European Journal of Orthodontics, 2023, **XX**, 1–11
https://doi.org/10.1093/ejo/cjad018
Original Article

The effect of tooth borne versus skeletally anchored Alt-RAMEC protocol in early treatment of Class III malocclusion: a single-centre randomized clinical trial

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Summary

Trial design: This was a randomized, controlled trial designed to compare outcomes between the use of dental and skeletal anchorage, using the Face mask/Alternate Rapid Maxillary Expansion and Contraction (FM/Alt-RAMEC) protocol.

Methods and participants: The study was carried out at Mater Dei Hospital, Malta and included prepubertal skeletal Class III malocclusion patients where the aetiology was primarily maxillary hypoplasia.

Interventions: Two groups were assigned. Group I was treated with FM/Alt-RAMEC and group II was treated with skeletally anchored FM/Alt-RAMEC. Wear-time (WT) of the FM was monitored using TheraMon microsensors. Patients were instructed to wear the FM for 12–14 hours/day for 9 months. Changes were evaluated with lateral cephalograms and analysed with Wilcoxon and Mann–Whitney *U* tests. ANOVA was used to analyse the effect of gender on compliance parameters. Spearman's correlation coefficient was used to assess the correlation between compliance and skeletal changes.

Objective: To compare the skeletal and dentoalveolar changes in patients treated with these two protocols.

Outcomes: The primary outcome was to assess skeletal and dentoalveolar outcomes in patients treated with skeletally anchored FM/RME and tooth-borne FM/RME; utilizing Alt-RAMEC protocol. The secondary outcome was compliance rate and adherence to FM wear among patients.

Randomization: Randomizer software and the sealed envelope technique were used to randomly allocate patients 1:1 into either group I (tooth-borne FM/Alt-RAMEC) or group II (skeletally anchored FM/Alt-RAMEC).

Blinding: It was not possible to blind to treatment allocation, but blinding was used when assessing the outcomes.

Results: Numbers randomized and analysed. Thirty-five patients were allocated. Group I consisted of 18 subjects and group II consisted of 17 subjects. One patient in group I dropped out due to illness, so 17 subjects in each group completed the study.

Outcomes: Post-treatment changes in group I showed significant increases in SNA (2.10°), ANB (3.90°), Wits (4.70 mm), and overjet (5.40 mm). Group II showed significant increases in ANB (3.10°), Wits (3.20 mm), and overjet (4.50 mm). Wearing time for group I patients was 7.87 ± 2.88 hours/day and for group II was 6.98 ± 2.68 hours/day, with no significant difference between the groups.

Limitations: Lack of long-term follow-up post-treatment, making the conclusion applicable only in the short term.

Harms: No harm was observed in both groups

Conclusion: Despite the large difference between the measured and the patient-reported daily WT, both tooth-borne and skeletally anchored FM/Alt-RAMEC showed positive, similar, skeletal and dental effects.

Clinical trial registration: ISRCTN12197405.

Introduction

Class III malocclusion is considered to be among the most challenging orthodontic problems in orthodontics. These patients display unique dentofacial growth discrepancies that appear as early as the age of 4 years and are characterized by a retrusive maxilla with reduced effective length, increased mandibular effective length, increased vertical measurements, and dentoalveolar compensation. A short anterior cranial base is often correlated with altered mandibular morphology and an increase in size, indicating a biological connection between the two (1). The skeletal base relation deteriorates during puberty, with peak mandibular growth occurring during cervical vertebra maturation (CVM) stages 3 and 4, and lasting, on average, 6 months longer than in non-Class III individuals, until young adulthood. The average increase in mandibular length is double the magnitude in girls and three-fold greater in boys, compared to individuals with normal occlusion (2). The inability of the maxilla to keep up with mandibular growth contributes to the worsening Class III maxillomandibular relationship (3).

Various combinations of sagittal and vertical developmental discrepancies have been described. A significant proportion of Class III individuals (25%) exhibit either pure maxillary retrognathia or a combination of maxillary retrognathism and mandibular prognathism (22.2%), meaning that almost half of these individuals have midface underdevelopment (1). It follows that maxilla retrognathia is one of the aetiological factors and modifying its forward growth would be a sound idea.

Background and objectives

Rapid maxillary expansion (RME) either with banded or bonded expanders, combined with a face mask (FM), results in maxillary protraction. The skeletal response to 6–9 months of FM/RME treatment in growing patients results in significant improvements in angular and linear measurements, with improvement of maxillary length and reduction of the negative Wits appraisal. The corresponding soft tissue changes follow those of the hard tissues, being equal to 50–79 per cent of the maxillary protraction and 71–81 per cent of the mandibular downward and backward movement, improving the outcome of Class III treatment (4).

FM/RME treatment is more effective when patients are in the early mixed dentition rather than in later dental development stages, especially with regard to the magnitude of maxillary advancement and the favourable post-pubertal modifications in both maxillary and mandibular structures (5). Treatment of 4- to 7-year-old and 7- to 10-year-old Class III patients has shown to result in greater forward and vertical maxillary movement when compared to identical treatment on 10–14 year olds (6).

A variation of RME, Alternate Rapid Maxillary Expansion and Constriction (Alt-RAMEC) was proposed with the rationale that the expansion-constriction cycles will further disarticulate the circum-maxillary sutures and subsequently enhance forward maxillary translation. Alt-RAMEC was proposed by Liou *et al*. The rationale of the expansion-constriction cycles is to further disarticulate the circum-maxillary sutures, aiding forward maxillary translation (7,8). The effectiveness of FM/Alt-RAMEC versus FM/RME was evaluated by Isci *et al*. They concluded that A point moved 4.13 mm forwards in the Alt-RAMEC group in comparison to 2.33 mm movement in the RME group (9). A 4-week Alt-RAMEC protocol was successfully used on tooth-borne acrylic FM/RME for early treatment of Class III patients (10). FM/Alt-RAMEC had more favourable short-term outcomes compared to FM/RME therapy, generating greater maxillary advancement and intermaxillary improvement as an early Class III treatment modality (11).

As these appliances are tooth-borne, dental side-effects, namely incisor proclination and anchorage loss due to mesial movement of the dentition are unavoidable (12). A recent meta-analysis reported that the Alt-RAMEC protocol in combination with bone-anchored appliances results in greater sagittal skeletal effects, with less vertical and dentoalveolar changes (13). The effects of skeletally anchored FM/RME and tooth-borne FM/RME have been investigated and the conclusions emphasized the need for higher-quality evidence (14).

The effectiveness of treatment with protraction headgear depends on patients' compliance and willingness to wear the appliance for long hours. Many factors may affect the willingness of children and adolescents to play an active role in their treatment. Age, gender, maturity, motivation, and personality traits as well as the type of device they are asked to wear, are all factors which have been investigated (15).

Several RCTs and systematic reviews have been published on patients' subjective reports of wearing time as this factor determines proportionately the treatment results. Thus, an accurate tool, independent of patients' subjective reports, is required to assess compliance (16). Schafer *et al*. used Theramon microchips (TheraMon Microsensor, Handelsagentur Gschladt, Hargelsberg, Austria) in order to assess compliance and found that the average wearing time of a removable appliance was 8 hours per day, well below the recommended wearing time of 15 hours per day (15). Schott found Theramon devices to accurately report wear time and temperature deviations both *in vivo* and in *vitro* (17).

Therefore, the present prospective, randomized, controlled single-centre study aimed to test the null hypothesis that there would be no difference in skeletal and dentoalveolar changes induced by FM in combination with skeletally anchored Alt-RAMEC or tooth-borne Alt-RAMEC protocols. No difference in patients' FM-wearing time was seen between skeletally anchored Alt-RAMEC or tooth-borne Alt-RAMEC groups.

Methods

Trial design

This study was designed, following Consort guidelines, to see whether the addition of skeletal anchorage to the conventional FM/Alt-RAMEC protocol conferred any dental or skeletal advantages. The protocol was approved by the Faculty of Dental Surgery Research Ethics Committee, University of Malta, Research Ethics Committee and the Research Ethics Committee at the Ministry for Health and Research (HEC04/19).

Eligibility criteria for participants

The sample was composed of children who had been referred to the Department of Orthodontics, Mater Dei Hospital Hospital, Malta, for treatment of their Class III malocclusion. The inclusion criteria were set to:

1. Prepubertal children, aged between 8 and 10.99 years.
2. Cervical Vertebral Maturation (CVM) Stage; CS 1 or 2 (18) Mixed dentition.
3. No previous history of orthodontic treatment.
4. Negative overjet of at least –2 mm and true skeletal Class III malocclusion, ANB at least –1 degree.
5. Caucasian ethnicity.

The exclusion criteria were:

1. Craniofacial growth anomalies including cleft lip and/or palate.
2. History of previous orthodontic treatment.
3. Positive overjet.
4. Class I or II occlusion.

The primary method of determining the onset of puberty was clinical and based on physical appearance (lack of secondary sexual characteristics), height records and age. The CVM method (18) was used to supplement the clinical impression.

Interventions for each group

Clinical procedures and treatment

Skeletal and dentoalveolar effects

One orthodontist (EA) treated all patients. Group I (tooth-borne FM-Alt-RAMEC) had a conventional HYRAX expander cemented on UR6, UL6, ULD, and URD (Figure 1). Group II (Skeletally anchored FM-Alt-RAMEC) had a similar expander cemented on UR6 and UL6, in addition to being attached to two 9 × 2 mm paramedian implants (Figure 2). The appliances in both groups had a buccal traction hook arm which was extended anteriorly to the canine region, in order to minimize maxillary rotation.

Mini implants of 9 mm were used (PSM, Germany). Cone beam computed tomography views to verify bicortical anchorage were not obtained, due to objections by the Ethics Research Committee. The mini implant was inserted using the NSK is900 electrical screwdriver. A pilot hole was made, followed by the insertion of the mini implant, with the screwdriver torque set to 35N. Following the fitting of the appliance, patients were asked to perform alternate cycles of expansion and constriction with the first week being a twice-daily opening cycle and the second week a twice-daily closing cycle, etc. The patients activated the appliance twice daily (one turn in the morning and one in the evening; with each turn widened the screw by 0.25 mm). At the end of the seventh week, FM traction was initiated and the use of FM was initiated in both groups, once the ALT-RAMEC protocol was completed.

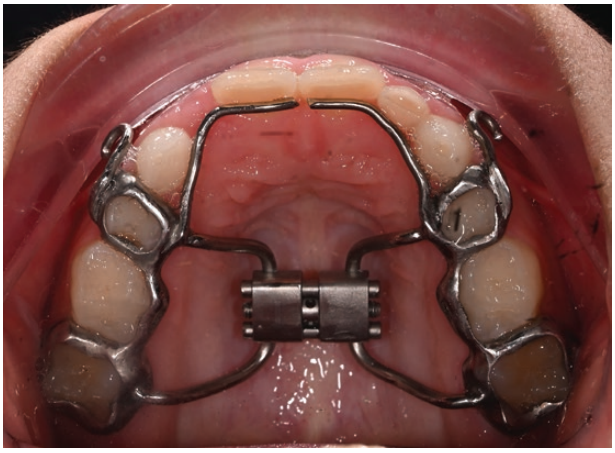

Figure 1 RME banded cemented on UR6, UL6, ULD, and URD with traction hooks extended to the maxillary canine region.

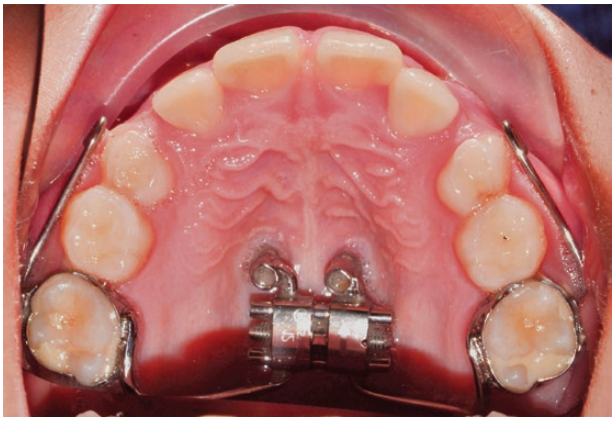

Figure 2 RME banded on UR6 UL6, with paramedian PSM 9 mm mini-implants. Traction hooks have been extended to the maxillary canine region.

In both groups, a Petit FM was used. Elastics with a protraction force of 450–500 g per side and an anteroinferior force vector of approximately 30 degrees to the occlusal plane were connected from the FM to the hooks on the intraoral appliance. The force delivered was measured with a strain gauge (Morelli, Brazil). The patients were instructed to change the extraoral elastics daily and to wear the FM between 12 and 14 hours per day until a 2 mm positive overjet was achieved. FM wear of 10 hours and above was considered to be a good compliance rate. All patients were followed up from the pre-treatment phase (T0) and till the end of treatment at 9 months (T1) to assess the skeletal, dentoalveolar, and soft tissue changes. The success of the clinical intervention was defined by achieving a Class I incisor relationship and eliminating any transverse discrepancies by the end of the treatment.

Compliance rate and adherence

A compliance sensor (TheraMon Microsensor, Handelsagentur Gschladt, Hargelsberg, Austria) was placed just underneath the surface of the forehead pad, with the patient and parents made aware of its presence. However, they were deceived as to its true function, being told that its role was to monitor fluctuations in FM pressure.

Cephalometric analysis

Pre- and post-treatment lateral cephalograms were digitized and calibrated using the Dolphin Imaging software (Dolphin Imaging, Chatsworth, CA, USA). The radiographs were pseudonymised and coded by a member of staff blinded as to the group of origin. Tracing was carried out by the principal investigator, using Dolphin Imaging (Chatsworth, CA, USA). Cephalometric radiographs were taken by an experienced radiographer at the beginning (T0) and the end of the FM treatment (T1), using the same cephalostat (Siemens Nanodor 2, Siemens AG, Munich, Germany). Lateral cephalograms were analysed using a composite analysis of the McNamara and Mills analysis (19,20) (Figure 3). Cephalometric analysis was used to assess the skeletal, dental, and soft tissue changes at T0 and T1. The comparison was made at two levels; inter-group and intra-group, in order to estimate the effect of change. All appliances and mini-implants were removed prior to taking the second (T1) cephalometric view, to ensure clinical blinding during tracing.

Outcomes

Primary outcome

Assessing skeletal and dentoalveolar outcomes in patients treated with skeletally anchored FM/RME and tooth-borne FM/RME; utilizing Alt-RAMEC protocol.

Secondary outcome

The compliance rate and adherence to FM wear among patients.

Sample size

The sample size was calculated based on a significance level of $\alpha = 0.05$ and a power of 80 per cent to detect a statistically and clinically meaningful difference of 1 degree (±0.97) change in SNA between the two groups for 12 hours of wear

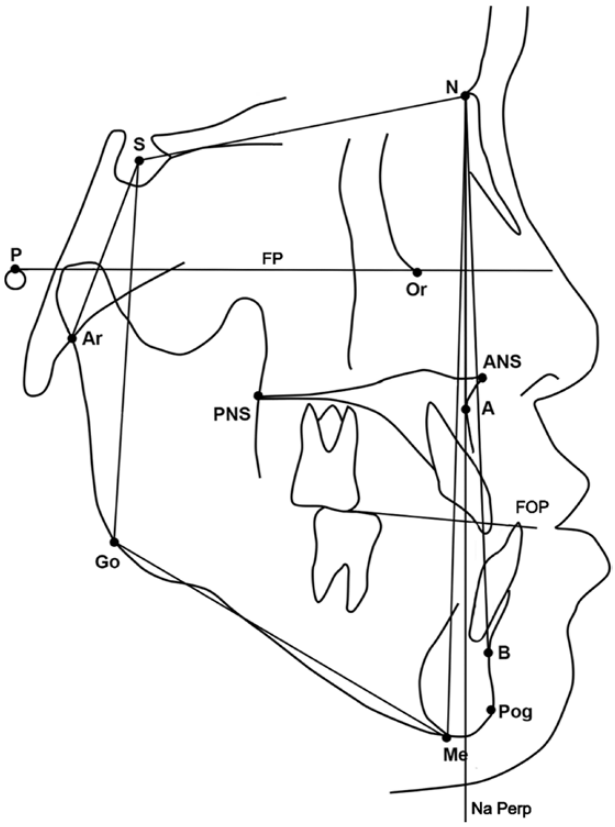

Figure 3 Cephalometric reference points and planes.

of the FM (21,22). The power analysis showed that 17 individuals were required in each arm.

Randomization: sequence generation

The selection was consecutive. An intermediary provided verbal and written information about the trial and invited all eligible patients and their parents to participate. After consent, randomization was undertaken by staff not involved in the trial. A randomization tool (Randomizer software) was used for assignation. The software generated codes for each patient, to pseudonymise the study and randomly allocate the patients 1:1 into one of two groups: group I (tooth-borne FM/Alt-RAMEC) and group II (skeletally anchored FM/Alt-RAMEC).

Allocation concealment mechanism

The sealed envelope technique was used to ensure randomization. The allocation sequence codes were contained within opaque envelopes that were handed to the patient via the intermediary and opened sequentially at the time of participant enrolment, thereby excluding the clinician entirely from the process.

Blinding

Because of the character of the trial, the operator and children could not be blinded to treatment allocation. However, blinding was used when assessing the outcomes. This was achieved by pseudonymising all data related to patients before and after treatment and by removal of the intraoral appliance just before the final cephalogram was taken. The statistician analysing the results was unaware of the nature of the groups.

Statistical analysis

Data analysis

Statistical analyses were performed using SPSS software (SPSS Inc., Chicago, IL, USA, version 25.0 for Windows). The significance level was set at 5 per cent ($\alpha = 0.05$). Differences between the groups for age and gender were determined by *T*-tests and Mann–Whitney *U* tests, respectively.

The majority of cephalometric variables did not follow a normal distribution at one or both time points, as determined by the Shapiro–Wilk test. Thus, the Wilcoxon signed-rank test was used to detect changes in cephalometric parameters, pre-treatment (T0) and post-treatment (T1) (intra-group).

The Mann-Whitney *U* test was used to compare the differences in cephalometric parameters between groups (inter-group).

The difference in compliance rate was evaluated with a two-tailed *t*-test. Two-way ANOVA was used to analyse the effect of gender on the compliance parameters. Spearman's correlation coefficient was estimated to assess the association between daily mean times of wear and skeletal changes.

Method error

The intra-examiner error for tracing, superimposition, measurement of the changes of the landmarks and estimating the CVM stage was calculated on the cephalograms of 10 randomly selected subjects. Another blinded clinician traced and measured the same lateral cephalograms to estimate inter-examiner error. All measurements were recorded independently, on two separate occasions, at a 2-week interval. For all the cephalometric variables, the difference between the independent repeated measurements of each individual before and after treatment was recorded. The intra-class correlation coefficient of reliability (R) was used to determine the reliability of cephalometric measurements.

Results

Participant flow

Thirty-five pre-pubertal Class III patients were recruited. Group I consisted of 18 patients: 13 males and 5 females. Group II consisted of 17 patients: 11 males and 6 females (Figure 4).

Losses and exclusions

One patient in group I developed leukaemia early in treatment and was unable to continue.

Baseline data

Sample description and demographics

Patient recruitment ran from October 2017 till December 2018. The patients were followed up till September 2019. The patients' mean age in group I was 8.2 ± 0.6 years old and in group II 8.8 ± 0.8 years old. Group I had 12 males (70.6%) and 5 females (29.4%) while group II had 11 males (64.7%) and 6 females (35.3%). There was no statistically significant difference between the groups as regards age or gender. All patients were primary school students (Table 1) and were prepubertal. All subjects were in CVM stage 2 at the start of treatment, which correlated well with their physical appearance.

Baseline demographic and clinical characteristics (group I vs group II)

The data showed a well-balanced group except for Mandibular length (Co-Gn) at T0 was significantly higher in group II (100.7 mm) than in group I (80.9 mm), (P = 0.022). On the other hand, group I maxillary length (CO-A point) was significantly shorter at 75.5 mm in comparison to group II at 90.7 mm (P = 0.021) (Table 2).

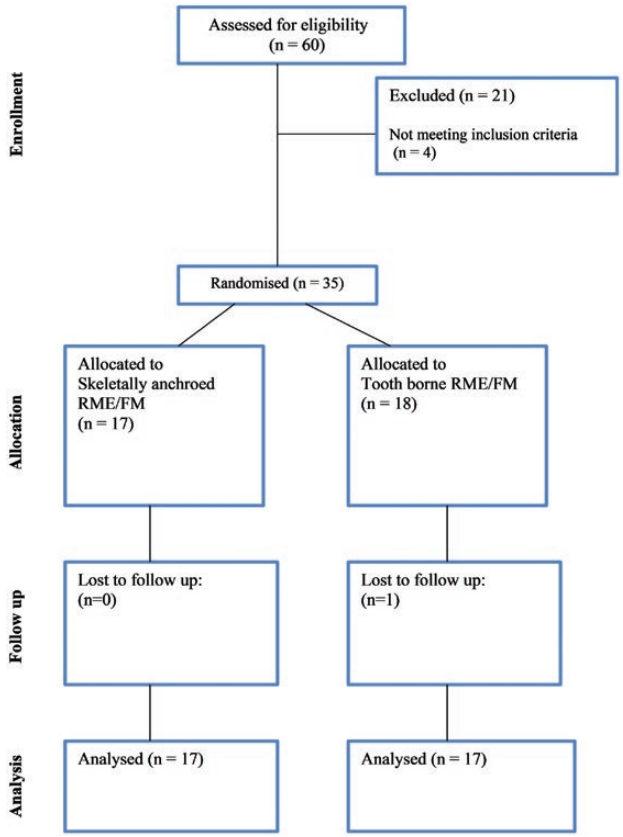

Figure 4 Flowchart of patients' allocations in the trial.

Numbers analysed

Thirty-five Class III malocclusion patients fulfilled all inclusion criteria, 1 (3%) of these patients discontinued treatment after randomization, having developed leukaemia. Thus, 34 patients, that is 17 in group I and 17 in group II, completed the study.

Outcomes and estimation

Inter-rater and intra-rater reliability

The correlations of all the cephalometric variables ranged from 0.88 to 0.96. The method of cephalometric analysis used in this study was deemed reliable and repeatable. The CVM inter-rater reliability coefficient (ICC) was 0.79 and the intra-rater reliability was 0.70, which reflects a very good agreement (Table 3).

Skeletal and dentoalveolar effects

The cephalometric differences were calculated by taking the mean of the medians of each group. The significance does not depend on the median of change. For example, a high median in a group does not imply that the P-value is smaller, or that significance was reached. When dealing with non-parametric tests, this is dependent on how many individuals show an increase, versus those that show a decrease in the value of the parameter under investigation.

Cephalometric analysis

Even though between the two groups several cephalometric variables changed within each group, no significant differences were noted in either skeletal or dentoalveolar parameters. Group I SNA showed a significant mean difference (T1–T0) of 2.10 degrees (0.90 5.20) (P = 0.007), but group II did not. Group I ANB showed a significant mean difference (T1–T0) of 3.90 degrees (2.40 4.90) (P = 0.001) and group II showed a significant mean difference (T1–T0) of 3.10 degrees (0.70 –4.20) (P = 0.007) (Table 4). Group I Wits appraisal showed a significant mean difference (T1–T0) of 4.70 mm (2.10 5.10) (P = 0.001). Group II showed a similar significant mean difference (T1–T0) of 3.20 mm (0.30 –4.40) (P = 0.002) (Table 4).

Table 1. Demographic data group I (tooth-borne FM/Alt-RAMEC) and group II (FM/Alt-RAMEC)

	Variable		Number	Clinical data	%
Duration	Group I		9 months	2 mm	
	Group II		9 months	2 mm	
Gender	Group I	Male	12		70.6
		Female	5		29.4
	Group II	Male	11		64.7
		Female	6		35.3
Age group (years)	Group 1		8.2 ± 0.6		
	Group II		8.8 ± 0.8		
Educational level	Group I (primary school students)		17		100
	Group II (primary school students)		17		100
Cervical maturational stage (CVM)	Group I	Male	12	CS2	
	Group II	Female	5	CS2	
		Male	11	CS2	
		Female	6	CS2	

Table 2. Cephalometric parameters inter-group at T0 (baseline)

	Group	T0	*P* value
Maxilla skeletal (Co-A point) mm	Group I	75.5 (80.0 90.5)	0.021*
	Group II	90.7 (80.5 105.2)	
Mand. skeletal (Pg-Na Perp)	Group I	1.80 (–5.00 5.00)	0.231
	Group II	3.50 (–1.40 6.40)	
Max. skeletal (A-N Perp)	Group I	–0.30 (–3.90 2.00)	0.760
	Group II	0.00 (–3.80 2.30)	
Mand. length (Co-Gn)	Group I	80.9 (75.0 99.5)	0.022*
	Group II	100.7 (86.5 115.2)	
SNA	Group I	78.8 (77.0 81.6)	0.812
	Group II	78.6 (78.0 80.2)	
SNB	Group I	79.6 (78.5 81.5)	0.274
	Group II	80.6 (79.0 82.6)	
ANB	Group I	–0.50 (–2.80 0.10)	0.339
	Group II	–1.40 (–3.30 –0.60)	
SN-maxillary plane	Group I	7.30 (5.70 10.0)	0.131
	Group II	8.40 (7.90 8.60)	
Palatal-mand. angle	Group I	25.5 (24.9 28.1)	0.433
	Group II	24.6 (21.3 26.9)	
Lafh/Tafh	Group I	55.0 (53.1 55.7)	0.259
	Group II	55.9 (54.3 56.2)	
Wits	Group I	–5.50 (–7.60 –3.20)	0.610
	Group II	–6.30 (–7.90 –3.90)	
Overjet	Group I	–2.00 (–2.40 –0.40)	0.150
	Group II	–1.30 (–1.80 –0.30)	
Overbite	Group I	–0.90 (–1.30 1.40)	0.586
	Group II	–0.40 (–1.10 1.40)	
U1-maxillary plane	Group I	114.1 (112.4 122.5)	0.683
	Group II	119.5 (108.5 122.8)	
IMPA	Group I	95.6 (89.5 99.7)	0.555
	Group II	88.9 (85.3 97.1)	
Interincisal angle	Group I	122.5 (121.2 125.2)	0.322
	Group II	129.9 (119.1 137.4)	
Nasolabial angle	Group I	120.2 (113.9 132.9)	0.099
	Group II	109.6 (94.0 124.3)	

Mann–Whitney test for comparisons between groups, *$P < 0.05$; **$P < 0.01$; ***$P < 0.001$. Group I: tooth-borne FM/Alt-RAMEC. Group II: skeletally anchored FM/Alt-RAMEC.

Dentoalveolar changes

Group I overjet showed a significant mean difference at (T1–T0) of 5.40 mm (4.10 5.70) ($P \leq 0.001$). Similarly, group II showed a significant mean difference of 4.50 mm (2.80 5.70) ($P = 0.001$). The lower incisor to the mandibular plane (IMPA) showed a significant mean difference (T1–T0) of –4.00 degrees (–11.4 0.00) ($P = 0.023$) in group I and group II showed a significant mean difference (T1–T0) of –6.10 degrees (–9.00 –0.50) ($P = 0.005$). The nasolabial angle for group I showed a significant mean difference increase (T0–T1) of 13.0 degrees (–20.4 3.1) ($P \leq 0.028$) but the change in group II was not significant 1.00 (–12.9 12.0) ($P = 0.717$) (Table 4).

Effect of compliance on skeletal changes

SNA angle: Spearman's correlation coefficient showed no correlation between the change in SNA angle and the compliance hours in group I ($r = –0.10$) and group II ($r = –0.07$) (Table 5).

ANB angle: Spearman's correlation coefficient showed no correlation between the change in ANB angle and the compliance hours (Table 5). Group I and II ($r = –0.09$ and $r = 0.15$), respectively.

Compliance

All patients reported full-time FM wear and excellent cooperation. However, according to the Theramon sensor recordings, group I patients wore the FM 7.87 ± 2.88 hours per day and group II wore the FM 6.98 ± 2.68 hours per day (Figure 5).

The compliance rate of group I was 9.57 ± 1.88 and 7.16 ± 2.98 hours per day for females and males, respectively. This difference was especially large within group I when compared to group II 7.19 ± 4.02 and 6.86 ± 1.83 hours per day for females and males, respectively. However, insignificant differences were found between genders, both intra-group (*P*

= 0.186) and inter-group (P = 0.309). The compliance regularity between males and females in both groups was insignificant (P = 0.563) (Table 6).

Harms

No harms or adverse events were reported throughout the study.

Discussion

Baseline characteristics

This was a randomized, controlled clinical trial that investigated the treatment outcomes for patients treated with tooth-borne FM/RME compared to skeletally anchored FM/RME; utilizing the Alt-RAMEC protocol. Allocation concealment was used to ensure randomization. This is a critical concept that aims to minimise selection bias. It involves concealing the treatment allocation sequence from those who are responsible for enrolling participants, thereby ensuring that the allocation process is randomized and unbiased. In this study, the sealed envelope technique was used. The mean age for group I was 8.2 ± 0.6 years and group II 8.8 ± 0.8 years. All patients were in CVM stage 2 at the start of treatment, which correlated well with their physical appearance. Thus, the two groups were of similar age, gender and growth status. CONSORT guidelines do not recommend baseline comparison; however, this shows that randomization has worked well. CVM is a controversial method of assessing skeletal maturation as variabilities between genders or low reproducibility and reliability among patients have been reported in the literature (23–25). while McNamara and Franchi also reported poor reproducibility for non-expert users (18). Perinetti *et al*. reported that with proper training, CVM reporting can reach a satisfactory level (23). The CVM assessment was conducted by a trained, calibrated clinician and was used to verify that the patient's skeletal age was consistent with their chronological age and physiological features.

Limitations

The power analysis indicated 17 subjects in each arm. A larger sample size was originally envisaged, but the Covid-19 pandemic severely restricted patient recruitment. The small sample size might be a limiting factor in this trial, longitudinal trials should consider recruiting larger numbers of patients. The study investigated the short-term effects of tooth-borne and skeletally anchored FM/Alt-RAMEC. A long-term follow-up study is required to assess the stability of the results.

Generalisability

The results of the present study apply to the ethnicity and age range under investigation, that is Caucasians aged 8–10.99 years.

Interpretation

According to Baccetti *et al*. (24)., significant forward displacement of maxillary structures can be achieved when tooth-borne maxillary expansion and FM therapy are performed at an early age. Two different multicentre randomized controlled trials, with 3- and 6-year follow-ups, confirmed the favourable effects of early Class III protraction FM treatment undertaken in patients under 10 years of age. On the other hand, the late treatment produces no significant skeletal improvement in maxillary growth with respect to controls, the only changes being dentoalveolar.

The mean age of patients in this investigation was similar to that of the Baccetti *et al*. early treatment group (25). The anterior movement of point A was reported as being 0.75 mm in group I and 1.00 mm in group II. This is less than the 2.33 mm produced by the traditional expansion and protraction headgear treatment investigated by Isci *et al*. (9) and

Table 3. Inter-examiner and intra-examiner reproducibility of cephalometric parameters: Intra-class correlation coefficient (CCI)

Inter-examiner			Intra-examiner	
	CCI	Assessment	CCI	Assessment
Mand. skeletal (Pg-Na Perp)	0.920	Excellent reliability	0.950	Excellent reliability
Max. skeletal (A-N Perp)	0.990	Excellent reliability	0.910	Excellent reliability
Mand. length (Co-Gn)	0.90	Excellent reliability	0.940	Excellent reliability
SNA	0.910	Excellent reliability	0.90	Excellent reliability
SNB	0.910	Excellent reliability	0.950	Excellent reliability
ANB	0.920	Excellent reliability	0.97	Excellent reliability
SN-maxillary plane	0.994	Excellent reliability	0.910	Excellent reliability
Palatal-mand. angle	0.980	Excellent reliability	0.920	Excellent reliability
Lafh/Tafh	0.90	Excellent reliability	0.90	Excellent reliability
Wits	0.930	Excellent reliability	0.910	Excellent reliability
Overjet	0.90	Excellent reliability	0.70	Good
Overbite	0.880	Excellent reliability	0.930	Excellent reliability
U1-maxillary plane	0.997	Excellent reliability	0.890	Excellent reliability
IMPA	0.889	Excellent reliability	0.984	Excellent reliability
Interincisal angle	0.990	Excellent reliability	0.890	Excellent reliability
Nasolabial angle	0.890	Excellent reliability	0.950	Excellent reliability

Table 4. Cephalometric parameters intra-group at baseline (T0) and the end of treatment (T1)

Intra-group						Inter-group
Parameters	**Group**	**T0**	**T1**	**Diff. T1–T0**	***P*-value**	***P*-value**
Mand. skeletal (Pg-Na Perp) mm	Group I	2.80 (–5.00 5.00)	0.80 (–3.90 1.00)	–2.00 (–9.60 1.10)	0.906	1.00
	Group II	3.50 (–1.40 6.40)	0.20 (–4.00 2.10)	–3.10 (–6.30 0.00)	0.129	
Max. skeletal (A-Na Perp) mm	Group I	–0.30 (–3.90 2.00)	0.20 (–2.30 2.20)	0,75 (–1.40 1.70)	0.449	0.683
	Group II	0.00 (–3.80 2.30)	1.00 (–4.50 1.30)	1.00 (–1.30 1.25)	0.277	
Mand. length (Co-Gn) mm	Group I	80.9 (75.0 99.5)	94.8 (93.8 97.4)	3.70 (–9.30 21.1)	0.332	0.680
	Group II	100.7 (86.5 115.2)	107.5 (101.8 112.1)	3.00 (–4.50 19.8)	0.121	
Maxilla skeletal (Co-A point) mm	Group I	75.5 (80.0 90.5)	93.8 (90.8 97.4)	8.70 (–9.30 21.1)	0.552	0.030*
	Group II	90.7 (80.5 105.2)	107.5 (100.8 110.1)	10.00 (–4.50 19.8)	0.481	
SNA (degrees)	Group I	78.8 (77.0 81.6)	80.9 (79.5 82.5)	2.10 (0.90 5.20)	0.007**	0.332
	Group II	78.6 (78.0 80.2)	81.0 (79.0 82.0)	2.50 (0.00 3.80)	0.88	
SNB (degrees)	Group I	79.6 (78.5 81.5)	79.7 (77.8 80.2)	–1.40 (–2.90 1.20)	0.201	0.946
	Group II	80.6 (79.0 82.6)	81.3 (79.0 81.8)	0.00 (–2.00 1.20)	0.530	
SN-maxillary plane	Group I	9.30 (5.70 10.0)	11.30 (6.90 9.30)	1.5 (–1.10 2.70)	0.495	0.120
	Group II	10.40 (7.90 8.60)	11.90 (2.90 7.30)	2.10 (–5.20 –0.40)	0.408	
ANB (degrees)	Group I	–0.50 (–2.80 0.10)	2.50 (1.10 3.80)	3.90 (2.40 4.90)	0.001**	0.812
	Group II	–1.40 (–3.30 –0.60)	1.00 (-0.90 2.40)	3.10 (0.70 4.20)	0.001**	
Palatal-mand. angle (degrees)	Group I	25.5 (24.9 28.1)	26.8 (18.9 28.2)	–0.20 (–4.40 1.90)	0.619	0.245
	Group II	24.6 (21.3 26.9)	26.3 (24.8 27.2)	0.30 (–0.60 4.80)	0.140	
Lafh/Tafh	Group I	55.0 (53.1 55.7)	53.6 (52.7 55.7)	–0.40 (–1.50 0.90)	0.148	0.160
	Group II	55.9 (54.3 56.2)	55.6 (54.9 57.1)	0.30 (–0.40 1.00)	0.352	
Wits (mm)	Group I	–5.50 (–7.60 –3.20)	–3.30 (–3.90 0.40)	4.70 (2.10 5.10)	0.001**	0.919
	Group II	–6.30 (–7.90 –3.90)	–2.80 (–4.50 –0.80)	3.20 (0.30 4.40)	0.002**	
Overjet (mm)	Group I	–2.00 (–2.40 –0.40)	3.30 (2.10 3.90)	5.40 (4.10 5.70)	<0.001***	0.496
	Group II	–1.30 (–1.80 –0.30)	2.90 (2.50 3.90)	4.50 (2.80 5.70)	<0.001***	
Overbite (mm)	Group I	–0.90 (–1.30 1.40)	0.10 (–1.10 3.10)	1.90 (–1.30 3.30)	0.093	0.322
	Group II	–0.40 (–1.10 1.40)	0.80 (0.40 2.50)	1.00 (0.00 3.70)	0.062	
U1-maxillary plane (degrees)	Group I	114.1 (112.4 122.5)	119.6 (116.4 122.6)	1.90 (–2.90 7.40)	0.245	0.812
	Group II	119.5 (108.5 122.8)	121.5 (110.0 127.1)	4.40 (–1.40 5.00)	0.162	
IMPA (degrees)	Group I	95.6 (89.5 99.7)	88.0 (85.6 96.7)	–4.00 (–11.4 0.00)	0.023*	0.786
	Group II	88.9 (85.3 97.1)	86.6 (81.8 91.0)	–6.10 (–9.00 –0.50)	0.005**	
Interincisal angle (degrees)	Group I	122.5 (121.2 125.2)	124.9 (121.7 131.5)	2.40 (0.20 4.40)	0.124	0.973
	Group II	129.9 (119.1 137.4)	129.6 (114.2 134.0)	0.60 (–4.10 4.00)	0.836	
Nasolabial angle (degrees)	Group I	120.2 (113.9 132.9)	124.0 (101.0 124.8)	13.0 (–20.4 3.1)	0.028*	0.540
	Group II	109.6 (94.0 124.3)	110.3 (108.9 120.8)	1.00 (–12.9 12.0)	0.717	

Wilcoxon test for comparisons within groups and Mann–Whitney *U*-test intergroup comparisons, **P* < 0.05; ***P* < 0.01; ****P* < 0.001. Group I: tooth-borne FM/Alt-RAMEC, group II: skeletally anchored FM/Alt-RAMEC.

the 4.3 mm reported by Miano *et al.* (4.33 mm) for their Alt-RAMEC protocol group (26). However, our sagittal cephalometric measurements were similar to the short-term results reported in the meta-analysis of Cordasco *et al.*, as was treatment duration (19). Significant sagittal skeletal improvement was achieved after 9 months of reverse headgear protraction. This was evidenced by the mean 2.10 degrees change in SNA and mean 4.7 mm change in Wits appraisal for group I. Group II showed a mean improvement of 2.50 degrees in SNA, which did not reach statistical significance; however, the 3.20 mm mean improvement in Wits appraisal was statistically significant. These results are in agreement with those reported by Nienkemper *et al.* (20). who used conventional FM/RME and obtained a mean improvement of 2.4 degrees in SNA and a 4.5 mm mean improvement in Wits appraisal. Our results also indicated that, as the skeletal sagittal improvement values in both group I and group II were similar, the use of skeletal anchorage did not add significant benefit in terms of skeletal sagittal correction in comparison to tooth-borne FM/Alt-RAMEC. In contrast, Koh and Chung (27) compared the treatment changes of skeletal versus tooth-borne FM and found a greater skeletal improvement in young Class III patients for the skeletal anchorage group.

It may seem contradictory that, although the mean increase in SNA for group II was larger than that of group I, the result of the smaller change was statistically significant, while that of the larger was not. As the data were not normally distributed, the difference between the two groups was determined using the mean of the medians of the different categories of

Table 5. SNA and ANB in correlation to compliance wearing time (Spearman's correlation coefficient)

Reference plane/angle		N	Spearman's correlation coefficient (r)	P value
SNA	Total	34	−0.10	0.609
	Group I	17	−0.10	0.693
	Group II	17	−0.07	0.786
ANB	Total	34	0.08	0.558
	Group I	17	−0.09	0.740
	Group II	17	0.15	0.558

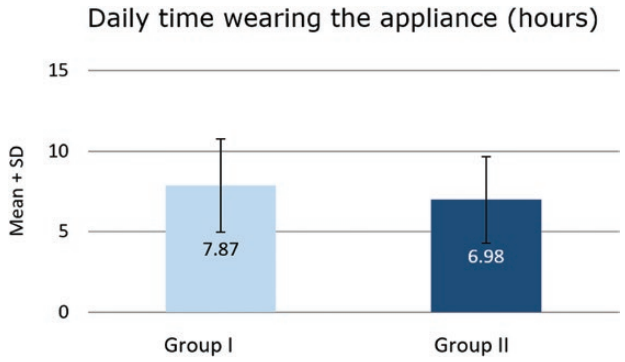

Figure 5 Daily compliance rate in conventional FM/Alt-RAMEC (group I) and skeletally anchored FM/Alt-RAMEC (group II).

Table 6. Compliance rate by gender: 2-way ANOVA model for comparisons of the mean within subjects

		Group I		Group II		P value
Wearing hours/day		Males	Females	Males	Females	0.30
	Mean	7.16	9.57	6.86	7.19	
	SD	2.98	1.88	1.83	4.02	
SD hours	Mean	3.71	3.12	3.77	3.75	0.56
	SD	1.15	1.64	1.06	1.79	

$^{*}P < 0.05$; $^{**}P < 0.01$; $^{***}P < 0.001$.

change between T0 and T1. Taking the case of the parameter SNA, it depends on how many patients showed an increase in SNA against how many showed a decrease. For example, in group I, there were 16 patients who increased SNA against one who decreased, while in group II, there were 14 patients who increased SNA, one who decreased and two showed no change. Consequently, group I reached significance, while group II did not. In both groups, dental changes were comparable to the tooth-borne FM/RME study by Westwood *et al.* (28). In Westwood's study, the overjet improved by 4.8 mm, compared to our findings of 5.40 mm and 4.50 mm for groups I and II, respectively. It is worth mentioning that upper incisor inclination in both groups increased; however, this response varied as depicted in the 95 per cent CIs and did not reach statistical significance. In the present study, the lower incisors retroclined −4.00 degrees in group I and −6.10 degrees in group II, which is in agreement with other studies (20,29). No change was noted in the maxillomandibular plane angle in both treatment protocols indicating that the direction of the applied forces, as recommended also by Nienkemper *et al.* (21)., maintained the vertical relationship.

The results indicate that tooth-borne and skeletally anchored FM/Alt-RAMEC had similar comparable skeletal and dental effects on young prepubertal patients. A possible explanation might be that, as the subjects were young and the circum-maxillary sutures were still patent, using skeletally anchored FM/Alt-RAMEC may not have any additional benefit in correcting the sagittal relationship in comparison to tooth-borne FM/Alt-RAMEC.

In this trial, the mini-implants were also found to remain stable. This stability might be related to the high bone quality of the insertion site and the stable screw coupling to the appliance. Both these factors might lead to an increased biomechanical load capacity (30,31). Compared to other anchorage modalities such as mini plates, the hybrid HYRAX is less invasive in both during insertion and removal. Mini-implants provide additional skeletal anchorage during RME, minimizing transverse and sagittal side effects (32).

Compliance with FM wear is crucial to achieving sagittal improvement in Class III patients; however, its measurement is difficult. Previous attempts to assess compliance with removable appliances, or to identify predictive factors for compliance, were contradictory or inconclusive (33,34). This inconsistency can be attributed to the fact that compliance is a complex multifactorial process, combined with the inability to objectively assess compliance accurately and reliably. Furthermore, previous studies suffered from methodological issues, such as sample size and gender or age matching. Therefore, data were likely to be skewed or obscured, leading to incorrect conclusions.

In this investigation, patients were instructed to wear the FM 12–14 hours per day. The average FM-wearing time was 7.87 ± 2.88 hours per day for group I and 6.98 ± 2.68 hours per day for group II. Only 23.5 per cent of the children in group I and 11.7 per cent in group II wore the FM for more than 10 hours. Female to male compliance rates were similar in both groups, with insignificant differences in wearing time. This is also in agreement with the literature, as compliance in younger patients is much better (35) and the sex difference in compliance seen in adolescents is not evident at this age (36).

All patients and parents reported wear times of over 12 hours per day, while the Theramon sensor did not confirm these numbers. This is consistent with the literature as Schott and Ludwig reported that children wore removable appliances for 9 hours, while the prescribed time was 12–15 hours (36). In this study, both patients and parents were made aware of the presence of the sensor, as it would have been difficult to hide. However, they were given the impression that its function was to record fluctuations in pressure and not hours of wear.

Even though only a small percentage of the groups wore their FMs for 10 hours or more, significant, positive sagittal changes took place, leading to the correction of the Class III malocclusion (37). This is in agreement with other studies (33,34) and suggests that even though patients did not wear the FM as instructed, the desired orthopaedic and

orthodontic movements were still accomplished. The implication is that treatment efficacy can be achieved with less wear time, reducing the burden of compliance both to patients and the supervising parents. The results of this study indicate that FM wear can be reduced to 5–7 hours daily or limited during night-time while still achieving considerable changes.

Conclusions

- The hybrid HYRAX FM/Alt-RAMEC and tooth-borne FM/Alt-RAMEC are equally effective orthopaedic treatment modalities in growing Class III patients.
- FM use of 5–10 hours daily or only during night-time can still achieve substantial and positive sagittal maxillary.

Registration

The study was registered as a Randomized Clinical Trial (RCT), https://doi.org/10.1186/ISRCTN12197405).

Funding

This project is fully funded by University of Malta grant number: CDORP02.

Conflicts of interest

The authors declare that there is no conflict of interest.

Data availability

The data underlying this article cannot be shared publicly due to ethical approval restrictions that govern the privacy of individuals' data that participated in the study. The data will be shared on reasonable request with the corresponding author.

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