Short-term Efficacy of an Occluding Dentifrice on Dentinal Hypersensitivity


Aim

To investigate the ability of an anhydrous 0.454% stannous fluoride test toothpaste to relieve dentine hypersensitivity after a single direct application and after 3 days twice-daily use, compared with a control toothpaste.

Study Products and Usage

- **Test toothpaste** containing 0.454% stannous fluoride (1100ppm fluoride) and 5% sodium tripolyphosphate.
- **Control toothpaste** containing 0.76% sodium monofluorophosphate (1000ppm fluoride).

**First Use (Direct Application):** Subjects used their finger to gently rub a pea-sized amount of their assigned toothpaste into the cervical margin area of each of the 2 selected sensitive (test) teeth (60 seconds per tooth).

**Home Use:** In the test group, subjects brushed the 2 test teeth first, then their whole mouth for ≥1 minute; in the control group, subjects brushed their whole mouth for ≥1 minute.

Methods

- Single-centre, randomised, controlled, examiner-blind, two-treatment, parallel-design study, stratified (by maximum baseline Schiff sensitivity score of the two selected test teeth); conducted in otherwise healthy adult subjects (18-65 years) with ≥2 clinically diagnosed sensitive teeth.

- Schiff sensitivity scale and tactile (Yeaple probe) threshold in grams (g) stimuli was assessed at Baseline, immediately after the first direct application treatment, and after 3 days twice-daily brushing.

Subject Numbers

Eligible subjects were randomly assigned to one of the two treatments (Test n=117; Control n=116).

Statistical Methods

The primary efficacy variable was change from Baseline to Day 3 in Schiff sensitivity score (subject level mean change of the 2 test teeth). Change from Baseline was analysed for each study outcome using Analysis of Covariance (ANCOVA).
Results

Subjects using the 0.454% stannous fluoride toothpaste showed greater reductions in both clinical measures of sensitivity after a single direct application treatment, and after 3 days of twice-daily brushing, compared to the control group, which was statistically significant (p<0.0001, Figures 1 and 2).

Figure 1. Schiff Sensitivity Score by Time and Treatment Group

![Schiff Sensitivity Score](image1)

Figure 2. Tactile Threshold by Time and Treatment Group

![Tactile Threshold](image2)

Conclusion

This study demonstrated the efficacy of an anhydrous test toothpaste containing 0.454% stannous fluoride for the immediate relief of dentine hypersensitivity, when applied by rubbing a pea-sized amount directly onto sensitive areas, compared with a regular fluoride toothpaste control. The difference between test and control products was statistically significant and considered clinically relevant.

The degree of relief obtained from the 0.454% stannous fluoride test toothpaste treatment was observed to increase from first use, when followed by 3 days of twice-daily brushing. The magnitude of the difference between test and the regular fluoride control toothpaste also increased over this period. This difference was statistically significant and considered clinically relevant.