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Research Article

The Effect of Repeated Fluoride Foam Applications on Demineralization Observed in Orthodontic Patients

Anil Ardeshna* and Rachel Bellan

Department of Orthodontics, Rutgers School of Dental Medicine, USA

***Corresponding Author:** Anil Ardeshna, Department of Orthodontics, Rutgers School of Dental Medicine, USA.

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Abstract

The purpose of this study was to investigate the effects of frequent (every 4 - 6 weeks) treatments of acidulated phosphate fluoride foam on demineralization in patients with fixed orthodontic appliances and to evaluate if a crossover effect was present when applying fluoride treatment to only one side of the maxillary dentition. This was a double-blinded, randomized, placebo-controlled clinical study, which took place over a 6 - 9 months period. A split-mouth study design was utilized, in which 50 patients (mean age 12.9 + 1.6), were divided into 2 groups. Group one received monthly fluoride treatments (Oral-B Minute-Foam; Procter and Gamble, Cincinnati, OH) on one side of the maxillary arch (F) and no treatment on the opposing side (FC). Group two received a placebo treatment on one side of the maxillary arch (P) and no treatment on the opposing side (PC). Three examiners scored initial and final photographs of maxillary lateral incisors to evaluate demineralization. A mean demineralization progression score (final-baseline) was determined for each of the four groups. The lowest incidence of demineralization unexpectedly occurred in the fluoride control group (1.20), followed by the fluoride (1.52), placebo control (1.57), and placebo group (1.75). No significant difference in demineralization was found between the any of the four groups, nor could a significant crossover effect be demonstrated. The only variable that was found to be significant was oral hygiene. It was concluded that frequent applications of acidulated phosphate fluoride foam on patients with fixed orthodontic appliances had no statistically significant effect on the incidence of demineralization. Good oral hygiene was the only factor to significantly reduce the incidence of demineralization.

Keywords: Fluoride Foam; Demineralization; Orthodontic Patients

Background

Demineralization is also referred to as decalcification, white spot lesion (WSL), or early enamel caries. Its development occurs when microbial plaque, a composition of bacteria that causes cavities, food debris, salivary components, and dead mucosal cells, form a sticky organic matrix on the tooth surface. When the cariogenic bacteria in the plaque encounter dietary carbohydrates, organic acid production occurs, leading to a decrease in the intra-oral pH. At a critical pH (5.5), the enamel surface begins to dissolve causing the release of calcium, phosphate, and carbonate; this is clinically manifested as a "White Spot Lesion." If this process continues, these lesions will progress into cavitations [1].

Patients undergoing fixed orthodontic treatment are at an increased risk of developing decalcification. This is because brackets allow for an increase in plaque retention to the tooth surface, oral hygiene is harder and more time consuming, the patient may lack inherent resistance and there is an increase sugar consumption of teenage orthodontic patients [2]. Patients with fixed orthodontic appliances have been reported to have a 49.6% incidence of having at least one tooth containing white spot formation, while untreated patients have only a 24% incidence [3]. Øgaard concluded that 5-years after treatment, orthodontic patients still had significantly more demineralization than those who had never undergone treatment [4]. Development may occur within a 4-weeks span, which is usually the time between regular orthodontic appointments [5]. Maxillary lateral incisors have been reported to have the highest incidence of decalcification in untreated and orthodontically treated patients. This may be due to the fact that they are not in an area of free-flowing saliva (no salivary glands nearby) and that there is a smaller distance between the gingiva and bracket than other teeth, allowing for an increased retention of plaque [3].

Orthodontic patients are considered to be in the high-risk group for development of cavities [6]. Additional measures must be taken to prevent white spot lesions and cavities in these patients. This is important for both the health and esthetics of the patient's dentition. Fluoride is considered to be the most important cavity preventive agent. When applied to the dentition, fluoroapatite crystals are formed on the tooth's surface and produce a lower solubility (less susceptible to break down) in the event of an acid attack. The critical pH (required for demineralization) becomes 4.5 rather than the normal 5.5; meaning a more acidic pH is needed to produce demineralization. This helps to inhibit demineralization and promote remineralization [7].

Orthodontists have utilized multiple fluoride-containing products in hopes of reducing white spot lesions in patients with fixed appliances. Some of these products include mouthrinses, toothpastes, fluoride varnishes, sealants, self-etching primers, glass ionomer cements, elastomeric ties and composite resins. Fluoride gels and foams are the most commonly used topical fluoride in the United States. Treatments are routinely applied every 6-months at regular dental visits. These products contain acidulated phosphate fluoride (APF), including 1.23% fluoride in the form of sodium fluoride at a 3.0 pH [6]. One product, Oral-B Minute-Foam (Procter & Gamble, Cincinnati, OH), only requires a one-minute application time according to manufacturer's instructions. If administered in the proper manner, using foam-lined trays and suction during treatment, the risk of side effects is said to be minimal [6].

Numerous studies have researched many of these fluoride-containing products to evaluate their effects on demineralization formation in patients undergoing fixed orthodontic treatment. Øgaard., *et al.* compared two parallel groups using either 0.2% sodium fluoride mouthrinse daily or no mouthrinse. Results showed that the group who utilized the fluoridated mouthrinse had an 80% reduction in mineral loss and a reduction in lesion depth by a factor of 3, when compared to the control group [8]. Stecksen-Blicks., *et al*. evaluated the effects of Fluor Protector (Ivoclar Vivadent, Schaan, Liechtenstein) fluoride varnish on white spot lesions in patients with fixed orthodontic appliances. The incidence of demineralization was found to be 7.4% in the fluoride varnish group compared to 25.3% in the placebo group [9]. Banks., *et al*. compared the use of fluoridated and non-fluoridated elastomeric ties to assess for white spot formation. There was found to be a 49% reduction in decalcification per tooth when fluoridated ties were used compared to the non-fluoridated ties [10].

The purpose of this investigation is to determine if frequent (every 4 - 6 week) treatments of acidulated phosphate fluoride (APF) foam will decrease the incidence of white spot lesions in orthodontic patients and to determine if there is a crossover effect when applying fluoride treatment to only one side of the maxillary dentition.

Methods and Materials

This was a double-blinded, randomized, placebo-controlled clinical study, which took place over a 6 - 9 months period for each patient. The subjects consisted of 50 consecutive patients (28 boys, 22 girls) between the ages of 11-17, who began comprehensive orthodontic treatment at the Dental School. The mean patient age was 12.9 + 1.6 years. Patient criteria for inclusion were that both maxillary lateral incisors had to be present and fully erupted, the patient had to be receiving at least maxillary fixed orthodontic appliances, and that maxillary lateral incisors had to be bracketed at initial bonding appointment. Exclusion criteria included patients with cavities or restorations (filling, veneer, crown) on either maxillary lateral incisor, who had diminutive or severely rotated maxillary lateral incisors, those patients not on a routine orthodontic schedule (4 - 6 weeks), those patients who missed any treatments within the 6 - 9 months study, and those patients who received fixed inter-arch appliances (MARA or Herbst). A questionnaire was administered to determine if patients utilized fluoridated water or toothpaste, how many times a day they brush and floss, if they are right or left handed, what other oral hygiene practices they utilize, and if they have had previous orthodontic treatment.

A split-mouth study design was utilized. There were two treatment groups each containing 25 subjects. Group one received fluoride treatment (Oral-B Minute-Foam; Procter and Gamble, Cincinnati, OH) on one side of the maxillary arch (Fluoride [F]) and no treatment on the opposing side (Fluoride Control [FC]). Group two received a placebo treatment on one side of the maxillary arch (Placebo [P]) and no treatment on the opposing side (Placebo Control [PC]). Patients were both the experimental group and their own control. The determination of which side of the mouth was to receive applications, as well as, which patient received the placebo versus the fluoride treatment was randomized. The same side received the application at each visit.

Baseline intra-oral photographs were taken of each patient prior to bracket placement. The teeth were free of debris and dried first. One photo of each (right and left) maxillary lateral incisor was taken (2 photos total). In order to standardize the photographic method, one investigator took all the photos (RB), the same digital camera (Fuji S2 SLR) was used along with standardized settings (manual (M) setting, point flash turned upside down, F-stop 27, Exposure 1/60 sec, 3024 X 2016 resolution), the pictures were all taken in the same location to avoid different effects of light, and the focal length of the camera was set at 10 inches so that the distance of the camera to the tooth was uniform among all subjects.

Orthodontic residents placed brackets using a standardized bonding technique. Victory series mini brackets, MBT or Roth prescription (3M Unitek, Monrovia, CA), were used in this study. After initial bonding and wire placement, patients were asked to brush and then received a unilateral "maxillary" application of APF foam or placebo treatment in a sectioned foam tray. Treatment was administered for 1-minute utilizing suction to prevent ingestion. A smaller sectional mouth tray was constructed to cover the contralateral (non-treated) lateral incisor to prevent exposure. Even with these precautionary measures, the risk of a crossover effect could be questioned within this study due to the potential leakage of the fluoride treatment. For this reason, two patient groups (fluoride and placebo) were included. These two groups were further divided, for a total of four groups, consisting of fluoride and fluoride control (same person) and placebo and placebo control (same person). This allowed studying the presence of a crossover effect. At the end of each routine Orthodontic appointment (4 - 6 weeks), patients were asked to brush to remove debris and the treatment was then administered to the assigned quadrant. Successful completion of the study occurred after 6 consecutive applications (6 - 9 months). Subjects were not asked to refrain from getting routine (every 6 months) fluoride applications from their general dentist.

At the visit following the subject's last (sixth) treatment, final intra-oral photos were taken using the standardization technique discussed. Teeth were free of debris and dried first. Five photos, captured from different angles, were taken of each maxillary lateral incisor: centered, gingival, mesial, distal, and occlusal (incisal). This was to avoid a shadow, which may be cast on the tooth from the bracket.

The maxillary lateral incisors of each patient were compared for incidence of decalcification. The examiners (3 orthodontic faculty) were blinded, as they were not involved in the clinical aspect of this research. All baseline and final photos were placed, in random order, into a PowerPoint presentation that was placed on a projector for evaluation. Six randomly selected lateral incisor photos were duplicated within the arrangement to determine intra-examiner reproducibility and inter-examiner agreement. Analysis of the white spot lesions occurred by use of the Enamel Decalcification Index (EDI) developed by Banks and Richmond [11]. This index (Figure 1) divides the tooth into 4 zones: mesial, distal, gingival and occlusal. Each zone is designated a number based on the incidence and severity of the demineralization and then all four numbers are added together for a cumulative tooth score. Allocation of scores: 0 = no demineralization; 1 = demineralization occupying < 50% of area; 2 = demineralization occupying > 50% of area; 3 = demineralization occupying 100% of area or severe demineralization with cavitation. Examiners were instructed and calibrated on the evaluation process prior to initiation.

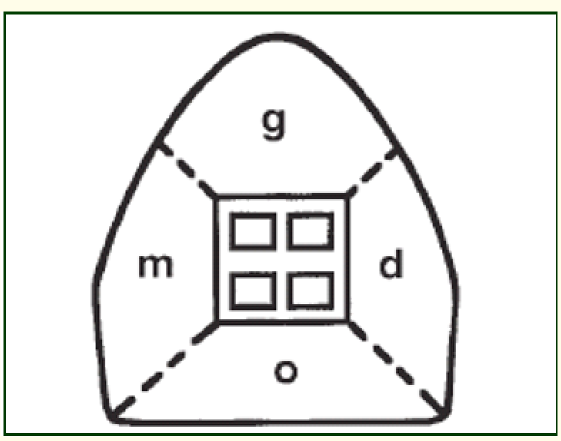

Figure 1: Enamel Decalcification Index [11].

Results

Sample size was calculated on the basis of demineralization incidence reported by Vivaldi-Rodrigues., *et al* [12]. Alpha (α) value was set at 0.05 and beta (β) value was set at 0.2. It was determined that twenty subjects were required to find a 20% difference between the treatment groups. Fifty subjects (25 - 25) were included to account for patient dropout rate, which was based on clinical experience. Of the 50 patients that were enrolled, 11 subjects were dropped from the study, leaving 39 completions. All dismissals were due to missed appointments.

Spearman correlation determined that the intra-examiner reproducibility for evaluator 1 was 0.708, evaluator 2 was 0.586, and evaluator 3 was 0.687. This analysis also determined that there was a 0.759 inter-examiner agreement.

The mean demineralization progression scores (final-baseline) for each group are displayed in the paired t test tables (Table 1 and 2). The placebo group developed the highest (1.75 + 1.87) incidence of demineralization. The placebo control had the second highest (1.57 + 1.13) amount of white spot development, followed by the fluoride group (1.52 + 2.54). The group with the lowest incidence of demineralization was the fluoride control (1.20 + 1.45).

Paired t test				
Group	**N**	**Mean**	**SD**	**P**
Fluoride (F)	18	1.52	2.54	0.621
Fluoride Control (FC)	18	1.20	1.45	

Table 1: Comparison of incidence of white spot lesions between fluoride group and fluoride control.

Paired t test				
Group	**N**	**Mean**	**SD**	**P**
Placebo (P)	21	1.75	1.87	0.642
Placebo Control (PC)	21	1.57	1.13	

Table 2: Comparison of incidence of white spot lesions between placebo group and placebo control.

A paired t test compared the mean demineralization progression scores between the lateral incisors that were treated with fluoride and those that were the fluoride control (Table I). Another paired t test was then used to compare the mean demineralization progression scores between the lateral incisors that were treated with the placebo and those that were the placebo control (Table II). Both paired t tests proved to be not statistically significant ($p > 0.05$) and therefore only the fluoride and placebo groups (not controls) were used for further analysis.

Analysis of Variance (ANOVA) was carried out utilizing the fluoride (F) and placebo (P) groups to determine if there was a difference in mean demineralization scores within variables and to establish if the variables had any independent effect on demineralization scores (Table 3). This analysis established that there was no significant difference in mean demineralization scores between fluoride and placebo groups in the presents of other variables ($p > 0.05$). Of all the variables, oral hygiene was the only variable to show a statistically significant difference in mean demineralization scores. The results indicated that the group with fair (F) oral hygiene had a higher marginal mean demineralization score (3.449) than the group with good (G) oral hygiene (1.371).

ANOVA					
Fluoride (F) and Placebo (P)					
Source	**Type III Sum of Squares**	**Df**	**Mean Square**	**F**	**Sig. (p)**
Group (F vs. P)	2.091	1	2.091	.460	.503
Age	.495	1	.495	.109	.744
Sex	1.718	1	1.718	.378	.543
Bracket Rx	.337	1	.337	.074	.787
Oral Hygiene	21.984	1	21.984	4.837	.035*
Other Oral Hygiene Practices	8.963	1	8.963	1.972	.170

Table 3: Analysis of Variance evaluating fluoride and placebo groups.

* p value showing a statistical significance

Analysis of Variance (ANOVA) was also conducted utilizing the fluoride control (FC) group and placebo (P) group (Table 4) to evaluate the presence of a crossover effect. There was no significant difference in mean demineralization scores found between the fluoride control and placebo groups in the presents of other variables ($p > 0.05$). Of all the variables, oral hygiene was once again the only one to have a statistically significant difference in mean demineralization scores. The results indicated that the group with fair (F) oral hygiene had a higher marginal mean demineralization score (2.605) than the group with good (G) oral hygiene (1.050).

ANOVA					
Fluoride Control (FC) and Placebo (P)					
Source	**Type III Sum of Squares**	**Df**	**Mean Square**	**F**	**Sig. (p)**
Group (FC vs. P)	7.148	1	7.148	2.771	.106
Age	2.502	1	2.502	.970	.332
Sex	1.592	1	1.592	.617	.438
Bracket Rx	.295	1	.295	.114	.737
Oral Hygiene	12.304	1	12.304	4.769	.036*
Other Oral Hygiene Practices	.069	1	.069	.027	.871

Table 4: Analysis of Variance evaluating fluoride control and placebo groups.

* p value showing a statistical significance.

Based on these results, frequent applications of acidulated phosphate fluoride on patients with fixed orthodontic appliances did not statistically decrease the incidence of demineralization when compared to placebo/control groups. No significant crossover effect could be demonstrated, as there was not a statistically significant decrease in decalcification found on the control side of the fluoride treatment group compared to the group treated with the placebo. Both null hypotheses were not rejected.

Discussion

This study investigated if frequent (every 4 - 6 week) treatments of acidulated phosphate fluoride foam would decrease the incidence of white spot lesions in orthodontic patients and if there was a crossover effect when applying fluoride treatment to only one side of the maxillary dentition. When the mean demineralization progression scores were compared between all 4 groups it was established that the order from highest to lowest incidence of decalcification was the placebo group, placebo control, fluoride group and fluoride control, respectively.

The lower decalcification incidence in the fluoride groups could indicate a fluoride benefit, but this study did not find the difference to be statistically significant. Interestingly, the fluoride control, and not the direct fluoride application group, had the lowest incidence of decalcification. The theory of blocked diffusion channels may be one explanation of why the fluoride control group developed less demineralization then the group that actually received the fluoride treatment. In an in vitro study by Johansson, demineralized, sectioned teeth were placed in saliva and calcifying solution. This was done in order to determine remineralization effects by use of polarized light microscopy. Results showed that the most rapid remineralization occurred in the first 24 hours and then tapered off over the next 48 hours. No additional changes were found over the next 3-weeks period. Based on these results, it was determined that these solutions may have caused a mineral barrier in the outer layer of enamel [13]. These mineral depositions blocked the channel pathways and prevented further remineralization from occurring. It is possible, that the repeated applications of fluoride in this study could have similarly blocked the diffusion channels in enamel, providing limited remineralization benefit. Meanwhile the increased levels of fluoride, where not being directly applied and blocking channels, i.e. the fluoride control group, could explain the lowest decalcification incidence observed.

One of the main strengths of this study was that it was a double-blinded, randomized, placebo-controlled clinical study. There was little bias incorporated into this design as examiners were not involved in the clinical aspect of the research, patients randomly selected their own treatment, and subjects were not aware of the treatment they were receiving. By utilizing a split-mouth design, where the subjects were both the experimental group and their own control, effect modifiers such as patient's caries status, level of water fluoridation, toothbrushing technique, general health, age, socioeconomic status, and oral hygiene were able to be controlled for [14]. These two patient groups (F and P) were further divided, into four groups (F, FC, P, and PC), allowing for each to have a control. By doing this, an evaluation for a crossover effect from one side of the mouth to the other was possible. Another strength of this study was that none of the subjects who successfully completed the study received a fluoride application from their general dentist. There were no interferences from other professionally applied fluoride treatments.

A number of weaknesses were also associated with this study. Use of a digital camera may have recorded details different than what could have been seen clinically [15]. It may have been difficult for examiners to differentiate between white spot lesions, plaque, and camera flash reflections. Though this study attempted to standardize each photo, it is difficult to repeat consistent lighting conditions and control for confounding factors such as the wetness of each patient's teeth [15]. Another weakness of this project was that the initial photos were taken prior to bracket placement and the final photos were taken with a bracket in place. More consistent results may have been established had lateral incisor brackets been removed prior to final photos or if initial photos were taken after bracket placement was completed.

This study demonstrated lower than expected inter- and intra-examiner agreement. Although one would have hoped that the examiners would have been more consistent with their scoring, especially since all measures were taken to give proper evaluation instructions and calibration, this indicates that each orthodontist defines white spot lesions in a different manner. It would be very difficult, if not impossible, to ever achieve a 100% agreement between three different orthodontists. For this reason, the average of all three examiner's scores was utilized.

Another issue that needs to be addressed is that the standard deviations were as high if not higher than the means in the analyses conducted. This may be due to the fact that either the examiners were not being consistent in their scoring or that the Enamel Demineralization Index is not a good tool for scoring white spot lesions. A better method of decalcification detection may need to be considered for future studies.

It could also be argued that had the length of this study been extended, a more accurate determination of the effect of fluoride on the incidence of demineralization could have been established. Although this may be true, Gorelick., et al. found that teeth bonded from 12 - 16 months showed the same incidence of white spot formation as those bonded for up to 36 months [3]. It has also been shown that the development of demineralization only takes 4 weeks [5]. Another possible weakness of this study was that each fluoride application was only administered for 1-minute. Although manufacturer's instructions were followed, studies have been published that demonstrate a more effective result with longer application time. Wei and Hattab concluded that there was significantly more enamel fluoride uptake when APF gel was administered for 4-minutes when compared to a 1-minute application. They recommend that dentists follow a 4-minutes protocol to achieve the most ideal results [16].

Another drawback to this study was a significant patient dropout rate. Of the 50 patients enrolled, only 39 successfully completed the trial. Had all 50 subjects completed this study, the power would have been stronger. The 11 patients who were dropped were all due to missed appointments. Improved measures could be taken to decrease patient no show rate.

Many of these weaknesses may have contributed to the differing results of this study when compared to previous research studies conducted using other fluoride-containing products. Hirschfield, who compared the daily use of APF mouthrinse to non-treated controls, concluded that patients who utilized the fluoridated mouthrinse had significantly ($p < 0.02$) less white spot lesion formation [17]. Vivaldi-Rodrigues., *et al.* who investigated the effectiveness of frequent fluoride varnish applications, concluded that there was 44.3% less demineralization on teeth treated with fluoride varnish than control teeth [12]. Marcusson., *et al.* who compared conventional glass ionomer cement (fluoridated) to no-mix composite resin, found that arches bonded with GIC had significantly less white spot lesions than those bonded with composite resin (24% and 40.5%, respectively) [18].

One finding of this study, which was of particular interest, was that the only variable that was found to be statistically significant was oral hygiene. This clearly indicated that patients who had good oral hygiene developed less white spot lesions than those who had fair brushing habits. Although this was patient self-assessed data, it can be concluded that subjects were accurate in their assessments. It can also be concluded that even with the use of other oral hygiene products, such as the APF foam treatment utilized in this study, good oral hygiene still seems to be the best method for prevention of demineralization.

Conclusions

1. Frequent (4 - 6 weeks) applications of acidulated phosphate fluoride foam on patients with fixed orthodontic appliances had no statistically significant effect on the incidence of demineralization.
2. The lowest incidence of demineralization unexpectedly occurred in the fluoride control group (1.20), followed by the fluoride (1.52), placebo control (1.57), and placebo group (1.75).
3. No significant crossover effect could be demonstrated.
4. Good oral hygiene was the only factor to significantly reduce the incidence of demineralization.

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