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Reversal of Primary Root Caries Using Dentifrices Containing 5,000 and 1,100 ppm Fluoride

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Key Words

Electrical caries monitor · Fluoride · Remineralisation · Reversal · Root caries

Abstract

This study compared the ability of two sodium fluoride dentifrices, one containing 5,000 ppm fluoride (Prevident 5000 Plus) and the other 1,100 ppm fluoride (Winterfresh Gel), to reverse primary root caries lesions (PRCLs). A total of 201 subjects with at least one PRCL each entered the study and were randomly allocated to use one of the dentifrices. After 6 months, 186 subjects were included in statistical analyses. At baseline and after 3 and 6 months, the lesions were clinically assessed and their electrical resistance measured using an electrical caries monitor. After 3 months, 39 (38.2%) of the 102 subjects in the 5,000 ppm F^- group and 9 (10.7%) of 84 subjects using the 1,100 ppm F^- dentifrice, had one or more PRCLs which had hardened ($p = 0.005$). Between baseline and 3 months, the $\log_{10}$ mean ± SD resistance values of lesions for subjects in the 1,100 ppm F^- group had decreased by 0.06 ± 0.55, whereas those in the 5,000 ppm F^- group had increased by 0.40 ± 0.64 ($p < 0.001$). After 6 months, 58 (56.9%) of the subjects in the 5,000 ppm F^- group and 24 (28.6%) in the 1,100 ppm F^- group had one or more PRCLs that had become hard ($p = 0.002$). Between baseline and 6 months, the $\log_{10}$ mean ± SD resistance values of lesions for subjects in the 1,100 ppm F^- group decreased by 0.004 ± 0.70, whereas in the 5,000 ppm F^- group, they increased by 0.56 ± 0.76 ($p < 0.001$). After 3 and 6 months, the distance from the apical border of the root caries lesions to the gingival margin increased significantly in the 5,000 ppm F^- group when compared with the 1,100 ppm F^- group. The plaque index in the 5,000 ppm F^- group was also significantly reduced when compared with the 1,100 ppm F^- group. The colour of the lesions remained unchanged. It was concluded that the dentifrice containing 5,000 ppm F^- was significantly better at remineralising PRCLs than the one containing 1,100 ppm F^-.

The restoration of root caries lesions is often difficult and every effort should be made to prevent their occurrence. With an increasing elderly dentate population who are potentially at risk of developing caries, the dental profession can expect an increasing demand and need for the prevention and treatment of root caries lesions. The delivery of fluoride, in various vehicles, has been shown to be effective in preventing and reversing such lesions. Clinical studies have demonstrated that water fluoridation [Hunt et al., 1989; O'Mullane and Whelton, 1992] and fluoride rinsing [Wallace et al., 1993] can reduce root caries. Brushing with a toothpaste containing 1,100 ppm F^- has also been shown to have the potential to arrest root carious lesions [Nyvad and Fejerskov, 1986; Jensen and Kohout, 1998]. In 1993, DePaola reported that after 1 year, 88% of subjects who used a combination of a fluoride dentifrice (1,100 ppm F^-) and Prevident Brush-on Gel (5,000 ppm F^-) had arrested root caries lesions, compared with 28% who used only a 1,100 ppm F^- dentifrice. That gel has since

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been reformulated to provide the benefits of a dentifrice, Prevident 5000, by the addition of an abrasive.

Existing clinical methods of diagnosing root caries are unable to discriminate between lesions with or without a remineralised surface layer without damaging the tooth surface. The electrical caries monitor (ECM) measures the electrical resistance of a site on the tooth, high measurements indicating well mineralised tissue and low values indicating demineralised tissue.

The aim of this study was to use clinical indices and the ECM to compare the ability of two sodium fluoride dentifrices, one, containing 5,000 ppm F^-, and another containing 1,100 ppm F^-, to remineralise primary root carious lesions (PRCLs).

Patients and Methods

Study Population

This 6-month study was carried out using a double-blind design, with patients recruited from those attending the Department of Conservative Dentistry at St. Bartholomew's and the Royal London School of Medicine and Dentistry. Ethical approval and a Clinical Trial Exemption Certificate were obtained prior to the commencement of the study. A total of 201 subjects, 114 (57%) male and 87 (43%) female, were recruited into the study. They were all more than 18 years of age, had at least 10 natural teeth and one or more PRCLs, had not participated in another clinical study in the previous 3 months and had signed a consent form. The mean age of the subjects at baseline was 59 ± 12.84 years, with a minimum of 27 and maximum of 90 years.

Study Design

Subjects were allocated to groups, by the study administrator, using randomised blocks stratified by the number of teeth with root carious lesions per subject. The examiner was unaware of the group assignment. Verbal and written instructions were given to brush at least once a day with their assigned toothpaste using a soft-bristled toothbrush. Patients were instructed to refrain from using any other fluoride-containing oral care product for the duration of the study. Additional toothpaste and toothbrushes were provided after 3 months, or earlier, by post if required.

Test Products

Both products were supplied in similar white containers to maintain the double-blind nature of the study. The products used were: positive control dentifrice, i.e. Winterfresh Gel 1,100 ppm F^- as sodium fluoride in a silica base, and test dentifrice, i.e. Prevident 5000 Plus 5,000 ppm F^- as sodium fluoride in a silica base.

Examinations

Each lesion was examined at baseline and after 3 and 6 months by a single examiner (A.B.) who had been trained to apply the various clinical criteria and the ECM.

Reproducibility

The intra-examiner reproducibility of the clinical examinations and the ECM readings were assessed by repeating examinations on 15 teeth in 12 subjects. There was perfect agreement in the classifications of hardness, texture, colour and cavitation. There was fair agreement in the assessment of plaque being present or absent (kappa = 0.50, SE = 0.185). There was excellent agreement between the first and second measurements of area [slope (SE) = 1.03 (0.05), intercept (SE) = 0.08 (0.32), $p < 0.001$], distance from the gingival margin [slope (SE) = 0.93 (0.01), intercept (SE) = 0.04 (0.03), $p < 0.001$] and ECM measurements [slope (SE) = 0.86 (0.2), intercept (SE) = 0.94 (1.1), $p < 0.001$]. The intraclass correlation coefficient [Bland and Altman, 1996] between the first and second measurements of area was 0.99 [95% confidence interval (CI) 0.96–1.00], for the distance to the gingival margin it was 0.99 (95% CI 0.99–1.00) and for the ECM measurement it was 0.75 (95% CI 0.41–0.91).

Clinical Criteria

Hardness. The hardness of each lesion was defined as follows: a soft lesion was one which permitted a sharp probe to penetrate the surface at 100 g of pressure with ease and there was no resistance to its withdrawal; a leathery lesion permitted a sharp probe to penetrate the surface at 100 g of pressure but there was some resistance to its withdrawal; a hard lesion was comparable in hardness to the surrounding root dentine. The probing force was standardised by repeat measurements of 50 PRCLs in mounted teeth fixed to a Metler PC 180 microbalance (Metler Instruments AG, Zurich, Switzerland) with silicone impression putty. The mean ± SD probing force was 102.1 ± 6.72 g.

Cavitation. The lesion was classified as cavitated if the distance from the existing surface of the lesion to the original root surface was estimated to be greater than 0.5 mm.

Dimensions. A standard periodontal probe, marked at 1-mm intervals, was used to determine the height and width of each lesion. The distance from the gingival margin of the lesion to the crest of the gingiva was also measured.

Colour. The colour of each lesion was assessed by reference to colour photographs which depicted 'yellow', 'light brown', 'dark brown' and 'black' lesions.

Dental Plaque. The amount of plaque overlying each lesion was measured using the Turesky modification of the Quigley-Hein Plaque Index [Turesky et al., 1970].

ECM Measurements

The ECM III (Lode Diagnostics BV, Groningen, The Netherlands) was used to measure the electrical resistance of each carious lesion. The ECM measures the electrical resistance of a site on the tooth during controlled drying. By drying the surface, the resistance is determined by the tooth structure, avoiding short circuiting to the soft tissues by the surface liquid (saliva). The electrical resistance was measured at 23.3 Hz and < 0.3 mA whilst drying the tooth for 5 s at an air flow rate of 5 $l \cdot min^{-1}$. During the ECM readings, the measuring probe was applied to a lesion, whilst the subject held the reference electrode. Measurements were taken at the centre, mesial, distal, occlusal and gingival points of each root carious lesion. The monitor recorded the value at the end of the drying period (end value) and the area under the curve during the drying period (integrated value). The end value was used in the statistical analysis.

Data Collection

Clinical data were transferred to a personal computer, and data from the ECM were collected using dedicated ECM software from Lode Diagnostics.

Statistical Analyses

Hardness. The difference in the number of subjects with at least one lesion becoming hard was tested using a multiple logistic regression model with the number of teeth examined for each subject and the baseline plaque scores as co-variables.

ECM Scores, Cavitation, Area, Distance from Gingival Margin and Plaque Index. The means of the five ECM resistance measurements for each lesion recorded at baseline, and after the 3 and 6 months examinations, were used in data analyses. These data were transformed using the $\log_{10}$ function to ensure a normal distribution and equalise the variance between study groups.

For lesions, the difference in ECM resistance (ΔR), plaque index (ΔPI) distance from the gingival margin (ΔDGM), and area (ΔA) measurements between baseline, and 3- and 6-month examinations was calculated by subtracting the 3- and 6-month values from the baseline reading. Subject scores for 3- and 6-months were then computed by calculating the sum of ΔR, ΔPI, ΔDGM and ΔA for all teeth scored, divided by the number of teeth examined. The statistical significance of the difference in mean ΔR, ΔPI, ΔDGM and ΔA between subjects in the two study groups was tested by fitting a multiple linear regression model. The number of teeth examined per subject and the mean of baseline scores for all teeth in each subject were used as co-variables. For the ΔECM, the baseline plaque score was also used as a covariable. All statistical tests were two-sided and threshold of significance was 0.05.

Results

Only subjects attending all three examinations (baseline, 3 and 6 months) were eligible for inclusion in the final data analyses. At baseline, 107 subjects (130 lesions) were recruited into the 5,000 ppm F^- group. Of these 2 subjects failed to attend for either the 3- or 6-month examination, 1 chose to withdraw from the study, 1 had the affected tooth extracted and 1 subject had missing data. Of the 94 subjects (132 lesions) recruited into the 1,100 ppm F^- group, 5 failed to attend for examination, 1 withdrew, 2 had the affected teeth filled and 2 had missing data. The mean number of affected teeth included per person in the 5,000 ppm F^- group was 1.23 (0.96), compared to 1.39 (0.69) in the 1,100 ppm F group (p = 0.17). The mean age was 58.9 ± 13.0 years, with a range of 27–90 years. No adverse effects of either product were observed during the course of the study.

Hardness

At baseline, all lesions, apart from 2, were of a leathery consistency (table 1). After 3 months, 47 (37.6%) of the 125 lesions in the 5,000 ppm F^- group had become hard, compared with 13 (11.1%) of the 117 lesions in the 1,100 ppm F^- group (table 1). After 6 months, 65 (52.0%) lesions in the 5,000 ppm F^- group and 30 (25.6%) in the 1,100 ppm F^- group had become hard. At 3 months, 39 (38.2%) of 102 subjects in the 5,000 ppm F^- group and 9 (10.7%) of the 84 subjects in the 1,100 ppm F^- group had 1 or more lesions that had become hard (p = 0.005). At 6 months, 58 (56.9%) of the subjects using the 5,000 ppm F^- dentifrice and 24 (28.6%) using the 1,100 ppm F^- dentifrice had 1 or more lesions that had become hard (p = 0.002).

At 3 months, a subject was 3.6 times (95% CI 1.8–6.9), and at 6 months, 2.0 times (95% CI 1.4–2.9) more likely to have 1 or more lesions becoming hard using the dentifrice containing 5,000 ppm F^- than 1,100 ppm F^-.

Cavitation

The relationship between cavitation and hardness at 3 and 6 months is shown in table 2. Non-cavitated lesions (< 0.5 mm) at baseline were more likely to become hard at 3 and 6 months in both groups. At 6 months, 76% of the non-cavitated lesions in the 5,000 ppm F^- group and 35% of lesions in the 1,100 ppm F^- group had become hard. In contrast, only 18.5% of cavitated lesions in the 5,000 ppm F^- group and 9.3% in the 1,100 ppm F^- group became hard.

Table 1. Cross tabulation of root caries hardness classification at baseline and changes after 3 and 6 months, by dentifrice grouping

Baseline	3 months			6 months		
	hard	leathery	soft	hard	leathery	soft
5,000 ppm F^-						
hard	0	0	0	0	0	0
leathery	47	76	1	65	58	1
soft	0	1	0	0	1	0
1,100 ppm F^-						
hard	0	0	0	0	0	0
leathery	13	103	0	30	85	1
soft	0	0	1	0	1	0

Table 2. Cross tabulation of cavitated and non-cavitated status of root caries lesions at baseline and hardness classification after 3 and 6 months, by dentifrice grouping

Baseline	3 months		6 months	
	hard	leathery/soft	hard	leathery/soft
5,000 ppm F^-				
cavitated	6 (11)	48 (89)	10 (19)	44 (82)
non-cavitated	39 (55)	32 (45)	54 (76)	17 (24)
1,100 ppm F^-				
cavitated	1 (2)	42 (98)	4 (9)	39 (91)
non-cavitated	12 (16)	62 (84)	26 (35)	48 (65)

Row percentages are shown in parentheses.

Table 3. Mean ± SD of distance from the gingival margin (mm) according to tooth and subject, by dentifrice grouping

	Tooth		Subject	
	5,000 ppm F^- (n = 125)	1,100 ppm F^- (n = 117)	5,000 ppm F^- (n = 102)	1,100 ppm F^- (n = 84)
Baseline	0.7±0.9	1.0±1.3	0.7±0.8	1.1±1.3
3 months	1.2±1.1	0.9±1.3	1.1±0.9	1.0±1.3
6 months	1.4±1.2	1.1±1.4	1.2±1.0	1.2±1.5
Baseline–3 months	–0.5±0.9	0.1±0.7	–0.4±0.7	0.1±0.6
Baseline–6 months	–0.7±1.1	–0.1±1.0	–0.6±0.9	–0.1±0.9

Table 4. Mean ± SD of lesion area (mm^2) according to tooth and subject, by dentifrice grouping

	Tooth		Subject	
	5,000 ppm F^- (n = 125)	1,100 ppm F^- (n = 117)	5,000 ppm F^- (n = 102)	1,100 ppm F^- (n = 84)
Baseline	6.8±4.6	5.3±3.9	6.5±4.7	5.2±3.9
3 months	6.5±4.4	5.5±3.8	6.3±4.5	5.3±3.7
6 months	6.6±4.6	5.2±3.6	6.3±4.6	5.0±3.4
Baseline–3 months	0.2±2.1	–0.1±2.4	0.2±1.8	–0.1±2.4
Baseline–6 months	0.1±2.7	0.2±2.9	0.2±2.6	0.2±2.9

Distance from the Gingival Margin

At the baseline examination, lesions for subjects in the 5,000 ppm F^- group tended to be closer to the gingival margin (table 3) than those in the 1,100 ppm F^- group ($p = 0.013$). During the 6 months of the study, there was a tendency for the distance to the gingival margin to increase in both groups. However, in the group using the 5,000 ppm F^- dentifrice, this difference was greater than in the 1,100 ppm F^- group, at both the 3- ($p < 0.001$) and 6-month ($p = 0.002$) examinations.

Area of the Lesion

The area of the lesions, for teeth and subjects, are shown in table 4. At baseline, the lesions in the 5,000 ppm F^- group were larger than in the 1,100 ppm F^- group ($p = 0.049$). During the 6 months of the study, lesions tended to get slightly smaller in both groups, but the differences were not statistically significant ($p = 0.89$).

Colour

During the course of the study, the colour of the lesions remained similar to that at baseline.

Plaque index

The mean plaque scores for teeth and subjects are shown in table 5. Plaque scores improved during the study in both groups, but the differences in plaque scores between baseline and the 3-month ($p = 0.008$) and 6-month ($p = 0.003$) examinations were greater in the 5,000 ppm F^- than in the 1,100 ppm F^- group.

Electrical Caries Monitor

The mean ECM scores are shown in table 6. Baseline ECM scores were similar for the two groups. The mean ECM scores for the group using the 1,100 ppm F^- dentifrice were similar at all three examinations. In contrast, the mean ECM scores of the lesions in the group using the 5,000 ppm F^- dentifrice tended to increase during the study. There were statistically significant differences in the changes in ECM scores between the two groups at both the 3- and 6-month examination points in the regression models ($p < 0.001$).

The greatest improvements in ECM scores were in those lesions that were non-cavitated at baseline (table 7).

Discussion

This study has demonstrated that it is possible to remineralise or arrest root carious lesions, and that Prevident 5000 Plus (5,000 ppm F^-) was significantly more effective in this process than Winterfresh Gel (1,100 ppm F^-). The potential of a toothpaste containing 1,100 ppm F^- to arrest

Table 5. Mean ± SD of plaque scores according to tooth and subject, by dentifrice grouping

	Tooth		Subject	
	5,000 ppm F^- (n = 125)	1,100 ppm F^- (n = 117)	5,000 ppm F^- (n = 102)	1,100 ppm F^- (n = 84)
Baseline	1.6±0.7	1.0±0.9	1.6±0.7	0.9±0.8
3 months	0.7±0.9	0.8±0.8	0.7±0.9	0.8±0.8
6 months	0.4±0.8	0.6±0.7	0.4±0.7	0.6±0.7
Baseline–3 months	0.9±1.0	0.2±1.1	0.9±1.0	0.1±0.9
Baseline–6 months	1.2±0.9	0.4±1.0	1.2±1.0	0.3±0.9

Table 6. Mean ± SD $\log_{10}$ ECM scores according to tooth and subject, by dentifrice grouping

	Tooth		Subject	
	5,000 ppm F^- (n = 125)	1,100 ppm F^- (n = 117)	5,000 ppm F^- (n = 102)	1,100 ppm F^- (n = 84)
Baseline	5.34±0.48	5.41±0.52	5.38±0.46	5.46±0.53
3 months	5.75±0.70	5.40±0.56	5.78±0.69	5.40±0.52
6 months	5.88±0.78	5.53±0.76	5.94±0.80	5.45±0.65
Baseline–3 months	–0.41±0.68	0.01±0.59	–0.40±0.64	0.06±0.55
Baseline–6 months	–0.41±0.78	–0.11±0.82	–0.56±0.76	0.004±0.70

root carious lesions [Nyvad and Fejerskov, 1986; Jensen and Kohout, 1988; DePaola, 1993; Nyvad et al.,1997] has been attributed to both the removal of plaque and the topical effect of fluoride. A previous study demonstrated that after 1 year, 88% of subjects who used both a fluoride toothpaste (1,100 ppm F^-) and Prevident Brush-on Gel (5,000 ppm F^-) had arrested root carious lesions, compared with 28% who used only the 1,100 ppm F^- dentifrice [DePaola, 1993]. The reformulation of the gel with a silica abrasive has provided the consumer with a more user-friendly dentifrice, Prevident 5000 Plus. An in vitro study of the gel and toothpaste formulations indicated comparable efficacy in terms of enamel fluoride uptake and reduction in enamel solubility [DePaola, 1997]. In the present study, 38% of lesions had become hard after 3 months and 52% after 6 months in the group using the high-fluoride dentifrice, compared with 11 and 26%, respectively, in the group using the 1,100 ppm F^- dentifrice. The presence or absence of cavitation at baseline was an important predictor of whether or not a lesion hardened. In the high-fluoride group, 39 (55%) of the 71 non-cavitated lesions at baseline had hardened after 3 months, increasing to 54 (76%) after 6 months. In comparison, only 10 (19%) of the 54 cavitated lesions had hardened after 6 months in this group. Although fewer lesions hardened in the 1,100 ppm F^- group, a similar pattern was seen; of the 74 non-cavitated lesions, 26 (35%) had become hard after 6 months, compared with only 4 (9%) of the 43 cavitated lesions. The influence of cavitation on the arrest of lesions has been observed previously by DePaola [1993]. He reported that after 1 year, 91% of non-cavitated lesions had arrested in the group using Prevident Brush-on Gel (5,000 ppm F^-) plus a 1,100 ppm F^- dentifrice, compared with 40% in the group using only the 1,100 ppm dentifrice. In comparison, 57% of cavitated lesions in the group using the 5,000 ppm F^- gel had arrested, compared with 8% in the 1,100 ppm F^- group. The less favourable response of cavitated lesions may indicate that the dentine is more demineralised and less able to provide a suitable substrate for rem-

Table 7. Difference from baseline in mean ± SD log10 ECM scores for lesions cavitated and non-cavitated at baseline, by dentifrice grouping

	Baseline to 3 months	Baseline to 6 months
5,000 ppm F^-		
cavitated (n = 54)	0.21±0.72	0.18±0.74
non-cavitated (n = 71)	0.55±0.62	0.81±0.71
1,100 ppm F^-		
cavitated (n = 43)	–0.12±0.41	–0.11±0.65
non-cavitated (n = 74)	0.05±0.67	0.25±0.88

ineralisation [Wefel et al.,1995; Heilman et al.,1997]. Alternatively, it may be more difficult to maintain an effective level of plaque control in such lesions.

At baseline, the mean plaque score for subjects in the 5,000 ppm F^- group was significantly higher than in the 1,100 ppm F^- group, and therefore plaque scores were included as a co-variable in the statistical analysis. After 3 and 6 months, the mean plaque scores for the two groups were similar, but because of imbalance at baseline, the improvement was greater in the 5,000 ppm F^- group. Whilst improved levels of plaque control may have played some part in the arrest of root surface lesions, this study has demonstrated the additional benefit of using a high fluoride dentifrice.

It has been suggested that the conversion of active into inactive root surface carious lesions is probably primarily a reflection of plaque removal and surface abrasion and that such inactive lesions should not be designated as remineralised lesions [Nyvad and Fejerskov, 1993]. Thus, in an in situ study Nyvad et al., [1997] observed that plaque removal with a 1,100 ppm F^- dentifrice resulted in mineral redistribution within the lesions. However, the body of the lesion persisted, with an increased mineral content in the surface layer. The mean ECM scores in the present study tended to increase in the group using the 5,000 ppm F^- dentifrice, whereas they remained essentially unchanged in the group using the 1,100 ppm F^- dentifrice. The ECM indicates the porosity of a tissue, and in this case the increase in values observed in the group using the 5,000 ppm F^- dentifrice do suggest that remineralisation of the surface has occurred. In vitro studies have indicated that fluoride concentrations as low as 0.02–2.0 ppm F^- can enhance mineral deposition in the surface layer of root lesions during acid challenges [Almqvist and Lagerlöf, 1993].

The colour of the lesions remained similar to that at baseline during the study period. It should be noted that colour alone is not an adequate indicator of lesion activity. There is a poor correlation between the colour and hardness of root caries [Hellyer et al., 1990; Schaeken et al., 1991].

A recent survey of adults aged more than 65 years in the UK reported that all were vulnerable to root decay and 80% had some evidence of caries or restoration of the root surfaces [Steele et al., 1998]. A more detailed analysis indicated that all of the unsound root surfaces were concentrated in 50% of the sample. The mean number of unsound root surfaces in those affected was 2.6, and around a quarter of the total sample accounted for 70% of all the lesions recorded. Individuals living in institutions had twice the number of unsound roots as those living at home. Such data suggested the need to provide the increasing elderly dentate population with a simple, effective means of preventing and reversing root caries. The evidence from this study suggests that root carious lesions can be treated non-operatively by the use of fluoride toothpaste, and that one containing 5,000 ppm F^- is significantly more effective than one containing 1,100 ppm F^-.

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