
Systematic review

Treatment effect of bone-anchored maxillary protraction in growing patients compared to controls: a systematic review with meta-analysis

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Summary

Objective: The aim of this systematic review was to determine which evidence level supports maxillary advancement after bone-anchored maxillary protraction (BAMP) in growing patients compared to controls.

Search methods: PubMed, Cochrane, Embase, Scopus, and Web-of-Science databases were searched with no restrictions on publication status or year.

Selection criteria: Prospective and retrospective human studies about BAMP, in at least three patients, were included. Authors were contacted when necessary, and reference lists of the included studies were screened.

Data collection and analysis: Two authors undertook independent data extraction with conflict resolution by a third author. Risks of bias were assessed. A meta-analysis for estimates of changes for ANB angle, Wits appraisal, and incisor to mandibular plane angle (IMPA) angle of BAMP treatment compared to control groups was performed.

Results: A total of 449 articles were initially retrieved; 28 full-text articles met the inclusion criteria. Sample sizes ranged from 3 to 52 patients. There was heterogeneity in cephalometric outcomes reported, which prevented the comparison of certain outcomes. ANB angle improved more with BAMP in the maxilla combined with facemask (bone-anchored facemask, BAFM) compared to traditional facemask therapy: this was statistically but not clinically significant (0.2 degrees). No data are available for BAMP with skeletal anchorage in both jaws in combination with Class III elastics (bone-anchored Class III elastics, BAC3E). Likewise, no statistically significant differences in Wits appraisal were found (less than 1 mm). Lower incisor retroclination and facial height seemed to be better controlled with BAC3E compared to BAFM.

Conclusions: The level of evidence available to support the maxillary advancement effect after BAMP was low. Publications reporting results based on identical samples tended to suggest overly positive results of BAMP. The differences in sagittal correction between BAMP and traditional facemask therapy were small and of questionable clinical significance. Long-term follow-up results are not available and, therefore, much needed.

Limitations: Most articles had a low level of evidence and some included a historical control group.

Registration: PROSPERO database number CRD42015023366.

Introduction

Rationale

Treating Class III malocclusion patients is a challenge. Orthodontists can use different treatment approaches or a combination of these: at an early age by growth stimulation and modification or later in life with orthodontic camouflage or orthognathic surgery when the patient is out of the growth stage. The traditional early treatment approach is facemask therapy, which has been shown to successfully advance the maxilla (1). Good clinical results in facemask treatment are dependent on patient compliance and the timing of treatment. To achieve greater skeletal effects, it has been advised to start treatment as early as possible (2). When treating Class III patients at a later stage, the result can be influenced by an unfavourable growth pattern during late adolescence, including the absence of catch-up growth of the maxilla, a more vertical direction of facial growth, and a long period of active mandibular growth (3). Treatment with rapid maxillary expansion (RME) and facemask have also been suggested (4), however, with inevitable side effects: downward and backward rotation of the mandible and forward movement of the maxillary teeth (5). Considering that the growth pattern cannot be predicted, the borderline between what can be successfully treated by orthodontic treatment alone and what requires orthognathic surgery is difficult to assess. Early orthodontic treatment may reduce the necessity of orthognathic surgery at a later stage or, at least, reduce the magnitude of such treatment, producing a more stable and predictable outcome (6). The question “How much can growth actually be altered”, for example, by stimulating the growth of a hypoplastic maxilla, is still relevant.

In the last decade, growing patients with Class III malocclusion have been treated with bone-anchored maxillary protraction (BAMP), where intermaxillary elastics are engaged on skeletal anchorage devices and on a facemask, with miniplates only in the maxilla (bone-anchored facemask, BAFM) or without the use of a facemask with skeletal anchorage in both maxilla and mandible in combination with Class III elastics (bone-anchored Class III elastics, BAC3E). Among others, Singer *et al.* showed a 4 mm forward and downward movement of the maxilla on a 12-year-old cleft-palate patient with maxillary hypoplasia (7). Later, osteosynthesis miniplates modified with intraoral attachments have been developed to serve as temporary skeletal anchorage devices (8). The treatment of Class III patients with BAMP was introduced by De Clerck *et al.* using Class III intermaxillary elastics between miniplates in both upper and lower jaws (BAC3E) (9). Miniplates have been shown to be well accepted by both patients and orthodontists (10), and the literature shows success rates for miniplates varying from 93 to 100 per cent (11). However, care should be taken when comparing the success rates as the definition of success and failure, the type of treatment, and the age of the patients varies considerably. Presenting a low failure rate and minimal skeletal and dental side effects, miniplates cause a limited number of problems to the patients, the surgeons, and the orthodontists.

Objective

A systematic review from 2017 concluded that BAMP treatment is an effective treatment for orthopedic correction of Class III malocclusion but that there is no clear evidence that skeletal anchorage provides significantly better results than traditional treatment (12). Because of the limitations of previous literature reviews and the presence of new scientific evidence, it was decided to perform a new review. This systematic review with meta-analysis aimed to determine

the level of evidence and to assess the scientific literature that has examined skeletal treatment effects as an outcome of BAMP in growing patients with Class III malocclusion compared to controls.

Materials and methods

Protocol and registration

This systematic review was performed according to the Cochrane Oral Health Group's Handbook for Systematic Reviews of Interventions (<http://ohg.cochrane.org>) and was registered with the number CRD42015023366 in the PROSPERO database.

Eligibility criteria

The PICOS outline (Population, Intervention, Comparison, Outcome, Study design) of this review is presented in Table 1. The included studies were retrospective studies, prospective controlled and non-controlled clinical trials evaluating maxillary and mandibular cephalometric measurements as an outcome after BAMP (temporary skeletal anchorage devices consisting of miniplates and/or miniscrews positioned in the maxilla and/or mandible) in growing patients with Class III malocclusion, including at least three subjects. The exclusion criteria were reviews, systematic reviews, opinion articles, book chapters, articles in other languages than English, German, French, or Italian, articles concerning patients with syndromes, patients with cleft lip and palate, treatments carried out with corticotomy, osteotomy or protraction on ankylotic teeth, and treatments carried out with fixed intermaxillary devices (e.g. Forsus® or similar) instead of removable elastics. Articles only using shape analysis were also excluded because of the absence of cephalometric data. No restrictions were placed on the publication status of the articles or year. The search was closed on 12 June 2019.

Information sources, search strategy, and study selection

A computerized systematic search was performed in five electronic databases up to June 2019: PubMed, Cochrane, Embase, Scopus, and Web of Science. It was conducted by two reviewers with the help of a senior librarian who specialized in health sciences. The search string is presented in Supplementary file 1. To find additional relevant articles that might have been missed in the electronic searches, a hand search of the reference lists of the included articles was carried out.

Data items and collection

All studies identified by applying the inclusion and exclusion criteria underwent assessment for validity and data extraction following a template by two reviewers who independently examined the studies. In case of doubt, the issue was discussed with a third reviewer. The authors of the articles were contacted by e-mail if further clarifications were judged necessary.

Table 1. Description of PICOS of this systematic review.

P	Growing Class III patients
I	Treatment with bone-anchored maxillary protraction
C	Comparison with controls
O	Cephalometric variables concerning maxillary and mandibular advancement
S	Retrospective studies, prospective controlled and non-controlled clinical trials

For each included study, qualitative and quantitative information were extracted, including year of publication; number and age of patients; location, number, and dimension of skeletal anchorage; use of facemask or RME, force magnitude, treatment duration, follow-ups, duration of recommended use per day, method of outcome assessment, treatment effect, and all the information needed for the methodological quality evaluation. The treatment effect was reported in terms of differences in means.

Risk of bias in individual studies

A quality scoring system for the assessment of bias of individual studies was adapted from previous publications (13,14). Consequently, the articles were scored by the reviewers according to study design, methodological soundness, and data analysis. This system resulted in the 11 criteria described in Table 2. The maximum score was 22. The articles were divided into low, medium, high, and very high levels of evidence.

Planned methods of analysis and risk of bias across studies

The data from the articles were considered suitable for pooling if similar interventions were used and similar outcomes were reported. A meta-analysis was performed separately for the studies with BAFM and for the studies using BAC3E as the skeletal and dental effects might be different. In both subgroups, a meta-analysis of the outcomes was performed only if reported in two or more studies.

The results from articles reporting mean differences (MDs) with standard deviation (SD) for ANB angle, Wits, and incisor to mandibular plane angle (IMPA) were combined in all meta-analyses. Pooled estimates of weighted mean differences (WMDs) in outcomes and weight were calculated between intervention groups and control groups, active or inactive. The MDs with standard error (SE) were chosen as effect measures for ANB angle, Wits, sella nasion line/maxillary plane (SN/NL) angle, and IMPA outcomes comparing before and after treatment, and results were expressed as treatment effect size (ES). All results were combined using a random-effects model (DerSimonian-Laird method) to adequately account for the different treatment protocols, appliances, patient characteristics, and measurement techniques.

The Cochran Q test was used to assess heterogeneity between studies and the I^2 test was used to measure the proportion of inconsistency in the combined estimates due to between-study heterogeneity. I^2 values lower than 30 per cent were regarded as representing low heterogeneity, values of 30 to 60 per cent as moderate heterogeneity, and values of over 60 per cent as substantial heterogeneity. Publication bias (including small-study effects) was assessed with Egger's linear regression test.

All analyses were performed using Stata 15 CI (StataCorp, College Station, Texas, USA). A two-tailed P value of 0.05 was considered significant for hypothesis testing, except for the test of heterogeneity and publication bias, where a P value of 0.01 was applied due to low power.

Results

Study selection and characteristics

Out of 449 articles, 36 were initially included after reading the abstracts. Figure 1 shows the flow chart of the selection process. Eight articles were excluded: two were in Chinese language (15,16), one was only a technical description (17), two were evaluating cases with

skeletal anchorage in the mandible but not in the maxilla (18,19), one was using a Forsus appliance instead of intermaxillary elastics (20), and two articles were excluded because the methodology used only shape analysis without any cephalometric outcome (21,22). Twenty-eight articles were finally included in the qualitative synthesis (5,9,23–48).

The articles from similar author groups with identical protocols were carefully investigated in order to address whether the published results could relate to the same patient sample. If so, the corresponding authors of the papers in question were contacted in order to know whether the same patients were used in the different articles. Five (43–47) authors were contacted: three (44,45,47) authors answered and confirmed that the results of identical patient samples were reported in different publications (Tables 3 and 4; Studies 7 and 10); two corresponding authors did not answer regarding the similarity of the samples; thus, the patient samples were considered identical (Tables 3 and 4; Studies 8 and 9) due to similarity in sample size, age, and gender distribution (23,43,46,48). Another author was contacted because it was not clear if two studies (Tables 3 and 4; Studies 11 (36) and 18 (37)) shared the same patients samples; no answer was received, but the articles were considered as separate studies because the mean ages of the two samples were too different (9.4 ± 0.9 and 10.4 ± 1.7) to be explained by a difference in sample size of only three patients. Similarly, two papers (32,34) were obviously reporting identical cephalometric data; therefore, the samples were considered identical without contacting the authors (Tables 3 and 4; Study 14). As a result, the 28 articles, after the merging process, were reduced into 18 studies (Tables 3 and 4). Throughout the text, the single publications will be referred to as “articles” and the grouped articles as “studies”.

Risk of bias within studies

Table 2 sums up the results of the quality score assessment. The 28 articles had an average score of 11. The lowest score was 3 points (9), whereas the highest score was 18 points (42). Only four articles had a high level of evidence, and no articles had a very high level of evidence.

Results of individual studies and additional analyses

The protocols of the 28 articles were examined. The findings of the different studies are summarized in Tables 3 and 4. Eleven articles had an active control group, and eight articles had an inactive control group of Class III growers. Different set-ups of skeletal anchorage were used, as well as different force levels of elastics. An extended description of those is reported in Supplementary file 2.

Cephalometric results

The cephalometric results were described in 2D in the majority of the papers. Some authors reported some results in 3D (Tables 3 and 4) (25,26,44) after having published the results of the same patient sample in 2D (9,24,33,45). Other authors reported also a 3D analysis of soft-tissue changes (34). The treatment effects are presented in terms of the difference between after and before treatment (T2–T1), as well as in terms of the difference between treated groups and active or inactive controls.

Evaluation of the 2D cephalometric results

The sagittal effects are reported in Tables 5 and 6: The T2–T1 difference in ANB varied from 1.4 to 6.3 degrees; the Wits appraisal varied (T2–T1) from 1.3 to 9.1 mm; the maxillary length (Co-A) between

Table 2. Quality assessment of the included bone-anchored maxillary protraction studies. FM, facemask; MP, miniplates.

Studies	Articles	Authors	Study design										Methodological soundness										Data analysis			Total score							
			Type of study		Consecutive cases		Sample size		Control group		Inactive control		Active control		Selection criteria		Sample size calculation		Outcome measure		Force magnitude		Sum		Error of the method		Statistical analysis		Data presentation		Sum		
			study	cases	size	group	control	control	control	control	control	control	control	control	control	control	control	control	control	control	control	control	control	control	control		control	control	control	control	control	control	control
1	1	Kircelli and Pektas (28)	0	1	0	0	0	No	No	No	No	No	No	0	0	0	1	1	1	1	2	1	2	1	2	2	2	2	5	8			
2	2	Cha and Ngan (4)	0	0	2	2	2	No	No	FM-RME	FM-RME	FM-RME	FM-RME	0	0	0	4	1	1	1	2	0	2	0	2	2	2	4	10				
3	3	Kaya et al. (29)	0	0	1	0	0	No	No	No	No	No	No	1	0	0	2	1	1	1	2	0	2	0	2	2	2	4	8				
4	4	Coscia et al. (27)	2	1	0	0	0	No	No	No	No	No	No	2	0	0	5	1	1	1	2	0	0	0	0	0	0	0	7				
5	5*	Ge et al. (30)	2	1	2	2	2	No	No	FM-RME	FM-RME	FM-RME	FM-RME	2	0	0	9	1	1	1	2	1	2	1	2	2	2	5	16				
6	6	Lee et al. (31)	0	0	0	2	2	No	No	FM-RME	FM-RME	FM-RME	FM-RME	2	0	0	4	1	1	1	2	1	2	1	2	2	2	5	11				
7	7	De Clerck et al. (8)	0	0	0	0	0	No	No	No	No	No	No	1	0	0	1	1	1	1	2	0	0	0	0	0	0	0	3				
8*	8*	Cevidane et al. (45)	2	1	2	2	2	No	No	FM-RME	FM-RME	FM-RME	FM-RME	2	0	0	9	1	1	1	2	2	2	2	2	2	2	6	17				
9*	9*	De Clerck et al. (33)	2	1	2	2	2	Yes	Yes	No	No	No	No	2	0	0	9	1	1	1	2	2	2	2	2	2	2	6	17				
10	10	Heymann et al. (24)	2	1	0	0	0	No	No	No	No	No	No	1	0	0	4	2	2	1	3	1	0	0	0	0	1	8					
11	11	Nguyen et al. (44)	2	1	2	0	0	No	No	No	No	No	No	2	0	0	7	1	1	1	2	0	0	0	0	1	1	10					
12	12	De Clerck et al. (26)	2	1	2	2	2	No	No	No	No	No	No	2	0	0	7	1	1	1	2	0	0	0	0	1	1	10					
13	13	Hino et al. (25)	2	0	2	2	2	No	No	FM-RME	FM-RME	FM-RME	FM-RME	2	0	0	8	1	1	1	2	1	2	1	2	2	2	5	15				
8	14	Sar et al. (46)	2	0	1	2	2	Yes	Yes	FM-RME	FM-RME	FM-RME	FM-RME	1	0	0	6	1	2	2	3	1	2	2	2	2	2	5	14				
15	15	Sar et al. (48)	2	0	1	2	2	Yes	Yes	**	**	**	**	1	1	1	7	1	1	1	2	1	2	1	2	1	4	13					
16	16	Nienkemper et al. (43)	0	0	1	0	0	No	No	No	No	No	No	1	0	0	2	1	2	2	3	2	2	2	2	2	6	11					
17	17	Nienkemper et al. (23)	0	1	1	2	2	Yes	Yes	FM-RME	FM-RME	FM-RME	FM-RME	0	1	1	5	1	2	2	3	1	2	2	2	2	5	13					
18	18	Ngan et al. (47)	0	1	1	2	2	Yes	Yes	FM-RME	FM-RME	FM-RME	FM-RME	2	0	0	6	1	2	2	3	1	2	2	2	2	5	14					
19*	19*	Aglarci et al. (42)	2	1	2	2	2	No	No	***	***	***	***	2	1	1	10	1	1	1	2	2	2	2	2	2	6	18					
20	20	Katyal et al. (36)	0	1	1	0	0	No	No	No	No	No	No	1	0	0	3	1	1	1	2	1	2	1	2	2	5	10					

Table 2. Continued

Studies	Articles	Authors	Study design		Methodological soundness							Data analysis									
			Type of study	Consecutive cases	Sample size	Control group	Inactive control	Active control	Selection criteria	Sample calculation	Sum	Outcome measure	Force magnitude	Sum	Error of the method	Statistical analysis	Data presentation	Sum	Total score		
12	21	Al-Mozany et al. (35)	2	1	1	0	No	No	1	0	5	1	1	2	1	2	1	2	2	5	12
13	22	Bozkaya et al. (41)	0	0	1	2	Yes	No	2	1	6	1	1	2	0	2	0	2	1	3	11
14	23	Elnagar et al. (32)	2	1	1	2	Yes	Gr1 versus Gr2	1	0	7	1	1	2	1	2	1	2	1	4	13
24		Elnagar et al. (34)	2	1	1	2	Yes	Gr1 versus Gr2	1	0	7	2	1	3	1	2	1	2	1	4	14
15	25	Kale and Buyukcavus (40)	0	0	0	0	No	No	2	0	2	1	2	3	0	0	0	0	0	0	5
16	26	Maino et al. (39)	2	1	2	0	No	No	1	0	6	1	1	2	0	2	0	2	1	3	11
17	27	Van Hevele et al. (38)	0	0	2	0	No	No	0	0	2	1	1	2	1	2	1	2	0	3	7
18	28	Willmann et al. (37)	0	1	1	2	No	Gr1 versus Gr2	2	0	6	1	1	2	1	2	1	2	2	5	13

Type of study: 0, if retrospective study; 2, if prospective study; 4, if randomized controlled clinical trial. Consecutive cases: 0, if sample comprised unconservative patients or if no information regarding this was provided; 1, if sample comprised consecutive patients. Sample size: 0, if ≤ 10 subjects; 1, if > 10 and ≤ 20 subjects; 2, if > 20 subjects. Control group: 0, if no control; 2, if active or inactive control. Selection criteria: 0, if no cephalometric or dental criteria reported; 1, if cephalometric or dental criteria reported; 2, if cephalometric and dental criteria reported. Sample size calculation: 0, no sample size calculation; 1, sample size calculation. Outcome measure: 0, no values reported; 1, cephalometric measurement or 3D color-coded map reported; 2, cephalometric measurement and 3D color-coded map reported. Force magnitude: 1, if stated; 2, if controlled by a force measurement device. Error of the method: 0, if method error not evaluated; 1, if partially adequate method error analysis; 2, if adequate method error. Statistical analysis: 0, if inadequate; 2, if adequate. Data presentation: 0, if inadequate; 1, if P value stated; 2, if any variability measures stated (standard deviation, confidence interval, or range). From 0 to 10 points: low level of evidence; from 11 to 15 points: medium level of evidence; from 16 to 18 points: high level of evidence; from 19 to 22 points: very high level of evidence. Gr: group; (groups are defined in Tables 3 and 4).

*Studies qualified with a high level of evidence.

**Mandibular MP + elastics to maxillary fixed appliance.

***Cemented appliance + elastics to FM.

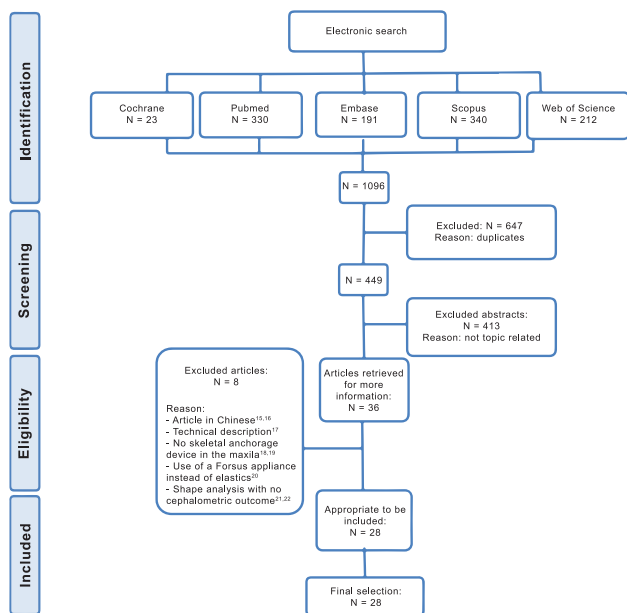


Figure 1. Flow diagram of the included studies.

Table 3. Protocols of the included bone-anchored maxillary protraction (BAMP) studies—part I. Gr, group; MP, miniplate; MS, miniscrew; SD, standard deviation.

Studies	Articles	Authors	Year	Number of subjects (excluding controls)	Age (average \pm SD; years)	Number of skeletal anchorage
1	1	Kircelli and Pektas (28)	2008	6	11.8 \pm 1.1	2 MP
2	2	Cha and Ngan (4)	2011	25 (14 had a pendulum)	11 \pm 1.4	2 MP
3	3	Kaya <i>et al.</i> (29)	2011	15	11.6 \pm 1.6	2 MP
4	4	Coscia <i>et al.</i> (27)	2012	6	10.9	2 MP
5	5	Ge <i>et al.</i> (30)	2012	20	10.3	2 MS
6	6	Lee <i>et al.</i> (31)	2012	10	11.2 \pm 1.2	2 MP
7	7	De Clerck <i>et al.</i> (8)	2009	Included in 13	11.9 \pm 1.8*	4 MP
	8	Cevitanes <i>et al.</i> (45)	2010	Included in 13		
	9	De Clerck <i>et al.</i> (33)	2010	Included in 13		
	10	Heymann <i>et al.</i> (24)	2010	Included in 13		
	11	Nguyen <i>et al.</i> (44)	2011	Included in 13		
	12	De Clerck <i>et al.</i> (26)	2012	Included in 13		
	13	Hino <i>et al.</i> (25)	2013	25		
8	14	Sar <i>et al.</i> (46)	2011	Included in 15	11.2 \pm 1.5	2 MP
	15	Sar <i>et al.</i> (48)	2014	17		
9	16	Nienkemper <i>et al.</i> (43)	2013	Included in 19	9.6 \pm 1.2	2 MS
	17	Nienkemper <i>et al.</i> (23)	2015	Included in 19		
	18	Ngan <i>et al.</i> (47)	2015	20		
10	19	Aglarci <i>et al.</i> (42)	2016	25	11.8 \pm 1.2	2 MS and 2 MP
11	20	Katyal <i>et al.</i> (36)	2016	14	10.4 \pm 1.7	2 MS and 1 MP (Mentoplate)
12	21	Al-Mozany <i>et al.</i> (35)	2017	14	12.0 \pm 1.1	4 MS
13	22	Bozkaya <i>et al.</i> (41)	2017	18	11.4 \pm 1.3	2 MP
14	23	Elnagar <i>et al.</i> (32)	2016	Included in 26	11.9 \pm 1.3 (Gr1)/	2 MP (Gr1)/
	24	Elnagar <i>et al.</i> (34)	2017	10 (Gr1) + 10 (Gr2)	12.2 \pm 1 (Gr2)	4 MP (Gr2)
15	25	Kale and Buyukcavus (40)	2018	3	12	2 MP
16	26	Maino <i>et al.</i> (39)	2018	28	11.4 \pm 2.5	2 MS
17	27	Van Hevele <i>et al.</i> (38)	2018	52	11.4	4 MP
18	28	Willmann <i>et al.</i> (37)	2018	17 (Gr1) + 17 (Gr2)	8.7 \pm 1.2 (Gr1)/ 9.4 \pm 0.9 (Gr2)	2 MS (Gr1)/2 MS and 1 MP (Mentoplate) (Gr2)

*In Nguyen *et al.* (44), the mean age at T1 in the abstract (11.1 \pm 1.1) differed from the mean age in the article itself (11.9 \pm 1.8). After emailing the corresponding author, the age of 11.9 \pm 1.8 was confirmed to be the correct age.

Table 4. Protocols of the included bone-anchored maxillary protraction (BAMP) studies—part II. Gr, group; MP, miniplate; MS, miniscrew; SD, standard deviation.

Studies	Skeletal anchorage location	Screw dimensions (diameter × length; mm)	Facemask	Rapid maxillary expansion	Force (g)	Duration of protraction (hours per day)	Treatment duration (average ± SD; years)	Follow-up
1 (28)	Lateral nasal wall	2 × 5	Yes	Yes	300 × 2	24	0.9 ± 0.2	Yes (on 4 patients)
2 (4)	Zygomatic buttress	NR	Yes	No	400 × 2	14–16	0.8 ± 0.2	No
3 (29)	Lateral nasal wall	2 × 5 or 7	Yes	Yes (Alt-RAMEC)	350–400 × 2	24	0.8* ± 0.2	No
4 (27)	Zygomatic buttress	1.3 × 6	No	No	250 × 2	24	NR (**between 0.8 and 1.5**)	Yes (on all)
5 (30)	Zygomatic buttress	2 × 14	Yes	No	200–250 × 2	14	0.9 ± NR	No
6 (31)	Zygomatic buttress	2 × 6	Yes	No	>400 × 2	12–14	1 ± 0.1	No
7 (8,24–26,33,44,45)	Zygomatic buttress and anterior mandible	2.3 × 5	No	No	250 × 2	24	1.2 ± 0.1	No
8 (46,48)	Lateral nasal wall	1.5 × 7	Yes	Yes	400 × 2	16	0.6 ± NR	No
9 (23,43,47)	Palate	2 × 9	Yes	Yes	380 × 2	12–14	0.6 ± 0.1	No
10 (42)	MS: between maxillary 2nd premolars and molars; MP: anterior mandible	MS: 1.6 × 10; MP: 2 × 7 or 9	No	No	200 × 2	18–20	0.8 ± 0.1	No
11 (36)	Palate and anterior mandible	NR	No	Yes	100 × 2	NR	0.9 ± 0.6	No
12 (35)	Palate and mandibular canine/lateral incisor	Maxilla: 2 × 9; mandible: 1.6 × 6	No	Yes (Alt-RAMEC)	400 × 2	24	0.2	No
13 (41)	Zygomatic buttress	2 × 5	Yes	No	400 × 2	24	1.1 ± 0.3	No
14 (32,34)	Zygomatic buttress (Gr1)/zygomatic buttress and anterior mandible (Gr2)	2 × 6	Yes (Gr1)/No (Gr2)	No	400–500 × 2 (Gr1)/250 × 2 (Gr2)	NR (Gr1)/24 (Gr2)	0.7 (Gr1)/0.7 (Gr2)	No
15 (40)	Lateral nasal wall	2 × 7	Yes	No	500 × 2	20	1.2	No
16 (39)	Palate	NR	Yes	Yes (Alt-RAMEC)	400 × 2	14	0.3	No
17 (38)	Zygomatic buttress and anterior mandible	2 × 5 or 7	No	No	100–250 × 2	NR	1.9	No
18 (37)	Palate (Gr1)/palate and anterior mandible (Gr2)	MS: 2 × 9; MP: NR	Yes (Gr1)/No (Gr2)	Yes	400 × 2 (Gr1)/200 × 2 (Gr2)	14–16 (Gr1)/24 (Gr2)	0.8 ± 0.3 (Gr1)/0.9 ± 0.3 (Gr2)	No

NR, not reported.

*Includes 8 weeks of Alt-RAMEC prior to maxillary protraction.

Table 5. Sagittal effects of bone-anchored maxillary protraction (BAMP) in included studies—part I. Gr. group.

Studies	SNA (degrees)				SNB (degrees)			
	Before treatment	Difference after—before BAMP	Difference active control group	Difference BAMP—inactive control group	Before treatment	Difference before BAMP	Difference active control group	Difference BAMP—inactive control group
1 (28)	75 ± 3.4	3.7* ± 1.5	—	—	80.3 ± 2.4	-2.3* ± 0.7	—	—
2 (4)	77.7 ± 3.5	3.3* ± 1.7	1.1*	—	80.0 ± 3.8	-1.1* ± 1.2	0.5*	—
3 (29)	76.8 ± 2.5	1.7*	—	—	78.2 ± 2.9	-1.2*	—	—
4 (27)	81.3 ± 5.3	4.8 NR ± 0.7	—	—	81.7 ± 6.6	0.5 NR ± 2	—	—
5 (30)	78.3 ± 3.3	2.6 NR ± 1.6	0 NS	—	81.9 ± 2.6	-1.8 NR ± 0.8	0.0 NS	—
6 (31)	79.3 ± 2.3	2.7* ± 1.7	1.6*	—	80.9 ± 3.4	-0.8* ± 0.8	1.6*	—
7 (8,24–26,33,44,45)	NR	NR	NR	NR	NR	NR	NR	NR
8 (46,48)	77.6 ± 3.1	3.1* ± 1.3	0.0 NS	2.9*	81.2 ± 2.9	-2.4* ± 1	0.5 NS	-3.5 NS
9 (23,43,47)	80.3 ± 4.7	1.6 NR	0.9 NR	1.3 NR ± 2.1	81.2 ± 4.2	-0.8 NR	0.9 NR	-1.3 NR ± 2
10 (42)	78.2 ± 4.0	1.6* ± 1.3	0.3 NS	—	80.2 ± 3.5	-1.5* ± 1.6	-0.4 NS	—
11 (36)	78.1 ± 4	2.1* ± 2	—	—	78.9 ± 3.4	0.2 NS ± 1.6	—	—
12 (35)	—	1.9* ± 1.1	—	—	82.1 ± 3.2	-2.0* ± 0.8	—	—
13 (41)	77.6 ± 2.7	2.2* ± 1.4	—	2.5*	81.4 ± 3.3	-1.3* ± 1.4	—	-1.2*
14 (32,34)	77.0 ± 2.1 (Gr1)/76.6 ± 2.1 (Gr2)	4.8* ± 1.1 (Gr1)/ 5.6* ± 0.8 (Gr2)	—	4.3* (Gr1)/5.2* (Gr2)	80.6 ± 2.3 (Gr1)/ 80.1 ± 1.6 (Gr2)	-1.2* ± 0.8 (Gr1)/ -0.4* ± 0.6 (Gr2)	—	-2.1* (Gr1) /-1.3* (Gr2)
15 (40)	75.5	3.9 NR	—	—	78.9	-0.6 NR	—	—
16 (39)	79.7 ± 3.7	2.5*	—	—	79.2 ± 3.8	-0.9*	—	—
17 (38)	79.4	1.9 NR	—	—	80.6	0.4 NR	—	—
18 (37)	79.4 ± 2.9 (Gr1)/79.2 ± 3.1 (Gr2)	2.2* ± 1.3 (Gr1)/ 2.2* ± 1.4 (Gr2)	—	—	80.5 ± 3.3 (Gr1)/ 80.1 ± 3.0 (Gr2)	-1.5* ± 1.1 (Gr1)/ -0.3 NS ± 1.0 (Gr2)	—	—

NR, not reported; NS, not statistically significant.

*Statistically significant.

Table 6. Sagittal effects of bone-anchored maxillary protraction (BAMP) in included studies—part II. Gr. group.

Studies	ANB (degrees)		Wits (mm)		Maxillary length Co-A (mm)				
	Difference after-before BAMP	Difference after-before BAMP	Difference after-before BAMP	Difference after-before BAMP	Difference BAMP-active control group	Difference BAMP-inactive control group	Difference after-before BAMP	Difference BAMP-active control group	Difference BAMP-inactive control group
1 (28)	6.1* ± 1.6	9.0* ± 1.5	—	—	—	—	5.4* ± 1.6	—	—
2 (4)	4.4* ± 1.7	NR	—	—	—	—	5.1* ± 2.6	1 NS	—
3 (29)	2.8*	4.2*	—	—	—	—	2.5*	—	—
4 (27)	6.3 NR ± 0.5	9.1 NR ± 1.1	—	—	—	—	NR	—	—
5 (30)	4.4 NR ± 1.7	4.8 NR ± 3	—	—	—	—	4.9 NR ± 2.1	-0.1 NS	—
6 (31)	3.8* ± 1.9	2.9* ± 2	—	—	—	—	3.0* ± 2.6	-0.1 NS	—
7 (8,24-26,33,44,45)	NR	5.9 NR ± 2.2	—	—	—	—	5.3 NR ± 2.0	2.9*	3.8*
8 (46,48)	5.5* ± 1.6	7.1* ± 1.6	—	—	—	—	NR	—	—
9 (23,43,47)	2.4 NR	2.6 NR	—	—	—	—	NR	—	—
10 (42)	3.1* ± 1.6	3.9* ± 2.6	—	—	—	—	3.4* ± 2.1	0.9 NS	—
11 (36)	1.9* ± 1.8	3.4* ± 2.7	—	—	—	—	—	—	—
12 (35)	3.9* ± 0.6	5.2* ± 1.5	—	—	—	—	—	—	—
13 (41)	3.8* ± 1.1	5.4* ± 2.0	—	—	—	—	—	—	—
14 (32,34)	6.0* ± 1.5 (Gr1)/ 6.0* ± 1.2 (Gr2)	7.0* ± 2.3 (Gr1) 7.3* ± 1.3 (Gr2)	—	—	—	—	4.0* ± 1.9	—	2.1*
15 (40)	4.3 NR	5 NR	—	—	—	—	4.8* ± 1.3 (Gr1) /5.7* ± 1.2 (Gr2)	—	3.6* (Gr1)/4.5* (Gr2)
16 (39)	3.4*	4.9*	—	—	—	—	7 NR	—	—
17 (38)	1.4 NR	1.3 NR	—	—	—	—	—	—	—
18 (37)	3.7* ± 1.4 (Gr1)/ 2.5* ± 1.0 (Gr2)	4.8* ± 1.4 (Gr1) /4.1* ± 1.2 (Gr2)	—	—	—	—	—	—	—

NR, not reported; NS, not statistically significant.

*Statistically significant.

Table 7. Vertical effects of bone-anchored maxillary protraction (BAMP) in included studies. ANS-Me, distance between menton and the anterior nasal spine; Gr, group; NL/ML, angle between the palatal plane and the mandibular plane; SNL/ML, angle between the sella-nasion plane and the mandibular plane; SNL/NL, angle between the sella-nasion plane and the palatal plane.

Studies	SNL/NL (degrees)			SNL/ML (degrees)			NL/ML (degrees)			ANS-Me (mm)		
	Difference BAMP after-before	Difference BAMP-ac-tive control group	Difference BAMP-inactive control group	Difference BAMP after-before	Difference BAMP-ac-tive control group	Difference BAMP-inactive control group	Difference BAMP after-before	Difference BAMP-ac-tive control group	Difference BAMP-inactive control group	Difference BAMP after-before	Difference BAMP-ac-tive control group	Difference BAMP-inactive control group
1 (28)	0.9 NS ± 1.5	—	—	NR	—	—	NR	—	—	NR	—	—
2 (4)	NR	—	—	NR	—	—	NR	—	—	2.4* ± 1.2	—	-1.8*
3 (29)	—	—	—	1.3*	—	—	—	—	—	2.9*	—	—
4 (27)	NR	—	—	0.7 NR ± 1.8	—	—	—	—	—	—	—	—
5 (30)	-1.1 NR ± 1.7	-2.0 NS	—	1.8 NR ± 1.5	-0.1 NS	—	—	—	—	—	—	—
6 (31)	—	—	—	—	—	—	—	—	—	—	—	—
7 (8,24-26, 33,44,45)	NR	NR	—	NR	NR	—	-0.8	-2.9*	-1.1*	2.1 NR ± 2.2 ⁽⁴⁵⁾ / 1.0 NR ± 1.6 ⁽³³⁾ **	-1.3*	-0.7 NS
8 (46,48)	NR	—	—	1.3* ± 1	-1.2*	2.2*	NR ± 1.4	—	—	2.6* ± 1.6	—	2.5 NS
9 (23,43,47)	0.1 NR	0.1 NR	-0.7 NR ± 2.2	0.2 NR	-2.1 NR	-0.3	—	—	—	NR	—	—
10 (42)	-0.6* ± 1.2	-0.2 NS	—	1.7* ± 1.9	0.4 NS	—	NR	—	—	4.2* ± 2.9	0.2 NS	—
11 (36)	-0.8* ± 0.9	—	—	—	—	—	1.0 ± 2.3	—	—	—	—	—
12 (35)	—	—	—	—	—	—	—	—	—	—	—	—
13 (41)	-0.3	—	-0.6 NS	1.5* ± 1.8	—	1.6*	—	—	—	3.2* ± 2.2	—	2.8*
14 (32,34)	NS ± 1.5	—	—	—	—	—	—	—	—	3.9* ± 1.8	—	—
	-0.6	—	—	2.0* ± 0.8	—	2.6*	—	—	—	2.9 NS ± 1.7	—	1.0 NS (Gr1)/
	NS ± 0.2	—	0 NS (Gr1)	(Gr1)/-1.0	(Gr1)	-0.4 NS	—	—	—	(Gr1)/1	—	-0.9 NS (Gr2)
	(Gr1)/-0.7	-0.1 NS	-0.1 NS	NS ± 0.5 (Gr2)	-0.4 NS	—	—	—	—	NS ± 0.2 (Gr2)	—	—
	NS ± 0.9	(Gr2)	(Gr2)	—	—	—	—	—	—	—	—	—
15 (40)	—	—	—	0.3 NR	—	—	—	—	—	—	—	—
16 (39)	-1.1*	—	—	1.6*	—	—	—	—	—	—	—	—
17 (38)	—	—	—	—	—	—	—	—	—	—	—	—
18 (37)	-0.7 NS ± 2.0	—	—	1.2 NS ± 1.5	—	—	1.9* ± 1.6	—	—	—	—	—
	(Gr1)/-0.5	—	—	(Gr1)/-0.5	—	—	(Gr1)/0.1	—	—	—	—	—
	NS ± 2.1	(Gr2)	(Gr2)	NS ± 1.1 (Gr2)	—	—	NS ± 2.1	—	—	—	—	—
	(Gr2)	—	—	—	—	—	(Gr2)	—	—	—	—	—

NR, not reported; NS, not statistical significant.

*Statistical significant.

**Unconsistent data.

Table 8. Dental effects of bone-anchored maxillary protraction (BAMP) in included studies. Gr, group; IMPA, angle between the long axis of the lower incisor and the mandibular plane; OB, overbite; OJ, overjet; U1-FH, angle between the long axis of the upper incisor and the Frankfurt plane; U1-NL, angle between the long axis of the upper incisor and the palatal plane; U1-SN, angle between the long axis of the upper incisor and the sella-nasion plane.

Studies	U1-SN (degrees)			U1-FH (degrees)			U1-NL (degrees)			IMPA (degrees)			OJ (mm)			OB (mm)		
	Difference after-BAMP	Difference BAMP -inactive control group	Difference BAMP -active control group	Difference after-BAMP	Difference BAMP -inactive control group	Difference BAMP -active control group	Difference U1-NL (degrees)	Difference BAMP -inactive control group	Difference BAMP -active control group	Difference after-BAMP	Difference BAMP -inactive control group	Difference BAMP -active control group	Difference after-BAMP	Difference BAMP -inactive control group	Difference BAMP -active control group	Difference after-BAMP	Difference BAMP -inactive control group	Difference BAMP -active control group
1 (28)	NR	—	NR	—	—	—	NR	—	—	-0.5 NS ± 3.8	—	—	7.4* ± 2.3	—	—	-1.8 NS ± 3.0	—	—
2 (4)	NR	—	1.6* ± 4.4	—	—	-1.5 NS	NR	—	—	-0.4 NS ± 5.7	1.2 NS	—	NR	—	NR	NR	—	—
3 (29)	0.2 NS	—	0.4 NS	—	—	—	NR	—	—	-1.6 NS	—	—	3.9*	—	3.9*	0.3*	—	—
4 (27)	0.5	—	—	—	—	—	—	—	—	4.0 NR ± 2.4	—	—	NR	—	NR	NR	—	—
5 (30)	NR ± 2.8	—	—	—	—	—	—	—	—	-5.6 NR ± 3.6	-1.6 NS	—	6.2 NR ± 1.8	—	6.2 NR ± 1.8	-2.0 NR ± 1.7	—	—
6 (31)	NR ± 3.5	—	2.3* ± 1.7	—	—	-3.0*	—	—	—	-2.0 NS ± 5.5	-0.2 NS	—	5.8* ± 2.7	—	5.8* ± 2.7	-0.8 NS ± 1.7	—	—
7 (8,24-26,33,44,45)	NR	—	NR	—	—	NR	0.6 NR ± 3.1	-0.3 NS	0.7 NS	1.9 NR ± 1.6	6.2*	1.7*	3.7 NR ± 1.9	1.4 NR ± 1.8	3.7 NR ± 1.9	1.4 NR ± 1.8	—	—
8 (46,48)	NR	—	NR	—	—	—	-0.1 NS ± 4.7	-4.6*	-2.0 NS	-6.1* ± 3.4	-14.3*	-5.9 NS	7.8* ± 1.1	-1.3 NS ± 1.8	7.8* ± 1.1	-1.3 NS ± 1.8	—	—
9 (23,43,47)	-2.0 NR	-4.2 NR ± 5.7	NR	—	—	—	NR	—	—	-1.7 NR	3.3 NR	-2.2 NR ± 3.8	3.5 NR	-0.1 NR	3.5 NR	-0.1 NR	—	—
10 (42)	NR	—	NR	—	—	—	3.0* ± 4.1	-2.9 NS	—	NR	—	—	0.4* ± 0.9	0.8* ± 1.1	0.4* ± 0.9	0.8* ± 1.1	—	—
11 (36)	—	—	—	—	—	—	0.9 NS ± 8.5	—	—	-0.2 NS ± 5.9	—	—	2* ± 2.2	0 NS ± 2.1	2* ± 2.2	0 NS ± 2.1	—	—
12 (35)	3.0* ± 2.7	—	—	—	—	—	—	—	—	-3.2* ± 3.4	—	—	5.6* ± 1.4	-1.2* ± 1.9	5.6* ± 1.4	-1.2* ± 1.9	—	—
13 (41)	—	—	—	—	—	—	1.7 NS ± 3.6	—	0.9 NS	-3.4* ± 4.0	—	-3.6*	5.7* ± 1.5	-1.1* ± 2.0	5.7* ± 1.5	-1.1* ± 2.0	—	—
14 (32,34)	—	—	—	—	—	—	0.2 NS ± 0.4	—	-0.3 NS (Gr1)/0.1 (Gr2)	-2.6* ± 1.8 (Gr1)/1.1 (Gr2)	—	(Gr1)/0.7 (Gr2)	7.1* ± 1.2 (Gr1)/7.1* ± 0.7* (Gr2)	-1.5* ± 1.5 (Gr1)/-0.7* (Gr2)	7.1* ± 1.2 (Gr1)/7.1* ± 0.7* (Gr2)	-1.5* ± 1.5 (Gr1)/-0.7* (Gr2)	—	—
15 (40)	—	—	—	—	—	—	NS ± 0.4 (Gr2)	—	NS (Gr2)	NS ± 0.2 (Gr2)	—	NS (Gr2)	1.6 (Gr2)	± 0.7 (Gr2)	1.6 (Gr2)	± 0.7 (Gr2)	—	—
16 (39)	—	—	—	—	—	—	-3.4 NR	—	—	-2 NR	—	—	4.7 NR	1.5 NR	4.7 NR	1.5 NR	—	—
17 (38)	—	—	—	—	—	—	-2.3 NS	—	—	—	—	—	—	—	—	—	—	—
18 (37)	—	—	—	—	—	—	-1.1 NS ± 6.4 (Gr1)/0.6 NS ± 5.5 (Gr2)	—	—	-3.8* ± 6.1 (Gr1)/-0.6 NS ± 3.8 (Gr2)	—	—	—	—	—	—	—	—

NR, not reported; NS, not statistically significant.
*Statistically significant.

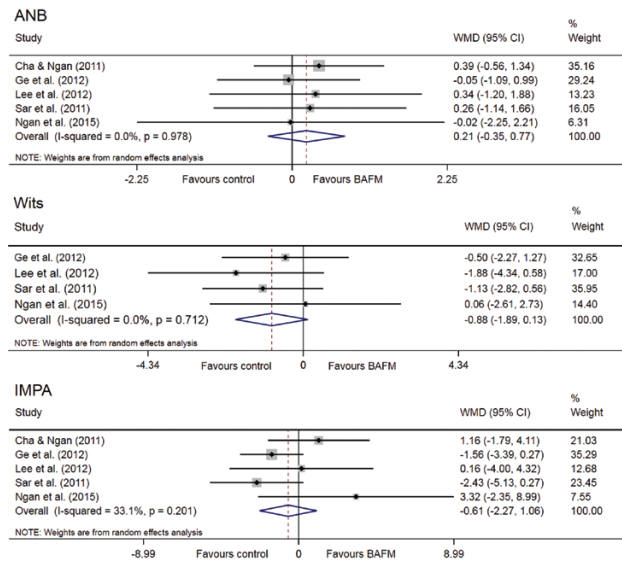


Figure 2. Forest plots of the difference for ANB, IMPA (on a total of 183 subjects including controls), and IMPA (on a total of 133 subjects, including controls) values between bone-anchored facemask (BAFM) treatment and tooth-borne facemask. CI, confidence interval; WMD, weighted mean difference.

outcomes were stated in three articles from Study 7 (25,26,44). Another article [Study 14 (34)] reported 3D outcomes regarding the soft-tissue changes comparing two treatment groups (one using BAC3E and one using BAFM) to an inactive control group. Significant displacement of the upper lips, cheeks, and midface between both treatment groups and the controls was reported only in the sagittal plane, with no difference between the two treatment groups. On the other hand, the lower lip and the chin experienced some growth restraint.

Meta-analysis

A meta-analysis comparing BAMP to controls could only be performed for the sagittal outcomes ANB and Wits, and for the dental outcome IMPA, on a total sample of 428 subjects, including controls. Unfortunately, there was insufficient data in order to perform a meta-analysis for the vertical outcomes, as well as for the dental outcomes describing the upper incisor proclination. An estimate of the effect size of BAFM and BAC3E subgroups was also calculated on a total of 187 and 122 subjects, respectively. Heterogeneity was high ($I^2 > 50\%$) for all subgroups except for BAFM versus traditional facemask.

BAFM results

Comparing BAFM to the traditional facemask, five studies (Studies 2, 5, 6, 8, and 9) were pooled to evaluate an estimate of the combined mean effect size of ANB and IMPA, and four studies (Studies 5, 6, 8, and 9) for the Wits values. In general, the mean effect was within the range of 1 degree or 1 mm and, therefore, not clinically significant (Figure 2).

Comparing BAFM to untreated controls, four studies (Studies 8, 9, 13, and 14) were pooled to evaluate an estimate of the combined mean effect size of ANB, Wits, and IMPA. The mean effect was 4-degree ANB correction, 5-mm Wits improvement, and 4-degree IMPA reduction, describing a statistically and clinically significant

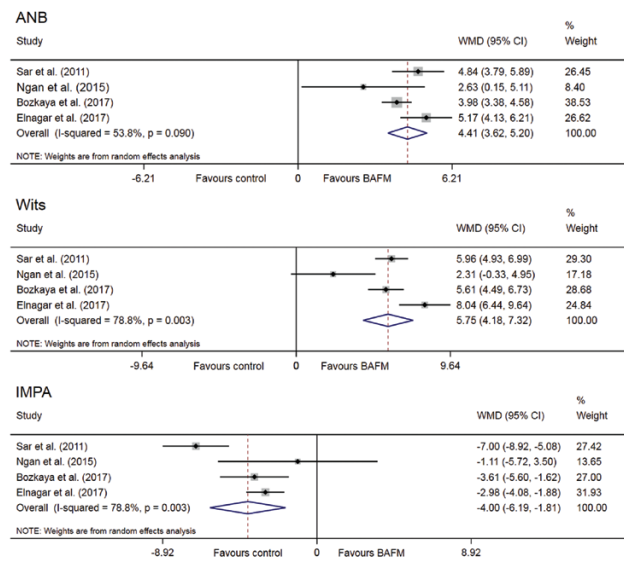


Figure 3. Forest plots of the difference for ANB, Wits, and IMPA values between bone-anchored facemask (BAFM) treatment and untreated controls (on a total of 126 subjects including controls). CI, confidence interval; WMD, weighted mean difference.

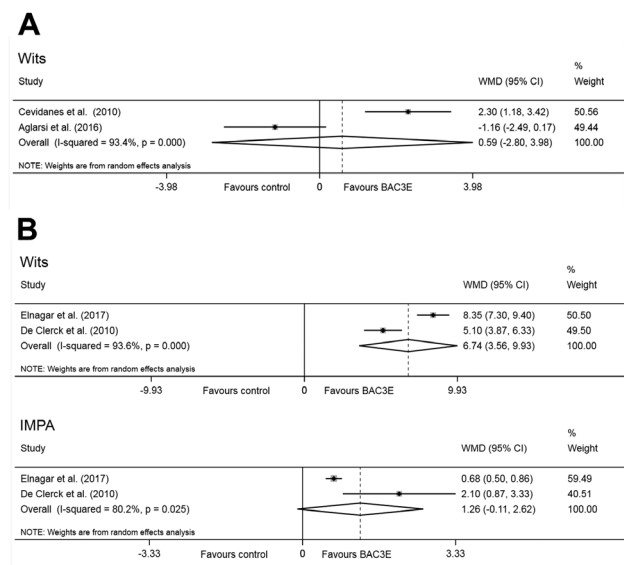


Figure 4. A, Forest plots of the difference for Wits values between BAMP treatment with miniplates and class III elastics (BAC3E) and tooth-borne facemask (on a total of 105 patients, including controls); B, Forest plots of the difference for IMPA and Wits values between BAMP treatment with miniplates and class III elastics (BAC3E) and untreated controls (on a total of 59 subjects, including controls). CI, confidence interval; WMD, weighted mean difference.

combined effect size for BAFM over untreated controls at least in the short term (Figure 3).

BAC3E results

Comparing BAC3E subgroup to the traditional facemask, two studies (Studies 7 and 10) were pooled to evaluate an estimate of the combined mean effect size of Wits value, which was not statistically and clinically significant (Figure 4). Comparing BAC3E to untreated

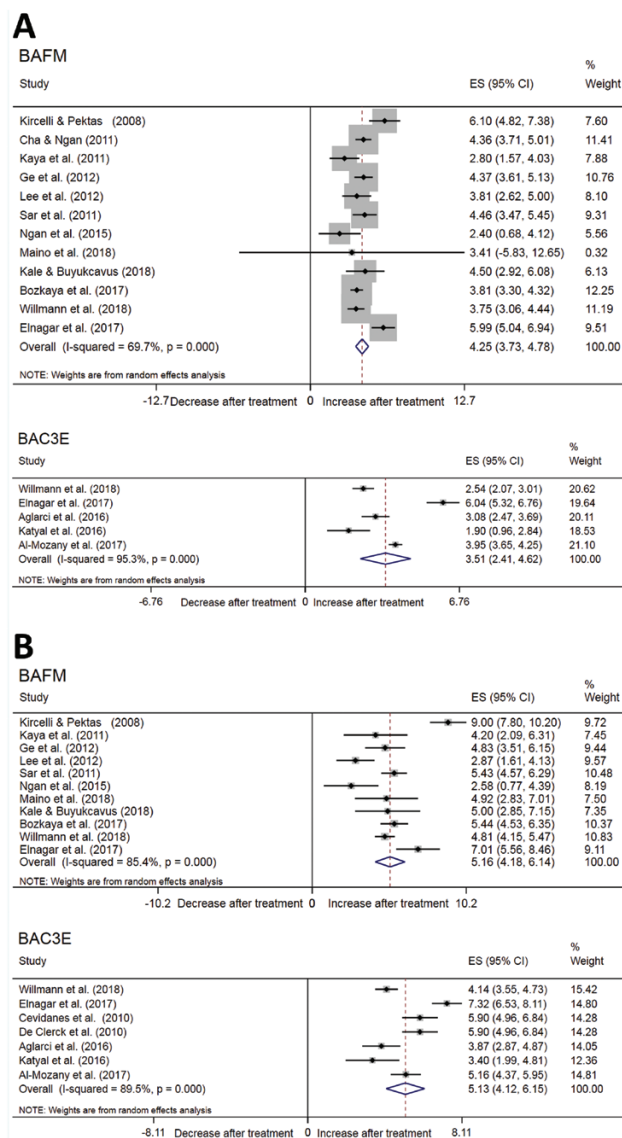


Figure 5. A, Forest plots for the effect size (ES) of ANB angle for the BAFM (187 subjects) and the BAC3E (73 subjects) groups. CI, confidence interval; B, Forest plots for the effect size (ES) of Wits appraisal for the BAFM (162 subjects) and the BAC3E (101 subjects) groups. CI, confidence interval.

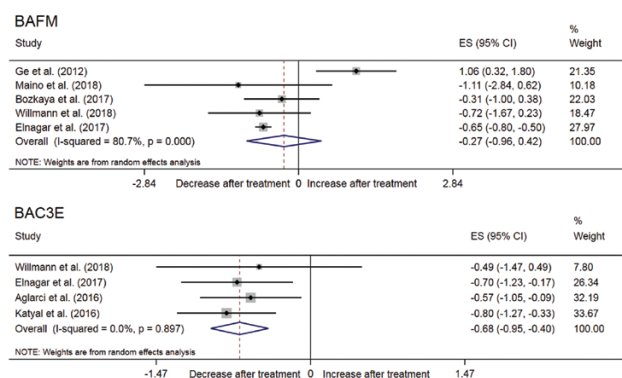


Figure 6. Forest plots for the effect size (ES) of SNL/NL angle for the BAFM (93 subjects) and the BAC3E (66 subjects) groups. CI, confidence interval.

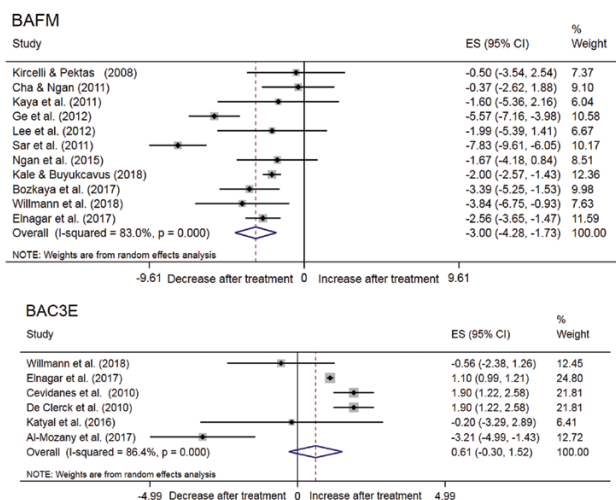


Figure 7. Forest plots for the effect size (ES) of IMPA for the BAFM (169 subjects) and the BAC3E (76 subjects) groups. CI, confidence interval.

controls, two studies (Studies 7 and 14) were pooled to evaluate an estimate of the combined mean effect size of Wits value, which showed a statistically and clinically significant effect of nearly 7 mm. The change in IMPA, however, was not statistically and clinically significant (Figure 4).

Comparison of BAFM and BAC3E treatment effect

Studies using BAFM treatment and studies using BAC3E treatment were pooled to evaluate an estimate of the effect size of ANB angle (Figure 5A), Wits appraisal (Figure 5B), SNL/NL angle (Figure 6), and IMPA angle (Figure 7). Both treatments showed a similar tendency, except for the IMPA angle that increased in the BAC3E group and decreased in the BAFM group.

Risk of bias across studies

The results of the Egger’s test for estimation of publication bias across the studies included in the meta-analysis are reported in Supplementary file 4 and showed non-significant results, suggesting the absence of publication bias.

Discussion

Summary of evidence

The aim of this systematic review was to investigate the evidence in the literature about the treatment effects after BAMP treatment in growing patients. Although ideally prospective studies only should be included in systematic reviews, retrospective studies had to be included in the present review because of a lack of prospective studies in the subject. Indeed, the information available from the literature would have been superficially reported if retrospective studies were avoided: the limited number of articles would have limited potential knowledge to be reported.

Several articles were published recently about BAMP. However, it appeared obvious that the patients’ samples were identical among different papers or that initially small case series were subsequently enlarged and included in larger patient samples. Academic pressure for publication might be responsible for the first phenomenon, while time sensitivity of new treatment protocols probably encourages the second phenomenon in the sense that new methods need to be

published fast. However, an increased number of publications based on the same sample of patients might overrule the publication results in the eyes of the reader, especially, when the redundancy of the samples is not mentioned in the publications. Such a problem might be limited by the registration of the patient samples, which, unfortunately, is not often the case in the orthodontic field and was not done for the papers included in the present review.

Therefore, in the present systematic review, we attempted to group all publications dealing with identical patient samples in order to give the appropriate weight to the included studies. As previously mentioned, if the same sample was suspected to be used in various publications of similar authors' groups (based on patient's age and protocol), the authors were contacted. After this process, seven articles were analyzed as one single study (Tables 3 and 4; Study 7), three articles were analyzed as one single study (Tables 3 and 4; Study 9), and two other publications were grouped into another single study (Tables 3 and 4; Study 8). In order to facilitate the elaboration of adequate systematic reviews or meta-analysis, it would be highly advisable that the authors report whether identical samples have been used in different publications. Study 7 (Tables 3 and 4), for instance, reports the results of the same samples in 11 different articles, of which 7 (9,24–26,33,44,45) are included in the present systematic review, while 4 (17,21,22,49) were excluded as they did not meet the inclusion criteria.

Surprisingly, although the authors confirmed that the samples were identical, mild differences in protocol descriptions were found in the included articles: force levels were different in the articles of Study 7 (Tables 3 and 4) (9,24–26,33,44,45), ranging from 100 to 200 gr. Another example of discordance was the distance ANS–Me, sometimes stated to be 2.1 mm (45) and elsewhere 1 mm (33) (Table 7).

Furthermore, there was large variability in the cephalometric measurement used, and even different articles referring to the same study used different reference systems. These aspects are described extensively in Supplementary file 2 and depicted in Supplementary files 5 and 6. Therefore, the major problem for comparing the reported cephalometric data was that the included articles did not report the same outcomes, which would be needed in order to compare the treatment effect. Indeed, no single common cephalometric sagittal, vertical or dental variable could be identified in all included studies. For example, even SNA angle was not reported in the papers of Study 7 (Tables 5 and 6), although SNA angle was reported in all other studies. Therefore, it was only possible to perform a meta-analysis for few outcomes (ANB, Wits, and IMPA), comparing BAFM with traditional facemask and with untreated controls and comparing BAC3E with traditional facemask and with untreated controls. It would have been interesting to compare also the effects on the position of the upper incisors and the vertical effects, but there were insufficient data to gather.

Comparison with previous systematic reviews

Previous systematic reviews have analyzed the treatment effects of BAMP (12,50,51). However, those reviews presented some drawbacks, which are addressed in the present systematic review. For example, Major *et al* (50) concluded that clinicians could expect greater orthopedic changes using BAMP compared to dental anchored maxillary protraction and that BAMP likely had fewer dental changes. This meta-analysis was based on four articles (5,33,45,46), which are also all included in the present systematic review. The first drawback is that two out of four studies (33,45) used identical samples but were analyzed as different. Second, the authors (45)

compared directly the outcomes of the articles even though different reference systems were used. Another systematic review (51) concluded that BAMP might produce a greater maxillary advancement effect and reduce skeletal and dental side effects compared to dental anchored maxillary protraction. However, this review included the same articles as Major *et al* (50) and faced, therefore, the same limitations. A recent systematic review (12) concluded that BAMP is an effective treatment for skeletal Class III malocclusion, but there is no clear evidence that the use of skeletal anchorage provides significant results over traditional facemask. Like the other two systematic reviews, this review included three studies out of nine that shared the same sample, thus, possibly, influencing their results.

BAMP treatment timing

To achieve greater skeletal effects in Class III patients, it is advised to start facemask therapy as early as possible (2). Good clinical results in facemask treatment are dependent on patient compliance and the timing of treatment. A disadvantage of BAMP treatment with four miniplates compared to traditional facemask treatment is that, in order to allow for the insertion of the mandibular miniplates, the lower canines need to be erupted. A potential problem postponing the start of the treatment after canine eruption is the risk of having less influence on the sutures of the maxilla. When the sutures are strongly interdigitated (52), the treatment effect is reduced. In order to allow earlier treatment, Wilmes *et al*. developed a bone-anchored treatment alternative, the Hybrid-Hyrax Mentoplate Combination (53). The mentoplate is inserted subapical to the lower incisors and can, therefore, be used in patients as young as 8-years old. The hyrax is skeletally anchored in the palate with miniscrews and has molar bands on the first molars. Class III elastics are used from the hooks of the molar bands in the upper arch to the hooks of the mentoplate. Indeed, the present review showed that the patients in Studies 9 and 18, both using mentoplate system, were younger (9.6 ± 1.2 years and 8.7 ± 1.2 years, respectively) compared to the age range among the other studies (Tables 3 and 4).

It is known that, when treating Class III patients, the result could be influenced by a possible unfavourable growth pattern during late adolescence, including the absence of catch-up of maxillary growth, a more vertical direction of facial growth, and a long period of active mandibular growth (3). A possibility to overcome this problem would be to maintain the protraction of the maxilla with elastics until growth has ceased. This is an issue for BAMP treatment with miniplates as leaving the miniplates, in the long run, is controversial since the miniplates will, then, be difficult to remove due to bone apposition over the miniplates (54).

BAMP treatment effects

Sagittal

The Wits appraisal depicts well the sagittal effects as this parameter was reported for all studies but one (5); the difference in Wits after-before treatment varied from 1.3 to 9.1 mm among the 17 studies reporting it (Tables 5 and 6). However, one must be realistic and take into consideration that the result is including growth as most of the studies did not include an inactive control group besides Studies 7, 8, and 9 (Tables 5 and 6). The ANB angle was reported in all studies except Study 7 (Tables 5 and 6).

The difference in Wits between BAMP-treated groups and inactive (historical) controls appeared very promising: 6.7 mm for Study 7 and 8.1 mm for Study 8 (Tables 5 and 6). Indeed, the results of the meta-analysis suggest that BAMP treatment with either BAFM or BAC3E has a significant effect on ANB and Wits values

when compared to untreated controls in the short term (Figures 3 and 4). However, this raises the question of the validity of the use of historical controls as, in Study 7 (Tables 5 and 6), the difference in Wits compared to inactive controls (6.7 mm) is greater than the treatment effect itself (5.9 mm: difference in Wits after–before treatment), including growth. This happens also in Study 8 (Tables 5 and 6), where the difference in Wits compared to inactive controls is 8.1 mm, while the treatment effect is 7.1 mm. However, the authors did not report relevant information on how they selected the 17 controls.

On the other hand, the evidence presented here does not suggest a real advantage of BAMP treatment over traditional facemask treatment in terms of sagittal correction since a difference of 0.2 degrees of ANB (Figure 2) for BAFM treatment cannot be considered clinically relevant. In that subgroup, the differences in Wits values compared to active controls were negative, indicating better results in active controls than in the BAMP groups. This might be related to an increased dental effect in the active controls compared to the BAMP-treated group. Regarding the BAC3E subgroup, a modest effect size of 0.6 mm of Wits increase over tooth-borne facemask (Figure 4) was shown (indicating a greater change in Wits appraisal with BAMP treatment compared to active controls), with one study reporting a greater effect of BAMP (Study 7, +2.3 mm, 95% CI 1.2–3.4 mm) and another study reporting an opposite result (Study 10, –1.2 mm, 95% CI –2.5–4.0). Such results should be interpreted with caution since only two studies were pooled.

The increase of the maxillary length Co-A was reported in ten of the studies (Tables 5 and 6) (9,24–26,28–31,33,42,44,45). The difference in the maxillary length after–before treatment varied from 2.5 to 7 mm. Statistically significant differences were reported by only one study (45) compared to an active control group and by three studies (Studies 7, 13, and 14) compared to untreated controls.

Regarding the effects of BAFM compared to BAC3E, both treatment modalities showed a similar effect in terms of ANB correction (4.2 degrees for the BAFM group and 3.5 degrees for the BAC3E group; Figure 5A) and Wits correction (5.1 mm for BAFM and BAC3E; Figure 5B).

Vertical

Overall, the vertical effects showed a very mild reduction of SN/NL, SN/ML, and NL/ML with BAMP treatment compared to active controls in the range of 2 degrees or less (Table 7). The largest effect was observed in Study 7, with an NL/ML angle reduced by 2.9 degrees compared to active controls and by 1.1 degrees compared to inactive controls. BAMP treatment seems, therefore, not to generate the typical increase in facial height observed with facemask therapy. However, these changes are very limited, and clinical significance can be questioned. Moreover, no meta-analysis regarding the treatment effect of BAMP compared to controls could be performed due to the lack of similar outcomes. Comparing the pooled effect size of BAFM and BAC3E treatment, a similar tendency of SNL/NL angle reduction can be observed with both treatment modalities (Figure 6).

Dental

The results of the present meta-analysis suggest that BAFM treatment produced a large retroclination of the lower incisors (IMPA) of 4.0 degrees compared to untreated subjects in the short term (Figure 3), which is most likely related to the use of the facemask (posterior and downward force on the mandible created by the chincup). The difference for incisors inclination between BAFM and

traditional tooth-borne facemask was around –0.6 degrees and clinically non-influent (Figure 2).

On the contrary, BAC3E treatment produced a lower incisor proclination of nearly 1.3 degrees (IMPA) compared to untreated controls in the short term (Figure 4), which might suggest a more favourable outcome with BAMP treatment without facemask, consisting in a reduced retroclination of the lower incisors. However, this should be interpreted cautiously since only two studies were included in the meta-analysis. The large difference observed in lower incisor retroclination compared to active controls treated with facemask therapy in Study 7 is likely due to the facemask. In fact, comparing the pooled estimates of effect size for the BAFM and the BAC3E treatment, a large difference in IMPA outcome can be observed between the two groups (Figure 7). Regarding the upper incisors, all the studies reported a smaller proclination when comparing BAMP treatment with conventional facemask therapy, the largest difference being –6.4 degrees as reported by Ge *et al.* (Table 8, Study 5).

BAMP and RME

Six studies (Tables 3 and 4, Studies 1, 8, 9, 11, 14, and 18) used RME in combination with facemask and skeletal anchorage. Three studies (Tables 3 and 4, Studies 3, 12, and 16) used the Alt-rapid maxillary expansion and contraction (RAMEC) protocol (55), again, in combination with facemask and skeletal anchorage. Several studies report effective treatment of Class III malocclusion with a combination of RME and facemask but without skeletal anchorage (2). A systematic review from 2018 concluded that there is limited evidence from studies at high risk of bias that RME can improve maxillary protrusion (56). A systematic review from 2008 concluded that RME and facemask therapy had a 75% success rate after a 5-year follow-up (57). Reed *et al.* showed good stability 2 years after RME and facemask therapy in primary and early mixed dentition (58). Some side effects were observed: downward and backward rotation of the mandible and forward movement of the maxillary teeth (5). From the few studies reported in this review proposing a BAMP approach combined with RME, it is not possible to draw conclusions regarding a possible increased efficiency due to RME. However, this question would definitely benefit from being further investigated.

Interindividual variability

Another question that remains unanswered from the present systematic review is related to the interindividual variability. The patient samples of the included articles are small and often recurrent and, therefore, it is not possible to identify, from the literature available so far, which patients will be good responders and which patients will be poor responders. More clinical trials, with carefully selected patients, are needed in order to answer this question.

Limitations

Regarding the assessment of the quality of the studies, the Cochrane collaboration risk of bias tool could not be used since only one randomized trial was included. Instead, it was decided to use a quality assessment score. With an average of 11 points out of a maximum 22 possible points regarding the evaluation of the quality of the studies, it was obvious that the articles presented an average low level of quality. No single article in this review was attributed the highest level of evidence. Eleven articles had a low level of quality. In the papers listed as Study 7 (Table 2), the level of evidence varied from 3 to 17 as, from the oldest papers throughout the most recent ones, the sample size increased and comparisons to active controls were

added. However, the article (33) from that group that reached the highest score (17/22) used historic control. It is known that interpreting clinical studies with historical untreated control groups has to be done with caution since overestimation of treatment effects was documented (59). Antoun *et al.* also pointed out that ‘secular trends are likely to result in modern craniofacial traits that are generally larger in size and different growth pattern than those of historical subjects, explaining why modern randomized clinical trials (RCTs) report smaller differences than studies using historical controls’ (60). Moreover, due to ethical reasons, longitudinal growth studies with X-rays of untreated subjects are no longer possible and, therefore, no databases with normative data in 3D are available (61,62). For this reason, the results of the studies with 3D results were compared not only with historical cephalometric findings but, obviously, also in 2D.

In general, there was a large heterogeneity among the included studies regarding the protraction force used, the treatment time, and the outcome measures, which made it difficult to perform a quantitative comparison of the results.

Regarding the number of patients, the maximum number of patients included in the studies was 52 patients. Only 4 (23,41,42,48) out of 28 publications reported a sample size calculation. Finally, no long-term results were reported.

Conclusions

1. There was a lack of uniformity in cephalometric outcomes reported, which hindered the comparisons of results.
2. Multiple publications of results of identical sample tended to suggest overly positive results of BAMP.
3. The clinical significance of the sagittal correction achieved with BAMP treatment compared to facemask therapy was questionable; BAFM, BAC3E, and conventional facemask therapy seem to deliver a similar maxillary protraction effect.
4. Lower incisor retroclination seemed to be better controlled in the absence of facemask using intermaxillary elastics between maxillary and mandibular bone anchors.
5. Within the limits of the present review, BAMP treatment seems to offer better control of the vertical dimension compared to facemask therapy.
6. The level of evidence available to support maxillary advancement effect after BAMP was low. Moreover, the findings of the meta-analyses should be interpreted with caution due to significant heterogeneity of the included studies. High-quality RCTs are needed.
7. Long-term follow-up results are needed.

Supplementary material

Supplementary materials are available at *European Journal of Orthodontics* online.

Supplementary file 1. Databases search strings.

Supplementary file 2. Extended description and discussion of the results of the present systematic review.

Supplementary file 3. Results of 3D measurements of the effects of BAMP in included studies.

Supplementary file 4. Publication bias in Egger’s test for meta-analysis of BAFM treatment compared to negative and positive controls, and for meta-analysis of effect size of BAFM and BAC3E treatment.

Supplementary file 5. De Clerck (33) versus Cevidane’s (45) reference lines. Cevidane’s SBL: This line is traced through the most superior point of the anterior wall of sella turcica at the junction with

tuberculum sella (point T), and it is drawn tangent to lamina cribrosa of the ethmoid bone. De Clerck’s SBL: Passing through FMN (no explanation of this point was given) and beyond the tangent to the lamina cribrosa of the ethmoid bone. SBL: Stable basicranial line. VerT: Vertical line to T point.

Supplementary file 6. Sar’s (46) versus Cha’s (4) reference lines. SN line (Sella-Nasion line).

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Conflict of interest

The authors declare that they have no conflict of interest.

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