

# 0511. Evaluation of Plaque Fluid Fluoride Retention after Dentifrice Application

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## Introduction

Topical fluorides in a wide variety of delivery systems have been proven to be clinically effective in the prevention of dental caries<sup>1</sup>. It is generally agreed that fluoride elicits its anticaries effect mainly by decreasing the rate of enamel demineralization and enhancing the rate of enamel remineralization<sup>2,3</sup>. Although the relative importance of the direct effects of fluoride on bacterial metabolism (acid production) is still a subject of contention, there appears to be a general consensus that the level of fluoride in plaque, specifically plaque fluid, may be directly related to the anticaries effect of fluoride<sup>4</sup>.

There have been several studies on the kinetics of fluoride in plaque fluid after topical fluoride application. Increased fluoride levels in pooled plaque fluid for 2 hours have been reported after rinsing with 20 mmol/L of sodium fluoride (NaF)<sup>5</sup>. Direct comparisons have also been made of fluoride in plaque fluid after NaF and sodium monofluorophosphate (NaMFP) rinses<sup>6,7</sup>.

In this exploratory study we compare the fluoride levels in plaque fluid after the use of different currently marketed fluoride dentifrice products.

## Objectives

- **Primary:** to compare four toothpastes (different forms of fluoride in different formulations) with respect to the change from baseline levels of fluoride in plaque fluid at various time points following a single use.
- **Secondary:** to determine the change in fluoride levels in plaque fluid at various time points following a single use of each of the four toothpastes.

## Methods

### Clinical procedure

Thirteen subjects participated in this randomized, double-blind, four-leg, crossover comparison of four toothpastes:

- Crest Cavity Protection (1100 ppm fluoride from NaF)
- Aim Cavity Protection (1100 ppm fluoride from NaMFP)
- Colgate Total (1100 ppm fluoride from NaF)
- a fluoride-free (0 ppm fluoride) control.

Two days prior to the start of the study, subjects received a prophylaxis and were instructed to refrain from all oral hygiene procedures. After collection of a baseline plaque sample, occlusal tooth surfaces were brushed with the assigned test toothpaste for 1 minute. Subjects then swished the resultant toothpaste slurry around their entire mouth for 10 seconds, followed with a tap water rinse for 10 seconds. Additional plaque samples were taken at 30 minutes, and 1, 2, and 4 hours post-brushing. Fluoride was analyzed using a previously described microanalytical methodology<sup>7</sup> (Figure 1). After a

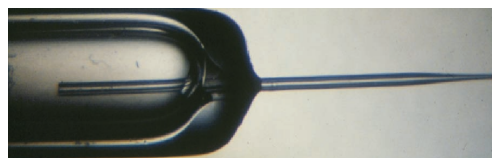


Figure 1. Micro-pipette.

washout period of at least 4 days, subjects returned to the site for a professional cleaning, followed by a 48-hour fluoride-free lead-in before the next test in the randomization scheme.

### Statistical methods

Three replicate fluoride measurements at each time point were averaged to obtain an average fluoride level at each time point for each subject. These values were natural logarithm transformed and used to calculate change from baseline fluoride levels. The statistical significance of the mean change from baseline was tested for each treatment group. Treatment groups were compared at each post-brushing time point. The analysis of covariance adjusted for baseline and treatment leg using a linear model that included treatment sequence and subject (a random factor). There was a statistical test for carryover.

## Results

- Comparisons of fluoride test toothpastes with control (0 ppm fluoride)
  - All fluoride toothpastes showed increases in plaque fluid fluoride levels from baseline and were directionally better than the control at all time points, with the exception of Aim at 4 hours.
  - All fluoride toothpastes had statistically significantly higher levels of fluoride than the control at 30 minutes and 1 hour post-brushing (Table 1).
  - At 2 hours post-brushing, the only study toothpaste that was statistically significantly better than the control was Crest.
- Comparisons among fluoride toothpastes
  - Crest versus Aim: Crest was directionally better than Aim at all time points post-brushing, but statistically significantly better at 30 minutes, 2 hours, and 4 hours post-brushing.
  - Crest versus Colgate Total: Crest was directionally better than Colgate Total at all time points post-brushing, but only statistically significantly better at 2 hours post-brushing.
  - Colgate Total versus Aim: Colgate Total was directionally better than Aim at all post-brushing time points, but not statistically significantly different at any of the time points.

- Plaque fluid fluoride levels for the NaF treatments (Crest and Colgate) were directionally better than Aim, which contains NaMFP. These findings are consistent with results from similar published studies<sup>6,7</sup>.
  - NaMFP requires hydrolysis via salivary phosphatase enzymes to release fluoride (as the free ion), whereas NaF does not. It is this hydrolysis step that is theorized to be the primary reason why formulations containing NaMFP typically show lower fluoride retention levels than similar NaF-containing formulations.

Table 1. Ratio\* of Post-Brushing Average Fluoride Level in Plaque Fluid to Pre-Brushing (Baseline) Fluoride Level in Plaque Fluid (Treatment Ratio/0 ppm Fluoride Ratio)

Post-brushing sample time	Crest	Aim	Colgate Total	0 ppm fluoride
30 minutes	4.69 (4.32) <sup>†</sup>	2.59 (2.38) <sup>†</sup>	3.73 (3.43) <sup>†</sup>	1.09
1 hour	2.09 (1.90) <sup>†</sup>	1.77 (1.61) <sup>†</sup>	2.04 (1.85) <sup>†</sup>	1.10
2 hours	1.84 (2.10) <sup>†</sup>	1.10 (1.25)	1.20 (1.36)	0.88
4 hours	1.15 (1.27)	0.73 <sup>‡</sup> (0.81)	1.02 (1.14)	0.90

\*Back-transformed from the natural logarithm scale using the estimate of mean change from baseline (in scale) taken from the statistical model.

<sup>†</sup>Statistically significant change from baseline (two-tailed  $p \leq 0.05$ ); the ratio for the treatment toothpaste was statistically significantly greater than the ratio for the 0 ppm fluoride toothpaste (two-tailed  $p \leq 0.05$ ).

<sup>‡</sup>Statistically significant change from baseline (two-tailed  $p \leq 0.05$ ); the post-brushing fluoride level was less than that at pre-brushing.

## Conclusion

- The consistent plaque fluoride clearance kinetics shown by this microanalytical technique demonstrates the utility of the methodology for future investigations.

## References

1. Mellberg JR, 1990. Evaluation of topical fluoride preparations. *J Dent Res* 69 (Special Issue):771-9.
2. Margolis HC, Moreno EC, 1990. Physicochemical perspectives on the cariostatic mechanisms of systemic and topical fluorides. *J Dent Res* 69 (Special Issue):606-13.
3. Featherstone JDB, 1990. Discussion of session II: fluoride and the caries process. Proceedings of a Joint IADR/ORCA International Symposium on Fluorides: Mechanisms of Action and Recommendations for Use, 1989. *J Dent Res* 69 (Special Issue):634-6.
4. Ekstrand J, Oliveby A, 1999. Fluoride in the oral environment. *Acta Odontol Scand* 57:330-3.
5. Tatevossian A, 1978. Distribution and kinetics of fluoride ions in the free aqueous and residual phases of human dental plaque. *Arch Oral Biol* 23:893-8.
6. Ekstrand J, 1997. Fluoride in plaque fluid and saliva after NaF or MFP rinses. *Eur J Oral Sci* 105:478-84.
7. Vogel GL, Mao Y, Chow LC, Proskin HM, 2000. Fluoride in plaque fluid, plaque, and saliva measured for 2 hours after a sodium fluoride monofluorophosphate rinse. *Caries Res* 34:404-11.

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