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

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This course is no longer offered for Continuing Education credit.

Overview

Dentinal hypersensitivity is a common complaint among dental patients. The condition is characterized by exposed dentinal tubules, often caused by gingival recession and loss of cementum through erosion, abrasion or other factors. Stannous fluoride has been used to treat hypersensitivity for years due to its ability to occlude dentinal tubules. A 0.454% stabilized stannous fluoride dentifrice containing sodium hexametaphosphate (SHMP) was introduced that offers a desensitizing benefit. This purpose of this course is to review findings from an 8-week clinical trial evaluating the desensitizing efficacy of this therapeutic dentifrice containing stannous fluoride and sodium hexametaphosphate.

Learning Objectives

Upon the completion of this course, the dental professional will be able to:

- Explain common contributing factors to dentinal hypersensitivity.
- Describe the desensitizing mechanism of action for stannous fluoride.
- Discuss two tools used to evaluate dentinal hypersensitivity in clinical research.
- Discuss clinical results of a trial comparing a stannous fluoride dentifrice to a negative control.
- Describe patient populations who could benefit from the stannous fluoride dentifrice.

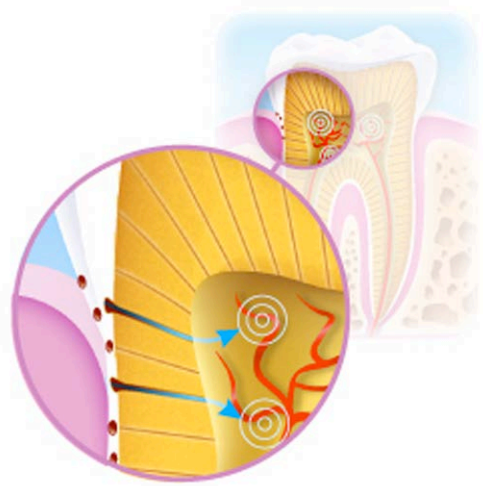
Course Contents

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]

A unique dentifrice formulation was introduced combining stannous fluoride, sodium hexametaphosphate (SHMP), and silica. This



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 0.454% stannous fluoride + SHMP dentifrice versus a negative control in the reduction of dentinal hypersensitivity over an eight week period.

Dentifrice Method of Action Video Clips

(To view the videos for the following topics, please go to http://www.dentalcare.com/en-US/education/ce87/pg01.jspx)

- Dentinal Hypersensitivity Reduction

Materials and Methods

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 dentifricea (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

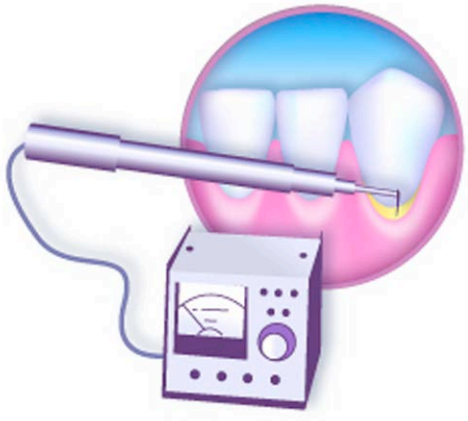
Tactile and thermal efficacy assessments were conducted at baseline and after four and eight weeks. Oral soft tissue examinations were performed prior to efficacy evaluations. Self-reported adverse events were also recorded.

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



[a] - Procter & Gamble, Cincinnati Ohio, USA

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 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 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

Table 1. Baseline demographic characteristics.

Evaluable Subjects			
Demographic Characteristic	**Negative control (n=45)[a]**	**Stannous fluoride/ 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

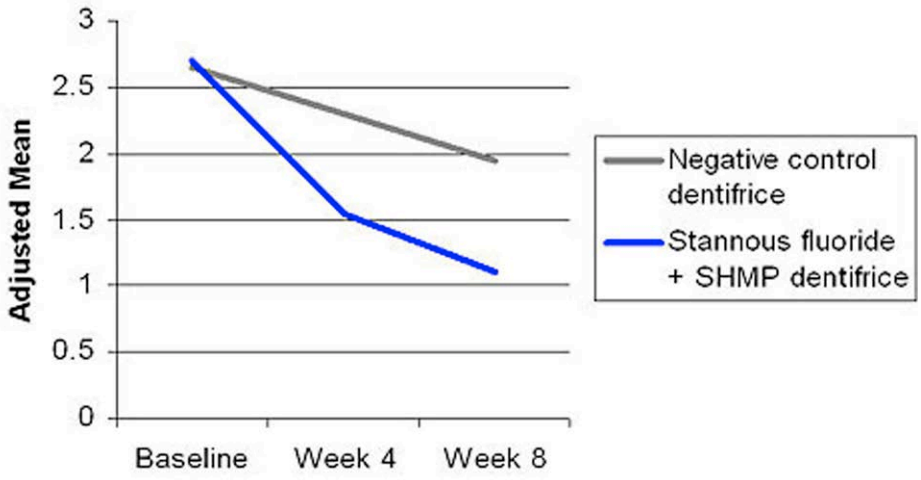


Figure 1. Schiff Air Index. Lower scores indicate less tooth sensitivity. The stannous fluoride + SHMP dentifrice was significantly different from the control at 4 and 8 weeks (p<0.0001).

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]

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

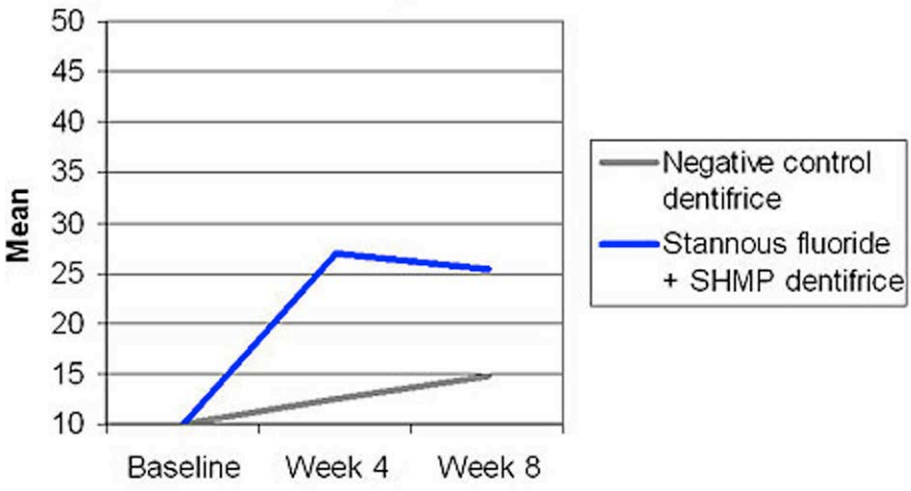


Figure 2. Yeaple Probe Index. Higher scores indicate less tooth sensitivity. The stannous fluoride + SHMP dentifrice was significantly different from the control at 4 and 8 weeks (p<0.0001).

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.

To receive Continuing Education credit for this course, you must complete the online test. Please go to **www.dentalcare.com** and find this course in the Continuing Education section.

Course Test Preview

1. Dentinal hypersensitivity is reported to affect ___ % to ___ % of the population.
a. 2 to 10
b. 34 to 71
c. 0 to 90
d. 4 to 57

2. Dentinal hypersensitivity is characterized by _____.
a. intrinsic stain
b. exposed dentinal tubules
c. bleeding gums
d. Class I occlusion

3. According to Brännström's 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.
a. True
b. False

4. Stannous fluoride helps control dentinal hypersensitivity by _____ dentinal tubules thus preventing the stimulation of free nerve endings.
a. occluding
b. expanding
c. remineralizing
d. None of the above.

5. The test dentifrice in the study contains _____ fluoride, sodium hexametaphosphate and silica.
a. amine
b. sodium
c. stannous
d. hydrogen

6. The stannous fluoride and sodium hexametaphosphate dentifrice tested in this study protects against which conditions:
a. Sensitivity
b. Caries and gingivitis
c. Calculus and surface stains
d. All of the above.

7. The trial described in this course was conducted according to the American Dental Association (ADA) guidelines for the Acceptance of Products for the Treatment of Dentinal Hypersensitivity.
a. True
b. False

8. The subject population in this trial was _____ Caucasian and _____ African American.

a. 93%, 7%
b. 64%, 36%
c. 72%, 28%
d. 55%, 45%

9. At 8 weeks, the stannous fluoride + SHMP dentifrice provided a _____% reduction in air-blast sensitivity scores versus the negative control.

a. 44%
b. 13%
c. 35%
d. 29%

10. Research indicates 60% to 98% of xerostomic patients report dentinal hypersensitivity.

a. True
b. False

11. About _____ of dentinal hypersensitivity sufferers claim they haven't consulted their dental professional about the condition.

a. one third
b. half
c. two thirds
d. one quarter

12. At Week 8, the stannous fluoride + SHMP dentifrice showed a 71% improvement over _____.

a. baseline
b. negative control
c. positive control
d. None of the above.

13. ___ adverse events were reported or observed in the trial.

a. Four
b. Five
c. Two
d. No

14. A score of 1 on the Schiff Air Index represents which of the following:

a. Tooth/subject does not respond to air stimulus
b. Tooth/subject responds to air stimulus but does not request discontinuation of stimulus
c. Tooth/subject responds to air stimulus and requests discontinuation or moves from stimulus
d. Tooth/subject responds to air stimulus, considers stimulus to be painful, and requests discontinuation of the stimulus

15. The Yeaple Probe measures:

a. Sensitivity to force (tactile response)
b. Sensitivity to hot
c. Sensitivity to product ingredients
d. None of the above.

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