Orthodontics & Craniofacial Research

REVIEW ARTICLE

G. Cordasco
G. Matarese
L. Rustico
S. Fastuca
A. Caprioglio
S. J. Lindauer
R. Nucera

Efficacy of orthopedic treatment with protraction facemask on skeletal Class III malocclusion: a systematic review and meta-analysis

Authors' affiliations:
G. Cordasco, G. Matarese, L. Rustico, S. Fastuca, R. Nucera, Department of Scienze Sperimentali Medico Chirurgiche ed Odontostomatologiche, Section of Orthodontics, School of Dentistry, University of Messina, Messina, Italy
A. Caprioglio, Department of Orthodontics, School of Dentistry, University of Insubria, Varese, Italy
S. J. Lindauer, Department of Orthodontics, School of Dentistry, Virginia Commonwealth University, Richmond, VA, USA

Correspondence to:
R. Nucera
Department of Scienze Sperimentali Medico Chirurgiche ed Odontostomatologiche
Section of Orthodontics
School of Dentistry
University of Messina
AOU Policlinico "G. Martino"
UOC di Odontoiatria e Odontostomatologia
Via Consolare Valeria
1 98100 Messina
Italy
E-mail: riccardo.nucera@gmail.com

Date:
Accepted 15 March 2014

DOI: 10.1111/ocr.12040

Cordasco G., Matarese G., Rustico L., Fastuca S., Caprioglio A., Lindauer S. J., Nucera R. Efficacy of orthopedic treatment with protraction facemask on skeletal Class III malocclusion: a systematic review and meta-analysis
Orthod Craniofac Res 2014; **17**: 133–143. © 2014 John Wiley & Sons A/S. Published by John Wiley & Sons Ltd

Abstract

The objective of this systematic review was to estimate the efficacy of protraction facemask on the correction of Class III malocclusion in the short term. A systematic review of articles was performed using different electronic databases (PubMed, Ovid, Cochrane Central Register of Controlled Trials, Web of Science, LILACS, and Google Scholar). Search terms comprised 'orthopedic treatment' and 'Class III malocclusion'. The selection criteria were set in order to include in this review only randomized clinical trials (RCTs) performed treating with facemask Class III growing patients. Studies' selection, data extraction, and risk of bias's assessment were executed independently by two authors using pre-defined data forms. All pooled analyses of data were based on random effects models. A pre-specified subgroup analysis was planned to evaluate the effect of preliminary rapid palatal expansion on facemask efficacy. Three RCTs met our inclusion criteria. In total, data from 155 patients (92 treated and 63 controls) were collected. The treated group showed the following significant changes: ANB° +3.66° [95%CI (2.58, 4.74)]; SNA° +2.10 [95%CI (1.14, 3.06)]; SNB° −1.54 [95%CI (−2.13, −0.95)]; SN-palatal plane −0.82° [95%CI (−1.62, −0.02)]; and SN-mandibular plane +1.51 [95%CI (0.61, 2.41)]. Heterogeneity varied from low to moderate (mean I^2 value: 41.4 ± 20.8). Facemask is effective correcting Class III malocclusion in the short term. The skeletal modifications induced by facemask are forward displacement of maxilla, backward displacement of mandible, clockwise rotation of the mandibular plane, and counterclockwise rotation of the maxillary plane.

Key words: human study; malocclusion; meta-analysis; protraction facemask; review article

Introduction

Treatment of skeletal Class III malocclusion is one of the most challenging orthodontic corrections (1). The potentially unfavorable growth pattern of the patients affected by this skeletal discrepancy (2), usually requires effective and early intervention. Facemask orthopedic therapy has been proved to be effective treating successfully growing Class III patients (3). This treatment alternative seems to affect all the skeletal components that can contribute to causing a Class III malocclusion (3,4).

Haas suggested the use of facemask in combination with palatal expansion when a posterior crossbite is present (5, 6). He reported that rapid maxillary expansion (RME) can produce a slightly forward movement of the maxilla (5, 6) and supposed that RME could weaken the circum-maxillary sutural forces, thereby facilitating the orthopedic effect of the facemask (5, 6). In 1966, Starnbach demonstrated that RME is able to promote the activity of surrounding maxillary sutures in non-human primates (7). The orthodontic literature is not unanimous, however, in supporting the use of RME to enhance the facemask's orthopedic effects. In 1995, Baik et al. (8) found that the use of RME improves, in growing subjects, facemask efficacy. More recently, some clinical trials found that palatal expansion did not affect the orthopedic facemask correction (9, 10).

Randomized controlled trials (RCTs) are original investigations providing the highest level of evidence and thus are considered the gold standard for evaluating the efficacy of various orthodontic treatment therapies.

The skeletal effects of facemask therapy used in combination with and without RME has been shown by different clinical studies (1, 3, 4, 8–10), systematic review (11), and meta-analysis (12). According to the GRADE Working Group (13), different levels of quality of a body of evidence exist for meta-analysis according to the level of evidence of the included studies. Only meta-analysis performed including well-designed RCTs can reach the highest level of evidence (14). To date, a meta-analysis evaluating the orthopedic effects of facemask including only RCTs has not been performed.

The aim of this meta-analysis was to evaluate the short-term skeletal effects of facemask treatment on growing Class III patients using published RCTs in order to achieve the highest quality of evidence on this particular topic (13, 14).

Material and methods

This meta-analysis was performed according the guidelines provided by the PRISMA statement (15) and the Cochrane Handbook for Systematic Reviews of Interventions version 5.1.0 (16).

A survey of articles published up to November 2012 about the effects of protraction facemask for treatment of Class III malocclusion was performed using several electronic databases: PubMed, Ovid (Ovid Medline and Embase), Cochrane Central Register of Controlled Trials, Web of Science, LILACS, and Google Scholar. All electronic searches were performed on November 22, 2012. The search strategy for PubMed was conducted according to Cochrane Collaboration guidelines (16) and reported in Table 1. In the other databases, the key words used to identify the eligible studies were 'orthopedic treatment' and 'Class III malocclusion'. A more restrictive search was performed for Google Scholar with the following terms: 'orthopedic treatment', 'Class III malocclusion', and 'randomized controlled trial'. Keywords and electronic search results used for every database are given in Table 2. No language restriction was applied during the research. The review protocol of this meta-analysis was not previously published.

Selection of studies

To be included in our study, each article had to fulfill the following requirements: related human clinical trials; had a comparable untreated control group; had subjects allocated randomly into

Table 1. **PubMed search history**

Keywords	Results
(1) Randomized controlled trial	417 185
(2) Randomized controlled trias	423 383
(3) Random allocation	77 152
(4) Double blind	142 901
(5) Double blind method	118 144
(6) Single blind	36 215
(7) Single blind method	29 595
(8) #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7	53 052
(9) Class III malocclusion	2806
(10) Malocclusion, angle class III/therapy	1742
(11) Orthopedic treatment class III	351
(12) #9 OR #10 OR #11	2934
(13) #8 AND #12	52
(14) #8 AND #12, limit: humans	49

the groups compared; had results evaluated by cephalometric analysis performed before and immediately after treatment; were studies conducted on growing patients without any craniofacial deformity; had treatment conducted without orthognathic surgery; had treatment conducted using protraction facemask; and had analyzed treatment effects which were not confounded by additional and concomitant procedures (extractions, fixed appliances, etc.)

Duplicate reports were excluded. Articles were not selected if they did not meet the inclusion criteria, if they did not relate to this topic, or if they were related but had a different aim. Abstracts, laboratory studies, descriptive studies, individual case reports, series of cases, reviews, studies of adult patients, controlled clinical trials, retrospective longitudinal studies, and meta-

Table 2. **Keywords and search results from various electronic databases**

Database	Keywords	Retrieved articles	Duplicates	Articles not related to the topic or related with different aim; different design than RCT	Selected
PubMed	Search history as described by Table 1	49	17	28	4
Cochrane Central Register of Controlled Trials	(1) Orthopedic treatment; (2) Class III malocclusion;#1 AND #2	14	12	1	1
Ovid	(1) Orthopedic treatment; (2) Class III malocclusion; #1 AND #2	95	32	63	0
Web of Science	(1) Orthopedic treatment; (2) Class III malocclusion; #1 AND #2	172	6	165	1
Google Scholar	(1) Orthopedic treatment; (2) Class III malocclusion; (3) Randomized Controlled Trial; #1 AND #2 AND #3	535	14	520	1
LILACS	(1) Orthopedic treatment; (2) Class III malocclusion; #1 AND #2	23	1	22	0
Hand search	Bibliographies of RCTs, RCTs known to the authors before this study, and RCTs encountered during searches for other projects	1	0	1	0
Total		889	82	800	7

analyses were also excluded. Articles reporting interim outcomes or updates were considered only once. RCTs including patients who had received previous or concomitant treatment for their Class III malocclusion were excluded. Two review authors (L.R. and S.F.) screened all titles and abstracts achieved from the database searches. The same authors reviewed the full texts of the potentially relevant articles and abstracts. The eligibility of the trials was assessed independently, and any disagreement was resolved after consulting a third author (R.N.). The level of agreement between the two reviewers was assessed with the Cohen kappa statistic.

Data extraction and management

Two authors (L.R. and S.F.) independently extracted study characteristics (appliance's features, sample size, age, sex, setting, time of treatment and observation, time of daily appliance wear, presence of follow-up) and outcomes from the selected studies using pre-defined data extraction forms. Any disagreements were resolved by discussion with a third author (R.N.). The Cohen kappa statistic was used to score the agreement between the two review authors. The following angular cephalometric parameters were collected as outcomes: SNA, SNB, ANB, SN-palatal plane, and SN-mandibular plane.

Assessment of risk of bias

A qualitative evaluation for assessment of risk of bias of the selected articles was performed using the Cochrane Collaboration's tool for assessing risk of bias by means of the specific software Review Manager [computer program] (version 5.2, Copenhagen, Denmark: Nordic Cochrane Centre, Cochrane Collaboration; 2012). A summary assessment of the risk of bias within and across the evaluated RCTs was performed according to Cochrane Collaboration guidelines (16). The qualitative assessment of risk of bias was undertaken autonomously and in duplicate by using separate printed forms by two reviewers (G.M. and A.C.). Any disagreement on the risk of bias assessment was resolved after consulting the third author (G.C.). The level of agreement between the two investigators was assessed with the Cohen kappa statistic. The following qualitative criteria of each article were examined: sequence generation; allocation concealment; blinding of participants, personnel, and outcome assessors; incomplete outcome data; selective outcome reporting; and other sources of bias. The risk of bias for each domain was judged as low risk, high risk, or unclear risk. Each randomized controlled trial was assigned an overall risk of bias in terms of low risk (low for all evaluated domains), high risk (high for one or more domains), and unclear risk (unclear for one or more domains).

Quantitative data synthesis

Data were analyzed by means of Review Manager computer program (version 5.2). For all the evaluated cephalometric parameters, difference in means and standard deviations of the continuous outcomes were used to summarize and combine data using the random effect model. A pre-specified subgroup analysis was planned with the aim to evaluate the capabilities of RME promoting facemask effectiveness. It was performed for particular outcomes (SNA, SNB, ANB), comparing the data of two subgroups treated with and without preliminary RME. A sensitivity analysis that excluded the studies with the higher risk of bias was performed in order to examine the influence of the study quality assessment on the overall estimates of effect.

Assessment of heterogeneity

Clinical heterogeneity among studies was evaluated by examining the types of participants and the interventions for the outcome in each included study. For all the performed analysis, heterogeneity was assessed by means of the I^2 index, which is an indicator of true heterogeneity in percentages. A value of 0% indicates no observed heterogeneity, and larger values show increasing heterogeneity with 25% indicating low, 50% moderate, and 75% high heterogeneity (17).

Results

Electronic searches identified the following items: 49 articles were retrieved from PubMed, 14 from Cochrane Central Register of Controlled Trials, 95 from Ovid, 23 from LILACS, 172 from Web of Science, and 535 from Google Scholar. Duplicates articles, studies that did not relate to our topic or related with a different aim, and those that were not RCTs were excluded (Table 2).

Of the remaining potentially appropriate RCTs, seven were identified as eligible RCTs to be included in this analysis (3, 9, 18–22). Four of the seven selected RCTs were withdrawn according to the exclusion criteria reported in Table 3. Three articles met all eligibility criteria and were selected for the final analysis. Figure 1 illustrates the flow diagram of the selection of the studies process according to the PRISMA guidelines (16).

Study characteristics

All of the selected RCTs evaluated orthopedic facemask treatment in growing children in the mixed dentition with Class III malocclusion. In total, data from 155 patients (92 treated and 63 controls) were collected. The samples were heterogeneous for the numbers and the ages of participants. Table 4 describes the study characteristics of the selected RCTs. Clinical sex heterogeneity was good for two RCTs (9, 18) and poor for one RCT that evaluated only female subjects (3). Weak heterogeneity was found in time of daily appliance wear that was around 10–14 h/day for all evaluated RCTs. Weak heterogeneity was also found for treatment and observation time ranging from 12 to 15 months. No article reported long-term results.

Evaluating the selected RCTs relatively to the performed subgroup analysis, it was found that Kilicoglu and Kirlic (3) evaluated a standalone facemask protocol, Mandall et al. (18) evaluated the RME + facemask protocol, and Vaughn et al. (9) assessed and compared both of the protocols previously mentioned. Vaughn et al. (9) reported mean values for each of the groups included in the RCT (i.e., facemask; RME+facemask, control). Because of these characteristics, the RCT of Vaughn et al. (9) was included in the meta-analysis as if it were two different substudies (RME+facemask and standalone facemask). Its control group was divided into two control subgroups (nine and eight subjects) presenting the same mean outcome. The subgroup of nine patients was associated with the 'RME + facemask' treatment substudy; the subgroup of eight patients was associated with the 'facemask standalone' treatment substudy. Using this method, the control subjects of the study of Vaughn et al. (9) were not included two times in the meta-analysis. Moreover, Vaughn et al. (9) reported the mean standard error (SE) of its coupled subgroup; consequently, the SE values for each

Table 3. **Studies excluded from the data analysis and reasons of exclusion**

Study	Authors	Reason of exclusion
Chin cup effects using two different force magnitudes in the management of Class III malocclusions	Abdelnaby & Nassar (19)	Different appliance from the facemask
Maxillary rotation following early orthopedic treatment of Class III malocclusion	Shargill (20)	Identified like a multiple report from the study of Mandall et al. (34)
The effects of the Fränkel's function regulator on the Class III malocclusion.	Ulgen & Firatli (21)	Different appliance from the facemask
Short-term soft- and hard-tissue changes following Class III treatment using a removable mandibular retractor: a randomized controlled trial	Saleh M et al. (22)	Different appliance from the facemask

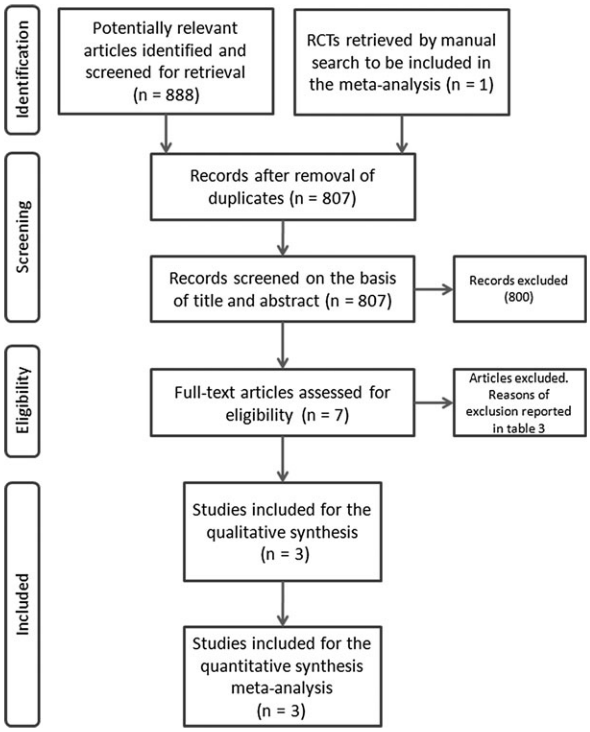

Fig. 1. Flow chart of the selection of the studies (performed according to the PRISMA guidelines).

group were calculated with systems of equations and then converted to standard deviation values. The other two selected RCTs (3, 18) reported mean values and standard deviations of the treatment and control groups, so it was possible to insert their data in the comprehensive data analysis without any conversion.

The results of risk of bias evaluation of the selected studies are shown in Table 5. Of three RCTs, two studies were assessed with a low risk of bias (9, 18), and one study was assessed with an uncertain risk of bias (3). Considering that most information of this meta-analysis raised from studies at low risk of bias (9, 18), the summary assessments of risk of bias across the studies were considered as low.

The agreement between the reviewers for study selection, data extraction, and risk of bias assessment was good, with kappa scores of 0.875, 0.942, and 0.852, respectively.

Quantitative data synthesis

The results of the meta-analysis including the subgroup analysis are shown in the forest plots reported as Figs 2–6. The selected RCTs showed a good homogeneity relative to the angular parameters that were used to evaluate the sagittal and vertical skeletal effects of facemask (ANB, SNA, SNB, SN-palatal plane, and SN-mandibular plane). To test how robust the results of this meta-analysis were, a sensitivity analysis was performed. A new meta-analysis was performed relative to the ANB parameter without the study presenting the highest risk of bias (3), with a substantially similar outcome of 3.16° (Fig. 7).

Discussion

To the best of our knowledge, this is the first meta-analysis that investigated the current literature with best evidence (RCTs) about the efficacy of protraction facemask treatment for Class III malocclusion.

Evidence is lacking about this topic because of the difficulties related to conducting RCTs (23). Despite an accurate and wide bibliographic search strategy, we found only three eligible trials (3, 9, 18). The results obtained from this meta-analysis showed that protraction facemask is an effective orthopedic approach to correct Class III malocclusion in the short term.

Relative to the vertical modifications induced by the facemask; results showed that palatal plane angulation changes significantly during treatment, averaging −0.82° ($p = 0.04$; Z = 2.01). Biomechanical studies on dry human skulls have demonstrated that the direction of the force is a critical factor in controlling rotation of the upper jaw during facemask therapy (24, 25). A force generated parallel to the maxilla produces counterclockwise rotation of the palatal plane (24, 25). Both of the RCTs used in this meta-analysis for the calculation of this finding (3, 9) applied the elastics with a downward inclination of 15–30°, and it is possible that this characteristic of the orthopedic force partially counteracted the rotation of the palatal plane reported in the literature (24, 25). The mandibular plane showed significant clockwise rotation with a standard mean difference of 1.51° ($p < 0.01$; $Z = 3.28$). The rotation of the mandibular plane is assumedly responsible for at least part of the SNB observed

Table 4. **Study characteristics of the selected RCTs**

Selected References	Appliances' features	Sample size	Age (years) ± SD	Sex	Setting	Treatment and observation time	Time of daily appliance wear	Methods of measurement	Follow-Up
Mandall et al. (18)	Facemask + RME	Treated = 33 Controls = 36	8.7 ± 0.9 9.0 ± 0.8	Female = 38 Male = 32	Eight UK hospital	15 months	Minimum of 14 h/day	SNA, SNB, ANB, SN/Maxillary plane	No
Vaughn et al. (9)	Facemask and Facemask + RME	Facemask = 22 FM + RME = 21 Controls = 17	8.1 ± 1.9 7.3 ± 1.9 6.6 ± 1.9	Female = 29 Male = 31	Seattle, Wash, Phoenix, Ariz, and Los Angeles, Calif	12 months	Full time at the beginning of treatment, then 14 h/day	SNA, SNB, ANB, SN/Palatal plane, SN/Go-Gn	No
Kılıçoğlu & Kirliç (3)	Facemask	Treated = 16 Controls = 10	8.6 ± 1.4 9.2 ± 1.4	Female = 26 Male = 0	Istanbul University, Turkey	12 months	Minimum of 10–12 h/day	SNA, SNB, ANB, SN/Go-Me	No

RME, rapid maxillary expansion; FM, facemask.

Table 5. **Summary assessment of risk of bias performed according the guidelines provided by the Cochrane Handbook for Systematic Reviews of Interventions (16)**

	Type of Bias						
Articles	Sequence generation	Allocation concealment	Blinding of outcome assessors	Incomplete outcome data	Selective outcome reporting	Other sources of bias	Overall risk of bias
Mandall et al. (33)	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk
Vaughn et al. (26)	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk
Kılıçoğlu & Kirliç (14)	Unclear	Unclear	Unclear	Unclear	Low risk	Low risk	Unclear

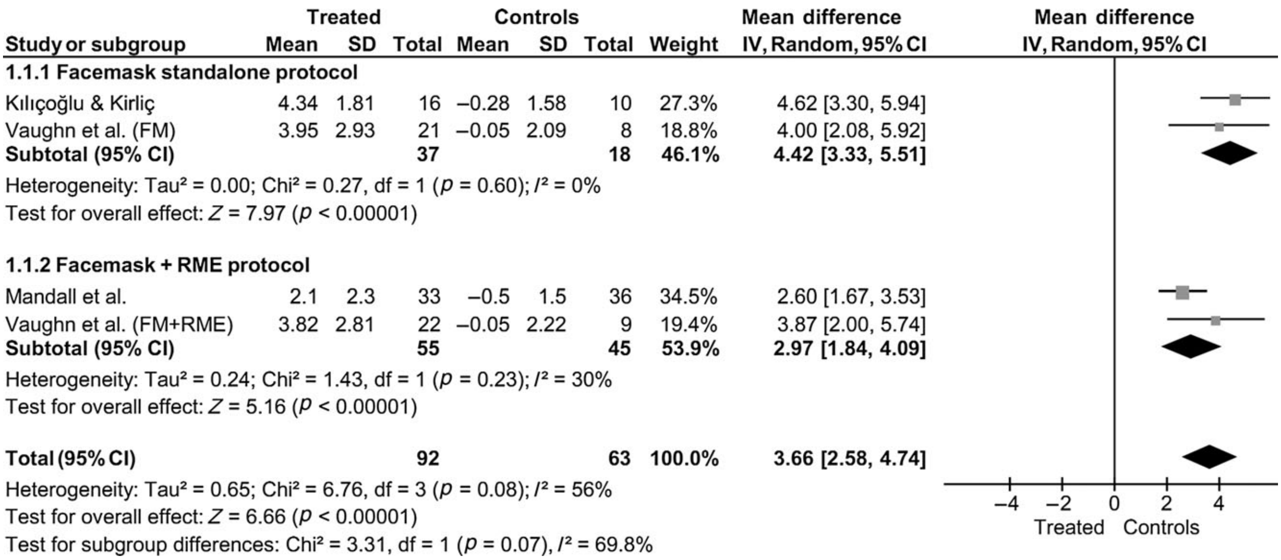

Fig. 2. Forest plot representing the effect of facemask on the ANB angle. A subgroup analysis was performed. Two subsamples were created and compared according the used protocol: facemask standalone or facemask + patal expansion.

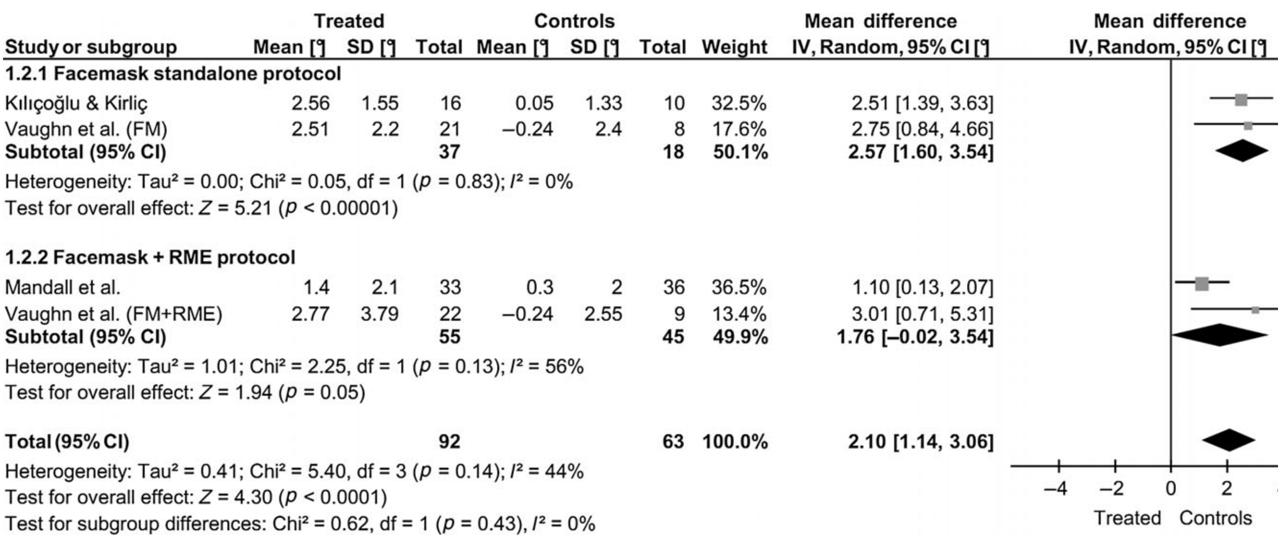

Fig. 3. Forest plot representing the effect of facemask on the SNA angle. A subgroup analysis was performed. Two subsamples were created and compared according the used protocol: facemask standalone or facemask + patal expansion.

	Treated			Controls				Mean difference
Study or subgroup	Mean [°]	SD [°]	Total	Mean [°]	SD [°]	Total	Weight	IV, Random, 95% CI [°]
1.3.1 Facemask standalone protocol								
Kılıçoğlu & Kirliç	−1.78	1.09	16	0.44	0.58	10	31.0%	−2.22 [−2.86, −1.58]
Vaughn et al. (FM)	−1.43	1.59	21	−0.2	1.2	8	18.7%	−1.23 [−2.30, −0.16]
Subtotal (95% CI)			**37**			**18**	**49.7%**	**−1.82 [−2.77, −0.87]**
Heterogeneity: Tau² = 0.29; Chi² = 2.40, df = 1 (p = 0.12); I^2 = 58%								
Test for overall effect: Z = 3.75 (p = 0.0002)								
1.3.2 Facemask + RME protocol								
Mandall et al.	−0.7	1.5	33	0.8	1.4	36	29.5%	−1.50 [−2.19, −0.81]
Vaughn et al. (FM+RME)	−1.06	1.55	22	−0.2	1.13	9	20.8%	−0.86 [−1.84, 0.12]
Subtotal (95% CI)			**55**			**45**	**50.3%**	**−1.28 [−1.88, −0.68]**
Heterogeneity: Tau² = 0.02; Chi² = 1.10, df = 1 (p = 0.30); I^2 = 9%								
Test for overall effect: Z = 4.21 (p < 0.0001)								
Total (95% CI)			**92**			**63**	**100.0%**	**−1.54 [−2.13, −0.95]**
Heterogeneity: Tau² = 0.19; Chi² = 6.26, df = 3 (p = 0.10); I^2 = 52%								
Test for overall effect: Z = 5.10 (p < 0.00001)								
Test for subgroup differences: Chi² = 0.90, df = 1 (p = 0.34), I^2 = 0%								

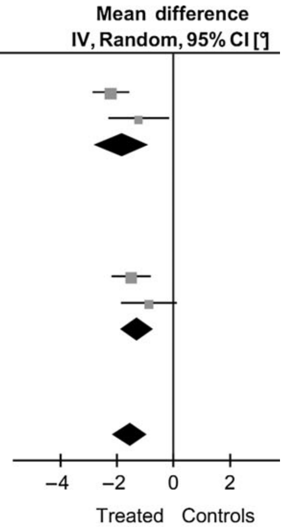

Fig. 4. Forest plot representing the effect of facemask on the SNB angle. A subgroup analysis was performed. Two subsamples were created and compared according the used protocol: facemask standalone or facemask + patal expansion.

	Treated			Controls				Mean difference
Study or subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
Kılıçoğlu & Kirliç	1.75	1.4	16	−0.61	1.24	10	35.8%	2.36 [1.33, 3.39]
Vaughn et al. (FM)	1.35	1.74	21	0.2	1.24	8	32.5%	1.15 [0.01, 2.29]
Vaughn et al. (FM+RME)	1.12	1.87	22	0.2	1.32	9	31.7%	0.92 [−0.24, 2.08]
Total (95% CI)			**59**			**27**	**100.0%**	**1.51 [0.61, 2.41]**
Heterogeneity: Tau² = 0.32; Chi² = 3.98, df = 2 (p = 0.14); I^2 = 50%								
Test for overall effect: Z = 3.28 (p = 0.001)								

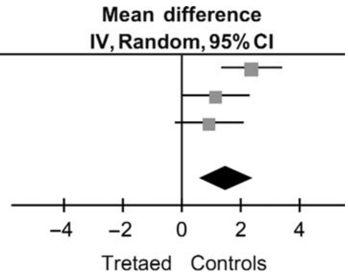

Fig. 5. Forest plot representing the effect of facemask on the SN-mandibular plane angle.

	Treated			Controls				Mean difference
Study or subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
Mandall et al.	−0.5	2.3	33	−0.3	2.5	36	46.0%	−0.20 [−1.33, 0.93]
Vaughn et al. (FM)	−0.89	2.4	22	0.54	1.7	9	27.2%	−1.43 [−2.93, 0.07]
Vaughn et al. (FM+RME)	−0.72	2.4	21	0.54	1.6	8	26.8%	−1.26 [−2.77, 0.25]
Total (95% CI)			**76**			**53**	**100.0%**	**−0.82 [−1.62, −0.02]**
Heterogeneity: Tau² = 0.03; Chi² = 2.11, df = 2 (p = 0.35); I^2 = 5%								
Test for overall effect: Z = 2.01 (p = 0.04)								

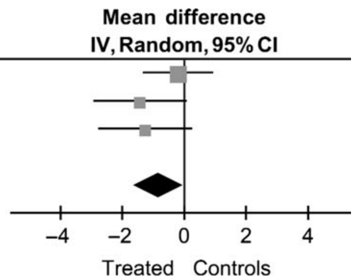

Fig. 6. Forest plot representing the effect of facemask on the SN-palatal plane angle.

variation. From this perspective, the 1.54° of SNB reduction could be the result of two different phenomena: anterior mandibular growth inhibition and/or clockwise mandibular plane rotation.

There is some evidence in the literature that when the mandibular plane rotates upward, in non-growing patients, an increase in the SNB angle occurs (26). As this meta-analysis found relatively larger effects of facemask treatment on the maxilla (SNA: +2.10°) than the mandible (SNB: −1.54°), and considering that the mandibular change could be partly due to mandibular rotation, it appears that facemask treatment induces a prevalent orthopedic effect on the maxilla rather than on the mandible.

The limitations of this review article are related to the small number of RCT (three) that was possible to include in the meta-analysis. The small number of included trails affects the I^2 index, underestimating the extent of between-study heterogeneity (17). It is important to consider this assumption to properly consider the

Study or subgroup	Treated Mean	Treated SD	Treated Total	Controls Mean	Controls SD	Controls Total	Weight	Mean difference IV, Random, 95% CI
Mandall et al.	2.1	2.3	33	−0.5	1.5	36	57.9%	2.60 [1.67, 3.53]
Vaughn et al. (FM)	3.95	2.93	21	−0.05	2.09	8	20.6%	4.00 [2.08, 5.92]
Vaughn et al. (FM+RME)	3.82	2.81	22	−0.05	2.22	9	21.5%	3.87 [2.00, 5.74]
Total (95% CI)			**76**			**53**	**100.0%**	**3.16 [2.21, 4.11]**

Heterogeneity: Tau² = 0.18; Chi² = 2.59, df = 2 (p = 0.27); I^2 = 23%
Test for overall effect: Z = 6.53 (p < 0.00001)

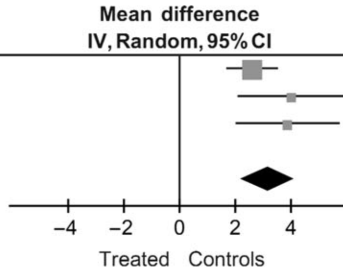

Fig. 7. Sensitivity analysis: forest plot representing the effect of protraction facemask on the ANB angle. The RCT presenting the highest risk of bias (3) was excluded.

reported heterogeneity among studies. The I^2 values described a total variation across the studies varying from low to moderate (mean value and standard deviation: 41.4 ± 20.8). This variation was presumably due to clinical heterogeneity rather than chance. Although the subjects included in the treatment and control samples of selected RCTs were of similar age and had a similar observation period of time and a comparable amount of daily time appliance wear (Table 4), they differed in some clinical characteristics. More specifically, in the overall sample, more females than males were included; in particular, one study was performed only on female subjects (3). It is known that female subjects undergo skeletal maturation earlier than males (27). Considering that there is evidence to support that skeletal maturation affects the response to facemask protraction (28), the sex characteristics of the sample could have potentially affected clinical heterogeneity.

Of the 92 subjects included in the final treatment sample, 55 subjects underwent RME before facemask therapy and 37 subjects did not. The subgroup analysis revealed on average a stronger orthopedic effect in the subgroup that did not perform preliminary RME, although no significant difference was found between the two groups. This finding supports the concept that RME is not required if performed primarily with the aim of improving protraction of the maxilla during facemask therapy.

Conclusions

Facemask therapy in growing subjects with Class III malocclusion is effective in the short term. The skeletal modifications induced by facemask are forward displacement of the maxilla, backward displacement of the mandible, clockwise rotation of the mandibular plane, and counterclockwise rotation of the maxillary plane. When used with the intent to enhance anterior maxillary movement during facemask therapy, preliminary rapid palatal expansion does not seem to affect the effectiveness of the orthopedic treatment. The results of this study refer only to the modifications induced by the facemask in the short term, and further studies are necessary to elucidate the effects of the facemask in the long term.

Clinical relevance

Protraction facemask therapy in growing Class III patients is effective in the short term. The skeletal modifications induced by facemask are forward dislocation of the maxilla, backward movement of the mandible, clockwise rotation of the mandibular plane, and counterclockwise rotation of the maxillary plane. Taking account of the protraction facemask's effects, it should ideally be used in Class III cases with counterclockwise rotation of mandibular plane. Preliminary rapid palatal expansion does not seem to improve the effectiveness of facemask.

References

1. Ngan P, Yiu C, Hu A, Hägg U, Wei SH, Gunel E. Cephalometric and occlusal changes following maxillary expansion and protraction. *Eur J Orthod* 1998;20:237–54.
2. Baccetti T, Franchi L, McNamara JA Jr. Growth in the untreated Class III subject. *Semin Orthod* 2007;13:130–42.
3. Kilicoglu H, Kirlic Y. Profile changes in patients with Class III malocclu-

sions after Delaire mask therapy. *Am J Orthod Dentofacial Orthop* 1998;113:453–62.
4. Lee DY, Kim ES, Lim YK, Ahn SJ. Skeletal changes of maxillary protraction without rapid maxillary expansion. *Angle Orthod* 2010;80:504–10.
5. Haas AJ. Treatment of maxillary deficiency by opening the midpalatal suture. *Angle Orthod* 1965;65:200–17.
6. Haas AJ. Palatal expansion: just the beginning of dentofacial orthopedics. *Am J Orthod* 1970;57:219–55.
7. Starnbach H, Bayne D, Cleall J, Subtelny JD. Facioskeletal and dental changes resulting from rapid maxillary expansion. *Angle Orthod* 1966;36:152–64.
8. Baik HS. Clinical results of the maxillary protraction in Korean children. *Am J Orthod Dentofacial Orthop* 1995;108:583–92.
9. Vaughn GA, Mason B, Moon HB, Turley PK. The effects of maxillary protraction therapy with or without rapid palatal expansion: a prospective, randomized clinical trial. *Am J Orthod Dentofacial Orthop* 2005;128:299–309.
10. Yavuz I, Halicioğlu K, Ceylan I, Dağsuyu IM, Erdem A. The effects of face mask therapy with and without rapid maxillary expansion in adolescent patients. *Aust Orthod J* 2012;28:63–71.
11. De Toffol L, Pavoni C, Baccetti T, Franchl L, Cozza P. Orthopedic treatment outcomes in Class III malocclusion. *Angle Orthod* 2008;78:561–73.
12. Kim JH, Viana MA, Graber TM, O-merza FF, BeGole EA. The effectiveness of protraction face mask therapy: a meta-analysis. *Am J Orthod Dentofacial Orthop* 1999;115:675–85.
13. Guyatt GH, Oxman AD, Vist G, Kunz R, Falck-Ytter Y, Alonso-Coello P et al. Rating quality of evidence and strength of recommendations GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. *BMJ* 2008;336:924–6.
14. Papadopoulos MA. Meta-analysis in evidence-based orthodontics. *Orthod Craniofac Res* 2003;6:112–26.
15. Liberati A, Altman DG, Tetzlaff J, Mulrow C, Gøtzsche PC, Ioannidis J et al. The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate health care interventions: explanation and elaboration. *J Clin Epidemiol* 2009;62:e1–34.
16. Higgins JPT, Green S, editors. *Cochrane Handbook for Systematic Reviews of Interventions [version 5.1.0, updated March 2011]*. The Cochrane Collaboration; 2011. Available from www.cochrane-handbook.org.
17. Higgins J, Thompson SG. Quantifying heterogeneity in a meta-analysis. *Stat Med* 2002;21:1539–58.
18. Mandall N, DiBiase A, Littlewood S, Nute S, Stivaros N, McDowall R et al. Is early Class III protraction facemask treatment effective? A multicentre, randomized, controlled trial: 15-month follow-up. *J Orthod* 2010;37:149–61.
19. Abdelnaby YL, Nassar EA. Chin cup effects using two different force magnitudes in the management of Class III malocclusions. *Angle Orthod* 2010;80:957–62.
20. Shargill I. Maxillary rotation following early orthopaedic treatment of class III malocclusion. *J Dent Res* 2010;89:131793.
21. Ulgen M, Firatli S. The effects of the Fränkel's function regulator on the Class III malocclusion. *Am J Orthod Dentofacial Orthop* 1994;105:561–7.
22. Saleh M, Hajeer MY, Al-Jundi A. Short-term soft- and hard-tissue changes following Class III treatment using a removable mandibular retractor: a randomized controlled trial. *Orthod Craniofac Res* 2013;16:75–86.
23. Papadopoulos MA, Gkiaouris I. A critical evaluation of meta-analyses in orthodontics. *Am J Orthod Dentofacial Orthop* 2007;131:589–99.
24. Tanne K, Sakuda M. Biomechanical and clinical changes of the craniofacial complex from orthopedic maxillary protraction. *Angle Orthod* 1991;61:145–52.
25. Itoh T, Chaconas SJ, Caputo AA, Matyas J. Photoelastic effects of maxillary protraction on the craniofacial complex. *Am J Orthod* 1985;88:117–24.
26. Park YC, Lee HA, Choi NC, Kim DH. Open bite correction by intrusion of posterior teeth with miniscrews. *Angle Orthod* 2008;78:699–710.
27. Proffit WR, Fields HW Jr, Sarver DM. *Contemporary Orthodontics*, 4th edn. St Louis, MO: Mosby; 2007.
28. Franchi L, Baccetti T, McNamara JA. Postpubertal assessment of treatment timing for maxillary expansion and protraction therapy followed by fixed appliances. *Am J Orthod Dentofacial Orthop* 2004;126:555–68.