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Evaluation of additional amine fluoride/stannous fluoride-containing mouthrinse during supportive therapy in patients with generalized aggressive periodontitis

A randomized, crossover, double-blind, controlled trial

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Abstract

Objectives: The objective of the present randomized controlled trial was to evaluate the efficacy of a mouthrinse containing a combination of AmF/SnF_2 in controlling supragingival plaque accumulation and gingival inflammation during a 12-week period in patients affected by generalized aggressive periodontitis (GAP).

Methods: Eighteen subjects, six males and 12 females, mean age: 32.2 years, were evaluated. One-half of the patients was either prescribed an AmF/SnF_2-containing mouthrinse (test mouthrinse) or a control mouthrinse in addition to mechanical plaque control for 12 weeks. After a 2-week wash-out period, the patients received the alternative mouthrinse. Before and after treatment plaque index (PlI), gingival index (GI), angulated bleeding index (AngBI), tooth stain (GMSI), and tongue stain were recorded.

Results: Test mouthrinse resulted in a statistically significant decrease in PlI ($p = 0.029$) and GI ($p = 0.017$). After treatment, PlI was significantly lower in test compared to control mouthrinse ($p = 0.027$). GMSI significantly increased post-treatment for both mouthrinse regimens ($p < 0.001$), a significantly higher score being observed for the test compared to control mouthrinse ($p = 0.002$).

Conclusions: The 12-week use of a AmF/SnF_2-containing mouthrinse as an adjunct to conventional mechanical oral hygiene procedures in GAP patients was effective in controlling the amount of supragingival plaque deposits.

Key words: aggressive periodontitis; antimicrobial agents; periodontal disease/treatment

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Proper plaque control is a key factor in the prevention of periodontal diseases. Most forms of plaque-associated periodontal diseases start as inflammatory lesions of the gingiva which, if left untreated, may progress over time and, eventually, involve and compromise the entire periodontal attachment apparatus.

Acceptable plaque control over prolonged periods of time by use of mechanical tooth cleaning, even in a well-maintained patient population, is difficult to achieve (Lindhe et al. 1984). Consequently, efforts have been made to utilize chemical agents, often incor-

porated in mouthrinses or toohpastes, as supplements to traditional oral hygiene procedures. Amine fluoride/stannous fluoride (AmF/SnF_2) formulations have been extensively studied and shown to have antibacterial effects and be useful as an antiplaque agents (Brecx et al. 1990, 1992, Zimmermann et al. 1993, Mengel et al. 1996, Hoffmann et al. 2001).

Generalized aggressive periodontitis (GAP), also known as generalized early onset periodontitis, belongs to a group of periodontal diseases characterized by severe destruction of periodontal support occurring at an early age (Page et al. 1983a, b, Watanabe 1990, Schenkein & Van Dyke 1994). Early occurrence of clinically detectable lesions is generally interpreted as being the expression of either aggressive causative agents, i.e. specific microbial species, or a high level of susceptibility of the individual patient, or a combination of the two (Van Dyke & Schenkein 1996). Aggressive forms of periodontitis are currently considered to be multi-factorial diseases developing as a result of complex interactions between modulating genes of the host and environmental factors. Susceptibility inheritance is probably insufficient for the development of disease: environmental exposure to potential pathogens endowed with specific virulence factors is also a necessary step (Hart et al. 1992).

Successful treatment of aggressive periodontitis, particularly in its generalized form, is considered to be dependent upon early diagnosis, directing therapy towards maximal suppression of the infecting microorganisms and, even more relevant, providing a supportive therapy conducive to long-term maintenance. Such supportive therapy needs, by necessity, to include maximum control of supragingival plaque accumulation, thus minimizing plaque-associated inflammatory response of periodontal tissues. In this respect, the use of antimicrobial agents in addition to conventional oral hygiene procedures on a long-term basis seems to be specifically recommended in aggressive periodontitis patients.

The objective of the present randomized, crossover, double-blind, controlled trial was to evaluate the efficacy of a mouthrinse containing a combination of AmF/SnF_2 in controlling supragingival plaque accumulation and gingival inflammation during a 12-week period in patients affected by GAP. A mouthrinse of similar formulation except for AmF/SnF_2 content was prescribed as control. Adverse effects, such as tooth and tongue staining, taste alteration as well as gingival/mucosal desquamation, ulceration and erythema were also evaluated. Patients used the experimental treatment as an adjunct to mechanical oral hygiene regimen during periodontal supportive therapy.

Material and Methods

Study population

Twenty-one systemically healthy GAP patients were selected for study among those undergoing periodontal supportive therapy at the Research Center for the Study of Periodontal Diseases, University of Ferrara. The clinical diagnosis at the time of the initial visit was based on a recent classification (Tonetti & Mombelli 1999). Eighteen subjects, six males and 12 females, aged 24–37 years (mean age: 32.2 years), completed the study. Five patients were smokers (smoking exposure: 3–9.8 packs*year). Two patients missed the second treatment phase, one patient was excluded during the first treatment phase because she had got pregnant. Only data stemming from 18 fully complying patients were included in the analysis.

Patients were enrolled if they were able and willing to provide informed consent and to ensure compliance throughout the study. Patients were excluded from the study if they met any of the following exclusion criteria: pregnancy or lactation; physical or mental handicap that could interfere with adequate oral hygiene performance; systemic and/or topical steroidal and non-steroidal anti-inflammatory drugs and antibiotics/antimicrobials during the last 6 weeks prior to the study; fixed or removable orthodontic device; oral soft tissue pathology, excluding GAP, based on visual examination; significant adverse effects following use of oral hygiene products such as mouthrinse or toothpaste; documented allergy to AmF/SnF_2-containing products; conditions requiring prophylactic antibiotic coverage prior to invasive dental procedures. Participants were exited from the study immediately upon: requesting to withdraw from further participation; development of acute dental/oral conditions requiring treatment; development of conditions requiring treatment that was in conflict with the exclusion criteria listed above; failure to comply with study instructions/requirements.

Experimental design

The present study was a monocentre, randomized, crossover, double-blind, controlled clinical trial. The study design is summarized in Fig. 1. Before entering the study, each subject received verbal and written details of the study and instructions for use of experimental products and gave signed and witnessed informed consent to participate. The study design was approved by the local ethics committee and was found to conform to the requirements of the ''Declaration of Helsinki'' as adopted by the 18th World Medical Assembly in 1964 and subsequently revised (www.wma.net/e/policy/17-c_e.html). Written informed consent was provided by all participants.

After selection and recruitment, the patients underwent 2 weekly sessions of pre-trial phase (at week -1 and -2) aimed at eliminating supra- and subgingival plaque and calculus deposits, removing tooth extrinsic stain, and controlling gingival inflammation. Pre-trial clinical sessions included supra- and subgingival debridement by means of ultrasonic instruments, and polishing. During the pre-trial phase the patients were provided with oral hygiene instructions (OHI), a medium toothbrush (Elmex Inter X, GABA International AG, Münchenstein, CH), and interdental cleaning devices as needed. An AmF/SnF_2-containing toothpaste (meridol® toothpaste, GABA International AG, Münchenstein, CH) was also dispensed. The patients were asked to use the toothpaste 3 times a day during morning, noon and evening toothbrushing.

At week 0 (baseline), the patients were assigned treatment mouthrinses according to a randomization list. Assignment was performed by a central randomization facility, and examiners were kept unaware of the randomization sequence (allocation concealment). One half of the patients was either prescribed an AmF/SnF_2-containing mouthrinse (test mouthrinse; meridol® mouthrinse, GABA International AG, Münchenstein, CH) or a non-AmF/SnF_2-containing mouthrinse (control mouthrinse). Both test and control mouthrinses were prescribed 10 ml twice daily, after morning and evening toothbrushing, for 12 weeks (from week 0 to week $+12$). OHI, including use of AmF/SnF_2-containing toothpaste, were reinforced.

At completion of the first 12-week treatment phase, a 2-week wash-out

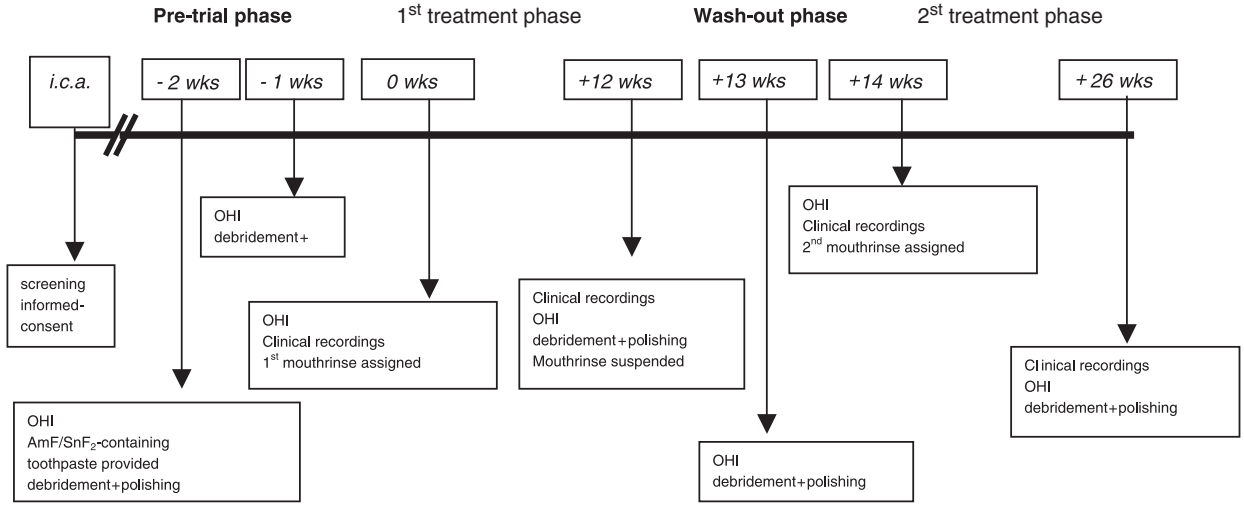

Fig. 1. Experimental design and procedures (i.c.a.: initial contact appointment; OHI: oral hygiene instructions; AmF/SnF_2: amine fluoride/stannous fluoride).

phase elapsed (from week +12 to week +14). During the wash-out phase the patients reversed to the oral hygiene regimen followed during the pre-trial phase. At week +12 and +13, the patients received OHI, polishing and ultrasonic debridement as needed for plaque/calculus/stain elimination and gingival inflammation resolution. At week +14 (baseline), the patients received the alternative mouthrinse for 12 weeks according to a crossover design. The patients who had received the test mouthrinse during the first treatment phase received the control mouthrinse during the second treatment phase, and vice versa. The patients were prescribed the AmF/SnF_2-containing toothpaste also throughout this second treatment phase. At week +26, an additional session of polishing and ultrasonic debridement was given.

The test and control mouthrinse formulations were identical except for the AmF/SnF_2 content. Specifically, the test mouthrinse contained 250 ppm F^- (125 ppm F^- from amine fluoride and 125 ppm F^- from SnF_2) and the control mouthrinse contained <1 ppm F^-. All mouthrinse bottles were identical so that neither the patient nor the investigator was aware of which treatment the patient had been assigned.

Clinical recordings

At week 0, +12, +14, and +26 the following periodontal parameters were recorded:

(a) Gingival index (GI), according to Löe & Silness (1963).

(b) Angulated bleeding index (AngBI) according to Van der Weijden et al. (1993). After lightly drying the gingiva with compressed air, a periodontal probe (PCP 12, Hu Friedy, Chicago, IL, USA) was held at an angle of approximately 60° to the longitudinal axis of the tooth and in contact with the sulcular gingival tissues. The absence or presence of bleeding within 30 s upon probing from each unit was recorded. AngBI was expressed as the percentage of bleeding sites.

(c) Presence of supragingival plaque according to Plaque index (PlI; Turesky et al. 1970). Plaque was visualized by means of a disclosing agent (Red Cote®, Butler, Montvale, NJ, USA).

(d) Presence of stain on teeth assessed by means of gingival modification of the stain index (GMSI) (Gründemann et al. 2000). Each examined tooth was divided into 4 zones and the intensity of each zone was subjectively scored, where 0 = no stain, 1 = light stain (yellow), 2 = medium stain (brown), and 3 = heavy stain (black).

(e) Presence of tongue stain (TS) assessed according to the method reported by Claydon et al. (2001). Stain on the dorsal anterior two-thirds of the tongue was scored as follows: (a) stain area (TSa): as a % where 0 = no stain; 1 = 1–25% coverage; 2 = 26–50% coverage; 3 = 51–75% coverage; 4 = 76–100% coverage and (b) stain intensity (TSi): subjectively scored as 0 = no stain; 1 = light stain (yellow); 2 = medium stain (brown); and 3 = dark stain (black). For intensity scores where mixed colours were observed, the higher score was applied.

PlI, GI and AngBI were recorded at six sites (mesio-buccal, buccal, disto-buccal, mesio-lingual, lingual, disto-lingual) on the following selected teeth: #1.6, #1.1, #2.4, #3.6, #3.1, #4.4. If one of these teeth was missing, the available adjacent tooth was examined. GMSI was recorded on the buccal aspect of teeth #12, #11, #21, #22, #32, #31, #41, and #42.

At the same observation intervals, taste alteration was assessed by asking each patient to quantify it on the basis of his own personal sensations on a 100-mm visual analogue scale (VAS), ranking from ''no alteration'' to ''complete loss of taste''. Presence and location of loss of integrity of the gingival epithelium (desquamation, ulceration) and gingival/mucosal erythema were also recorded.

All clinical assessments (measurements) were carried out under the same conditions by one trained and calibrated examiners who was blinded to treatment assignment. Records of earlier examinations were not available to the examiner at the time of re-examination.

Statistical analysis

The patient was regarded as the statistical unit, therefore we averaged the scores recorded on six sites on selected

teeth to obtain individual, patient-based values. Data were expressed by either median and inter-quartile range (IR) for non-parametric variables, or mean ± standard deviation (SD) for parametric variables. For PlI, GI, and AngBI whole-mouth scores as well as scores from posterior teeth (i.e. teeth #1.6, #2.4, #3.6, #4.4) and interproximal sites (i.e. mesio-buccal, disto-buccal, mesio-lingual, disto-lingual aspects of all examined teeth) were computed. For GMSI the average value and the percentage of tooth surfaces showing GMSI > 0 were calculated.

To test the effect of ''sequence'', ''time'', and ''treatment'' on response variables, ANOVA for repeated measures or Friedman's test for parametric and non-parametric variables, respectively, were used. Post hoc comparisons were performed to explore intra- and inter-treatment differences. The level of significance was set at 5%.

Results

Supragingival plaque accumulation

Tables 1–3 show whole-mouth, posterior-teeth and interproximal-site PlI scores, respectively, for test and control mouthrinses as recorded at baseline and after 12 weeks of treatment. A statistically significant decrease in whole-mouth PlI was observed for the test mouthrinse from baseline scores ($p = 0.029$). In contrast, the control mouthrinse did not produce any significant change in PlI over time. After treatment PlI was significantly lower in test compared to control mouthrinse ($p = 0.027$) (Table 1).

When the analysis was based on posterior teeth, a significant PlI reduction was observed for the test mouthrinse only ($p = 0.005$) (Table 2). Moreover, post-treatment PlI was significantly lower after test than control mouthrinse at both posterior teeth and interproximal sites ($p = 0.022$ and $p = 0.043$, respectively) (Tables 2 and 3).

Gingival inflammation

Descriptive statistics of whole-mouth, posterior-teeth and interproximal-site GI and AngBI, as assessed for test and control mouthrinses over time, are summarized in Tables 1–3, respectively. The test mouthrinse resulted in a statistically significant decrease in GI scores for whole-mouth, posterior teeth and interproximal sites as compared to baseline scores ($p = 0.017$, 0.012, and $p = 0.008$, respectively). For the control mouthrinse, similar GI scores were recorded at baseline and at week 12 post treatment. No significant differ-

Table 1. Plaque index (PlI; mean ± SD), gingival index (GI; mean ± SD) and angulated bleeding index (AngBI, in %; median and interquartile range, IR) for test and control mouthrinses as recorded on a *whole-mouth basis* at baseline and post treatment

	Test mouthrinse		Control mouthrinse		*p*-Value
	N	mean ± SD	*N*	mean ± SD	
PlI					
baseline	18	0.79 ± 0.366	18	0.84 ± 0.392	N.S.
post treatment	18	0.64 ± 0.418	18	0.79 ± 0.362	0.027
p-value		0.029		NS	
GI					
baseline	18	0.22 ± 0.140	18	0.18 ± 0.115	NS
post treatment	18	0.15 ± 0.080	18	0.17 ± 0.099	NS
p-value		0.017		NS	
AngBI		median (IR)		median (IR)	
baseline	18	2.8% (0.0–8.3)	18	2.8% (0.0–8.3)	NS
post treatment	18	1.4% (0.0–5.6)	18	5.6 (0.0–11.1)	NS
p-value		NS		NS	

NS, not significant.

Table 2. Plaque index (PlI; mean ± SD), gingival index (GI; mean ± SD) and angulated bleeding index (AngBI, in %; median and interquartile range, IR) for test and control mouthrinses as recorded at *posterior teeth* at baseline and post treatment

	Test mouthrinse		Control mouthrinse		*p*-Value
	N	mean ± SD	*N*	mean ± SD	
PlI					
baseline	18	0.95 ± 0.379	18	0.97 ± 0.428	N.S.
post treatment	18	0.72 ± 0.405	18	0.90 ± 0.356	0.022
p-value		0.005		NS	
GI					
baseline	18	0.26 ± 0.184	18	0.20 ± 0.123	NS
post treatment	18	0.17 ± 0.096	18	0.22 ± 0.135	NS
p-value		0.012		NS	
AngBI		median (IR)		median (IR)	
baseline	18	4.2% (0.0–8.3)	18	4.2% (0.0–4.2)	NS
post treatment	18	2.1% (0.0–4.2)	18	6.3% (0.0–12.5)	NS
p-value		NS		NS	

NS, not significant.

Table 3. Plaque index (PlI; mean ± SD), gingival index (GI; mean ± SD) and angulated bleeding index (AngBI, in %; median and interquartile range, IR) for test and control mouthrinses as recorded at *interproximal sites* at baseline and post treatment

	Test mouthrinse		Control mouthrinse		*p*-Value
	N	mean ± SD	*N*	mean ± SD	
PlI					
baseline	18	0.94 ± 0.446	18	1.00 ± 0.426	NS
post treatment	18	0.79 ± 0.490	18	0.95 ± 0.407	0.043
p-value		0.05		NS	
GI					
baseline	18	0.30 ± 0.176	18	0.23 ± 0.142	NS
post treatment	18	0.20 ± 0.108	18	0.23 ± 0.132	NS
p-value		0.008		NS	
AngBI		median (IR)		median (IR)	
baseline	18	4.2% (0.0–12.5)	18	4.2% (0.0–8.3)	NS
post treatment	18	2.1% (0.0–8.3)	18	8.3% (0.0–12.5)	NS
p-value		NS		NS	

NS, not significant.

ences were noted in post-treatment GI between mouthrinses.

Whole-mouth AngBI decreased from 2.8% (IR 0.0–8.3%) to 1.4% (IR 0.0–5.6%) for the test mouthrinse, and increased from 2.8% (IR 0.0–8.3%) to 5.6% (IR 0.0–11.1%) for control mouthrinse (Table 1). No significant differences in AngBI were observed within and between mouthrinse regimens. Posterior-teeth and interproximal-site analysis confirmed a similar trend (Tables 2 and 3).

Table 4. Gingival modification of the stain index (GMSI; mean ± SD) for test and control mouthrinses as recorded at baseline and post treatment

	Test mouthrinse		Control mouthrinse		*p*-Value
	N	mean ± SD	*N*	mean ± SD	
GMSI					
baseline	18	0.08 ± 0.089	18	0.10 ± 0.153	0.705
post treatment	18	0.53 ± 0.304	18	0.40 ± 0.341	0.002
p-value		<0.001		<0.001	
GMSI (%)					
baseline	18	7.6 ± 8.04	18	8.3 ± 13.21	0.458
post treatment	18	34.9 ± 15.51	18	29.5 ± 21.09	0.010
p-value		<0.001		<0.001	

Tooth/TS and taste alteration

GMSI significantly increased from baseline to 12 weeks post treatment for both mouthrinses ($p<0.001$). Between-mouthrinse comparison revealed a significantly higher score for the test compared to control mouthrinse at 12 weeks ($p=0.002$; Table 4). Frequency of sites showing GMSI>0 increased from 7.6 ± 8.0% at baseline to 34.9 ± 15.5% at 12 weeks ($p<0.001$) for the test mouthrinse, and from 8.3 ± 13.2% to 29.5 ± 21.1% for the control treatment ($p<0.001$). 12-week GMSI (%) was significantly higher in test compared to control mouthrinse ($p=0.01$; Table 4).

Frequency distributions of patients according to TSa and TSi scores for test and control mouthrinses, as recorded at baseline and 12 weeks post treatment, are represented in Figs 2 and 3, respectively. Statistical analysis did not detect any difference within and between mouthrinse regimens in both the area and intensity of TS.

Out of 18 patients, a positive VAS recording for taste alteration was reported by 1 patient following the test mouthrinse (patient #15, VAS = 51), and 3 patients following the control mouthrinse (patient #2, VAS = 27; patient #4, VAS = 4; patient #15, VAS = 68). Due to limited number of patients experiencing the symptom, statistical analysis was not performed. In no cases, either loss of integrity of the gingival epithelium (desquamation, ulceration) or gingival/mucosal erythema was observed.

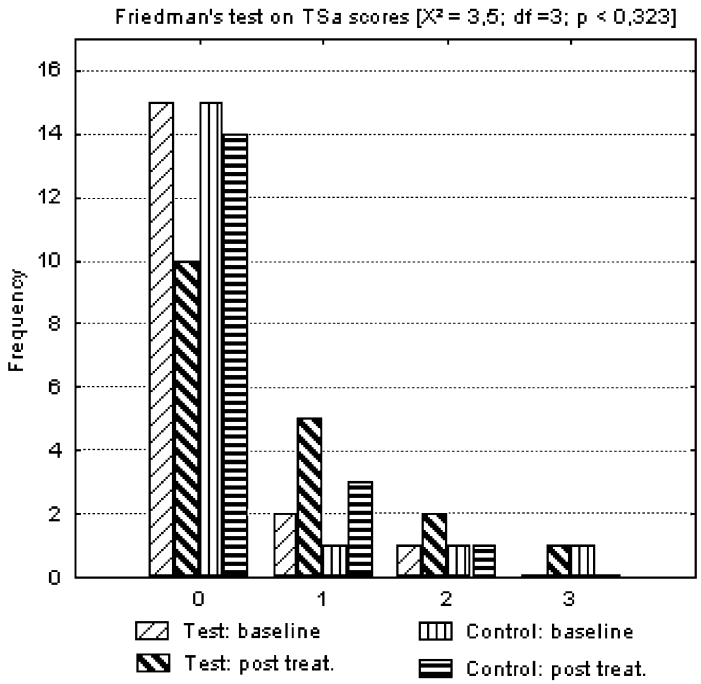

Fig. 2. Frequency distribution of patients according to tongue stain area (TSa) scores for test and control mouthrinse as recorded at baseline and post treatment.

Discussion

The results of the present study indicate that the 12-week use of a AmF/SnF_2-containing mouthrinse as an adjunct to conventional mechanical oral hygiene procedures in GAP patients was effective in controlling the supragingival plaque accumulation. Specifically, the amount of plaque deposits were significantly less following the test mouthrinse compared to control. Although the difference between post-treatment GI and AngBI did not reach the statistical significance, a trend towards a greater improvement in the inflammatory status of the gingival tissues was observed for the test mouthrinse, but not for the control.

In the present study, only patients presenting GAP and included in a periodontal supportive programme were selected. The marked disproportion between the amount of bacterial deposits and the severity of the periodontal lesions observed in aggressive periodontitis patients has led to a general acceptance of a hypothesis that aggressive periodontitis patients have high susceptibility to periodontal infections (Tonetti & Mombelli 1999). Previous results indicated that an antimicrobial-supplemented oral hygiene regimen was effective in reducing the plaque deposits and improving the inflammatory status of the gingival tissues in individuals with different susceptibility to plaque-induced gingivitis (Trombelli et al. 2004). In this context, a relationship between susceptibility to periodontitis and susceptibility to gingivitis has been reported (van der Velden et al. 1985). The studies of van der Velden et al. (1985) indicated that patients with greater periodontitis susceptibility exhibited greater susceptibility to gingivi-

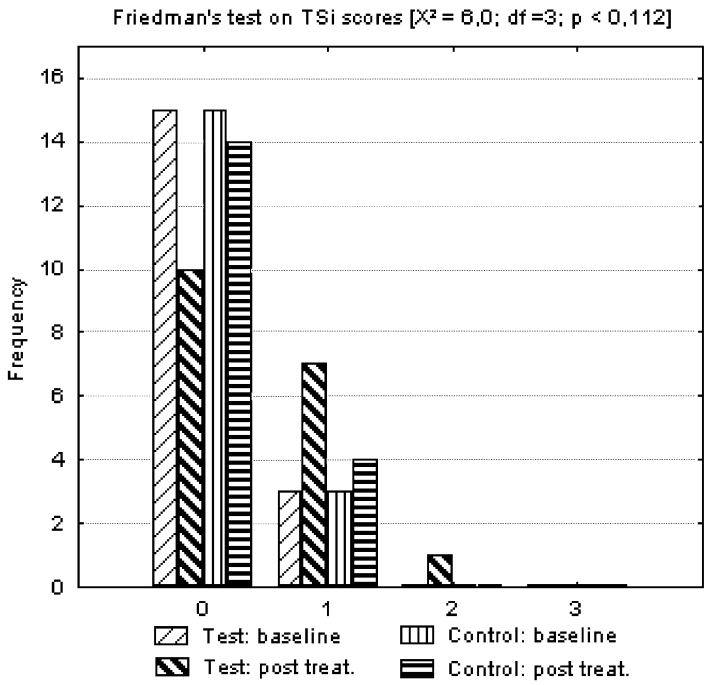

Fig. 3. Frequency distribution of patients according to tongue stain intensity (TSi) scores for test and control mouthrinse as recorded at baseline and post treatment.

tis. Therefore, the presence of host-related factors exacerbating the gingival inflammatory response to supra-gingival plaque may reasonably represent an indication to supplement the mechanical plaque control with antimicrobial agents.

A significant reduction in supragingival plaque deposits was recorded after the test mouthrinse, but not after the control mouthrinse, despite the high oral hygiene standard maintained by the patients throughout the study. The adjunctive use of test mouthrinse may have limited the extent of plaque accumulation by adding an active antibacterial chemical component to the mechanical oral hygiene regimen (Brecx et al. 1990, 1992, Zimmermann et al. 1993, Mengel et al. 1996, Hoffmann et al. 2001). It was previously demonstrated that a mouthrinse containing AmF/SnF_2 was effective in controlling plaque accumulation in 3-day (Netuschil et al. 1995), 3-week (Brecx et al. 1990, 1992), and 3-month (Brecx et al. 1993) clinical trials. A combination of habitual self-performed and non-supervised oral hygiene with this mouthwash regimen has been shown more beneficial for plaque control than the use of mechanical oral hygiene alone (Brecx et al. 1992, Hoffmann et al. 2001) or in combination with a placebo mouthrinse (Brecx et al. 1993). In contrast, the use of AmF/SnF_2 mouthrinse as a substitute to mechanical plaque control has resulted in a non-significant plaque reduction (Riep et al. 1999). It is noteworthy that, in our material, the reduction in supragingival plaque was also evident in areas, such as posterior teeth and interproximal sites, where proper mechanical plaque control appeared more difficult to achieve (Lang et al. 1973) and which are associated with higher susceptibility to periodontal breakdown (Löe et al. 1978).

In the present study, a significant decrease in GI was observed for the test mouthrinse; however, the difference in post-treatment GI between mouthrinses did not reach the statistical significance. This finding apparently contrasts with those by Brecx et al. (1993) and Zimmermann et al. (1993) where significantly lower GI scores were noted following 3–7-month use of AmF/SnF_2 mouthrinse compared to placebo mouthrinse. The discrepancy may be ascribed to several methodological differences between the studies. For instance, our material pre-trial clinical sessions of polishing and supra- and subgingival debridement resulted in low levels of gingival inflammation at baseline evaluation. We have recently reported that additional AmF/SnF_2 toothpaste and mouthrinse as an adjunct to oral hygiene regimen was effective in reducing plaque-associated gingivitis, regardless of the pre-existing severity of gingival inflammation (Trombelli et al. 2003). However, the level of improvement in gingival status was dependent on pre-existing severity of the inflammatory condition. In addition to the antimicrobial activity of the fluoride compounds, AmF and SnF_2 have been shown to enhance the oxygen-dependent antibacterial activity of neutrophils, with the combination of the two being far more effective than each one alone (Shapira et al. 1997). This effect may have contributed to the improvement of gingival status observed in the test group.

The test mouthrinse resulted in a trend, although not statistically significant, towards a decrease in the % of bleeding site at the 3-month recall. Of all the parameters evaluated in the present study, only the presence of bleeding upon probe stimulation has been associated with future progression of periodontal disease (Joss et al. 1994). Although the high level of plaque control maintained during the study, it is noteworthy that the test mouthrinse decreased AngBI to a level 3–4-fold lower than control. Based on this finding, one can theorize that use of the meridol®-supplemented oral hygiene regimen used in the present study may have long-term benefits, particularly for subjects with a higher tendency/susceptibility to destructive periodontal disease. Testing of this hypothesis will necessitate appropriate long-term studies.

Although our results seem to emphasize the efficacy of AmF/SnF_2 mouthrinse on plaque accumulation and gingival status, a synergistic effect between AmF/SnF_2 mouthrinse and AmF/SnF_2 toothpaste cannot be excluded. Mengel et al. (1996) have demonstrated more pronounced clinical and microbiological effects when patients were administered a treatment regimen based on combined AmF/SnF_2 mouthrinse and toothpaste compared to AmF/SnF_2 plus NaF treatment combinations. Consistently, the clinical efficacy of AmF/SnF_2 toothpaste on plaque and gingivitis has shown to be increased by the adjunctive use of AmF/SnF_2 mouthrinse (Bánóczy et al. 1989).

Pre-trial polishing resulted in complete elimination of visible stains, therefore the 12-week TS index reflects only those accretions which accumulated during the treatment phase. Additional use of both test and control mouthrinses resulted in a significant increase in tooth stain; however, the discolouration was

significantly more pronounced after test mouthrinse than control. This finding is consistent with previous reports indicating that the prolonged use of AmF/SnF_2-containing mouthrinse may produce extrinsic stain on teeth (Brecx et al. 1993, Horwitz et al. 2000). About one third of the tooth surfaces in the aesthetic area showed a stain intensity ranging from *no stain* to *light stain*. Tooth stain may impair patient compliance and require additional time to clean the dentition during recall sessions. Clinicians and patients should be aware of this adverse effect when evaluating the cost-benefit ratio of this oral hygiene regime.

Acknowledgments

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