Comparison of three self-applied topical fluoride preparations for control of decalcification

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Previous studies have indicated that decalcification is a significant clinical liability during orthodontic treatment with fixed appliances, especially among patients with poor oral hygiene.[1-8] Other studies have shown that various fluoride preparations such as neutral fluoride toothpastes,[2,6,7] SnF_2 gels[3] and NaF rinses[1,2,4,8] reduce decalcification during orthodontic treatment with fixed appliances. However, there is nothing in the literature to indicate which one of these three methods is more effective than the others in controlling decalcification during orthodontic treatment.

SnF_2 gels, unlike NaF rinses or toothpastes, have also been shown to be effective antimicrobial agents, especially against Streptococcus mutans, in both animal and human studies.[9-11] In addition, SnF_2 gels have been shown to be effective in reducing gingivitis,[12-17] whereas NaF toothpastes and rinses have not shown this ability. Thus, the SnF_2 gels may potentially be more effective for control of decalcification than either NaF rinses or NaF toothpastes because of their antimicrobial activity, especially against S. mutans. In addition, SnF_2 gels may also be more effective for orthodontic patients because of their ability to reduce gingivitis, since gingivitis generally increases during orthodontic treatment.[4,18]

The purpose of this longitudinal clinical trial was

Abstract

The purpose of this study was to compare the effectiveness of a 1100 ppm fluoride toothpaste used alone, or together with a 0.05% NaF rinse used once daily or a 0.4% SnF_2 gel applied twice daily, in controlling the decalcification that often accompanies orthodontic treatment. Ninety-five consecutively treated adolescent patients were matched for age and sex and assigned to one of these three regimens. Single blind assessments of decalcification were performed on all labial surfaces of all erupted teeth before appliances were placed and 3 months after appliances were removed. Because the first molars had the highest decalcification scores, data for the whole mouth and for first molars were analyzed separately.

When pre-treatment levels of decalcification were subtracted from post-treatment values, significantly lower decalcification scores ($p < 0.05$) were found for both whole mouth and first molars in the rinse and gel groups as compared with the control group (toothpaste alone). Although the gel group consistently had less decalcification than the rinse group, this difference only approached statistical significance. These results indicate that twice daily use of a 1100 ppm fluoride toothpaste and either a once-daily 0.05% NaF rinse or a twice-daily 0.4% SnF_2 gel provides additional protection against decalcification beyond that achieved with toothpaste alone.

Key Words

Topical fluorides • Decalcification • Orthodontic treatment

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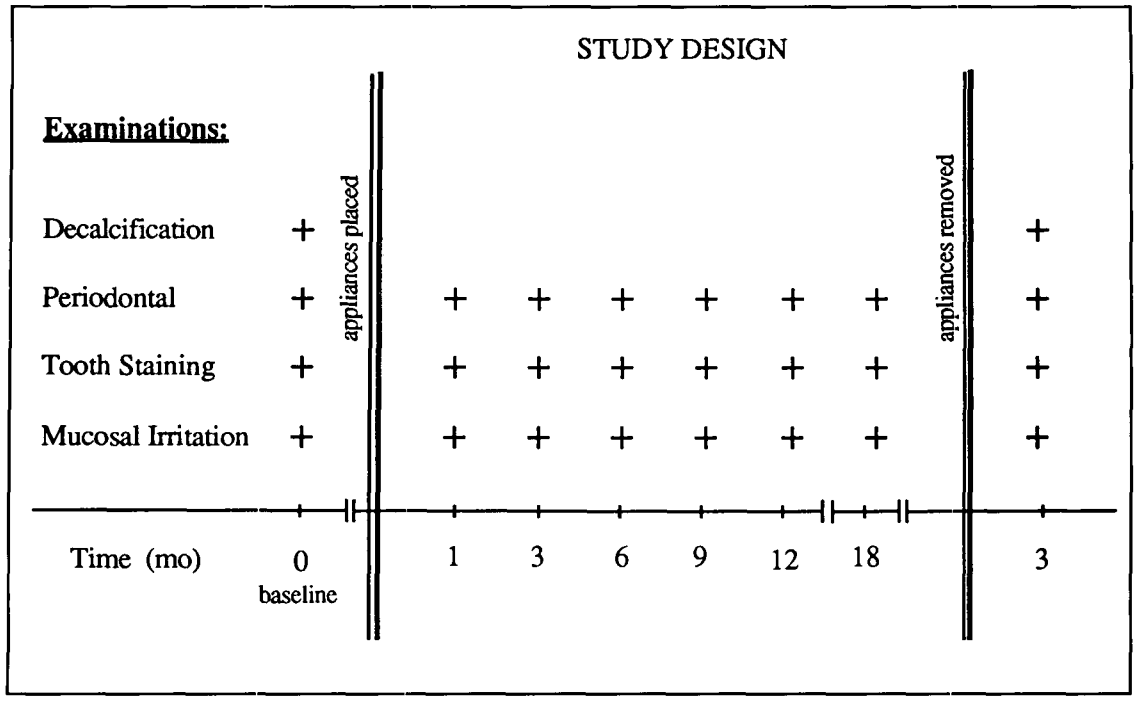

Figure 1
Study design for this clinical trial. Examination times for decalcification, periodontal status, tooth staining and mucosal irritation are indicated with a +. Toothbrushing instructions and reinforcement for all three groups, as well as rinse or gel instructions and reinforcement for the two treatment groups, were provided at monthly intervals throughout the study.

to study three groups of adolescent orthodontic patients for differences in decalcification occurring during orthodontic treatment. All three groups used the same type of manual toothbrush and had toothbrushing instructions at monthly intervals throughout the study. The first group (control group) used a 1100 ppm fluoride toothpaste, the second group used this toothpaste and a once-daily 0.05% NaF rinse (rinse group), and the third group used this same toothpaste and a twice-daily, self-applied 0.4% SnF_2 gel (gel group).

Materials and methods

Study population

Ninety-five consecutive adolescent patients were selected from among those who were to receive fixed (edgewise) orthodontic treatment at the Orthodontic Clinic of the School of Dentistry, University of California San Francisco. Informed consent to participate in the study was obtained from both patients and their parents. Patients with a history of rheumatic fever, congenital heart disease, blood dyscrasias or diabetes mellitus were not included. Patients were also excluded if they were diagnosed as having juvenile periodontitis according to the criteria of Kornman and Robertson.[19] In addition, none of the patients had used antibiotics during the 6 months prior to orthodontic treatment. The study population was non-randomly divided into a control group (n=35) and two treatment groups (n=30 and n=30) who were approximately matched for age and sex distribution. The mean age of the control group was 12.9 years (range, 9 to 16 years), while the first treatment (rinse) group had a mean age of 13.2 years (range, 9 to 18 years) and the second treatment (gel) group had a mean age of 13.4 years (range, 11 to 17 years). There were 22 female and 13 male patients in the control group, 19 female and 11 male patients in the rinse group, and 18 female and 12 male patients in the gel group.

Clinical examinations

Baseline clinical examinations were performed to assess decalcification and periodontal status (Figure 1). These examinations were performed by two calibrated clinical examiners who did not know the group identity of any of the subjects. Decalcification was evaluated using the following criteria for the facial surfaces of all permanent teeth present:

- Score 0 = No visible white spots or surface disruption (no decalcification).
- Score 1 = Visible white spot without surface disruption (mild decalcification).
- Score 2 = Visible white spot lesion having a roughened surface but not requiring a restoration (moderate decalcification).
- Score 3 = Visible white spot lesion requiring a restoration (severe decalcification).

These evaluations were done in each of four evenly divided quadrants on all facial surfaces of all study teeth. In this manner, the location and size of the white spot lesions could be identified as being either incisal or gingival and/or mesial or distal. Decalcification status was also determined again 3 months after fixed orthodontic appliances had been removed (Figure 1). The amount of decalcification that occurred during orthodontic treatment was

calculated by computer operation by subtracting baseline scores from the scores obtained after orthodontic treatment.

Periodontal status was determined at six standard locations before appliances were placed (baseline) and again at 1, 3, 6, 9, 12, and 18 months after appliances were placed (Figure 1), using the Plaque Index,[20] Gingival Index,[21] and bleeding tendency.[22] If a study tooth was missing, the corresponding tooth on the contralateral side was examined. The periodontal status of the control group and the gel group during the first 9 months of orthodontic treatment[16] and again after 18 months[23] has been previously reported. Intra- and interexaminer calibrations were conducted before the study and then at 6-month intervals throughout the study to maintain 85% reproducibility for both decalcification and periodontal measurements. The methods of the error calculations for the periodontal measurements have been previously reported.[16,23]

If present, clinically significant staining of the tongue or teeth and generalized mucosal irritation were recorded at each clinical examination.

Preventive treatment

After baseline assessment, all study patients received instructions in toothbrushing. They were instructed to use an end-rounded, soft-bristle conventional toothbrush (Pycopay Softtex, Block Drug Co., Jersey City, NJ) and the horizontal scrub technique.[4] The therapist reinforced these instructions using a disclosing system (Plaklite, Bristol-Myers, Stamford, CT) at subsequent banding/bonding visits (2-3 sessions) and at each monthly orthodontic treatment visit for the duration of orthodontic treatment. All study subjects were further instructed not to use dental floss or any plaque-removal devices except for the method of brushing shown to them, and to use an ADA-approved sodium fluoride toothpaste (Crest, Proctor & Gamble, Cincinnati, OH).

The subjects in the rinse group were also instructed to use a 0.05% NaF mint-flavored mouthrinse (Flurigard, Colgate Hoyt, Canton, MA) once a day at bedtime after toothbrushing. They were told to keep 1/2 ounce of the rinse in their mouth for one minute and then to expectorate but not rinse with water after using the rinse. These instructions were also reinforced at each monthly visit.

Subjects in the gel group were instructed to use a 0.4% SnF_2 gel (Scherer Corp., Dallas, TX) twice daily. Their instructions were to brush first, then rinse their toothbrush and mouth with water and apply the gel with their toothbrush, but not to rinse or eat for 1 hour thereafter.

When baseline clinical assessments were completed, all subjects received a prophylaxis consisting of coronal tooth polishing. In addition, patients were requested to have routine dental examinations and prophylaxis with their general dentists every six months.

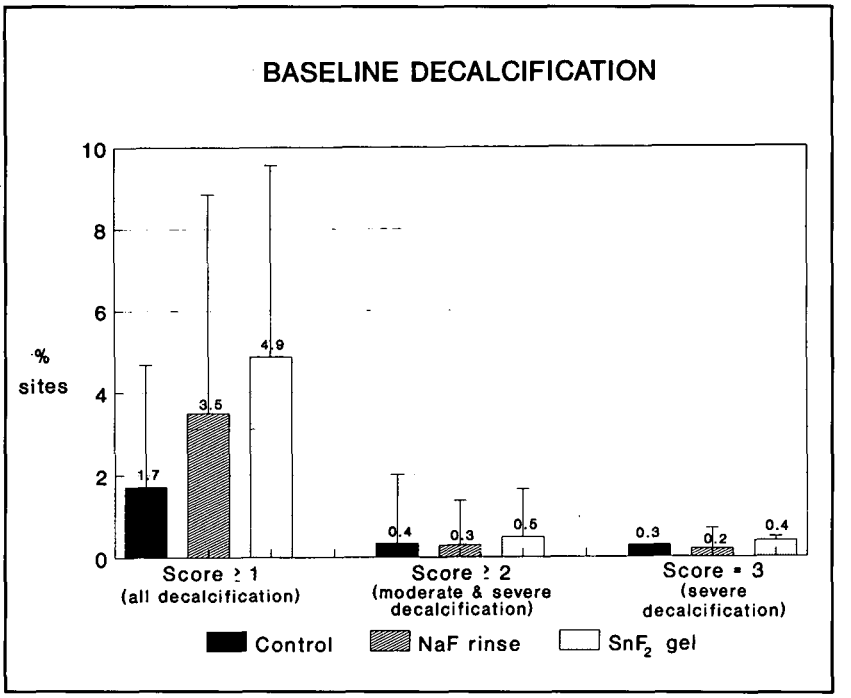

Figure 2

Figure 2
Pretreatment (baseline) mean percentages and standard deviations for sites in the control, NaF rinse and SnF_2 gel groups with scores ≥ 1 (all decalcification), scores ≥ 2 (moderate and severe decalcification) and scores = 3 (severe decalcification). Scoring criteria for decalcification levels are explained in Methods. No significant differences were found between the groups for any level of decalcification with either the ANOVA or ANCOVA analysis.

Orthodontic treatment

In all study subjects, all erupted teeth were generally direct-bonded with preadjusted edgewise appliances, except for first or second molars, which were generally banded.

Statistical analysis

One-way analyses of variance (ANOVA) and covariance (ANCOVA) were performed to test for differences between groups for the percentages of sites having any decalcification (scores 1, 2 and 3 combined), moderate and severe decalcification (scores 2 and 3 combined) and severe decalcification (score 3). These analyses were done at baseline (pretreatment) and again after treatment by subtracting the baseline scores from the scores 3 months after treatment (posttreatment). The ANCOVA used the posttreatment scores as the dependent variable with the baseline scores as the covariate. Bonferroni (Dunn) t-tests were used with the ANOVA to distinguish differences between groups. For the ANCOVA, Planned Comparisons were done using the Least Square Means Test to identify significant differences between groups. A p value of less than 0.05 was considered statistically significant.

All data were entered twice into the computer from the original raw data forms to reduce the chance of error in transferring the data. If a discrepancy between the twice-entered data was found, the

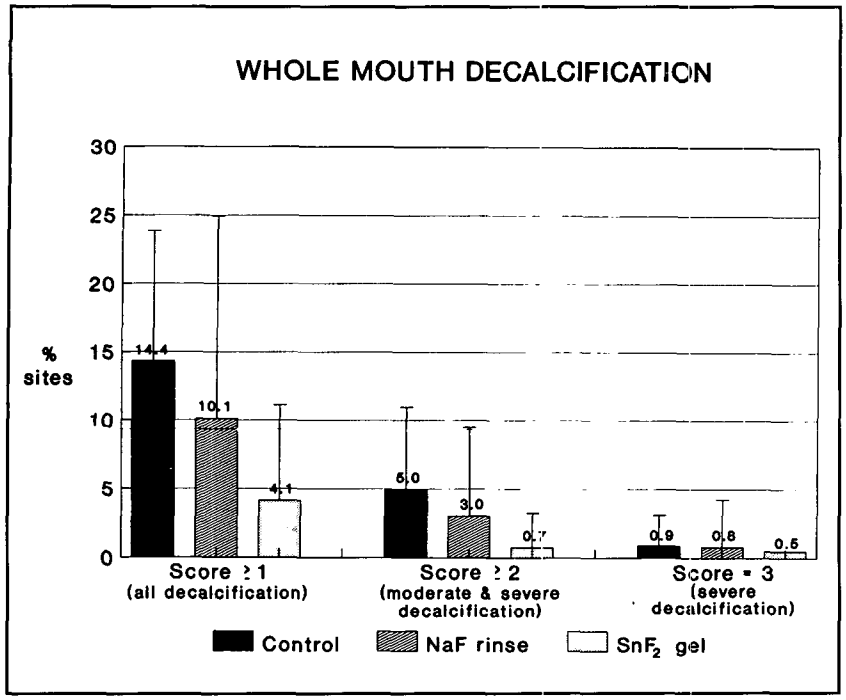

Figure 3

Figure 3
Posttreatment mean percentages and standard deviations for whole mouth decalcification scores for the three groups. Baseline decalcification scores were subtracted from posttreatment scores to determine the levels of decalcification that had occurred during orthodontic treatment. Both the ANOVA and ANCOVA analyses found significantly fewer sites with decalcification scores of ≥1 and ≥2 for the NaF rinse and the SnF_2 gel groups than for the control group ($p<0.05$). Although the SnF_2 gel group had lower decalcification scores than the rinse group, this difference was only of borderline significance ($p = 0.06$).

computer identified the discrepancy so that the entry could be corrected.

The decalcification scores, which are ordinal data, were converted to percentages of sites having scores of 0, > 1, > 2 or 3 to permit analysis by ANOVA and ANCOVA, parametric analyses which require interval data.

Results

Complete data were obtained for 32 control subjects, 26 NaF rinse subjects, and 24 SnF_2 gel subjects. The subjects who withdrew from the study did so because they moved away from the area and transferred their orthodontic care or missed multiple examination visits. No subjects dropped out of the study because they disliked the flavor of the toothpaste, rinse or gel. The average time in fixed appliances was 26.2 months for the control group, 24.3 months for the NaF rinse group, and 26.7 months for the SnF_2 gel group.

No differences in decalcification were found at baseline between the three groups by either ANOVA or ANCOVA (Figure 2). However, when baseline whole mouth decalcification scores were subtracted from the 3-month post-treatment scores, both of these analyses found that the rinse and gel groups had significantly fewer sites with combined scores of 1 or more and combined scores of 2 or more than the control group (Figure 3). Although the gel group showed less decalcification than the rinse group, the difference was of borderline ($p = 0.06$) significance. There were no significant differences between any of the groups for decalcification scores of 3.

For first molars, both the ANOVA and ANCOVA analyses showed that there were significantly fewer sites in the gel and rinse groups than in the control group with decalcification scores of 1 or more and 2 or more (Fig. 4). Although the gel group had less decalcification than the rinse group, the difference was not significant ($p = 0.16$). No significant differences were found between the groups for molar decalcification scores of 3.

Compliance data for use of the toothpaste showed that patients from all three groups missed fewer than 3 days per month on average during orthodontic treatment. The compliance data also showed that patients in the the NaF rinse group missed using the rinse an average of 3.2 days per month, and that patients in the gel group missed using the gel an average of 3.5 days per month.

No patients in any of the three study groups developed clinically significant generalized mucosal irritation or staining of the tongue during the study period. Although no control or rinse subjects developed tooth staining during orthodontic treatment, in the SnF_2 gel group one subject developed mild generalized staining and two subjects developed moderate generalized staining.

Discussion

The results of this study show that the twice-daily use of a 1100 ppm fluoride toothpaste together with either a once-daily 0.05% NaF rinse or twice-daily 0.4% SnF_2 gel is significantly more effective than the use of this toothpaste alone in preventing whole mouth decalcification in adolescents undergoing treatment with fixed orthodontic appliances. Although the SnF_2 gel group showed greater reductions in decalcification than the NaF rinse group, the differences were of borderline statistical significance. In a previously published study of the control and NaF rinse groups,[24] the teeth with the greatest amount of decalcification were found to be first molars, which agrees with previous studies showing that molars present conditions making it more difficult to maintain adequate plaque control.[1,7,8,25] In this study, when first molars were considered separately, the SnF_2 gel and NaF rinse were both superior to the toothpaste alone in preventing decalcification. As with whole mouth scores, molar teeth in the SnF_2 gel group showed lower levels of decalcification than molars in the NaF rinse group, but the difference was not statistically significant.

Although group sizes for this study were adequate to determine significant differences in periodontal variables,[16,23] larger group sizes were no doubt needed to determine with greater certainty

whether the gel was more effective than the rinse in preventing decalcification in this population. A possible explanation for the trend toward lower levels of decalcification in the gel group compared to the rinse group may have been the more frequent use of the SnF_2 gel (twice daily) than the NaF rinse (once daily). This regimen was chosen because previous studies have shown that SnF_2 gels should be used twice daily to achieve the most effective reductions in gingivitis,[10,11,13,16,17,23] while other studies have shown that once daily use of NaF rinses[4,6,7] is the optimum frequency for prevention of decalcification.

The three groups that were selected were chosen from consecutively treated subjects who were matched for age and sex distribution but were not randomly assigned to the individual groups. Although this may have introduced bias which may have influenced the results, it is not known what specific effects this bias may have had.

The number of subjects differed slightly between the groups, which may also have affected the results, although the analyses of variance and covarience compensate for different numbers of subjects. In addition, the ability to distinguish significant differences between the groups for the less frequently occurring severe decalcification scores may have been lost because these lesions occurred so infrequently.

In our previously published studies of gingivitis in the control group and the SnF_2 gel group of this study,[16,23] we found that the SnF_2 group had significantly lower gingivitis scores than the control group throughout the 18-month study period. In addition, the study of the first nine months of that trial[16] showed that the SnF_2 gel group had lower gingivitis scores than another group using a different SnF_2 gel with less than 2% available Sn^{++} ion concentration. The SnF_2 gel used in this study had more than 90% available Sn^{++} ion, which has previously been established as necessary for such a gel to achieve an antimicrobial effect.[9-11,17] Thus, the use of a SnF_2 gel with greater than 90% available Sn^{++} is a more effective preventive agent for adolescent orthodontic patients than a NaF rinse or fluoride toothpaste alone because of its dual effect of preventing both gingivitis and decalcification.

Although orthodontic decalcification has not been studied in adults, gingivitis does increase in adults during treatment with fixed appliances.[18] A SnF_2 gel with greater than 90% available Sn^{++} could also potentially be an effective preventive adjunct for adults, especially if increased decalcification was noted.

Compliance with the use of the toothpaste, rinses and gels was high during orthodontic treatment,

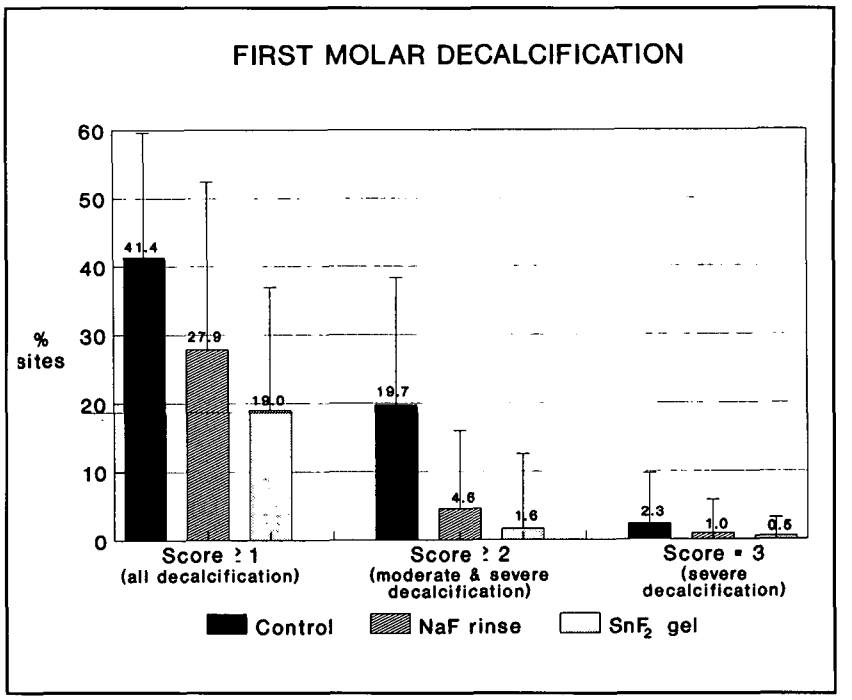

Figure 4

with fewer than four days missed per month with all products. This was an improvement over the compliance achieved during the first nine months.[16] This improvement was most likely the result of the continued monthly reinforcement of product use. Another recent 18-month study[26] of the use of NaF and SnF_2 gels for control of gingivitis showed that a less frequent reinforcement schedule led to lower compliance with the gels, especially during the last six months of the study. This may explain why the reductions in gingivitis in that study did not reach statistical significance.

It is important to note that the present data show that significant decalcification may occur in adolescents even when they have had comprehensive initial toothbrushing instructions, used a standard NaF dentifrice, and received monthly follow-up instructions and reinforcement in toothbrushing. If the patients in this study had not been given structured brushing instructions or had the use of products reinforced, the benefits of the NaF rinse or SnF_2 gel on decalcification may not have been attained. A recent study has shown that demineralized tooth surfaces remain as esthetic concerns even more than five years after orthodontic treatment.[8]

The low levels of decalcification before orthodontic treatment shown by these adolescent subjects (Figure 2) undoubtedly resulted from their having lived for many years in a community in which the water was fluoridated at approximately 0.8 ppm F. Only two studies[6,7] have evaluated the effectiveness of NaF rinses in preventing decalcification during orthodontic treatment in adolescents who were

Figure 4
Posttreatment mean percentages and standard deviations for first molar decalcification scores for the three groups. Scores were determined as described in Figure 3. The NaF rinse and SnF_2 gel groups had significantly fewer sites with scores of ≥ 1 and ≥ 2 than the control group. Again, the SnF_2 gel group had less decalcification but the difference was not statistically significant ($p = 0.16$) for scores ≥ 1.

raised in a community with fluoridated water. Subjects in those studies also had low levels of decalcification before orthodontic treatment and received an additional level of decalcification protection from the rinse beyond that provided by daily use of a 1100 ppm F toothpaste.

The longitudinal study design of the present clinical trial also allowed baseline levels of decalcification to be subtracted from posttreatment decalcification scores, which removed any white spot lesions associated with systemic fluoride uptake[27] from being classified as decalcification.

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