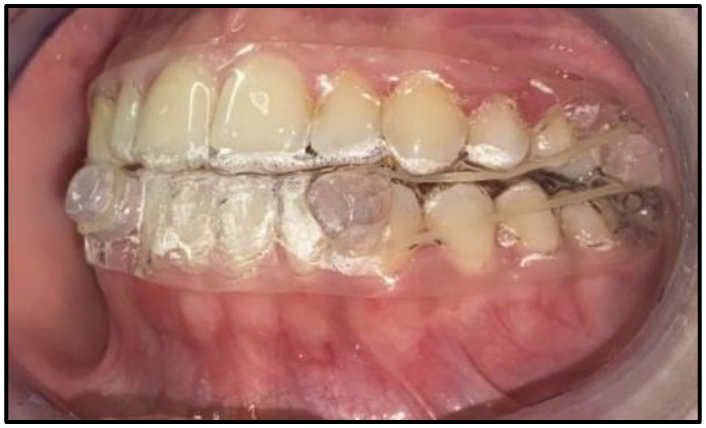


Fig 9 (f): Side view showing class III splint on patient's left side.

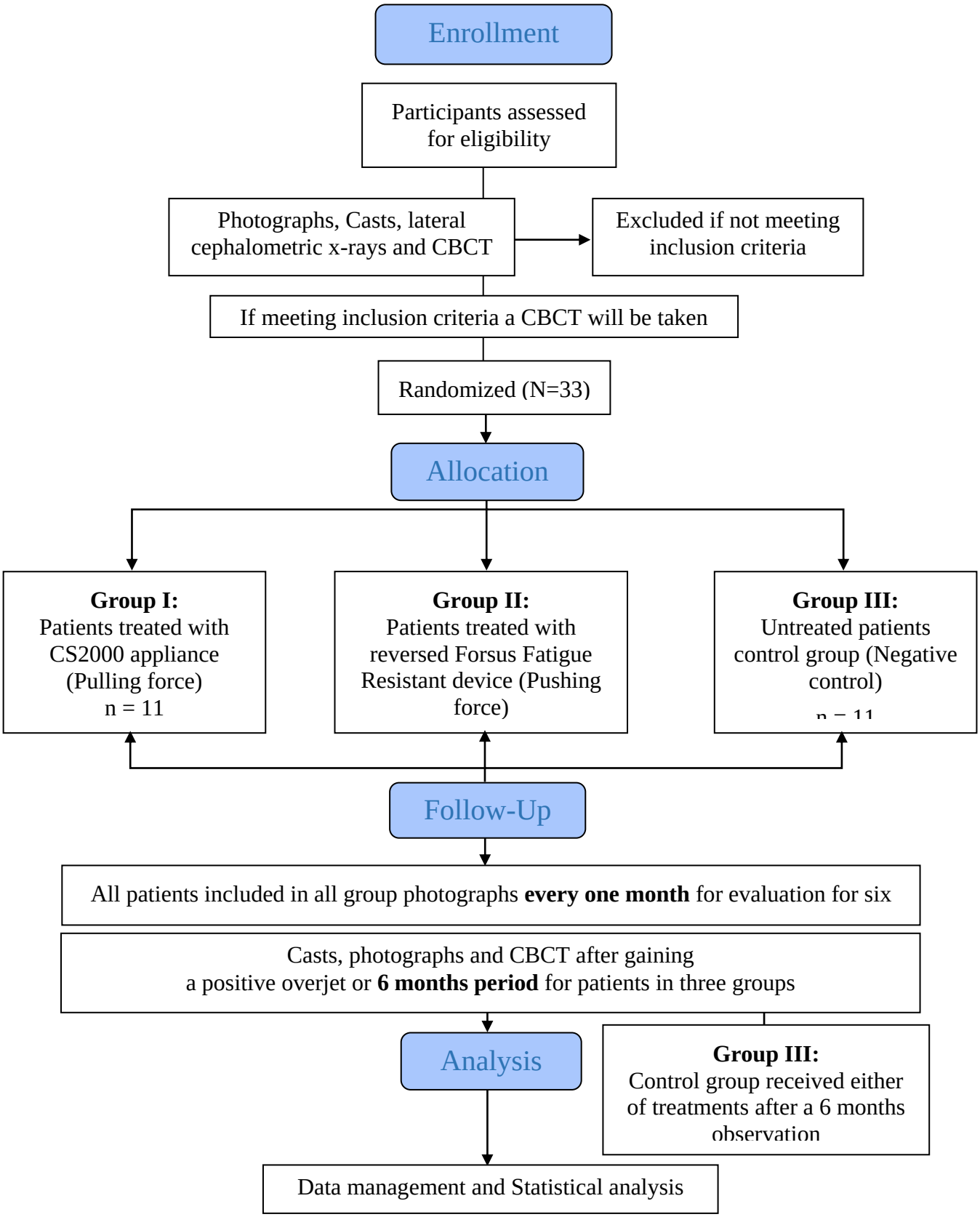


Fig. (10): Research design flow chart based on CONSORT statement guidelines.