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Adhesives for fixed orthodontic bands (Review)

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[Intervention Review]

Adhesives for fixed orthodontic bands

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ABSTRACT

Background

Orthodontic treatment involves using fixed or removable appliances (dental braces) to correct the positions of teeth. It has been shown that the quality of treatment result obtained with fixed appliances is much better than with removable appliances. Fixed appliances are, therefore, favoured by most orthodontists for treatment. The success of a fixed orthodontic appliance depends on the metal attachments (brackets and bands) being attached securely to the teeth so that they do not become loose during treatment. Brackets are usually attached to the front and side teeth, whereas bands (metal rings that go round the teeth) are more commonly used on the back teeth (molars). A number of adhesives are available to attach bands to teeth and it is important to understand which group of adhesives bond most reliably, as well as reducing or preventing dental decay during the treatment period.

Objectives

To evaluate the effectiveness of the adhesives used to attach bands to teeth during fixed appliance treatment, in terms of:

(1) how often the bands come off during treatment; and

(2) whether they protect the banded teeth against decay during fixed appliance treatment.

Search methods

The following electronic databases were searched: Cochrane Oral Health's Trials Register (searched 2 June 2016), Cochrane Central Register of Controlled Trials (CENTRAL; 2016, Issue 5) in the Cochrane Library (searched 2 June 2016), MEDLINE Ovid (1946 to 2 June 2016) and EMBASE Ovid (1980 to 2 June 2016). We searched ClinicalTrials.gov and the World Health Organization International Clinical Trials Registry Platform for ongoing trials. No restrictions were placed on the language or date of publication when searching the electronic databases.

Selection criteria

Randomised and controlled clinical trials (RCTs and CCTs) (including split-mouth studies) of adhesives used to attach orthodontic bands to molar teeth were selected. Patients with full arch fixed orthodontic appliance(s) who had bands attached to molars were included.

Data collection and analysis

All review authors were involved in study selection, validity assessment and data extraction without blinding to the authors, adhesives used or results obtained. All disagreements were resolved by discussion.

Main results

Five RCTs and three CCTs were identified as meeting the review's inclusion criteria. All the included trials were of split-mouth design. Four trials compared chemically cured zinc phosphate and chemically cured glass ionomer; three trials compared chemically cured glass ionomer cement with light cured compomer; one trial compared chemically cured glass ionomer with a chemically cured glass phosphonate. Data analysis was often inappropriate within the studies meeting the inclusion criteria.

Authors' conclusions

There is insufficient high quality evidence with regard to the most effective adhesive for attaching orthodontic bands to molar teeth. Further RCTs are required.

PLAIN LANGUAGE SUMMARY

Adhesives for fixed orthodontic bands

There is insufficient evidence to determine the most effective adhesive for attaching orthodontic bands to molar teeth in patients with full arch fixed orthodontic appliances.

Orthodontic treatment involves using fixed or removable appliances (braces) on teeth to correct their position. It has been shown that the quality of treatment result obtained with fixed dental appliances is much better than with removable appliances. The success of a fixed dental appliance depends on the metal attachments (brackets and bands) being securely attached to the teeth so that they do not become loose during treatment. Brackets are usually attached to teeth other than molars, where bands (metal rings that go round the teeth) are more commonly used. There is insufficient evidence with regard to the most effective adhesive for attaching orthodontic bands to molar teeth.

BACKGROUND

Orthodontic treatment involves using fixed or removable appliances (dental braces) to correct the positions of teeth. In England and Wales between April 2001 and March 2002, claims for fixed appliances were made by the General Dental Services at an approximate cost of GBP 57 million to the National Health Service (DPB 2002).

In Finnish municipal health centres, the cost of orthodontic treatment per patient up to the age of 18 was, on average, FIM 7358, ranging from FIM 1299 to FIM 24,751 (Pietila 1998). In the US, orthodontic treatment accounted for 39% of the costs (~ USD 2480 +/- USD 364) of surgical-orthodontic treatment in community hospital care (Panula 2002).

Who receives orthodontic treatment?

The majority of orthodontic treatment is carried out for children aged 10 to 14 years and is primarily concerned with correcting severe crowding and rotations, buried teeth or very prominent teeth. In the UK, epidemiological data reveal that two thirds of 11 to 12 year old children have either a moderate or severe need for orthodontic treatment (Evans 1987; Holmes 1992). There is also a great demand for treatment with an average time on UK hospital waiting lists of 16 months (Russell 1999). Demand and need for orthodontics, however, is increasing among adults who now make up almost 25% of cases in US orthodontic practices (Keim 2002a).

Adhesives for fixed orthodontic appliances

It has been shown that the quality of treatment result obtained with fixed appliances is much better than with removable appliances

(O'Brien 1993; Richmond 1993). Fixed appliances, are therefore, favoured by most orthodontists for treatment.
The success of a fixed appliance depends on the metal attachments (brackets and bands) being attached to the teeth so that they do not become detached during treatment. Brackets are usually attached to teeth other than molars, where bands (metal rings that go round each tooth) are more commonly used (Stirrups 1991). There should be a low rate of failure of brackets and bands. The need to replace bands, during a 2-year course of treatment, slows down the progress of treatment with a fixed appliance. It can also be costly in terms of clinical time, materials and time lost from education/work for the patient. Loose bands also predispose the tooth surface under the band to dental decay.

Ideal properties of adhesive for banding fixed orthodontic appliances

Orthodontic bands are subjected to a large number of forces in the mouth resulting in a complex distribution of stresses within the adhesive and its junctions with the enamel and the band interior (Durning 1994; Millett 1992).
Ideally the adhesive strength should be.
(1) Strong enough to keep the band on the tooth for the length of the treatment.
(2) Not so strong that the tooth surface is damaged when the band is removed.
The adhesive should ideally be.
(1) Easy to use clinically.
(2) Protective against dental caries (decay).
(3) Of reasonable cost.
Zinc phosphate, zinc silicophosphate and zinc polycarboxylate cements were used as principal band cements until the early 1990s (Gottlieb 1996). These cements are chemically-cured (Brown 1989; Øilo 1991). Zinc phosphate cements are usually supplied as a powder (which is principally zinc oxide) and a liquid, comprising an aqueous solution of phosphoric acid. Zinc silicophosphate cements are also supplied as powder and liquid; the powder is a mixture of zinc oxide and aluminosilicate glass and the liquid is an aqueous solution of phosphoric acid with buffers. Zinc polycarboxylate cements are supplied as either powder and acidic liquid or as powder which is mixed with water. For the former, the powder is finely ground zinc oxide which on occasion contains small quantities of other oxides, such as magnesium oxide. The liquid is an aqueous solution of about 40% polyacrylic acid. For the powder/water materials, the powder is zinc oxide and freeze-dried polyacrylic acid. The setting reaction of zinc polycarboxylate cements is by an acid-base reaction.
Some of these cements are still used by a small proportion of orthodontists for band cementation although most orthodontists now use a glass ionomer or glass ionomer based cement for this purpose (Keim 2002b). These newer cements may be classified as follows (McCabe 1998).
(1) Glass ionomer cements supplied as a powder with acidic liquid, or powder with water.
(2) Polyacid-modified composite resin (compomer) which are resin-matrix composites, similar to 'white' filling materials, and have some glass ionomer filler particles.
(3) Resin-modified glass ionomer cements which are hybrids of their resin-matrix and glass ionomer parent groups.
Glass ionomer cements set by an acid-base reaction (chemical-curing) similar to that of zinc polycarboxylate cements whereas polyacid-modified composite resin (compomer) sets via free radicle polymerisation of the methacrylate groups, which is often light-activated (light-curing); there is no acid-base reaction. Resin-modified glass ionomers often have a tri-cure mechanism of setting: an acid-base reaction, a light-cured polymerisation reaction and a self cure polymerisation reaction.
With the number of adhesives available to apply bands to teeth, it is important to understand which group bonds most reliably, as well as reducing or preventing dental decay during the treatment period.
Null hypothesis:
There is no difference in the effectiveness of different types of adhesives in terms of how often the bands come off during treatment and whether they protect the banded teeth against decay during fixed orthodontic appliance treatment.
Working hypothesis:
Some types of orthodontic adhesives are better at bonding metal bands to teeth and protecting the teeth against decay during fixed orthodontic appliance treatment.

OBJECTIVES

To evaluate the effectiveness of the adhesives used to attach bands to teeth during fixed appliance treatment, in terms of:

(1) how often the bands come off during treatment; and

(2) whether they protect the banded teeth against decay during fixed appliance treatment.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised and controlled clinical trials, including those that use a split-mouth design, were included in this review.

Types of participants

Any patient with full arch fixed orthodontic appliance(s) who had bands attached to molars were included. Patients with cleft lip or palate were excluded due to the higher prevalence of molar crossbite in this group, which has been shown to significantly affect molar band failure rate and band survival time (Hodges 2001). Patients with other craniofacial syndromes were also excluded.

Types of interventions

Adhesives used to attach orthodontic bands to molar teeth. This excludes adhesives used to cement brackets (metal squares) to teeth which has been the subject of a separate review (Mandall 2003). Studies which compare any of the six types of adhesive, zinc silicophosphate, zinc phosphate, zinc polycarboxylate, conventional glass ionomer, polyacid-modified composite resin (compomer), resin-modified glass ionomer with any other, were included.
Studies were excluded that:
(1) used headgear to molar bands;
(2) used intermaxillary elastic traction to molar bands;
(3) used soldered lingual or palatal arches to molar teeth;
(4) used bands cemented to primary molars or premolars or different molar types on opposite sides of the mouth; and
(5) followed patients for less than 6 months.

Types of outcome measures

Dichotomous data on the success of each adhesive (whether the metal band stays cemented to the tooth or not) were recorded. Where these data were not available, annualised failure rates of adhesives, i.e. the rate at which the metal bands become detached during treatment, were noted.
Dichotomous data on the presence or absence of decay (decalcification) associated with or around the bands were recorded. If data exist on size/area of decalcifications, these were also included.

Search methods for identification of studies

To identify studies for this review, we developed detailed search strategies for each database searched. These were based on the search strategy developed for MEDLINE (Ovid) but revised appropriately for each database. The search strategy used a combination of controlled vocabulary and free text terms and was linked with the Cochrane Highly Sensitive Search Strategy (CHSSS) for identifying randomised trials (RCTs) in MEDLINE: sensitivity maximising version (2008 revision) as referenced in Chapter 6.4.11.1 and detailed in box 6.4.c of the *Cochrane Handbook for Systematic Reviews of Interventions* Version 5.1.0 (updated March 2011) (Higgins 2011). Details of the MEDLINE search are provided in Appendix 3. The Embase subject search was linked to an adapted version of the Cochrane Embase Project filter for identifying RCTs in EMBASE via Ovid (see http://www.cochranelibrary.com/help/central-creation-details.html for information).

Electronic searches

.We searched the following electronic databases:

- Cochrane Oral Health's Trials Register (searched 2 June 2016) (Appendix 1);
- Cochrane Central Register of Controlled Trials (CENTRAL; 2016, Issue 5) in the Cochrane Library (searched 2 June 2016) (Appendix 2);
- MEDLINE Ovid (1946 to 2 June 2016) (Appendix 3);
- EMBASE Ovid (1980 to 2 June 2016) (Appendix 4).

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

Searching other resources

We searched the following trial registries for ongoing studies (see Appendix 5 for information on the search terms used):

- US National Institutes of Health Ongoing Trials Register ClinicalTrials.gov (ClinicalTrials.gov; searched 2 June 2016);
- the World Health Organization International Clinical Trials Registry Platform (apps.who.int/trialsearch; searched 2 June 2016).

All the first authors of trial reports were contacted in an attempt to identify any unpublished studies and clarify information about the published trials (including missing data, method of randomisation, blinding and withdrawals).
Manufacturers were contacted to confirm the cement/adhesive type and were also asked about their knowledge of any unpublished or ongoing clinical trials or both.
Only handsearching done as part of the Cochrane Worldwide Handsearching Programme and uploaded to CENTRAL was included.
We searched the reference lists of included studies and relevant systematic reviews for further studies.

Data collection and analysis

(1) All review authors were involved in study selection, validity assessment and data extraction without blinding to the authors, adhesives used or results obtained.
(2) The selection of papers, decision about eligibility and data extraction were carried out independently by all members of the review team. All disagreements were resolved by discussion.
A statistician was to be consulted with regard to data analysis and where doubt existed about inclusion.
(3) The following data were entered on a customised data collection form.

- Date that the study was conducted.

- Year of publication.
- Treatments including details of type of adhesive used to cement molar bands and type of fixed appliance used.
- Sample size by study group.
- Age of subjects.
- Number of male subjects and female subjects per study group.
- Details of withdrawals by study group.
- Outcome measures.

The primary outcome measures were band adhesive failure rate and decalcification. Data on adverse events (i.e. illness, allergy, bad taste), damage to teeth on band removal, length of treatment, treatment cost and time to replace bands with an adhesive were also recorded.
(4) The quality of eligible trials was assessed according to the following criteria.
- Clarity of inclusion and exclusion criteria.
- Whether a sample size calculation was reported.
- Means used to calculate sample size.
- Method of allocation of randomisation.
- Concealment of randomisation.
- Whether groups were treated identically other than the named intervention.
- Completeness of follow-up.
- Details of how withdrawals were reported.
- Details of management of study dropouts.
- Blinding of clinicians, patients and outcome assessors.

Assessment of the appropriateness of statistical analysis

All eligible studies were assessed for the appropriateness of their analysis. The statistical analysis was considered inappropriate if:
(1) a split-mouth design did not take the clustering of the teeth or 'pairing' into account;
(2) all failures were included without taking into account multiple failures on the same tooth.

Data synthesis

Comparisons were made firstly between any of the six main types of adhesive. If possible, comparisons were to be made within groups and, where appropriate, between chemical and light-cured adhesives as follows:
(1) zinc phosphate cement - variables on powder and liquid (product is not light-cured);
(2) zinc silicophosphate cement - variables on powder and liquid (product is not light-cured);
(3) zinc polycarboxylate - variables on powder and liquid (product is not light-cured);
(4) glass ionomer cement - conventional (variables on glass and acid);
(5) polyacid-modified composite resin (compomer) - variables on composite matrix and glass ionomer particles;
(6) resin-modified glass ionomer cement - variables on type of acid, resin and polymerisation mechanism; and
(7) glass phosphonate - variables of type of glass, phosphonate.
Within group comparisons assessing products of different brand names to see if any adhesive of the same type performs better than another of the same type, were also to be undertaken if data allowed.
The following data synthesis was planned if data allowed.
(1) Heterogeneity was to be assessed by inspection of a graphical display of the estimated treatment effects from the trials along with their 95% confidence intervals and by Cochran's test for homogeneity undertaken before each meta-analysis. Any heterogeneity was to be investigated.
(2) Meta-analyses were to be undertaken only on studies of similar comparisons reporting the same outcome measures. The Cochrane Statistical Methods Group guidelines were to be followed, calculating risk ratios along with 95% confidence intervals and they were to be combined using a random-effects model. The number needed to treat (NNT) was to be calculated to prevent one extra band failing, as appropriate.
(3) Heterogeneity was to be investigated for aspects of study quality and for potential sources of heterogeneity specified a priori as follows: excluding/including unpublished studies, excluding/including studies of low quality and excluding/including one or more large studies to assess how much they dominate the results. Identification of studies of low quality was undertaken using the criteria given in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2006). The association of these factors with estimated effects was to be examined by performing random-effects metaregression analysis in Stata version 7.0 (Stata Corporation, USA), using the program Metareg. Further potential sources of heterogeneity were to be investigated as determined from the study reports, although these would have been clearly identified as 'post-hoc' analyses and the results treated with caution.

RESULTS

Description of studies

Five randomised controlled trials (RCTs) (Clark 2003; Gillgrass 2001; Kvam 1983; Stirrups 1991; Williams 2005) and three controlled clinical trials (CCTs) (Durning 1989; Fricker 1997; Galarraga 2003) were identified as meeting the review's inclusion criteria with regard to study design, participants, intervention and outcome. A description of each trial is presented in the Characteristics of included studies table.

Study design

All the included trials were of split-mouth design. In four of the trials diagonally opposing first molars were randomly allocated to a single adhesive (i.e. upper right/lower left receive adhesive A, and upper left/lower right received adhesive B) (Clark 2003; Gillgrass 2001; Stirrups 1991; Williams 2005). In one trial only upper first molars were included and the adhesives randomly allocated to either the left or right of the mouth (Kvam 1983). In a fifth trial, both upper and lower molars were included but the adhesives were allocated "on a rotational basis" to either the left or right of the mouth (Fricker 1997). Galarraga and Croce (Galarraga 2003) allocated one adhesive to the right side of the mouth and the other adhesive to the left hand-side. Durning 1989 alternated between left and right when allocating the adhesives.

Participants

All participants required fixed appliance therapy. The gender mix was only stated in four trials (Clark 2003; Durning 1989; Galarraga 2003; Gillgrass 2001) and only three trials reported participants age (mean pretreatment age for males was 19.1 years (standard deviation (SD) 3.7 years) and 17.8 years (SD 3.0 years) for females (Gillgrass 2001); 13 to 19 years (Galarraga 2003); mean age 15.23 years (SD 3.41 years) (Durning 1989)).

Interventions

Adhesive type:

- Zinc phosphate cement

Four trials compared chemically cured zinc phosphate and chemically cured glass ionomer (Durning 1989; Galarraga 2003; Kvam 1983; Stirrups 1991).

- Glass ionomer cement

Four trials compared chemically cured glass ionomer and chemically cured zinc phosphate (Durning 1989; Galarraga 2003; Kvam 1983; Stirrups 1991). Two trials compared chemically cured glass ionomer cement with light-cured compomer (Fricker 1997; Gillgrass 2001). The trial by Fricker and colleagues had a third comparison arm of light-cured resin-modified glass ionomer (Fricker 1997). One trial compared chemically cured glass ionomer with a chemically cured glass phosphonate (Clark 2003).

- Polyacid-modified composite resin (compomer)

Two trials compared light-cured compomer with chemically cured glass ionomer (Fricker 1997; Gillgrass 2001). The trial by Fricker and colleagues had a third comparison arm of light-cured resin-modified glass ionomer (Fricker 1997). A third trial compared light-cured compomer with chemically cured resin-modified glass poly(alkenoate) cement (Williams 2005).

- Resin-modified glass ionomer cement

Only one trial included a light-cured, resin-modified glass ionomer and compared it with a light-cured compomer and a chemically cured glass ionomer (Fricker 1997). A second trial compared a chemically cured resin-modified glass poly(alkenoate) cement with a light-cured polyacid-modified composite resin (compomer) (Williams 2005).

No trial was identified that examined the effectiveness of zinc silicophosphate cement or zinc polycarboxylate.

Outcomes

All trials reported failure, typically defined as band loosening. Only two trials stated the date used for assessment of failure, with one trial recording the date the patient returned for band recementation (Gillgrass 2001) and another recording the date the patient became aware of band loosening (Stirrups 1991).

Only two trials clearly reported follow up of patients until the end of the treatment period (Galarraga 2003; Gillgrass 2001). In one study the observation period was unclear (Stirrups 1991).

Risk of bias in included studies

Additional Table 1 presents the results of the validity assessment. The generation of the random number sequence was considered adequate in only three trials (Clark 2003; Stirrups 1991; Williams 2005). All three trials used a random numbers table. The generation of the sequence was unclear in three trials (Galarraga 2003; Gillgrass 2001; Kvam 1983) and in the other trials adhesives were allocated using a quasi-random method (Durning 1989; Fricker 1997).

Only one of the trials reported adequate allocation concealment (Williams 2005) and in none of the trials was it clear whether outcome assessment was truly blind. Only one of the trials reported an a priori sample size calculation (Williams 2005).

In four trials there were no dropouts (Clark 2003; Durning 1989; Kvam 1983; Williams 2005). In two trials the number of drop outs was clearly described although the reasons were not reported (Galarraga 2003; Gillgrass 2001). In two trials, the number of dropouts was unclear (Fricker 1997; Stirrups 1991).

Effects of interventions

A total of 24 trials were deemed to be potentially relevant to the review and full articles of these trials were retrieved. Following subsequent assessment of the papers only eight were found to meet the inclusion criteria (Clark 2003; Durning 1989; Fricker 1997; Galarraga 2003; Gillgrass 2001; Kvam 1983; Stirrups 1991; Williams 2005); 16 were excluded for reasons listed under Characteristics of excluded studies. For five trials, the study design was unclear and the authors have been contacted (Dincer 2002; Fricker 1985; Fricker 1987; Maijer 1988; Seeholzer 1988). These studies will be excluded until further clarification is received.

Data analysis was not always appropriate within the studies meeting the inclusion criteria.

Chemically cured zinc phosphate and chemically cured glass ionomer

Four trials compared chemically cured zinc phosphate and chemically cured glass ionomer (Durning 1989; Galarraga 2003; Kvam 1983; Stirrups 1991). However, Stirrups 1991 presented failure of bands by site (upper/lower, right/left molars) but information as to the number of patients experiencing a failed band is not presented. Galarraga and Croce (Galarraga 2003) recruited 40 participants. A total of 160 bands were placed. The data regarding the number of lost, loose or broken bands are not presented at a patient level. However, data regarding demineralisation show that a total of eight participants experienced demineralisation (one with glass ionomer only, four with zinc phosphate only and three with both adhesives).

Kvam 1983 recruited 28 participants. In each patient one molar band was cemented with a chemically cured zinc phosphate and one cemented with glass ionomer cement. No band loosenings were identified for either cement type at 1 year. When teeth were examined for decalcification, four teeth were affected with small spots that were reversed by polishing and fluoride application. All cases occurred with the zinc phosphate cement.

Durning 1989 recruited 69 participants. Two bands were placed in each participant; one band was cemented using a chemically cured zinc phosphate and one cemented with glass ionomer cement. Allocation was determined by alternation. The author reports that at approximately 12 months the failure rate was 34.78% for bands cemented with zinc phosphate and 26% for bands cemented with glass ionomer ($P > 0.05$). No statistically significant difference was seen with regard to mean survival time between the cemented band groups (470.9 days versus 523.6 days for zinc phosphate and glass ionomer respectively).

Chemically cured glass ionomer cement with light-cured compomer

Three trials compared chemically cured glass ionomer cement with light-cured compomer (Fricker 1997; Gillgrass 2001; Williams 2005). The data from Fricker 1997 are not presented in an appropriate format. Although failure rates are presented, neither the number of bands per person or the number of failures per person are presented. Gillgrass 2001 compared chemically cured glass ionomer cement with light-cured compomer in a split-mouth study (98 participants; 140 band pairs). Four participants had a single band fail when attached using chemically cured glass ionomer cement (Ketac-Cem) compared to seven band failures (in seven participants) for those attached with the light-cured compomer (Band-Lok). The authors of the trial report that a comparison of changes in mean enamel white spot lesion scores during treatment showed no statistically significant difference between the two cement types ($P = 0.16$).

A third trial compared chemically cured glass ionomer cement with light-cured polyacid-modified composite resin (Williams 2005). The study was split-mouth in design, with 30 participants receiving a total of 120 bands (60 with each band adhesive). Data on the number of failures per patient are not presented; however, the number of failures was very low for each band adhesive over the initial 12-month assessment period (two failures with the glass ionomer; one failure with the composite resin). A statistically significant difference, in favour of the glass ionomer, was seen for patient preference with regard to taste.

Chemically cured glass ionomer with a chemically cured glass phosphonate

One trial compared chemically cured glass ionomer with a chemically cured glass phosphonate (Clark 2003). Data are presented for failure rates for each adhesive group, based on the number of bands failing in each group (overall proportion of band failure for each material was 0.048). However, there are no data provided for the number of failures on a patient basis. There was also no statistically significant difference between the taste of the two cements but the authors caution this finding as both cements were used at the same sitting with the possibility that the taste of one cement may have affected that of the other.

DISCUSSION

Following application of the exclusion criteria adopted for this review, four of the eight trials identified compared chemically cured zinc phosphate with chemically cured glass ionomer. Fewer studies made comparison of chemically cured glass ionomer with light-cured compomer or chemically cured glass phosphonate. Five studies were excluded because they did not compare two band adhesives and a further seven studies were removed because the study design was unclear or has not been clarified to date by the authors. It is disappointing that several authors did not present the study plan in greater detail.

Of the included studies, band failure has been reported for each adhesive group (Clark 2003; Fricker 1997; Williams 2005) or per site (Stirrups 1991) but not on a per patient basis. This precluded the undertaking of a meta-analysis.

The method of randomisation was only adequate in three of the included trials. In the four other trials, the risk of bias would be regarded as moderate to high (Additional Table 1). In one trial, allocation concealment was adequate with sealed envelopes being used for cement and quadrant allocation (Williams 2005). Blinding the operator to outcome assessment was unclear in all trials. Regretably, a sample size calculation was only reported in one trial (Williams 2005). Five studies had no dropouts; one dropout occurred in one trial but the number of dropouts was not adequately clarified in two trials.

Furthermore insufficient reporting of band failure rate was made in all studies. Greater care is required to ensure that the statistical analyses are most appropriate for the trial design adopted. Split-mouth trials can be used when the adhesives being assessed do not release an agent that could influence failure or decalcification. However, where a split-mouth design is used, the mean failure rate or mean survival time per band adhesive type per patient should be reported along with standard deviation or 95% confidence intervals. Where individual patients are allocated to one or other band adhesive type, then the outcome data with respect to adhesive failure /survival should be reported in the same manner.

Only two trials report outcome assessment at the completion of the treatment period (Galarraga 2003; Gillgrass 2001). A previously published systematic review examining the effectiveness of adhesives for fixed orthodontic brackets excluded all trials that did not follow patients until the end of the appliance treatment period (Mandall 2003). Whilst the current review has been less restrictive in its inclusion criteria, future trials should report outcomes following the completion of treatment to enable a more objective assessment of the effectiveness of one band adhesive over another.

Qualitative comparison of orthodontic band adhesives

Due to the inherent bias in most of the study designs, the information from those included in this review should be interpreted with great caution. From the limited information available, only suggestions in the broadest sense are possible.

Chemically cured zinc phosphate versus chemically cured glass ionomer

There is insufficient evidence to support or refute the use of one adhesive (chemically cured zinc phosphate or glass ionomer) over the other with regard to band failure (Durning 1989; Galarraga 2003; Kvam 1983; Stirrups 1991). Trials did not present data at the patient level (Galarraga 2003; Stirrups 1991); identified no band loosening at 12 months (Kvam 1983); or showed no statistically significant difference between groups (Durning 1989).
There is weak evidence from two trials (Galarraga 2003; Kvam 1983) that there is less decalcification on teeth where bands had been cemented with glass ionomer rather than zinc phosphate (no statistical analysis was undertaken in either trial).

Chemically cured glass ionomer cement versus light-cured compomer (poly-acid modified composite)

Again, there is insufficient evidence to support or refute the use of one adhesive (chemically cured glass ionomer or light-cured componer) over the other with regard to band failure (Fricker 1997; Gillgrass 2001; Williams 2005). One trial presented data in an inappropriate format (Fricker 1997); two trials showed low band failure rates for both adhesives (Gillgrass 2001; Williams 2005), although one of the trials did not present the number of failures per person (Williams 2005).
There is weak evidence from one trial that there is no statistically significant difference in enamel decalcification with either cement (Gillgrass 2001).

Chemically cured glass ionomer with a chemically cured glass phosphonate

One trial compared chemically cured glass ionomer with a chemically cured glass phosphonate. Low band failure rates were recorded; however, there is insufficient evidence to support or refute the use of one adhesive over the other (Clark 2003).

Reporting quality

Concealment allocation was particularly poor in the trials included, with only one trial reporting this. There were overall high rates of patient follow-up which suggest that it is possible to minimize sample attrition bias in trials of orthodontic band adhesives. However, in two trials the number of dropouts was unclear. Blinding to the study outcome measure(s) was also very poorly reported. Provided the band adhesives being compared had the same curing mechanism and mixing requirements, then blinding of patient and operator to the adhesive type would be possible. Where different curing mechanisms exist between the two adhesives being compared, blinding of the patient only could be done if the explanations were carried out carefully.

AUTHORS' CONCLUSIONS

Implications for practice

There is insufficient evidence to make firm recommendations for the use of one band adhesive over another.

Implications for research

In view of the poor quality of the trials identified for this systematic review, conclusions cannot be drawn. However, in designing future trials, the following should be considered.

- Clear inclusion/exclusion criteria should be set.
- Involvement of a statistician in study design (single blind or double blind if feasible), sample size calculation and projected data analyses.
- Allocate a single adhesive per patient, rather than a split-mouth study with two adhesives per patient, if either adhesive releases an agent that could influence failure or decalcification.

- Treatment, except for the intervention, should be similar for each trial subject.

- Occlusal interferences that may affect band failure should be recorded.

- Patients should be followed to the end of treatment.

- All dropouts and withdrawals should be recorded and included in any analysis.

- The failure rate of each adhesive and the change in decalcification score with treatment should be presented on a per patient basis.

- Assessors should be calibrated with regard to assessment of decalcification.

- Include standard deviation (or 95% confidence interval (CI)) with mean number of failures or mean survival time for each adhesive system.

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

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

Clark 2003

Methods	RCT, split-mouth design. 6-month observation period.	
Participants	31 consecutive participants undergoing 2-arch fixed appliance therapy, 124 bands to first molars. M/F 14/17. Age not stated.	
Interventions	Gp 1. Glass phosphonate cement, Diamond, KemDent Associated Dental Products Ltd. Chemical curing (62 bands). Gp 2. Glass polyalkenoate cement, Ketac-Cem, ESPE America Inc. Chemical curing (62 bands)	
Outcomes	Band failure (not defined) and taste.	
Notes	Overall treatment time not stated. Data on number of failures per patient not known.	
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Durning 1989

Methods	CCT, split-mouth design. 12-month observation period.
Participants	69 participants, 138 bands for Bioprogressive Edgewise fixed appliance. M/F 27/42. Mean age 15.23 (SD 3.41) years.
Interventions	Gp 1. Zinc phosphate, Orthocent, Espe Gmbh. Chemical curing (69 bands). Gp2. Glass ionomer, Ketac-Cem, Espe Gmbh. Chemical curing (62 bands)
Outcomes	Band failure defined as band loosening.
Notes	
Risk of bias	

Durning 1989 (*Continued*)

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	D - Not used

Fricker 1997

Methods	CCT, split-mouth design. 1 year observation period.
Participants	50 consecutive participants, 188 bands to first molars. M/F not stated. Age not stated.
Interventions	Gp 1. Resin-modified glass ionomer, Fuji II LC, GC Int. Light activated dual cure (69 bands). Gp 2. Resin with added glass, Bandlok, Reliance Orthodontic Products. Light activated dual cure (62 bands). Gp 3. Glass ionomer cement, Ketac-Cem, ESPE America Inc. Chemical curing (57 bands). 2 of the 3 cements were selected for each patient by the chairside assistant on a rotational basis
Outcomes	Failure defined as loose molar band. Weld failures requiring recementation and/or transfer of patient to another practice were removed from the sample
Notes	Data on number of bands per patient or number of failures per patient not known

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	High risk	C - Inadequate

Galarraga 2003

Methods	RCT, split-mouth design. Mean treatment period of 26.1 months
Participants	40 participants, 80 pairs of bands to first permanent molars. M/F 14/24 (data not available for 1 participant). Age 13 to 19 years.
Interventions	Gp 1. Zinc phosphate. Assumed chemical curing (80 bands). Gp 2. Glass ionomer. Assumed chemical curing (80 bands).
Outcomes	Failure defined as lost, loose or broken.

Galarraga 2003 (*Continued*)

Notes	Data taken from translation (Country of origin: Venezuela).	
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Gillgrass 2001

Methods	RCT, split-mouth design. Observed for duration of treatment (mean 20.3 months) time.	
Participants	98 participants, 140 band pairs cemented to first permanent molars. M/F 32/66. Mean pretreatment ages (M/F) 19.1 years (SD 3.7) / 17.8 years (SD 3.0)	
Interventions	Gp 1. Modified composite, Band-Lok. Light cured (140 bands). Gp 2. Conventional glass ionomer, Ketac-Cem Chemically cured (140 bands). In all participants, preadjusted edgewise appliances were used	
Outcomes	Band failure defined as band loosening. Failure date recorded as the day the patient returned for recementation	
Notes		
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Kvam 1983

Methods	RCT, split-mouth design. 1 year observation period.
Participants	28 participants, 56 bands to first upper molars. 2% neutral NaF applied prior to cementation. M/F not stated. Age not stated ("Young patients").
Interventions	Gp 1. Fine grain phosphate cement. Manufacturer not stated. Assumed chemical curing (28 bands). Gp 2. Glass ionomer. Manufacturer not stated. Assumed chemical curing (28 bands)

Kvam 1983 (*Continued*)

Outcomes	Gingival, plaque, enamel and cement indices. Definition of band failure unclear. Visual examination for demineralisation (enamel index graded 0 to 3)
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Stirrups 1991

Methods	RCT, split-mouth design. Observation period/treatment time not stated.
Participants	142 consecutive participants, 568 bands cemented to first molars. M/F not stated. Age not stated.
Interventions	Gp 1. Experimental glass ionomer, Dentsply Ltd. Curing mechanism unclear (284 bands). Gp 2. Zinc phosphate, OrthoGold, Orhtomax Ltd. Chemical cured (284 bands)
Outcomes	Failure defined as loose band. Failure date recorded as day patient became aware of loosening (where possible)
Notes	No information as to the number of patients experiencing a failed band

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Williams 2005

Methods	RCT, split-mouth design. 1 year observation period.
Participants	30 participants, 120 bands to first permanent molars. M/F not stated. Age not stated.
Interventions	Gp 1. Polyacid-modified composite resins (compomers). Light cured (60 bands). Gp 2. Resin-modified glass poly(alkenoate) cement. Chemically cured (60 bands)

Williams 2005 (*Continued*)

Outcomes	Band failure (not defined) and taste.	
Notes	Data on number of failures per patient not known, although failure rates very low	
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Allocation concealment (selection bias)	Low risk	A - Adequate

CCT = controlled clinical trial; RCT = randomised controlled trial; SD = standard deviation; M/F = male/female.

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

Study	Reason for exclusion
Adriaens 1990	Not comparison of two adhesives.
Akkaya	Outcome enamel fluoride concentrations.
Dincer 2002	Study design unclear. Authors contacted for clarification.
Fricker 1985	Awaiting clarification of study design from authors.
Fricker 1987	Awaiting clarification of study design from authors.
Fricker 1989	Not comparison of two adhesives.
Glasspoole 2001	In vitro.
Gorelick 1982	Not an RCT.
Maijer 1988	Study design unclear. Authors contacted for clarification.
Mizrahi 1979	Not an RCT.
Mizrahi 1979a	Not comparison of two adhesives.
Neumann 1976	Not comparison of two adhesives.
Norris 1986	In vitro.
Rezk-Lega 1991	Premolars not molars.

(*Continued*)

Seeholzer 1988	Study design unclear. Authors contacted for clarification.
van der Linden 1998	Not comparison of two adhesives.

RCT = randomised controlled trial.

DATA AND ANALYSES

This review has no analyses.

ADDITIONAL TABLES

Table 1. Validity assessment of included trials

Trial	Concealed allocation	Sequence generation	Blind outcome	Withdrawals	Risk of bias
Clark 2003	Unclear	Adequate	Unclear	No dropouts	Medium
Durning 1989	Not used	Inadequate	No	No dropouts	High
Fricker 1997	Inadequate	Inadequate	Unclear	No dropouts	High
Galarraga 2003	Unclear	Unclear	Unclear	One dropout - no intention-to-treat analysis	High
Gillgrass 2001	Unclear	Unclear	Unclear	Clear description but no intention-to-treat analysis	High
Kvam 1983	Unclear	Unclear	Unclear	No dropouts	High
Stirrups 1991	Unclear	Adequate	Unclear	Unclear	Medium
Williams 2005	Adequate	Adequate	Unclear	No dropouts	Low

WHAT'S NEW

Last assessed as up-to-date: 2 June 2016.

Date	Event	Description
1 November 2016	Review declared as stable	This review will not be updated until a substantial body of evidence on the topic becomes available. If trials are conducted and found eligible for inclusion in the future, the review would then be updated accordingly

HISTORY

Protocol first published: Issue 4, 2003

Review first published: Issue 3, 2006

Date	Event	Description
21 September 2016	New search has been performed	An update search of all databases was conducted 2nd June 2016. No additional studies were identified
21 September 2016	New citation required but conclusions have not changed	New search, no new studies identified. Only search methods sections updated. Minor edits
13 August 2008	Amended	Converted to new review format.
21 February 2007	New search has been performed	An update search of all databases was conducted 29th January 2007. No additional studies were identified

CONTRIBUTIONS OF AUTHORS

Declan Millett (DTM), Anne-Marie Glenny (AMG) and Nicola Mandall (NAM) wrote the protocol with input from Rye Mattick (CRM) and Joy Hickman (JH). The review was written by DTM and AMG with input from NAM. DTM and AMG co-ordinated the review. AMG wrote letters to the authors. DTM, AMG, CRM, JH and NAM independently assessed the eligibility of the trials, extracted data and assessed the quality of the trials.

DECLARATIONS OF INTEREST

None known.

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NOTES

This review will not be updated until a substantial body of evidence on the topic becomes available. If trials are conducted and found eligible for inclusion in the future, the review would then be updated accordingly.

INDEX TERMS

Medical Subject Headings (MeSH)

*Orthodontic Brackets; Adhesives [*standards]; Clinical Trials as Topic; Dental Bonding; Dental Caries [*prevention & control]; Dental Cements [*standards]; Glass Ionomer Cements [standards]; Molar; Orthodontics [*standards]; Resin Cements [standards]; Zinc Phosphate Cement [standards]

MeSH check words

Humans