European Journal of Orthodontics 22 (2000) 401–407

Fluoride-releasing elastomerics—a prospective controlled clinical trial

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SUMMARY A prospective controlled clinical trial was undertaken to evaluate the effectiveness of stannous fluoride-releasing elastomeric modules (Fluor-I-Ties) and chain (Fluor-I-Chain) in the prevention of enamel decalcification during fixed appliance therapy. Forty-nine patients (782 teeth) were included in the experimental group, where the fluoride-releasing elastomerics were used. Forty-five patients (740 teeth) who received non fluoride-releasing elastomerics formed the control group. All patients had their elastomerics replaced at each visit. Enamel decalcification incidence and distribution were recorded using an index by direct clinical observation.

In the control group enamel decalcification occurred in 73 per cent of patients and in 26 per cent of all teeth. In the experimental group the corresponding incidence was 63 and 16 per cent, respectively. The overall reduction in score per tooth produced by the fluoride-releasing elastomerics was 49 per cent, a highly significant difference ($P < 0.001$). A significant difference was seen in all but the occlusal enamel zones. The majority (over 50 per cent) of lesions occurred gingivally. The teeth most severely affected were the maxillary lateral incisors and mandibular second premolars. There was no difference in treatment duration between groups.

Introduction

The prevention of enamel decalcification during fixed appliance treatment remains a challenge to the orthodontist. Daily use by patients of fluoride mouthwashes has been recommended, but suffers from the unpredictability of co-operation which applies to any home medication system (Zachrisson, 1975). Use of enamel sealants to protect the facial enamel surfaces before bracket bonding has been shown to be of minimal benefit (Banks and Richmond, 1994). Sealants currently available either have inadequate durability or do not cure satisfactorily on surface applications.

Fluoride-releasing orthodontic bonding adhesives have been available for several years but long-term clinical trials have shown them to be ineffective in preventing enamel damage (Mitchell, 1992; Turner, 1993; Trimpeneers and Dermaut, 1996; Banks *et al.*, 1997). These composites generally release fluoride over a short time span, which is insufficient to provide protection throughout a 2-year treatment period. Glass ionomer cements have been suggested as alternative bracket bonding materials. Although these provide greater fluoride release, their bond strengths are considered inadequate for clinical use (Millett and McCabe, 1996; Ashcraft *et al.*, 1997; Örtendahl *et al.*, 1997).

Long duration, low-dose fluoride release appears to increase the caries-resistant fluorapatite concentration in enamel (Wiltshire and Janse van Rensburg, 1993) and to reduce demineralization during orthodontic treatment (O'Reilly and Featherstone, 1985). Fluoride released from elastomeric modules and chains would appear to provide such conditions. Wiltshire (1996) measured release from fluoride-releasing elastomeric modules (Fluor-I-Ties) *in vitro*. The results showed that 35 per cent of the total fluoride leached out at day 1, 63 per cent by the end of the first week, and 83 per cent at the end of the first month. The average total fluoride released per 20 modules (the total number normally used in the fully bonded orthodontic clinical case) was 46.22 μgF/ml during the first 5 days, 1.42 μgF/ml after the second week and 0.84 μgF/ml after the fourth week. The magnitude of fluoride released by these modules was considerably higher than that reported for fluoride-releasing chain (Fluor-I-Chain; Joseph *et al*., 1993; Storie *et al*., 1994) and monthly changes of the elastomerics were recommended. It has been suggested that, in such circumstances, sufficient fluoride is released to inhibit enamel demineralization and to promote remineralization (Storie *et al*., 1994).

Fluoride-releasing elastomers have been shown to reduce significantly the salivary levels of *Streptococcus mutans* (Wilson and Gregory, 1995) and to increase significantly enamel micro-hardness levels at 20 μm after 1 month in the mouth (Wilson and Love, 1995). This may offer some protection as it has been shown that natural caries produces a demineralized sub-surface area (Crabb, 1968). The degree of clinical protection to be gained from fluoride-releasing elastomerics remains unproven.

The aim of this investigation was to determine whether fluoride-releasing elastomerics reduce enamel decalcification significantly during fixed appliance therapy when compared with standard elastomerics.

Subjects and method

Two groups of patients were included in this study (Table 1). All subjects were taken from the treatment waiting lists and had been diagnosed as requiring fixed appliance therapy. All patients had to meet a predetermined standard of oral hygiene and gingival health (no plaque deposits visible to the naked eye, but minor deposits detected only by probing permitted; no gingival bleeding on blunt probing around gingival margins permitted). The trial was co-ordinated by one of the authors (PAB) from one hospital unit (Burnley). Patients were allocated alternately to either the control or experimental group. This was performed blind so that the operators had no prior knowledge of the group to which the patient would be assigned. The ratio of male to female patients and mean age before treatment was tested to ensure that the groups showed equivalence. Consent was given and ethical approval for the study was obtained from the local Research Ethics Committee.

Table 1 Patient samples.

	Control group	Experimental group
Male patients	15	16
Female patients	30	33
Total patients	45	49
Mean age (years)	16.5 ± 6.1	15.5 ± 3.5
Maxillary teeth	385	412
Mandibular teeth	355	370
Total number of teeth	740	782

The control group comprised 45 patients (740 teeth) where standard elastomeric modules and chain were to be used during treatment [Elast-O-Loop Ligating Modules, Durachain, Ortho-Care (UK) Limited, West Yorkshire, UK].

The experimental group included 49 patients (782 teeth) where fluoride-releasing modules and chain (Fluor-I-Ties, Fluor-I-Chain, Ortho Arch Company Inc., Illinois, USA) were used, which both release stannous fluoride during intra-oral use. Elastomerics in both patient groups were replaced at each visit (4–6-weekly intervals).

Sample size calculations were based on demonstrating a 20 per cent difference between the groups (with a power of 0.85 and alpha = 0.05) and aimed for a minimum of 40 patients in each group completing treatment. Assignment continued until 50 patients had started treatment in each group.

Patients were treated at the orthodontic departments of two district general hospitals (Burnley General Hospital, Blackburn Royal Infirmary) by three of the authors.

All patients had standard size pre-adjusted edgewise steel brackets and a non-fluoride-releasing, no-mix chemical curing bonding resin (Rely-a-Bond®, Reliance Orthodontic Products Inc., Illinois, USA). All teeth were bonded, apart from molars that were banded and excluded from the study. Enamel etching was confined as far as possible to the area in which the bracket base would be positioned. After bonding, excess composite was removed before setting was complete. Standardized dietary and hygiene advice was given to patients both verbally (by orthodontist and nurse) and by written advice sheets. This included twice daily brushing with conventional and inter-proximal type brushes, and the once daily use of a fluoride mouthwash (Colgate FluoriGuard Daily Rinse—Colgate Palmolive Limited, Guildford, Surrey, UK). To exclude the possibility of pre-treatment scores, teeth with facial restorations or pre-existing white spots or decalcification were excluded.

At the completion of treatment all patients were scored by one clinician (SMC) using an Enamel Decalcification Index (EDI) for individual teeth which has been described and validated previously (Banks and Richmond, 1994). The index is described in Figure 1a. All teeth were dried before scoring was carried out and a dental light was used during the examination. A clinical example of the use of the EDI is shown in Figure 1b.

To test reproducibility 20 patients were re-scored at a subsequent appointment 8 weeks later and the scores were compared using the kappa statistic.

The results were entered into computer spreadsheet files and non-parametric tests were applied using the SPSS 7.5 program [SPSS (UK) Ltd, Woking, Surrey, UK].

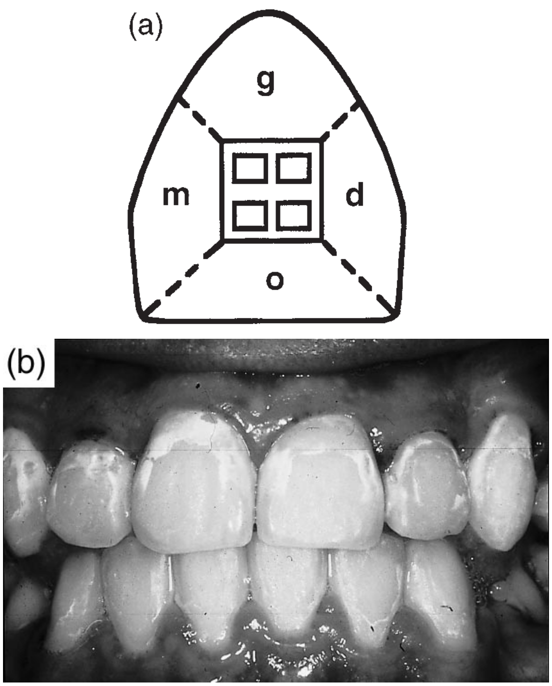

Figure 1 (a) Enamel Decalcification Index (EDI). Each tooth facial surface was divided into four zones: g = gingival; m = mesial; d = distal; o = occlusal. A score was recorded for each zone: 0 = no decalcification, 1 = decalcification covering <50 per cent of the area, 2 = decalcification covering >50 per cent of the area, 3 = decalcification covering 100 per cent of the area or severe decalcification with cavitation. Total score per tooth calculated by summation of individual zonal scores for each tooth. (b) Clinical example of the use of the EDI: 1/ gingival zone shows severe decalcification with cavitation—score = 3. Other scores: mesial = 2, distal = 1, occlusal = 0. Total score for 1/ = 6.

Results

Pre-treatment equivalence of groups

There was no difference between the control and experimental groups for mean age (P = 0.998 using Chi-squared test with continuity correction) or for sex distribution (P = 0.316 using two-tailed t-test) in each group.

Treatment completion rate

Initially, 50 patients started treatment in each group, but four patients from the control group and one from the experimental group were eliminated because treatment was discontinued prematurely. One patient from the control group had incomplete records and was also removed from the study.

Reproducibility

Re-testing EDI scores for reproducibility on 20 cases showed agreement using kappa (Table 2).

Table 2 Reproducibility of EDI scores.

Area	Kappa	Lower 95% CI
Gingival	0.73	0.61
Mesial	0.89	0.77
Distal	1.00	1.00
Occlusal	0.90	0.73

Table 3 Frequency distribution of EDI scores per tooth.

	Total EDI score per tooth											
	0	1	2	3	4	5	6	7	8	9	10	11
Experimental	689	89	30	11	7	1	0	0	0	0	0	0
%	83	11	4	1	1	0	0	0	0	0	0	0
Control	518	95	50	16	6	4	1	4	4	0	0	1
%	74	13	7	2	1	1	0	1	1	0	0	0

Post-treatment decalcification incidence

The proportion of patients with some decalcification at the end of treatment was 73 per cent for the control group and 63 per cent for the experimental group. Sixteen per cent of teeth in the fluoride group showed some decalcification, which was significantly lower than in the control group (26 per cent; $P < 0.001$) using the Chi-squared test with continuity correction. There was a significantly lower score per tooth (49 per cent difference, $P < 0.001$) in the experimental group (median 0.00; range 0.00–6.00) than in the control group (median 0.00; range 0.00–11.00) using the Mann–Whitney test.

Incidence of severe decalcification

In the control group some patients exhibited more severe decalcification than those in the experimental group (Table 3). The maximum EDI score for any patient in the latter group was 14. In the former group, however, there were nine patients (20 per cent) scoring more than this, with the maximum score being 58. It can therefore be seen that the patients in the fluoride-releasing elastomeric group appeared to be protected from the more extreme manifestations of decalcification. Investigating total scores per tooth, only 5.6 per cent of experimental teeth showed a score greater than 1, compared with 12.3 per cent for control group teeth.

Effect upon maxilla and mandible

Comparing total EDI scores for maxillary and mandibular teeth separately, a significant reduction in the experimental group was seen in both using the Mann–Whitney test (maxilla $P < 0.001$; mandible $P < 0.001$).

Zonal distribution of decalcification

The distribution of enamel decalcification was similar in both patient groups (Figure 2). Approximately half occurred in the gingival zones and least was found occlusally. Analysing scores for each tooth zone, a significant difference between the experimental and control groups was detected in the gingival ($P < 0.001$) mesial and distal (both $P < 0.05$) enamel areas using the Mann–Whitney test. The occlusal zones showed no difference ($P = 0.249$).

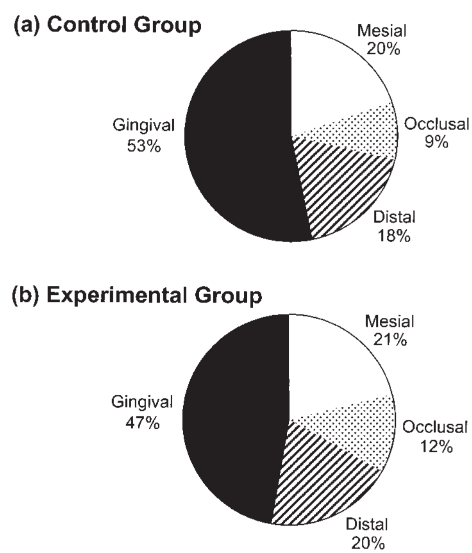

Figure 2 Pie charts showing the zonal distribution of post-treatment Enamel Decalcification Index scores: (a) control group; (b) experimental group.

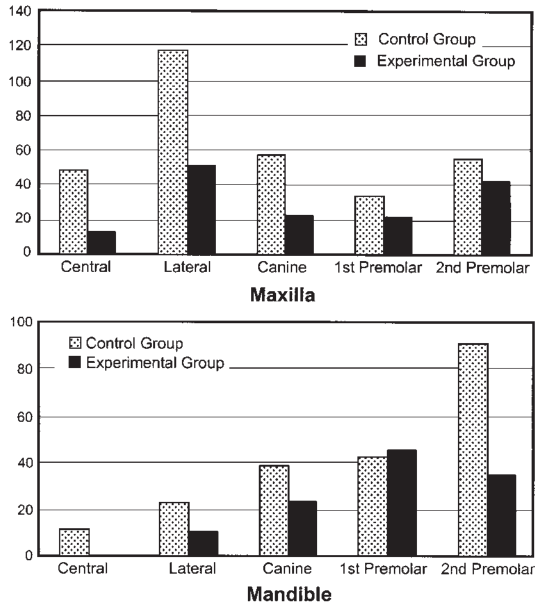

Figure 3 Enamel Decalcification Index expressed as a total score per 100 teeth for individual tooth types.

Severity of decalcification in different tooth types

The differences for individual tooth types are shown in Figure 3. In the maxilla the lateral incisors and in the mandible the second premolars suffered the most decalcification in the control group. In the experimental group, however, this was greatly reduced by over 50 per cent for each.

Treatment time

There was no significant difference in treatment time between the groups (mean for control group 1.7 ± 0.66 years; mean for experimental group 1.6 ± 0.42 years) using the independent t-test ($P = 0.25$).

Discussion

This clinical trial supports some of the *in vitro* studies that have suggested that fluoride released from elastomeric modules and chains is sufficient to provide significant enamel protection throughout a full course of multi-bond treatment. Although the incidence of lesions in patients was still high in the experimental group, significantly fewer teeth were affected. The overall 49 per cent reduction in decalcification scores compared with the control group was clinically significant and worthwhile. This shows that benefit was gained both by a reduction in the incidence and the severity of decalcification. The presence of minor decalcified lesions after treatment is less likely to be of such clinical concern. To gain maximum protection, fluoride-releasing elastomerics should be used as a part of a preventive regime of good oral hygiene, including fluoride toothpaste and fluoride mouthwashes although, as mentioned above, these are dependent upon good patient compliance, which cannot be predicted accurately.

The zonal distribution of lesions is broadly consistent with that of two earlier publications (Banks and Richmond, 1994; Banks *et al*., 1997), although the occlusal zone showed a higher incidence in this study. This may reflect the inter-examiner variability. A significant reduction in decalcification was seen in all enamel areas except in the occlusal zone. This can be explained by the fact that it is the least common site for lesions and provides easiest access for toothbrushing. The gingival zone showed the greatest reduction. This would be anticipated as oral hygiene measures are more problematic in this area, particularly in the presence of gingival hyperplasia. In addition, earlier research has shown that the area of greatest demineralization occurs immediately cervical to the bracket (O'Reilly and Featherstone, 1987).

It was encouraging to note that the tooth types most badly affected by decalcification in the control group (maxillary lateral incisors, mandibular second premolars) together with the maxillary central incisors showed the greatest benefit from the fluoride released in the experimental group. All individual tooth types showed less decalcification in the experimental group teeth than in the control group teeth, apart from the mandibular first premolars. This reversal could not be readily accounted for, but was small numerically.

The incidence of decalcification in the control group was comparable with that in a previous study (Banks and Richmond, 1994), but was slightly higher than that in a later investigation (Banks *et al*., 1997). This may reflect differences in patient samples or variability of scoring produced by different clinicians. Although decalcification incidence in this study appears high, only a small percentage of teeth were severely affected.

It was also important that treatment times were not prolonged, as the clinical impression was that the fluoride-releasing elastomerics used showed a more rapid deterioration in the oral cavity with swelling and apparent loss of elastic properties 2–3 weeks after insertion. This is probably explained by the deterioration in elastic properties occurring after initial tooth movement was complete. Baty *et al*. (1994) reviewed the force degradation of synthetic elastomeric chains. After 1 week in distilled water, conventional grey chain retained 38 per cent of its initial force, whilst Fluor-I-Chain retained only 14 per cent. Fortunately, this loss of properties did not result in elastomeric failure in this study and generally replacements were not required outside the normal scheduled visits.

A minor disadvantage of the fluoride-releasing elastomerics was their apparently reduced ease of use clinically. The modules were less elastic, rendering figure-of-eight ligating impossible. Patients disliked the staining and swelling of the elastomerics. Finally, the modules are not currently available in different colours, which may be problematic in some practice situations. Improvements in these areas would be a worthwhile development for future products.

Conclusions

1. The use of fluoride-releasing elastomeric modules and chains reduced post-fixed appliance treatment enamel decalcification scores per tooth by 49 per cent. This difference was highly significant ($P < 0.001$).
2. Enamel decalcification after treatment was seen in 26 per cent of teeth and in 73 per cent of patients in the control group where standard elastomeric modules and chain were used. For the experimental group where fluoride-releasing modules and chain were used, 16 per cent of teeth and 63 per cent of patients were affected. The reduction in the incidence of decalcification in the experimental teeth was highly significant ($P < 0.001$).
3. Significant differences in decalcification between groups were seen in all but the occlusal enamel zones.
4. There was no difference in treatment time between the two groups.
5. Fluoride-releasing elastomerics appear to provide a clinically worthwhile reduction in enamel decalcification during fixed appliance therapy when they are changed at each treatment visit.

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Acknowledgements

The authors wish to thank Professor K. O'Brien for advice on the design of the trial.

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