Fluoride-releasing materials for orthodontic appliances

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Citation for published version (APA):
CHAPTER 7

Summary and conclusions

As described in Chapter 1, there were two primary objectives in these investigations:

1) To determine methods of obtaining adequate bond strengths to enamel for a number of fluoride-releasing materials that are potentially useful in bonding orthodontic brackets and

2) To examine the fluoride release of these same materials and their potential for reducing demineralization of enamel adjacent to orthodontic brackets. The studies are summarized below.

Bonding to enamel

In most bonding studies, brackets are bonded to intact human enamel. However, in the investigations described in Chapters 2, 3 and 5, cylinders of the tested materials were bonded to ground bovine enamel. Bovine enamel is commonly substituted for human enamel in restorative bonding studies and is believed to be an appropriate substitute when flat ground. Grinding the enamel surfaces produces a more uniform bonding surface free of defects and aprismatic enamel. Test reliability is also improved by providing a flat surface for a more precise alignment of the shear apparatus. Brackets were not used because they can introduce complications in interpretation of results. As mentioned in Chapter 1, failure at the bracket interface is common and bracket design influences the bond strength achieved. The intent of these investigations was to examine the effect on bond strength of various enamel pretreatments used with specific materials. This seemed best done by not introducing another interface such as a bracket.

The challenge in using this method as described for these bond strength studies, is to relate the results to published bonding studies and clinical failure rates, in order to determine the suitability of the tested materials for orthodontic bracket applications. Typical clinical treatments use resin-based composite bonding
materials and phosphoric acid etching of the enamel. While some 4-10% of these bonds fail, this is considered the benchmark for bracket bonding [Chapter 1 ref #76,77]. In laboratory testing using a shear/peel type test on unground enamel, the bond strengths range from about 4-11 MPa [Chapter 1 ref # 78,79]. Using a shear only test, bond strengths to unground enamel are in the range of 14-15 MPa [Chapter 1 ref # 101, 106]. However, bonds measured by a shear only method on ground enamel are typically greater than 20 MPa. The experimental resin-based composite described in Chapter 5 had a shear bond strength to ground enamel of 22 MPa, similar to many control resin-based composite materials. Therefore, this experimental material is likely to be suitable for bonding orthodontic brackets.

The compomer described in Chapter 3 also produced a shear bond strength of 24-27 MPa when used with typical phosphoric acid etching of enamel. Laboratory shear bond strength studies of other compomers on unground etched enamel gave bond strengths of around 14 MPa [Chapter 1 ref # 102,113], which is similar to resin-based composite bonds tested in the same way. A clinical study of a compomer bonded with acid etching gave equivalent results to that obtained with a resin-based composite control [Chapter 1 ref # 57]. These results suggest that compomer, bonded in combination with an acid etch pretreatment, is also suitable for orthodontic bracket use.

In Chapter 3, an alternative conditioning agent (primer), that has substantially reduced etching capacity, was used with the compomer to evaluate the shear bond strength to ground enamel. The bond strengths measured were 11 MPa, when the conditioner was not agitated during the application time, and 17 MPa when it was agitated and replenished during this time. However on unground enamel, the degree of etching would be reduced by the presence of aprismatic enamel, so one might expect the bonds to such enamel to be lower. Based on the above observations, it would appear that the primer treatment without agitation may not provide an adequate bond for orthodontic brackets. Though the bond strength is somewhat improved by agitating the primer, it's uncertain whether that bond is adequate for bracket bonding, and would require further clinical verification.

The effect of various surface treatments on the bond strength of glass-ionomers to enamel was examined in Chapter 2. Evidence of micromechanical bonding was
identified and acidic conditioning of the enamel resulted in enhanced micromechanical bonding and substantially increased bond strengths for both conventional and resin-modified glass-ionomers (RMGI). Even though the bond strength of a conventional glass-ionomer was doubled by etching, it was still quite low (~7 MPa), and clinical studies have shown that conventional glass-ionomers are unacceptable as orthodontic bracket cements due to high failure rates, as noted in Table 3 of Chapter 1.

On the other hand, resin-modified glass-ionomers have been found to perform comparably to resin-based composite materials in clinical evaluations, particularly with enamel conditioning [Chapter 1 ref # 111,112], as shown in Table 5 of Chapter 1. In the investigation of Chapter 2, both of the RMGI's studied showed significant improvement in bond strength to enamel when conditioned/etched with polyacrylic acid (PAA) or phosphoric acid (PA). Bond strengths of 17-20 MPa were attained in shear bond testing to ground enamel and resin tag penetration was observed in the conditioned/etched enamel surfaces. Published studies using a similar test method and another RMGI obtained values comparable to those found in this investigation, as shown in Table 4 of Chapter 1 [ref # 98,103]. These results suggest that RMGI's, when used with conditioning or etching, are suitable for bracket bonding. Additional durability studies and clinical testing would be useful in confirming this observation.

It should be noted that without conditioning or etching, the shear bond strengths of RMGI's found in Chapter 2 were only about 4-7 MPa. Similar bond strength values are found in the literature for unground enamel, as shown in Table 4 of Chapter 1. There is evidence that bond strengths of this magnitude are likely to be too low to provide adequate retention of orthodontic brackets, and this appears to be confirmed by clinical evaluation, as shown in Table 5 of Chapter 1.

**Fluoride release and reduction of enamel demineralization**

In Chapter 4, the effect on demineralization of polymer remaining in the etched enamel porosities following surface cleanup and subsequent polymerization was examined. It was found that such polymer reduces the ability of acids to demineralize the enamel. When fluoride was added to the polymer, there was
some evidence that this effect was enhanced, but experimental difficulties complicated the interpretation. This study also was conducted to verify the premise that remaining polymer resin penetrated into the etched enamel subsurface surrounding orthodontic brackets can give a false impression of the effectiveness of fluoride release from a bracket bonding material. The results of this study suggest that a reduction in demineralization from polymer penetration of the etched enamel surrounding a non-fluoride bracket bonding material could, potentially, be as great at the reduction caused by fluoride from a bracket material where the surrounding enamel was not pre-coated with resin monomers. Study designs for both in vitro and in vivo studies where the effect of fluoride on demineralization is being evaluated, must incorporate methods that prevent resin from contact with the surrounding enamel.

Chapter 5 describes a novel fluoride-releasing resin-based composite material that was developed with the goal of having relatively high fluoride release, while maintaining physical properties. This material provided linear fluoride release with time at a level of about 2.0 µg/cm² per day, which is higher than other fluoride-releasing resin-based composites. Using the cumulative fluoride release through 7 days, and the 24-hour release at 7 days, comparisons can be made to other resin-based composite materials as shown in Table 2 of Chapter 1. The experimental material has a cumulative fluoride release at 7 days of about 21 µg/cm² and a 24-hour release of about 2.0 µg/cm². With the exception of FluorEver®, all the other resin-based composite materials had lower fluoride release, some being substantially lower. FluorEver has a relatively high fluoride release through 7 days, but by 100 days, its 24-hour release is down to 0.4 µg/cm², well below that of the experimental material. It should be noted that the experimental material has 24-hour fluoride release at 100 days that is greater than most glass-ionomer materials, and is comparable to KetacFil®, which had the highest release rate of the materials investigated, as shown in Table 4 of Chapter 1.

A compomer material was examined for its bonding characteristics in Chapter 3. Fluoride release was also measured for this material, though not presented in the bonding article, and its cumulative fluoride release was about 24 µg/cm² at 7 days and 73 µg/cm² at 100 days. Its average daily release at 7 days was about 1.5 µg/cm² and at 100-days was about 0.3 µg/cm². The daily fluoride release of
another compomer, Dyract®, at 7 days was 1.1 µg/cm² (averaged from 5 studies; see Table 2, Chapter 1). For both of these compomers, the fluoride release is lower than glass-ionomers and also the experimental resin-based composite as shown in Table 4 of Chapter 5. Glass-ionomers characteristically release fluoride at a relatively high rate in the first few days after water immersion, but after 1-2 weeks, exhibit a slow decrease in the rate of release. This behavior is illustrated in Figure 1 of Chapter 5 and described in Chapter 6 as having a t½ time dependence. Table 4 of Chapter 5 and Table 2 of Chapter 1, show that the cumulative and daily fluoride release rates for glass-ionomers exceed those for most resin-based composite and compomer materials. An exception is the experimental resin-based composite at times beyond about 2 months as discussed above.

The effectiveness of fluoride released from materials, in reducing demineralization adjacent to orthodontic appliances, was examined with an in vitro model described in Chapter 6. This model showed that demineralization can be reduced by the fluoride released from the materials. The distance and magnitude of the reduction is directly related to the amount of the fluoride release, and appeared to have a logarithmic dose response relationship (see Figures 3 and 4 of Chapter 6). This model clearly shows that the quantity of fluoride available is important. However, the demineralization period in this model took place over 4 days, which is the time period when most materials have their highest release, and may not be predictive of the long-term protective effect of individual materials that have different fluoride-release characteristics over time. For example, the long-term comparison of protective effects might favor materials such as the experimental resin-based composite over a material like Vitremer, because the total cumulative fluoride-release and incremental daily fluoride release become greater for the experimental composite after about a month. It’s not known if the early burst of fluoride associated with glass-ionomer materials is more important than a steady release over a long period of time. However, it is a general concept in caries that the continual presence of low levels of fluoride is important in prevention of demineralization.

There is insufficient evidence from clinical trials to provide validation of the in vitro model as mentioned in Chapter 1, where Table 3 provides data from applicable studies. Only 3 studies showed a significant reduction in incidence of
demineralization between a fluoride-releasing material and a non-fluoride control; each of these 3 studies used a test material with a relatively high level of fluoride release. In studies where the test material released relatively low levels of fluoride, there was no significant difference between test materials and controls. However, the relationship between fluoride release and demineralization is made less clear because 2 of the studies using glass-ionomers also saw no significant difference in demineralization compared to resin-based composite controls. The clinical results tend to support the in vitro evidence, but additional carefully designed studies are needed to determine the effectiveness of fluoride release of materials in preventing white spot lesions around orthodontic brackets. Moreover, the effect on reduction of demineralization by other components in the material, alone or in combination with fluoride, require further investigation.