Review Article

Rapid maxillary expansion effects in Class II malocclusion: *A systematic review*

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ABSTRACT

Objective: To evaluate the effectiveness of rapid maxillary expansion (RME) on the sagittal dental or skeletal parameters of growing children with Class II malocclusion.

Materials and Methods: A systematic review intended to identify relevant literature was conducted. The search was performed on Medline, Embase, Cochrane Library, and Scopus databases. Reference lists of the included articles were also screened for relevant documents. The qualitative assessment was performed according to the Methodological Index for Non-Randomized Studies (MINORS) tool, and the resultant data were grouped and analyzed concerning dental and skeletal sagittal effects of RME.

Results: Of 25 screened studies, seven articles met eligibility criteria and were included. Study samples were observed during mixed dentition stage and characterized as having either Class II dental malocclusion or skeletal discrepancy. None of the included studies was a randomized clinical trial. Included controlled studies presented several inadequacies related to control group or lacked appropriate comparative statistical analysis. Besides being frequently based on deficient methodology, dental and skeletal sagittal effects of RME were either controversial or lacked clinical relevance.

Conclusion: The effect of RME on the sagittal dimension of Class II malocclusions has not been proved yet. Future randomized controlled clinical trials are still needed to definitely address this question. (*Angle Orthod.* 2015;85:1070–1079.)

KEY WORDS: Palatal expansion technique; Malocclusion; Angle Class II

INTRODUCTION

Class II malocclusion is one of the most common orthodontic discrepancies,[1–3] and it is likely to produce significant negative esthetic[4] and social[5] effects on children's lives, affect their dental health,[6] or predispose them to dental trauma.[7]

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Plenty of evidence is available to support that Class II, division 1 individuals have smaller transverse maxillary dental or skeletal dimensions.[8–11] For this reason, it has been proposed that the treatment of this malocclusion should comprise previous maxillary expansion.[12–15] It has been reported that after expansion, a "spontaneous" correction of the Class II malocclusion takes place as a result of a forward posturing of the mandible.[13–15] However, such observations have mostly relied upon clinical experience, and the research intended to analyze that question is controversial and presents diverse study methods.[16–22]

Therefore, the objective of this investigation was to evaluate the effectiveness of rapid maxillary expansion (RME) on the sagittal dental or skeletal parameters of growing children with Class II malocclusion through a systematic review of available clinical trials.

MATERIALS AND METHODS

The Preferred Reporting Item for Systematic Review and Meta-Analysis (PRISMA) checklist[23] was used as a guideline for conducting and reporting this review.

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Articles were selected if growing individuals who underwent orthodontic treatment with RME for Class II malocclusion were investigated. Studies including adults or growing patients treated with any orthodontic Class II treatment method other than RME were excluded.

In order to be included, the study outcomes should have referred to either dental (molar relationship) or skeletal (cephalometric mandibular parameters) status of Class II malocclusion, and evaluations should have been performed both before and after RME treatment. In addition, included articles should have necessarily presented results derived from inferential statistics.

No language or time restrictions were applied to the searches. Case reports, literature reviews, editorials, interviews, and letters were not considered. Interventional clinical trials, including randomized and nonrandomized controlled studies, as well as case series were accepted.

The following databases were searched: Medline, Embase, Cochrane Library and Scopus. The key words used for this literature search were "maxillary expansion," "palatal expansion," and "Class II," A search strategy was designed first for Medline (Appendix 1) and was applied accordingly to all other databases. The electronic database searching was conducted between September 10 and 15, 2014. A hand search of the reference lists of selected articles was conducted to identify any additional relevant publications that might have been missed by the database search.

Once the search was completed, duplicate results were removed. In the first phase of the selection, two reviewers independently evaluated titles and abstracts, when available. Clinical studies that reported the use of RME for the correction of Class II malocclusion in growing individuals were considered as preselected after phase I screening. Full articles were then retrieved for those preselected publications, as well as for those with inadequate or unavailable abstracts. In the final phase of the study selection, the same reviewers independently evaluated the full-text articles according to critical application of the remaining eligibility criteria. Disagreements between reviewers in any selection phase were resolved through consensus.

The following variables were extracted from the final selected studies: sample and treatment characteristics; examination methods and parameters used to evaluate treatment effects, as well as main results, including baseline status; treatment effect (Δ) observed in the experimental group; net difference (Net Δ) between values observed in the treatment and control groups after observation period; and inferential statistics, which referred to either treatment vs control analysis if a control group was present, or initial vs final analysis in the case of noncontrolled studies. Two reviewers extracted the data independently, and all of the authors reviewed them afterwards. The extracted data were then combined and compared for accuracy, and discrepancies were resolved by reexamination of the literature. Authors were eventually contacted if any information appeared to be unclear.

Two reviewers appraised the selected studies according to the Methodological Index for Non-Randomized Studies (MINORS) (Appendix 2).[24] This tool was conceived and validated to assess methodological quality for nonrandomized studies, whether comparative or noncomparative.

RESULTS

A flowchart illustrating the selection of studies for this systematic review is presented in Figure 1. After the first phase selection, 25 full texts were obtained for the second phase evaluation, of which 18 articles[13–15,25–39] were excluded. The reasons for exclusion are listed in Table 1. Finally, seven clinical trials met the eligibility criteria and were considered for this systematic review.[16–22]

A summary of the key methodological data and study characteristics can be found in Table 2. Study samples were observed during the mixed dentition phase and presented a wide spectrum of Class II malocclusions. Samples were characterized as having either dental[18–20] or skeletal discrepancies.[16,17,21,22] Transverse maxillary deficiency was reportedly present in the sample of part of the studies.[16,19,21,22]

All subjects in the included studies were treated with RME, either as a sole treatment approach,[16,21,22] or associated with other appliances, such as passive transpalatal arches.[17–19] The subjects were observed for varying periods of time, according to different outcomes, which related to either skeletal[16–19,21,22] or dental characteristics.[18–20]

Methodological appraisal of the selected studies is presented in Table 3. None of the included studies was a randomized clinical trial. All of the researches[16–22] clearly stated the aim of the investigation, presented an appropriate period of observation, and reported no sample loss during follow-up. However, limitations were identified for most of the studies, such as the retrospective enrollment of the sample and collection of the data[20,22] or unclear report of these features.[16,17] None of the studies[16–22] reported if the outcome examiners were blinded during the end-point evaluation, and two trials[18,19] utilized a critical examination method (cephalometry) to assess the molar relationship outcome. These two studies,[18,19] however, were the only ones that demonstrated that their samples were appropriate in size.

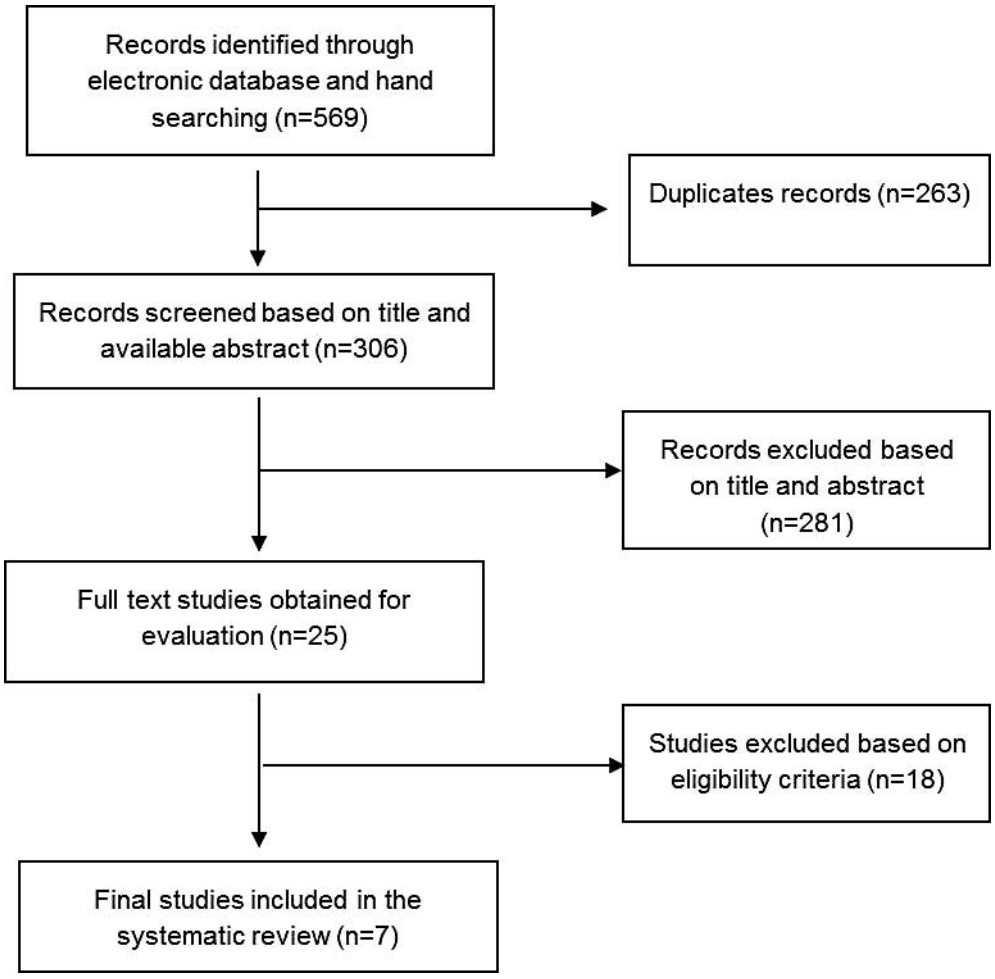

Figure 1. Flowchart of study selection process.

Table 1. Articles Excluded After Full Text Evaluation Based on Eligibility Criteria

Reference	Reason for Exclusion
Gray[25]	Not exclusively Class II sample
Hesse et al.[26]	Not exclusively Class II sample
McNamara[13]	No inferential statistics
Basciftci and Karaman[27]	Not exclusively Class II sample
McNamara[14]	No inferential statistics
Garib et al.[28]	Not exclusively Class II sample
Wendling et al.[29]	No inferential statistics
McNamara[15]	No inferential statistics
Lima Filho and Ruellas[30]	Association with Class II-specific appliance
Lima Filho and Ruellas[31]	Association with Class II-specific appliance
Marini et al.[32]	Not exclusively Class II sample
Lima Filho and Ruellas[33]	Association with Class II-specific appliance
Lima Filho[34]	Literature review
Baratieri et al.[35]	No outcome of interest
Kolokitha and Papadopoulou[36]	Case report
Farronato et al.[37]	Not exclusively Class II sample
Hilgers[38]	Technique or novel appliances introductory papers
Silvestrini-Biavatia et al.[39]	Not exclusively Class II sample

Table 2. Summary of Study Characteristics and Results of the Included Studies[a]

Study	Sample: Treatment Groups	Sample: Control Groups	RME Treatment Characteristics	Outcome Measures	Outcome Measures Results: Baseline	Δ	Net Δ	Inferential Statistics (Test; *P* Value)
Cozza et al.[16]	n = 20; 10 M, 10 F; 8 y	n = 20; 10 M, 10 F; 8 y	Butterfly (Hyrax)	Cephalometric analysis				
	Mixed dentition		Observation period: 6 mo (treatment), 8 mo (control)	SNB, degrees	74.4 ± 3.2	−0.5 ± 1.7	0.0	–
	Mild skeletal Class II (ANB: 4.0° ± 0.7°)	Mild skeletal Class II (ANB: 3.8° ± 2.6°)		ANB, degrees	3.8 ± 2.6	0.1 ± 0.7	0.0	–
	Vertical growth pattern (FMA: 26.7° ± 1.6°; SNGoGn: 37.5° ± 2.9°)	Vertical growth pattern (FMA: 28.6° ± 4.8°; SNGoGn: 37.9° ± 4.8°)		Wits, mm	1.3 ± 3.9	0.1 ± 1.5	−0.2	–
	Posterior crossbite (unilateral/bilateral)			Pog-Nperp, mm	−8.1 ± 5.8	−0.3 ± 2.8	−0.1	–
Lambot et al.[17]	n = 22; 8.5 y	n = 8; 8.9 y	Hyrax	Cephalometric analysis				
	Mixed dentition	–	TPA	SNB, degrees	75.3 ± 0.7	−0.4	−0.5	–
	Class II (ANB > 4°)		Observation period: 1.2 y	ANB, degrees	5.0 ± 0.2	−0.5	−0.5	–
	Tooth-size arch length discrepancy	–						
McNamara et al.[18]	n = 462; 8.8 ± 1.1 y	n = 109; 9.3 ± 0.9 y	Bonded splint	Cephalometric analysis				Independent sample Student's *t*-test
	Early mixed dentition		Removable maintenance plate (at least 1 y)	6/6, mm				
	Class II tendency (−0.5 mm ≤ 6/6 ≤ 0.5 mm) (n = 166)	Class II tendency (−0.5 mm ≤ 6/6 ≤ 0.5 mm) (n = 51)	TPA (during transition to permanent dentition)	Class II tendency	0.0 ± 0.3	1.4 ± 1.0	0.8	$P < .001$
	Class II (6/6 > 0.5 mm) (n = 130)	Class II (6/6 > 0.5 mm) (n = 58)	Observation period: 3.7 y	Class II	−1.4 ± 0.9	1.8 ± 1.2	1.5	$P < .001$
				Overjet, mm				Independent sample Student's *t*-test
				Class II tendency	4.2 ± 1.8	−0.2 ± 1.4	0.1	NS
				Class II	5.5 ± 2.0	−0.5 ± 1.5	−0.4	NS
				Pog-Nperp, mm				Independent sample Student's *t*-test
				Class II tendency	−7.1 ± 4.8	1.6 ± 3.3	−0.2	NS
				Class II	−8.1 ± 5.0	1.5 ± 3.2	0.3	NS
				Improvement[b], %				Z test
				Class II tendency	–	69	40	$Z = 4.93$; $P < .001$
				Class II	–	81	55	$Z = 7.09$; $P < .001$

Table 2. Continued

Study	Sample: Treatment Groups	Sample: Control Groups	RME Treatment Characteristics	Outcome Measures	Outcome Measures Results: Baseline	Δ	Net Δ	Inferential Statistics (Test; *P* Value)
Guest et al.[19]	n = 50; 19 M, 31 F; 8.8 ± 1.1 y	n = 50; 28 M, 22 F; 8.9 ± 0.9 y	Bonded splint	Cephalometric analysis				Independent sample Student's *t*-test
	Early mixed dentition		Removable plate (n = 48); TPA (n= 2) for maintenance					
	Class II, Division 1 (both Class II tendency and full cusp Class II)		TPA (during transition to permanent dentition)	6/6, mm	−0.8 ± 0.8	1.8 ± 1.0	1.7	$P < .001$
	Maxillary constriction (transpalatal width ≤ 30 mm)	–	Brackets on 12, 11, 21, 22 (n = 35)	U6H, mm	–	1.2 ± 1.4	−0.2	NS
			Observation period: 4.0 y (treatment) 4.1 y (control)	L6H, mm	–	2.0 ± 1.4	0.0	NS
				Overjet, mm	5.9 ± 1.8	−0.8 ± 1.6	−1.0	$P < .01$
				SNB, degrees	76.2 ± 3.5[c]	1.2 ± 1.4	0.1	NS
				Pog-Nperp, mm	–	1.9 ± 1.9	1.1	$P < .01$
				Co-Gn, mm	98.1 ± 4.2	9.1 ± 2.9	1.3	$P < .05$
				ANB, degrees	5.1 ± 1.8	−0.9 ± 1.3	−0.5	$P < .05$
				Wits, mm	1.4 ± 1.7	−0.5 ± 1.5	−1.2	$P < .01$
				Mx/Mn difference, mm	–	4.0 ± 2.2	1.6	$P < .01$
Volk et al.[20]	n = 13; 10.2 y	–	Hyrax (n = 12)	Mounted models analysis				Student's *t*-test for paired differences
	Mixed dentition	–	Haas (n = 1)	Molar relationship[d] (right/left), mm				
	Class II (at least 2 mm on one side)		Brackets on 12, 11, 21, 22 (n = 7)	Centric occlusion	4.6 ± 1.3	0.5 ± 1.3	–	NS
	No posterior crossbite		Observation period: 6 mo		5.2 ± 1.3	0.4 ± 0.9	–	NS
				Maximal intercuspation	3.2 ± 1.6	0.2 ± 1.3	–	NS
					3.5 ± 1.8	0.1 ± 0.8	–	NS
				Overjet, mm	5.7 ± 2.5	1.2 ± 2.0	–	NS
Baratieri et al.[21]	n = 17; 8 M, 9 F; 10.3 y	–	Haas	Cone-beam computed tomography				Student's *t*-test for paired differences
	Class II Division 1 (at least 2 mm towards Class II molar relationship and ANB > 4°)		Observation period: 6 mo	Sagittal position[e] (right/left), mm				
	Skeletal maxillary constriction[40]	–		Co	8.9 ± 2.3	0.2 ± 1.1	–	NS
					9.1 ± 2.5	0.0 ± 1.3	–	NS
				Go	18.5 ± 3.7	0.3 ± 1.2	–	NS
					18.2 ± 3.6	0.5 ± 1.5	–	NS
				Me	72.7 ± 7.5	0.7 ± 1.2	–	$P < .05$

Table 2. Continued

Study	Sample		RME Treatment Characteristics	Outcome Measures	Outcome Measures Results			
	Treatment Groups	Control Groups			Baseline	Δ	Net Δ	Inferential Statistics (Test; *P* Value)
Farronato et al.[22]	n = 55; 8.8 ± 1.4 y Class II (ANB > 4°)	–	Hyrax Observation period: 6 mo	Cephalometric analysis				Student's *t*-test for paired differences
	Bilateral crossbite			SNB, degrees	74.0 ± 2.0	2.2	–	$P < .01$
				ANB, degrees	5.8 ± 1.0	−1.8	–	$P < .01$

[a] RME indicates rapid maxillary expansion; Δ, treatment effect (difference between baseline and final value observed in the treatment group); Net Δ, treatment effect in relation to control (difference between final values observed in the treatment and control groups). M, male subjects; F, female subjects; and NS, not significant. Landmarks: SNB, formed by the intersection of the line S-N and N-B and indicates the sagittal position of the mandible; ANB, formed by the intersection of the line S-N and N-B and indicates the sagittal relationship between maxilla and mandible. FMA, (Frankfort-mandibular plane angle) formed by the intersection of the Frankfort horizontal plane and the mandibular plane and indicates the inclination of the mandible plane; SNGoGn, formed by the intersection of the line S-N and Go-Gn and indicates the inclination of the mandible plane; Wits, distance between the perpendicular projections of the points A and B in the occlusal plane and indicates the sagittal relationship between maxilla and mandible; Pog-Nperp, (pogonion to nasion perpendicular) horizontal distance between Pog and a line perpendicular to the Frankfort horizontal plane through N and indicates the sagittal position of the mandible; TPA, transpalatal arch; 6/6, molar relationship (horizontal distance between two vertical lines perpendicular to the occlusal plane and tangent to the mesial surfaces of the upper and lower first permanent molars); U6H, horizontal position of the upper first molar; L6H, horizontal position of the lower first molar; Co-Gn, linear distance between condylion to gnathion and indicates mandibular length; Mx/Mn difference, the sagittal relationship between maxilla and mandible; Co, condylion; Go, gonion; and Me, menton.

[b] Improvement: 6/6 shift greater than 1 mm towards Class I.

[c] Significantly higher than the control group (74.9° ± 2.6°); ($P < .05$, independent sample Student's *t*-test).

[d] Horizontal distance between the mesiobuccal cuspid of the maxillary first molar to the buccal groove on the mandibular first molar.

[e] Sagittal position in relation to coronal axis (passing through right and left porium).

Table 3. Methodological Appraisal of the Selected Studies, According to MINORS Assessment Tool

	Reference						
	Cozza et al.[16]	Lambot et al.[17]	McNamara et al.[18]	Guest et al.[19]	Volk et al.[20]	Baratieri et al.[21]	Farronato et al.[22]
Study features							
1. A clear stated aim	2	2	2	2	2	2	2
2. Inclusion of consecutive patients	0	0	2	2	1	2	1
3. Prospective collection of data	0	0	2	2	1	2	1
4. Endpoints appropriate to the aim of the study	2	2	1	1	2	2	2
5. Unbiased assessment of the study endpoint	0	0	0	0	0	0	0
6. Follow-up period appropriate to the aim of the study	2	2	2	2	2	2	2
7. Loss to follow up less than 5%	2	2	2	2	2	2	2
8. Prospective calculation of the study size	0	0	2	2	0	0	0
Additional criteria in the case of comparative study							
9. An adequate control group	2	2	2	2	–	–	–
10. Contemporary groups	0	0	0	0	–	–	–
11. Baseline equivalence of groups	2	2	2	1	–	–	–
12. Adequate statistical analyses	1	1	2	2	–	–	–
Total	13	13	19	18	10	12	10

Three[20–22] of the seven included articles were noncontrolled studies. The other controlled studies[16–19] presented adequate paired control groups, although none of them reported if control and experimental groups were contemporary. Among the controlled studies,[16–19] two[16,17] lacked statistical analysis for comparison between the experimental and control groups changes. Of the remaining two controlled studies,[18,19] one of them[19] had a baseline difference between the experimental and control groups.

Due to the large variability among the included studies, this systematic review was not designed in a meta-analysis format. Nonetheless, a comprehensive extraction of the study data can be found in Table 2.

Molar Relationship

The dental changes after RME treatment were investigated in three[18–20] of the included studies. The first clinical trial[18] demonstrated that molar occlusal relationship significantly improved after RME, for both Class II tendency (end-to-end) and Class II (more severe) treated groups. Another included study[19] also presented significant positive molar changes following RME treatment. The Class II treatment group demonstrated significant improvement of the molar relationship in comparison with the matched control.[19] However, another study[20] performed a noncontrolled trial in which Class II patients showed no significant differences regarding molar relationship after treatment, neither in centric occlusion nor maximum intercuspation positions.

Skeletal Mandibular Effects

Among the included studies, six[16–19,21,22] evaluated mandibular changes following RME therapy. According to the first one,[16] RME did not produce any significant difference in Class II individuals. Among the anteroposterior mandibular parameters investigated by Lambot et al.,[17] however, a statistically significant increase in SNB measurement was found for the treated group. In both studies,[16,17] when the experimental and control group changes were compared, differences did not reach clinical relevance for all the parameters.

McNamara et al.[18] did not observe skeletal differences between treated and control groups in relation to the amount of the mandibular displacement. However, Guest et al.[19] demonstrated statistically significant increases in mandibular length and advancement of the symphysis when Class II patients were compared to untreated controls. The RME also produced significant effects on the anteroposterior relationship of the maxillary and the mandibular bones of the treated group, as compared to matched controls.[19]

According to Baratieri et al.,[21] significant anterior displacement of the mandibular symphysis was observed during the RME retention period. In another study, Farronato et al.[22] also reported that in Class II subjects, the mandible moved forward in a significant manner, and the ANB angle statistically decreased, improving the skeletal Class II after RME.

DISCUSSION

The results observed during this systematic review are not only contradictory, but also frequently based on deficient methodology, or lack clinical relevance. Even though important studies have been published,[16–22] more solid scientific evidence based on reliable methods of assessment and proper study designs is still lacking in order to thoroughly test whether dental correction or mandibular anterior shift and/or supplementary growth take place after RME in Class II individuals.

According to Volk et al.,[20] maxillary expansion did not predictably improve Class II molar relationships. And even though the best evidence available[18,19] reported statistically significant occlusal improvements, these changes could be attributed to other reasons, eg, the use of passive transpalatal arches during transition from mixed to permanent dentition. As previously documented,[9,41,42] most of the flush terminal planes are naturally converted to solid first molar Class I during transition. This fact had been wisely mentioned before,[43] and it indicates that most of the end-to-end Class II cases in mixed dentition are self-corrected, and demand neither RME nor transpalatal arches to assure first molar adjustment.

The transformation into a Class I molar relationship, during transition to permanent dentition, depends on a number of dental and facial skeletal changes.[44] However, if one assumes that it is possible to preserve additional space by preventing upper molars mesial drift with transpalatal arches, as suggested,[45] even more severe than end-to-end Class II occlusions might be supposedly exempt from RME to attenuate their sagittal occlusal imbalances. Unless space management is critical, or transversal discrepancies are proved to be present, RME for sole attenuation of Class II malocclusion thus seems unnecessary.

As for the mandibular skeletal changes, most of the selected studies[16–18,20] indicated no mandibular shift, nor supplementary growth after RME. One may claim that the mandibular changes demonstrated by Guest et al.[19] might have been a result of the mandibular shift or growth, but differences still seem clinically irrelevant. Moreover, other Class II standard therapies, such as functional removable appliances,[46] headgears,[43] or bite-jumping appliances,[47] have already proved to be effective for the Class II correction; in addition, these therapies promote maxillary expansion, that reduces the usefulness of RME in skeletal Class II cases with no transverse deficiency.

Even though Baratieri et al.[21] and Farronato et al.[22] have presented data indicating significant mandibular anterior displacement, these changes were not compared to a control group, which considerably decreases the scientific relevance of these evidences.

In order to have a better predictability of the effectiveness of any therapy, it is advisable to consider not only controlled groups, but also randomization.[48] Unfortunately, no randomized controlled trial has been performed on that matter so far, and those that were carried out with paired control groups still lack methodological accuracy. Because of the absence of randomized trials, the investigators had to choose to include nonrandomized controlled trials and case series in this systematic review. Unfortunately, no meta-analysis could be executed because of the many methodological differences among the selected studies and the excessively large variability observed in relation to the sample characteristics, treatment features, follow-up period, and outcome measurements.

RME is considered to be one of the safest and most predictable therapies in orthodontic practice.[49] However, the effect of maxillary expansion on the sagittal dimension of Class II is still controversial and has not been substantially proved yet. The demonstration of the induced change theory[12] still requires methodological concerns, principally in relation to clinical trials design, which should ideally enroll adequate control subjects, randomization, and blindness during outcome assessment.

During performance of future studies, special emphasis must be directed to objectively identify those Class II patients more likely to present favorable sagittal responses to RME therapy. Moreover, long-term studies would be advisable in order to investigate the stability of effects, if present, as well as to verify if RME therapy is likely to avoid Class II specific therapy in late mixed dentition or diminish comprehensive orthodontic treatment time.

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APPENDIX 1

Search Strategy Designed for Medline Database Search

Search Groups	Key Words
1	Maxillary expansion
2	Palatal expansion
3	Class II
((1) OR (2) AND (3))	Total search results: 254

APPENDIX 2

MINORS Assessment Tool

	Score[a]
Methodological Index for Non-Randomized Studies	
1. A clearly stated aim. The question addressed should be precise and relevant in the light of available literature.	
2. Inclusion of consecutive patients. All patients potentially fit for inclusion (satisfying the criteria for inclusion) have been included in the study during the study period (no exclusion or details about the reasons for exclusion).	
3. Prospective collection of data. Data were collected according to a protocol established before the beginning of the study.	
4. Endpoints appropriate to the aim of the study. Unambiguous explanation of the criteria used to evaluate the main outcome, which should be in accordance with the question addressed by the study. Also, the endpoints should be assessed on an intention-to-treat basis.	
5. Unbiased assessment of the study endpoint. Blind evaluation of objective endpoints and double-blind evaluation of subjective endpoints. Otherwise, the reasons for not blinding should be stated.	
6. Follow-up period appropriate to the aim of the study. The follow-up should be sufficiently long to allow the assessment of the main endpoint and possible adverse events.	
7. Loss to follow up less than 5%. All patients should be included in the follow up. Otherwise, the proportion lost to follow up should not exceed the proportion experiencing the major endpoint.	
8. Prospective calculation of the study size. Information of the size of detectable difference of interest with a calculation of 95% confidence interval, according to the expected incidence of the outcome event, and information about the level for statistical significance and estimates of power when comparing the outcomes.	
Additional Criteria in the Case of Comparative Study	
9. An adequate control group. Having a gold standard diagnostic test or therapeutic intervention recognized as the optimal intervention according to the available published data.	
10. Contemporary groups. Control and studied group should be managed during the same time period (no historical comparison).	
11. Baseline equivalence of groups. The groups should be similar regarding the criteria other than the studied endpoints. Absence of confounding factors that could bias the interpretation of the results.	
12. Adequate statistical analyses. Whether the statistics were in accordance with the type of study with calculation of confidence intervals or relative risk.	

[a] The items are scored 0 (not reported), 1 (reported but inadequate) or 2 (reported and adequate).