Rapid Desensitizing Efficacy of a Stannous-Containing Sodium Fluoride Dentifrice

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Abstract

- **Objective:** To evaluate the efficacy of an experimental stannous-containing sodium fluoride dentifrice (1450 ppm fluoride) in the reduction of dentinal hypersensitivity over a three-day period as compared to a positive control dentifrice containing 8% arginine, calcium carbonate, and 1450 ppm fluoride as sodium monofluorophosphate.
- **Methods:** This study, conducted in China, had a controlled, randomized, examiner-blind, two-treatment, parallel-group design. Eighy-one healthy adult subjects with moderate dentinal hypersensitivity were enrolled, two bicuspid or cuspid teeth in different quadrants demonstrating reproducible thermal (cold air) sensitivity with a score of > 1 on the Schiff Air Sensitivity Scale were chosen for each subject. Subjects also assessed their own level of pain on a Visual Analog Scale (VAS). Subjects were randomized to treatment with either the experimental or positive control dentifrice. At the baseline visit, sensitivity to thermal stimuli was assessed by both the examiner (Schiff Air Sensitivity) and the subject (pain VAS), and subjects were instructed to brush with their assigned study dentifrice according to the manufacturer's instructions provided. Immediately after brushing, thermal sensitivity for each enrolled tooth was reassessed by both examiner and subject. Subjects used their assigned dentifrices at home for three days, after which thermal sensitivity was reassessed by both examiner and subject. Subjects received an oral soft tissue examination at baseline and on Day 3.
- **Results:** Forty subjects in the experimental group and 41 subjects in the positive control group completed all study procedures. On the Schiff Air Sensitivity Scale, the experimental dentifrice provided statistically significant ($p < 0.001$) reductions of 14.8% and 54.1% in sensitivity relative to the positive control dentifrice immediately after first use and at Day 3, respectively. On the pain VAS, the experimental dentifrice provided statistically significant ($p < 0.001$) reductions of 22.3% and 74.1% in sensitivity relative to the positive control dentifrice immediately after first use and at Day 3, respectively. No adverse events were reported for any subject.
- **Conclusion:** An experimental stannous-containing sodium fluoride dentifrice provided significantly better dentin hypersensitivity relief relative to a positive control dentifrice both immediately and after three days of product use.

(J Clin Dent 2011;22:40–45)

Introduction

Dentin hypersensitivity is generally reported by patients as a sharp, transient pain caused by certain external stimuli (*e.g.*, cold air, air movement, pressure changes). Loss of cervical enamel (tooth wear) due to attrition, abrasion, and erosion could account for dentin hypersensitivity, but the condition is usually associated with loss of periodontal tissue (gingival recession) and accompanying dentin exposure.[1,2] Although prevalence figures for dentin hypersensitivity vary,[1] it is generally agreed to be a common condition that could be under-reported by patients and even on the increase in the general population.[2,3] For many individuals, the discomfort of dentin hypersensitivity could become a daily experience with a significant impact on their quality of life.

The mechanism of dentin hypersensitivity can be explained by the hydrodynamic theory.[4] According to this theory an external stimulus triggers the pain of tooth sensitivity by causing the movement of fluid from the surface of the dentin to the tooth nerve within the exposed and open dentin tubules. Stannous-containing agents (in the form of gels, solutions, or dentifrices) have proven desensitizing properties, and the mechanism for this action is thought to be the occlusion of open dentin tubules by precipitation of insoluble metal compounds on the dentin surface.[2,5-7] The multiple benefits of stannous fluoride for oral health (*i.e.*, reduced hypersensitivity, caries protection, gingival health) are well documented, but there are known disadvantages (*i.e.*, chemical instability in aqueous solution, unpleasant taste, minor extrinsic tooth staining).[8] The introduction in 2005 of a stabilized stannous fluoride formulation with sodium hexametaphosphate offered the oral health advantages of stannous fluoride, together with breath malodor advantages, and the extrinsic whitening and calculus inhibition properties of sodium hexametaphosphate, all within a single dentifrice.[9,10]

The benefits of stabilized stannous fluoride are also available in an innovative dentifrice recently launched in Asia and certain Western European markets, and aimed at being globally accessible with an impact on a broad range of oral health concerns.[11] Sodium fluoride (1450 ppm F^-) is the active ingredient in this novel dentifrice and stannous chloride is the key excipient. A stable, bioavailable stannous fluoride complex is produced during tooth brushing to give the dental health benefits of stabilized stannous fluoride (including protection from caries, gingivitis,

dentin hypersensitivity, breath malodor), along with polychelation technology for inhibition of extrinsic stain and calculus formation.[11] A number of different clinical studies have shown this dentifrice offers a range of oral care benefits to consumers worldwide. These studies, on multiple continents, have shown the benefits of this dentifrice for reducing plaque[12] and gingivitis,[13] inhibiting extrinsic stain inhibition,[14] and improving breath malodor.[15] Desensitizing effectiveness has also been evaluated. In a four-week clinical study that assessed thermal sensitivity using an air blast, the experimental stannous-containing sodium fluoride dentifrice showed significant desensitizing advantages over a sodium fluoride negative control dentifrice.[16] In an eight-week clinical study, the desensitizing advantages of this stannous-containing sodium fluoride dentifrice were tested using a Yeaple Probe for tactile sensitivity and an air blast with the Schiff Air Sensitivity Scale for thermal sensitivity; reductions in hypersensitivity were found to be similar to those of a marketed 5.0% potassium nitrate positive control toothpaste after both four and eight weeks of treatment.[17] The present study was a three-day efficacy comparison between this experimental dentifrice and a positive control dentifrice that evaluated the desensitizing efficacy of the experimental dentifrice at earlier time points than those investigated previously. By choosing a recently developed positive control dentifrice with published dentin hypersensitivity benefits (8.0% arginine, calcium carbonate, and 1450 ppm fluoride as sodium monofluorophosphate)[18,19] and by selecting early assessment time points (immediately after treatment and after three days of treatment), the focus for the present comparative study was to evaluate further the relative benefits of this experimental dentifrice and, in particular, to assess its clinical potential for rapid desensitizing efficacy.

Materials and Methods

This was a three-day, randomized, examiner-blind, two-treatment, parallel-group, controlled clinical trial conducted in China to evaluate the desensitizing efficacy of an experimental dentifrice versus a positive control dentifrice. The experimental dentifrice was a stannous-containing, 1450 ppm sodium fluoride dentifrice (marketed as blend-a-med Pro-Expert in parts of Europe, Procter & Gamble Co., Cincinnati, OH, USA); the positive control dentifrice was 8.0% arginine, calcium carbonate, and 1450 ppm fluoride as sodium monofluorophosphate (Colgate® Pro-Relief™, Colgate-Palmolive Co., New York, NY, USA).

Subjects in good general health, between 18 and 65 years of age, were recruited. They were required to possess a minimum of two hypersensitive teeth; *i.e.*, a score of > 1 on the Schiff Air Sensitivity Scale[10,20] for either bicuspid or cuspid teeth, located in different quadrants, with signs of facial/cervical erosion, abrasion, and/or gingival recession, and were required to be using a fluoride dentifrice (not desensitizing). They were required to comply with the visit schedule and follow study procedures. They were also required to agree, for the duration of the study, not to participate in any other oral/dental product studies and to refrain from the use of any non-study oral hygiene products, although regular floss users were permitted to continue flossing in their customary manner. Individuals were excluded from the study if they had a history of allergies or hypersensitivity to ingredients in commercial dental products or cosmetics, or if they were taking daily any anticonvulsant medication, sedatives, tranquilizers, or any other mood-altering drug that could reasonably be expected to interfere with the subject's response to painful stimuli in this study. Subjects taking analgesics, antihistamines, or anti-inflammatory drugs were required to refrain from taking such medication 48 hours prior to all study evaluations. Other exclusion criteria were participation in a desensitizing dentifrice study within the last two months, having received a dental prophylaxis within the two weeks prior to study baseline, evidence of gross oral neglect, or the need for extensive dental therapy. Self-reported pregnancy or nursing were also exclusion criteria. Teeth were excluded if they had deep, defective, or facial restorations, or were used as abutments for fixed or removable partial dentures, if they had full crowns, extensive caries, or cracked enamel, presented with bleeding upon probing, if there had been periodontal surgery within the previous six months, or if they had been scaled or root planed within the past three months.

An independent Institutional Review Board approved the study before the start of any procedures. At an initial screening clinic visit, subjects who gave written informed consent were given a thermal air sensitivity test by the examiner and were assigned a Schiff Air Sensitivity Score on 12 of their teeth.[10,20] Subjects themselves also assessed their level of pain induced by the air challenge using a visual analogue scale (VAS). Subjects whose teeth showed reproducible sensitivity, and who satisfied all other study eligibility criteria, were identified and had two of their bicuspid or cuspid teeth selected for study enrollment. The subjects were randomized to one of the two treatments, with stratification based on age, gender, and the average cold air VAS score on the two enrolled teeth. At the next clinic visit (baseline), sensitivity to thermal stimuli was assessed by both the examiner (Schiff Air Sensitivity) and the subjects (pain VAS). Subjects received an oral soft tissue examination by the examiner to assess their overall oral health. Subjects were given study treatment kits that contained a soft manual toothbrush, the assigned study dentifrice overwrapped in a white tube to ensure blinding, written product instructions, and a timer. All treatment kits were identical in appearance, and the examiner was blinded to randomization, product distribution, and product instruction. At the baseline visit, subjects were asked to brush their teeth twice daily for the duration of the study, and the instruction sheet was verbally reviewed with the subjects. Subjects in the positive control group were instructed, according to the manufacturer's usage instructions, to make sure they brushed all sensitive areas of the teeth, and were informed by the instructions that the product could also be directly applied to the sensitive tooth with the finger tip and gently massaged for one minute, once a week or less frequently. Subjects in the experimental group were instructed to brush twice daily (once in the morning, once in the evening), covering the full head of the toothbrush with toothpaste, brushing each of the two enrolled sensitive teeth for 30 seconds per tooth, and then to finish by brushing the rest of the teeth thoroughly for one minute, resulting in a total brushing time of two minutes. At the baseline visit, subjects then brushed their teeth according to the

instructions. After brushing their teeth, subjects received an immediate post-treatment thermal sensitivity assessment for each enrolled tooth by the examiner (Schiff Air Sensitivity) and the subjects themselves evaluated their sensitivity (pain VAS).

Subjects were instructed to use their study kits with the assigned dentifrice at home for three days and to return to the clinic on Day 3. Appointments were either morning or afternoon according to the time of day for their baseline assessment to minimize diurnal variations. Subject eligibility to continue in the study according to relevant inclusion and exclusion criteria was assessed, the teeth enrolled at baseline were reassessed for thermal sensitivity by the examiner (Schiff Air Sensitivity Scale) and by the subjects themselves (pain VAS), and finally the subjects received an oral soft tissue examination.

Thermal Air Sensitivity Assessments

A clinical examiner delivered a one-second application of cold air to the tooth being tested from a standard dental unit syringe at 40–60 psi at a temperature of 70 ± 5˚F. The examiner assessed the level of pain to the cold air blast by assigning a Schiff Air Sensitivity Score to each tooth according to the observed subject response, where lower scores indicated less tooth sensitivity, as follows: [10,20]

0 = Tooth/Subject does not respond to air stimulus.
1 = Tooth/Subject responds to air stimulus but does not request discontinuation of stimulus.
2 = Tooth/Subject responds to air stimulus and requests discontinuation or moves from stimulus.
3 = Tooth/Subject responds to air stimulus, considers stimulus to be painful, and requests discontinuation of the stimulus.

Following the examiner's Schiff Air Sensitivity assessment, the subject was asked to rate pain induced by the thermal air challenge. Subjects used a 10 cm VAS to assign a number to the level of pain experienced, from 0 (no tooth pain/discomfort) to 10 (worst tooth pain/discomfort ever experienced), such that lower scores indicated less sensitivity.

Statistical Methods

Sensitivity scores for the two enrolled teeth were averaged for each subject and separately for each visit and measure. Baseline and demographic data were summarized by treatment group to assess baseline comparability. For each post-baseline visit, the mean change from baseline in the cold air sensitivity Schiff score and the cold air VAS were compared to zero for each treatment group using a paired t-test. Analysis of covariance models with baseline scores as the covariates were used to compare treatment groups. All statistical comparisons were two-sided with a level of significance of $\alpha = 0.05$.

Results

Study Population

Eighty-one subjects met the study inclusion criteria and were randomized to one of the two treatment groups: 40 to the experimental group and 41 to the positive control group. All subjects completed the study procedures. The demographic characteristics of the study population are summarized by treatment group in Table I; the two groups did not differ significantly ($p > 0.2$) in terms of age or gender. Baseline cold air VAS scores were also balanced ($p > 0.59$) between the two treatment groups.

Table I
Subject Demographic Characteristics

	Number of Subjects		Age (Years)	
Treatment Group	Male	Female	Mean (SD)	Range
Experimental	3	37	42.1 (8.91)	20–62
Positive Control	3	38	44.4 (7.76)	25–58

Efficacy Data

Table II shows a summary of baseline mean scores and treatment changes from baseline scores for the experimental and positive control dentifrice groups; Table III shows baseline-adjusted mean treatment scores and group comparisons.

Table II
Sensitivity Assessments:
Baseline and Treatment Changes from Baseline

	Mean (SD)		
		Change vs. Baseline	
Treatment Group	Baseline	Immediate	Day 3
Schiff Air Sensitivity			
Experimental	2.26 (0.375)	– 0.35 (0.4)[a]	– 1.29 (0.5)[a]
Positive Control	2.38 (0.430)	– 0.05 (0.2)[c]	– 0.15 (0.3)[b]
Pain VAS			
Experimental	6.98 (1.118)	– 1.62 (0.9)[a]	– 5.38 (1.3)[a]
Positive Control	7.13 (1.427)	– 0.06 (0.3)[c]	– 0.64 (0.7)[a]

[a] $p < 0.0001$
[b] $p = 0.01$
[c] $p \geq 0.10$

Table III
Sensitivity Assessments: Group Comparisons

	Mean (SD)	Analysis of Covariance Adjusted Mean (SE)	
Treatment Group	Baseline	Immediate	Day 3
Schiff Air Sensitivity			
Experimental	2.26 (0.375)	1.95 (0.0)	1.01 (0.1)
Positive Control	2.38 (0.430)	2.29 (0.0)	2.20 (0.1)
Treatment Comparison:			
p-value	0.202	< 0.001	< 0.001
Pain VAS			
Experimental	6.98 (1.118)	5.43 (0.1)	1.66 (0.2)
Positive Control	7.13 (1.427)	6.99 (0.1)	6.42 (0.2)
Treatment Comparison:			
p-value	0.593	< 0.001	< 0.001

Thermal Schiff Air Sensitivity. No significant group differences were seen at baseline ($p > 0.2$). Reductions from baseline for the experimental and positive control groups were 0.35 ($p < 0.0001$) and 0.05 ($p = 0.10$), respectively, immediately after treatment, and 1.29 ($p < 0.0001$) and 0.15 ($p = 0.01$), respectively, on Day 3. Changes from baseline for each treatment group at each post-treatment time point are summarized in Table II. The adjusted mean sensitivity scores for the experimental group were 14.8% and 54.1% lower (*i.e.*, indicating less sensitivity) than those of the positive control at the immediate and Day 3 post-treatment time points, respectively. Relative to the positive

control dentifrice group, the experimental group showed a statistically significant improvement ($p < 0.001$) at both time points. The adjusted mean treatment scores are presented for both groups in Figure 1 and Table III. In addition, there was a statistically significant ($p < 0.001$) time point by treatment interaction, indicating that the treatment group differences in sensitivity increased over time.

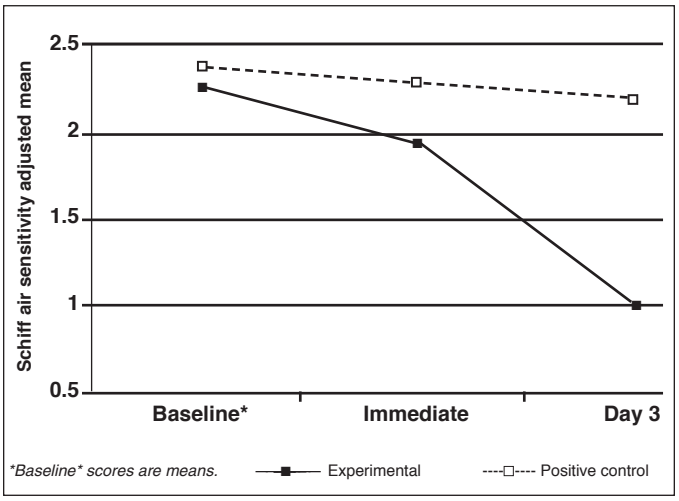

Figure 1. *Schiff Air Sensitivity adjusted treatment means.*

Thermal Air VAS Pain. Treatment groups were balanced at baseline ($p > 0.59$). Reductions from baseline for the experimental and positive control groups were 1.62 ($p < 0.0001$) and 0.06 ($p = 0.24$), respectively, immediately after treatment, and 5.38 ($p < 0.0001$) and 0.64 ($p < 0.0001$), respectively, on Day 3. Changes from baseline for each treatment group at each post-treatment time point are summarized in Table II. The adjusted mean VAS scores for the experimental group were 22.3% and 74.1% lower (*i.e.,* indicating less sensitivity) than those of the positive control at the immediate and Day 3 post-treatment time points, respectively. Relative to the positive control dentifrice group, the experimental group showed a statistically significant improvement ($p < 0.001$) at both time points. The adjusted mean treatment scores for both groups are illustrated in Figure 2 and Table III. In addition, there was a statistically significant

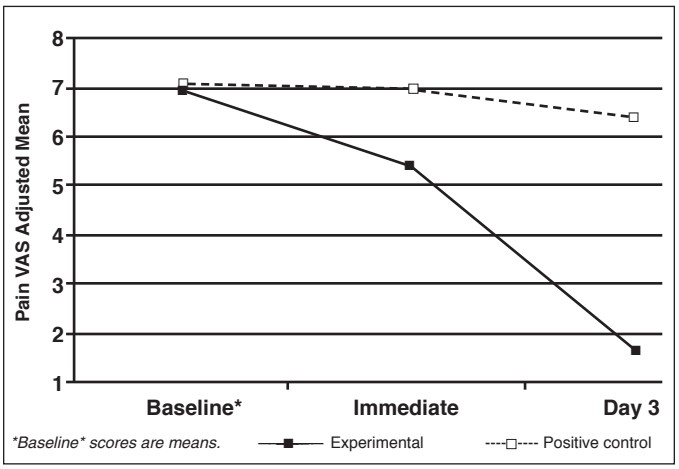

Figure 2. *Pain VAS adjusted treatment means.*

($p < 0.001$) time point by treatment interaction, indicating that the treatment group differences in sensitivity increased over time.

Safety Data

No adverse events were reported during the study in either the experimental or positive control group.

Discussion

Dentin hypersensitivity is common, but the exact prevalence in populations of various countries is difficult to estimate given different research methodologies. Bartold found an incidence of 10-30% across the general population globally, noting the incidence can vary greatly based on the cohort.[21] A prevalence figure of 15% of all dentate adults has consistently been reported.[1] In research among periodontal patients, hypersensitivity prevalence is even higher, with reports of 68%[22] and 84%[23] in the literature. In 2002, a global survey of 11,000 adults showed that approximately half of the patients suffering from sensitive teeth consulted a dentist.[1] For dental health professionals, the appropriate management and treatment of this painful condition remains a significant challenge. A good understanding of the etiology of the condition should help prevent dentin hypersensitivity and ensure its effective management.[24] Dentin hypersensitivity is generally associated with gingival recession and the exposure of dentin at buccal cervical sites. Multiple etiological factors could contribute to an individual's dentin hypersensitivity, but periodontal disease and tooth wear through physical (*e.g.*, poor tooth brushing technique) and chemical (*e.g.*, dietary acids) processes are the main factors thought to be responsible.[1]

Informing and educating patients on the causes of sensitive teeth are important preventive steps, especially in those individuals where dentin exposure can be related to dietary habits or tooth brushing methods, and a change in behavior is required. In addition to the need for better awareness, however, patients suffering symptoms of hypersensitivity require effective treatment and management for the alleviation of their ongoing pain and discomfort. In most patients, these symptoms can benefit from treatment in a simple, non-invasive, cost-effective way by twice-daily use of a dentifrice containing a desensitizing agent. The exact mechanism by which desensitizing agents act may not be fully understood, but it is the movement of fluid within the dentinal tubules, triggered by certain stimuli such as cold air on exposed dentin, that excites nerves and causes pain according to the widely accepted hydrodynamic theory of dentin hypersensitivity.[4] In dentifrices with stannous fluoride as an active ingredient, stannous ions are thought to occlude dentin tubules and prevent the stimulation of nerve endings and the pain response. The positive control dentifrice based on a novel arginine-calcium carbonate technology (8.0% arginine, calcium carbonate, and 1450 ppm fluoride as sodium monofluorophosphate) that was used in the present study is thought to work in a similar way, by triggering the deposition of phosphate and physically sealing dentin tubules with a plug containing arginine, calcium carbonate, and phosphate.[24]

The recently marketed stannous-containing sodium fluoride dentifrice assessed in the present study has been shown to have multiple oral care benefits, specifically antiplaque,[12] antigingivitis,[13] stain inhibition,[14] and improving breath malodor.[15]

Dentin hypersensitivity benefits with this experimental dentifrice were seen in a comparative four-week clinical study as reduced sensitivity versus a sodium fluoride negative control dentifrice,[16] and in an eight-week clinical study as comparable reductions in dentin hypersensitivity to a potassium nitrate positive control toothpaste.[17] The same commonly used thermal sensitivity methodology (air-blast/Schiff Air Index[10,20]) for measuring the pain of dentin hypersensitivity as that used in the earlier eight-week comparative study[17] was used in the present three-day study, which was aimed at determining whether this dentifrice has the potential to offer sufferers the highly desirable benefit of rapid relief. The study compared desensitizing efficacy of this experimental stannous-containing sodium fluoride dentifrice with the arginine-calcium carbonate dentifrice[25] as a positive control. Both products provided a statistically significant reduction in sensitivity at Day 3 versus baseline; however, only the stannous-containing dentifrice provided a significant benefit immediately post-brushing. Moreover, results showed significantly ($p < 0.001$) less sensitivity in the experimental group compared to the positive control group both immediately after treatment (14.8% lower) and after three days of treatment (54.1% lower). The results were supported by the subject's own assessment of the pain using a visual analog scale. Scores were significantly lower at Day 3 versus baseline for both products, but only the stannous-containing sodium fluoride dentifrice provided a significant benefit immediately after use. Results also showed significantly ($p < 0.001$) less sensitivity in the experimental group compared to the positive control group, both immediately after treatment (22.3% lower) and after three days of treatment (74.1% lower). These results, showing the efficacy superiority of this experimental stannous-containing sodium fluoride dentifrice, together with the results of earlier comparative studies over a four-week treatment period[16] and an eight-week treatment period[17] of product use, provide evidence that this dentifrice can give sufferers of dentin hypersensitivity meaningful relief (*i.e.*, both instant and longer-term) from the pain and discomfort of this condition.

The results of comparative clinical studies shape commercial advances in oral healthcare products, and allow consumers and dental professionals to make informed choices based on scientific evidence. Recent developments in dentifrice technology mean there is now the potential to combine multiple oral health benefits within a single product, and this has the appeal of being both cost-effective and convenient. Hypersensitivity is a common oral health problem that can have a debilitating effect on patients in their daily lives. Given the global nature of oral healthcare problems and the manufacturer's desire that this dentifrice should be accessible worldwide,[11] the data from the present study, which was conducted in China, taken together with evidence from studies that have demonstrated the efficacy of this dentifrice for other major dental conditions (antiplaque, antigingivitis, stain inhibition, improved breath malodor),[12-15] are of value in supporting the promotion of this advanced multi-benefit dentifrice to users across the globe.

Acknowledgment: The authors are grateful to Dr. Jane Mitchell (MWS Ltd, UK) for assistance with manuscript preparation. This study was supported by the Procter & Gamble Company.

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