Orthodontic treatment for distalising upper first molars in children and adolescents (Review)

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[Intervention Review]

Orthodontic treatment for distalising upper first molars in children and adolescents

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ABSTRACT

Background

When orthodontic treatment is provided with fixed appliances, it is sometimes necessary to move the upper molar teeth backwards (distalise) to create space or help to overcome anchorage requirements. This can be achieved with the use of extraoral or intraoral appliances. The most common appliance is extraoral headgear, which requires considerable patient co-operation. Further, reports of serious injuries have been published. Intraoral appliances have been developed to overcome such shortcomings. The comparative effects of extraoral and intraoral appliances have not been fully evaluated.

Objectives

To assess the effects of orthodontic treatment for distalising upper first molars in children and adolescents.

Search methods

We searched the following electronic databases: the Cochrane Oral Health Group's Trials Register (to 10 December 2012), the Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library* 2012, Issue 11), MEDLINE via OVID (1946 to 10 December 2012) and EMBASE via OVID (1980 to 10 December 2012). No restrictions were placed on the language or date of publication when searching the electronic databases.

Selection criteria

Randomised clinical trials involving the use of removable or fixed orthodontic appliances intended to distalise upper first molars in children and adolescents.

Data collection and analysis

We used the standard methodological procedures expected by The Cochrane Collaboration. We performed data extraction and assessment of the risk of bias independently and in duplicate. We contacted authors to clarify the inclusion criteria of the studies.

Main results

Ten studies, reporting data from 354 participants, were included in this review, the majority of which were carried out in a university dental hospital setting. The studies were published between 2005 and 2011 and were conducted in Europe and in Brazil. The age range of participants was from nine to 15 years, with an even distribution of males and females in seven of the studies, and a slight

predominance of female patients in three of the studies. The quality of the studies was generally poor; seven studies were at an overall high risk of bias, three studies were at an unclear risk of bias, and we judged no study to be at low risk of bias.

We carried out random-effects meta-analyses as appropriate for the primary clinical outcomes of movement of upper first molars (mm), and loss of anterior anchorage, where there were sufficient data reported in the primary studies. Four studies, involving 159 participants, compared a distalising appliance to an untreated control. Meta-analyses were not undertaken for all primary outcomes due to incomplete reporting of all summary statistics, expected outcomes, and differences between the types of appliances. The degree and direction of molar movement and loss of anterior anchorage varied with the type of appliance. Four studies, involving 150 participants, compared a distalising appliance versus headgear. The mean molar movement for intraoral distalising appliances was -2.20 mm and -1.04 mm for headgear. There was a statistically significant difference in mean distal molar movement (mean difference (MD) -1.45 mm; 95% confidence interval (CI) -2.74 to -0.15) favouring intraoral appliances compared to headgear (four studies, high or unclear risk of bias, 150 participants analysed). However, a statistically significant difference in mean mesial upper incisor movement (MD 1.82 mm; 95% CI 1.39 to 2.24) and overjet (fixed-effect: MD 1.64 mm; 95% CI 1.26 to 2.02; two studies, unclear risk of bias, 70 participants analysed) favoured headgear, i.e. there was less loss of anterior anchorage with headgear. We reported direct comparisons of intraoral appliances narratively due to the variation in interventions (three studies, high or unclear risk of bias, 93 participants randomised). All appliances were reported to provide some degree of distal movement, and loss of anterior anchorage varied with the type of appliance.

No included studies reported on the incidence of adverse effects (harm, injury), number of attendances or rate of non-compliance.

Authors' conclusions

It is suggested that intraoral appliances are more effective than headgear in distalising upper first molars. However, this effect is counteracted by loss of anterior anchorage, which was not found to occur with headgear when compared with intraoral distalising appliance in a small number of studies. The number of trials assessing the effects of orthodontic treatment for distilisation is low, and the current evidence is of low or very low quality.

PLAIN LANGUAGE SUMMARY

Orthodontic treatment with appliances which move the upper molar teeth backwards

Review question

The main question addressed by this review is how effective are orthodontic appliances in moving the upper teeth backwards in children and adolescents.

Background

Orthodontic treatment is a type of dental care that corrects crooked or sticking out teeth by moving the teeth into different positions. When orthodontic treatment is provided with braces it is sometimes necessary to move the upper molar teeth backwards (distalise). This is achieved by special types of braces (appliances) that are placed either before or at the same time as the normal braces. Appliances which move the upper molar teeth backwards can be placed inside the mouth (intraoral appliance) or attached to the back of the head (extraoral appliance). The most commonly used extraoral appliance is headgear. The biggest disadvantage of headgear is that children and adolescents must wear it for prolonged hours during the day. In addition, serious eye injuries have been reported while wearing headgear. As an alternative, several intraoral appliances have been developed. Unfortunately, their effects have not been completely evaluated.

Study characteristics

This review of existing studies was carried out by the Cochrane Oral Health Group, and the evidence is current as of December 2012. In this review there are 10 studies published between 2005 and 2011 in which a total of 354 children were randomised to receive treatment with a distalising orthodontic appliance and compared to either no treatment, headgear or another distalising appliance. The age range of children in nine of the studies was from 11 to 15 years, although the children recruited to one study were younger, from nine to 10 years old. Both girls and boys participated in the studies.

Where it was mentioned, the funding was from a university or dental research foundation. The authors did not assess the impact of the funding sources.

Key results

When intraoral appliances are compared to headgear they will probably move the upper molar teeth backwards more than headgear. However, the use of intraoral appliances was also associated with movement of the upper front teeth when compared to extraoral appliances in four studies. This is an unwanted effect that was not observed with the use of the headgear appliances.

Harm, injury from the appliances and other characteristics of the appliances which may be important to patients were not reported in the studies.

Quality of the evidence

The evidence presented is generally of low quality. The main shortcomings were related to trial design.

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

Orthodontic appliance compared to untreated control for distalising first molars

Patient or population: children and adolescents undergoing orthodontic treatment
Settings: university or private orthodontic clinic
Intervention: orthodontic appliance
Comparison: untreated control

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Untreated control	Orthodontic appliance				
Movement of upper first molars (mm)	Not estimated	Not estimated	Meta-analysis not appropriate	74 (2 studies)	⊕⊕◯◯ **low**[1,2]	No pooled estimate due to different types of appliances (First Class and distalising) used in the studies
Movement of upper incisor teeth (mm)	Not estimated	Not estimated	Meta-analysis not appropriate	74 (2 studies)	⊕⊕◯◯ **low**[1,2]	No pooled estimate due to different types of appliances (First Class and distalising) used in the studies
Change in overjet (mm)	Not estimated	Not estimated	Meta-analysis not appropriate	74 (2 studies)	⊕⊕◯◯ **low**[1,2]	No pooled estimate due to different types of appliances (First Class and distalising) used in the studies

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

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

[1]One study at high risk of bias; one study at unclear risk of bias
[2]Evidence based on two studies with a low number of participants

BACKGROUND

Description of the condition

When orthodontic treatment is provided with braces it is sometimes necessary to move the upper molar teeth backwards (distalise) to create space or help to overcome anchorage requirements. It is crucial to have reliable methods and appliances that can distalise molars in order to plan and treat many malocclusions optimally. However, appliances that claim to provide distal movement can also have adverse or unwanted effects. These are primarily eye injuries (Samuels1996), minor soft tissue injuries and unwanted tooth movement (Antonarakis 2008).

Description of the intervention

Molar distalisation is a phase of comprehensive orthodontic treatment in which the distalisation appliances are inserted prior to or in conjunction with the fixed orthodontic appliance. When the molar teeth have been sufficiently moved in the distal direction, the distalisation appliances are either removed or continued for retention, and the fixed orthodontic appliances are continued until the end of treatment.

Appliances that distalise molars may be categorised as intraoral or extraoral appliances/systems. The most common distalising appliance is extraoral headgear. In the late 1800s, Kingsley and Angle used occipital headgear to move the top front teeth backwards (Pavlick 1998). In the early 1900s, Case was the first orthodontist to use headgear to distalise molar teeth (Pavlick 1998). Several authors (Blueher 1959; King 1957; Klein 1957; Moore 1959a; Moore 1959b; Newcombe 1958; Silverstein 1954) have reported on the effects that extraoral headgear has on restricting maxillary growth, moving molars distally or both.

Unfortunately, the use of extraoral headgear to move molars distally requires considerable patient co-operation. In order for extraoral headgear to achieve its goal of distal movement, it must be adjusted to apply an appropriate force level, and it must be worn by the patient for the prescribed amount of time. This is usually from 12 to 14 hours per day. Numerous studies of headgear compliance have shown that patients find this difficult (Brandao 2006; Cureton 1993; Cole 2002). In addition, a number of serious ocular injuries have been reported with external headgear (Samuels1996). These injuries occurred through dislodgement during sleep, improper removal or improper use.

Alternative orthodontic appliances and systems which claim to minimise or eliminate the need for patient compliance and which reduce the risk of serious injury have been developed. These are intraoral appliances/systems which are inserted by the orthodontist and remain in the mouth full time. In most instances they can only be removed by the orthodontist. It is stipulated that these can be used to distalise upper molars with minimal patient co-operation because these appliances can only be inserted and removed by the orthodontist. In addition, they are aesthetically more acceptable being less visible than extraoral headgear. A large number of different intraoral appliances and systems which are used to distalise molars have been described in the orthodontic literature. Among the most frequently used in clinical practice are: the pendulum appliance (Hilgers 1992), Wilson's arch (Muse 1993), distal jet appliance (Carano 1996), Jones Jig appliance (Jones 1992), First Class appliance (Fortini 1999), repelling magnets (Bondemark 1994) and superelastic coil springs (Gianelly 1991).

How the intervention might work

All distalising appliances or systems have two main components. The first component applies a force to the upper first molar teeth, and a second component prevents an unwanted reciprocal force by anchoring the appliance to a structure inside or outside of the mouth. When external headgear is used a force is generated by elastics through the attachment of a facebow to bands cemented to molar teeth. A reciprocal force is prevented by anchoring the facebow to a stable structure which is the back of the head. In order for headgear to achieve its goal of distal movement, it must be adjusted to apply an appropriate force level, and it must be worn by the patient for a prescribed amount of time. Intraoral appliances work by applying a distal force to the upper molar teeth using springs, coils or wires, against a stable structure inside the mouth which may be the palate, the teeth, any other intraoral structure, or any combination of these. Intraoral appliances can further be divided into two groups according to the arch to which they are anchored; appliances anchored to the palate or teeth (or both) within the maxillary arch such as the pendulum appliance (Hilgers 1992), and appliances anchored to teeth or other structure in the mandibular arch (or both) such as the Jasper Jumper (Jasper 1995). Intraoral appliances are worn full time.

Why it is important to do this review

Despite the established clinical use of molar distalising devices, there is equivocacy regarding the relative effects of intraoral and extraoral appliances and systems when directly compared or compared to no treatment. For example, an earlier systematic review undertaken on molar distalisation which included trials published between 1988 and 1998 reported that evidence on any specific appliance to move molars distally was inconclusive (Atherton 2002). Another systematic review, which included both retrospective and prospective comparative studies, concluded that these studies had serious flaws in their quality (Feldmann 2006). An updated systematic review, which includes formal quality assessment to standardised criteria, of the relative effects of orthodontic treatment would be beneficial.

OBJECTIVES

To assess the effects of orthodontic treatment for distalising upper first molars in children and adolescents.

METHODS

Criteria for considering studies for this review

Types of studies

Parallel-group, randomised controlled trials evaluating orthodontic appliances which are intended to move upper first molars distally. Studies reporting clinical evaluation at any point during orthodontic treatment were included. There was no restriction on publication language. Where studies were reported in abstract form we searched the literature for full publication. Due to the nature of the interventions, split-mouth trials were excluded. Trials comparing active intervention with no treatment were included, as were trials directly comparing one active intervention with another.

Types of participants

Children aged 16 years or less, at the start of treatment, who receive orthodontic treatment intended to move the upper molars distally. Patients with cleft lip and palate, or other craniofacial problems, were excluded.

Types of interventions

1. Active interventions: removable or fixed orthodontic appliances intended to distalise upper first molars
2. Control: no treatment or another active intervention (removable or fixed orthodontic appliance) intended to distalise upper first molars

Types of outcome measures

Primary outcomes

1. Movement of upper first molars (measured in mm). Both mesial movement (recorded and reported as a positive value (mm)) and distal movement (recorded and reported as a negative value (mm)) were evaluated.
2. Loss of anterior anchorage (measured in mm) reported as either mesial movement of upper incisor teeth or change in overjet.

Secondary outcomes

Duration of treatment, non-compliance, number of attendances required to complete treatment.

Main outcomes for 'Summary of findings' table

The following outcomes were included the 'Summary of findings' tables: movement of upper first molars, mesial movement of upper incisor teeth and change in overjet.

Adverse effects

Injuries associated with headgear, health of gums, damage to the teeth, e.g. tooth decay, root resorption.

Search methods for identification of studies

Electronic searches

We developed detailed search strategies for each database. Individual search strategies were based on the search strategy developed for MEDLINE (Appendix 1), but revised appropriately for each database.

The MEDLINE search used a combination of controlled vocabulary and free-text terms, in conjunction with the Cochrane Highly Sensitive Search Strategy for identifying reports of randomised controlled trials (as published in Box 6.4.c in the *Cochrane Handbook for Systematic Reviews of Interventions*, version 5.1.0, updated March 2011) (Higgins 2011a). The search of EMBASE was linked to the Cochrane Oral Health Group filters for identifying RCTs.

We searched the following electronic databases:

- Cochrane Oral Health Group's Trials Register (to 10 December 2012) (Appendix 2);
- Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library* 2012, Issue 11) (Appendix 3);
- MEDLINE via OVID (1946 to 10 December 2012) (Appendix 1);
- EMBASE via OVID (1980 to 10 December 2012 (Appendix 4).

Language

No restrictions were placed on the language or date of publication when searching the electronic databases.

Searching other resources

Handsearching

The following journals have been identified for handsearching for this review. We handsearched journal issues that have not already

been searched as part of the Cochrane Oral Health Group's journal handsearching programme:

- *American Journal of Orthodontics and Dentofacial Orthopedics* (2005 to January 2013)
- *The Angle Orthodontist* (2007 to January 2013)
- *Clinical Implant Dentistry and Related Research* (2003 to December 2012)
- *Clinical Oral Implant Research* (2001, 2003 to December 2012)
- *European Journal of Orthodontics* (2006 to December 2012)
- *International Journal of Oral and Maxillofacial Implants* (2004 to December 2012)
- *Journal of Orthodontics* (formerly *British Journal of Orthodontics*) (2008 to December 2012)
- *Journal of Dental Research* (1999 to 2000, 2004 to January 2013)
- *Journal of Dentistry* (2004 to December 2012)
- *Journal of Clinical Orthodontics* (1991 to December 2012)
- *Orthodontics and Craniofacial Research* (1998 to 2001 *Clinical Orthodontics and Research*) (2000 to November 2012)
- *Seminars in Orthodontics* (2005 to December 2012).

We checked the bibliographies of potentially relevant clinical trials for references to trials published outside the handsearched journals. In addition, we checked non-Cochrane systematic reviews for potentially relevant studies.

Unpublished studies

We searched trial registries to identify ongoing studies. The most recent search for all trial registries was January 2013. This included the following.

- www.clinicaltrials.gov: The clinical trials.gov website was searched by topic selecting mouth and tooth diseases. We searched all records under 'malocclusion' and 'Malocclusion Angle Class II'. In addition, we conducted a keyword search (Appendix 5).
- The IFMPA clinical trials portal (http://clinicaltrials.ifpma.org/clinicaltrials/no_cache/en/clinical-trial-advanced-search/index.htm). This was searched by using the following terms from the 'site language': 'orthodontic procedure' and 'dental braces complication'.
- Current Controlled Trials (isrctn.org). We searched the current controlled trials website by using the key words individually: dental, orthodontic and molar distalisation.

Data collection and analysis

Selection of studies

We examined the titles and abstracts of the search results to remove obviously irrelevant reports. This was performed by three review authors independently and in duplicate. Disagreements were resolved through discussion.

We retrieved the full text of the potentially relevant reports and examined them for eligibility. There was no restriction by language on the studies to be retrieved. Assessment of eligibility was performed by three review authors independently and in duplicate. We attempted correspondence with investigators to clarify study eligibility where information was unclear or unreported in the primary studies. We made final decisions on study inclusion through discussion.

Data extraction and management

The review authors performed data extraction independently and in duplicate. We used pre-defined data extraction forms to record information on methods, participants, interventions, primary and secondary outcomes and reported results.

Assessment of risk of bias in included studies

We used the Cochrane 'Risk of bias' tool to assess the methodological quality of the studies as described in the *Cochrane Handbook for Systematic Reviews of Interventions* version 5.1.0 (Higgins 2011d). This was undertaken independently and in duplicate by the review authors as part of the data extraction process. Six specific domains were important for this review: sequence generation, allocation concealment, blinding of outcome assessor, incomplete outcome data, selective outcome reporting and other bias. We gave each domain a judgement of low, high or unclear risk of bias. We did not evaluate blinding of operator and participant as blinding to the intervention was unfeasible in most circumstances.

Following assessment of each domain, we assessed the overall risk of bias for each study. All domains contributed equally to the overall study risk of bias: we considered a study at high risk of bias when at least one domain was judged as high risk of bias; we considered studies with at least one unclear domain at an unclear risk of bias; we considered studies with all risk of bias domains judged as low as low risk of bias.

Measures of treatment effect

For dichotomous outcomes, the measure of treatment effect was the risk ratio; for continuous outcomes the measure of treatment effect was the mean difference. We calculated 95% confidence intervals alongside the treatment effect. Where insufficient information was reported to enable these effect measures to be calculated we reported summary measures narratively.

Unit of analysis issues

We considered multiplicity of reporting of clinical outcomes at many time points. We extracted the most clinically relevant time point(s).

Dealing with missing data

We recorded missing data due to attrition as reported in the publication. We did not undertake data imputation.

Assessment of heterogeneity

We assessed clinical heterogeneity by examining the type of participants and interventions in each study. We undertook meta-analysis only when studies were of similar comparisons reporting comparable outcome measures. We used the Chi^2 test and I^2 statistic as measures of statistical heterogeneity in random-effects meta-analyses (Higgins 2011a).

Data synthesis

We undertook a random-effects meta-analysis when there were more than three studies and data synthesis was clinically and statistically appropriate.

In multi-arm studies with more than two intervention groups, we made only single pair-wise comparisons. We selected the intervention groups relevant to the review objective and the specific meta-analysis. Any additional intervention group which was not used in the review was detailed in the Characteristics of included studies table. In cases where multiple groups were found relevant to the review objective and specific meta-analysis, we combined all relevant intervention groups of the study into a single group, and combined all relevant control groups into a single control group. For continuous outcomes, we combined means and standard deviations using formulae described in the *Cochrane Handbook for Systematic Reviews of Interventions* Version 5.1.0 (Higgins 2011a). For comparisons where a meta-analysis could not be carried out we provided a narrative reporting of the summary measures and treatment effects. This consisted of the magnitude and direction of the treatment effect and 95% confidence interval, and evaluation of consistency of effect estimate across studies.

We planned sensitivity analysis, restricting comparisons to studies with similar risk of bias.

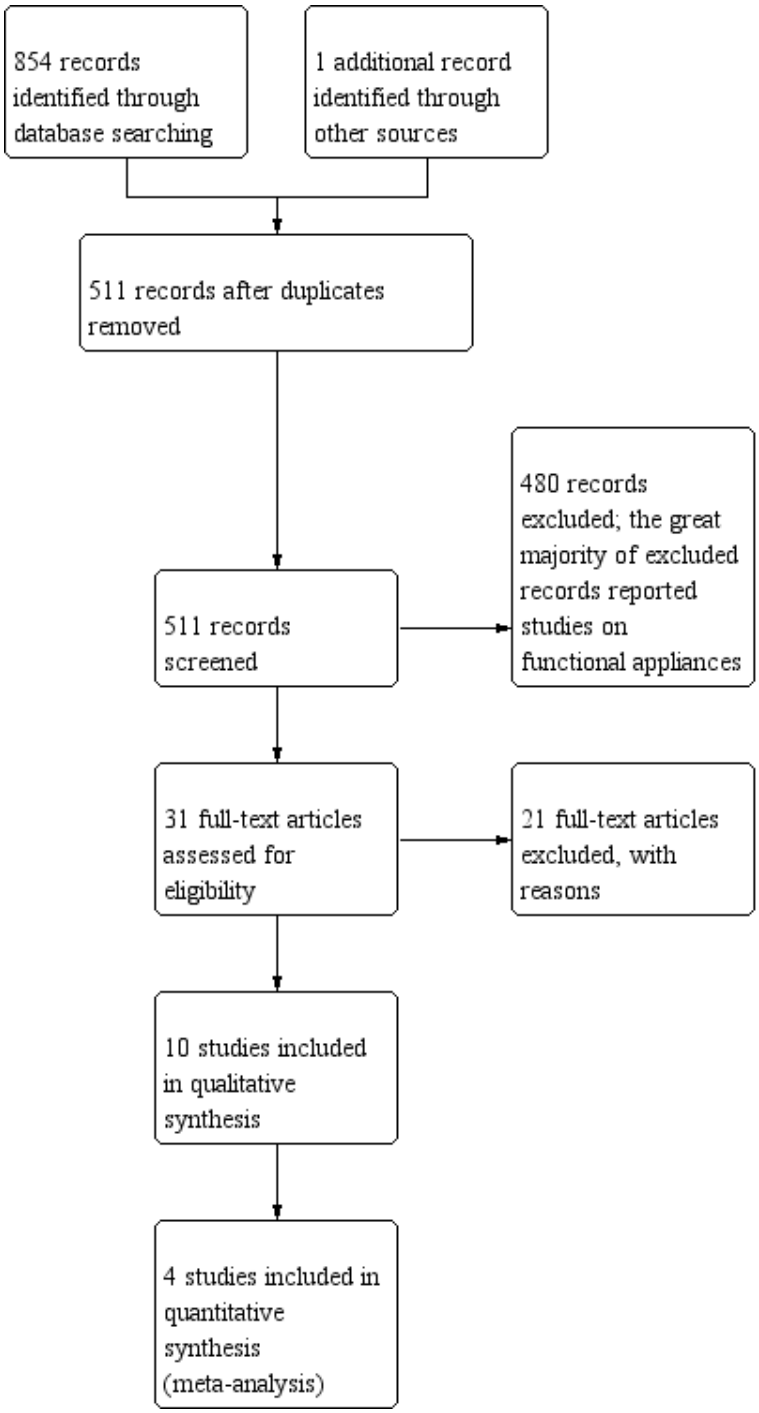
RESULTS

Description of studies

Results of the search

The search was carried out in December 2012. A total of 854 records were identified through database searching and one other potentially relevant study from other sources (see flowchart Figure 1). After duplicates were removed 511 titles and abstracts remained. We discarded 480 records; the great majority of these records reported studies on functional appliances, and those remaining were clearly not relevant. We assessed 31 full-text records for eligibility, of which 21 were excluded and reasons recorded in the Characteristics of excluded studies table. Ten trials, involving data from 354 analysed participants were included in this review; seven two-arm trials (Acar 2010; Altug-Atac 2008; Bondemark 2005; De Oliveira 2007; Papadopoulos 2010; Paul 2002; Toy 2011) and three three-arm trials (Armi 2011 (only two interventions were applicable to this review); Baccetti 2008; Karacay 2006). The included trials were published between 2005 and 2011.

Figure 1. Study flow diagram.



No ongoing studies were identified.

Included studies

Summary details are given in Characteristics of included studies.

Characteristics of the trial settings

Nine included trials were conducted in university settings with patients attending a dental clinic, and one (Karacay 2006) was carried out in a military medical academy. Four trials were carried out in Turkey (Acar 2010; Altug-Atac 2008; Karacay 2006; Toy 2011), two were carried out in Italy (Armi 2011; Baccetti 2008) and the remaining four were carried out in Sweden (Bondemark 2005), Brazil (De Oliveira 2007), Greece (Papadopoulos 2010) and the UK (Paul 2002). Eight were single-centre trials and two (Armi 2011; De Oliveira 2007) were carried out in two centres.

The duration of four of the included studies ranged from 6 to 6.5 months (Bondemark 2005; Papadopoulos 2010; Paul 2002; Toy 2011), two studies had a duration of 18 months (Armi 2011; Baccetti 2008) and one study had a duration of 12 weeks (Acar 2010). In two studies (De Oliveira 2007; Karacay 2006), the duration of the study was not stated.

Characteristic of participants

The Papadopoulos 2010 trial provided treatment for children with a mean age of 9.2 to 9.7 years. The remaining trials provided treatment to adolescent children; the average age across the trials ranged from 11.45 years to 14.75 years. The gender distribution was comparable in most of the trials (Acar 2010; Armi 2011; Bondemark 2005; De Oliveira 2007; Karacay 2006; Papadopoulos 2010; Paul 2002; Toy 2011). However, there was a slight predominance of female participants in the Altug-Atac 2008 and Baccetti 2008 trials, with the female participants constituting 69% and 61% of the total sample, respectively. The Bondemark 2005 and Paul 2002 trials had a total of 26 and 23 participants, respectively. The remaining trials had a sample ranging from 30 to 69 participants (Acar 2010; Altug-Atac 2008; Armi 2011; Baccetti 2008; De Oliveira 2007; Karacay 2006; Papadopoulos 2010; Toy 2011).

Characteristics of the interventions

Four trials included in this review compared intraoral appliances (Karacay 2006; Papadopoulos 2010) or an extraoral appliance (cervical headgear) (Armi 2011; Baccetti 2008) to an untreated control group.

Four of the included trials compared an intraoral distalising appliance to an extraoral appliance (headgear); the Acar 2010 and Toy 2011 trials used the pendulum appliance, the De Oliveira 2007 trial used the Jasper Jumper and the Bondemark 2005 trial used an intraoral appliance with superelastic coils.

Another three studies compared different intraoral appliances; two types of distalisation arches were compared in the Altug-Atac 2008 trial, the Karacay 2006 trial compared Jasper Jumper to the Forsus Nitinol Flat Spring and the Paul 2002 trial compared an upper removable appliance with finger springs to the Jones Jig appliance.

Characteristics of the outcomes

The main outcomes reported in the trials were dental and skeletal variables on pretreatment and post-treatment lateral cephalometric radiographs and time needed for distalisation. One study also reported the overall time of treatment (De Oliveira 2007). The number of attendances required to complete treatment and adverse effects were not reported by any of the studies. Additional Table 1 provides a summary of all of the outcomes relevant to this review as reported by each study.

Excluded studies

Summary details are given in Characteristics of excluded studies.

Twenty-one studies were excluded for the following reasons:

- 13 were not randomised trials (Angelieri 2008; Cetinsahin 2010; Erverdi 1997; Gelgor 2007; Kinzinger 2010; Kucukkeles 2007; Mossaz 2007; Oncag 2007; Sari 2003; Schutze 2007; Taner 2003; Ucem 1998; Uzel 2007);
- four were not relevant to this review because the allocation to treatment groups was not based on the types of distalising appliances as described in the protocol (Kinzinger 2003; Kinzinger 2004; Kinzinger 2005; Kinzinger 2006); and
- four did not have relevant intervention(s) (Abed 2010; Kaya 2009; Liu 2009; Silvola 2009).

Kinzinger et al reported several studies evaluating the pendulum appliance, however these were excluded because participants in this study were grouped according to dental maturation stage or the tooth used for anchorage (Kinzinger 2003; Kinzinger 2004; Kinzinger 2005; Kinzinger 2006). In one of the Kinzinger studies, there was no comparative intervention (Kinzinger 2010). The Angelieri study, which compared the pendulum appliance to cervical headgear, was excluded because it was retrospective in nature (Angelieri 2008). The Taner study compared cervical headgear and pend-x appliance and was excluded because it was not a randomised trial (Taner 2003). Correspondence with the author of the Uzel study confirmed that randomisation was not undertaken (Uzel 2007).

Risk of bias in included studies

Summary details are given in Characteristics of included studies, Figure 2 and Figure 3.

Figure 2. 'Risk of bias' summary: review authors' judgements about each risk of bias item for each included study.

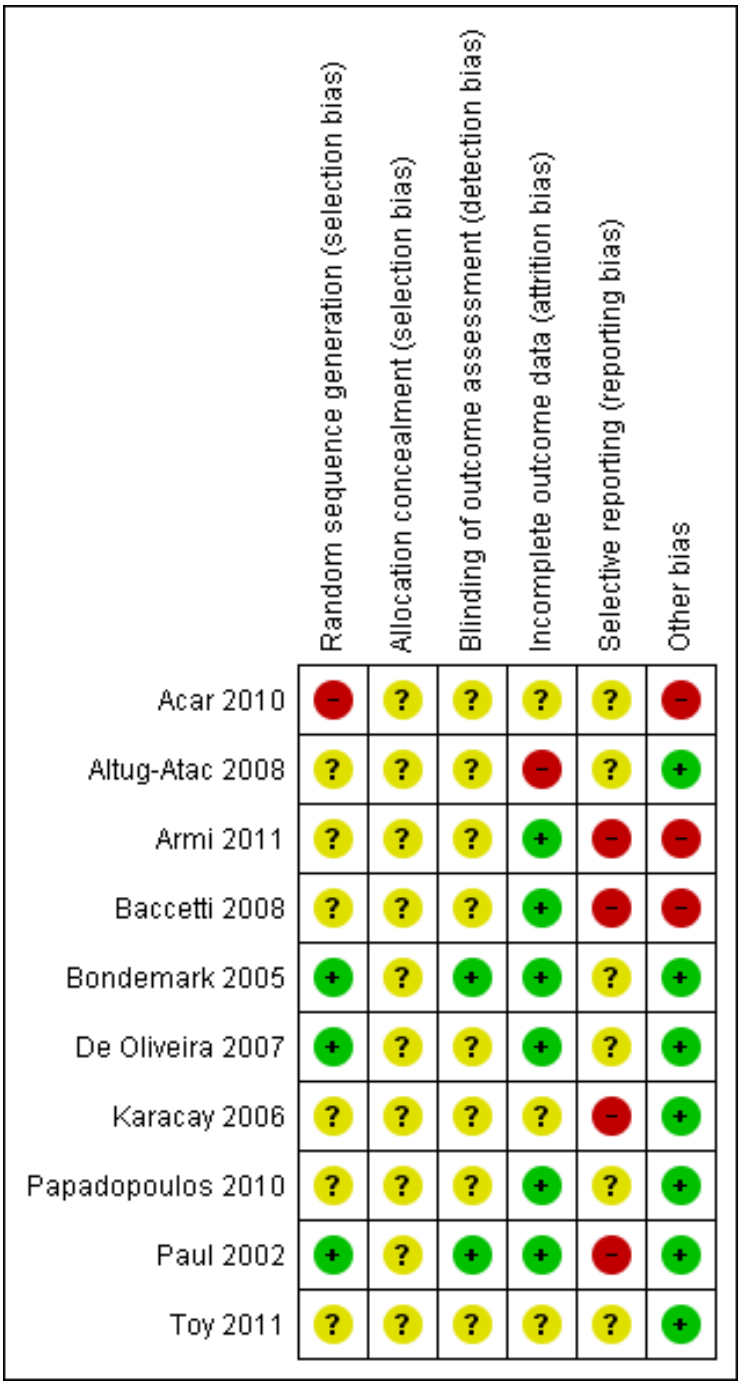
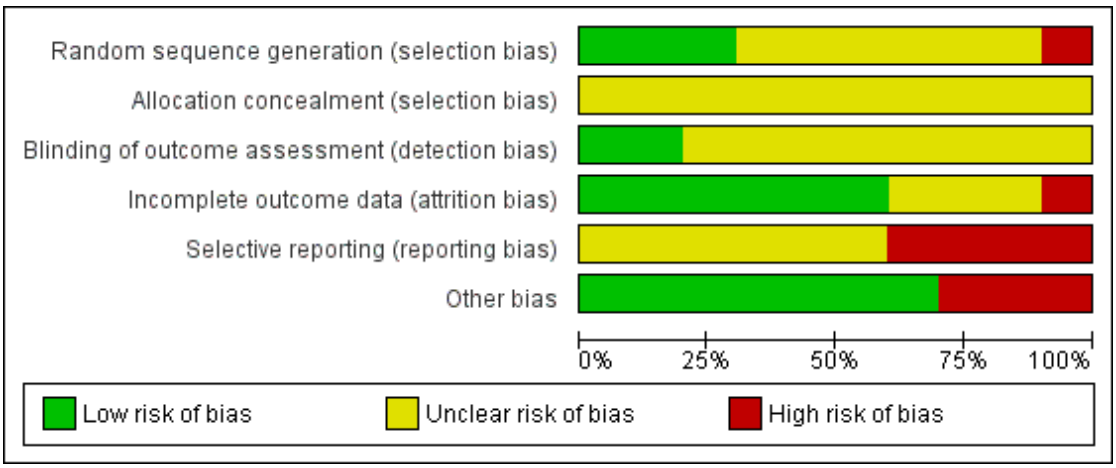


Figure 3. 'Risk of bias' graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.



Allocation

For the domain 'sequence generation', three studies were at a low risk of bias (Bondemark 2005; De Oliveira 2007; Paul 2002), one was at a high risk of bias (Acar 2010) and the remaining six were at unclear risk of bias (Altug-Atac 2008; Armi 2011; Baccetti 2008; Karacay 2006; Papadopoulos 2010; Toy 2011).

Two studies reported the nature of randomisation (Bondemark 2005; Paul 2002), but they did not describe fully the method for generation of the randomisation sequence. In another two studies (Acar 2010; De Oliveira 2007) the authors reported that randomisation was obtained by toss of a coin. The Acar 2010 study was reported in two publications, with conflicting reporting of the method of randomisation. The remaining studies (Altug-Atac 2008; Armi 2011; Baccetti 2008; Karacay 2006; Papadopoulos 2010; Toy 2011) did not report how the randomisation sequence was generated.

Furthermore, none of the included studies reported if and how the allocation sequence was concealed.

Blinding

In this domain, there were two studies at low risk of bias (Bondemark 2005; Paul 2002) and the remaining eight studies were at unclear risk of bias.

In all these studies, the interventions were different types of appliances. Therefore it was not possible to blind the operator or participants. However, it may be possible to blind the outcome assessor. Three of the included studies described the method for blinding the outcome assessor (Acar 2010; Bondemark 2005; Paul 2002). In the Acar 2010 study blinding of the outcome assessor was done by evaluating the cephalometric radiographs in a random order. However, it was unclear if the appliances could be seen on the radiographs and if the assessor was independent. An independent assessor in the Bondemark 2005 study scored and coded the radiographs. In the Paul 2002 study, it was explicitly stated that the outcome assessor was blind to the treatment intervention, but the exact method was not described. The Altug-Atac 2008, Armi 2011, Baccetti 2008, De Oliveira 2007, Karacay 2006, Papadopoulos 2010 and Toy 2011 studies did not state if the outcome assessor was blinded to the treatment allocation.

Incomplete outcome data

There were six studies with a low risk of bias for this domain (Armi 2011; Baccetti 2008; Bondemark 2005; De Oliveira 2007; Papadopoulos 2010; Paul 2002), one with a high risk of bias (Altug-Atac 2008) and three with an unclear risk of bias (Acar 2010; Karacay 2006; Toy 2011).

All randomised patients were included in the final analysis in two studies (Bondemark 2005; De Oliveira 2007). In the Papadopoulos 2010 and Paul 2002 studies the number of drop-outs was low and the reasons for the drop-outs were explained, therefore we judged them as having low risk of bias. The Armi 2011 and Baccetti 2008 studies also had a small number of drop-outs. The Acar 2010, Karacay 2006 and Toy 2011 studies did not address this domain. In the Altug-Atac 2008 study the high (24%) drop-out rate was due to non co-operation. No further information was given on the nature of non co-operation, however this is an important factor to consider when evaluating orthodontic appliances and is closely linked to compliance. A high drop-out rate due to non co-operation would bias the results towards over-estimating the effect of the intervention. Therefore we gave this study a judgement of high risk of bias for this domain.

Selective reporting

We judged four studies at a high risk of bias (Armi 2011; Baccetti 2008; Karacay 2006; Paul 2002) and judged the remaining six at an unclear risk of bias for this domain.

None of the included trials had published protocols, therefore it is not possible to know for sure if all outcomes were reported. The Armi 2011 and Baccetti 2008 studies had incomplete data reporting, as only the mean distal movement was reported without standard deviations or any other data. The Karacay 2006 study reported the baseline and follow-up data for the molar and incisor teeth position: the difference in means and standard deviations were calculated from these data. In the Paul 2002 study, loss of anterior anchorage was not assessed.

Other potential sources of bias

Seven studies were at a low risk of bias for this domain (Altug-Atac 2008; Bondemark 2005; De Oliveira 2007; Karacay 2006; Papadopoulos 2010; Paul 2002; Toy 2011), and three studies were at a high risk of bias (Acar 2010; Armi 2011; Baccetti 2008).

The Acar 2010 study had errors in reporting data related to the skeletal effects of the intervention. Although these data were not collected as part of this review, this is a potential source of bias in the study as a whole.

The Armi 2011 and Baccetti 2008 studies were reported as two different studies, however the participant characteristics in the control groups in these two studies are very similar. This may be a suggestion that the control group in these two studies was not involved in the randomisation process or that the Armi 2011 study is an extension of the Baccetti 2008 study after more participants were recruited. We contacted the authors of these two studies but no response was received.

Study risk of bias

We assessed the overall risk of bias for each study. We judged the following studies as high risk of bias: Acar 2010; Altug-Atac 2008; Armi 2011; Baccetti 2008; Karacay 2006; Paul 2002. In the Acar 2010 study, there was conflicting evidence in the reports and from the authors' correspondence regarding the randomisation process. In addition there were some errors in the reporting of some skeletal variables. The Altug-Atac 2008 study had a high drop-out rate, and the attrition was due to problems with patient co-operation. The Armi 2011 and Baccetti 2008 studies had incomplete reporting of summary statistics related to an important primary outcome, distal movement. In the Karacay 2006 study there was selective reporting of outcomes as there was no estimate of variability for change by group. We judged the Paul 2002 study at high risk of bias because it did not report an outcome which measures loss of anterior anchorage such as mesial movement of upper incisor teeth or overjet change. This was a primary outcome of this review, and it would be expected to be reported in such a study. The De Oliveira 2007 study did not report all of the summary statistics relating to the duration of distalisation of headgear. However, we did not judge this study at high risk of bias because the duration of overall treatment was reported completely and the duration until distalisation was a secondary outcome in this review.

The remaining four studies were at unclear risk of bias (Bondemark 2005; De Oliveira 2007; Papadopoulos 2010; Toy 2011). In the Bondemark 2005 study, the method of concealment of the allocation sequence was not mentioned and it was unclear if there was selective reporting of outcomes. Similarly the De Oliveira 2007 study did not state how the allocation sequence was concealed and it was unclear if there was selective reporting of outcomes. In addition this study did not address blinding of outcome assessment. In the Papadopoulos 2010 study four risk of bias domains were unclear due to insufficient information: selection bias (randomisation sequence generation and concealment of the sequence), blinding of outcome assessment and selective reporting of outcomes. There was insufficient information in the Toy 2011 study to permit a judgement on any of the 'Risk of bias' domains.

Effects of interventions

See: **Summary of findings for the main comparison** Orthodontic appliance compared to untreated control for distalising first molars; **Summary of findings 2** Intraoral appliance compared to headgear for distalising first molars; **Summary of findings 3** Intraoral appliance compared to other intraoral appliance for children and adolescents

For the purposes of analysis, the comparisons were as follows.

1. Trials that compared a distalising appliance to an untreated control.
2. Trials which compared an intraoral appliance to an extraoral appliance.
3. Trials which compared two different intraoral appliances.

Additional Table 1 lists the presence or absence of the outcomes reported in the primary studies that are pertinent to this review.

Comparison of a distalising appliance to untreated control

See Summary of findings for the main comparison.

Four studies with 159 analysed participants compared a distalising appliance to an untreated control (Armi 2011; Baccetti 2008; Karacay 2006; Papadopoulos 2010). The overall quality of studies was low. Both extraoral and intraoral appliances were assessed in these studies: the First Class appliance (Papadopoulos 2010), the Forsus Nitinol Flat Spring and the Jasper Jumper (Karacay 2006), and cervical headgear (Armi 2011; Baccetti 2008). Incomplete reporting of study data in the form of missing standard deviations or expected outcomes meant that a meta-analysis of all four studies could not be undertaken.

Primary outcomes

Movement of upper first molars

See Analysis 1.1.

Mean difference for distal movement favoured the First Class appliance (mean difference (MD) -4.04 mm; 95% confidence interval (CI) -5.49 to -2.59) and Forsus Spring and Jasper Jumper (groups combined) (MD -1.60 mm; 95% CI -2.20 to -1.00). No pooling was undertaken due to substantial observed heterogeneity (I^2 = 98%). On average there was no distal movement of the upper first molars in the untreated groups due to growth/maturation (0.04 to 0.1 mm mesial movement was reported) (Karacay 2006; Papadopoulos 2010).

The mean amount of distal movement was negligible in two studies with incomplete outcome data that reported that "the average amount of sagittal displacement of the upper first molar ...was close to zero (0.2 mm) whereas it was 2.32 mm in the CG" (Armi 2011) and similarly "the average amount of sagittal displacement of the upper first molar ...was close to zero (0.24 mm), while it was 2.32 mm in the CG" (Baccetti 2008).

Two studies with incomplete outcome data reported that "the amount of mesial movement of the upper first molars was significantly smaller in the HG...groups compared with the CG (P < .01)" (Armi 2011) and similarly "the amount of mesial movement of the upper first molars was significantly less in the EHG when compared with ... the CG (P < .01)" (Baccetti 2008).

Loss of anterior anchorage

See Analysis 1.2 and Analysis 1.3.

Greater mean loss of anterior anchorage was observed for the First Class appliance over the untreated controls (Papadopoulos 2010), though this was only statistically significant for the difference in overjet (MD 1.18 mm; 95% CI 0.26 to 2.10) and not for mesial movement of anterior teeth (MD 1.32 mm; 95% CI -1.14 to 3.78). Conversely, significant distal movement of anterior teeth (MD -1.40 mm; 95% CI -2.38 to -0.42) and reduction in overjet (MD -3.55 mm; 95% CI -4.53 to -2.57) was observed with the Forsus and Jasper Jumper (groups combined) interventions (Karacay 2006).

Loss of anterior anchorage was not reported in two studies (Armi 2011; Baccetti 2008).

Secondary outcomes and adverse effects

Duration of treatment, non-compliance, number of attendances required to complete treatment and adverse effects were not reported in these studies.

Comparison of intraoral distalising appliances to headgear

See Summary of findings 2.

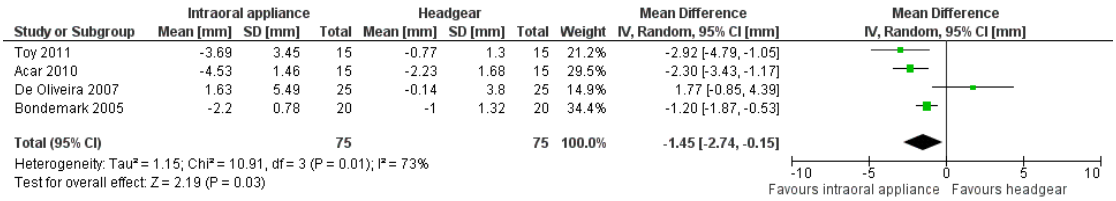
We performed meta-analyses, involving 150 analysed participants, on four studies (Acar 2010; Bondemark 2005; De Oliveira 2007; Toy 2011). The intraoral appliances investigated were the intraoral appliance with superelastic coils (Bondemark 2005), the Jasper Jumper (De Oliveira 2007), the pendulum appliance with K-loops (Acar 2010) and the pendulum appliance with midline screw (Toy 2011).

Primary outcomes

Movement of upper first molars

See Figure 4.

Figure 4. Forest plot of comparison: 2 Intraoral appliance versus headgear, outcome: 2.1 Movement of upper first molar [mm].



The mean molar movement for intraoral distalising appliances was -2.20 mm and -1.04 mm for headgear (distal molar movement). The meta-analysis showed that there was significantly greater mean distal molar movement for the intraoral appliance group as compared to the headgear group (MD -1.45 mm; 95% CI -2.74 to -0.15). There was substantial heterogeneity though three of the four studies favoured the intraoral appliance (Chi^2 10.91, 3 degrees of freedom (df), P value = 0.01, I^2 = 73%). The high level of heterogeneity can be due to the different types of appliances in the intervention groups. In addition, one of the studies (De Oliveira 2007) reported movement of the upper first molars at the end of active orthodontic treatment, while the remaining four studies reported this outcome at the end of molar distalisation. The overall quality of the studies reporting this outcome was very low. Removing the high risk of bias study (Acar 2010) did not alter the interpretation (random effect MD -1.01 mm; 95% CI -2.95 to 0.92).

Loss of anterior anchorage

See Figure 5 and Figure 6.

Figure 5. Forest plot of comparison: 2 Intraoral appliance versus headgear, outcome: 2.2 Movement of upper incisor teeth [mm].

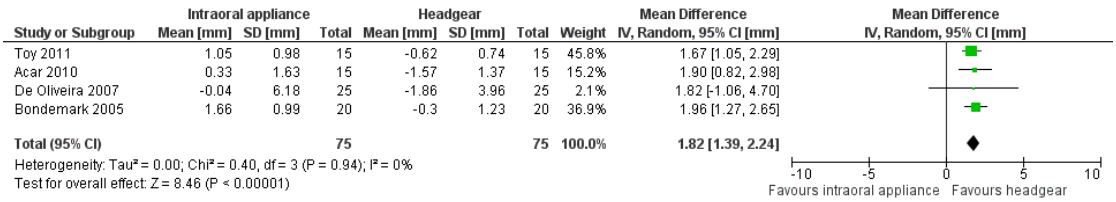
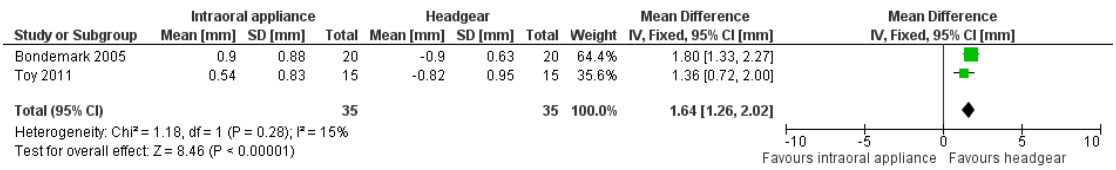


Figure 6. Forest plot of comparison: 2 Intraoral appliance versus headgear, outcome: 2.3 Change in overjet [mm].



When the effect on anterior movement of the upper incisors was evaluated there was mean mesial movement reported in three of the four studies of the intraoral appliance, but distal movement in all four of the studies of headgear. The overall quality of the studies was low. There was a statistically significant difference in

mean anterior movement in favour of the headgear group (MD 1.82 mm; 95% CI 1.39 to 2.24, Chi^2 0.40, 3 df, P value = 0.94, I^2 = 0%). Removing the high risk of bias study (Acar 2010) did not alter the interpretation (fixed-effect MD 1.80 mm; 95% CI 1.34 to 2.26).

Only two low-quality studies with a total of 70 analysed participants additionally reported the mean change in overjet (Bondemark 2005; Toy 2011), also favouring the headgear group (MD 1.64 mm; 95% CI 1.26 to 2.02, Chi^2 = 1.18, 1 df, P value = 0.28, I^2 = 15%). The De Oliveira 2007 and Acar 2010 studies did not report the change in overjet.

Secondary outcomes and adverse effects

Duration of treatment

Duration of treatment was reported by three studies, involving 120 analysed participants (Bondemark 2005; De Oliveira 2007; Toy 2011). The Acar 2010 study did not report this outcome.

The following table summarises the duration of treatment for the distalising appliances as reported by these three studies:

Study ID	Time point	Appliance	Duration of treatment
Bondemark 2005	End of molar distalisation	Intraoral appliance with superelastic coils	5.2 months (standard deviation (SD) 1)
	End of molar distalisation	Headgear	6.4 months (SD 0.97)
De Oliveira 2007	End of molar distalisation	Jasper Jumper	6 months (range 3 to 12)
	End of molar distalisation	Headgear	8 to 12 months
	End of active orthodontic treatment	Jasper Jumper	1.96 years (range 0.93 to 3.98)
	End of active orthodontic treatment	Headgear	1.88 years (range 0.95 to 3.35)
Toy 2011	End of molar distalisation	Pendulum appliance	4.83 months (SD 0.96)
	Predetermined by a pilot study	Headgear	N/A*

The remaining secondary outcomes and adverse effects were not reported by these studies.

Comparison of two types of intraoral appliances

See Summary of findings 3.

Three studies, involving a total of 93 analysed participants directly compared one type of intraoral appliance to another (Altug-Atac 2008; Karacay 2006; Paul 2002). The appliances compared were the three-dimensional bimetric maxillary distalisation arches (3D BMDA) to the modified Begg intraoral distalisation system (MBIDS) (Altug-Atac 2008), the Jasper Jumper to the Forsus Nitinol Flat Spring (Karacay 2006) and the upper removable appliance with finger springs to the Jones Jig appliance (Paul 2002). The quality of the studies was very low according to the GRADE approach. The small number of studies and different intraoral appliances precluded a meta-analysis. However, a comparison between the results of these studies for the following outcomes is provided.

Primary outcomes

Movement of upper first molars

Mean distal movement was achieved by all intraoral appliances in these three studies (Analysis 3.1).

The most clinically significant mean distal molar movement (> 3.3 mm) was achieved with 3D BMDA and the MBIDS in the Altug-Atac 2008 study (MD -0.28 mm; 95% CI -0.63 to 0.07). The Jasper Jumper, Forsus Nitinol Flat Spring upper removable appliance with finger springs and Jones Jig appliance had a mean distal movement ranging from 1.1 mm to 1.9 mm. The distal molar movement statistically favoured the Forsus Nitinol Flat Spring over the Jasper Jumper (MD 0.80 mm; 95% CI 0.12 to 1.48),

however it was statistically similar for the removable appliance with finger spring and the Jones Jig (MD -0.13 mm; 95% CI -1.50 to 1.24).

Loss of anterior anchorage

There was a variation in the direction of movement of the anterior teeth among the appliances, however all the intraoral appliances in this group provided a reduction in the overjet (Analysis 3.2; Analysis 3.3).

A minimal amount of anterior anchorage (< 0.5) was lost with both distalisation arches (Altug-Atac 2008); the mean difference was not statistically significant (MD -0.39 mm; 95% CI -1.43 to 0.65). Distal movement of anterior teeth (-1.4 mm) was observed with both the Jasper Jumper and the Forsus Nitinol (MD 0.50 mm; 95% CI -0.04 to 1.04) (Karacay 2006). The Paul 2002 study did not report this outcome.

Secondary outcomes and adverse effects

Duration of treatment

This outcome was reported by the Altug-Atac 2008 and the Karacay 2006 studies only; the Paul 2002 study did not report this outcome.

Duration of treatment was statistically shorter for the 3D bimetric distalising arch (3.4 months) than for the Modified Begg intraoral distalising system (6.5 months) (MD -3.10; 95% CI -3.49 to -2.71), but similar for the Jasper Jumper (5.23 months) and Forsus Nitinol Flat Spring (5.28 months) (MD -0.05; 95% CI -0.87 to 0.77).

The remaining secondary outcomes and adverse effects were not reported by these studies.

ADDITIONAL SUMMARY OF FINDINGS *[Explanation]*

Intraoral appliance compared to headgear for distalising first molars

Patient or population: children and adolescents undergoing orthodontic treatment
Settings: university or private orthodontic clinic
Intervention: intraoral appliance
Comparison: headgear

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk[1]	Corresponding risk				
	Headgear	Intraoral appliance				
Movement of upper first molars (mm)	The mean movement of upper first molars (mm) in the headgear group was -1.04 mm (distal movement)	The mean movement of upper first molars (mm) in a distal direction for the intraoral appliance group was **1.45 mm more** (-2.74 to -0.15)		150 (4 studies)	⊕◯◯◯ **very low**[2,3]	Movement of the upper first molars in a distal direction is the desired type of tooth movement. This result indicates that the intraoral appliance is superior to headgear for this outcome
Movement of upper incisor teeth (mm)	The mean movement of upper incisor teeth (mm) in the headgear group was -1.09 mm (distal movement)	The mean movement of upper incisor teeth (mm) in a mesial direction for the intraoral appliance group was **1.82 mm more** (1.39 to 2.24)		150 (4 studies)	⊕⊕◯◯ **low**[2,4]	Movement of the upper incisor teeth in a mesial direction is an unwanted tooth movement and indicates that the intraoral appliance is inferior to headgear for this outcome
Change in overjet (mm)	The mean loss of anchorage (mm) in the headgear group was -0.86 mm (reduction in overjet)	The mean change (increase) in overjet (mm) in the intraoral appliance group was **1.64 mm more** (1.26 to 2.02)		70 (2 studies)	⊕⊕◯◯ **low**[5]	An increase in overjet is unwanted and indicates that the intraoral appliance is inferior to headgear for this outcome

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

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

[1]The basis for the assumed risk was the mean of the control groups across studies
[2] Three studies at unclear risk of bias; one study at high risk of bias
[3] Evidence based on the results of four small studies with equivocal results
[4] Evidence based on the results of four studies with a low number of participants
[5] Evidence based on the results of two studies with a low number of participants, at unclear risk of bias

Intraoral appliance compared to other intraoral appliance for children and adolescents

Patient or population: children and adolescents undergoing orthodontic treatment
Settings: university or private orthodontic clinic
Intervention: intraoral appliance
Comparison: other intraoral 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				
	Other intraoral appliance	Intraoral appliance				
Movement of upper first molars (mm)	Not estimated	Not estimated	Meta-analysis not appropriate	93 (3 studies)	⊕◯◯◯ **very low**[1,2]	No pooled estimate due to different types of appliances used in the studies
Movement of upper incisor teeth (mm)	Not estimated	Not estimated	Meta-analysis not appropriate	70 (2 studies)	⊕◯◯◯ **very low**[3,4]	No pooled estimate due to different types of appliances used in the studies
Change in overjet (mm)	Not estimated	Not estimated	Meta-analysis not appropriate	70 (2 studies)	⊕◯◯◯ **very low**[3,4]	No pooled estimate due to different types of appliances used in the studies

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

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

[1]Three studies at high risk of bias

[2] Evidence based on the results of three small studies with a low number of participants and equivocal results
[3] Two studies at high risk of bias
[4] Evidence based on the results of two studies with a low number of participants

DISCUSSION

Summary of main results

Comparison of distalising appliance to untreated control

In general, when a distalising appliance is compared to no treatment, a degree of distal molar movement will occur. This is not surprising, as these appliances are mechanically designed to move the molar teeth distally. However, loss of anterior anchorage, which varied according to the type of appliance, may be a limiting factor in the clinical use of these appliances. The First Class appliance showed greater mesial movement and increase in the overjet than the untreated controls. The Forsus Nitinol Flat Spring and Jasper Jumper appear to achieve distal movement of the molars without loss of anterior anchorage. Less anchorage loss was observed with cervical headgear when compared to untreated controls. Therefore a general statement regarding the effect of appliances on anterior anchorage cannot be made here.

Comparison of intraoral distalising appliances to headgear

We found evidence from four trials that orthodontic treatment with intraoral appliances results in greater distal movement of the upper molars when compared to headgear (mean difference (MD) -1.45 mm; 95% confidence interval (CI) -2.74 to -0.15). However, this result is counteracted by greater unwanted mesial movement of the upper incisors with the intraoral appliance when it was compared to headgear (MD 1.82 mm; 95% CI 1.39 to 2.24). In addition, there was a statistically significant increase in the overjet with the intraoral appliance (MD 1.64 mm; 95% CI 1.26 to 2.02). Therefore, it is suggested that there is some evidence that intraoral appliances are more effective than headgear in distalising upper first molars, however they are also associated with loss of anchorage anteriorly.

These results were based on three studies that were assessed as at unclear risk of bias and one study at high risk of bias. Limited evidence from empirical studies confirms that there is a difference in bias between studies that were judged at unclear risk of bias and studies that were judged at high risk of bias (Higgins 2011d). In addition, in the study with high risk of bias in this meta-analysis, the shortcomings were related to a very important risk of bias domain: selection bias. We therefore undertook a sensitivity analysis to exclude this study; the resulting interpretation of the analysis did not change.

It was surprising to find that there was less distal movement with the headgear. This could be attributed to the short duration of the majority of the trials included in the study, and perhaps the intraoral appliances were more efficient in obtaining distal movement. In addition, only one of the included studies reported results after comprehensive treatment with fixed appliances. It would be clinically relevant to know how distalising appliances work in conjunction with or followed by a phase of a fixed orthodontic appliance. Finally, the finding that headgear was less effective than intraoral appliances could in fact be due to poor compliance, an important outcome that was unreported. However, there is uncertainty about the quality of the studies. Therefore these results should be interpreted with caution.

The duration of treatment is an important outcome when considering orthodontic treatment. An appliance which can distalise the molar teeth in a shorter time would be desirable as it will decrease the overall burden of treatment on the patient. All four trials reported the time taken for distalisation, however only one trial also reported the duration of overall treatment. The knowledge of overall treatment time not only gives insight on whether molar distalisation was maintained throughout treatment, but is very likely an important outcome from the patient's perspective. It may be important for patients to know how long they will be wearing certain appliances, but they are likely to be more interested in how long the overall treatment may take.

These four trials were conducted in three different countries and therefore represent a large general population. However, it is interesting to note that the great majority of these are European countries. This may be due to different clinician and patient values in other parts of the world which may influence compliance with headgear. The use of headgear and compliance may also be a reflection of the fee or payment structure for healthcare providers in various areas around the world. Clinicians and patients living in countries in which orthodontic treatment and the provision of headgear is provided by a national health service with no direct cost to them may exhibit different attitudes to their malocclusion and compliance with treatment in comparison to those living in countries in which the treatment has to paid for directly or through healthcare insurance.

Comparison of two types of intraoral appliances

We did not perform a meta-analysis because there was not a sufficient number of studies comparing the same types of interventions. However, the findings suggest that all types of intraoral appliances provide some degree of distal molar movement. Distal movement with the assessed appliances ranged from 1.3 mm to 3.55 mm. The lower range of distal movement may not be clinically significant, and could be achieved clinically by less complicated techniques such as Class II elastics, bearing in mind that Class II elastics are also subject to a degree of patient compliance. The higher range of the distal movement was achieved by the 3D-BMDA and the MBIDS. The setup of these appliances is more complicated than the other intraoral appliances in this study and they also involve bonding of the maxillary and mandibular arches as part of the system for distalisation.

The anterior movement of the upper central incisors varied with the type of intraoral appliance. A very slight mesial movement

of less than 0.5 mm was observed with the 3D-BMDA and the MBIDS, and a distal incisor movement with the Jasper Jumper and the Forsus appliances. Moreover, there was a reduction in the overjet with these appliances. Therefore, it is suggested that in these appliances molar distalisation is not counteracted by a loss of anterior anchorage. However, the trade-off is the use of more complicated appliances, in which the adverse effects on the surrounding oral tissues and the degree of comfort to the patient is unknown. There are limited data on the treatment time associated with these appliances as reported in this review, however there is an insufficient number of studies to allow a judgement on the efficiency of these appliances in providing distal movement.

Overall completeness and applicability of evidence

The objective of this review was to assess the effects of orthodontic treatment for distalising upper first molars in children and adolescents. Case reports describe a large number of appliances designed to distalise upper first molars, however scientific evidence on their effectiveness is clearly lacking. Studies included in this review report some common distalising appliances, however they are small in number and of low quality. Therefore the studies identified are insufficient to address the objectives of the review. Only suggestions can be made regarding their effects. In addition, important patient-related outcomes such as acceptability and comfort of the appliances have not been addressed.

Quality of the evidence

See Summary of findings for the main comparison, Summary of findings 2, Summary of findings 3, Figure 2 and Figure 3.

All the studies included in this review were of low to very low quality according to the GRADE approach. Despite being randomised controlled trials, they were all downgraded due to low numbers of participants, high risk of bias domains and/or studies yielding equivocal results.

The overall risk of bias of trials in this review ranged from unclear to a high risk of bias. There was a lot of uncertainty in the judgement of bias for the risk of bias domains. It is recognised that this may be due to inadequate reporting of the trials, however the description in the reports and subsequent email correspondence were still unclear and incomplete, and in one instance contradictory. Judgements on the risk of bias were sometimes made after much deliberation and after repeatedly considering the text in the reports and in the e-mail correspondence. The main risk of bias across all studies was due to unclear reporting of how the randomisation sequence was generated and blinded. In particular the method of concealment of the allocation sequence was not addressed in any of the included studies. Blinding of patients and personnel was not considered important in this review because it is not possible to blind the treatment allocation in these trials. However, we did not adopt the same reasoning for outcome assessment, as in most cases the outcome assessor can be blinded to the treatment. For example, this could be done by masking the appliances on the radiographs or the analysis of the radiographs could be performed by a practitioner unaware of the objectives of the trial, or both. In addition, blinding of outcome assessment was considered important due to the nature of the measurements. Measurements of tooth movement are made on a very small scale of millimetres, so that even a low level of detection bias can have a significant effect on the results.

Potential biases in the review process

There are a small number of low-quality studies in this review and when considering the primary outcome of distal movement of the first molars, the results were not consistent among the studies. There were limitations in the obtaining of information to confirm study methodology and summary data.

We systematically searched the most important electronic resources, in addition to carrying out an extensive handsearch. We searched for unpublished studies in trial databases. Time limitations prevented searching of additional databases and sources which may have potentially led to identifying additional published and unpublished studies.

Finally, we did not conduct an extensive search to identify adverse effects. The identification of adverse effects was limited to known adverse effects which were reported in the randomised studies.

Agreements and disagreements with other studies or reviews

The results of this review are in agreement with other systematic reviews on the topic with less rigorous methodology. The methodology of these reviews has often involved limited search strategies and a large variation in included study designs including retrospective studies and studies with single interventions. The most common appliances were the pendulum, Nance, Jones Jig and distal jet appliances. The outcomes commonly investigated in these reviews were the distal movement of the molars and loss of anchorage (mesial movement of premolar and anterior teeth). Distalising appliances moved the upper molar distally by a mean of 2.9 mm (95% CI 2.4 to 3.3) (Antonarakis 2008) and 2.71 mm (standard deviation (SD) 0.79) (Feldmann 2006). In another review the distal molar movement ranged from 1.4 mm (SD 2.06) to 6.1 mm (SD 1.8) across different appliances (Kinzinger 2008). Reported anchorage loss was also in agreement with this review. Mean anchorage loss (mesial movement of premolars, anterior teeth or both) was 1.8 mm (95% CI 1.7 to 2.0) (Antonarakis 2008) and 1.25 mm (SD 0.74) (Feldmann 2006). The mesial movement of

the incisors was also reported, ranging from 0.25 mm (SD 1.09) to 2.30 mm (SD 2.25) (Kinzinger 2008).

AUTHORS' CONCLUSIONS

Implications for practice

It is suggested that intraoral appliances are more effective than headgear in distalising upper first molars. However, this effect is counteracted by loss of anterior anchorage, which was not found to occur with headgear when compared with intraoral distalising appliance in a small number of studies. The number of trials assessing the effects of orthodontic treatment for distilisation is low, and the current evidence is of low or very low quality. Some types of intraoral appliances might be associated with a slight amount of distal molar movement without compromising anchorage anteriorly. However, the trade-off is more complicated appliances (for which there are limited data on effectiveness), patient comfort and cost-effectiveness. It is important to acknowledge that the results of this review are based on studies with an unclear to high level of bias.

Implications for research

This review highlights the importance of appropriately reporting the conduct and results of randomised controlled trials.

Current evidence on the effectiveness of distalising appliances is based on randomised trials in which the level of bias is unknown. Future research should ensure that the allocation sequence is appropriately concealed and further thought should be given to blinding outcome assessment. Trials should be reported according to the Consolidated Standards of Reporting Trials (CONSORT) checklist (CONSORT 2010). It is also advised that the CONSORT checklist be consulted when planning a trial, along with the SPIRIT checklist for protocols (SPIRIT 2013).

The samples included in the studies are appropriate in that they are patients of an age that would benefit from these type of appliances. There was variation in the sample sizes used, and a recommendation for future studies would be to perform a sample size calculation prior to undertaking the study. In addition to patients, the study should consider the effects of the operators delivering the interventions. This is especially relevant when determining reasons for non-compliance. Operator values, expertise and attitudes may influence the uptake and degree of compliance of certain interventions. This would most likely be in the form of qualitative research, such as focus groups and in-depth interviews.

Interventions and comparisons should concentrate on distalising appliances that result in the least amount of anterior loss of anchorage, as those found in this review, or by conducting a pilot study, if feasible, on the interventions. In addition to the endpoint of molar distalisation, an overall endpoint of the end of treatment should be considered.

The outcomes considered important for this review were distal movement and loss of anterior anchorage measured by changes in overjet and mesial movement of the anterior teeth. All trials in this review reporting the effect of an intraoral distalising appliance reported these outcomes, except for one trial. In addition, other types of tooth movement were reported in individual trials, such as tipping of the molar teeth. While the CONSORT guidelines can aid in planning the methodology of trials, it does not provide much guidance on selection of outcomes. Future research should include reaching a consensus on the minimal clinically relevant outcomes for specific interventions.

The rationale for developing intraoral appliances for distalising upper molar teeth as an alternative to headgear was the non-compliance and harm associated with using headgear. Understandably, none of these trials measured the compliance associated with the appliances, as it would be difficult to find a single measure of compliance that is common to all appliances. For example 'hours of headgear wear' is a measure of compliance with headgear, but it cannot be used for a pendulum appliance that is fixed inside the mouth and worn full time. However, since the ultimate objective of compliance is the success of treatment, perhaps future research should report the success of the appliances in providing distal movement of molar teeth as a measure of compliance. Success could then be defined according to treatment objectives. For example an appliance would be successful in distal movement if it achieves at least 2 mm distal molar movement with no increase in overjet, or if it achieves at least 3 mm of distal molar movement that is maintained until the end of treatment.

In addition to clinically relevant outcomes, there is a clear lack of studies reporting outcomes which may be important to patients. These are likely to include harm, the degree of comfort of the appliance, the influence on eating, talking or other daily activities, socially acceptability, etc. Qualitative research is indicated to find out which outcomes are important to patients and to give us patient-oriented insight on the reasons for non-compliance.

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

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

Acar 2010

Methods	• Trial design: single-centre RCT (parallel-group) • Location: Baskent University, Turkey • Recruitment period: not stated • Funding source: not stated • Source of participants: patients attending clinic • Study duration: 12 weeks • Time points at which follow-up is reported: 1) start of treatment, 2) end of molar distalisation
Participants	• 30 participants in total, mean age 14.6 years • 15 in pendulum appliance group: mean age 15 years (SD 3.4), 8 males and 7 females • 15 in cervical headgear group: mean age 14.2 years (SD 2.9), 5 males and 10 females • Inclusion criteria 1. Dental Class II malocclusion due to mesial migration of upper first molar 2. Minor arch length discrepancies • Exclusion criteria 1. No vertical or transverse skeletal or dental problem
Interventions	• **Comparison 1: Pendulum appliance supported with K-loop buccally** 1. Hilger's pendulum appliance was used which exerted a force of 230 g when the springs were activated 90° 2. The K-loop was made from 0.017 X 0.025 inch TMA wire and positioned between the upper first molar and first premolar 3. Patients were recalled every 3 weeks and the K-loop activated every 6 weeks • **Comparison 2: Headgear** 1. Cervical pull 2. 400 g force was used 3. Patients instructed to wear it for 16 to 20 hours a day
Outcomes	1. Treatment time 2. Skeletal and dental changes assessed from cephalometric radiographs 3. Dental changes (rotation of molars and premolars) from study models
Notes	Errors in reported values

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Quote (from report): "Patients in both groups were matched according to GoGnSN angle and length of treatment"

Acar 2010 (*Continued*)

		Quote (from correspondence of main report): "patients were allocated to the two treatment groups randomly by coin tossing" Quote (from correspondence of other report of the same study): "the patients were enrolled to the pendulum K-loop first and after completion of a predetermined number of patients (15).... additional 15 patients with dental Class II malocclusion that matched the first group by GoGnSN angle were treated with headgear" Comment: probably not done
Allocation concealment (selection bias)	Unclear risk	Method of concealment is not described
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Quote: "The cephalograms were traced by one investigator in a random order" Comment: it is not mentioned whether the assessor was blinded to the type of treatment; the appliance could have been visible in the radiograph
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Total analysed 30 (15 in group 1 and 15 in group 2)
Selective reporting (reporting bias)	Unclear risk	Selective reporting of outcomes: insufficient information to permit judgement
Other bias	High risk	There were errors in the reporting of skeletal variables in the paper

Altug-Atac 2008

Methods	• Trial design: single-centre RCT (parallel-group) • Location: Department of Orthodontics, Ankara University, Turkey • Recruitment period: not stated • Funding source: Ankara University Research Foundation • Source of participants: patients attending clinic • Study duration: 6.5 months • Time points at which follow-up is reported: 1) start of treatment, 2) end of distalisation (Class I molars)
Participants	• 38 participants in total, age 12 to 16.58 years • 21 in the distalisation arch group: mean age 14.7 years (SE 1.5), 9 males and 12 females • 17 in the Begg system group: mean age 14.4 years (SE 1.4), 3 males and 14 females

	• Inclusion criteria 1. Skeletal Class I and II malocclusions and dental Class II relationship on both sides 2. Non-extraction treatment plan 3. SN/GoGn angle less than 40° 4. No/minimal crowding in the mandibular dental arch 5. Erupted maxillary and mandibular second molars in occlusion
Interventions	• **Comparison 1**: **3-dimensional bimetric maxillary distalisation arches** 1. The distalisation arches consist of an upper arch wire with an open coil spring and Class II elastics 2. A full-bonded lower arch was used as an anchorage unit for the Class II elastics 3. Patients were recalled at 10-day intervals and the elastic loads were checked and adjusted at each visit • **Comparison 2**:**modified Begg intraoral distalisation system** 1. Maxillary 0.018 inch Australian wire distalisation arch with bilateral double-twisted single vertical loop 2. Full-bonded maxillary and mandibular arches 3. Uprighting springs to activate the mandibular anchorage 4. Class II elastics
Outcomes	1. Primary: treatment time for distalising upper first molars for molar correction 2. Secondary: all skeletal and dental cephalometric measurements
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Quote: "The patients were randomly selected and distributed to the treatment groups" Comment: insufficient information about the sequence generation process to permit judgement
Allocation concealment (selection bias)	Unclear risk	Method of concealment is not described
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Insufficient information to permit judgement
Incomplete outcome data (attrition bias) All outcomes	High risk	• 50 participants randomised, 38 included in the analysis • 24% (12 participants) drop-out rate due to poor co-operation • Number of exclusion per group not stated; poor co-operation is an important outcome that could influence the results

Altug-Atac 2008 (*Continued*)

Selective reporting (reporting bias)	Unclear risk	Selective reporting of outcomes: insufficient information to permit judgement
Other bias	Low risk	Study appears to be free of other sources of bias

Armi 2011

Methods	• Trial design: single-centre RCT (parallel-group) • Location: University of Florence and University of Roma, Italy • Recruitment period: not stated • Funding source: not stated • Source of participants: participants enrolled in a prospective study at the department of orthodontics • Study duration: average 18 months • Time points at which follow-up is reported: 1) initial observation, 2) 18 months after initial observation
Participants	• 60 participants in total, mean age 11.51 years • 17 in headgear group: mean age 11.9 years, 9 males and 8 females • 21 in rapid maxillary expansion/headgear group: mean age 11.1 years, 9 males and 12 female • 22 in the untreated control group: mean age 11.6 years, 9 males and 13 females • Inclusion criteria 1. White ancestry 2. Either unilateral or bilateral palatally displaced canines on a panoramic radiograph 3. Dental age older than 8 years and younger than 13 years 4. Skeletal age showing active phases of skeletal growth according to the cervical vertebral maturation method 5. Presence of mild crowding at the maxillary arch and/or molar relation showing Class II tendency • Exclusion criteria 1. Previous orthodontic treatment 2. Craniofacial syndromes, odontomas, cysts, cleft lip and/or palate, sequelae of traumatic injuries to the face, or multiple and/or advanced caries 3. Aplasia or severe hypoplasia of the crown of upper lateral incisors
Interventions	• **Comparison 1: Headgear group** 1. Cervical pull headgear used alone for 1 year for 12 to 14 hours a day • **Comparison 2: Rapid maxillary expansion/headgear group** 1. Banded rapid maxillary expander with 7 mm of active expansion 2. At the end of expansion all patients retained the expander for 6 months 3. Followed by the use of a cervical headgear like the headgear group • **Comparison 3: Untreated control group**
Outcomes	1. Successful or unsuccessful eruption of the palatally displaced canines 2. Mesiodistal movement of the upper first molars

Armi 2011 (*Continued*)

Notes	1. The main aim of this study was to evaluate the effectiveness of the interventions on the eruption of palatally displaced canines 2. Only 2 of the comparison groups were used in this review because of their relevance: the headgear group and the untreated control group

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "All subjects with PDCs were assigned randomly to one of the following three groups" Comment: insufficient information about the sequence generation process to permit judgement
Allocation concealment (selection bias)	Unclear risk	Method of concealment is not described
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Insufficient information to permit judgement
Incomplete outcome data (attrition bias) All outcomes	Low risk	• Number randomised: 64 • Drop-outs: 4, not stated in which group • Reason for drop-outs: participants moved from the area or asked to be transferred to other clinicians
Selective reporting (reporting bias)	High risk	• Selective reporting of outcomes: insufficient information to permit judgement • Selective reporting of data: incomplete reporting of the distal movement outcome; means were presented without standard deviations
Other bias	High risk	The control group in this study has very similar characteristics to the Baccetti 2008 study. We contacted the authors for clarification but no response was received

Baccetti 2008

Methods	• Trial design: single-centre RCT (parallel-group) • Location: University of Florence and University of Roma, Italy • Recruitment period: not stated • Funding source: not stated • Source of participants: patients enrolled in a prospective study at the department of orthodontics • Study duration: average 18 months • Time points at which follow-up is reported: 1) initial observation, 2) 18 months after initial observation
Participants	• 69 participants in total • 23 in headgear group: mean age 11.7 years, 8 males and 15 females • 24 in extraction/headgear group: mean age 11.9 years, 10 males and 14 females • 22 in the untreated control group: mean age 11.6 years, 9 males and 13 females • Inclusion criteria 1. White ancestry 2. Either unilateral or bilateral palatally displaced canines on a panoramic radiograph 3. Dental age older than 8 years and younger than 13 years 4. Skeletal age showing active phases of skeletal growth according to the cervical vertebral maturation method • Exclusion criteria 1. Previous orthodontic treatment 2. Craniofacial syndromes, odontomas, cysts, cleft lip and/or palate, sequelae of traumatic injuries to the face, or multiple and/or advanced caries 3. Crowding in the upper arch, as evaluated by means of intraoral inspection 4. Aplasia or severe hypoplasia of the crown of upper lateral incisors
Interventions	3 comparisons in total • **Comparison 1: Extraction group** 1. Extraction of the primary canine corresponding to the palatally displaced permanent canine was performed • **Comparison 2: Extraction/headgear group** 1. Extraction of the primary canine corresponding to the palatally displaced permanent canine was followed by use of a cervical-pull headgear 2. Patients in this group started their headgear therapy in the 3 months after extraction 3. They were instructed to wear the headgear for 12 to 14 hours a day • **Comparison 3: Untreated control group**
Outcomes	1. Successful or unsuccessful eruption of the palatally displaced canines 2. Mesiodistal movement of the upper first molars
Notes	1. The main aim of this study was to evaluate the effectiveness of the interventions on the eruption of palatally displaced canines 2. Only 2 of the comparison groups were used in this review because of their relevance: the headgear group and the untreated control group
Risk of bias	

Baccetti 2008 (*Continued*)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "All PDC subjects were assigned randomly to one of the following three groups" Comment: insufficient information about the sequence generation process to permit judgement
Allocation concealment (selection bias)	Unclear risk	Method of concealment is not described
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Insufficient information to permit judgement
Incomplete outcome data (attrition bias) All outcomes	Low risk	• Number randomised: 75 • Drop-outs: 5, not stated in which group, 1 participant not accounted for • Reason for drop-outs: participants moved from the area or asked to be transferred to other clinicians
Selective reporting (reporting bias)	High risk	• Selective reporting of outcomes: insufficient information to permit judgement • Selective reporting of data: incomplete reporting of the distal movement outcome; means were presented without standard deviations
Other bias	High risk	The control group in this study has very similar characteristics to the Armi 2011 study. We contacted the authors for clarification but no response was received

Bondemark 2005

Methods	• Trial design: single-centre RCT (parallel-group) • Location: Malmo University, Sweden • Recruitment period: not stated • Funding source: Swedish Dental Society and Skane County Council, Sweden • Source of participants: patients attending clinic in Malmo • Study duration: 6.5 months • Time points at which follow-up is reported: 1) start of treatment, 2) end of molar correction

Bondemark 2005 (*Continued*)

Participants	• 40 participants in total, mean age 11.45 years • 20 in the intraoral appliance group: mean age 11.4 years (SD 1.37), 10 males and 10 females • 20 in the extraoral appliance group: mean age 11.5 years (SD 1.25), 8 males and 12 females • Inclusion criteria 1. No orthodontic treatment before distalisation 2. A non-extraction treatment plan 3. Maxillary first permanent molars in occlusion and no erupted second permanent molars 4. Class II molar relationship, defined by at least end-to-end molar relationship
Interventions	• **Comparison 1: Intraoral appliance with superelastic coils** 1. Bands on upper first molars and first and second premolars 2. 1.1 mm tube soldered to the lingual of the molar band 3. A Nance acrylic button was soldered to the appliance • **Comparison 2: Headgear** 1. Cervical pull 2. 400 g force was used for the first 2 weeks and 500 g afterwards 3. Patient instructed to wear appliance at least 12 hours a day 4. Patients recalled every 5 weeks
Outcomes	• Treatment time to achieve molar correction • Distal movement and tipping of maxillary first permanent molars • Anterior movement and inclination of maxillary central incisors, i.e. anchorage loss • Movement of mandibular first permanent molars • Movement and inclination of mandibular central incisors • Skeletal changes of maxilla and mandible • Bite opening effect
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Quote: "A restricted randomisation method was used in blocks of 10"
Allocation concealment (selection bias)	Unclear risk	Method of concealment is not described
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "the cephalograms were scored and coded by an independent person unaware of the group allocation"
Incomplete outcome data (attrition bias) All outcomes	Low risk	• Number randomised 40, number included in the analysis 40

Bondemark 2005 (*Continued*)

		• No drop-outs
Selective reporting (reporting bias)	Unclear risk	• Selective reporting of outcomes: insufficient information to permit judgement
Other bias	Low risk	Study appears to be free of other sources of bias

De Oliveira 2007

Methods	• Trial design: 2-centre RCT (parallel-group) • Location: University of Sao Paulo, Brazil; Lavras Dental School, Brazil • Recruitment period: not stated • Funding source: research submitted as partial fulfilment of MSc degree • Source of participants: patients attending clinic at university • Study duration: not stated • Time points at which follow-up is reported: 1) start of treatment, 2) removal of fixed orthodontic appliance
Participants	• 50 participants in total, mean age 11.45 years • 25 in the Jasper Jumper group: mean age 11.86 years (range, 9.45 to 14.94), 13 males and 12 females • 25 in the cervical headgear group: mean age 12.29 years (range, 9.95 to 15.24), 13 males and 12 females • Inclusion criteria 1. Angle Class II molar relationship 2. Class II division 1 with no subdivision malocclusion 3. Early permanent dentition with all permanent first molars, and first and second premolars • Exclusion criteria 1. No craniofacial syndrome or systemic disease 2. No tooth agenesis or missing permanent teeth
Interventions	• **Comparison 1: Jasper Jumper** 1. Jasper Jumpers attached to the maxillary and mandibular arches, in conjunction with: 2. Standard edgewise appliance with a 0.022 inch slot 3. Transpalatal arch in the maxilla • **Comparison 2: Cervical headgear** 1. Cervical headgear exerting 150 to 300 g of force on each side with an average wear of 14 to 16 hours per day 2. Standard edgewise appliance with a 0.022 inch slot
Outcomes	Skeletal and dentoalveolar measurements on initial and final cephalometric radiographs
Notes	There was also an untreated control group in the study, but it was not involved in the randomisation process

De Oliveira 2007 (*Continued*)

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Quote (from correspondence): "The randomization process was performed as follows: the patients were placed into one of the groups by the use of a coin-toss"
Allocation concealment (selection bias)	Unclear risk	Method of concealment is not described
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Insufficient information to permit judgement
Incomplete outcome data (attrition bias) All outcomes	Low risk	All randomised patients were included in the final analysis
Selective reporting (reporting bias)	Unclear risk	• Selective reporting of outcomes: insufficient information to permit judgement • Selective reporting of data: the duration of treatment to distalise the molar teeth was reported as a range; this is a secondary outcome of this review
Other bias	Low risk	Study appears to be free of other sources of bias

Karacay 2006

Methods	• Trial design: RCT (parallel-group) • Location: Gulhane Military Medical Academy, Ankara, Turkey • Recruitment period: not stated • Funding source: not stated • Source of participants: patients attending clinic • Study duration: not stated • Time points at which follow-up is reported: 1) attachment of distalising appliance, 2) end of molar correction
Participants	• 48 participants in total, mean age 13.8 years • 16 in the Forsus Nitinol Flat Spring group: mean age 13.6 years (SD 1.2), 9 males and 7 females • 16 in the Jasper Jumper group: mean age 14.0 years (SD 1.9), 10 males and 6 females • 16 in the control group: mean age 13.8 years (SD 1.4), gender distribution not stated

Karacay 2006 (*Continued*)

Interventions	• **Comparison 1: Forsus Nitinol Flat Spring (FNFS)** 1. Size determined by adding 12 mm to the distance between the mesial edge of the headgear tube and the distal edge of the mandibular canine bracket when the patient was in centric occlusion 2. Attached to headgear tube of maxillary molar and auxiliary arch in mandible between canine and first premolar brackets 3. Patients recalled every 3 weeks • **Comparison 2: Jasper Jumper (JJ)** 1. Size determined by adding 12 mm to the distance between the mesial edge of the headgear tube and the distal edge of the mandibular canine bracket when the patient was in centric occlusion 2. Attached to headgear tube of maxillary molar and auxiliary arch in mandible between canine and first premolar brackets 3. Patients recalled every 3 weeks • **Comparison 3: Untreated control**
Outcomes	• Skeletal and dentoalveolar measurements on initial and final cephalometric radiographs • Inter-molar and inter-canine widths on study models
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Quote: "The patients were randomly divided into three groups" Comment: insufficient information about the sequence generation process to permit judgement
Allocation concealment (selection bias)	Unclear risk	Method of concealment is not described
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Insufficient information to permit judgement
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	• 48 patients were included in the analysis • Number of drop-outs not addressed
Selective reporting (reporting bias)	High risk	Selective reporting of outcome data: no estimate of variability for change by group
Other bias	Low risk	Study appears to be free of other sources of bias

Papadopoulos 2010

Methods	• Trial design: single-centre RCT (parallel-group) • Location: Department of Orthodontics, Aristotle University of Thessaloniki, Greece • Recruitment period: not stated • Funding source: none • Source of participants: patients attending clinic • Study duration: 6.5 months • Time points at which follow-up is reported: 1) start of distalisation, 2) end of distalisation
Participants	• 26 participants in total, age 7.1 to 11.9 years • 15 in the First Class appliance group: mean age 9.2 years (range: 7.6 to 10.8), 8 males and 7 females • 11 in the 'no treatment' group: mean age 9.7 years (range: 7.1 to 11.9), 5 males and 6 females • Inclusion criteria 1. Bilateral Class II molar relationship (quarter to 1 molar cusp) • Exclusion criteria 1. Past orthodontic treatment 2. Crossbites 3. Severe carious lesions 4. Poor oral hygiene 5. Mobility of the maxillary deciduous molars 6. Flat palate 7. Ectopic maxillary canines 8. Anterior open bites 9. Vertical growth pattern 10. Tongue habits
Interventions	• **Comparison 1: First Class appliance** 1. Banded first molars and second premolars or second primary molars 2. 2 buccally positioned activation screws 3. 2 palatally positioned open nickel-titanium coil springs 4. Buccal and palatal tubes 5. Large modified Nance button • **Comparison 2: Untreated control**
Outcomes	Cephalometric and dental cast variables
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Quote: "They were randomized into 2 groups" Comment: insufficient information about the sequence generation process to permit

Papadopoulos 2010 (*Continued*)

		judgement
Allocation concealment (selection bias)	Unclear risk	Method of concealment is not described
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Insufficient information to permit judgement
Incomplete outcome data (attrition bias) All outcomes	Low risk	27 randomised, 1 dropped out because of broken appliance
Selective reporting (reporting bias)	Unclear risk	Selective reporting of outcomes: insufficient information to permit judgement
Other bias	Low risk	Study appears to be free of other sources of bias

Paul 2002

Methods	• Trial design: single-centre RCT (parallel-group) • Location: University Dental Hospital, Manchester • Recruitment period: not stated • Funding source: none • Source of participants: patients referred for treatment • Study duration: 6 months • Time points at which follow-up is reported: 1) start of distalisation, 2) end of distalisation
Participants	• 23 participants in total, age 10 to 16 years • 12 in the removable appliance group: mean age 13.5 years (SD 1.58) • 11 in the Begg system group: mean age 14.75 years (SD 1.75) • Inclusion criteria 1. Patient 10 to 16 years old at start of treatment 2. Upper second premolars present and erupted (required for the Jones Jig)
Interventions	• **Comparison 1: Upper removable appliance** 1. Adam's cribs on upper first premolars 2. Southend clasp on the upper central incisor 3. Occlusal stops on the upper canine 4. Palatal finger springs to distalise the molars • **Comparison 2: Jones Jig** 1. Bands on the upper second premolars 2. Nance palatal arch 3. The jig main frame attached to headgear slot on molar bands 4. Niti coil spring
Outcomes	Primary outcomes 1. Changes in the position of upper first molar in terms of • distal movement

	• distal tipping • disto-palatal rotation (molar straightening) Secondary outcomes 1. Mesial movement of the upper first premolars (loss of anchorage) 2. Reported discomfort
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Quote: "A restricted randomisation method was used in blocks of 12"
Allocation concealment (selection bias)	Unclear risk	Method of concealment is not described
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "the examiner measuring the models was blind until all the data were recorded"
Incomplete outcome data (attrition bias) All outcomes	Low risk	• Number randomised: 27, number evaluated: 23 • 15% drop-out rate: 1. URA (2) (reasons: repeated breakage and did not attend after fit) 2. Jones Jig (2) (reasons: treatment plan changed and patient did not want treatment)
Selective reporting (reporting bias)	High risk	• Selective reporting of outcomes: insufficient information to permit judgement • Selective reporting of data: there were no data on loss of anterior anchorage; this is an important outcome that is expected to be reported
Other bias	Low risk	Study appears to be free of other sources of bias

Toy 2011

Methods	• Trial design: single-centre RCT (parallel-group) • Location: Hacettepe University, Turkey • Recruitment period: not stated • Funding source: not stated • Source of participants: patients referred to orthodontic clinic • Study duration: 6.4 months • Time points at which follow-up is reported: 1) start of treatment, 2) end of molar distalisation or in the case of the headgear group, after 4.96 +/- 0.35 months
Participants	• 30 participants in total, mean age 11.59 • 15 in the intraoral pendulum appliance group: mean age 11.45 years (SD 1.54), 6 males and 9 females • 15 in the cervical headgear group: mean age 11.72 years (SD 1.24), 5 males and 10 females • Inclusion criteria 1. Skeletal Class I malocclusion with bilateral Class II molars 2. Radiographic confirmation that at least one-third of the roots of the unerupted maxillary second molars had developed 3. A non-extraction treatment plan 4. Good oral hygiene 5. No or minimal crowding in the mandibular dental arch 6. No signs of temporomandibular joint disorder
Interventions	• **Comparison 1: Intraoral pendulum appliance with a midline expansion screw** 1. Palatal acrylic button anchored to the maxillary first and second premolars with bonded occlusal rests 2. A midline screw and bilateral 0.032 inch TMA cantilever springs were inserted into lingual sheaths on the first molar bands 3. Springs were initially activated 90° 4. Participants were monitored at 3-week intervals 5. Participants were instructed to turn the expansion screw a quarter turn once a week • **Comparison 2: Headgear group** 1. Cervical pull headgear 2. Activated to deliver a force of 500 g 3. Participants were instructed to wear the appliance for 12 to 14 hours per day 4. Participants were monitored at 3-week intervals
Outcomes	1. Mesiodistal movement of the upper first molars 2. Anterior movement of upper incisor 3. Overjet 4. Other cephalometric variables
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement

Toy 2011 (*Continued*)

Random sequence generation (selection bias)	Unclear risk	Quote: "The subjects were randomly allocated to ..." Comment: insufficient information about the sequence generation process to permit judgement
Allocation concealment (selection bias)	Unclear risk	Method of concealment is not described
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Insufficient information to permit judgement
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	• 30 patients were included in the analysis • Number of drop-outs not addressed
Selective reporting (reporting bias)	Unclear risk	• Selective reporting of outcomes: insufficient information to permit judgement
Other bias	Low risk	Study appears to be free of other sources of bias

FNFS: Forsus Nitinol Flat Spring; GoGnSN: mandibular plane angle; JJ: Jasper Jumper; PDC: palatally displaced canines; RCT: randomised controlled trial; SD: standard deviation; SE: standard error; URA: upper removable appliance

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

Study	Reason for exclusion
Abed 2010	Did not involve treatment with a distalising appliance; outcomes are not relevant; retrospective study
Angelieri 2008	Retrospective study
Cetinsahin 2010	Not a randomised trial; patient allocation depended on anchorage need. Did not involve treatment with a distalising appliance
Erverdi 1997	Not a randomised trial
Gelgor 2007	Not a randomised trial
Kaya 2009	Did not involve treatment with a distalising appliance
Kinzinger 2003	Not relevant; participants in this study were grouped according to dental maturation stage

(*Continued*)

Kinzinger 2004	Not relevant; participants in this study were grouped according to second and third molar maturation stage
Kinzinger 2005	Not relevant; participants in this study were grouped according to the tooth used for anchorage
Kinzinger 2006	Not relevant; participants in this study were grouped according to dental maturation stage
Kinzinger 2010	No comparison intervention
Kucukkeles 2007	Not a randomised trial
Liu 2009	Did not involve treatment with a distalising appliance; all patients over 16 years of age
Mossaz 2007	Not a randomised trial, patients chose their intervention
Oncag 2007	Not a randomised trial
Sari 2003	Not a randomised trial
Schutze 2007	Not a randomised trial
Silvola 2009	The comparative intervention was not relevant to this review
Taner 2003	Not a randomised trial
Ucem 1998	Not a randomised trial
Uzel 2007	Correspondence with author confirmed it was not randomised

DATA AND ANALYSES

Comparison 1. Appliance versus untreated control

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Movement of upper first molars	2		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
1.1 First Class appliance versus untreated controls	1	26	Mean Difference (IV, Fixed, 95% CI)	-4.04 [-5.49, -2.59]
1.2 Distalising appliance (Forsus and Jasper Jumper) versus untreated control	1	48	Mean Difference (IV, Fixed, 95% CI)	-1.6 [-2.20, 1.00]
2 Movement of upper incisor teeth	2		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
2.1 First Class appliance versus untreated controls	1	26	Mean Difference (IV, Fixed, 95% CI)	1.32 [-1.14, 3.78]
2.2 Distalising appliance (Forsus and Jasper Jumper) versus untreated control	1	48	Mean Difference (IV, Fixed, 95% CI)	-1.4 [-2.38, -0.42]
3 Loss of anchorage (overjet mm)	2		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
3.1 First Class appliance versus untreated controls	1	26	Mean Difference (IV, Fixed, 95% CI)	1.18 [0.26, 2.10]
3.2 Distalising appliance (Forsus and Jasper Jumper) versus untreated control	1	48	Mean Difference (IV, Fixed, 95% CI)	-3.55 [-4.53, -2.57]

Comparison 2. Intraoral appliance versus headgear

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Movement of upper first molar	4	150	Mean Difference (IV, Random, 95% CI)	-1.45 [-2.74, -0.15]
2 Movement of upper incisor teeth	4	150	Mean Difference (IV, Random, 95% CI)	1.82 [1.39, 2.24]
3 Change in overjet	2	70	Mean Difference (IV, Fixed, 95% CI)	1.64 [1.26, 2.02]

Comparison 3. Intraoral appliance versus other intraoral appliance

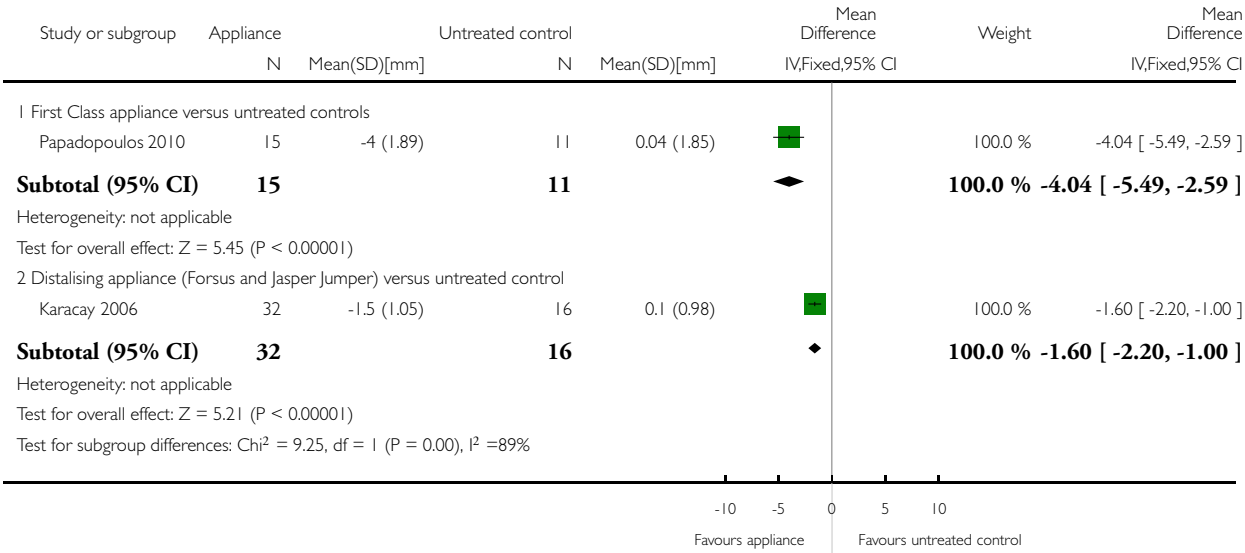
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Movement of upper first molars	3		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
1.1 Three-dimensional bimetric distalising arch versus modified Begg intraoral distalising system	1	38	Mean Difference (IV, Fixed, 95% CI)	-0.28 [-0.63, 0.07]
1.2 Jasper Jumper versus Forsus Nitinol Flat Spring	1	32	Mean Difference (IV, Fixed, 95% CI)	0.80 [0.12, 1.48]
1.3 Upper removable appliance with finger springs versus Jones Jig appliance	1	23	Mean Difference (IV, Fixed, 95% CI)	-0.13 [-1.50, 1.24]
2 Movement of upper incisor teeth	2		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
2.1 Three-dimensional bimetric distalising arch versus modified Begg intraoral distalising system	1	38	Mean Difference (IV, Fixed, 95% CI)	-0.39 [-1.43, 0.65]
2.2 Jasper Jumper versus Forsus Nitinol Flat Spring	1	32	Mean Difference (IV, Fixed, 95% CI)	0.0 [-0.80, 0.80]
3 Loss of anchorage (overjet)	2		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
3.1 Three-dimensional dimetric distalising arch versus modified Begg intraoral distalising system	1	38	Mean Difference (IV, Fixed, 95% CI)	-0.43 [-0.74, -0.12]
3.2 Jasper Jumper versus Forsus Nitinol Flat Spring	1	32	Mean Difference (IV, Fixed, 95% CI)	0.5 [-0.04, 1.04]
4 Duration of treatment	2		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
4.1 Three-dimensional bimetric distalising arch versus modified Begg intraoral distalising system	1	38	Mean Difference (IV, Fixed, 95% CI)	-3.1 [-3.49, -2.71]
4.2 Jasper Jumper versus Forsus Nitinol Flat Spring	1	32	Mean Difference (IV, Fixed, 95% CI)	-0.05 [-0.87, 0.77]

Analysis 1.1. Comparison 1 Appliance versus untreated control, Outcome 1 Movement of upper first molars.

Review: Orthodontic treatment for distalising upper first molars in children and adolescents

Comparison: 1 Appliance versus untreated control

Outcome: 1 Movement of upper first molars

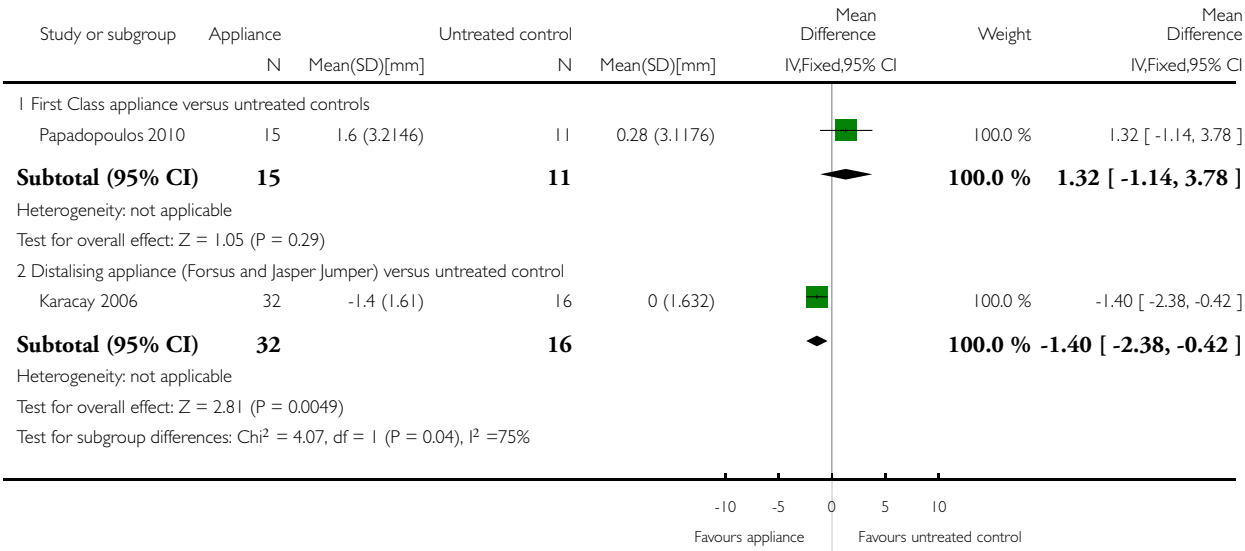


Analysis 1.2. Comparison 1 Appliance versus untreated control, Outcome 2 Movement of upper incisor teeth.

Review: Orthodontic treatment for distalising upper first molars in children and adolescents

Comparison: 1 Appliance versus untreated control

Outcome: 2 Movement of upper incisor teeth



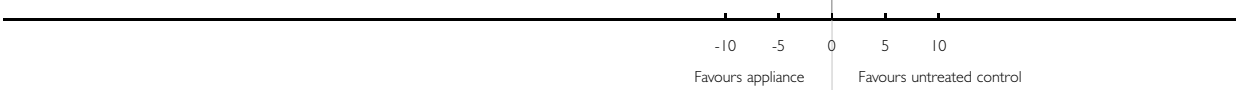
Analysis 1.3. Comparison 1 Appliance versus untreated control, Outcome 3 Loss of anchorage (overjet mm).

Review: Orthodontic treatment for distalising upper first molars in children and adolescents

Comparison: 1 Appliance versus untreated control

Outcome: 3 Loss of anchorage (overjet mm)

Study or subgroup	Appliance N	Mean(SD)[mm]	Untreated control N	Mean(SD)[mm]	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
1 First Class appliance versus untreated controls							
Papadopoulos 2010	15	0.68 (1.2)	11	-0.5 (1.16)		100.0 %	1.18 [0.26, 2.10]
Subtotal (95% CI)	**15**		**11**			**100.0 %**	**1.18 [0.26, 2.10]**
Heterogeneity: not applicable							
Test for overall effect: Z = 2.53 (P = 0.012)							
2 Distalising appliance (Forsus and Jasper Jumper) versus untreated control							
Karacay 2006	32	-3.45 (1.63)	16	0.1 (1.63)		100.0 %	-3.55 [-4.53, -2.57]
Subtotal (95% CI)	**32**		**16**			**100.0 %**	**-3.55 [-4.53, -2.57]**
Heterogeneity: not applicable							
Test for overall effect: Z = 7.11 (P < 0.00001)							
Test for subgroup differences: Chi^2 = 47.87, df = 1 (P = 0.00), I^2 =98%							



Analysis 2.1. Comparison 2 Intraoral appliance versus headgear, Outcome 1 Movement of upper first molar.

Review: Orthodontic treatment for distalising upper first molars in children and adolescents

Comparison: 2 Intraoral appliance versus headgear

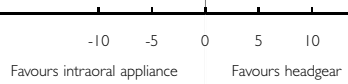
Outcome: 1 Movement of upper first molar

Study or subgroup	Intraoral appliance N	Mean(SD)[mm]	Headgear N	Mean(SD)[mm]	Mean Difference IV,Random,95% CI	Weight	Mean Difference IV,Random,95% CI
Toy 2011	15	-3.69 (3.45)	15	-0.77 (1.3)		21.2 %	-2.92 [-4.79, -1.05]
Acar 2010	15	-4.53 (1.46)	15	-2.23 (1.68)		29.5 %	-2.30 [-3.43, -1.17]
De Oliveira 2007	25	1.63 (5.49)	25	-0.14 (3.8)		14.9 %	1.77 [-0.85, 4.39]
Bondemark 2005	20	-2.2 (0.78)	20	-1 (1.32)		34.4 %	-1.20 [-1.87, -0.53]
Total (95% CI)	**75**		**75**			**100.0 %**	**-1.45 [-2.74, -0.15]**

Heterogeneity: $Tau^2 = 1.15$; $Chi^2 = 10.91$, df = 3 (P = 0.01); $I^2 = 73\%$

Test for overall effect: Z = 2.19 (P = 0.028)

Test for subgroup differences: Not applicable



Analysis 2.2. Comparison 2 Intraoral appliance versus headgear, Outcome 2 Movement of upper incisor teeth.

Review: Orthodontic treatment for distalising upper first molars in children and adolescents

Comparison: 2 Intraoral appliance versus headgear

Outcome: 2 Movement of upper incisor teeth

Study or subgroup	Intraoral appliance		Headgear		Mean Difference	Weight	Mean Difference
	N	Mean(SD)[mm]	N	Mean(SD)[mm]	IV,Random,95% CI		IV,Random,95% CI
Toy 2011	15	1.05 (0.98)	15	-0.62 (0.74)		45.8 %	1.67 [1.05, 2.29]
Acar 2010	15	0.33 (1.63)	15	-1.57 (1.37)		15.2 %	1.90 [0.82, 2.98]
De Oliveira 2007	25	-0.04 (6.18)	25	-1.86 (3.96)		2.1 %	1.82 [-1.06, 4.70]
Bondemark 2005	20	1.66 (0.99)	20	-0.3 (1.23)		36.9 %	1.96 [1.27, 2.65]
Total (95% CI)	**75**		**75**			**100.0 %**	**1.82 [1.39, 2.24]**

Heterogeneity: $Tau^2 = 0.0$; $Chi^2 = 0.40$, df = 3 (P = 0.94); $I^2 = 0.0\%$

Test for overall effect: Z = 8.46 (P < 0.00001)

Test for subgroup differences: Not applicable

Analysis 2.3. Comparison 2 Intraoral appliance versus headgear, Outcome 3 Change in overjet.

Review: Orthodontic treatment for distalising upper first molars in children and adolescents

Comparison: 2 Intraoral appliance versus headgear

Outcome: 3 Change in overjet

Study or subgroup	Intraoral appliance		Headgear		Mean Difference	Weight	Mean Difference
	N	Mean(SD)[mm]	N	Mean(SD)[mm]	IV,Fixed,95% CI		IV,Fixed,95% CI
Bondemark 2005	20	0.9 (0.88)	20	-0.9 (0.63)		64.4 %	1.80 [1.33, 2.27]
Toy 2011	15	0.54 (0.83)	15	-0.82 (0.95)		35.6 %	1.36 [0.72, 2.00]
Total (95% CI)	**35**		**35**			**100.0 %**	**1.64 [1.26, 2.02]**

Heterogeneity: $Chi^2 = 1.18$, df = 1 (P = 0.28); $I^2 = 15\%$

Test for overall effect: Z = 8.46 (P < 0.00001)

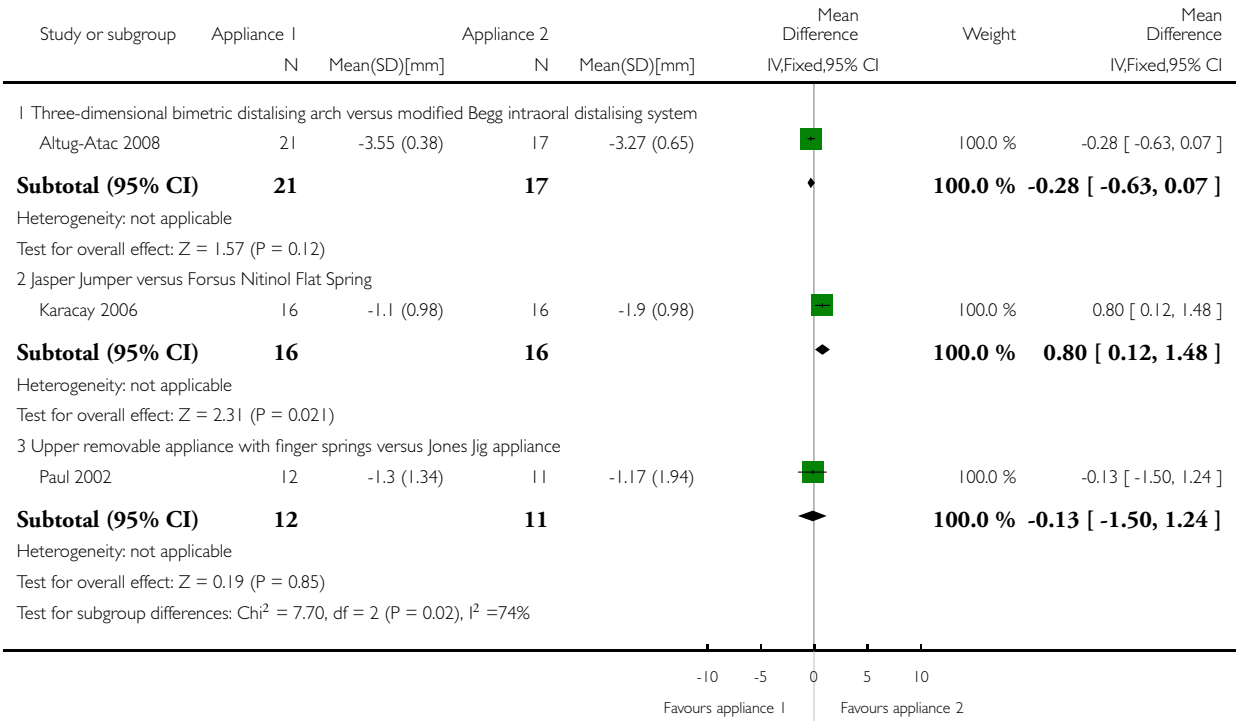
Test for subgroup differences: Not applicable

Analysis 3.1. Comparison 3 Intraoral appliance versus other intraoral appliance, Outcome 1 Movement of upper first molars.

Review: Orthodontic treatment for distalising upper first molars in children and adolescents

Comparison: 3 Intraoral appliance versus other intraoral appliance

Outcome: 1 Movement of upper first molars



Analysis 3.2. Comparison 3 Intraoral appliance versus other intraoral appliance, Outcome 2 Movement of upper incisor teeth.

Review: Orthodontic treatment for distalising upper first molars in children and adolescents

Comparison: 3 Intraoral appliance versus other intraoral appliance

Outcome: 2 Movement of upper incisor teeth

Study or subgroup	Appliance 1		Appliance 2		Mean Difference	Weight	Mean Difference
	N	Mean(SD)[mm]	N	Mean(SD)[mm]	IV,Fixed,95% CI		IV,Fixed,95% CI
1 Three-dimensional bimetric distalising arch versus modified Begg intraoral distalising system							
Altug-Atac 2008	21	0.06 (0.47)	17	0.45 (2.14)		100.0 %	-0.39 [-1.43, 0.65]
Subtotal (95% CI)	**21**		**17**			**100.0 %**	**-0.39 [-1.43, 0.65]**
Heterogeneity: not applicable							
Test for overall effect: Z = 0.74 (P = 0.46)							
2 Jasper Jumper versus Forsus Nitinol Flat Spring							
Karacay 2006	16	-1.4 (1.15)	16	-1.4 (1.15)		100.0 %	0.0 [-0.80, 0.80]
Subtotal (95% CI)	**16**		**16**			**100.0 %**	**0.0 [-0.80, 0.80]**
Heterogeneity: not applicable							
Test for overall effect: Z = 0.0 (P = 1.0)							
Test for subgroup differences: Chi^2 = 0.34, df = 1 (P = 0.56), I^2 =0.0%							

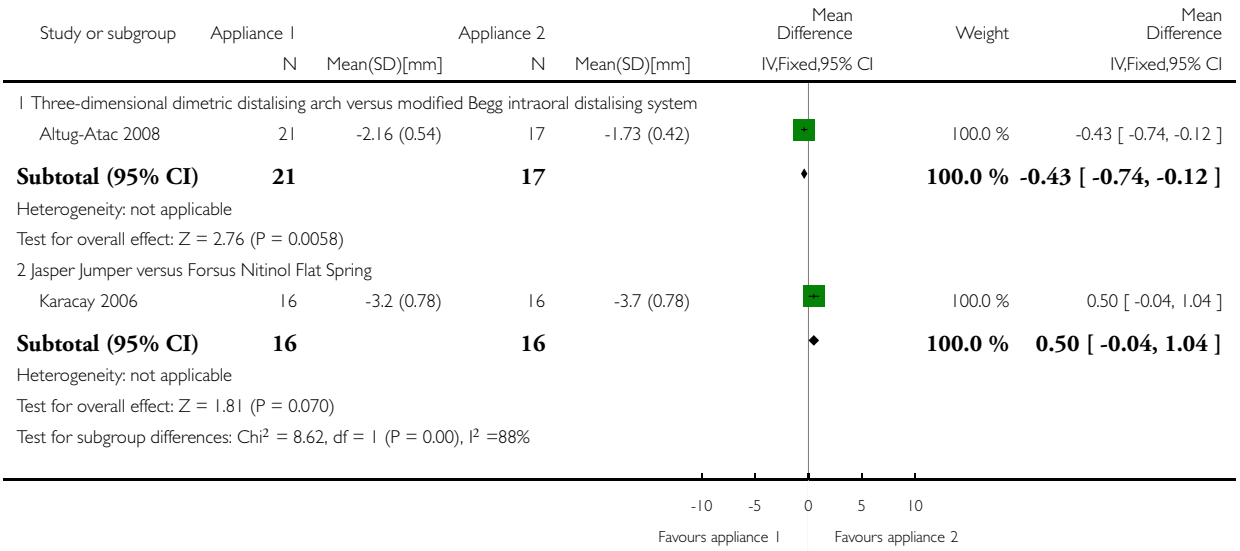
Analysis 3.3. Comparison 3 Intraoral appliance versus other intraoral appliance, Outcome 3 Loss of anchorage (overjet).

Review: Orthodontic treatment for distalising upper first molars in children and adolescents

Comparison: 3 Intraoral appliance versus other intraoral appliance

Outcome: 3 Loss of anchorage (overjet)

Study or subgroup	Appliance 1		Appliance 2		Mean Difference	Weight	Mean Difference
	N	Mean(SD)[mm]	N	Mean(SD)[mm]	IV,Fixed,95% CI		IV,Fixed,95% CI
1 Three-dimensional dimetric distalising arch versus modified Begg intraoral distalising system							
Altug-Atac 2008	21	-2.16 (0.54)	17	-1.73 (0.42)		100.0 %	-0.43 [-0.74, -0.12]
Subtotal (95% CI)	**21**		**17**			**100.0 %**	**-0.43 [-0.74, -0.12]**
Heterogeneity: not applicable							
Test for overall effect: Z = 2.76 (P = 0.0058)							
2 Jasper Jumper versus Forsus Nitinol Flat Spring							
Karacay 2006	16	-3.2 (0.78)	16	-3.7 (0.78)		100.0 %	0.50 [-0.04, 1.04]
Subtotal (95% CI)	**16**		**16**			**100.0 %**	**0.50 [-0.04, 1.04]**
Heterogeneity: not applicable							
Test for overall effect: Z = 1.81 (P = 0.070)							
Test for subgroup differences: Chi^2 = 8.62, df = 1 (P = 0.00), I^2 =88%							

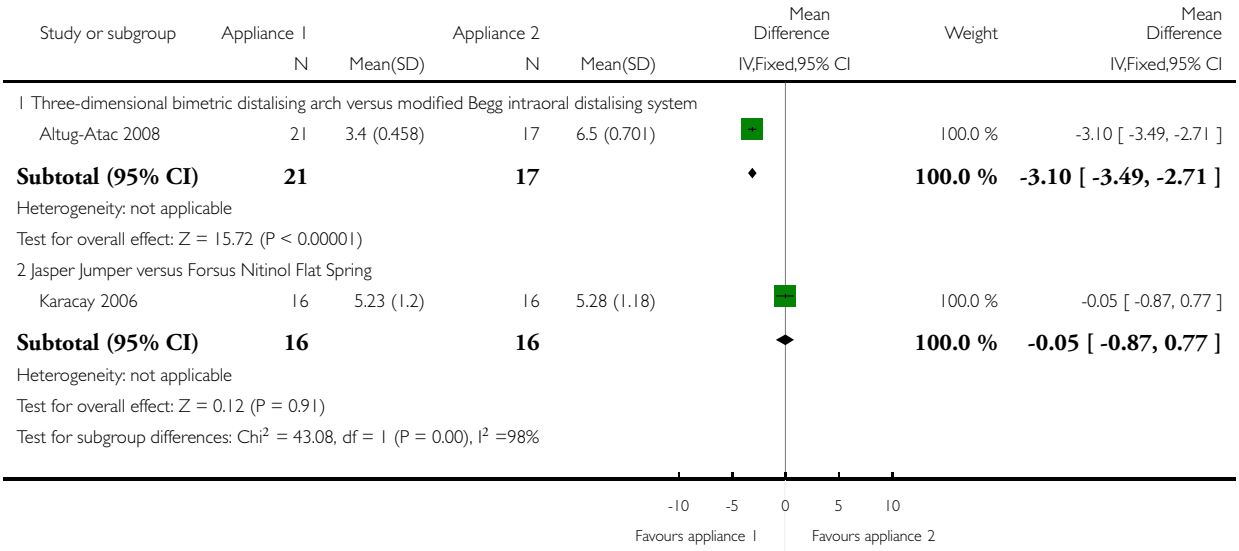


Analysis 3.4. Comparison 3 Intraoral appliance versus other intraoral appliance, Outcome 4 Duration of treatment.

Review: Orthodontic treatment for distalising upper first molars in children and adolescents

Comparison: 3 Intraoral appliance versus other intraoral appliance

Outcome: 4 Duration of treatment



ADDITIONAL TABLES

Table 1. Reported outcomes in included studies which are relevant to this review

Study ID	Movement of molar teeth	Anterior movement of incisor teeth	Overjet	Duration of treatment	Number of attendances	Adverse effects
Acar 2010	Yes	Yes	No	No	No	No
Altug-Atac 2008	Yes	Yes	Yes	Yes	No	No
Armi 2011	Yes	No	No	No	No	No
Baccetti 2008	Yes	No	No	No	No	No
Bondemark 2005	Yes	Yes	Yes	Yes	No	No
De Oliveira 2007	Yes	Yes	No	Yes	No	No

Table 1. Reported outcomes in included studies which are relevant to this review (*Continued*)

Karacay 2006	Yes	Yes	Yes	Yes	No	No
Papadopoulos 2010	Yes	Yes	Yes	No	No	No
Paul 2002	Yes	No	No	Yes	No	No
Toy 2011	Yes	Yes	Yes	Yes	No	No

APPENDICES

Appendix 1. MEDLINE (OVID) search strategy

1. Malocclusion, Angle Class II/
2. "Class II" AND (Angle$ OR malocclusion$ OR bite$)
3. (("distal molar movement") OR (distal$ adj4 molar$))
4. or/1-3
5. exp Orthodontic appliances, Functional/
6. exp Orthodontic appliances, Removable/
7. ((extraoral or extra-oral or "extra oral") adj4 appliance$)
8. ("head gear" or headgear or head-gear)
9. ((intraoral or intra-oral or "intra oral") adj4 appliance$)
10. ("pendulum appliance$" or "Wilson's arch$" or "distal jet appliance$" or Jones or "jig appliance$" or "repelling magnets" or (super elastic adj3 spring$) or (super-elastic adj3 spring$) or ("super elastic" adj3 spring$) or Herbst or Frankel or Bass or Harvold).ti,ab.
11. or/5-10
12. 4 AND 11

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

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

Appendix 2. The Cochrane Oral Health Group's Trials Register search strategy

This search was done in the Cochrane Oral Health Group's Trials Register via the Cochrane Register of Studies using the search strategy below:
#1 (("class II" AND (Angle* or malocclusion* or bite*))) AND (INREGISTER)
#2 (("class 2" AND (Angle* or malocclusion* or bite*))) AND (INREGISTER)
#3 (("class two" AND (Angle* or malocclusion* or bite*))) AND (INREGISTER)
#4 ((distal and molar)) AND (INREGISTER)
#5 (#1 or #2 or #3 or #4) AND (INREGISTER)
#6 (orthodontic*) AND (INREGISTER)
#7 ((extraoral or extra-oral or "extra oral" or headgear or head-gear or "head gear" or intraoral or intra-oral or "intra oral" or "pendulum appliance*" or "wilson* arch*" or "distal jet appliance*" or Jones or "jig appliance*" or "repelling magent*" or "superelastic spring*" or "super-elastic spring*" or "super elastic spring*" or Herbst or Frankel or Bass or Harvold)) AND (INREGISTER)
#8 (#6 or #7) AND (INREGISTER)
#9 (#5 and #8) AND (INREGISTER)

Previous searches for this review were conducted in the Cochrane Oral Health Group's Trials Register using the ProCite software and the search strategy below:

((orthodontic* or extraoral or extra-oral or "extra oral" or headgear or head-gear or "head gear" or intraoral or intra-oral or "intra oral" or "pendulum appliance*" or "wilson* arch*" or "distal jet appliance*" or Jones or "jig appliance*" or "repelling magent*" or "superelastic spring*" or "super-elastic spring*" or "super elastic spring*" or Herbst or Frankel or Bass or Harvold) AND ((angle* or malocclusion* or bite*) AND ("class two" or "class II" or "class 2")))

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

#1 MeSH descriptor Malocclusion, Angle Class II this term only
#2 ("Class II" in All Text and (Angle* in All Text or malocclusion* in All Text or bite* in All Text))
#3 "distal molar movement" in All Text
#4 (distal* in All Text near/4 molar* in All Text)
#5 (#1 or #2 or #3 or #4)
#6 MeSH descriptor Orthodontic Appliances, Functional explode all trees
#7 MeSH descriptor Orthodontic Appliances, Removable explode all trees
#8 ((extraoral in All Text or extra-oral in All Text or "extra oral" in All Text) and appliance* in All Text)
#9 ("head gear" in All Text or headgear in All Text or head-gear in All Text)
#10 ((intraoral in All Text or intra-oral in All Text or "intra oral" in All Text) and appliance* in All Text)
#11 ("pendulum appliance*" in Title, Abstract or Keywords or "Wilson* arch*" in Title, Abstract or Keywords or "distal jet appliance*" in Title, Abstract or Keywords or Jones in Title, Abstract or Keywords or "jig appliance*" in Title, Abstract or Keywords or "repelling magnet*" in Title, Abstract or Keywords or "superelastic spring*" in Title, Abstract or Keywords or "super-elastic spring*" in Title, Abstract or Keywords or "super elastic spring*" in Title, Abstract or Keywords or Herbst in Title, Abstract or Keywords or Frankel in Title, Abstract or Keywords or Bass in Title, Abstract or Keywords or Harvold in Title, Abstract or Keywords)
#12 (#6 or #7 or #8 or #9 or #10 or #11)
#13 (#5 and #12)

Appendix 4. EMBASE (OVID) search strategy

1. Malocclusion, Angle Class II/
2. "Class II" AND (Angle$ OR malocclusion$ OR bite$)
3. (("distal molar movement") OR (distal$ adj4 molar$))
4. or/1-3
5. exp Orthodontic appliances, Functional/
6. exp Orthodontic appliances, Removable/
7. ((extraoral or extra-oral or "extra oral") adj4 appliance$)
8. ("head gear" or headgear or head-gear)
9. ((intraoral or intra-oral or "intra oral") adj4 appliance$)
10. ("pendulum appliance$" or "Wilson's arch$" or "distal jet appliance$" or Jones or "jig appliance$" or "repelling magnets" or (superelastic adj3 spring$) or (super-elastic adj3 spring$) or ("super elastic" adj3 spring$) or Herbst or Frankel or Bass or Harvold).ti,ab.
11. or/5-10
12. 4 AND 11

The above subject search was linked to the Cochrane Oral Health Group filter for identifying RCTs in 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

Appendix 5. Clinicaltrials.gov search strategy

An advanced search using the following 'search terms' and 'conditions':
Class II OR Class 2 OR distalise OR distal AND movement OR distal AND molar OR orthodontic OR headgear OR distal AND jet OR pendulum OR wilson AND arch OR Jones AND jig OR repelling AND magnet OR superelastic AND spring | orthodontic OR Malocclusion OR Class II

CONTRIBUTIONS OF AUTHORS

- Development of the protocol: Safa Jambi (SJ), Kevin O'Brien (KOB), Badri Thiruvenkatachari (BT), Tanya Walsh (TW).
- Examination of titles and abstracts: SJ, BT, KOB.
- Retrieval of full-text reports: SJ.
- Examination of full-text reports and final decisions on study inclusion: SJ, BT, KOB.
- Development of data collection forms: SJ, BT.
- Data extraction and management: SJ, BT, TW, KOB.
- Risk of bias assessment: SJ, BT, TW, KOB.
- Data synthesis: SJ, BT, TW.
- Writing the review: SJ supervised by TW, KOB.

DECLARATIONS OF INTEREST

One of the authors of this review, Kevin O'Brien, was involved as an author in one of the included studies (Paul 2002). Decisions on study inclusion, data extraction and management for the Paul 2002 study were performed independently of this author.

Safa Jambi: no interests to declare.

Badri Thiruvenkatachari: no interests to declare.

Tanya Walsh: 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

Changes from the protocol

1. Interventions assessing functional appliances were included in the protocol but not in the review. The rationale for this change was that studies in which functional appliances were used did not have the same treatment objective as studies which were specifically intended for distal movement of molars.
2. The handsearched journals were expanded to also include the following journals:

- *Clinical Implant Dentistry and Related Research*
- *Clinical Oral Implant Research*
- *International Journal of Oral and Maxillofacial Implants*
- *Journal of Dentistry*.

Methods not implemented

The following outcomes were not assessed because they were not reported by any of the included studies.

1. Number of attendances required to complete treatment.
2. Non-compliance rate of intervention.
3. Adverse effects, including headgear injuries, health of gingiva and damage to teeth.

INDEX TERMS

Medical Subject Headings (MeSH)

*Molar; *Orthodontic Appliances; Extraoral Traction Appliances; Maxilla; Randomized Controlled Trials as Topic; Tooth Movement [instrumentation; *methods]

MeSH check words

Adolescent; Child; Female; Humans; Male