Research Supported by P&G

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Clinical Study Evaluating the Short-term Stain Removal Effects of a Direct Application Bleaching Film and Whitening Toothpaste

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Objectives: The aim of the study was to compare the short term effectiveness of a new tooth bleaching system at removing tooth stain versus a commercially available whitening toothpaste. **Methods**: A randomized, parallel group, examiner-blind, placebo controlled study was undertaken requiring subjects to use their assigned products according to the manufacturers instructions for 2 weeks. Participants were systemically healthy, with non-carious, non–restored anterior teeth. A total of 76 subjects were randomised to one of the following treatment groups: 19% sodium percarbonate bleaching film (Test product - Crest® Night Effects™), Placebo (negative control) or currently marketed whitening toothpaste (Colgate® Sensation Whitening). Study groups were balanced for smoking and baseline tooth colour values. At baseline, 7 and 14 days of treatment, oral soft tissue examinations and L*a*b* assessments of tooth stain were performed. Stain removal efficacy was determined by comparing changes in tooth yellowness and brightness as expressed by delta b and delta L respectively. Treatment comparisons were made using analysis of covariance. **Results**: Adjusting for baseline tooth color, the test group experienced a statistically significant greater reduction in b* (delta b -0.75 at day 7, -1.17 at day 14) compared to the whitening toothpaste (delta b 0.02 at day 7, -0.10 at day 14), $p < 0.0001$. Also a significant increase in tooth brightness was observed for the test group (delta L 0.74 at day 7, 0.54 at day 14) as compared to the whitening toothpaste (delta L 0.20 at day 7, -0.01 at day 14). The active bleaching product was also statistically significantly different from placebo L* and b* colour values at all time-points. **Conclusions**: In the short term Crest® Night Effects™ delivers a significant stain removal benefit versus negative control and a currently marketed whitening toothpaste. Furthermore there were no observed differences in effect between the whitening toothpaste and placebo control.

Thursday, June 26

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Placebo-controlled Clinical Trial Evaluating the Efficacy, Tolerability, and Duration Effect of a 19% Sodium Percarbonate Bleaching Film

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Objective: A double blind, randomized, placebo controlled clinical trial was conducted to evaluate the efficacy and safety of a direct application liquid bleaching film, containing 19% sodium percarbonate (equivalent to 5.3% hydrogen peroxide). **Methods**: After balancing for age and baseline colour, 52 healthy adults were randomized to either bleaching film, Crest® Night Effects™ (test group-25 persons) or placebo gel (control group-27 persons). Test products were self–applied to the facial surfaces of the maxillary and mandibular anterior teeth and left overnight. Teeth were treated daily for 2 weeks. Control examinations were performed on day 7, day 14 and at a 3 month follow-up visit. At each visit a case history was collected, digital images of the teeth were taken and an intra-oral clinical examination was performed. Whitening efficacy was assessed by evaluating changes in tooth yellowness (delta b*) and tooth brightness (delta L*) compared to baseline, as determined by Digital Image Analysis. Statistical analysis was by ANCOVA. **Results**: After 14 days the test group showed a highly significant ($p < 0.0001$) reduction in tooth yellowness of –1.60 delta b* units and an increase in brightness of 1.66 delta L* compared to baseline.The control group showed a significantly lower overall tooth colour change ($p < 0.0001$) delta b* 0.00 and delta L*0.26. This initial change in tooth colour was sustained at the 3 month follow-up evaluations with no significant difference in colour values measured at this time-point from those recorded at the end of treatment. The experimental whitening gel was well tolerated, with transient tooth sensitivity and oral irritation being observed in 3 cases each. No persistent or new treatment-related adverse events observed in 3-month period. **Conclusions**: The study demonstrates the bleaching film to be well-tolerated and provides a significant initial colour change which is sustained 3 months after bleaching has occurred. (Supported by Procter & Gamble.)