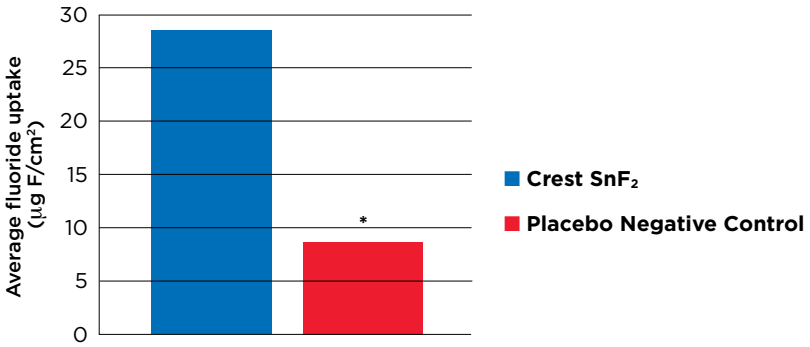
Crest Gum and Sensitivity Stannous Fluoride Dentifrice Strengthens Exposed Dentin: Results from Two *In Vitro* Studies

KEY FINDINGS

- In Fluoride Uptake testing, Crest Gum and Sensitivity dentifrice with bioavailable stannous fluoride (SnF_2) fluoridated demineralized dentin lesions as well as the positive control and significantly better than the negative control. See Figure 1 and Table 1.
- Under pH Cycling conditions, Crest Gum and Sensitivity dentifrice protected exposed dentin against the loss of calcium better than the negative control. In addition, the Crest SnF_2 dentifrice passed the half-rule non-inferiority test, confirming its effectiveness relative to a clinical reference standard.[1] See Table 2.

Figure 1. Crest SnF_2 dentifrice is effective at fluoridating demineralized dentin. See full data set in Table 1.



* Groups statistically significantly different, see Table 1.

Table 1. Results and statistical grouping for fluoride uptake.

Treatment	F Level (ppm)	Average Fluoride Uptake (µg F/cm²)	Statistical Group*
Crest SnF_2 dentifrice	1100	28.38	A
Clinically effective Positive Control	1100	31.65	A
Placebo Negative Control	0	8.45	B

* Student's T test, α=0.05.

Table 2: Crest SnF_2 dentifrice protects against Total Calcium Loss. Results and statistical grouping.

Treatment	F Level (ppm)	Total Ca Loss ± SD (ppm)	Statistical Group*
Crest SnF_2 dentifrice	1100	66.8 ± 9.7	A
Clinically effective Positive Control	1100	77.1 ± 14.2	A
Placebo Negative Control	100	90.1 ± 10.0	B

* Student's T test, α=0.05.

OBJECTIVE

To evaluate the effectiveness of Crest Gum and Sensitivity dentifrice with bioavailable SnF_2 to strengthen exposed dentin by measuring its ability to: 1) fluoridate dentin; and 2) enable treated dentin to resist demineralization.

METHODS

- This overall assessment made use of modified versions of two well-credentialed *in vitro* performance models: 1) the US FDA's Method 40,[2] an accepted model for demonstrating the fluoridating efficiency of dentifrices; and 2) the Featherstone pH cycling model,[3] a validated method for demonstrating anticaries effectiveness. In each study, human dentin specimens were used in place of the standard human enamel specimens.
- Dentifrices tested in each study were as follows:

Fluoride (ppm F) in Test Product	Study	Dentifrice	Fluoride Type
1100	Fluoride Uptake pH Cycling	Crest Gum and Sensitivity with Bioavailable SnF_2 (Procter & Gamble)	Stannous Fluoride
1100	Fluoride Uptake pH Cycling	Positive Control, USP SnF_2 Reference Standard with clinically demonstrated anti-caries efficacy	Stannous Fluoride
100	pH Cycling	Negative Control USP SnF_2 Reference Standard (diluted)	Stannous Fluoride
0	Fluoride Uptake	Negative Control, Placebo	—

- For F uptake testing, dentin specimens were demineralized for 48 hours (23 °C), rinsed in deionized water and then treated for 30 minutes with the supernatant of a centrifuged slurry (prepared with 1-part dentifrice and 3 parts deionized water, w:v). Following treatment, specimens were again rinsed with deionized water and then analyzed for fluoride content using the microdrill biopsy technique.[4] This technique removes a small sample of the dentin, which is then dissolved, buffered and analyzed for F content using a calibrated F^- ion-selective electrode.
- In the pH cycling study, an assessment of calcium loss as an indication of mineral strength replaced cross-sectional microhardness analyses. Human dentin specimens were subjected to an accelerated, 5 day version of the original pH cycling protocol.[1] On day 1, specimens were suspended in a demineralizing solution at 37°C for 6 hours, rinsed, treated for 1 minute in a 1:3 (w:v) dilution of toothpaste:water and then suspended in a remineralizing solution for 18 hours at 37°C. On days 2–5, the dentifrice slurry treatment was done both before and after the specimens were placed in the demineralizing solution. The demineralizing solution (pH 4.3) contained 0.2% Carbopol 907 (Noveon, Inc.), approximately 80ppm Ca and 62ppm P. The remineralizing solution (pH 7.0), contained approximately 32ppm Ca and 74ppm P. The demineralizing solution from treatment days 2–5 was analyzed by ICP for calcium content, with the cumulative amount of Ca lost from each specimen used to determine the demineralization protection potential of each treatment.

CLINICAL COMMENT

In modified versions of two well-credentialed *in vitro* performance models, Crest Gum and Sensitivity dentifrice with bioavailable SnF_2 was shown to strengthen exposed dentin by fluoridating dentin and enabling treated dentin to resist demineralization. It was shown to be as effective as a positive control with clinically demonstrated anti-caries efficacy and significantly better than a negative control. By strengthening exposed dentin, Crest Gum and Sensitivity dentifrice helps prevent root caries and dentinal hypersensitivity, two common oral conditions.

References

1. Stookey GK, Featherstone JDB, Rapozo-Hilo M, Schemehorn BR, et al. The Featherstone laboratory pH cycling model — a prospective multi-site validation exercise. *Am J Dent*. 2011; 24:322–328.
2. Food and Drug Administration. Biological testing procedures for fluoride dentifrices. Food and Drug Administration Docket No. 80N-0042: Test Methods 40–44.
3. Featherstone JDB, Stookey GK, Kaminski MA, Faller RV. Recommendation for a non-animal alternative to rat-caries testing. *Am J Dent*. 2011; 24:289–294.
4. Sakkab NY, Cilley WA, Haberman JP. Fluoride in deciduous teeth from an anti-caries clinical study. *J Dent Res*. 1984; 63: 1201–1205.

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