

Fluoridating Efficiency of a New Antitartar Toothpaste

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ABSTRACT

The U.S. Food and Drug Administration (FDA) requires manufacturers to confirm the fluoridating ability of new toothpaste formulations relative to clinically proven benchmarks. One method for demonstrating performance, adopted in 1978, is FDA Test Method 40, which calls for the artificial induction of lesions into human enamel, treatment in a toothpaste/saliva (or water) mixture, and an assessment of fluoride incorporation into enamel using a technique known as the acid etch method. A newer method of analysis (microdrill biopsy), allows for the removal of a micro quantity of enamel from each specimen, leaving the remainder available for other assessments (Mobley: J. Dent. Res. 1981). The purpose of this study was to demonstrate the fluoridating efficiency of a new antitartar toothpaste, relative to appropriate controls, using both the acid etch and the microdrill biopsy methods. Test Method 40 protocol was used. Test products were: a) Crest MultiCare Advanced Cleaning Toothpaste (1100ppm F as NaF, polypyrophosphate [antitartar agent]; b) Crest Standard Toothpaste-1100ppm F as NaF; c) 250ppm F (NaF)-dose response control; and d) placebo (0ppm F). Specimens (n=8) were included in each test group, with 4/group analyzed by each method. F uptake values ($\mu\text{g}/\text{cm}^2$) [acid etch/microdrill \pm S.D.] were: a) $19.3 \pm 2.1/16.5 \pm 3.4$; b) $20.8 \pm 1.8/18.7 \pm 0.9$; c) $8.0 \pm 1.2/7.4 \pm 0.7$; d) $4.4 \pm 1.2/3.8 \pm 1.5$. ANOVA (LSD, $p < 0.05$) confirmed $a=b > c > d$ for each method. **These data confirm: 1) the new antitartar toothpaste exhibits fluoridating efficiency that is not significantly different from the clinically proven benchmark; and 2) the comparability of results between acid etch and microdrill biopsy techniques.**

INTRODUCTION

Demonstration of fluoridating efficiency has long been a requirement by regulatory bodies, with decisions to allow products into the market dependent on the ability of a new formulation to provide results equivalent to a clinically proven formulation containing similar base ingredients. In this particular case, in which a formulation has been modified to contain sodium hexametaphosphate (polypyrophosphate) as a non-therapeutic cleaning agent, the appropriate base

formulation for comparison is one containing sodium fluoride as the anticaries agent and silica as the abrasive agent. Laboratory methods designed to demonstrate effectiveness of test products were first introduced into the Caries Monograph in 1978. One such method (Test Method 40) utilizes the acid etch technique for demonstrating fluoride incorporation into artificially demineralized enamel. Time saving methods, such as the microdrill biopsy technique, have been suggested as a replacement for the more labor-intensive acid etch method. The data generated in this study directly compares the original acid etch technique to the newer microdrill biopsy technique, comparing the ability of these two methods to demonstrate fluoride uptake into artificially demineralized enamel.

PURPOSE

The purpose of this study was to demonstrate the fluoridating efficiency of a new antitartar toothpaste, relative to appropriate controls, using both the acid etch and the microdrill biopsy methods.

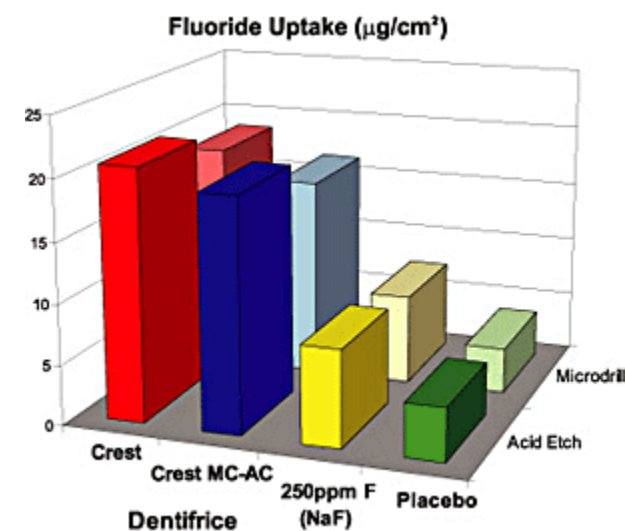
MATERIALS AND METHODS

Treatment protocols with both the acid etch technique and the microdrill biopsy techniques are similar. In this study, eight specimens were treated with each of the four test dentifrices. Four specimens from each group were analyzed using the standard acid etch technique. The additional four specimens were analyzed using the microdrill biopsy procedure. A general protocol noting similarities and differences between the two procedures is noted below (Figure 1.):

RESULTS

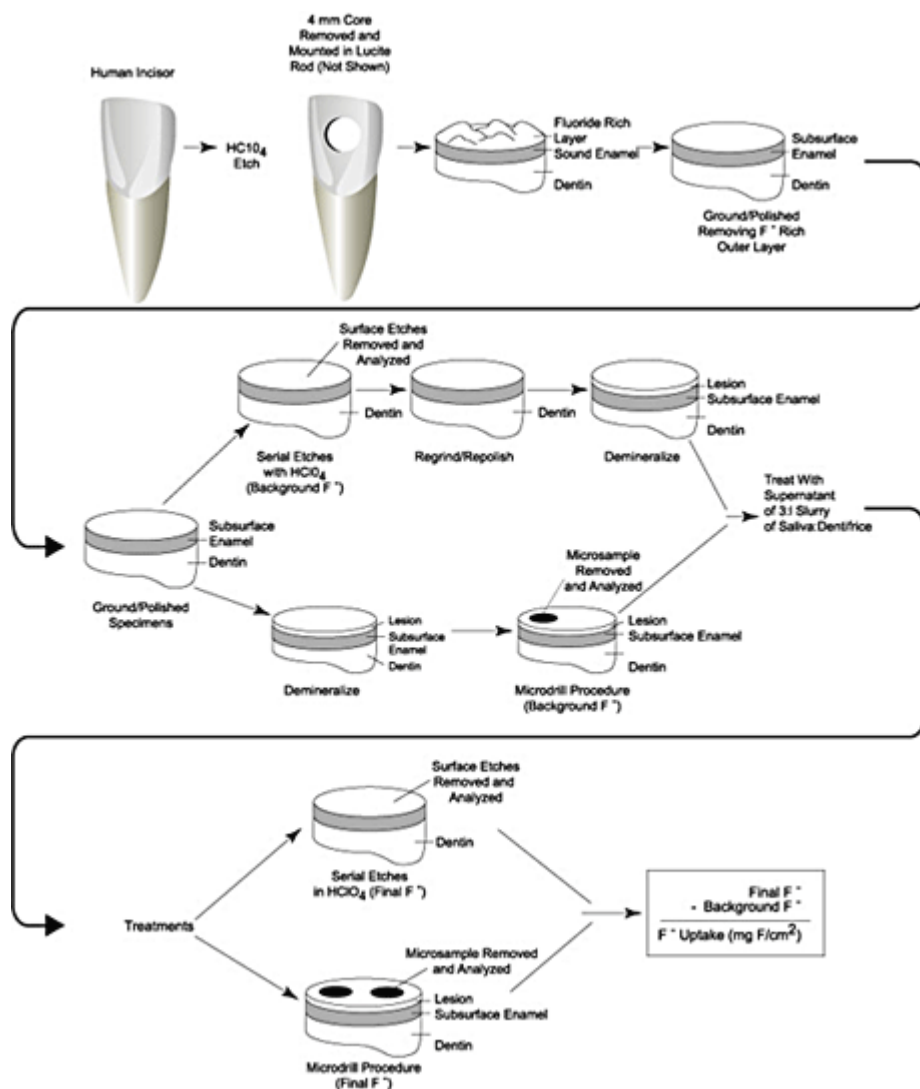
Identical trends with insignificant differences were noted between the acid etch and microdrill biopsy techniques. In the case of the acid etch technique, serial etches of enamel were added together to obtain a net level of fluoride found in the sample. The procedure is time and labor intensive, requiring a number of successive acid etches that must be compiled in order to obtain a total F measure both before and after treatment. In the case of the microdrill biopsy technique, however, the analyst removes a small quantity of sample both before and after the treatment with dentifrice, then dissolves and analyzes the sample immediately. In each method, results can be calculated on the basis of $\mu\text{g}/\text{cm}^2$ of surface sampled. Thus, results can be directly compared between the two methods. The two methods provide similar results in terms of fluoride dose as well as comparison between test products.

DATA



FIGURES AND TABLES

Figure 1.



CONCLUSION

The data confirm the fluoridating efficiency for a new dentifrice formulation containing sodium hexametaphosphate as the antitartar agent, with results equivalent to those provided by the gold standard for anticaries efficacy. Further, the results of the two analytical methods included in this study confirm the similarities between measurements using either the original, acid etch technique or the newer microdrill biopsy method of analysis.