

## An Anticalculus Dentifrice with Sodium Hexametaphosphate and Stannous Fluoride: A Six-month Study of Efficacy

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### Abstract

**Aim:** To compare the anticalculus efficacy of an experimental dentifrice (0.454% stabilized stannous fluoride/sodium hexametaphosphate) with a negative control.

**Methods and Materials:** This was a randomized, examiner-blind, parallel group study. After a three-month run-in, qualifying subjects were randomized to the experimental or control dentifrice to use twice a day for six months. Volpe-Manhold Index (V-MI) and oral soft tissue examinations were conducted at baseline, three, and six months. Additional analyses were performed separately at three and six months on three subgroups categorized into high, medium, and low calculus-forming subjects.

**Results:** Compared to the control group, the experimental dentifrice group had a mean calculus score statistically significantly lower at both three months (50%) and six months (55%) post-treatment ( $p < 0.001$ ). Compared to control scores, mean experimental dentifrice calculus scores at three and six months were statistically significantly lower at both points in time for high, medium, and low calculus forming sub-groups ( $p < 0.001$ ). Both products were generally well tolerated.

**Conclusion:** The experimental dentifrice revealed significant anticalculus efficacy compared to the control regardless of levels of baseline calculus formation.

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**Clinical Significance:** The stannous fluoride/sodium hexametaphosphate dentifrice technology is an effective calculus inhibitor for home care.

**Keywords:** Calculus, plaque, stannous fluoride, sodium hexametaphosphate, dentifrice, oral hygiene

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## Introduction

Supragingival calculus is the result of calcium phosphate mineralization in dental plaque above the free gingival margin<sup>1</sup> and is a widespread oral hygiene problem.<sup>2</sup> It often forms along the gingival margin, particularly on lingual surfaces<sup>3</sup> (Figure 1). Once formed, it cannot be eliminated through home-based dental care because of its hard and tenacious properties.<sup>4</sup> Thus, calculus removal must be undertaken by dental professionals at the time of routine dental treatment. Inhibiting its formation between dental visits would result in improved oral hygiene and is, therefore, highly desirable.<sup>5</sup>



**Figure 1.** Supragingival calculus.<sup>6</sup>

(From: White DJ, Gerlach RW. Anticalculus Effects of a Novel, Dual-Phase Polypyrophosphate Dentifrice: Chemical Basis, Mechanism, and Clinical Response. *J Contemp Dent Pract* 2000;(1)4: 001-019.)

Innovations to assist the public with the inhibition of calculus formation include the development of a dentifrice that combines the antibacterial,<sup>7</sup> anticaries,<sup>8</sup> and antigingivitis<sup>9,10</sup> properties of stannous fluoride with sodium hexametaphosphate, a calcium phosphate mineralization inhibitor,<sup>11,12</sup> to produce an advanced antiplaque, anticalculus, and whitening formulation (Figure 2).

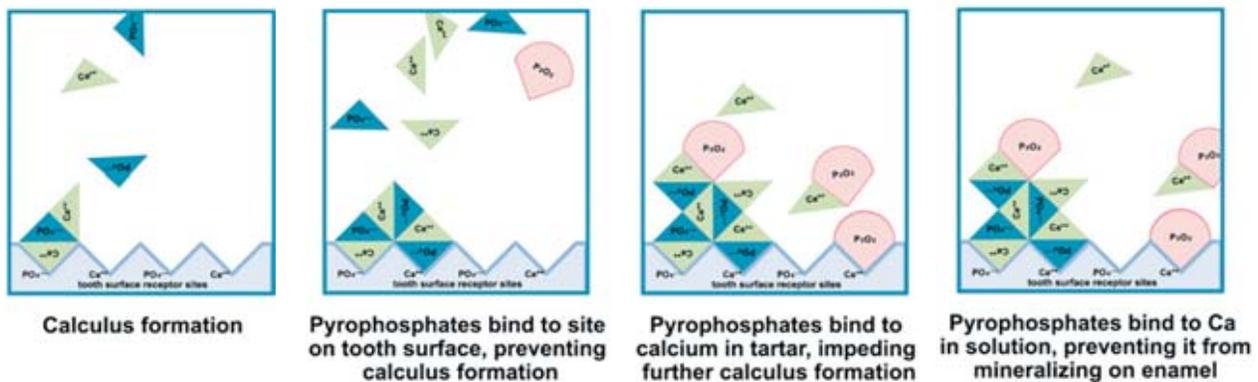


**Figure 2.** Inhibition of stain and calculus formation with sodium hexametaphosphate. Go to [www.thejcdp.com](http://www.thejcdp.com) and click on the image to view a short video.

(Courtesy, the Procter & Gamble Company, Cincinnati, OH, USA.)

The calculus control achieved by mineralization inhibitors, such as pyrophosphates which are present in a number of calculus control dentifrices, can be variable as the quality and extent of their activity can be limited or rendered ineffective by reactions at the tooth surface.<sup>11</sup> However, sodium hexametaphosphate is a polymeric phosphate that is more resistant to deactivation in the mouth and, thereby, shows improved efficacy. In combination with the known benefits of stannous fluoride<sup>7-10</sup> this has produced a dentifrice technology with a comprehensive range of therapeutic and cosmetic benefits<sup>13-19</sup> (Figure 3).

This study, conducted in an unsupervised, home-based setting, evaluated the anticalculus benefits and safety of an experimental dual-



**Figure 3.** Animation of anticalculus activity of pyrophosphates and other mineralization inhibitor molecules to control of the mineral formation within dental plaque.

(From: White DJ, Gerlach RW. Anticalculus Effects of a Novel, Dual-Phase Polypyrophosphate Dentifrice: Chemical Basis, Mechanism, and Clinical Response. *J Contemp Dent Pract* 2000;(1)4: 001-019.)

phase dentifrice containing stannous fluoride and sodium hexametaphosphate versus a standard sodium fluoride dentifrice containing no anticalculus agents (i.e., negative control).

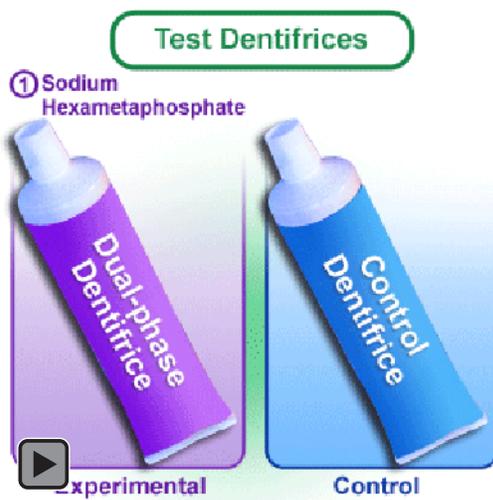
### Methods and Materials

#### General Study Design

This study had a single center, randomized, examiner-blind, parallel group design and compared an experimental dual-phase 0.454% stabilized stannous fluoride plus sodium hexametaphosphate dentifrice (Procter & Gamble Company, Cincinnati, OH, USA) with a 0.243% sodium fluoride negative control dentifrice (Crest® Cavity Protection, Procter & Gamble, Cincinnati, OH, USA) that did not contain an anticalculus agent over a six-month period of unsupervised home use.

Before the start of the study, the protocol was approved by the University of the Pacific Institutional Review Board. Informed consent was conveyed by subjects before participating in any study procedures. Individuals with poor general or dental health, presented with fewer than six mandibular anterior teeth, sensitivity to tartar control toothpastes, fixed orthodontic appliances, or dental implants in the mandibular anterior region, used chlorhexidine, or had other factors that may have affected the ability to measure calculus were excluded from participation.

At the beginning of the study, subjects were given a thorough dental prophylaxis to remove dental plaque, stain, and calculus. Subjects then entered a three-month run-in phase to identify rapid calculus formers. These individuals were defined as those who formed at least 1.5 mm of calculus per graded tooth during which they brushed unsupervised using the negative control dentifrice (Crest Cavity Protection). At the end of the three months (the baseline of the six-month test phase), the teeth of the subjects were graded for calculus using the Volpe-Manhold Index (V-MI).<sup>20</sup> Prior to grading, teeth were dried with a stream of air. The height and width of calculus on the lingual surfaces of the lower six anterior teeth (where calculus is most likely to form) was then measured (in 0.5 mm increments) in three planes using a standard periodontal probe placed on the inferior border. A zero score denoted the absence of calculus at that site. Each subject's V-MI score was calculated



by summing the scores over all the graded sites. Qualifying subjects were those who formed a minimum of 1.5 mm of calculus per graded tooth. Qualifying subjects also received an oral tissue examination.

After calculus measurements had been taken, qualifying subjects received a further dental prophylaxis and were randomly assigned to two groups (stratified according to gender and baseline calculus scores) and given one of two products; either the experimental stannous fluoride plus sodium hexametaphosphate dentifrice (i.e., experimental group) or the sodium fluoride dentifrice (i.e., negative control group). All subjects brushed unsupervised twice daily for six months with their assigned products. Further V-MI scores were obtained at three and six months to assess treatment effectiveness.



Subjects also received oral soft tissue examinations at three and six months to evaluate safety. Examinations were made of the gingiva (free and attached), hard and soft palate, oropharynx and uvula, buccal mucosa, tongue, floor of the mouth, labial mucosa, mucobuccal and mucolabial folds, lips, and perioral area. Any abnormalities not present at the inception of the study or which exacerbated during test-product usage were classified as adverse events and monitored to resolution.

### Statistical Analysis

Analysis of covariance (ANCOVA) with treatment as a factor and baseline V-MI score as the covariate was used to assess treatment effect separately for three and six months post-treatment. The treatment by baseline score interaction was not statistically significant at

either time point and, therefore, excluded from all final statistical models. Additionally, sub-group analyses were performed using the ANCOVA model separately for three and six months post-treatment. Three sub-groups were defined by categorizing baseline calculus levels using the tertiles of V-MI distribution, high, medium, and low for each time point. Month three sub-groups were defined as follows:

1. Baseline less than 24.5 mm.
2. Baseline equal to or greater than 24.5 mm but less than 30 mm.
3. Baseline equal to or greater than 30 mm.

Month six sub-groups were defined as follows:

1. Baseline less than 24.5 mm.
2. Baseline equal to or greater than 24.5 mm but less than 31 mm.
3. Baseline equal to or greater than 31 mm.

All comparisons were two-sided at the 0.05 level of significance. Analysis of the month three data was performed as an interim analysis by a statistician not otherwise involved with this study. Prior to database lock, treatment assignment for individual subjects was only made available to the statistician who performed the interim analysis.

### Results

Following the three-month run-in phase of the study, 142 subjects (72 females and 70 males) were considered evaluable and entered into the six-month treatment phase. Demographic details are shown in Table 1.

At months three and six, the experimental group had adjusted mean calculus scores 50% lower and 55% lower, respectively, than those of the control group. Group differences at both three and six months were statistically significant ( $p < 0.001$ ). Adjusted mean V-MI calculus scores are shown in Table 2 and Figure 4.

Mean experimental sub-group scores (high, medium, and low calculus-forming subjects) at three and six months were 43% lower at both time points for the high calculus forming sub-group, 51% and 62% lower, respectively, for the medium sub-group and 61% and 66% lower, respectively, for the low sub-group. All experimental sub-groups had statistically

significantly lower ( $p < 0.001$ ) scores than the control groups at both months three and six (Table 3, Figure 5).

### Safety

The two products were both generally well tolerated, with only one adverse event reported during the six months: one subject from the

experimental dentifrice group experienced desquamation.

### Discussion

This study showed significant anticalculus benefits for the experimental dual-phase stannous fluoride and sodium hexametaphosphate dentifrice.

These findings are consistent with other reports

**Table 1. Baseline demographic characteristics.**

	Treatment Group		Overall
	SnF <sub>2</sub> + SHMP	Negative control	
<b>Sex<sup>a</sup></b>			
Female	38 (52%)	34 (49%)	72 (51%)
Male	35 (48%)	35 (51%)	70 (49%)
<b>Age</b>			
Mean (SD)	33 (9.72)	35 (9.46)	34 (9.60)
Min-Max	19 - 60	22 - 63	19-63
<b>Race<sup>a</sup></b>			
Asian	32 (44%)	35 (51%)	67 (47%)
African American	2 (3%)	2 (3%)	4 (3%)
White	39 (53%)	32 (46%)	71 (50%)
<b>Baseline Calculus (Volpe-Manhold Index)</b>			
N <sup>b</sup>	73	69	142
Min-Max	11.5-49	11.5-45	11.5-49
Mean	27.28	27.84	27.55
Standard Deviation	8.79	7.81	8.30

a Number (percent) of subjects.

b Number of subjects randomized to treatment.

SnF<sub>2</sub> Stannous fluoride; SHMP Sodium hexametaphosphate

**Table 2. V-MI analysis of covariance.**

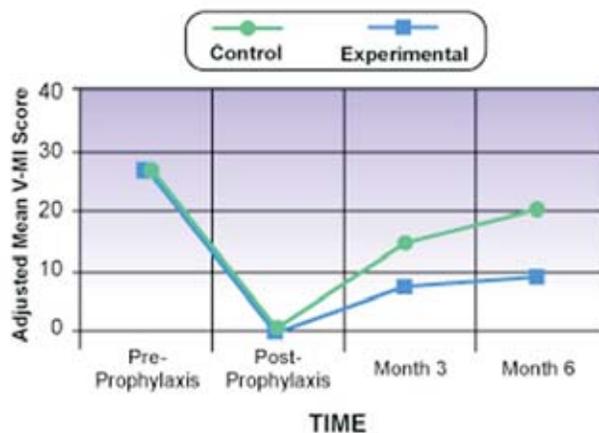
Time / Treatment group	N <sup>a</sup>	Baseline Mean	Adjusted Mean (se) <sup>b</sup>	P-value <sup>c</sup>
<b>Month 3 (Mean SE=31.57)</b>				
Negative control	68	27.79	14.96 (0.68)	<0.001
SnF <sub>2</sub> + SHMP	71	26.96	7.43 (0.67)	
<b>Month 6 (Mean SE=39.44)</b>				
Negative control	69	27.84	20.78 (0.76)	<0.001
SnF <sub>2</sub> + SHMP	69	27.21	9.27 (0.76)	

a N = number of subjects used in analyses.

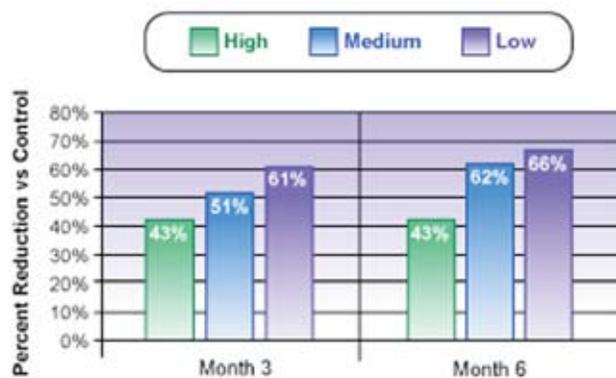
b Means adjusted for Baseline values.

c All comparisons are two-sided at the 0.05 level of significance.

SE standard error; SnF<sub>2</sub> stannous fluoride; SHMP sodium hexametaphosphate



**Figure 4.** Adjusted mean V-MI calculus scores. The experimental (stannous fluoride/sodium hexametaphosphate) dentifrice versus negative control dentifrice.



**Figure 5.** Percent reduction in adjusted mean V-MI scores for high, medium, and low forming calculus sub-groups for stannous fluoride/sodium hexametaphosphate dentifrice versus negative control dentifrice.

**Table 3.** V-MI analysis of covariance by tertiles: high-, medium-, and low- calculus-forming sub-groups.

Time/Sub-Group <sup>a</sup>	Treatment	N <sup>b</sup>	Baseline Mean	Adjusted Mean (se) <sup>c</sup>	P-value <sup>d</sup>
<b>Month 3</b>					
High	Negative control	25	35.88	17.67 (1.39)	<0.001
	SnF <sub>2</sub> + SHMP	25	36.60	10.03 (1.39)	
Medium	Negative control	24	26.58	13.68 (0.92)	<0.001
	SnF <sub>2</sub> + SHMP	19	26.66	6.70 (1.03)	
Low	Negative control	19	18.68	13.39 (1.15)	<0.001
	SnF <sub>2</sub> + SHMP	27	18.26	5.28 (0.97)	
<b>Month 6</b>					
High	Negative control	23	36.43	24.00 (1.33)	<0.001
	SnF <sub>2</sub> + SHMP	24	36.88	13.73 (1.30)	
Medium	Negative control	27	26.96	21.10 (1.20)	<0.001
	SnF <sub>2</sub> + SHMP	19	26.89	8.01 (1.43)	
Low	Negative control	19	18.68	16.96 (1.49)	<0.001
	SnF <sub>2</sub> + SHMP	26	18.52	5.68 (1.27)	

a Sub-groups were defined using the tertiles of the baseline Volpe-Manhold Index distribution for each time point.

Month 3: baseline < 24.5, 24.5 ≤ baseline < 30, baseline ≥ 30.

Month 6: baseline < 24.5, 24.5 ≤ baseline < 31, baseline ≥ 31.

b N = number of subjects used in analyses.

c Means adjusted for baseline values.

d All comparisons are two-sided at the 0.05 level of significance.

SE standard error; SnF<sub>2</sub> stannous fluoride; SHMP sodium hexametaphosphate

in the literature showing positive anticalculus benefits for sodium hexametaphosphate when formulated in a sodium fluoride or stannous fluoride dentifrice compared to a positive control with triclosan/copolymer.<sup>14,21</sup> Schiff et al.<sup>14</sup> compared a single-phase stannous fluoride/sodium hexametaphosphate dentifrice to the triclosan/copolymer dentifrice and showed a significant advantage for the stannous fluoride dentifrice at three and six months.

Results from a study by Liu and colleagues also showed superior calculus inhibition properties for a sodium fluoride/sodium hexametaphosphate dentifrice versus the same triclosan/copolymer positive dentifrice control.<sup>21</sup>

There are two particularly salient aspects to this trial. Treatment was a normal (unsupervised) home-based oral hygiene procedure, and the dentifrice under investigation (an experimental, dual-phase stannous fluoride/sodium hexametaphosphate



dentifrice) was a new anti-calculus formulation. Studies of oral hygiene products, including anticalculus dentifrices, may produce positive results, but the benefits of supervised procedures need to be reproducible at home if they are to provide a meaningful solution to the problems of oral hygiene, in general, and dental calculus formation, in particular. Leveratt et al.<sup>22</sup> and Wolff et al.<sup>23</sup> report studies on plaque and/or gingivitis where subjects' failure to follow normal oral hygiene procedures led to suboptimal results. The fact unsupervised home-based use provided positive, statistically significant results underscores the anticalculus benefits of this stannous fluoride/sodium hexametaphosphate dentifrice innovation.

The challenge of improving cleaning effectiveness and the attendant problems of the association between plaque, gingivitis, and calculus are well known and have led to the inclusion of antimicrobials and anticalculus agents in

dentifrices for some time.<sup>24</sup> Dentifrices typically contain agents that remain on the teeth after brushing and, thus, continue to exert an effect against plaque, calculus, caries, and bacteria. However, the ability to tackle these many therapeutic areas with one dentifrice has been limited in the past by product formulation and stability challenges.<sup>25</sup> Stannous fluoride has long been used in dental products as an agent against gingivitis and caries, but its use has been limited by technical and aesthetic considerations, such as lack of stability in aqueous environments and formulation problems with acceptable flavourings and abrasives.<sup>26</sup> Recent technological advances have allowed it to be formulated now in a dentifrice so its efficacy against microbes, plaque, gingivitis, caries, and hypersensitivity can be fully recognized.<sup>25</sup> Additionally, the use of longer-chain mineralization inhibitors, such as sodium hexametaphosphate, has enhanced the anticalculus and whitening potential of dentifrice. Sodium hexametaphosphate is a polyphosphate and because of its chemical composition has enhanced attraction to tooth enamel and dentin compared to other mineral inhibitors and so remains stable on the tooth surface to provide superior mineral inhibition and stain control.<sup>11</sup> Sodium hexametaphosphate has been proven to have superior efficacy as both an anticalculus and antistaining agent.<sup>14,19</sup>

## Conclusions

- This research shows the experimental dual-phase dentifrice containing 0.454% stabilized stannous fluoride and sodium hexametaphosphate had significantly superior ( $p < 0.001$ ) anti-calculus efficacy compared to a standard fluoride negative control dentifrice.
- Superior efficacy was marked and sustained (50% reduction at three months; 55% reduction at six months) and was expressed regardless of the different levels (high, medium, or low) of baseline calculus formation.
- The experimental 0.454% stabilized stannous fluoride plus sodium hexametaphosphate dentifrice was well-tolerated.
- Results for this prototype dentifrice are consistent with other research that demonstrates the anticalculus benefits of stannous fluoride plus sodium hexametaphosphate dentifrice technology.

- This study of a home care regimen of unsupervised brushing showed the combination of stannous fluoride and sodium hexametaphosphate provides a dentifrice that can be effective at inhibiting calculus formation between dental visits and, therefore, beneficial for improving general oral hygiene.



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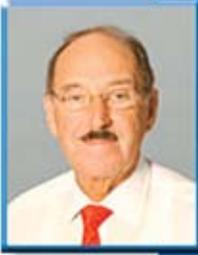
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