

# *In situ* efficacy of an experimental toothpaste on enamel remineralization and prevention of demineralization

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## Aim

- To determine the ability of a Test toothpaste which includes a copolymer (PVM/MA) and sodium lactate at a low pH to enhance remineralization of enamel previously softened with dietary acid; to promote fluoride uptake to that surface; and to inhibit subsequent demineralization of the remineralized surface
- To compare the Test toothpaste with a marketed stannous fluoride-zinc citrate competitor toothpaste and a fluoride-free placebo using an established enamel erosion model in an *in situ* study

## Study design

- An *in situ* dental erosion-remineralization model developed by Zero et al.<sup>1</sup> *In situ* studies enable enamel surfaces to be prepared in advance and changes measured outside of the mouth while treatment and remineralization occur in the mouth; measurements are relatively precise, control of treatment conditions is high and changes occur on short time-scales.
- Randomized, investigator-blind crossover study
- Participants completed four study visits: screening, then three treatment visits at which each of the treatments were evaluated in a cross over manner. Each treatment visit was separated by a washout period of at least 3 days that included at least 1 day of use of the participant's regular toothpaste and 2 days use of a non-fluoridated toothpaste immediately prior to the visit using a provided brush
- The *in situ* model was designed to monitor erosive demineralization and remineralization processes representing typical daily behavior

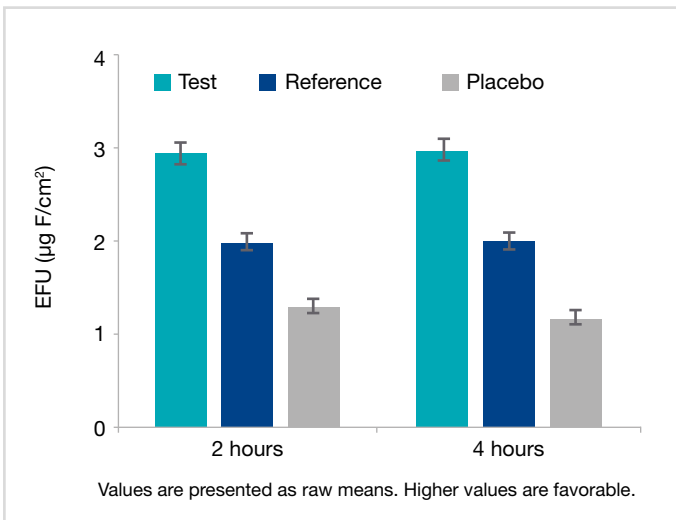
## Study treatments

- 62 participants aged 18-65 years were randomized and completed the study
- **Test toothpaste:** Sensodyne Pronamel Intensive Repair Toothpaste (0.254% w/w NaF (1150 ppm fluoride), 5% KNO<sub>3</sub>, polyvinylmethylether-maleic acid (PVM/MA) copolymer, sodium lactate at a low pH)
- **Placebo toothpaste:** fluoride free version of the Test toothpaste (non-marketed)
- **Competitor toothpaste:** Crest Pro-Health Sensitivity and Enamel Shield (Smooth formula) (0.454% SnF<sub>2</sub> (1100 ppm fluoride), zinc citrate)

## Methods

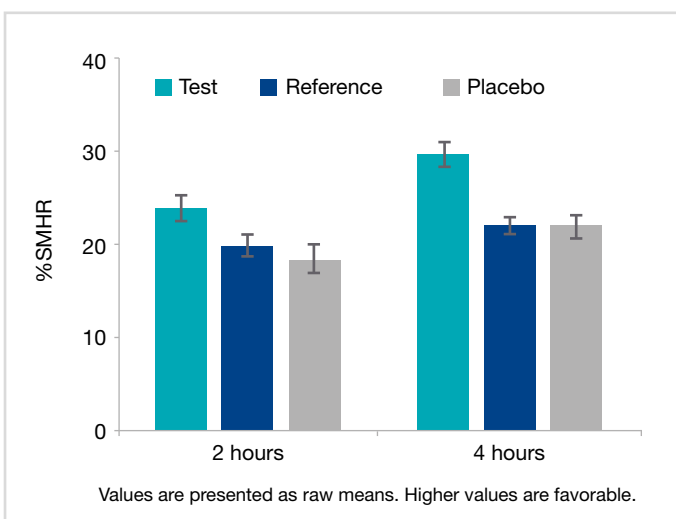
- Participants wore palatal appliances holding eight bovine enamel specimens with pre-formed erosive lesions (demineralized by immersion in 35 ± 1 mL grapefruit juice with no stirring for 25 minutes and then thoroughly rinsed with deionized water). They brushed their natural teeth with either the Test, Placebo or Reference toothpaste, then swished with the resultant slurry to cover the bovine enamel specimens. Specimens were removed at 2 and 4h post-brushing and exposed to an *ex vivo* acid challenge
- Surface microhardness was measured at each stage, enamel fluoride uptake (EFU) was measured after *in situ* remineralization. Surface microhardness recovery (SMHR), relative erosion resistance (RER), EFU and acid resistance ratio (ARR) were calculated for all treatments at both timepoints. All analyses are of the modified intent-to-treat population, methods described in Creeth et al., 2018.<sup>2</sup>

## Results



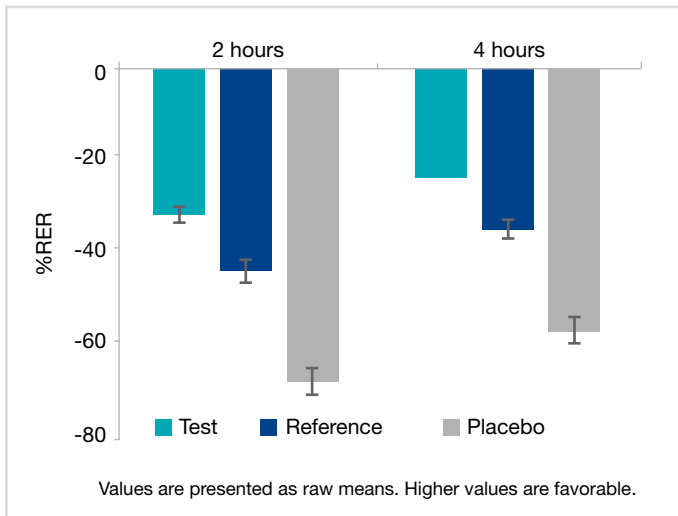
**Figure 1.** Mean  $\pm$  standard error of enamel fluoride uptake (EFU) by treatment group (modified intent-to-treat population)

This figure shows that more fluoride was delivered into enamel surfaces due to using the Test toothpaste than using the Reference toothpaste, which in turn delivered more fluoride than the fluoride-free Placebo toothpaste, at both time points.



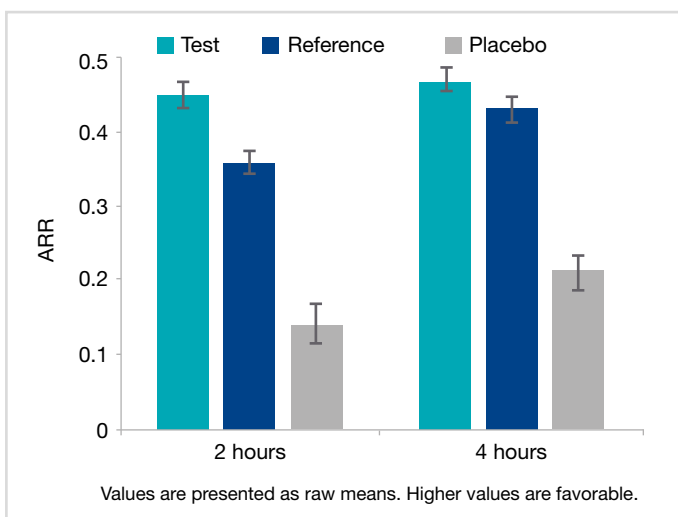
**Figure 2.** Surface microhardness recovery (%SMHR) by treatment group (Mean  $\pm$  standard error)

This figure shows that using the Test toothpaste led to greater surface microhardness (SMH) recovery, a key measure of enamel remineralization, than either of the other toothpastes, at both timepoints. There was no difference between the Reference and Placebo toothpaste in terms of remineralization after brushing at either timepoint.



**Figure 3.** Mean  $\pm$  standard error of percent relative erosion resistance (%RER) by treatment group

Relative Erosion Resistance (RER) is a measure of the overall impact of a product on protecting enamel from acid attack. It measures the effect of treatment on pre-softened enamel surfaces after a single remineralization-demineralization cycle. This figure shows that using the Test toothpaste led to a harder enamel surface after a remineralization-demineralization cycle than using the Reference toothpaste at both time points. In turn, using the Reference toothpaste gave a greater RER than using the Placebo toothpaste, also at both time points.



**Figure 4.** Mean  $\pm$  standard error of acid resistance ratio (ARR) by treatment group (modified intent-to-treat population)

The Acid Resistance Ratio (ARR) is a measure of the acid resistance of the newly remineralized enamel surface after treatment with a product. This figure shows that the enamel surface formed after a 2-hour remineralization period following use of the Test toothpaste was more acid-resistant than the surface formed after using the Reference toothpaste. After 4 hours remineralization, the difference between these products was not statistically significant. Using either fluoride product led to a more acid resistant enamel surface than using the Placebo toothpaste, at both time points.

## Conclusions

- In this *in-situ* model the novel formulation sodium fluoride Test toothpaste **enhanced enamel remineralization and overall protection against demineralization**. The remineralized surface was more acid-resistant
- Versus a competitor stannous fluoride-zinc citrate control, remineralization, demineralization and fluoride delivery were all enhanced

1. Zero DT, Hara AT, Kelly SA, et al. Evaluation of a desensitizing test dentifrice using an in situ erosion remineralization model. J Clin Dent 2006; 17(4): 112-116
2. Creeth J, Parkinson C, Burnett F, et al. Effects of a sodium fluoride- and phytate-containing dentifrice on remineralisation of enamel erosive lesions – an in situ randomised clinical study. Clinical Oral Investigations 2018; 22: 2543-2552