

RANDOMIZED CONTROLLED TRIAL EVALUATING THE EFFICACY AND SAFETY OF 0.454% STANNOUS FLUORIDE TOOTHPASTE FOR THE RELIEF OF DENTIN HYPERSENSITIVITY

Haleon Data on File, Study 300104 (2024).

Twice-daily brushing with stannous fluoride (SnF₂) toothpaste resulted in greater reduction in dentin hypersensitivity and improves the oral health-related quality of life of people with dentin hypersensitivity.

STUDY OBJECTIVE

The study evaluated the efficacy and safety of a toothpaste containing 0.454% stannous fluoride (SnF₂) compared to regular fluoride toothpaste in alleviating dentin hypersensitivity (DH) after 4 to 8 weeks of twice-daily use.

STUDY PRODUCTS

PRODUCT	FUNCTIONAL INGREDIENT
Test toothpaste	0.454% stannous fluoride (1100 ppm Fluoride)
Control toothpaste (Crest Cavity Protection)	1100 ppm Fluoride

STUDY METHODOLOGY

- Single-center, randomized, examiner-blind, parallel-group controlled clinical trial
- Adults aged 18–65 with self-reported tooth sensitivity lasting >6 months and ≤10 years, and at least two non-adjacent teeth showing DH confirmed by tactile sensitivity ≤20 g and Schiff sensitivity score ≥2 were considered.
- Subjects underwent 14–28 days of acclimatization period and brushed twice daily (morning and evening) with the provided toothbrush and toothpaste.
- After acclimatization period, subjects completed DHEQ-48* questionnaire to assess Oral Health related Quality of Life (OHRQoL), underwent oral soft tissue (OST) exam and DH assessments (Schiff score and Tactile threshold) to confirm eligibility.
- Eligible subjects received the treatment as illustrated in the following diagram on page 2.

*DHEQ-48: Dentin Hypersensitivity Experience Questionnaire

STUDY METHODOLOGY (CONTINUED)

119 subjects were screened, 115 enrolled, 113 in safety population, 112 in mITT, 102 completed the study (56 in test group, 56 in control group).

Safety and tolerability were monitored over 56 days through reported TEAEs**.

Two 'test teeth' were selected per subject for DH assessments. Number of sensitive teeth identified using the Schiff sensitivity score (≥ 2). Subject-perceived DH was investigated using Labelled Magnitude Scale (LMS).

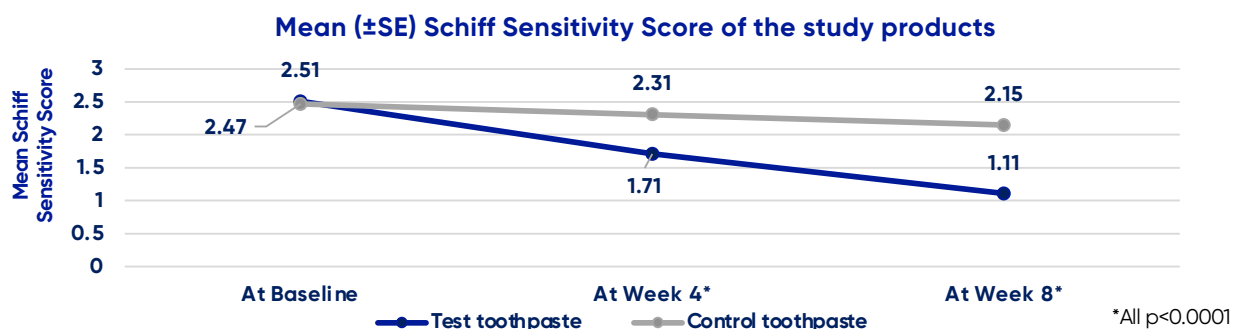
Subjects completed DHEQ-48* questionnaire, OST examination, DH assessment, LMS questionnaires at Week 4 & 8, and Numeric Rating Scale (NRS) at Week 8

Subjects brushed twice daily (morning and evening) with either the test or control toothpaste for 8 weeks and recorded their usage in a provided diary. Assessments were conducted at Week 4 and Week 8.

STUDY RESULTS

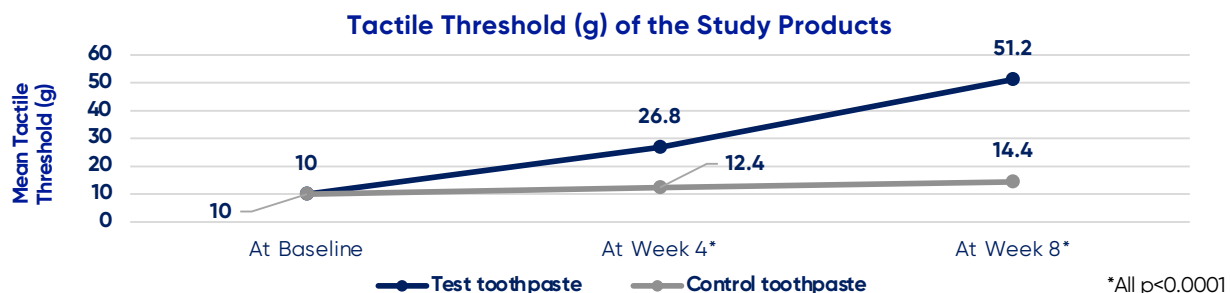
Primary endpoints

- The test toothpaste containing 0.454% stannous fluoride significantly reduced the Schiff sensitivity score ($p < 0.0001$) for the two test teeth at Week 8 compared with the control toothpaste group.



Secondary endpoints

- Schiff Sensitivity Score also showed statistically significant ($p < 0.0001$) results at Week 4 in the test toothpaste group compared with the control group.
- The test toothpaste significantly increased Tactile threshold ($p < 0.0001$) for the 2 test teeth at Week 4 and Week 8 compared with the control toothpaste, showing superior anti-sensitivity efficacy.



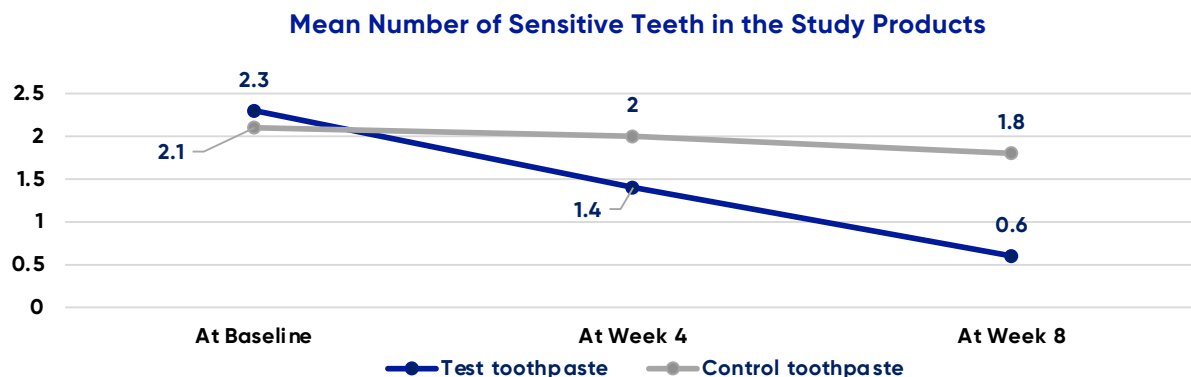
- Oral health-related quality of life (OHRQoL) measured using DHEQ-48 questionnaire was significantly improved ($p < 0.0001$) in the test toothpaste group compared with control toothpaste from Baseline.
- DHEQ Section 1: Intensity (Q7) and bothered (Q8) reduced at Week 4 & 8; tolerability (Q9) reduced at Week 8
- DHEQ Section 2: Restrictions, Adaptation, Emotional Impact, Effect on Life Overall score reduced at Week 4 and Week 8, whereas Social Impact, Identity, Global Oral Health score domains reduced at Week 8.

*DHEQ-48: Dentin Hypersensitivity Experience Questionnaire; **TEAEs: Treatment-emergent adverse events

STUDY RESULTS (CONTINUED)

Exploratory endpoints

- 58.9% subjects in the test toothpaste group experienced improvement in the mean number of sensitive teeth compared with 14.3% subjects in the control toothpaste group at Week 8 with a notable decrease in the mean number of sensitive teeth.



- The subject-perceived changes in DH to an air stimulus as measured by Labelled magnitude scale (LMS) – intensity, duration, tolerability, and description—from baseline showed statistically significant reduction ($p < 0.0001$) in the test group compared with control group at Week 4 and Week 8.
- Numerical Rating Scale (NRS) reported higher satisfaction ($\text{NRS} \geq 8$) in the majority of subjects (51.8%) using the test toothpaste compared with the control group.

Safety analysis

- Only one (1.8%) subject from the control toothpaste group reported 2 treatment-related TEAEs (bronchitis and seasonal allergy) and both were resolved at the end of the study
- There were no treatment-related TEAEs reported in the test group and all products were generally well tolerated.

CONCLUSION

Twice daily brushing with a toothpaste containing 0.454% SnF_2 resulted in significantly greater reduction in dentinal hypersensitivity compared to regular fluoride toothpaste over 4 and 8 weeks. Statistically significant were observed in both clinical measures including Schiff sensitivity score and Tactile threshold (all $p < 0.0001$) as well as in patient-reported outcomes, including oral health-related quality of life (OHRqoL) using DHEQ and pain experience using NRS. The test toothpaste consistently outperformed the control toothpaste, with over 51.8% of users reporting high satisfaction in the test toothpaste group compared with 44.6% in the control toothpaste group in managing DH. All study products were generally well tolerated.