The erosion protection efficacy of a stabilized stannous fluoride dentifrice: An *in situ* randomized clinical trial

Nicola X. West, BDS FDS RCS PhD FDS RCS (Rest Dent)[1], Nikki Hellin, RDN[1], Rachelle Eusebio, MAS[2], Tao He, DDS, PhD[2]

[1]Periodontology, Bristol Dental School, University of Bristol, Lower Maudlin Street, Bristol, BS1 2LY, UK
[2]The Procter & Gamble Company, Mason Business Center, 8700 Mason-Montgomery Rd, Mason, OH USA 45040.

Prof. West is Principal Investigator and Professor, Periodontology Clinical Trials Unit; Ms. Hellin is a Dental Nurse; Bristol Dental School, Bristol, UK. Dr. He is Principal Clinical Scientist and Ms. Eusebio is a Biostatistician, The Procter & Gamble Company, Mason, OH, USA.

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Short title: Erosion protection from SnF_2 dentifrice

Corresponding Author:
Professor Nicola West, Periodontology Clinical Trials Unit, Bristol Dental School, Lower Maudlin Street, Bristol, BS1 2LY, UK. Tel.: +44 (0)117 342 9638. Fax: +44 (0)117 342 4000
E-mail: n.x.west@bristol.ac.uk

Abstract

Purpose: To compare the enamel protection efficacy of a stabilized stannous fluoride dentifrice to a triclosan-containing sodium fluoride dentifrice using a 10-day *in situ* erosion model, in accordance with the American Dental Association Seal of Acceptance guidelines for enamel erosion control. ***Methods***: In this single-center, double-blind, randomized, supervised-usage, 2-treatment, 4-period, crossover study, healthy adult subjects were randomized to a treatment sequence involving the following products: a 0.454% stannous fluoride (1100 ppm F) dentifrice (Procter & Gamble) and a control dentifrice containing 0.243% sodium fluoride (1100 ppm F) and 0.3% triclosan (NaF/triclosan, Colgate-Palmolive). Each study period consisted of 10 treatment days. Subjects wore an intra-oral appliance fitted with 2 polished human enamel samples for 6 hours per treatment day. While wearing the appliance, subjects swished with their assigned dentifrice slurry for 60 seconds twice daily and with 250 ml orange juice over a 10-minute period 4 times daily. After 10 days, enamel specimens were removed and measured for surface loss using contact profilometry. ***Results***: Thirty-six subjects were enrolled and 33 completed the study (mean age = 41.8 years). The stannous fluoride dentifrice demonstrated 90.3% less enamel loss than the NaF/triclosan dentifrice ($P < 0.001$) at Day 10, with median enamel loss of 0.279 µm and 2.877 µm, respectively. Both products were well tolerated. ***Clinical Significance:*** The stannous fluoride dentifrice provided significantly greater protection against dental erosion relative to the NaF/triclosan dentifrice.

Introduction

Dental erosion has gained considerable interest as a common clinical problem impacting both children and adults.[1-6] Dental erosion is the loss of dental hard tissues by chemical action not involving bacteria.[7] When observed in children and adolescents, the condition is reported to progress rapidly without intervention and can have long-term adverse effects on dentition and quality of life.[6] The incidence of dental erosion is increasing globally[8] and prevalence figures are high.[6] A study of young European adults found that close to one-third showed signs of erosive tooth wear.[1]

While the etiology of dental erosion is multifactorial, lifestyle influences like nutrition are thought to play a primary role, particularly in children and adolescents.[6] Dietary acids contribute to demineralization and softening of tooth surfaces; once softened, these surfaces are highly susceptible to abrasion and attrition.[3,9] The increase in consumption of acid-containing drinks among young people over the last several decades is well documented.[10.11] Sugary, acidic drinks (soft drinks, energy drinks, sports drinks, and flavored water) were reported as the top calorie source among 14- to -18 year-olds in a study examining diets of children and adolescents.[12] A comprehensive pH assessment found that 93% of nonalcoholic beverages commercially available in the US have erosive potential (pH <4).[13]

A clinical diagnosis of dental erosion can be made based on the pattern of surface loss of enamel and/or dentin. The Basic Erosive Wear Examination (BEWE), introduced by Bartlett and colleagues in 2008, is used to make such an assessment.[14] The BEWE assigns severity scores between 0 (no erosive tooth wear) and 3 (hard tissue loss $\geq$ 50% of surface) that can be transferred into risk levels to guide clinical management. It would be ideal to identify erosion at

a much earlier stage by measuring surface changes, however at present this is difficult to do outside of the laboratory and techniques currently available are not suitable for a busy clinic.[15] Unlike caries, which can be reversed at early stages through remineralization, dental erosion is essentially irreversible and results in permanent damage to the tooth structure.[16] Therefore, prevention is the preferred management approach. Routine daily hygiene including dentifrice is an economical and convenient preventative strategy.[3] Stannous fluoride is a unique fluoride compound that provides a broad range of benefits, including an anti-erosion benefit, when used in dentifrice.[17-24]

The objective of this study was to determine the erosion protection efficacy of a new stabilized stannous fluoride smooth texture dentifrice formulation versus a marketed multi-benefit dentifrice formulated with sodium fluoride and triclosan (NaF/triclosan).

Materials and methods

Study population

Healthy male and female volunteers aged 18 years or older were recruited from a UK dental school <<*name removed for blinding*>> from May to August 2017. A screening visit was conducted up to one month before the study began. Potential subjects received study information and agreed to delay elective dentistry and to refrain from participation in other product studies and from use of any non-study dentifrice or other oral hygiene products. All subjects provided written informed consent to participate. A medical history and oral soft tissue examination was undertaken and subjects with dental erosion, aphthous ulcers, susceptibility to acid regurgitation, excessive gingival inflammation or severe periodontal disease were excluded

from the study. Thirty-six subjects who met all entrance criteria were enrolled in the study and scheduled to return for treatment.

Ethical considerations

Ethical approval was granted by the UK National Research Ethics Service (REC Ref:17/SW/007). The study was conducted in accordance with Good Clinical Practice guidelines at a UK Dental School.

Randomization

Subjects were randomly assigned to one of four computer-generated treatment sequences (AABB, BBAA, ABBA or BAAB; letters indicate the two study treatments) that determined use of one of the two test dentifrices during each of the four study periods: A) a 0.454% stabilized stannous fluoride dentifrice (Crest® Pro-Health™ smooth texture formulation, Procter & Gamble, Cincinnati, OH, USA; 1100ppm fluoride); or B) a marketed dentifrice control containing 0.243% sodium fluoride and 0.3% triclosan/copolymer (Colgate® Total®, Colgate-Palmolive, New York, NY, USA; 1100ppm fluoride).

In situ study design

This single-center, double-blind, randomized, 2-treatment, 4-period crossover study used a modified version of a protocol previously published by Hooper *et al*.[20] and was conducted in compliance with the American Dental Association Seal of Acceptance Guidelines for enamel erosion control.[25] At the screening visit, subjects were given a non-treatment 0.32% sodium fluoride (1450 ppm fluoride) marketed dentifrice (Crest® Decay Protection dentifrice, Procter &

Gamble) and manual toothbrush (Oral-B® 35 manual toothbrush, Procter & Gamble). Subjects were instructed to use both products at home instead of their normal oral care products twice daily (morning and evening) prior to and throughout the duration of the study, including treatment days and weekends.

An alginate impression was taken and each subject was fitted with an upper palatal intra-oral appliance (Fig. 1) that retained two enamel samples derived from unerupted third molars from a Tooth Tissue Bank in the UK (NRES REC Ref, 16/NI/0192, HTA license 12200). Subjects collected their appliances upon arrival at the clinical trials unit on treatment days and wore the appliance for approximately 6 hours on each of the 10 treatment days per study period. Test dentifrice treatment and erosive challenge occurred while subjects were wearing the appliance at the clinical site.

The treatment and acid challenge schedule is shown in Figure 2. For test dentifrice treatment, clinical site personnel made dentifrice slurries by mixing three (3.0) grams of dentifrice with 10 mL of water. Subjects rinsed with the dentifrice slurry twice for 60 seconds and were blinded to the product identity of their assigned treatment. The investigator and personnel performing and documenting surface profilometry assessments were also blinded to product identities and did not have access to the product dispensing room during treatments. For the erosive challenge, subjects sipped 25 mL of orange juice (Sainsbury's Supermarkets Ltd, London, UK) for one minute, swished, and expectorated. This was repeated until the subject had swished 10 consecutive times, for a total of 10 minutes, to expose the enamel samples to 250 mL of orange

juice. Each study period consisted of 10 treatment days, with treatments being done only on weekdays (Monday – Friday) over a span of approximately 2 weeks.

Preparation and analysis of enamel samples

Before the study began, two baseline readings were obtained for each enamel specimen using a calibrated contact surface profilometer (Mitutoyo (UK) Ltd, Andover, Hampshire UK). Readings were taken across a demarcated 2- to 3-mm area which was exposed to test treatments, either side of this area the enamel was protected by PVC tape. To determine surface loss, enamel samples were remeasured (2 readings) at the end of the treatment phase of each study period using the same profilometry method in the same demarcated area. Prior to the study, enamel specimens were soaked in sodium dichloroisocyanurate (20,000 ppm available chlorine) for a minimum of 24 hours before rinsing in copious amounts of deionized water. Samples in each appliance were replaced with fresh human enamel samples at the beginning of each study period. The procedures related to the acquisition, sterilization, preparation and analysis of human enamel test specimens have been described previously.[22]

Determination of sample size

A sample size of 36 subjects provided a power of at least 80% to detect a 2-sided 5% significant difference between the two treatments, assuming the natural log scale effect size was at least 0.70 for this crossover design.

Statistical methods

The primary efficacy measure was the amount of dental erosion that occurred after 10 days of treatment as assessed by profilometry. For each subject, the average of four erosion measurements was recorded from each of the two enamel specimens at every visit. Since the enamel loss distribution at Day 10 is right-skewed, the data were transformed using the natural log function before performing statistical analysis. A general linear mixed model was used to compare treatments with a statistical model that included period and treatment as fixed effects, baseline as covariate, and subject as a random effect. The carry-over effect was not statistically significant ($P = 0.31$) and was not included in the final analysis model. Estimated means on the natural log scale from the statistical model were back-transformed using the exponential function (e^{mean}) to obtain the estimated medians or 50^{th} percentiles on the original scale (µm), as well as the associated standard errors and/or 95% confidence intervals (CI). Statistical comparisons were two-sided at a 5% significance level.

The null hypothesis tested at Day 10 in this human *in situ* clinical study was that the mean dental erosion was equal between the two treatment dentifrices. The alternative hypothesis was that the mean dental erosion was not equal between the two treatment dentifrices.

Results

Thirty-six subjects were enrolled and 34 were randomized to treatment. Subjects ranged in age from 21 – 60 years (mean age 41.8 years). Twenty-four subjects (71%) were female. The population was 76% Caucasian, 12% multi-racial, 9% Asian Indian, and 3% Asian Oriental (Table 1). One subject voluntarily withdrew from the study after randomization. Thirty-three subjects completed the study, and all study data were deemed evaluable.

The stabilized stannous fluoride dentifrice provided a statistically significant ($P < 0.001$) 90.3% better protection against erosion versus the NaF/triclosan, multi-benefit dentifrice at Day 10. The estimated enamel loss median (95% CI) was 0.279 µm (0.22, 0.35) for the stabilized stannous fluoride dentifrice and 2.877 µm (2.29, 3.61) for the NaF/triclosan dentifrice (Table 2, Fig. 3). Figure 4 shows a Distribution Box Plot of enamel loss by treatment, demonstrating marked differences in performance between the two test dentifrices at Day 10.

Both dentifrices were well tolerated. There were no adverse events reported.

Discussion

In this clinical trial, the stabilized stannous fluoride dentifrice resulted in significantly less enamel loss due to acid erosion relative to the dentifrice formulated with NaF/triclosan. These findings corroborate previously published *in vitro* and *in situ* studies showing greater protection from erosion with use of stabilized stannous fluoride dentifrices versus dentifrices containing different fluoride compounds, including those formulated with sodium fluoride,[18-20, 26] sodium monoflurophosphate,[22,26] and amine fluoride.[26] Professional organizations have also recognized stabilized stannous fluoride dentifrices for this benefit.[27,28] The original Crest Pro-Health formulation was the first dentifrice to obtain the American Dental Association Seal of Acceptance in the enamel erosion category,[27] while an independent consensus statement issued by the European Federation of Conservative Dentistry acknowledged stannous fluoride dentifrices for their ability to reduce erosive tooth wear.[28]

Mechanistic studies demonstrate that stannous fluoride is unique among fluoride compounds in that it deposits a barrier layer onto enamel surfaces that is highly resistant to acids.[26,29,30] The deposition starts with the first use. This barrier increases with continued dentifrice use and is retained on the tooth surface for hours, providing extended protection against erosive acids.

Stannous fluoride has inherent formulation challenges that must be overcome to provide its full range of therapeutic benefits in a dentifrice. Namely, stannous fluoride must be delivered in a stable and bioavailable way. Because of the distinct properties of stannous fluoride, not all dentifrices containing this ingredient can be presumed to be equal, and clinical evidence of benefit is essential. The stannous fluoride dentifrice evaluated in the current study has been formulated to circumvent these instability and bioavailability challenges.[31]

Stabilized stannous fluoride dentifrice should be considered as part of overall prevention and management plan for patients at risk for dental erosion.[28,31,32] In addition to providing benefits against dental erosion, stannous fluoride offers protection against a broad range of other therapeutic and cosmetic conditions, including dentinal hypersensitivity.[31] Patients with dental erosion often experience pain and hypersensitivity[33] and it is thought that dental erosion can both initiate and localize the lesion through loss of the tooth minerals that cover dentin tubules and the tubule opening.[34] The protective surface layer formed by stabilized stannous fluoride that acts against erosion also inhibits sensitivity through sealing exposed dentin tubules.[35] The ability of stannous fluoride dentifrice to provide anti-hypersensitivity benefits has been demonstrated in numerous clinical trials.[36-37]

The stannous fluoride dentifrice evaluated in the current study is the latest generation of Crest Pro-Health formulation advancements. This new high-water formulation has improved esthetics and is a "smooth texture" variant that uses zinc citrate as the anti-calculus agent instead of sodium hexametaphosphate. The new formulation shows anti-erosion benefit consistent with the earlier formulation, offering patients at risk for dental erosion, particularly those concerned about dentinal hypersensitivity, the broadest range of protection available in a dentifrice. In addition, the novel formulation studied here has the potential to improve compliance among patients who prefer a smooth texture dentifrice, allowing them to achieve the full range of possible benefits.

Conclusion

The stannous fluoride dentifrice evaluated in this randomized clinical trial demonstrated significantly greater erosion protection efficacy relative to the NaF/triclosan dentifrice. While lifestyle modifications are needed to curb the global increase in dental erosion, healthy dietary habits can be difficult for some patients to establish and maintain. A clinically proven stannous fluoride dentifrice is a convenient and economical way to incorporate a preventative strategy for dental erosion into patients' daily oral hygiene regimen.

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Figure 1. Intraoral appliance.

Figure 2. Treatment and acid challenge schedule.

Figure 3. Median change in enamel surface loss, showing 90.3% better protection for the stabilized stannous fluoride (SnF_2) dentifrice compared to the NaF/triclosan dentifrice.

Figure 4. Box plot of data showing individual and averaged enamel loss data points for each of the two test dentifrices.

Figure 1. Intraoral appliance.

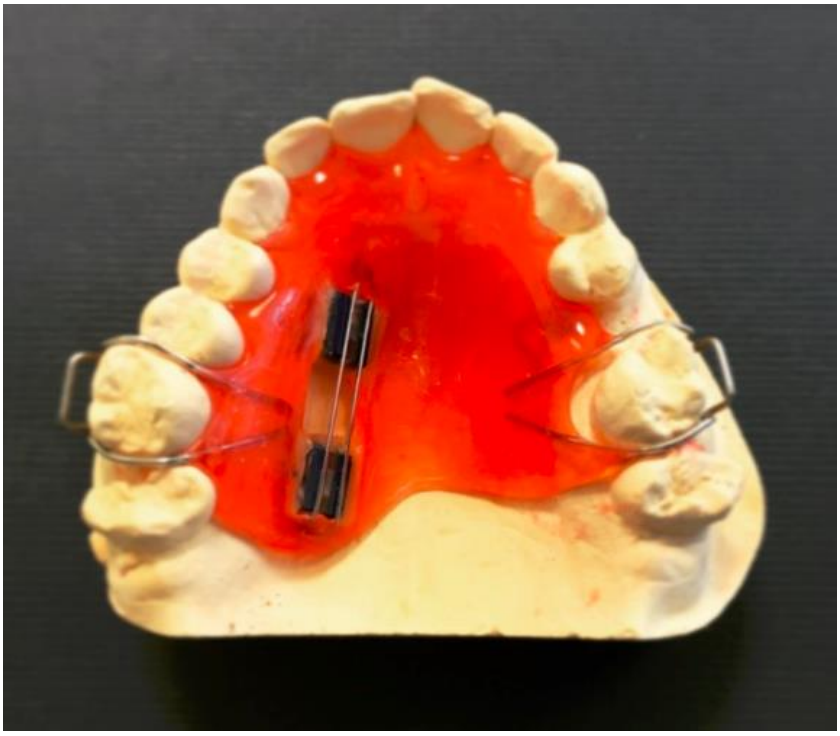
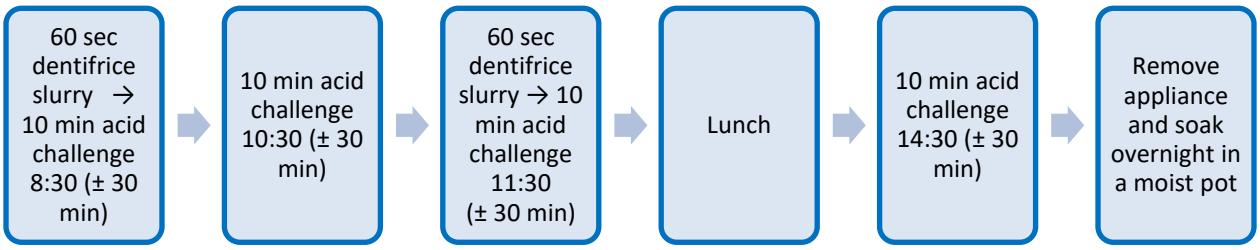


Figure 2. Treatment and acid challenge schedule.



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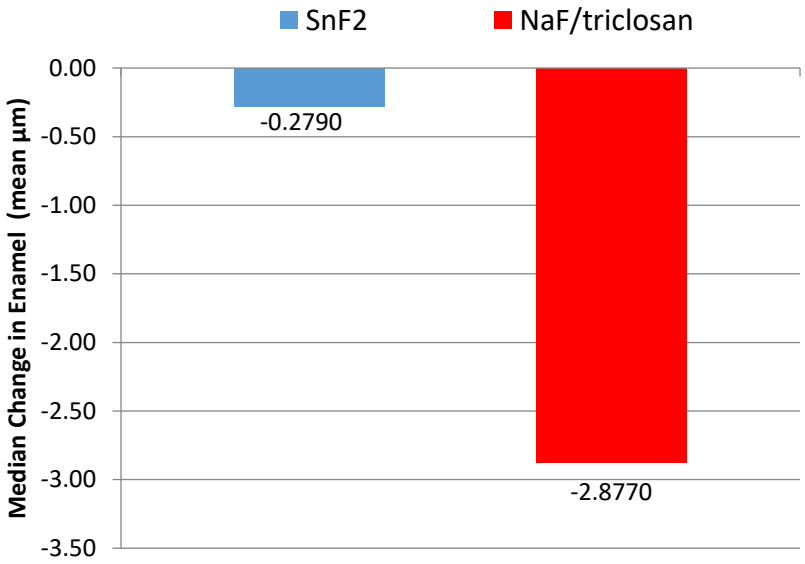

Figure 4. Box plot of data showing individual and averaged enamel loss data points (μm) for each of the two test dentifrices.

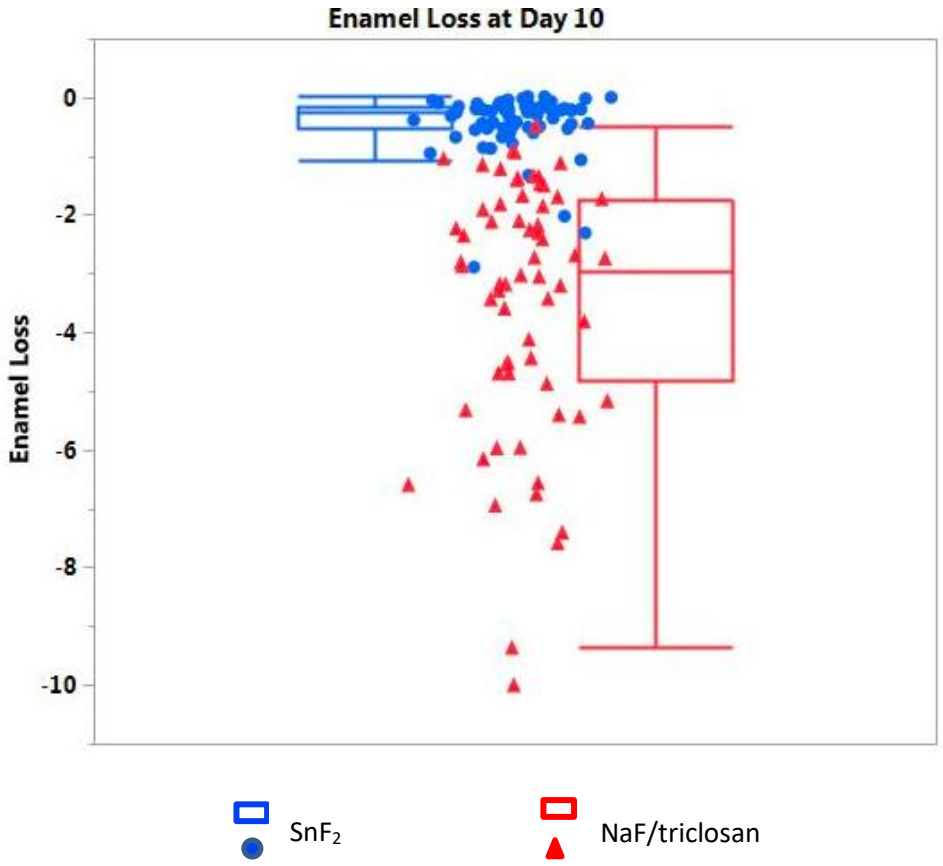

Table 1. Study demographics.

Table 2. Enamel loss (µm) treatment comparison at Day 10.

Table 1. Study demographics.

Demographic	Statistic or Category	Value
Age (Years)	Mean (SD)	41.8 (12.35)
	Min. – Max.	21 - 60
Ethnicity[a]	Asian Indian	3 (9%)
	Asian Oriental	1 (3%)
	Caucasian	26 (76%)
	Multi-Racial	4 (12%)
Gender[a]	Female	24 (71%)
	Male	10 (29%)
[a]The number and percent of subjects in each category		

Table 2. Enamel loss (µm) treatment comparison at Day 10.

Treatment	Original scale in µm estimated median[a] (95% CI)	Natural Log Scale Mean (SE)	% less erosion vs. NaF/triclosan (*P*-value)[b]
Stannous fluoride	0.279 (0.22, 0.35)	-1.276 (0.114)	90.3% ($P < 0.001$)
NaF/triclosan	2.877 (2.29, 3.61)	1.057 (0.114)	

[a]Estimated medians in µm were obtained by using the exponential function on the means from the natural logarithm scale (e^{mean}) and 95% CI were calculated; [b]Calculated from estimated medians in µm as 100% (NaF/triclosan – Stannous fluoride divided by NaF/triclosan).