A REAL-WORLD EVIDENCE STUDY EVALUATING ORAL HEALTH RELATED QUALITY OF LIFE WITH USE OF A STANNOUS FLUORIDE ANTI-SENSITIVITY TOOTHPASTE FOR DENTIN HYPERSENSITIVITY MANAGEMENT

Haleon Data on File; CSR - 300058; Creeth et al. AADOCR New York, 2025

Sensodyne Repair and Protect significantly improved the oral health related quality of life and participants reported reduction in pain and high treatment satisfaction.

STUDY OBJECTIVE

The study evaluated the impact of a 0.454% stannous fluoride (SnF_2) anti-sensitivity toothpaste on oral health-related quality of life (OHrQoL), changes in self-reported pain intensity, treatment satisfaction, and oral hygiene habits in individuals with self-reported dentin hypersensitivity (DH) symptoms over a 24-week period.

STUDY PRODUCTS

PRODUCT	FUNCTIONAL INGREDIENT
Sensodyne Repair and Protect Toothpaste	0.454% stannous fluoride (1100 ppm Fluoride)

STUDY METHODOLOGY

- Study design: Decentralized, real-world, prospective, monadic design, open-label
- Participant recruitment was done through various digital platforms, after clicking on an advertisement or study link. Interested individuals completed an initial pre-screening questionnaire on a landing page.
- Adult participant aged ≥18 and ≤65 years with self-reported tooth sensitivity and willing to complete all study activities on their smart devices were considered
- Eligible participants received a unique ID and were invited to download the ObvioHealth app to sign the electronic informed consent form and get any support during the study
- Participants received the treatment as per the below diagram:

680 participants were screened, 536 enrolled, 498 safety population, 491 mITT and 460 completed the study.

Prior to treatment, participants completed: DHEQ-48* to assess oral health-related quality of life (OHrQoL), OHQ** to assess hygiene habits, NPRS*** to assess DH-related pain.

Participants were instructed to brush sensitive areas with the test toothpaste for 24 weeks (at least 1 minute, 2–3 times daily)

During the treatment, DHEQ-48 repeated at Weeks 4, 8, 12, 16, 20, and 24; NPRS completed at Weeks 1, 2, 4, 8, 12, 16, 20, and 24.

At study completion, participants rated their satisfaction using the Numeric Rating Scale (NRS) and answered End-of-Study survey questions.

Self-reported adverse events (AEs) were collected remotely

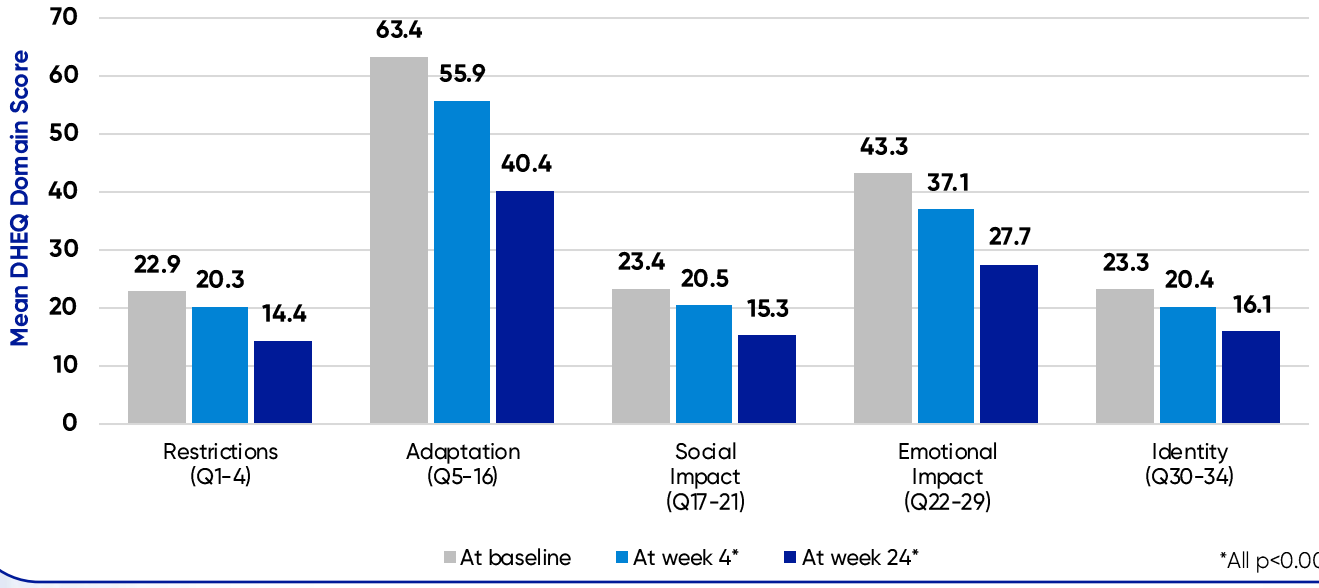
*DHEQ-48 : Dentin Hypersensitivity Experience Questionnaire ; OHQ : **Oral Hygiene Questionnaire ; ***NPRS : Numeric Pain Rating Scale

STUDY RESULTS

Primary endpoints

- Sensodyne Repair and Protect showed statistically significant (p<0.0001) reductions (improvements) in the DHEQ total score (Q1-34) and each domain score at Week 4 and for each subsequent time point with continued improvements over the 24-week period.

Primary DHEQ Endpoints (Q1-34) at Week 4 & 24

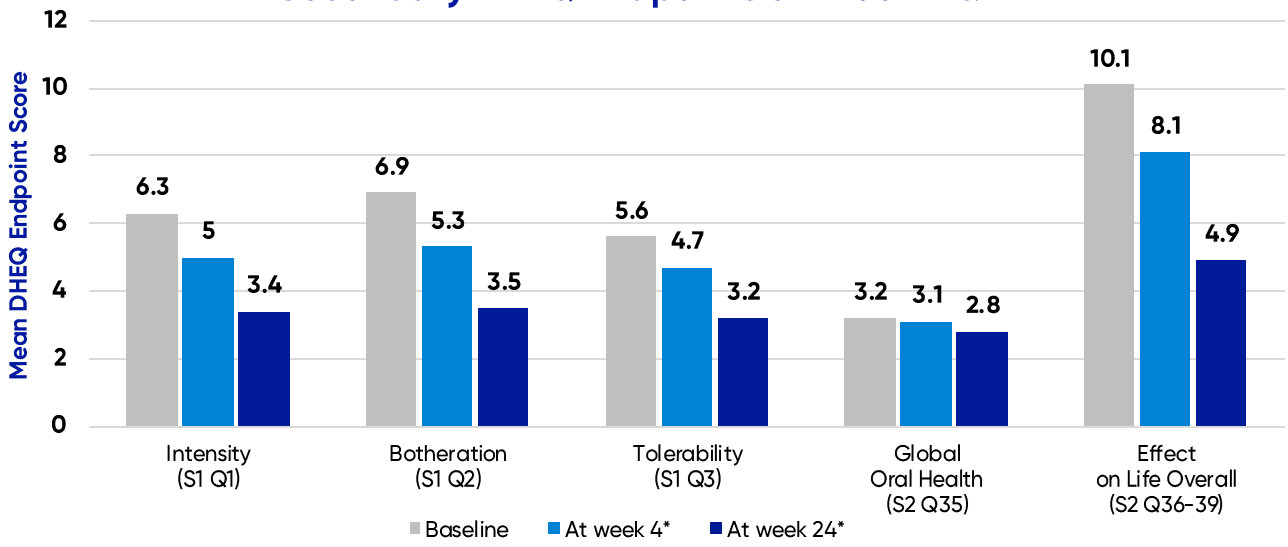


*All p<0.0001

Secondary endpoints

- Sensodyne Repair and Protect significantly improved (p<0.0001) Impact on Everyday Life (Q1 [intensity], Q2 [botheration], Q3 [tolerability]), on Life overall score (Q36-39), also improved (p<0.05) Global Oral Health Score (Q35) from Week 4 in DH sensations. This was sustained at all time points up to Week 24 (p<0.0001)

Secondary DHEQ Endpoints at Week 4 & 24



*All p<0.0001 except for Global Oral Health (S2 Q35)

STUDY RESULTS (CONTINUED)

- At baseline, 98.2% of DH sufferers found the sensations annoying (Q27 – Emotional Impact Domain), and 97.6% had trouble eating ice cream (Q4 – Restriction Domain). By Week 24, Q27 dropped to 55.9% and Q4 to 53.5%, showing significant improvement.
- A statistically significant reduction ($p < 0.0001$) in NPRS scores was observed as early as Week 1, and for each subsequent time point, with continuous improvements over the 24-week period.
- Participants reported a mean satisfaction score of 7.8 (SD = 2.10) on an 11-point NRS, with 66.2% scoring ≥8. Notably, 92.2% indicated they would adopt the study product as their regular toothpaste.

Safety analysis

- The product was well tolerated in DH participants, with ~1% treatment-related TEAEs. In the 24-week study, five oral TEAEs related to the product resolved, except one aphthous ulcer (loss to follow-up).

CONCLUSION

The use of a sensitivity toothpaste containing 0.454% SnF2, demonstrated statistically significant ($p<0.0001$) improvements in OHrQoL as early as Week 4 with continuous improvements over the 24-week period, as measured by the Total DHEQ score. An improvement in OHrQOL in each of the DHEQ domains of restrictions on daily life activities, adaptations to habits, social and emotional impact, and identity perception was demonstrated. Effectiveness was demonstrated by statistically significant reductions in participant perceived pain and high satisfaction with treatment as evidenced by the 11-point NPRS and NRS scores. Overall, the study product was well tolerated in participants with DH, with ≈1% treatment related TEAEs for this study.

DATE OF PREPARATION: October 17, 2025