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Original Article

Long-term maxillary three dimensional changes following maxillary protraction with or without expansion: A systematic review and meta-analysis

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KEYWORDS
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Background/purpose: Maxillary protraction with or without expansion appears to be an effective orthopedic treatment in skeletal class III growing patients, but the long-term effect on maxilla changes is less clear. The aim of this meta-analysis was to evaluate long-term three dimensional skeletal effects on maxilla through face mask (FM) with or without rapid maxillary expansion (RME) in skeletal CIII growing patients.
Materials and methods: We searched database including PubMed, Science Direct, Embase and Web of Science through Feb 2020. Inclusion criteria were randomized controlled trials or cohort studies recruiting growing patients who received maxillary protraction and/or expansion and comparing the treatment groups with untreated controls. The follow-up periods were more than 3 years. Risk of bias was assessed using the Cochrane tools (RoB2.0 and ROBINS-I). GRADE was used to qualify the evidence.
Results: This meta-analysis included 6 studies comprising 327 participants in total. No statistically significant changes were observed on the degree of Sella-Nasion-A point (SNA) in the

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treated groups when compared with the untreated controls. However, significant increase on maxillary rotation degree (mean difference: 8.20, 95% CI = 6.87–9.53, $p < 0.001$) and maxillary base width (mean difference: 2.27, 95% CI = 1.39–3.15, $p < 0.001$) in the treated groups, if compared with untreated controls.
Conclusion: Our results indicated that FM and FM/RME treatments might not be long-term effective on correcting maxillary anteroposterior hypoplasia in growing patients. Additionally, more long-term studies are still necessary to further assess its skeletal benefits on maxilla in vertical and transverse dimension.

Introduction

Treatment of skeletal Class III malocclusion in growing patients is one of the most challenging orthodontic problems.[1] In order to treat the patients with the unfavorable growth potential, growth modification including maxillary protraction, chin cap or functional regulator[2–4] was intervened to accomplish orthopedic treatment. In the past, facemask (FM) and rapid maxillary expansion (RME) have been widely known in orthopedic treatment in young patients with midfacial hypoplasia and maxillary transverse deficiency.[5–10] In addition, bone anchored assisted maxillary protraction or alternate rapid maxillary expansions and constrictions (Alt-RAMEC) combined with maxillary protraction were introduced to encourage the therapeutic effect on midface deficiency.[8,11–14]

FM orthopedic treatment has been proved to be effective in treating growing Class III patients.[9,10] Furthermore, FM and RME were combined as a treatment method for improving the maxillary transverse and midface deficiency. However, the skeletal effect on the enhancement of maxillary growth over time has been debated and still controversial. Some studies demonstrated that maxillary protraction significantly improve midface deficiency,[4,8,15] whereas no significant or limited evidence was observed in correcting midface deficiency.[7,9] Furthermore, some studies claimed that it was only short-term effective on correcting class III growing patients.[16,17] Although many systematic reviews have been published on similar topics in the past,[16–21] there is no systematic review and meta-analysis regarding long term evaluation of the orthopedic treatment outcome in skeletal class III growing patients.

This study was aimed to evaluate long-term three dimensional skeletal changes on maxilla using maxillary protraction with or without expansion in skeletal class III young patients when compared to the untreated controls through the meta-analysis.

Materials and methods

Literature search

Studies that reported the growing patients with midface or transverse maxillary deficiency received maxillary protraction, expansion or combination were included. In these studies, the skeletal changes after the orthopedic treatment were evaluated and compared with those untreated control groups.

The question was that "What is the long-term skeletal changes in maxillary anteroposterior, vertical and transverse dimension after maxillary protraction or expansion?". Four electronic databases, including PubMed, Embase, Science Direct and Web of Science, were selected and used to identify the studies. The PICO (participants, interventions, comparisons, outcomes and study design) principle was followed and needed as keywords. The search terms included "maxilla constriction" or "midfacial deficiency" or "Class III malocclusion" or "RME" or "rapid maxillary expansion" or "maxilla expansion" or "maxillary protraction" or "facemask" or "FM" or "Alt-MAMEC" or "maxillary protraction/expansion" or "bone-anchored" or "Class III elastics" AND "children/adolescence" or "growing" or "growth" AND "long-term".

Inclusion and exclusion criteria

The PRISMA checklist is described in Table S1. The included studies are randomized controlled trials (RCT) and observational studies with at least 3 years follow up duration that published from January 1990 to January 2020 without language restricted. Other inclusion criteria were following the PICO principle. Type of participant (P): the patients selected were those with Class III malocclusion with maxillary hypoplasia or transverse maxillary deficiency, from the early mixed dentition to early permanent dentition (age ranged from 6 to 16 years old). Type of interventions (I): the intervention was the selection of different treatment of FM and FM/RME. Type of comparisons (C): treated group was compared to untreated control group. Type of outcomes (O): long term (>3 year) maxillary changes in sagittal, vertical and transverse dimensions. PICOS criteria for the systematic review were summarized in Table 1. We retrieved the studies that matched the inclusion criteria and assessed by the exclusion criteria: (1) patients with craniofacial anomaly and (2) less than 3 years follow up periods.

Data extraction

In the included studies, we composed the standardized form by extracting and collecting the following variables: authors, publication years, study design, classification of

Table 1 PICOS criteria for the systematic review.

Populations(P)	Growing patients with skeletal class III malocclusion with maxillary hypoplasia or transverse maxillary deficiency
Intervention(I)	Orthopedic maxillary protraction with or without expansion
Comparison(C)	Untreated controls
Outcome(O)	Maxillary changes in sagittal, vertical and transverse dimensions.
Study design(S)	Randomized clinical trials and controlled clinical trials
Focus questions	What are the long-term (≥ 3 years) skeletal effects on maxillary three dimensions after maxillary protraction with or without expansion?

patients, number of participants, mean age, sex, follow up duration, treatment method and the clinical result. Three reviewers (WCL, CHL and YFL) individually confirmed the data in the included studies. Subsequently, we overcome the disagreements by discussion with the help of a fourth reviewer (CSH) to achieve the final determination.

Quality assessment of the included studies

Cochrane risk of bias (RoB 2.0)[22] or risk of bias in non-randomized studies of interventions (ROBINS-I)[23] was used to assessed each randomized controlled trial or controlled clinical trial's quality, respectively. In the RoB 2.0, it includes the bias in the randomization process, deviations from the intended interventions, missing outcome data, measurement of the outcome, selection of the reported result, and overall bias. In the ROBINS-I, it includes the bias in the pre intervention, at intervention, post intervention and overall bias.

Statistical analysis

Review Manager Version 5.4 software was used to achieve the mean difference (MD) and 95% CI. MD was used for continuous data in statistical pooling. I^2 statistical test was also used to assess the heterogeneity of the included studies. The I^2 ranged from 0 to 100%. $I^2 = 0\%$ meant no heterogeneity, whereas ≥75% proposed a high heterogeneity.[24] In general, the fixed effect models are employed when heterogeneity is low, while the random effect models are employed when heterogeneity is high. Comprehensive Meta-analysis version 3 software was used to obtain funnel plots by to investigate the potential small study bias by Egger's test and visual inspection.

Results

Studies characteristics

The PRISMA flow diagram is presented in Fig. 1. The initial search generated **327** articles from database and other sources. 26 full-text articles were assessed for eligibility. At the final step of article selection, twenty of the 26 articles were excluded because of assessment of skeletal changes less than 3 years (Table 2). After 20 exclusions, 6 articles were included in this meta-analysis, as reported in Fig. 1. Of the 6 included studies, two study was RCT and four were cohort studies involving 327 patients were finally included in this meta-analysis. The included studies were published from 1996 to 2016. The treatment groups received the maxillary protraction with or without rapid maxillary expansion. The control participants were defined as untreated skeletal Class III malocclusion. The patient's mean age ranged from 6.36 to 11.83 years and the follow up duration ranged from 3.57 to 9.5 years (Table 3).

Assessment of risk of bias

Two of the included studies were RCTs and we used the revised Cochrane Risk of Bias (RoB 2.0) tool to assess the risk of bias. Low risk of bias was found for this included RCT. For observational studies, we used the ROBINS-I tool to evaluate the risk of bias among the studies into one of the four levels (low, moderate, serious and critical). The

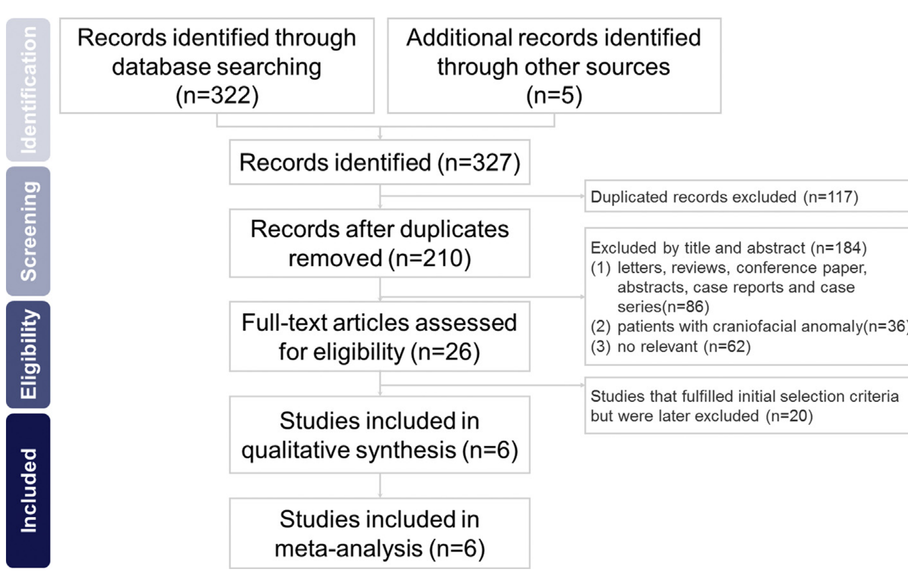

Figure 1 PRISMA flow diagram of the search results from the databases.

Table 2 Studies that fulfilled initial selection criteria but were later excluded (n = 20). RCT, randomized controlled trial. CS, cohort study.

Author, year	Reasons for exclusion
Kilicoglu et al., 1998	Only short-term changes
Ucem et al., 2004	Only short-term changes
Vaughn et al., 2005	Only short-term changes
Baccetti et al., 2010	Only short-term changes
Chen et al., 2012	Treated group and untreated controls were not matched in mean age and retention periods
Akin et al., 2015	Only short-term changes
Baloş et al., 2015	Only short-term changes
Gencer et al., 2015	Only short-term changes
Chang et al., 1997	No mention about skeletal maxillary transverse dimension
Guest et al., 2010	No mention about skeletal maxillary transverse dimension,
El et al., 2014	Only short-term changes, CBCT measurement rather than cephalometry
Baratieri et al., 2014	Only short-term changes
Yuksel et al., 2001	Only short-term changes
Xu et al., 2001	Only short-term changes
Kajiyama et al., 2004	Only short-term changes
Sar et al., 2011	Only short-term changes
Masucci et al., 2014	Only short-term changes in FM/ALT-RAMEC treatment
De Clerck et al., 2010	Only short-term changes in bone anchored maxillary protraction
Sar et al., 2014	Only short-term changes in bone anchored maxillary protraction
Elangar et al., 2016	Only short-term changes in bone anchored maxillary protraction

overall result of the assessment showed that 3 studies presented a low risk of bias, while the other one were at moderate risk of bias (Table 4). The most problematic domains involved selection bias.

Outcome on three dimensions of maxilla

Anteroposterior dimension (SNA)

Primary outcome on the SNA is shown in Fig. 2. SNA angle was measured as indication of the anteroposterior changes of the maxilla. 251 participants across the 5 studies[3,7,9,25,26] were included in this meta-analysis, with 135 in the maxillary protraction group (FM/FM + RME) and 116 in the untreated control group. In the group of FM/FM + RME versus untreated controls, the pooled data showed that FM/FM + RME therapy had no better treatment effect on SNA than controls (mean difference = 0.31°; 95% CI = −0.34-0.95, $p = 0.35$ and $I^2 = 0\%$). In addition, no significant heterogeneity was seen among the included studies.

Vertical dimension (maxillary rotation degree)

Primary outcome on the maxillary rotation degree is shown in Fig. 3. In the maxillary rotation degree, the changes between group with and without treatment of FM were statistically different (mean difference: 8.20, 95% CI = 6.87—9.53, $p < 0.001$ for maxillary rotation degree), but the analysis was achieved in only one study collected.

Transverse dimension (maxillary base width)

Primary outcome on the maxillary base width is shown in Fig. 4. In the maxillary base width, the changes between group with and without treatment of RME were statistically different (mean difference: 2.27, 95% CI = 1.39—3.15, $p < 0.001$ for maxillary base width), but the analysis was achieved in only one study collected.

Publication bias

To evaluate potential publication bias, we assessed funnel plots and Egger's regression models. The funnel plot for mean difference of SNA is presented in Fig. 5 with symmetrical graphical funnel plot was investigated. No significant publication bias regarding the overall mean difference in SNA ($p = 0.09$ in the group of FM/FM + RME versus untreated controls) which was evaluated by Egger's test.

GRADE

GRADE was used to evaluate overall evidence of both RCTs and observational studies in three dimensional changes of maxilla. Low quality of evidence shows that maxillary expansion may have benefit when compared to untreated control in maxillary base width. The level of evidence for maxillary base width was downgraded due to selection bias and only one small trial in outcome assessment.

The GRADE table is in Table 5.

Discussion

This meta-analysis evaluated the long term three dimensional changes on maxilla, defined as SNA in anteroposterior dimension, maxillary rotation change in

Table 3 Characteristics of included studies (n = 6). RCT, randomized controlled trial. CS, cohort study.

Author, year	Design	Type of malocclusion	Appliance (type of intervention)	Number	Mean age in years	Mean Follow up duration	Authors' conclusion
Cong et al., 1996	CS	Skeletal CIII	A = FM B = untreated control	n = 22 n = 12	6.80 ± 1.13 6.36 ± 0.54	3.57 years	No differences were observed between the treated patients and control during the posttreatment follow up
Mandall et al., 2012	RCT	Skeletal CIII	A = FM B = untreated control	n = 35 n = 38	8.7 8.7	3 years	Protraction treatment effect at SNA is not statistically significantly better than the CG
Mandall et al., 2016	RCT	Skeletal CIII	A = FM B = untreated control	n = 35 n = 32	8.7 ± 0.9 9 ± 0.8	6 years 6 years	Early CIII protraction by FM reduces the need for OGS. However, this effect cannot be explained by the maintenance of skeletal cephalometric change.
Westwood et al., 2003	CS	Skeletal CIII	A = FM/RME B = untreated control	n = 34(M = 14, F = 20) n = 22(M = 9, F = 13)	8.25 ± 1.83 8.08 ± 2.16	6.33 ± 2.25ys 6.42 ± 2.17ys	No significant difference on SNA between the treated patients and untreated controls in the long-term follow up
Masucci et al., 2011	CS	Skeletal CIII	A = FM/RME B = untreated control	n = 22(M = 9, F = 13) n = 13(M = 8, F = 5)	9.2 ± 1.6 8.4 ± 0.9	9.4 ± 2.5 years 9.5 ± 1.8 years	In the long-term, successful outcomes in about 73% of the Class III patients and mainly due to significant improvements in the sagittal position of the mandible.
Cameron et al., 2002	CS	Maxillary transverse deficiency	A = RME B = untreated control	n = 42(M = 17, F = 25) n = 20(M = 11, F = 9)	11.83 11.83	8.67 years 5.84 years	Effective in skeletal and dental transverse dimension

Table 4 Methodological quality assessment of included studies.

Randomized controlled trials evaluated using the revised Cochrane Risk of Bias (RoB 2.0) tool

Author, year	Bias arising from the randomization process	Bias due to deviations from the intended interventions	Bias due to missing outcome data	Bias in the measurement of the outcome	Bias in the selection of the reported result Low	Overall bias
Mandall et al., 2012	Low	Low	Low	Low	Low	Low
Mandall et al., 2016	Low	Low	Low	Low	Low	Low

Non-randomized controlled trial studies evaluated using the Risk of Bias in Non-randomized Studies of Interventions (ROBINS-I) tool

Author, year	Pre intervention		At intervention	Post intervention				Overall bias
	Bias due to confounding	Selection bias	Bias in the classification of interventions	Deviation from the intended interventions	Bias due to missing data	Bias in the measurement of outcomes	Bias in the selection of reported results	
Cong et al., 1996	Low	Low	Low	Low	Low	Low	Low	Low
Westwood et al., 2003	Low	Low	Low	Low	Low	Low	Low	Low
Masucci et al., 2011	Low	Low	Low	Low	Low	Low	Low	Low
Cameron et al., 2002	Low	Moderate	Low	Low	Low	Low	Low	Moderate

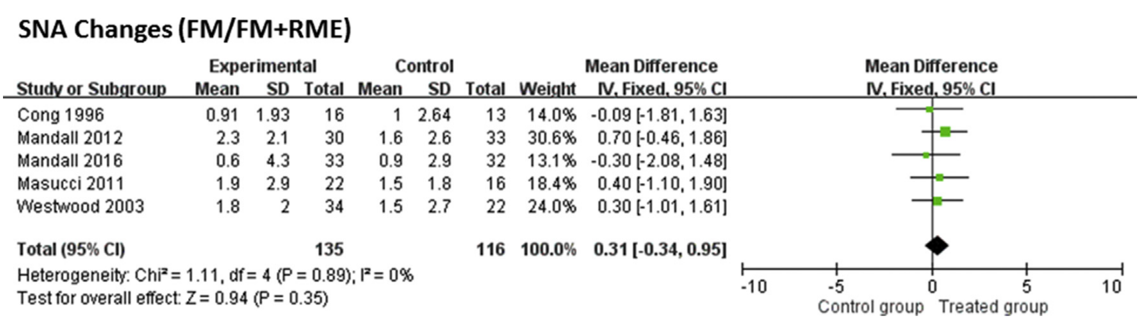

Figure 2 Forest plot to evaluate maxillary anteroposterior changes in the SNA following maxillary protraction with or without expansion. The FM/FM + RME treated group versus control group.

vertical dimension and maxillary base width in transverse dimension, following maxillary protraction with or without expansion including FM and FM + RME. In anteroposterior dimension, it included 5 studies to evaluate the orthopedic effect on SNA. It showed that there was no significant increase in SNA after maxillary protraction treatment in the group of FM/FM + RME versus untreated controls with follow up periods more than three years. Instead, the changes between group with and without treatment were statistically different in vertical and transverse dimension in the long-term follow up.

This meta-analysis of the included studies did not demonstrate SNA degree increase in participants who receive maxillary protraction treatment compared with untreated controls in the long-term follow up period that more than three years. Previous studies demonstrated a positive association between maxillary protraction and SNA degree increase.[8,11,27] However, some studies

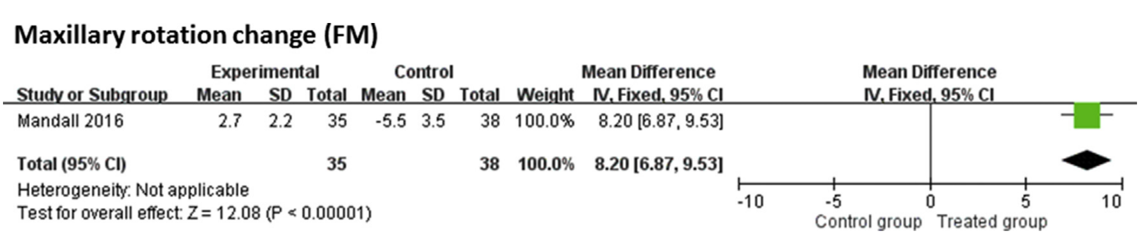

Figure 3 Forest plot to evaluate maxillary maxillary rotation changes following maxillary protraction. The FM treated group versus control group.

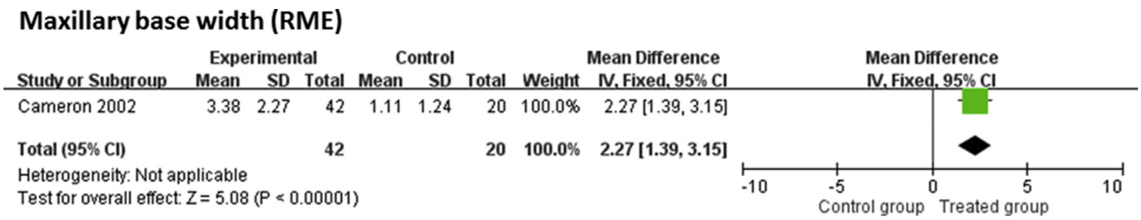

Figure 4 Forest plot to evaluate maxillary maxillary base width changes following maxillary expansion. The RME treated group versus control group.

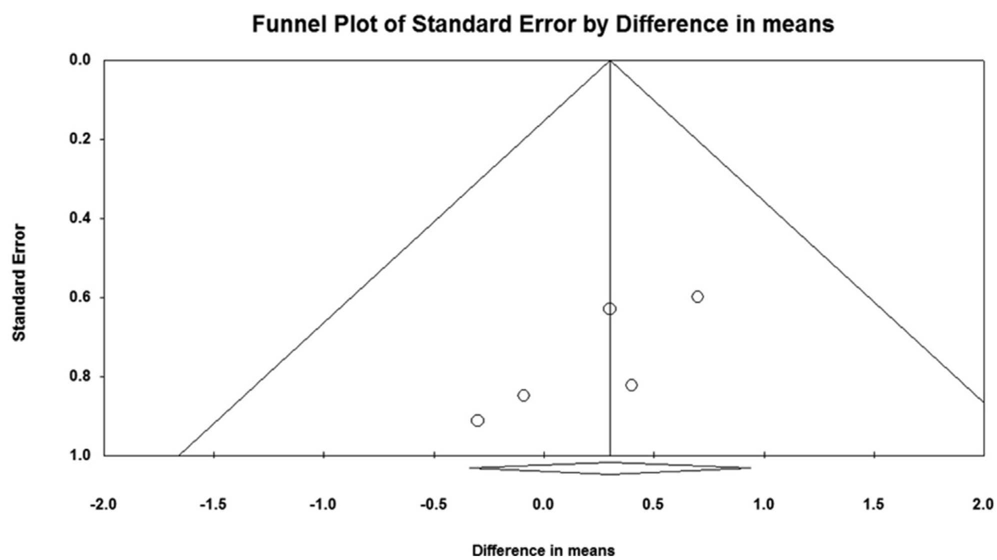

Figure 5 Funnel plots of the studies in SNA changes. Analysis of SNA changes used the Egger's test to evaluate actual heterogeneity. No statistical heterogeneity was found (*p*-value of Egger's test: 0.09).

suggested this positive association was only short-term effective.[17–19] Thus, the discordance of findings among these studies is likely to reflect confounding by different follow up time. We also found that the long-term changes in vertical (maxillary rotation degree)[26] and transverse dimension (maxillary base width)[28] were statistically significant increase in treated groups when compared to untreated controls. And these two dimensions might be the only long-term clinically significant effect maintained on maxilla.

It has been reported that ALT-RAMEC + FM treatment could assist in maxillary protraction due to the mechanism of opening the circumaxillary suture before maxillary protraction, leading to positive encouragement on maxilla.[29–31] Several systematic reviews[16,21] also have demonstrated that ALT-RAMEC + FM treatment could enhance the maxillary protraction effect on maxilla. However, the studies they included were short-term retention period or no mention about follow up time. Furthermore, a number of studies[8,11–14] including bone anchored maxillary protraction demonstrated that this method could enhance the therapeutic influence on the midface deficiency. Other systematic review[32] also concluded that skeletal anchored maxillary protraction is an effective therapy to improve skeletal Class III malocclusion, but they claimed no clear evidence that skeletal anchorage is better than traditional treatment such as FM + RME for improving skeletal Class III malocclusion. Instead, those studies were short-term retention periods rather than long-term follow up.

This meta-analysis had several limitations. Firstly, the sample size of the included studies is small and the outcomes might not demonstrate strong evidence to verify the associations between SNA degree changes and maxillary protraction treatment. Furthermore, although low statistical heterogeneity was measured in three dimensional of maxilla, clinical heterogeneity has to be noticed such as variation in treatment protocols, timing of treatment or sex etc. In addition, only three measurements were used to represent three dimension of maxilla even though many measurements were used.[7,9,26,28]

The conclusion of this study is that the sagittal change on maxilla after maxillary protraction treatment is gradually decreasing with time in the long-term follow-up and it might not be long-term effective on correcting maxillary

Table 5 Overall summary of the evidence (GRADE).

Certainty assessment							No of patients		Effect		Certainty	Importance
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Treated group	Untreated control	Relative (95% CI)	Absolute (95% CI)		
SNA changes (FM/FM + RME versus untreated control) (follow up: range 3 years—9 years)												
2	randomised trials	not serious	not serious	not serious	not serious	none	63	65	—	MD **0.399 degree higher** (0.583 lower to 1.38 higher)	⊕⊕⊕⊕ HIGH	IMPORTANT
SNA changes (FM/FM + RME versus untreated control) (follow up: range 3 years—9 years)												
3	observational studies	not serious	not serious	not serious	not serious	none	72	51	—	MD **0.227 degree higher** (0.616 lower to 1.071 higher)	⊕⊕⊕⊕ HIGH	IMPORTANT
Maxillary rotation degree (FM versus untreated control) (follow up: mean 6 years)												
1	randomised trials	not serious	not serious	not serious	serious[b]	none	35	38	—	MD **8.2 degree higher** (6.845 higher to 9.555 higher)	⊕⊕⊕◯ MODERATE	IMPORTANT
Maxillay base width (RME versus untreated control) (follow up: mean 6 years)												
1	observational studies	serious[a]	not serious	not serious	serious[b]	none	42	20	—	MD **2.27 mm higher** (1.204 higher to 3.336 higher)	⊕⊕◯◯ LOW	CRITICAL

CI: Confidence interval; **MD:** Mean difference.
[a] Downgraded one level for risk of bias: Most of the studies presented with unclear risk of bias.
[b] Downgraded one level for imprecision: Only one small trials.

hypoplasia in young patients. In this meta-analysis, even though maxillary protraction and expansion might be effective for increasing maxillary rotational changes and maxillary base width, more long-term studies are still necessary to further assess its skeletal benefits on maxilla to corroborate these findings.

Declaration of Competing Interest

The authors have no conflicts of interest relevant to this article.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jds.2020.06.016.

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