Effects of hybrid-Hyrax, Alt-RAMEC and miniscrew reinforced heavy Class III elastics in growing maxillary retrusive patients. A four-year follow-up pilot study

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Introduction: The aim of this study was to evaluate the short- and long-term effects of hybrid-Hyrax, Alt-RAMEC and applied, miniscrew reinforced, heavy intermaxillary elastics on a modified lingual arch in growing skeletal Class III patients.

Methods: Fifteen subjects (seven male, eight female) were included, with an average age of 12.52 ± 0.94 years, of cervical vertebrae maturation (CVM) stage CS2-CS4 and skeletal Class III malocclusions due to a retrognathic maxilla. Nine weeks of Alt-RAMEC were followed by eight to nine weeks of maxillary protraction with heavy 400 gm Class III elastics worn 24 h/day. Treatment was finalised with orthodontic fixed appliances. Cone beam computed tomographic (CBCT) scans were taken initially (T1), at the end of maxillary protraction (T2) and four years after active orthopaedic treatment (T3). Cephalometric measurements were performed on reconstructed lateral cephalograms and the differences between time intervals were calculated using an analysis of variance (ANOVA).

Results: A positive overjet was achieved in all but one subject. From T1 to T2, A point advanced 3.12 ± 3.42 mm and from T2 to T3 advanced a further 2.21 ± 3.49 mm. Significant initial increases in SNA of 1.05° ± 1.10° (p = 0.004), ANB of 2.71° ± 1.01° (p = 0.00), Wits of 4.49 ± 2.21 mm (p = 0.00) and overjet of 4.90 ± 1.66 mm (p = 0.00) were accomplished and maintained without significant changes in the vertical dimension. Upper and lower incisor inclinations were not affected by the protraction protocol but significantly increased (U1-PP: 8.39° ± 5.59°) between T2 and T3. SNB decreased initially by 1.67° ± 1.34° (p = 0.00) but relapsed due to residual mandibular growth and a counterclockwise rotation of the mandibular plane. Conclusion: The hybrid-Hyrax Alt-RAMEC combined with miniscrew reinforced heavy Class III elastics resulted in a favourable and stable Class III correction.

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Introduction

Rapid Maxillary Expansion (RME) in conjunction with facemask (FM) protraction has been a treatment option in Class III correction when maxillary retrusion is a contributing factor in the aetiology of the malocclusion.1,2 In addition, Class III subjects show larger mandibular plane angles, gonial angles, mandibular ramus and corpus length and a lower face height, whereas maxillary length, ANB and the Wits appraisal are, and remain, much smaller from six to 16 years of age compared with Class I subjects.3 This aberrant pattern of craniofacial growth, expressed
as a worsening of maxillomandibular relationships over time, makes management of Class III patients a challenge in clinical practice.

Significant favourable effects of RME/FM treatment include forward maxillary movement, a reduction of mandibular projection and an improvement in the relative intermaxillary discrepancy, with the long-term stability of observed skeletal changes attributed mainly to the early establishment of positive overbite and overjet relationships. The effectiveness of orthopaedic treatment is increased when applied during the early mixed or late deciduous dentition stage instead of during the late mixed dentition period of development. Late treatment resulted mainly in a restriction of mandibular growth, whereas early treatment produced favourable skeletal effects in both maxillary and mandibular bases. Even though overall occlusal correction was attributed to skeletal rather than dental changes in the early and late treated groups, improvements in mandibular size were related to significant changes in mandibular shape only in early treated subjects. In addition, RME/FM can result in straightening of the skeletal profile and an improvement in the incisal relationship, both of which subsequently improve soft tissue profile and lip posture. Correlations between hard and soft tissue changes have shown that forward soft tissue movement was 50–79% of the corresponding maxillary hard tissue movement, while downward and backward movement of the soft tissues was 71–81% of the changes seen in the mandibular hard tissues.

Despite a skeletal contribution in the correction of the maxillomandibular discrepancy, FM treatment with or without RME has been also related to individual variations in treatment response and a series of dentoalveolar side effects. These include forward movement of the maxillary dentition, increased proclination of the maxillary incisors, retroclination of the mandibular incisors, a counterclockwise rotation of the maxillary plane of development, increased dentoalveolar side effects. These include forward maxillary movement, a reduction of mandibular projection and an improvement in the relative intermaxillary discrepancy, with the long-term stability of observed skeletal changes attributed mainly to the early establishment of positive overbite and overjet relationships. The effectiveness of orthopaedic treatment is increased when applied during the early mixed or late deciduous dentition stage instead of during the late mixed dentition period of development. Late treatment resulted mainly in a restriction of mandibular growth, whereas early treatment produced favourable skeletal effects in both maxillary and mandibular bases. Even though overall occlusal correction was attributed to skeletal rather than dental changes in the early and late treated groups, improvements in mandibular size were related to significant changes in mandibular shape only in early treated subjects. In addition, RME/FM can result in straightening of the skeletal profile and an improvement in the incisal relationship, both of which subsequently improve soft tissue profile and lip posture. Correlations between hard and soft tissue changes have shown that forward soft tissue movement was 50–79% of the corresponding maxillary hard tissue movement, while downward and backward movement of the soft tissues was 71–81% of the changes seen in the mandibular hard tissues. Despite a skeletal contribution in the correction of the maxillomandibular discrepancy, FM treatment with or without RME has been also related to individual variations in treatment response and a series of dentoalveolar side effects. These include forward movement of the maxillary dentition, increased proclination of the maxillary incisors, retroclination of the mandibular incisors, a counterclockwise rotation of the maxilla and a clockwise rotation of the mandible.

In an effort to minimise the dentoalveolar component of Class III correction, the point of force application for maxillary protraction is transferred away from the dentition and closer to the centre of resistance of the maxilla. Alternative treatment approaches have been developed utilising temporary skeletal anchorage such as titanium miniplates and/or mini-implants and miniscrews. Bone Anchored Maxillary Protraction (BAMP) with titanium miniplates loaded with elastic forces directly on the skeletal plates has produced promising results, with an overall success rate of 97% related to miniplate stability. Compared with untreated Class III patients and patients treated with conventional RME/FM, intermaxillary elastics attached to miniplates induced significant sagittal advancement of maxillary skeletal and soft tissue components, which was accompanied by posterior displacement of the mandible. Remodelling of the glenoid fossa consisted of bone apposition on the anterior eminence and bone resorption at the posterior wall within one year of BAMP treatment. A counterclockwise rotation of the maxillary plane and proclination of the maxillary incisors was not observed in the BAMP group, whereas almost 50% of the RME/FM group revealed greater dental than skeletal change and significant vertical maxillary displacement.

The BAMP technique has been shown to produce reliable Class III correction with true skeletal change rather than forward movement of the maxillary dentition. However, anatomic limitations may pose additional challenges when applied to young patients. The maxillary alveolar process may lack adequate height, making infra-zygomatic miniplate placement and adaptation difficult, while mandibular miniplates may jeopardise lower canine eruption by causing trauma to the developing tooth bud. In this context, less invasive procedures that could disarticulate the maxilla efficiently and achieve a reliable and stable forward movement were sought. A new protocol for maxillary protraction was therefore developed and further introduced on growing Class III cleft patients by using a tooth-borne expander. The process involved repetitive weekly alternate rapid maxillary expansion and constriction (Alt-RAMEC) with expansion of 1 mm/day for one week followed by the same rate and amount of constriction for the following week, over a total of seven to nine weeks, with the aim of obtaining greater maxillary disarticulation. In this initial introduction of the technique, Alt-RAMEC combined with intraoral maxillary protraction springs resulted in 5.8 mm of forward movement of A point, which was 3.2 mm greater than that achieved by a conventional RME. Further modifications included maxillary protraction using FM either combined with Alt-RAMEC on tooth-borne expanders or, to maximise skeletal anchorage, by the use of a...
HYBRID-HYRAX, ALTRAMEC AND MINISCREW REINFORCED HEAVY CLASS III ELASTICS FOR MAXILLARY PROTRACTION

hybrid-Hyrax appliance that is anchored simultaneously on maxillary molars and palatal implants. Intermaxillary improvement has been reported to be greater using the Alt-RAMEC/FM compared with the RME/FM irrespective of when FM protraction was initiated, either simultaneously with Alt-RAMEC or after its completion. The current literature is devoid of long-term data that could substantiate the stability of Class III correction when the Alt-RAMEC procedure is part of Class III orthopaedic treatment.

The aim of the present study was to quantify the effects of hybrid-Hyrax, Alt-RAMEC and miniscrew reinforced heavy intermaxillary Class III elastic treatment in growing maxillary retrusive patients. An assessment of the long-term treatment stability and relapse of both skeletal and dental components was also conducted.

Materials and methods

Subjects

Fifteen patients (seven male, eight female) with an average age of 12.52 ± 0.94 years, from the treatment waiting list of the Department of Orthodontics, Sydney Dental Hospital, were enrolled in this study. Ethics approval was obtained from the Human Research Ethics Committee of New South Wales Health (Approval number X10-010). The study was also registered in the ANZ clinical trial registry (ACTRN12610000220066). Case selection was performed according to inclusion criteria which involved a skeletal Class III malocclusion, a retrognathic maxilla, anterior crossbite, dental Class III molars and canines, no previous orthodontic or orthopaedic treatment, no congenital abnormalities such as facial clefts and/or syndromes, and a Cervical Vertebrae Maturation (CVM) Stage of 2–4. All patients, parents or guardians were informed of the study protocol, the advantages of treatment and complications associated with the treatment including possible ineffectiveness and future relapse. Informed consent was obtained.

Treatment protocol

Infiltration local anaesthesia (2% lignocaine with 1:80,000 adrenaline) was administered prior to Temporary Anchorage Device (TAD) insertion. Two self-drilling 1.6 × 6 mm Aarhus™ miniscrews (American Orthodontics, WI, USA) were inserted between the mandibular canines and lateral incisors. Two palatal TADS of 2 × 9 mm BENEFit™ (PSM, Tuttingen, Germany) were placed bilateral to the mid-palatal suture, in the area distal to the canines. Polyvinylsiloxane (PVS) impressions were obtained and a bonded RME with acrylic coverage of the posterior teeth was constructed and welded to the respective implant abutments connecting the RME to the palatal TADS. The tooth-borne / bone-borne maxillary expander (hybrid-Hyrax) was cemented with glass-ionomer cement (Transbond™ Plus Light Cure Band Adhesive, 3M Monrovia, CA, USA) and secured through its abutments to the palatal implants. A modified mandibular lingual arch (Remanium® wire of 1 mm diameter, Dentaurun, Ispringen, Germany) attached to the first molar bands was also cemented while its lingual extensions and ‘S’ hooks were bonded with composite resin (Transbond™ XT Light Cure Adhesive) to the lingual surfaces of the incisors and buccal surfaces of the canines (Figure 1).

Patients were instructed to expand and constrict the maxilla according to the Alt-RAMEC protocol. Expansion was delivered at 1 mm/day for seven days followed by constriction of 1 mm/day for seven days. Alternating expansions and constrictions were continued for a total of nine weeks, when mobility of the maxilla was subjectively assessed. The forehead and bridge of the nose were held with one hand while the maxillary incisors were held with the other. In this way, maxillary ‘disarticulation’ was verified in a back and forth motion and, if achieved, intermaxillary protraction with Class III elastics was commenced.

Two sectional 0.019 × 0.025 inch stainless steel wires were secured passively with flowable composite resin into the head of miniscrews and the labial surface of the mandibular incisors on both sides. Heavy Class III elastics of 400 gm were applied from the posterior and anterior ball clasps embedded in the acrylic of the hybrid-Hyrax, to the ‘S’ hooks of the modified lingual arch. The patients were instructed to wear the elastics 24 hours/day and change them daily for eight to nine weeks. An assessment was performed every two weeks. Upon completion of protraction, the appliances were removed and orthodontic treatment was finalised using full fixed appliances.
Cephalometric analysis

Cone beam computed tomographic (CBCT) images were obtained with a NewTom 3G machine (Cone Beam 3D Imaging, Verona, Italy) with a 12” field of view (FOV) and 0.4 mm voxel size initially (T1), at the end of active maxillary protraction phase (T2) and four years after the protraction phase (T3). The DICOM data were reconstructed and lateral cephalograms rendered with the orthogonal tool of Dolphin Imaging System (Version 11.0, Dolphin Imaging & Management Systems, CA, USA). All cephalograms were digitally traced and measured by the same operator (AKP). Fifteen lateral cephalograms were retraced and remeasured after two weeks in order to determine the method error. Thirty-eight conventional angular and linear cephalometric measurements were used for skeletal, dental and soft tissue evaluation. An x-y co-ordinate system was constructed with a horizontal reference line (HR) rotated down 7° from SN and a vertical reference line (VR) drawn perpendicular to HR from Sella. Fifteen linear measurements were performed using the x-y co-ordinate system as a reference for describing landmark movements in the horizontal and vertical planes of space (Figure 2).

Statistical analysis

Statistical analysis was performed using the Statistical Package for Social Sciences (SPSS, version 17.0, SPSS Inc., IL, USA). Descriptive statistics were applied to illustrate means, standard deviations and ranges at T1, T2 and T3. An Analysis of Variance (ANOVA) was carried out for each cephalometric value with time as a fixed factor and subject as a random factor. Individual time points were compared post hoc with a Bonferroni adjustment for multiple comparisons to estimate differences. The level of significance was set at 0.05 for P values with a 95% Confidence Interval (CI). The method error was assessed as the root mean square error to provide an estimate of the variability of the measurements.

Results

The proposed treatment protocol was completed by all patients. Two patients could not be contacted for
Figure 2. Skeletal, dental and soft tissue variables. Linear and angular cephalometric measurements.
T3 records. The palatal implants remained stable throughout active treatment. One mandibular miniscrew was lost prior to the application of the Class III elastic force. It was replaced and subsequently remained stable. The fracture of one buccal canine attachment of a lingual arch occurred and was replaced on the same day and so unimpeded Class III elastic force was continued. The root mean square error ranged between 0.13° (SNB) and 1.77° (interincisal angle: U1-L1) for the angular measurements and between 0.13 mm (overbite and U lip-S line) and 0.75 mm (VR-Pog) for the linear measurements. The treatment duration with fixed appliances after active maxillary protraction was 2.64 ± 1.28 years. All patients but one had their Class III malocclusion corrected and the second phase treatment with fixed appliances was completed prior to the four-year FM follow-up. Data from the patient who showed an unfavourable growth response to the proposed maxillary protraction protocol were included and analysed for the reason of eliminating ‘reporting bias’. Future correction with orthognathic surgery will be performed once growth has ceased in this patient. Descriptive statistics and comparisons between T1, T2 and T3 are shown in Tables I and II.

T1-T2 changes

SNA and ANB increased by 1.05° ± 1.10° (p = 0.004) and 2.71° ± 1.01° (p = 0.000), respectively, while SNB decreased by 1.67° ± 1.34° (p = 0.000). Maxillary length (Co-A) gained 3.16 ± 3.33 mm (p = 0.005). Point A showed 2.32 ± 1.79 mm (p = 0.000) of forward movement and Pogonion showed 2.40 ± 2.70 mm (p = 0.008) of backward movement relative to N-Perpendicular line. The Y-axis increased 1.64° ± 1.34° (p = 0.000) and the Facial Axis decreased 2.05° ± 1.66° (p = 0.000). Lower anterior face height (ANS-Me) increased by 2.65 ± 2.84 mm (p = 0.006). All other skeletal measurements did not show significant change (p > 0.05). A mean increase of 4.90 ± 1.66 mm (p = 0.000) in overjet and 2.25 ± 2.07 mm (p = 0.001) decrease in overbite was noted. Wits appraisal improved by 4.49 ± 2.21 mm (p = 0.000). The upper and lower incisor inclinations in relation to their apical bases did not show any major changes (p > 0.05). Significant soft tissue effects were noted only as increases in upper lip projection to S line (1.5 ± 1.24 mm, p = 0.000) and H angle (3.22° ± 1.97°, p = 0.000).

Co-ordinate system measurements showed significant forward movement of A point (3.12 ± 3.42 mm, p = 0.007) in relation to the VR line. The upper dentition also moved forwards as measured from the first molars (4.16 ± 3.41 mm, p = 0.000) and central incisor tip (3.46 ± 3.25 mm, p = 0.002) without significant vertical movements. Soft tissue changes were not significant except for subnasale (Sn) point moving 2.27 ± 3.15 mm (p = 0.037) forwards.

T2-T3 changes

Between T2 and T3, SNA and SNB increased by 0.99° ± 1.12° (p = 0.011) and 2.02° ± 1.37° (p = 0.000) respectively and ANB decreased by 0.99° ± 1.03° (p = 0.006). Changes in A point were insignificant but Pogonion moved 4.18 ± 2.75 mm forwards (p = 0.000) in relation to N-Perpendicular line. A counterclockwise rotation of the mandible occurred with significant reduction of the mandibular plane angle (SN-MP: 2.46° ± 2.08°, p = 0.001). The Y-axis decreased (1.64° ± 1.34°, p = 0.001) and the Facial Axis increased (1.75° ± 1.69°, p = 0.003). Maxillary length increased by 1.95 ± 3.39 mm but the change was not statistically significant (p = 0.146 > 0.05), while mandibular length significantly increased (Go-Me: 3.90 ± 2.81 mm, p = 0.000 and Co-Gn: 6.26 ± 3.95 mm, p = 0.000). The dental changes involved a significant increase in the inclination of the upper incisors (U1-SN: 8.31° ± 5.74°, p = 0.000 and U1-PP: 8.39° ± 5.59°, p = 0.000). The Wits analysis, overjet, overbite and lower incisor inclination did not significantly change (p > 0.05). The nasolabial angle, H angle and upper lip projection to S line all decreased significantly.

In the co-ordinate system, A Point (3.06 ± 2.78 mm, p = 0.002) and the upper molars (4.79 ± 3.25 mm, p = 0.000) moved downwards in relation to the HR line. Point A moved forwards 2.21 ± 3.49 mm to the VR line but this change was not statistically significant (p = 0.093 > 0.05). All other points moved significantly forwards relative to the VR line.

T1-T3 changes

The overall changes between T1 and T3 included notable increases in SNA (2.05° ± 1.09°, p = 0.000), ANB (1.72° ± 1.06°, p = 0.000), forward movement of A point to N-Perpendicular (2.36 ± 1.81 mm, p = 0.000), upper (N-ANS: 2.56 ± 2.06 mm,
### HYBRID-HYRAX, ALTRAMEC AND MINISCREW REINFORCED HEAVY CLASS III ELASTICS FOR MAXILLARY PROTRACTION

**Table I.** Descriptive statistics and comparisons with mean differences and standard deviation (SD) between T1, T2 and T3. N.S: non-significant, *P < 0.05, **P < 0.01, ***P < 0.001. Sig.: significance. RMSE: Root Mean Square Error.

|                  | Mean  | SD   | Mean  | SD   | Mean  | SD   | Sig. | RMSE |
|------------------|-------|------|-------|------|-------|------|------|------|
| **Skeletal**     |       |      |       |      |       |      |      |      |
| SNA°             | 78.48 | 0.79 | 79.53 | 0.80 | 80.53 | 0.81 | 1.10 | 0.004 |
| SNB°             | 81.90 | 0.96 | 80.23 | 0.97 | 82.42 | 0.98 | 1.67 | 0.000 ** |
| ANB°             | -3.41 | 0.72 | -1.69 | 0.73 | -0.7 | 0.74 | 2.71 | 0.000 *** |
| A-NPerpendicular | 4.45  | 3.13 | 3.52  | 3.14 | 2.62  | 3.15 | 0.81 | 0.000 *** |
| Pog-NPerpendicular | -1.80 | 3.13 | 0.52  | 3.31 | 0.56  | 2.81 | 2.32 | 0.000 *** |
| SN-Ba°           | 130.38| 1.29 | 130.06| 1.32 | 129.62| 1.34 | 0.32 | 1.82  |
| S-Go/N-Me (%)    | 62.67 | 1.64 | 62.55 | 1.66 | 64.87 | 1.69 | 0.12 | 2.30  |
| N-ANS (mm)       | 56.57 | 1.48 | 57.42 | 1.50 | 59.13 | 1.53 | -0.84 | 2.07 |
| ANS-Me (mm)      | 71.33 | 2.02 | 73.97 | 2.06 | 76.59 | 2.09 | -2.65 | 2.84 |
| UFU (%)          | 44.27 | 0.84 | 43.74 | 0.86 | 43.60 | 0.86 | 0.53 | 1.18 |
| LFH (%)          | 55.73 | 0.84 | 56.26 | 0.86 | 56.40 | 0.87 | -0.53 | 1.18 |
| SN-FH°           | 9.95  | 1.39 | 9.52  | 1.41 | 10.15 | 1.43 | 0.42 | 1.94 |
| SN-PP°           | 8.75  | 1.54 | 8.60  | 1.57 | 8.70  | 1.59 | 1.69 | 2.84 |
| PP-MP°           | 27.84 | 1.95 | 29.06 | 1.99 | 26.51 | 2.01 | -1.22 | 2.74 |
| SN-MP°           | 36.58 | 1.46 | 37.70 | 1.48 | 35.22 | 1.50 | -1.10 | 2.04 |
| SN-Oc.plane°     | 16.41 | 1.77 | 15.65 | 1.80 | 14.32 | 1.83 | 0.76 | 2.48 |
| Ar-Go-Me°        | 127.65| 2.39 | 126.81| 2.43 | 127.53| 2.47 | 0.83 | 3.35 |
| Y Axis°          | 67.74 | 0.94 | 69.38 | 0.95 | 67.74 | 0.97 | -1.64 | 1.31 |
| Facial Axis°     | 89.71 | 1.18 | 87.66 | 1.20 | 89.42 | 1.22 | 2.05 | 1.66 |
| S-N (mm)         | 71.28 | 1.18 | 71.94 | 1.20 | 73.14 | 1.22 | -0.67 | 1.66 |
| Go-Me (mm)       | 77.04 | 1.97 | 77.80 | 2.00 | 81.70 | 2.03 | -0.76 | 2.76 |
| Co-Gn (mm)       | 124.96| 2.76 | 127.35| 2.81 | 133.61| 2.85 | -2.39 | 3.87 |
| Co-A (mm)        | 87.86 | 2.37 | 91.02 | 2.41 | 92.97 | 2.45 | -3.16 | 3.33 |
| Mx/Md diff.(mm)  | 37.09 | 2.23 | 36.34 | 2.27 | 40.66 | 2.31 | 0.75 | 3.13 |
| **Dental**       |       |      |       |      |       |      |      |      |
| U1-SN°           | 103.46| 4.02 | 104.18| 4.08 | 112.49| 4.15 | -0.72 | 5.63 |
| U1-PP°           | 112.19| 3.92 | 112.81| 3.98 | 121.20| 4.05 | -0.61 | 5.49 |
| L1-MP°           | 83.67 | 3.78 | 80.79 | 3.89 | 81.99 | 3.90 | 2.87 | 5.29 |
| U1-L1°           | 136.31| 6.04 | 137.37| 6.14 | 130.29| 6.24 | 1.06 | 8.46 |
| U1-NPog (mm)     | 0.29  | 1.66 | 4.45  | 1.68 | 4.05  | 1.70 | -1.22 | 2.84 |
| U1-APog (mm)     | 2.66  | 1.58 | 5.16  | 1.61 | 5.70  | 1.63 | -1.47 | 2.80 |
| L1-Apog (mm)     | 6.38  | 0.88 | 3.52  | 0.90 | 4.17  | 0.91 | 1.69 | 2.86 |
| WITS (mm)        | -9.95 | 1.57 | 5.46  | 1.60 | 4.91  | 1.64 | 2.49 | 2.21 |
| Overjet (mm)     | -3.21 | 1.19 | 1.71  | 1.21 | 1.85  | 1.23 | 1.02 | 2.23 |
| Overbite (mm)    | 2.67  | 1.47 | 1.41  | 1.50 | 0.99  | 2.25 | 2.32 | 1.97 |

*P < 0.05, **P < 0.01, ***P < 0.001. Sig.: significance. RMSE: Root Mean Square Error.*
PAPADOPOULOU, DALCI, PETOCZ AND DARENDELLER

any restraining effect on mandibular growth, which significant, indicating that treatment did not exert (Go-Me, Co-Gn), changes were not statistically although linear mandibular measurements increased length (Co-Gn: 8.65 ± 3.84 mm, p = 0.000), maxillary (Co-A: 5.11 ± 3.30 mm, p = 0.000) and mandibular length (Co-Gn: 8.65 ± 3.84 mm, p = 0.000), Go-Me: 4.66 ± 2.74 mm, p = 0.000), upper incisor inclination (U1-SN: 9.03° ± 5.59°, p = 0.000), U1-PP: 9.01° ± 5.45°, p = 0.000) and projection (U1-NPog: 3.76 ± 2.30 mm, p = 0.000, U1-APog: 3.13 ± 2.19 mm, p = 0.000), Wits (3.04 ± 2.19 mm, p = 0.000) and overjet (5.05 ± 1.65 mm, p = 0.000).

A significant reduction was seen in the occlusal plane angle (SN-Oc.plane: 2.09° ± 2.46°, p = 0.015), incisal angle (U1-L1: 6.03° ± 8.39°, p = 0.048), lower incisor projection (L1-APog: 3.13 ± 2.19 mm, p = 0.000), overbite (1.67 ± 2.05 mm, p = 0.021) and nasolabial angle (4.23° ± 5.92°, p = 0.049). All other measurements did not show significant changes between T1 and T3 (p > 0.05).

An analysis of the co-ordinate system showed a significant forward and downward movement of all included skeletal, dental and soft tissue points (p < 0.05).

Discussion

In this prospective clinical trial, the short-term and long-term effects of the hybrid-Hyrax appliance combined with the Alt-RAMEC protocol for nine weeks followed by eight to nine weeks of miniscrew reinforced bilateral 400 gm Class III elastics on a modified lingual arch were evaluated in Class III maxillary retrusive, growing subjects. All appliances and forces were exerted without the use of any extraoral anchorage. The patients were reviewed over a four-year period after active orthopaedic treatment and records were gathered in order to assess long-term stability and relapse.

Changes immediately after active orthopaedic treatment indicated that maxillary protraction had been achieved successfully and was expressed as forward movement of A point to Na-Perpendicular line and VR line, as well as an increase in maxillary length (Co-A) and SNA angle. SNB decreased and, although linear mandibular measurements increased (Go-Me, Co-Gn), changes were not statistically significant, indicating that treatment did not exert any restraining effect on mandibular growth, which was possibly due to the short period of only four months from the initial assessment. However, the relative sagittal intermaxillary relationship improved significantly, by 2.71° and 4.5 mm as measured by the differences in the ANB angle and the Wits appraisal, respectively. Interestingly, despite the great improvement in the Wits analysis, it still remained negative. In addition, Pogonion decreased by 2.4 mm relative to the N-Perpendicular line, a result that contributed positively in improving the hard tissue profile. The Alt-RAMEC protocol with either intraoral protraction springs or Class III elastics and FM had been introduced and achieved 5.8 mm of forward maxillary movement in Class III maxillary retrusive patients with a cleft palate.21,27 This amount of maxillary protraction was greater compared with the results obtained in the present study. This might be explained by differences in the skeletal structure between the studied groups as the presence of a cleft palate could possibly have reduced resistance to maxillary forward advancement. In comparison with the present results, when the Alt-RAMEC protocol was used in combination with FM for nine months in non-cleft patients, approximately 3.04 mm of maxillary advancement was achieved. However, this was accompanied by a counterclockwise rotation of the palatal plane and a clockwise rotation of the mandibular plane. Even though these rotations were smaller in the Alt-RAMEC group compared with the conventional RME group, they were still not eliminated.28

In the present study, the vertical skeletal relationships remained unchanged as the differences in the inclination of palatal, mandibular and occlusal planes to the anterior cranial base did not reach statistical or clinical significance. This finding was also verified by the minimal downward movement of A point (0.86 mm) and the upper maxillary molars (1.32 mm) in relation to the HR line in the x-y co-ordinate system. The explanation of unwanted rotations might be related to the possible bite-block effect and the efficient disarticulation of the maxilla with the hybrid-Hyrax and Alt-RAMEC protocol, both of which permitted maxillary movement in a forward direction over a short period of time. However, when Gn was used in measurements (Y-axis and Facial Axis), an initial mandibular clockwise rotation of 2° was observed. Dental measurements showed forward movement of 4.16 mm of the upper molars and 3.46 mm of the
HYBRID-HYRAX, ALT-RAMEC AND MINISCREW REINFORCED HEAVY CLASS III ELASTICS FOR MAXILLARY PROTRACTION

Table II. Measurements in the x-y co-ordinate system. Descriptive statistics and comparisons with mean differences and standard deviation (SD) between T1, T2 and T3.

|                  | T1 Mean | SD  | T2 Mean | SD  | T3 Mean | SD  | P    | Sig. | RMSE |
|------------------|---------|-----|---------|-----|---------|-----|------|------|------|
| Skeletal         |         |     |         |     |         |     |      |      |      |
| VR-A             | 64.54   | 5.73| 67.64   | 6.23| 69.85   | 6.23| 0.007| **   | 0.36 |
| VR-B             | 67.00   | 9.04| 65.90   | 9.33| 70.91   | 10.19| 0.11 | 0.36 |
| VR-Pog           | 67.09   | 10.55| 66.36  | 10.65| 73.14   | 12.68| 0.72 | 0.40 |
| HRA              | 52.06   | 3.69| 52.93   | 2.86| 55.98   | 3.24| 0.86 | 0.61 |
| Dental           |         |     |         |     |         |     |      |      |      |
| VR-U6mes         | 42.26   | 6.46| 46.43   | 6.06| 47.88   | 6.78| 0.007| **   | 0.40 |
| VR-L6mes         | 45.43   | 6.51| 44.12   | 6.27| 51.05   | 7.24| 0.007| **   | 0.40 |
| VR-U1tip         | 68.50   | 7.16| 71.96   | 7.48| 76.79   | 8.86| 0.007| **   | 0.40 |
| VR-L1tip         | 71.65   | 7.48| 70.57   | 6.92| 75.45   | 8.05| 0.007| **   | 0.40 |
| HR-U6mes.cusp    | 69.97   | 3.89| 71.28   | 4.02| 76.07   | 2.86| 0.007| **   | 0.40 |
| Soft tissues     |         |     |         |     |         |     |      |      |      |
| VR-Subnasale     | 81.67   | 5.55| 83.94   | 5.60| 86.94   | 6.80| 0.007| **   | 0.33 |
| VR-A soft        | 80.58   | 5.55| 82.97   | 5.73| 85.26   | 6.70| 0.007| **   | 0.33 |
| VR-L superior (UL)| 84.33 | 6.86| 86.65   | 6.53| 89.51   | 8.22| 0.007| **   | 0.33 |
| VR-L inferior (UL)| 85.51 | 7.79| 85.25   | 7.40| 90.29   | 8.71| 0.007| **   | 0.33 |
| VR-B soft        | 79.17   | 8.12| 79.59   | 8.17| 83.43   | 9.73| 0.007| **   | 0.33 |
| VR-Pog soft      | 80.01   | 10.21| 79.86  | 10.22| 85.63   | 12.30| 0.007| **   | 0.33 |

NS: non-significant, * P < 0.05, ** P < 0.01, *** P < 0.001. Sig.: significance. RMSE: Root Mean Square Error.

In previous studies, the Alt-RAMEC protocol had been combined with FM on mouth-borne expanders. After nine months of protraction, maxillary and upper incisor inclinations were measured twice in the present study. First, the movement of the maxillary incisors was not affected by the greater magnitude and longer duration of the protraction forces. Nevertheless, the upper and lower incisor inclinations with only RME/FM treatment. The sagittal and upper incisor tip in relation to the VR Line. As hard tissue A point moved 3.16 mm forwards in relation to the VR line, it is apparent that only 1 mm of forward movement of the posterior maxillary dentition and less than 0.5 mm of incisor change took place, indicating that the corrections were primarily due to skeletal maxillary protraction and secondly to forward movement of the lower lip. After nine months of protraction, maxillary and upper incisor inclinations were measured.

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vertical skeletal changes in the Alt-RAMEC group were similar to those of the present study, with the only difference noted in the greater improvement of the Wits appraisal in the present study.

The initiation of FM protraction, after or in conjunction with tooth-borne Alt-RAMEC, did not yield any differences in the final skeletal or dental results between the two groups. Even though correction was achieved in a similar time frame as the present study, changes in the mandible and subsequently the maxillomandibular relationship were more pronounced following FM. Specifically, mandibular growth was more effectively controlled and ANB as well as the Wits appraisal showed more favourable improvement with FM treatment compared with miniscrew reinforced Class III elastics. However, forward movement of the upper dentition and changes in the inclination of the upper incisors were greater, a finding that could possibly be attributed to the tooth-borne nature of the Hyrax expander instead of the hybrid-Hyrax appliance that was used in the present study.

An effort to enhance the effects of tooth-borne Alt-RAMEC and FM treatment was made by applying maxillary protraction forces of 350–400 gm on skeletal plates secured on the lateral nasal walls. Total treatment duration, including eight weeks of Alt-RAMEC, was 9.9 ± 2.63 months. The results showed 2 mm of forward maxillary movement and a 3 mm increase in maxillary length (Co-A) with an almost undetectable maxillary counterclockwise rotation (0.8°) and incisor compensations. As all changes were similar to those of the present study, the present protocol can be considered similarly efficient but faster, and a preferable option as it eliminates extensive surgical procedures of skeletal plate placement/removal and application of extra-oral appliances such as FM.

The hybrid-Hyrax appliance has been used for maxillary protraction combined either with FM or with a Mentoplaste. Treatment duration until correction was similar to the current timing, and the significant improvements in skeletal sagittal values not accompanied by unwanted maxillary dental movements or vertical skeletal changes. The hybrid-Hyrax/FM system resulted in positive increases in maxillary skeletal measurements while the relative position of the maxilla in relation to the mandible improved. Mandibular growth was not impeded as Co-Gn gained 1.1 mm; however, the amount of growth was 2.3 mm less than the control group. Similar results were also obtained by the use of hybrid-Hyrax appliance combined with a Mentoplaste. A comparison of the treatment alternatives with the results of the present study show that the proposed protocol similarly avoids vertical or dental side effects over time but produces a greater positive increase in maxillary length (Co-A) and forward movement of A point, which can be attributed to more efficient disarticulation of the circum-massillary sutures with the Alt-RAMEC protocol, whilst the requirements of skeletal anchorage in the mandible are minimal.

The present post-protraction findings at the four-year follow-up (T3) included orthodontic fixed appliance treatment effects. A comparison between T2 and T3 showed that sagittal maxillary position continued to improve as SNA increased by 1° and both maxillary length (Co-A) and A point to VR increased by 2 mm, which indicated that the initial correction was followed by a continuous favourable maxillary response. This reflects that the proposed technique was associated with positive results in the maxilla that not only remained stable over time, but also contributed to unrestricted residual maxillary growth. The mandible showed significant linear growth of almost 6.3 mm measured at Co-Gn, while other measurements indicated 5 mm and approximately 7 mm of forward movement of B point and Pogonion, respectively, in relation to VR. The maxillomandibular difference therefore showed that the mandible outgrew the maxilla in the horizontal direction by 4.32 mm. The mandibular plane showed a counterclockwise rotation. The upper and lower anterior face heights increased significantly and this was accompanied by a downward movement of the anterior maxilla (HR-A: 3 mm) and the maxillary dentition (HR-U6: 4.8 mm). The overjet remained unchanged due to dentoalveolar compensation as a result of excessive mandibular growth. The upper incisor inclination increased significantly and, even though both upper and lower incisors showed forward advancement of approximately 5 mm in relation to VR, for the lower incisors this was equivalent to B point advancement and occurred without any inclination changes relative to MP. All soft tissue points expressed forward horizontal advancement. These findings are in agreement with previous studies that evaluated the long-term treatment effects of conventional RME/FM
treatment and reflect the growth pattern of Class III individuals.7,8,34

The time period between T1 and T3 revealed the overall changes, which were substantial and favourable in relation to Class III correction. The changes consisted of significant and stable horizontal skeletal maxillary advancement with improvements in all parameters which describe maxillary position. However, restraint of mandibular growth was not achieved during treatment and the mandible showed significant overall linear growth. Even though the mandible outgrew the maxilla, mean overjet at the four-year follow-up was 2 mm, showing an overall and stable correction of 5 mm in the incisal relationship. The vertical plane angulations and direction of growth were not affected, indicating that Class III correction did not include a backward rotation of the mandible. All skeletal, dental and soft tissue parameters showed forward and downward changes in the x-y co-ordinate system. Nevertheless, as A point horizontal advancement (5.32 mm) was almost equivalent to upper first molar forward movement (5.62 mm), it can be assumed that unwanted forward movement of the maxillary posterior teeth was avoided. Rather, the maxilla as a whole, including its dentition, moved forwards. Similarly, B point forward advancement (3.91 mm) equalled lower incisor tip forward movement (3.8 mm), indicating that lower incisor movement was in line with that of the apical base. This was also reflected by a stable inclination of the lower incisors in relation to the MP plane, showing that the modified lingual arch and Class III elastic reinforcement with miniscrew stabilisation of the lower incisors prevented retro-inclination of those teeth. Contrary to this, maxillary incisor inclination significantly increased, which could be attributed to the fixed appliance treatment and the dentoalveolar compensation associated with remaining Class III growth. The overbite was reduced, reflecting the increased post-retraction vertical movement of the maxillary molars and the increases in anterior face height due to growth.

Research on the long-term results and stability of Class III correction in growing patients is mainly available for conventional RME/FM treatment. A multicentre, randomised, controlled clinical trial that investigated the effectiveness of bonded Hyrax-FM therapy followed by treatment with fixed appliances demonstrated that conventional treatment significantly improved maxillary position (SNA) and relative maxillomandibular relationships (ANB, overjet) compared with controls in a three-year follow-up.35 Although the effects on the mandible (SNB) were minimal, these were greater in the treated group and, at the end of the observation period, 70% of those patients still had a positive overjet. When the sample was re-evaluated in a six-year follow-up, it was found that 36% of the treated group required correction by orthognathic surgery compared with 66% of the control group.36 Treated patients showed clockwise rotations while the control subjects showed counterclockwise rotations, with the conclusion that, even though conventional Hyrax-FM appliance treatment did not maintain its effects based on cephalometric values, it seemed to reduce the need for orthognathic surgery. Only one of the 15 patients included in the present study did not show initial and overall favourable response, whereas all corrected patients remained stable and did not require orthognathic surgery at the four-year follow-up. A review of all patients over a longer period may provide additional insights into the effectiveness of the proposed protocol in reducing the need for extensive orthognathic surgical correction of Class III maxillary retrusive subjects.

The limitations of the present study include a lack of matched controls of untreated Class III and/or Class I subjects; however, this was not possible for ethical reasons. In addition, the small sample size, sexual dimorphism, ethnic differences and inter-individual variability in the level of treatment response suggest that caution is required in the interpretation of the results and general applicability of the proposed treatment protocol. An additional confounding factor is that the data collected at the four-year follow-up also included the effects of treatment produced by orthodontic fixed appliances. This means that the overall effects cannot be considered as net maxillary protraction. Direct comparison with other studies should also be made with care as the time points of data collection, the duration of treatment and co-ordinate systems used for cephalometric measurements differ. Possible future studies may focus on the standardisation of the Alt-RAMEC protocol in regards to the overall duration of alternating expansions and constrictions as well as to the appropriate maxillary protraction auxiliaries. Gaining information about the ideal force magnitude, duration and vectors correlated to
patient age and overall growth pattern would also be of great benefit in customising treatment according to individual patient needs, skeletal characteristics and growth potentials.

From the present results, it may be concluded that forward movement of the maxilla was accomplished without opening of the vertical planes and unwanted dental side effects. The correction of the maxillomandibular sagittal relationship was primarily due to maxillary advancement as the mandible was not significantly affected. The effects remained stable four years post-protraction.

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Conflicts of interest
The authors confirm that there is no conflict of interest.

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