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ABSTRACT

Objective: The objective of this study was to determine the enamel remineralization potential and fluoride bioavailability of three dentifrices, a negative control with 0% fluoride (NC), Crest® Cavity Protection containing 0.243% Sodium Fluoride (PC) and TheraBreath® Whitening with 0.243% Sodium Fluoride and 20% Sodium Bicarbonate (TBW).

Methods: This single-center, randomized, double-blind, 3x3 cross-over study investigated three dentifrices over three 9-day test periods. Subjects ≥18 years of age wore an acrylic palatal dental appliance day and night with 4 demineralized human enamel specimens. During each test period, enamel specimens were exposed daily to a two-minute dentifrice treatment morning and night and three separate ex vivo 10-minute sucrose challenges. During washout period of ≥4 days, subjects brushed twice daily with a fluoride-free dentifrice. On the last day of each test period, specimens were assayed for percent Surface Microhardness Recovery (%SMHR) and enamel fluoride concentration (EFC) using a microdrill biopsy technique. Treatment comparisons were performed by ANCOVA [%SMHR, α=0.05] and ANCOVA [enamel fluoride concentration, α=0.05].

Results: Thirty-one subjects were randomized to a treatment sequence, and 27 subjects completed all phases of the study. TBW provided significantly greater (p<0.001) mean ± SD %SMHR (35.9 ± 8.4) compared to NC (11.2 ± 4.3). EFC concentration was significantly higher for TBW (1687.6 ± 573.6) compared to NC (257.1 ± 119.6) with p<0.001. PC exhibited statistically significantly greater change in %SMHR vs NC and EFC compared to the negative control. The %SMHR mean and mean EFC for TBW were significantly greater than the mean of the negative control and positive control toothpastes, p<0.001 and p<0.026, respectively.

Conclusion: In this in situ study, the anti-caries efficacy of TheraBreath® Whitening was “as good as” that of the respective comparative benchmark toothpaste (Crest® Cavity Protection).

METHODS

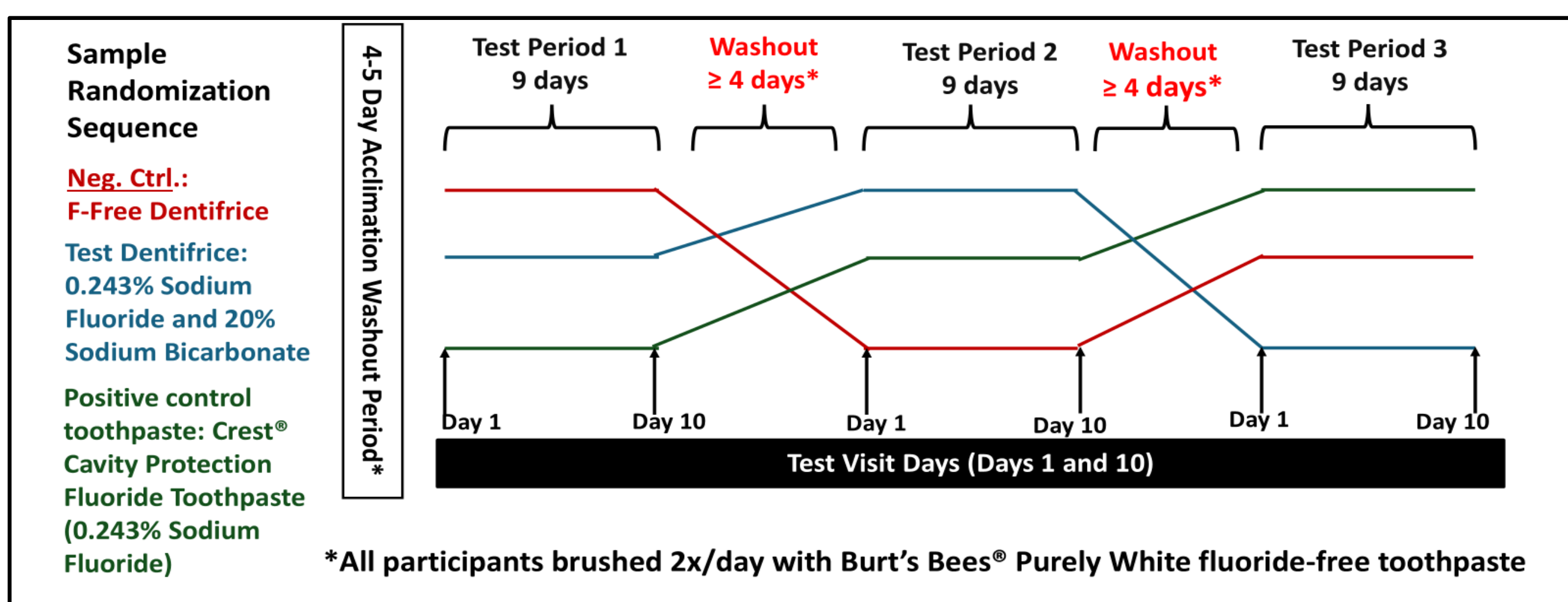
Key Inclusion Criteria:

- ≥18 years of age; generally healthy; able to provide informed consent
- Sufficient maxillary dentition (≥16 teeth) to support a palatal appliance
- Adequate salivary flow (≥1.5 mL unstimulated saliva in 5 minutes)
- No advanced periodontal disease, oral pathology, or untreated caries

Treatment Groups:

- Negative control dentifrice: 0% fluoride (Burt’s Bees® Purely White)
- Positive control dentifrice: 0.243% NaF (Crest® Cavity Protection)
- Test dentifrice: 0.243% NaF and 20% NaHCO₃ (TheraBreath® Whitening)

Fig. 1 Overall Study Design



Intraoral Palatal Appliance:

For each test period, participants wore a custom acrylic palatal appliance with 4 demineralized enamel specimens. Specimens were covered with steel gauze to promote plaque accumulation & secured with dental floss & soft dental wax. See Fig. 2

Fig. 2 Palatal Dental Appliance



Enamel Specimen Preparation:

- Extracted human teeth collected with informed consent (Indianapolis, IN)
- Enamel cores prepared (3 mm diameter; 1.5–2.5 mm length)
- Sterilized by autoclaving; rinsed with deionized water
- Mounted in acrylic rods, polished, and screened for defects
- Baseline surface microhardness measured by Knoop indentation (50g, 15s; 5 indentations/specimen)

In-Situ Oral Appliance Phase (9 days):

- Worn day and night by participants (removed only for meals & ex vivo sucrose challenges)
- Twice daily, 2-minute toothbrushing and rinsing with toothpaste slurry
- Appliance removed for ex vivo 10% sucrose challenge (10 minutes, 3x daily)
- Safety assessed with respect to Adverse Events (AEs) and oral tolerability

Laboratory Analysis:

- Day 10, appliances retrieved for specimen extraction & analyses
- Percent Surface Microhardness Recovery^{1,2} (%SMHR):

$$\% \text{ SMHR} = \frac{(D1 - R)}{(D1 - B)} \times 100$$
 B = baseline indentation length
 D1 = 1st in-vitro post-demineralization length
 R = in-situ post-remineralization length
- Post-treatment enamel fluoride concentration³ (EFC): measured using a - microdrill enamel biopsy technique



Treatment comparisons for both %SMHR and EFC were performed by ANCOVA with α=0.05.

Action standards required p<0.05 for all three comparisons:

- Positive control vs negative control, to validate the test
- Test vs negative control, to demonstrate superiority to negative control
- Test vs the average of positive & negative controls (Non-inferiority Threshold), to demonstrate non-inferiority to positive control.⁴ See Fig. 3 & 4

RESULTS

Demographics:

- Thirty-one subjects were screened and randomized; 27 completed all phases of the study
- Mean age of 45.5 ± 13.6 years (range 27–75); sex: 67% female, 33% male

Safety:

No treatment-related oral AEs were observed. Three AEs were reported, all unrelated to study products; One mild AE related to the oral appliance, and the participant completed the study.

Measure	Comparison	p-value	Conclusion
% SMHR	Positive Control to Negative Control	<0.001	Test Valid
	TheraBreath to Negative Control	<0.001	Superior to Negative Control
	TheraBreath to Average of Positive and Negative Controls	<0.001	Non-inferior to Positive Control
EFC	Positive Control to Negative Control	<0.001	Test Valid
	TheraBreath to Negative Control	<0.001	Superior to Negative Control
	TheraBreath to Average of Positive and Negative Controls	0.026	Non-inferior to Positive Control

Fig. 3 Percent Surface Microhardness Recovery

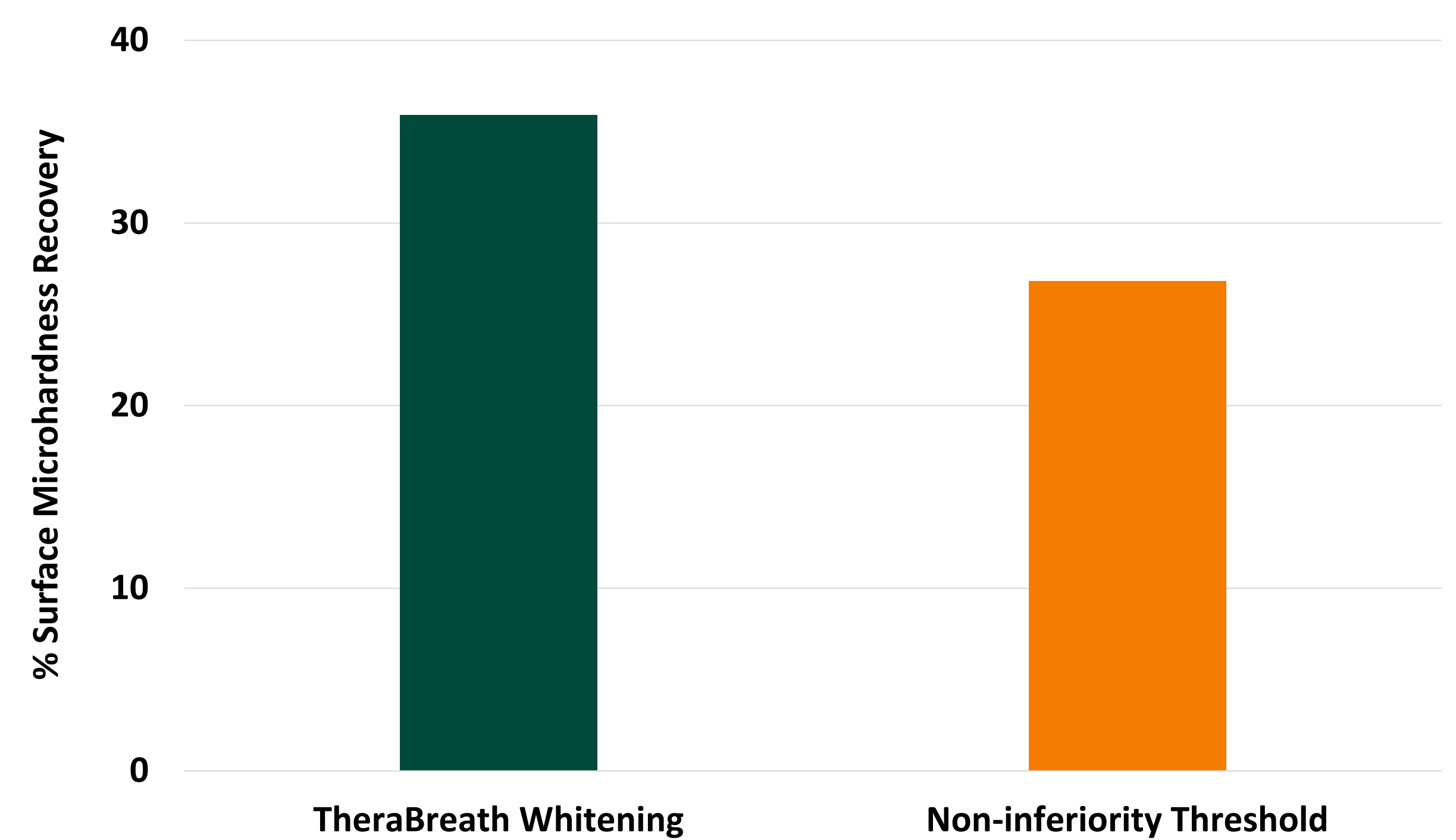
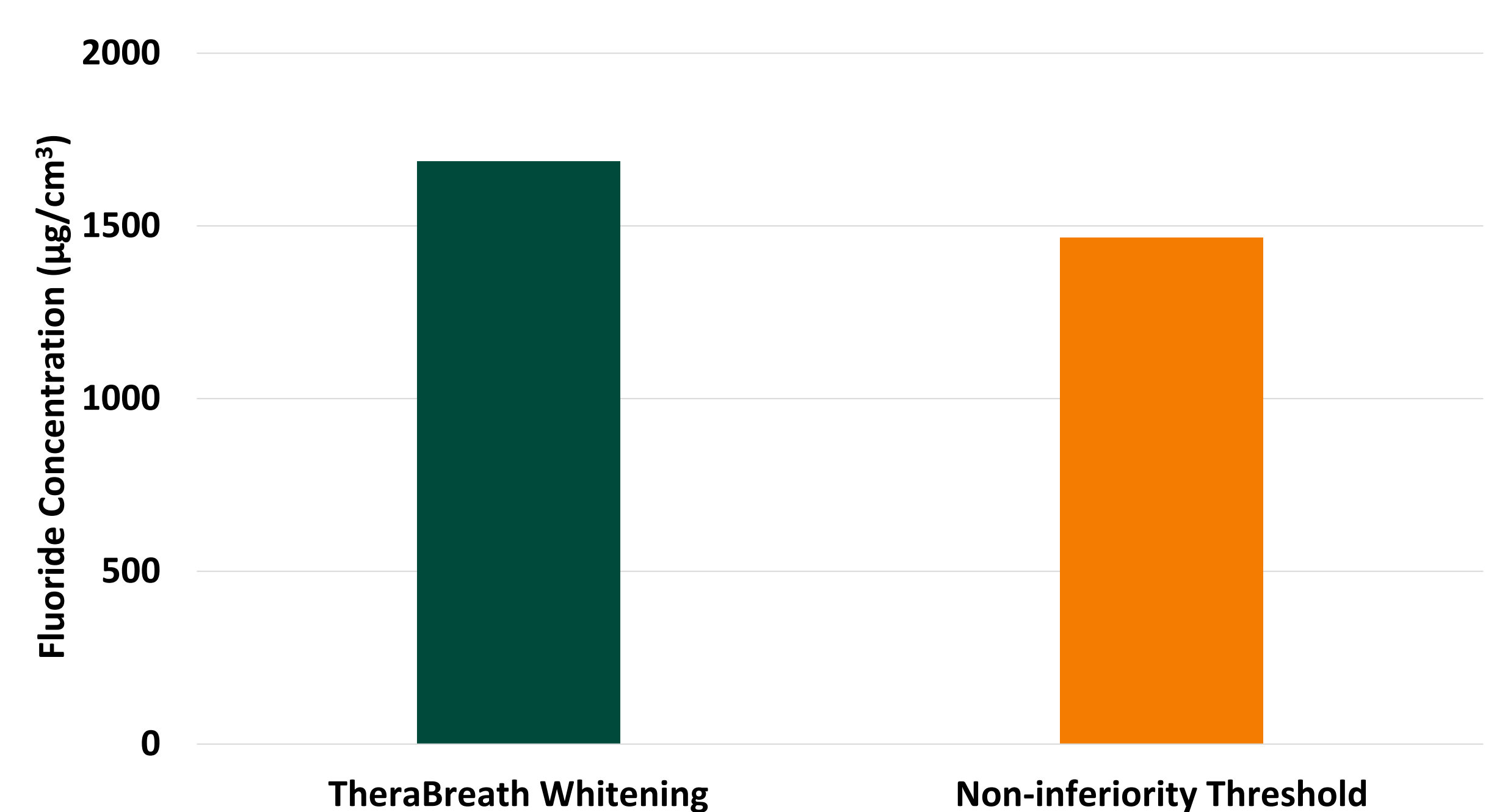


Fig. 4 Enamel Fluoride Uptake



CONCLUSIONS

- This study demonstrated that TheraBreath® Whitening dentifrice with 0.243% Sodium Fluoride + 20% Sodium Bicarbonate can provide enamel remineralization and fluoride uptake.
- This study confirms that TheraBreath® Whitening dentifrice delivers anticavity benefits.
- All dentifrice formulations were well-tolerated.

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