

ABSTRACT

Well controlled *in vitro* pH cycling studies have been shown to be useful tools in the anticaries assessment of various toothpaste formulations (Featherstone, *et al*, 1988, 1989, 1992). The aim of this study was to determine, using either a standard pH cycling model or a reverse cycling model, how a new 'remineralizing' toothpaste (Enamelon™) formulated with sodium fluoride (NaF), calcium and phosphate compares to a conventional NaF toothpaste which is considered to be the clinical 'gold standard' (Crest®) in anticaries efficacy. Crowns of human molars (8 groups, 10 teeth/group) were split into two sets of 4 groups each. One set of 4 groups was subjected to 14 days of alternating demin (6hr, pH 4.3, Ca/P/acetate) and remin (17 hr, pH 7, Ca/P) with dentifrice treatment (1:3 slurry in DDW) 2x daily for 1 minute each (before and after the demin period). The other set of 4 groups received the reverse treatment: demin (17 hr, pH 4.3, Ca/P/acetate) and remin: (6 hr, pH 7, Ca/P), with treatments before and after the remin period. Dentifrices compared in both models were: a) a conventional 1100ppm F (NaF) toothpaste (Crest®); b) a new 'remineralizing' toothpaste, containing 1100ppm F (NaF) plus calcium and phosphate in a dual phase tube (Enamelon™); c) an elevated [dose response] control: 2800ppm F (NaF); and d) a lower [dose response] control: 250ppm F (NaF). All products were formulated with hydrated silica as an abrasive. Enamel crowns were assessed by cross-sectional microhardness, and mineral loss calculated (DZ, vol. % min x mm). Mean (SD) DZ values, standard model: a) 1870 (453); b) 2776 (924); c) 1593 (354); and d) 2828 (439), with c=a<b=d (p<0.05). Reverse cycling model: a) 7738 (431); b) 12370 (3196); c) 5779 (1862); and d) 12330 (2421), with c<a<d=b (p<0.05). **Based on the results of both of these well-controlled studies, we conclude the conventional NaF toothpaste provides significantly greater level of remineralization and/or inhibition of demineralization than a new so-called 'remineralizing' toothpaste.**

INTRODUCTION

It is often useful, when assessing the anticaries efficacy of new formulations, to compare test and control products simultaneously in different models, as well as in variations of the same model systems.

The standard model system used in this presentation has been previously correlated with human studies. With respect to product performance in this model system, it is difficult to assess products that may be more effective than the positive control (1100ppm F as NaF), as the performance of this control is close to maximum under the conditions of the model system. A reversal of the remin/demin parameters helps lower the performance of the 1100ppm F control, such that products which may be more effective (e.g. higher F concentration, new product improvements, etc.) than this positive control can be assessed.

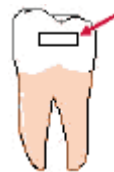
OBJECTIVE

The purpose of this study was to assess the performance of a new so-called "remineralizing" toothpaste relative to the "gold standard" for anticaries efficacy in two calibrated model systems.

MATERIALS AND METHODS

Figure 1: Treatments

14 day cycling procedure utilized in this study



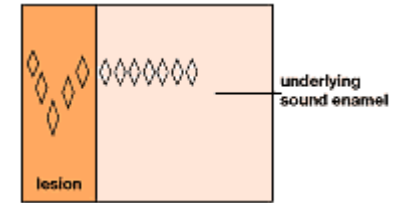
Enamel crown was covered with an acid-resistant nail varnish, except for the exposed window

Standard Model: Treatment (1 min.) P Demineralization (6 hrs.) P Treatment (1 min.) P Mineralizing Solution (17 hrs.) Repeat 14 days

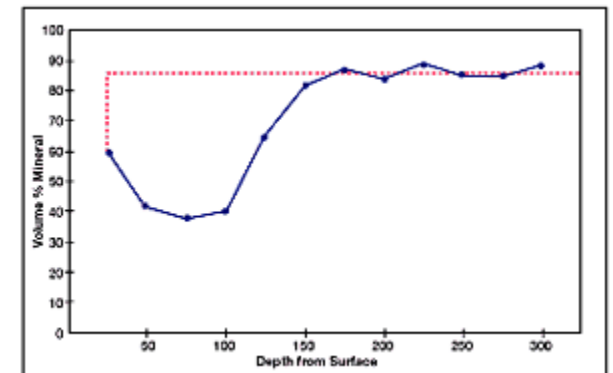
Reverse Cycling Model: Treatment (1 min.) P Demineralization (17 hrs.) P Treatment (1 min.) P Mineralizing Solution (6 hrs.) Repeat 14 days

Figure 2: Analysis

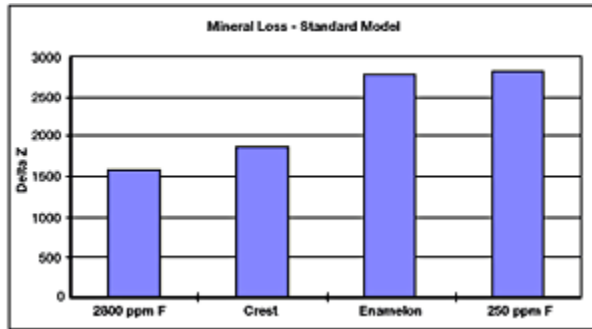
Representation of embedded sample showing lesion area and Knoop hardness impressions



Graphic representation of mineral profile



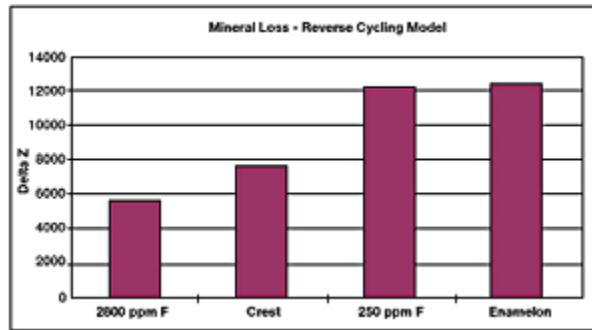
RESULTS



The Crest[®] and 2800 ppm F products were significantly more effective than Enamelon[™] and the 250 ppm F control at remineralizing/inhibiting demineralization in the standard pH cycling model.

CONCLUSION

Based on the results of these two, well-controlled studies, the conventional NaF toothpaste provides significantly greater levels of remineralization and or/inhibition of demineralization than the new so-called "remineralizing toothpaste".



The Crest[®] and 2800 ppm F products were significantly more effective than Enamelon[™] and the 250 ppm F control at remineralizing/inhibiting demineralization in the reverse pH cycling model.