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.

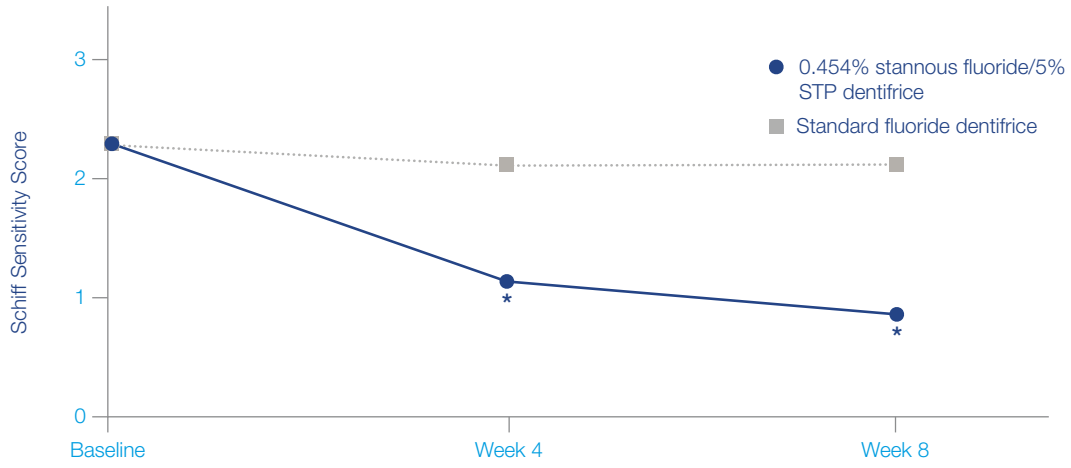
Methods

- Examiner-blind, two arm, randomised and stratified (by maximum baseline Schiff Sensitivity Score) clinical study in healthy adult subjects with ≥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 dentine 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.

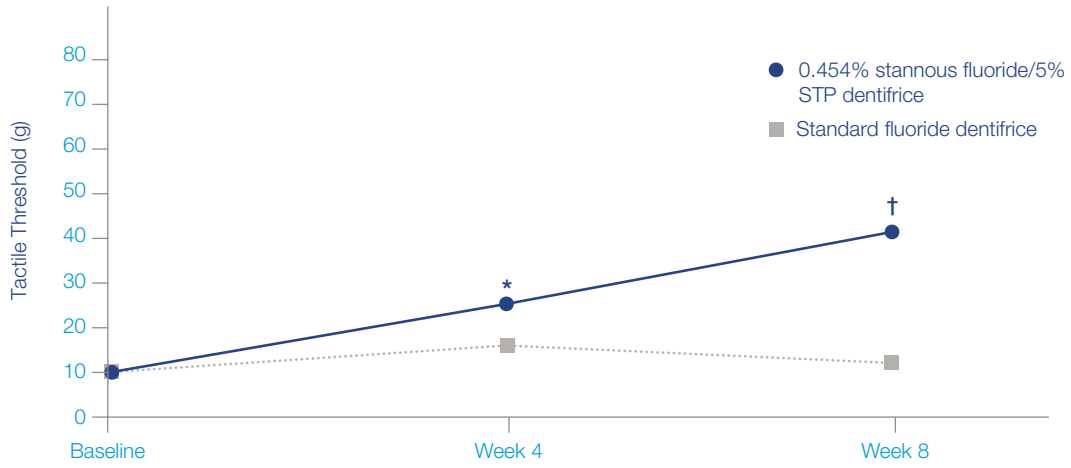
Figure 1. Schiff Sensitivity Score by Time and Treatment Group



*p<0.0001

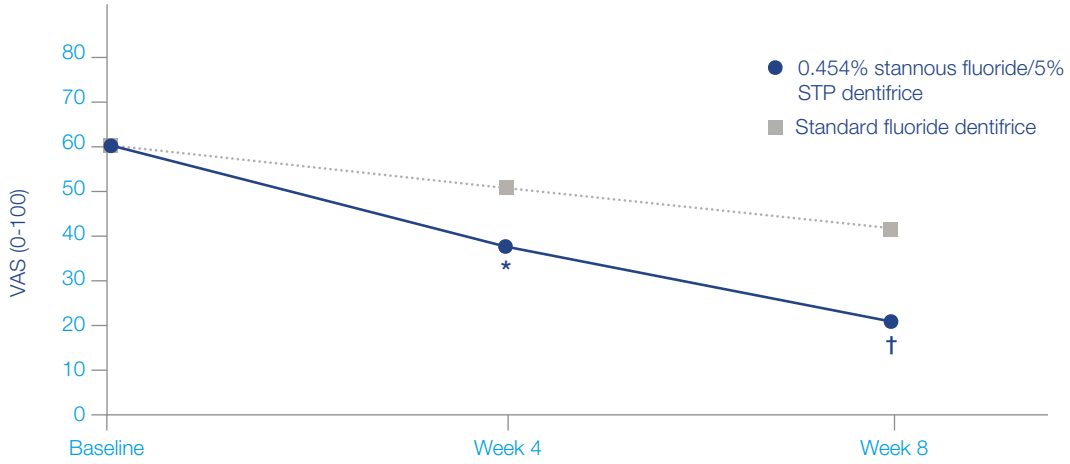
(Unadjusted Means ± SE). For the Schiff Sensitivity Score, a reduction indicates reduced sensitivity.

Figure 2. Tactile Threshold by Time and Treatment Group



*p=0.01
†p<0.0001
(Unadjusted Means ± SE). For the Tactile Threshold, an increase indicates reduced 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 reduced 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.

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