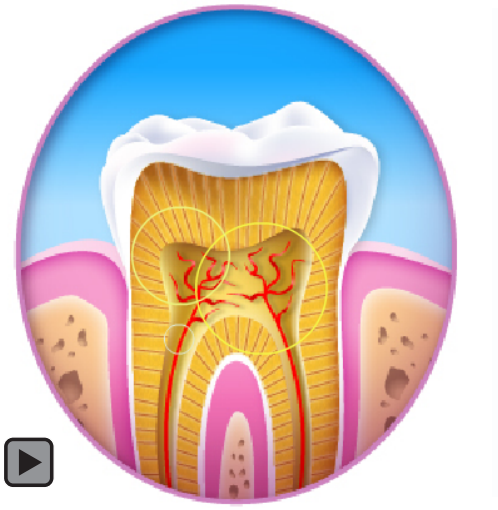
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Efficacy and Safety of a Novel Stabilized Stannous Fluoride and Sodium Hexametaphosphate Dentifrice for Dental Hypersensitivity

Thomas Schiff, DMD; Tao He, DDS, PhD;
Lisa Sagel, MA; Robert Baker, MS



Abstract

Purpose: Dentinal hypersensitivity is a common complaint among dental patients. Recently, a novel 0.454% stabilized stannous fluoride dentifrice containing sodium hexametaphosphate (SHMP) was introduced that offers a desensitizing benefit. This trial was conducted to assess the desensitizing efficacy of this new dentifrice relative to a sodium fluoride control dentifrice.

Methods and Materials: This was a double-blind, parallel-group, randomized clinical trial conducted according to the American Dental Association (ADA) Guidelines for the Acceptance of Products for the Treatment of Dentinal Hypersensitivity. Ninety subjects who met the entrance criteria were stratified based on age, gender, and baseline sensitivity scores and randomly assigned to either the stabilized stannous fluoride + SHMP dentifrice (Crest® Pro-Health) or the sodium fluoride control dentifrice. Subjects were instructed to brush twice daily for eight weeks. Efficacy assessments were made, including tactile (Yeaple probe) and thermal (Schiff Air Index) sensitivity, and an oral soft tissue examination was conducted at baseline, week four, and week eight.

Results: The mean sensitivity score based on the Schiff Air Index for the stannous fluoride + SHMP group was statistically significantly lower than that of the control group, at both weeks four and eight ($P < .0001$). At week eight, the stannous fluoride + SHMP dentifrice group had an adjusted mean 44% lower than that of the control group. The mean tactile sensitivity score for the stannous fluoride + SHMP group was statistically significantly

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higher, indicating a reduction in sensitivity, than that of the control group, at both weeks four and eight ($P < .0001$). At week eight, the stannous fluoride + SHMP dentifrice group had a mean desensitizing improvement of 71% greater than the control.

Conclusion: The stabilized stannous fluoride + SHMP dentifrice provided statistically significant reductions in dentinal hypersensitivity at four and eight weeks compared to the sodium fluoride control dentifrice.

Keywords: stannous fluoride, sensitivity, clinical trial, sodium hexametaphosphate, Crest Pro-Health

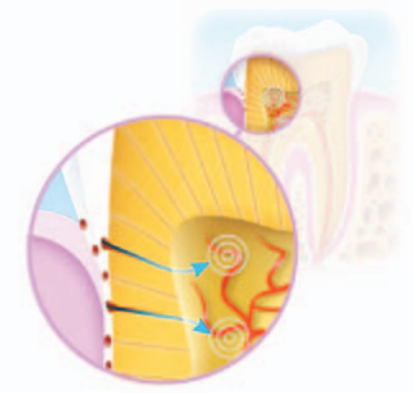
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Introduction

Dentinal hypersensitivity is a common problem seen by dental professionals. Reports in the literature indicate the prevalence of dentinal hypersensitivity ranges from 4% to 57%.[1,2] The condition is characterized by exposed dentinal tubules most often due to gingival recession and loss of cementum through erosion, abrasion, or other factors.[3] Brännström's hydrodynamic theory is broadly accepted as explaining the mechanism of tooth sensitivity.[3] According to the hydrodynamic theory, pain occurs when the dentin surface is exposed to various stimuli, such as thermal, tactile, or osmotic changes that provoke rapid fluid movement in the tubules.[4-6] Fluid flow stimulates nerve terminals, thereby, triggering the sensation of pain. Routine activities like tooth brushing or drinking cold beverages can elicit this type of sharp, transient pain.

Active ingredients such as stannous fluoride have been incorporated into oral hygiene products to reduce dentinal hypersensitivity for decades.[7,8] The mechanism of action for stannous fluoride is chemical precipitation of stannous ions which occludes dentinal tubules, thus, preventing the stimulation of free nerve endings.[9] Stannous fluoride has been clinically shown to reduce hypersensitivity in various product forms.[10-13]

Recently, a novel dentifrice formulation was introduced combining stannous fluoride, sodium hexametaphosphate (SHMP), and silica. This unique patented formula was designed to deliver the therapeutic benefits of stannous fluoride including protection from dentinal hypersensitivity, caries, and gingivitis, with the cosmetic benefits of extrinsic stain and calculus control from SHMP and silica. The objective of this study was to



compare the efficacy of this novel 0.454% stannous fluoride + SHMP dentifrice versus a negative control in the reduction of dentinal hypersensitivity over an eight week period. (Go to the on-line article to view animations of the method of action for this novel dentifrice formulation.)



Methods and Materials

This study was a single center, randomized, double blind, parallel group clinical trial conducted according to the American Dental Association (ADA) guidelines for the Acceptance of Products for the Treatment of Dentinal Hypersensitivity.[14] Following review and approval of the protocol by the institutional review board, subjects with moderate dentinal hypersensitivity were enrolled in the study at the University of the Pacific School of Dentistry. A soft tissue examination and efficacy assessment, including tactile and thermal sensitivity evaluations, were conducted at baseline. Subjects were then randomized to either the 0.454% stannous fluoride + SHMP

dentifrice or the negative control and instructed to brush twice daily for 60 seconds with their assigned product for eight weeks. Soft tissue and efficacy examinations were conducted again after four and eight weeks of treatment.

Subject Population

Generally healthy subjects, between 18-65 years of age with moderate dentinal hypersensitivity, as indicated by tactile and air blast sensitivity scores, were enrolled in the study after providing written informed consent. Subjects were required to have a minimum of two bicuspid or cuspid teeth meeting the sensitivity criteria: Yeaple probe score = 10 grams and Schiff Air Sensitivity Scale score > 1 at the baseline evaluation.[15,16,17]



Subjects were excluded from the trial if there was evidence of chronic diseases, oral pathoses, participation in a desensitizing dentifrice study within the last two months, or if they were pregnant or nursing. Subjects were also excluded if they had any of the following: deep, defective, or facial restorations; teeth being used as abutments for partial dentures; full crowns; extensive caries or cracked enamel; periodontal surgery within the previous six months; scaling and root planing within the previous three months; or dental prophylaxis within two weeks prior to baseline.

Treatments

Qualified subjects were stratified based on age, gender, and baseline sensitivity scores and randomized to one of two treatment groups:

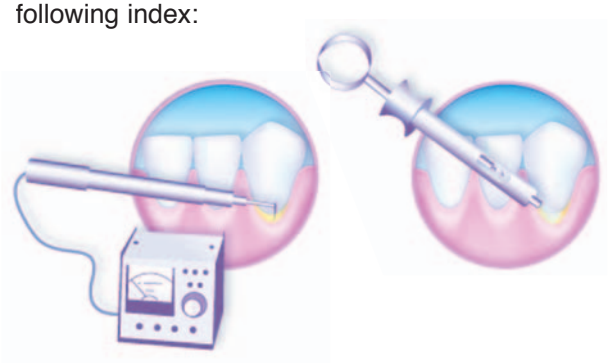
- 0.454% stannous fluoride + SHMP dentifrice[a] (Crest® Pro-Health)
- Negative control 0.243% sodium fluoride dentifrice group (Crest Cavity Protection)[a]

Each subject was provided with a kit containing two tubes of dentifrice (overtubed for blinding purposes), one Oral-B® 40 soft toothbrush[a], one 60-second timer, and one instruction sheet. Subjects were instructed to cover the full head of a pre-wet toothbrush with dentifrice and brush all surfaces of all the teeth for one minute before expectorating or diluting with water.

Clinical Assessment

Tactile and thermal efficacy assessments were conducted at baseline and after four and eight weeks. Oral soft tissue examinations were performed prior to efficacy evaluations. Self-reported adverse events were also recorded.

At baseline, teeth anterior to the first molars were examined for tactile response. The labial surfaces of the teeth were tested with the Yeaple probe (Model 200A Yeaple Electronic Force Sensing Probe) at a force setting of 10 grams. Teeth responding at 10 grams were rechallenged at 10 grams. Only teeth responding positively to both challenges were evaluated in the trial. Next, the examiner assessed the response of teeth anterior to the molars to a one-second application of cold air delivered from a standard dental unit syringe at 40–60 psi at a temperature of 70 ± 5°F. The Schiff Air Sensitivity Score was recorded using the following index:



Schiff Air Sensitivity Scale

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

Teeth scored as one or greater were evaluated at subsequent visits. During the four and eight week examinations, tactile testing started at 10 grams and increased by 10 gram increments up to a maximum of 50 grams. Each successive challenge increased until a force was found eliciting two positive responses. If no sensitivity

[a] Procter & Gamble, Cincinnati Ohio, USA

was found at 50 grams, the threshold was recorded as > 50 grams.

Statistical Methods

Four and eight week tactile scores were analyzed separately using analysis of variance with treatment as a factor. Four and eight week cold air sensitivity scores were analyzed separately using analysis of covariance with baseline score as a covariate. All efficacy comparisons were two-sided and used a 0.05 level of significance.

Results

A total of 90 subjects (45 in each treatment group) were enrolled in this study. All subjects were evaluable and included in all statistical analyses. Table 1 summarizes baseline demographic data. There were 48 females (53%) and 42 males (47%) in this study. The mean age was 32.2 years. The population was 72% Caucasian and 28% African American. Ninety-nine percent of subjects were non-smokers.

Air-blast sensitivity scores are presented in Table 2 and Figure 1. Treatment groups were well balanced with respect to baseline tooth sensitivity with Schiff Air Index means of 2.64 and 2.69, respectively, in the negative control and stannous fluoride + SHMP treatment groups. The adjusted mean cold air sensitivity score for the stannous fluoride + SHMP dentifrice group was statistically significantly lower than the negative control group, at both weeks four and eight ($p<0.0001$). The lower cold air sensitivity score indicates decreasing sensitivity. At week four, the stannous fluoride + SHMP dentifrice group had an adjusted mean 33% lower than the negative control group. At week eight, the stannous fluoride + SHMP dentifrice group had an adjusted mean 44% lower than the negative control group.

Table 1. Baseline demographic characteristics.

Evaluable Subjects			
Demographic Characteristic	Negative control (n=45)[a]	Stannous flouride/ SHMP Dentifrice (n=45)[a]	Overall (N=90)
Age (Years)			
Mean (SD)	32.2 (10.6)	32.3 (9.6)	32.2 (10.0)
Minimum-Maximum	20 – 64	22 – 56	20 – 64
Sex[b]			
Female	25 (56%)	23 (51%)	48 (53%)
Male	20 (44 %)	22 (49%)	42 (47%)
Race[b]			
African American	9 (20%)	16 (36%)	25 (28%)
Caucasian	36 (80%)	29 (64%)	65 (72%)
Smoke[b]			
No	45 (100%)	44 (98%)	89 (99%)
Yes	0 (0%)	1 (2%)	1 (1%)

[a] n=number of subjects included in analysis in each treatment group.
[b] Number and percent of subjects in each category.
SHMP = Sodium hexametaphosphate

Table 2. Schiff Air Index analysis of covariance.

Lower scores indicate less tooth sensitivity				
Time / Treatment	**N[a]**	**Baseline Mean**	**Adj. Mean (std err)[b]**	***P*-value[c]**
Week 4 (MSE= 0.34)				
Negative control dentifrice	45	2.64	2.29 (0.09)	<0.0001
Stannous fluoride + SHMP dentifrice	45	2.69	1.54 (0.09)	
Week 8 (MSE= 0.36)				
Negative control dentifrice	45	2.64	1.95 (0.09)	<0.0001
Stannous fluoride + SHMP dentifrice	45	2.69	1.10 (0.09)	

[a] N = number of subjects used in analyses.
[b] Means adjusted for Baseline values.
[c] All comparisons are two-sided at the 0.05 level of significance.
SHMP = Sodium hexametaphosphate; MSE = Mean squared error

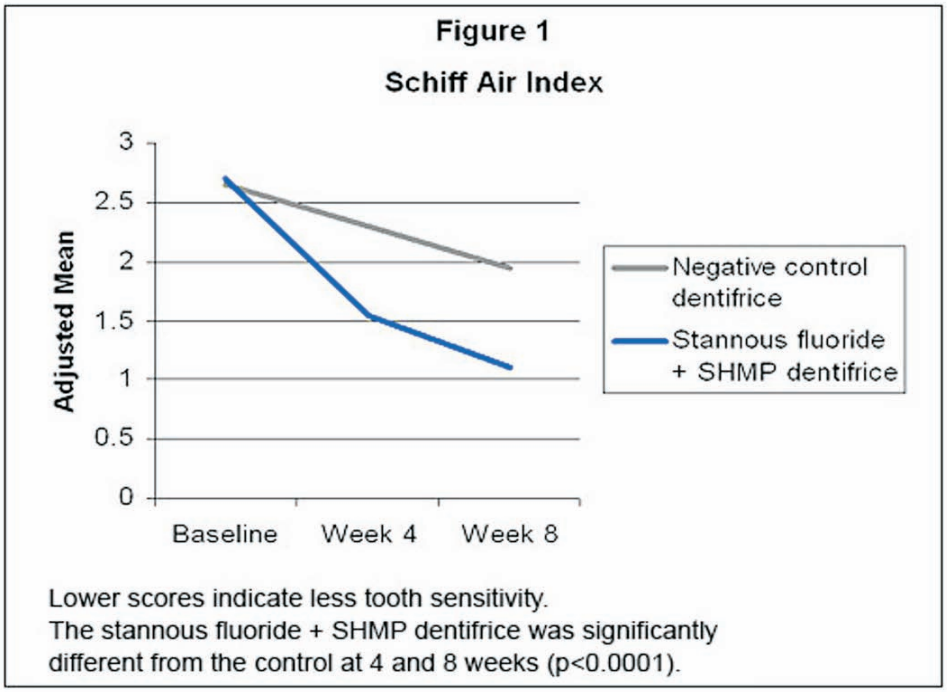


Figure 1.

Table 3 and Figure 2 summarize tactile sensitivity results. The mean tactile sensitivity score for the stannous fluoride + SHMP dentifrice group was statistically significantly greater than the negative control group, at both weeks four and eight ($p<0.0001$). Higher tactile sensitivity scores indicate increasing tolerability to pressure applied (i.e., less tooth sensitivity). At week four, the stannous fluoride + SHMP dentifrice group had a mean approximately 14 units higher than the negative control group, representing a mean desensitizing improvement of 114% greater than the negative control. At week eight, the experimental dentifrice group had a mean approximately 11 units higher than the negative control group, representing a mean desensitizing improvement of 71% greater than the negative control.

No adverse events were reported or observed during this study.

Discussion



In this trial the stabilized 0.454% stannous fluoride + SHMP dentifrice provided a statistically significant improvement for the control of both thermal and tactile sensitivity when compared to a negative control. A benefit was observed after four weeks of use and maintained at the eight week evaluation. This study corroborates previously published research showing the stannous fluoride + SHMP dentifrice is an effective and well-tolerated agent for the treatment of dentinal hypersensitivity.[17]

Unlike other desensitizing treatments, this unique stannous fluoride + SHMP dentifrice offers the advantage of providing a broad range of additional therapeutic and cosmetic benefits. Stannous fluoride has a long history of use in oral care products for protection against caries, pathogenic bacteria, plaque, gingivitis, hypersensitivity, and breath malodor. An extensive body of research published during the last four decades provides substantial evidence of stannous fluoride's benefits in these areas.[9,10,18-24]

In fact stannous fluoride is the only fluoride found in several monographs (final and developing) for over-the-counter drugs. Recent advances in dentifrice technology made it possible to combine stabilized stannous fluoride with SHMP, an advanced calcium-sequestering agent having a strong reactivity to enamel surfaces. SHMP's substantial anticalculus and extrinsic whitening effects in the oral cavity has been demonstrated in clinical research both in dentifrice and chewing gum forms.[25-29] The patented dentifrice technology combining stabilized stannous fluoride and SHMP has been clinically shown to deliver the advantages of each individual ingredient.[17,30-36]

The unique breadth of benefits offered by this formula is particularly important since patient groups with dentinal hypersensitivity generally have additional oral health needs (e.g., caries protection) and/or desires (e.g., white teeth). Periodontal patients represent one group with a higher prevalence of dentinal hypersensitivity, with 60% to 98% reporting the condition.[37-39] The reduction in gingival bleeding and inflammation[30,31] along with the desensitizing benefit[17] provided by the novel stannous fluoride dentifrice would be particularly useful for this cohort. Adults in the 20-30 year age range are another group reported to experience a greater incidence of tooth sensitivity.[40] The dentifrice's extrinsic whitening benefit[35] may appeal to this age group, allowing them to alleviate their sensitivity while simultaneously obtaining the esthetic benefits many desire. Beyond specific patient groups, the stannous fluoride + SHMP dentifrice should also be considered for the broad patient population. Since roughly half of sufferers claim they haven't consulted their dental professional about dentinal hypersensitivity[41], use of this multi-benefit dentifrice ensures uncompromised protection for patients who fail to mention the condition to their dental professional.

Conclusion



This research shows the stannous fluoride + SHMP dentifrice provides significant desensitizing benefits at four and eight weeks relative to a negative control.

Table 3. Yeaple Probe Index analysis of variance.

Higher scores indicate less tooth sensitivity				
Time / Treatment	**N[a]**	**Baseline Mean [b]**	**Mean (std err)[c]**	***P*-value[d]**
Week 4 (MSE=22.1)				
Negative control dentifrice	45	10	12.56 (0.70)	<0.0001
Stannous fluoride + SHMP dentifrice	45	10	26.89 (0.70)	
Week 8 (MSE=38.8)				
Negative control dentifrice	45	10	14.78 (0.93)	<0.0001
Stannous fluoride + SHMP dentifrice	45	10	25.33 (0.93)	

[a] N = number of subjects used in analyses.
[b] Baseline score of 10 required per protocol
[c] Means for each treatment at each time point .
[d] All comparisons are two-sided at the 0.05 level of significance.
SHMP = Sodium hexametaphosphate; MSE = Mean squared error

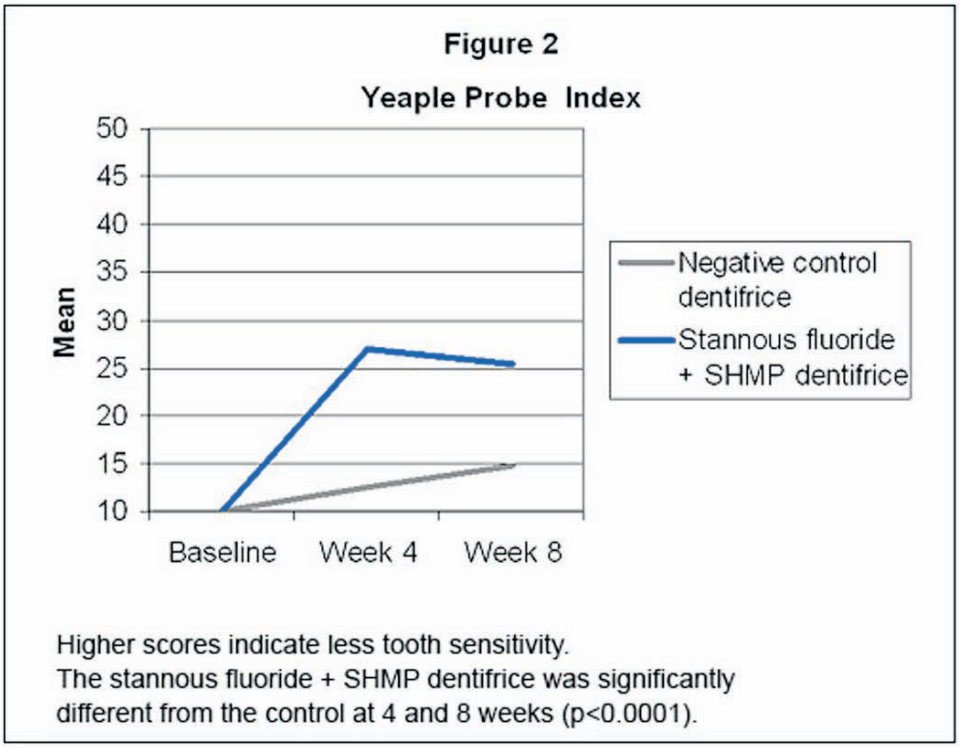


Figure 2.

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About the Authors

Thomas Schiff, DMD



Dr. Schiff is a Professor and the Chairman of the Department of Maxillofacial Radiology. He was born in Budapest, Hungary, and educated at the Semmelweiss Medical School. He immigrated to the United States and received his dental degree from the School of Dentistry at the University of Alabama in 1961. He has served on the faculty of Washington University for 20 years and the University of the Pacific School of Dental Medicine since 1993. He received his advanced training in oral and maxillofacial radiology at the University of Texas Health Science Center in San Antonio, Texas. Dr. Schiff is a Fellow of the International Academy of Maxillofacial Radiology and has received an honorary degree at Semmelweiss University Medical School.

Tao He, DDS, PhD



Dr. He is a Senior Clinical Scientist in Oral Care Worldwide Clinical Investigations at the Procter & Gamble Company, Cincinnati, OH, USA. She received a DDS degree from the Capital University of Medicine (Beijing) and a PhD degree in Periodontology from the Tokyo Medical & Dental University in Tokyo, Japan. Her current research interests include periodontal therapy, design of clinical trials, dentifrices, and the effectiveness of mouthrinses (gingivitis, hypersensitivity, breath, stain removal, caries, and calculus). Dr. He has published her research extensively in more than 40 peer-reviewed publications.

e-mail: he.t@pg.com

Lisa Sagel, BS, MA



Ms. Sagel manages oral care scientific communications at Procter & Gamble. Prior to this position, she was a Principal Researcher in Oral Care Research & Development. She has an MA in Latin American development from the University of Kentucky, where she worked as a Spanish translator in dental and medical clinics affiliated with the Kentucky Migrant Health Program.

Robert Baker, MS



Mr. Baker is a Section Head in Biometrics at the Procter & Gamble Health Care Research Center in Cincinnati, OH, USA. Following receipt of a BS in Mathematics from the Rochester Institute of Technology and an MS in Statistics from Purdue University, he has spent his career supporting oral care clinical trials and health care consumer research. He has authored numerous clinical study reports as well as peer-reviewed publications.

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