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ORIGINAL RESEARCH

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The Removable Mandibular Retractor *vs* the Bone-anchored Intermaxillary Traction in the Correction of Skeletal Class III Malocclusion in Children: A Randomized Controlled Trial

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ABSTRACT

Background: No randomized controlled trial has tried to compare early class III treatment outcomes between the removable mandibular retractor (RMR) and the bone-anchored intermaxillary traction (BAIMT). The objective of this study was to evaluate skeletal, dental, and soft-tissue changes following early class III treatment with these two treatment modalities.

Materials and methods: A parallel group randomized controlled trial was conducted on patients with class III malocclusion, treated at the University of Al-Baath Dental School in Hamah, Syria. Ninety-three children with skeletal class III malocclusion were evaluated and 41 children fulfilled the inclusion criteria. Randomization was performed using computer-generated tables; allocation was concealed using sequentially numbered opaque and sealed envelopes. Thirty-eight participants were analyzed (mean age 11.46 ± 1.28 years). They were randomly distributed into two groups receiving either the RMR or the BAIMT technique with 19 children in each (1:1 allocation ratio). The primary outcome measure was the horizontal movement of points A, B, and Pogonion.

Results: Point A showed greater anterior movement in the BAIMT group ($\bar{x} = 1.69$ mm) than in the RMR group ($\bar{x} = 1.05$ mm; $p < 0.001$). Points B and Pog showed posterior movement in the BAIMT group ($\bar{x} = -3.01$ and –2.51 mm respectively) and anterior movements in the RMR group ($\bar{x} = 0.22$ and 0.78 mm respectively).

Conclusion: The BAIMT appeared to be more effective than the RMR in the correction of mild to moderate class III malocclusion in growing patients.

Clinical significance: Bone-anchored intermaxillary elastics appears to be a promising solution for class III growing patients with mild to moderate degrees of skeletal discrepancy.

Keywords: Bone-anchored traction, class III malocclusion, Correction of malocclusion, Intermaxillay traction, Removable mandibular retractor.

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INTRODUCTION

Treatment of class III malocclusion is a major challenge in orthodontic contemporary practice.[1] Several methods have suggested for the treatment of class III malocclusion by growth modification in the primary or mixed dentitions, such as the facial mask,[2] Frankel III Appliance,[3] the class III Bionator,[4] the chin cup,[5] and the removable mandibular retractor (RMR).[6] The ability of the RMR of changing growth pattern in the early treatment of class III deformities has been shown in several papers either in the early or late mixed dentitions.[6,7] New methods of class III treatment have emerged recently, and one of these methods is the bone-anchored intermaxillary traction (BAIMT) system using upper and lower miniplates to provide skeletal anchorage.[8] De Clerck et al[8-16] have demonstrated (in a series of published papers) an improvement in the skeletal relationships when correcting class III problems. However, the involvement of surgical interventions when inserting or removing these miniplates has been shown to be a considerable source of pain and discomfort to patients.[17] This method was later simplified by Jamilian and Showkatbakhsh,[18] who suggested using mini-implants in the lower jaw instead of mini-plates providing bilateral lower anterior gingival hooks to which intermaxillary traction was attached. In the upper jaw, they suggested the use of an upper removable appliance (URA) with two hooks located at the level of upper first molars instead of maxillary posterior mini-plates. The proposed technique was retrospectively evaluated by the same group of researchers comparing 10 patients treated by the BAIMT technique with 10 patients treated by conventional facial mask.[19] Despite the retrospective nature of their study, the sample size was small and the comparison made between the facial mask group and the BAIMT group does not appear to be valid since facial mask therapy is generally indicated for patients with maxillary deficiency-based class III deformities, whereas the BAIMT technique has been shown to affect primarily the lower jaw.[13] Meanwhile, the RMR is commonly used in our teaching hospitals in Syria in modifying growth pattern of class III growing patients with an underlying slight mandibular prognathism and has been shown to be well accepted by children.[20]

Therefore, the aim of the current randomized controlled trial (RCT) was to compare the efficacy of the mini-implant-based BAIMT system with the commonly used RMR in growing class III patients in late mixed dentition and in early permanent dentition.

MATERIALS AND METHODS

Estimation of the Sample Size

Sample size calculation was undertaken using Minitab® 16 (Minitab Inc, State College, PA, USA). The smallest difference in the ANB angle requiring detection was assumed to be 1.5° and the standard deviation of this variable was found to be 1.6° in a previous publication.[17] Therefore, employing a two-sample t test with a power of 80 and a 5% significance level, 19 patients were required for each group in this study.

Patients' Recruitment and Assignment

A parallel group RCT was conducted at the Orthodontic Department of University of Al-Baath Dental School. This research project was approved by University Al-Baath Dental School (UBDS-2072-2011PG) Ethics Committee and was funded by the University of Al-Baath Postgraduate Research Budget (73401201184DEN).

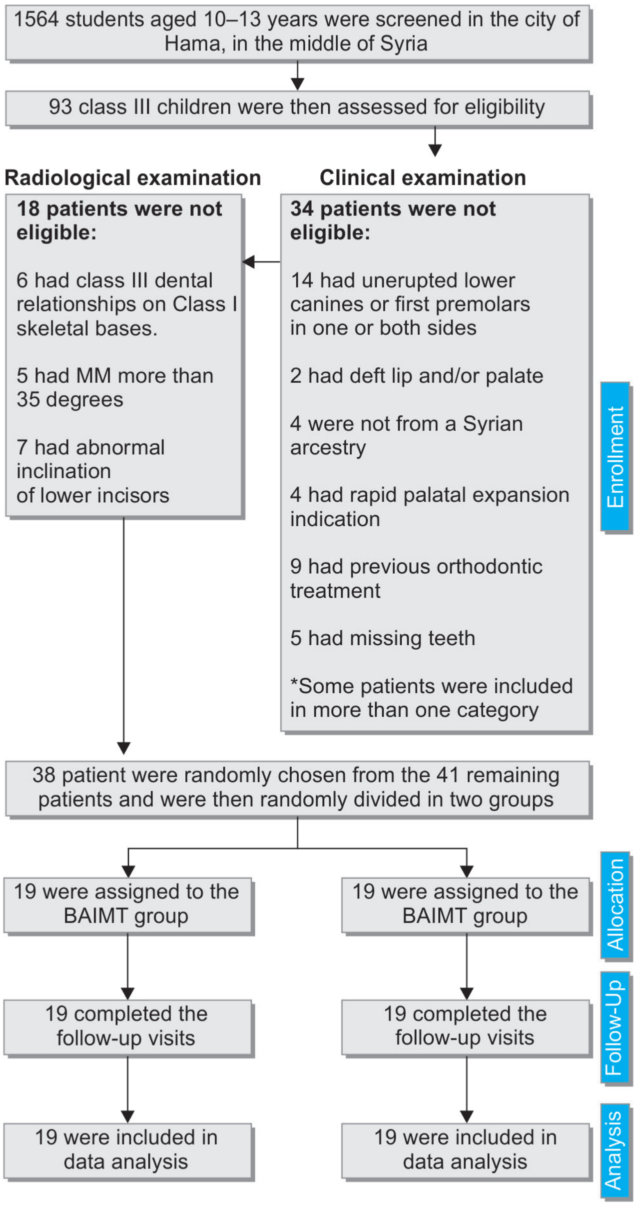
A screening of 1,564 primary school students was conducted at six primary schools chosen at random from 12 schools in the city of Hama. Those children who exhibited class III relationships, assessed primarily on the presence of anterior crossbites ($n = 93$), were asked to visit the dental school with their parents for a further in-depth evaluation. From those eligible to enter the RCT, 38 patients were randomly selected and were then assigned to the two groups in a 1:1 allocation ratio. Simple randomization was performed by creating a randomization list using Minitab® V16 (Minitab Inc., Pennsylvania, PA, USA) with an allocation ratio of 1:1. The allocation sequence was concealed from the principal researcher (AMRM) enrolling and assessing participants in sequentially numbered opaque and sealed envelopes. To prevent subversion of the allocation sequence, the name and date of birth of each participant was written on the envelope, and these data were transferred onto the allocation card inside each envelope. Corresponding envelopes were opened only after completing all baseline assessments and when the time came to allocate the intervention. Patients who did not meet the inclusion criteria or those who were not selected for enrolment in the RCT were treated by postgraduate students. Flow Chart 1 shows patients' recruitment, follow-up, and their entry into data analysis.

Inclusion and Exclusion Criteria

The inclusion criteria were (1) Angle's class III malocclusion, (2) anterior crossbite on two teeth or more or an edge-to-edge bite with or without an anterior shift of the mandible during the closure, (3) skeletal class III relationship judged clinically and confirmed radiographically ($-4 < ANB < +1$), (4) normal inclination of the lower incisors with an incisor mandibular plane angle (IMPA) not exceeding 100° and not less than 85°, (5) no facial asymmetry or minimal facial asymmetry (less than 2 mm of deviation of the mandibular midline from the facial midline), (6) patients in late mixed dentition or at the beginning of permanent dentition (dental age between 9 years 6 months and 13 years approx.), (7) the lower canines and first premolars should have fully erupted on both sides, (8) no craniofacial syndromes or cleft lip and/or palate abnormalities, (9) absence of supernumerary teeth or missing teeth except for the third molars, (10) no previous orthodontic treatment, and (11) Syrian ancestry.

The exclusion criteria were (1) Skeletal class III relationship caused predominantly by maxillary deficiency (SNA angle should have been less than 78 with a normal SNB angle), (2) severe skeletal class III resulting primarily from mandibular prognathism (ANB less than – 4° with no functional shift on closure), (3) patients with diseases that prevent the application of mini-implants (e.g., osteoporosis – treated with cortisone and its derivatives treated with radiation), (4) a convergence between the roots of the canine and first premolar assessed radiographically, (5) an indication for rapid maxillary expansion, and

Flow Chart 1: Patients' recruitment, follow-up, and entry to data analysis



(6) MM angle greater than 35° or SN-MP angle greater than 40°.

Thirty-eight patients (17 females and 21 males) were included in this trial and their baseline sample characteristics are given in Table 1. Information sheets were given and their informed consents were obtained.

Intervention group: Bone-Anchored Intermaxillary Traction

This treatment modality consisted of (1) Upper acrylic plate with posterior smooth bite plate, (2) labial arch 0.7 mm of stainless steel, (3) Adam's clasps on the upper first permanent molars (0.7 stainless steel wire), (4) and hooks (made of 0.9-mm stainless steel wire) for attaching elastic bands placed distal to the first molars (Fig. 1).

Two self-drilling mini-implants (O.S.A.S., Dewimed®, Tuttlingen, Germany; 1.6-mm diameter, 8-mm length) were inserted under local anesthesia into the buccal alveolar bone between the mandibular canine and the first premolar roots on both sides with an insertion angle of about 45 to 60° with the alveolar process. A periapical radiograph was taken beforehand to assure proper insertion without damaging the neighboring roots.

Intermaxillary elastics (American Orthodontics, Sheboygan, WI, USA) were applied between URAs' hooks and the mandibular anterior mini-implants (Fig. 2), generating a 100-g force on each side of the jaw in the first week (5/16-inch) followed by 3/16 medium size in order to generate an orthodontic force of about 200 g on each side until the end of treatment. Patients were asked to wear elastics for 18 hours per day and replace elastics on a daily basis or when they get damaged.

Control group: The Removable Mandibular Retractor

The shape of this URA is given in Figure 3 and its components are given in detail elsewhere.[6] Patients were asked to wear the RMR for 16 hours per day, including bedtime. The appliance was activated monthly to adjust the anteroposterior location of the reverse arch in order to maintain the passive contact with the cervical regions of the lower anterior teeth.

All patients in the two groups were seen within 1 week, following appliance's first insertion, 2 weeks following first insertion, and then at monthly visits to observe the change in incisor relationship, monitor patient's compliance, and tighten Adam's clasps. A change in the incisor relationship from a negative overjet (i.e., class III incisor relationship) into a positive

Table 1: Baseline sample characteristics

	BAIMT group	*RMR group*
Number of patients	19	19
Sex distribution	9 females, 10 males	8 females, 11 males
Mean age (SD)	11.3 years (1.2 years)	11.5 years (1.5 years)
Dentition	Late mixed dentition	Late mixed dentition
Incisor relationship	Anterior crossbite (two teeth at least)	Anterior crossbite (two teeth at least)
Posterior crossbite (no/yes)	14/5	13/6
Crowding (no/minimal)	17/2	16/3

SD: Standard deviation

Fig. 1: The URA designed for the BAIMT system

Fig. 2: Intraoral photograph showing the BAIMT system

Fig. 3: The removable mandibular retractor

overjet (i.e., +1.5 mm or greater) was considered the sign of a successful treatment.[6] All appliances used in the treatment were fabricated by one dental technician.

Cephalometric Analysis and Primary Outcome Measures

Lateral standardized cephalograms were taken before treatment (T1), after the end of the active phase of treatment (T2), and 12 months after the beginning of treatment (T3). The active phase of treatment is the stage of the application of maximum hours, and this ends when arriving at clinically normal incisor relationship, that is, a positive overjet (≥1.5 mm).

The linear and angular measurements employed in the current work are shown in Figures 4 and 5 and their definitions are given in Table 2, according to Jacobson[21] and Riolo et al.[22] The primary outcome measures were the horizontal movement of point A, point B, and Pogonion. A coordinate system was constructed on the baseline radiographic cephalogram and was transferred to the T2 and T3 tracings, employing a software-based superimposition for T2 and T3 tracings onto the T1 tracing, using the anterior cranial base as a reference plane and registering at N point. This was followed by calculating landmarks' displacements. Figure 5 shows the positions of these landmarks as well as the coordinate system used. All digital cephalograms had a 265-dpi resolution and were saved as BMP files. All measurements were taken by one researcher (AMRM). Points and measurements were obtained by a dedicated cephalometric program

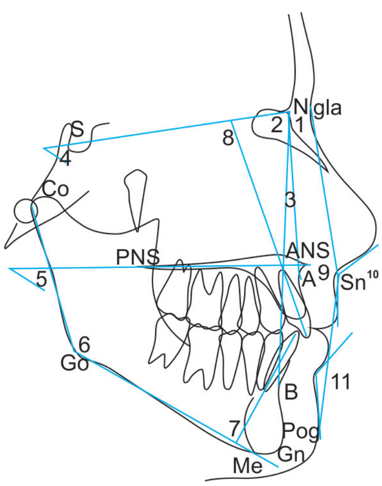


Fig. 4: Angular measurements. 1: SNA, 2: SNB, 3: ANB, 4: SN.GoMe, 5: MM, 6: Co.Go.Me, 7: LI.GoMe, 8: UI.SN, 9: Gla. Sn.pog, 10: Nasolabial angle, 11: Mentolabial fold

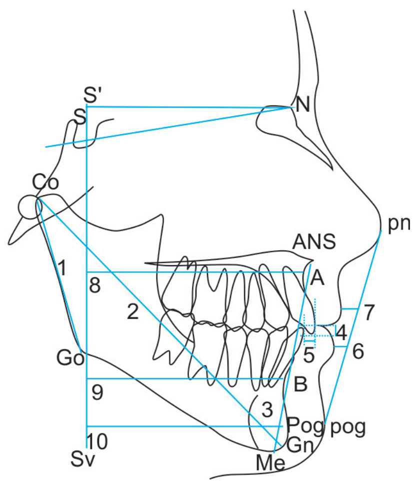


Fig. 5: A horizontal plane (SN') was constructed by a clockwise rotation of the Sella-Nasion plane 7° and a line perpendicular to it through Sella was constructed (S_vertical or Sv). 1: Co-Go, 2: Co-Gn, 3: ANS-Me, 4: Ovb, 5: Ovj, 6: Li-E line, 7: Ls-E line, 8: A_H, 9: B_H, 10: Pog_H

Table 2: Definitions of angular and linear measurements used in this study[21,22]

SNA*	The angle between the anterior cranial base and NA plane
SNB*	The angle between the anterior cranial base and NB plane
ANB*	SNA minus SNB (skeletal relationship in the midsagittal plane)
SN.GoMe*	The angle between the anterior cranial base and the mandibular planes
MM*	The angle between the maxillary and the mandibular planes
Co.Go.Me*	The angle between the remus and the body of the mandibular planes
Co-Go**	The length of the remus
Co-Gn**	The length of the mandibule
ANS-Me**	The height of the lower third of the face
LI.GoMe*	The angle between the mandibular plane and the lower incisor axis
UI.SN*	The angle between the anterior cranial base and the upper incisor axis
Ovb**	The overbite
Ovj**	The overjet
gla.sn.pog*	The facial convexity angle
Li-Esth**	The distance between the Labrale inferius and E-Line of Ricketts
Ls-Esth**	The distance between the Labrale superius and E-Line of Ricketts
NasoLab*	The nasolabial angle
MentoLab*	The mentolabial angle
A_H**	The horizontal distance between the upper incisal tip and S_vertical (Sv) plane
B_H**	The horizontal distance between the upper incisal apex and Sv plane
Pog_H**	The horizontal distance between the upper canine hook and Sv plane

*Angular measurements (measured in degrees) are shown in Fig. 4
**Linear measurements (measured in mm) are shown in Fig. 5

(Viewbox®, version 4.0.0.98 dHAL Software, Kifissia, Greece), and data were exported as Excel (Office Excel 2007, Microsoft Corporation, Redmond, Washington, USA) files for further statistical analysis.

Error of the Method

The error of the measurement method was calculated based on double measurements on 20 randomly selected lateral cephalograms using Dahlberg's formula.[23] The measurements were repeated after an interval of 1 month for the selected patients. The error of the method ranged from 0.2 to 0.34 for linear measurements and from 0.34 to 0.44 for angular measurements and was considered low (Table 3). No systematic error was detected when the paired t-test was applied.[24] Intraclass correlation coefficient analysis confirmed the high reliability of the measuring procedure with R values ranging from 0.983 to 0.995.

Statistical Analysis

Descriptive and inferential statistics were performed using Minitab® V16 (Minitab Inc., Pennsylvania, PA, USA). Anderson–Darling normality tests were performed to check the distribution of data. Parametric (two-sample t) tests or nonparametric (Mann–Whitney U test) tests were used as appropriate to detect significant differences between the two groups, with the level of significance set at 0.05. A Bonferroni correction of the significance level was used to adjust for multiple testing (i.e., a result with a p-value less than 0.017 was considered significant).

RESULTS

The average active phase of treatment (T2 – T1) was accomplished within 6.3 and 3.4 months in the BAIMT and the RMR groups respectively. Descriptive statistics of cephalometric measurements at the three assessment times are given in Table 4.

There was an overall (T3 – T1) significant increase in the ANB angle in the BAIMT group (3.41°, $p = 0.003$, Table 5) and in the RMR group (1.64°, $p < 0.001$, Table 6). This was associated with an overall (T3 – T1) significant anterior movement of point A in the BAIMT group (1.69 mm, $p < 0.001$, Table 5) and in the RMR group (1.05 mm, $p < 0.001$, Table 6). Also, this was accompanied with an overall (T3 – T1) significant posterior movement of point B in the BAIMT group (–3.01 mm, $p < 0.001$, Table 5), whereas point B showed an insignificant mean anterior movement in the RMR group (0.22 mm, $p = 0.031$, Table 6).

Vertically, the height of the lower third of the face had a significant mean increase in the overall assessment of change in both groups (5.10 and 2.56 mm respectively, $p < 0.001$). The overall changes in the MM angle were significant in both groups (1.62° and 0.45° respectively, $p < 0.001$). The maxillary incisors' inclination to the cranial base had an overall mean increase in the BAIMT and RMR groups (2.71° and 5.21° respectively, $p < 0.001$), whereas lower incisors–mandibular plane angle had a mean increase of 0.88° in the BAIMT group and a mean decrease of 2.55° in the RMR group.

There was a significant mean reduction in the facial convexity angle (gla.sn.pog) in the BAIMT and RMR groups (–7.11° and –4.81° respectively, $p < 0.001$) as well as the nasolabial and mentolabial angles, which showed significant reductions in both groups.

Generally, significant differences were detected between the two groups in relation to the changes observed at three time comparisons (Table 7). The BAIMT technique presented a better correction of the skeletal

Table 3: Error of the method and intraobserver reliability

Measurements	Dahlberg's error of the method[23]	Systematic error* Mean difference	Systematic error* p-value	Intraclass correlation coefficients**
SNA	0.21°	–0.13	0.988	0.993
SNB	0.21°	–0.01	0.891	0.992
ANB	0.23°	–0.05	0.989	0.995
SN.GoMe	0.20°	–0.03	0.915	0.943
MM	0.18°	0.03	0.992	0.999
Co.Go.Me	0.20°	–0.12	0.989	0.998
Co-Go	0.16 mm	0.04	0.964	0.999
Co-Gn	0.18 mm	–0.05	0.984	0.998
ANS-Me	0.14 mm	–0.04	0.981	0.997
LI.GoMe	0.14°	0.06	0.975	0.998
UI.SN	0.13°	–0.01	0.976	0.998
Ovb	0.12 mm	–0.14	0.989	0.994
Ovj	0.13 mm	–0.02	0.819	0.991
gla.sn.pog	0.13°	0.02	0.995	0.998
Li-Esth	0.11 mm	0.10	0.993	0.999
Ls-Esth	0.10 mm	0.01	0.947	0.999
Nasolab	0.08°	–0.06	0.995	0.994
Mentolab	0.12°	0.10	0.963	0.990
A_H	0.21 mm	0.03	0.945	0.998
B_H	0.21 mm	0.12	0.986	0.999
Pog_H	0.18 mm	0.05	0.945	0.999

*Systematic error was assessed using paired t-tests; **Intraclass correlation coefficients for random error assessment; Variables' definitions are given in Table 2

Table 4: Descriptive statistics of angular and linear cephalometric measurements of the BAIMT and RMR groups at the three assessment times

	BAIMT group						RMR group					
	T1		T2		T3		T1		T2		T3	
Variable	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
SNA	79.06	0.55	80.26	0.57	80.53	0.57	79.06	1.06	79.54	1.01	79.71	1.02
SNB	80.78	1.08	79.23	1.00	78.85	0.97	80.71	1.10	79.95	1.13	79.72	1.14
ANB	–1.73	0.83	1.03	0.79	1.69	0.75	–1.65	0.89	–0.41	0.87	–0.01	0.86
SN.GoMe	35.81	2.13	36.85	2.11	37.01	2.10	36.00	2.12	35.92	2.12	35.95	2.12
MM	27.43	2.66	28.79	2.61	29.05	2.61	28.76	3.96	29.07	3.94	29.21	3.96
Co.Go.Me	130.58	1.25	131.15	1.32	131.27	1.31	131.06	1.68	131.49	1.72	131.61	1.74
Co-Go	45.85	1.02	49.07	1.09	49.85	1.01	45.92	1.28	47.42	1.39	47.74	1.40
Co-Gn	102.14	1.26	104.76	1.46	105.71	1.41	101.96	1.48	104.82	1.73	105.31	1.72
ANS-Me	55.32	1.51	59.48	1.73	60.42	1.73	55.78	1.14	57.96	1.36	58.34	1.29
LI.GoMe	87.44	0.92	88.16	1.29	88.32	1.35	87.46	1.03	85.36	0.81	84.91	0.80
UI.SN	98.71	1.02	100.52	1.64	101.42	1.65	98.39	1.12	102.63	1.12	103.60	1.05
Ovb	3.08	0.78	1.48	0.39	1.28	0.35	3.08	0.57	1.36	0.45	1.18	0.41
Ovj	–2.51	0.87	2.07	0.33	2.40	0.36	–2.55	0.71	1.40	0.29	1.65	0.30
gla.sn.pog	189.69	1.83	183.64	1.43	182.58	1.44	189.07	1.73	184.92	1.79	184.26	1.82
Li-Esth	0.54	0.93	0.20	0.91	0.01	0.90	0.68	0.75	0.45	0.85	0.35	0.86
Ls-Esth	–3.72	0.71	–2.73	0.62	–2.31	0.57	–3.66	0.69	–3.36	0.66	–3.21	0.66
Nasolab	128.27	2.05	124.08	2.03	122.63	1.98	127.72	1.85	124.56	1.58	124.00	1.58
Mentolab	142.65	2.08	135.86	2.51	134.06	2.58	142.08	1.59	138.09	1.79	137.18	1.87
A_H	60.07	1.33	61.45	1.31	61.76	1.28	60.07	1.25	60.93	1.23	61.12	1.27
B_H	58.27	1.00	55.90	0.99	55.27	0.99	58.75	1.36	58.92	1.38	58.96	1.37
Pog_H	56.24	1.14	54.13	1.07	53.73	1.00	56.42	1.45	57.08	1.40	57.20	1.39

Variable definitions are given in Table 2. T1: At the beginning of treatment; T2: After finishing the active treatment period; T3: At the end of treatment

Table 5: Descriptive statistics of the observed changes between assessment times in the BAIMT group and their statistical significance† (n = 19)

	T2 – T1			*T3 – T2*			*T3 – T1*		
	Active treatment period			*Follow-up period*			*Overall changes*		
Variable	*Mean*	*SD*	*p-value*	*Mean*	*SD*	*p-value*	*Mean*	*SD*	*p-value*
SNA	1.20	0.15	<0.001(***)	0.27	0.05	<0.001(***)	1.48	0.14	<0.001(***)
SNB	–1.56	0.20	<0.001(***)	–0.38	0.06	<0.001(***)	–1.94	0.23	<0.001(***)
ANB	2.76	0.24	<0.001(***)	0.66	0.09	<0.001(***)	3.41	0.26	<0.001(***)
SN.GoMe	1.05	0.22	<0.001(***)	0.16	0.04	<0.001(***)	1.20	0.23	<0.001(***)
MM	1.36	0.26	<0.001(***)	0.26	0.08	<0.001(***)	1.62	0.27	<0.001(***)
Co.Go.Me	0.57	0.28	<0.001(***)	0.12	0.03	<0.001(***)	0.69	0.28	<0.001(***)
Co-Go	3.23	0.36	<0.001(***)	0.78	0.37	<0.001(***)	4.00	0.39	<0.001(***)
Co-Gn	2.62	0.64	<0.001(***)	0.95	0.67	<0.001(***)	3.57	0.83	<0.001(***)
ANS-Me	4.16	0.46	<0.001(***)	0.94	0.42	<0.001(***)	5.10	0.59	<0.001(***)
LI.GoMe	0.72	1.04	0.008(**)	0.16	0.08	0.008(**)	0.88	1.09	0.002(**)
UI.SN	1.81	0.93	<0.001(***)	0.90	0.19	<0.001(***)	2.71	0.94	<0.001(***)
Ovb	–1.60	0.52	<0.001(***)	–0.20	0.11	<0.001(***)	–1.80	0.56	<0.001(***)
Ovj	4.57	0.64	<0.001(***)	0.33	0.08	<0.001(***)	4.90	0.66	<0.001(***)
gla.sn.pog	–6.05	0.73	<0.001(***)	–1.05	0.24	<0.001(***)	–7.11	0.67	<0.001(***)
Li-Esth	–0.33	0.13	<0.001(***)	–0.19	0.05	<0.001(***)	–0.53	0.13	<0.001(***)
Ls-Esth	0.98	0.26	<0.001(***)	0.42	0.09	<0.001(***)	1.41	0.29	<0.001(***)
Nasolab	–4.19	1.19	<0.001(***)	–1.45	0.28	<0.001(***)	–5.64	1.21	<0.001(***)
Mentolab	–6.79	1.20	<0.001(***)	–1.80	0.22	<0.001(***)	–8.59	1.30	<0.001(***)
A_H	1.38	0.37	<0.001(***)	0.31	0.38	0.003(**)	1.69	0.42	0.003(**)
B_H	–2.37	0.34	<0.001(***)	–0.63	0.35	<0.001(***)	–3.01	0.46	<0.001(***)
Pog_H	–2.12	0.28	<0.001(***)	–0.39	0.35	<0.001(***)	–2.51	0.40	<0.001(***)

†Employing paired t tests (or Wilcoxon matched-pairs signed-rank tests when appropriate); Variables' definitions are given in Table 2; **p < 0.01, ***p < 0.001

Table 6: Descriptive statistics of the observed changes between assessment times in the RMR group and their statistical significance† (n = 19)

	T2 – T1			*T3 – T2*			*T3 – T1*		
	Active treatment period			*Follow-up period*			*Overall changes*		
Variable	*Mean*	*SD*	*p-value*	*Mean*	*SD*	*p-value*	*Mean*	*SD*	*p-value*
SNA	0.48	0.17	<0.001(***)	0.18	0.05	<0.001(***)	0.65	0.19	<0.001(***)
SNB	–0.76	0.22	<0.001(***)	–0.23	0.03	<0.001(***)	–0.99	0.20	<0.001(***)
ANB	1.24	0.32	<0.001(***)	0.40	0.07	<0.001(***)	1.64	0.34	<0.001(***)
SN.GoMe	–0.08	0.03	<0.001(***)	0.03	0.01	<0.001(***)	–0.05	0.04	<0.001(***)
MM	0.31	0.22	<0.001(***)	0.14	0.06	<0.001(***)	0.45	0.24	<0.001(***)
Co.Go.Me	0.43	0.22	<0.001(***)	0.12	0.05	<0.001(***)	0.55	0.24	<0.001(***)
Co-Go	1.51	0.56	<0.001(***)	0.32	0.28	<0.001(***)	1.82	0.51	<0.001(***)
Co-Gn	2.86	1.15	<0.001(***)	0.49	0.65	0.004(**)	3.35	1.17	<0.001(***)
ANS-Me	2.18	0.96	<0.001(***)	0.38	0.31	<0.001(***)	2.56	0.82	<0.001(***)
LI.GoMe	–2.10	0.71	<0.001(***)	–0.45	0.13	<0.001(***)	–2.55	0.70	<0.001(***)
UI.SN	4.25	1.20	<0.001(***)	0.97	0.21	<0.001(***)	5.22	1.19	<0.001(***)
Ovb	–1.72	0.59	<0.001(***)	–0.18	0.06	<0.001(***)	–1.91	0.56	<0.001(***)
Ovj	3.95	0.75	<0.001(***)	0.25	0.08	<0.001(***)	4.20	0.74	<0.001(***)
gla.sn.pog	–4.15	1.45	<0.001(***)	–0.66	0.18	<0.001(***)	–4.81	1.48	<0.001(***)
Li-Esth	–0.23	0.15	<0.001(***)	–0.10	0.03	<0.001(***)	–0.34	0.16	<0.001(***)
Ls-Esth	0.31	0.11	<0.001(***)	0.15	0.06	<0.001(***)	0.45	0.14	<0.001(***)
Nasolab	–3.16	1.22	<0.001(***)	–0.56	0.18	<0.001(***)	–3.72	1.29	<0.001(***)
Mentolab	–3.99	1.44	<0.001(***)	–0.91	0.23	<0.001(***)	–4.90	1.59	<0.001(***)
A_H	0.86	0.47	<0.001(***)	0.19	0.37	0.041(*)	1.05	0.50	<0.001(***)
B_H	0.18	0.38	0.059	0.04	0.35	0.624	0.22	0.40	0.031(*)
Pog_H	0.66	0.40	<0.001(***)	0.12	0.32	0.125	0.78	0.39	<0.001(***)

†Employing paired t-tests (or Wilcoxon matched-pairs signed-rank tests when appropriate); Variable definitions are given in Table 2; *p < 0.05, **p < 0.01, ***p < 0.001

Table 7: p-values of significance tests† of the observed changes between the two groups

	BAIMT vs RMR groups		
	T2 – T1	T3 – T2	T3 – T1
	Effective treatment period	Follow-up period	Overall changes
Variable	(p-values)	(p-values)	(p-values)
SNA	<0.001(***)	<0.001(***)	<0.001(***)
SNB	<0.001(***)	<0.001(***)	<0.001(***)
ANB	<0.001(***)	<0.001(***)	<0.001(***)
SN.GoMe	<0.001(***)	<0.001(***)	<0.001(***)
MM	<0.001(***)	<0.001(***)	<0.001(***)
Co.Go.Me	0.102	0.958	0.110
Co-Go	<0.001(***)	<0.001(***)	<0.001(***)
Co-Gn	0.838	0.035(*)	0.381
ANS-Me	<0.001(***)	<0.001(***)	<0.001(***)
LI_GoMe	<0.001(***)	<0.001(***)	<0.001(***)
UI.SN	<0.001(***)	0.282	<0.001(***)
Ovb	0.521	0.585	0.579
Ovj	0.018(*)	0.011(*)	0.007(**)
gla.sn.pog	<0.001(***)	<0.001(***)	<0.001(***)
Li-Esth	0.079	<0.001(***)	<0.001(***)
Ls-Esth	<0.001(***)	<0.001(***)	<0.001(***)
Nasolab	0.012(*)	<0.001(***)	<0.001(***)
Mentolab	<0.001(***)	<0.001(***)	<0.001(***)
A_H	0.001(**)	0.353	<0.001(***)
B_H	<0.001(***)	<0.001(***)	<0.001(***)
Pog_H	<0.001(***)	<0.001(***)	<0.001(***)

†Employing two-sample t-tests (or Mann–Whitney U tests when appropriate); Variables' definitions are given in Table 2; *$p < 0.05$, **$p < 0.01$, ***$p < 0.001$

relationship assessed by the ANB angle than the RMR appliance in the overall assessment (about 1° difference). This was accompanied by anterior movement of Point A in both groups. However, the mandibular point (B point) displacement had a statistically significant difference between the two groups in the overall assessment, which showed a posterior movement in the BAIMT group (mean = –3.01 mm) and an anterior movement in the RMR group (mean = 0.22 mm).

Vertically, the overall changes in the height of the lower third of the face and the MM angle increased to a greater extent in the BAIMT group than the RMR group (5.10, 2.56 mm respectively). Maxillary incisor flaring was statistically less prominent in the BAIMT group compared with the RMR group. Overbite decreased in both groups without any significant difference ($p = 0.579$). The difference in overjet correction between the two groups was statistically significant though clinically unimportant (about half a millimeter difference).

Statistically significant greater improvements in soft-tissue variables were detected in the BAIMT group compared with the RMR group in relation to the facial convexity angle, the nasolabial and mentolabial angles. Three of the mini-implants failed (7.89%) and these were replaced.

DISCUSSION

The current study seems to be the first RCT designed to evaluate the efficacy of the recently suggested system based on temporary anchorage devices in the treatment of class III deformities with mild mandibular protrusion compared with the traditional RMR that is widely used in our teaching hospitals in XXX for such deformities.[6,25]

In including patients in this RCT, it was stressed that the IMPA angle should not exceed 100° and should not be less than 85° to make patients' enrolment in either techniques justified. If patients with an IMPA angle more than 100° were included in the current RCT, it would have been more appropriate to use the RMR,[6] whereas if the IMPA angle was less that 85°, this would have rendered the RMR unfavorable due to the fact that the RMR has been shown to have a paramount lingual tipping effect on lower incisiors' inclination.[6]

In the BAIMT group, the skeletal relationship underwent a significant improvement by a mean increase in the angle ANB by 3.41° after 12 months of treatment. This amount of change is greater than double of what was observed in the mini-implant group of Jamilian et al's[19] study (an average increase of 1.4°). This could be attributed to the differences between the two studies regarding the wearing time (12 hours in their study compared with 18 hours in the current study), the amount of retention of the URAs (hooks soldered on Adams' clasps in their study compared with separated rigid hooks in the current study), and the diameter of the orthodontic elastics used (5/16, 128-g in their study compared with 3/16, 128-g in the current study).

The magnitude of the ANB correction in this study was similar to an RCT comparing face mask (FM) therapy with and without rapid maxillary expansion. The FM study found an approximate mean ANB correction of 3.8°.[26] It may be inferred that the BAIMT technique can be considered as an alternative to the bulky extraoral devices when a skeletal correction is sought in patients with a combination of maxillary deficiency and mandibular prognathism.

When examining the overall changes in maxillary and mandibular landmarks' displacements, it was found that the magnitude of posterior movement of the mandibular landmarks (Pogonion and B points) was almost twice that of the anterior movement of the maxillary landmark (A point), indicating that two-thirds of the improvement in the ANB angle was related to mandibular skeletal changes in the BAIMT group.

Skeletal changes induced by the current approach were not as large as those achieved by intermaxillary traction based on upper and lower mini-plates' anchorage.[17] The mean anterior movement of A point was reported to be 5.2 mm, indicating that the mini-plates are more effective skeletally. However, the increased efficacy when using mini-plates does not hide the untoward high levels of pain and discomfort associated with the surgical procedures performed when placing and removing these mini-plates at the beginning and end of this treatment.[17]

The maxillary-mandibular (MM) plane angle increased a mean of 1.36° in the active treatment period. A similar change was observed by the retrospective study of Jamilian et al.[19] A clinically insignificant increase of this magnitude in the vertical dimension does not justify preclusion of patients with normal or slightly increased facial heights from being treated by the BAIMT technique. When this RCT was designed, it was planned to exclude patients with significantly increased facial heights (i.e., with MM angle greater than 35° and MP-SN angle greater than 40°), and the current findings confirmed the soundness of this exclusion criterion.

Although no protruding springs were used in the URA, the overall change in upper incisors' inclination ($\bar{x} = 2.71°$) may be due to the correction of the anterior crossbite that released the upper incisors from their forced palatal inclination.[19,27] The overall change in lower incisors' inclination was not clinically significant, but the observed slight proclination may indicate that the lower incisors started to return to their normal inclination after being forced in a compensatory dentoalveolar lingual inclination. Overbite decreased and became less than normal overbite ($\bar{x} = 1.28$) at the end of the follow-up period, while the overjet increased a mean of 4.9 mm (i.e., changing from a mean of 2.5 mm to a mean of 2.4 mm). Overbite reduction might be due to the vertical changes associated with the application of the BAIMT (i.e., the observed increase in the MM angle and the dimensional changes observed in the mandible).[19]

Overall soft-tissue changes in the BAIMT group occurred as a result of the skeletal sagittal correction that included anterior movement for the maxilla (anterior displacement of point A), posterior movement for the mandible (posterior displacement of points B and Pog), and normalization of the facial convexity angle (172.58° on average).

In the RMR group, there was an overall significant increase in the ANB angle, although this increase was small ($\bar{x} = 1.64°$). This was associated with little anterior displacement in all points: A, B, and Pog – a finding similar to other studies that have shown that the use of a RMR inhibits the normal anterior growth of the mandible and causes only little anterior displacement of mandibular points.[6,7,28] Additionally, the overall vertical skeletal changes did not exceed 1 mm and they were considered clinically unimportant. This insignificant vertical change is consistent with Saleh et al's[6] findings, although they applied the RMR in a younger age group. The same results regarding vertical dimensions assessed by the MM and MP-SN angles were observed in a previous retrospective study, employing the RMR on a group of patients whose age range was similar to that of the current study.[7] The height of the lower third of the face (ANS-Me) increased by a mean of 2.56 mm in the overall assessment. These findings agree with other similar papers.[6,7] Mandibular inhibition occurred due to the effect of the reversed labial bow, which touched the cervical regions of the mandibular anterior teeth.[6] The overall dental changes of the upper and lower incisors go in line with those of other published papers.[6,7]

Both devices were able to correct the anterior crossbites, but the RMR predominantly accomplished this by dental changes, whereas the BAIMT induced skeletal changes in general. Therefore, causing dental changes by the RMR required a mean of 3.4 months compared with 6.3 months in the BAIMT group. In other words, the RMR was faster than the BAIMT in the apparent correction of the anterior crossbites. Dental and skeletal changes observed in the follow-up period (T3 – T2) were clinically not important in both groups, indicating that the protocol of reducing wearing hours was successful in maintaining the achieved results in the active treatment phase.

In the overall assessment for both groups, skeletal relationships improved to a larger extent in the BAIMT group, which indicates that the intermaxillary traction based on skeletal anchorage is more effective in inducing skeletal alterations than the employed functional appliance. A better performance of the BAIMT system, using mini-plates over an extraoral device (i.e., the FM) supplemented with an RME procedure, was also found by a recent retrospective case–control study comparing both techniques.[17] However, the BAIMT system in the current RCT relied on mini-implants and not mini-plates. Maxillary advancement by extraoral devices (i.e., the FM) has been evaluated and the magnitude of change in some studies was similar to what is found in the BAIMT group of this study.[19]

The greater increase in the vertical lower third of the face, which was observed in the BAIMT group compared with the RMR group, may be a result of the difference in the applied force vectors. In the BAIMT group, the force vector had an oblique direction with two components: One horizontal and the other vertical. Therefore, the vertical changes accompanying this approach were more prominent than in the RMR group, where the force vector had a predominantly horizontal direction due to the contact between the reverse arch and lower incisors' cervical regions.[6] The counterclockwise rotation seen on the palatal plane, which increased the MM angle, may also be explained by the direction of the applied force that extended between lower mini-implants and the upper removable device and was located under the center of resistance of the maxilla.[19]

The BAIMT system was found to be better in improving soft tissues' profile than the RMR as the nasolabial angle and labiomental fold decreased to a greater extent in the BAIMT group. This could be explained by the greater amount of skeletal and dental changes that reflected more pronounced soft-tissue changes.

The application of the new technique (the BAIMT system) involves some problems, such as mini-implants loosening, and the failure rate was found to be 7.8%. Soft-tissue ulceration was observed around the mini-implants and this was recorded to be 15.7%. Many patients (79%) complained about pain, discomfort, speech problems, and swallowing impairment, but this was noted in the first 2 weeks following mini-implants' insertion.

The short follow-up period is one of the limitations of the current study and longer observational periods are required. In addition, the analysis of psychosocial parameters would have given additional information regarding the new treatment modality (BAIMT) and would have enabled us to compare the current results with those of Saleh et al,[20] for example. Future research work should compare the therapeutic effects of the intermaxillary traction anchored by mini-plates with that anchored by mini-implants.

CONCLUSION

The current RCT indicates that the BAIMT with mini-implants anchorage is an effective method and may be a better choice compared with the RMR for treating class III malocclusion with mild to moderate mandibular protrusion in growing patients. However, more long-term investigations are needed to evaluate long-term skeletal stability and relapse.

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