

Poster Presentations - Research Supported by P&G

Saturday, March 11



1647

Clinical Trial Comparing Peroxide Whitening Pre-Rinse and Negative Control

G. KUGEL², S. FERREIRA², S. SHARMA², M.L. BARKER¹, and R.W. GERLACH¹

¹ P&G, Mason, OH, USA

² Tufts University, Boston, MA, USA

Objective: This randomized, double-blind, parallel-group, clinical trial evaluated the efficacy and safety of a whitening pre-brushing mouthrinse compared to a negative control (water rinse). **Methods:** 29 subjects were randomly assigned to either a 2% hydrogen peroxide, alcohol-containing pre-rinse (Listerine® Whitening Pre-Brush Rinse) or a water control. Both groups used 15 mL of the assigned rinse (peroxide-containing or water) for 60 sec twice daily over a 16 day period. Subjects were evaluated at Baseline and again at Days 8 and 17. Tooth color ($L^*a^*b^*$) was measured objectively from standardized digital images of the maxillary anterior teeth, while safety was assessed from clinical examination and subject report. **Results:** Mean (SD) age of the study population was 33 (10.4), 79% of whom were female. At the intermediate visit Day 8, groups did not differ significantly ($p > 0.36$) with respect to change in yellowness (Δb^*) or brightness (ΔL^*). There was no evidence of incremental color improvement from Day 8 to Day 17. At that end-of-treatment visit, mean (SE) Δb^* was 0.04 (0.12) for the peroxide pre-rinse compared to 0.28 (0.13) for the water control. For brightness, mean (SE) ΔL^* was 0.11 (0.14) and 0.12 (0.15) for the peroxide rinse and control groups, respectively. At Day 17, treatments did not differ significantly ($p > 0.17$) with respect to either Δb^* or ΔL^* . Water rinsing was well-tolerated, with no product-related symptoms or clinical findings. The most common adverse event was oral irritation, primarily tongue and mouth burning. This was reported by 60% of subjects in the peroxide pre-rinse group versus 0% in control, with groups differing significantly ($p = 0.0007$). **Conclusion:** While there were no between-group differences in whitening effectiveness, twice daily use of a peroxide alcohol mouthrinse resulted in additional reported oral irritation relative to water rinsing.

Saturday, March 11



1651

Clinical Trial of Laser-Aided, In-Office Tooth Whitening

J.F. SIMON¹, J. HARRISON¹, M.A. LACKEY¹, M.L. BARKER², and R.W. GERLACH²

¹ University of Tennessee, Memphis, USA

² P&G, Mason, OH, USA

Objectives: This clinical study evaluated a laser-aided, in-office tooth whitening system, in order to assess the contribution of the laser to the overall whitening response. **Methods:** 22 adults were randomly assigned to either the BIOLASE LaserSmile™ system using the peroxide gel with laser activation, or the peroxide gel alone without laser activation. After gingival protection, the peroxide gel was professionally-applied on the maxillary and mandibular anterior teeth, followed by the laser (one group only). The peroxide gel was removed by rinsing with air/water spray, and the entire process was repeated. Efficacy was measured objectively as $L^*a^*b^*$ color change using digital images of the anterior teeth immediately after treatment, and at post-treatment Days 7 and 30. **Results:** Subjects ranged from 18-58 years of age. Immediate (end-of-treatment) adjusted means (SE) for Δb^* yellowness were -1.3 (0.17) for the gel+laser group compared to -1.1 (0.15) for the gel alone. Both groups exhibited significant ($p < 0.05$) rebound over time. At 30 days post-treatment, adjusted means (SE) for Δb^* were -0.8 (0.13) for the gel+laser group compared to -0.5 (0.12) for the gel alone. Groups did not differ significantly ($p > 0.40$) in immediate or 30-day post-treatment Δb^* , or other color parameters. While there were no significant contributions of the laser to efficacy, occurrence of tooth sensitivity was significantly ($p < 0.03$) higher in the gel+laser group (70%) compared to the gel group alone (17%). **Conclusion:** Use of a laser for in-office treatment did not contribute significant incremental tooth whitening, but did result in additional tooth sensitivity versus a peroxide gel without laser activation.