Fluoride-containing orthodontic adhesives and decalcification in patients with fixed appliances: A systematic review

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Introduction: Our objectives were to (1) systematically review the literature on the effectiveness of fluoride-containing adhesives in controlling decalcification in fixed orthodontic patients, (2) determine which fluoride-containing adhesives provide protection against decalcification, and (3) make recommendations on the usage of fluoride-containing adhesives in patients with fixed orthodontic appliances. Methods: In this systematic review, we searched published and unpublished material in any language using general and specialist databases; key orthodontic journals were searched by hand. Predefined inclusion criteria based on objective outcome measures for decalcification, presence of a comparison group, and the study design were applied to select the studies. Included studies were double extracted onto predesigned data extraction sheets. Results: A qualitative analysis of 5 randomized controlled trials and 5 clinical trials is presented. Conclusions: It is impossible to make recommendations on the use of fluoride-containing orthodontic adhesives during fixed orthodontic treatment. However, there is evidence to suggest that (1) glass ionomer cement is more effective than composite resin in preventing white spot formation, but the evidence is weak; (2) further research is required to determine the effectiveness of the various fluoride-containing orthodontic adhesives; and (3) common outcome measures and reporting standards would assist future researchers. (Am J Orthod Dentofacial Orthop 2010;138:390.e1-390.e8)

Orthodontic treatment is almost always an elective procedure to improve the patient’s dentofacial appearance. A major barrier in achieving this goal is the potential for patients to develop areas of decalcification adjacent to orthodontic brackets and bands.1-3 In the context of fixed orthodontic treatment, such lesions could be considered iatrogenic. The effects of decalcification vary from no perceptible change to white spots on the enamel, or even cavitation. They appear as unsightly lesions on previously healthy teeth at the end of orthodontic treatment. They can require further treatment after orthodontic treatment to mask or remove them.4

Studies have shown that decalcification is a significant risk during fixed orthodontic treatment, with rates reported between 2% and 96%.5 Research suggests that topical fluorides might decrease decalcification during orthodontic treatment.1,6,7 One method of applying fluoride is to incorporate it into the adhesive.

The numbers of fluoride-containing adhesives for orthodontic use increase each year, and both fluoride-containing glass ionomer and composite adhesives have been shown to decrease decalcification in patients with fixed appliances.8-10 However, the ability to prevent decalcification is not the only attribute of concern to clinicians, and the volume of information makes it difficult to stay up to date and make a valid conclusion about the most appropriate type of bonding agent to use.

One way to overcome this is to carry out a systematic review of the literature. Information from randomized controlled trials and clinical controlled trials can then be collated, summarized, and regularly updated to aid clinicians in their decisions, enabling them to make an evidence-based choice.

The objectives of this review were to determine whether fluoride-containing orthodontic adhesives are effective in preventing decalcification during fixed appliance treatment and, if possible, to make recommendations for their usage during fixed orthodontic treatment.
MATERIAL AND METHODS

Our search strategy for identification of studies followed the methodology outlined by the guidelines of the NHS Centre for Research and Dissemination. The search strategies were cross-disciplinary and included internationally published research. Review articles, published bibliographies, relevant citations in articles, and all languages were included.

Initial searches were carried out on Medline, Embase, CINAHL, the Cochrane Library, and Web of Science. The full search was built on a preliminary scoping search and also the strategy used by the Cochrane review on orthodontic adhesives.

Specialist databases such as the Health Technology Assessment were also searched by using appropriately modified terms. Unpublished “gray” literature was identified by searching SIGLE, ISI Conference Proceedings, Current Controlled Trials Register, and the National Research Register (Table I).

After the electronic literature search, a hand search to identify recent but uncited publications was undertaken. After liaising with the Cochrane Oral Health group, a selection of journals was identified as incompletely hand-searched and therefore not listed in the Cochrane Oral Health Group’s Trials Register. The following relevant journals were searched once: American Journal of Orthodontics and Dentofacial Orthopedics, Journal of Orthodontics (formerly, British Journal of Orthodontics), Angle Orthodontist, European Journal of Orthodontics, and Journal of Clinical Orthodontics.

The search was expanded by secondarily searching the references of the selected stage 1 articles and the listed references of the Cochrane systematic reviews on fluoride, orthodontic adhesives, and bands.

The complete search was rerun and updated in October 2008.

Studies that included comparison groups were considered. Thus, randomized controlled trials, clinical trials, and prospective observational studies with concurrent or historic comparison groups were included in the review.

To be of clinical benefit, the fluoride-containing adhesive must be able to prevent decalcification throughout treatment; therefore, this review was restricted to clinical studies of patients who had completed a full course of fixed orthodontic treatment. No reports were excluded on the basis of population or study setting.

From the titles and abstracts derived from the searches, articles were included on the basis of human studies, clinical studies, fluoride-containing adhesives, and fixed orthodontic treatment.

The outcome measure was decalcification at the baseline and the end point of the study. When possible, the total numbers of white spots, decalcifications, and decayed, missing, or filled teeth were recorded for the start and finish of the trial for both subjects and teeth.

Effect modifiers were other factors that might increase or decrease a patient’s likelihood of developing decalcification during orthodontic treatment. The following were identified and, when reported, recorded: level of water fluoridation, caries status of subjects, general health of subjects, oral hygiene of subjects, oral hygiene reinforcement program, socioeconomic status of subjects, use of topical fluoride (other than toothpaste), compliance with topical fluoride regimen, and debonds.

Ten articles were used as a pilot test for the 2 reviewers (S.R., B.C.) to clarify the inclusion and exclusion criteria and to train the reviewers to ensure that the criteria were consistently applied. This phase was also used to refine the data extraction sheet.

In stage 1, all titles and abstracts were reviewed by 1 reviewer (S.R.) to determine whether each article met the predetermined inclusion and exclusion criteria. If, containing adhesives), or the entire period of fixed orthodontic treatment was not covered.

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with the information available, it was determined that an article definitely did not meet the inclusion criteria, it was excluded. If there was any doubt, then the full article was retrieved, and the opinion of the second reviewer was sought (B.C.).

In stage 2, all selected articles were examined by 2 independent reviewers (S.R., B.C.) to determine whether the eligibility criteria were met. At this stage, articles with inappropriate study designs or no outcome measures at both baseline and end point were excluded. For all included studies, a note was made of any flaws in the study design.

In stage 3, all included articles were read, data were extracted, and methodologic quality was assessed by 2 reviewers independently, in duplicate, using specially designed data extraction forms, in accordance with the guidelines of the NHS Centre for Research and Dissemination. Any disagreement was discussed, and a third reviewer was consulted when necessary (E.T.). Five authors were contacted for more information, and 2 responses were received.

RESULTS

Nine studies were excluded at stage 2. Eight studies were bonding studies, reporting on comparative bond strengths, with no assessment of decalcification, and the other study was not relevant (Fig). The 10 included studies used different methodologies, reporting strategies, and various orthodontic adhesives, making a meta-analysis impossible. A qualitative analysis was therefore undertaken. Details of the included studies are given in Table II.

The single feature common to all included studies was the use of a split-mouth technique. Five compared fluoride releasing with conventional composite, 3 studies compared glass ionomer cement with composite, and 1 study compared compomer with composite. The final study compared compomer with composite for orthodontic bands. Only four studies assessed the full mouth for decalcification.

There were 7 indexes used to quantify decalcification. The most commonly used index was a 0-to-3 score. It is an ordinal scale, with 0, indicating no white spots, to 3, indicating cavitation, based on either the index of Gorelick et al or the system used by Mizrahi.

Three studies assessed decalcification by direct vision, and the rest used photography. Most studies assessed decalcification at debond, with only 1 study scoring at 1 week after debond.

Fig. Flow diagram of the studies identified.
Two studies reviewed decalcification over longer times: from debond to a 12-month review\textsuperscript{14} and from debond to a review 1 and 2 years later.\textsuperscript{9} Both studies reported an overall reduction in decalcification for both groups. However, it was still greater than before treatment.

Only 3 studies reported statistically significant differences in decalcification between the control and the experimental adhesives.\textsuperscript{8,9,29} Most studies based the assessment of decalcification on the number of teeth and not on the number of patients. Only 3 studies reported patient numbers.\textsuperscript{14,28,30}

Millett et al\textsuperscript{14} reported the mean numbers of teeth affected by decalcification per patient. They also reported an increase by about 30\% during the treatment time: from 2.1 to 2.8 for the experimental adhesive, and 2.1 to 2.7 for the control group. This amounted to an additional tooth affected in both groups.

Trimpeneers and Dermaut\textsuperscript{28} assessed remineralization, not decalcification, with their patient numbers, and reported no significant difference between both types of adhesive. In the experimental adhesive group, remineralization was noted in 5 of 19 patients with initial white spots, whereas, in the control adhesive group, this was the case in 14 of 23 patients ($P > 0.05$).

Gillgrass et al\textsuperscript{30} reported the mean enamel white spot lesion scores per patient and the number of patients with decalcification (Table II).

The only effect modifier reported in any detail was debonded brackets, which was included by all but 2 studies.\textsuperscript{9,28} In the 4 studies comparing fluoride-releasing and conventional composites, bracket failure rates were similar between the control and the experimental groups (Table II).\textsuperscript{8,16,17,27} The 1 study comparing compomer with conventional composite also found similar debond rates with both materials.\textsuperscript{29} In contrast, the 2 studies comparing glass ionomer

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CT, clinical trial; RCT, randomized controlled trial; NS, not stated; t, teeth; s, subjects; LC, light cured; GI, glass ionomer; MW, mouthwash; TP, toothpaste. *Debonds were not included in the decalcification analysis; †Debonded teeth were rebonded with the same material and included in the decalcification analysis.
with composite reported substantially more failures in the glass ionomer group: 11 of 14915 and 5 of 12014 debonded brackets in the composite groups compared with 37 of 14915 and 20 of 12014 in the glass ionomer groups.30

The final study compared the band failure rates of a compomer with a conventional glass ionomer and found no significant difference between the failure patterns of the 2 cement groups.30

**DISCUSSION**

It is only possible to qualitatively report this systematic review because the lack of homogeneity in the data and deficiencies in reporting made it impossible to undertake a meta-analysis. Only 3 studies provided patient numbers.14,28,30 The failure to report both the numbers of teeth and subjects means it is not possible to determine whether the reported decalcification is spread across the population as a whole or confined to only a few at-risk patients.

A meta-analysis is properly applicable only if the data summarized is homogenous.33 With regard to the materials used, the studies involved could be considered nonhomogenous. The adhesives can all be described as containing fluoride, but they essentially have different chemical properties. The aqueous nature of glass ionomer cements enables fluoride ions to be taken up and released from the material,34 whereas the matrix of the composite resins is less hydrophilic, and fluoride incorporated into the material is released only in small amounts.35,36

All included studies used a split-mouth design, allowing the patients to act as their own controls. In theory, differences in outcome between the 2 materials are 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. However,
when considering fluoride products, it is possible that the fluoride released will affect all quadrants, not just those using the experimental material; the possibility of some crossover effect to the control side must be considered. Although topically applied fluoride has been reported to have a mostly local effect, another report suggested that a slight crossover of fluoride occurs via saliva. This would reduce the difference in effect between the 2 test materials and the power of the experiment to find a difference.

Until better understanding of how fluoride released on 1 side of the mouth influences the other side, a parallel study design might be the most appropriate.

In our review, 2 methods were used to assess decalcification: direct visual assessment and photography. Both methods have potential problems. Visual inspection requires the assessors to be calibrated at the start and at regular intervals during the experiment; blinding can also be more difficult, particularly if the operator is also the assessor. Several studies were unclear in reporting whether the operator and the assessor were separate persons.

Photographs have the advantage that assessment can be made by several people, and consensus can be achieved. Photographs can be viewed in random order, with the assessors blinded to group allocation. An error analysis can be carried out, and, because the assessment can be performed in a short time, the problem of examiner drift is reduced. They also provide a permanent record of the appearance of the teeth.

A problem with photographs is achieving consistency in lighting, developing, and reducing reflections that can mask or mimic white spot lesions, although a careful photographic technique can overcome these problems.

When examining the effectiveness of a fluoride product in preventing decay, 2 aspects should be considered: (1) whether the fluoride product reduces the number of white spots during treatment and (2) whether it reduces the severity in terms of the area of the tooth affected; this might the greater concern to the patient.

The most commonly used index in this review was a 0-to-3 scoring system. This scale addresses the presence or absence of decay and to a certain extent the severity, but not the areas of the teeth covered by the white spots. An index that includes an assessment of the area covered by decalcification was used by 1 study, and another study also assessed decalcification quantitatively with tracings. It is almost impossible to assume that the studies were diagnosing decalcification at the same level. This could lead to either a falsely increased or decreased report of the incidence and prevalence of white spot lesions.

Several studies lacked reports on examiner calibration or whether a reproducibility study was undertaken before the application of the chosen index.

Debonds can be a significant problem in orthodontics, and how they are handled in a trial affects the results. In this review, 5 approaches were identified.

1. Two studies comparing composites reported similar acceptable differences between groups but did not report what happened to the teeth after they were debonded. It is not clear what they were rebonded with or whether these teeth were included in the decalcification scores.

2. Three studies rebonded failed brackets with the same material that they had originally been bonded with and included these teeth in the decalcification assessment. A total of 70 of 828 brackets were rebonded. In these cases, the potential of additional fluoride released from fresh material might have an effect.

3. In 1 study, brackets from both groups were rebonded with a nonfluoride-releasing material so as not to introduce a fresh source of ionic fluoride; they were not counted in the decalcification assessment.

4. Bands from both groups were recemented with the glass ionomer control material and were eliminated from the decalcification assessment.

5. The rebonding protocol was not stated, but debonded teeth were not assessed for decalcification.

All of these protocols have implications for both clinical practice and research. Is it sensible to model conventional practice and rebond the bracket with the same material and include it in the decalcification assessment? Or is it a better research method to increase the power and precision of the study and use a nonfluoride-releasing material for rebonding and discard the debond from further study, even though this might decrease the numbers of teeth assessed? For example, I study had 40 patients at the beginning, but, because of the debond rate, only 23 patients had no failed brackets, and the authors then confined the assessment of decalcification to this subgroup of patients. Thus, 17 patients and 102 teeth on which to assess decalcification were lost from the trial.

Inclusion of the debond rate is also important as an effect modifier because the material must have sufficient bond strength to be useful in the clinical setting. From a clinician’s point of view, no matter how significantly a material reduces the incidence of decalcification, if it has a high debond rate, it will not be used. This would prevent progression of orthodontic treatment, increasing the number and length of appointments, the treatment
time, and the costs, and ultimately cause both patient and clinician dissatisfaction.

From studies assessing debonds, the findings suggest that, for bracket retention, glass ionomer cement has a higher bond failure rate compared with conventional resin; the compomer, Dyract Ortho, and fluoride-containing composites all have similar survival times compared with a conventional composite. These reports correspond to other in-vivo reports of similar materials. A Cochrane review of orthodontic adhesives also supported the use of a composite resin adhesive over a conventional glass ionomer adhesive.

Blinding to the study outcome was, in general, poorly reported; 3 studies did not state whether decalcification assessment was blind. If the adhesives being compared had the same curing mechanism and mixing requirements, then blinding of the patient and the operator to the adhesive type would be possible. When different curing mechanisms are used, a double-blind design is almost impossible.

The CONSORT statement suggested providing a checklist and a flow diagram to aid in complete reporting of trials. No studies in this systematic review included a CONSORT diagram. Five studies had missing data with regard to incomplete reporting of numbers at the baseline and the end point for decalcification.

Suggestions were also made by CONSORT regarding the analysis of the results: “to express them in absolute numbers when feasible.” This is important because, when only percentages are reported, it is impossible to identify the numbers of teeth or patients affected.

Future researchers should use a common reporting format, as outlined by the CONSORT guidelines. Which fluoride-containing orthodontic adhesives provide protection against decalcification? There is limited evidence to suggest that Aquachem decreases the incidence of decalcification during fixed orthodontic treatment compared with a conventional composite adhesive. However, this conclusion comes from only 1 trial of 60 patients. This evidence can be considered to be weak. But it is a well-designed randomized controlled trial with clear reporting of binding and inter-examiner reproducibility. This finding corresponds with that of Benson et al.

Of the 2 other studies reporting a statistically significant difference in decalcification, 1 study incompletely reported data. The other reported a different method for debridement after debond for the fluoride-containing adhesive that involved an ultraviolet light source on the experimental sites, and the remaining composite was removed with a tungsten carbide bur (the material fluoresces under ultraviolet light). The control composite was removed similarly but without the ultraviolet light. It is possible to postulate that the more thorough approach to removal of the experimental composite might reduce the incidence of decalcification. However, the authors reported that the fluorescence had little value during debonding.

The following are our recommendations for usage of fluoride-containing orthodontic adhesive during fixed orthodontic treatment. From the results of this systematic review, it is not possible to make any recommendation for fluoride-containing adhesives.

Although Aquachem might help to decrease decalcification, it cannot be recommended, since other studies of glass ionomer cements did not show satisfactory clinical bond strength compared with other fluoride-containing materials. The Aquachem study did not report the debond rate; either there were no debonded brackets or debonds were not reported.

Therefore, the only materials reported to protect against decalcification with satisfactory clinical bond strengths were Fluor-Ever and Dyract Ortho. The Fluor-Ever study had a small sample size, lacked randomization, used an operator as an assessor, reported no calibration or reliability data, and used a different debond protocol for the 2 composites. The Dyract Ortho study failed to report the final numbers of teeth affected by decalcification at the end of the trial. Both materials require larger controlled studies to confirm their acceptability.

CONCLUSIONS

1. In this systematic review, we found some evidence that the use of glass ionomer cement as an orthodontic adhesive is more effective in preventing decalcification during fixed appliance treatment than a conventional composite resin, but the evidence is weak. Because of the limitations of successful bonding with a glass ionomer adhesive, it cannot be recommended.

2. From this systematic review, it was impossible to make any current recommendations on the usage of fluoride-containing adhesives during fixed orthodontic treatment, but some materials are worthy of further investigation.

3. Standard reporting methods for future clinical trials are recommended for fluoride-containing adhesives in orthodontics; a standard decalcification assessment tool and protocol for handling debonds is needed. Furthermore, the split-mouth approach should be reassessed.
REFERENCES


