Fluoridating Efficiency and the Integrity of Product Delivery Systems

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ABSTRACT

Dual phase dentifrice packaging offers the potential for simultaneously delivering active ingredients that are otherwise non-compatible in a single phase tube. Upon being exuded from the tube, phases presumably mix in a pre-determined ratio, then are applied to the teeth. The purpose of this study was to determine if a new, patented, dual phase delivery system maintains the integrity (and thus the anticaries efficacy) of two otherwise non-compatible phases (Ca/F+P) over the sink-life of the tube, relative to a conventional, single phase (F) product. Two *in vitro* pH cycling models were used: 1) a standard pH cycling model (Faller, *et al*: Caries Res. 1991;25:66); and 2) a modified, brushing-pH cycling model that is designed to more closely mimic actual human use of a product. Test products included: a) a conventional, single phase, 1100ppm F (NaF) toothpaste (Crest®); and b) a dual phase toothpaste, containing 1100ppm F (NaF) plus phosphate in one phase and calcium in the other (Enamelon™). For each test product, tubes were tested 'fresh' (not beyond 1/2 empty) or 'used' (first 1/2 of product was squeezed out in ~ 1gram increments, simulating actual use). Thus, 4 test groups were compared. In addition, a 250ppm F (NaF) group was included as a further clinical reference. This product was only tested as a fresh product in the standard pH cycling model. F uptake results (standard model/brushing model) were: Crest®, 1st half: 32.9/26.9, 2d half: 33.2/26.5; Enamelon™, 1st half: 28.1/22.7; 2d half: 21.4/13.5; 250ppm F: 10.5. **The results in both model systems demonstrated no significant difference (p=0.05, LSD) in fluoridating efficiency for the conventional, single phase, NaF toothpaste between the first ½ and second ½ of each tube. However, the second ½ of the dual phase toothpaste was significantly less effective at incorporating F into demineralized enamel than the first ½. These data indicate the fluoridating efficiency of the dual phase product is significantly compromised during the sink life of the product.**

INTRODUCTION

Most currently marketed dentifrices can be tested using relatively routine testing methods, such as our standard pH cycling protocol.

It is possible, as dentifrice technology evolves, that products will be marketed that have a higher level of dependence on the kinetics of the delivery of actives. A testing method that includes a preparation step requiring product:diluent mixtures to mix for a prolonged period of time prior to specimen treatment could result in biased results against a product whose performance is dependent on the kinetics of a reaction occurring within the first minute of mixing. Protocols that closely simulate realistic product usage minimize the possibility of producing results that are a function of the test method rather than true product performance. The brushing/cycling model described in this presentation was created to mimic, as closely as possible, the *in vivo* breakdown of product as it combines with saliva. Data are compared relative to our standard pH cycling model.

MATERIALS AND METHODS

Treatments, Standard model
Crest® first ½ of tube
Crest® second ½ of tube
Enamelon™ first ½ of tube
Enamelon™ second ½ of tube
250 ppm F control dentifrice

Treatments, Brushing model
Crest® first ½ of tube
Crest® second ½ of tube
Enamelon™ first ½ of tube
Enamelon™ second ½ of tube

4mm human enamel chips→

Chips ground and polished to remove outer 50 microns of natural enamel surface→

96 hr carbopol lesion
↓

Treatment Schedule:

1 hr. saliva bath (initial pellicle formed)
1 min. treatment (1:3 slurry of dentifrice:saliva)
1 hr. saliva bath
1 min. treatment (1:3 slurry of dentifrice:saliva)
1 hr. saliva bath
3 hr. exposure to demineralizing solution
1 hr. saliva bath
1 min. treatment (1:3 slurry of dentifrice:saliva)
1 hr. saliva bath
1 min. treatment (1:3 slurry of dentifrice:saliva)
saliva bath overnight

↓ Repeat cycle for 6 days ↓

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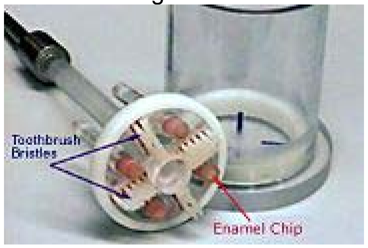
Standard Treatment Model

4 to 5 min. slurry prepared
↓

New Brushing Treatment Model



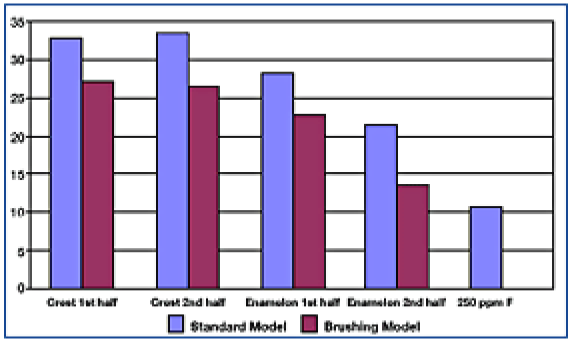
chips treated for 1 min. at the same
time slurry is being prepared
↓

Chips treated with slurry for 1 min.→

Fluoride Uptake by Microdrill Biopsy

RESULTS

The following figure shows fluoride uptake (mg/cm^2) into demineralized enamel from the conventional and the new brushing model.



DISCUSSION

Under the conditions of these two model studies, there was no significant difference in fluoridating efficiency for the two test products containing 1100ppm F. Both products performed significantly better than the 250ppm F control. However, when comparing the performance of the product dispensed from the first half of the tubes to the performance of product from tubes that were half used, the results demonstrated significant differences in product performance for the dual-phase product containing fluoride, calcium and phosphate (Enamelon™), with a dramatic reduction in efficacy noted between the second half of the tubes compared to freshly opened tubes. The results for the conventional, single-phase, NaF product (Crest®) remained consistent throughout this study, as the product has been demonstrated to be a highly fluoride compatible formulation.

CONCLUSION

The results highly suggest the fluoridating efficiency of the dual phase product is significantly compromised during the sink life of the product. These results are consistent with human use data comparing the same products (Abstract # 3083).

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