P&G Oral Presentations

Thursday, March 4

83 Image Analysis of Tooth Whitening: Standard Development and Method Application

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Objectives: Tooth color standards for digital image analysis were developed from a large clinical database and applied in a prospective, randomized, negatively controlled trial to assess validity. **Methods:** A meta-analysis was conducted involving digital images of tooth color from 4418 subjects in 90 clinical studies. RGB values of teeth were mapped to L*a*b* values with multiple regression (r^2 > 0.981) using new color standards (Munsell) that were developed to encompass the tooth color region. These standards were then applied in a prospective clinical trial where adults were randomized to 10% hydrogen peroxide strips (Crest® Whitestrips® Premium) and regular anticavity paste (strips + dentifrice group) or negative control (dentifrice group). Strips were applied twice daily on only the maxillary arch, and both groups used the assigned dentifrice over a 1-week period. Tooth color was measured separately for the anterior maxillary and mandibular teeth at Baseline and Day 8 with a JVC KY-F75U CCD camera system. Analysis of covariance was used to compare group responses on both the strip-treated and untreated arches. **Results:** 26 subjects, 27-62 years of age, completed the prospective study. Relative to the control, the strips + dentifrice group demonstrated significant ($p < 0.0001$) mean improvements in yellowness (–1.95 Δb*) and lightness (1.76 ΔL*) on the strip-treated maxillary arch at Day 8. Response on the mandibular control arch was ± 0.19 color units and not significantly ($p > 0.48$) different. Measurements of color standards were highly repeatable and reproducible with intra-class correlations exceeding 0.987. **Conclusions: Color standards were developed to map RGB tooth color to L*a*b*, and then used in prospective clinical testing to appropriately measure tooth color change with 10% hydrogen peroxide strips and no significant change with the negative control.**

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84 Meta-analysis of Tooth Whiteners: High-Adhesion Strips Versus Professional Products

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Objectives: This analysis was conducted to systematically evaluate the clinical effectiveness and safety of 19 peroxide-based whitening systems. **Methods:** A meta-analysis was conducted using an inclusive dataset from 16 randomized clinical trials involving 11 professionally dispensed (at-home) trays and strips, 7 professionally administered (in-office) light, laser and gel systems and 1 retail high dhesion whitening strip product. All studies used similar entrance criteria and methods, with efficacy measured objectively as L*a*b* color change using digital image analysis, and safety assessed from examinations and interviews. Treatments varied with respect to peroxide form, concentration and dose, daily regimen, total days of use and administration (at-home or in-office). For the meta-analysis, subject level data were pooled and adjusted mean color improvements were estimated for each product using a general linear mixed model adjusting for age and baseline color. **Results:** The pooled sample included 455 subjects, 18-66 years of age. Baseline b* color ranged from 12.2 to 23.3, and baseline L* color ranged from 64.0 to 79.1. The retail high-adhesion whitening strips had adjusted end-of-treatment Δb* and ΔL* means of –2.31 and 1.76, respectively. For the 18 professional systems, the adjusted end-of-treatment means for Δb* ranged from –0.80 to –4.58 and the adjusted end-of treatment means for ΔL* ranged from 1.02 to 4.43, with medians of adjusted means equal to -1.77 and 1.44 for Δb* and ΔL* respectively. Tooth sensitivity and oral irritation occurred most frequently and accounted for 26% and 18%, respectively across all products with approximately 0.6% of subjects discontinuing treatment due to these events. **Conclusion: An inclusive meta-analysis showed that use of retail high adhesion whitening strips provided whitening efficacy comparable to the median response of 18 professionally dispensed and administered treatments.**

Research presented at the
39th Annual Meeting of the AADR, March 3-6, 2010, Washington, D.C.
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