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Thursday, March 17
1476 Instant Sensitivity Relief of a Stannous-containing Sodium fluoride Dentifrice

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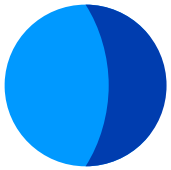
Objectives: To evaluate the effect of a stannous-containing sodium fluoride dentifrice in the reduction of dentinal hypersensitivity relative to a negative control.

Methods: This was a 3-day, parallel-group, examiner-blind, randomized and controlled clinical trial. A total of 88 healthy adults with at least two teeth demonstrating moderate hypersensitivity were enrolled into the study. Following baseline examinations, subjects were randomly assigned to one of the two test products: an experimental Stannous-containing sodium fluoride dentifrice (0.321% Sodium fluoride) or a negative control dentifrice (Colgate Cavity Protection®). Subjects performed their first product use on site and then used the product at home, according to the manufacturer's usage instruction, twice daily over the 3-day period. Subjects in the experimental dentifrice group brushed the sensitive tooth first for 30 seconds. Safety and efficacy (tactile evaluation using Yeaple Probe by an experienced examiner and thermal evaluations based on Schiff Air Index by the same examiner and Visual Analog Scale -VAS by the study subjects) measurements were made at Baseline and Day 3. Immediately following the first product application, thermal evaluations were performed to allow for instant sensitivity relief assessment. All statistical comparisons were two-sided at the 0.05 level of significance.

Results: Immediately following the first product application, the experimental dentifrice resulted in statistically significantly lower mean thermal sensitivity scores as assessed by both the examiner ($p=0.0004$) and the study subjects ($p<0.0001$) when compared to the negative control. At Day 3, the experimental dentifrice provided statistically significantly lower mean thermal sensitivity scores ($p<0.0001$ for both Schiff air index and VAS) and significantly higher pressure tolerance ($p<0.0001$ for Yeaple probe) against the negative control. All test products were well tolerated.

Conclusions: The research demonstrated the instant hypersensitivity relief benefit of the stannous-containing sodium fluoride dentifrice relative to the negative control dentifrice.



Friday, March 18
2042 Measurement Reproducibility of L*a*b* Tooth Color with Digital Image Analysis

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Objective: This research assessed reproducibility of a digital image analysis method used to measure natural tooth color.

Methods: After training, a naïve operator collected replicate tooth color measures from 20 healthy dentate adult volunteers over a two-day period. At each visit, subjects were oriented using a chin rest, and images were collected using a high resolution digital camera (JVC CCD), zoom lens and fixed lighting conditions. Paired images were captured over two days to assure subject repositioning as part of the reproducibility assessment. With each image, maxillary anterior tooth pixels were classified and counted, and average L*a*b* tooth colors were derived using standard methods. Intra-class correlations (ICC) and 95% lower confidence bounds (LCB) were calculated on a 0-to-1 scale, where 0 represented no agreement and 1 represented perfect agreement.

Results: The 20 subjects ranged from 19-60 years of age, and all subject data were included in the analyses. For area, tooth pixel count means were 106,139 and 106,212 at Days 1 and 2, differing by less than 0.07%. For color, the Day 1 means (SE) were 15.82 (0.63) for b*, 74.32 (0.79) for L*, and 5.85 (0.20) for a*. At Day 2, b*L*a* means (SE) were 15.63 (0.67), 73.96 (0.78), and 5.75 (0.20), respectively. The measurements exhibited appreciable reproducibility across visits. The ICC (95% LCB) for pixel count was 0.978 (0.953). The ICC (95% LCB) was 0.985 (0.967) for b* yellowness, 0.982 (0.948) for L* lightness, and 0.971 (0.930) for a* redness.

Conclusion: Use of digital image analysis demonstrated highly reproducible clinical measurements of tooth area (pixels) and color (L*a*b*) parameters from research conducted in a clinical trials setting.

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