

# REDUCING DENTINAL HYPERSENSITIVITY IMPROVES ORAL HEALTH-RELATED QUALITY OF LIFE

Hall C, et al. J Dent Res 2017;96:B062, Haleon Data on File Study RH01897; 2014

## INTRODUCTION

Dentinal hypersensitivity (DH) is reported in individuals with both 'good' and 'poor' oral hygiene.<sup>1</sup> Overly aggressive oral hygiene can expose the dentine via enamel loss/gingival recession;<sup>2</sup> poor oral hygiene is associated with chronic gingival inflammation, which can lead to gingival recession and exposed dentine.<sup>1</sup> DH is reported to hinder toothbrushing due to avoidance of painful areas<sup>3</sup> and can impact oral health-related quality of life (OHRQoL).<sup>4,5</sup> Toothpastes containing calcium sodium phosphosilicate (CSPS) (Novamin) have clinically demonstrated anti-sensitivity efficacy.<sup>6</sup>

This study investigated the effect of long-term DH management with an anti-sensitivity toothpaste (5% CSPS) on supra-gingival plaque accumulation, gingival health and OHRQoL, and relationships between these parameters.

## METHOD

### Design

An exploratory, single-centre, single-blind (study subjects), non-comparative clinical study. Two of the sensitive teeth that met the study criteria were selected as 'test teeth'. Subjects brushed twice daily with anti-sensitivity toothpaste for 24 weeks.

### Subjects

Adults with  $\geq$  two sensitive non-adjacent teeth at baseline (tactile threshold [TT]<sup>7</sup>  $\leq$ 20 g; Schiff sensitivity score [SSS]<sup>8</sup>  $\geq$ 2).

### Study toothpaste:

5% CSPS toothpaste, with 1426 ppm fluoride as sodium monofluorophosphate (Sensodyne containing Novamin).

### Assessments

**Dentine Hypersensitivity:** assessed at baseline and 1, 2, 4, 8, 12, 18 and 24 weeks.

Examiner-assessed SSS (two test teeth; all 'qualifying' sensitive teeth) and TT (two test teeth only); subject-completed labelled magnitude scales (LMS: intensity, duration, tolerability, description). Decreasing SSS/LMS and increasing TT (g) indicative of decreasing DH.

### Oral health status

Turesky Plaque Index (TPI)<sup>9</sup> and Modified Gingival Index (MGI)<sup>10</sup> assessed at baseline and 12 and 24 weeks.

### Subject-perceived OHRQoL

Dentine Hypersensitivity Experience Questionnaire (DHEQ)<sup>11</sup> completed at baseline and 12 and 24 weeks. Dentine Hypersensitivity Experience Questionnaire (DHEQ)<sup>11</sup> completed at baseline and 12 and 24 weeks.

### Safety:

Assessed from oral soft tissue examination and adverse events (AEs).

### Statistical analysis

Mean scores for DH measures, mean DHEQ scores (total/sensation scores) and mean TPI and MGI scores plotted over time. Correlation of DH measures with TPI and DHEQ measures, and TPI with DHEQ measures and MGI, at 12 and 24 weeks.

*Intent-to-treat (ITT) population, 5% significance level (two-sided)*

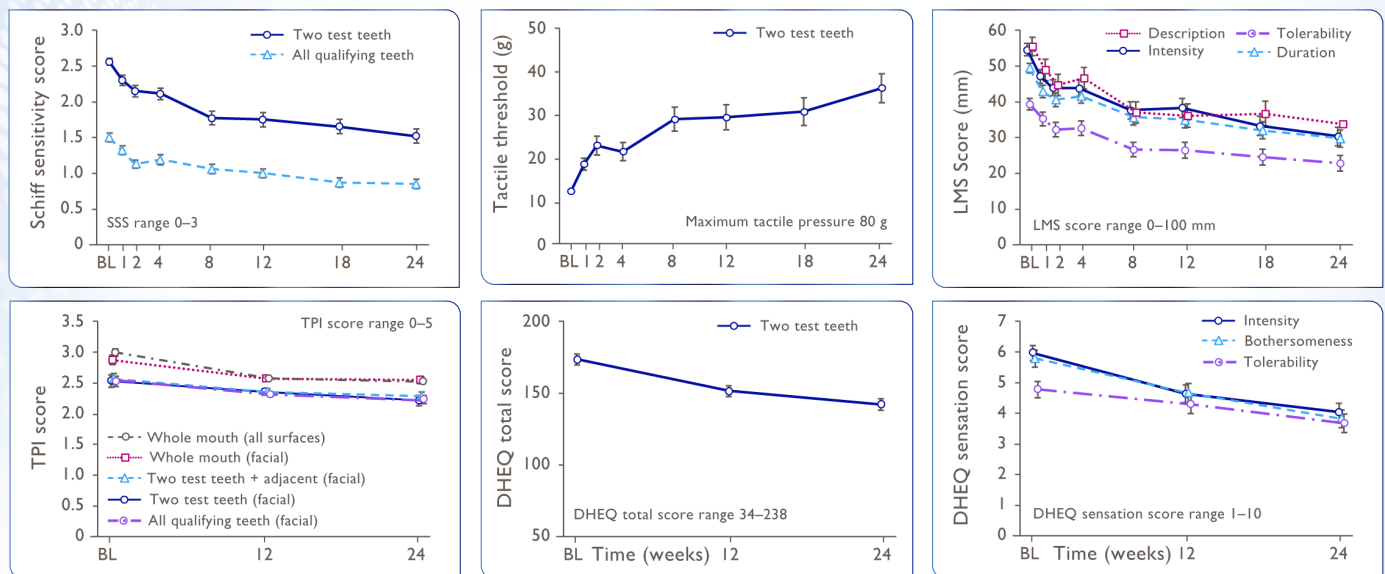
## RESULTS

75 subjects (female 81.3%; mean age 44.9 y).

- Over the 24-week treatment period
  - All sensitivity measures demonstrated ongoing reductions in DH compared with baseline
  - All DHEQ measures (except global oral health rating) showed ongoing improvements in OHRQoL
  - Mean TPI scores decreased on teeth associated with sensitivity (two test teeth; two test teeth plus adjacent teeth; all 'qualifying' teeth) and were always lower than whole-mouth mean scores
  - MGI scores showed little change
- Several statistically significant correlations were detected between DHEQ measures vs DH measures, most notably with SSS on two test teeth/'qualifying' teeth, and with LMS tolerability/duration
- DHEQ total score, social impact and emotional impact were most often correlated with DH parameters
- No correlations were detected between changes in DH parameters vs TPI scores, or between changes in TPI vs MGI scores

**RESULTS**

**Mean sensitivity, TPI and DHEQ scores over time (± standard error) (ITT population)**



Data are offset for clarity where necessary; BL = Baseline (Week 0)

**Correlations (p-value) between changes from baseline in Schiff sensitivity score and DHEQ measures**

DHEQ measure	Schiff sensitivity score			
	Two test teeth		All qualifying teeth	
	Week 12	Week 24	Week 12	Week 24
Total score	0.0033	0.0014	0.0134	0.0014
Intensity	0.0003	0.0267	0.0433	NS
Bothersomeness	0.0016	0.0063	0.0085	NS
Tolerability Bothersomeness	0.0035	NS	0.0045	NS
Restrictions	NS	0.0111	NS	0.0297
Adaptation	0.0071	0.0040	NS	0.0102
Social impact	0.0078	0.0001	NS	0.0004
Emotional impact	0.0092	0.0081	0.0064	0.0108
Identity	0.0112	NS	0.0203	0.0041
Extent	0.0129		NS	0.0173
GOHR	NS	NS	NS	0.0033
Effect on life overall	NS	NS	NS	NS

GOHR = global oral health rating; NS = not significant

**Safety:** 52 subjects reported 122 AEs (64 oral); only one AE considered treatment-related (mild oral mucosal exfoliation).

**CONCLUSION**

- Twice-daily brushing with a 5% CSPS toothpaste (such as Sensodyne with Novamin) produced ongoing, continual reductions in DH across the 24-week study period
- The ongoing, clinically significant improvements in DH were associated with improved OHRQoL, as measured by DHEQ
- The results did not indicate a relationship between DH and oral hygiene parameters
- Product was well tolerated

**References and Acknowledgements**

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