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Friday, June 27

1802
New pH-cycling Model Discriminates among High-concentration Fluoride Products

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Laboratory demin/remineralization models have been used successfully to evaluate the likely efficacy of fluoride (F) toothpastes with 1100 ppm F or less, but these have not been able to differentiate among higher F concentrations. **Objective**: To design and test a new pH-cycling model that would demonstrate a fluoride dose response and discriminate between 1100 and 2800 ppm F. **Methods**: A series of experiments led to the following model. The mineralizing solution composition was formulated based upon analyses of natural saliva with the same Ca/P ratio but with a lower degree of supersaturation. Crowns of human molars (15 teeth/group, based on power analyses) were subjected to 14 days of alternating demineralization (6hr, pH 4.3, acetate, 2.0 mM Ca and P) and remineralization (17 hr, pH 7.0, 0.8 mM Ca, 2.4 mM P) with dentifrice treatment (1:3 slurry in DDW) 2x daily for 1 minute each (before and after the demin period). F dose response dentifrice formulations (NaF in hydrated silica abrasive) were: a) 250 ppm F, b) 1100 F, c) 2800 F, d) 5000 F. Results were assessed by cross-sectional microhardness, and mineral loss was calculated (ΔZ, vol. % mineral x μm). **Results**: Mean ± SD ΔZ values were: a) 2846 ± 967; b) 1689 ± 801 ; c) 712 ± 604; d) 485 ± 168, with a > b> c = d ($p < 0.05$ ANOVA/Tukey). The dose response for log F versus ΔZ was linear (r squared = 0.990). **Conclusions**: This new pH cycling model readily discriminates between 1100 and 2800 ppm F in dentifrice formulations and has an excellent fluoride dose response.

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Fluoride Dose Response and Discrimination in a Modified De/Remineralization Model

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In vitro pH cycling studies have been shown to be useful tools in the anticaries assessment of various toothpaste formulations (Featherstone, et al, 1988, 1989, 1992). **Objective**: To establish a fluoride dose response in a modified de/remineralization model and to test the model's ability to discriminate ineffective products. **Methods**: Crowns of human molars (10 teeth/group) were subjected to 14 days of alternating demineralization (6hr, pH 4.4, Ca/P/acetate) and remineralization (17 hr, pH 7, Ca/P) with dentifrice treatment (1:3 slurry in DDW) 2x daily for 1 minute each (before and after the demin period). F dose response dentifrice formulations (NaF in hydrated silica abrasive) were: a) 1100 ppm F, b) 650 F, c) nominal 250 F {actual 360}, d) placebo (approx 2 ppm F). Formulations compared were e) 1100 F plus 3.3% pyrophosphate anti-tartar, and f) 1100 F as NaF in a calcium carbonate abrasive system. Results were assessed by cross-sectional microhardness, and mineral loss was calculated (ΔZ, vol. % min x μm). **Results**: Mean ± SD ΔZ values were: a) 965 ± 396; b) 1106 ± 364; c) 2182 ± 585; d) 4506 ± 870, with a = b < c < d ($p < 0.05$ ANOVA/Tukey). The dose response for log F versus ΔZ was linear (r squared = 0.960). The clinically proven antitartar formulation (e), and the F/calcium carbonate (f) ΔZ values were 596 ± 281 and 1591 ± 352 respectively with a=e < f = c < d ($p < 0.05$). As expected the calcium carbonate markedly reduced the fluoride efficacy. **Conclusions**: This new pH cycling model shows a clear fluoride dose response and is able to discriminate a clinically inferior fluoride dentifrice formulation. The method shows promise as an alternative to animal models in anti-caries fluoride product evaluations.