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Short-term effectiveness of modified removable mandibular retractor appliance for treatment of class III malocclusion: A Clinical Randomized Controlled Trial

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Skeletal Class III, RMR, Lip-pads, Early-stage mixed dentition.

ABSTRACT

This study aimed to investigate short-term outcomes of hard- and soft tissue changes induced by modified removable mandibular retractor appliance in Class III patients and compare them to those of conventional removable mandibular retractor appliance. The sample included 40 patients, their ages ranged between 7-9 years, who were randomly divided into two groups: Group1: Twenty patients treated with a modified mandibular removable retractor device(M-RMR). Group 2: Twenty patients treated with a conventional mandibular removable retractor device (RMR). All patients had skeletal class III with crossbite on at least two anterior teeth. Cephalometric images were performed for each patient before applying the device T1, and after obtaining a positive overjet (2-3) mm T2, the changes between (T1-T2) were studied for each group. Then the results were compared between the two groups. The results showed better sagittal progression of the maxillary in the M-RMR group compared to the traditional RMR. slight increase in the vertical dimension of the face in both devices, and a noticeable improvement of the soft tissues in both devices. The modified mandibular retractor device showed effective treatment of skeletal class III. The presence of the lip- pads was very effective in maxillary protrusion.

1. Introduction

Widespread development has been traced of class III malocclusion in approximately 10% of inhabitants of the Middle Eastern countries [1], the prevalence rate of class III among a sample of children with a mixed dentition in Syria is 14%, while this percentage among adults is 10% [2].

The issue of treating such cases entails correct diagnosis to be delivered at the appropriate timing. Another measure towards this impending clinical need is to establish a distinction between the protrusion of the lower jaw and the retraction of the upper jaw, As, the optimal treatment probably relies on accurate

diagnosis [3]. Class III malocclusion may readily be recognized yet difficult to be thoroughly successfully treated. A number of therapeutic methods to handle this malocclusion exists, through extra oral appliances, such as facemask [4], chin cap [5], and intraoral functional appliances, such as Frenkel III[6], the Class III Activator [7] , and removable mandibular retractor (RMR) [8].

Addressing problems like this takes multiple approaches, the recent and famous of which is to employ “lip pads”; adding them to the reverse twin block device might entail improvement in the skeletal results. Lately, it has been theorized that an increase in maxillary protraction could be due to using or attaching lip pads in the appliance itself [9]. Similarly in this current investigation the RMR has been modified by adding lip pads. Henceforth, the purpose of our study is to compare the effectiveness of this modified RMR with the traditional RMR.

2 Materials and Methods

This present investigation is a two-arm parallel randomized prospective clinical trial; The study hosted a sample of 40 patients with class III malocclusion, whose ages range from 7 to 9 years and allocation of 1:1 ratio (Fig. 1, Table 1).

The trial was registered at German Clinical Trials database (Identifier: DRKS00027155), and received approval from the university review board and Ethical committee of Damascus University (Identifier: DN-290122-14).

And took place in the Orthodontics Department at the Faculty of Dental Medicine, Damascus University, between January 2021 April 2022. Fourteen elementary schools in the city of Damascus were screened by the first author by means of disposable diagnostic kits in each school’s health clinics. In total, 860 schoolchildren were examined, only 96 official letters were forwarded to parents of those with suspected class III malocclusions, to invite them to the Orthodontics Department for supplementary clinical examination. They were clearly informed about the possibility to allow their children to participate in this research project. Only 78 accepted the invitation; their children were then examined methodically to reach a decision whether they are eligible to be included in the study or not (Figure 1), according to the following inclusion\exclusion criteria.

Inclusion criteria:

- 7-9 years old with first permanent molars erupted
- Class III molar relationship in the early mixed dentition
- Anterior crossbite on incisors (2 teeth at least) without mandibular displacement on closure
- Skeletal class III relationship confirmed radiographically (-4 < ANB < 1)
- Be of Syrian ancestry.

Exclusion criteria:

- Severe skeletal class III, primarily from mandibular prognathism
- Brognathism with ANB less than -4°.
- Class III patient with craniofacial syndromes
- Cleft lip and palate history
- Have previous orthodontic treatment

Sample size determination: The number of participants enrolled in this study was calculated via operationalizing the G*Power software (Franz Faul, University of Kiel, Germany, v 3.1.3). The smallest

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difference in the "point A-Nasion-point B" (ANB) angle that requires detection was theoretically presumed to be 0.99°. Likewise, the standard deviation of this variable was detected to reach 0.88° in a previous study [10]. Hence, engaging a two-sample t-test with a probability power of 80 and a 5% significance level was thought to be optima; Accordingly, 20 patients were enrolled for each group in the current research:

- Modified removable mandibular retractor (M-RMR): 20 cases _ Group 1
- Removable mandibular retractor (RMR): 20 cases_ Group 2

Each patient along with their parents were thoroughly informed of the method and purpose of the study, and written consent was taken from each participant's parents.

Randomization

The sample was distributed by (1:1) allocation ratio into both groups using the simple computer random method using Minitab® program (Version 20; Minitab, LLC, State College, Pa)

Blinding

Blinding of both the examiner and the patient was not applicable, but blinding was performed during the measurements to avoid detection bias.

Data extraction: For each participant lateral cephalograms were obtained at beginning of the treatment (T1), and after seven months of the treatment (T2), in both of groups. Or when positive incisor over jet was achieved in any of the treatment groups.

Modified removable mandibular retractor appliance (Figure 2):

- Two connected upper lip pads were used with two activating loops in front of Adams clasps.
- upper acrylic base plate with posterior bite planes.
- retentive elements were utilized: mainly two Adams clasps on the upper first permanent molars or/and the second upper deciduous molars.
- Upper reversed labial bow (0.9-mm stainless steel) was established extending to the cervical edges of the mandibular anterior teeth; from the labial surface of one lower primary canine to the labial surface of the contralateral tooth [11].

Removable mandibular retractor appliance:

The appliance in this group followed the design by [11].

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 for 16 hours a day at least. All patients were seen within 1 week after appliance first fitting. Afterwards, the check-up was delivered once every three weeks to observe and record the change in incisor relationship, activate the devices and ensure the stability of the device.

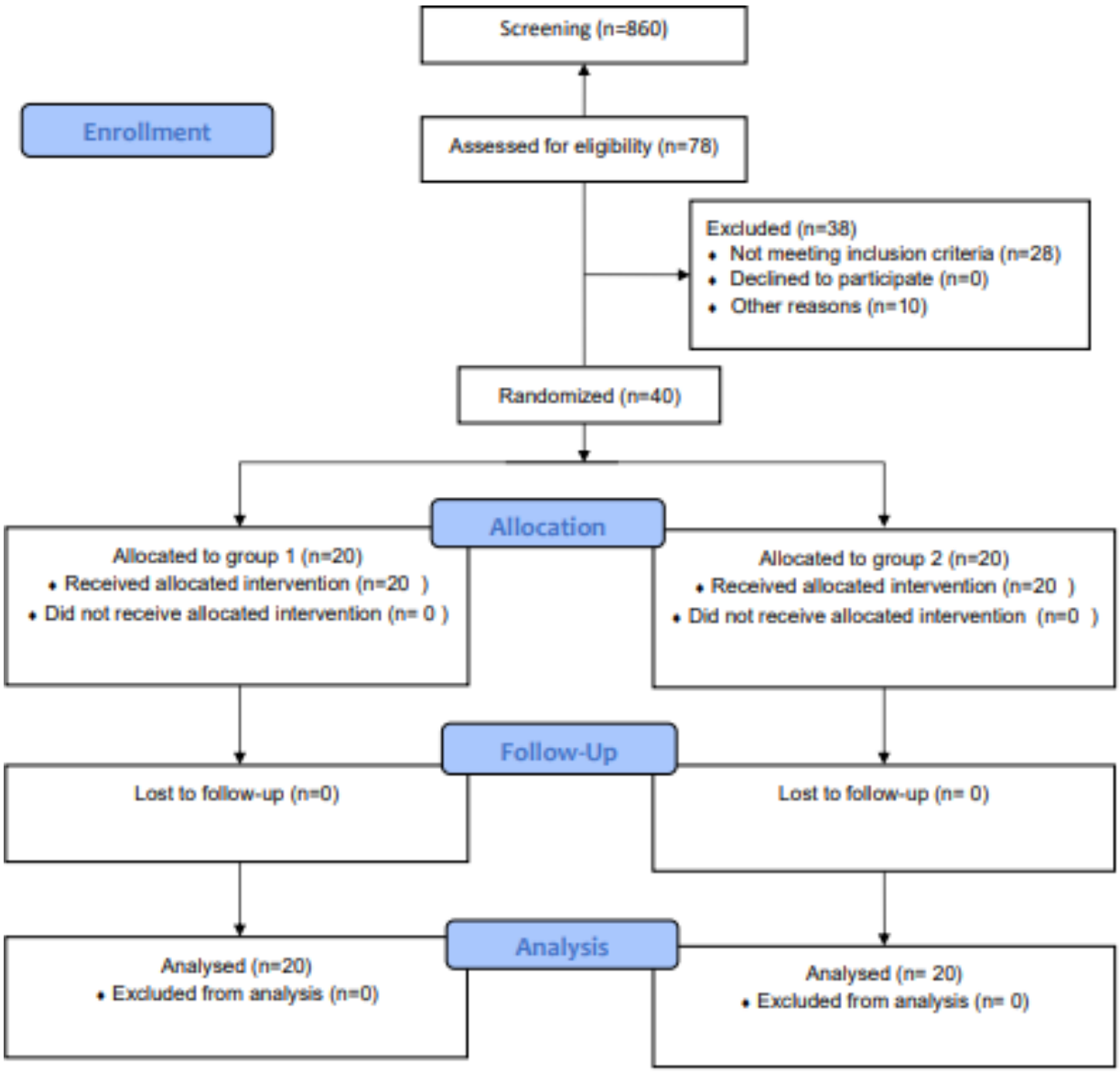

Figure 1. Study flow chart

Table 1. Baseline sample characteristics

	M-RMR	RMR
Number of patients	20	20
Sex distribution	8 females, 12 males	11females, 9males
Age (mean ± SD)	8 ±0.6	8 ±0.5
Incisor relation	Anterior crossbite (2 teeth at least)	Anterior crossbite (2 teeth at least)

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Figure 2. Modified removable mandibular retractor (M-RMR) appliance

The reference lines:
Three reference lines were used as follows:
The pre-treatment tracing T-W line is set, with T being the most superior point of the anterior wall of the sella turcica at the junction with tuberculum sella, and W being the point where the middle cranial fossa is intersected by the sphenoid bone [12]. This was referenced as the horizontal reference line. Furthermore, the vertical T line is set as the vertical line perpendicular to T-W at point T; it was referenced as the vertical plane. Thirdly, the S-N plane, the anterior cranial base.

Using these reference planes, the needed linear and angular measurements were done (Table 2) (Figures 3 and 4).

Table 2. Definitions of angular and linear measurements used in this study [12]

Measurement	**Definition**
T point	**most superior point of the anterior wall of the Sella turcica the at the junction with tuberculum Sella**
W point	**the point where the middle cranial fossa is intersected by the sphenoid bone**
T W plane	**the horizontal reference line between T point and W point**
T V plane	**A vertical line perpendicular to T-W at point T**
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**
A-TV	**Distance between point A and vertical T line**

B-TV	**Distance between point B and vertical T line**
NL-TW	**Angle between nasal line and TW line**
ML-TW	**Angle between mandibular line and TW line**
NL-ML	**Angle between nasal line and mandibular line**
Co-A	**Distance between condylion and point A**
Co-Gn	**Distance between condylion and gnathion**
ANS-Me	**Distance between anterior nasal line and menton**
N-S-AR	**Angle between Nasion, sella , and articulare**
S-AR-GO	**Angle between sella , and articulare,and gonion**
AR-GO-ME	**Angle between articulare, gonion, and menton**
Bjork's sum	**NS^Ar+SAr^ Go + ArGo^Me**
Pr-Vert T	**Distance between pronasale and vertical T line**
Id-Vert T	**Distance between infradentale and vertical T line**
LI.GoMe	**Angle between lower incisor and mandibular line plane**
UI.SN	**upper incisor and anterior cranial base Angle between**
UI.SPP	**Angle between upper incisor and nasal line**
Ovj	**Overjet**
gla.sn-.pog	**Angle between glabella and soft subnasal and soft pogonion**
Li-Esth	**Distance between labialis inferior and Esth – esthetics line of Ricketts (E-line)**
Ls-Esth	**Distance between labialis superior and Esth – esthetics line of Ricketts (E-line)**
NasoLab	**Angle between Cm'-Sn'-Ls'**
LI-TV	**Distance between labialis inferior and vertical T line**
LS-TV	**Distance between labialis superior and vertical T line**

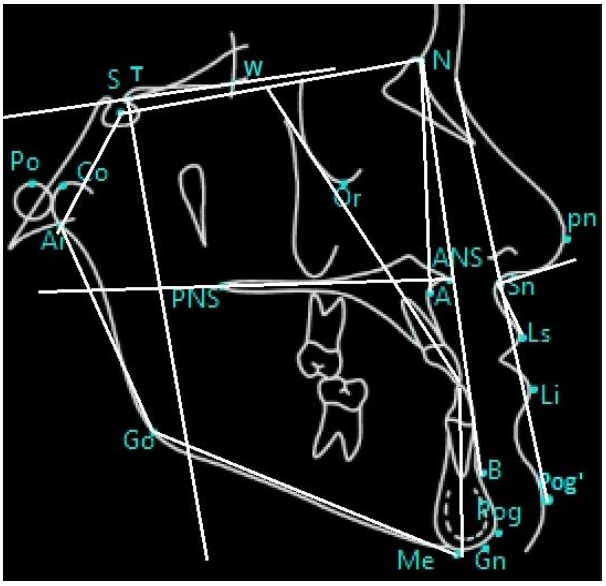

Figure 4. Angular measurements

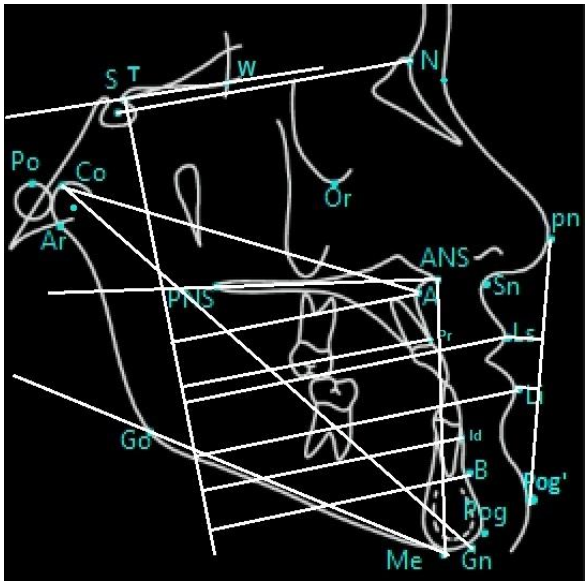

Figure 3. Linear measurements

3. Results

As shown in Table (3,4) a statistically significant sagittal improvement was observed with a p-value < 0.01. There was significant increase in SNA angle and a significant decrease in SNB angle, which was seen in the two groups between T1 and T2, with significant greater improvement detected in SNA angle in the modified device M-RMR compared to the traditional scheme of RMR. Similarly superior changes in the means of ANB were found that in the M-RMR group (mean=2.38± 0.89), while in the RMR group it was (mean = 2.18±0.88).

The linear measurements revealed significant forward maxilla repositioning with (A- TV) p < 0.05 in both of the utilized appliances. This was also significant in the M-RMR group (mean = 3.32±1.46) than that in the RMR (mean = 2.08±1.33). The sagittal mean value forward movement at the Pr-Vert T was significant

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between T1 and T2 in both groups. The changes in B-TV showed no statistically significant differences, with a very slight decrease in both groups. As well, the mean change difference in the infradentale to the T line (Id-Vert T) in the M-RMR group was -1.01 and in the RMR group was -1.25. Total maxillary length (Co-A) increased significantly in both groups, with significant increase in M-RMR group for (Co-A). Correspondingly, a significant increase in the mandibular length (Co-Gn) in both groups.

An increase in the lower anterior facial height was observed in both groups with a p-value < 0.05. The gonial angle was noticed to open up in a non-significant manner in both groups. The clinical compensation in maxillary incisors proclination (UI-SN) (UI-SPP) was less in M-RMR group (3.36±2.6) (2.75±3.03) respectively, than that of RMR group (4.23±3.10) (4.84±1.25) respectively. There was a significant decrease in the lower incisors angle in both groups. The over jet was corrected in both groups with a significant difference between them p-value < 0.01.

Table 3. Descriptive statistics of angular and linear cephalometric measurements of the M-RMR and RMR groups at the two assessment times.

	M-RMR				**RMR**			
	T1		T2		T1		**T2**	
Variable	MEAN	SD	MEAN	SD	MEAN	SD	MEAN	**SD**
SNA	77.50	1.33	79.75	1.73	77.71	0.91	79.34	**0.82**
SNB	79.01	1.92	78.37	1.71	79.06	1.19	78.49	**1.00**
ANB	-1.35	0.99	1.03	0.57	-1.32	1.11	0.86	**0.91**
N-S-AR	121.67	4.91	123.03	4.32	121.60	5.52	123.31	**5.64**
A-TV	58.61	5.73	61.93	8.18	60.31	3.30	62.39	**3.57**
B-TV	61.80	4.35	61.23	5.46	64.28	3.48	64.16	**6.15**
Co-A	84.51	3.58	89.08	6.88	83.83	2.32	86.80	**2.44**
Co –Gn	110.45	4.38	114.80	5.20	108.19	4.08	112.53	**4.44**
Pr-Vert T	59.53	3.80	62.95	4.93	60.93	4.62	63.17	**3.90**
Id-Vert T	59.02	4.68	58.04	5.75	62.43	4.25	61.18	**5.17**
NL-TW	7.96	3.04	9.49	3.66	7.44	2.83	8.87	**2.11**
ML-TW	34.96	3.61	37.84	3.88	31.82	3.67	33.25	**3.40**
NL-ML	26.71	4.76	28.28	4.21	26.39	3.23	27.34	**3.17**
ANS-ME	66.01	3.91	67.06	5.57	64.29	4.00	65.58	**4.61**
AR-GO-ME	130.21	3.71	131.59	3.73	127.99	4.11	128.75	**4.55**
Bjorks sum	393.98	3.91	395.95	1.87	392.27	3.12	394.58	**4.83**
UI.SN	101.97	6.72	105.33	6.21	102.70	4.93	106.94	**4.49**
UI.SPP	111.46	8.37	114.21	6.21	110.05	4.17	114.89	**3.70**
LI.GOME	93.44	2.61	87.16	3.76	95.12	2.28	90.00	**2.90**
Ovj	-2.56	1.16	2.62	0.64	-1.99	1.00	1.96	**0.45**
gla.sn.pog	-166.81	5.47	-161.90	4.80	-165.79	3.91	-161.52	**3.85**
Li-Esth	-0.06	3.16	-0.86	2.31	-0.39	3.10	-0.87	**2.02**
Ls-Esth	-4.64	2.55	-2.17	1.57	-4.31	2.87	-1.47	**1.89**
NasoLab	109.34	5.69	104.75	4.33	111.52	6.01	108.02	**3.25**

LI-TV	72.72	9.50	72.33	12.98	73.85	6.89	72.57	**6.82**
LS-TV	72.91	8.01	78.28	10.55	75.17	5.67	77.59	**4.34**

The facial convexity angle exhibited a significant increase in both of the groups with a p-value ($p< 0.05$). Upper lip presented a significant improvement in LS-VT and its proximity to the Ricketts line in both groups. The nasolabial angle exhibited a statistically significant reduction in both group $p< 0.05$. There was also a significant improvement in LI for the Ricketts line. No significant retraction was found in LI-VT $p> 0.05$ in both groups

Generally, no significant differences were found between the two groups in soft-tissue variables.

Table 4: Changes occurring in each group during the study period (T2-T1)

	M-RMR			RMR			**M-RMR vs RMR**
	T2- T1			T2-T1			
Variable	MEAN	SD	p-value	MEAN	SD	p-value	**p-value**
SNA	2.25	0.76	0.000(**)	1.63	0.69	0.000(**)	**0.011(*)**
SNB	-0.64	0.16	0.001(**)	-0.57	0.58	0.000(**)	**0.317**
ANB	2.38	0.89	0.000 (**)	2.18	0.88	0.000(**)	**0.478**
N-S-AR	1.36	1.23	0.000(**)	1.72	1.77	0.000(**)	**0.439**
A-TV	3.32	1.46	0.014(*)	2.08	1.31	0.000(**)	**0.029(*)**
B-TV	-0.58	2.76	0.708(NS)	-0.13	2.31	0.812(NS)	**0.780**
CO-A	4.57	1.29	0.001(**)	2.97	1.47	0.000(**)	**0.199**
GO-Gn	4.35	2.38	0.016(*)	4.34	1.58	0.014(*)	**0.148**
Pr-Vert T	3.42	2.10	0.021(*)	2.24	1.93	0.000(**)	**0.415**
Id-Vert T	-1.01	1.40	0.041(*)	-1.25	1.45	0.034(*)	**0.183**
NL-TW	1.53	0.64	0.018(*)	0.43	1.04	0.351(NS)	**0.152**
ML-TW	2.88	1.89	0.000(**)	1.43	0.59	0.001(**)	**0.057**
NL-ML	1.57	1.00	0.002(**)	0.95	0.36	0.006(**)	**0.262**
ANS-ME	1.05	1.65	0.019(*)	1.29	1.98	0.009(**)	**0.658**
AR-GO-ME	1.38	0.77	0.118(NS)	0.76	0.93	0.398(NS)	**0.614**
Bjorksum	1.97	1.29	0.026(*)	2.31	0.94	0.017(*)	**0.448**
UI.SN	3.36	1.60	0.022(*)	4.23	1.10	0.000(**)	**0.062**
UI.SPP	2.75	2.03	0.024(*)	4.84	1.25	0.000(**)	**0.079**
LI.GOME	-6.28	3.12	0.000(**)	-5.12	3.40	0.000(**)	**0.268**
Ovj	5.18	1.17	0.000(**)	3.95	1.15	0.000(**)	**0.002(**)**
gla.sn.pog	4.91	2.95	0.000(**)	4.26	2.94	0.000(**)	**0.496**
Li-Esth	-0.80	1.44	0.022(*)	-0.48	1.68	0.222(NS)	**0.513**
Ls-Esth	2.47	1.57	0.000(**)	2.85	1.64	0.000(**)	**0.464**
NasoLab	-4.59	2.24	0.022(*)	-3.50	2.34	0.076(*)	**0.678**

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LI-TV	-0.39	0.96	0.829(NS)	-1.28	2.85	0.058(NS)	**0.639**
LS-TV	5.37	3.11	0.008(**)	2.42	1.07	0.002(**)	**0.136**
***Significant**			****Highly significant**				

4. Discussion

Several functional appliances have been used to treat Class III malocclusion in growing stage. One of these functional appliances is the removable mandibular retractor (RMR). Studies have reported that RMR effects are mainly dental, with minimal skeletal changes [13], [10], [14].

In this study conventional RMR was modified by adding upper lip pads that may increase skeletal effects in the upper jaw. Upper lip pads remove limiting pressure on the underdeveloped maxilla by hold upper lip away, and apply periosteal tension at the depth of maxillary sulcus to stimulate bone growth [9].

According to the results of this study in sagittal dimension, the M-RMR group showed greater effect on maxillary advancement than the control group (SNA, A-TV, CO-A). This is comparatively similar to a previous study that used reverse twin block with lip pads [9], similar positive results were traced with RMR appliances by other studies [10], [14]. In this study, the sagittal changes were seen in the upper jaw are significantly more than those in removable mandibular retractor (RMR). This could be credited to the additional lip pads to (M-RMR) in the present study. Similar improvement in maxillary advancement has also been noted with the Fränkel (FRIII) appliance [15], [16].

The mean of SNB angle and (B-TV) values were decreased indicating a posterior position of the mandible, which was confirmed similarly the results reported by studies used (RMR) appliance [17], [10].

The increase in ANB angle was comparable in both groups of this study. Similar positive results were recorded with RMR appliance used in pervious study [10], although it was greater in the current study than theirs, which may be attributed to the difference in the age of sample which was greater in their study.

Similar findings have been previously reported in other removable functional appliances, such as modified reverse twin block [9] and the Fränkel (FRIII) appliance [18], [15].

These effects were in contrast to one study which reported no effects on SNA,SNB,ANB with removable mandibular retractor (RMR) [13].

On the other hand the mandibular length (Co-Gn), was increased significantly in both groups, similar to the results reported using (RMR) device [11], [14], [10].

Our result indicated that the protrusion in dentoalveolar maxilla was increased in both groups, which agrees with the results reported with RMR therapy [14], and with modified revers twin-block [9].

Our result indicated that the (Id-Vert T) was decreased in both groups, that indicates that dentoalveolar remodeling occurred in both groups. These effects were in contrast to study which had reported slightly increase in (Id-Vert T) with RMR [14].

In vertical dimension, an increase in the vertical lower third of the face occurred in both groups, the mandibular plane rotation (ML-TW), (ANS-ME), and Bjork's sum were increased significantly. Similarly to the results reported with RMR therapy [10], and we contrasted with others, as they found that there was

no significant increase in the vertical variables [17], [11], this may be attributed to the long duration of treatment in their studies, which exceeded two years, thus, a relative intrusion occurred as a result of the posterior bite planes.

The upper incisors inclination (UI-SN, UI-SPP) showed proclination in both groups, while the lower incisors inclination (LO-GOME) showed retroclination in both groups, because of the reversed labial bow which rests on the necks of the lower incisors. Consequently, the overjet was corrected in both groups as result of skeletal and dentoalveolar effects. Similar results were traced with RMR appliances by other studies [11], [17], [14], [10].

The results of this present study exposed an improvement in the angle of the facial convexity and the lateral profile, confer to previous study [14]. Such improvement might have resulted from the retraction of mandibular and the progression of maxilla, where the (Gla.Sn.Pg) angle increased in both groups. It is immediately connected, we claim, to better values in the LS –VT and its proximity to the Ricketts line. This naturally leads to, as in our study did, improvement in nasolabial angle.

There has also been a significant improvement traced in LI in regard to the Ricketts line. It was statistically determined that (LI) decreased in both groups. Similar positive results were traced with RMR appliance by [10].

5. Conclusion

According on our clinical and cephalometric findings throughout both treatment groups, it is concluded that:

- M-RMR appliances have proven efficient in yielding promising soft- and hard-tissue changes when utilized to correct skeletal class III deformities for short terms.
- Both M-RMR and RMR have indicated satisfactory outcomes, yet M-RMR has greater impact regarding maxillary improvement.

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