

A clinical evaluation of the effectiveness of including fluoride into an orthodontic bonding adhesive

P. A. Banks*, A. Burn* and K. O'Brien**

*Department of Orthodontics, Fairfield General Hospital, Bury and **Department of Dental Medicine and Surgery, University Dental Hospital, Manchester, UK

SUMMARY A clinical trial was undertaken to assess the value of incorporating fluoride released from a commercially available bonding adhesive (Rely-a-Bond) to determine the extent of any protection provided against enamel decalcification. Fifty patients undergoing fixed appliance therapy were included in the trial. Contralateral quadrants were used as controls where no fluoride was present in the adhesive. Enamel decalcification after treatment and bond failure rates during treatment were investigated.

A total of 366 experimental and 371 control teeth were included in the study. The results showed that 50 per cent of patients and 13.5 per cent of teeth exhibited post-treatment decalcification. The addition of fluoride to the adhesive did not significantly reduce the incidence of enamel decalcification. Bond failure rates were satisfactory for both experimental and control teeth (all under 5 per cent).

Introduction

Enamel decalcification is still a significant problem occurring during fixed appliance treatment (Mitchell, 1992a). Previous attempts have been made to address this problem by the use of various topical fluoride schemes (Zachrisson, 1975; Sadowsky *et al.*, 1981), as well as by oral hygiene and dietary advice. Although these are of value, they do require good patient compliance and therefore are not always successful. Methods are being sought where greater enamel protection can be provided without such an emphasis on co-operation. Recently interest has been shown in the use of new types of enamel sealants to protect the facial surfaces of teeth to which brackets are bonded (Banks and Richmond, 1994), but these have proved to be of minimal benefit over the protracted course of treatment.

Other research has investigated the possible benefits of fluoride release from orthodontic bonding adhesives. Frequent exposure of enamel to low levels of fluoride ions increases enamel fluoride content (Ericson, 1977), and exerts its anticariogenic properties by the formation of various fluoridated apatites in the outer enamel surface (Levine, 1976). Both direct leaching of

ions and dissolution of the resin are thought to contribute towards the release of fluoride into plaque and saliva (Shen, 1985). More recently a fluoride exchanging resin (FER) has been developed which exchanges fluoride ions for other anions in the oral environment without dissolution of the material (Underwood *et al.*, 1989). Plaque has a greater tendency to form on composite resins than on enamel (Smales, 1981), but fluoride has been shown to inhibit the activity of *Streptococcus mutans* (Menaker, 1980).

So far the testing of fluoride-containing composites has yielded inconsistent results. Laboratory studies have shown that the quantity of fluoride released is small and the duration of release is short (Forsten and Paunio, 1972; Chan *et al.*, 1990; Fox, 1990; Bishara *et al.*, 1991; Ghani *et al.*, 1994; Chadwick and Gordon, 1995). Glass ionomer cement was shown to provide much greater protection than Bis GMA resin for bovine enamel subjected to an artificial caries medium (Valk and Davidson, 1987). Other studies have cast doubts upon the clinical value of fluoride-releasing resins by suggesting that bond strengths are compromised (Chan *et al.*, 1990; Bishara *et al.*, 1991; McCourt *et al.*, 1991),

although others have found no clinical difference in bond failure rates (Mitchell, 1992b; Turner, 1993).

Clinical studies have not consistently demonstrated the value of including fluoride into orthodontic composite resins. Eliades *et al.* (1992) investigated fluoride uptake from composites in 16 human premolars, and after 9 months found no difference between an experimental fluoride-releasing material (VP-862) and control materials. However, Øgaard *et al.* (1992) found a significant reduction of early carious lesions after 4 weeks using the same material. Sonis and Snell (1989) compared an experimental composite (FluorEver, 206 brackets) with a control resin (Aurafill, 205 brackets) in treating 22 patients for an average time of 25 months. They found that 12.6 per cent of control teeth but no experimental teeth showed demineralization after treatment. Underwood *et al.* (1989), comparing an experimental FER with Concise, showed a 93 per cent reduction of early carious lesions after 60 days in the experimental group, but did not follow the patients through to completion of treatment.

Other clinical trials have failed to demonstrate any benefit in the addition of fluoride to adhesives. Mitchell (1992b) compared fluoride releasing Direct with control adhesive Right-On and found no significant difference, with an overall decalcification prevalence of 18.5 per cent in 24 patients after a mean treatment time of 10.5 months. Turner (1993) compared an experimental fluoride-containing composite (K32 De Trey Dentsply) with Concise (203 experimental, 203 control teeth, mean treatment time 1.6 years) but found no difference in white spot lesions.

The aim of this study was to evaluate the effect of using a fluoride-releasing no-mix adhesive upon the incidence of decalcification and bracket failure rate in a sample of patients who attended our clinics for fixed appliance orthodontic treatment.

Subjects and methods

Fifty patients were included in the study, all of whom were treated using the Straight-Wire Appliance ('A'-Company, Roth 0.022" prescrip-

Table 1 Samples (fifty patients were included in the study).

Teeth included	Fluoride	Control	All
Maxillary teeth	192	198	390
Mandibular teeth	174	173	347
Total	366	371	737

tion). The samples are shown in Table 1, and included 366 experimental and 371 control teeth. Teeth with labial restorations, decalcification or significant pre-existing white spots were excluded from the study.

All teeth for bonding were etched in the normal way. Contralateral quadrants were randomly allocated as experimental and control so that where both arches were treated the allocation was reversed in the opposing arch. Experimental quadrants were bonded with fluoride-releasing Rely-a-Bond composite (Reliance Orthodontic Products, Inc., Itasca, IL). This is a recent modification of the commercially available no-mix adhesive. Control quadrants were bonded with standard Rely-a-Bond (non-fluoride-releasing). All brackets were standard twin design, without hooks or ball arms. Bonded brackets were used on all tooth types apart from molars, which were banded. After bonding, the usual clinical practice was followed of giving oral hygiene instruction and written instructions recommending the use of a daily fluoride mouthrinse.

Enamel decalcification index (EDI)

After debond all teeth were scored by the same operator using the index described previously (Banks and Richmond, 1994). This is a modification of the index used by Årtun and Brobakken (1986). In use decalcification in each of the four areas (opposite the gingival, occlusal, mesial and distal edges of the bracket) was scored according to the following scheme: no decalcification = 0; mild but clinically visible decalcification affecting less than 50 per cent of the area = 2; moderate to severe decalcification extending over more than 50 per cent of the area = 1; and decalcification covering the whole area with obvious surface breakdown or caries = 3.

Table 2 Enamel decalcification index showing frequency distribution of individual tooth scores.

	Total EDI score per tooth						
	0	1	2	3	4	5	6
Fluoride	87.6	10.3	1.6	0	0.4	0	0
Control	85.3	10.3	3.6	0.4	0.4	0	0

The scores for each group were evaluated, and a total decalcification score per 100 teeth was calculated for experimental and control teeth. Statistical analysis was carried out using an IBM-compatible computer and the SPSS software program (version for PC+).

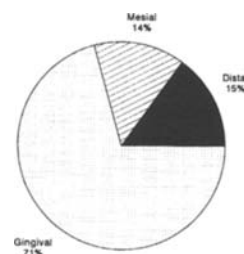
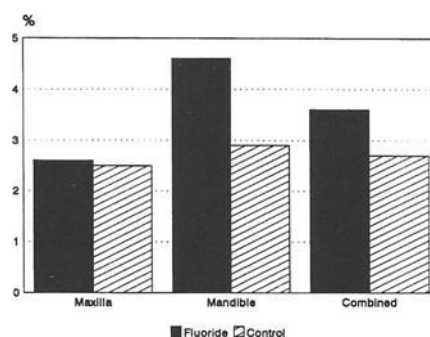
Bond failure rates

Bond failures were recorded during treatment for first time failures only per tooth. An adhesive remnant index (ARI; Årtun and Bergland, 1984) was used to record the amount of residual composite following bracket loss.

Results

The mean treatment time was 16.3 months overall. Enamel decalcification was found in 50 per cent of patients after debond. For experimental teeth the incidence was 12.4 per cent, for control teeth 14.6 per cent and overall 13.5 per cent. The EDI scores per 100 teeth were compared for the experimental and control groups using the Wilcoxon matched pairs test which showed no significant difference ($P = 0.18$). There were similar findings for scores comparing upper and lower control teeth only ($P = 0.16$) and upper and lower experimental teeth only ($P = 0.77$). The frequency distribution of EDI scores is shown in Table 2. Generally the proportion of teeth that were severely affected was low. Only 2 per cent of experimental teeth and 4.4 per cent of controls showed EDI scores of 2 or more.

The zonal distribution of decalcification is shown in Figure 1. This is similar to that found previously (Banks and Richmond, 1994), with over two-thirds occurring in the gingival areas,

**Figure 1** Percentage distribution of EDI scores for each tooth area.**Figure 2** Bracket failure rates (per cent).

almost one-third in the mesial and distal areas combined, and no lesions occlusally.

Bracket failure rates were clinically satisfactory for both experimental and control teeth (13 brackets, 3.6 per cent experimental; 10 brackets, 2.7 per cent control) the number of bracket failures was too small for statistical testing. The results are illustrated in Figure 2. The distribution of EDI scores for the maxilla and mandible are shown in Figure 3. The amount of composite remaining attached to enamel after bond failure was similar between experimental and control materials (ARI = 0.85, 0.90 respectively).

Discussion

The results of this investigation suggested that the use of a fluoride-releasing adhesive did not result in a reduction in decalcification for our group of patients. This agrees with the findings of other clinical trials by Mitchell (1992b) and Turner (1993) but disagrees with those of Sonis and Snell (1989) and Underwood *et al.* (1989),

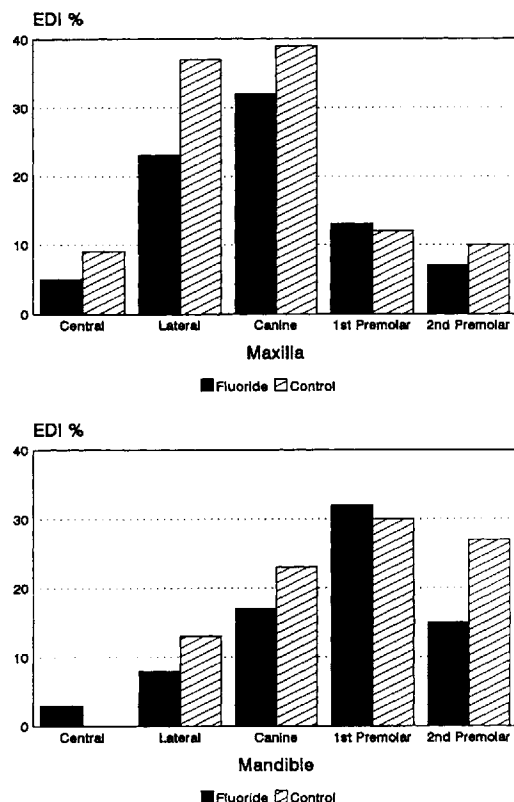


Figure 3 Enamel decalcification index expressed as a total score per 100 teeth for individual tooth types. (a) Maxillary teeth; (b) mandibular teeth.

who found a marked reduction in white spot formation for the fluoride-releasing materials. These differences can be explained partly by the nature of the bonding materials and the duration of the studies. Sonis and Snell (1989) suggested that the FluorEver adhesive they tested has a burst effect of fluoride release within several hours of placement, followed by a slow sustained rate of release. As a result fluoride is released over a greater length of treatment time. More importantly, their experimental observation time was noticeably shorter than the present investigation.

It has been shown that glass ionomer-based materials release significantly more fluoride than resin-based materials, and that for a variety of bonding materials 70 per cent of fluoride is released in the first month (Chadwick and Gordon, 1995). Clearly this is of limited benefit

during the full extent of a course of orthodontic treatment. Further work is required to develop a material which shows greater fluoride release, as the glass ionomer types do, whilst providing adequate bond strength and clinical performance, as do the current resin-based adhesives.

Clinical trials can be divided into two main types: those that evaluate the influence of treatment in terms of (i) efficacy, in which the study is carried out under strict conditions and all the subjects are made to adhere to a regimen; and (ii) effectiveness, in which normal clinical practice is followed. The advantage of an effectiveness study is that the findings are directly applicable to clinical practice. Ethical considerations were such that patients in this investigation were given a fluoride mouthrinse. A criticism of this could be that patient compliance was not assessed and the 'actual' fluoride exposure is undefined. In a report by Geiger *et al.* (1992) it has been shown that compliance with a fluoride mouthrinsing programme was as low as 13 per cent in the 206 study participants. This must, therefore, bring into question the effectiveness of such a procedure and highlight the variability of the trial. However, this should not influence the conclusions of this investigation since the split mouth design, in which bonding was carried out in each patients using the two types of adhesive, compensates for the effects of any individual variation in compliance.

Conclusions

1. The use of fluoride-releasing Rely-a-Bond adhesive did not influence the incidence of decalcification in this study population.
2. This study adds weight to the evidence that the use of fluoride-releasing resins does not result in a reduction in decalcification during fixed appliance therapy.

Address for correspondence

Mr P. A. Banks
Department of Orthodontics
Fairfield General Hospital
Bury BL9 7TD
Greater Manchester, UK

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