Original Article

Effects of Self-Applied Topical Fluoride Preparations in Orthodontic Patients

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Abstract: The purpose of this study was to compare the effectiveness of toothbrushing followed by fluoride rinsing, fluoride gel brushing, or fluoride gel dentifrice brushing alone in controlling the demineralization that often follows orthodontic treatment. Seventy-eight consecutive adolescent patients undergoing orthodontic care were divided into 3 groups: group 1 (control) used a low-potency, high-frequency fluoride rinse; group 2 used a high-potency, high-frequency fluoride brush-on gel; and group 3 used a high-potency, high-frequency fluoride gel dentifrice. When pretreatment levels of demineralization were subtracted from posttreatment values, both gel groups displayed a significant difference ($P < .05$) in smooth surface demineralization sites when compared to controls. Reversal of white-spot lesions occurred in 15% of sites that exhibited pathology as a result of the fluoride and preventive regimen. These results indicate that a daily use of a 5000-ppm fluoride gel along with toothbrushing with a fluoride paste or brushing twice daily with a 5000-ppm fluoride dentifrice alone provides greater protection beyond that of toothbrushing with a fluoride paste (1000 ppm) and rinsing with a 0.05% sodium fluoride rinse. (*Angle Orthod* 2000;70:000–000.)

Key Words: Decalcification; Demineralization; High-potency fluoride dentifrice; Self-application; White-spot reversals

INTRODUCTION

The changes that have occurred in the caries picture in the United States during the last 25 years are believed to be caused by the ubiquitous availability of fluoride, especially through the fluoridation of public water supplies and the use of fluoride-containing dentifrices.[1] It has also been recognized that about 80% of new carious lesions were found in about 20% of children. In other words, the majority of the disease was concentrated in a few highly susceptible individuals. Three changes were recognized in the epidemiology of the disease: (1) the prevalence of dental caries had declined, (2) the intraoral distribution of the disease was modified so that, at least in children, most carious lesions were located in pit and fissure surfaces, with little smooth surface involvement, and (3) the progress of lesions through enamel and dentin had slowed. The focus of this paper will concentrate on statement 2, particularly on how it applies to orthodontic care.

These several changes in the caries picture have mandated a review of the way dentists diagnose, prevent, and treat dental caries. For example, if a small group of people exhibit most of the disease, analytical variables must be employed that enable dentists to recognize highly susceptible children so that the initiation of the disease in them can be prevented. Therefore, the emphasis in dental care, as a direct result of fluoride and sealant therapy, has shifted from treating disease to monitoring children in a disease-free state.[2] Unlike the typical school-aged population, in which pit and fissure surfaces are the predominant site of attack, orthodontic patients display a pattern of disease that has mostly been eliminated in the general population. This paradigm for dental caries, however, cannot be applied to the orthodontic patient since white-spot lesions still represent a significant liability for patients treated with fixed appliances.[3,4]

Early carious lesions are first seen as white spots in caries-susceptible locations around bracket margins and in the gingival third of teeth in patients undergoing orthodontic care. Histologically, a well-mineralized surface layer covers a severely demineralized subsurface zone. The remineral-

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ization-demineralization anatomy is the result of the chemical equilibrium between the hard tissues and the saliva.[5–7] The demineralization process is inhibited with increasing concentrations of calcium, phosphate, and fluoride at the time of cariogenic challenge. An increasing reservoir of fluoride in the saliva and in dental plaque will promote remineralization. Frequent exposure to fluoride through solutions, dentifrices, gels, and varnishes is capable of enhancing remineralization and reversing the early carious lesion.[8]

White-spot lesions are not unique to orthodontic patients alone and have been observed in 3% to 82% of children who have not received orthodontic treatment.[9–14] The orthodontic population, however, reports a range of white-spot occurrence ranging from 8.5% to 44% on the anterior teeth and 7.7% to 71% on the posterior teeth.[15] The data from these investigations cannot be compared because of variability, types of appliances used, and presence of systemic supplementation and community water fluoridation. Of significance in this study, and for the general concern of all patients for whom esthetics is a primary goal, the incidence of demineralization for the anterior teeth consistently showed an increase when compared to controls within the same investigation.[10,13,14]

In an effort to prevent the occurrence of white-spot lesions, a regimen for self-applied topical fluoride preparations is indicated in overall orthodontic treatment and may very well represent the standard of care in the orthodontic community. As with any successful treatment procedure, patient compliance is crucial, and the benefit of fluoride may be directly related to the degree of cooperation shown by the individual patient. Unfortunately, these products are entirely patient dependent, and less than ideal utilization may occur. Consequently, the simplest forms of disease prevention may be the best. It becomes advantageous that a 1-step fluoride regimen be implemented as an adjunct toward clinical care. When faced with the choice of either a multistep or single-step preventive process, the patient will most likely choose and be more successful with the simpler procedure. The purpose of this study, therefore, was to evaluate and compare the efficiency in preventing demineralization of a single-step self-applied fluoride procedure to a protocol that would require a patient to implement a multistep approach.

MATERIALS AND METHODS

Study population

Seventy-six consecutive adolescent patients with a permanent dentition who were born and raised in a nonfluoridated community were selected to receive fixed orthodontic treatment at the Faculty Practice Plan of the State University of New York at Stony Brook. Informed consent for treatment and for participation in the study was obtained from both patients and parents. The study population was randomly divided into a control group (n = 22) and 2 treatment groups (n = 25 and n = 29). The mean age of the control group, which received toothbrush instruction and a low-potency, high-frequency fluoride rinse program, was 14.5 years (range = 12 to 16 years). The first treatment group, which received toothbrush instruction and a high-potency, high-frequency (daily usage) fluoride gel, had a mean age of 13.8 years (range 11 to 14 years). The second treatment group, which received toothbrush instruction with a high-frequency, high-potency fluoride dentifrice, had a mean age of 13.5 years (range 12 to 14 years). There were 10 girls and 12 boys in the control group, 14 girls and 11 boys in the first treatment group, and 15 girls and 14 boys in the second treatment group.

TABLE 1. Enamel Demineralization Scale

0 = No enamel opacity or surface disruption
1 = An opacity without surface disruption, or mild demineralization
2 = An opacity having a roughened surface, or moderate demineralization
3 = An opacity requiring a restoration, or severe demineralization

Clinical examination

Baseline clinical examinations were performed to assess enamel developmental defects and demineralization status. The author and another calibrated examiner who did not know the group identity of any of the subjects performed the examinations. The examination was repeated 4 weeks later in an effort to eliminate examiner drift in assessing the white-spot lesions. After air-drying and visual and tactile explorer examination, demineralization of the facial surfaces of all present permanent teeth was evaluated with the criteria in Table 1, in which the severity of the decalcified area was scored on a scale of 0 to 3, similar to the system used by Curzon and Spector,[16] Mizrahi,[10] and Boyd.[3]

Although demineralization scores of 1 may appear visually as mild enamel fluorosis and are, therefore, difficult to differentiate from actual demineralization, tactile examinations of decalcified lesions usually show rough-surface features as opposed to their hard, smooth, and glassy mildly fluorosed counterparts. The distinction between the lesions is, therefore, discernible, and the examiners are confident in their distinction for this diagnosis.

These evaluations were done on all facial surfaces of all teeth in the study and repeated after the first month of treatment and at 3-month intervals until treatment was completed. The amount of demineralization that occurred as a result of treatment was calculated by subtracting baseline scores from the scores obtained after orthodontic treatment according to the method of Boyd.[3]

Preventive protocol

After baseline evaluation, all patients received instructions in toothbrushing and oral hygiene procedures. Al-

though the plaque removal ability of each patient was not determined, all participants were exposed to the same level and time of patient education. The children were instructed to use a soft-bristle conventional toothbrush and the horizontal scrub technique at least twice daily. The orthodontist reinforced this instruction initially by using a plaque disclosing system (gum; Red Cote, Butler Co, Chicago, Ill). The toothbrushing technique was reviewed at each monthly visit for the duration of treatment.

The subjects in the control group used an American Dental Association–approved sodium fluoride toothpaste (Crest, Proctor & Gamble, Cincinnati, Ohio; or Colgate Paste, Colgate-Palmolive Co, Canton, Mass) and were instructed to use a 0.05% acidulated phosphofluoride rinse (Phosflur; Colgate-Palmolive Co) once a day after toothbrushing before bedtime. They were instructed to swish with 10 mL of the rinse for 1 minute and then to expectorate without rinsing. These instructions were reviewed monthly.

Subjects in the first treatment group followed the same toothpaste-use protocol, but it was supplemented with Prevident Neutral Sodium Fluoride Brush-On Gel (Colgate-Palmolive) at bedtime. This product is a 1.1% sodium fluoride and is not designed as a dentifrice but is used as a caries preventive agent. After use of a thin ribbon of gel brushed onto the teeth for 1 minute, the patients were instructed to expectorate and rinse with water because of the high-potency fluoride preparation of this product.

Subjects in the second treatment group were instructed to use Prevident 5000 Plus Dental Cream twice a day, once in the morning and once before bedtime. The product is a 1.1% sodium fluoride dentifrice. After brushing for 2 minutes, the patients were instructed to expectorate and rinse thoroughly with water because of the high-fluoride potency of this product, as well as to remove the dentifrice abrasives from the oral cavity.

Compliance with the Phosflur Rinse, Prevident Gel, and Prevident 5000 Plus was established monthly by parental signatures and by a materials request basis as each subject depleted the supply of the products.

Orthodontic treatment

All patients were treated with a modified bidimensional technique that utilized preadjusted edgewise appliances (GAC, Central Islip, NY). The entire labial surface of the teeth was etched with phosphoric acid and sealed with a fluoride-releasing sealant. All erupted teeth were direct-bonded with Phase II with fluoride (Reliance, Itasca, Ill), except for first and second molars, which were generally banded and cemented with Optiband Glass Ionomer fluoride-releasing cement (Ormco, Glendora, Calif). Immediately after appliance placement, all patients were treated with Colgate Thixo-flur acidulated phosphate fluoride topical gel trays (Colgate-Palmolive) for 4 minutes at chairside. Treatment time ranged from 22 to 29 months, with an average treatment period of 26 months.

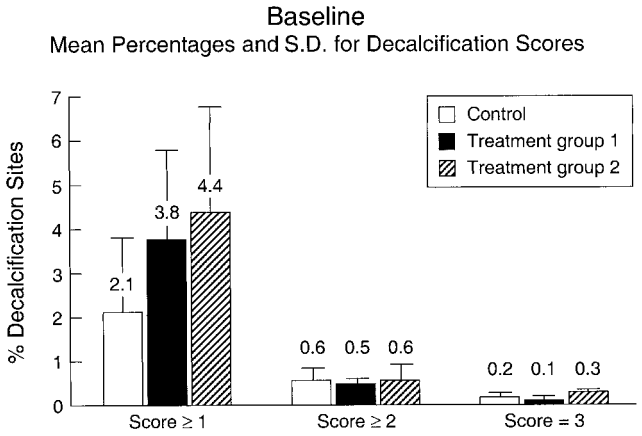

FIGURE 1. Baseline mean percentages and standard deviations for demineralization scores of orthodontic patients.

Statistical analysis

One-way analyses of variance (ANOVA) and covariance (ANCOVA) were performed to test for significance between groups for the percentage of sites having demineralization. The ordinal data demineralization scores of the facial surfaces were converted to percentages of sites having scores of 0, 1, 2, or 3 to permit analysis by ANOVA and ANCOVA.[3] The ANCOVA used the posttreatment scores as the dependent variable with the baseline scores as the covariate. These analyses were done at baseline (pretreatment), one month after appliance placement, and again one month after the completion of treatment by subtracting the pretreatment scores from the 1-month and posttreatment scores. A P value of less than .05 was considered statistically significant.

RESULTS

The entire control and first treatment group remained in the study, whereas 4 members of the second treatment group withdrew because they moved away from the area. Complete data were, therefore, obtained for 74 patients from all 3 groups. The mean treatment time was 24.8 months for the control group in fixed appliances, 27.1 months for the gel group, and 26.4 months for the Prevident 5000 group. Although oral hygiene measures were taught and reinforced monthly, a mild to moderate gingivitis developed in the majority of patients after the first month of treatment and did not vary considerably during the course of care. This is consistent with reported findings of gingival health and orthodontic therapy[3,17] and did not result in the removal of subjects from the study.

No statistically significant differences in demineralization were found at baseline among the 3 groups (Figure 1). After 1 month of wearing the appliances, a score of 1 or greater

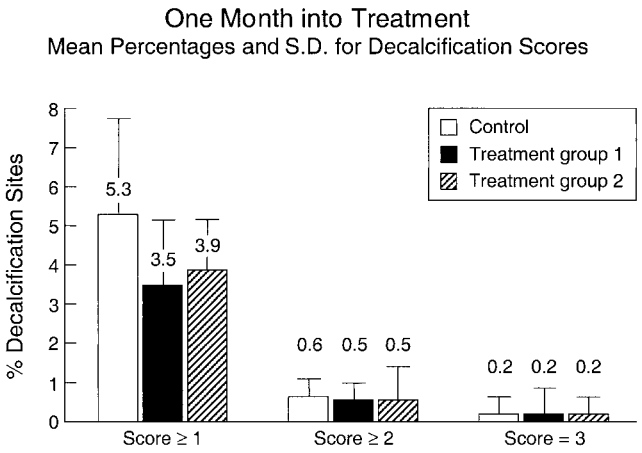

FIGURE 2. One month into treatment mean percentages and standard deviations for demineralization scores.

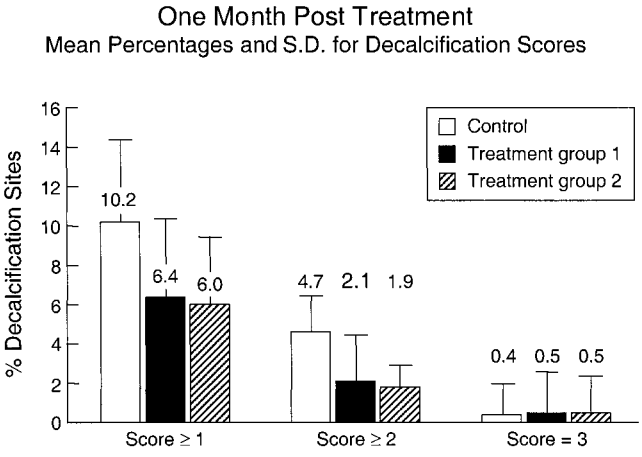

FIGURE 3. One month after treatment mean percentages and standard deviations for demineralization scores.

in the percentage of sites that displayed demineralization in the control group increased; this was significantly different from pretreatment scores (Figure 2). The percentage of demineralization sites in the control group increased from 2.1% to 5.3%, whereas the 2 treatment groups remained basically unchanged. Scores of 2 and 3 did not display any statistical significance at this time. When baseline scores were compared to scores obtained 1 month after appliance removal, both treatment groups had statistically fewer sites of demineralization with combined scores of 1 or more and combined scores of 2 or more than the control group (Figure 3). For the control group, the percentage of demineralization sites increased from 2.1% at baseline to 10.2% 1 month after treatment with combined scores of 1 or more, and from 0.6% to 4.7% with combined scores of 2 or more. Neither gel group displayed statistically significant differences in demineralization scores. No significant differences were observed among any of the groups for demineralization scores of 3.

As expected, the overall amount of demineralization increased during the course of treatment; however, both gel groups displayed lower levels of white-spot lesions when compared to the control group. When compared to the entire dentition, the anterior teeth exhibited a lower percentage of demineralization sites for all 3 groups of patients examined in the study (Figure 4); however, no statistical significance between the anterior dentition and the whole dentition was noted. For the control group, the percentage of demineralization sites for the anterior teeth increased from 1.8% at baseline to 5.6% 1 month after treatment with combined scores of 1 or more, whereas both treatment groups remained basically similar from baseline until after treatment. Scores of 2 or greater increased from 0.2% to 3% for the control group and 0.3% to 1.8% and 0.2% to 1.6%, respectively, for treatment groups 1 and 2, but they were not statistically significant. The 6 maxillary anterior teeth showed no statistically significant difference in the 3 groups for demineralization scores of 1, 2, and 3 one month after treatment. Less overall demineralization was noted in the Prevident 5000 Plus group, but this was not significant ($P = .2$; Figure 5).

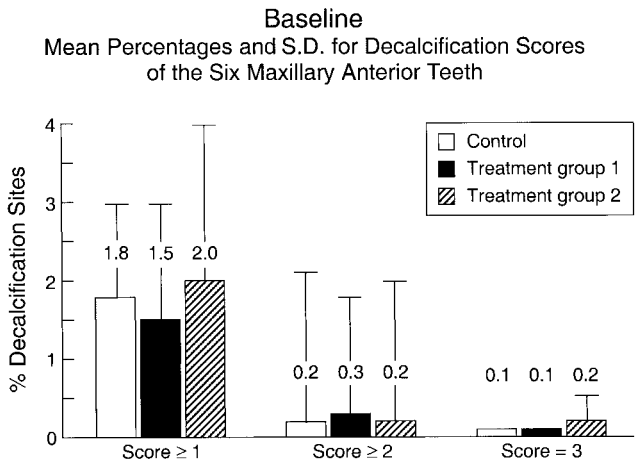

FIGURE 4. Baseline mean percentages and standard deviations for demineralization scores of the 6 maxillary anterior teeth.

The reversal of white-spot lesions occurred in 11% of the sites that appeared after 1 month of appliance placement and in 15% of the sites occurring after this time and up to the completion of treatment. These values were determined by subtracting the number of lesions observed after 1 month of orthodontic care from the original lesions observed at the initiation of treatment and by subtracting the number of lesions observed at the completion of treatment from the number calculated at 1 month into therapy. White-spot reversal was determined, therefore, when lesions were clinically absent in 1 month or at the end of therapy. Neither value from all 3 groups was statistically significant when compared with those lesions that were present at the beginning of the study.

Parental signatures on a monthly returned checklist, which indicated daily use of the rinse or gel products, as-

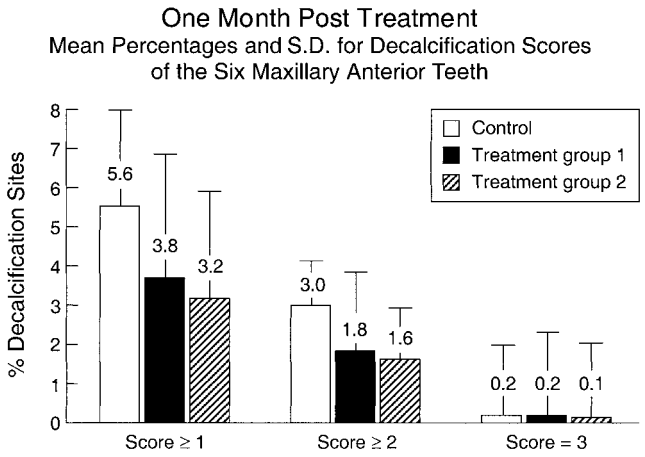

FIGURE 5. One month after treatment and standard deviations for demineralization scores of the 6 maxillary anterior teeth.

TABLE 2. Average Fluoride Rinse or Gel Exposure Period During Treatment Course

Group	Exposure No.
Control group (standard dentifrice and Phosflur rinse)	744
Treatment group 1 (standard dentifrice and Prevident gel)	813
Treatment group 2 (Prevident 5000 Plus)	1584

sessed compliance. Other supporting data that indicated high patient compliance was the distribution upon request of the Phosflur rinse (every 50–60 days) and of the Prevident Gel and Prevident 5000 Plus (every 4 months). Because of the nature of the oral hygiene protocol, the control group was exposed to a fluoride product other than over-the-counter dentifrice 744 times on average during the course of treatment. The Prevident Gel group was exposed 813 times and the Prevident 5000 Plus Group 1584 times. The greater number of high-potency fluoride exposures in the last group was caused by the twice-daily brushing with the high-potency formula because treatment times for all 3 groups were similar (Table 2).

DISCUSSION

Enamel demineralization as a result of orthodontic treatment still remains a problem in the adolescent population. The results of this study show that the daily use of a 5000-ppm fluoride gel along with conventional toothbrushing with an over-the-counter fluoride toothpaste or the twice-daily use of a 5000 ppm gel dentifrice is significantly more effective in preventing demineralization than the use of toothpaste and mouth rinsing with a 0.05% fluoride solution. On the basis of the overall low incidence of white spots observed on a clinical level, the use of the high-potency fluoride is an improvement in preventing demineralization when compared to an already effective preventive regimen of toothbrushing and low-potency fluoride mouth rinsing. The importance in preventing early demineralization in the orthodontic population cannot be overemphasized. Enamel lesions appear as early as 1 month into appliance placement, as seen in this and other reports;[18–20] this suggests that substantial mineral loss around bracket peripheries can occur without being observed clinically. Scanning electron micrographs have demonstrated that although enamel translucency appeared normal, a physical lack of mineral can be observed in the immediate area of the bracket.[21] Poor oral hygiene, which results in an alteration of the microbial environment around the bracket area,[22] in turn leads to the cariogenic condition. As a result, various fluoride delivery systems have been advocated, including gel programs and fluoride-releasing resins, varnishes, ligatures, and rinses. All of these methods have resulted in mixed success rates in the prevention of demineralization.[3,17,23–32] The ideal caries-preventive system operates independently of patient cooperation. No such mechanism exists. In this study, however, compliance was determined to be high as a result of the low incidence of demineralization observed in the control and experimental groups. As a function of compliance, reports demonstrate that 79% of cooperative patients had no white-spot lesions when compared to non-compliant groups who showed only a 51% absence of demineralization when exposed infrequently to fluoride preparations.[27] Interestingly, for those patients who manifest poor oral hygiene during orthodontic therapy and are compliant with fluoride programs, the incidence of white spots is significantly reduced.[27] This may be explained by the mechanism of fluoride action. Fluoride is not only responsible for the reduction in solubility and remineralization of enamel,[6] but synergistically acts within the plaque reservoir in much higher concentrations than in saliva.[33] This in turn can result in slower white-spot formation and support the observations in which decreased caries levels have been reported in patients who use fluoride supplements but display mediocre to poor oral hygiene measures.

Since strict compliance and a simple oral hygiene method may be the best course in the prevention of incipient caries, one would expect demineralization levels to be lowest in the Prevident 5000 Plus group, which only had to brush twice daily with the high-potency formula. Both high-potency groups, however, displayed equal protection against white-spot lesions, indicating for this study that a single daily exposure to a high-potency fluoride is sufficient to prevent disease, that the additional brushing procedure in the gel group did not burden the oral hygiene measures on a daily basis, or that the additional brushing served to enhance the mechanical removal of cariogenic material from the bracket periphery.

Although previously published reports have indicated that the molars are more susceptible to white-spot formation because of difficulties in maintaining plaque control,[3,19,34–36] the 6 maxillary anterior teeth were considered separately

for 2 reasons: the incidence of white-spot formation has been reported to be high in this area,[27] and the orthodontic patient population is extremely cognizant in the appearance of the ''esthetic six,'' the 6 maxillary anterior teeth, through public marketing and fashion tabloids. In this study, when the maxillary anterior teeth were considered separately, all 3 groups displayed no significant difference in demineralization scores. Clinically, however, the Prevident 5000 Plus group's overall demineralization was lower but not statistically significant. As was expected because of easier and more efficient plaque control and fluoride delivery, the anterior teeth displayed lower overall percentages of demineralization than the whole-mouth scores.

The phenomenon of white-spot reversal is not new to the caries literature.[37–41] Attempts have been made to produce clinical remineralization of incipient caries. In the majority of cases, fluoride is the material used. Although only an 11–15% reversal was observed in this study at 1 month and at the completion of treatment, respectively, reports as high as 25% have been seen after application of stannous fluoride[42] to nonorthodontic patients. It should be realized that the lower reversal numbers seen here may be the result of appliance placement and continued cariogenic challenge in patients undergoing treatment. Studies by Artun and Thylstrup[43] confirm that orthodontic appliances impair the removal of bacterial deposits, which can lead to this form of enamel scarring. Furthermore, over a period of 3 years, the regression of the white-spot lesion can be attributed in part to surface abrasion.

It is not unusual for natural remineralization of white-spot lesions to occur, because dental mineral is in equilibrium with its environment. Many early white-spot lesions disappear with time. Of a total of 72 white spots observed, Backer-Dirks[44] reported that 51% of them disappeared over a 6-year period, whereas 36% showed no change and 13% progressed to cavitations. For this phenomenon to occur, the caries challenge must be reduced or eliminated, and sufficient mineral must be introduced into the voids of the white-spot lesion. Since orthodontic appliances represent a barrier to normal oral hygiene techniques, the risk factor is never really removed during treatment, and attempts of remineralization must include effective anticaries agents. It should be realized that natural or therapeutic remineralization produces enamel that has a greater resistance to further dissolution.[45,46] This is caused by the replacement by larger, less soluble crystals, which occupy the space vacated by the most soluble components of the enamel during early demineralization.

Studies with high- and low-fluoride dentifrice concentrations in nonorthodontically treated populations have reported equivocal results in caries inhibition.[47,48] Although these studies were all positive in caries inhibition scores, they do not support the conclusion that a high-potency dentifrice is more effective in caries control than its less potent competitors. Interestingly, the results reported here indicate a greater caries protective level when gels or dentifrice containing 5000 ppm fluoride are used. The difference in these findings may be the result of the higher caries challenge in the orthodontic population and in the variability of the earlier clinical trials.

It was noted that the Prevident 5000 Plus group was exposed to the high-potency dentifrice an average of 1584 times during the study when compared with the Prevident Gel group, which was exposed an average of 813 times. When compared with each other, the high-potency groups did not display any statistically significant difference in overall demineralization scores, nor were severe demineralization areas statistically evident in all 3 groups. This may indicate that low-potency, high-frequency fluoride treatment and high-potency, high-frequency fluoride treatment are very effective in the prevention or inhibition of severe levels of demineralization when used appropriately and conscientiously by the patient. Additionally, since both gel types were used at bedtime, oral clearance of the fluoride may be decreased and more beneficial than the morning brushing of the fluoride gel dentifrice, which is most likely cleared rapidly from the oral cavity.[49] This speculation may have directly resulted in a more equal exposure of both formulations and similar patient responses to demineralization levels that were observed.

CONCLUSIONS

Regarding the effects of self-applied fluoride rinses, gels, and dentifrice applications to orthodontic patients, the following can be concluded:

1. The exposures to both low-potency, high-frequency fluoride preparations and high-potency, high-frequency fluoride preparations serve to prevent the appearance of moderate to severe demineralization in patients who undergo orthodontic therapy. Dentifrice and an over-the-counter rinse have a very good effect in preventing demineralization; however, high-concentration fluoride products produce a greater degree of protection.
2. A single daily exposure of a high-potency fluoride dentifrice or a twice-daily exposure to a high-potency gel appears to give equal protection in patients who exhibit white-spot pathology.
3. The maxillary anterior dentition exhibited a lower percentage of demineralization sites than the whole dentition.

Reversal of white lesions at the end of active care occurred in 11% and 15% of patients who exhibited demineralization as early as 1 month into treatment and during the course of treatment, respectively.

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