

# An *in vitro* Study to Evaluate the Hardness and Acid Resistance of the Layer Formed on Dentine Following Treatment with Two Dentifrices for Dentine Hypersensitivity

Adapted from ML584, GSK Data on File.

## Aim

To compare the hardness and acid resistance of a hydroxyapatite-like layer formed over the surface of dentine following 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 micro indentation *in vitro* model on human dentine before and after treatment with study dentifrice, including an acid challenge with either 1% citric acid solution, pH 3.75, or 5 mM phosphoric acid, pH 2.5, before the Day 4 microhardness measurement.

Approximately 2 mm square dentine blocks were sectioned from sound, disease-free human molars, mounted in resin discs and polished to expose the dentine. The microhardness of each dentine block was determined by indentation, using a Vickers diamond-tip indenter, taking the average of 6 individual measurements made centrally on each specimen (using 0.5 N force over an indent time of 20 seconds).

At the start of each of the 4 test days, each disc was treated with approximately 0.5 g study dentifrice for 10 seconds, using a rotary toothbrush. The discs were left to soak in the formulation for 2 minutes and then incubated in artificial saliva at 37°C for at least 6 hours before the microhardness of each dentine block was re-measured at the end of each day. On Day 4, after incubation in the artificial saliva for 6 hours, the discs were placed into 100 ml of either citric acid or phosphoric acid for 1 minute.

Microhardness data were analysed by day, using analysis of covariance (ANCOVA).

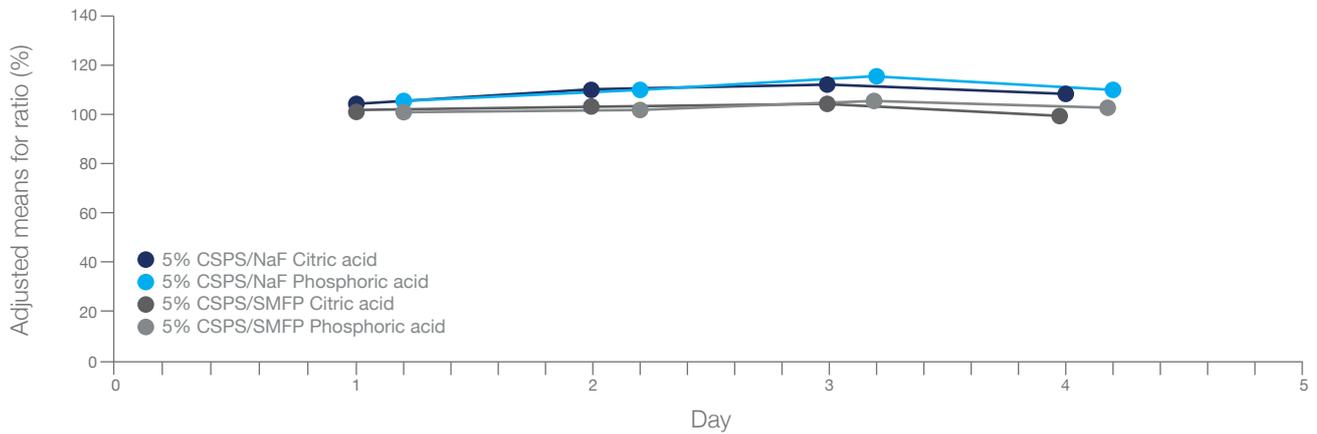
## Results

Treatment with both study dentifrices resulted in a gradual increase in dentine microhardness over Days 1, 2 and 3, followed by a decrease after the acid challenge on Day 4 (Figure 1). Dentine samples were harder after treatment with the 5% CSPS/NaF formulation than with the 5% CSPS/SMFP formulation, and these differences were significant for Days 2, 3 and Day 4 ( $p < 0.05$ ), favouring the NaF formulation (for both acid challenge methods).

For the 5% CSPS/NaF dentifrice, dentine samples were significantly harder than baseline on Days 2 and 3, and remained so at Day 4, even with the decrease in hardness observed after acid challenge (for both citric and phosphoric acids).

For the 5% CSPS/SMFP dentifrice, similar changes in hardness profile were observed over the 4-day treatment period. Dentine samples were significantly harder than baseline by Day 3, but not at Day 4, following the acid challenge (for both citric and phosphoric acids).

**Figure 1: Ratio of Vickers Hardness Number (VHN) compared to baseline over days for the two formulations under each acid challenge.**



## Conclusion

Overall, the microhardness data generated following treatment with two 5% CSPS/fluoride dentifrices provide evidence to suggest that the layer formed by the 5% CSPS/NaF formulation is significantly harder than that formed by the 5% CSPS/SMFP formulation, even after acid challenge.