Orthodontic treatment for prominent upper front teeth (Class II malocclusion) in children (Review)

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[Intervention Review]

Orthodontic treatment for prominent upper front teeth (Class II malocclusion) in children

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ABSTRACT

Background

Prominent upper front teeth are a common problem affecting about a quarter of 12-year old children in the UK. The correction of this condition is one of the most common treatments performed by orthodontists. This condition develops when the child's permanent teeth erupt and children are often referred to an orthodontist for treatment with dental braces to reduce the prominence of the teeth. These teeth are more likely to be injured and their appearance can cause significant distress.

If a child is referred at a young age, the orthodontist is faced with the dilemma of whether to treat the patient early or to wait until the child is older and provide treatment in early adolescence.

Objectives

To assess the effects of orthodontic treatment for prominent upper front teeth when this treatment is initiated when the child is seven to 11 years old compared to when they are in early adolescence, or when treatment uses different types of orthodontic braces.

Search methods

We searched the following databases: Cochrane Oral Health Group's Trials Register (to 17 April 2013), CENTRAL (*The Cochrane Library* 2013, Issue 3), MEDLINE (OVID) (1946 to 17 April 2013) and EMBASE (OVID) (1980 to 17 April 2013). There were no restrictions regarding language or publication date.

Selection criteria

Randomised controlled trials of children and/or adolescents (age $\leq$ 16 years) on early treatment (either one or two-phase) with any type of orthodontic braces (removable, fixed, functional) or head-braces compared with late treatment with any type of orthodontic braces or head-braces; or, on any type of orthodontic braces or head-braces compared with no treatment or another type of orthodontic brace or appliance (with treatment starting in children of similar ages in both groups) to correct prominent upper front teeth.

Data collection and analysis

Review authors screened the search results, extracted data and assessed risk of bias independently, used odds ratios (ORs) and 95% confidence intervals (CIs) for dichotomous outcomes, mean differences (MDs) and 95% CIs for continuous outcomes and a fixed-effect model for meta-analyses as there were fewer than four studies.

Main results

We included 17 studies based on data from 721 participants.

Three trials (n = 343) compared early (two-phase) treatment (7-11 years of age) with a functional appliance, with adolescent (one-phase) treatment. Statistically significant differences in overjet, ANB and PAR scores were found in favour of functional appliance when the first phase of early treatment was compared with observation in the children due to receive treatment in adolescence. However, at the end of treatment in both groups, there was no evidence of a difference in the overjet (MD 0.21, 95% CI -0.10 to 0.51, P = 0.18) (low quality evidence), final ANB (MD -0.02, 95% CI -0.47 to 0.43, P = 0.92), PAR score (MD 0.62, 95% CI -0.66 to 1.91, P = 0.34) or self concept score (MD 0.83, CI -2.31 to 3.97, P = 0.60). However, two-phase treatment with functional appliance showed a statistically significant reduction in the incidence of incisal trauma (OR 0.59, 95% CI 0.35 to 0.99, P = 0.04) (moderate quality evidence). The incidence of incisal trauma was clinically significant with 29% (54/185) of patients reporting new trauma incidence in the adolescent (one-phase) treatment group compared to only 20% (34/172) of patients receiving early (two-phase) treatment.

Two trials (n = 285), compared early (two-phase) treatment using headgear, with adolescent (one-phase) treatment. Statistically significant differences in overjet and ANB were found in favour of headgear when the first phase of early treatment was compared with observation in the children due to receive treatment in adolescence. However, at the end of treatment in both groups, there was no evidence of a difference in the overjet (MD 0.22, 95% CI -0.56 to 0.12, P = 0.20) (low quality evidence), final ANB (MD -0.27, 95% CI -0.80 to 0.26, P = 0.32) or PAR score (MD -1.55, 95% CI -3.70 to 0.60, P = 0.16). The incidence of incisal trauma was, however, statistically significantly reduced in the two-phase treatment group (OR 0.47, 95% CI 0.27 to 0.83, P = 0.009) (low quality evidence). The adolescent treatment group showed twice the incidence of incisal trauma (47/120) compared to the young children group (27/117).

Two trials (n = 282) compared different types of appliances (headgear and functional appliance) for early (two-phase) treatment. At the end of the first phase of treatment statistically significant differences, in favour of functional appliances, were shown with respect to final overjet only. At the end of phase two, there was no evidence of a difference between appliances with regard to overjet (MD -0.21, 95% CI -0.57 to 0.15, P = 0.26), final ANB (MD -0.17, 95% CI -0.67 to 0.34, P= 0.52), PAR score (MD -0.81, 95% CI -2.21 to 0.58, P = 0.25) or the incidence of incisal trauma (OR 0.79, 95% CI 0.43 to 1.44, P = 0.44).

Late orthodontic treatment for adolescents with functional appliances showed a statistically significant reduction in overjet of -5.22 mm (95% CI -6.51 to -3.93, P < 0.00001) and ANB of -2.37° (95% CI -3.01 to -1.74, P < 0.00001) when compared to no treatment (very low quality evidence).

There was no evidence of a difference in overjet when Twin Block was compared to other appliances (MD 0.01, 95% CI -0.45 to 0.48, P = 0.95). However, a statistically significant reduction in ANB (-0.63°, 95% CI -1.17 to -0.08, P = 0.02) was shown in favour of Twin Block. There was no evidence of a difference in any reported outcome when Twin Block was compared with modifications of Twin Block.

There was insufficient evidence to determine the effects of Activator, FORSUS FRD EZ appliances, R-appliance or AIBP.

Authors' conclusions

The evidence suggests that providing early orthodontic treatment for children with prominent upper front teeth is more effective in reducing the incidence of incisal trauma than providing one course of orthodontic treatment when the child is in early adolescence. There appears to be no other advantages for providing treatment early when compared to treatment in adolescence.

PLAIN LANGUAGE SUMMARY

Orthodontic treatment for prominent upper front teeth in children

Review question

This review, carried out by authors of the Cochrane Oral Health Group, has been produced to assess the effects of orthodontic treatment (treatment by dentists who specialise in the growth, function and position of teeth and jaws) for prominent upper front teeth in children. The review question looks at when this treatment is best provided, either initiated at seven to 11 years old (in one or two phases), and compares this to when the child's treatment is initiated in adolescence, aged 11 to 16 years (one-phase). The use of different types of braces was also assessed.

Background

Prominent (or sticking out) upper front teeth are a common problem affecting about a quarter of 12-year old children in the UK. The correction of this condition is one of the most common treatments performed by orthodontists (dentists who specialise in the growth, function and position of teeth and jaws). This condition develops when the child's permanent teeth erupt and children are often referred to an orthodontist for treatment with dental braces to reduce the prominence of the teeth. Prominent upper front teeth are more likely to be injured and their appearance can cause significant distress.

If a child is referred at a young age, the orthodontist is faced with the dilemma of whether to treat the patient early or to wait until the child is older and provide treatment in early adolescence.

In 'two-phase treatment' - treatment is given first at an early age (seven to 11 years old) and again in adolescence (11 to 16 years old).

In 'one-phase treatment' - there is only one course of treatment in adolescence (11 to 16 years old).

As well as the timing of treatment this review also looked at the different types of braces used, either removable, fixed, functional, or head-braces.

Study characteristics

The evidence on which this review is based was up to date as of April 2013. Seventeen trials including 721 participants formed the basis for the review. Participants were children and adolescents aged under 16 years who had prominent upper front teeth (Class II Division 1 malocclusion).

One study included had been stopped early because of harms. In the initial analysis of the comparison between two appliances, the Twin Block and Dynamax, the Twin Block was shown to be more effective in reducing the overjet of the protruding upper front teeth and also caused less harms.

Key results

The evidence suggests that providing orthodontic treatment, for children with prominent upper front teeth, in two phases appears to significantly reduce the incidence of damage to incisor teeth (middle four teeth at the top) as compared to treatment that is provided in one phase when the child is in early adolescence. There are no other advantages for providing a two-phase treatment i.e. early from age seven to 11 years and again in adolescence compared to one phase in adolescence.

When functional appliance treatment is provided in early adolescence it appears that there are minor beneficial changes in skeletal pattern, however, these are probably not clinically significant. Similarly, the choice of functional appliance when compared to the Twin Block does not result in any advantageous effects.

Quality of the evidence

The overall quality of the evidence was low.

SUMMARY OF FINDINGS FOR THE MAIN COMPARISON *[Explanation]*

Early (2-phase) intervention with functional appliance compared with adolescent (1-phase) treatment with functional appliance

Patient or population: Children and/or adolescents (age <16 years) receiving orthodontic treatment to correct prominent upper front teeth
Intervention: Early (2-phase) intervention with functional appliance
Comparison: Adolescent (1-phase) treatment with functional appliance

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Adolescent (1-phase) treatment with functional appliance	Early (2-phase) intervention with functional appliance				
Overjet (mm) (smaller value better) Follow-up: end of orthodontic treatment	The mean overjet ranged across control groups from 2.6 mm to 4.3 mm	The mean overjet in the 2-phase treatment group was 0.21 mm more (0.10 mm less to 0.51 mm more)	MD 0.21 (-0.10 to 0.51)	343 (3)	⊕⊕ **low**[2,3]	A statistically significant difference in overjet was seen at the end of the first phase of early treatment (functional appliance versus no treatment)
Incidence of incisal trauma Follow-up: end of orthodontic treatment	16 per 100[1]	11 per 100 (8 to 16)	OR 0.59 (0.35 to 0.99)	357 (3)[2,3]	⊕⊕⊕ **moderate**[2]	
Harms Follow-up: end of orthodontic treatment						None reported

*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% CI) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI)

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] Based on average in control group
[2] Downgraded as 2 of the 3 studies at high risk of bias
[3] Downgraded due to heterogeneity (heterogeneity: $Chi^2 = 5.23$, degrees of freedom (df) = 2 (P value = 0.07); $I^2 = 62\%$)

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 breath. The need for orthodontic treatment can be decided by looking at the effect any particular tooth position has 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 upper front teeth (Class II malocclusion) may be due to any combination of the jaw, tooth and/or lip position. The upper jaw (maxilla) can be too far forward or, more usually, the lower jaw (mandible) is too far back. The upper front teeth (incisors) may stick out if the lower lip catches behind them or due to a habit (e.g. thumb sucking). This gives the patient an appearance that may be a target for teasing (Shaw 1980) and bullying (Seehra 2011) which impacts on a patient's quality of life (Johal 2007). When front teeth stick out (more than 3 mm) they are twice as likely to be injured (Nguyen 1999). Prominent upper front teeth (Class II malocclusion) is one of the most common problems seen by orthodontists and affects about a quarter of 12 year old children in the UK (Holmes 1992). However, there are racial differences. Prominent upper front teeth (Class II malocclusion) are most common in whites of Northern European origin and least common in black and oriental races and some Scandinavian populations (El-Mangoury 1990; Proffit 1993; Silva 2001).

Description of the intervention

Several dental brace (orthodontic) treatments have been suggested to correct prominent upper front teeth (Class II malocclusions). Some treatments aim to move the upper front teeth backwards whilst others aim to modify the growth of the upper or lower jaw or both to reduce the prominence of the upper front teeth. Treatment can involve the use of one or more types of orthodontic brace.

How the intervention might work

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 (headgear) that allow a force to be applied to the teeth and jaws from the back of the head. Treatment is usually carried out either early (early treatment), when the patients have a mixture of their baby and adult teeth present (around seven to 11 years of age) or later (adolescent treatment) when all the adult teeth have come into the mouth (around 12 to 16 years of age). In severe cases and some adult patients, orthodontic treatment may need to be combined with jaw surgery to correct the position of one or both jaws.

Why it is important to do this review

The correction of prominent upper front teeth is one of the most common treatments performed by orthodontists in the United Kingdom. Even though we have several brace types to correct prominent upper front teeth, new braces are being introduced in the market to overcome the drawbacks of previous ones and there is currently little evidence of the relative effectiveness of the different braces that can be used. It is very important that we identify the most effective type of brace to give the best available treatment for patients.

OBJECTIVES

To assess the effects of orthodontic treatment for prominent upper front teeth (Class II malocclusion) when this treatment is initiated when the child is seven to 11 years old compared to when they are in early adolescence, or when treatment uses different types of orthodontic braces.

METHODS

Criteria for considering studies for this review

Types of studies

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

Types of participants

Children or adolescents (age 16 years or less) or both receiving orthodontic treatment to correct prominent upper front teeth (Class II malocclusion).

Trials including participants with a cleft lip or palate or both, or other craniofacial deformity/syndrome were excluded. Trials that recruited patients who had previously received surgical treatment for their Class II malocclusion were excluded.

Types of interventions

- Early treatment (either one or two-phase) with any type of orthodontic braces (removable, fixed, functional) or head-braces compared with late treatment with any type of orthodontic braces (removable, fixed, functional) or head-braces. Early treatments were defined as those commencing in children aged between seven and 11 years of age.
- Any type of orthodontic braces (removable, fixed, functional) or head-braces compared with no treatment or another type of orthodontic brace or appliance. For this comparison, treatment should have been started in children of similar ages in both groups.

Types of outcome measures

We recorded clinically important outcomes at the most common endpoints that were reported. If we identified harms these were recorded and reported in descriptive terms.

Primary outcomes

Prominence of the upper front teeth (overjet measured in millimetres or by any index of malocclusion).

Secondary outcomes

- Relationship between upper and lower jaws, self esteem, patient satisfaction, any injury to the upper front teeth, jaw joint problems, number of attendances required to complete treatment.
- Harms: Health of the gums, damage to the teeth (e.g. tooth decay).

Search methods for identification of studies

We developed detailed search strategies for the identification of studies for each database searched. These were initially based on the search strategy developed for MEDLINE and then revised appropriately for each database. Our subject search strategy used a combination of controlled vocabulary and free text terms based on the search strategy for MEDLINE, and the MEDLINE strategy 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 1. The search of EMBASE was linked to the Cochrane Oral Health Group filter for identifying RCTs (Appendix 4).

Electronic searches

We searched the following databases.

- The Cochrane Oral Health Group's Trials Register (to 17 April 2013) (Appendix 2).
- The Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library* 2013, Issue 3) (Appendix 3).
- MEDLINE via OVID (1946 to 17 April 2013) (Appendix 1).
- EMBASE via OVID (1980 to 17 April 2013) (Appendix 4).

There were no restrictions based on language applied to the searches of the electronic databases. We would have sought translation of any non-English language papers that met the inclusion criteria.

Searching other resources

We obtained articles that were identified as part of the Cochrane Oral Health Group's handsearching programme (*see* the Cochrane Masterlist for issues searched to date) from the following journals:

- *American Journal of Orthodontics and Dentofacial Orthopedics*
- *The Angle Orthodontist*
- *European Journal of Orthodontics*
- *Journal of Orthodontics*
- *British Journal of Orthodontics.*

In addition, we handsearched the following journals from their inception to December 2006:

- *Seminars in Orthodontics* (from 1995 to December 2006)
- *Clinical Orthodontics and Research* (from 1998 to December 2006)
- *Australian Journal of Orthodontics* (from 1956 to December 2006).

The bibliographies of the clinical trials that we identified were checked for references to trials published outside the handsearched journals, including personal references. The first named authors of all trial reports were contacted in an attempt to identify unpublished studies and to obtain any further information about the trials.

Data collection and analysis

Selection of studies

Two review authors independently and in duplicate assessed the eligibility of all reports that were identified by the search strategy as being potentially relevant to the review. They were not blinded to author(s), institution or site of publication. Disagreements were resolved by discussion or following clarification from authors.

Data extraction and management

Two review authors then independently and in duplicate extracted data using a specially designed data extraction form. We recorded the year of publication, interventions assessed, outcomes, sample size and age of subjects.

The primary outcome was prominence of the upper front teeth and the secondary outcomes were relationship between upper and lower jaws, self esteem, patient satisfaction, jaw joint problems, number of attendances required and any injury to the upper front teeth. Harms (e.g. health of the gums, damage to the teeth).

We grouped the outcome data into those measured at the end of treatment provided for young children and at the end of treatment provided for adolescent children.

Assessment of risk of bias in included studies

This was conducted using the recommended approach for assessing risk of bias in studies included in Cochrane reviews (Higgins 2011). We used the two-part tool, addressing six specific domains (namely sequence generation, allocation concealment, blinding of outcome assessors, incomplete outcome data, selective outcome reporting and other bias). Each domain included one specific entry in a 'Risk of bias' table. Within each entry, the first part of the tool involved describing what was reported to have happened in the study. The second part of the tool involved assigning a judgement relating to the risk of bias for that entry, either 'low risk', 'high risk' or, where there was insufficient information on which to base a judgement, 'unclear risk'.

The risk of bias assessments were undertaken independently and in duplicate by two review authors as part of the data extraction process with assistance from the Cochrane Oral Health Group when necessary.

After taking into account the additional information provided by the authors of the trials, studies were grouped into the following categories.

- Low risk of bias (plausible bias unlikely to seriously alter the results) for all key domains.
- Unclear risk of bias (plausible bias that raises some doubt about the results) if one or more key domains were assessed as unclear.
- High risk of bias (plausible bias that seriously weakens confidence in the results) if one or more key domains were assessed to be at high risk of bias.

A 'Risk of bias' table was completed for each included study and results were presented graphically.

Measures of treatment effect

For dichotomous outcomes, the estimates of effect of an intervention were expressed as odds ratios together with 95% confidence intervals (CIs). For continuous outcomes, mean differences, together with 95% CIs, were used to summarise the data for each group.

Assessment of heterogeneity

The significance of any discrepancies in the estimates of the treatment effects from the different trials was assessed by means of Cochran's test for heterogeneity and the I^2 statistic, which describes the percentage total variation across studies that is due to heterogeneity rather than chance.

Data synthesis

A meta-analysis was performed only if there were studies with similar comparisons that reported the same outcome measures. Odds ratios were combined for dichotomous data, and mean differences for continuous data, using random-effects models if there were more than three studies in the meta-analysis, and fixed-effect models if there were only two or three studies.

Subgroup analysis and investigation of heterogeneity

Clinical heterogeneity was assessed by examining the types of participants and interventions for all outcomes in each study.

Sensitivity analysis

It was planned to undertake sensitivity analyses to examine the effect of the study quality assessment on the overall estimates of effect. In addition, the effect of including unpublished literature on the review's findings was also to be examined, but there were insufficient trials to undertake this.

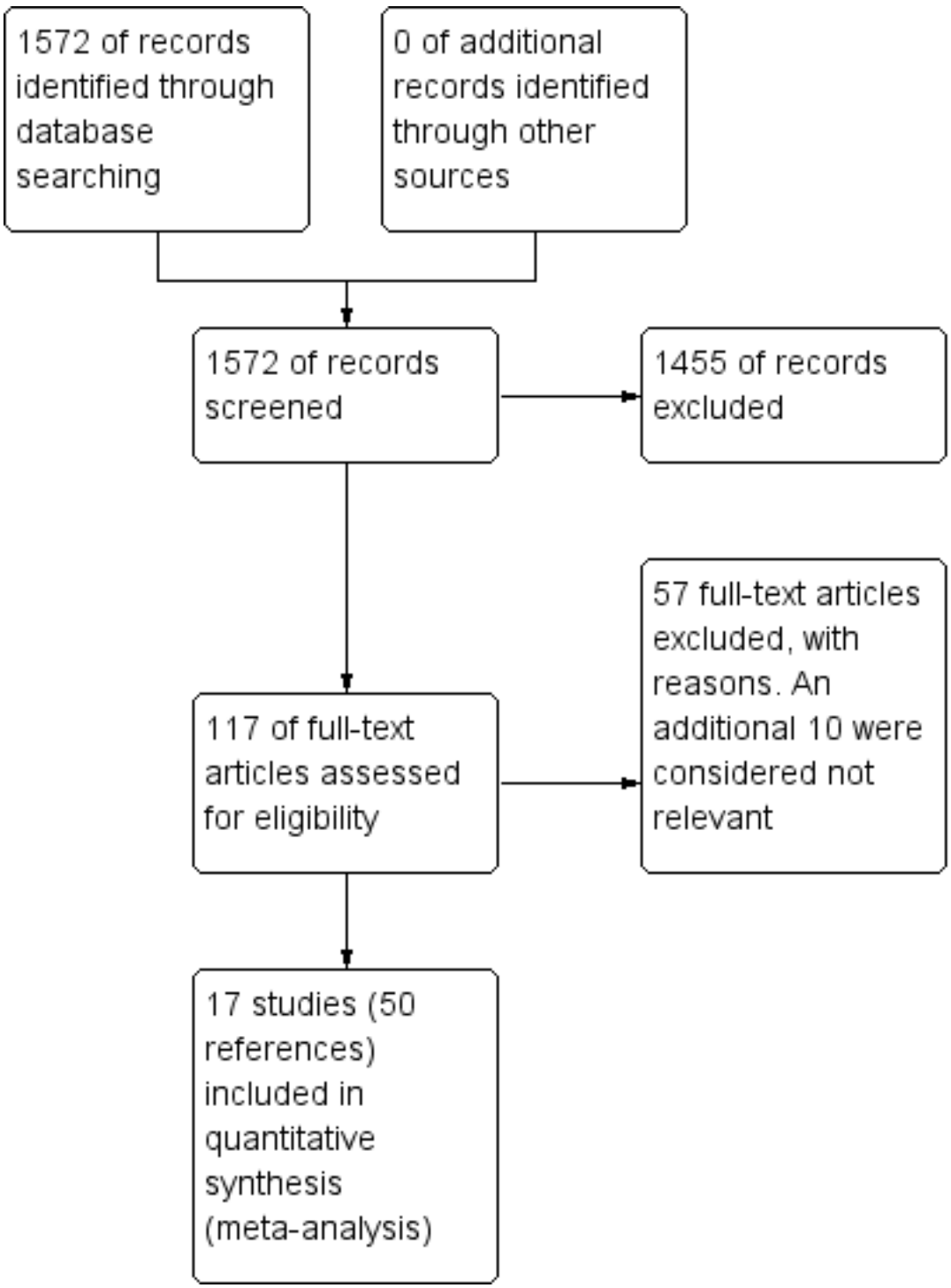
RESULTS

Description of studies

Results of the search

The initial review was published in 2007. Searches to date (April 2013) have identified a total of 1572 records, of which 117 full-text records have been assessed. Of these 117 records 57 articles were excluded; 10 additional studies were considered not relevant to this review. Seventeen trials met the inclusion criteria (published in 50 papers). *See* 'Study flow diagram' (Figure 1).

Figure 1. Study flow diagram.



Included studies

See Characteristics of included studies table.

Characteristics of the trial settings and investigators

Of the 17 included trials, seven were conducted in the United Kingdom (Banks 2004; Lee 2007; London 1998; Thiruvenkatachari 2010; UK (11-14) 2003; UK (Mixed) 2009; Yaqoob 2012), three were carried out in North America (Florida 1998; Ghafari 1998; North Carolina 2004), one was conducted in China (Mao 1997), one in New Zealand (New Zealand 2000), one in Australia (Bilgiç 2011), one in Turkey (Cura 1997), two in Iran (Jamilian 2011; Showkatbakhsh 2011) and one in Brazil (Cevidanes 2003). All trials had a parallel group design. Four were multicentre studies (Banks 2004; Thiruvenkatachari 2010; UK (11-14) 2003; UK (Mixed) 2009). Seven of the trials had more than one publication. Four of the trials received external funding. The providers and assessors were dental staff.

Characteristics of the participants

For the 17 trials included in the review the results are based on data from 721 participants who presented with Class II Division 1 malocclusion. The number of participants in each treatment/control group ranged from 12 to 95. Five trials provided treatment for children aged between seven and 11 years old (Florida 1998; Ghafari 1998; New Zealand 2000; North Carolina 2004; UK (Mixed) 2009). Twelve provided treatment for children who were 10 to 15 years old (Banks 2004; Bilgiç 2011; Cevidanes 2003; Cura 1997; Jamilian 2011; Lee 2007; London 1998; Mao 1997; Showkatbakhsh 2011; Thiruvenkatachari 2010; UK (11-14) 2003; Yaqoob 2012;). Two of the trials had an active recruitment strategy that involved screening school children and providing incentives, such as reduced fees for participation (Florida 1998; North Carolina 2004). The percentage of patients lost to follow-up varied from 0% to 26%.

Characteristics of the intervention

All of the trials provided a clear description of the treatment protocols.

We classified the interventions for the treatment of Class II malocclusion as.

Early orthodontic treatment for Class II Division 1 malocclusion

- There were three trials that compared early (two-phase) intervention with adolescent (one-phase) treatment (Florida 1998; North Carolina 2004; UK (Mixed) 2009).
- Three trials compared two different types of appliances for early treatment (Florida 1998; Ghafari 1998; North Carolina 2004).

In this group of trials, treatment of Class II malocclusion started when participants were aged nine years and comprised two treatment phases. In phase one, participants were randomised to receive one of two types of appliance or to a control group which received no early treatment. When phase one of the trials was completed, participants who had early treatment had a second phase of treatment, and participants who were in the no treatment group had one single phase of adolescent treatment. Outcome measures were compared between those who had received both adolescent and early treatment and those who received adolescent treatment only.

Late orthodontic treatment for Class II Division 1 malocclusion

Twelve trials compared various approaches to treating Class II malocclusion in adolescents (one-phase treatment).

- Four trials compared functional appliances with no treatment (Cevidanes 2003; Cura 1997; Mao 1997; New Zealand 2000).
- Eight trials compared different types of appliances.
    - Twin Block appliances were compared with other types of appliances in five trials (Jamilian 2011; Lee 2007; London 1998; Thiruvenkatachari 2010; UK (11-14) 2003).
    - Twin Block appliances were compared with various modifications to twin blocks in two trials (Banks 2004; Yaqoob 2012).
    - R-appliance was compared with Anterior Inclined Bite Plate in one trial (Showkatbakhsh 2011).
    - The final trial in this group compared a fixed functional appliance with a functional appliance (Bilgiç 2011).

Excluded studies

Of the 57 studies that were excluded:

- 51 were not a randomised controlled trial;
- three did not involve treatment of patients with a Class II Division 1 malocclusion;
- two had only abstracts and did not have sufficient information to determine whether they met the inclusion criteria of the review;
- one study looked at the outcome of temporomandibular joint changes only.

See Characteristics of excluded studies table for further details.

Risk of bias in included studies

Allocation

Sequence generation

In eight studies (Banks 2004; Jamilian 2011; North Carolina 2004; Showkatbakhsh 2011; Thiruvenkatachari 2010; UK (11-14) 2003; UK (Mixed) 2009; Yaqoob 2012) the method of random sequence generation was clearly described and these studies were assessed as being at low risk of bias for this domain. Four of these studies used minimisation software as a method of sequence generation (Banks 2004; Thiruvenkatachari 2010; UK (11-14) 2003; UK (Mixed) 2009). One study used stratified block randomisation (Yaqoob 2012), two studies used random number tables (Jamilian 2011; Showkatbakhsh 2011) and one used Proc plan in SAS (North Carolina 2004). Seven studies did not report on method of generation of randomisation sequence and were judged at unclear risk of bias (Cevidanes 2003; Cura 1997; Ghafari 1998; Lee 2007; London 1998; Mao 1997; New Zealand 2000). Two studies were judged as at high risk of bias (Bilgiç 2011; Florida 1998). Florida 1998 reported an inadequate method of randomisation, filling up the partially filled blocks in stratified block randomisation due to slow rate of entry. Bilgiç 2011 reported that patients were selected and matched between groups according to the inclusion criteria. Additionally, they did not report on method of random sequence generation and were judged as high risk of bias.

Allocation concealment

In five studies (Banks 2004; Thiruvenkatachari 2010; UK (11-14) 2003; UK (Mixed) 2009; Yaqoob 2012) allocation concealment was clearly described and therefore these studies were judged at low risk of bias for this domain. Eleven studies did not report any information about allocation concealment and were assessed as being at unclear risk of bias for this domain (Bilgiç 2011; Cevidanes 2003; Cura 1997; Florida 1998; Ghafari 1998; Jamilian 2011; Lee 2007; London 1998; Mao 1997; North Carolina 2004; Showkatbakhsh 2011). One study (New Zealand 2000) reported that randomisation was matched in triads according to age and sex and randomly assigned to either the three intervention groups. It is possible that allocation could be predictable within the triad time. As a result, we felt that this study was at high risk of bias for this domain (New Zealand 2000).

Blinding

Blind assessment of all outcomes was reported in seven studies and these were assessed as at low risk of bias (Banks 2004; Cevidanes 2003; Florida 1998; Jamilian 2011; UK (11-14) 2003; UK (Mixed) 2009; Yaqoob 2012). Blind outcome assessment was not reported in eight studies and they were judged at unclear risk of bias (Bilgiç 2011; Cura 1997; Ghafari 1998; Lee 2007; London 1998; Mao 1997; New Zealand 2000; Showkatbakhsh 2011). An additional study reported clinical measures only and blinding was not possible. This was judged as at unclear risk of bias (Thiruvenkatachari 2010). One study stated that the assessors were not blinded and was judged as at high risk of bias (North Carolina 2004).

Incomplete outcome data

Trials of orthodontic treatment typically last for at least five or more years and consequently there is a high rate of attrition, some of which is related to the orthodontic treatment offered, and some due to factors such as families moving to a different area. Attrition rates in the studies included in this review ranged from 6% to 28% of participants initially randomised to treatments. In assessing risk of attrition bias we looked at the overall rate of attrition in the study, the relative loss for each arm of each study and the reasons given to explain these.

Six studies (Bilgiç 2011; Jamilian 2011; Lee 2007; Showkatbakhsh 2011; UK (Mixed) 2009; Yaqoob 2012) were assessed as being at low risk of attrition bias. UK (Mixed) 2009 had high overall attrition (19%) but the reasons given and the numbers were similar in each treatment arm and we considered that attrition bias was unlikely. The final study (Yaqoob 2012) had low overall attrition (6%) and reasons and numbers were similar in each treatment arm.

A further four studies were assessed as being at unclear risk of attrition bias (Cevidanes 2003; Mao 1997; North Carolina 2004; Thiruvenkatachari 2010). In two of these studies (Cevidanes 2003; North Carolina 2004) the overall rate of attrition was 10% to 19%, but there was incomplete information on the rates and reasons for participants being excluded from the analysis in each treatment group within the study. Mao 1997 provided no information about the number of participants included in the outcome evaluation. The study by Thiruvenkatachari 2010 was stopped early and had more than twice as many participants lost from the Twin Block treatment group compared to the Dynamax group.

The remaining seven studies (Banks 2004; Cura 1997; Florida 1998; Ghafari 1998; London 1998; New Zealand 2000; UK (11-14) 2003) were assessed as being at high risk of attrition bias. Six of these studies (Banks 2004; Cura 1997; Florida 1998; Ghafari 1998; London 1998; New Zealand 2000) had more than 20% attrition and a significant difference in the rate and reason for participants being excluded from the analysis in each arm of the study. The UK (11-14) 2003 had a lower overall attrition rate

of 15% but the drop-out rate was significantly different between groups.

Selective reporting

Fourteen studies reported all of the outcomes specified in the methodology and were judged at low risk of reporting bias (Banks 2004; Bilgiç 2011; Cura 1997; Florida 1998; Ghafari 1998; Jamilian 2011; Lee 2007; London 1998; New Zealand 2000; North Carolina 2004; Thiruvenkatachari 2010; UK (11-14) 2003; UK (Mixed) 2009; Yaqoob 2012). One study reported only on few cephalometric measurements and no clinical measurements and was judged as at unclear risk of bias (Showkatbakhsh 2011). One study used a complicated reporting method from which data could not be extracted for meta-analysis and this study was judged at unclear risk of reporting bias (Cevidanes 2003). The study by Mao 1997 had reported data, but these were not clear and data could not be extracted for meta-analysis, so this study was also assessed at unclear risk of reporting bias.

Other potential sources of bias

There was no other potential source of bias identified in 11 studies (Banks 2004; Bilgiç 2011; Florida 1998; Ghafari 1998; Jamilian 2011; New Zealand 2000; North Carolina 2004; Showkatbakhsh 2011; UK (11-14) 2003; UK (Mixed) 2009; Yaqoob 2012) and these were judged as at low risk of bias.

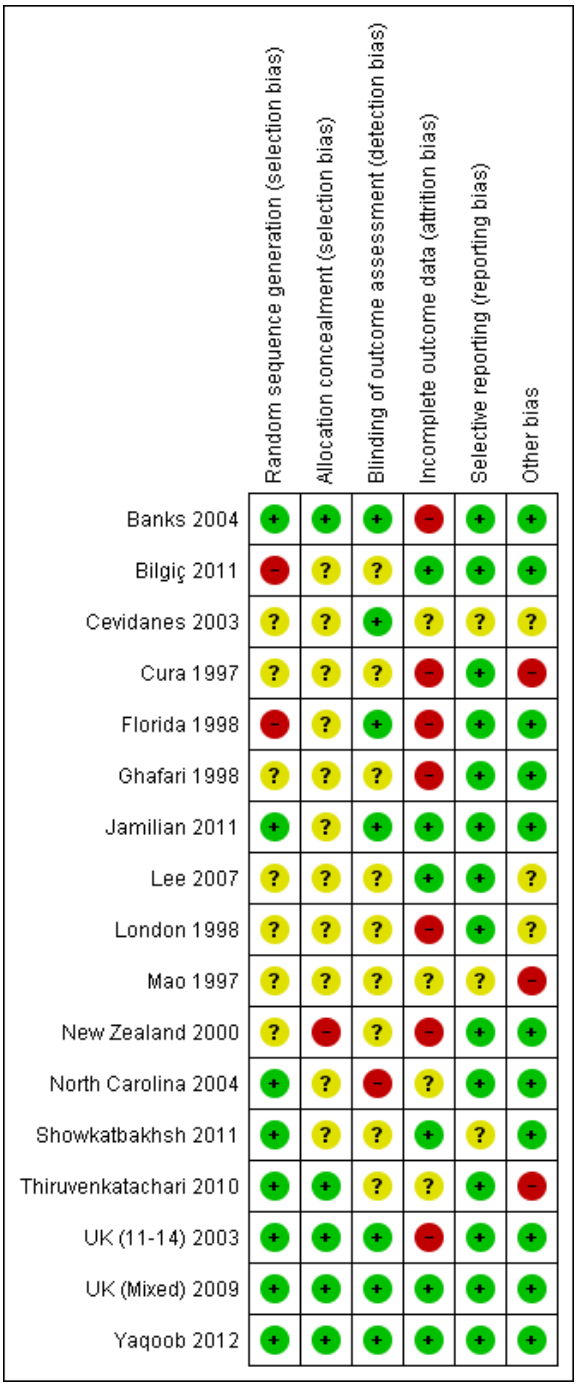
Three studies were judged as being at unclear risk of other bias (Cevidanes 2003; Lee 2007; London 1998). One study did not report baseline characteristics within groups (Cevidanes 2003). One study had differences in age at baseline between randomised groups. Although this was not statistically significant (which may be due to small numbers in each group), this study was assessed as at unclear risk of other bias (London 1998). Lee 2007 had higher incidence of appliance breakages in the Dynamax group than in the Twin Block group.

Three studies (Cura 1997; Mao 1997; Thiruvenkatachari 2010) were assessed at high risk of other bias. Cura 1997 had gender imbalance at baseline between groups which may have led to a bias due to the different responses of boys and girls to orthodontic treatment. Mao 1997 did not report data clearly and also had gender imbalance between groups at baseline (Bionator group 18 males, six females and untreated group nine males and 17 females). One study stopped prematurely due to excessive adverse events and statistically significant difference between groups at the first interim analysis and hence was assessed as at high risk of bias (Thiruvenkatachari 2010).

Overall risk of bias

In a summary, 11 studies were considered to be at high risk of bias in at least one domain and were therefore assessed as at high risk of bias overall (Banks 2004; Bilgiç 2011; Cura 1997; Florida 1998; Ghafari 1998; London 1998; Mao 1997; New Zealand 2000; North Carolina 2004; Thiruvenkatachari 2010; UK (11-14) 2003). Two studies were considered to be at low overall risk of bias (UK (Mixed) 2009; Yaqoob 2012) and four studies at unclear overall risk of bias (Cevidanes 2003; Jamilian 2011; Lee 2007; Showkatbakhsh 2011) (Figure 2).

Figure 2. 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**; **Summary of findings 2**

We divided the trials into two main groups.

- Early orthodontic treatment for Class II Division 1 malocclusion

i) Comparison 1: Early (two-phase) intervention versus adolescent (one-phase) treatment

a) Outcomes at the end of phase one (Comparisons 1.1 to 1.4)

b) Outcomes at the end of phase two (Comparisons 1.5 to 1.8)

ii) Comparison 2: Early orthodontic treatment (two-phase): different types of appliances

a) Outcomes at the end of phase one (Comparisons 2.1 and 2.2)

b) Outcomes at the end of phase two (Comparisons 2.3 and 2.4)

- Late orthodontic treatment for Class II Division 1 malocclusion (adolescent only patients)

i) Comparison 3: Late treatment with functional appliances versus no treatment (Comparison 3.1)

ii) Comparison 4: Different types of appliances used for late treatment (Comparisons 4.1 to 4.4).

Four studies were not included in the meta-analysis (Cevidanes 2003; Ghafari 1998; Lee 2007; Thiruvenkatachari 2010).

Cevidanes 2003 looked at the effects of functional appliances (Frankel appliance) on the temporomandibular joint. This study did not carry out any dental measurements and therefore had no data to contribute to the meta-analysis.

Ghafari 1998 did not publish data at the end of the study. There were several interim publications which included part of the data which could not be included in the analysis.

Lee 2007 reported medians and interquartile range and these non-parametric data could not be used in the meta-analysis. However, this study reported that there was no difference in overjet change between Twin Block and Dynamax appliances.

Thiruvenkatachari 2010 stopped this trial early due to harms. The incidence of adverse events with the Dynamax appliance (82%) was significantly greater than the Twin Block appliance (12%) (P value < 0/001) and the Twin Block appliance was more effective for overjet reduction. However, insufficient data were available to be used in the meta-analysis.

Early orthodontic treatment for Class II division 1 malocclusion

Early (two-phase) intervention versus adolescent (one-phase) treatment

Outcomes at the end of phase one

Treatment with functional appliance

Three trials (two at high risk of bias, one at low risk of bias), involving 432 participants, compared treatment for young children, using a functional appliance, with adolescent (one-phase) treatment (Florida 1998; North Carolina 2004; UK (Mixed) 2009). Data were available comparing outcomes at the end of phase one for the early treatment group with observation only in the adolescent treatment group. The meta-analysis (Analysis 1.1) showed that there was a statistically significant difference in final overjet of the functional appliance treatment group compared with the observation group (mean difference (MD) -4.17 mm; 95% confidence interval (CI) -4.61 to -3.73, Chi^2 = 117.02, 2 degrees of freedom (df), P value < 0.00001, I^2 = 98%).

When we evaluated the effect of treatment on the final ANB, we found that there was a statistically significant mean difference between the treatment and control groups (MD -0.89°; 95% CI -1.38° to -0.40°, Chi^2 = 9.17, 2 df, P value = 0.0004, I^2 = 78%).

Early treatment also had a statistically significant effect on the PAR score in favour of early treatment (MD -11.16; 95% CI -12.86 to -9.46, Chi^2 = 56.53, 2 df, P value < 0.00001, I^2 = 96%) (Analysis 1.1).

Early treatment did not show any significant difference in self concept score (MD 3.63; 95% CI -0.40 to 7.66, P value = 0.08) (Analysis 1.1) and new incidence of incisor trauma (odds ratio (OR) 0.72; 95% CI 0.35 to 1.49, P value = 0.38) (Analysis 1.2) when compared with untreated control group patients.

Treatment with headgear

Two trials, both at high risk of bias (n = 285), compared treatment for young children, using headgear, with adolescent (one-phase) treatment (Florida 1998; North Carolina 2004). The comparison of the effect of treatment with headgear at the end of phase one (early treatment group), compared with observation (adolescent treatment group), revealed a statistically significant effect of headgear treatment on the overjet (MD -1.07 mm; 95% CI -

1.63 mm to -0.51 mm, Chi^2 = 0.05, 1 df, P value = 0.0002, I^2 = 0%) (Analysis 1.3). Similarly, headgear resulted in a statistically significant reduction of -0.72° (95% CI -1.18° to -0.27°, Chi^2 = 0.34, 1 df, P value = 0.002, I^2 = 0%) in final ANB (Analysis 1.3). However, there was no statistically significant difference in incisal trauma (OR 0.82; 95% CI 0.41 to 1.64, Chi^2 = 0.27, 1 df, P value = 0.57, I^2 = 0%) between the two groups (Analysis 1.4).

Outcomes at the end of phase two

Treatment with functional appliance

Three trials (two at high risk of bias, one at low risk of bias), with data on 343 participants, compared treatment for younger children with a functional appliance versus treatment for adolescent children (Florida 1998; North Carolina 2004; UK (Mixed) 2009). When we evaluated the effects of a course of treatment at a young age with a functional appliance and at the end of all orthodontic treatment during adolescence, we found that there were no statistically significant differences in the overjet (MD 0.21 mm; 95% CI -0.10 mm to 0.51 mm, Chi^2 = 5.23, 2 df, P value = 0.18, I^2 = 62%) (Analysis 1.5), final ANB (MD -0.02°; 95% CI -0.47° to 0.43°, Chi^2 = 2.62, 2 df , P value = 0.92, I^2 = 24%) (Analysis 1.5), PAR score (MD 0.62; 95% CI -0.66 to 1.91, Chi^2 = 6.43, 2 df, P value = 0.34, I^2 = 69%) (Analysis 1.5), or self concept score (MD 0.83; 95% CI -2.31 to 3.97, P value = 0.60). However, the incidence of new incisal trauma showed statistically significant results in favour of functional appliance two-phase treatment (OR 0.59; 95% CI 0.35 to 0.99, Chi^2 = 1.38, 2 df, P value = 0.04, I^2 = 0%) (Analysis 1.6) compared with one-phase treatment during adolescence only. The incidence of new incisal trauma was clinically significant with 29% (54/185) of patients reporting new trauma incidence in the adolescent treatment group compared to only 20% (34/172) of patients reporting incisal trauma in early treatment group.

Treatment with headgear when younger

Two trials, both at high risk of bias, with data from 285 children, compared treatment for young children, using headgear, with adolescent (one-phase) treatment (Florida 1998; North Carolina 2004). There were no statistically significant effects of an early course of headgear treatment at a young age followed by treatment when adolescence with respect to overjet (MD -0.22 mm; 95% CI -0.56 mm to 0.12 mm, Chi^2 = 1.27, 1 df, P value = 0.20, I^2 = 21%) (Analysis 1.7), final ANB (MD -0.27°; 95% CI -0.80° to 0.26°, Chi^2 = 0.10, 1 df, P value = 0.32, I^2 = 0%) (Analysis 1.7), or PAR score (MD -1.55; 95% CI -3.70 to 0.60, Chi^2 = 0.39, 1 df, P value = 0.16, I^2 = 0%) (Analysis 1.7) compared with treatment as usual. However, the incidence of new incisal trauma showed a statistically significant reduction in the young children treatment group (OR 0.47; 95% CI 0.27 to 0.83, Chi^2 = 0.72, 1 df, P value = 0.009, I^2 = 0%) (Analysis 1.8). The adolescent treatment group showed twice the incidence of new incisal trauma (47/120) as compared to the young children group who had headgear treatment (27/117).

Early orthodontic treatment (two-phase): different types of appliances

Outcomes at the end of phase one

Two trials, at high risk of bias, compared the use of different types of appliances (headgear and functional appliance) for early, two-phase treatment (Florida 1998; North Carolina 2004). When we compared the effects of treatment between headgear and the functional appliances when younger we found statistically significant differences with respect to final overjet (MD 0.75 mm; 95% CI 0.21 mm to 1.29 mm, Chi^2 = 12.54, 1 df, P value = 0.006, I^2 = 92%) (Analysis 2.1) in favour of functional appliances, but no difference with respect to final ANB (MD -0.04°; 95% CI -0.49° to 0.41°, Chi^2 = 0.03, 1 df, P value = 0.85, I^2 = 0%) (Analysis 2.1), or new incisal trauma (OR 1.10; 95% CI 0.53 to 2.30, Chi^2 = 0.59, 1 df, P value = 0.80, I^2 = 0%) (Analysis 2.2).

Outcomes at the end of phase two

An evaluation of the effect of treatment between headgear and functional appliance at a young age followed by adolescent treatment revealed no significant difference in overjet (MD -0.21 mm; 95% CI -0.57 mm to 0.15 mm, Chi^2 = 0.01, 1 df, P value = 0.26, I^2 = 0%) (Analysis 2.3), final ANB (MD -0.17°; 95% CI -0.67° to 0.34°, Chi^2 = 1.58, 1 df, P value = 0.52, I^2 = 37%) (Analysis 2.3), PAR score (MD -0.81; 95% CI -2.21 to 0.58, Chi^2 = 0.09, 1 df, P value = 0.25, I^2 = 0%) (Analysis 2.3), or the incidence of incisal trauma (OR 0.79; 95% CI 0.43 to 1.44, Chi^2 = 0.09, 1 df, P value = 0.44, I^2 = 0%) (Analysis 2.4) (Florida 1998; North Carolina 2004).

Late orthodontic treatment for Class II Division 1 malocclusion (adolescent only patients)

Late orthodontic treatment for adolescent patients: functional appliance versus no treatment

There was a statistically significant reduction in overjet of -5.22 mm (95% CI -6.51 to -3.93, P value < 0.00001) for the functional appliance group compared with an untreated control (Analysis 3.1). However, this is based on a single study at high risk of bias (Cura 1997).

The evaluation of the effect of functional appliance on ANB revealed a statistically significant reduction in ANB of -2.37° (95% CI -3.01° to -1.74°, Chi^2 = 1.90, 1 df, P value < 0.00001, I^2 = 47%). This is based on two studies (Cura 1997; Mao 1997), both at high risk of bias (Analysis 3.1).

Late orthodontic treatment for adolescent patients: different types of appliances

Twin Block functional appliance versus other functional appliances

This was based on three studies, two at high risk of bias and one at unclear risk of bias (Jamilian 2011; London 1998; UK (11-14) 2003). This comparison revealed that there was a statistically significant reduction on ANB with the Twin Block when compared to other functional appliances. The results showed a difference of only -0.63° between groups (95% CI -1.17° to -0.08°, Chi^2 = 0.63, 2 df, P value = 0.02, I^2 = 0%) (Analysis 4.1). However, there was no statistically significant effect of the type of appliance on final overjet (MD 0.01 mm; 95% CI -0.45 mm to 0.48 mm, Chi^2 = 6.06, 2 df, P value = 0.95, I^2 = 67%) (Analysis 4.1).

Twin Block functional appliance versus other modifications of Twin Block appliances

Two trials compared a Twin Block functional appliance versus other modifications of Twin Block appliances; one trial was at high risk of bias and one at low risk of bias (Banks 2004; Yaqoob 2012). There were no statistically significant differences with respect to final overjet (MD -0.23 mm; 95% CI -0.67 mm to 0.22 mm, Chi^2 = 2.59, 1 df, P value = 0.32, I^2 = 61%) (Analysis 4.2) and ANB (MD -0.24°; 95% CI -1.17° to 0.69°, P value = 0.61) (Analysis 4.2).

Activator functional appliance versus fixed functional (FORSUS FRD EZ) appliances

The results in this section are based on one study at high risk of bias (Bilgiç 2011). Reduction in overjet favoured the FORSUS appliance (MD 2.19 mm; 95% CI 0.58 mm to 3.80 mm, P value = 0.008) (Analysis 4.3) but final ANB favoured the Activator group (MD -1.74°; 95% CI -3.28° to -0.20°, P value = 0.03) (Analysis 4.3).

R-appliance versus anterior inclined bite plate (AIBP)

A single trial at unclear risk of bias showed no statistically significant difference between the two groups with respect to final ANB (MD -0.30°; 95% CI -0.99° to 0.39°, P value = 0.40) (Analysis 4.4) (Showkatbakhsh 2011).

ADDITIONAL SUMMARY OF FINDINGS *[Explanation]*

Early (2-phase) intervention with headgear appliance compared with adolescent (1-phase) treatment with headgear

Patient or population: Children and/or adolescents (age <16 years) receiving orthodontic treatment to correct prominent upper front teeth
Intervention: Early (2-phase) intervention with headgear
Comparison: Adolescent (1-phase) treatment with headgear

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Adolescent (1-phase) treatment with headgear	Early (2-phase) treatment with headgear				
Overjet (mm) (smaller value better) Follow-up: end of orthodontic treatment	The mean overjet ranged across control groups from 2.4 mm to 3.48 mm	The mean overjet in the 2-phase treatment group was 0.22 mm less (0.56 mm less to 0.12 mm less)	MD -0.22 (-0.56 to 0.12)	238 (2)	⊕⊕ **low**[2]	A statistically significant difference in overjet was seen at the end of the first phase of early treatment (headgear versus no treatment)
Incidence of incisal trauma Follow-up: end of orthodontic treatment	40 per 100[1]	24 per 100 (16 to 35)	OR 0.47 (0.27 to 0.83)	237 (2)	⊕⊕ **low**[2]	
Harms Follow-up: end of orthodontic treatment						None reported

*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% CI) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI)
CI: confidence interval; **MD:** mean difference; **OR:** odds ratio

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] Based on average in control group
[2] Downgraded twice as both studies at high risk of bias

DISCUSSION

Summary of main results

Two-phase versus one-phase treatment

We have found evidence that when orthodontic treatment is provided for children with prominent upper front teeth, when they are aged 7 to 11 years old (young children), this results in clinically and statistically significant reduction in incisor prominence. This effect occurs if the child received treatment with a functional appliance or headgear. This treatment also resulted in some changes in the relationship of the upper and lower jaws. However, while these changes or differences at the end of phase one were statistically significant they were unlikely to be clinically significant.

When we considered the final outcome of treatment at the end of a second phase of treatment when the child was in early adolescence, we found that the treatment was effective, in that incisor prominence had been reduced. There were no differences in treatment outcome between the groups of children who had received treatment at a younger age or treatment as usual for all variables except for the incidence of new incisal trauma. The results showed a significant reduction in incisor trauma in the young children treatment group as compared to the adolescent treatment group.

Treatment provided in one phase in early adolescence

We found two studies that measured the effect of treatment with a functional appliance versus an untreated control. The analysis revealed that the treatment resulted in a reduction in overjet and a change in skeletal pattern, but again this change was so small that it may not be of clinical significance.

We also found that several investigators had compared the effect of the Twin Block functional appliance against other similar appliances, for example, the Bionator and Herbst appliances. We found that while there was a statistically significant difference in ANB, this was so small that it was unlikely to be of clinical significance. We did not find any other significant differences.

There were two studies that compared a conventional Twin Block appliance with modified Twin Blocks (e.g. single step advancement or with labial bow). However, we did not find any statistically or clinically significant difference between the two groups.

There was one study that compared Activator functional appliance versus FORSUS fixed functional appliance. The results showed a statistically significant difference in final overjet and ANB measurements between the groups.

There was one study that compared R-appliance versus anterior inclined bite plate (AIBP). The results showed no statistically significant difference in final ANB between the two groups.

Overall completeness and applicability of evidence

One important finding from this review was that while we identified 17 randomised controlled trials, they had been published in 50 different papers. Furthermore, several of the investigators had not only reported outcomes at the end of early treatment but they had produced several papers that were confined to analysis of subsets of subjects, to form interim reports or 'updates'. While they may have had good reasons to follow this publication strategy, in terms of having to compete for the renewal of grant funding, this did result in difficulty interpreting the results of these studies. We approached this problem by identifying the most relevant outcomes and data points and then produced composite data extraction for these studies. We would like to suggest that studies are not reported until they are completed. The registration of trials will come some way to addressing some of these issues, where each trial has a unique identity number which will appear on all publications.

In this review we have analysed data at the end of phase one and phase two in studies that evaluated the effect of early treatment. This is because these trials were carried out to evaluate the effectiveness of early treatment provided when the children were 8 to 10 years old. These studies were then extended to the completion of all orthodontic treatment and included in this review. It could be suggested that we should only report the final findings of these trials. However, we feel that the 'early' treatment studies should be included to illustrate that there were some short-term benefits, for example, reduction in overjet and increase in self esteem. Nevertheless, these findings do not detract from the overall conclusions that early treatment is of limited benefit.

Finally, there was great variation in the outcome measures that were adopted by the investigators. This was particularly marked with the use of cephalometric analyses and is not surprising when we consider that there are many different types of analysis. We would suggest that when future studies are planned uniformly applied cephalometric analyses are utilised, so that adequate comparisons between trials can be achieved.

Quality of the evidence

In this review we found 17 studies looking at patients with prominent upper front teeth (Class II malocclusion). The overall quality of evidence in this review was low (Summary of findings for the main comparison; Summary of findings 2), with only two of the 17 trials assessed as at low risk of bias. There were three young children treatment studies (Florida 1998; North Carolina 2004; UK (Mixed) 2009) and 14 adolescent studies (Banks 2004; Bilgiç 2011; Cevidanes 2003; Cura 1997; Jamilian 2011; Ghafari 1998; Lee 2007; London 1998; Mao 1997; New Zealand 2000; Showkatbakhsh 2011; Thiruvenkatachari 2010; UK (11-14) 2003; Yaqoob 2012). UK (Mixed) 2009 and Yaqoob

2012 were the only two studies that were assessed as at low risk of bias. It is important to mention that carrying out a trial of a two-phase study (treatment for young children followed by treatment at adolescence) is much more difficult and potentially more prone to bias. However, in this review the two-phase studies were of better quality as compared to most one-phase studies.

It is important to point out that one study did not report complete set of data. Although six different articles were published, none of them included a complete data set and did not give reasons (Ghafari 1998).

It is interesting to note that one study was prematurely stopped due to harms (Thiruvenkatachari 2010). The study compared the Twin Block and the Dynamax appliances and showed a statistically significant overjet reduction in the Twin Block group at the end of the first interim analysis. The study also reported significantly greater incidence of harms with the Dynamax appliance.

Potential biases in the review process

We avoided reporting bias by carrying out a broad search with no restrictions on language or publication status.

Agreements and disagreements with other studies or reviews

There are several systematic reviews that have been performed on the effects of functional appliances for patients with increased overjet (Antonarakis 2007; Barnett 2008; Cozza 2006; Flores-Mir 2007; Perillo 2012). Antonarakis 2007 reported that functional appliances show a statistically significant reduction in overjet and ANB value when compared with untreated controls. However, the authors have included prospective and retrospective studies and did not separate early and late treatment. This makes it difficult to compare with the present review. Similarly Barnett 2008; Cozza 2006; Flores-Mir 2007 and Perillo 2012 have included non-randomised studies. Cozza 2006 evaluated the effects of functional appliances on mandibular length and did not report on other dental measurements. Barnett 2008 and Flores-Mir 2007 reviews were confined to the Herbst appliance, whereas Perillo 2012 evaluated the Frankel appliance. This makes it impossible to compare the results with the present review.

AUTHORS' CONCLUSIONS

Implications for practice

Orthodontic treatment for young children, followed by a later phase of treatment when the child is in early adolescence, appear to significantly reduce the incidence of incisal trauma as compared to treatment that is provided in one phase when the child is in early adolescence. There are no other advantages for providing a two-phase treatment compared to one-phase in early adolescence.

When functional appliance treatment is provided in early adolescence it appears that there are minor beneficial changes in skeletal pattern, however, these are probably not clinically significant. Similarly, the choice of functional appliance when compared to the Twin Block does not result in any advantageous effects.

Implications for research

Consideration needs to be given to forming a consensus on the type of measures that are used in orthodontic trials, this is particularly relevant for cephalometric measurement and analysis. In addition, studies should be carried out at the same time points and reported according to the Consolidated Standards of Reporting Trials (CONSORT) guidelines.

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

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

Banks 2004

Methods	Location: United Kingdom Number of centres: 3 centres, 4 operators Recruitment period: Not stated Funding source: British Orthodontic Society 1998 Research & Audit award Trial design: Parallel group RCT
Participants	Inclusion criteria: Overjet of 7 mm or more; no previous appliance therapy; permanent dentition stage, age 10-14 years; and no significant medical history Exclusion criteria: None stated Age at baseline: Mean age group 12.6 years Number randomised: 203 (14 incorrectly included or protocol deviation), 189 started treatment Number evaluated: 136 (76/95 and 60/94)
Interventions	**Comparison:** Gp A (n = 95): Twin Block with stepwise incremental advancement Gp B (n = 94): Twin Block with single step advancement
Outcomes	(1) Cephalometric radiographs (2) Number and magnitude of bite advancements during treatment (3) Patient's date of birth (4) Patient's postal code (used to obtain data on level of social deprivation, according to the Carstairs index, a composite index of deprivation derived from United Kingdom national census data) (5) Reasons for treatment discontinuation (6) Patient's clinical record
Notes	Duration of randomised treatment (months): Gp A = 7.02 (6.34 to 7.70), Gp B = 7.40 (6.71 to 8.09) Sample size calculation: "A 20% difference between the groups in compliance rate was thought to be clinically significant. On this basis, with alpha at 0.05 and the study power at 0.85, we needed 80 patients per group. To allow for 20% treatment discontinuation, we recruited over 200 patients with an intention to treat analysis"

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"The patients were randomized to either the control or the experimental group". The randomisation was made at the start of the study with pre-prepared random number tables with a block stratification on centre and sex (unpublished data)

Banks 2004 (*Continued*)

Allocation concealment (selection bias)	Low risk	"We performed manual allocation using sealed envelopes to blind the operator during enrolment of patients in the study"
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"When measuring the cephalograms, the examiner was unaware of the group to which the patient had been allocated"
Incomplete outcome data (attrition bias) All outcomes	High risk	Experimental group - Recruited 95, completed 76 (loss 20%) Control group - Recruited 94, completed 60 (loss 36%) Reasons for discontinuation not specified
Selective reporting (reporting bias)	Low risk	All variables reported
Other bias	Low risk	No other sources of bias identified

Bilgiç 2011

Methods	Location: Diyarbakir, Turkey Number of centres: 1: Dicle University, Turkey Recruitment period: Not specified Funding source: Not specified Trial design: Parallel group
Participants	Inclusion criteria: Active growth period; Class II skeletal relationship due to retrognathic mandible; increased overjet; normal or reduced incisor mandibular plane angle; well-aligned lower arch; normal or forward growth pattern Exclusion criteria: None specified Age at baseline: Forsus FRD EZ group 12.31 years (SD 1.09), Activator group 12.67 years (SD 1.24) Number randomised: 24 (12 in each group) Number evaluated: 24
Interventions	Gp A (n = 12): Forsus FRD EZ fixed functional appliance Gp B (n = 12): Activator (Andresent-type) appliance
Outcomes	All cephalometric variables reported
Notes	Duration of active treatment - 6 months Sample size: "A power test (Minitab 14.0) between pre-treatment and post-treatment primary result variables determined that a minimum of 20 subjects was necessary for difference comparisons"
Risk of bias	

Bilgiç 2011 (*Continued*)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	"The patients were randomly divided into two groups" and "Patients were selected and matched" Method of sequence generation not described
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not described
Incomplete outcome data (attrition bias) All outcomes	Low risk	No drop-outs or losses to follow-up mentioned. 24 randomised and 24 analysed
Selective reporting (reporting bias)	Low risk	All variables reported
Other bias	Low risk	No other source of bias identified

Cevidanes 2003

Methods	Location: North Carolina, Brazil and Ohio Number of centres: 1: Sao Paulo, Brazil Recruitment period: Not specified Funding source: Grants from FAPESP and CNPq, Brazil Trial design: Parallel group RCT
Participants	Inclusion criteria: Class II Division 1 malocclusion, with greater than or equal to three-fourths cusp Class II molars and overjet ranging from 4.5 to 10 mm Exclusion criteria: None specified Age at baseline: Frankel group 10.3 years (SD 0.9), untreated control group 10.9 years (SD 0.7) Number randomised: 56 (28 in each group) Number evaluated: Not reported
Interventions	Gp A: Frankel appliance Gp B: Untreated control
Outcomes	Counterpart analysis using cephalogram. Measurements included: -mandibular retrusive/protrusive effects -middle cranial fossa and posterior maxilla relative alignment -ramus alignment -ramus/middle cranial fossa relative to posterior maxilla vertical dimension -gonial angle

Cevidanes 2003 (*Continued*)

Notes	Duration of randomised treatment 18 months Sample size calculation not reported	
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	"Class II children were randomly allocated to 2 subgroups, treated and control, to avoid bias in the group comparison" Method of sequence generation not reported
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"Tracings were performed with blinding procedure"
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	2-phase trial. Unclear data. Number of children evaluated at 18 months not stated
Selective reporting (reporting bias)	Unclear risk	The authors have not reported regular cephalometric variables. They have done counterpart analysis which does not include regular cephalometric measurements
Other bias	Unclear risk	Baseline characteristics (gender) not reported

Cura 1997

Methods	Location: Turkey Number of centres: 1 Recruitment period: Not stated Funding source: University of Istanbul Research Fund Trial design: Parallel group RCT
Participants	Inclusion criteria: Children with Class II Division 1 malocclusion, defined by Class II molar relationship and ANB difference of 5° Exclusion criteria: Poor co-operation Age at baseline: 11 years Number randomised: 60 (35 and 25 to Bass and control groups) Number evaluated: 47 (27/35 and 20/25 respectively)
Interventions	**Comparison:** Gp A (n = 27): Bass functional appliance Gp B (n = 20): Untreated control

Cura 1997 (*Continued*)

Outcomes	Skeletal discrepancy measured by ANB on cephalogram, skeletal development	
Notes	Duration of randomised treatment: 6 months Sample size calculation: Not reported	
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	"The sample was randomly divided into a treatment group of 35 cases and a control group of 25 cases" Method of sequence generation not described
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinded assessment not reported
Incomplete outcome data (attrition bias) All outcomes	High risk	13 drop-outs (22%). 8/35 patients in treatment group and 5/25 in control group. Reasons given - Poor co-operation and lack of communication Drop-out patients not included in analysis, but percentage similar in each group
Selective reporting (reporting bias)	Low risk	All outcome variables reported
Other bias	High risk	Gender imbalance at baseline

Florida 1998

Methods	Location: University of Florida, USA Number of centres: 1 Recruitment period: Not stated Funding source: Funded by NIH (DE08715) Trial design: Randomised parallel group study over 10 years
Participants	Inclusion criteria: Third or fourth grade at school, at least bilateral 1/2 cusp Class II molars or 1 side < 1/2 cusp Class II if other side greater than 1/2 cusp Class II. Fully erupted permanent first molars, emergence of not more than 3 permanent canines or premolars and positive overbite and overjet Exclusion criteria: Not willing to undergo orthodontic treatment or to be randomly allocated to treatment type. Poor general health, active dental or periodontal pathology Age at baseline: Mean 9.6 years

Florida 1998 (*Continued*)

	Screened child population (360) then referred to clinic for treatment Number randomised: 325 randomised, 277 started treatment: 95, 100 and 82 in bionator, headgear and control respectively Number evaluated: end of treatment phase (I) 79/95, 92/100, 78/82, end of retention phase 75/95, 85/100 and 75/82, and end of follow-up (II) 70/95, 81/100, 74/82 in bionator, headgear and control groups respectively
Interventions	Gp A: Bionator appliance Gp B: Cervical pull headgear with removable bite plane Gp C: Delayed treatment control 3 phases of treatment: 2 years of early treatment plus 6 months retention plus further 6 months follow-up
Outcomes	(i) Overjet (ii) Skeletal discrepancy (iii) Dental alignment measured with the PAR index
Notes	Duration of randomised treatment: 2 years initially Sample size calculation not reported

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	High risk	A stratified block randomisation procedure was used "Subjects initially were selected in blocks of six and randomized to the treatment protocols. This procedure of assigning subjects to groups only after a block had filled was modified in year 3, after we recognised slow entry rate and many partially filled blocks (23% of the sample) were randomized to groups"
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"All cephalometric radiographs were encoded by the staff assistant and then decoded for analysis"
Incomplete outcome data (attrition bias) All outcomes	High risk	Clear information on withdrawals. Drop-outs: 24%. Number of drop-outs approximately equal in each group but rate of withdrawal was significantly higher for non-whites
Selective reporting (reporting bias)	Low risk	All variables reported

Florida 1998 (*Continued*)

Other bias	Low risk	No other sources of bias identified

Ghafari 1998

Methods	Location: The University of Pennsylvania, USA Number of centres: 1 Recruitment period: Not stated Funding source: This study was supported by grants RO1-DE08722 and RR-00040 (NIH) Trial design: Randomised parallel group study
Participants	Inclusion criteria: Class II, Division 1 malocclusion associated with bilateral distocclusion (unilateral Class I excluded) and a minimum ANB angle of 4.5°; between 7 and 12.5/13 years of age; no prior orthodontic treatment; and expected residential stability of 3 years Exclusion criteria: Children with systemic, mental, behavioural, bleeding, and craniofacial disorders were excluded. If siblings presented with the same malocclusion, only 1 of them was recruited because they share in both the genetic background and environment Age at baseline: Chronological age range 7 years 2 months to 13 years 4 months. Skeletal age range at baseline 5 years 9 months to 13 years 9 months and was basis of grouping participants into early (< 10 years for girls and < 10.5 years for boys) and late childhood Number randomised: 84 Number evaluated: 63
Interventions	**Comparison:** Gp A (n = 35/41): Headgear - straight pull headgear inserted into the buccal tubes of bands cemented on permanent maxillary front molars Gp B (n = 28/43): Frankel function regulator type II to be worn at least 16 hours per day
Outcomes	Skeletal measurements from cephalograms, occlusal changes
Notes	Duration of randomised treatment: 2 years Sample size calculation: Not specified

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Randomised. "Within each severity group, the children were assigned at random to treatment with either a headgear (n = 41) or a Frankel FR (n = 43)" Sequence generation method not described
Allocation concealment (selection bias)	Unclear risk	Not described

Ghafari 1998 (*Continued*)

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not described
Incomplete outcome data (attrition bias) All outcomes	High risk	"Non cooperative children were those patients who, at some point in time, refused to receive treatment, despite all efforts to retain them. The largest percentage of these children were girls who wore the Fränkel regulator (42%); by contrast, the smallest number discontinued were girls in the headgear group (5%). The difference between these two groups of girls was statistically significant (P < 0.05). The percentages of boys lost to the study were similar in the headgear (24%) and FR (25%) groups" Drop-outs in headgear 6/41 (15%), Frankel 15/43 (35%). This statistically significant difference between groups is likely to introduce bias
Selective reporting (reporting bias)	Low risk	All variables reported
Other bias	Low risk	No other sources of bias identified Complete set of data not reported. Data for only 26/84 patients reported

Jamilian 2011

Methods	Location: University of Islamic Azad and Shahid Beheshti, Tehran, Iran Number of centres: Not specified Recruitment period: Not stated Funding source: Not stated Trial design: Randomised parallel group study
Participants	Inclusion criteria: ANB > 4°, SNB < 78° degrees, overjet ≥ 5 mm at the start of treatment, no syndromic or medically compromised patients, no previous surgical intervention, no use of other appliances before or during the period of functional treatment, a normal mandibular growth pattern: neither horizontal nor vertical, no skeletal asymmetry Age at baseline: R-appliance group 10.5 (SD 0.7) years and Twin Block group 11.3 (SD 1.3) years Number randomised: 55 Number evaluated: 55 (no drop-outs)
Interventions	**Comparison:** Gp A (n = 30): R-appliance - Tooth and tissue born functional appliance worn full time Gp B (n = 25): Twin Block appliance with upper labial bow worn full time

Jamilian 2011 (*Continued*)

Outcomes	Skeletal measurements from cephalograms, occlusal changes
Notes	Duration of randomised treatment: R-appliance 16.2 months (SD 0.3) months, Twin Block appliance 16.1 (SD 1.4) months Sample size calculation: Not specified

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomised. "..patients were randomly divided to two groups using random number tables" (unpublished data)
Allocation concealment (selection bias)	Unclear risk	Allocation concealment not clearly described. "Specific codes were assigned to each patient for their concealment" (unpublished data)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Outcome assessors were blinded (unpublished data). However, the method of blinding was not described
Incomplete outcome data (attrition bias) All outcomes	Low risk	No drop-outs
Selective reporting (reporting bias)	Low risk	All variables reported
Other bias	Low risk	No other bias detected

Lee 2007

Methods	Location: London, UK Number of centres: 1 Recruitment period: Not stated Funding source: Not stated Trial design: Randomised parallel group study
Participants	Inclusion criteria: Class II Division 1 malocclusion, minimum overjet of 7 mm, mandibular retrognathia contributing to the Skeletal II pattern as assessed clinically. Male Caucasians aged 11-14 years and female Caucasians aged 10-13 years Exclusion criteria: Previous orthodontic treatment or extraction of permanent teeth Age at baseline: 28 males 12-14.7 years, 34 females 10.6-13.7 years Number randomised: 62 Number evaluated: 56

Interventions	**Comparison:** Gp A (n = 31): Twin Block without upper labial bow. Blocks designed to interlock at inclination of approximately 70° Gp B (n = 31): Dynamax functional appliance
Outcomes	Skeletal discrepancy measured by cephalometric radiographs, soft tissue changes measured by optical surface laser scanner
Notes	Duration of randomised treatment: 9 months Sample size calculation: "The recruitment of 62 subjects allowed the creation of 31 matched pairs who were subsequently randomly allocated. This was the minimum number of patients required to satisfy the statistical power calculation" Email sent to authors requesting clarification of sequence generation procedure. No reply to date

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	"...patients were matched for gender and age and then randomly allocated to an appliance group by a non-clinician" Method of sequence generation not reported
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not specified
Incomplete outcome data (attrition bias) All outcomes	Low risk	6 participants failed to complete trial. 3 in Twin Block group and 3 in Dynamax group. Reasons not specified
Selective reporting (reporting bias)	Low risk	All variables reported
Other bias	Unclear risk	"A higher percentage of subjects were found to present with appliance breakages in the Dynamax group (55%) than in the Twin Block group (35%)"

London 1998

Methods	Location: London, UK Number of centres: 1 Recruitment period: Not stated Funding source: Not stated Trial design: Parallel group RCT (3 interventions randomly allocated)
Participants	Inclusion criteria: Children aged 8-15 years old with Class II Division 1 malocclusion and an overjet greater than 7 mm. Moderate Skeletal II base relationship with mandibular retrognathia Exclusion criteria: Previous orthodontic therapy or extraction of permanent teeth, or significant adverse medical history Age at baseline: Mean 12 years Number randomised: 58 (18, 21, 19 to Gps A, B and C respectively) Number evaluated: 47 (13, 18, 16 from Gps A, B and C respectively)
Interventions	**Comparison:** Gp A (n = 13): Bass appliance Gp B (n = 18): Bionator appliance Gp C (n = 16): Twin Block appliance
Outcomes	(i) Overjet (ii) Skeletal discrepancy - ANB method unclear (iii) Soft tissue variables
Notes	Duration of randomised treatment: 9 months Sample size calculation: Not reported. Numbers of participants completing trial are very small and trial likely to be underpowered

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Randomised to treatment groups and control group not randomised Method of sequence generation not described
Allocation concealment (selection bias)	Unclear risk	Unclear
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	High risk	Clear information on withdrawals. Drop-outs: 19%. 58 enrolled and 47 completed Drop-outs 5 (27%), 3 (15%) and 3 (17%) in Bass, Bionator and Twin Block group respectively. Reasons not reported

London 1998 (*Continued*)

Selective reporting (reporting bias)	Low risk	All variables reported
Other bias	Unclear risk	Differences in age at baseline between randomised groups. Not statistically significant but this may be due to small numbers in each group

Mao 1997

Methods	Location: China Number of centres: 1 Recruitment period: From 1994 Funding source: Not stated Trial design: Parallel group RCT
Participants	Inclusion criteria: Children aged 8-11 years old with Class II Division 1 malocclusion Exclusion criteria: Not stated Age at baseline: Range 8-11 years mean 9.5 years Number randomised: 52 Number evaluated: 52
Interventions	**Comparison:** Gp A (n = 26): Bionator/headgear appliance Gp B (n = 26): No orthodontic treatment
Outcomes	Skeletal discrepancy measured by ANB, occlusion. Reporting of outcomes unclear
Notes	Duration of randomised treatment: Unclear Sample size calculation: Not reported

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Randomly allocated. "The 52 children were randomly divided into two groups, treated group (n = 26, 18 males and 8 females) and untreated group (n = 26, 9 males and 17 females)" Method of sequence generation not specified
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Unclear on blinding

Mao 1997 (*Continued*)

Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Drop-outs not specified
Selective reporting (reporting bias)	Unclear risk	Reporting of data not clear
Other bias	High risk	Data reported unclear. Groups very different at baseline (Bionator group 18 males, 6 females and untreated group 9 males and 17 females)

New Zealand 2000

Methods	Location: New Zealand Number of centres: 1 Funding source: Medical Research Council of New Zealand Trial Design: Parallel group RCT (3 groups)
Participants	Inclusion criteria: Children in clinic with Class II Division 1 malocclusion Exclusion criteria: None specified Age at baseline: Range 10-13 years, mean age (boys) 11.28 (SD 0.91) and girls 11.89 (SD 0.68) Number randomised: 54 (18 'triads') Number evaluated: 42 (12, 13, 17 in Gps A, B and C respectively)
Interventions	**Comparison:** Gp A: Harvold Activator functional appliance Gp B: Frankel functional regulator (FR-2) Appliances to be worn for 14 hours per day (times of wearing slowly increased over first month of treatment) Gp C: Untreated control group
Outcomes	(i) Change in skeletal pattern represented by ANB (ii) Change in overjet (iii) PAR score
Notes	Duration of randomised treatment: 18 months Sample size calculation: "The study was large enough to have a power of about 80% of detecting a 1 standard deviation difference with $P < 0.05$"

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	"...were matched in triads according to age and sex and randomly assigned to either the control group (C), the Frainkel function regulator group (FFR), or the Harvold activator group (HA)"

New Zealand 2000 (*Continued*)

		Method of sequence generation not described
Allocation concealment (selection bias)	High risk	Not described. Allocation likely to be predictable within each group of 3
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	High risk	54 enrolled and 42 completed. Drop-outs: 23% Reasons for drop-outs reported "Six children were removed from the study because they either repeatedly failed appointments or refused to wear the appliance as instructed. Two children moved to another region." All drop-outs from the 2 treatment groups. 3/16 (19%) from Frankel group and 5/17 (29%) from Activator group
Selective reporting (reporting bias)	Low risk	All variables reported
Other bias	Low risk	Groups were similar at baseline for age group and gender

North Carolina 2004

Methods	Location: USA Number of centres: 1 Recruitment period: August 1988 to November 1993 Funding source: Grants from NIH, and Orthodontic Fund, Dental Foundation of North Carolina Trial design: Parallel group RCT with 2 treatment phases
Participants	Inclusion criteria: Children with mixed dentition, with all permanent teeth developing, with growth potential throughout phase 1 of treatment. Overjet > 7 mm, all incisors erupted, second molars not erupted Exclusion criteria: Clinically obvious facial asymmetry, cleft or syndrome patients, more than 2 standard deviations from normal vertical proportionality, and those with prior orthodontic treatment Age group: Mean 9.4 years (SD 1.0) Screened child population (2164) then referred to clinic for treatment Number randomised: 192 randomised, 175 started treatment Number evaluated: 53, 52, 61 at the end of phase 1 and 39, 47, 51 at the end of phase 2 for bionator, headgear and control groups respectively

North Carolina 2004 (*Continued*)

Interventions	Gp A (n = 53): Functional appliance - modified bionator with the bite taken with 4-6 mm of protrusion and minimal vertical opening. Reactivation of appliance when necessary was by construction of a new appliance Gp B (n = 52): Headgear - Combination headgear with supershort outer bow, adjusted to deliver 8-10 ounces to the headcap, with neck strap force just sufficient to prevent buccal flaring of upper molars All appliances delivered within 1 month of patients initial records being taken Gp C (n = 61): Control (observation only)
Outcomes	Skeletal growth changes; maxilla, mandible, skeletal relationship, dental relationship
Notes	Duration of intervention: phase 1 - 15 months and phase 2 - 25.5, 30.1 and 34.5 for functional, headgear and control group Frequency of treatment visits: Every 6-8 weeks for active treatment groups and every 6 months for control group Sample size calculation: Sample size of 40 per group was calculated as necessary to detect a mean difference between any 2 groups equivalent to the doubling in annualised change of SNPg (with alpha = 0.01 and power = 0.90) Patients were re-randomised at the end of phase 2 for different clinicians

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"Randomization was performed within gender in blocks of six patients with Proc Plan in SAS"
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of outcome assessment (detection bias) All outcomes	High risk	Because the molar bands were not removed at the end of phase 1, the technician was not masked as to these patients' treatment group
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Number of patients randomised in different groups not reported 192 randomised, 175 started, 166 finished phase 1 and 137 finished phase 2 Drop-out rate of 13.5% (low risk) for phase 1 and 28.6% (high risk) for phase 2. Reasons for drop-outs reported, but not for each treatment group
Selective reporting (reporting bias)	Low risk	All variables reported
Other bias	Low risk	No other bias found

Showkatbakhsh 2011

Methods	Location: Tehran, Iran Number of centres: Not specified Recruitment period: Not stated Funding source: Not stated Trial design: Randomised parallel group study
Participants	Inclusion criteria: ANB > 4°, SNB < 78°, overjet > 5 mm in the initial lateral cephalogram. No syndromic or medically compromised patients, no surgical intervention, no use of other appliances before or during the period of functional treatment, normal growth pattern of the mandible (MP-SN), symmetric relationship between maxilla and mandible Exclusion criteria: Not stated Age at baseline: R-appliance mean age 10.4 (SD 0.8). Anterior Inclined Bite Plate (AIBP) 9 (SD 1.2) years Number randomised: 50 randomised, 50 started treatment Number evaluated: 50 at the end of funtional phase (no drop-outs) (unpublished data)
Interventions	Gp A (n = 25): R-appliance Gp B (n = 25): Anterior Inclined Bite Plate (AIBP)
Outcomes	Skeletal growth changes; maxilla, mandible, skeletal relationship reported. Dental measurements were not reported
Notes	Duration of intervention: Group A (R-appliance): 11 (SD 2) months. Group B: 9 (SD 1.2) months Sample size calculation: Not specified

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"Patients were randomly assigned to two groups using standardised random number table"
Allocation concealment (selection bias)	Unclear risk	Not specified
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not stated
Incomplete outcome data (attrition bias) All outcomes	Low risk	No drop-outs
Selective reporting (reporting bias)	Unclear risk	Only skeletal measurements reported. No linear dental measurements reported
Other bias	Low risk	No other bias detected

Thiruvenkatachari 2010

Methods	Location: United Kingdom Number of centres: 2 Recruitment period: January 2008 to January 2009 Funding source: Not stated Trial design: Randomised parallel group trial
Participants	Inclusion criteria: Children aged 10-14 years with overjet greater than 6 mm Exclusion criteria: Craniofacial syndrome, previous orthodontic treatment or premolar extractions Age group: Not stated Number randomised: 64 Number evaluated: 64
Interventions	**Comparison:** Gp A (n = 32): Twin Block appliance Gp B (n = 32): Dynamax appliance Patients were asked to wear appliances 24 hours per day except during contact sports and swimming
Outcomes	Skeletal measurement from cephalometric radiographs. Clinical measure of overjet. Appliance breakages and adverse events
Notes	Duration of randomised treatment: Trial stopped early based on planned interim analysis Sample size calculation: "The sample size calculation was based on the data from a previous investigation into the effectiveness of the Twin-block and Herbst appliances.3 We considered that a minimum clinically meaningful difference in treatment duration between 2 competing treatments was 4 months (common SD 4.61). For a trial with a power of 80% and an alpha of 0.05, a sample of 32 patients in each group was required, with an estimated noncompliance rate of 30%"

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Central randomisation allocation and allocation by a computer using minimisation software "Patients were then allocated by using minimization to one of the treatments by using MINIM software, with sex as a prognostic factor"
Allocation concealment (selection bias)	Low risk	Allocation carried out using central telephone line and performed by people independent from the trial
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Overjet measurements done by clinicians and not possible The DMC assessors and the trial statisti-

Thiruvenkatachari 2010 (*Continued*)

		cian were blinded to treatment allocation
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Trial stopped early due to adverse events and clinical improvement 7/32 Twin Block patients and 3/32 Dynamax patients dropped out of the trial Reasons for drop-outs: 9 failed to attend the follow-up appointment and 1 required headgear
Selective reporting (reporting bias)	Low risk	Not all outcome variables (cephalometric data) assessed due to premature termination
Other bias	High risk	Trial stopped early based on interim analysis

UK (11-14) 2003

Methods	Location: United Kingdom Number of centres: 13 centres Recruitment period: March 1997 to June 1998. Funding source: Medical Research Council (99410454) Trial design: Randomised parallel group trial
Participants	Inclusion criteria: Children aged 11-14 with overjet greater than 7 mm, and second premolars erupted Exclusion criteria: Craniofacial syndrome Age at baseline: Gp A mean 12.41 (95% CI 12.17 to 12.63), Gp B 12.74 (95% CI 12.48 to 12.99) Number randomised: 215 Number evaluated: 183
Interventions	**Comparison:** Gp A: Twin Block appliance Gp B: Herbst appliance Participants were requested to wear the appliances 24 hours per day except during contact sports or swimming. Treatment with functional appliances was followed by treatment with fixed appliances if necessary
Outcomes	(i) Overjet (ii) Skeletal discrepancy measured by Pancherz analysis (iii) Dental alignment measured with the PAR index (iv) Duration of treatment
Notes	Duration of intervention: As required to reduce overjet. Gp A = 11.22 (9.58 to 12.86), Gp B = 5.81 (5.13 to 6.48) Sample size calculation: "We based our sample size calculation for the number of patients necessary to achieve 80% power with an alpha of 0.05 on a clinically meaningful

	difference in peer assessment rating (PAR) scores of 15% between the study groups.10 The calculation showed that we needed to recruit 80 patients into each arm of the study to account for an estimated non-completion rate of 15%"

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"...the patient was randomized to receive treatment with either a Twinblock or a Herbst appliance. ....At the beginning of the study, random number tables were used to prepare randomization lists, stratified by centre and sex into permuted blocks"
Allocation concealment (selection bias)	Low risk	Randomisation performed using a central telephone line
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"Cephalograms and study casts were both scored with the examiner unaware of the group to which the patient had been allocated"
Incomplete outcome data (attrition bias) All outcomes	High risk	215 enrolled and 183 evaluated. 25/110 (23%) lost in Twin Block group and 7/105 (7%) in Herbst appliance group. Reasons for drop-outs specified (unpublished data) . Drop-outs significantly different between groups Herbst group: 5 had problems with appliance and discontinued, 1 moved away/lost to follow-up Twin Block group: 14 had multiple DNAs and were discharged with no follow-up records, 5 moved away/lost to follow-up, 5 refused to wear the appliance, 1 fitted with wrong appliance
Selective reporting (reporting bias)	Low risk	All variables reported
Other bias	Low risk	Groups appear similar at baseline

UK (Mixed) 2009

Methods	Location: United Kingdom Number of centres: 13 centres Recruitment period: March 1997 to August 1999 Funding source: Medical Research Council (G9410454) Trial design: Randomised parallel group trial
Participants	Inclusion criteria: Children in the mixed dentition with overjet greater than 7 mm, and willingness of the patient and a parent to participate in the study. The patients had to be in the mixed dentition with at least the permanent incisors and first molars erupted, but there was no age criterion Exclusion criteria: Craniofacial syndromes Age at baseline: The average age was 9.7 (SD 0.98) years for the treatment group and 9. 8 (SD 0.94) years for the control group Number randomised: 174 Number evaluated: 127
Interventions	**Comparison:** Gp A: Twin Block early treatment: randomised 89, completed 67 Gp B: Twin Block delayed treatment: randomised 85, completed 73
Outcomes	(i) Overjet (ii) Skeletal discrepancy measured by Pancherz analysis (iii) Dental alignment measured with the PAR index (iv) Socio-psychological effects of treatment
Notes	Duration of intervention: 15 months Sample size calculation: "This showed that the mean duration of treatment for patients who had later treatment after early treatment was 25 months (SD 11). It was decided that a meaningful difference between the treatment duration for children who did, or did not, receive early treatment was 6 months. To give a study a power of 80% and an alpha of 0.05, the sample size needed to be 60 in each group"

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"The randomization was made at the start of the study with pre-prepared random number tables with a block stratification on centre and sex"
Allocation concealment (selection bias)	Low risk	Randomisation was carried out using a central telephone line and minimisation software
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Assessor blinded to outcomes. "The cephalograms and the study casts were scored with the examiner unaware of the patient's group"

UK (Mixed) 2009 (*Continued*)

Incomplete outcome data (attrition bias) All outcomes	Low risk	Clear information on withdrawals, but rates different in each group. 22/89 (25%) in the Twin Block group and 12/85 (14%) in the control group Reasons for exclusion specified (unpublished data) Control group: 4 refused to consent for phase 2 treatment, 1 withdrew due to illness, 3 had multiple DNAs with no final records, 1 moved away/lost contact, 2 had Twin Blocks fitted in phase 1 in error, 1 had sore mouth and required treatment in phase 1 Treatment group: 2 moved away/lost contact, 9 had multiple DNA with no follow-up records, 4 did not start as eligibility criteria was not met, 5 refused to continue, 1 had poor oral health, 1 removed from study due to health problems
Selective reporting (reporting bias)	Low risk	All variables reported
Other bias	Low risk	Groups appear similar at baseline

Yaqoob 2012

Methods	Location: United Kingdom Number of centres: 1 (Kent and Canterbury Hospital) Recruitment period: Not stated Funding source: Not stated Trial design: Randomised parallel group trial.
Participants	Inclusion criteria: Children aged 10-14 years with Class II Division 1 incisor relationship (British Standards Institute), overjet greater than 6 mm, molar relationship at least a half unit Angle Class II, white ethnic origin Exclusion criteria: Previous history of orthodontic therapy or permanent tooth extraction, no significant or adverse medical history or craniofacial syndrome Age at baseline: mean Gp A 12.5 years (range 10.5-13.5 years), Gp B 12.3 years (range 10.8-13.2 years) Number randomised: 64 Number evaluated: 60
Interventions	Gp A: Twin Block appliance with a passive upper labial bow (CTB-LB) Gp B: Twin Block appliance was constructed with no labial bow (CTB-NLB) Both appliances to be worn full time and only removed for cleaning or during participation of child in contact sports

Outcomes	(i) Overjet (ii) Skeletal discrepancy
Notes	Duration of intervention: 12 months Sample size calculation: "Based on previous research and statistical analysis, a minimum of 52 subjects were required (26 in each group) for the study to have a power of 0.95 to detect a significant difference of 5 degrees in upper incisor retroclination at the 5% significance level. To compensate for attrition of the sample, 64 subjects were recruited overall. Power calculations were performed on G*Power 3 (Institute for Experimental Psychology, Dusseldorf, Germany)"

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"A stratified allocation sequence was generated using an electronic computer program. Patients were stratified according to age and gender. All patients were placed into age- (62 mo) and gender-matched pairs. Pairs of patients were matched according to age and sex, with one patient from each pair randomly selected and allocated to either treatment group (using www.random.org)"
Allocation concealment (selection bias)	Low risk	Allocation performed using a central website
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"Tracings were carried out in a blind manner by one researcher"
Incomplete outcome data (attrition bias) All outcomes	Low risk	4 drop-outs. 2 in CTB-LB and 2 in CTB-NLB Reasons for drop-outs: failed to attend the follow-up appointment. Unlikely to have introduced bias
Selective reporting (reporting bias)	Low risk	All variables reported
Other bias	Low risk	No other sources of bias identified

CI = confidence interval; Gp = group; mm = millimetre; RCT = randomised controlled trial; SD = standard deviation

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

Study	Reason for exclusion
Aknin 2000	Comparative study but not randomly allocated to interventions
Ashmore 2002	Not RCT
Baccetti 2009	Not RCT
Bishara 1995	Not RCT
Chintakanon 2000	Not RCT
Collett 2000	Not RCT
Cura 1996	Not RCT
Dahan 1989	Not RCT
De Almeida 2002	Not RCT
DeVincenzo 1989	Comparative study but not randomly allocated to interventions
Du 2002	Comparative study but not randomly allocated to interventions
Erverdi 1995	Not RCT Contacted authors. No response was received
Falck 1989	Not RCT
Firouz 1992	Not RCT
Franco 2002	Imaging study of effects of orthodontic treatment on TMJ. Not relevant
Freeman 2009	Not RCT
Ghiglione 2000	Abstract only. No subsequent publication identified. Insufficient information to include in review
Gianelly 1983	Not RCT
Guner 2003	Not RCT
Hagg 2002	Comparative study but not randomly allocated to interventions
Harvold 1971	Not RCT
Hiyama 2002	Not RCT
Ingervall 1991	Comparative study but not randomly allocated to interventions

(*Continued*)

Iscan 1997	Comparative study but not randomly allocated to interventions
Janson 2003	Not RCT
Jarrell 2001	Abstract only. No subsequent publication found and insufficient information to include in review
Kalra 1989	Not RCT
Keski-Nisula 2003	Not RCT
Kumar 1996	Not RCT
Lange 1995	Not RCT
Lund 1998	Not RCT
Malmgren 1987	Not RCT
Malta 2010	Not RCT
Meral 2004	Inclusion criteria not increased overjet
Muniandy 2000	Not Class II
Nelson 2000	Comparative study but not randomly allocated to interventions
Op Heij 1989	Not RCT
Ozturk 1994	Comparative study but no randomisation
Pangrazio 1999	Retrospective
Pangrazio 2003	Not RCT
Parkin 2001	Not RCT
Phan 2006	Not RCT
Pirttiniemi 2005	Only 20% of participants had Class II malocclusion
Reukers 1998	Included participants with Class II Division 2 malocclusion
Sari 2003	Comparative study but not randomly allocated to interventions
Schaefer 2004	Not RCT
Shannon 2004	Not RCT

(*Continued*)

Siara-Olds 2010	Not RCT
Siqueira 2007	Not RCT
Taner 2003	Comparative retrospective study
Thuer 1989	Comparative study but not randomly allocated to interventions
Tumer 1999	Comparative study but not randomly allocated to interventions
Ucem 1998	Comparison of matched groups
Ucuncu 2001	Comparison of matched groups
Wey 2007	Not RCT
Wieslander 1984	Not RCT
Witt 1999	Comparison of matched groups

RCT = randomised controlled trial; TMJ = temporomandibular joint

DATA AND ANALYSES

Comparison 1. Early orthodontic treatment: 2-phase versus adolescent treatment

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Outcomes at the end of phase I: functional versus observation	4		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
1.1 Final overjet	3	432	Mean Difference (IV, Fixed, 95% CI)	-4.17 [-4.61, -3.73]
1.2 Final ANB	3	419	Mean Difference (IV, Fixed, 95% CI)	-0.89 [-1.38, -0.40]
1.3 PAR score	3	380	Mean Difference (IV, Fixed, 95% CI)	-11.16 [-12.86, -9.46]
1.4 Self concept	1	135	Mean Difference (IV, Fixed, 95% CI)	-3.63 [-7.66, 0.40]
2 Incidence of new incisal trauma during phase I treatment: functional versus observation	2	281	Odds Ratio (M-H, Fixed, 95% CI)	0.72 [0.35, 1.49]
3 Outcomes at the end of phase I: headgear versus observation	2		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
3.1 Final overjet	2	278	Mean Difference (IV, Fixed, 95% CI)	-1.07 [-1.63, -0.51]
3.2 Final ANB	2	277	Mean Difference (IV, Fixed, 95% CI)	-0.72 [-1.18, -0.27]
4 Incidence of new incisal trauma during phase I treatment: headgear versus observation	2	285	Odds Ratio (M-H, Fixed, 95% CI)	0.82 [0.41, 1.64]
5 Outcomes at the end of phase II: functional (2-phase) versus adolescent (1-phase) treatment	3		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
5.1 Final overjet	3	343	Mean Difference (IV, Fixed, 95% CI)	0.21 [-0.10, 0.51]
5.2 Final ANB	3	347	Mean Difference (IV, Fixed, 95% CI)	-0.02 [-0.47, 0.43]
5.3 PAR score	3	360	Mean Difference (IV, Fixed, 95% CI)	0.62 [-0.66, 1.91]
5.4 Self concept	1	132	Mean Difference (IV, Fixed, 95% CI)	-0.83 [-3.97, 2.31]
6 Incidence of new incisal trauma during phase II treatment: functional (2-phase) versus adolescent (1-phase) treatment	3	357	Odds Ratio (M-H, Fixed, 95% CI)	0.59 [0.35, 0.99]
7 Outcomes at the end of phase II: headgear (2-phase) versus adolescent (1-phase) treatment	2		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
7.1 Final overjet	2	238	Mean Difference (IV, Fixed, 95% CI)	-0.22 [-0.56, 0.12]
7.2 Final ANB	2	231	Mean Difference (IV, Fixed, 95% CI)	-0.27 [-0.80, 0.26]
7.3 PAR score	2	177	Mean Difference (IV, Fixed, 95% CI)	-1.55 [-3.70, 0.60]
8 Incidence of new incisal trauma during phase II treatment: headgear (2-phase) versus adolescent (1-phase) treatment	2	237	Odds Ratio (M-H, Fixed, 95% CI)	0.47 [0.27, 0.83]

Comparison 2. Early orthodontic treatment: 2-phase appliance 1 (headgear) versus appliance 2 (functional)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Outcomes at the end of phase I: headgear versus functional	2		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
1.1 Final overjet	2	271	Mean Difference (IV, Fixed, 95% CI)	0.75 [0.21, 1.29]
1.2 Final ANB	2	271	Mean Difference (IV, Fixed, 95% CI)	-0.04 [-0.49, 0.41]
2 Incidence of new incisal trauma during phase I treatment: headgear versus functional	2	282	Odds Ratio (M-H, Fixed, 95% CI)	1.10 [0.53, 2.30]
3 Outcomes at the end of phase II: headgear versus functional	2		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
3.1 Final overjet	2	225	Mean Difference (IV, Fixed, 95% CI)	-0.21 [-0.57, 0.15]
3.2 Final ANB	2	222	Mean Difference (IV, Fixed, 95% CI)	-0.17 [-0.67, 0.34]
3.3 PAR score	2	224	Mean Difference (IV, Fixed, 95% CI)	-0.81 [-2.21, 0.58]
4 Incidence of new incisal trauma during phase II treatment: headgear versus functional appliance	2	226	Odds Ratio (M-H, Fixed, 95% CI)	0.79 [0.43, 1.44]

Comparison 3. Late orthodontic treatment for adolescence: functional versus no treatment

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Functional versus no treatment	2		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
1.1 Final overjet	1	47	Mean Difference (IV, Fixed, 95% CI)	-5.22 [-6.51, -3.93]
1.2 Final ANB	2	99	Mean Difference (IV, Fixed, 95% CI)	-2.37 [-3.01, -1.74]

Comparison 4. Late orthodontic treatment for adolescence: different types of appliances used for late treatment

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Twin Block versus other (R-appliance, Bionator and Herbst) functional appliances	3	429	Mean Difference (IV, Fixed, 95% CI)	-0.25 [-0.61, 0.10]
1.1 Final ANB	3	210	Mean Difference (IV, Fixed, 95% CI)	-0.63 [-1.17, -0.08]
1.2 Final overjet	3	219	Mean Difference (IV, Fixed, 95% CI)	0.01 [-0.45, 0.48]
2 Twin Block conventional versus other Twin Block modifications	2		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
2.1 Final overjet	2	196	Mean Difference (IV, Fixed, 95% CI)	-0.23 [-0.67, 0.22]
2.2 ANB change	1	60	Mean Difference (IV, Fixed, 95% CI)	-0.24 [-1.17, 0.69]

3 Functional (Activator) versus fixed functional (FORSUS FRD EZ)	1	48	Mean Difference (IV, Fixed, 95% CI)	0.14 [-0.98, 1.26]
3.1 Final overjet	1	24	Mean Difference (IV, Fixed, 95% CI)	2.19 [0.58, 3.80]
3.2 Final ANB	1	24	Mean Difference (IV, Fixed, 95% CI)	-1.74 [-3.28, -0.20]
4 R-appliance versus AIBP	1	50	Mean Difference (IV, Fixed, 95% CI)	-0.30 [-0.99, 0.39]
4.1 Final ANB	1	50	Mean Difference (IV, Fixed, 95% CI)	-0.30 [-0.99, 0.39]

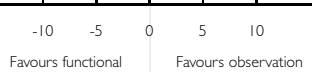
Analysis 1.1. Comparison 1 Early orthodontic treatment: 2-phase versus adolescent treatment, Outcome 1 Outcomes at the end of phase I: functional versus observation.

Review: Orthodontic treatment for prominent upper front teeth (Class II malocclusion) in children

Comparison: 1 Early orthodontic treatment: 2-phase versus adolescent treatment

Outcome: 1 Outcomes at the end of phase I: functional versus observation

Study or subgroup	Functional N	Mean(SD)	Observation N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
1 Final overjet							
Florida 1998	85	3.88 (1.9)	79	5.42 (2.67)		38.3 %	-1.54 [-2.25, -0.83]
North Carolina 2004	41	5.38 (2.67)	54	8.94 (1.84)		21.5 %	-3.56 [-4.51, -2.61]
UK (Mixed) 2009	89	3.7 (2.27)	84	10.7 (2.4)		40.2 %	-7.00 [-7.70, -6.30]
Subtotal (95% CI)	**215**		**217**			**100.0 %**	**-4.17 [-4.61, -3.73]**
Heterogeneity: Chi² = 117.02, df = 2 (P<0.00001); I² =98%							
Test for overall effect: Z = 18.49 (P < 0.00001)							
2 Final ANB							
Florida 1998	85	3.96 (1.95)	78	4.49 (2.19)		59.0 %	-0.53 [-1.17, 0.11]
North Carolina 2004	41	4.82 (2.08)	54	5.77 (2.08)		33.7 %	-0.95 [-1.79, -0.11]
UK (Mixed) 2009	87	3.85 (1.8)	74	7.35 (7.8)		7.3 %	-3.50 [-5.32, -1.68]
Subtotal (95% CI)	**213**		**206**			**100.0 %**	**-0.89 [-1.38, -0.40]**
Heterogeneity: Chi² = 9.17, df = 2 (P = 0.01); I² =78%							
Test for overall effect: Z = 3.55 (P = 0.00039)							
3 PAR score							
Florida 1998	94	17.7 (7.4)	84	22 (9.2)		47.4 %	-4.30 [-6.77, -1.83]
New Zealand 2000	15	14.75 (8.21)	16	30.94 (5.86)		11.4 %	-16.19 [-21.24, -11.14]
UK (Mixed) 2009	87	18.04 (7.3)	84	35.7 (10.1)		41.3 %	-17.66 [-20.31, -15.01]
Subtotal (95% CI)	**196**		**184**			**100.0 %**	**-11.16 [-12.86, -9.46]**
Heterogeneity: Chi² = 56.53, df = 2 (P<0.00001); I² =96%							
Test for overall effect: Z = 12.86 (P < 0.00001)							



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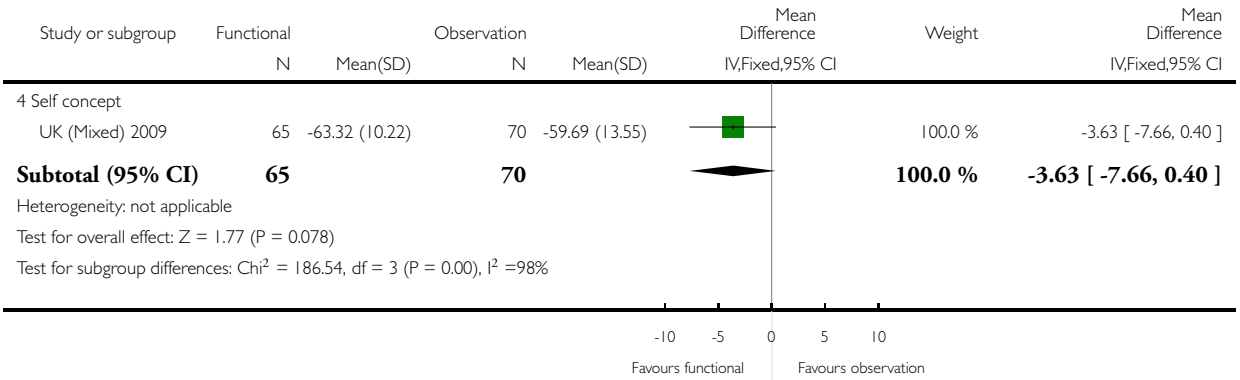
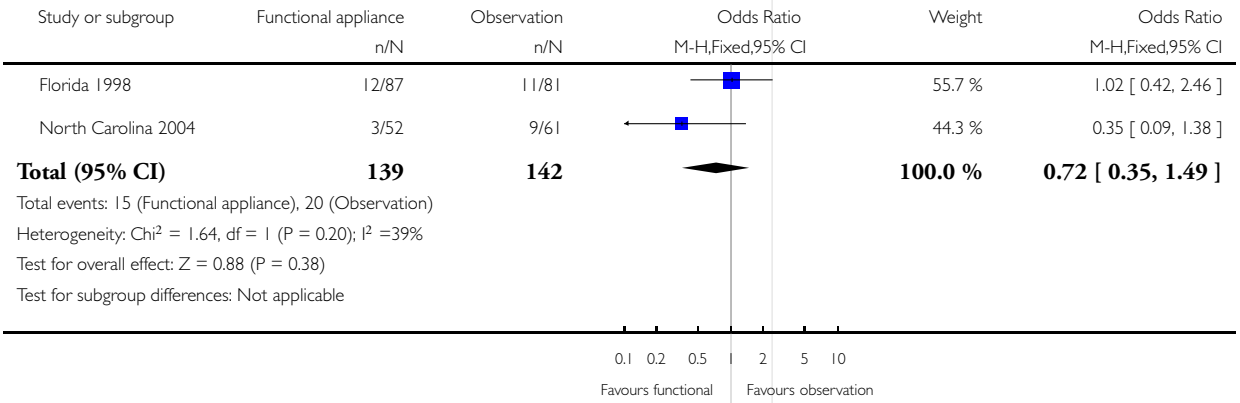


Analysis 1.2. Comparison 1 Early orthodontic treatment: 2-phase versus adolescent treatment, Outcome 2 Incidence of new incisal trauma during phase I treatment: functional versus observation.

Review: Orthodontic treatment for prominent upper front teeth (Class II malocclusion) in children

Comparison: 1 Early orthodontic treatment: 2-phase versus adolescent treatment

Outcome: 2 Incidence of new incisal trauma during phase I treatment: functional versus observation



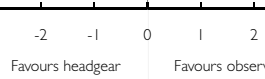
Analysis 1.3. Comparison 1 Early orthodontic treatment: 2-phase versus adolescent treatment, Outcome 3 Outcomes at the end of phase I: headgear versus observation.

Review: Orthodontic treatment for prominent upper front teeth (Class II malocclusion) in children

Comparison: 1 Early orthodontic treatment: 2-phase versus adolescent treatment

Outcome: 3 Outcomes at the end of phase I: headgear versus observation

Study or subgroup	Headgear N	Mean(SD)	Observation N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
1 Final overjet							
Florida 1998	95	3.99 (2.33)	79	5 (2.67)		55.8 %	-1.01 [-1.76, -0.26]
North Carolina 2004	50	7.8 (2.48)	54	8.94 (1.84)		44.2 %	-1.14 [-1.98, -0.30]
Subtotal (95% CI)	**145**		**133**			**100.0 %**	**-1.07 [-1.63, -0.51]**
Heterogeneity: Chi^2 = 0.05, df = 1 (P = 0.82); I^2 =0.0%							
Test for overall effect: Z = 3.72 (P = 0.00020)							
2 Final ANB							
Florida 1998	95	3.89 (1.85)	78	4.49 (2.19)		55.0 %	-0.60 [-1.21, 0.01]
North Carolina 2004	50	4.83 (1.5)	54	5.7 (2)		45.0 %	-0.87 [-1.55, -0.19]
Subtotal (95% CI)	**145**		**132**			**100.0 %**	**-0.72 [-1.18, -0.27]**
Heterogeneity: Chi^2 = 0.34, df = 1 (P = 0.56); I^2 =0.0%							
Test for overall effect: Z = 3.12 (P = 0.0018)							
Test for subgroup differences: Chi^2 = 0.88, df = 1 (P = 0.35), I^2 =0.0%							



Analysis 1.4. Comparison 1 Early orthodontic treatment: 2-phase versus adolescent treatment, Outcome 4 Incidence of new incisal trauma during phase I treatment: headgear versus observation.

Review: Orthodontic treatment for prominent upper front teeth (Class II malocclusion) in children

Comparison: 1 Early orthodontic treatment: 2-phase versus adolescent treatment

Outcome: 4 Incidence of new incisal trauma during phase I treatment: headgear versus observation

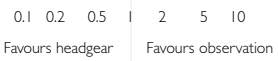
Study or subgroup	Headgear n/N	Observation n/N	Odds Ratio M-H,Fixed,95% CI	Weight	Odds Ratio M-H,Fixed,95% CI
Florida 1998	12/93	11/81		58.4 %	0.94 [0.39, 2.27]
North Carolina 2004	5/50	9/61		41.6 %	0.64 [0.20, 2.06]
Total (95% CI)	**143**	**142**		**100.0 %**	**0.82 [0.41, 1.64]**

Total events: 17 (Headgear), 20 (Observation)

Heterogeneity: $Chi^2 = 0.27$, df = 1 (P = 0.61); $I^2 = 0.0\%$

Test for overall effect: Z = 0.57 (P = 0.57)

Test for subgroup differences: Not applicable



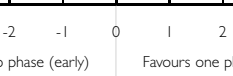
Analysis 1.5. Comparison 1 Early orthodontic treatment: 2-phase versus adolescent treatment, Outcome 5 Outcomes at the end of phase II: functional (2-phase) versus adolescent (1-phase) treatment.

Review: Orthodontic treatment for prominent upper front teeth (Class II malocclusion) in children

Comparison: 1 Early orthodontic treatment: 2-phase versus adolescent treatment

Outcome: 5 Outcomes at the end of phase II: functional (2-phase) versus adolescent (1-phase) treatment

Study or subgroup	Two phase (Early tx) N	Mean(SD)	One phase (delayed tx) N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
1 Final overjet							
Florida 1998	67	2.6 (1.12)	68	2.49 (1.08)		65.9 %	0.11 [-0.26, 0.48]
North Carolina 2004	39	3.72 (2.04)	51	3.99 (1.75)		14.2 %	-0.27 [-1.07, 0.53]
UK (Mixed) 2009	56	4.3 (2.15)	62	3.44 (1.49)		20.0 %	0.86 [0.19, 1.53]
Subtotal (95% CI)	**162**		**181**			**100.0 %**	**0.21 [-0.10, 0.51]**
Heterogeneity: Chi^2 = 5.23, df = 2 (P = 0.07); I^2 =62%							
Test for overall effect: Z = 1.34 (P = 0.18)							
2 Final ANB							
Florida 1998	65	3.7 (1.9)	62	3.49 (2.35)		36.2 %	0.21 [-0.54, 0.96]
North Carolina 2004	39	3.72 (2.12)	51	4.36 (2.06)		26.4 %	-0.64 [-1.51, 0.23]
UK (Mixed) 2009	62	4 (1.99)	68	3.81 (2.28)		37.3 %	0.19 [-0.54, 0.92]
Subtotal (95% CI)	**166**		**181**			**100.0 %**	**-0.02 [-0.47, 0.43]**
Heterogeneity: Chi^2 = 2.62, df = 2 (P = 0.27); I^2 =24%							
Test for overall effect: Z = 0.10 (P = 0.92)							
3 PAR score							
Florida 1998	66	6 (5)	70	6 (4.4)		65.6 %	0.0 [-1.59, 1.59]
North Carolina 2004	39	8.4 (7.7)	51	9.3 (8.1)		15.3 %	-0.90 [-4.18, 2.38]
UK (Mixed) 2009	64	10.42 (10.42)	70	6.44 (6.23)		19.1 %	3.98 [1.04, 6.92]
Subtotal (95% CI)	**169**		**191**			**100.0 %**	**0.62 [-0.66, 1.91]**
Heterogeneity: Chi^2 = 6.43, df = 2 (P = 0.04); I^2 =69%							
Test for overall effect: Z = 0.95 (P = 0.34)							
4 Self concept							
UK (Mixed) 2009	62	-68.87 (8.32)	70	-68.04 (10.09)		100.0 %	-0.83 [-3.97, 2.31]
Subtotal (95% CI)	**62**		**70**			**100.0 %**	**-0.83 [-3.97, 2.31]**
Heterogeneity: not applicable							
Test for overall effect: Z = 0.52 (P = 0.60)							
Test for subgroup differences: Chi^2 = 1.59, df = 3 (P = 0.66), I^2 =0.0%							



Analysis 1.6. Comparison 1 Early orthodontic treatment: 2-phase versus adolescent treatment, Outcome 6 Incidence of new incisal trauma during phase II treatment: functional (2-phase) versus adolescent (1-phase) treatment.

Review: Orthodontic treatment for prominent upper front teeth (Class II malocclusion) in children

Comparison: 1 Early orthodontic treatment: 2-phase versus adolescent treatment

Outcome: 6 Incidence of new incisal trauma during phase II treatment: functional (2-phase) versus adolescent (1-phase) treatment

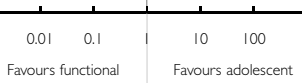
Study or subgroup	Functional n/N	Adolescent treatment n/N	Odds Ratio M-H,Fixed,95% CI	Weight	Odds Ratio M-H,Fixed,95% CI
Florida 1998	19/67	23/69		42.0 %	0.79 [0.38, 1.64]
North Carolina 2004	11/42	24/51		41.4 %	0.40 [0.17, 0.96]
UK (Mixed) 2009	4/63	7/65		16.7 %	0.56 [0.16, 2.02]
Total (95% CI)	**172**	**185**		**100.0 %**	**0.59 [0.35, 0.99]**

Total events: 34 (Functional), 54 (Adolescent treatment)

Heterogeneity: $Chi^2 = 1.38$, df = 2 (P = 0.50); $I^2 = 0.0\%$

Test for overall effect: Z = 2.02 (P = 0.044)

Test for subgroup differences: Not applicable



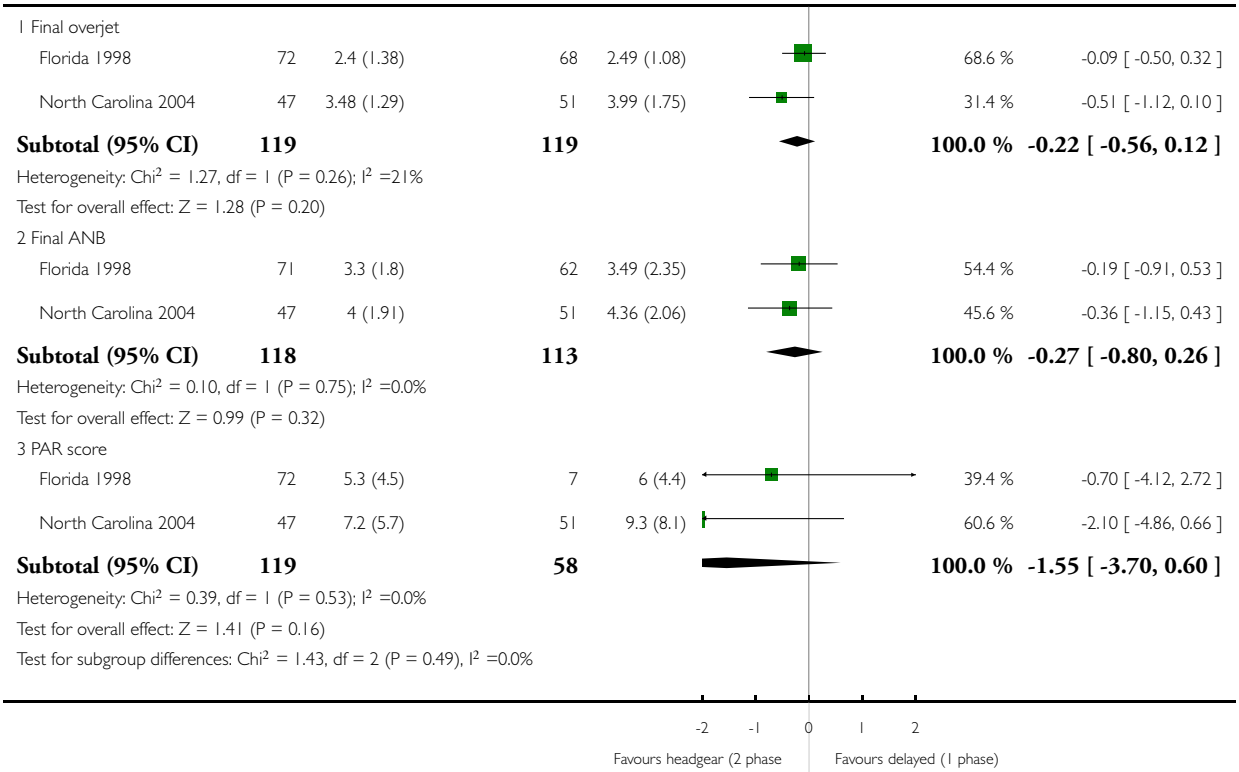
Analysis 1.7. Comparison 1 Early orthodontic treatment: 2-phase versus adolescent treatment, Outcome 7 Outcomes at the end of phase II: headgear (2-phase) versus adolescent (1-phase) treatment.

Review: Orthodontic treatment for prominent upper front teeth (Class II malocclusion) in children

Comparison: 1 Early orthodontic treatment: 2-phase versus adolescent treatment

Outcome: 7 Outcomes at the end of phase II: headgear (2-phase) versus adolescent (1-phase) treatment

Study or subgroup	Headgear (two phase) N	Mean(SD)	Delayed (one phase) N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
1 Final overjet							
Florida 1998	72	2.4 (1.38)	68	2.49 (1.08)		68.6 %	-0.09 [-0.50, 0.32]
North Carolina 2004	47	3.48 (1.29)	51	3.99 (1.75)		31.4 %	-0.51 [-1.12, 0.10]
Subtotal (95% CI)	**119**		**119**			**100.0 %**	**-0.22 [-0.56, 0.12]**
Heterogeneity: Chi^2 = 1.27, df = 1 (P = 0.26); I^2 =21%							
Test for overall effect: Z = 1.28 (P = 0.20)							
2 Final ANB							
Florida 1998	71	3.3 (1.8)	62	3.49 (2.35)		54.4 %	-0.19 [-0.91, 0.53]
North Carolina 2004	47	4 (1.91)	51	4.36 (2.06)		45.6 %	-0.36 [-1.15, 0.43]
Subtotal (95% CI)	**118**		**113**			**100.0 %**	**-0.27 [-0.80, 0.26]**
Heterogeneity: Chi^2 = 0.10, df = 1 (P = 0.75); I^2 =0.0%							
Test for overall effect: Z = 0.99 (P = 0.32)							
3 PAR score							
Florida 1998	72	5.3 (4.5)	7	6 (4.4)		39.4 %	-0.70 [-4.12, 2.72]
North Carolina 2004	47	7.2 (5.7)	51	9.3 (8.1)		60.6 %	-2.10 [-4.86, 0.66]
Subtotal (95% CI)	**119**		**58**			**100.0 %**	**-1.55 [-3.70, 0.60]**
Heterogeneity: Chi^2 = 0.39, df = 1 (P = 0.53); I^2 =0.0%							
Test for overall effect: Z = 1.41 (P = 0.16)							
Test for subgroup differences: Chi^2 = 1.43, df = 2 (P = 0.49), I^2 =0.0%							



Analysis 1.8. Comparison 1 Early orthodontic treatment: 2-phase versus adolescent treatment, Outcome 8 Incidence of new incisal trauma during phase II treatment: headgear (2-phase) versus adolescent (1-phase) treatment.

Review: Orthodontic treatment for prominent upper front teeth (Class II malocclusion) in children

Comparison: 1 Early orthodontic treatment: 2-phase versus adolescent treatment

Outcome: 8 Incidence of new incisal trauma during phase II treatment: headgear (2-phase) versus adolescent (1-phase) treatment

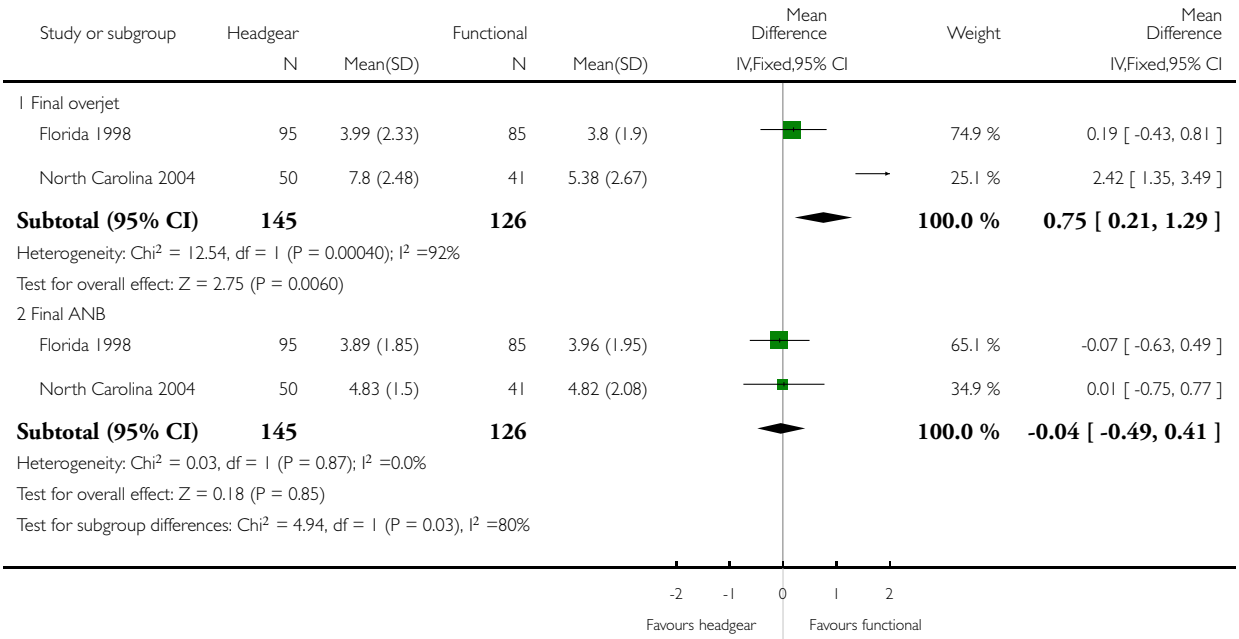
Study or subgroup	Headgear n/N	Adolescent treatment n/N	Odds Ratio M-H,Fixed,95% CI	Weight	Odds Ratio M-H,Fixed,95% CI
Florida 1998	16/71	23/69		51.1 %	0.58 [0.28, 1.23]
North Carolina 2004	11/46	24/51		48.9 %	0.35 [0.15, 0.85]
Total (95% CI)	**117**	**120**		**100.0 %**	**0.47 [0.27, 0.83]**
Total events: 27 (Headgear), 47 (Adolescent treatment)					
Heterogeneity: Chi^2 = 0.72, df = 1 (P = 0.40); I^2 =0.0%					
Test for overall effect: Z = 2.61 (P = 0.0089)					
Test for subgroup differences: Not applicable					

Analysis 2.1. Comparison 2 Early orthodontic treatment: 2-phase appliance 1 (headgear) versus appliance 2 (functional), Outcome 1 Outcomes at the end of phase I: headgear versus functional.

Review: Orthodontic treatment for prominent upper front teeth (Class II malocclusion) in children

Comparison: 2 Early orthodontic treatment: 2-phase appliance 1 (headgear) versus appliance 2 (functional)

Outcome: 1 Outcomes at the end of phase I: headgear versus functional



Analysis 2.2. Comparison 2 Early orthodontic treatment: 2-phase appliance 1 (headgear) versus appliance 2 (functional), Outcome 2 Incidence of new incisal trauma during phase 1 treatment: headgear versus functional.

Review: Orthodontic treatment for prominent upper front teeth (Class II malocclusion) in children

Comparison: 2 Early orthodontic treatment: 2-phase appliance 1 (headgear) versus appliance 2 (functional)

Outcome: 2 Incidence of new incisal trauma during phase 1 treatment: headgear versus functional

Study or subgroup	Headgear n/N	Functional n/N	Odds Ratio M-H,Fixed,95% CI	Weight	Odds Ratio M-H,Fixed,95% CI
Florida 1998	12/93	12/87		80.3 %	0.93 [0.39, 2.19]
North Carolina 2004	5/50	3/52		19.7 %	1.81 [0.41, 8.03]
Total (95% CI)	**143**	**139**		**100.0 %**	**1.10 [0.53, 2.30]**
Total events: 17 (Headgear), 15 (Functional)					
Heterogeneity: Chi^2 = 0.59, df = 1 (P = 0.44); I^2 =0.0%					
Test for overall effect: Z = 0.26 (P = 0.80)					
Test for subgroup differences: Not applicable					

Analysis 2.3. Comparison 2 Early orthodontic treatment: 2-phase appliance 1 (headgear) versus appliance 2 (functional), Outcome 3 Outcomes at the end of phase II: headgear versus functional.

Review: Orthodontic treatment for prominent upper front teeth (Class II malocclusion) in children

Comparison: 2 Early orthodontic treatment: 2-phase appliance 1 (headgear) versus appliance 2 (functional)

Outcome: 3 Outcomes at the end of phase II: headgear versus functional

Study or subgroup	Headgear N	Mean(SD)	Functional N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
1 Final overjet							
Florida 1998	72	2.4 (1.38)	67	2.6 (1.12)		75.9 %	-0.20 [-0.62, 0.22]
North Carolina 2004	47	3.48 (1.29)	39	3.72 (2.04)		24.1 %	-0.24 [-0.98, 0.50]
Subtotal (95% CI)	**119**		**106**			**100.0 %**	**-0.21 [-0.57, 0.15]**
Heterogeneity: Chi² = 0.01, df = 1 (P = 0.93); I² =0.0%							
Test for overall effect: Z = 1.13 (P = 0.26)							
2 Final ANB							
Florida 1998	71	3.3 (1.8)	65	3.7 (1.9)		65.5 %	-0.40 [-1.02, 0.22]
North Carolina 2004	47	4 (1.9)	39	3.72 (2.12)		34.5 %	0.28 [-0.58, 1.14]
Subtotal (95% CI)	**118**		**104**			**100.0 %**	**-0.17 [-0.67, 0.34]**
Heterogeneity: Chi² = 1.58, df = 1 (P = 0.21); I² =37%							
Test for overall effect: Z = 0.64 (P = 0.52)							
3 PAR score							
Florida 1998	72	5.3 (4.5)	66	6 (5)		77.0 %	-0.70 [-2.29, 0.89]
North Carolina 2004	47	7.2 (5.7)	39	8.4 (7.7)		23.0 %	-1.20 [-4.11, 1.71]
Subtotal (95% CI)	**119**		**105**			**100.0 %**	**-0.81 [-2.21, 0.58]**
Heterogeneity: Chi² = 0.09, df = 1 (P = 0.77); I² =0.0%							
Test for overall effect: Z = 1.14 (P = 0.25)							
Test for subgroup differences: Chi² = 0.74, df = 2 (P = 0.69), I² =0.0%							

Analysis 2.4. Comparison 2 Early orthodontic treatment: 2-phase appliance 1 (headgear) versus appliance 2 (functional), Outcome 4 Incidence of new incisal trauma during phase II treatment: headgear versus functional appliance.

Review: Orthodontic treatment for prominent upper front teeth (Class II malocclusion) in children

Comparison: 2 Early orthodontic treatment: 2-phase appliance 1 (headgear) versus appliance 2 (functional)

Outcome: 4 Incidence of new incisal trauma during phase II treatment: headgear versus functional appliance

Study or subgroup	Headgear n/N	Functional n/N	Odds Ratio M-H,Fixed,95% CI	Weight	Odds Ratio M-H,Fixed,95% CI
Florida 1998	16/71	19/67		63.4 %	0.73 [0.34, 1.59]
North Carolina 2004	11/46	11/42		36.6 %	0.89 [0.34, 2.33]
Total (95% CI)	**117**	**109**		**100.0 %**	**0.79 [0.43, 1.44]**
Total events: 27 (Headgear), 30 (Functional)					
Heterogeneity: Chi^2 = 0.09, df = 1 (P = 0.77); I^2 =0.0%					
Test for overall effect: Z = 0.77 (P = 0.44)					
Test for subgroup differences: Not applicable					

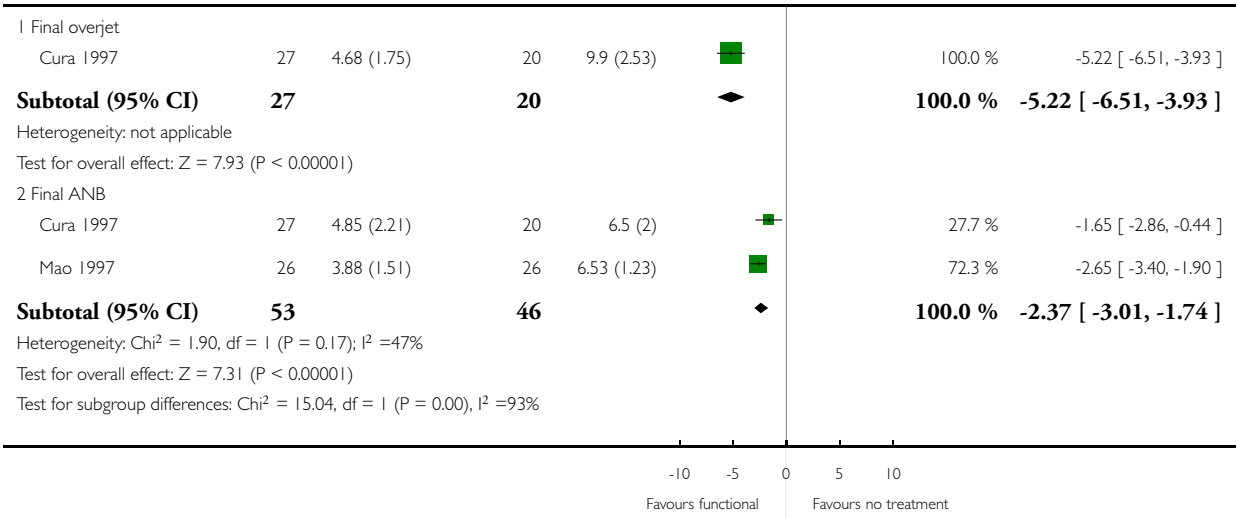
Analysis 3.1. Comparison 3 Late orthodontic treatment for adolescence: functional versus no treatment, Outcome 1 Functional versus no treatment.

Review: Orthodontic treatment for prominent upper front teeth (Class II malocclusion) in children

Comparison: 3 Late orthodontic treatment for adolescence: functional versus no treatment

Outcome: 1 Functional versus no treatment

Study or subgroup	Functional N	Mean(SD)	No treatment N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
1 Final overjet							
Cura 1997	27	4.68 (1.75)	20	9.9 (2.53)		100.0 %	-5.22 [-6.51, -3.93]
Subtotal (95% CI)	**27**		**20**			**100.0 %**	**-5.22 [-6.51, -3.93]**
Heterogeneity: not applicable							
Test for overall effect: Z = 7.93 (P < 0.00001)							
2 Final ANB							
Cura 1997	27	4.85 (2.21)	20	6.5 (2)		27.7 %	-1.65 [-2.86, -0.44]
Mao 1997	26	3.88 (1.51)	26	6.53 (1.23)		72.3 %	-2.65 [-3.40, -1.90]
Subtotal (95% CI)	**53**		**46**			**100.0 %**	**-2.37 [-3.01, -1.74]**
Heterogeneity: Chi^2 = 1.90, df = 1 (P = 0.17); I^2 =47%							
Test for overall effect: Z = 7.31 (P < 0.00001)							
Test for subgroup differences: Chi^2 = 15.04, df = 1 (P = 0.00), I^2 =93%							



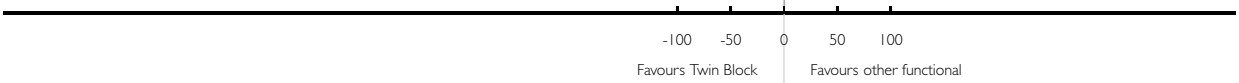
Analysis 4.1. Comparison 4 Late orthodontic treatment for adolescence: different types of appliances used for late treatment, Outcome 1 Twin Block versus other (R-appliance, Bionator and Herbst) functional appliances.

Review: Orthodontic treatment for prominent upper front teeth (Class II malocclusion) in children

Comparison: 4 Late orthodontic treatment for adolescence: different types of appliances used for late treatment

Outcome: 1 Twin Block versus other (R-appliance, Bionator and Herbst) functional appliances

Study or subgroup	Twin Block N	Mean(SD)	Other functional applianc N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
1 Final ANB							
Jamilian 2011	25	4.2 (2.2)	30	4.7 (1.6)		11.6 %	-0.50 [-1.54, 0.54]
London 1998	16	4.8 (1.8)	18	5 (2.4)		6.2 %	-0.20 [-1.62, 1.22]
UK (11-14) 2003	52	3.8 (2)	69	4.6 (2)		23.9 %	-0.80 [-1.52, -0.08]
Subtotal (95% CI)	**93**		**117**			**41.7 %**	**-0.63 [-1.17, -0.08]**
Heterogeneity: Chi^2 = 0.63, df = 2 (P = 0.73); I^2 =0.0%							
Test for overall effect: Z = 2.26 (P = 0.024)							
2 Final overjet							
Jamilian 2011	25	2.8 (1.3)	30	3.5 (1.5)		22.7 %	-0.70 [-1.44, 0.04]
London 1998	16	4.5 (2.8)	18	4.4 (2.1)		4.4 %	0.10 [-1.58, 1.78]
UK (11-14) 2003	63	4.05 (2.3)	67	3.53 (1.14)		31.2 %	0.52 [-0.11, 1.15]
Subtotal (95% CI)	**104**		**115**			**58.3 %**	**0.01 [-0.45, 0.48]**
Heterogeneity: Chi^2 = 6.06, df = 2 (P = 0.05); I^2 =67%							
Test for overall effect: Z = 0.06 (P = 0.95)							
Total (95% CI)	**197**		**232**			**100.0 %**	**-0.25 [-0.61, 0.10]**
Heterogeneity: Chi^2 = 9.79, df = 5 (P = 0.08); I^2 =49%							
Test for overall effect: Z = 1.41 (P = 0.16)							
Test for subgroup differences: Chi^2 = 3.10, df = 1 (P = 0.08), I^2 =68%							



Analysis 4.2. Comparison 4 Late orthodontic treatment for adolescence: different types of appliances used for late treatment, Outcome 2 Twin Block conventional versus other Twin Block modifications.

Review: Orthodontic treatment for prominent upper front teeth (Class II malocclusion) in children

Comparison: 4 Late orthodontic treatment for adolescence: different types of appliances used for late treatment

Outcome: 2 Twin Block conventional versus other Twin Block modifications

Study or subgroup	Twin Block conventional N	Mean(SD)	Twin Block modifications N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
1 Final overjet							
Banks 2004	76	1.23 (2.013)	60	1.77 (1.471)		57.6 %	-0.54 [-1.13, 0.05]
Yaqoob 2012	30	2.2 (1.4)	30	2 (1.3)		42.4 %	0.20 [-0.48, 0.88]
Subtotal (95% CI)	**106**		**90**			**100.0 %**	**-0.23 [-0.67, 0.22]**
Heterogeneity: Chi^2 = 2.59, df = 1 (P = 0.11); I^2 =61%							
Test for overall effect: Z = 1.00 (P = 0.32)							
2 ANB change							
Yaqoob 2012	30	-3.07 (1.51)	30	-2.83 (2.12)		100.0 %	-0.24 [-1.17, 0.69]
Subtotal (95% CI)	**30**		**30**			**100.0 %**	**-0.24 [-1.17, 0.69]**
Heterogeneity: not applicable							
Test for overall effect: Z = 0.51 (P = 0.61)							
Test for subgroup differences: Chi^2 = 0.00, df = 1 (P = 0.98), I^2 =0.0%							

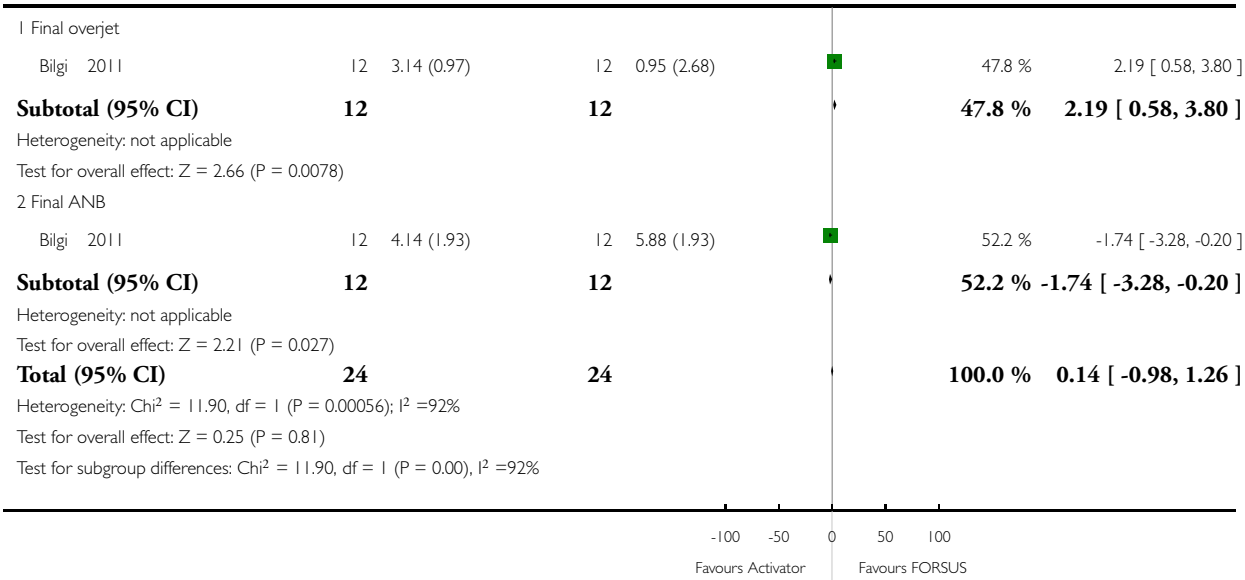
Analysis 4.3. Comparison 4 Late orthodontic treatment for adolescence: different types of appliances used for late treatment, Outcome 3 Functional (Activator) versus fixed functional (FORSUS FRD EZ).

Review: Orthodontic treatment for prominent upper front teeth (Class II malocclusion) in children

Comparison: 4 Late orthodontic treatment for adolescence: different types of appliances used for late treatment

Outcome: 3 Functional (Activator) versus fixed functional (FORSUS FRD EZ)

Study or subgroup	Functional (Activator) N	Mean(SD)	fixed functional (FORSUS FRD EZ) N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
1 Final overjet							
Bilgi 2011	12	3.14 (0.97)	12	0.95 (2.68)		47.8 %	2.19 [0.58, 3.80]
Subtotal (95% CI)	**12**		**12**			**47.8 %**	**2.19 [0.58, 3.80]**
Heterogeneity: not applicable							
Test for overall effect: Z = 2.66 (P = 0.0078)							
2 Final ANB							
Bilgi 2011	12	4.14 (1.93)	12	5.88 (1.93)		52.2 %	-1.74 [-3.28, -0.20]
Subtotal (95% CI)	**12**		**12**			**52.2 %**	**-1.74 [-3.28, -0.20]**
Heterogeneity: not applicable							
Test for overall effect: Z = 2.21 (P = 0.027)							
Total (95% CI)	**24**		**24**			**100.0 %**	**0.14 [-0.98, 1.26]**
Heterogeneity: Chi^2 = 11.90, df = 1 (P = 0.00056); I^2 =92%							
Test for overall effect: Z = 0.25 (P = 0.81)							
Test for subgroup differences: Chi^2 = 11.90, df = 1 (P = 0.00), I^2 =92%							

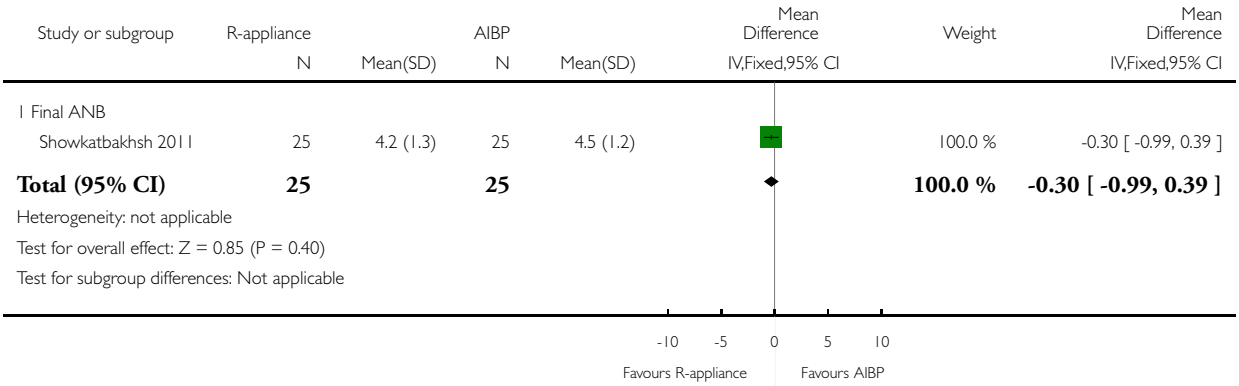


Analysis 4.4. Comparison 4 Late orthodontic treatment for adolescence: different types of appliances used for late treatment, Outcome 4 R-appliance versus AIBP.

Review: Orthodontic treatment for prominent upper front teeth (Class II malocclusion) in children

Comparison: 4 Late orthodontic treatment for adolescence: different types of appliances used for late treatment

Outcome: 4 R-appliance versus AIBP



APPENDICES

Appendix 1. MEDLINE (OVID) search strategy

1. exp Orthodontics/
2. (appliance$ adj5 (function$ or remova$ or fix$)).mp.
3. (orthodontic$ and (brace$ or band$ or wire$)).mp.
4. (orthodontic$ and (extract$ or remov$)).mp.
5. (orthodontic$ and (headgear$ or "head gear$" or head-gear$)).mp.
6. (device$ adj5 (function$ or remova$ or fix$)).mp.
7. ((appliance$ or device$) adj5 (intraoral or "intra oral" or intra-oral or extraoral or "extra oral" or extra-oral)).mp.
8. (activator adj appliance$).mp.
9. (Frankel or "twin$ block$" or FR-II).mp.
10. ((growth adj3 modif$) and (jaw$ or maxilla$ or mandible$ or mandibular)).mp.
11. (two-phase and (treatment or therapy) and (orthodontic$ or malocclusion$)).mp.
12. ((orthopedic$ or orthopaedic$) and (dental or orthodontic$ or facial)).mp.
13. or/1-12
14. Malocclusion, Angle Class II/
15. Retrognathism/
16. (("class II" or "class 2") adj3 malocclusion$).mp.
17. (posterior adj3 occlusion$).mp.
18. (distoclusion$ or disto-occlusion$ or distocclusion$).mp.
19. retrognath$.mp.

20. (prominent adj3 upper adj3 teeth).mp.
21. (overjet$ or "over jet$" or over-jet$).mp.
22. or/14-21
23. 13 and 22

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] (Higgins 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 2. Cochrane Oral Health Group's Trials Register search strategy

A search update of the Cochrane Oral Health Group's Trials Register was conducted in April 2013 using the Cochrane Register of Studies and the search strategy below:

#1 (orthodontic*:ti,ab) AND (INREGISTER)
#2 ((appliance* or device*):ti,ab) AND (INREGISTER)
#3 ((function* or remov* or fix* or intraoral or "intra oral" or intra-oral or extraoral or "extra oral" or extra-oral):ti,ab) AND (INREGISTER)
#4 ((brace* or band* or wire* or headgear* or "head gear*" or head-gear*):ti,ab) AND (INREGISTER)
#5 (#2 and #3) AND (INREGISTER)
#6 (("activator appliance*" or Frankel or "twin* block*" or FR-II or "growth modif*" or "Two phase"):ti,ab) AND (INREGISTER)
#7 ((orthopedic and dental):ti,ab) AND (INREGISTER)
#8 ((orthopaedic and dental):ti,ab) AND (INREGISTER)
#9 (#1 or #4 or #5 or #6 or #7 or #8) AND (INREGISTER)
#10 ((retrognathi* or "posterior occlusion*"):ti,ab) AND (INREGISTER)
#11 (("class II" and malocclusion*):ti,ab) AND (INREGISTER)
#12 ((distocclusion* or disto-occlusion* or distoclusion* or "prominent upper front teeth" or overjet* or over-jet* or "over jet*"):ti,ab) AND (INREGISTER)
#13 (("Class 2" and malocclusion*):ti,ab) AND (INREGISTER)
#14 (#10 or #11 or #12 or #13) AND (INREGISTER)
#15 (#9 and #14) AND (INREGISTER)

A previous search of the Cochrane Oral Health Group's Trials Register was conducted in February 2012 using the Procite software and the search strategy below:

(orthodontic* or (appliance* and (function* or remov* or fix* or intraoral or "intra oral" or intra-oral or extraoral or "extra oral" or extra-oral)) or brace* or band* or wire* or headgear* or "head gear*" or head-gear* or (device and (function* or remov* or fix* or intraoral or "intra oral" or intra-oral or extraoral or "extra oral" or extra-oral)) or "activator appliance*" or Frankel or "twin* block*" or FR-II or "growth modif*" or "Two phase" or (orthopedic and dental) or (orthopaedic and dental)) AND (retrognathi* or "posterior occlusion*" or ("class II" and malocclusion*) or ("Class 2" and malocclusion*) or distocclusion* or disto-occlusion* or distoclusion* or "prominent upper front teeth" or overjet* or over-jet* or "over jet*")

Appendix 3. Cochrane Central Register of Controlled Trials (CENTRAL) search strategy

#1 MeSH descriptor Orthodontics explode all trees
#2 ((appliance* in All Text near/5 function* in All Text) or (appliance* in All Text near/5 remov* in All Text) or (appliance* in All Text near/5 fix* in All Text) or (appliance* in All Text near/5 intraoral in All Text) or (appliance* in All Text near/5 "intra oral" in All Text) or (appliance* in All Text near/5 intra-oral in All Text) or (appliance* in All Text near/5 extraoral in All Text) or (appliance* in All Text near/5 "extra oral" in All Text) or (appliance* in All Text near/5 extra-oral in All Text))
#3 ((device* in All Text near/5 function* in All Text) or (device* in All Text near/5 remov* in All Text) or (device* in All Text near/5 fix* in All Text) or (device* in All Text near/5 intraoral in All Text) or (device* in All Text near/5 "intra oral" in All Text) or (device* in All Text near/5 intra-oral in All Text) or (device* in All Text near/5 extraoral in All Text) or (device* in All Text near/5 "extra oral" in All Text) or (device* in All Text near/5 extra-oral in All Text))
#4 (orthodontic* in All Text and (brace* in All Text or band* in All Text or wire* in All Text))
#5 (orthodontic* in All Text and (extract* in All Text or remov* in All Text))
#6 (orthodontic* in All Text and (headgear* in All Text or "head gear*" in All Text or head-gear in All Text))
#7 "activator appliance*" in All Text
#8 (Frankel in All Text or "twin* block*" in All Text or FR-II in All Text)
#9 ((growth in All Text near/3 modif* in All Text) and (jaw* in All Text or maxilla* in All Text or mandib* in All Text))
#10 (two-phase in All Text and (treatment in All Text or therapy in All Text) and (orthodontic* in All Text or malocclusion* in All Text))
#11 ((orthopedic* in All Text or orthopaedic* in All Text) and (dental in All Text or orthodontic* in All Text or facial in All Text))
#12 (#1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11)
#13 MeSH descriptor Malocclusion, Angle Class II this term only
#14 MeSH descriptor Retrognathism this term only
#15 (("class II" in All Text near/3 malocclusion* in All Text) or ("class 2" in All Text near/3 malocclusion* in All Text))
#16 (posterior in All Text near/3 occlusion* in All Text)
#17 (distoclusion* in All Text or disto-occlusion* in All Text or distocclusion* in All Text)
#18 retrognath* in All Text
#19 "prominent upper front teeth" in All Text
#20 (overjet* in All Text or "over jet*" in All Text or over-jet* in All Text)
#21 (#13 or #14 or #15 or #16 or #17 or #18 or #19 or #20)
#22 (#12 and #21)

Appendix 4. EMBASE (OVID) search strategy

1. exp Orthodontics/
2. (appliance$ adj5 (function$ or remova$ or fix$)).mp.
3. (orthodontic$ and (brace$ or band$ or wire$)).mp.
4. (orthodontic$ and (extract$ or remov$)).mp.
5. (orthodontic$ and (headgear$ or "head gear$" or head-gear$)).mp.
6. (device$ adj5 (function$ or remova$ or fix$)).mp.
7. ((appliance$ or device$) adj5 (intraoral or "intra oral" or intra-oral or extraoral or "extra oral" or extra-oral)).mp.
8. (activator adj appliance$).mp.
9. (Frankel or "twin$ block$" or FR-II).mp.
10. ((growth adj3 modif$) and (jaw$ or maxilla$ or mandible$ or mandibular)).mp.
11. (two-phase and (treatment or therapy) and (orthodontic$ or malocclusion$)).mp.
12. ((orthopedic$ or orthopaedic$) and (dental or orthodontic$ or facial)).mp.
13. or/1-12
14. Retrognathia/
15. (("class II" or "class 2") adj3 malocclusion$).mp.
16. (posterior adj3 occlusion$).mp.
17. (distoclusion$ or disto-occlusion$ or distocclusion$).mp.
18. retrognath$.mp.
19. (prominent adj3 upper adj3 teeth).mp.

20. (overjet$ or “over jet$” or over-jet$).mp.
21. or/14-20
22. 13 and 21
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

WHAT'S NEW

Last assessed as up-to-date: 17 April 2013.

Date	Event	Description
4 March 2014	Amended	Minor edit to forest plots.

HISTORY

Protocol first published: Issue 1, 2002

Review first published: Issue 3, 2007

Date	Event	Description
14 November 2013	Amended	Minor edit.
7 November 2013	New search has been performed	Searches updated to April 2013.

(*Continued*)

7 November 2013	New citation required and conclusions have changed	New methods including risk of bias implemented. Inclusion criteria modified to exclude controlled clinical trials and quasi-randomised trials. 9 new included trials, conclusions changed. Summary of findings tables added
23 June 2008	Amended	Converted to new review format.

CONTRIBUTIONS OF AUTHORS

The original review was conceived by Jayne Harrison (JH), Kevin O'Brien (KOB) and Bill Shaw (Cochrane Oral Health Group). Previous work, that was the foundation of current study, was undertaken by JH and KOB.

The update was co-ordinated by Badri Thiruvenkatachari (BT) and KOB. Anne Littlewood (Cochrane Oral Health Group) developed the search strategy and undertook the electronic searches. All review authors screened the search results and retrieved papers, undertook the risk of bias assessment of the papers and extracted data from them. BT and KOB analysed the data and interpreted the results. BT and KOB wrote the results, conclusions and discussion sections of the review.

DECLARATIONS OF INTEREST

Kevin O'Brien was involved in acquiring funding, running and reporting of the UK (11-14) 2003; UK (Mixed) 2009 and Banks 2004 trials; however, he was not involved in the quality assessment of these trials.

Badri Thiruvenkatachari and Helen Worthington are among the authors of UK (Mixed) 2009; however, they were not involved in the quality assessment of this trial.

Badri Thiruvenkatachari and Kevin O'Brien were involved in running and reporting the Thiruvenkatachari 2010 (Dynamax) study; however, they were not involved in the quality assessment of this trial.

Jayne E Harrison: no interests to declare.

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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.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

In this update of the review it was decided that only truly randomised controlled trials would be included. Quasi-randomised trials are now excluded from this review. Controlled clinical trials are now also excluded.

INDEX TERMS

Medical Subject Headings (MeSH)

*Orthodontic Appliances, Functional; *Orthodontic Retainers; Age Factors; Extraoral Traction Appliances; Malocclusion, Angle Class II [*therapy]; Orthodontics, Corrective [*methods]; Randomized Controlled Trials as Topic; Treatment Outcome

MeSH check words

Adolescent; Child; Humans