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Orthodontic treatment for prominent lower front teeth (Class III malocclusion) in children (Review)

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TABLE OF CONTENTS

[Intervention Review]

Orthodontic treatment for prominent lower front teeth (Class III malocclusion) in children

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ABSTRACT

Background

Prominent lower front teeth (termed reverse bite; under bite; Class III malocclusion) may be due to a combination of the jaw or tooth positions or both. The upper jaw (maxilla) can be too far back or the lower jaw (mandible) too far forward, or both. Prominent lower front teeth can also occur if the upper front teeth (incisors) are tipped back or the lower front teeth are tipped forwards, or both. Various treatment approaches have been described to correct prominent lower front teeth in children and adolescents.

Objectives

To assess the effects of orthodontic treatment for prominent lower front teeth in children and adolescents.

Search methods

We searched the following databases: Cochrane Oral Health Group's Trials Register (to 7 January 2013), the Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library* 2012, Issue 12), MEDLINE via OVID (1946 to 7 January 2013), and EMBASE via OVID (1980 to 7 January 2013).

Selection criteria

Randomised controlled trials (RCTs) recruiting children or adolescents or both (aged 16 years or less) receiving any type of orthodontic treatment to correct prominent lower front teeth (Class III malocclusion). Orthodontic treatments were compared with control groups who received either no treatment, delayed treatment or a different active intervention.

Data collection and analysis

Screening of references, identification of included and excluded studies, data extraction and assessment of the risk of bias of the included studies was performed independently and in duplicate by two review authors. The mean differences with 95% confidence intervals were calculated for continuous data. Meta-analysis was only undertaken when studies of similar comparisons reported comparable outcome measures. A fixed-effect model was used. The I^2 statistic was used as a measure of statistical heterogeneity.

Main results

Seven RCTs with a total of 339 participants were included in this review. One study was assessed as at low risk of bias, three studies were at high risk of bias, and in the remaining three studies risk of bias was unclear. Four studies reported on the use of a facemask, two on the chin cup, one on the tandem traction bow appliance, and one on mandibular headgear. One study reported on both the chin cup and mandibular headgear appliances.

One study (n = 73, low quality evidence), comparing a facemask to no treatment, reported a mean difference (MD) in overjet of 4.10 mm (95% confidence interval (CI) 3.04 to 5.16; P value < 0.0001) favouring the facemask treatment. Two studies comparing facemasks to untreated control did not report the outcome of overjet. Three studies (n = 155, low quality evidence) reported ANB (an angular measurement relating the positions of the top and bottom jaws) differences immediately after treatment with a facemask when compared to an untreated control. The pooled data showed a statistically significant MD in ANB in favour of the facemask of 3.93 ° (95% CI 3.46 to 4.39; P value < 0.0001). There was significant heterogeneity between these studies (I^2 = 82%). This is likely to have been caused by the different populations studied and the different ages at the time of treatment.

One study (n = 73, low quality evidence) reported outcomes of the use of the facemask compared to an untreated control at three years follow-up. This study showed that improvements in overjet and ANB were still present three years post-treatment. In this study, adverse effects were reported but due to the low prevalence of temporomandibular (TMJ) signs and symptoms no analysis was undertaken.

Two studies (n = 90, low quality evidence) compared the chin cup with an untreated control. Both studies found a statistically significant improvement in ANB, and one study also found an improvement in the Wits appraisal. Data from these two studies were not suitable for pooling.

A single study of the tandem traction bow appliance compared to untreated control (n = 30, very low quality evidence) showed a statistically significant difference in both overjet and ANB favouring the intervention group.

The remaining two studies did not report the primary outcome of this review.

Authors' conclusions

There is some evidence that the use of a facemask to correct prominent lower front teeth in children is effective when compared to no treatment on a short-term basis. However, in view of the general poor quality of the included studies, these results should be viewed with caution. Further randomised controlled trials with long follow-up are required.

PLAIN LANGUAGE SUMMARY

Treatment for prominent lower front teeth in children

Review question

There are many different ways of treating patients with prominent (or sticking out) lower front teeth. Orthodontic treatment for children and adolescents is one method used. This review, carried out by authors of the Cochrane Oral Health Group, sought to establish which is the most effective type of orthodontic treatment when carried out in childhood; whether these treatments reduce the need for treatment as an adult; and at what age these treatments are best carried out to ensure that changes made to the shape of the jaw and the positioning of the teeth last until the end of growth and can be maintained into adulthood.

In severe cases, people may need surgery as adults to correct this condition. If a successful approach to treatment in childhood were to be found, with long-lasting effects, this kind of surgery may not be necessary. Additionally, the risk of damage to teeth and joints, together with the negative psychological effects associated with the condition, could be lessened or avoided.

Background

Prominent lower front teeth can be an important problem for some people and are usually due to the way the jaws meet together. This condition may be the source of teasing, problems eating, and occasionally problems with speech. The condition may also give rise to problems with the jaw joints in later life. Orthodontic treatment relies on the use of appliances of various kinds either inside or outside of the mouth that are fixed in some way to the teeth, and sometimes placed on parts of the head, to influence the growth of the jaws and position of teeth.

This review looked at the use of four different types of orthodontic treatment for correcting prominent lower front teeth in children.

-Facemask: an appliance rests on the forehead and chin, connected to the upper teeth with elastic bands that are placed by the wearer. Through this arrangement a balanced force is applied, which it is hoped will pull the upper teeth and jaw forwards and downward to correct the prominent lower teeth.

-Chin cup: an appliance rests on the chin with a strap around the back of the head. Forward growth of the lower jaw is resisted, correcting the prominence of the lower front teeth. Nothing is placed in the mouth.

-Mandibular headgear: a strap rests on the back of the head and is connected to the lower teeth. This resists forward growth of the lower teeth and jaw in order to correct the prominent lower front teeth.

-Tandem traction bow appliance: attachments are fixed to the top and bottom teeth. In the top attachment there is a hook on each side. A metal bar is placed in the lower attachment, which sits in front of the lower teeth. An elastic band can then be placed on each side to pull the top jaw forward and bottom jaw backwards, to correct the prominent lower teeth.

Study characteristics

The evidence on which this review is based was found to be up to date as of 7 January 2013.

A total of seven suitable studies were identified and included in this review; they included 339 children aged from five to 11 years. There were roughly equal numbers of girls and boys in each study and participants were from different ethnic groups depending on where the study was carried out. Studies included were conducted in Turkey, Egypt, China, the United States of America and the United Kingdom.

Key results

This review found some evidence that the use of a facemask appliance can help to correct prominent lower front teeth on a short-term basis. There was no evidence available to show whether or not these short-term changes will still be maintained until the child is fully grown. There was not enough evidence to support any other types of treatment for prominent lower front teeth.

Quality of the evidence

The quality of the evidence for the use of a facemask was moderate to low, whilst the quality of the rest of the evidence was very low.

SUMMARY OF FINDINGS FOR THE MAIN COMPARISON [Explanation]

Facemask compared to no treatment for prominent lower front teeth in children

Patient or population: children with prominent lower front teeth
Settings: dental hospital
Intervention: facemask
Comparison: no treatment

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	No treatment	Facemask				
Overjet - 1 year treatment Follow-up: at end of treatment		The mean overjet - 1 year follow-up in the intervention groups was **4.1 higher** (3.04 to 5.16 higher)		69 (1 study)	⊕⊕⊕◯ **moderate**[1]	
Overjet - 1 year treatment Follow-up: mean 2 years post-treatment		The mean overjet - 3-year follow-up in the intervention groups was **2.5 higher** (1.21 to 3.79 higher)		63 (1 study)	⊕⊕⊕◯ **moderate**[1]	
ANB - 1 year follow-up Follow-up: mean 1 year		The mean ANB - 1 year follow-up in the intervention groups was **3.93 higher** (3.46 to 4.39 higher)		155 (3 studies)	⊕⊕◯◯ **low**[2,3]	

ANB - 3-year follow-up		The mean ANB - 3-year follow-up in the intervention groups was **1.4 higher** (0.43 to 2.37 higher)	63 (1)	⊕⊕⊕○ **moderate**[1]

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: confidence interval.

GRADE Working Group grades of evidence.
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

[1] Downgraded because only one study with this comparison reported overjet.
[2] Downgraded because one study at low risk of bias, and two at unclear risk of bias.
[3] Downgraded due to heterogeneity: $Chi^2 = 11.29$, degrees of freedom (df) = 2 (P value = 0.004); $I^2 = 82\%$

BACKGROUND

Description of the condition

Orthodontics is the branch of dentistry concerned with the growth of the jaws and face, the development of the teeth, and the way the teeth and jaws bite together. It also involves treatment of the teeth and jaws when they are irregular or bite in an abnormal way, or both. There are many reasons why the teeth may not bite together correctly. These include the position of the teeth, jaws, lips, tongue and/or cheeks, or may be due to a habit or the way people breathe. All of these factors can be influenced by genetics or by the environment. The need for treatment can be decided by looking at the effect of any particular tooth position on the life expectancy of the teeth or the effect that the appearance of the teeth has on how people feel about themselves, or both (Shaw 1991).

Prominent lower front teeth (termed reverse bite; under bite; Class III malocclusion) may be due to a combination of the jaw or tooth position, or both, resulting from genetic factors or environmental influence or both. The upper jaw (maxilla) can be too far back or the lower jaw (mandible) too far forward, or both. Prominent lower front teeth can also occur if the upper front teeth (incisors) are tipped back or the lower front teeth are tipped forwards or both. Prominent lower front teeth can give a person an aggressive appearance, which may be the source of teasing (Shaw 1980). Patients with prominent lower front teeth often report that they have problems eating, and occasionally problems with speech. Prominent lower front teeth can give rise to problems with the jaw joints in later life (Mohlin 1980). Prominent lower front teeth are most common in oriental (15%) and black races (10%) and are relatively uncommon in Caucasian (4%) populations (el-Mangoury 1990; Proffit 1993; Silva 2001). Prominent lower front teeth are usually due to the way the jaws meet together with either the upper jaw being too small, the lower jaw being too large, or a combination of both.

Description of the intervention

Several dental brace (orthodontic) treatments have been suggested to correct prominent lower front teeth. Some treatments aim to tip the upper front teeth forwards and the lower front teeth backwards whilst others aim to modify the growth of the upper or lower jaw or both to reduce or correct the prominence of the lower front teeth. Treatment can involve the use of one or more types of orthodontic brace. Some braces apply a force directly to the teeth and can either be removed from the mouth or fixed to the teeth with special glue during treatment. Other types of brace are attached, via the teeth, to devices (for example chin cup, reverse headgear, facemask) that allow a force to be applied to the teeth and jaws from the chin or forehead, or both. A further, more recently described technique has been the use of bone-anchors surgically placed to the jaw bones prior to activation with elastics (De Clerck 2010). Treatment is usually carried out either early, when the patients have a mixture of their baby and adult teeth present (around seven to 11 years of age), or later when all the adult teeth have come into the mouth (around 12 to 16 years of age). However, in some cases treatment is carried out early, before six years of age, when the patients only have their baby teeth present or later when the patient is an adult. In severe cases, and with some adult patients, orthodontic treatment may need to be combined with jaw surgery to correct the position of one or both jaws.

How the intervention might work

There are several ways in which the intervention may correct the prominence of the lower front teeth. It may move the top jaw forwards, the top teeth forwards, the bottom jaw backwards, the bottom teeth backwards, or often a combination of these factors. Some interventions may also have an influence on the vertical position of the jaws, which in turn influences the antero-posterior position of the jaws due to the rotation of the jaws during growth.

Why it is important to do this review

There is currently a multitude of different appliances available to try to correct the prominence of lower front teeth in children. There is, however, little consensus as to which of these approaches may be best. There is also little known about the long-term effects of these approaches. If a successful approach that has effects that last until the end of growth could be found this may prevent the need for surgical treatment when the patient is older.

OBJECTIVES

To assess the effects of orthodontic treatment for prominent lower front teeth in children and adolescents.

METHODS

Criteria for considering studies for this review

Types of studies

All randomised controlled trials of orthodontic treatments to correct prominent lower front teeth.

Types of participants

Studies were eligible for inclusion in the review if they had recruited children or adolescents or both (age 16 years or less) receiving orthodontic treatment to correct prominent lower front teeth. Studies including patients with a cleft lip or palate or both, or other craniofacial deformity or syndrome, were excluded as were studies that had recruited less than 80% children or adolescents as participants, or patients who had previously received surgical treatment for their prominent lower front teeth.

Types of interventions

Active interventions: orthodontic braces (removable, fixed, functional), chin cups, facemasks, reverse headgear, bone-anchored appliances, or any other intra or extra-oral appliance aimed at correcting prominent lower front teeth.
Control: may be no treatment, delayed treatment, or another active intervention.

Types of outcome measures

Primary outcomes

Prominence of the lower front teeth (measured in mm or by any index of malocclusion).

Secondary outcomes

Relationship between upper and lower jaw:

- psychosocial measures;
- patient satisfaction;
- jaw joint problems.

Adverse effects: health of the gums (gingivae); damage to the teeth (e.g. tooth decay).
Outcomes were recorded at all the ages reported. The results were reported according to the most common endpoints. Adverse effects were recorded and the results reported in descriptive terms.

Search methods for identification of studies

For the identification of studies to be included or considered for this review, we developed detailed search strategies for each database searched. These were based on the search strategy developed for MEDLINE (OVID) but revised appropriately for each database. The search strategy used a combination of controlled vocabulary and free text terms and was linked with the Cochrane Highly Sensitive Search Strategy (CHSSS) for identifying randomised trials (RCTs) in MEDLINE: sensitivity maximising version (2008 revision) as referenced in Chapter 6.4.11.1 and detailed in box 6.4.c of the *Cochrane Handbook for Systematic Reviews of Interventions* Version 5.1.0 (updated March 2011) (Higgins 2011).

Details of the MEDLINE search are provided in Appendix 3. The search of EMBASE was linked to the Cochrane Oral Health Group filters for identifying RCTs (Appendix 4).

Databases searched

The following databases were searched.

- The Cochrane Oral Health Group's Trials Register (to 7 January 2013) (Appendix 1).
- The Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library* 2012, Issue 12) (Appendix 2).
- MEDLINE via OVID (1946 to 7 January 2013) (Appendix 3).
- EMBASE via OVID(1980 to 7 January 2013) (Appendix 4).

Handsearching

Only handsearching done as part of the Cochrane Worldwide Handsearching Programme and uploaded to CENTRAL was included (see the Cochrane Masterlist for details of journal issues searched to date).
The bibliographies of the clinical studies that were identified were checked for references to studies published outside the handsearched journals.
Personal references were checked.

Language

Databases were searched to include all languages and non-English language papers were translated.

Data collection and analysis

Selection of studies

The titles and abstracts of the search results were examined to remove obviously irrelevant reports. This was done by two of the review authors (either Simon Watkinson (SW), Jayne Harrison (JH) or Sue Furness (SF)) independently and in duplicate. Disagreements were resolved by discussion between these review authors. If arbitration was required, it was provided by Annabel Teague (AT).
Full text reports of potentially eligible studies were examined for compliance with the eligibility criteria. This was performed by two review authors (SW, JH or SF) independently and in duplicate. We corresponded with investigators, where appropriate, to clarify study eligibility. Disagreements were resolved by discussion between these review authors. If arbitration was required, it was

provided by AT. If additional information was required, the corresponding author of the study was contacted and the study categorised as awaiting assessment. The study eligibility process was performed with the aid of a piloted study eligibility form.
A list of excluded studies was recorded, giving the primary reason for exclusion, following the screening of the titles and abstracts stage.

Data extraction and management

Data extraction was performed independently and in duplicate by two review authors (SW, JH or SF). A piloted data extraction form was used independently to record the year of publication, interventions assessed, outcomes, adverse effects, sample size and age of the participants.
Outcome data were grouped into those measured immediately after treatment and those measured at any other times reported.

Assessment of risk of bias in included studies

The Cochrane risk of bias tool was used to assess the methodological quality of the studies. This was undertaken independently and in duplicate by two review authors (SW, JH or SF) as a part of the data extraction process. Six specific domains were investigated: sequence generation; allocation concealment; blinding of participants, personnel and outcome assessors; incomplete outcome data; selective outcome reporting; and 'other sources of bias'.
Each domain was given a judgement that could be high, low, or unclear. 'High' indicated a high risk of bias, 'Low' a low risk of bias, and 'Unclear' indicated an unclear or unknown level of bias. The risk of bias tool was applied as described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). Sequence generation was assessed for the study as a whole. Blinding, incomplete outcome data and selective outcome reporting were assessed at the level of the study and for each outcome as appropriate.

Measures of treatment effect

The Cochrane Collaboration statistical guidelines were followed and the data analysed using Review Manager (RevMan) 5 software (RevMan 2012) and reported according to Cochrane Collaboration criteria.
For dichotomous data, the estimates of the effect of an intervention would have been expressed as risk ratios together with 95% confidence intervals.
For continuous outcomes, mean differences and 95% confidence intervals were used to summarise the data for each group where the mean differences and standard deviations were calculable from the data presented.

Dealing with missing data

If there were any missing data, an attempt was made to contact the original study investigators. A study was not excluded from the review because of missing summary data, however the potential implications of their absence from any meta-analysis were discussed.

Assessment of heterogeneity

Clinical heterogeneity was assessed by examining the type of participants, interventions and outcomes in each study. Meta-analysis was only used when studies of similar comparisons reported comparable outcome measures. A random-effects model was planned for use for all analyses with more than three studies, otherwise a fixed-effect model was used. The I^2 statistic was used as a measure of statistical heterogeneity.

Assessment of reporting biases

Only a proportion of research projects conducted are ultimately published in an indexed journal and so become easily identifiable for inclusion in systematic reviews. Reporting biases arise when the reporting of research findings is influenced by the nature and direction of the findings of the research (Easterbrook 1991). We investigated and attempted to minimise potential reporting biases including publication bias, multiple (duplicate) publication bias and language bias in this review.
If there were more than 10 studies for one outcome we planned to construct a funnel plot. If there was asymmetry in the funnel plot, indicating possible publication bias, we planned to undertake statistical analysis using the methods introduced by Egger 1997 (continuous outcome) and Rücker 2008 (dichotomous outcome). Insufficient studies were identified to investigate reporting biases.

Data synthesis

A random-effects meta-analysis, using the inverse variance method, was planned for use with all primary and secondary outcomes, for all analyses with more than three studies. Studies of each intervention were analysed and presented separately.
A general framework for data synthesis was used to report the adverse effects. The following questions were considered when analysing these effects.

- What was the size of the effect?
- Was the effect consistent across studies?
- What was the strength of evidence for the effect?

Subgroup analysis and investigation of heterogeneity

We planned to investigate clinical heterogeneity by examining: the nature of the interventions; ages, background and number of participants; and reported outcomes. No subgroup analyses were planned.

Sensitivity analysis

Providing there were sufficient studies for each intervention and outcome, we planned to undertake sensitivity analysis based on risk of bias (including low risk of bias studies only).

Presentation of main results

A summary of findings table was developed for the primary outcomes of this review using GRADEPro software. The quality of the body of evidence was assessed with reference to the overall risk of bias of the included studies; the directness of the evidence; the consistency of the results; the precision of the estimates; the risk of publication bias; and the magnitude of the effect. The quality of the body of evidence for each of the primary outcomes was categorised as high, moderate, low or very low, and summary of findings tables have been produced for the main outcomes of this review.

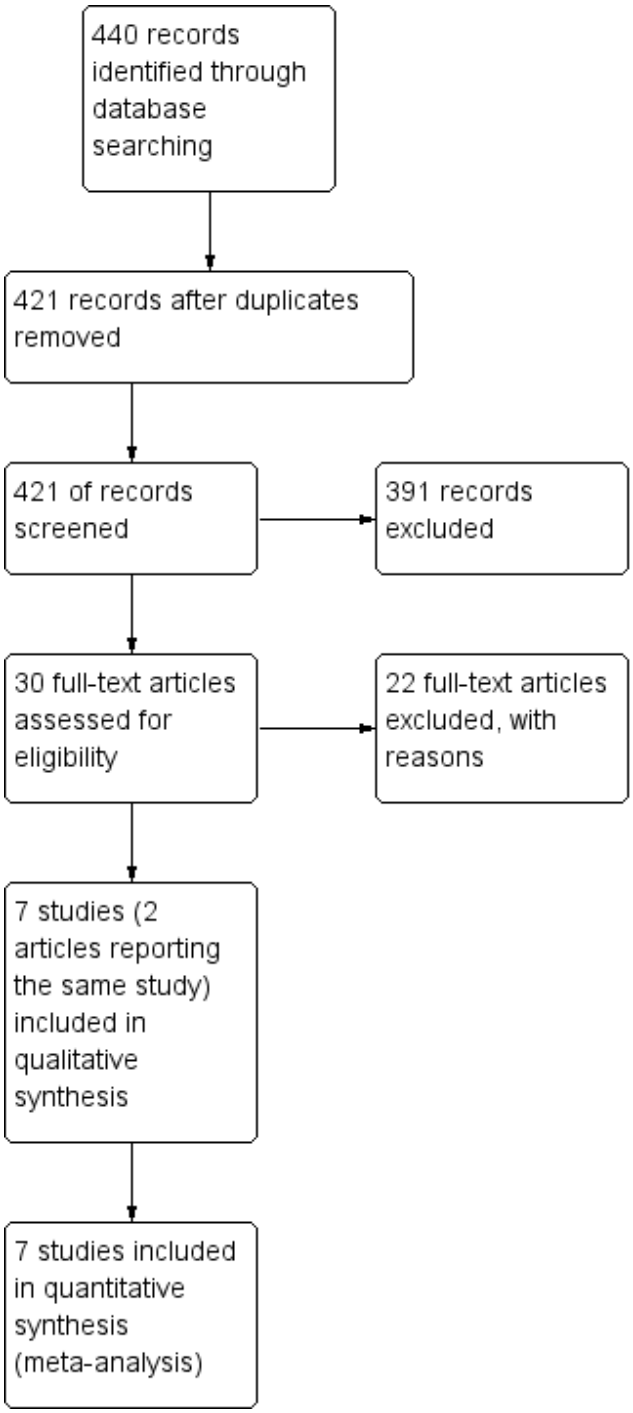
RESULTS

Description of studies

Results of the search

The database search identified 440 articles. Of these 19 were duplicates. Of the remaining 421, 391 were discarded during the screening of the titles and abstracts. Of the remaining 30 articles, for which the full text was examined, 22 were excluded leaving eight included articles two of which were reporting the outcomes of the same study, at different time points, leaving seven randomised controlled trials (RCTs) to be included in this review (Figure 1).

Figure 1. Study flow diagram.



Included studies

Seven studies were included in this review. All studies were parallel group randomised controlled trials. Three studies were conducted in Turkey (Arun 1994; Atalay 2010; Keles 2002), one in Egypt (Abdelnaby 2010), one in the United Kingdom (Mandall 2010), one in the United States of America (Vaughn 2005) and one in China (Xu 2001). Six studies reported outcome data solely immediately post-treatment. One study had outcomes reported at both 15 months and three years after the start of treatment (Mandall 2010) (Characteristics of included studies).

Characteristics of the study setting and investigators

All of the included studies were conducted in college or university orthodontic departments. Six of the studies were carried out in a single institution (Abdelnaby 2010; Arun 1994; Atalay 2010; Keles 2002; Vaughn 2005; Xu 2001) and one in eight centres in the same country (Mandall 2010).
Orthodontists provided the care for the children in all the studies.
Only one paper (Vaughn 2005) stated they had two operators, the remainder did not disclose the number of operators.
Only one study (Mandall 2010) disclosed external funding.

Characteristics of the participants

All studies were conducted on children aged between five and 11 years. They were from different ethnic backgrounds, which were dependant on the study setting. There were between 20 (Keles 2002) and 73 (Mandall 2010) children included in the seven studies, with a median of 46. Approximately equal numbers of boys and girls were included in each study.

Characteristics of the interventions

Four different types of intervention were compared with an untreated control group in the seven included studies. Control groups had either no treatment or delayed treatment. As such, during the experimental period patients in the control groups received no active treatment and were solely monitored for natural growth and development. The comparisons were the following.

- Facemask versus untreated control (Mandall 2010; Vaughn 2005; Xu 2001).
- Facemask with expansion versus facemask only (Vaughn 2005).
- Nanda facemask versus conventional facemask (Keles 2002).
- A 600 g chin cup versus 300 g chin cup versus untreated control (Abdelnaby 2010).
- Tandem traction bow appliance versus untreated control (Atalay 2010).
- Mandibular headgear versus chin cup versus untreated control (Arun 1994).

Characteristics of the outcomes

Five outcomes were presented in the results for the seven included studies.

- Overjet (Atalay 2010; Mandall 2010).
- ANB (Abdelnaby 2010; Arun 1994; Atalay 2010; Keles 2002; Mandall 2010; Vaughn 2005; Xu 2001).
- Wits appraisal (Abdelnaby 2010; Vaughn 2005).
- Piers Harris children's self concept scale (Mandall 2010).
- Oral Aesthetic Subjective Impact Score (OASIS) (Mandall 2010).

Excluded studies

Of the 22 excluded studies:

- 13 were excluded as they were not RCTs;
- six used retrospective control groups;
- one was entirely retrospective;
- one did not report an outcome of interest to this review;
- one reported outcomes for patients over the age of 16 years.

Risk of bias in included studies

Allocation

Sequence generation

Sequence generation was adequate for four of the studies (Arun 1994; Atalay 2010; Mandall 2010; Vaughn 2005) and unclear for the remaining studies. Whilst the Arun 1994 and Atalay 2010 papers were unclear in the text, contact with the authors revealed the use of a random number generator for patient assignment on registration to the study. Mandall 2010 used randomisation blocks of 10 with stratification according to gender and a computer generated randomisation sequence. Vaughn 2005 also used a block randomisation table to assign participants to one of the three groups. The remaining papers did not mention how a sequence was generated and no response has been received from the authors for further clarification.

Allocation concealment

Allocation concealment was adequate in only one of the included studies, Mandall 2010, who used a sequence that was concealed centrally and each clinician telephoned the research assistant for allocation once the patient was registered. It was unclear for four of the studies (Abdelnaby 2010; Keles 2002; Vaughn 2005; Xu 2001) in which there was no mention of allocation concealment in the articles and there has been no response from the authors providing clarification. There was a high risk of bias from the remaining two articles (Arun 1994; Atalay 2010), with whom contact was made and they disclosed that no allocation concealment was used.

Blinding

The blinding of participants would not have been possible in six of the seven studies due to the nature of the treatments in comparison with other treatments and the untreated controls. However, it may have been possible to blind patients in the Abdelnaby 2010 study, which compared the strength of force of the chin cups. No mention of an attempt to do this was mentioned in the paper and the author has not responded to clarify the situation.
The blinding of the personnel taking part in the studies would not have been possible due to the nature of the treatments being used.
The blinding of the outcome assessment would have been possible in all cases as cephalometric measures were used as outcomes in all studies. There was a low risk of bias in the Mandall 2010 study in which the researchers measuring the radiographs and study models, as well as the statistician, were all blinded. There was also low risk of bias in the Vaughn 2005 study as the principal investigator carrying out the analysis was blinded to the patient assignment. The blinding of outcome assessment was unclear in the Abdelnaby 2010; Keles 2002 and Xu 2001 studies in which no mention of blinding was made and no response from the authors has been received to clarify this. The authors of Arun 1994 and Atalay 2010 confirmed that there were no attempts at blinding at any stage in these studies and therefore the risk of bias was high.

Incomplete outcome data

There was a low risk of attrition bias for the Arun 1994; Atalay 2010; Mandall 2010 and Xu 2001 studies as the participants included in the analysis were exactly those randomised in the study. The number of drop-outs in the remaining three studies (Abdelnaby 2010; Keles 2002; Vaughn 2005) was unclear and the authors have not responded to clarify the question, so the risk of attrition bias in these studies was assessed as unclear.

Selective reporting

There was a low risk of reporting bias for all studies. All studies reported on the outcomes that they set out to report and there were no obvious anomalies.

Other potential sources of bias

The Abdelnaby 2010 study stated that the groups were randomly allocated yet there were 20 patients in groups 1 and 2 and only 10 in group 3. Clarification on the exact method of randomisation has not been possible as the author has not responded to our contact, however this leads to an assumption of high risk of bias.
The authors of the Arun 1994 and Atalay 2010 studies have clarified all our questions regarding other bias, and these have been assessed as at low risk of other bias.
The Mandall 2010 paper disclosed that some patients included in this study had a centric relation to centric occlusion displacement. This may have influenced the perception of the skeletal discrepancy from the lateral cephalogram. The actual effects of this on the results were unclear. Therefore, this has resulted in a decision to classify this study as at unclear risk of bias.
There were no other obvious potential sources of bias for the Keles 2002 or Vaughn 2005 studies.

Overall risk of bias

The study by Mandall 2010 showed overall low risk of bias. Three studies (Abdelnaby 2010; Arun 1994; Atalay 2010) were assessed at high risk of bias due to the absence of allocation concealment, blinding of outcome assessment (Arun 1994; Atalay 2010) and inadequate randomisation (Abdelnaby 2010). The remaining three studies (Keles 2002; Vaughn 2005; Xu 2001) were assessed as having unclear risk of bias (Figure 2; Figure 3).

Figure 2. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

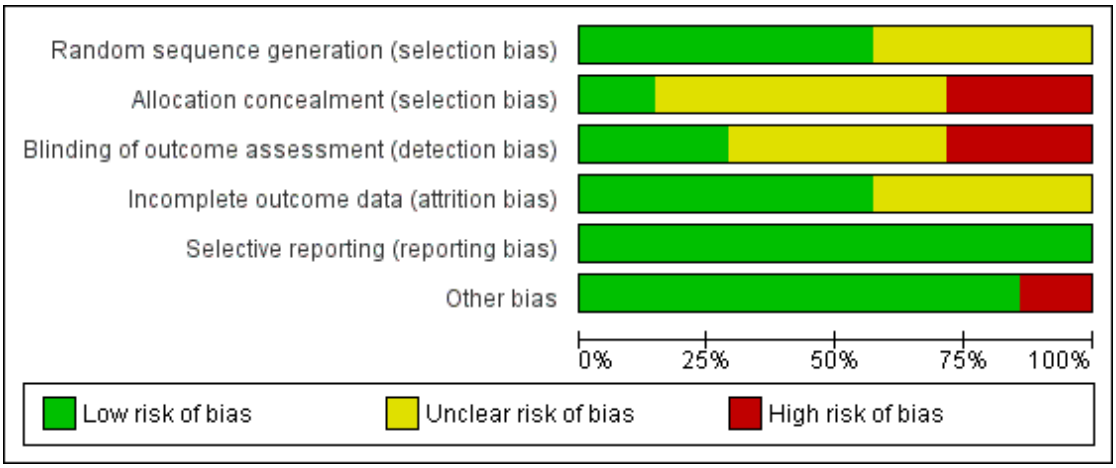
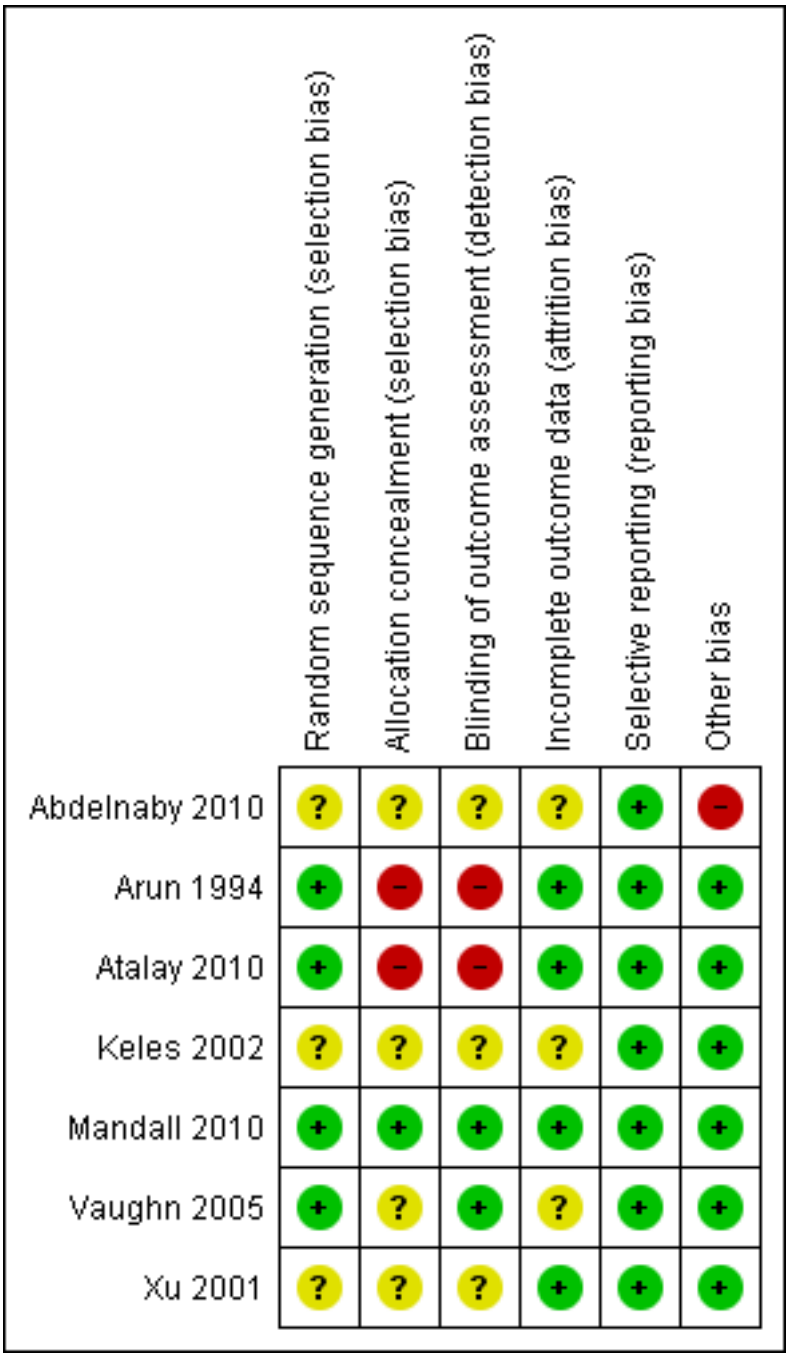


Figure 3. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.



Effects of interventions

See: **Summary of findings for the main comparison** Facemask compared to no treatment for prominent lower front teeth in children; **Summary of findings 2** Chin cup compared to no treatment for prominent lower front teeth in children; **Summary of findings 3** Tandem traction bow appliance compared to no treatment for prominent lower front teeth in children

There were eight comparisons in the seven included studies. The results for each comparison are summarised below. Any results for a comparison including a single study are given in Additional Table 1, with forest plots being shown for the only comparison with more than one study.

Facemask versus untreated control

Three studies (n = 179) investigated the use of a facemask versus an untreated control (Mandall 2010; Vaughn 2005; Xu 2001). We have combined the results from the study using the facemask with and with out rapid maxillary expansion as these groups showed no statistical difference (see later) (Vaughn 2005). The only outcome considered by all three studies was ANB. The Mandall 2010 study also assessed overjet and self esteem measures whilst Vaughn 2005 also assessed Wits appraisal (another measure of the relative positions of the maxilla and mandible). The Mandall 2010 study reported outcomes at the end of treatment and at three years follow-up.

Overjet

One study reported overjet (Mandall 2010) and found a statistically significant difference of 4.10 mm (95% confidence interval (CI) 3.04 to 5.16; P value < 0.0001) in favour of the facemask post-treatment. The study also found a statistically significant difference of 2.50 mm (95% CI 1.21 to 3.79; P value = 0.0001) at three years follow-up.

ANB

Three studies included the outcome ANB (Mandall 2010; Vaughn 2005; Xu 2001) and it was possible to undertake a meta-analysis at the post-treatment stage. The pooled estimate was 3.93 ° (95% CI 3.46 to 4.39; P value < 0.0001) in favour of the facemask. There was substantial heterogeneity (P value = 0.004; I^2 = 82%) between the studies, which may have been due to several factors including: different inclusion criteria, different ethnic groups, different populations, and different ages of the patients at the start of treatment. However, each study demonstrated a statistically significant benefit for the facemask and we thought it appropriate to pool the results. The random-effects model gave rise to a similar estimate of 3.70 ° (95% CI 2.50 to 4.91; P value < 0.0001) compared to the fixed-effect model.

One study assessed ANB at three years follow-up (Mandall 2010) and found that a statistically significant benefit persisted in favour of the facemask (mean difference (MD) 1.4 °, 95% CI 0.43 to 2.37; P value = 0.004).

Wits appraisal

One study looked at Wits appraisal (Vaughn 2005) and showed a benefit in favour of the facemask of -3.84 mm (95% CI -5.31 to -2.37; P value < 0.0001).

Self esteem

There was no difference between the facemask and untreated control groups in the Mandall 2010 study in the outcome of self esteem measured on the Piers-Harris self esteem index at either the post-treatment or three years follow-up time points (Additional Table 1).

The OASIS assessment of self esteem, however, did demonstrate a statistically significant benefit for the facemask at the post-treatment stage of -4.00 (95% CI -7.40 to -0.60; P value = 0.02). However, there was no significant difference at three years follow-up (MD -3.40, 95% CI -7.99 to 1.19; P value = 0.15).

Adverse effects

One study (Mandall 2010) reported on temporomandibular joint (TMJ) signs and symptoms. These were assessed by looking at pain (lateral and intra-auricular), clicking, crepitus, locking, muscle tenderness (temporalis, masseter, and lateral pterygoid), and restriction of jaw movement (maximum opening and lateral movement). In addition, the presence of forward mandibular displacement on closure was recorded. It was noted that due to the low prevalence of TMJ signs and symptoms at all time points no statistical analysis was carried out.

Facemask with expansion versus facemask only

Only one study (n = 46) compared the facemask with and without expansion (Vaughn 2005). There was no evidence of a difference between treatment using a facemask with or without the use of rapid maxillary expansion for the outcomes of ANB (MD -0.13 °, 95% CI -1.40 to 1.14; P value = 0.84) and Wits appraisal (MD -0.16 mm, 95% CI -1.63 to 1.31; P value = 0.83) (Analysis 2.1; Analysis 2.2; Additional Table 1).

Nanda facemask versus conventional facemask

Only one study (n = 20) compared the Nanda facemask versus a conventional facemask (Keles 2002). There was weak evidence of a difference in ANB between the groups using each design of facemask in favour of the Nanda facemask (MD 1.29 °, 95% CI 0.16 to 2.42; P value = 0.02) (Analysis 3.1; Additional Table 1).

Chin cup versus control

Two studies (n = 90) compared the chin cup with an untreated control group in three-arm studies (Abdelnaby 2010; Arun 1994). Both studies showed that the chin cup improved ANB and Wits appraisal when compared to the untreated control (Analysis 4.1; Analysis 4.2; Additional Table 1). However, the results were not meta-analysed as we were unable to use the data from one of the studies (Arun 1994).

Chin cup 600 g versus 300 g

Outcome data on use of 600 g versus 300 g were reported in one study (Abdelnaby 2010). There was no difference in ANB (MD 0.10 °, 95% CI -0.31 to 0.51; P value = 0.63) or Wits appraisal (MD -0.30 mm, 95% CI -1.12 to 0.52; P value = 0.47) (Analysis 5.1; Analysis 5.2; Additional Table 1).

Mandibular headgear versus chin cup

One study (n = 60) provided outcome data for ANB. However, no standard deviations were given and P values from the Mann-Whitney test were presented (Arun 1994) so we were unable to use the data (Analysis 7.1). There was no statistically significant difference between the two active interventions (P value > 0.05).

Mandibular headgear versus untreated control

One study (n = 60) comparing mandibular headgear with control provided data for ANB (Arun 1994). We were unable to use the data since standard deviations were not reported; however, P values for the Mann-Whitney test showed that mandibular headgear provided a statistically significant benefit for ANB compared to the control (P value < 0.001).

Tandem traction bow appliance versus untreated control

One study (n = 30) compared the Tandem traction bow appliance versus control (Atalay 2010). Two outcomes, overjet and ANB, were reported and both demonstrated a statistically significant benefit in favour of the Tandem traction bow appliance: overjet 3.30 mm (95% CI 2.46 to 4.14; P value < 0.0001); ANB 1.70 ° (95% CI 1.09 to 2.31; P value < 0.0001) (Analysis 6.1).

ADDITIONAL SUMMARY OF FINDINGS *[Explanation]*

Chin cup compared to no treatment for prominent lower front teeth in children

Patient or population: children with prominent lower front teeth
Settings: dental hospital
Intervention: chin cup (300 g, 600 g or 480 to 500 g)
Comparison: no treatment

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	No treatment	Chin cup				
Chin cup **ANB** Follow-up: mean 1 year	No treatment	See comment		90[1] (2 studies)	⊕○○○ **very low**	2 studies: Unable to pool data, however, a statistically significant benefit was found for ANB. Insufficient evidence from 2 studies at high risk of bias to determine whether or not chin cup is an effective treatment

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: confidence interval.

GRADE Working Group grades of evidence.
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

[1] Downgraded because both studies were at high risk of bias with only one study providing outcome data.

Tandem traction bow appliance compared to no treatment for prominent lower front teeth in children

Patient or population: children with prominent lower front teeth
Settings: dental hospital
Intervention: Tandem traction bow appliance
Comparison: control

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	No Treatment	Tandem traction bow appliance				
Overjet at end of 1 year of treatment		The mean overjet in the intervention groups was **3.3 higher** (2.46 to 4.14 higher)		30[1] (1 study)	⊕○○○ **very low**	Insufficient evidence from a single study at high risk of bias to determine whether or not tandem traction bow is an effective treatment
ANB at end of 1 year of treatment		The mean ANB in the intervention groups was **1.7 higher** (1.09 to 2.31 higher)		30[1] (1 study)	⊕○○○ **very low**	Insufficient evidence from a single study at high risk of bias to determine whether or not tandem traction bow is an effective treatment

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: confidence interval.

GRADE Working Group grades of evidence.
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Very low quality: We are very uncertain about the estimate.

[1] Downgraded because only one small study at high risk of bias reported this outcome.

DISCUSSION

Summary of main results

Facemask therapy

We found some evidence that facemask therapy was more effective at improving overjet, ANB and Wits appraisal immediately post-treatment when compared with an untreated control. The improvements in overjet and Wits appraisal were still statistically significant at three years follow-up, although reduced in comparison to the changes immediately post-treatment. These changes remained of clinical significance. Whilst immediately following treatment there was a statistically significant improvement in the OASIS score, there was no evidence that facemask treatment produced clinically important changes in patients' self esteem measures.

There was insufficient evidence to determine whether there was a difference between the outcomes reported in a comparison between facemask with and without the use of rapid maxillary expansion from the single small study which evaluated this comparison. Therefore, its use solely as an adjunct to improve the efficacy of facemask therapy can not be recommended.

One study (Keles 2002) compared the use of a Nanda facemask (force applied at parallel to the Frankfort plane at a level 20 mm above the occlusal plane) with a conventional facemask (force applied at 30 ° at the level of the occlusal plane). This very small study showed weak evidence of a difference in ANB between the two appliances in favour of the Nanda facemask, however, due to the size of the study and its risk of bias, no recommendation can be made to support one design over the other.

The ultimate aim of facemask treatment is to correct the jaw discrepancy at an early stage so reducing the need for any orthognathic surgical intervention at a later stage. It must be noted that only one published study has reported data beyond the end of orthodontic treatment (Mandall 2010) and this only at three years follow-up, so no evidence was found for a long-term benefit for facemask therapy beyond three years.

Only one study (Mandall 2010) reported on adverse effects and showed no changes in TMJ signs and symptoms as a result of facemask therapy.

Chin cup therapy

We found two studies (Abdelnaby 2010; Arun 1994) showing evidence that the use of a chin cup led to statistically significant benefit in ANB when compared to an untreated control. A meta-analysis was not possible due to missing data from one study (Arun 1994). Again, the studies were short-term and there was no evidence of any long-term benefit.

There was no statistically significant difference found between the use of 300 g and 600 g forces when used with the chin cup.

Tandem traction bow appliance (TTBA)

One study (Atalay 2010) reported results on the use of the TTBA when compared with an untreated control. It showed that there was a statistically significant benefit in favour of the TTBA. Again, the study was short-term and there was no evidence for long-term benefit.

Mandibular headgear

One study (Arun 1994) reported results on the use of mandibular headgear compared to an untreated control and the chin cup. Statistical analysis was not possible due to missing data, however it was reported that there was significant benefit in favour of the mandibular headgear with respect to ANB when compared to the untreated control. There was no statistically significant difference between the mandibular headgear and the chin cup.

Overall completeness and applicability of evidence

Overall, seven studies were found investigating multiple comparisons to treat prominent lower front teeth in children; they reported multiple outcomes. Four of the studies investigated the facemask, two the chin cup, one the Tandem traction bow appliance and one mandibular headgear. Only one study investigated outcomes beyond the treatment phase and, to date, that was only at three years follow-up. This has major implications for the applicability of the evidence. An aim of early intervention for a Class III malocclusion is to prevent subsequent need for corrective orthognathic surgery. The current evidence does not allow us to assess if any of the interventions have succeeded in this aim due to their short-term nature.

The concern of many patients seeking treatment for a Class III malocclusion is that their lower front teeth meet in front of their upper front teeth and therefore they have a reverse overjet. However, only two of the studies (Atalay 2010; Mandall 2010) reported overjet as an outcome.

Only one study (Mandall 2010) carried out an a priori sample size calculation and it is likely that the Keles 2002 and Vaughn 2005 studies were underpowered to find a difference between their facemask groups.

The lack of accurate reporting, especially with respect to unclear methodology and, in one case, missing statistical data, means much of the evidence was of low or very low quality and the results must be interpreted with caution.

Quality of the evidence

The overall quality of the evidence can be seen in the 'Summary of findings' tables (Summary of findings for the main comparison; Summary of findings 2; Summary of findings 3).

The evidence regarding overjet and ANB changes when comparing the use of a facemask with an untreated control has been graded as moderate. This implies that further research is likely to have an important impact on our confidence in the estimate of effect. It may change the estimate but is unlikely to overturn the direction of the effect.

All other comparisons and outcomes have been graded as a low or very low level of evidence. The reasons for this are the low number of studies and participants, the unclear or high risk of bias in these studies, and in the meta-analysis the high level of heterogeneity.

Potential biases in the review process

Bias has been reduced in this systematic review by using a broad, sensitive search of multiple databases with no restrictions on language. We have also searched for unpublished studies and data, and have included studies reported in all languages.

Agreements and disagreements with other studies or reviews

Five other reviews were found that reported on similar comparisons and outcomes to this study (de Toffol 2008; Dermaut 1996; Jager 2001; Kim 1999; Liu 2011).

de Toffol 2008; Jager 2001 and Kim 1999 all report the efficacy of the facemask with greater confidence than we have reported. The difference in confidence is due to the greater number of studies that the other systematic reviews have included. This discrepancy is due to the different inclusion criteria used in our systematic review when compared to the previous reviews. We have only included prospective randomised controlled trials, whilst the other reviews have included retrospective studies, which are more susceptible to bias.

The review by Kim 1999 supports the use of rapid maxillary expansion prior to facemask therapy, whilst we have found insufficient evidence to support this protocol. Again, the difference is due to the inclusion of retrospective studies in the previous review.

Liu 2011 reports on the efficacy of the chin cup appliance and agrees with our conclusion that there are insufficient data in the current studies to make clear recommendations regarding the efficacy of chin cup therapy.

Due to the lack of evidence we remain uncertain as to the benefits of any other appliances in the early treatment of prominent lower front teeth in children.

Implications for research

In view of the quality of the studies identified in this systematic review, it has been difficult to draw definitive conclusions. This review suggests the need for more long-term, well designed and reported randomised controlled clinical studies to assess the efficacy of early orthodontic treatment of prominent lower front teeth.

When designing future studies, the following need to be considered.

- Clear inclusion and exclusion criteria should be set.
- An a priori sample size calculation should be carried out.
- The use of outcomes relevant to the patient (not solely a list of cephalometric measures) should be used. We recommend the following:
    - overjet;
    - overjet change;
    - correction of an anterior crossbite;
    - ANB;
    - psychosocial measures.
- The following methodological points are recommended:
    - recording if there is a discrepancy between intercuspal position and retruded contact position;
    - all lateral cephalograms should be taken in the retruded contact position.
- Adverse effects should be reported.
- Long-term follow-up to assess fully if the treatment has been successful at the end of growth should be considered.
- Reports on clinical trials would be improved by following the guidelines produced by the CONSORT group to ensure that all relevant information is provided.

AUTHORS' CONCLUSIONS

Implications for practice

There is low quality evidence that the use of facemask therapy between the ages of six to 10 years leads to short-term improvements in overjet and ANB. There is insufficient high quality evidence to comment on the long-term benefits.

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Abdelnaby 2010

Methods	3-arm parallel randomised controlled trial
Participants	**Number recruited:** 50 growing patients (26 males and 24 females) **Mean age:** 9.7 years (range not given) **Inclusion criteria:** Patients had skeletal Class III (ANB < 1 °) and mandibular prognathism (SNB > 80 °) and an anterior crossbite. Assessed for skeletal maturation with hand-wrist radiographs and shown to have not passed the peak of the pubertal growth spurt **Exclusion criteria:** Not reported **Setting:** Recruited from the Faculty of Dentistry, Mansoura University, Mansoura, Egypt
Interventions	**Comparison:** 600 g chin cup versus 300 g chin cup versus untreated control Group 1: Occipital pull soft chin cup (Dentaurum, Ispringen, Germany) with an acrylic occlusal bite plane of a thickness that just freed the occlusion anteriorly. Force applied was 600 g force per side. Patients were instructed to wear the appliance for 14 hours each day (n = 20) Group 2: As above using 300 g per side (n = 20) Group 3: No orthodontic or orthopaedic treatment (n = 10)
Outcomes	All measures taken prior to treatment and after 1 year Outcomes relevant to the review: ANB
Notes	Sample size calculation was not described

Risk of bias ***Risk of bias***

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The method of randomisation was not described. Attempts were made to contact the authors for clarification but we are yet to receive a response
Allocation concealment (selection bias)	Unclear risk	The method of allocation concealment was not described. Attempts were made to contact the authors for clarification but we are yet to receive a response
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	There was no mention of blinding of the assessor. Attempts were made to contact the authors for clarification but we are yet to receive a response

Abdelnaby 2010 (*Continued*)

Incomplete outcome data (attrition bias) All outcomes	Unclear risk	There was no mention of any loss of patients during the study. Attempts were made to contact the authors for clarification but we are yet to receive a response
Selective reporting (reporting bias)	Low risk	The authors solely aimed to report on cephalometric measures and all were reported
Other bias	High risk	Stated that patients "randomly divided into three groups" however groups 1 and 2 have double the number of patients compared to group 3

Arun 1994

Methods	3-arm parallel randomised controlled trial
Participants	**Number recruited:** 60 patients (26 males and 34 females) **Mean age:** 8.23 years. Range 7.44 to 8.97 years **Inclusion criteria:** ANB < 2.5 °, Jarabak ratio greater than 59%, antegonial notch depth less than 2 mm **Exclusion criteria:** Not reported **Setting:** Treated in the Marmara University Dental Faculty, Turkey
Interventions	**Comparison:** Mandibular headgear versus chin cup versus untreated control Group 1: Mandibular headgear group: Prefabricated tubeless bands were thoroughly adapted to the lower molar teeth. They were then removed from the mouth and orthobuccal tubes were spot welded in the middle of their buccal surfaces. The bands were seated back on the molar teeth and a facebow, with downward facing U bends of its inner bow, was inserted in to the tubes. The desired force was applied to the facebow. The bands were cemented and the patients instructed to use their appliance 24 hours later. The outer bow was initially positioned parallel to the inner bow. Later, its arms were bent downwards in the parallel position (n = 20) Group 2: Chin cup group: Force directed obliquely on a line from the symphysis to the condyle. The head straps of the chin cup passed 1 cm above the earlaps in the temporal region and enwrapped the cranial vault. Topical application of the talcum powder was recommended in case the metal connections of the chin cup caused allergic reactions In both treatment groups, the first review was 1 week after the insertion of the appliance and thereafter at 3-week intervals. Both groups were advised to use the appliances 16 hours per day during the 1 year treatment period. Forces were maintained at 480-500 g in both groups. The effects of any anterior crossbite were eliminated and the mandibular distal movement freed from occlusal interferences through application of posterior bite planes (n = 20) Group 3: No treatment (n = 20)

Arun 1994 (*Continued*)

Outcomes	Open and closed mouth lateral cephalograms were taken of all 60 patients at the beginning and end of the 12-month treatment and control period. The condylion point was first traced on the open-mouth lateral cephalogram then, using its mandibular projection as a guide, it was superimposed on the closed-mouth lateral cephalogram on which 18 cephalometric points were selected for analysis Outcomes relevant to this review: ANB
Notes	Sample size calculation was not described

Risk of bias ***Risk of bias***

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Contact from author confirms that a random number generator was used for patient assignment on registration to the study
Allocation concealment (selection bias)	High risk	Contact from author confirms there was no allocation concealment used
Blinding of outcome assessment (detection bias) All outcomes	High risk	Contact from author confirms there was no blinding of any assessors during the study
Incomplete outcome data (attrition bias) All outcomes	Low risk	All patients completed the study and were included in the analysis
Selective reporting (reporting bias)	Low risk	All cephalometric measurements were recorded and analysed
Other bias	Low risk	Authors clarified all other queries

Atalay 2010

Methods	2-arm parallel randomised controlled trial
Participants	**Number recruited:** 30 patients (16 males and 14 females) **Mean age:** 8.04 years **Inclusion criteria:** Skeletal Class III (ANB < 0 °), due to maxillary retrusion, or a combination of maxillary retrusion and mandibular protrusion. Angle Class III malocclusion with an anterior crossbite. An optimum SN/GoGn angle (between 26 ° and 38 °). Fully erupted maxillary incisors **Exclusion criteria:** Congenitally missing teeth or congenital syndromes such as a cleft lip/palate. Previous orthodontic treatment **Setting:** Patients recruited from Gazi University, Turkey

Atalay 2010 (*Continued*)

Interventions	**Comparison:** Tandem traction bow appliance (TTBA) versus untreated control Group 1: The modified TTBA: After dental casts were obtained, a wax construction bite was obtained with a 5-6 mm vertical opening at the molar region and without any sagittal activation. The modified TTBA comprised an upper splint, a lower splint, and a traction bow. The upper splint had Adams' clasps in the posterior region for retention and elastic hooks between the maxillary central and lateral incisors. The upper splint covered the palatal and occlusal surfaces, in addition to 1-2 mm of the buccal surfaces of the maxillary teeth. The lower splint covered the buccal and lingual surfaces of the mandibular teeth. Activator tubes were embedded in the posterior region of the lower splint. A conventional headgear facebow was modified and used as the traction bow. The outer bows of the facebow were cut to approximately 3 cm and shaped as a letter 'S'. 2 elastics that exerted a force of 400-500 g on 1 side were worn between the labial hooks and the traction bow. The elastic force was directed between 35 ° and 40 ° to the occlusal plane by arranging the position of the outer traction bows. The patients were instructed to wear the appliance approximately 14-16 hours a day. The average treatment time for this group was 9 months (n = 15) Group 2: Control group: Observed without treatment for 8 months (n = 15)
Outcomes	Lateral cephalometric radiographs were taken before treatment and after a Class I molar relationship and a minimum overjet of 2 mm was obtained Pre- and post-treatment lateral cephalograms were traced by hand and measured by 1 author. 21 parameters were evaluated Outcomes relevant to this review: Overjet, ANB
Notes	Sample size calculation was not described

Risk of bias ***Risk of bias***

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Contact from author confirms the use of random sequence generator using the patient application numbers
Allocation concealment (selection bias)	High risk	Contact from author confirms no allocation concealment was used
Blinding of outcome assessment (detection bias) All outcomes	High risk	Contact from author confirms that no blinding of assessors was used
Incomplete outcome data (attrition bias) All outcomes	Low risk	All patients completed the study and were accounted for in the analysis
Selective reporting (reporting bias)	Low risk	All cephalometric measurements were recorded and analysed
Other bias	Low risk	Authors clarified all other queries

Keles 2002

Methods	2-arm parallel randomised controlled trial
Participants	**Number recruited:** 20 patients (10 males and 10 females) **Mean age:** 8.54 years. Range 7.3-10.9 years **Inclusion criteria:** Healthy patients without any hormonal or growth discrepancy. Anterior crossbite with Class III molar relationship. True Class III patients. Class III patients with maxillary retrognathism **Exclusion criteria:** Pseudo or functional Class III **Setting:** Recruited from Marmara University, Istanbul, Turkey
Interventions	**Comparison:** Nanda facemask versus conventional facemask Group 1: Facemask with modified angle of force direction (Nanda group): Composed of 3 parts: a modified full-cover acrylic cap splint expansion appliance, a specially designed facebow, and a Petit type protraction headgear. The cap splint expansion appliance was modified by adding 2 tubes (3M Unitek, USA, item no. 325-303) on the buccal side of the acrylic in the premolar area. The tubes were soldered to the RME screw (Leone, item A620-09) and the acrylic was constructed. The purpose of these tubes was to accommodate the inner bows of the specially designed facebow. The facebow was constructed from an adjustable facebow (Ormco, item 200- 0227 Glendora, CA, USA) . The inner bows of the facebow ended in the mouth with a special U-shaped bend in order to enter the buccal tubes from the distal, and thus be able to retain itself when an anterior pull was applied. In order to carry the level of force application above the occlusal plane, the outer bows of the facebow were bent in a 30 ° upward direction and ended with 2 hook bends in order to hold the elastics used for the facemask. These hooks were positioned around the root tips of the first and second premolars and 500 g of force was applied parallel to the Frankfort plane in an anterior direction. The same Petit-type facemask was used and the direction of the force was adjusted by moving the wire piece upward on the facemask for elastic engagement (n = 11) Group 2: Conventional facemask: This consisted of a cap splint-type rapid palatal expander modified by adding 2 hooks in the canine area. The purpose of these hooks was to hold the elastics in place for protraction. The protraction headgear was a Petit type (Ormco Corporation, Glendore, Calif), and a force of 500 g was applied to each hook at a 30 ° angle to the occlusal plane (n = 9) In both groups, treatment was started with 10 days of rapid maxillary expansion. Following the expansion, a facemask was applied to the patients of both groups and the appliance was used for 6 months after the onset of treatment. Patients were advised to wear the facemask for a minimum of 16 hours per day in the first 3 months and 12 hours in the second 3 months. In both groups a 500 g force was used. In group 1 the force was applied parallel to the Frankfort horizontal plane, in group 2 it was angled downward 30 ° to the occlusal plane
Outcomes	Lateral cephalometric films were taken both at the beginning and the end of treatment (6 months). 18 linear and angular cephalometric measurements were made for all patients Outcomes relevant to this review: ANB
Notes	Sample size calculation was not described

Risk of bias	***Risk of bias***

Keles 2002 (*Continued*)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The method of randomisation was not described. Attempts were made to contact the authors for clarification but we are yet to receive a response
Allocation concealment (selection bias)	Unclear risk	The method of allocation concealment was not described. Attempts were made to contact the authors for clarification but we are yet to receive a response
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	There was no mention of blinding of the assessor. Attempts were made to contact the authors for clarification but we are yet to receive a response
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	There was no mention of any loss of patients during the study. Attempts were made to contact the authors for clarification but we are yet to receive a response
Selective reporting (reporting bias)	Low risk	The authors solely aimed to report on cephalometric measures and all were reported
Other bias	Low risk	None detectable

Mandall 2010

Methods	2-arm parallel randomised controlled trial
Participants	**Number recruited:** 73 patients (34 males and 39 females) **Mean age:** 8.86 years **Inclusion criteria:** 7-9 years old at the time of registration. 3 or 4 incisors in crossbite in the intercuspal position. Clinical assessment of a Class III skeletal problem **Exclusion criteria:** Child of non-Caucasian origin. Cleft lip and palate and/or craniofacial syndrome. A maxillo-mandibular planes angle greater than 35 ° or lower face height greater than 70 mm. Previous history of TMJ signs or symptoms. Lack of consent **Setting:** Patients were recruited through UK orthodontic departments at 5 district general hospitals and 3 university teaching hospitals. Patient recruitment was optimised by writing to all general dental practitioners, who referred to each unit, explaining the type of patient we were looking to recruit. Additionally, the consultant orthodontist in each centre screened up to 5 local primary schools for suitable children in the 8-9 years old age group

Interventions	**Comparison:** Facemask versus untreated control Group 1: Facemask group: A bonded maxillary acrylic expansion device was placed. This consisted of a metal framework and a midline expansion screw to which 3 mm acrylic was adapted. The appliance was modified, if needed, with acrylic extending over the upper incisor edges to increase appliance retention. 1 vestibular hook was located, on each side, in the upper deciduous first molar position, for elastic traction. The appliance was cemented with glass ionomer cement, but if it later debonded, it was re-cemented with composite, following acid etching of the buccal and palatal cusps of the upper first permanent molars. For patients with posterior crossbites, the expansion screw was activated one quarter turn (0.25 mm) per day until the lingual cusps of the upper posterior teeth approximated the buccal cusps of the lower posterior teeth. If no transverse change was required, the maxillary splint was still activated once a day for 7-10 days in order to disrupt the circum-maxillary sutures. A commercially available adjustable facemask was used (TP Orthodontics), which had bilateral vertical rods connected to both chin and forehead pads. This design was adjustable vertically to customize the fit. If patients experienced chin reddening, ventilation holes were drilled through the plastic chin pad or soft padding was added. Elastics were connected bilaterally to the adjustable midline crossbow in a downwards and forwards direction. Patients were asked to wear the facemask for 14 hours per day, continuously, during the evening and night. A co-operation calendar was used in an attempt to increase treatment compliance, although this was not formally statistically evaluated. Extra-oral elastics of increasing strength were used (3/80 8 oz elastics for 1-2 weeks; then 1/20 14 oz elastics; then 5/160 14 oz elastics) until a force of 400 g per side was delivered. The direction of elastic traction was downwards and forwards 30 ° from the vestibular hooks on the bonded maxillary expander to the adjustable crossbar of the facemask. Additionally, the elastics could be crossed over to prevent catching or interference (n = 35) Group 2: Control: Following collection of initial records the patients allocated to the control group received no clinical intervention. They were recalled 15 months after registration for collection of final records (n = 38) Both groups were then recalled for follow-up at 3 years
Outcomes	Data were collected at the following time points: DC1: baseline data at study registration DC2: 15 months after baseline data collection DC3: 3 years after baseline data collection Cephalometric and occlusal measurements: The lateral cephalograms were traced by an experienced clinician who was blinded as to group allocation. To determine the rotations of the maxillary and occlusal planes superimposition of the DC1, DC2 and DC3 lateral cephalometric radiographs was undertaken by another author using Bjork's structural method which employs the anterior zygomatic process as the reference landmark. PAR scores were measured by a calibrated examiner. Overjet measurements were recorded from study models, with a steel millimetre ruler, by an experienced examiner Psychosocial measures: The short form of the Piers-Harris children's self concept scale (60 questions) (Piers 2002) was used to evaluate self concept. This may have been influenced by receiving early Class III treatment. Psychosocial/oral health related quality of life effects of treatment were assessed using the OASIS (Mandall 2000), which sums the impact of concern about appearance of teeth, including nice comments, unpleasant comments, teasing, avoidance of smiling, covering the mouth because of the teeth and self perceived aesthetic component of the Index of Orthodontic Treatment Need

	TMJ examination: All the orthodontists involved in the study received training from a TMJ specialist before the start of the study to ensure that the TMJ examination was standardized. This TMJ specialist also advised that an examination appropriate for this age group of children should assess pain (lateral and intra-auricular), clicking, crepitus, locking, muscle tenderness (temporalis, masseter, and lateral pterygoid), and restriction of jaw movement (maximum opening and lateral movement). In addition, the presence of forward mandibular displacement on closure was recorded. TMJ signs or symptoms were recorded at DC1 to ensure no patients might be treated with protraction facemask that may exacerbate any TMJ problems through potential downwards and backwards rotation at the chin point. No patients were excluded at baseline because of pre-existing TMJ signs or symptoms Outcomes relevant to this review: Overjet, ANB, Piers-Harris score, OASIS score, TMJ outcomes
Notes	Sample size calculation estimated that 23 children per group would give 90% power to detect a PAR reduction of 25% with a 0.05 2-sided significance level

Risk of bias ***Risk of bias***

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	The randomisation list was generated in randomisation blocks of 10 with stratification according to gender. Stratification meant that a separate randomisation list was generated for girls and boys, since gender was considered to be a potential confounding factor. This was because girls and boys will grow at different times during the study and, thus, potentially confound Class III skeletal measurements
Allocation concealment (selection bias)	Low risk	The computer generated randomisation sequence was concealed centrally and each clinician telephoned a research assistant to receive the treatment allocation after each patient was registered
Blinding of outcome assessment (detection bias) All outcomes	Low risk	The lateral cephalograms were traced by an experienced clinician who was blinded as to group allocation It was not possible to blind the clinician or the patient in this study. However, the study was single-blind, as the researchers measuring the radiographs and study models and the statistician were blinded to the treatment/control allocation until the data were analysed and the code broken. Ideally the clinician collecting the records at the

Mandall 2010 (*Continued*)

		15-month DC2 time point would have also been blinded as to group allocation. However, this was not attempted, because with only 1 operator was involved at each centre they would have had the patient's notes in front of them at the time of data collection. Also, it was likely that the clinicians would have remembered who had received protraction facemask treatment
Incomplete outcome data (attrition bias) All outcomes	Low risk	2 patients were lost to follow-up in each group, and excluded from the analysis. This is unlikely to have introduced bias
Selective reporting (reporting bias)	Low risk	Cephalometric and occlusal measurements, psychosocial measures and TMJ examination results were planned and reported
Other bias	Low risk	Some patients included in this study had a centric relation to centric occlusion displacement. This may have influenced the perception of the skeletal discrepancy from the lateral cephalogram, but we consider the resulting risk of bias to be minimal

Vaughn 2005

Methods	3-arm parallel randomised controlled trial
Participants	**Number recruited:** 46 patients (24 male and 22 female) **Mean age:** 7.33 years (range not given) **Inclusion criteria:** 0 or negative overjet on 2 or more incisors, Class III molar relationship with the mesiobuccal cusp of the maxillary permanent first molar distal to the buccal groove of the mandibular first permanent molar, or a mesial step terminal plane relationship of 3.0 mm or more if the deciduous molars were present (measured clinically). When the clinical or dental criteria were borderline, cephalometric criteria of ANB angle of 0 ° or less, Wits analysis of 3 mm or more, and nasion perpendicular to A-point of 2 mm or less **Exclusion criteria:** Any craniofacial anomaly, psychosocial impairment or skeletal open bite **Setting:** University hospital in USA
Interventions	**Comparison:** Facemask with expansion versus facemask only versus untreated control Group 1: Facemask with expansion group: Treated with palatal expansion with facemask therapy. A banded, soldered, jackscrew palatal expansion appliance was used for each subject. 2 teeth per side were banded: the first and second deciduous molars, the first permanent molar and the second deciduous molar, or the first permanent molar and

	premolar. The appliance was activated twice daily (0.5 mm/day) for a minimum of 7 days. Soldered hooks (.045 in) were extended to the mesial of the canine for attachment of the force-delivering elastics. Each facemask was fabricated on a model made from an impression of the patient's face. The facemask was fitted 7 to 10 days after the placement of the palatal appliance. Elastics, directed 15 ° to 30 ° downward from the occlusal plane, delivered a force of 300 to 500 g per side, as determined by a force gauge. The participants were instructed to wear the appliance full time at the beginning of treatment. Compliance was closely monitored with timecards. Once positive overjet and overbite and Class I molar occlusion were obtained, facemask wear was reduced to 14 hours a day. In anticipation of some relapse, over correction, approaching an end-to-end molar relationship and overjet of 4 to 5 mm, were the treatment objectives. The treatment results were maintained for 3 to 6 months with nighttime wear (n = 15) Group 2: Facemask only group: The protocol in group 2 was identical to that for group 1 except that the palatal expander was not activated. If patients required transverse expansion, this was performed after final records (T2) were obtained (n = 14) Group 3: Control group: Initial records (T0) were taken at enrolment and 1 year later (n = 17)
Outcomes	Lateral cephalometric radiographs were taken at T0, T1, and T2 for the control group, and at T1 and T2 for the 2 treatment groups. 55 standard cephalometric landmarks were digitised in a pre-determined order with a digitiser accurate to 0.001 mm. Traditional cephalometric measurements were used to describe changes between pre-treatment, post-treatment, and control lateral cephalograms. Measurements included a combination of the Steiner, McNamara, Ricketts, Riedel, and Wits analyses. Changes in 55 landmarks were also evaluated relative to an x-y coordinate system. The Johnston analysis also was used to differentiate between skeletal and dental changes and to provide a method to evaluate the combined treatment effects (skeletal and dental) along the mean functional occlusal plane Outcomes of relevance to the review: ANB, Wits
Notes	No sample size calculations reported, and study likely to be under powered to detect a difference between groups 1 and 2

Risk of bias ***Risk of bias***

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Quote: "We used a block randomisation table to assign the subjects to 1 of 3 groups after obtaining proper informed consent"
Allocation concealment (selection bias)	Unclear risk	There was no method of allocation concealment. Attempts were made to contact the authors for clarification but we are yet to receive a response
Blinding of outcome assessment (detection bias) All outcomes	Low risk	The principal investigator (GAV) was blinded to the assignment

Vaughn 2005 (*Continued*)

Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Number of drop-outs was not clear in the text. Attempts were made to contact the authors for clarification but we are yet to receive a response
Selective reporting (reporting bias)	Low risk	All cephalometric measures recorded and reported as intended
Other bias	Low risk	None detectable

Xu 2001

Methods	2-arm parallel randomised controlled trial
Participants	**Number recruited:** 60 patients (27 male and 33 female) **Mean age:** 9.3 years. Range 8 to 11 years **Inclusion criteria:** Children with skeletal anterior crossbite and abnormal facial morphology **Exclusion criteria:** Tooth or functional Class III patients. This lead to the exclusion of 20 of the 60 patients leaving 40 to be randomised **Setting:** University hospital in China
Interventions	**Comparison:** Facemask versus untreated control Group 1: A jackscrew rapid palatal expander welding with the bands of maxillary first molar and first premolar was attached to the patient's posterior teeth. The protraction hook was located in the position of maxillary canines. After the first week of expander placement, the expander was activated with 90 ° winding each time twice per day. After 2 weeks, active expansion treatment was stopped and the maxillary protraction started. The protraction treatment used a force of 400-500 g lasted 12 hours per day (n = 20) Group 2: Observation only (n = 20) Duration of treatment: 11-13 months (mean 11.3 months)
Outcomes	Lateral cephalometric films taken at baseline and 11-13 months (right after the treatment) , on which 9 linear and 6 angular measurements were made Outcomes relevant to this review: ANB
Notes	Sample size calculation not described

Risk of bias ***Risk of bias***

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	The article states "the children were randomly divided into two groups" but no further details were given. Attempts were made to contact the authors for clarification but we are yet to receive a response

Allocation concealment (selection bias)	Unclear risk	The method of allocation concealment was not described. Attempts were made to contact the authors for clarification but we are yet to receive a response
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	There was no mention of blinding of the assessor. Attempts were made to contact the authors for clarification but we are yet to receive a response
Incomplete outcome data (attrition bias) All outcomes	Low risk	All the participants with skeletal Class III were assessed
Selective reporting (reporting bias)	Low risk	All measures targeted were reported
Other bias	Low risk	No other sources of bias identified

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Altug 1989	Retrospective control group therefore not a prospective RCT
Arman 2004	Retrospective control group therefore not a prospective RCT
Arman 2006	Retrospective control group therefore not a prospective RCT
Baik 1995	Retrospective control group therefore not a prospective RCT (author contacted)
Barrett 2010	Retrospective control group therefore not a prospective RCT
Biren 1993	Not RCT
Cozza 2004	Not RCT
El 2010	Analysed condylar position during treatment, not an outcome of interest to this review
Gokalp 2010	Not RCT
Goyenc 2004	Not RCT
Isci 2010	Not RCT
Jamilian 2011	Not RCT

(*Continued*)

Kurt 2011	Not RCT
Mucedero 2007	Not RCT
Pavoni 2009	Not RCT
Sar 2011	Not RCT
Tortop 2007	Retrospective control group therefore not a prospective RCT
Ucem 2004	Not RCT
Ulgen 1994	Not RCT (contact with author)
Wilmes 2009	Patients over 16
Yagci 2010	Not RCT
Yagci 2011	Retrospective

RCT = randomised controlled trial.

DATA AND ANALYSES

Comparison 1. Facemask versus untreated control (combined facemask groups)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Overjet	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
1.1 1 year follow-up	1	69	Mean Difference (IV, Fixed, 95% CI)	4.10 [3.04, 5.16]
1.2 3-year follow-up	1	63	Mean Difference (IV, Fixed, 95% CI)	2.5 [1.21, 3.79]
2 ANB	3		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
2.1 1 year follow-up	3	155	Mean Difference (IV, Fixed, 95% CI)	3.93 [3.46, 4.39]
2.2 3-year follow-up	1	63	Mean Difference (IV, Fixed, 95% CI)	1.4 [0.43, 2.37]
3 Piers-Harris self concept	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
3.1 1 year follow-up	1	69	Mean Difference (IV, Fixed, 95% CI)	1.5 [-0.96, 3.96]
3.2 3-year follow-up	1	63	Mean Difference (IV, Fixed, 95% CI)	0.6 [-2.57, 3.77]
4 OASIS	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
4.1 1 year follow-up	1	69	Mean Difference (IV, Fixed, 95% CI)	-4.0 [-7.40, -0.60]
4.2 3-year follow-up	1	63	Mean Difference (IV, Fixed, 95% CI)	-3.40 [-7.99, 1.19]
5 Wits	1	46	Mean Difference (IV, Fixed, 95% CI)	-3.84 [-5.31, -2.37]

Comparison 2. Facemask with expansion versus facemask only

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 ANB	1	29	Mean Difference (IV, Fixed, 95% CI)	-0.13 [-1.40, 1.14]
2 Wits	1	29	Mean Difference (IV, Fixed, 95% CI)	-0.16 [-1.63, 1.31]

Comparison 3. Nanda facemask versus conventional facemask

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 ANB	1	20	Mean Difference (IV, Fixed, 95% CI)	1.29 [0.16, 2.42]

Comparison 4. Chin cup versus untreated control

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 ANB [Degrees]	1	50	Mean Difference (IV, Fixed, 95% CI)	1.96 [1.58, 2.34]
2 Wits [mm]	1	50	Mean Difference (IV, Fixed, 95% CI)	4.94 [4.45, 5.42]

Comparison 5. 600 g chin cup versus 300 g chin cup

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 ANB	1	40	Mean Difference (IV, Fixed, 95% CI)	0.10 [-0.31, 0.51]
2 Wits	1	40	Mean Difference (IV, Fixed, 95% CI)	-0.30 [-1.12, 0.52]

Comparison 6. Tandem traction bow appliance versus untreated control

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Overjet	1	30	Mean Difference (IV, Fixed, 95% CI)	3.30 [2.46, 4.14]
2 ANB	1	30	Mean Difference (IV, Fixed, 95% CI)	1.7 [1.09, 2.31]

Comparison 7. Mandibular headgear versus chin cup

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 ANB			Other data	No numeric data

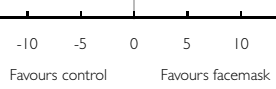
Analysis 1.1. Comparison 1 Facemask versus untreated control (combined facemask groups), Outcome 1 Overjet.

Review: Orthodontic treatment for prominent lower front teeth (Class III malocclusion) in children

Comparison: 1 Facemask versus untreated control (combined facemask groups)

Outcome: 1 Overjet

Study or subgroup	Facemask N	Mean(SD)[mm]	Control N	Mean(SD)[mm]	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
1 1 year follow-up							
Mandall 2010	33	4.4 (2.7)	36	0.3 (1.6)		100.0 %	4.10 [3.04, 5.16]
Subtotal (95% CI)	**33**		**36**			**100.0 %**	**4.10 [3.04, 5.16]**
Heterogeneity: not applicable							
Test for overall effect: Z = 7.59 (P < 0.00001)							
2 3-year follow-up							
Mandall 2010	30	3.6 (2.6)	33	1.1 (2.6)		100.0 %	2.50 [1.21, 3.79]
Subtotal (95% CI)	**30**		**33**			**100.0 %**	**2.50 [1.21, 3.79]**
Heterogeneity: not applicable							
Test for overall effect: Z = 3.81 (P = 0.00014)							
Test for subgroup differences: Chi^2 = 3.54, df = 1 (P = 0.06), I^2 =72%							



Analysis 1.2. Comparison 1 Facemask versus untreated control (combined facemask groups), Outcome 2 ANB.

Review: Orthodontic treatment for prominent lower front teeth (Class III malocclusion) in children

Comparison: 1 Facemask versus untreated control (combined facemask groups)

Outcome: 2 ANB

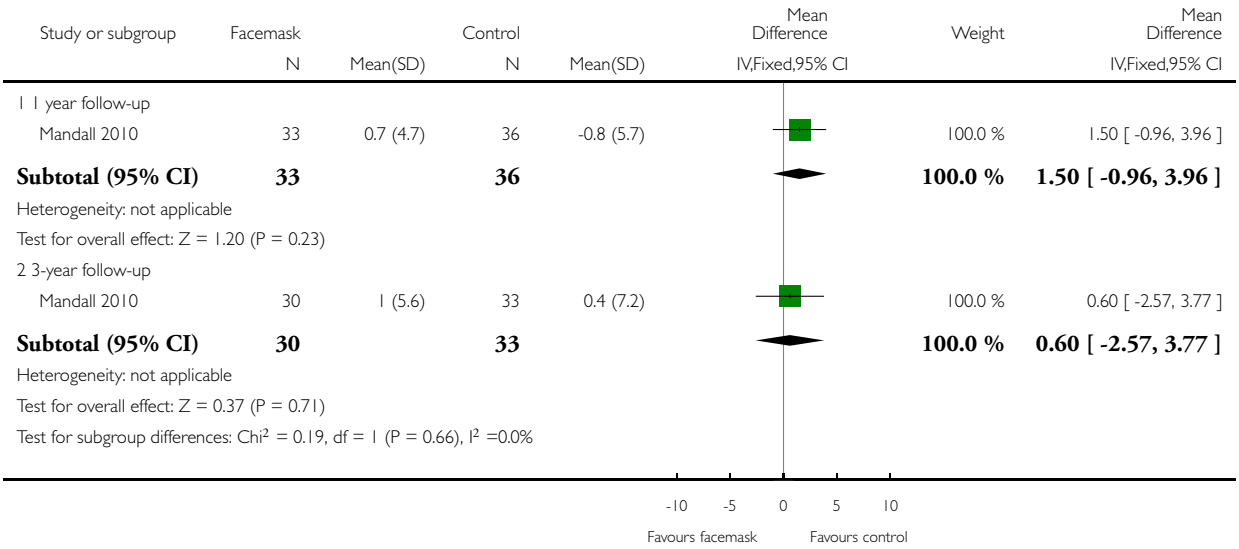
Study or subgroup	Facemask N	Facemask Mean(SD)[Degrees]	Control N	Control Mean(SD)[Degrees]	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
1 1 year follow-up							
Vaughn 2005	29	3.88 (1.83)	17	-0.05 (1.976)		16.4 %	3.93 [2.78, 5.08]
Mandall 2010	33	2.1 (2.3)	36	-0.5 (1.5)		25.3 %	2.60 [1.67, 3.53]
Xu 2001	20	3 (1.07)	20	-1.5 (0.89)		58.3 %	4.50 [3.89, 5.11]
Subtotal (95% CI)	**82**		**73**			**100.0 %**	**3.93 [3.46, 4.39]**
Heterogeneity: Chi^2 = 11.29, df = 2 (P = 0.004); I^2 =82%							
Test for overall effect: Z = 16.52 (P < 0.00001)							
2 3-year follow-up							
Mandall 2010	30	1.5 (2)	33	0.1 (1.9)		100.0 %	1.40 [0.43, 2.37]
Subtotal (95% CI)	**30**		**33**			**100.0 %**	**1.40 [0.43, 2.37]**
Heterogeneity: not applicable							
Test for overall effect: Z = 2.84 (P = 0.0045)							
Test for subgroup differences: Chi^2 = 21.31, df = 1 (P = 0.00), I^2 =95%							

Analysis 1.3. Comparison 1 Facemask versus untreated control (combined facemask groups), Outcome 3 Piers-Harris self concept.

Review: Orthodontic treatment for prominent lower front teeth (Class III malocclusion) in children

Comparison: 1 Facemask versus untreated control (combined facemask groups)

Outcome: 3 Piers-Harris self concept



Analysis 1.4. Comparison 1 Facemask versus untreated control (combined facemask groups), Outcome 4 OASIS.

Review: Orthodontic treatment for prominent lower front teeth (Class III malocclusion) in children

Comparison: 1 Facemask versus untreated control (combined facemask groups)

Outcome: 4 OASIS

Study or subgroup	Facemask N	Mean(SD)	Control N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
1 1 year follow-up							
Mandall 2010	33	-3.7 (7.7)	36	0.3 (6.6)		100.0 %	-4.00 [-7.40, -0.60]
Subtotal (95% CI)	**33**		**36**			**100.0 %**	**-4.00 [-7.40, -0.60]**
Heterogeneity: not applicable							
Test for overall effect: Z = 2.31 (P = 0.021)							
2 3-year follow-up							
Mandall 2010	30	-2 (9.1)	33	1.4 (9.5)		100.0 %	-3.40 [-7.99, 1.19]
Subtotal (95% CI)	**30**		**33**			**100.0 %**	**-3.40 [-7.99, 1.19]**
Heterogeneity: not applicable							
Test for overall effect: Z = 1.45 (P = 0.15)							
Test for subgroup differences: Chi^2 = 0.04, df = 1 (P = 0.84), I^2 =0.0%							

Analysis 1.5. Comparison 1 Facemask versus untreated control (combined facemask groups), Outcome 5 Wits.

Review: Orthodontic treatment for prominent lower front teeth (Class III malocclusion) in children

Comparison: 1 Facemask versus untreated control (combined facemask groups)

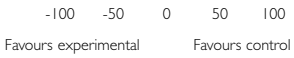
Outcome: 5 Wits

Study or subgroup	Facemask N	Mean(SD)[mm]	Control N	Mean(SD)[mm]	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
Vaughn 2005	29	-3.9 (2.4553)	17	-0.06 (2.4553)		100.0 %	-3.84 [-5.31, -2.37]
Total (95% CI)	**29**		**17**			**100.0 %**	**-3.84 [-5.31, -2.37]**

Heterogeneity: not applicable

Test for overall effect: Z = 5.12 (P < 0.00001)

Test for subgroup differences: Not applicable



Analysis 2.1. Comparison 2 Facemask with expansion versus facemask only, Outcome 1 ANB.

Review: Orthodontic treatment for prominent lower front teeth (Class III malocclusion) in children

Comparison: 2 Facemask with expansion versus facemask only

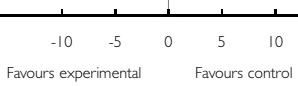
Outcome: 1 ANB

Study or subgroup	With expansion N	Mean(SD)[Degrees]	Without expansion N	Mean(SD)[Degrees]	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
Vaughn 2005	15	3.82 (1.7491)	14	3.95 (1.7491)		100.0 %	-0.13 [-1.40, 1.14]
Total (95% CI)	**15**		**14**			**100.0 %**	**-0.13 [-1.40, 1.14]**

Heterogeneity: not applicable

Test for overall effect: Z = 0.20 (P = 0.84)

Test for subgroup differences: Not applicable

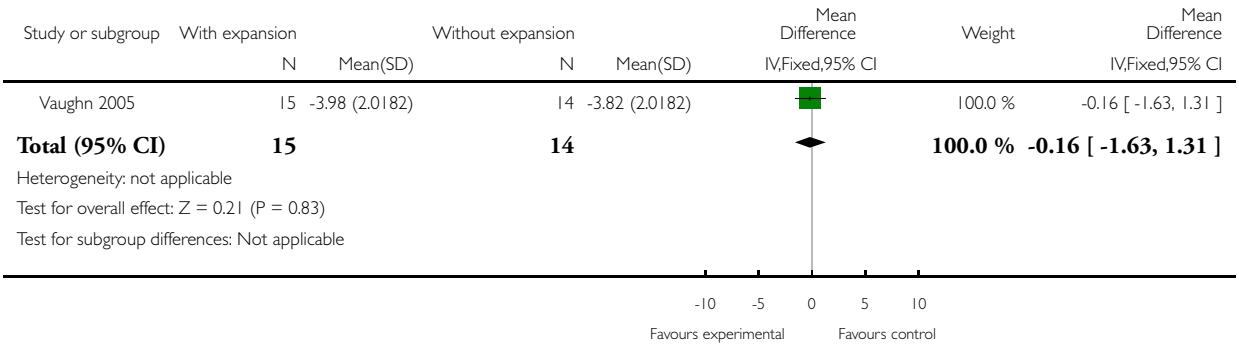


Analysis 2.2. Comparison 2 Facemask with expansion versus facemask only, Outcome 2 Wits.

Review: Orthodontic treatment for prominent lower front teeth (Class III malocclusion) in children

Comparison: 2 Facemask with expansion versus facemask only

Outcome: 2 Wits

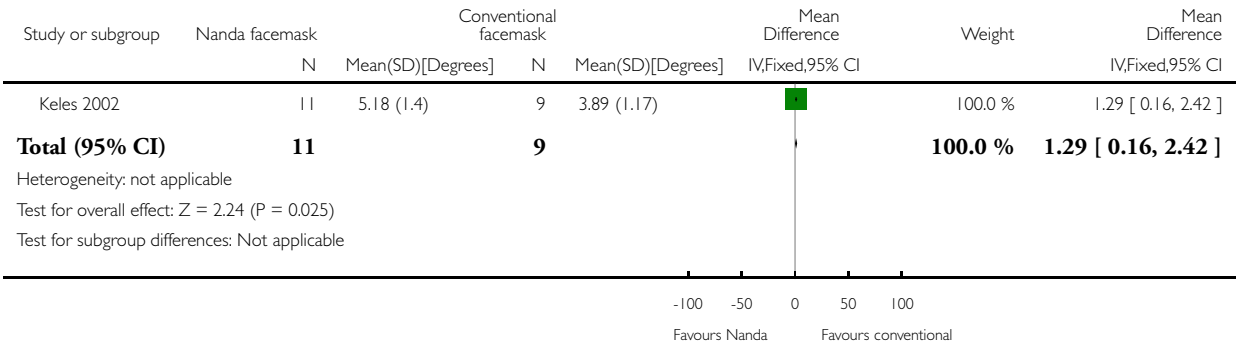


Analysis 3.1. Comparison 3 Nanda facemask versus conventional facemask, Outcome 1 ANB.

Review: Orthodontic treatment for prominent lower front teeth (Class III malocclusion) in children

Comparison: 3 Nanda facemask versus conventional facemask

Outcome: 1 ANB



Analysis 4.1. Comparison 4 Chin cup versus untreated control, Outcome 1 ANB [Degrees].

Review: Orthodontic treatment for prominent lower front teeth (Class III malocclusion) in children

Comparison: 4 Chin cup versus untreated control

Outcome: 1 ANB [Degrees]

Study or subgroup	Chin cup N	Mean(SD)	Control N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
Abdelnaby 2010 (1)	20	2.4 (0.79)	5	0.5 (0.52)		44.0 %	1.90 [1.33, 2.47]
Abdelnaby 2010 (2)	20	2.5 (0.51)	5	0.5 (0.52)		56.0 %	2.00 [1.49, 2.51]
Total (95% CI)	**40**		**10**			**100.0 %**	**1.96 [1.58, 2.34]**

Heterogeneity: $Chi^2 = 0.07$, df = 1 (P = 0.80); $I^2 = 0.0\%$

Test for overall effect: Z = 10.09 (P < 0.00001)

Test for subgroup differences: Not applicable

(1) 300g chin cup versus no treatment

(2) 600g chin cup versus no treatment

Analysis 4.2. Comparison 4 Chin cup versus untreated control, Outcome 2 Wits [mm].

Review: Orthodontic treatment for prominent lower front teeth (Class III malocclusion) in children

Comparison: 4 Chin cup versus untreated control

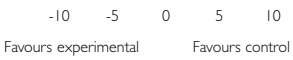
Outcome: 2 Wits [mm]

Study or subgroup	600g+300g Chin cup N	Mean(SD)	Control N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
Abdelnaby 2010 (1)	20	4.6 (1.23)	5	-0.2 (0.42)		54.8 %	4.80 [4.15, 5.45]
Abdelnaby 2010 (2)	20	4.9 (1.41)	5	-0.2 (0.42)		45.2 %	5.10 [4.38, 5.82]
Total (95% CI)	**40**		**10**			**100.0 %**	**4.94 [4.45, 5.42]**

Heterogeneity: $Chi^2 = 0.37$, df = 1 (P = 0.54); $I^2 = 0.0\%$

Test for overall effect: Z = 20.01 (P < 0.00001)

Test for subgroup differences: Not applicable



(1) 600g chin cup versus no treatment

(2) 300g chin cup versus no treatment

Analysis 5.1. Comparison 5 600 g chin cup versus 300 g chin cup, Outcome 1 ANB.

Review: Orthodontic treatment for prominent lower front teeth (Class III malocclusion) in children

Comparison: 5 600 g chin cup versus 300 g chin cup

Outcome: 1 ANB

Study or subgroup	600 g chin cup N	Mean(SD)[Degrees]	300 g chin cup N	Mean(SD)[Degrees]	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
Abdelnaby 2010	20	2.5 (0.51)	20	2.4 (0.79)		100.0 %	0.10 [-0.31, 0.51]
Total (95% CI)	**20**		**20**			**100.0 %**	**0.10 [-0.31, 0.51]**

Heterogeneity: not applicable

Test for overall effect: Z = 0.48 (P = 0.63)

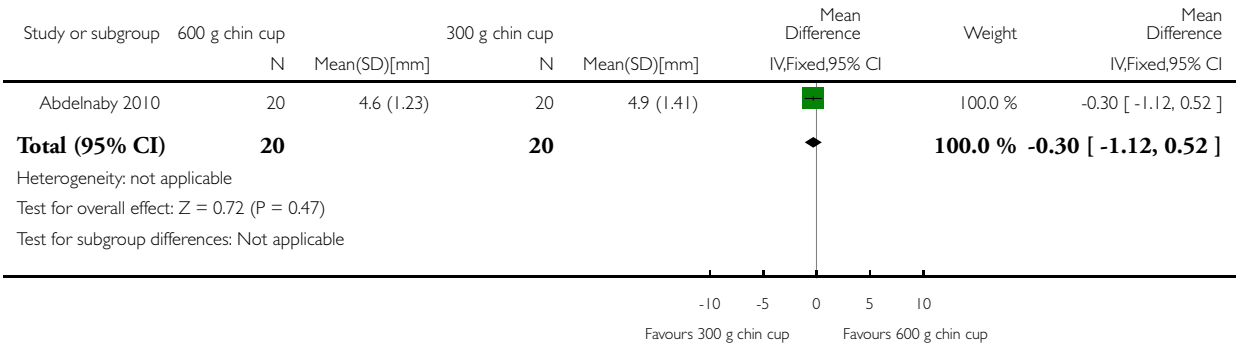
Test for subgroup differences: Not applicable

Analysis 5.2. Comparison 5 600 g chin cup versus 300 g chin cup, Outcome 2 Wits.

Review: Orthodontic treatment for prominent lower front teeth (Class III malocclusion) in children

Comparison: 5 600 g chin cup versus 300 g chin cup

Outcome: 2 Wits

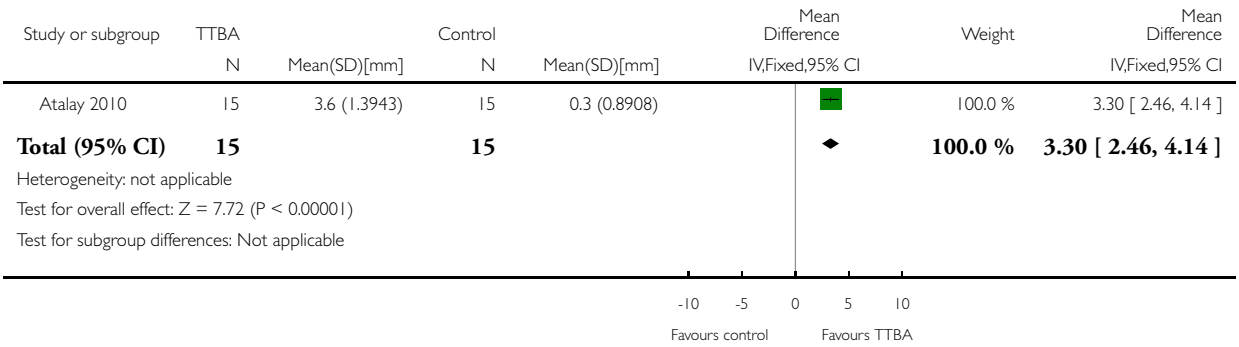


Analysis 6.1. Comparison 6 Tandem traction bow appliance versus untreated control, Outcome 1 Overjet.

Review: Orthodontic treatment for prominent lower front teeth (Class III malocclusion) in children

Comparison: 6 Tandem traction bow appliance versus untreated control

Outcome: 1 Overjet

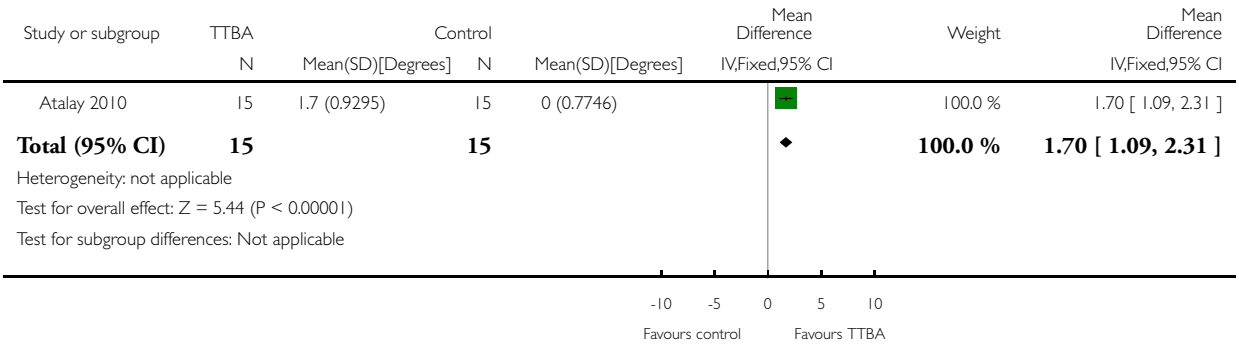


Analysis 6.2. Comparison 6 Tandem traction bow appliance versus untreated control, Outcome 2 ANB.

Review: Orthodontic treatment for prominent lower front teeth (Class III malocclusion) in children

Comparison: 6 Tandem traction bow appliance versus untreated control

Outcome: 2 ANB



Analysis 7.1. Comparison 7 Mandibular headgear versus chin cup, Outcome 1 ANB.

ANB

Study	Mandibular mean	Chin cup mean	Control mean	Mann-Whitney P value mandibular versus control	Mann-Whitney P value chin cup versus control
Arun 1994	1.0	1.2	-0.5	<0.001	<0.001

ADDITIONAL TABLES

Table 1. Data for comparisons with single study

Comparison	Outcome	Study	Effect measure	P value
Facemask versus control	Overjet (post-treatment)	Mandall 2010	4.10 mm (95% CI 3.04 to 5.16)	< 0.0001
	Overjet (3 years follow-up)	Mandall 2010	2.50 mm (95% CI 1.21 to 3.79)	0.0001
	Piers-Harris (post-treatment)	Mandall 2010	1.50 (95% CI -0.96 to 3.96)	0.23
	Piers-Harris (3 years follow-up)	Mandall 2010	0.60 (95% CI -2.57 to 3.77)	0.71

Table 1. Data for comparisons with single study (*Continued*)

	OASIS (post-treatment)	Mandall 2010	-4.00 (95% CI -7.40 to -0. 60)	0.02
	OASIS (3 years follow-up)	Mandall 2010	-3.40 (95% CI -7.99 to 1. 19)	0.15
Facemask with expansion versus facemask only	ANB	Vaughn 2005	-0.13 ° (95% CI -1.40 to 1. 14)	0.84
	Wits	Vaughn 2005	-0.16 mm (95% CI -1.63 to 1.31)	0.83
Nanda facemask versus conventional facemask	ANB	Keles 2002	1.29 ° (95% CI 0.16 to 2. 42)	0.02
Chin cup versus control	ANB	Abdelnaby 2010	1.96 ° (95% CI 1.58 to 2. 34)	< 0.00001
	Wits	Abdelnaby 2010	4.94 mm (95% CI 4.45 to 5.42)	< 0.00001
600 g chin cup versus 300 g chin cup	ANB	Abdelnaby 2010	0.10 ° (95% CI -0.31 to 0. 51)	0.63
	Wits	Abdelnaby 2010	-0.30 mm (95% CI -1.12 to 0.52)	0.47
Tandem traction bow appliance versus control	Overjet	Atalay 2010	3.30 mm (95% CI 2.46 to 4.14)	< 0.0001
	ANB	Atalay 2010	1.70 ° (95% CI 1.09 to 2. 31)	< 0.0001

CI = confidence interval.

APPENDICES

Appendix 1. Cochrane Oral Health Group's Trials Register search strategy

A search was undertaken using the Cochrane Register of Studies and the search strategy below:
#1 ("prominent lower front teeth" or underbite* or under-bite* or "under bite*" or reverse-bite* or "reverse bite*" or prognath* or "Malocclusion Angle Class III" or "Angle* class III") AND (INREGISTER)
#2 (("Class III" AND (malocclusion or bite))) AND (INREGISTER)
#3 (#1 or #2) AND (INREGISTER)
#4 (("orthodontic appliance*" OR "orthodontic device*" OR "removable appliance*" OR "removable device*" OR "functional appliance*" OR "functional device*" OR "fixed appliance*" OR "growth modif*" or brace* OR ((extraoral OR "extra oral" or extra-oral) AND traction) OR "chin cap*" or chin-cap* or chincap* OR "chin cup*" or chin-cup* or chincup* or "face mask*" OR facemask* or face-mask* OR "reverse head gear" OR "reverse head-gear")) AND (INREGISTER)
#5 (((orthopedic* OR orthopaedic*) AND (dental OR orthodontic* OR facial))) AND (INREGISTER)
#6 (#4 or #5) AND (INREGISTER)
#7 (#3 AND #6) AND (INREGISTER)
A previous search of the Register was undertaken in July 2011 using the Procite software and the search strategy below:
(("prominent lower front teeth" or underbite* or under-bite* or "under bite*" or reverse-bite* or "reverse bite*" or prognath* or "Malocclusion Angle Class III" OR "Angle* class III" OR ("Class III" AND (malocclusion* OR bite))) AND ("orthodontic appliance*" OR "orthodontic device*" OR "removable appliance*" OR "removable device*" OR "functional appliance*" OR "functional device*" OR "fixed appliance*" OR "growth modif*" or brace* OR ((extraoral OR "extra oral" or extra-oral) AND traction) OR "chin cap*" or chin-cap* or chincap* OR "chin cup*" or chin-cup* or chincup* or "face mask*" OR facemask* or face-mask* OR "reverse head gear" OR "reverse head-gear" OR ((orthopedic* OR orthopaedic*) AND (dental OR orthodontic* OR facial))))

Appendix 2. Cochrane Central Register of Controlled Trials (CENTRAL) search strategy

#1 MeSH descriptor Malocclusion, Angle Class III
#2 ("Class III" in All Text and (Angle in All Text or Angle's in All Text or malocclusion* in All Text or bite* in All Text))
#3 (underbite* in All Text or under-bite* in All Text or "under bite*" in All Text or "reverse bite*" in All Text or reverse-bite* in All Text or prognath* in All Text)
#4 "prominent lower front teeth"
#5 (#1 or #2 or #3 or #4)
#6 MeSH descriptor Orthodontic Appliances, Functional explode all trees
#7 MeSH descriptor Orthodontic Appliances, Removable explode all trees
#8 ("growth modif*" in All Text and (jaw in All Text or maxilla* in All Text or mandible in All Text))
#9 (("fixed appliance*" in All Text or brace* in All Text) and orthodontic* in All Text)
#10 ((extraoral in All Text or extra-oral in All Text or "extra oral" in All Text) and traction in All Text)
#11 ("chin cap*" in All Text or chin-cap* in All Text or chincap* in All Text)
#12 (("face mask*" in All Text or face-mask* in All Text or facemask* in All Text or "reverse head-gear" in All Text or "reverse headgear" in All Text) and orthodontic* in All Text)
#13 ((orthopedic* in All Text or orthopaedic* in All Text) and (dental in All Text or orthodontic* in All Text or facial in All Text))
#14 (#6 or #7 or #8 or #9 or #10 or #11 or #12 or #13)
#15 (#5 and #14)

Appendix 3. MEDLINE (OVID) search strategy

1. Malocclusion, Angle Class III/
2. ("Class III" and (Angle or Angle's or malocclusion$ or bite$)).mp.
3. (underbite$ or under-bite$ or "under bite$" or "reverse bite$" or reverse-bite$ or prognath$).mp.
4. "prominent lower front teeth".mp.
5. or/1-4
6. exp Orthodontic Appliances, Functional/
7. exp Orthodontic Appliances, Removable/
8. ("growth modif$" and (jaw or maxilla$ or mandible)).mp.
9. (("fixed appliance$" or brace$) and orthodontic$).mp.
10. ((extraoral or extra-oral) and traction).mp.
11. "chin cap$".mp.
12. (("face mask$" or facemask$ or face-mask$ or "reverse head-gear" or "reverse headgear") and orthodontic$).mp.
13. ((orthopedic$ or orthopaedic$) and (dental or orthodontic$ or facial)).mp.
14. or/6-13
15. 5 and 14

The above subject search was linked to the Cochrane Highly Sensitive Search Strategy (CHSSS) for identifying randomised trials in MEDLINE: sensitivity maximising version (2008 revision) as referenced in Chapter 6.4.11.1 and detailed in box 6.4.c of the*Cochrane Handbook for Systematic Reviews of Interventions,* Version 5.1.0 (updated March 2011).

1. randomized controlled trial.pt.
2. controlled clinical trial.pt.
3. randomized.ab.
4. placebo.ab.
5. drug therapy.fs.
6. randomly.ab.
7. trial.ab.
8. groups.ab.
9. or/1-8
10. exp animals/ not humans.sh.
11. 9 not 10

Appendix 4. EMBASE (OVID) search strategy

1. Malocclusion/
2. ("Class III" and (Angle or Angle's or malocclusion$ or bite$)).mp.
3. (underbite$ or under-bite$ or "under bite$" or "reverse bite$" or reverse-bite$ or prognath$).mp.
4. "prominent lower front teeth".mp.
5. or/1-4
6. Orthodontic device/
7. ("growth modif$" and (jaw or maxilla$ or mandible)).mp.
8. (("fixed appliance$" or brace$) and orthodontic$).mp.
9. ((extraoral or "extra oral" or extra-oral) and traction).mp.
10. ("chin cap$" or chin-cap$ or chincap$).mp.
11. ((facemask$ or face-mask$ or "face mask$" or "reverse headgear" or "reverse head-gear") and orthodontic$).mp.
12. ((orthopedic$ or orthopaedic$) and (dental or orthodontic$ or facial)).mp.
13. or/6-12
14. 5 and 13

The above subject search was linked to the Cochrane Oral Health Group filter for EMBASE via OVID:

1. random$.ti,ab.
2. factorial$.ti,ab.
3. (crossover$ or cross over$ or cross-over$).ti,ab.
4. placebo$.ti,ab.

5. (doubl$ adj blind$).ti,ab.
6. (singl$ adj blind$).ti,ab.
7. assign$.ti,ab.
8. allocat$.ti,ab.
9. volunteer$.ti,ab.
10. CROSSOVER PROCEDURE.sh.
11. DOUBLE-BLIND PROCEDURE.sh.
12. RANDOMIZED CONTROLLED TRIAL.sh.
13. SINGLE BLIND PROCEDURE.sh.
14. or/1-13
15. ANIMAL/ or NONHUMAN/ or ANIMAL EXPERIMENT/
16. HUMAN/
17. 16 and 15
18. 15 not 17
19. 14 not 18

HISTORY

Protocol first published: Issue 1, 2002

Review first published: Issue 9, 2013

Date	Event	Description
23 June 2008	Amended	Converted to new review format.

CONTRIBUTIONS OF AUTHORS

The review was co-ordinated by Jayne Harrison (JH) and Simon Watkinson (SW). SW undertook the handsearching. SW, JH and Sue Furness (SF) screened the search results and retrieved papers, appraised the quality of the papers and extracted data from them. SF checked the data extraction. SF and Helen Worthington (HW) analysed and interpreted the data. SW, SF, HW and JH wrote the review.

DECLARATIONS OF INTEREST

Simon Watkinson: no interests to declare.

Jayne E Harrison: no interests to declare.

Susan Furness: no interests to declare.

Helen V Worthington: no interests to declare.

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PDC 97-303

- Cochrane Oral Health Group Global Alliance, UK.

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Disclaimer:

The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the NIHR, NHS or the Department of Health

INDEX TERMS

Medical Subject Headings (MeSH)

*Orthodontic Appliances; Extraoral Traction Appliances; Malocclusion, Angle Class III [*therapy]; Masks; Orthodontics, Corrective [*methods]; Randomized Controlled Trials as Topic

MeSH check words

Adolescent; Child; Humans