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SCIENTIFIC SECTION

Fluoridated elastomers: effect on disclosed plaque

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Objective: *To investigate the effect of fluoridated elastomers on the quantity of disclosed dental plaque surrounding an orthodontic bracket* in vivo.

Design: *A randomized, prospective, longitudinal clinical trial, employing a split mouth, crossover design.*

Setting: *The Orthodontic Departments of Liverpool and Sheffield Dental Hospitals.*

Subjects and methods: *The subjects were 30 individuals about to start fixed orthodontic treatment. The study consisted of two experimental periods of 6 weeks with a washout period between. Fluoridated elastomers were randomly assigned at the first visit to be placed around brackets on 12, 11, 33 or 22, 21, 43. Non-fluoridated elastomers were placed on the contra-lateral teeth. After 6 weeks (visit 2) the elastomers were removed, the teeth disclosed and a photograph taken. Non-fluoridated elastomers were placed on all brackets for one visit to allow for a washout period. At visit 3, fluoridated elastomers were placed on the contra-lateral teeth to visit 1. At visit 4, the procedures at visit 2 were repeated. The photographs were scanned, then the area and proportion of the buccal surface covered with disclosed plaque was measured using computerized image analysis. A mixed-effects ANOVA was carried out with the dependent variable being the area or percentage area of disclosed plaque.*

Results: *There was no evidence of a systematic error and substantial agreement for the repeat readings of the same images. The only significant independent variable for the area of disclosed plaque was the subject ($p < 0.001$). The significant independent variables for the proportion of disclosed plaque were the subject ($p < 0.001$) and the tooth type ($p = 0.002$). The independent variable describing the use of fluoridated or non-fluoridated elastomers was not significant for either the area or the proportion of disclosed plaque.*

Conclusion: *Fluoridated elastomers do not affect the quantity of disclosed plaque around an orthodontic bracket.*

Key words: *Orthodontics, dental plaque, fluoride, elastomers, randomized clinical trial, image analysis*

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Introduction

Fluoridated elastomers have been shown to release fluoride for up to 6 months[1] *in vitro*. A micro-hardness study[2] on enamel from teeth extracted for orthodontic reasons after four weeks with either fluoridated or non-fluoridated elastomers has suggested that the teeth with fluoridated elastomers had harder surface enamel. Two clinical trials[3,4] have suggested that the use of fluoridated elastomers reduces the severity and possibly the incidence of demineralization during orthodontic treatment. When bacterial colonization is considered, Wilson and Gregory[5] demonstrated a significant reduction in the salivary *Streptococcus mutans* count of patients after 1 week with fluoridated elastomers. However, levels rose to baseline values after 2 weeks.

The objective of this study was to investigate the effect of fluoridated elastomers on the area of disclosed dental plaque surrounding an orthodontic bracket *in vivo* after a clinically relevant time in the mouth.

Materials and methods

This was a prospective, randomized clinical trial, employing a split mouth, crossover design. Volunteers were recruited from patients about to start their orthodontic treatment with upper and lower fixed appliances in the orthodontic departments of Liverpool University Dental Hospital and the Charles Clifford Dental Hospital, Sheffield. It was a requirement at both departments that patients demonstrated good oral hygiene prior to starting

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treatment. Patients who were pregnant, diabetic, using an antimicrobial mouthwash, using any complicating medicine or patients with a history of antibiotic use in the last 2 months were excluded.

Ethical approval was obtained from the two Local Ethics Committees. Eligible patients were invited to participate in the study at a visit before the fixed appliances were placed. Informed, written consent was given by the patients and their parents agreeing to enter the study on the visit the appliances were placed. This was usually 2 weeks after the initial discussion.

The following procedures were carried out.

Visit 1

The fixed appliance brackets and bonds were placed. The patients were randomly allocated to having the fluoridated elastomers (Fluor-I-Ties; OrthoArch, Schaumburg, IL 60173, USA) either on the upper left lateral incisor, upper left central incisor and lower right canine, or the upper right lateral incisor, upper right central incisor and lower left canine. These teeth were chosen because they demonstrate a high prevalence of post-orthodontic demineralization[6] and their visibility at the front of the mouth makes prevention of unsightly white spots important. The randomization was carried out by the principal author (PEB), using computer generated random numbers in a block design. Most of the patients were recruited and treated by the third author (IFC). The allocation was concealed in consecutively numbered, sealed, opaque envelopes, which were opened just prior to placing the first elastomers. No attempt was made to mask the patients or clinician to the allocation. Conventional non-fluoridated elastomers were placed on the remaining teeth. The patients were provided with a standard fluoridated toothpaste (Aquafresh; monofluorophosphate 0.75% w/w and sodium fluoride 0.01% w/w total fluoride 1055 ppm SmithKline Beecham Consumer Healthcare, SB House, Great West Road, Brentford, Middlesex TW8 9BD, UK), with no antimicrobial ingredients and a daily fluoride mouth rinse [Fluorigard, 0.05% NaF Colgate-Palmolive (UK) Ltd, Colgate Oral Care, Guildford, Surrey, GU2 5BR, UK].

Visit 2

Six weeks later, at the first adjustment appointment, the elastomers on the upper incisors and lower canines were removed. The teeth were disclosed with a disclosing agent (Plaque Finder™, Rotadent, St Neots, PE13 3TP, UK) the patient rinsed out for at least 30 seconds. Self-retaining cheek retractors were placed. A jig constructed of 0.021×0.028 inch stainless steel wire was placed in the bracket slot and an elastomeric ligature used to hold it in place (Figure 1). The jig consisted of one long and one short arm, which were lined up to achieve a consistent angle to the photograph. The photographs were taken using a standardized technique as previously described.[7]

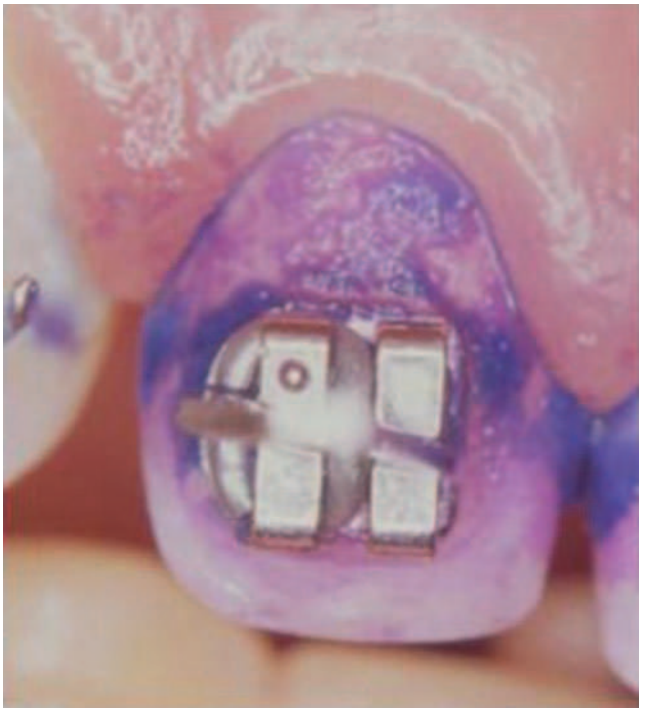

Figure 1 Image of a lateral incisor with disclosed plaque showing the aligning jig in the bracket slot

Following the photographs, the adjustment to the appliance was carried out and non-fluoridated elastomers were placed on all the teeth to allow for a washout period of at least 6 weeks.

Visit 3

The appliance was adjusted and the fluoridated elastomers placed on the contra-lateral teeth to the first appointment. Therefore, if at appointment 2 the patient had the fluoridated module placed on the upper left incisors and lower right canine, at appointment 3 the fluoridated module was placed on the upper right incisors and lower left canine. Non-fluoridated elastomers were placed on the remaining teeth.

Visit 4

Six weeks later, the procedures carried out during appointment 2 were repeated.

Capturing the images

The images were captured using a slide scanner (Cano Scan 2700F; Canon Inc., Tokyo, Japan) and computer

software (Scancraft FS version 3.1.1 Canon Inc., Tokyo, Japan). They were converted to high-resolution TIFF images. They were recoded by one investigator (PEB), placed in a random order and measured by another investigator (AAS) who was blind to the coding and reasons for the study. The method used to measure the disclosed plaque has been previously described.[8] The area of disclosed plaque was measured using the known width of the bracket (measured using an electronic caliper) to calibrate the image. The bracket was digitally removed from the image prior to measurement, to exclude any plaque on the bracket, rather than the tooth surface. The proportion of the buccal surface covered by disclosed plaque was assessed by measuring the total area of the labial surface and expressing the area of disclosed plaque as a proportion of this figure.

Statistics

Sample size calculation. This investigation was part of a wider study into the effect of fluoridated elastomers on the *Streptococcus mutans* count. The sample size calculation was based on this wider study. Using data from two previous studies,[9,10] it was calculated that a sample size of 30 would be sufficient to detect a difference in *Strep. mutans* count of 30% to a power of 0.85 with a significance level of 0.05.

Reproducibility. This was assessed from the results of the repeat readings on 30 images using an intra-class correlation coefficient for random error and the one-sample *t*-test for systematic error.

Hypothesis testing. A mixed effects ANOVA was used. The dependent variable was either the area or the percentage area of disclosed plaque. These data were log transformed as they were found to be positively skewed. The random variable was the subject. The fixed factors included gender of patient, visit, fluoride or non-fluoride elastomeric, upper or lower jaw, side of mouth, dominant or non-dominant tooth brushing hand side, and tooth type. Covariates included age and the number of days the elastomer was in place.

Results

Thirty-four patients were recruited to the study. There were 22 females and 12 males. It was decided to recruit increased numbers, because more samples were lost due to failure of the elastomers between appointments and debonding of brackets than was expected. The average age was 14.0 years (SD 1.8, range 11.8–20.6). A total of 333 images were collected. Ten images were too dark to analyse and one was out of focus.

Table 1 Reproducibility carried out on repeated readings from 30 slides, where ICC is intra-class correlation coefficient and p is the significance level of the one sample t-test

	ICC	p
Area of plaque	0.79	0.20
Percentage area of plaque	0.71	0.86

The results of the reproducibility study are shown in Table 1. There was no evidence of a systematic error. The intra-class correlation coefficient was 0.79 for the measurement of plaque area and 0.71 for the percentage surface covered, which suggests acceptable agreement.

The result of the mixed effects ANOVA for the area of disclosed plaque is shown in Table 2. The only significant independent variable was the subject ($p < 0.001$). The result of the mixed effects ANOVA for the percent area of disclosed plaque is shown in Table 3. The significant independent variables were the subject ($p < 0.001$) and the tooth type ($p = 0.002$). The independent variable describing the use of fluoridated or non-fluoridated elastomers was not significant for either the area or the proportion of disclosed plaque. To examine the effect of tooth type on the percent area of disclosed plaque boxplots showing the median, interquartile and range values are displayed (Figure 2). These suggest that the lateral incisors have a slightly higher proportion of the buccal surface covered by plaque than the central incisors and the right side is slightly higher than the left.

Discussion

This study has shown that, after a clinically relevant period of time in the mouth, there were no significant differences in the area or percentage area of the tooth covered with disclosed plaque when fluoridated elastomers were used compared with conventional elastomers. It must be concluded, therefore, that fluoridated elastomers are not effective at reducing plaque surrounding an orthodontic bracket.

The reason for this might be explained by the current theories concerning the mechanism of action of fluoride in the prevention of demineralization. Although it has been shown that fluoride influences many metabolic and growth activities in bacteria, the general view is that this occurs at levels of fluoride far higher than that reached in the mouth.[11] While a large amount of fluoride is released from fluoridated modules in the first few days, this quickly descends to a low level that is unlikely to affect plaque bacteria.[1] Wilson and Gregory[5] found that the number of salivary *Streptococcus mutans* was reduced in

Table 2 Results of the mixed effects ANOVA where the dependent variable was the area of disclosed plaque

Variable	*p*
Fluoride or non-fluoride ligature	0.243
Tooth type	0.321
Upper or lower	0.988
Left or right	0.404
Tooth brushing hand	0.455
Visit	0.116
Subject	<0.001
Age	0.298
Gender	0.615
Number of days in the mouth	0.501

Table 3 Results of the mixed effects ANOVA where the dependent variable was the percentage area of disclosed plaque

Variable	*p*
Fluoride or non-fluoride ligature	0.139
Tooth type	0.002
Upper or lower	0.587
Left or right	0.316
Tooth brushing hand	0.596
Visit	0.506
Subject	<0.001
Age	0.183
Gender	0.563
Number of days in the mouth	0.881

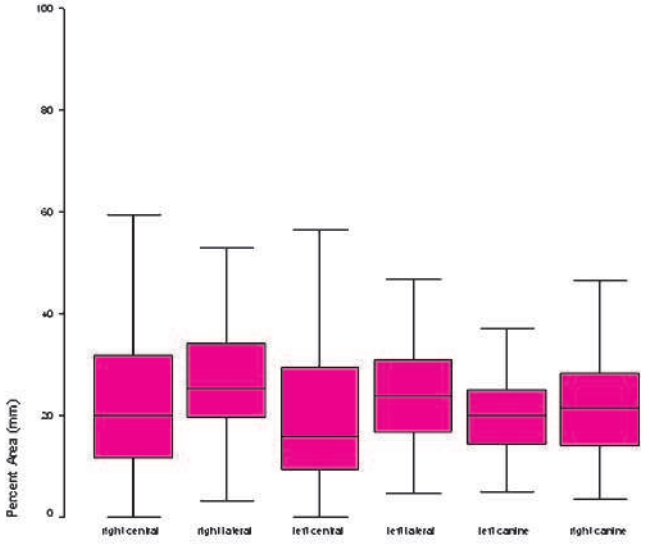

Figure 2 Boxplots showing the median, interquartile and range for the percentage area of disclosed plaque for the six tooth types studied

patients with fixed appliances after 1 week wearing fluoridated elastomerics. However, the number of bacteria rose to baseline levels during the second week.

This study might be criticized for using a split mouth design. A split mouth design is a common method of investigating the effects of materials in the mouth and was used in a previous clinical trial of fluoridated elastomerics.[4] Theoretically, because the material is being testing in the same mouth at the same time, it reduces the inter-participant differences and increases the power of a study. However, fluoride from the fluoridated elastomers might have crossed the mouth and affected the elastomers on the non-fluoride side, thereby reducing the effectiveness of the fluoridated elastomers. Wiltshire recognized this in his split mouth study.[12] It is unlikely that, after several days, the levels of fluoride absorbed by the non-fluoridated elastomers from the fluoridated elastomers will be sufficient to affect the metabolism of plaque bacteria. In addition, this amount of fluoride will be small in comparison with the overall exposure of the elastomer to dietary and therapeutic fluoride in the form of toothpastes and mouth rinses.

This study might also be criticized for having too small a sample size to detect a significant difference. The estimation carried out before the start of the study of a suitable sample size was made for a wider investigation into the effect of fluoridated elastomers on the *Streptococcus mutans* count. There was a lack of data upon which to base a sample size calculation for a primary outcome of reduction in plaque area. However, when this is the case, it is possible to use the actual data from the study to estimate the power of the study retrospectively. When this was performed we estimate that the present investigation has a power of over 0.90 to detect a 20% reduction in plaque, which we consider to be a clinically significant level.

The only independent variable that was statistically significant for both the area and proportion of the buccal surface covered with disclosed plaque was the subject. This highlights the need for clinicians to give advice to individual patients concerning levels of oral hygiene required to adequately maintain fixed appliances.

We found no significant differences in plaque by gender or age. However, tooth type was a significant variable for the percentage area of the buccal surface covered with plaque. It appeared that lateral incisors have a higher proportion of the buccal surface covered with plaque than central incisors. It is a common finding that lateral incisors have a higher prevalence of white spot lesions following orthodontic treatment than central incisors.[6] It would also appear that the right side had a higher proportion of the tooth surface covered with plaque than the left. This would agree with other studies[13,14] that have found a higher amount of plaque on the right side of right-handed tooth brushers than on the left. Most of the participants in this study were right-handed.

The reproducibility was slightly lower than a previous study using the same technique.[8] There was no evidence of a systematic error, but the random error showed substantial, rather than excellent agreement. The teeth in the current investigation had orthodontic brackets on the labial surface. To obtain an accurate measurement of the plaque on the tooth surface it was necessary to trace around the bracket by hand, using the computer mouse and remove it from the image. This introduced several extra steps in the assessment process and may explain why the random error is increased.

Although fluoridated elastomers have not been shown to be effective against plaque, they might still have a positive effect on the de/remineralization balance, thereby reducing the prevalence[3] and severity[4] of white spot lesions following orthodontics. The concentration of fluoride at the plaque-enamel interface is important in preventing enamel caries.[15] It has been shown that very low levels of fluoride (sub ppm) can have a positive effect on enamel de/remineralization.[16] The use of glass ionomer cement to bond orthodontic brackets has been shown to increase salivary[17] and plaque fluoride.[18] Fluoridated elastomers release small amounts of fluoride *in vitro* for up to 6 months,[1] potentially increasing plaque fluoride sufficiently to tip the balance toward remineralization of enamel, rather than demineralization.

It is also possible that elastomers imbibe fluoride from the oral environment as well as release it. Wiltshire[12] found that both the fluoridated and non-fluoridated elastomers collected after 4 weeks in the mouth released more fluoride when placed in a test tube for 24 hours, than the equivalent elastomers that had been placed in a test tube for one month. By retaining the fluoride close to the enamel, this might also be an effective means of reducing demineralization. The effect of fluoride release and recharge from both fluoridated and non-fluoridated elastomers on the levels of fluoride in plaque would be a useful area of further investigation.

Conclusions

1. Fluoridated elastomers do not affect the quantity of disclosed plaque around an orthodontic bracket.
2. The individual patient's level of oral hygiene is the most important factor determining the area or proportion of the buccal surface covered with disclosed plaque.
3. Further work is required to determine the effect of fluoridated elastomers on plaque fluoride levels.

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Contributors

Philip Benson was responsible for study design, obtaining funding, administrative support and data interpretation, and the drafting, critical revision and final approval of the article. Isla Campbell was responsible for recruitment of participants and data collection, critical revision and final approval of the article. Anwar Shah was responsible for data collection, critical revision and final approval of the article. Philip Benson is the guarantor.

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