

# Importance of Testing Product Modifications to assure Fluoride Bioavailability

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## SUMMARY SENTENCE

An *in vitro* fluoride uptake study confirmed the need for all product changes to be properly tested in order to ensure fluoridating efficiency is not lost as a function of formulation modifications.

## BACKGROUND

Our laboratory routinely conducts analyses of marketed fluoride toothpastes in order to compare the relative fluoridating efficiency of the various formulations that are offered for sale to the public. These routine investigations have identified a number of potential problems regarding fluoride bioavailability of various marketed products.

During a recent study in our laboratory comparing the fluoridating potential of currently marketed German dentifrice products, a surprising difference in fluoride (F) uptake between two products (Elmex® and 1100ppm F as NaF) was noticed. Previous testing (Faller, ORCA 1991) suggested these two formulations provide similar levels of F uptake.

An investigation to determine the discrepancy in results between the German comparative study and the 1991 study confirmed a formulation change in the Elmex® toothpaste. The Elmex® product included in the 1991 study contained a combination of two amine fluorides: Cetyl - hydrofluoride + Bis-(hydroxyethyl) - aminopropyl - N - hydroxyethyl - oktadecylamin - dihydro - fluoride in a base of insoluble sodium metaphosphate abrasive, while the currently marketed Elmex® formula contains only Bis - (hydroxyethyl) - aminopropyl - N - hydroxyethyl -oktadecylamin - dihydro - fluoride, formulated with a silica abrasive system.

In order to verify the results of the German comparative study, a third investigation was made. In this third study, we were able to directly compare the currently marketed product with the same batch of product that was tested in the 1991 study; the product having been stored at 35°F since the time of the 1991 study.

## PROTOCOL

Subsurface human enamel specimens were placed in 25ml of a solution containing 0.5M/L lactic acid, 0.2% Carbopol 907 (B.F. Goodrich Co.), 50% saturated with respect to HAP, pH 5.0 for 96 hours at 37°C. After demineralization, specimens were thoroughly rinsed, then analyzed for surface microhardness with a Leitz miniloader tester at a constant load of 200g. Hardness numbers using the Vicker's scale were taken three times on each specimen, then averaged. Specimens were then placed, four to a group, in such a way that the average hardness for each group of specimens was not significantly different. After placing specimens in their respective groups of four, each group was placed in 20ml of fresh, pooled human saliva for a period of one hour to form an initial layer of pellicle on the demineralized enamel surfaces. Dentifrice slurries were prepared by thoroughly mixing 5g of dentifrice with 15g pooled, human saliva for a period of not less than 4, nor more than 5 minutes prior to use. A fresh slurry was prepared for each treatment. Treatments were made four times per day for a total of six treatment days, following the daily treatment schedule pictured below. Upon completion of pH cycling, specimens were analyzed for fluoride content, to a constant depth of 100µm, using the microdrill biopsy technique.

### Daily Treatment Schedule:

- 1 hr. saliva bath (initial pellicle formed) \*
  - 1 min. treatment in 1:3 slurry of dentifrice: saliva \*
  - 1 hr. saliva bath
  - 1 min. treatment in 1:3 slurry of dentifrice: saliva \*
  - 1 hr. saliva bath
  - 3 hr. exposure to demineralization solution
  - 1 hr. saliva bath \*
  - 1 min. treatment in 1:3 slurry of dentifrice: saliva \*
  - 1 hr. saliva bath
  - 1 min. treatment in 1:3 slurry of dentifrice: saliva \*
  - saliva bath overnight \*
- \* indicates fresh saliva used

## RESULTS

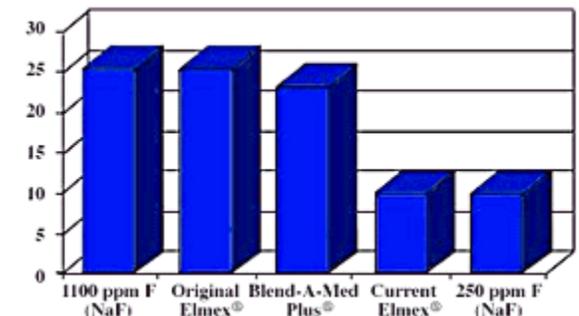
Products Tested	Fluoride Uptake (µg/cm <sup>2</sup> )*
1100ppm F (NaF)	25.5 ± 6.0 **
Original Elmex <sup>®(1)</sup>	25.5 ± 5.2
Blend-a-Med Plus <sup>®(2)</sup>	23.4 ± 5.1
Current Elmex <sup>®(1)</sup>	10.1 ± 2.4
250ppm F (NaF)	9.9 ± 1.4

\* Mean ± S.D. (N=4)

\*\* Values within brackets are not significantly different (p < 0.05) as determined by Least Significant Difference Analysis

(1) Elmex<sup>®</sup> is manufactured by: Wybert Lorrach

(2) Blend-a-Med<sup>®</sup> is manufactured by: Procter & Gamble Co.



## CONCLUSION

-Recent formulation changes in Elmex® toothpaste have resulted in a significant decrease in the ability of the currently marketed product to fluoridate demineralized enamel, relative to the previously marketed formula.

-These data highlight the need for manufacturers to test and confirm that product modifications have not adversely effected the fluoridating ability and thus the anticaries effectiveness, of toothpaste formulations.