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Short-term soft- and hard-tissue changes following Class III treatment using a removable mandibular retractor: a randomized controlled trial

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Structured Abstract

Objective – To evaluate the effects of a Class III functional appliance [the removable mandibular retractor (RMR)] in the early treatment of skeletal Class III deformities.

Set-up – Randomized controlled trial.

Setting – Orthodontic Department, University of Al-Baath Dental School, Hamah, Syria.

Material and Methods – Sixty-seven skeletal Class III patients were recruited, distributed randomly into two groups: 1) treatment group (T) with the RMR: 33 patients (17 males and 16 females) with a mean age of 7.5 ± 1.33 years, 2) control group (C): 34 patients (15 males and 19 females) with a mean age of 7.3 ± 1.58 years. Lateral cephalograms were taken at the start of treatment (T1-T) or at the start of the observation period (T1-C) and after 14.5 ± 0.1 months (both groups). Soft- and hard-tissue changes in both groups were evaluated.

Results – The main significant findings in the treatment group were 1) anterior morphogenetic rotation of the mandible as a result of upward and forward condylar growth; 2) significant increase in maxillary length; 3) significant increase in maxillary dentoalveolar protrusion; 4) significant decrease in mandibular dentoalveolar protrusion; 5) significant protrusion of the upper lip; 6) significant retrusion of the lower lip; and 7) significant reduction in nasolabial angle.

Conclusion – The RMR is an effective appliance in the treatment of skeletal Class III patients in the early mixed dentition in the short term.

Key words: cephalometry hard-tissue changes; early intervention; malocclusion, angle Class III; orthodontic appliances, functional; soft-tissue changes

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Introduction

Class III malocclusion has been reported to develop in 5–10% of white populations (1–3). In children with Class III malocclusions, it is important to identify whether the aetiology is dental, functional or skeletal. Skeletal Class III malocclusions are easy to diagnose but are very difficult to treat (3). Class III skeletal malocclusion may result from: maxillary retrognathism, mandibular prognathism or combined maxillary retrognathism and mandibular prognathism (4).

Early treatment of Class III malocclusion has been recommended by many authors because of the expected favourable results on growth and occlusal relationships (5,6). Typically, treatment approaches for young patients with skeletal Class III malocclusions have been directed at growth modification. Growth modification of Class III skeletal cases includes facial mask treatment for patients with maxillary deficiency (7), chincup therapy for patients with increased mandibular growth (8) or Class III functional appliances (9). Facemask therapy has been extensively evaluated either alone (10–14) or in conjunction with rapid maxillary expansion (15,16). Some studies evaluated the craniofacial effects of using a chincup alone (17,18) or in association with fixed appliances (19). Functional appliances such as the Fränkel III and the Bionator III have been assessed in the literature but to a lesser extent (4,20,21). The main concern of most studies was oriented towards hard-tissue changes although soft-tissue changes are more important from the patients' points of view (22).

The removable mandibular retractor (RMR) has been proposed as a simple functional appliance in the treatment of Class III patients in the deciduous and mixed dentitions and has been first evaluated by Tollaro et al. at University of Florence in Italy (23,24). In a recent systematic review of orthopaedic treatment outcomes in Class III malocclusion, Toffol et al. (25) identified 18 prospective and retrospective clinical controlled trials (CCTs) as well as one randomized controlled trial (RCT) comparing treated Class III patients with untreated subjects. Surprisingly, their review appeared to overlook three important CCTs evaluating the effectiveness of the RMR in the treatment of Class III malocclusion in different age groups (23,24,26). Despite the widespread use of this appliance at different orthodontic institutions in Syria, no RCTs have been yet accomplished to give a true picture of its treatment outcomes when employed in the primary and mixed dentitions.

RCTs are considered the gold standard in evidence-based practice, and the only published RCTs in relation to Class III correction in growing patients are those of Vaughn et al. (27) and Mandall et al. (28), in which facemask therapy was the treatment modality under inspection. The aim of the current study was to evaluate the effectiveness of the RMR appliance in treating skeletal Class III patients in the early mixed dentition and to differentiate changes induced by treatment from those induced by growth only through the use of an RCT study design. The working hypothesis in this research was 'The RMR appliance is effective in correcting skeletal Class III malocclusions and the changes observed in treated patients are different from those induced by growth only'.

Material and methods

Estimation of the sample size

From the clinical point of view, it was postulated that the smallest difference requiring detection for the movement of point A in the mid-sagittal plane was 1.5 mm. The following assumptions were used to calculate the required sample size: 1) the significance level of two-sided tests was set at 0.05; 2) the statistical power was set at 80%; 3) the standard deviation (SD) of point A change in the mid-sagittal plane in a previous publication was found to be 2.1 mm (24); and 4) the intended inferential statistics approach was two-sample *t*-tests (if the assumptions of parametric tests were met, for example normality). The calculation revealed that a sample size of 32 patients was required (i.e. 64 patients should be recruited for both treatment and control groups). It was accepted by the research team that additional 6–10 patients should also be recruited in case of withdrawal or inability to follow-up throughout the observation period (assuming a 10% attrition rate).

Study setting

This investigation took place at the Orthodontic Department of Al-Baath Dental School in Hamah, Syria, from December 2005 to April 2008. The project was funded by the University of Al-Baath, Syria. All elementary schools in Hamah city were screened by the first author (MS) using disposable diagnostic kits in each school's health clinic. 3187 schoolchildren were examined, and formal letters were sent to 141 parents of children with apparently Class III malocclusions inviting them to bring their children to the Orthodontic Department at the Dental School for additional clinical examination. They were informed about the possibility to enrol their children in a research project. One hundred and twenty-three parents of children with Class III malocclusions accepted the invitation and were then examined thoroughly for eligibility to be included in the study. Ethical approval was obtained from the Local Research Ethics Committee at University of Al-Baath Dental School.

Inclusion and exclusion criteria

The following clinical inclusion criteria were used:

- 5–9 years of age at the time of assessment with first permanent molars erupted;
- Class III molar relationship in the early mixed dentition;
- anterior crossbite on two or more incisors with or without mandibular displacement on closure;
- clinical assessment of a skeletal Class III relationship;
- no cleft lip/palate and/or other craniofacial syndromes;
- no or minimal facial asymmetry (less than 2 mm of dental midline discrepancy with the midfacial plane);
- no previous orthodontic treatment;
- the child should be of a Syrian ancestry.

It was not ethical to expose all candidate children to radiographic examination. Therefore, the assessment of skeletal Class III malocclusion was based on clinical judgment. Each patient was examined, while his/her mandible was kept at its retruded contact position to evaluate both jaws in space. Patients with apparently protrusive mandibles or retrusive maxillae were not excluded, because the RMR appliance was thought to be effective in these two skeletal types of Class III deformities. Those who met the inclusion criteria (77 schoolchildren) were then sent to the radiographic department, and lateral cephalometric radiographs were obtained.

The following radiographic exclusion criteria were applied:

- ANB >0° (i.e. not Class III skeletal pattern)
- Wits appraisal >−2 mm (i.e. not Class III skeletal pattern).

The radiographic lateral cephalograms were obtained in the patients' habitual occlusion. A radiograph in centric relation was not made for ethical reasons. Finally, 72 schoolchildren were found to be appropriate for inclusion in this study. The excluded patients were treated by other MSc postgraduate students at the Department of Orthodontics under the supervision of the second and third authors (MYH and AJ).

Patient assignment and randomized allocation

Parents or legally authorized representatives of eligible patients were approached, and additional information was given. Written informed consents were obtained from both the child and his/her parent (or legally authorized representative). The randomization procedure of these 72 skeletal Class III patients was performed manually by simply asking each participant to pickup a concealed opaque envelope from a black plastic box. This box contained 72 envelopes with 36 containing the letter T (denoting treatment group) and the other 36 containing the letter C (i.e. control group). No stratification was made with regard to gender.

Three patients in the treatment group failed to complete the study because of lack of compliance and were excluded from analysis. On the other hand, two patients in the control group were excluded from the study because they moved to another country. Therefore, the final number of patients who had full records and who entered data analysis procedure was 67 patients (32 boys, 35 girls). Sample size, sex and age distribution of the subjects are given in Table 1. A flow chart of participants' recruitment, follow-up and entry into data analysis is given in Fig. 1.

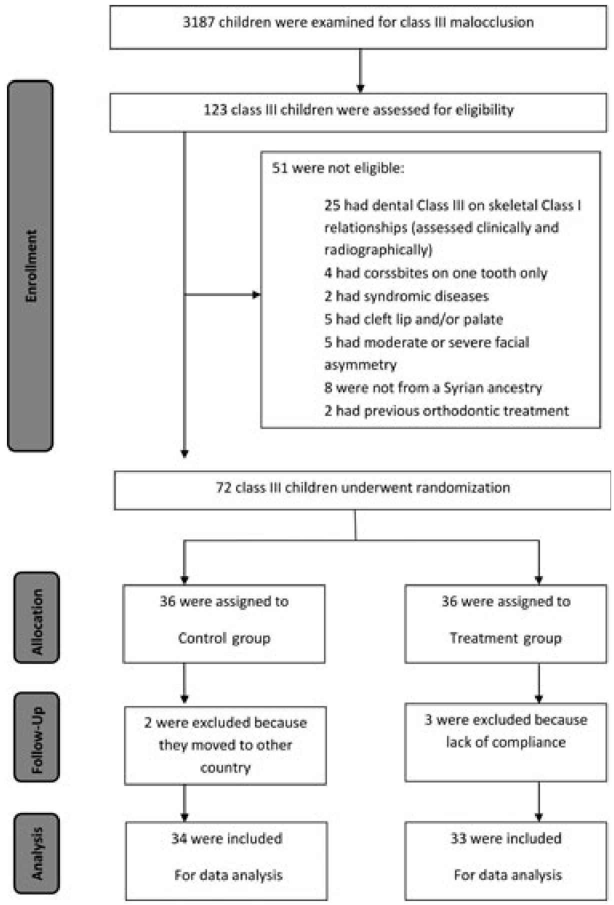

Fig. 1. Flow chart of patients' recruitment, follow-up and their entry into data analysis.

Treatment group

All patients in the treatment group were treated by one specialist orthodontist 'MS' using the RMR (Figs 2 and 3). The appliance consisted of the following elements: 1) upper acrylic base plate with posterior bite planes; 2) retentive elements: mainly two Adam's clasps on the upper first permanent molars or second upper deciduous molars; 3) upper reversed labial bow (0.9-mm stainless steel) extending to the cervical edges of the mandibular anterior teeth from the labial surface of the lower primary canine on one side to the other labial surface of the contralateral tooth (Fig. 3). This bow was activated to hold the mandible in its maximum posterior position; and (4) auxiliary devices: a screw or springs to procline the upper permanent incisors when diagnosed as retroclined or an expansion screw to expand the maxillary dental arch in cases with upper constricted dental arches. All appliances used in the treatment were fabricated by one dental technician.

The patients and parents received both oral and written information on the treatment, oral hygiene and maintenance of the appliance. The appliance was worn at least 16 h a day (night-time included). Degree of compliance of appliance wear was good, and this was confirmed by using 'compliance charts' which were completed by children's parents. All patients in the treatment group were seen within 1 week after appliance first fitting, 2 weeks after appliance fitting and then at monthly visits to observe the change

Table 1. Age and sex characteristics of the current sample

Variable	Treatment (n = 33)	Control (n = 34)	Both groups (n = 67)	*p*-Value
Age, mean ± SD	7.5 ± 1.33	7.3 ± 1.58	7.4 ± 1.41	0.255*
Sex: n (%)				
Male	17 (51.5%)	15 (44.1%)	32 (47.7%)	0.784†
Female	16 (48.5%)	19 (55.9%)	35 (52.3%)	

*Two-sample *t*-test, level of significance set at 0.05.
†Pearson's chi-squared test, level of significance set at 0.05.

Fig. 2. The removable mandibular retractor appliance (occlusal view).

Fig. 3. The removable mandibular retractor appliance in the mouth (lateral view).

in incisor relationship, monitor patient's compliance, adjust the position of the inferiorly extended labial bow, tighten Adams clasps and control expansion in patients with expansion screws. A change in the incisor relationship from a negative overjet (i.e. Class III incisor relationship) into a positive overjet (i.e. +1.5 mm or greater) was considered as a sign of successful treatment.

Control group

The untreated group received no orthodontic treatment during the observation period. According to the Dental School Local Research Ethics Committee's guidelines, all children in the untreated group were provided orthodontic treatment after the end of the observational period of the study at no cost.

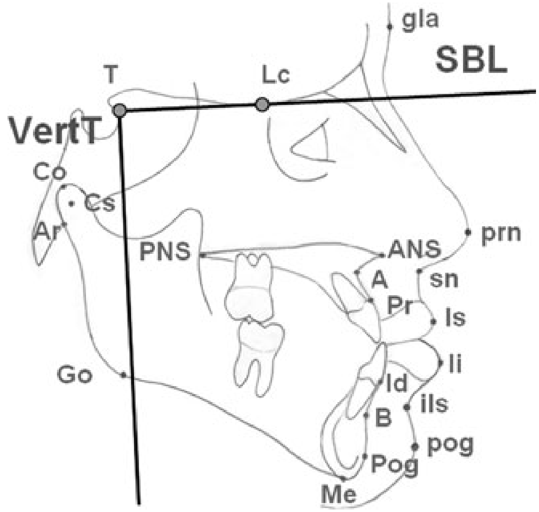

Fig. 4. The two reference planes and the landmarks used in the study. The first reference plane was the stable basicranial line (SBL). This line was traced through the most superior point of the anterior wall of the sella turcica at the junction with tuberculum sellae (point T; 29), and it is tangent to lamina cribrosa (Lc) of the ethmoid. These basicranial structures do not undergo remodelling from the age of 4 to 5 years (30). The second reference plane was 'T Vertical' (TV) which was a line perpendicular to SBL passing through point T.

Lateral cephalometric analysis: outcome measures

Lateral standardized cephalograms were taken in all patients directly prior to treatment (T1) and after a mean observation period of 14.5 ± 0.1 months (T2) for both groups. All cephalograms were taken by the same radiographic apparatus and by the same technician. Focus-mid-sagittal-plane distance was fixed at 152 cm, and film-mid-sagittal-plane distance was fixed at 17 cm.

To evaluate the dentofacial soft- and hard-tissue changes following treatment, a cephalometric analysis based on two reference planes originally proposed by Tollaro et al. (24) was employed in the current study and is shown in Fig. 4. The reference planes depended on anatomical structures that do not undergo remodelling from the age of 4 or 5 years (29,30).

The following points were used to construct the cephalometric analysis: point A (A), point B (B), prosthion (Pr), infradentale (Id), pogonion (Pog), menton (Me), gonion (Go), articulare (Ar), condylion (Co), centre of the condyle (Cs), anterior nasal spine (ANS), posterior nasal spine (PNS), glabella (gla), pronasale (prn), subnasale (sn), labrale superius (ls), labrale inferius (li), infralabial sulcus (ils) and pogonion soft tissue (pog, Fig. 4). The definitions of all these landmarks are given by Björk (31), Ødegaard (32) and Riolo et al. (33).

Sagittal and horizontal distances between each landmark (A, Pr, Id, B, Pog, sn, ls, li and pog) and the two reference planes were measured. The cephalometric analysis included the measurements of maxillary length (ANS-PNS), mandibular total length (Co-Pog), mandibular body length (Me-Go), and mandibular ramus height (Co-Go). The following angular measurements were used to assess the mandibular ramus and condylar inclinations: ArGo-TV and ConAx-TV. Angular measurements for assessment of vertical relationships were 1) mandibular plane angle (ManP-SBL), 2) maxillary plane angle (MaxP-SBL) and 3) maxillary-mandibular plane angle (MaxP-ManP). Soft-tissue angular measurements were 1) facial convexity angle (gla.sn.pog), 2) nasolabial angle (col.sn.ls) and 3) labiomental angle (li.ils.pog).

All measurements were taken by one researcher (MS). To avoid assessment bias, a blinding procedure for the radiographs was performed by the second and third authors (MYH and AJ). This was performed not to let the principal researcher (MS) recognize to which group or assessment time the radiograph belonged either in the landmark identification stage or in the cephalometric analysis stage. Landmarks were drawn manually on the cephalograms with a pointed pen (Faber-Castell®, Nuremberg, Germany) in a fully darkened room. All cephalograms were then scanned by a backlight scanner (Epson Perfection 4990 Photo®, Epson America, Inc., Long Beach, CA, USA) at a 350-dpi resolution and were stored as JPEG files. Measurements were obtained by a special cephalometric program (ADOrth-2007®, Arab Dent, Damascus, Syria), 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 method was evaluated using Dahlberg's formula (34) on 20 cephalograms (10 from treatment group and 10 from control group). These radiographs were randomly selected 2 months after the first assessment of radiographs and re-measured by the same principal researcher (MS).

Statistical analysis

Descriptive and inferential statistics were performed using Minitab® V14 (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.

Results

Error of the method

The error of the method of cephalometric measurements ranged between 0.11 and 0.71 mm for linear measurements and between 0.21° and 0.44° for angular measurements.

General

No significant differences were found between the two groups regarding age or sex at the baseline records (Table 1). All the anterior crossbites were corrected in the treatment group, and a positive overjet (+1.5 mm or more) was achieved in all subjects within the first few weeks after the commencement of treatment giving a success rate of 100%.

Cephalometry

Cephalometric measurements in both groups at T1 and T2 are shown in Table 2. Soft- and hard-tissue changes were calculated for each group and compared with each other (Table 3).

The hard-tissue points representing the upper anterior region of the maxilla showed a statically significant more forward movement in the treatment group compared with the control group (e.g. point A moved forward a mean of 1.87 mm

Table 2. **Cephalometric measurements in the treatment and control groups at the two assessment times**

	Treatment group (n = 33)		Control group (n = 34)	
	T1	T2	T1	T2
Measurements	Mean (SD)		Mean (SD)	
A	56.05 (2.52)	57.92 (2.52)	56.07 (2.48)	56.47 (2.48)
Pr	56.76 (2.46)	58.67 (2.55)	56.85 (2.65)	57.35 (2.68)
Id	57.35 (2.22)	57.70 (2.25)	57.46 (2.67)	59.35 (2.68)
B	56.84 (2.28)	57.01 (2.30)	56.57 (2.90)	58.61 (2.90)
Pog	56.39 (2.56)	57.67 (2.67)	55.79 (3.05)	57.94 (3.15)
ANS-PNS	47.38 (2.42)	49.51 (2.62)	46.93 (2.84)	47.72 (2.87)
Co-Pog	99.19 (2.30)	101.36 (2.41)	98.97 (2.61)	102.89 (2.74)
Go-Co	47.95 (2.53)	49.91 (2.59)	47.55 (2.81)	49.48 (2.80)
Go-Me	66.50 (2.93)	68.22 (3.16)	66.09 (2.78)	67.93 (2.85)
sn	70.43 (3.34)	75.22 (3.20)	68.30 (2.70)	69.30 (2.80)
ls	73.88 (3.66)	78.86 (3.72)	72.90 (3.14)	74.4 (3.23)
li	71.70 (3.53)	72.05 (3.53)	72.40 (2.33)	73.95 (2.42)
pog	66.69 (3.65)	69.25 (3.79)	67.80 (3.35)	70.04 (3.74)
Ar.Go.Me (°)	130.2 (2.87)	128.50 (2.49)	130.10 (2.54)	130.61 (2.56)
ArGo-TV (°)	9.43 (0.96)	7.60 (0.86)	9.50 (1.18)	9.65 (1.19)
ConAx-TV (°)	24.28 (3.11)	20.66 (2.71)	24.43 (2.62)	25.47 (2.73)
MaxP-SBL (°)	4.03 (1.02)	4.08 (1.03)	3.85 (1.05)	3.84 (0.98)
ManP-SBL (°)	31.76 (2.92)	31.70 (3.07)	31.27 (2.75)	31.27 (2.75)
MaxP-ManP (°)	27.56 (3.90)	27.34 (2.98)	27.38 (2.81)	27.34 (2.70)
gla.sn.pog (°)	184.7 (3.68)	190.00 (3.50)	185.30 (4.18)	185.41 (4.02)
col.sn.ls (°)	106.05 (7.92)	98.15 (7.86)	108.50 (8.17)	109.90 (7.6)
li.ils.pog (°)	131.57 (6.66)	136.80 (6.67)	133.70 (7.29)	134.40 (6.99)

SD, standard deviatio; ANS, anterior nasal spine; A, point A; B, point B; Pr, prosthion; Id, infradentale; Pog, pogonion; Me, menton; Go, gonion; Ar, articulare; Co, condylion; PNS, posterior nasal spine; gla, glabella; prn, pronasale; sn, subnasale; ls, labrale superius; li, labrale inferius; ils, infralabial sulcus..

Measurements ended with the degree (°) symbol indicate angular measurements, and the rest are linear measurements. Hard- and soft-tissue landmarks are measured horizontally and vertically from the reference planes. Here, the horizontal measurements are presented.

in the treatment group compared with a mean of 0.40 mm in the control group; $p < 0.001$). The same changes were observed in relation to soft-tissue points on the upper lip and the nasal base ($p < 0.001$). Soft- and hard-tissue points in relation to the lower lip and the anterior portion of the mandible exhibited statistically significant less forward movement in the treatment group in comparison with the control group (i.e. points Id, B, Pog, li and pog; $p < 0.001$). Point B, for example, moved forward a mean of 0.17 mm in the treatment group compared with a mean of 2.04 mm in the control group ($p < 0.001$), indicating a certain degree of restriction to the anterior growth of the mandible. The maxillary length (ANS-PNS) showed significantly larger increments in the treatment group ($p < 0.001$) compared with the control group, whereas the mandibular length (Co-Pog) showed significantly smaller increments in the treatment group ($p < 0.001$).

No statistically significant differences were detected in the length of the mandibular ramus (Co-Go) and mandibular body length (Go-Me) as well as in the angles, which represented the maxillary and mandibular rotations (MaxP-SBL,

***Table 3.* Changes observed in the two groups between T2 and T1**

	Treatment group					Control group					
Measurement	Median	Mean	SD	Q1	Q3	Median	Mean	SD	Q1	Q3	*p*-Value
A	1.7	1.87	0.53	1.50	2.42	0.50	0.40	0.61	0.20	0.90	<0.001*
Pr	1.8	1.92	0.53	1.52	2.20	0.50	0.50	0.23	0.40	0.60	<0.001*
Id	0.30	0.35	0.35	0.10	0.50	1.90	1.89	0.50	1.75	2.15	<0.001*
B	0.1	0.17	0.20	0.0	0.27	2.0	2.04	0.44	1.80	2.40	<0.001*
Pog	1.05	1.28	0.70	0.72	1.87	2.20	2.15	0.42	1.90	2.40	<0.001*
ANS-PNS	2.0	2.13	0.67	1.92	2.40	1.00	0.80	0.28	0.50	1.0	<0.001*
Co-Pog	2.0	2.17	0.63	1.72	2.37	3.9	3.92	0.85	3.60	4.1	<0.001*
Go-Co	2.05	1.96	0.50	2.00	2.20	2.00	1.93	0.24	1.90	2.10	=0.07*
Go-Me	2.0	1.73	1.82	2.0	2.1	2.0	1.84	0.75	1.90	2.10	=0.22*
sn	4.75	4.79	1.07	4.0	5.32	0.90	0.90	0.37	0.60	1.15	<0.001†
ls	5.10	4.99	0.99	4.72	5.47	1.0	0.99	0.48	0.75	1.10	<0.001†
li	0.40	0.35	0.58	0.0	0.6	1.50	1.56	0.57	1.05	2.00	<0.001*
pog	1.50	1.48	0.78	0.72	2.15	3.20	3.38	0.94	2.90	4.05	<0.001†
Ar.Go.Me (°)	−2.35	−2.49	1.00	−3.1	−1.82	0.00	0.00	0.19	−0.10	0.05	<0.001*
ArGo-TV (°)	−1.55	−1.83	0.89	−2.47	−1.2	0.10	0.15	0.11	0.05	0.20	<0.001*
ConAx-TV (°)	−3.5	−3.62	1.29	−4.75	−2.78	1.30	1.03	1.74	0.45	2.15	<0.001*
MaxP-SBL (°)	0.0	0.05	0.39	−0.1	0.27	0.0	−0.01	0.25	−0.1	0.10	0.25*
ManP-SBL (°)	−0.05	−0.06	0.45	−0.1	0.2	−0.1	0.00	0.00	−0.1	0.2	0.93*
MaxP-ManP (°)	0.050	−0.23	2.19	−0.37	−0.37	0.0	−0.04	0.38	−0.1	0.1	0.90*
gla.sn.pog (°)	5.15	5.13	1.52	4.15	6.4	0.0	0.11	0.67	−0.15	0.20	<0.001*
col.sn.ls (°)	−8.45	−8.87	1.92	−10.77	−7.3	2.0	2.16	1.39	1.0	3.0	<0.001†
li.ils.pog (°)	5.3	5.24	1.20	4.52	6.1	0.8	0.58	1.54	−0.45	2.0	<0.001†

SD, standard Deviation; Q1, first quartile; Q3, third quartile; ANS, anterior nasal spine; A, point A; B, point B; Pr, prosthion; Id, infradentale; Pog, pogonion; Me, menton; Go, gonion; Ar, articulare; Co, condylion; PNS, posterior nasal spine; gla, glabella; sn, subnasale; ls, labrale superius; li, labrale inferius; ils, infralabial sulcus.
Measurements ended with the degree (°) symbol indicate angular measurements, and the rest are linear measurements. Hard- and soft-tissue landmarks are measured horizontally and vertically from the reference planes. Here, the horizontal displacements are presented.
*Two-sample *t*-tests.
†Mann–Whitney *U*-tests.

ManP-SBL, MaxP-ManP) between the two groups.

Soft-tissue analysis revealed that the nasolabial angle (col.sn.ls) exhibited a statistically significant reduction in the treatment group (−8.87 mm) in comparison with the control group (+2.16; $p < 0.001$), whereas the facial convexity angle (gla.sn.pog) and labiomental angle (li.ils.pog) exhibited a significantly larger increase in the treatment group ($p < 0.001$). No significant differences were assessed between two groups in the vertical distances for the following points: A, Pr, Id, B, Pog, sn, ls, li and pog (data not presented in Tables 2 and 3).

Discussion

Many functional appliances have been used to correct Class III deformities in the mixed dentition, and one of these functional appliances is the removable mandibular retractor (23,24,26). An RCT was performed to evaluate the effects of this appliance in treating skeletal Class III cases in the early mixed dentition. In RCTs, the researcher should include all the randomized patients in the primary analysis (i.e. the intention-to-treat analysis; ITT) and, ideally, no withdrawals or exclusions should be allowed (35). But in reality and with relatively long follow-up periods (such as that of the current study), we should expect some non-compliance or withdrawals by the passage of time. Three patients in the treatment group did not follow the instructions and reacted carelessly to the given guidance. Therefore, the RMR treatment was stopped, and they were asked to come back for their final assessment's radiographs but they did not respond (even after several telephone calls). Therefore, T2 records were missing for those patients, and the ITT analysis could not be conducted. The attrition rate of 8% may have biased the results slightly (35). In the control group, we were unable to obtain T2 radiographs of two untreated cases after approximately 15 months of their baseline data. No contact details were available, so we had an attrition rate of about 5% in the control group. Some authors believe that this loss-to-follow-up rate has little effects (bias) on the results (36).

The mean age of the current sample was less than 8 years, so the reliance in the cephalometric analysis was placed on the stable basicranial line (SBL) drawn using cranial structures claimed to be stable from age 4 to 5 years old (30). The evaluation of the method error did not show that employing this technique would increase the systematic or random error in horizontal and vertical measurements of landmark positions in relation to the two reference planes.

Several statistically significant changes in the dentofacial complex were observed in treated children when compared to the untreated ones. The significant anterior movement of A point could be a result of the anterior force transmitted from the mandible (held in the most posterior position) to the maxilla through the reversed labial bow, the effect of the screw or springs used to procline upper permanent incisors (37) and the correction of the anterior crossbite which freed the constrained maxilla and led to greater expression of maxillary growth (38).

The inhibition of the anterior movement of point B can be explained by the effect of the reversed labial bow which contacted the cervical edges of the mandibular anterior teeth producing lingual tipping of lower incisors and the significant smaller increments in the total length of the mandible. The smaller significant increments of anterior movement of Pog point could be a result of the significant smaller increments in the total length of the mandible. This can be attributed to the significant reduction in the gonial angle as a consequence of a significant upward-forward direction of condylar growth. The change in the direction of condylar growth during the observation period showed statistically significant differences between the control and treated group, and this was evident in the significant reduction in the angle between the condylar line Co-Cs and the TV line (ConAx-TV) in the treated group.

According to the results of the current study, there were no RMR treatment effects on the rotations of the maxilla or the mandible. However, a skeletal change in mandibular shape was observed in the treated group. This has been called 'anterior morphogenetic rotation of the mandible' according to Lavergne & Gasson's definitions (39, Fig. 5). The results of this study showed that there were no significant differences between the two groups in mandibular ramus length (Co-Go) and mandibular body length (Go-Me). This means that the treatment with the RMR did not restrict mandibular growth but changed its shape through a mandibular anterior morphogenetic rotation as a compensatory process to the excess mandibular growth (23,39).

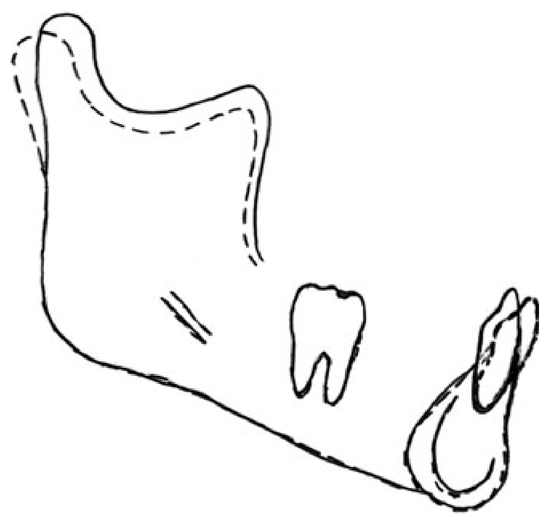

Fig. 5. Superimposition on mandibular stable structures shows the anterior morphogenetic rotation. T1, dotted line, T2, continues line.

The changes detected in both upper and lower jaws contributed to the overall correction observed in the treated sample with the RMR and compare favourably with the other two published facemask-based RCTs in the literature (27,28). Direct comparisons of positional changes of landmarks with the study of Mandall et al. (28) are not possible because they employed SNA, SNB and ANB angles to assess horizontal maxillary-mandibular changes, whereas in the current study, displacements of landmarks due to growth and/or treatment were used. However, Mandall et al. showed a mean of 2.1° improvement in the ANB angle which was attributed to both facemask-induced maxillary advancement and mandibular backward rotation, and this was observed in a follow-up period similar to that of the current study (28). The improvements in maxillary-mandibular relationships were even higher in Vaughn's study with a mean ANB increase of 3.95° in the non-expansion facemask group and 3.82° in the expansion facemask group (27). Vaughn et al. reported a mean of 3.09 mm forward displacement of point A which is higher than that of the current study, giving an impression that facemask therapy is more effective than the RMR in producing maxillary advancement.

With regard to soft tissues, the upper lip moved forward significantly in the treated group as a result of a significant increase in the maxillary dentoalveolar protrusion and a significant increase in the maxillary length. This forward movement decreased the nasolabial angle significantly. The smaller significant anterior movement of the lower lip in the treated group could be a result of a significant decrease in the mandibular dentoalveolar protrusion and a significant decrease in the total mandibular length, and this decreased the mentolabial angle significantly. It seems to be that the facial convexity increased significantly in the treated group because of a significant forward movement of the point subnasale (sn) and the smaller significant increments of anterior movement of soft-tissue pogonion (pog). In general, the soft tissue changes in the treated group during the observation period were favourable. Among all published articles about treatment effects of the RMR (23,24,26,40,41), the current study seems to be the first to evaluate soft-tissue changes following Class III correction in the short term.

As has been mentioned above, Tollaro et al. (23,24) and Baccetti and Tollaro (26) explored the treatment effects of the RMR on Class III deformities in the mixed and deciduous dentitions. Results of these studies revealed that skeletal changes could only be achieved in the deciduous dentition, whereas the current study showed that skeletal changes can be achieved in the early mixed dentition. This may be a result of the use of posterior bite planes which were added to the RMR design in addition to the increased duration of patients' appliance wear.

The follow-up period of 14.5 months is short in the overall evaluation of treatment outcomes of skeletal Class III correction. This is one of the limitations of the current study, and longer observational periods are required. Analysis of study models as well as psychosocial parameters would have given additional information regarding this treatment modality and would have enabled us to compare the current results with those of Mandall et al. (28), for example.

Complications during this study can be summarized as: 1) breakages of appliance (42.2%), 2) loss of appliances (0.06%) and 3) missing appointments (5.6%). Most of the breakages occurred at the labial bow, and this high percentage of breakages was probably due to the high level of force transmitted from the mandible when patients used to occlude. From the clinical point of view, patients should be warned beforehand about such complications and children should be warned not to exert too much pressure on the inferiorly extended labial bow. Future research work should evaluate long-term effects of this appliance when facial growth has ceased as well as the stability of the achieved results at different age groups.

Conclusions

The RMR appliance is effective in producing favourable soft- and hard-tissue changes when it is used in the correction of skeletal Class III deformities in the short term. It should be considered as one of the options at the orthodontist's disposal for treating growing Class III patients in the early mixed dentition.

Clinical relevance

Several treatment approaches are used to correct Class III malocclusions at different ages. Functional appliances have been widely used, but few attempts have been made to evaluate the efficacy and treatment outcomes of using the RMR in the early treatment of anterior crossbites as well as Class III malocclusions. The RMR proved to be very effective in producing favourable soft- and hard-tissue changes after approximately 15 months of observation. The current study recommends the implementation of this appliance (the RMR) as an option in the daily practice of orthodontics when correcting Class III dentofacial deformities.

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