

Animal Caries Efficacy of Conventional and 'Remineralizing' Toothpastes

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ABSTRACT

Remineralization is one of the key mechanisms through which fluoride exerts its anticaries effects. Some toothpastes have been demonstrated to provide this key benefit, using conventional clinical studies as well as *in vitro*, *in situ* and animal studies. Other products have been claimed to provide (or even enhance) this process through the addition of calcium to the formula, although the clinical benefits for such claims have never been successfully demonstrated. The purpose of this study was to compare the anticaries efficacy of a so called 'remineralizing' toothpaste (Enamelon™) relative to the clinical "gold standard" for anticaries efficacy (Crest®). Products were evaluated using a well defined animal (rat) caries model (Francis, *et al.* Arch Oral Biol 1966; 11:141). Test products included: a) a conventional, single phase, 1100ppm F (NaF) toothpaste (Crest®); b) a dual phase toothpaste, containing 1100ppm F (NaF) plus phosphate in one phase and calcium in the other (Enamelon™); c) an elevated fluoride product (dose response) containing 1450ppm F as NaF; d) a reduced fluoride (dose response) product containing 250ppm F as NaF; and e) placebo - 0ppm F. All test products contained hydrated silica as the abrasive system. Results, reported as average number of hypomineralized areas [x HMA] and concurrent % reduction in caries (relative to placebo) were as follows: a: 64.2 (51); b: 91.6 (29); c: 60.6 (53); d: 117.2 (10); e: 129.7 (0), with $c=a>b>d=e$ ($p = 0.05$, ANOVA). **These results demonstrate, using a conventional, well controlled animal caries model, that the single phase NaF 'gold standard' toothpaste provided significantly greater reduction in caries than a new so-called 'remineralizing' toothpaste, which is formulated with fluoride, calcium and phosphate. As the new 'remineralizing' toothpaste is formulated with the same level (1100ppm) and type of F as the 'gold standard' (NaF), the results suggest the activity of the fluoride phase in this toothpaste has been significantly compromised.**

METHODS

ANIMALS: Harlan Sprague Dawley rats (22-23 days old)
ANIMALS PER GROUP: 20

DIET: High Cariogenic Diet #469 (63% sucrose); food and water *ad libitum*.

DENTIFRICE APPLICATION: Cotton swabs, toothpaste diluted 1:1 with deionized water

TREATMENT PROTOCOL: 2X/day/15 days (excluding Saturdays and Sundays)

SPECIMEN PREPARATION: Upon completion of treatments, animals were sacrificed, jaws stained with 2% silver nitrate, then sectioned longitudinally.

GRADING MAGNIFICATION: 30X

TEETH GRADED: First, second and third molars of each quadrant.

METHOD OF GRADING: Each fissure was divided by an imaginary line through the middle of its bottom, and each side of the fissure assigned a severity grade. Both halves of each quadrant were graded and the most severe grade recorded for each corresponding surface. Severity based on a 0-3 scale, with 0: no stain in the enamel or dentin, 1: dark brown stain in enamel only, 2: dark brown stain in the enamel extending to the dentin/enamel junction, and 3: stain through the enamel and into the dentin.

TOTAL SEVERITY SCORE: Smooth surface and half-fissure grades for each animal in the group were totaled. A mean caries severity score (x HMA) was then calculated.

CALCULATION OF PERCENT DIFFERENCE: Determined by subtracting the test group score from the placebo control group score, dividing by the placebo group score, and converting to percent.

STATISTICAL ANALYSES: Standard ANOVA testing. Treatments ranked by a Duncan's Multiple Range Test analysis.

INTRODUCTION

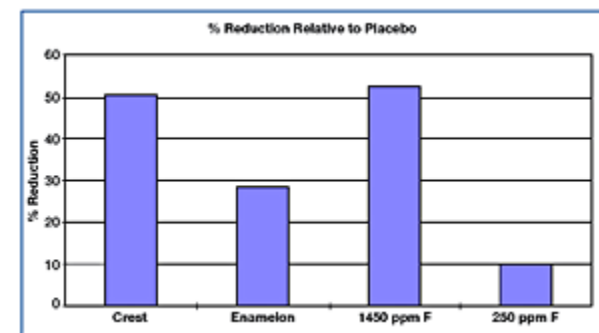
Animal caries models can be very useful in helping to assess the anticaries efficacy of new toothpaste formulations. One such model creates lesions in the animal (rats) in the absence of fluoride, and then measures the ability of products to remineralize the lesions (Best, *et al.*, JDR 77 AADR Abst.#1124, 1998).

Other models measure the ability of test products to inhibit lesion formation during the caries development process. This particular study focuses on the latter type of model, in which product efficacy is assessed relative to its ability to inhibit lesion formation.

OBJECTIVE

The purpose of this study was to compare the anticaries efficacy in the rat model of a new so-called 'remineralizing' toothpaste, Enamelon™, with that of Crest®, the clinical 'gold standard'.

RESULTS



CONCLUSION

Under the conditions of this study, the so-called "remineralizing" toothpaste (Enamelon™) was significantly less effective at inhibiting lesion formation than the single phase, NaF "gold standard" (Crest®). These results are consistent with previous animal studies, *in vitro* pH cycling studies, and a human *in situ* evaluation which compared the same two products for anticaries activity.