

# A Clinical Study Investigating the Efficacy of a Dentifrice in Providing Long-Term Relief from Dentinal Hypersensitivity

Parkinson CR et al. *Am J Dent.* 2015 Aug; 28(4):190–196.

## Aim

To compare the clinical efficacy of an anhydrous test dentifrice containing 0.454% w/w stannous fluoride, for the relief of dentinal hypersensitivity (DH), against a standard fluoride dentifrice (negative control) after 8 weeks of twice-daily use.

## Study products and usage

- Anhydrous test dentifrice containing 0.454% stannous fluoride and 5% sodium tripolyphosphate (STP).
- Standard fluoride dentifrice (containing 1000ppm fluoride as sodium monofluorophosphate (SMFP), Colgate Cavity Protection®).
- Subjects brushed twice daily with a full brush head of their allocated study product.

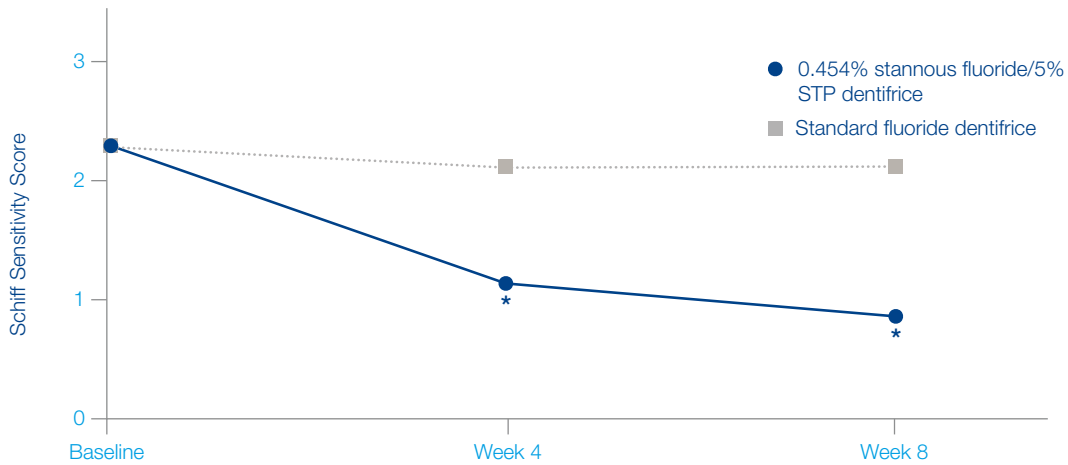
## Methods

- Examiner-blind, two arm, randomised and stratified (by maximum baseline Schiff Sensitivity Score) clinical study in healthy adult subjects with  $\geq 2$  sensitive teeth but otherwise good oral health.
- 119 subjects were randomly assigned to one of two treatment groups: 59 subjects to the anhydrous test dentifrice containing 0.454% stannous fluoride group, 60 subjects to the standard fluoride dentifrice group.
- Tooth sensitivity was measured in three ways; evaporative air blast (Schiff score; Visual Analogue Scale (VAS)) and tactile stimulus (Yeaple probe), prior to subjects starting use of either treatment (baseline), and then after 4 and 8 weeks' treatment.

# Results

Subjects using the anhydrous test dentifrice demonstrated statistically significant ( $p < 0.0001$ ) better relief from dentin hypersensitivity compared to the standard fluoride dentifrice, for all efficacy parameters (Schiff Sensitivity Score, tactile threshold, and VAS score) after both 4 and 8 weeks of twice daily treatment, Figures 1-3.

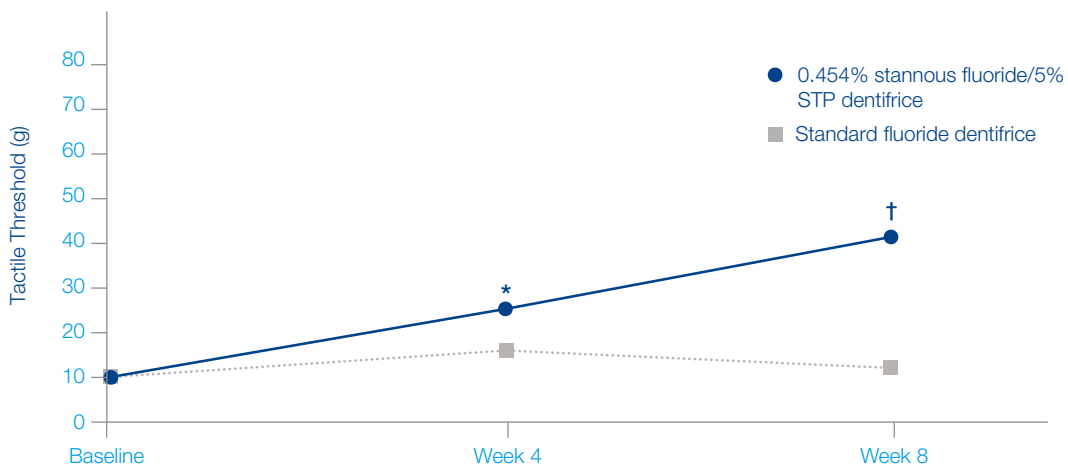
**Figure 1. Schiff Sensitivity Score by Time and Treatment Group**



\* $p < 0.0001$

(Unadjusted Means  $\pm$  SE). For the Schiff Sensitivity Score, a reduction indicates improved sensitivity.

**Figure 2. Tactile Threshold by Time and Treatment Group**

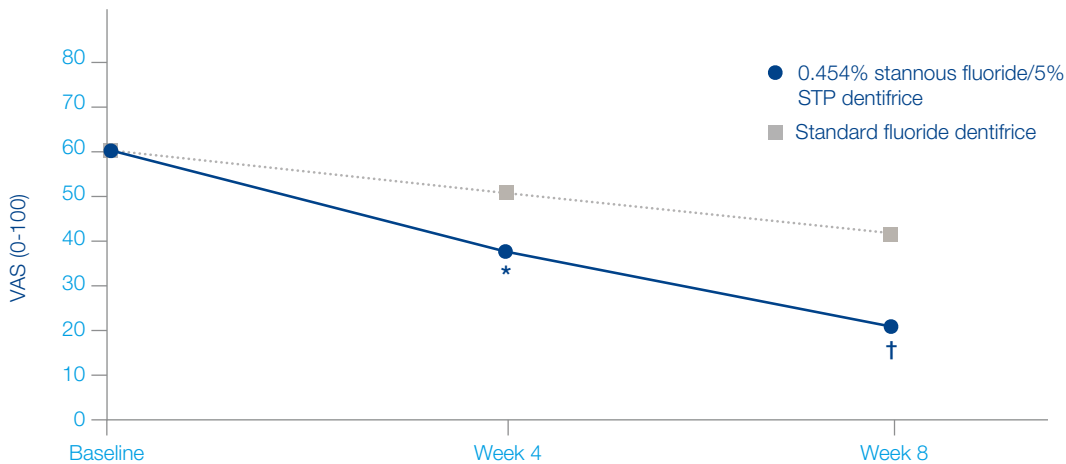


\* $p = 0.01$

† $p < 0.0001$

(Unadjusted Means  $\pm$  SE). For the Tactile Threshold, an increase indicates improved sensitivity.

**Figure 3. VAS Score by Time and Treatment Group**



\*p=0.0003

†p<0.0001

(Unadjusted Means ± SE). For the VAS, a decrease indicates improved sensitivity.

## Safety

Three treatment emergent adverse events (TEAEs) were reported by 3 subjects. An oral TEAE of dysgeusia (distortion of the sense of taste) was reported by a subject in the anhydrous test dentifrice group and was considered to be treatment-related. An oral TEAE of mouth injury and a non-oral TEAE of influenza were reported by two subjects in the standard fluoride dentifrice group; neither was considered to be treatment-related. All AEs were of mild intensity and resolved by the end of the study. There were no serious AEs.

## Conclusion

Statistically significant differences between treatment were observed for all efficacy measures at all time points in favour of the anhydrous test dentifrice containing 0.454% stannous fluoride, compared to the standard dentifrice. The reductions in dentine hypersensitivity (compared to baseline) observed at 4 and 8 weeks for the test dentifrice and the magnitude of the between-treatment differences, are considered clinically relevant.

Study treatments were considered to be well tolerated.