Effect of adding daytime Class III Elastics to the alternate rapid maxillary expansion-constriction and reverse headgear therapy - A randomized clinical trial

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Abstract:
OBJECTIVE: To evaluate the skeletal, dental and soft tissue cephalometric changes by addition of daytime Class III elastics to the Alternate Rapid Maxillary Expansion-Constriction (AltRAMEC) and Reverse Headgear (RH) protocol in skeletal Class III patients with maxillary retrusion.

MATERIAL AND METHODS: 54 patients with maxillary retrusion and CVMI (Cervical vertebral maturity index) <CS3 were randomly allocated to an AltRAMEC/RH group (group 1) and AltRAMEC/RH/Class III elastics group (group 2). Each group underwent 5 weeks of AltRAMEC using bonded RME (Rapid Maxillary Expansion) appliance, followed by reverse headgear therapy with a Petit type facemask for 4-5 months. The protraction so obtained was maintained by the use of daytime Class III elastics in group 2. A total of twenty skeletal, dental and soft tissue parameters were evaluated by a blinded examiner. Results were evaluated statistically.

RESULTS: Significant forward movement of the maxilla with counter-clockwise rotation, improved intermaxillary relationships, downward and backward movement of the mandible, and favourable soft tissue changes were observed in both the groups under study. The results were more pronounced in group 2. Increase in vertical dimensions, proclination of maxillary and retroclination of mandibular incisors was also observed. Statistically significant differences were present between the two groups for all of the maxillary and mandibular skeletal, intermaxillary and two of the soft tissue parameters tested; while the differences were not found to be significant for dental parameters.

CONCLUSION: Addition of Class III elastics to the AltRAMEC/RH protocol yielded more pronounced, favourable and statistically significant results.

Keywords: Class III elastics, rapid maxillary expansion/constriction, reverse headgear, skeletal Class III

Introduction

The skeletal Class III malocclusion is characterized by mandibular prognathism, maxillary deficiency or both. Maxillary deficiency clinically presents with a retrusion of the nasomaxillary area and resultant concave profile.1,2 The impact of the Class III malocclusion on the oral health related quality of life has been well documented, with reported negative impact on the masticatory efficiency as well as psychological well-being.3 The use of Rapid Maxillary Expansion (RME) and Reverse Headgear (RH) therapy is widely accepted as the cornerstone of early orthopedic interception in skeletal Class III cases with maxillary retrusion.4-6 The average amount...
of protraction obtained by RME and RH is reported to be 1.5-3 mm in 10-12 months.\textsuperscript{[6,7]}

To open the circum-maxillary sutures more extensively and to improve the effectiveness of maxillary protraction, a novel protocol was presented by Eric Liou,\textsuperscript{[6-10]} which consisted of repetitive maxillary expansion and constriction (AltRAMEC), followed by maxillary protraction. The amount of maxillary protraction achieved was 5-6 mm. Yilmaz et al. have supported these findings.\textsuperscript{[11]} Do-de-Latour and colleagues have, however, disagreed, as they found no significant difference in the amount of maxillary advancement between Alt-RAMEC and RME.\textsuperscript{[12]} This has also been supported by Luz Vieira et al.\textsuperscript{[13]}

Liou’s original system used a double-hinged expander screw, the extensions of which were soldered to maxillary premolar and molar bands.\textsuperscript{[9]} He also advocated the use of intraoral maxillary protraction springs for advancement of the maxilla. The protraction springs were replaced by the reverse headgear for maxillary protraction in the subsequent studies related to this technique.

Banded appliances on the maxilla were used by both Do-de-Latour et al.\textsuperscript{[12]} (with double hinged expander) and Isci et al.\textsuperscript{[14]} (with Hyrax screw). Significant increase in both posterior and anterior face heights was reported, possibly due to molar extrusion seen with the banded expanders. Lorenzo Franchi and colleagues\textsuperscript{[15]} introduced a modified AltRAMEC/RH protocol using deciduous teeth as anchorage, with bonded expanders in a report of two cases. Vertical effects were less pronounced in this study. Previous studies have shown a tendency for increased lower anterior facial vertical dimensions in Class III patients, which can be further worsened by the use of bonded expanders. Cohen and Silverman\textsuperscript{[16]} suggested that bonded RME appliances not only control the vertical dimension, but expand the maxillary halves in a more bodily and symmetrical fashion. Also, the inter-occlusal acrylic is thought to prevent further vertical increase in some hyper divergent patients by an intrusive force to the maxillary and mandibular teeth.

Stephen L-K Yen\textsuperscript{[17]} has reported an added dimension to the Alt-RAMEC protocol being used at the Children’s Hospital Los Angeles to protract the maxilla in cleft patients during adolescence. This includes the use of Class III elastics during daytime to prevent recoil of the gain obtained at night by RH wear. Saad A. Al-Mozany\textsuperscript{[18]} has reported the use of full time Class III elastics worn in conjunction with temporary anchorage devices to protract the maxilla after expansion with the Alt-RAMEC protocol.

A recent meta-analysis by Mohammed Almuzian\textsuperscript{[19]} reported that there was limited evidence with high risk for bias to show that using the Alt-RAMEC protocol in conjunction with Reverse headgear can produce a statistically significant increase in maxillary protraction as compared to the conventional RME.

In the face of conflicting results in the existing literature, more studies to identify the most efficient protocol with minimal side effects is called for. There has been no clinical trial in the literature till date that has combined the beneficial effects of AltRAMEC (with bonded expanders), RH, and Class III elastics for improving facial profile in developing skeletal Class III malocclusion.\textsuperscript{[18-20]}

### Specific objectives/hypotheses

This study aims to quantify the skeletal, dental and soft tissue changes obtained with a protocol of AltRAMEC, RH, and daytime Class III elastics. The null hypothesis generated is that there may be no difference in skeletal, dental and soft tissue changes associated with a modified AltRAMEC protocol using additional daytime Class III elastics as compared to the conventional protocol.

### Methods

#### Trial design

This was a single-blind, parallel-group study with an allocation ratio of 1:1. A control group for which no treatment was given was not included in the study due to ethical issues associated with the deliberate denial of treatment.

#### Participants, eligibility criteria, and setting

This randomized clinical trial was conducted in Department of Orthodontics, Government Dental College, on a sample of skeletal Class III patients with retrusive maxilla. Approval from the Institutional Ethics Committee (IEC no 17/2012/DCC) and informed consent from the parents and patients were obtained. 60 patients were initially selected for the study based on the following criteria: Cervical Vertebral Maturity Index (CVMI) stage < CS3,\textsuperscript{[11]} skeletal Class III with maxillary retrusion as evidenced by ANB < 0, negative or zero overjet and Class III molar relationship with no signs of functional Class III malocclusion. Patients with craniofacial abnormalities, congenitally missing teeth, vertical growth pattern, TMJ disorders, and previous orthodontic or orthopaedic treatment were excluded from the study.

#### Interventions

The patients were randomly allocated into an AltRAMEC/RH group (Group 1) and an AltRAMEC/RH/Class III elastics group (Group 2). The patients in each group underwent 5 weeks of Alternate Rapid Maxillary Expansions and Constrictions using bonded RME appliance.\textsuperscript{[14]} Hyrax RME screws (A2620 Rapid expander, Leone Orthodontic Products,
Sesto Fiorentino, Firenze, Italy) were used for expansion/contraction. Each patient was instructed to expand 1 mm/day (two turns in the morning and two in the evening) for 7 days. A week later, the patients reported for assessment of the expansion achieved. Expansion was evaluated clinically by the presence of midline diastema and the palatal grooves of maxillary teeth approximating the buccal cusps of the mandibular teeth. An occlusal radiograph was also taken at this point to ensure radiographic evidence of opening of the midpalatal suture. If satisfactory, the patients were then instructed to constrict the bonded RME 1 mm/day for 7 days by unwinding the expander. Sufficient time was spent with the patients and parents to make sure that they were able to do this properly. The patients then present a week later for assessment of the constriction. This expansion-contraction cycle was continued for another 3 weeks. After 5 weeks of alternating expansion and contraction, the mobility of the maxilla was subjectively assessed. This was done by supporting the forehead and bridge of nose with one hand and holding the maxillary incisors with another. The maxilla was then moved in a back and forth motion. Intermaxillary protraction was commenced when “disarticulation” was achieved as evidenced clinically by mobility of the maxilla in the anteroposterior direction.

Maxillary protraction facemask therapy was achieved with a Petri type facemask (Ormco Corporation, Glendora [CA], USA) for 14 hrs/day (night-time wear) for 4-5 months. A force of 500 gm per side with the force vector directed approximately 30 degrees anteroinferiorly to the occlusal plane was applied from hooks placed in the canine region of the buccal surface of bonded expanders. The protraction force was measured using a Dontrix gauge (American Orthodontics, Sheboygan, Wis). The protraction obtained thus was maintained by ¼ inch (4.5 oz), blue Class III elastics (TP Orthodontics Inc., La Porte, Indiana, USA), during day time, only in Group 2 [Figure 1]. The Class III elastics were worn from hooks incorporated in the canine region of mandibular splints to hooks incorporated in the molar region of buccal surface of the bonded maxillary RME appliance. The position of hooks was adjusted to deliver approximately 4.5 oz. force in each patient as measured by the Dontrix gauge. Patients were instructed to keep a record of the daily use of the appliance.

**Outcomes and any changes after trial commencement**

Treatment results were evaluated cephalometrically. For each patient, the first lateral cephalogram was taken at the initiation of treatment (T1) and a second cephalogram (T2) was taken at the end of reverse headgear therapy. In this way, (T2 - T1) represented the effect as a result of appliance therapy. A control group of patients, to whom no treatment was given, was not included in this study due to ethical issues. All lateral cephalograms were taken with Frankfurt Horizontal plane parallel to the floor, lips in relaxed position and with the teeth in maximum intercuspal position. All the radiographs were taken by a trained radiographic technician of the institution using the same cephalostat in a standardized manner. The Plan Meca 2002 CC Proline Cephalostat was used. Lateral cephalograms were traced and superimposed with the Nemotec software for the selected parameters. Digitized cephalograms were imported into the computer software Nemotec Dental Studio NX 2005. Calibration was done to the SN (Sella-Nasion) plane in order to ensure same proportions for the pre- and post-treatment cephalograms. Hard and soft tissue reference points were identified, which enabled the software to perform the analysis. A customized analysis was done in the software in which FH plane was used as X-axis (Horizontal Reference Line) and a line perpendicular to the X axis through Pt (Pterygomaxillare) served as the Y-axis (Vertical Reference Line-VRL). A total of 20 skeletal, dental and soft tissue parameters were evaluated which included 11 linear and 9 angular measurements [Table 1].

**Sample size calculation**

The sample size was calculated using PS (Power and Sample size program). According to data from a previous study for the parameter VRL-A (Vertical Reference Line to Point A), with pooled standard deviation 1.25, if the true difference between the means is 1.17, we will need to study 25 subjects from each group to be able to reject the null hypothesis that the population means of the two groups are equal with probability (power) 0.9. The Type I error probability associated with testing of this null hypothesis was 0.05. To increase the power of the study and compensate for possible dropouts during the study period, it was decided to include more patients.
Randomization, allocation concealment and blinding
Subjects were randomly allotted to group 1 or group 2 with an allocation ratio of 1:1. For the execution of planned single blinded study, blocks of random numbers were assigned using computer generated tables. The random numbers were generated and allocated by a data monitoring person to make sure that the principal investigator and the study subjects were not involved in the allotment of treatment arms. Blinding was possible only with regard to evaluation of cephalometric radiographs. The tracings were performed randomly, by a blinded examiner, well versed with the software. The tracings were later reassembled into specific groups. After two weeks, 15 radiographs were selected and all procedures including tracing, identification of landmarks and measurements were repeated by the same clinician.

Statistical analysis
All the statistical analyses were performed using a Statistical Product and Service Solutions (SPSS Inc., Chicago III, version 16) for windows. Intra-examiner reliability was tested using the ICC (Intraclass Correlation Coefficient) [Table 2]. The independent t test was used to compare the treatment changes of group 1 with group 2. In this study, the level of significance was set as \( P < 0.05 \).

Results

Data of 60 skeletal Class III patients who reported to the department were examined by two clinicians (unrelated to the study). Out of these 4 patients failed to meet one or more of the eligibility criteria. 2 patients expressed their unwillingness to participate in the trial. The remaining 54 patients were randomised and allocated into an AltRAMEC/RH group (group 1) or an AltRAMEC/RH/Class III elastics group (group 2). Two patients (one each from Group 1 and Group 2) discontinued treatment during the course of intervention one owing to discomfort during the intervention and the other patient due to lack of sufficient skill on the parent’s side for activation of the hyrax screws. Eventually 26 patients each in group 1 and group 2 were analysed [Figure 2]. Average treatment time was 6 months. 52 patients completed maxillary protraction therapy.

Tests of normality and evaluation of the baseline data
The comparisons of the chronological ages, gender and maturation distribution [Table 3], showed that the groups were well matched. The Shapiro-Wilk test showed that the data was normally distributed. Therefore, parametric tests were used. The results of the Student’s \( t \)-test comparing the initial measurements between the groups are shown in Table 4. No statistically significant differences were observed between the groups for any of the variables tested.

Evaluation of the intergroup differences
Both the groups under study showed forward movement of the maxilla [Table 5]. Group 2 showed a statistically significant higher change \( (P < 0.001) \) as evidenced by SNA, FH N–A and VRL A. Backward movement of mandible was also observed to be significantly more in Group 2, resulting in highly significant difference in the intermaxillary parameters \( (P < 0.001) \). There was an increase in vertical dimensions in both groups as evidenced by Go–Gn to SN, ANS-PNS to Go-Gn and Ant Facial Height, with higher change in Group 2 \( (P < 0.05) \). Group 2 also showed more significant changes in nasolabial angle and Ls to E line \( (P < 0.001) \). Inclination of lower incisors to mandibular plane decreased in both groups, but to a lesser extent in Group 2.

Harms
Although no serious harms were observed during intervention, patients did report pain and discomfort especially during the AltRAMEC phase of treatment. Also varying degrees of gingival inflammation and bleeding was observed after removal of the bonded splints.

Discussion

Limitations of the study
Patient compliance was a key factor during treatment while using facemask and Class III elastics. Also, it was
Interpretations

It has been reported that facemask should be started at early ages because sutures become highly inter-digitated as age advances and dental, rather than skeletal changes are obtained at older ages. Hence the rationale for including subjects with CVMI < 3 as sample for this study.

Maxilla is articulated with nine other bones of the craniofacial complex. Palatal expansion helps to initiate the cellular response which in turn helps to disarticulate the maxilla from the craniofacial complex by opening the sagittal as well as circummaxillary sutures. The AltRAMEC protocol disarticulates the circummaxillary sutures without over-expansion. Liou’s original system used a 2 hinged rapid maxillary expander and an intraoral tooth borne maxillary protraction spring. Frequent breakages necessitating replacements at almost every appointment has been reported by Yen in 2011. Moreover, the intraoral protraction springs reportedly produced open bite during the protraction. Hence the present study modified the original technique to use standard HYRAX rapid maxillary expansion appliance and Petit type reverse pull headgear utilizing a downward direction of pull. The use of such a standard technique makes the AltRAMEC technique accessible to most orthodontists. After wearing a facemask to “pull” the maxilla forward during the night, use of Class III elastics to “hold” the results obtained has been

### Table 2: Intraclass correlation co-efficient (ICC) showing the level of agreement

| Cephalometric parameter | ICC  |
|-------------------------|------|
| SNA                     | 0.988|
| VRLA                    | 0.997|
| VRLB                    | 1.000|
| Overjet                 | 0.993|

### Table 3: Comparisons of the Demographic Data Between the Groups

|                      | GROUP 1     | GROUP 2     | P     |
|----------------------|-------------|-------------|-------|
| Chronological age    | 10.00±1.240 | 10.23±1.013 | 0.603 |
| Maturation stages    | 2.00±0.961  | 1.92±0.862  | 0.829 |
| Gender distribution  | 16/10       | 12/14       | 0.785 |

not possible to blind the principle investigator or study subjects. Hence, evaluation was performed by another blinded investigator.

### Generalizability

As this research was performed at a single centre, generalizability would be limited. Multi-centre trials in future are warranted to overcome this limitation. Also only patients whose maturity status < CVMI stage 3 were included in this study and older patients may have different growth characteristics and respond differently to the treatment.
advocated by Stephen L K Yen. This is the protocol being followed at the Children’s Hospital Los Angeles for late maxillary protraction in cleft patients. If a patient did not wear Class III elastics, it is postulated that any gain obtained at night would recoil back during the day and there would be no net gain in antero-posterior correction. However, whether the use of daytime Class III elastics in addition to maxillary protraction offers any additional benefit to the patient has, thus far, not been investigated.

Table 4: Comparison of initial measurements between the groups

| Parameter               | Group 1 | Group 2 | Significance |
|-------------------------|---------|---------|--------------|
|                         | Mean    | Standard deviation | Mean     | Standard deviation |          |
| Maxillary               |         |                     |          |                      |
| SNA (°)                 | 76.99   | 2.857               | 76.70    | 3.124               | 0.726    |
| FH-N-A (mm)             | -6.64   | 4.267               | -6.28    | 2.764               | 0.724    |
| SN/ANS-PNS (°)          | 8.54    | 4.274               | 10.55    | 3.107               | 0.064    |
| U1 to palatal plane (°) | 121.12  | 3.58                | 119.02   | 5.471               | 0.099    |
| VRL-A (mm)              | 45.87   | 5.037               | 45.51    | 2.838               | 0.749    |
| Mandibular              |         |                     |          |                      |
| SNB (°)                 | 82.112  | 4.214               | 79.99    | 3.871               | 0.065    |
| Go-Gn to SN (°)         | 31.50   | 5.237               | 31.027   | 5.237               | 0.782    |
| L1/MandP (°)            | 69.51   | 6.063               | 69.792   | 7.5075              | 0.883    |
| VRL-B (mm)              | 47.53   | 8.939               | 47.82    | 4.924               | 0.399    |
| VRL-Pog (mm)            | 46.14   | 11.009              | 45.25    | 5.338               | 0.713    |
| Intermaxillary          |         |                     |          |                      |
| ANB (°)                 | -3.60   | 2.499               | -3.04    | 2.302               | 0.408    |
| ANS-PNS/Go-Gn (°)       | 23.94   | 5.950               | 24.70    | 5.555               | 0.634    |
| Overbite (mm)           | 1.569   | 1.456               | 1.488    | 1.856               | 0.862    |
| Overjet (mm)            | -1.54   | 1.309               | -1.69    | 1.704               | 0.227    |
| Soft tissue             |         |                     |          |                      |
| Ls-E line (mm)          | -3.83   | 2.462               | -3.77    | 2.079               | 0.923    |
| Li-E line (mm)          | 0.80    | 1.846               | 1.19     | 1.837               | 0.446    |
| Nasolabial angle (°)    | 105.04  | 8.038               | 108.219  | 7.911               | 0.158    |
| VRL-Pgs (mm)            | 57.419  | 10.091              | 55.25    | 4.776               | 0.335    |

Table 5: Statistical Analyses of the difference in mean treatment changes between groups

| Parameter               | Post-treatment changes | Difference between groups |
|-------------------------|------------------------|--------------------------|
|                         | Mean   | Standard deviation | Mean   | Standard deviation | Mean Diff | 95% Confidence Interval of the difference |
|                         | Group 1 |                     | Group 2 |                      |          | Lower       | Upper       |
| SNA (°)                 | 2.93   | 1.29                | 5.45   | 2.36                | 0.002    | 2.523       | 3.583       | 1.462       |
| FH-N-A (mm)             | 3.20   | 1.66                | 7.28   | 3.59                | 0.001    | 4.080       | 5.639       | 2.522       |
| SN/ANS-PNS (°)          | 0.41   | 0.43                | 0.50   | 0.00                | 0.322    | 0.0846      | 0.254       | 0.085       |
| U1 to palatal plane (°) | 0.58   | 1.01                | 1.02   | 0.69                | 0.073    | -0.442      | -0.927      | -0.042      |
| VRL-A (mm)              | 3.26   | 1.40                | 5.13   | 1.91                | 0.001    | 1.861       | 2.796       | 0.926       |
| SNB (°)                 | -0.38  | 1.51                | -1.07  | 0.49                | 0.032    | 0.692       | 0.063       | 1.321       |
| Go-Gn to SN (°)         | 1.36   | 1.49                | 2.5    | 1.51                | 0.009    | 1.138       | 1.975       | 0.301       |
| PFH                     | 1.57   | 1.69                | 2.10   | 2.92                | 0.427    | 0.530       | 1.861       | 0.800       |
| AFH                     | 2.62   | 3.71                | 4.34   | 1.47                | 0.033    | 1.719       | 3.294       | 0.144       |
| L1/MandP (°)            | -4.64  | 2.53                | -2.36  | 3.05                | 0.046    | -2.28       | -2.453      | -0.199      |
| VRLB                   | -1.50  | 1.50                | -2.65  | 1.23                | 0.004    | -1.142      | -0.374      | -1.909      |
| VRLPog                 | -1.23  | 3.91                | -2.86  | 1.31                | 0.049    | -1.630      | -0.005      | -3.256      |
| ANB                    | 3.31   | 1.43                | 4.66   | 1.09                | 0.003    | 1.346       | 2.058       | 0.633       |
| ANS-PNS/Go-Gn (°)       | 2.00   | 2.38                | 3.31   | 1.73                | 0.027    | 1.319       | 2.481       | 0.156       |
| OBIT                    | -0.23  | 1.7                 | -2.41  | 2.71                | 0.001    | 2.183       | 0.911       | 3.455       |
| OJET                   | 4.88   | 1.84                | 8.22   | 2.03                | 0.001    | 3.334       | 4.417       | 2.251       |
| Ls-E line (mm)          | 1.76   | 1.83                | 4.33   | 2.65                | 0.002    | 2.561       | 3.832       | 1.290       |
| Li-E line (mm)          | -0.60  | 1.65                | -1.38  | 1.49                | 0.079    | -0.784      | -0.094      | -1.663      |
| Nasolabial angle (°)    | -1.21  | 1.26                | -4.06  | 3.64                | 0.001    | 2.850       | 1.329       | 4.370       |
| VRL-Pgs (mm)            | -2.88  | 3.01                | -2.45  | 1.70                | 0.522    | -0.438      | -1.803      | -0.927      |
The present study aimed to combine the beneficial effects of AltRAMEC (with bonded expanders to eliminate unwanted increase in vertical dimensions), RH, and Class III elastics, for improving facial profile in developing skeletal Class III malocclusion and to assess if there are statistically significant differences between the two groups with respect to the parameters selected.

Maxillary parameters

In previous studies, in which maxilla was protracted following AltRAMEC protocol, similar values to that found in group 1 (2.93 ± 1.29 mm) for forward movement of point A were noted by Luz Vieira[,] (2.33 mm), Do deLatour[,] (1.8 mm) and Kaya[,] (2 mm using AltRAMEC and miniscrews). Higher values for the same were found in studies by Liu[,] (5.8 ± 2.3 mm), Isci[,] (3.2 ± 1.2 mm in first 6 months), Canturk[,] (3.02 ± 1.04), Liu (3.04), and Saad A. Al-Mozany (3.34 ± 1.54).]

The amount of forward movement of point A in group 2 (5.45 ± 2.363) was comparable to that gained by Liu, Isci, Canturk, and Liu.[]

It should be noted here that in Liou’s study, 3 mm of protraction was attributed to the biomechanical properties of double hinged expander which was used in their study and only 2.9 mm to the intra-oral protraction springs.[] According to them, presence of the 2 hinges in their expander makes each half of the maxilla rotate outward and forward around the maxillary tuberosities, rather than around the PNS (posterior nasal spine) as the HYRAX (Hygienic rapid maxillary expander) does. Also the protraction springs provided a continuous force for 24 hours. Similarly the increased movement of point A reported by Isci and Canturk, can be attributed to longer durations of facemask wear (approx. 16-20 hrs) and higher total treatment time (approx. 7-12 months). In the present study, in spite of using simple Hyrax RME screws for expansion-constriction, a smaller duration of protraction (14 hours/day) and lesser total treatment time (6-7 months), greater forward movement of point A was obtained in group 2. This may probably be due to the fact that the protraction gained by night-time use of facemask was maintained and prevented from relapsing due to daytime wear of Class III elastics. The benefit of using daytime Class III elastics was the ability to reduce facemask use to night time wear alone, with results simulating 24 hours a day. From our experience, 14 hours seems to be a reasonable duration of wear that can be expected from school going children.

There is also the counter clockwise rotation of the maxilla in both groups, in spite of the downward direction of protraction force applied. This could be due to the point of application of force being below the centre of resistance.[]

The direction of rotation of maxilla is in agreement with previous studies.[] The upper incisor proclination was negligible in group 1 (0.58 ± 1.017), which is in agreement with Luz Vieira, Kaya and Liu. It is lesser than that reported by Isci (1.5 mm), Canturk (2.8 mm) and Saad Al-Mozany (2.98). But, higher values have also been obtained in previous studies by Do deLatour (5.5 mm) and Liu (7.1 ± 4.0), possibly due to the double-hinged expander used by both, which has a lingual bar that extends forward and touches the maxillary incisors’ cingulum area. The intraoral protraction spring used by Liu could also have contributed to a higher dental change in his sample.[]

The slightly higher amount of upper incisor proclination found in Group 2 (1.023 ± 0.693) in the present study, although not statistically significant, could be attributed to the effect of Class III elastics.

Mandibular parameters

There was a downward and backward rotation of the mandible in both groups, as evidenced by SNB, VRL-B (Vertical reference line to point B) and VRL-Pog (Vertical reference Line to Pogonion). There was also increase in the vertical dimensions in both groups as evidenced Go–Gn toSN and Ant Facial Height N–Me. These changes in general showed higher values in Group 2, which could be attributed to the addition of Class III elastics, and the difference between the groups was found to be statistically significant. Similar changes were found in nearly all of the previous studies.[]

Lower incisors were retroclined in both groups, as evidenced by L1/MandP (lower incisor to mandibular plane angulation), but more so in Group 1. The retroclination in Group 2 was less probably due to the splints placed in the lower arch for engagement of Class III elastics, which would have prevented retroclination of lower incisors to an extent.

Intermaxillary

ANB, ANS–PNS/Go–Gn (maxillo-mandibular plane angle) and Overjet increased, while the overbite decreased in both the groups and these findings were in line with those of previous studies.[] Improvement in all the intermaxillary parameters was more pronounced in Group 2 and the difference was statistically significant for all parameters.

Soft tissues

The upper lip moved forward, the lower lip and soft tissue pogonion backward and nasolabial angle increased in both groups, thus improving the soft tissue profile. The changes were significantly more pronounced in Group 2 for upper lip and nasolabial angle than soft tissue pogonion and lower lip. The soft tissue changes in both the groups was in agreement with findings of Kaya, Isci and Canturk. But Liu and co-workers found a more pronounced change in the lower lip than
the upper lip in their study group. Rest of the studies focused primarily on the dento-skeletal effects rather than the soft tissue effects.

**Conclusion**

The results of this trial show that including Class III elastics in the AltRAMEC/RH protocol has clinically and statistically significant benefits, as compared to using the AltRAMEC/RH protocol alone. These include an increase in skeletal effects like maxillary protraction, backward rotation of the mandible and improvement in sagittal maxilla-mandibular relationship, reduced dental effects like retroclination of lower incisors and better soft tissue response in the form of forward movement of the upper lip.

To summarize, favourable skeletal, dental and soft tissue cephalometric changes towards correction of the skeletal Class III malocclusion were obtained in both groups under study but the results were significantly more pronounced when Class III elastics were used in addition to the AltRAMEC/RH protocol.

Registration: This trial was registered under the Clinical trials Registry. (CTRI/2013/09/004027).

Protocol: The protocol was not published before trial commencement.

**Declaration of patient consent**

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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**Conflicts of interest**

There are no conflicts of interest.

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