

An *in-vitro* Study to Investigate Fluoride Uptake to Dentine After Treatment with Two Dentifrices for Dentine Hypersensitivity

Adapted from 142234, GSK Data on File.

Background and aim

Dynamic Secondary Ion Mass Spectrometry (DSIMS) is an *in-vitro* technique which provides quantitative information on the elemental composition of the surface region of a sample from a few nanometers (nm) to several hundreds of microns (μm) in depth. DSIMS has been used in this study to investigate uptake of fluoride into the dentine following treatment with a fluoride-containing dentifrice.

To compare the penetration of fluoride into human dentine using DSIMS after treatment with either a test dentifrice containing 5% w/w calcium sodium phosphosilicate (CSPS) and 1426 ppm fluoride as sodium fluoride (NaF), or a commercially available dentifrice containing 5% w/w CSPS and 1426 ppm fluoride as sodium monofluorophosphate (SMFP) [Sensodyne Repair & Protect].

Study design

The study design comprised a 4-day *in-vitro* model on human dentine after treatment with one of the two formulations. Before the measurement on Day 4, the dentine was challenged with a 1% citric acid challenge. The dentine samples were analysed using a combination of DSIMS imaging and depth-profiling at 2, 5, 10, 20 and 40 μm .

Methods

Study samples were sectioned from sound, disease-free human molars, and polished to expose the dentine. Samples were treated daily, using approximately 0.5 g study toothpaste (either 5% CSPS/SMFP or 5% CSPS/NaF), applied using a rotary toothbrush for 10 seconds, for up to 4 days. Between treatments, dentine samples were incubated in artificial saliva at 37°C for at least 6 hours. On Day 4, after incubation in the artificial saliva for 6 hours, the discs were placed into 1% citric acid for 2 minutes. Samples brushed with water on Day 1 were used as a control. At the end of the study all samples were sent for DSIMS analysis.

Dentine samples were analysed for fluoride uptake (5 samples per treatment, per time point) – 5% CSPS/SMFP at Days 1, 2, 3 and 4 plus control samples; 5% CSPS/NaF at Days 1, 2, 3 and 4 plus control samples – using a combination of DSIMS imaging and depth-profiling.

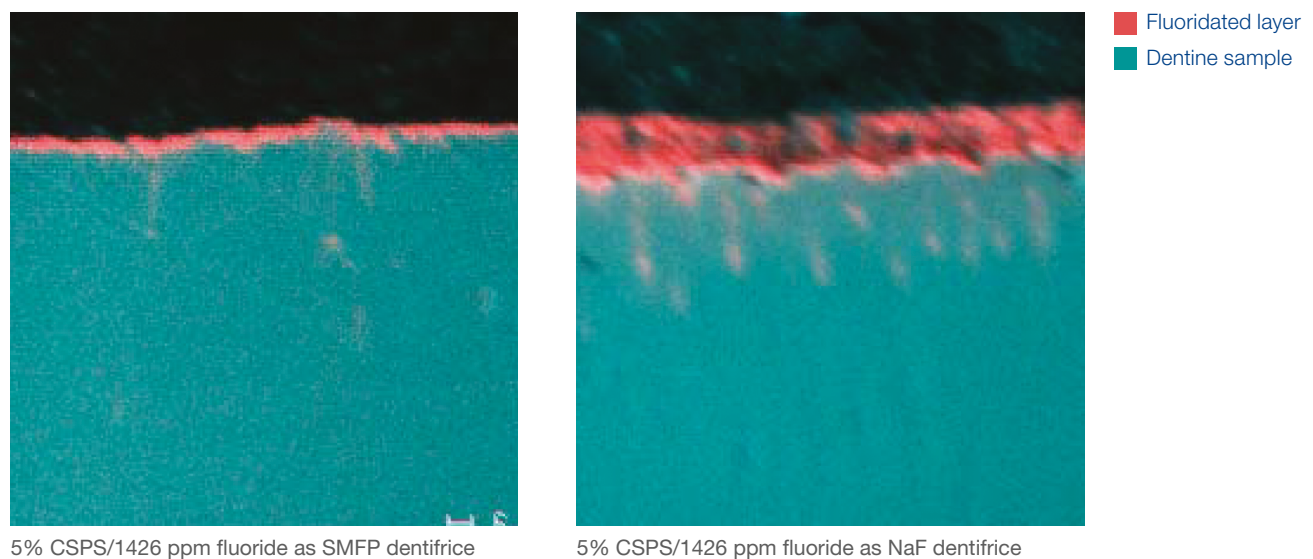
Results

DSIMS imaging and depth-profiling confirmed the uptake of fluoride into the dentine surface following treatment with both dentifrices. The most significant differences were detected in the outermost 5 μm of the dentine, consistent with the gradient of fluoride concentration from the surface (highest fluoride) towards the bulk dentine (lowest fluoride) seen in the DSIMS images and depth profiles.

As anticipated fluoride levels were lowest in the control samples. Levels increased across the 4-day treatment period, and were higher for the 5% CSPS/NaF containing dentifrice compared to the 5% CSPS/SMFP, at all profile depths and at all time points.

The highest fluoride levels were observed on Day 3 and Day 4 for both treatments. Statistically significant ($p < 0.05$) between treatment differences, in favour of the 5% CSPS/NaF dentifrice, were observed at all depths up to 20 μm , and directionally favoured the 5% CSPS/NaF dentifrice at 40 μm ($p < 0.10$) (Figure 1).

Figure 1: Example DSIMS images after 4 days of treatment



Conclusion

Greater fluoride uptake into dentine was demonstrated from a dentifrice containing 5% w/w CSPS and 1426 ppm fluoride as NaF in comparison to a dentifrice containing 5% w/w CSPS and 1426 ppm fluoride as SMFP using DSIMS imaging and depth-profiling.