

# A Randomized Clinical Trial to Assess the Desensitizing Benefit of a Stabilized Stannous Fluoride Dentifrice

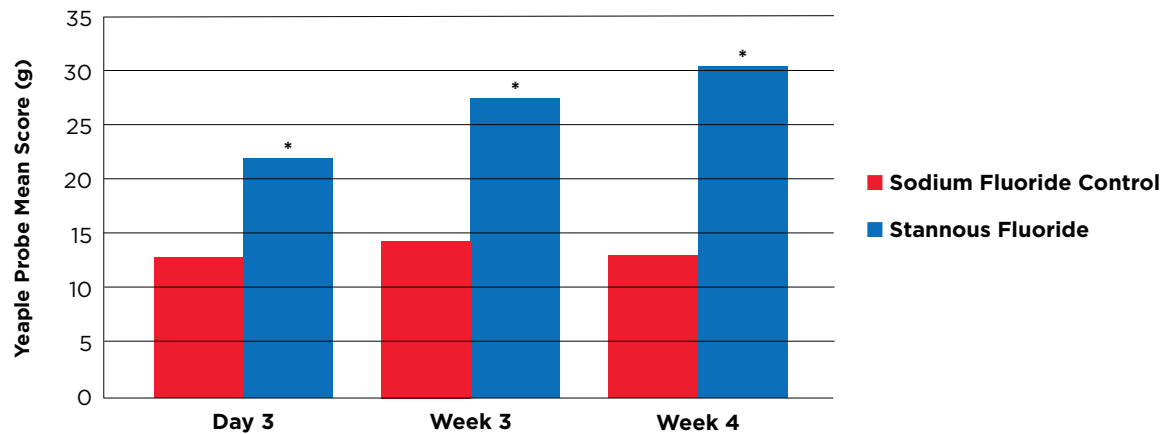
Data on file, 2018.

## KEY CLINICAL FINDINGS

- Crest Gum & Sensitivity dentifrice with stabilized stannous fluoride showed significantly greater tactile sensitivity relief — demonstrated by greater tolerance to a tactile stimulus — compared to a sodium fluoride negative control dentifrice at Day 3, Week 3 and Week 4. See Figure 1. The percent improvement for the stannous fluoride dentifrice versus the sodium fluoride control ranged from 75% to 135% across all 3 timepoints.
- 97% of subjects using the stannous fluoride dentifrice had relief from tactile sensitivity at Week 4 compared to only 28% in the control group ( $P < 0.0001$ ). The number of subjects showing improvement was significantly greater for the stannous fluoride dentifrice group versus the control group at all 3 timepoints. See Figure 2.

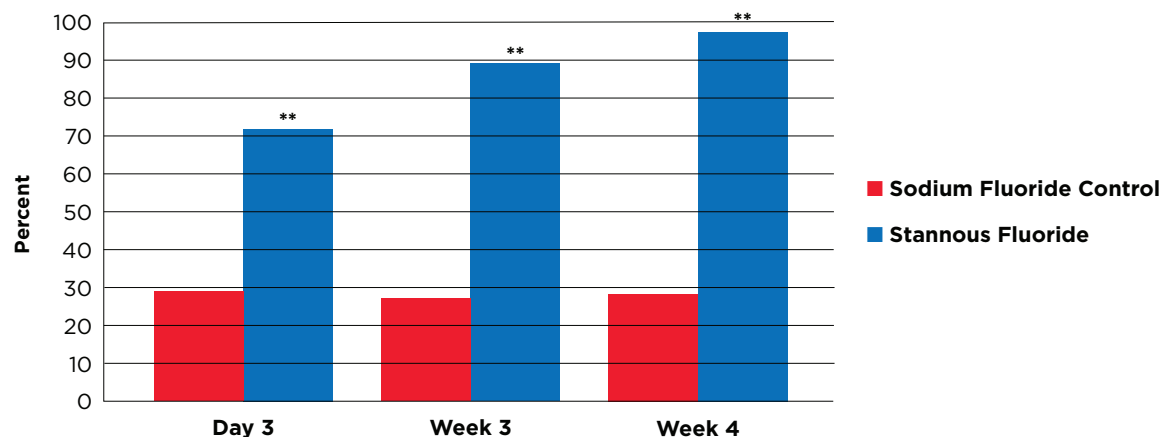
**Figure 1. Yeaple Probe Mean Scores by Visit and Treatment**

(higher number indicates greater tolerance to tactile stimulus)



\* $P < 0.0001$  between groups

**Figure 2. Percent of Subjects with Improvement in Tactile Sensitivity**



\*\* $P \leq 0.0002$  between groups

## OBJECTIVE

To assess the desensitizing efficacy of a stabilized stannous fluoride dentifrice versus a sodium fluoride negative control.

## METHODS

This was a randomized, parallel-group, double-blind, controlled clinical trial involving 80 generally healthy adults with dental hypersensitivity in at least 2 teeth.

Qualifying subjects were randomly assigned to one of the following treatment groups (40 per group):

- 0.454% stabilized stannous fluoride dentifrice (Crest Gum & Sensitivity, Procter & Gamble). Subjects brushed twice daily, brushing the 2 sensitive teeth for 30 seconds each and then finishing with brushing the remaining teeth thoroughly.
- 0.32% sodium fluoride negative control dentifrice (Crest Cavity Protection, Procter & Gamble). Subjects brushed as they normally do.

Both groups brushed with an Oral-B Indicator P35 soft manual toothbrush (Procter & Gamble).

The Yeaple probe was used to assess tactile sensitivity at Baseline, Day 3, Week 3 and Week 4. The labial surfaces of the teeth were tested with the Yeaple probe at a force setting of 10 g. Tactile testing began at 10 g and increased in 10-g increments. Each successive challenge increased until a force was found that elicited 2 consecutive positive responses or until a maximum force of 50 g was applied.

## CLINICAL COMMENT

Dentinal hypersensitivity is a common condition that can negatively impact patients' quality of life as well as their oral hygiene, as they may avoid cleaning sensitive areas for fear of pain. Patients typically manage dentinal hypersensitivity by using a dentifrice containing a desensitizing agent, such as stannous fluoride. Stannous fluoride has been shown to occlude open dentin tubules immediately after the first use, reducing fluid flow in response to stimuli and thereby reducing pain.

Stabilized stannous fluoride dentifrice has demonstrated superior relief from dentinal hypersensitivity versus negative and positive controls.<sup>1</sup> Consistent with published literature, the Crest Gum & Sensitivity stannous fluoride dentifrice tested in this trial showed significant relief in tactile sensitivity that was sustained to 4 weeks. In addition to its desensitizing benefit, with twice daily use stabilized stannous fluoride dentifrice also protects against caries, kills plaque bacteria to reduce inflammation that can contribute to recession, reduces gingival bleeding, protects against erosion, inhibits calculus, reduces breath odor and provides a whitening benefit. Crest Gum & Sensitivity dentifrice has been specially formulated with betaine for a gentle brushing experience that is important to patients with sensitive teeth. Dental professionals can recommend this dentifrice with confidence that it will provide relief from sensitivity and a brushing experience designed to promote compliance.

1. Walters P. Dentinal Hypersensitivity: A Review. Updated June 2018; dentalcare.com CE Course #200.