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Fluoride-releasing Elastomeric Modules Reduce Decalcification: a Randomized Controlled Trial

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Abstract
Objective: *To determine whether fluoride releasing elastomeric modules reduced the incidence of decalcification around orthodontic brackets during a complete course of orthodontic treatment.*
Design: *A randomised controlled, split mouth design.*
Setting: *The study was carried out in the orthodontic department of Newcastle-upon-Tyne Dental Hospital, UK.*
Subjects and methods: *21 consecutive patients (126 teeth) undergoing fixed appliance therapy were studied. A split mouth technique was adopted to examine the upper labial segment, where one side (left or right) was randomly assigned to the experimental group, and the opposite side served as a control throughout their course of orthodontic treatment.*
Interventions: *The control teeth were ligated to the archwire using conventional modules. The experimental teeth were ligated to the archwire using Fluoride releasing elastomeric modules.*
Outcome measures: *Standardised photographs were taken of the upper labial segment before and after completion of orthodontic treatment, and the degree of decalcification assessed in each tooth quadrant, using a modification of the Enamel Defect Score.*
Results: *Decalcification was found to occur in both treatment groups, though to a significantly greater degree on the control side ($p = 0{\cdot}002$). The fluoride module side showed significantly fewer serious decalcified lesions than the control ($p = 0{\cdot}013$). No patients withdrew from the study.*
Conclusions: *It would appear that the use of fluoride releasing elastomeric modules reduces the degree of decalcification experienced during orthodontic treatment.*

Index words: Decalcification, Fluoride-releasing Elastomeric Module, Randomized Controlled Trial.

Introduction

Iatrogenic demineralization of enamel during orthodontic treatment occurs in 50 per cent of patients (Gorelick *et al*., 1982) These lesions (or in severe cases cavitation) are unsightly and may lead to early discontinuation of treatment. This is frustrating for the orthodontist who is not able to achieve treatment objectives and distressing to the patient.

The dynamic equilibrium between enamel demineralization and remineralization is affected by several factors, including the frequency of refined carbohydrate intake, consumption of carbonated drinks and efficacy of oral hygiene measures. Low levels of fluoride (0·03–0·05 ppm) can tilt the equation in favour of remineralization (Levine, 1976) and is also known to inhibit the development of plaque, which may further inhibit decalcification (Zacchrison, 1978). The availability of fluoride during orthodontic treatment reduces decalcification and fluoride mouthwashes are successful (Geiger *et al*., 1992). Unfortunately, this relies on patient compliance and those patients most at risk form decalcification are arguably, also those least likely to comply with additional preventative methods. Non-compliance methods have been investigated, but are associated with disadvantages:

1. Application of fissure sealants is technique sensitive (Frazier *et al*., 1996).
2. Fluoride releasing bonding agents result in lower bond strengths (Fox *et al*., 1990; Millett and McCabe, 1996).
3. Topical application of fluoride varnish increases chair-side time (Todd *et al*., 1999).

One solution to this problem, may be the use of elastomeric modules impregnated with fluoride that would promote fluoride uptake around orthodontic brackets. This is a particularly attractive method of fluoride delivery, since it would not interfere with routine clinical practice and ensures 'fresh' delivery of fluoride at each visit

The aim of the following research was to establish if there was a clinical benefit in using fluoride-releasing modules.

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Materials and Methods

Consecutive patients starting fixed orthodontic appliance therapy within the orthodontic department at Newcastle Dental Hospital were enrolled into the study providing that the following criteria were met:

1. Fixed appliances were to be worn in the upper arch (standard or pre-adjusted edgewise) from first molar to first molar.
2. Elastomeric modules could be used to secure the arch-wire throughout treatment

Twenty-one young people were enrolled in the study. They were treated by four experienced clinicians.

This investigation was designed as a randomized, controlled, prospective study, utilizing a split mouth design. The upper labial segment was considered as 'two halves', each consisting of an adjacent central incisor, lateral incisor, and canine. At the initial visit, one half of the segment (left or right) was randomly assigned as the experimental side, the opposite side serving as a control. Prior to bonding, the teeth were polished with a coarse grade prophypaste in a rubber cup. Standardized photographs (transparencies) were taken (Mitchell, 1992). The appliances were bonded using composite resin (Right-on®, TP Orthodontics, UK). Fluoride releasing elastomeric modules (Fluor-I-Ties®, Ortho Arch Company Inc.) were used to secure the arch-wire to the experimental teeth throughout treatment. The control side was secured with conventional non-fluoride-releasing elastomeric modules. The modules on all teeth were changed at each visit. At the end of treatment a second set of standardized transparencies were taken for comparison.

The degree of enamel decalcification was measured subjectively by two examiners, only one of whom had been involved in the treatment. Each transparency was viewed individually over a desktop radiographic light box, in a darkened room. Extraneous light was eliminated by use of a black card 'cut out' over the slide. The examiners sat together and viewed each transparency in turn. The degree of decalcification was assessed by both examiners using a semi-quantitative index based on the Enamel Defect Score (EDS) (Artun and Brobakken, 1986):

0 no visible lesions;
1 grey discoloration;
2 white decalcification (less than half surface area studied);
3 white decalcification (more than half surface area studied);
4 cavitation.

For ease of scoring the clinical crown was theoretically divided into four quadrants, horizontally along the midline and vertically along the clinical long-axis of the crown. Each quadrant was scored, and so four decalcification scores were agreed and recorded for each tooth at each viewing. The transparencies were viewed on two occasions, no less than 1 month apart. Where there was dispute between the examiners a consensus decision was made.

A Wilcoxon signed rank test was used to analyse the non-parametric data.

Results

The patients underwent treatment that involved an average of 17 visits per patient to complete active treatment (at 6-week intervals) over a period of 11–34 months. All 63 control and 63 test teeth were used for analysis, no debonding had occurred during treatment. Table 1 shows the decalcification scores for each tooth type.

TABLE 1 *The mean enamel defect scores before and after orthodontic treatment for each tooth type, with both control and with fluoridated elastomeric modules*

	Pretreatment	Post-treatment
Control		
Median	2	8
Range	0–12	0–13
Fluoridated modules		
Median	2	4
Range	0–11	0–14

There was no statistically significant significance in demineralization at the start of treatment between the experimental and control groups ($P = 0{\cdot}234$).

There was however, a statistically significant difference in the degree of decalcification between the two groups at the end of treatment ($P = 0{\cdot}002$). The experimental side experienced fewer defects than the control side.

Analysis also revealed that more control teeth experienced grade 3 and 4 lesions following treatment than the control side ($P = 0{\cdot}013$).

Discussion

The results of this study revealed that, during the period of treatment, the incidence of decalcification increased for both the control and experimental teeth, and this is in agreement with the literature (Gorelick *et al*., 1982). The difference in the degree of decalcification at the end of treatment was significantly different for control and experimental teeth, with the control group experiencing more decalcification. These results indicate that the fluoride from the elastomers is having a significant and ameliorating effect on the factors causing decalcification.

No patient with active dental disease was accepted for orthodontic treatment or admitted into this trial. Subsequent demineralization was therefore assumed to be due to accumulation of plaque around the orthodontic brackets. The participants of this study were residents of Newcastle upon Tyne, which has a fluoridated water supply, optimized to 1 ppm. Consequently, the incidence of mottling is likely to be higher than non-fluoridated areas, which explains the high incidence of white 'lesions' at the start of treatment. Pre-treatment cavitation in some patients was not as a result of dental caries, but due to small areas of severe fluorosis. Fluorosis is not cumulative after eruption and subsequent cavitation after orthodontic treatment is assumed to be due to decalcification.

The protocol was devised to simulate 'real world' clinical situations: All patients were advised to use a fluoride mouthwash, which is standard departmental policy. If there was accidental loss of modules or debonding during treatment, then at repair the module was replaced by another of the same type as that which was lost. No experimental or control teeth were debonded accidentally during treatment.

When we considered the clinical use of the ties, the clinicians' agreed that these ties were easy to use and were effective in securing the archwire. However, the fluoride ties were noticed to swell slightly between visits, which might have been thought to accumulate more plaque, but this did not appear to eliminate the effectiveness of the fluoride release.

Conclusions

1. The use of fluoride releasing elastomeric modules significantly reduces, but does not eliminate the incidence of decalcification following orthodontic treatment.
2. It is a simple technique requiring no change to clinical practice.
3. The use of fluoride releasing elastomeric modules is a useful adjunct for the orthodontist to minimize iatrogenic decalcification.

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