# Evaluation of a novel stannous fluoride dentifrice stabilized with amino acid glycine: Effects on plaque regrowth and tin retention in gingival crevicular fluid

Klukowska M, Anastasia MK, Conde E, Gabbard M, Ramsey D, Combs C, Rattanaudompol U, McClenathan D, Ramji N. Data on file, 2020.

KEY RESULTS

- The novel stannous fluoride (SnF_2) dentifrice stabilized with the amino acid glycine was significantly better at preventing plaque regrowth versus the negative control ($P \leq 0.005$). The benefit for the novel SnF_2 dentifrice relative to the negative control was:
  - 13% lower for whole mouth plaque (see Fig. 1)
  - 12% lower for buccal plaque (unbrushed) and
  - 16% lower for lingual plaque (brushed)

- The novel SnF_2 dentifrice also delivered statistically significantly more tin, a marker for SnF_2, subgingivally than the negative control ($P < 0.0001$) and a positive control SnF_2 dentifrice ($P = 0.04$). See Figure 2. Specifically, the novel SnF_2 dentifrice delivered 180% more tin into the biofilm compared to the positive control.

Figure 1. Whole Mouth Plaque Scores
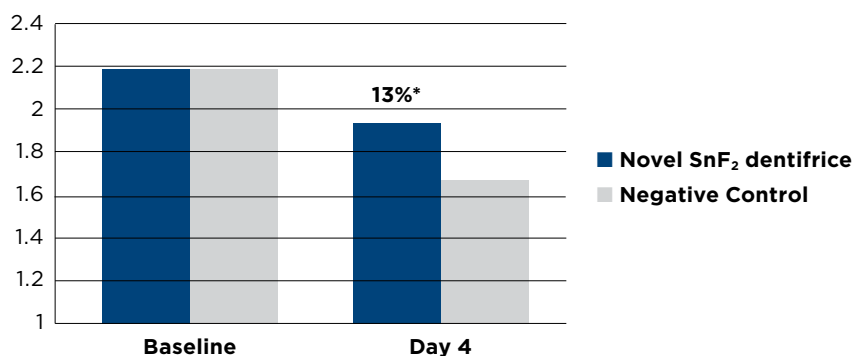
N=26; P<0.001 between treatment groups.

Figure 2. Box Plot of Natural Log Sn Level in GCF Results by Treatment
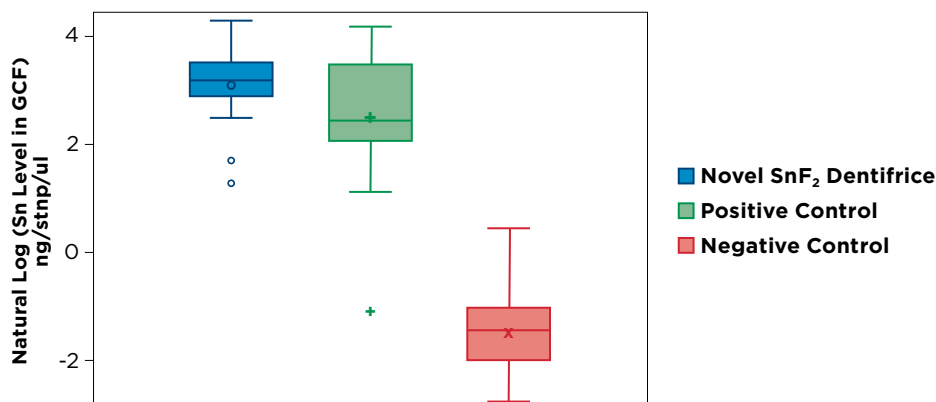
OBJECTIVE

To determine the efficacy of a novel SnF_2 dentifrice stabilized with amino acid glycine as a stabilizer for plaque regrowth inhibition and subgingival tin penetration compared to negative and positive control dentifrices.

METHODS

This was a controlled, double-blind, randomized, 3-treatment, 3-period cross-over design, 4-day partial brushing model plaque study evaluating 3 dentifrices:

- Novel 0.454% SnF_2 dentifrice with amino acid as a stabilizer (Crest® Gum Restore™, Procter & Gamble)
- Positive control 0.454% SnF_2 dentifrice (Crest® PRO-HEALTH™, Procter & Gamble)
- Negative control 0.76% sodium monofluorophosphate dentifrice (Colgate Cavity Protection, Colgate-Palmolive)

Adult subjects received a dental prophylaxis prior to study initiation. Each study period took place over a span of 4 days. Treatment periods were separated by a washout period of approximately 7 days. In each treatment period, baseline visit involved an Oral Soft Tissue (OST) examination and a plaque examination using the Turesky modification of Quigley Hein Plaque Index (TMQHPI) followed by a dental polishing and repeated lingual brushing and swishing with the assigned paste.

Subjects used the product assigned in their sequences twice daily for 4 days. Subjects brushed their lingual surfaces for 30 seconds with their assigned dentifrice and an ADA manual toothbrush. After expectoration, each brushing was immediately followed by swishing with the dentifrice slurry for 60 seconds.

Clinical examinations were conducted after 4 days of treatment. Subjects received an OST exam, then supragingival plaque was removed and Gingival Crevicular Fluid (GCF) was collected from the mesiobuccal sulcus of first and second molars of the maxillary right and maxillary left site of the first twenty subjects. Sites used for GCF collection were excluded from the plaque analyses. A plaque examination using the TMQHPI was then conducted. Plaque scores were analyzed using a general linear model.

CLINICAL COMMENT

SnF_2 dentifrice has been recognized to provide gingival health benefits.[1] However, efficacy has been shown to be dependent upon formulation as it impacts SnF_2 stability and bioaviailability.[2] In this randomized clinical trial, the novel SnF_2 dentifrice stabilized with the amino acid glycine demonstrated significantly greater plaque reduction than a negative control and significantly greater tin retention subgingivally than a positive control SnF_2 dentifrice. The amino acid glycine is used as a stabilizer for SnF_2, promoting deeper penetration and improved retention of SnF_2 within the plaque biofilm relative to SnF_2 formulations without the glycine chelant.[3] Results from this trial indicate that the novel SnF_2 dentifrice is a significant advancement in dentifrice technology to improve gingival health.

1. Biesbrock AR et al. *J Clin Periodontol* 2019 Dec; 46(12): 1205–1216.
2. He T et al. *Am J Dent* 2020; 33: 218-224.
3. R Strand, Y Shi. Oral care compositions for promoting oral health. US Patent 10,596,089. March 24, 2020.