J Clin Periodontol 2005; 32: 757–764 doi: 10.1111/j.1600-051X.2005.00750.x

Journal of Clinical Periodontology

The effect of a dentifrice and mouth rinse combination containing amine fluoride/stannous fluoride on plaque and gingivitis: a 6-month field study

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Paraskevas S, Versteeg PA, Timmerman MF, Van der Velden U, Van der Weijden GA. The effect of a dentifrice and mouth rinse combination containing amine fluoride/stannous fluoride on plaque and gingivitis: a 6-month field study. J Clin Periodontol 2005; 32: 757–764. doi: 10.1111/j.1600-051X.2005.00750.x. © Blackwell Munksgaard 2005.

Abstract

Aim: To examine the effect of amine fluoride/stannous fluoride (AmF/SnF_2)-containing dentifrice and mouth rinse on plaque formation and gingivitis as compared with habitual oral hygiene procedures with a regular sodium fluoride (NaF) dentifrice.

Material and Methods: In total, 22 general practices participated in this research project. The participants ($N = 281$) were randomly assigned into two groups: the test group received an AmF/SnF_2 dentifrice–mouth rinse combination and the control group received a NaF-containing dentifrice. The patients were requested to brush twice daily for approximately 2 min. The subjects of the test group had to rinse additionally in the evening for 30 s with 10 ml of the mouth rinse.

Results: Both groups started with comparable scores of plaque, bleeding and staining. At 6 months, the plaque scores were 0.95 for the AmF/SnF_2 group and 0.99 for the NaF group (decrease of 16% and 10%, respectively). Bleeding scores, although significantly different from baseline, did not show differences between the two regimes. At the end of the experimental period, the overall staining was more pronounced in the AmF/SnF_2 group (41%) than the NaF group (26%). Both plaque reduction and increase in staining seemed to be correlated to the amount of mouth rinse used in the test group.

Conclusion: In instruction-resistant patients recruited from dental practices, the combined use of AmF/SnF_2 did not decrease gingivitis at a significant level in comparison with the regular regime of two times daily brushing with an NaF-containing dentifrice. However, the above-mentioned combination resulted in greater plaque reduction than that observed with the use of the conventional dentifrice. When used according to the manufacturer's instructions, this effect on plaque scores was more pronounced.

Key words: amine fluoride; dentifrice; field study; gingivitis; mouth rinse; plaque; staining; stannous fluoride; tin fluoride

Accepted for publication 13 December 2004

Daily oral hygiene aims at controlling plaque formation and is a key factor in preventing periodontal disease (Suomi 1971, Axelsson & Lindhe 1981). Plaque, if left unhindered to accumulate along the gingival margin, will result in gingivitis (Löe et al. 1965). The most common and undisputed means of performing oral hygiene is the use of a toothbrush and fluoridated dentifrice (Frandsen 1986). However, daily oral hygiene also depends on the dexterity of individuals (MacGregor & Rugg-Gunn 1979). In order to deal with the potential deficiencies of the mechanical plaque

control, mouth rinses have been introduced (Mandel 1988). Since their introduction, a number of agents have been evaluated with respect to their plaque growth-reducing or inhibiting capacities, among others, chlorhexidine (Addy et al. 1991b), triclosan (Ramberg et al. 1995), essential oils (Gordon et al. 1985), sanguinarine (Ramberg et al. 1992), and amine fluoride/stannous fluoride (AmF/SnF_2) (Brecx et al. 1990, 1993, Zimmerman et al. 1993). Ideally, the adjunctive effect of a mouth rinse on the daily mechanical plaque control should be evaluated in long-term studies. However, such studies are by virtue of their parallel design, group size and length, costly (Addy & Moran 1997).

It is well known that SnF_2 (Mayhew & Brown 1981) and AmF (Kay & Wilson 1988) display bactericidal activity against oral bacteria. The antibacterial properties of these two fluorides are strengthened when AmF and SnF_2 are combined (Brecx et al. 1990, 1993, Zimmerman et al. 1993). In short-term mouth rinsing experiments, this combination showed a much better inhibition of plaque accumulation than these two substances separately, and a favourable effect on oral hygiene and gingivitis was reported in several clinical trials (Brecx et al. 1990, 1993, Zimmerman et al. 1993). Shapira et al. (1999) examined the efficacy of the long-term use of a dentifrice containing AmF/SnF_2 as opposed to a control group using sodium fluoride (NaF) dentifrice. Both groups showed similar plaque reductions after 6 months, but only the AmF/SnF_2 combination was found to be effective in reducing gingivitis. Banoczy et al. (1989) examined the effect of an AmF/SnF_2 mouth rinse as an adjunct to an AmF/SnF_2 dentifrice on plaque and gingivitis of 92 schoolchildren. It was observed that the clinical efficacy of the tested AmF/SnF_2 dentifrice could be increased by the combined use of mouth rinse containing the same substances. In a 9-month study, Mengel et al. (1996) compared three different combinations of dentifrice/mouth rinse containing either AmF/SnF_2 or NaF. Although changes were seen for all three groups, the most pronounced drop in plaque and gingivitis indices was noticed in the AmF/SnF_2 dentifrice and mouth rinse group.

Studies designed to assess the efficacy of oral health products (such as toothbrushes, dentifrices, mouth rinses) have originally taken place as single-centre studies and usually under strict research conditions in a university environment. Such single-centre studies have limitations. Their results do not necessarily reflect conditions applicable to the clinical situation (Fleiss 1986, Eaton et al. 1997). It might be difficult to enrol sufficient numbers of subjects to overcome measurement variability (Imrey 1986). These problems can be overcome if these studies involve more centre, and not only university departments (Eaton et al. 1997).

The objective of the present study was to investigate the effect of the daily use of a combination of a dentifrice and mouthrinse containing AmF/SnF_2 on plaque formation and gingivitis as compared with habitual oral hygiene procedures with a regular NaF dentifrice, in a clinical single-blind 6-month field trial.

Material and Methods

The study protocol was approved by the Medical Ethical Committee (MEC) of the Academic Medical Center Amsterdam (AMC) (MEC 01/182 # 01.17.969).

A letter containing information about the research project was sent to approximately 800 general practitioners in the Netherlands with the request to participate in the field study. In total, 22 practitioners decided to contribute to the study, and disposed their practices for research purposes. In accordance to the study protocol, they had to make a selection of their own patients according to the following criteria, as described in the original letter:

- over 18 years of age,
- in good health,
- inadequate oral hygiene and $>50\%$ bleeding, which the dentist or oral hygienist has tried to improve but has never seen a positive change,
- no interdental cleaning on a regular daily basis,
- not using any mouth rinse,
- at least five evaluable teeth in each quadrant,
- no pockets >5 mm,
- no removable dentures, orthodontic appliances or retention wires,
- no use of antibiotics during the previous 6 months,
- no use of anti-inflammatory drugs on a regular basis,
- no physical handicap that might interfere with mechanical oral hygiene.

All selected patients of the same practice were scheduled for an appointment on the same day.

During the first appointment (baseline), all suitable subjects were informed about the outline and purpose of the study, and signed a written consent. They were asked to fill out a health questionnaire and were screened by the examiner (P. A. V.) for suitability according to the inclusion criteria.

All patients were randomly assigned into two groups with an equal distribution of both groups within each dental practice by means of a random numbers list. The test group received dentifrice and mouth rinse, both containing AmF/SnF_2(Dentifrice: Meridol®, GABA Int., Münchenstein, Switzerland (1400 p.p.m. F^-), Mouthrinse: Meridol®, GABA Int (250 p.p.m. Amine Fluoride/Stannous Fluoride)). The control group received only a dentifrice containing NaF (Everclean Fluor, HEMA B.V., Amsterdam (1450 p.p.m. F) the Netherlands), with the intention to minimize the influence of participating in this field study on the daily oral hygiene behaviour but standardizing the choice of dentifrice. All patients received a sufficient amount of products to last for at least 6 months. The different products were placed in black non-transparent plastic bags, in such a way that their identification by the examiner or the participants was not possible. A sealed envelope containing information about the products and the way they should be used accompanied the plastic bags. The subjects were requested to use the products according to the instruction as delivered in the envelope, and were instructed to continue toothbrushing according to their own technique. It was, however, attempted to standardize the brushing time and frequency: all subjects were requested to brush two times per day for approximately 2 min. In case of the dentifrice–mouthrinse combination, they were asked to rinse additionally every evening for 30 s with 10 ml of the mouth rinse.

The baseline scores were obtained in two randomly selected contra-lateral quadrants (Bentley & Disney 1995). The measurements were performed by one and the same examiner (P. A. V.), who was unaware of the group allocation. The clinical variables were as follows:

- Modified plaque index (modification of Silness & Löe, 1964 index, as

described by Danser et al. 2003) at six sites per tooth.
- Bleeding on marginal probing (BOMP): The marginal gingiva were probed according to the angulated bleeding index as described by Van der Weijden et al. (1994b). Bleeding was scored within 30 s after probing on a dichotomous scale (0, no bleeding. 1, bleeding).

In addition, in order to evaluate possible side effects of the use of both regimes, tooth discoloration was measured by means of the Gründemann modified staining index (Gründemann et al. 2000; four surfaces, two interproximal, one gingival and one incisal, at which staining is assessed according to the intensity stain index).

Third molars were excluded from the clinical measurements.

Smoking habits were recorded since they were considered as factors that could affect the presence of bleeding and the development of staining.

During the second appointment (6 months after baseline), the same clinical parameters were obtained by the same examiner who had also been responsible for the baseline measurements (P. A. V.).

The patients were asked to return their assigned products in order to obtain an indication of their compliance.

Data analysis

The sample size was selected a priori based on the assumption that a standard deviation of approximately 0.35 for the plaque index could be expected. With a sample size of 150 subjects per group, a difference of 0.12 with 80% power could be detected.

Mean plaque indices were computed for baseline and end scores. Percentage scores were obtained for bleeding and staining. For staining, an overall index value as well as index scores for different aspects of the tooth surface (incisal, gingival and approximal) were calculated. With respect to different regions of interest, additional analysis of the proportion of stained surfaces and the distribution of the proportion of the discoloration intensity 1, 2 or 3 was performed to investigate the origin of differences observed in the overall analyses.

Differences between groups were analysed using a repeated-measures analysis, entering baseline-and end-trial scores as dependent variables and age, gender and smoking status as covariates. The outcomes were corrected for the (possible) systematic effects between the different practices. Analysis of residuals was performed in order to confirm the validity of the *P* values as calculated with the repeated measures analysis.

To further explore the influence of the quantity of product(s) used on the clinical parameters, correlation coefficients were calculated for the amount of the dentifrice and/or mouth rinse used in the test group and for the amount of dentifrice used in the control group, with the observed change in clinical parameters.

P-values < 0.05 were accepted as statistically significant.

Results

Altogether, 327 patients were preselected by their own dentists as being suitable for taking part in the research project. At baseline, 14 patients did not meet their appointment and 12 patients were excluded from the research protocol after screening by the examiner (three insufficient plaque and bleeding scores, three recent extractions, one recent oral surgery, two retention wires and three compromised general health and/or use of medications).

In total, 281 patients completed the 6-month evaluation and were available for analysis. There had been 20 dropouts. Fourteen subjects did not show up during the second examination, one subject did not comply with the study protocol and five (belonging to the test group) discontinued with the research because they felt that the staining was interfering with their social activities.

All but two practices contributed with 14–16 patients. One practice contributed with only 5 and another with 17 evaluable patients. The demographic characteristics of the study population are described in Table 1. Eighty-three subjects were smokers.

Sixteen individuals had used antibiotics during the 6-month period. Separate analysis for this patient category revealed no differences with respect to the clinical parameters when compared with those who had not received antibiotics. Consequently, they were included in the overall data analysis.

Plaque scores

The mean plaque index at baseline was comparable for both groups: 1.16 for the test group and 1.13 for the control group, respectively (Table 2). At 6 months, a statistically significant decrease in plaque scores was noticed for both groups in comparison with the

Table 1. Demographic characteristics of the two study groups at baseline

	AmF/SnF_2	NaF
Number of subjects	134	147
Males/females (*N*)	61/73	58/89
Age	34.6 (10.6)	35.7 (12.3)
Smokers males/females (*N*)	21/25	14/23

Standard deviations in parentheses.
AmF, amine fluoride; SnF_2, stannous fluoride; NaF, sodium fluoride.

Table 2. Mean plaque scores (plaque pndex) and frequency distribution for the scores 0, 1, 2 and 3 of the plaque index

	Baseline	6 months	Difference	% plaque reduction
AmF/SnF_2 (N = 134)	1.16 (0.4)	0.95 (0.4)*	0.21 (0.3)**	16
Score 0	23% (17)	34% (20)	+11%	
Score 1	38% (14)	38% (13)	0%	
Score 2	40% (24)	29% (23)	−11%	
Score 3	0 % (0.2)	0.1% (1)		
NaF (N = 147)	1.13 (0.4)	0.99 (0.4)*	0.14 (0.3)	10
Score 0	25% (18)	32% (20)	+7%	
Score 1	38% (14)	38% (12)	0%	
Score 2	37% (25)	30% (23)	−7%	
Score 3	0.1% (0.1)	0.1% (1)		

Standard deviations in parentheses.
*Significantly different in comparison with baseline (repeated-measures analysis $p < 0.0001$).
**Significantly different between groups (repeated-measures analysis $p = 0.032$).
AmF, amine fluoride; SnF_2, stannous fluoride; NaF, sodium fluoride.

baseline, i.e. 0.21 and 0.14 for the test and control group, respectively ($p<0.001$). Repeated-measures analysis controlling for age, gender, smoking and practice effects demonstrated a significant difference between groups ($F=4.64$, $p=0.032$). The overall analysis showed that age ($F=9.13$, $p=0.0028$), gender ($F=14.85$, $p=0.002$) and smoking status ($F=5.36$, $p=0.0215$) had a significant effect on the amount of plaque. More specifically, older individuals harboured more plaque that younger participants, males had more plaque than females and smokers had more plaque than non-smoking subjects. Separate analysis for approximal and mid-vestibular/lingual surfaces revealed that the plaque reduction followed the same pattern as for the total plaque scores (data not shown).

Bleeding scores

Table 3 also shows the mean BOMP for the test and control group. A decrease in the mean BOMP was noticed for both groups in comparison with the baseline (from 0.77 to 0.71 for the test group and from 0.78 to 0.73 for the control group). Repeated-measures analysis controlling for age, gender, smoking and practice demonstrated that this difference was significant in comparison with baseline ($F=38.52$, $p=0.000$). However, no significant difference was observed between groups ($p=0.293$). Smoking had a significant effect on the bleeding scores ($F=16.13$, $p=0.0001$) i.e. smokers exhibited less bleeding in comparison with non-smokers.

Staining scores

Table 4 shows the mean percentage of staining for both groups. Data were analysed as the overall percentage of sites with staining and separately as percentages with scores 1, 2 and 3, respectively. An increase in the percentage of sites with staining was noticed for both groups in comparison with the baseline ($F=265.81$, $p=0.000$). Repeated-measures analysis controlling for age, gender, smoking and practice demonstrated that the AmF/SnF_2 group had significantly more staining than the NaF group ($F=98.36$, $p=0.000$). With increasing age, the observed staining prevalence was greater ($F=30.85$, $p=0.000$). Smokers demonstrated more staining in comparison with non-smokers ($F=7.79$, $p=0.0057$).

Compliance

Not all patients complied to the full extent with the instructions for use of the test mouth rinse (Table 5). The majority (74%) of the participants in the test group used four bottles of mouth rinse or more. A small proportion (7%) never rinsed or rinsed very seldom. Accordingly, the plaque reduction observed was parallel to the user compliance (Table 5). For each group, correlation coefficients were calculated to explore whether the quantity of the products (how many tubes of dentifrice and/or bottles of mouth rinse were used in total per individual) had an effect on the clinical parameters measured in the present study. In the control group, a small but significant negative correlation was found between the amount of dentifrice used and the change of plaque scores (cc $=-0.165$, $p=0.046$, Fig. 1). In the test group, the change in plaque scores was correlated to the amount of mouth rinse used (cc $=0.229$, $p<0.01$, Fig. 2), but the amount of dentifrice showed no significant correlation with the plaque reduction (cc $=-0.033$, $p=0.709$, Fig. 1). However, in the test group, a positive correlation was observed between the amount of mouth rinse and amount of dentifrice used (cc $=0.439$, $p<0.05$).

No significant correlations were found for both groups between the amount of the used products and the decrease in BOMP.

The presence of staining showed no correlation with the amount of dentifrice used in both the test and control group. In the test group, the increment in staining was, however, positively correlated to the amount of mouthrinse used (cc $=0.171$, $p<0.05$, Fig. 3).

Discussion

Field studies are conducted in the patient's natural environment: home, school, workplace, private dental office. In such situations, the treatment is provided under real conditions (Kornman et al. 1992). These studies have access to a larger number of patients and a wide

Table 3. Mean bleeding on marginal probing

	Baseline	6 months	Difference	Range of the difference	% bleeding reduction
AmF/SnF_2 ($N=134$)	0.77 (0.16)	0.71 (0.16)*	0.06 (0.13)	−0.33 to 0.46	6
			NS		
NaF ($N=147$)	0.78 (0.17)	0.73 (0.17)*	0.05 (0.12)	−0.33 to 0.38	3

Standard deviations in parentheses.
*Significantly different in comparison with baseline (repeated-measures analysis $p<0.0001$).
AmF, amine fluoride; SnF_2, stannous fluoride; NaF, sodium fluoride.

Table 4. Percentage of stained surfaces and % for scores 1, 2 and 3 separately at baseline and 6 months for the test and control group, respectively

	Baseline	6 months	difference
% of stained surfaces†			
AmF/SnF_2 ($N=134$)	21 (12)	41 (16)*	20 (14)◆
NaF ($N=147$)	21 (14)	26 (14)*	5 (11)
% score 1			
AmF/SnF_2	19 (12)	34 (13)§,¶	
NaF	19 (12)	24 (12)§	
% score 2			
AmF/SnF_2	1 (2)	7(10)§,¶	
NaF	1 (3)	2 (4)	
% score 3			
AmF/SnF_2	0.1 (1)	0.05 (0.5)	
NaF	0.5 (4)	0.1 (0.5)	

Standard deviations in parentheses.
†Scores 1, 2 and 3 combined.
*Significantly different in comparison with baseline (repeated-measures analysis $p<0.0001$).
◆Significantly different between groups (repeated measures analysis $p<0.0001$).
§Significantly different from baseline (Wilcoxon's signed-rank test $p<0.01$).
¶Significantly different between groups (Wilcoxon's signed-rank test $p<0.01$).
AmF, amine fluoride; SnF_2, stannous fluoride; NaF, sodium fluoride.

Table 5. Number of subjects in relation to the number of bottles of mouth rinse used

AmF/SnF_2 group ($N = 134$)	# bottles mouthrinse	N	PLI baseline	PLI at 6 months	Difference	Range of the difference	% plaque reduction
	0–2.5	10	1.13 (0.24)	1.15 (0.32)	− 0.02 (0.29)	− 0.55 to 0.39	− 4 (27)
	3–3.5	21	1.08 (0.38)	0.91 (0.40)	0.17 (0.32)	− 0.32 to 0.79	14 (32)
	4–4.5	38	1.12 (0.43)	0.91(0.43)	0.21 (0.35)	− 0.39 to 1.03	17 (28)
	5–5.5	35	1.22 (0.36)	0.95 (0.43)	0.27 (0.41)	− 0.55 to 1.09	18 (41)
	6	30	1.22 (0.39)	0.94 (0.41)	0.28 (0.26)	− 0.13 to 0.93	23 (21)
Overall mean		134	1.16 (0.28)	0.95 (0.41)	0.21 (0.34)	− 0.55 to 1.09	16 (32)
NaF group ($N = 147$)							
Overall mean		147	1.13 (0.42)	0.99 (0.42)	0.14 (0.33)	− 0.82 to 1.26	10 (30)

Explorative analysis of % plaque reduction. Standard deviations in parentheses.
AmF, amine fluoride; SnF_2, stannous fluoride; PLI, plaque index; NaF, sodium fluoride.

variety of patient groups. Their results may allow for more powerful inferences since they closely reflect the real daily-life situation (Kornman et al. 1992). On the other hand, multi-centre studies require stringent control for uniformity in order to be successful (Goodson 1992). The present study was conducted outside the university environment and could be considered as reflecting the ''real-life'' situation. The stringency of inclusion criteria was initially guaranteed by the dental practitioners and subsequently by a second screening by the research examiner at baseline. It was the intention of this field study to minimize the intervention in the control group. Basically, their normal oral hygiene routine should not be influenced. Since manufacturers claim antibacterial effects of some of the dentifrices, it was, however, deliberately decided to standardize the dentifrice in this group and not to leave them with their own choice. This could potentially have been a jumbled mixture of all sorts of dentifrice ingredients.

Both groups demonstrated a decrease in plaque scores in relation to the baseline. The decrease in plaque was greater in the test group. Such a decrease in plaque has been documented earlier in the literature (Brecx et al. 1993, Zimmerman et al. 1993). In periodontitis patients receiving periodontal maintenance care, the combination dentifrice and mouth rinse containing AmF/SnF_2 resulted in a $\pm$ 25% reduction in plaque scores (Paraskevas et al. 2004). Compared with these results, the plaque reduction in the test group in the present study (16%) is not of the same magnitude. This might be explained by the unsupervised nature of the present study and the differences in study design and study population (e.g. gingivitis *versus* treated periodontitis patients, different baseline plaque and bleeding levels).

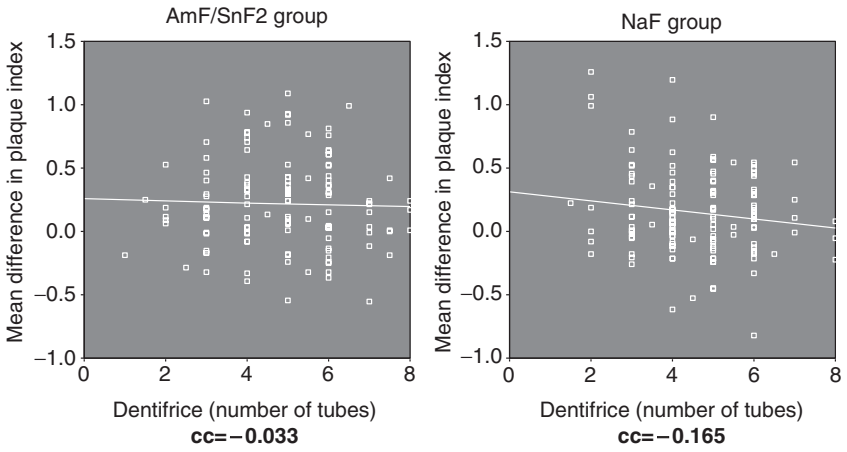

Fig. 1. Scatter plots demonstrating the correlations between the number of tubes of dentifrice and plaque changes.

The findings of two other studies on the adjunctive effect of the use of AmF/SnF_2 (Banoczy & Nemes 1991, Mengel et al. 1996) do not support the results of the present study with respect to the reduction in plaque index over the study period. In a 9-month double blind study, Mengel et al. (1996)examined the effect of three regimes (NaF dentifrice and NaF mouth rinse, AmF/SnF_2 dentifrice and mouth rinse and AmF/SnF_2 dentifrice and NaF mouth rinse) on the plaque accumulation, gingivitis and microbial composition. No significant differences between the three regimens were observed. The authors attributed the improvements seen in all three groups partly to the ''study effect'' since the patients had to be recalled regularly (4–6 weeks intervals) for check-ups and their motivation was reinforced with respect to the use of the products during the study examinations. In the present study, no effort was made to recall the patients for reinforcement, as this could not reflect the actual situation. In a 5-month double-blind

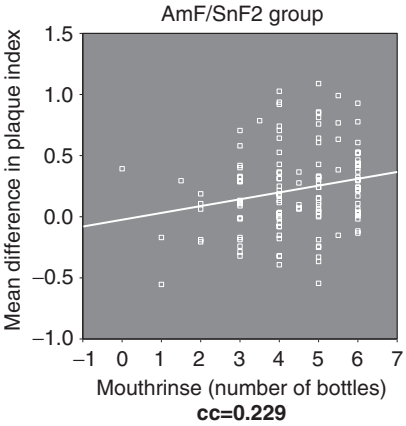

Fig. 2. Scatter plot demonstrating a linear correlation between the number of bottles of mouth rinse and plaque changes.

study, Banoczy et al. (1991) compared the effectiveness of a dentifrice and mouthwash containing AmF/SnF_2 on dental plaque, gingivitis and root-surface caries as opposed to a regime of regular use of NaF dentifrice and NaF mouthwash. Inter-group comparisons

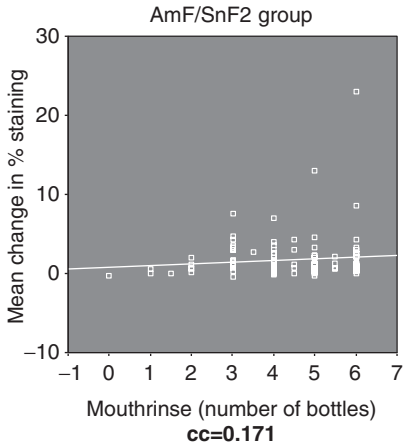

Fig. 3. Scatter plot showing the linear correlation between the number of bottles of mouth rinse and increase in % staining.

revealed no statistically significant differences. Dissimilarity in baseline characteristics such as age, plaque or bleeding values could account for the discrepancy in results observed between the present and the Banoczy et al. (1991) study. Another explanation could be the relatively small sample size i.e. the study might not have had sufficient power in order to detect statistically significant differences on a clinically relevant level. Both the above-mentioned studies did not provide information on the compliance of the individuals with the instructions of using the products. At the end of the present study, such information was obtained from the participants. It was of interest to explore the impact of the quantity of products on the changes in plaque scores. The change in plaque levels was correlated to the quantity of products used by the panelists (tube dentifrice and bottle mouth rinse). The correlation between the number of dentifrice tubes and the extent of plaque reduction appeared to be negative (Fig. 1). This suggests that the more the dentifrice use, the less the plaque removal. This finding is rather surprising since it contradicts the commonly accepted belief that one of the most important functions of a dentifrice is to improve plaque removal (Forward et al. 1997). Relatively few studies have evaluated the plaque-removing efficacy of brushing with and without dentifrice. The results are contradictory. Some observed an enhanced efficacy of toothbrushing when a dentifrice is used (Eid & Talic 1991, Johannsen et al. 1993), some showed no added effect (Binney et al. 1993, Parizotto et al. 2003) and some even found a reduced efficacy (Jakober & Perrit 1991, Cronin et al. 2000). In these findings, differences in relative dentine abrasion (RDA) values of the dentifrices might have played a role. Higher RDA values have been shown to be associated with increased plaque removal (Johannsen et al. 1993). The correlation between the number of bottles of mouth rinse and the plaque reduction appeared to be positive (Fig. 2). This suggests that more plaque reduction can be accomplished when individuals tend to be more compliant with the given instructions. An earlier study (Leverett et al. 1984) also reported on the compliance of their panelists. They found that almost two-thirds of the study population followed the rinsing instructions at 75% or more of the opportunities. For these subjects, a separate analysis was performed showing that the plaque reductions were even greater in comparison with the whole population. Both the present and the Leverett et al. (1984) studies suggest that compliance of the individuals with the given instructions may have an additional impact on the clinical parameters.

In the present study, small but statistically significant reductions of bleeding on marginal probing were observed for both groups in relation to the baseline. There was, however, no significant difference between groups. Several explanations could be considered for this finding. The subjects of the present study were selected on the basis of persistently insufficient oral hygiene and $>50\%$ bleeding score in their mouth despite all efforts by their dentists and/or oral hygienists to improve their gingival condition. One could suggest that these patients represent a ''refractory'' population, possibly because of their insufficient motivation or unawareness of how to brush. No effort was made to change the brushing habits of the individuals during the study since this would not reflect the ''real-life'' situation. Further analysis showed a weak correlation between changes in plaque scores and changes in bleeding scores ($cc = 0.271$, $p = 0.002$ for the test and $cc = 0.338$, $p < 0.001$ for the control group; data not shown). Khocht et al. (1992) and Spindel et al. (1986) have reported on the apparent lack of association between plaque score improvements and changes in bleeding sores, although the reasons for this finding are not presently known. According to Van der Weijden et al. (1994b), there appears to be a ''lag period'' between the changes in plaque level and changes in bleeding scores. It can be suggested that a 6-month period was not long enough for this ''refractory'' gingivitis patient population to show more prominent differences in gingival bleeding between groups. An alternative explanation might be the extent of the change in plaque scores seen in both groups. The literature does not provide specific information on the magnitude of a plaque reduction that is sufficient to result in a change of the level of gingivitis. One could speculate that there is a certain threshold of plaque reduction beyond which changes in bleeding level can be clinically detected. The change in plaque levels seen for both groups (reduction of 16% for the test *versus* 10% in the control group) may have been too small to produce pronounced differences in bleeding tendency. Also, one should realize that the number of sites that show no plaque will probably more strongly influence the gingival bleeding tendency than the number of sites with plaque. Possibly, the 4% difference in increase of plaque-free surfaces between the two groups (11% for the test group *versus* 7% for the control group, Table 2) was not enough to result in statistically significant differences in gingival health.

In contrast to the rather small difference in gingivitis level between the two groups, the difference in staining was more prominent during the 6-month study period. The AmF/SnF_2 dentifrice and mouth rinse combination resulted in an increase of staining at 6 months when compared with baseline. Stain development as a result of the use of various SnF_2 formulations has been reported earlier in the literature (Leverett et al. 1986, Wolff et al. 1989, Brecx et al. 1993, Boyd & Chun 1994, Mankodi et al. 2002, Paraskevas et al. 2004). The mean increase in overall staining during the 6-month period in the AmF/SnF_2 group (20%) parallels the findings of an earlier study by Paraskevas et al. 2004, who also reported a 25% increase in overall staining after 3 months of AmF/SnF_2 use. In both the present and the earlier study (Paraskevas et al. 2004), the control group also developed staining, although to a lesser degree as compared with the AmF/SnF_2 group. The reason for this is not fully understood. Smoking, as an important factor

in relation to staining, was included in the analysis. Even after controlling for the effect of smoking, the use of the test products had a significant impact on the development of staining. Further analysis showed that the amount of staining observed was directly related to the amount of the mouth rinse used rather than to the amount of dentifrice. Possibly, other factors besides smoking play a role (dietary habits such as coffee, tea, red wine consumption).

In summary, in patients recruited from dental practices and who were unable to maintain good oral hygiene in spite of great efforts, the combined use of AmF/SnF_2 did not decrease gingivitis at a significant level in comparison with the regular regime of two times daily brushing with an NaF-containing dentifrice. However, the above-mentioned combination resulted in greater plaque reduction than that observed with the use of the conventional dentifrice. When used according to the manufacturer's instructions, this effect on plaque scores was more pronounced.

Acknowledgements

The authors would like to express their gratitude to GABA Int for sponsoring this research project.

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