Long-Term Study to Investigate the Effect of Changes in Dentinal Hypersensitivity on Oral Health Parameters

Adapted from RH01897, GSK Data on File.

Aim

To investigate the effect of long-term (24 week) management of dentine hypersensitivity (DH), with twice daily use of a 5% w/w NovaMin/1426 ppm fluoride toothpaste, on changes in oral hygiene, gingival health and oral health-related quality of life using the Dentine Hypersensitivity Experience Questionnaire (DHEQ).

Study product and usage

Subjects brushed with 5% w/w NovaMin/1426 ppm fluoride as sodium monofluorophosphate (SMFP) for 1 minute, twice daily (morning and evening) for 24 weeks, following a lead-in period of up to 3 weeks with a standard fluoride dentrifice.

Methods

Single centre, non-comparative study including 75 healthy adult subjects with ≥2 sensitive teeth but otherwise good oral health.

- All 75 subjects received study treatment and were included in the Intention To Treat and Safety Populations
- 67 subjects completed the 24 week study

At baseline two non-adjacent test teeth were selected and tooth sensitivity assessed by evaporative air blast (examiner-assessed Schiff Sensitivity Score followed by Labelled Magnitude Scales [LMS]) and tactile stimulus (Yeaple probe) after 1, 2, 4, 8, 12, 18 and 24 weeks of treatment.

Sensitivity of the remaining eligible teeth (based on erosion/abrasion/recession (EAR), gingival index (GI) ≤1, and tooth mobility=0 at screening, with no dentition exclusions) were assessed at each visit by Schiff Sensitivity Score.

A DHEQ was completed at baseline, 12, and 24 weeks to investigate subject-perceived changes in sensitivity.

Gingival health and supra-gingival plaque levels were assessed at baseline, 12 and 24 weeks, using Modified Gingival Index (MGI) and Turesky modification of the Quigley & Hein Plaque Index (TPI), respectively.

Correlation of TPI vs DH, MGI and DHEQ measures, and DHEQ vs DH measures were assessed at weeks 12 and 24.

Results

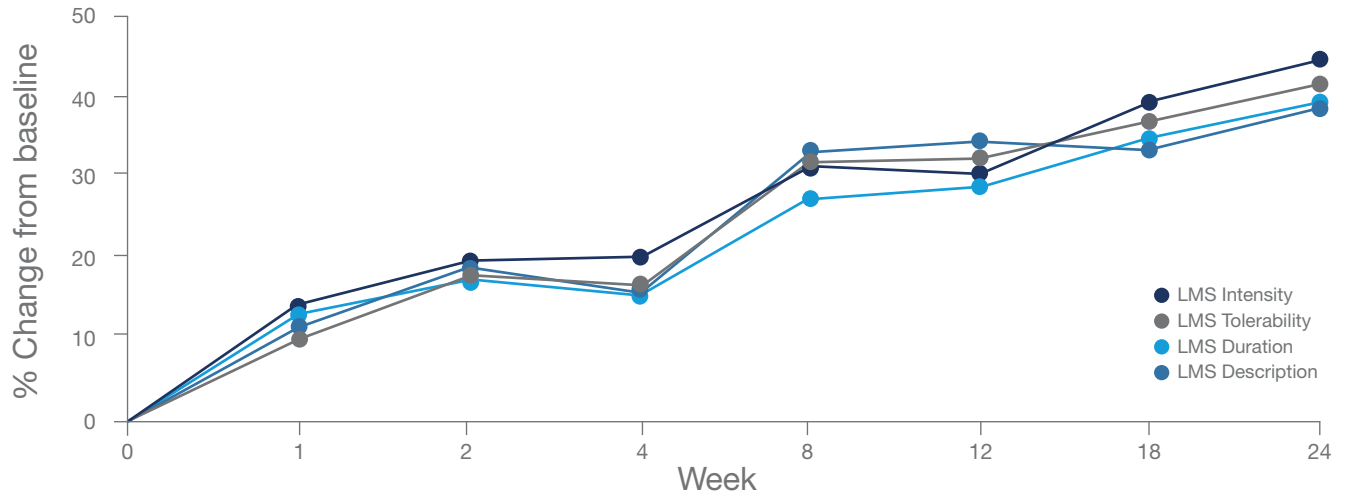
Dentine Hypersensitivity

Results demonstrate that subjects using 5% w/w NovaMin/1426 ppm fluoride toothpaste show a reduction in examiner- and self-perceived DH as early as week 1 and continuous reductions for all measures – Schiff, LMS (Figure 1), tactile, and % sensitive teeth (Figure 2) over 24 weeks of twice daily treatment.

By the end of the 24-week treatment period:

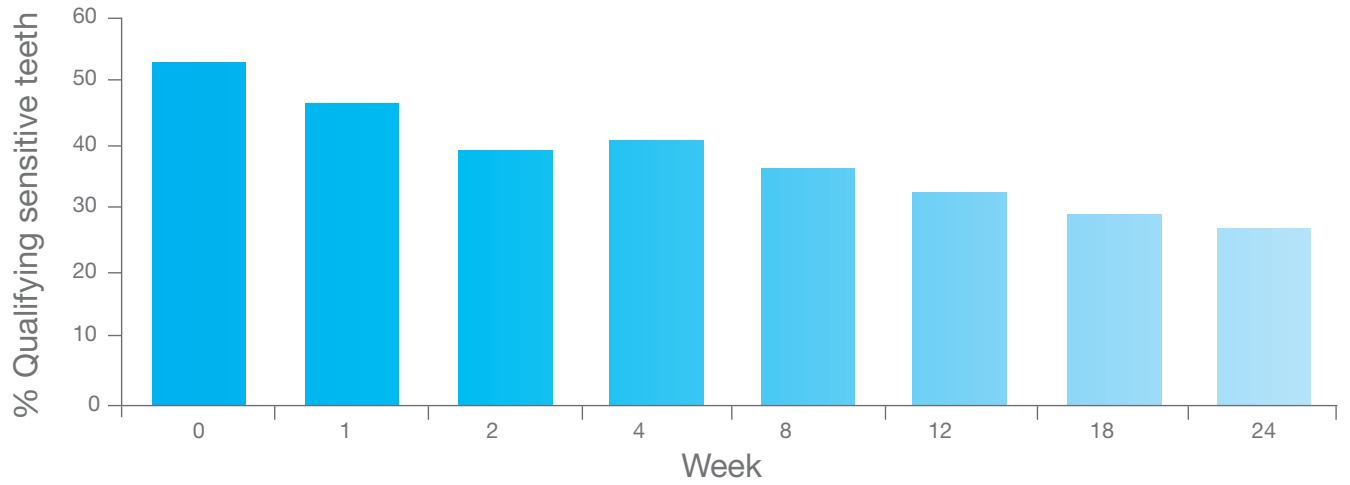
- LMS responses improved by 39–44% (Figure 1)
- Tactile responses improved by x 2.2
- % sensitive teeth reduced by 53% (Figure 2)

Figure 1: % Change in LMS responses from baseline over time (Intent to Treat Population analyses)



LMS range was 0–100 mm.
A decrease in LMS responses indicate improved subject sensitivity.

Figure 2: % Change in proportion of sensitive teeth* from baseline over time (Intent to Treat Population analyses)



*Qualifying sensitive teeth met the following inclusion criteria: signs of EAR, GI ≤1, clinical mobility=0, no dentition exclusion, and sensitivity to a qualifying air blast.

DHEQ Measures

All DHEQ measures, except the Global Oral Health Rating, demonstrated progressive subject-perceived improvements over the 24 week treatment period. By the end of the study, DHEQ Total Scores had improved by 20.5% from baseline.

Statistically significant correlations were found between improvements in DHEQ and DH measures (Schiff, LMS) with Total Score, Social Impact and Emotional Impact measures most often correlated with improvements in DH measures.

Plaque Levels and Gingival Health

Reductions in supra-gingival plaque were observed over the treatment period; gingival health was unchanged. There were no statistically significant correlations between changes in DH, plaque levels and gingival health.

Conclusion

It can be concluded that continuous use of 5% w/w NovaMin/1426 ppm fluoride toothpaste progressively improved DH over a 24 week treatment period, and that these improvements were associated with patient-perceived improvements in DHEQ measures.