



# 0502 Efficacy of Marketed Dentifrices Using an *In situ* Caries Model

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## Objective

To compare the enamel fluoride uptake and remineralization potential of two commercially available dentifrices – containing either sodium fluoride/silica or sodium monofluorophosphate/sodium fluoride/dicalcium phosphate.

## Materials and Methods

### Study design

Forty-eight subjects participated in this 4 test period crossover and laboratory evaluator-blinded study. There was a 1-week washout period between each test leg, during which a dental prophylaxis was administered, followed by 2–3 days' use of a non-fluoride dentifrice. Subjects' mandibular partial dentures were modified to hold partially demineralized enamel specimens in the buccal flange. Each test dentifrice was used twice a day for a 2-week period.

### *In situ* Caries Model



### Test Dentifrices

Designation	Treatment
675 ppm F	Aquafresh Fresh 'n Minty toothpaste containing 675 ppm F from sodium fluoride in a silica base
<b>1350 ppm F*</b>	<b>Aquafresh Fresh 'n Minty toothpaste containing 1350 ppm F from sodium fluoride in a silica base (UK marketed)</b>
2700 ppm F	Aquafresh Fresh 'n Minty toothpaste containing 2700 ppm F from sodium fluoride in a silica base
<b>Colgate*</b>	<b>Colgate Cavity Protection, Regular Flavor toothpaste containing 1450 ppm F (1000 ppm F from sodium monofluorophosphate, 450 ppm F from sodium fluoride) in a dicalcium phosphate base (UK marketed)</b>

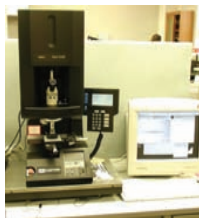
\*Marketed dentifrice products are in bold; the other two dentifrice treatments were included as dose-response controls to validate the model.

### Analytical methods

The surface microhardness (SMH) test was used to assess changes in the mineral status of partially demineralized enamel specimens.

Enamel fluoride uptake (EFU) of partially demineralized enamel specimens was determined using the microdrill enamel biopsy technique<sup>1</sup>.

Wilson 2100 Hardness Tester



Custom-Made Microdrill



## Results

### Summary of %SMH Recovery Scores and Least Square Means: Evaluable Subjects

Treatment	Raw Score Summary			Least Square Means*		95% Confidence Interval*	
	N	Mean	Standard Deviation	Mean	Standard Error	Lower Endpoint	Upper Endpoint
675 ppm F	39	39.89	17.64	39.56	3.39	32.59	46.54
1350 ppm F	39	45.74	19.42	45.69	3.39	38.71	52.66
2700 ppm F	39	51.31	20.92	51.59	3.39	44.61	58.57
Colgate	39	39.32	18.59	38.75	3.39	31.77	45.73

\*The least square means, standard error, and 95% confidence intervals for %SMH Recovery scores were obtained from an analysis of variance that included the factor sequence order, subject within sequence order, treatment, and period. Calculations were performed using SAS PROC MIXED.

### Summary of Fluoride Uptake Scores and Least Square Means: Evaluable Subjects

Treatment	Raw Score Summary			Least Square Means*		95% Confidence Interval*	
	N	Mean	Standard Deviation	Mean	Standard Error	Lower Endpoint	Upper Endpoint
675 ppm F	39	14.99	8.23	15.10	1.37	12.24	17.96
1350 ppm F	39	22.51	12.97	22.48	1.84	18.77	26.20
2700 ppm F	39	29.55	16.48	29.50	2.27	24.94	34.06
Colgate	39	13.25	6.30	13.41	1.47	10.33	16.50

\*The least square means, standard error, and 95% confidence intervals for Fluoride Uptake scores were obtained from an analysis of variance that included the factor sequence order, subject within sequence order, treatment, and period. Calculations were performed using SAS PROC MIXED and adjusted to include a provision for the unequal variability in the treatment groups through the addition of a REPEATED statement.

### Summary of Between-Treatment Comparisons with Respect to %SMH Recovery Scores and Fluoride Uptake Scores: Evaluable Subjects

	%SMH Recovery*	Fluoride Uptake**
675 ppm F vs 1350 ppm F	0.0055	<0.0001
675 ppm F vs 2700 ppm F	<0.0001	<0.0001
675 ppm F vs Colgate	0.7065	0.0952
1350 ppm F vs 2700 ppm F	0.0073	0.0040
<b>1350 ppm F vs Colgate</b>	<b>0.0018</b>	<b>&lt;0.0001</b>
2700 ppm F vs Colgate	<0.0001	<0.0001

\*Two-tailed p-values from pairwise treatment comparisons with respect to %SMH Recovery scores were obtained from an analysis of variance that included the factor sequence order, subject within sequence order, treatment, and period. No adjustment to p-values was made for multiplicity as the primary objective of the study was to compare the two marketed dentifrices. Calculations were performed using SAS PROC MIXED.

\*\*Two-tailed p-values from pairwise treatment comparisons with respect to Fluoride Uptake scores were obtained from an analysis of variance that included the factor sequence order, subject within sequence order, treatment, and period. No adjustment to p-values was made for multiplicity as the primary objective of the study was to compare the two marketed dentifrices. Calculations were performed using SAS PROC MIXED and adjusted to include a provision for the unequal variability in the treatment groups through the addition of a REPEATED statement.

## Conclusion

This *in situ* study demonstrated that a dentifrice containing 1350 ppm F from sodium fluoride/silica base had significantly greater remineralization potential and fluoride uptake than a dentifrice containing a combination of 1000 ppm F from sodium monofluorophosphate and 450 ppm F from sodium fluoride in a dicalcium phosphate base.

A dose response was demonstrated for the sodium fluoride dentifrices.

## Reference

1. Sakkab NY, Cilley WA, Haberman JP, 1984. Fluoride in deciduous teeth from an anti-caries clinical study. *J Dent Res* 63:1201-5.

## Acknowledgment

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