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Amine fluoride/stannous fluoride and incidence of root caries in periodontal maintenance patients

A 2-year evaluation

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Abstract

Aim: The purpose of the present study was to evaluate in a group of periodontal maintenance patients, the effect of using a dentifrice and mouthrinse containing amine fluoride (AmF) and stannous fluoride (SnF_2) as compared with a dentifrice and mouthrinse both containing sodium fluoride (NaF) with regard to their root caries experience.

Material: In total, 80 patients who had been treated for moderate-to-severe periodontitis agreed to participate in this study. Subjects received supportive periodontal therapy at regular intervals of 3–4 months for at least a period of 1 year. The patients were randomly divided into two groups: (1) the test group used an AmF/SnF_2 dentifrice and mouthrinse and (2) the control group used an NaF-containing dentifrice and mouthrinse. Root caries was recorded at four sites per tooth at baseline and 24 months.

Results: An increase in number of the exposed root surfaces was noted for both groups during the experimental period ($p<0.05$). The mean number of active caries lesions at baseline was 2.1 and 1.8 for the test group and control group, respectively. At 24 months, the corresponding values were 1.8 for the test and 2.2 for the control group. An increase of the mean number of restored surfaces was noted for the AmF/SnF_2 group (from 7.3 to 13.4) and the control group (from 7.9 to 14.7) during the course of the study. This increase was found to be statistically significant for both groups in comparison with the baseline values ($p\leqslant0.01$). No statistically significant differences were noted between groups. Further analysis of the restored surfaces revealed that the major increase in number of the restorations was associated with restorations involving three to four root surfaces in the same tooth. Molars and premolars were the teeth receiving most new restorations.

Conclusion: The present study did not detect a difference in terms of root caries development between the two groups. Root caries development is a common finding associated with surfaces developing recession in patients once treated for periodontal problems.

Key words: dentifrice; mouthrinse; periodontitis; plaque; root caries; supportive therapy

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The presence of root caries will become a growing concern for the dental practitioner (Gustavsen et al. 1988). As a result of the increase of life expectancy, the number of the elderly patients who visit the dental office has increased and the retention of teeth for a longer period of time will result in a greater number of root surfaces at risk for developing root caries (Beck & Hunt 1985). Changes in social and medical status of the elderly, development of recession as result of aging, traumatic toothbrushing, ongoing periodontal disease or pre-administered periodontal treatment will contribute to this effect (Serino et al. 1994).

Dental plaque is the main etiologic factor of dental diseases and one of the most frequently reported risk factors for development of root caries (Ravald et al. 1986, 1993, Ravald & Birkhed

1992, Reiker et al. 1999). The addition of fluorides to oral hygiene products is one of the cornerstones of prevention and oral health promotion. Fluorides act not only through the remineralization process (Allen et al. 1999), but also exert antimicrobial activity (van Loveren 2001). Consequently, incorporation of a fluoride dentifrice in the daily oral hygiene is one of the simplest and cost-effective manners of reducing the root caries risk (Newbrun 1999). Brushing with a dentifrice containing 1100 ppm F^- has been shown to arrest root caries lesions (Nyvad & Fejerskov 1986). Rinsing with fluoride is reported to be also a simple approach of diminishing the root caries prevalence in the elderly populations (Wallace et al. 1993). The anticaries activity of fluorides is greater when they are associated with cations that exert an intrinsic antibacterial activity such as the Sn^{2+} ion or the amine group from the organic amine fluoride (AmF) compound (Miller et al. 1994, van Loveren 2001).

Stannous fluoride (SnF_2) has been widely used in dentifrices for more than 30 years for the control of dental caries. However, it is clear from the many reports on the use of stannous solutions that the stability of the ion is critical with respect to its antimicrobial activity.

Amine fluorides (AmFs) show high fluoride incorporation into enamel because of their slightly acidic pH and exert considerable activity against cariogenic microorganisms (Stephen 1994, Newbrun 1999).

By adding AmF to SnF_2, the latter becomes more stable and both fluorides demonstrate synergistic plaque-reducing effect (Mühlemann 1981, Brecx et al. 1990, 1993, Zimmerman et al. 1993). The combined use of these fluorides has shown to be effective even when microorganisms were incorporated in biofilms (Arweiler et al. 2001, Shapiro et al. 2002).

Although the literature provides abundant information with regard to prevention of enamel caries, there is still a great need of information with respect to root caries. Periodontally treated patients develop recessions as result of treatment and are in risk in developing root surface caries. Longitudinal studies concerning root caries development in patients treated for periodontal disease are limited (Ravald & Hamp 1981, Ravald et al. 1993). In a recent study (Paraskevas et al. 2004, the combined use of an AmF/SnF_2 dentifrice and mouthrinse was compared with a combination of dentifrice and mouthrinse both containing sodium fluoride (NaF) in patients receiving supportive periodontal care. It was found that the AmF/SnF_2 regimen was more efficient in terms of plaque reduction when compared with NaF regimen. This observation was not sustained for the parameters of gingival inflammation. As part of the regular examinations, the presence and activity of root caries on exposed root surfaces were also measured. This paper describes the root caries experience in this same patient population in the light of the effect of the two above-mentioned regimes.

Material and Methods

In total, 80 patients, 30–65 years of age, participated in this study.

Inclusion criteria were:

- healthy non-institutionalized, male and female patients;
- at least three natural teeth in every quadrant;
- regular supportive periodontal care (3–4 months) for at least 1 year after the completion of the active periodontal treatment.

Exclusion criteria were:

- antibiotic therapy within 3 months prior to entering the study;
- hypersensitivity to SnF_2, NaF or AmF;
- systemic disorders or medication that could affect the condition of the periodontal tissues.

During the study, the use of mouthrinses or dentifrices other than the investigated products was not allowed. All participants were explained the outline, purpose and duration of the study and all signed an ''informed consent'' form before entering the study.

The study protocol was approved by the Medical Ethical Committee of Academic Medical Center.

The patients were randomly divided in two groups: the test group used a dentifrice (Meridol®, GABA INT., Switzerland (1400 ppm F)) and alcohol-free mouthrinse (Meridol®, 250 ppm F) both containing AmF/SnF_2 and the control group used a dentifrice and mouthrinse containing NaF of the same formulation and fluoride content. The products were provided in identical tubes and bottles having as only identification point the subject number. So, at no point during the study were the examiner or the patients aware of the group assignment. Patients continued having supportive maintenance care throughout the study. Normal oral hygiene procedures including both brushing and interdental cleaning were allowed and, if necessary, were reinforced during the regular maintenance appointments.

Clinical parameters

All examination procedures were performed by the same experienced examiner (M. M. D.). Prior to the beginning of the study training of the examiner included visual means (slides) as well as clinical examination on a series of patients in order to obtain high reproducibility. Records of previous examinations were not available to the examiner at the time of re-examination. Plaque was assessed according to the Plaque Index (Silness & Löe 1963) at baseline, 6, 12 and 24 months. Root caries was recorded at four sites per tooth (mesio-vestibular, mid-vestibular, disto-vestibular and mid-lingual) at baseline and 24 months. It was defined as active or inactive according to the definitions of Nyvad & Fejerskov (1986); an active lesion: greasy, yellowish or light brownish and soft on light probing; an inactive lesion: brownish tan or dark, smooth and hard on probing. When a lesion showed signs of active and inactive root caries the lesion was recorded as active. The presence of restorations confined to root surface or extending from the root surface to the coronal portion of the clinical crown was recorded. At the restoration outlines, the presence of active or inactive lesions was determined.

Every 6 months, patients received a sufficient amount of their assigned products to last during the period that extended to the next appointment. The patients were scheduled for an appointment with the dental hygienist at their regular intervals. The dental hygienist was not aware of the content of the provided products.

Data analysis

The total number of subjects that completed the study was 71. The reasons for dropouts and description of periodontal condition have been presented earlier by Paraskevas et al. (2004).

The primary efficacy variables were plaque and gingival bleeding. As part of the examination the presence of caries was also evaluated. Considering the patient as unit of measurement, scores for different types of lesions were pooled within these patients. The percentage of sites showing plaque was calculated. The main effect on plaque reduction was analyzed by using a repeated measures analysis with baseline values as covariate. Normality of residuals was assessed to be able to accept p values as computed with this analysis.

For root caries, the frequencies per patient were calculated. Differences between and within groups were tested by means of paired or unpaired t-tests as appropriate. The number of restorations was assessed and patient-level scores were calculated. In order to further explore changes in placement of restorations, analysis of the total number of restorations was carried out for baseline and 24 months.

P-values <0.05 were accepted as statistically significant.

Results

The test group comprised 33 individuals (25 females and eight males; mean age, 48 years) with a mean of 24.3 teeth. The control group consisted of 38 individuals (25 females and 13 males; mean age, 50 years) with a mean number of 24.5 teeth. Smokers were equally distributed between groups (10 smokers in each group).

During the 2-year study period, the mean plaque scores remained almost at the same level for the NaF group, whereas a reduction of plaque was noted for the AmF/SnF$_2$ group. The difference between test and control groups was statistically significant during the whole experimental period (Table 1). Further analysis of the plaque scores revealed that the reduction in plaque observed in the test group was associated with an increase of the percentage of plaque-free surfaces (from 71% to 79%) and a decrease of the percentage of surfaces associated with plaque score 1 (from 14% to 10%) (Table 2). The percentage of surfaces with plaque score 2 remained statistically significant in comparison with the baseline during the first year of the study. For the control group, such changes were not observed with the exception of the surfaces associated with plaque score 1 at 6 months (Table 2).

Table 1. Mean plaque scores (PI) at different evaluation moments in the AmF/SnF$_2$ and NaF groups

	Baseline	6 months	12 months	24 months
Total sites AmF/SnF$_2$	97.1	97.1	96.7	96.5
Total sites NaF	97.9	97.7	97.6	97.5
Plaque				
AmF/SnF$_2$	0.43 (0.27)	0.28 (0.18)†† *	0.27 (0.20)†† *	0.31 (0.20) *
NaF	0.40 (0.29)	0.44 (0.28)	0.40 (0.28)	0.43 (0.25)

Data are reported on patient level. Standard deviations in parentheses. PI, Plaque Index; AmF, amine fluoride; SnF$_2$, stannous fluoride; NaF, sodium fluoride.
*Significant differences between groups: $p \leqslant 0.05$.
††Significant differences from baseline: $p \leqslant 0.01$.

Table 2. Mean percentages of surfaces with plaque scores 0, 1, 2 and 3 in the two groups throughout the study

	Score 0	Score 1	Score 2	Score 3
Baseline				
AmF/SnF$_2$	71 (15)%	14 (7)%	14 (11)%	0.1 (0.2)%
NaF	73 (16)%	14 (6)%	13 (13)%	0.1 (0.3)%
6 months				
AmF/SnF$_2$	80 (11) %§§ **	12 (5)%§ **	8 (7)%§§ *	0
NaF	70 (15)%	16 (6)%§	14 (13)%	0
12 months				
AmF/SnF$_2$	82 (13)%§§ *	9 (6)%§§ *	9 (8)%§	0
NaF	73 (16)%	15 (7)%	12 (12)%	0
24 months				
AmF/SnF$_2$	79 (11)%§ *	10 (4)%§§ *	11 (9)%	0
NaF	72 (14)%	12 (5)%	16 (11)%	0

Data are reported on patient level. Standard deviations in parentheses. AmF, amine fluoride; SnF$_2$, stannous fluoride; NaF, sodium fluoride
*Statistically significant between groups ($p<0.05$).
**Statistically significant between groups ($p<0.01$).
§Statistically significant in comparison to baseline ($p<0.01$).
§§Statistically significant in comparison to baseline ($p<0.05$).

The mean number of exposed root surfaces increased significantly for both groups during the study period (Table 3). A statistically significant increase of the number of restorations present on root surfaces was observed for both groups at 24 months ($p \leqslant 0.01$). The mean number of active caries lesions decreased from 2.1 to 1.8 lesions at 24 months for the AmF/SnF$_2$ group. In the NaF group, an increase from 1.9 to 2.2 lesions was noted. For both groups, however, these changes failed to reach the level of statistical significance. There were no differences noted between groups.

The distribution of the number of new caries lesions per patient and the changes in root caries activity in the period of 24 months are given in Table 4. Thirty patients (91%) in the test and 34 (89%) in the control group developed at least one new caries lesion (restorations included) in the 2-year-study period. The mean number of new active caries lesions that developed in this period was 8.2 for the test and 8.4 for the control group. There were no statistically significant differences between the two groups.

It was assumed that a professional dental intervention (placement of new restorations) would indicate caries activity. Table 5 provides a separate analysis of the restored surfaces according to the number of surfaces involved. The mean number of restorations involving one or two root surfaces of the same tooth was slightly increased during the 24-month period. The greatest proportion of the new restorations however, was associated mainly with

Table 3. Mean number of exposed, sound and affected root surfaces per patient

	Baseline		24 months	
	AmF/SnF_2 ($N = 33$)	NaF ($N = 38$)	AmF/SnF_2 ($N = 33$)	NaF ($N = 38$)
Exposed root surfaces	61.2 (20.5)	63.4 (20.0)	65.1 (19.5)*	66.7 (18.8)*
Sound exposed surfaces	51.5 (19.0)	53.0 (19.0)	49.6 (18.2)	50.0 (20.3)
Decayed and/or filled root surfaces	7.3 (9.3)	7.9 (9.5)	13.4 (13.2)**	14.7 (15.6)**
Surfaces with root lesions	2.7 (3.3)	2.8 (2.6)	2.5 (2.7)	2.5 (2.4)
Active root caries lesions	2.1 (3.0)	1.9 (2.2)	1.8 (2.1)	2.2 (2.4)
active lesions associated with exposed non-restored surfaces	1.9 (2.7)	1.7 (2.2)	1.5 (1.9)	1.9 (2.3)
active root lesions associated with restored root surfaces	0.2 (0.5)	0.2 (0.4)	0.3 (0.6)	0.3 (0.8)
Inactive root lesions	0.6 (1.6)	0.9 (1.2)	0.8 (1.8)	0.3 (0.55)
inactive root lesions associated with exposed non-restored surfaces	0.5 (1.4)	0.8 (1.0)	0.6 (1.8)	0.2 (0.5)
inactive root lesions associated with restored root surfaces	0.1 (0.2)	0.1 (0.3)	0.1 (0.4)	0.1 (0.3)

Standard deviations in parentheses. AmF, amine fluoride; SnF_2, stannous fluoride; NaF, sodium fluoride.
*Significant difference from baseline ($p \leqslant 0.05$).
**Significant difference from baseline ($p \leqslant 0.01$).

Table 4. Distribution of root caries lesions and changes in the development of new root caries lesions during the study period (baseline to 24 months)

	AmF/SnF_2 group ($N = 33$)	NaF group ($N = 38$)	Total ($N = 71$)
patients with $\geqslant 1$ active caries lesion	30	34	64
number of patients with $\geqslant 1$ arrested caries lesions	2	1	3
total mean active lesions that develops within 2 years	8.2 (7.9)	8.4 (8.9)	8.3 (8.4)
number of new lesions the develops in 2 years	8.5 (7.9)	8.2 (8.8)	8.4 (8.3)

AmF, amine fluoride; SnF_2, stannous fluoride; NaF, sodium fluoride.

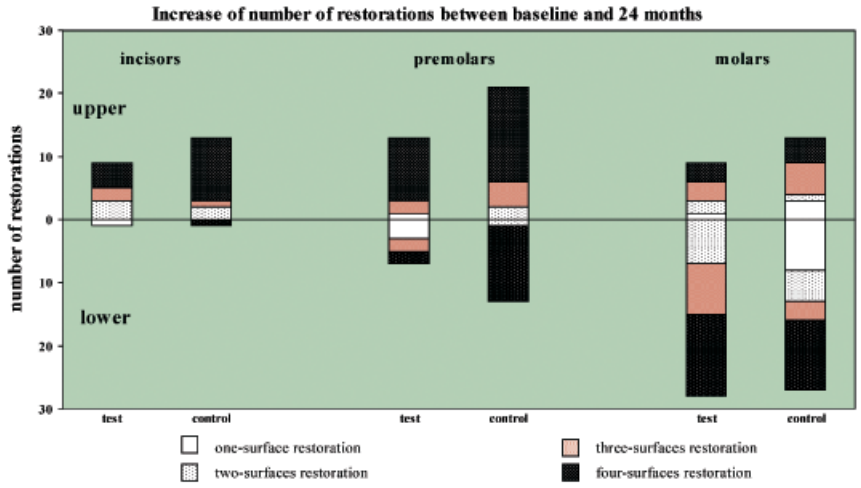

Fig. 1. Increase of the number of restorations for both groups and their distribution according to different tooth categories and number of involved root surfaces.

restorations involving three or four surfaces of the same tooth. The increase of the number of the restorations for both groups for three different tooth categories (molars, premolars and front teeth) is presented in Fig. 1 (data are presented on site level). It shows that although the restorations involving one and two root surfaces showed slight changes during the 24-month period, the majority of new restorations had been placed mainly in the region of molars and premolars and involved three to four root surfaces.

Discussion

Exposed root surfaces developing as a result of aging, traumatic brushing habits, existing periodontal disease or already pre-administered periodontal treatments are considered at risk for development of root surface caries. Periodontitis patients are clearly at risk because they develop recessions as a result of periodontal treatment. In the present study, 91% of the individuals of the test group and 89% in the control group developed at least one new root caries lesion over the study period of 2 years. These percentages are much higher than those reported by Ravald & Hamp (1981). They found that 20 out of 31 patients (65%) developed at least one new root caries lesions over a period of 4 years. The difference between the two studies can be attributed to several factors. In the study by Ravald & Hamp (1981), the caries measurements were performed on the basis of definition by Hix & O'Leary (1976), which refers to the presence of ''a cavitation or softened area in the root surface which might or might not involve adjacent enamel or existing restorations (primary and recurrent lesions)''. In the present study, the definitions by Nyvad & Fejerskov (1986) were adopted which make a distinction between active and inactive root caries based on the color and texture of the lesions. Additionally, at the start of the present investigation the baseline values of exposed root surfaces were greater than those of the study by Ravald & Hamp (1981), thereby contributing to a higher number of surfaces at risk for root caries (Table 3). Finally, although not assessed, diet and sugar clearance as well as salivary buffer capacities are also considered important factors associated with higher risk of root caries development (Hoppenbrouwers et al. 1987, Fure & Zickert 1990a, b, Faine et al. 1992) and could account for the discrepancy observed.

The clinical diagnosis of root caries is based on a number of signs both visual (color, contour, surface cavitation) and tactile (surface texture) (Banting 1993, 2001). The major component of the caries experience indices is the number of the restored root surfaces (Banting 2001). In the present study, an increase of the restored root surfaces was noted at 24 months for both the test and control groups (Table 3). This increase was found to be statistically

Table 5. Mean number of restored teeth per patient grouped by number of involved surfaces

	Number of restored surfaces per tooth			
	one	two	three	four
Baseline				
AmF/SnF_2	2.0 (2.2) ($N = 66$)	0.4 (0.7) ($N = 14$)	0.3 (0.8) ($N = 11$)	0.9 (1.9) ($N = 28$)
NaF	1.8 (1.7) ($N = 69$)	0.5 (1.0) ($N = 18$)	0.7 (1.7) ($N = 27$)	0.7 (1.3) ($N = 28$)
total	1.9 (1.9) ($N = 135$)	0.5 (0.9) ($N = 32$)	0.5 (1.3) ($N = 38$)	0.8 (1.6) ($N = 56$)
24 months				
AmF/SnF_2	2.1 (2.1) ($N = 71$)	0.7 (1.0) ($N = 24$)	0.8 (1.2) ($N = 28$)	1.8 (2.5) ($N = 60$)
NaF	2.0 (1.7) ($N = 75$)	0.7 (1.0) ($N = 27$)	0.9 (1.5) ($N = 35$)	2.1 (2.9) ($N = 81$)
total	2.0 (1.8) ($N = 146$)	0.7 (1.0) ($N = 51$)	0.9 (1.4) ($N = 63$)	1.9 (2.7) ($N = 141$)

Standard deviations in parentheses. In the second parentheses *N* is the total number of restorations. AmF, amine fluoride; SnF_2, stannous fluoride; NaF, sodium fluoride.

significant in comparison with baseline for both groups. It was assumed that the presence of new restorations was indicative of disease activity. This hypothesis however involves certain biases. The study population consisted of patients returning regularly (every 3–4 months) to the Department of Periodontology for supportive maintenance care. Meanwhile, they were visiting their own dentists for the regular checkups. Although restorations are mainly placed because of decay or tooth wear, repairing lost tooth structure is often subjected to the personal treatment preferences of the individual dentist and possibly also to the health-care system in which dentists work (Elderton & Nuttall 1983, Bader et al. 1993, Bader & Shugars 1995). During the study, it was not assessed why restorations had been placed. Therefore, it may well be possible that some of the placed restorations were associated with factors other than root decay. Consequently, including the placement of restorations in the assessment of caries activity in a prospective study may introduce a bias. Preferably, monitoring the changes in caries activity would require no intervention from the part of the dental practitioner. This would however be unacceptable for obvious ethical reasons. An attempt to illustrate the impact of the inclusion of restorations when measuring caries activity was performed in Table 5. This table shows that the difference in increase of restorations between baseline and 24 months was greatly influenced by the placement of restorations associated with three and four tooth surfaces. It is reasonable to assume that four restored surfaces per tooth could very likely represent the presence of a crown. Frequently, the placement of a crown requires the apical or lateral extension of the preparation into healthy tooth (root) structure. Therefore, the inclusion of all four restored surfaces results in an overestimation of the caries incidence. On the other hand, excluding all restorations extending from the root to the coronal part of the tooth may lead to an underestimation of the root caries incidence. Although the problem cannot be totally solved either way, it might be suggested that, for future prospective studies, the type of restorations and the number of involved surfaces should be recorded, as it would give more insight information regarding the development of root caries.

The interpretation of the results of the present study should be done with caution taking into consideration its descriptive nature. The design of the study permitted sufficient power for plaque assessments. As part of the examinations information on the presence of root caries was collected but was not included in the primary variables of the study. With this in mind, a descriptive manner of presentation of data considering root caries development was deliberately chosen. This fact is also related to the size of the population studied in the present investigation. It is well known from the literature that not all patients will develop root caries and the susceptibility to it varies considerably between individuals of the same population. The increment of new root caries lesions that develops within a certain period is rather low (5% of exposed surfaces according to Ravald & Hamp 1981). The results of the present investigation are in accordance to this finding; the prevalence values at baseline and 24 months for both groups were also low (Table 3).

Facing the difficulties of restoring root caries (visibility, moisture control, access to carious lesions, proximity of the pulp and gingival margin, and the high organic content of dentine) and the relative limitations of the present restorative materials (poor marginal adaptation and microleakage) (Taylor & Lynch 1992, Lynch & Baysan 2001), it seems reasonable to conceive that the solution of the problems asks rather for a preventive concept than a restorative one. As it has been already shown in the literature, daily oral hygiene remains crucial in controlling the development of root caries (Nyvad & Fejerskov 1986, Johansen et al. 1987). Studies dealing with identification of risk factors or indicators in periodontal patients showed that the presence of supragingival plaque is positively correlated with the root caries activity (Ravald & Birkhed 1991, Ravaldet al. 1993, Reiker et al. 1999). Reiker et al. (1999) observed in a cross-sectional study in periodontitis patients that 90% of sites with active root caries lesions harbored plaque, whereas plaque was only recovered at 40% of sites with inactive root caries. In this respect, self-performed oral hygiene plays an important role in controlling the development of root caries in susceptible patient populations. As active root caries lesions can be converted into inactive by fluoride treatment and effective oral hygiene measures (Nyvad & Fejerskov 1986, Johansen et al. 1987, Ravald & Birkhed 1991), one could assume that every possible method that helps reducing the plaque levels in the mouth would be beneficial for susceptible individuals. In the present study, it was found that the test group had approximately 25% mean Plaque Index reduction (from 0.43 to 0.31 at 24 months) as a result of the combined use of the dentifrice and mouthrinse containing AmF/SnF_2. This reduction was not noted for the control group. The number of new caries lesions, however, was not significantly different between the two groups. This study could not confirm the data obtained from earlier studies (Ueberschär & Günay 1991, Nemes & Banoczy 1992). Both groups used the (modified) Root Caries Index from Katz (1984). Nemes & Banoczy (1992) found in their short-term study that the group ($N = 20$) using AmF and SnF_2 mouthrinse and dentifrice for 20 weeks had significantly less active lesions compared with the NaF group ($N = 24$) which they interpreted as the result of a better remineralizing effect. Ueberschär & Günay (1991) investigated

over a 16-month period the caries protective effect of an AmF/SnF_2 containing rinse on the exposed root surfaces from patients who had undergone periodontal surgery. They found a lower root surface caries incidence after long-term application of the AmF/SnF_2 containing rinse ($N = 19$) compared with the control group ($N = 30$) which did not rinse at all.

One could question whether this discrepancy is related to a limitation of the Plaque Index used in the present study (Silness & Löe 1963). This index takes into account only the plaque located along the gingival margin. However, the study by Lynch & Beighton (1994) showed that active caries lesions are located at the closest distance from the gingival margin. Therefore, it seems unlikely that the Plaque Index did not give sufficient information concerning the presence of plaque associated with the root caries lesions.

The plaque analysis as presented in Table 2 shows that the plaque reduction observed in the AmF/SnF_2 group can be explained by the increase of the percentage of the sites without plaque (plaque score 0), the decrease in sites having scores 1 and 2 and the elimination of sites with score 3. At 24 months, 79% of the sites had no plaque in the AmF/SnF_2 group, whereas 72% of the sites in the control group were found plaque free. It is possible that the increase of 8% of the sites with absence of plaque (score 0), as observed in the test group, was not sufficient in order to create an obvious clinical difference between the two groups in terms of root caries development.

In conclusion, the present study did not detect a difference in terms of root caries development between the two groups. Root caries development is a common finding associated with surfaces showing recession in patients once treated for periodontal problems, but additional research is necessary to identify factors that might be of importance in preventing development of root caries in susceptible individuals.

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