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# Fluorides for the prevention of white spots on teeth during fixed brace treatment (Review)

Benson PE, Parkin N, Millett DT, Dyer F, Vine S, Shah A



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[Intervention Review]

## Fluorides for the prevention of white spots on teeth during fixed brace treatment

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### ABSTRACT

#### Background

White spots can appear on teeth during fixed brace treatment because of early decay around the brace attachments. Fluoride is effective at reducing decay in susceptible individuals and is routinely prescribed in various different forms to patients during orthodontic treatment.

#### Objectives

To evaluate the effectiveness of fluoride in preventing white spots during orthodontic treatment and to compare the different modes of delivery of fluoride.

#### Search methods

We searched the Cochrane Oral Health Group's Trials Register (January 2004); CENTRAL (*The Cochrane Library* 2002, Issue 3); MEDLINE (January 1966 to July 2003); EMBASE (January 1980 to July 2003). Authors of trials were contacted for further data.

#### Selection criteria

Trials were selected if they met the following criteria: a randomised or quasi-randomised clinical trial, involving the use of a fluoride-containing product compared with no use or use of a non-fluoride control and enamel demineralisation was assessed during or after orthodontic treatment.

#### Data collection and analysis

Six reviewers independently, in duplicate, extracted data. The primary outcome was the difference in the presence or absence of white spots between experimental and control patients for parallel design studies, and between experimental and control quadrants, for split-mouth design studies. Potential sources of heterogeneity were examined. Sensitivity analyses were undertaken for the items assessed for quality and publication bias.

## Main results

The primary outcome of the review was the presence or absence of white spots by patient at the end of treatment. Secondary outcomes included any quantitative assessment of enamel mineral loss or lesion depth. Other outcomes such as differences in size and severity of white spots, any patient based outcomes, such as perception of white spots could not be included because there were insufficient data.

Fifteen trials, with 723 participants, provided data for this review. None of the studies fulfilled all of the methodological quality assessment criteria.

There is some evidence that a daily sodium fluoride mouthrinse reduces the severity of enamel decay surrounding a fixed brace (weighted mean difference for lesion depth -70.0; 95% CI -118.2 to -21.8) and that use of a glass ionomer cement for bracket bonding reduces the prevalence (Peto OR 0.35; 95% CI 0.15 to 0.84) and severity of white spots (weighted mean difference for mineral loss -645 vol%. $\mu$ m; 95% CI -915 to -375) compared with composite resins.

## Authors' conclusions

There is some evidence that the use of topical fluoride or fluoride-containing bonding materials during orthodontic treatment reduces the occurrence and severity of white spot lesions, however there is little evidence as to which method or combination of methods to deliver the fluoride is the most effective. Based on current best practice in other areas of dentistry, for which there is evidence, we recommend that patients with fixed braces rinse daily with a 0.05% sodium fluoride mouthrinse. More high quality, clinical research is required into the different modes of delivering fluoride to the orthodontic patient.

## PLAIN LANGUAGE SUMMARY

### Fluorides for the prevention of white spots on teeth during fixed brace treatment

There is some evidence that a daily fluoride mouthrinse or a fluoride-containing cement will reduce tooth decay if used during treatment with fixed braces.

Tooth decay, in the form of unsightly white spots, can occur on teeth being straightened with fixed braces if they are not cleaned properly. The review found that a daily sodium fluoride mouthrinse reduces the depth of decay that develops on a tooth during treatment with fixed braces. Also, one fluoride-containing cement reduced the number of white spots and the amount of tooth material lost to decay. More high quality research is needed to be sure which is the best way to get the fluoride to the tooth surface in patients during treatment with braces and whether there are any adverse effects. Based on current best practice in other areas of dentistry for which there is evidence, we recommend that patients with fixed braces rinse daily with a 0.05% sodium fluoride mouthrinse.

## BACKGROUND

White spots can appear on teeth during brace treatment because of early decay developing around the brace attachments. This can be a significant problem, due to the poor appearance of the teeth following straightening. In severe cases holes can develop which require a filling. The white spot appears because enamel is damaged when sugar in the diet is turned into acid and the tooth surface is dissolved. The acid is produced by dental plaque that is not properly cleaned from around the attachment during treatment.

One cross-sectional study (Gorelick 1982) found that 50 per cent of individuals undergoing brace treatment had a non-developmental white spot compared with 25 per cent of controls. Another

study (Ogaard 1989b) found that, even 5 years after treatment, orthodontic patients had a significantly higher incidence of white spots than a control group of patients who had not had orthodontic treatment.

Fluoride is important in the prevention of dental decay (Margolis 1990). Marinho 2003a found a definite reduction in caries in children and adolescents who have regular supervised rinsing with a fluoride mouthwash. It has also been shown that fluoride may reduce the number of white spots developing during brace treatment. Geiger et al (Geiger 1992) found a 30 per cent reduction in the number of patients and a 25 per cent reduction in the incidence of teeth affected by white spots, when orthodontic patients

used a fluoride mouthrinse. Many orthodontists recommend the use of a daily fluoride mouthrinse throughout brace treatment to prevent white spots, but there are no clear guidelines for patients.

There are several methods of delivering fluoride (in addition to fluoridated toothpaste) to teeth in patients during orthodontic treatment. These include:

- (1) Topical fluorides (eg. mouthrinse, gel, varnish, toothpaste).
- (2) Fluoride-releasing materials (eg. glues, elastics).

Several systematic reviews have investigated the effect of delivering fluoride in various modes on dental caries in children and adolescents (Marinho 2003a; Marinho 2003b; Marinho 2003c; Marinho 2003d), however these did not examine the effect on patients wearing fixed orthodontic braces.

## OBJECTIVES

The primary objective of this review was to evaluate the effectiveness of fluoride in preventing the occurrence of white spots on the teeth during orthodontic treatment. The secondary objective was to examine the effectiveness of the different modes of delivery.

### Null hypotheses

- (1) There is no difference in the incidence of white spots between patients undergoing fixed brace treatment who receive fluoride and those that do not.
- (2) There is no difference in the incidence of white spots between patients undergoing fixed brace treatment who receive fluoride in the different ways.

## METHODS

### Criteria for considering studies for this review

#### Types of studies

Randomised or quasi-randomised controlled clinical trials in which fluoride is delivered by any method, to prevent enamel white spot formation during orthodontic treatment.

#### Types of participants

Patients of any age undergoing orthodontic treatment with fixed braces.

### Types of interventions

- Topical fluoride in the form of toothpaste, mouthrinse, gel and varnish at any dose, frequency, duration or method of administration and with any of the following active agents/ ingredients: NaF (sodium fluoride), SMFP (sodium monofluorophosphate), SnF (stannous fluoride), APF (acidulated phosphate fluoride), amine F (amine fluoride).
- Materials containing fluoride that is released during treatment including: fluoride-releasing composite resin bonding materials, glass ionomer cements, compomers and resin-modified glass ionomers for bonding or banding, slow release fluoride devices, fluoride-releasing elastomeric ligatures.
- The control group was either individuals or teeth within the same individual (including the split-mouth technique for application of fluoride via bonding or cementing agents and ligatures) not subjected to the fluoride intervention, either through a placebo, such as a non-fluoride toothpaste and mouthrinse or absence of the intervention. Studies involving a control subjected to an alternative fluoride intervention were also included.

### Types of outcome measures

For parallel group studies the outcome measure was the presence/absence of new white spot lesions by the patient at the end of treatment. If the number of white spots was not recorded at the start of treatment then the outcome was the presence or absence of white spots at the end of treatment. For split-mouth studies a cross tabulation by treatment was calculated showing presence/absence of white spot lesions per quadrant. Secondary outcomes included differences in size and severity of white spots between experimental and control groups and any quantitative assessment of enamel mineral loss, either directly using contact microradiography or indirectly using techniques such as enamel hardness testing. Also included were any patient based outcomes, such as perception of white spots and quality of life data.

### Search methods for identification of studies

For the identification of studies included or considered for this review detailed search strategies were developed for each database searched. These were based on the search strategy developed for MEDLINE via OVID but revised appropriately for each database. The MEDLINE search strategy used a combination of controlled vocabulary and free text terms and was combined with all three levels of the Cochrane Optimal Search Strategy for recognising clinical trials (Appendix 1).

## Searched databases

- Cochrane Oral Health Group's Trials Register (January 2004)
- Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library* 2002, Issue 3)
- MEDLINE (1966 to July 2003)
- EMBASE (1980 to July 2003) .

The bibliographies of identified randomised controlled clinical trials (RCTs) and review articles were checked for studies outside the handsearched journals. Personal references were also searched.

## Language

There were no language restrictions. Translations of foreign language articles were produced by contacts within the Cochrane Oral Health Group.

## Unpublished studies

Personal contacts were used to identify ongoing or unpublished RCTs. Authors of the identified CCTs and RCTs were written to in an attempt to identify unpublished or ongoing studies.

## Handsearching

The following journals were identified as being important for this review:

*American Journal of Orthodontics and Dentofacial Orthopedics*  
*Angle Orthodontics*  
*European Journal of Orthodontics*  
*[British] Journal of Orthodontics*  
*Clinical Orthodontics and Research*  
*Journal of Dental Research*  
*Journal of Dentistry*  
*Caries Research*  
*Journal of Clinical Orthodontics.*

As

these journals are included in the Cochrane Oral Health Group's ongoing handsearching programme ([www.ohg.cochrane.org](http://www.ohg.cochrane.org)), no further handsearching was undertaken.

## Data collection and analysis

### Study selection

Two reviewers independently examined the title, keywords and abstract of reports identified from electronic searching for evidence of three criteria.

- A randomised or quasi-randomised clinical trial.
- Involving the use of a fluoride-containing product compared with no use or use of a non-fluoride control.

- Enamel demineralisation was assessed during or after orthodontic treatment.

For studies appearing to meet the inclusion criteria, or for which there were insufficient data in the title and abstract to make a clear decision, the full report was obtained.

## Data extraction

Data were extracted by two reviewers independently, in duplicate using specially designed data extraction forms. The data extraction forms were piloted on several papers and modified as required before use. Any disagreement was discussed and a third reviewer consulted where necessary. All authors were contacted for clarification of missing information. Data were excluded until further clarification becomes available or if agreement could not be reached. All studies meeting the inclusion criteria then underwent validity assessment and data extraction. Studies rejected at this or subsequent stages were recorded, with the reasons for exclusion, in the table of excluded studies.

For each trial the following data were recorded.

- Year of publication and country of origin.
- Details of the participants including demographic characteristics and criteria for inclusion.
- Details of the type of intervention (method of delivery of fluoride, dose, duration of use).
- Details of the outcomes reported (number, size and severity of white spot lesions) including method of assessment and mean duration of study.

## Quality assessment

The quality assessment of the included trials was undertaken independently and in duplicate by two reviewers, as part of the data extraction process.

Four main quality criteria were examined:

(1) Method of randomisation, recorded as:

(A) Yes - adequate, as described either in the text or after contacting the author.

(B) No - inadequate, as described in the text or after contacting the author.

(C) Unclear - unclear in the text and unable to contact the author.

(D) Not used, as described in the *Cochrane Reviewers' Handbook*.

(2) Allocation concealment, recorded as:

(A) Yes - adequate, as described either in the text or after contacting the author.

(B) No - inadequate, as described in the text or after contacting the author.

(C) Unclear - unclear in the text and unable to contact the author.

(D) Not used, as described in the *Cochrane Reviewers' Handbook*.

(3) Outcomes assessors blinded to intervention, recorded as:

(A) Yes - adequate, as described either in the text or after contacting the author.

(B) No - inadequate, as described in the text or after contacting the author.

(C) Unclear - unclear in the text and unable to contact the author.

(D) Not used, as described in the *Cochrane Reviewers' Handbook*.

(4) Completeness of follow up (was there a clear explanation for withdrawals and drop outs in each treatment group?) assessed as:

(A) Yes - numbers in the methods and results were not the same and drop outs were explained.

(B) No - numbers in the methods and results were not the same and drop outs were not explained.

(C) None - no drop outs or withdrawals, as shown by the same number of participants in the methods and results.

Other methodological criteria examined included.

- Presence or absence of a sample size calculation.
- Comparability of groups at the start.
- Clear inclusion/exclusion criteria.
- Presence/absence of an estimate of measurement error ie.

the validity and reproducibility of the method of assessment.

Agreement between reviewers, concerning methodological quality, was assessed by calculating Kappa values.

### Data synthesis

A weighted treatment effect was calculated and the results expressed as weighted mean differences (WMD) and 95% confidence intervals (CI) for continuous outcomes and Peto odds ratio (OR) and 95% CI for dichotomous outcomes, using random-effects models. Pooling of data and meta-analysis was only carried out if there were sufficient similarities between studies in the types of participants, interventions and outcomes, including the time of the outcome measurement. Data from intraindividual (split-mouth) and parallel group studies were combined in the review for the continuous or dichotomous outcome variables using the generic inverse variance procedure in RevMan. Other analyses were also conducted in RevMan. Stata 8.0 was used to calculate odds ratios for split-mouth studies using exact procedures and these are shown in an additional table as they are sometimes slightly different to those shown in the RevMan graphs, these values are given in the rest of the results section. Variance imputation methods were used to estimate appropriate variance estimates in split-mouth studies, where the appropriate standard deviation of the differences were not included in study reports (Follmann 1992). The significance of discrepancies in the estimates of the treatment effects from the different trials were assessed by means of Cochran's test for heterogeneity and any heterogeneity investigated. Publication bias was examined using both the Begg and Mazumdar rank correlation test and the Eggar regression asymmetry test.

It was planned to undertake sensitivity analyses to examine the effect of the quality assessment items on the assessment of the overall estimates of effect. In addition, the effect of including unpublished literature on the review's findings was to be examined.

## RESULTS

### Description of studies

See: [Characteristics of included studies](#); [Characteristics of excluded studies](#).

The search identified 191 publications of which 101 were excluded after reviewing the title or abstract. Full articles were obtained for the remaining 90. From the full articles, 58 publications proved ineligible. Of the remaining 32 publications, two reports were abstracts of trials more fully detailed in other publications and 18 authors were contacted for further information concerning 29 reports. Twelve of these publications were excluded, mainly because the authors were unable to provide further data and three are pending further information from the authors, therefore 14 publications with details of 15 trials, fulfilled all the criteria for inclusion. For details of the studies examined and reasons for inclusion or exclusion please see [Characteristics of included studies](#) and [Characteristics of excluded studies](#).

The studies for inclusion in this review represent examples of the two main methods of delivery of fluoride to the orthodontic patient: topical fluoride, in the form of mouthrinses (three studies) or varnish (one study) and fluoride-releasing materials, including composite (one study), glass ionomer cement (five studies), compomer (two studies) and elastics (one study). No study examined the intervention fluoridated versus non-fluoridated toothpaste.

### Risk of bias in included studies

The assessments for the four main methodological quality items are shown in Additional [Table 1](#). The study was assessed to have a high risk of bias if it did not record a 'Yes' in three or more of the four main categories, moderate if two out of the four categories did not record a 'Yes' and low if randomisation, assessor blinding and completeness of follow up were considered adequate. Three studies ([Chung 1998a](#); [Chung 1998b](#); [Gorton 2003](#)) recorded a 'Yes' in all four major categories.

### Randomisation and allocation concealment

Of the 15 publications, four involved controlled clinical experiments with non-random allocation to test and control materials ([Banks 2000](#); [Hirschfield 1978](#); [Millett 2000](#); [Sonis 1989](#)). Following examination of the publications and further contact with the authors, if necessary, the method of randomisation was considered adequate for seven trials ([Chung 1998a](#); [Chung 1998b](#); [Gillgrass 2001](#); [Gorton 2003](#); [Marcusson 1997](#); [Ogaard 2001](#); [Pascotto 2004](#)), but the method of allocation concealment was adequate in only four of these ([Chung 1998a](#); [Chung 1998b](#); [Gillgrass 2001](#); [Gorton 2003](#)). The method of randomisation and



allocation concealment was inadequate or unclear for the remaining four publications (Czochrowska 1998; Dyer 1982; Ogaard 1986; Twetman 1997).

### Blinding

Blinding for outcome evaluation was reported in six trials (Chung 1998a; Chung 1998b; Gorton 2003; Marcusson 1997; Millett 2000; Pascotto 2004).

### Completeness of follow up

The reporting and analysis of withdrawals and drop outs was considered adequate for ten trials (Banks 2000; Chung 1998a; Chung 1998b; Czochrowska 1998; Gillgrass 2001; Gorton 2003; Marcusson 1997; Pascotto 2004; Sonis 1989; Twetman 1997).

The other minor methodological quality criteria examined are shown in Additional Table 2.

Only one study (Banks 2000) fulfilled all the minor methodological quality criteria.

### Sample size

Only one study (Banks 2000) undertook an a priori calculation for the sample size to detect a 20% difference between two parallel groups.

### Comparability at baseline

Three studies (Banks 2000; Marcusson 1997; Pascotto 2004) carried out a comparison to assess comparability of the experimental and control groups at baseline.

### Inclusion/exclusion criteria

Two studies (Banks 2000; Hirschfield 1978) had clear inclusion and exclusion criteria.

### Estimation of measurement error

Six studies (Banks 2000; Chung 1998a; Chung 1998b; Marcusson 1997; Millett 2000; Twetman 1997) carried out an estimate of measurement error.

The Kappa scores and percentage agreements between the two raters assessing the major methodological quality of the studies were: randomisation 0.56, 82%; concealment 0.62, 91%; blinding 1.00, 100% and withdrawals 0.64, 83%.

## Effects of interventions

### Acid-phosphate-fluoride mouthrinse versus mouthrinse (Comparison 1 Outcome 1.1)

One trial (Hirschfield 1978) compared daily acid-phosphate-fluoride mouthrinse with a no mouthrinse regimen. This was a controlled clinical trial involving 60 patients treated with orthodontic fixed appliances (banded) aged 10 to 14 years. Participants were allocated alternately to either the experimental group (daily acid-phosphate-fluoride mouthrinse) or control (no mouthrinse). The outcome measure was the number of new white spots on the lateral incisors and first permanent molars. There was no statistically significant difference between the experimental and control groups in the proportion of patients with white spot lesions, Peto OR 0.41 (95% CI 0.14 to 1.20).

The authors have some reservations about including this study. We were unable to contact the original author of this paper to clarify the methodology. The risk of bias was judged high, because it failed to fulfil any of the major methodological criteria and only one of the minor methodological criteria (clear inclusion/exclusion criteria). Also, the results described in the text disagree with that in Tables 01 and 02 (the latter were used).

### Sodium fluoride mouthrinse versus no mouthrinse (Comparison 2 Outcomes 2.1 - 2.1.1 & 2.1.2)

One trial (Ogaard 1986) compared two parallel groups of patients, each requiring the extraction of premolars as part of their orthodontic treatment to relieve crowding. Poorly fitting bands were placed on the premolars for 4 weeks, during which the experimental group rinsed daily with a neutral solution of 0.2% sodium fluoride and the control group received no fluoride supplementation. The outcomes were mineral loss and lesion depth measured using contact microradiography on the enamel of the teeth after they had been extracted. The results showed no difference in mineral loss between the experimental and the control groups, but a significantly decreased lesion depth in the experimental group, although the standard deviation of the experimental group was nearly half that of the control group mean difference -70 mm (95% CI -118 to -22).

This study did not address the primary outcome of this review, however the secondary outcomes of mineral loss and lesion depth were investigated. The author was contacted and confirmed that patients were randomly allocated to experimental and control groups, however the method of random generation was still not clear. Neither was it clear what material was used to cement the bands. The study was judged to have a high risk of bias, as it failed to fulfil any of the major or minor methodological criteria. The relevance of the trial is questionable as the experimental method is not applicable to contemporary orthodontic treatment, where

well fitting bands on posterior teeth and bonded brackets for anterior teeth are used.

### **MFP versus stannous fluoride mouthrinses (Comparison 3 Outcome 3.1)**

One clinical trial (Dyer 1982) compared two parallel groups who rinsed daily with either a 0.1% solution of stannous fluoride (experimental) or a 0.184% solution of sodium monofluorophosphate (control). The method of allocation to the groups was not stated in the text and we were unable to contact the author. The number of white spots was recorded before banding and 1 year after banding. Two out of 10 patients in the control group developed new or enlarged white spots, whereas none of the 12 patients in the experimental group. The odds ratio for these results is not significant Peto OR 0.10 (95% CI 0.01 to 1.72). The study was judged to have a high risk of bias as it failed to fulfil any of the major or minor criteria for methodological quality. We were unable to contact the author.

### **Fluoride and antimicrobial varnish versus fluoride varnish (Comparison 4 Outcome 4.1)**

One study (Ogaard 2001) examined the differences between a group of patients treated with a combination of an antimicrobial varnish (Cervitec, 1% chlorhexidine, 1% thymol; Vivadent, Schaan, Liechtenstein) and a fluoride varnish (Fluor Protector, 5% difluorosilane; Vivadent) applied alternately at treatment visits (each varnish every 12 weeks) and a control group that received a placebo varnish (Cervitec without the chlorhexidine and thymol) instead of the antimicrobial varnish and the fluoride varnish (Fluor Protector) alternately at each treatment visit. White spots were scored clinically using a four-point scale. There were no significant differences between the control and experimental group in the proportion of patients with white spots, Peto OR 0.89 (95% CI 0.52 to 1.53). The study was judged to have a high risk of bias because following contact with the author it fulfilled one out of the four major methodological quality criteria (method of randomisation). It however failed to fulfil any of the minor methodological criteria.

### **Fluoridated versus non-fluoridated composite for bonding (Comparison 5 Outcome 5.1)**

See Additional Table 3. One split-mouth study (Sonis 1989) compared a fluoridated composite (FluorEver; Macrochem Corp, Woburn, MA) with a non-fluoridated composite (Aurafill; Johnson & Johnson Dental Care Co, East Windsor, NJ). Allocation of experimental and control materials was not random, with the upper right and lower left designated for the control and the matched contralateral quadrants for the test material. They enrolled 22 patients and the average treatment time was 25 months. It is not clear from the publication how the assessment was carried out.

Photographs were taken after the brackets were removed, but the text suggests that the teeth were scored clinically using a four-point scale. There was no significant difference in the number of white spots between the two materials OR 0.00 (95% CI 0.00 to 1.52). The study was assessed as a high risk of bias, because it fulfilled only one major methodological quality criteria (accounting for withdrawals and drop outs), but no minor criteria.

### **Glass ionomer cement versus composite for bonding (Comparison 6 Outcomes 6.1 & 6.2 - 6.2.1, 6.2.2)**

See Additional Table 3. Six studies compared GIC (experimental, fluoride group) and composite (control, non-fluoride group) for bonding brackets. The first trial (Tvetman 1997) compared a conventional GIC (AquaCem; DeTrey, Dentsply, Konstanz, Germany) with a conventional composite resin (Concise; 3M Dental Products, St Paul, MN). They studied 22 premolars in 20 individuals. They used a split-mouth technique, with random allocation of the test material to either the right or the left. The study period was short as the teeth were extracted after 6 to 8 weeks. The assessment was carried out by visual inspection of the extracted teeth under stereomicroscope by two investigators, using a four-point scale. There was no significant difference between the materials using this experimental technique, however, the number of teeth with white spots was high (15 out of 22). This is probably because of the method of assessment (you are more likely to see a white spot under a microscope). The odds ratio was estimated to be 0.00 (95% CI 0.00 to 5.33). The study was judged to be a high risk of bias. It fulfilled one major methodological quality criteria (reporting and analysis of withdrawals and drop outs) and one minor criteria (an estimation of measurement error was carried out).

The second trial (Marcusson 1997) compared a conventional GIC (AquaCem; DeTrey, Dentsply, Konstanz, Germany) with a no-mix composite resin (Unite; Unitek, Monrovia, CA). They used a split mouth design on 60 patients with the two test materials being selected randomly for each jaw. White spots were assessed from pre and post-treatment photographs by three judges using a four-point scale. Disagreements were resolved by consensus and an error analysis was carried out. The results show that the GIC quadrants had a significantly reduced number of white spots during orthodontic treatment (mean length of treatment 22 months) compared with the composite quadrants OR 0.35 (95% CI 0.13 to 0.86). The study was assessed as a low risk of bias. Although following contact with the author, the method of allocation concealment was not clear, there was no a priori sample size calculation or clear exclusion criteria, the study was well-designed and considered unlikely to have significant bias.

The third trial (Chung 1998a) compared a resin-modified GIC (Vitremere; 3M Dental Products, St Paul, MN) with a no-mix composite resin (Right-on; T.P. Orthodontics, La Porte, IN). This was a split mouth study with the upper right and lower left premolars bonded with the test material. The patients used a non-

fluoride toothpaste so that the true effect of the fluoride in the material could be studied. White spot assessment was carried out from the before and after treatment photographs by one calibrated and blinded examiner using a three-point scale. The test period was again short as the premolar teeth were extracted after 4 weeks. There was no significant difference in the number of white spots between the two materials OR 0.00 (95% CI 0.00 to 1.52). The study was rated as having a moderate risk of bias, because it fulfilled two major criteria and only one minor criteria for methodological quality.

The fourth trial (Gorton 2003) compared a resin-modified GIC (Fuji Ortho LC; GC America Inc, Chicago, IL) and a light cured composite resin (Transbond XT; 3M Unitek, Monrovia, CA). They compared two parallel groups with random allocation to either the test or experimental material. The sample size was small (21 individuals; 11 test and 10 control) and the study time was short, as premolars due for extraction as part of the treatment, were studied. This was a well conducted study with proper randomisation, allocation concealment and blinding and therefore the risk of bias was rated as low (Additional Table 1). The outcome was the estimation of enamel mineral loss using microhardness testing. The results demonstrated significantly increased mineral loss with the light cured composite, mean difference  $-645 \text{ vol}\%.\mu\text{m}$  (95% CI  $-915$  to  $-375$ ). This study investigated the secondary outcomes of the review and not the primary outcome. It was judged to be a low risk of bias, because it fulfilled all the major methodological criteria. It, however, failed to fulfil any of the minor criteria.

The fifth study (Pascotto 2004) also investigated the resin-modified GIC (Fuji Ortho LC; GC America Inc, Chicago, IL) and compared it with a conventional composite resin (Concise; 3M Dental Products, St Paul, MN). The study was very similar to the previous study (Gorton 2003) involving two parallel groups with random allocation to the test and experimental material. There were also a small number of individuals (14 patients, seven in each group) studied for a short time, as the teeth were extracted and the outcome was an estimation of enamel mineral loss using cross-sectional microhardness testing. Many results are presented representing different depths and distances from the bracket. Arends 1992 state that for microhardness measurements, the outer  $25 \mu\text{m}$  should not be included, therefore the data for mineral loss at a depth of  $30 \mu\text{m}$  were chosen for comparison. There was no difference between the Knoop hardness values for the GIC ( $324.1 \pm 23.9$ ) and the composite resin ( $322.4 \pm 26.1$ ). The study has been assessed as a low risk of bias, because it fulfilled three major methodological criteria and one minor.

The sixth study (Czochrowska 1998) investigated a resin-modified GIC (Vitremere; 3M Dental Products, St Paul, MN) compared with a conventional composite resin (Concise; 3M Dental Products, St Paul, MN). The study used a split-mouth design with random allocation of nine premolar pairs, in seven individuals, to either the experimental or control material. The premolars were extracted after 4 weeks and the teeth subjected to contact micro-

radiography to measure mineral loss and lesion depth of the surrounding enamel. There was a significant difference both between the mineral loss of enamel surrounding the experimental material ( $742.0 \text{ vol}\%.\mu\text{m} \pm 167.6$ ) and the control ( $1696.1 \text{ vol}\%.\mu\text{m} \pm 1211.1$ ) and the lesion depth of enamel surrounding the experimental material ( $18.0 \mu\text{m} \pm 6.0$ ) and the control ( $64.3 \mu\text{m} \pm 52.7$ ). The study was judged to have a high risk of bias, as it fulfilled one major and one minor methodological quality assessment. The author has been contacted and a reply is awaited.

### Compomer versus composite for bonding (Comparison 7 Outcome 7.1)

See Additional Table 3. Two controlled clinical trials, from the same research group, are included in this comparison. The first (Chung 1998b) compared a fluoride-containing compomer (Dyract Ortho; DeTrey, Dentsply, Konstanz, Germany) with a non-fluoride containing, no-mix composite resin (Right-on; T.P., La Porte, Indiana) in 13 individuals. This study used the same design and was reported in the same publication as the GIC trial outlined above (Chung 1998b). The experimental time was short (4 weeks) and there was no statistically significant difference in the number of white spots between the two materials, OR 0.00 (95% CI 0.00 to 2.42). The study was judged to be a moderate risk of bias.

The second trial (Millett 2000) used the same materials as Chung 1998b, however the material was studied over a mean treatment time of 21 months. A split-mouth design was used on 45 patients with compomer resin alternately allocated treatment to either the right or left side of each arch. White spots were assessed from before and after clinical photographs, scored by a single experienced judge on a four-point scale. An estimation of error was carried out. Although the odds ratio suggests that there is a reduction of white spots when using the compomer (Additional Table 1) the confidence interval is wide and crosses the line of no difference, therefore this is not statistically significant OR 0.22 (95% CI 0.02 to 1.07). The study was considered to be a high risk of bias, as it fulfilled one major and one minor criteria for the methodological quality assessment.

### Compomer versus GIC for banding (Comparison 8 Outcome 8.1)

One trial (Gillgrass 2001) compared a fluoride-containing, light cured compomer material (Band-Lok; Reliance Orthodontic Products, Itasca, IL) with a conventional non-fluoride containing, chemical cure GIC (Ketac-Cem; ESPE, GmbH, Seefeld Oberbay, Germany) for banding molars in 98 individuals. This was a split-mouth study, with random allocation of materials to the left or right of the first arch and the opposite quadrant of the opposing arch. The mean time of banding was 20.3 months and in eight individuals the white spot score was not obtained. Assessment of white spots was by visual inspection, before and after treatment,

using a four-point scale. There was no significant difference in the proportion of patients with new white spots between the two materials OR 0.29 (95% CI 0.03 to 1.50). Following contact with one of the authors, the study was judged to be a moderate risk of bias, because it fulfilled three major (there was no assessor blinding), but no minor methodological criteria assessments.

### **Fluoridated versus non-fluoridated elastics (Comparison 9 Outcome 9.1)**

One controlled clinical trial with parallel groups (Banks 2000), alternately allocated to receive either fluoridated or non-fluoridated elastomeric ligatures (elastics to hold the wire in place) throughout treatment. The primary outcome was the number of patients with white spots at the end of treatment. This figure was high for both groups and there was no statistically significant difference in the odds ratio between the fluoridated elastics group (31 patients out of 49) compared with the non-fluoridated elastics group (33 out of 45), Peto OR 0.63 (95% CI 0.27 to 1.50). The study was judged to be a high risk of bias, because although it fulfilled all the minor criteria for methodological quality, it did not fulfil any of the major criteria. The main concerns of the reviewers about this study were the method of allocation (alternate) and the assessment blinding. One individual carried out the final recording and undertook an estimation of error, however the assessor was one of three clinicians who had treated the patients and no method of blinding for allocation was discussed.

### **Investigation of heterogeneity**

No meta-analyses, combining more than one study, were undertaken so this did not apply.

### **Sensitivity analyses**

No meta-analyses, combining more than one study, were undertaken so this did not apply.

### **Publication bias**

No meta-analyses, combining more than one study, were undertaken so this did not apply.

### **Secondary outcomes**

Other outcomes such as interaction of fluoride with plaque control, patients perception of white spots or quality of life data were not recorded for any of the studies.

There is evidence that the use of fluoride toothpaste (Marinho 2003b), fluoride mouthrinse (Marinho 2003a) and fluoride gels (Marinho 2003c) in children and adolescents leads to a reduction in dental caries. As a consequence, it is common clinical practice to prescribe or advise orthodontic patients to use a fluoride mouthrinse daily to prevent decay, particularly in the form of white spots on the outer surface of the teeth, during orthodontic treatment.

This review has found some evidence that a daily sodium fluoride mouthrinse will reduce the severity of decay around braces and that glass ionomer cement used for attaching orthodontic brackets to the teeth reduces the incidence and severity of white spots compared with a composite resin. However, considering the widespread use of fluoride products during orthodontic treatment there is little evidence as to which method or combination of methods to deliver the fluoride is the most effective. It is clear that more research is required into the different modes of delivery. Most of the studies indicated that the fluoride product might have a beneficial effect, but the confidence intervals were wide and there were few statistically significant results. It is important to note that only two studies included in this review (Gorton 2003; Marcusson 1997) met all the explicit criteria used to assess the validity of the study and were rated a low risk of bias. In addition, only one study (Banks 2000) had carried out an a priori sample size calculation. When future studies are planned, much more thought must be given to the design of the study to reduce bias and the number of patients required to show a significant difference, if one exists.

The way the fluoride is delivered is important. A fluoride mouthrinse will only work if it is used regularly by the patient and therefore relies on patient compliance to succeed. However, there is evidence to suggest that compliance with mouthrinsing is poor. One study (Geiger 1992) found that only 42% of patients rinsed with a sodium fluoride mouthrinse at least every other day. They also showed that those who complied least with fluoride rinsing regimens tended to have more white spots. A fluoride cement or elastic will release fluoride without help from the patient and therefore might be more successful. In addition, these materials deliver the fluoride close to the bracket where it is most needed. However, many fluoridated materials release large amounts of fluoride initially, but the level drops rapidly and might not be sufficient to prevent decay over the whole course of orthodontic treatment.

When examining the effectiveness of a fluoride product in preventing dental decay, two aspects should be considered. Firstly, whether the fluoride product reduces the number of white spots appearing during treatment and secondly whether it reduces the severity in terms of the size or area of the tooth surface affected or the amount of mineral lost or depth of the decay. Many studies used an index first described by Gorelick et al (Gorelick 1982). This is an ordinal scale of 0 - no white spot to 3 - frank cavitation. This index addresses the presence or absence of decay and to a certain extent the severity, but not the area of tooth covered by the

## **DISCUSSION**

white spot, which may be of concern to the patient. Banks et al (Banks 2000) developed the Enamel Decalcification Index, which is also an ordinal index, but includes an assessment of the area covered. An assessment of size of the lesion is a useful outcome measure.

Several of the studies only recorded the appearance of the teeth at the end of the experiment. Ideally the appearance of the tooth should be recorded before and after orthodontic treatment so that the change in appearance of the tooth is measured (incidence), not just the appearance at the end (prevalence). The measurement of both incidence and severity will depend upon the method of recording the white spot lesions. There are two main methods of recording white spot lesions: visual inspection and clinical photographs. Both methods have problems. The problem with visual inspection is that the examiner or examiners will require calibration at the start and regular recalibration throughout the experimental period, to ensure consistency of measurement. The length of the experiment might be quite long because, as discussed later, the product should ideally be tested over the entire length of orthodontic treatment. This can take between 18 months and 2 and a half years. A second problem with visual recording is blinding. To reduce bias the examiner should be blind to group allocation at the time of recording, which might complicate the way the experiment is run.

Photographs have the advantage of providing a permanent record of the appearance of the tooth. Assessment of the teeth can be carried out by several people independently or in groups, whereby a consensus can be achieved. The photographs can be placed in a random order and the judges blinded to group allocation. An error analysis can be carried out. In addition, because the assessment can be performed over a short period of time the problem of examiner drift, whereby an assessor might subtly change their assessment over time, will be reduced. The problem with photographs is achieving consistency in lighting, developing and reducing reflections that can mask or mimic white spot lesions. However, with a careful photographic technique the advantages of photographs outweigh the potential disadvantages. There are a number of optical methods of measuring lesions on teeth (Angmar-Mansson 1996). These require specialised equipment, which would add considerably to the cost of a clinical study, but would provide an objective measurement of the amount of decay.

One variable that was not constant between the different studies was the length of time over which the materials were studied. When a quantitative method of measuring the amount of mineral lost from enamel or the depth of a carious lesion is used, such as transverse microradiography or hardness testing, the tooth being examined has to be extracted and cut into sections. Short experimental periods are inevitable, as delaying the extraction of the tooth will also delay the orthodontic treatment. However, a short experimental period might benefit materials that release a large amount of fluoride initially preventing white spots, but then the

fluoride release drops off dramatically to a level that does not prevent decay. Ideally the material should be tested over the entire length of orthodontic treatment.

When a product, such as a bonding material can be applied to single teeth it is tempting to use an experimental design whereby the material being tested is used in two quadrants of the mouth and the control material is used in the other two quadrants. This is called a split-mouth design. The main advantage of the split-mouth design over a conventional parallel group design of study, in which the two materials are tested in two separate groups of individuals, is that the experimental material is tested in the same mouth, under the same conditions as the control material. In theory, any differences in outcome between the two materials is due only to their properties and not to other factors, such as differences in oral hygiene and diet between patients, that can occur in parallel studies or even differences of oral hygiene and diet over time within patients, that can occur in crossover studies. Because the number of confounding variables is decreased, the variability of the outcome measurement should be decreased. This will increase the power of the study and fewer patients will need to be recruited.

The split-mouth technique is very useful when examining outcomes in which the performance of one material will not affect the performance of the other, for example a bond failure study. Unfortunately, when examining the ability of fluoride products to reduce decay, it is highly unlikely that the fluoride released will be confined to only the quadrants in which the experimental material has been placed and there will inevitably be some crossover effect onto the control side. This will reduce the difference in outcome between the materials and reduce the power of the experiment to find a difference. We were not able to test the theory that split-mouth studies are less likely to produce a difference compared with parallel studies, because there were so few suitable studies, but until we understand how fluoride released on one side of the mouth will influence conditions on the other side of the mouth, we would recommend that a parallel design of study is used to examine the true effect of the fluoride material.

## AUTHORS' CONCLUSIONS

### Implications for practice

There is some evidence that regular rinsing with a fluoride mouthwash is effective at reducing the severity of white spots in people undergoing orthodontic treatment, but it is not very strong. Until high quality trials are conducted, we would recommend that best practice is daily rinsing with 0.05% sodium fluoride mouthrinse. This is based on research carried out in non-orthodontic patients, which shows that regular supervised use of a fluoride mouthrinse (Marinho 2003a), in addition to a fluoridated toothpaste (Marinho 2003c), is associated with a reduction

in caries for children and adolescents; the principal age group of orthodontic patients.

There is also some evidence that the use of a glass ionomer cement to attached orthodontic brackets is more effective at preventing enamel demineralisation and post-orthodontic white spot lesions, than a conventional composite resin, but again the evidence is weak.

### Implications for research

More evidence is required to determine the most effective way of delivering fluoride to the orthodontic patient. In particular, methods that do not require patient compliance should be studied. Studies should be carried out comparing one method of fluoride delivery with a non-fluoride placebo to demonstrate the true effect of the fluoride. These studies should be double blind, parallel group studies, with appropriate randomisation, allocation concealment and masking of outcome assessment and based on a satisfactory sample size calculation to ensure adequate power. Once the efficacy of the method is shown, differences between fluoridated products can be studied.

The effectiveness of the product over the full length of orthodontic treatment should be assessed. Short term studies might be biased toward those materials that release a large amount of fluoride in a short period of time.

The use of photographs to record the condition of the tooth before and after treatment should be encouraged. They provide a permanent record, allowing before and after comparisons of incidence and severity of white spots with proper assessment blinding, error analysis and consensus measures. However, to provide a reproducible method of recording white spots a standard photographic technique is required, with thought given to reduction of flash reflection, magnification and drying of the teeth. Optical methods of providing a quantitative measurement of mineral loss should also be encouraged if budget allows.

Studies should assess patient centred outcomes, including the effect of white spots on quality of life, particularly 6 months or a year after treatment.

Other factors, such as the fluoridation of water supplies or increased use of non-fluoride toothpaste and how these affect the incidence and severity of post orthodontic white spot lesions have not been assessed.

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\* Indicates the major publication for the study

## CHARACTERISTICS OF STUDIES

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

#### Banks 2000

Methods	CCT; 2 parallel groups.	
Participants	49 expt; 45 control.	
Interventions	Fluoridated versus non-fluoridated elastomeric ligatures.	
Outcomes	Number and severity of white spots - assessed with Enamel Decalcification Index	
Notes	No assessor blinding. Withdrawals - 1 expt and 5 control pts	
<b><i>Risk of bias</i></b>		
<b>Item</b>	<b>Authors' judgement</b>	<b>Description</b>
Allocation concealment?	Unclear	D - Not used

#### Chung 1998a

Methods	RCT; split-mouth design.	
Participants	13 patients.	
Interventions	Resin-modified GIC (Vitremer) versus conventional composite (Right-on) for bracket bonding	
Outcomes	Number and severity of white spots - assessed with modified Gorelick Index from before and after treatment photographs by one blinded examiner	
Notes	Randomisation prepared by one clinician on guidance from statistician. Allocation by selecting unseen from a container. Assessor blinding carried out. Withdrawals - 0 pts; 1 control tooth	
<b><i>Risk of bias</i></b>		
<b>Item</b>	<b>Authors' judgement</b>	<b>Description</b>
Allocation concealment?	Yes	A - Adequate



**Chung 1998b**

Methods	RCT; split-mouth design.
Participants	13 patients.
Interventions	Compomer (Dyract) versus conventional composite (Right-on) for bracket bonding
Outcomes	Number and severity of white spots - assessed with modified Gorelick Index from before and after treatment photographs by one blinded examiner
Notes	Randomisation prepared by one clinician on guidance from statistician. Allocation by selecting unseen from a container. Assessor blinding carried out. Withdrawals - 0 pts; 1 control tooth

***Risk of bias***

Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

**Czochrowska 1998**

Methods	RCT; split-mouth design.
Participants	7 patients, 9 pairs of teeth.
Interventions	Resin-modified GIC (Vitremmer) versus conventional composite (Concise) for bonding brackets
Outcomes	Mineral loss and lesion depth on extracted premolars assessed with contact microradiography
Notes	Withdrawals - 0 pts, 0 teeth.

***Risk of bias***

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

**Dyer 1982**

Methods	CCT; 2 parallel groups; followed for 1 year.
Participants	12 patients used SnF mouthrinse; 10 used MFP mouthrinse.
Interventions	SnF (0.1%) mouthrinse versus MFP (0.184%) mouthrinse. Both have 242 ppm F
Outcomes	Number of new white spots and severity, assessed by clinical exam

**Dyer 1982** (Continued)

Notes	No assessor blinding; withdrawals not described.	
<b>Risk of bias</b>		
<b>Item</b>	<b>Authors' judgement</b>	<b>Description</b>
Allocation concealment?	Unclear	B - Unclear

**Gillgrass 2001**

Methods	RCT; split-mouth design.	
Participants	98 patients.	
Interventions	Modified composite (Bandlock) versus GIC (Ketac-Cem) for band cementation	
Outcomes	Number and severity of white spots assessed by clinical exam before and after treatment (Gorelick Index)	
Notes	Randomisation prepared by one clinician on guidance from a statistician. Allocation by selecting unseen from a container. No assessor blinding carried out. Withdrawals - 8 pts	
<b>Risk of bias</b>		
<b>Item</b>	<b>Authors' judgement</b>	<b>Description</b>
Allocation concealment?	Yes	A - Adequate

**Gorton 2003**

Methods	RCT; parallel groups.	
Participants	25 patients (4 drop outs).	
Interventions	GIC (Fuji) versus composite (Transbond).	
Outcomes	Mineral loss and lesion depth on extracted premolars assessed with microhardness testing	
Notes	Assessor blinding carried out. Withdrawals - 3 pts and excluded 1	
<b>Risk of bias</b>		
<b>Item</b>	<b>Authors' judgement</b>	<b>Description</b>
Allocation concealment?	Yes	A - Adequate

**Hirschfield 1978**

Methods	CCT; 2 parallel groups; allocated alternately; treatment time 20 to 28 months
Participants	30 expt; 30 control.
Interventions	Daily acid-phosphate fluoride mouthrinse versus nothing.
Outcomes	Number and severity of white spots assessed by clinical exam before and after treatment (modified Gorelick Index). No evidence of blinding
Notes	Reservations; results from tables different from that quoted in results; no blinding for assessment; no error assessment; withdrawals not described

***Risk of bias***

Item	Authors' judgement	Description
Allocation concealment?	Unclear	D - Not used

**Marcusson 1997**

Methods	RCT; split-mouth design.
Participants	60 patients.
Interventions	Conventional GIC (AquaCem) versus conventional composite (Unite)
Outcomes	Number and severity of white spots assessed with modified Gorelick Index from after photographs
Notes	Allocation taken from a list of random numbers on the clinic. One material was allocated odd and the other even numbers. Assessor blinding carried out. Withdrawals - 0 pts; 18 teeth (? 9 pairs)

***Risk of bias***

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

**Millett 2000**

Methods	CCT; alternate allocation; split mouth design.
Participants	45 patients
Interventions	Compomer (Dyract) v Composite (Right-on)
Outcomes	Number and severity of white spots assessed with modified Gorelick index from after treatment photographs

**Millett 2000** (Continued)

Notes	Assessor blinding carried out. Withdrawals - 2 patients, but 123 expt and 123 control teeth	
<b>Risk of bias</b>		
<b>Item</b>	<b>Authors' judgement</b>	<b>Description</b>
Allocation concealment?	Unclear	D - Not used

**Ogaard 1986**

Methods	RCT; parallel groups.	
Participants	10 patients (5 expt with 10 teeth, 5 control with 5 teeth).	
Interventions	Daily 0.2% NaF mouthrinse versus nothing for 4 weeks.	
Outcomes	Mineral loss and lesion depth on extracted premolars with contact microradiography performed	
Notes	Author contacted and stated they were randomly allocated, method not given; no assessor blinding; withdrawals not described	
<b>Risk of bias</b>		
<b>Item</b>	<b>Authors' judgement</b>	<b>Description</b>
Allocation concealment?	Unclear	B - Unclear

**Ogaard 2001**

Methods	RCT; 2 parallel expt groups; historical untreated control.	
Participants	110 patients in each group.	
Interventions	Fluoride varnish and chlorhexidine varnish versus fluoride varnish only every visit	
Outcomes	Visual inspection of white spots.	
Notes	No assessor blinding carried out. Withdrawals - not clear (?no pts)	
<b>Risk of bias</b>		
<b>Item</b>	<b>Authors' judgement</b>	<b>Description</b>
Allocation concealment?	Unclear	B - Unclear

**Pascotto 2004**

Methods	RCT; 2 parallel groups.
Participants	14 patients (23 teeth).
Interventions	Resin modified glass ionomer cement (Fuji Orth LC) versus composite resin (Concise)
Outcomes	Mineral loss and lesion depth on extracted premolars using cross-sectional microhardness
Notes	Withdrawals - 0 pts; 4 expt, 6 control teeth.

***Risk of bias***

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

**Sonis 1989**

Methods	CCT; split-mouth design.
Participants	22 patients.
Interventions	Fluoridated composite (FluorEver) with a non-fluoridated composite (Aurafill)
Outcomes	Number and severity of white spots assessed from clinical exam or photographic assessment after treatment
Notes	No assessor blinding. Withdrawals - no pts or teeth.

***Risk of bias***

Item	Authors' judgement	Description
Allocation concealment?	Unclear	D - Not used

**Twetman 1997**

Methods	RCT; split-mouth design.
Participants	20 patients; 22 pairs of premolars; extracted after 6 to 8 weeks
Interventions	GIC (Aqua-Cem) versus composite (Concise).
Outcomes	White spots on extracted premolars after staining with erythrocin and evaluated under stereomicroscope (6-12x )
Notes	No assessor blinding. Withdrawals - 0 pts; 0 teeth.

**Twetman 1997** (Continued)

<b>Risk of bias</b>		
<b>Item</b>	<b>Authors' judgement</b>	<b>Description</b>
Allocation concealment?	Unclear	B - Unclear

CCT = controlled clinical trial

Expt = experimental

GIC = glass ionomer cement

NaF = sodium fluoride

Pts = patients

RCT = randomised controlled clinical trial

SnF = stannous fluoride

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

<b>Study</b>	<b>Reason for exclusion</b>
Aasrum 1993	An in vitro bond strength study (PB, AS).
Adair 1998	A review article (PB, AS).
Adriaens 1990	Contacted author (LR Dermaut). Unable to provide further data for statistical analysis (PB, AS)
Akkaya 1996	Measured fluoride uptake into enamel not white spots (DM, SV, PB)
Al-Khateeb 1998	An observational, not interventional study (PB, AS).
Alacam 1996	Assessed urinary and salivary fluoride levels not white spots (DM, SV)
Alexander 2000	Clinical assessment carried out 1 month after debond not immediately after (DM, PB)
Alwi 1994	Contacted author. Unable to provide sufficient data for analysis (PB, AS)
Ashcraft 1997	An in vitro study (PB, AS).
Banks 1997	Split-mouth study analysed by individual teeth. Author contacted but original data discarded (PB, AS)
Basdra 1996	An in vitro study (PB, AS).
Bishara 1989	An in vitro bond testing study (PB, AS).
Bishara 1991	An in vitro fluoride release study (PB, AS).

(Continued)

Blanco 1988	Translated from Spanish. An interventional RCT comparing a fluoride rinse and a no fluoride rinse groups. 78 patients in the control group and 15 in the experimental so randomisation not very good. Data poorly presented by tooth type
Boyd 1992	Demineralisation assessed 3 months after debond rather than immediately (PB, AS)
Boyd 1993	Demineralisation assessed 3 months after debond rather than immediately (DM, SV)
Boyd 1994a	A review paper (DM, SV).
Boyd 1994b	Gingivitis and staining assessed not white spots (DM, SV).
Boyd 1994c	Demineralisation assessed 3 months after debond rather than immediately (DM, SV)
Braden 1978	A review (PB, AS).
Brown 1978	Looked at enamel loss not demineralisation (PB, AS).
Bryant 1985	An in vitro bond testing study (PB, AS).
Buyukyilmaz 1993	Author contacted (B Ogaard). Unable to supply further data for analysis of this split-mouth study (PB, AS)
Buyukyilmaz 1994	Author contacted (B Ogaard). Unable to supply further data for analysis of this split-mouth study (PB, AS)
Capilouto 1990	Measured fluoride uptake into enamel not white spots (DM, SV)
Chadwick 1994	A review article (PB, AS).
Chan 1990	An in vitro fluoride release study (PB, AS).
Chang 1999	Demineralisation not measured (PB, AS).
Chung 1996	Abstract; no additional information from main paper (Chung 1998) which is included (PB, AS)
Clark 1977	Insufficient data (PB, AS).
Cooley 1989	An in vitro study (PB, AS).
Coonar 2001	An in vitro study (PB, AS).
Corbett 1980	Not a controlled clinical trial. Used an historical control (PB, AS)
Croll 2000	2 case reports (PB, AS).
Cruz 1992	Experiment carried out on blocks of enamel from wisdom teeth not on bracketed teeth (PB, AS)

(Continued)

de Almeida Cruz 1989	An in vitro study (PB, AS).
Denes 1988	Assessed DMFS not white spot lesions (PB, AS).
Denes 1989	Assessed DMFS not white spot lesions (PB with translation).
Denes 1991	Assessed DMFS not white spot lesions (DM, SV, PB).
Dimitriadis 1974	Methodology was sound, but reproducibility of the scoring was low and insufficient data are available to use in the review (PB, AS)
Doherty 2000	Measures mineral loss in a slab of enamel not around the bracket (DM, SV, PB)
Doherty 2002	Measures mineral loss in a slab of enamel not around the bracket (DM, SV, PB)
Endo 1989	Clear from the abstract this is not a clinical trial (PB, AS)
Erickson 1995	A review article (PB, AS).
Flaitz 1988	An in vitro study (PB, AS).
Foley 2002	An in vitro study (PB, AS).
Fornell 2002	Tested an hydrophobic coating not containing fluoride (PB, AS)
Fowler 1998	A clinical study of bond failure (PB, AS).
Fox 1990	An in vitro fluoride release study (PB, AS).
Fricker 1985	A CCT split-mouth study comparing GIC and Zn phosphate cements allocation method unclear. Results after 12 months. Author contacted for further details, but insufficient to include (PB, AS)
Fricker 1987	A CCT split-mouth study comparing GIC and Zn phosphate cements allocation method unclear. Results after 24 months. Author contacted for further details, but insufficient to include (PB, AS)
Fricker 1989a	Assesses band failure not white spots (PB, AS).
Fricker 1989b	Assesses band failure not white spots (PB, AS).
Fricker 1992	Assesses band failure not white spots (PB, AS).
Fricker 1994	Assesses bond failure not white spots (PB, AS).
Fricker 1996	Describes the clinical technique, no assessment of white spots (PB, AS)
Fricker 1997a	Assesses retention of bands not white spots (PB, AS).



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Fricker 1997b	Describes the clinical use of Fuji (PB, AS).
Fricker 1998	Assesses bracket failure rate not white spots (PB, AS).
Fuzisawa 1987	An in vitro study (PB, AS).
Gaworski 1999	GIC (Fuji) placed on alternate teeth with light cure composite control. One author (AJ Borislow) contacted and supplied further data, but due to nature of allocation (alternate teeth not quadrants), study rejected on statistical advice (PB, HW)
Gedalia 1995	In situ enamel slab study using removable orthodontic appliances with volunteers (PB, AS)
Gedalia 1995 1	An in situ study using removable appliances in volunteers (PB, AS)
Geiger 1988	A fluoride rinsing study, but not a CCT or RCT as they used an historic control (PB, AS)
Geiger 1992	A fluoride rinsing study but not a CCT or RCT as there was no control (PB, AS)
Ghani 1994a	An in vitro study (PB, AS).
Ghani 1994b	An in vitro study (PB, AS).
Glasspoole 2001	An in vitro study (PB, AS).
Glatz 1987	No fluoride product included (PB, AS).
Goracci 2001	An in vitro bond strength study (PB, AS).
Gorelick 1982	Observational not interventional study (DM, SV).
Hallgren 1993	Assesses fluoride concentration in plaque (DM, SV).
Hallgren 1994	Assesses lactic acid production in plaque (DM, SV).
Harazaki 2001	Assesses treatment of white spots. Unclear what was done to the control. Allocation unclear (PB, AS)
Hegarty 2002	Investigated bracket failure rate (PB, AS).
Hein 1977	An epidemiology study (PB, AS).
Hirschfield 1974	Demineralisation induced in all subjects due to in vivo banding technique. Demineralisation severity ranked and analysed, but this ranking cannot be generally applied to other studies (PB, AS)
Kindelan 1996	An in vitro study (PB, AS).
Kleber 1999	Carried out in orthodontic patients with white spots after active orthodontic treatment (PB, AS)

(Continued)

Klockowski 1989	An in vitro bond strength testing study (PB, AS).
Kocadereli 1995	An in vitro bond strength testing study (PB, AS).
Komori 2003	An in vitro, fluoride release study (PB, AS).
Krawczuk-Moleda 1998	An epidemiological study of school children, not orthodontic patients (PB, AS)
Kukleva 1998	A clinical study but not in orthodontic patients (PB, AS).
Kukleva 2000	An in vitro study (PB, AS).
Kunzel 1971	Review article (PB, AS).
Kuramoto 2000	An in vitro study of microleakage (PB, AS).
Linton 1996	An in vitro study (PB, AS).
Mackie 1990	A case report (PB, AS).
Magness 1979	Not a RCT or CCT; used a historical control (PB, AS).
Majjer 1988	Not a CCT or RCT. The first 300 consecutive cases had one material, the next 125 had the other (PB, HW)
Mandall 2002	Systematic review - no data on demineralisation (PB, AS).
Marcushamer 1993	An in vitro study (PB, AS).
Marcusson 1993	Abstract; no additional information from main paper (Chung 1998) which is included (PB, AS)
Marcusson 1995	Abstract; no additional information from main paper (Chung 1998) which is included (PB, AS)
Marini 1999	White spots not the primary outcome (NP); ? historical control (PB); insufficient data (NP, PB, FD)
Massara 2002	Paediatric dentistry patients not orthodontic and chemical analysis not demineralisation (PB, AS)
Mattila 2001	A case control epidemiology study (PB, AS).
McEniery 1979	An epidemiology study (PB, AS).
McNeill 2001	An in vitro study (PB, AS).
Meng 1997	An in vitro study (PB, AS).
Meng 1998	An in vitro study (PB, AS).

(Continued)

Meyers 1952	No fluoride product tested (PB, AS).
Millett 1999	Contacted author. Unable to provide sufficient data for analysis (PB, AS)
Mitchell 1992	Split-mouth study looked at matched teeth not quadrants. Author contacted, but was unable to supply further data (PB, AS)
Miwa 2001	An in vitro bond testing study (PB, AS).
Myers 1973	Primary outcome fluoride uptake into enamel (FD, NP, PB). White spots not assessed.
Neumann 1976	Insufficient data, dated technique (PB, AS).
Newman 2001a	An in vitro bond testing study (PB, AS).
Newman 2001b	An in vitro study (PB, AS).
Norris 1986	An in vitro study (FD, NP).
Nouri 2001	A case report (PB, AS).
Nowak 1990	A review article (PB, AS).
O'Reilly 1987	Insufficient data in the publication; contacted second author who was unable to find original data (PB, AS)
Ogaard 1980	Primary outcome plaque reduction. White spots not assessed (FD, NP)
Ogaard 1983	Examined solubility of enamel not demineralisation (PB, AS).
Ogaard 1988a	Fluoride product not assessed (FD, NP).
Ogaard 1988b	Not a CCT or RCT (PB, HW).
Ogaard 1989a	An observational study (PB, AS).
Ogaard 1989b	An observational study (PB, AS).
Ogaard 1990	Volunteers wearing removable appliances, not patients with fixed appliances (FD, NP, PB)
Ogaard 1991	An in vivo study using slabs of extracted teeth placed in removable appliances worn by volunteers (PB, AS)
Ogaard 1992	Author contacted (B Ogaard). Unable to supply further data for analysis of this split-mouth study (PB, AS)

(Continued)

Ogaard 1996	Author contacted (B Ogaard). Unable to supply further data for analysis of this split-mouth study (PB, AS)
Ogaard 1997a	Primary outcome was fluoride levels in saliva. White spots not assessed (FD, NP)
Ogaard 1997b	Both groups had fluoride varnish. The experimental group had in addition an antimicrobial varnish, therefore the study looks at the efficacy of the antimicrobial varnish rather than the fluoride varnish (PB, AS)
Ortendahl 1997	Primary outcome is levels of S.mutans in plaque. White spots barely covered (FD, NP, PB)
Ovrebo 1990	White spots not assessed during orthodontic treatment (FD, NP)
Pang 1999a	In vitro study (PB, AS).
Pang 1999b	In vitro study of bond strength (PB, AS).
Papagiannoulis 2002	Not evaluating demineralisation around a bracket (PB, AS).
Pavic 1990	An investigation into the microbiology not white spots (PB, AS)
Percinoto 1995	An in vitro study looking at occlusal fissures of extracted premolars not around orthodontic brackets (PB, AS)
Petersson 1995	Measured fluoride levels in enamel (PB, FD). Not clear how they measured lesion depth (PB). ? CCT ? No statistics. Data difficult to interpret (NP).
Phijaisanit 1997	A bond strength study (PB, AS).
Phu 2003	Compared two non-fluoride containing products (PB, AS).
Rezk-Lega 1991	Historical control for non GIC. Author contacted (B Ogaard), but unable to supply further data for the two GICs (PB, AS)
Sadowsky 1982	An in vitro study (FD, NP).
Sadowsky 1983	An in vitro study (FD, NP).
Saloum 1987	Review article (PB, AS).
Salzmann 1976	Insufficient data (PB, AS).
Shannon 1978	Allocation method not stated therefore not able to state whether this was a CCT or RCT; no mention of blinding for assessment; no error assessment. Unable to contact the authors (PB, AS)

(Continued)

Shannon 1979	Allocation method not stated therefore not able to state whether this was a CCT or RCT; no mention of blinding for assessment; no error assessment. Unable to contact the authors (PB, AS)
Shannon 1980	An in vitro study (PB, AS).
Silverman 1995	Observational not a clinical trial. White spots not assessed (PB, AS)
Skold 1994	Children with fixed appliances were excluded (PB, AS).
Smales 2000	An in vitro study (PB, AS).
Souganidis 1981	Examined fluoride uptaking following filling of teeth (PB, AS)
Stephen 1977	A review article (PB, AS).
Stratemann 1974	Unclear whether this was prospective. Control unclear. Evaluated at different points throughout treatment (PB, AS)
Tanaka 2000	An in vitro study (PB, AS).
Tezel 2002	An in vitro study (PB, AS).
Tillery 1976	An in vitro study (PB, AS).
Todd 1999	An in vitro study (PB, AS).
Trask 1975	Technique report, not a clinical trial, concerned with after orthodontic treatment (PB, AS)
Trimpenneers 1996	Contacted author (LR Dermaut). Unable to provide further data for statistical analysis (PB, AS)
Ullsfooss 1994	Both groups had fluoride mouthrinse. The experimental group had in addition an antimicrobial mouthrinse, therefore the study looks at the efficacy of the antimicrobial mouthrinse rather than the fluoride mouthrinse (PB, AS)
Underwood 1989	Data for incidence of white spots on sites, but not for patients. Imbibition data not a modern technique for assessing demineralisation and difficult to interpret for the review. Would have to be quoted for patients not teeth (PB, AS)
Valenzuela 1994	An in vitro study (PB, AS).
van der Linden 1998	Contacted author (LR Dermaut). Unable to provide further data for statistical analysis (PB, AS)
Vorhies 1998	An in vitro study (PB, AS).
Wang 1991	A bond strength study (PB, AS).
Wang 2001	An in vitro study (PB, AS).

(Continued)

Wefel 1990	A review article (PB, AS).
Wenderoth 1999	F-releasing sealant placed on alternate teeth with no barrier (control). Rejected after statistical advice (PB, HW)
Wilson 1995	The microhardness results would be difficult to summarise meaningfully for this review. The results could be compared for each depth tested, but this would produce unwieldy tables. Results for individual patients, rather than individual teeth would need to be produce (PB, AS)
Wilson 2001	An in vitro study (PB, AS).
Wiltshire 1996	An in vitro study (PB, AS).
Wiltshire 1999	Measures fluoride release not white spot lesions (PB, AS).
Wisth 1977	Measured caries rather than white spots in treated and untreated groups. No fluoride product involved (PB, AS)
Wright 1996	Assesses bond failures and plaque scores (PB, AS).
Zachrisson 1975	A survey into the then current uses of fluoride (PB, AS).
Zachrisson 1977	No control; mainly assesses bond failure (PB, AS).

AS = Anwar Shah  
DM = Declan Millett  
FD = Fiona Dyer  
HW = Helen Worthington  
NP = Nicola Parkin  
PB = Philip Benson  
SV = Suzy Vine

## DATA AND ANALYSES

### Comparison 1. Acid-phosphate-fluoride mouthrinse versus no mouthrinse

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Number of patients with new white spots	1		Peto Odds Ratio (Peto, Fixed, 95% CI)	Totals not selected

### Comparison 2. Sodium fluoride mouthrinse versus no mouthrinse

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Measurement of enamel demineralisation	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
1.1 Mineral loss	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
1.2 Lesion depth	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable

### Comparison 3. Stannous fluoride versus MFP mouthrinse

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Number of patients with new white spots	1		Peto Odds Ratio (Peto, Fixed, 95% CI)	Totals not selected

### Comparison 4. Fluoride & antimicrobial varnish versus fluoride varnish

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Number of patients with white spots	1		Peto Odds Ratio (Peto, Fixed, 95% CI)	Totals not selected

### Comparison 5. Fluoridated versus non-fluoridated composite for bonding

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Fluoridated v non-fluoridated composite for bonding	1		odds ratio (Fixed, 95% CI)	Totals not selected

### Comparison 6. GIC versus composite for bonding

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Number of patients with white spots	3		odds ratio (Fixed, 95% CI)	Totals not selected
2 Measurement of enamel demineralisation	3	93	Mean Difference (IV, Fixed, 95% CI)	-9.35 [-24.16, 5.46]
2.1 Mineral loss	3	75	Mean Difference (IV, Fixed, 95% CI)	-1.09 [-17.47, 15.29]
2.2 Lesion depth	1	18	Mean Difference (IV, Fixed, 95% CI)	-46.31 [-80.96, -11.66]

### Comparison 7. Compomer versus composite for bonding

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Number of patients with white spots	2		odds ratio (Fixed, 95% CI)	Totals not selected

### Comparison 8. Compomer versus GIC for banding

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Number of patients with white spots	1		odd ratio (Fixed, 95% CI)	Totals not selected



## Comparison 9. Fluoridated versus non-fluoridated elastics

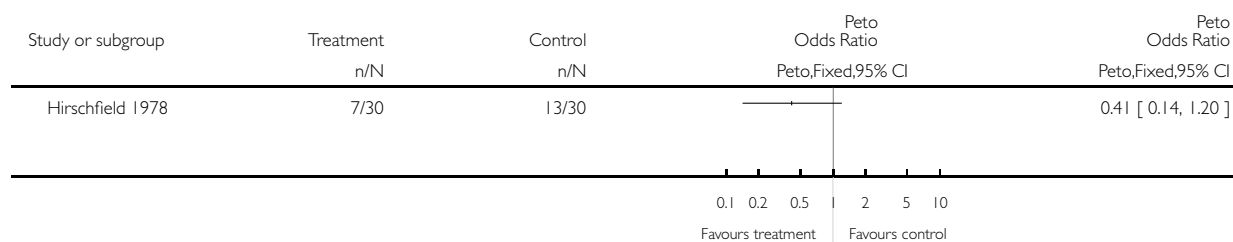
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Number of patients with white spots	1		Peto Odds Ratio (Peto, Fixed, 95% CI)	Totals not selected

### Analysis 1.1. Comparison 1 Acid-phosphate-fluoride mouthrinse versus no mouthrinse, Outcome 1 Number of patients with new white spots.

Review: Fluorides for the prevention of white spots on teeth during fixed brace treatment

Comparison: 1 Acid-phosphate-fluoride mouthrinse versus no mouthrinse

Outcome: 1 Number of patients with new white spots

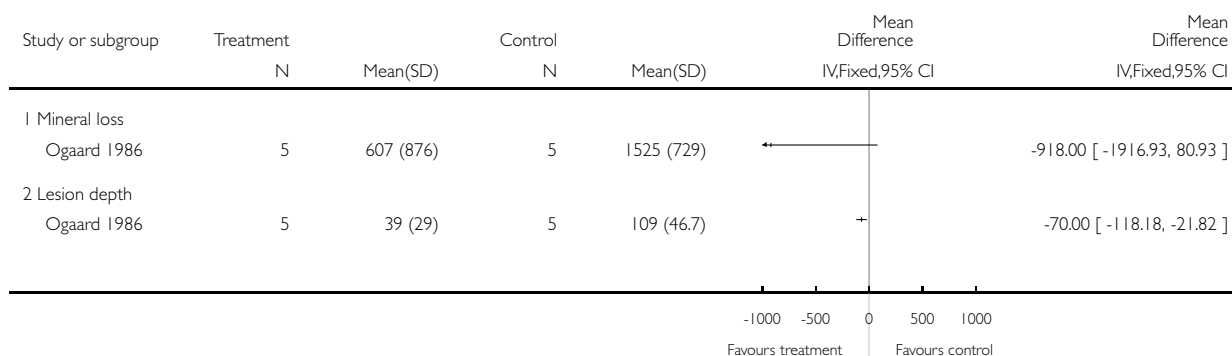


### Analysis 2.1. Comparison 2 Sodium fluoride mouthrinse versus no mouthrinse, Outcome 1 Measurement of enamel demineralisation.

Review: Fluorides for the prevention of white spots on teeth during fixed brace treatment

Comparison: 2 Sodium fluoride mouthrinse versus no mouthrinse

Outcome: 1 Measurement of enamel demineralisation

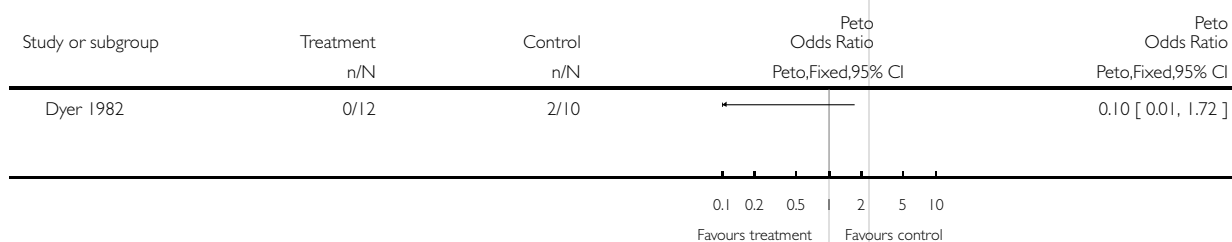


### Analysis 3.1. Comparison 3 Stannous fluoride versus MFP mouthrinse, Outcome 1 Number of patients with new white spots.

Review: Fluorides for the prevention of white spots on teeth during fixed brace treatment

Comparison: 3 Stannous fluoride versus MFP mouthrinse

Outcome: 1 Number of patients with new white spots

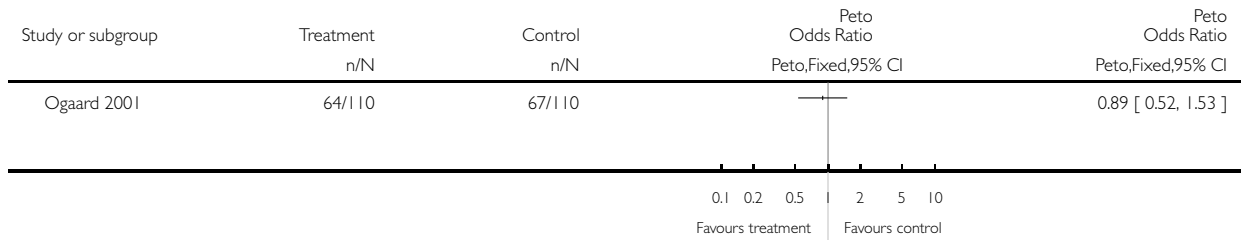


**Analysis 4.1. Comparison 4 Fluoride & antimicrobial varnish versus fluoride varnish, Outcome 1 Number of patients with white spots.**

Review: Fluorides for the prevention of white spots on teeth during fixed brace treatment

Comparison: 4 Fluoride % antimicrobial varnish versus fluoride varnish

Outcome: 1 Number of patients with white spots



**Analysis 5.1. Comparison 5 Fluoridated versus non-fluoridated composite for bonding, Outcome 1 Fluoridated v non-fluoridated composite for bonding.**

Review: Fluorides for the prevention of white spots on teeth during fixed brace treatment

Comparison: 5 Fluoridated versus non-fluoridated composite for bonding

Outcome: 1 Fluoridated v non-fluoridated composite for bonding

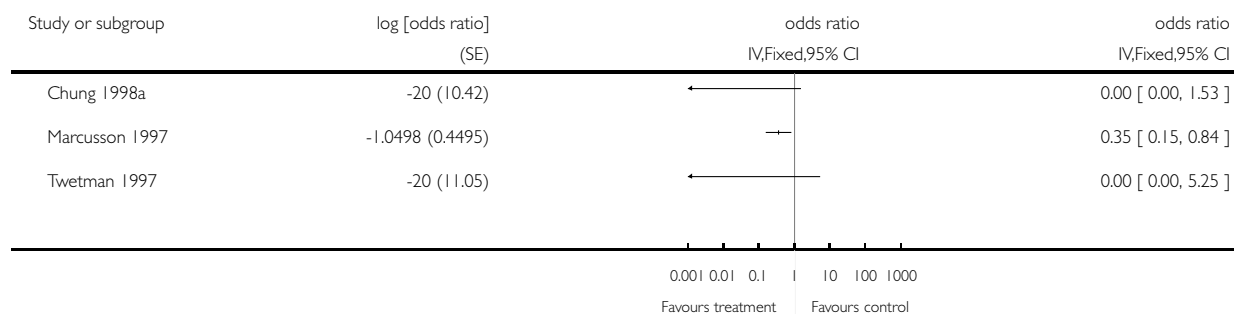


### Analysis 6.1. Comparison 6 GIC versus composite for bonding, Outcome 1 Number of patients with white spots.

Review: Fluorides for the prevention of white spots on teeth during fixed brace treatment

Comparison: 6 GIC versus composite for bonding

Outcome: 1 Number of patients with white spots

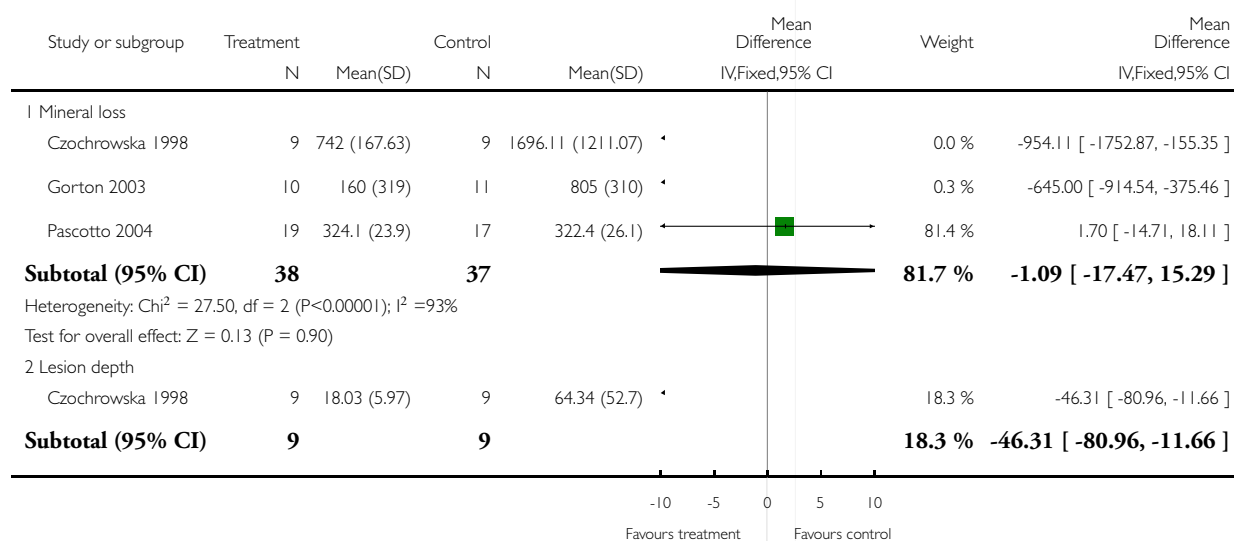


### Analysis 6.2. Comparison 6 GIC versus composite for bonding, Outcome 2 Measurement of enamel demineralisation.

Review: Fluorides for the prevention of white spots on teeth during fixed brace treatment

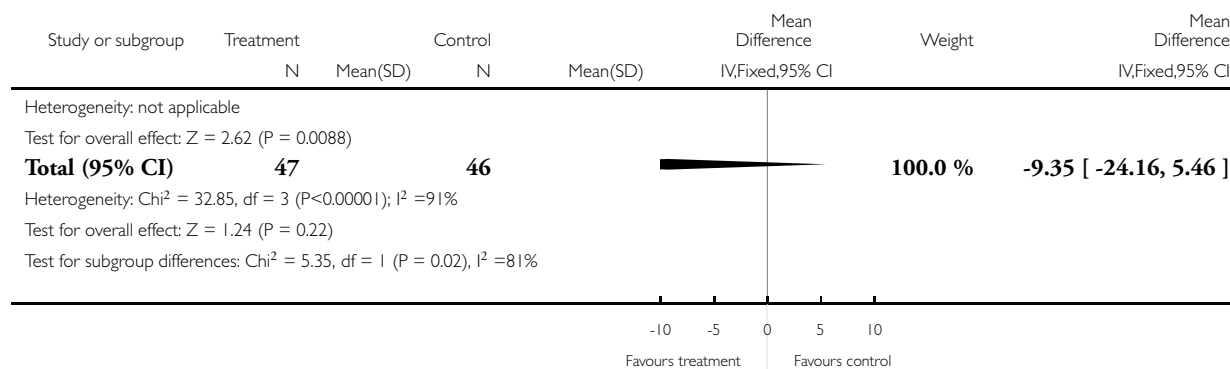
Comparison: 6 GIC versus composite for bonding

Outcome: 2 Measurement of enamel demineralisation



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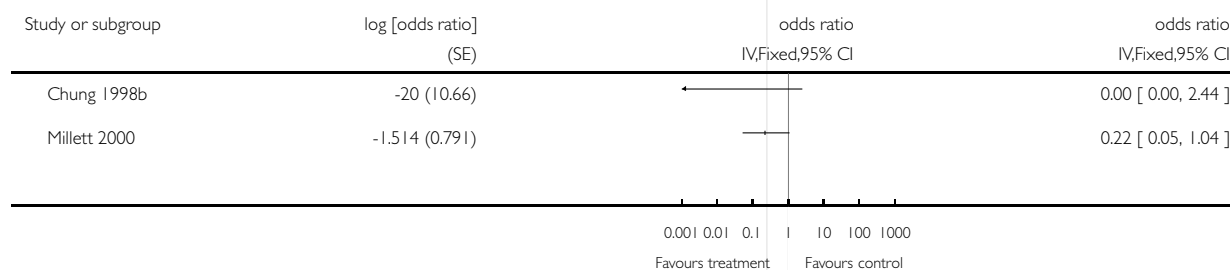


### Analysis 7.1. Comparison 7 Compomer versus composite for bonding, Outcome 1 Number of patients with white spots.

Review: Fluorides for the prevention of white spots on teeth during fixed brace treatment

Comparison: 7 Compomer versus composite for bonding

Outcome: 1 Number of patients with white spots



**Analysis 8.1. Comparison 8 Compomer versus GIC for banding, Outcome 1 Number of patients with white spots.**

Review: Fluorides for the prevention of white spots on teeth during fixed brace treatment

Comparison: 8 Compomer versus GIC for banding

Outcome: 1 Number of patients with white spots

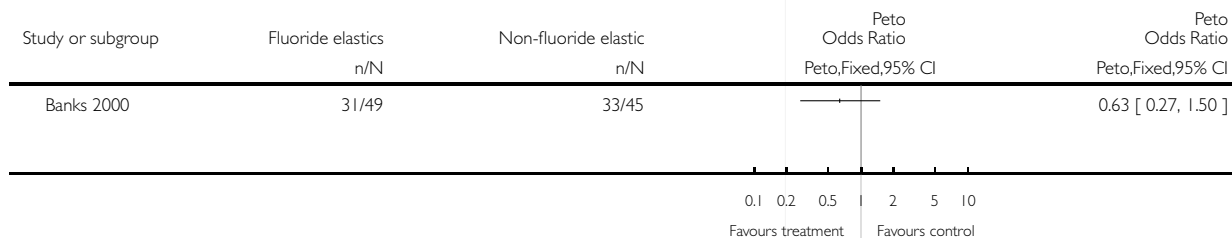


**Analysis 9.1. Comparison 9 Fluoridated versus non-fluoridated elastics, Outcome 1 Number of patients with white spots.**

Review: Fluorides for the prevention of white spots on teeth during fixed brace treatment

Comparison: 9 Fluoridated versus non-fluoridated elastics

Outcome: 1 Number of patients with white spots



**ADDITIONAL TABLES**

Table 1. Quality assessment - Major criteria

Study	Randomisation	Allocation concealed	Assessor blinding	Drop outs described	Risk of bias
Banks 2000	No	No	No	Yes	High

**Table 1. Quality assessment - Major criteria** (Continued)

Chung 1998a	Yes	Yes	Yes	Yes	Low
Chung 1998b	Yes	Yes	Yes	Yes	Low
Czochrowska 1998	No	No	No	Yes	High
Dyer 1982	Unclear	Unclear	No	Unclear	High
Gillgrass 2001	Yes	Yes	No	Yes	Moderate
Gorton 2003	Yes	Yes	Yes	Yes	Low
Hirschfield 1978	No	No	No	Unclear	High
Marcusson 1997	Yes	Unclear	Yes	Yes	Low
Millett 2000	No	No	Yes	Unclear	High
Ogaard 1986	No	Unclear	No	Unclear	High
Ogaard 2001	Yes	Unclear	No	Unclear	High
Pascotto 2004	Yes	Unclear	Yes	Yes	Low
Sonis 1989	No	No	No	Yes	High
Twetman 1997	Unclear	Unclear	No	Yes	High

**Table 2. Quality assessment - Minor criteria**

Study	Sample justified	Baseline comparison	I/E criteria	Method error
Banks 2000	Yes	Yes	Yes	Yes
Chung 1998a	No	Unclear	No	Yes
Chung 1998B	No	Unclear	No	Yes
Czochrowska 1998	No	No	Yes	No
Dyer 1982	No	Unclear	No	No
Gillgrass 2001	No	Unclear	No	No
Gorton 2003	No	Unclear	No	No

**Table 2. Quality assessment - Minor criteria** (Continued)

Hirschfield 1978	No	Unclear	Yes	No
Marcusson 1997	No	Yes	Unclear	Yes
Millett 2000	No	Yes	No	Yes
Ogaard 1986	No	Unclear	No	No
Ogaard 2001	No	No	No	No
Pascotto 2004	No	Yes	No	No
Sonis 1989	No	Unclear	No	No
Twetman 1997	No	Unclear	No	Yes

**Table 3. Split-mouth studies**

Comparison	Study	a	b	c	d	N	Odds Ratio & 95% CI
Fluoridated versus non-fluoridated composite for bonding (Comparison 5)	Sonis 1989	0	4	0	18	22 (subjects)	0.00 (0.00, 1.52)
GIC versus composite for bonding (Comparison 6)	Chung 1998 A	0	4	0	9	13 (subjects)	0.00 (0.00, 1.52)
	Marcusson 1997	14	20	7	19	60 (subjects)	0.35 (0.13, 0.86)
	Twetman 1997	15	2	0	5	22 (quadrants) 20 subjects	0.00 (0.00, 5.33)
Com-pomer versus composite for bonding (Comparison 7)	Chung 1998 B	1	3	0	9	13 (subjects)	0.00 (0.00, 2.42)



**Table 3. Split-mouth studies** (Continued)

	Millett 2000	13	9	2	15	45 (subjects)	0.22 (0.02, 1.07)
Com-pomer versus GIC for banding (Comparison 8)	Gillgrass 2001	4	7	2	79	92 (subjects)	0.29 (0.03, 1.50)

## APPENDICES

### Appendix I. MEDLINE (OVID) search strategy

#1 ORTHODONTICS\*:ME

#2 ORTHODONTIC\*

#3(#1 or #2)

#4 CARIOSTATIC AGENTS\*:ME

#5 FLUORIDES-TOPICAL:ME

#6 fluoride\*

#7 topical next fluoride\*

#8 NaF

#9 GLASS-IONOMER-CEMENT\* ME

#10 glass NEXT ionomer\*

#11#4 or #5 or #6 or #7 or #8 or #9 or #10

#12 DENTAL-ENAMEL-SOLUBILITY:ME

#13 TOOTH-DEMINERALIZATION\*:ME

#14 reminerali\* or deminerali\* OR decalcif\*

#15 white NEXT spot\*

#16 #12 OR #13 OR #14 OR #15#17

#17 #3 and #11 and #16

## WHAT'S NEW

Last assessed as up-to-date: 20 May 2004.

Date	Event	Description
12 August 2008	Amended	Converted to new review format.

## **HISTORY**

Protocol first published: Issue 3, 2002

Review first published: Issue 3, 2004

## **CONTRIBUTIONS OF AUTHORS**

Philip Benson wrote the protocol and co-ordinated the review. Philip Benson, Fiona Dyer, Declan Millett, Nicola Parkin, Anwar Shah and Suzy Vine independently and in duplicate assessed the eligibility of trials, extracted data and assessed the quality of the trials. Philip Benson contacted authors, entered the data, carried out the statistical analysis (with help from Helen Worthington) and wrote the review. Declan Millett proof read the review.

## **DECLARATIONS OF INTEREST**

None known.

## **SOURCES OF SUPPORT**

### **Internal sources**

- School of Clinical Dentistry, University of Sheffield, UK.
- Glasgow Dental Hospital and School, UK.

### **External sources**

- No sources of support supplied

## **INDEX TERMS**

### **Medical Subject Headings (MeSH)**

Dental Caries [\*prevention & control]; Fluorides [\*therapeutic use]; Mouthwashes [\*therapeutic use]; Orthodontic Brackets [\*adverse effects]; Randomized Controlled Trials as Topic

### **MeSH check words**

Humans