

# P&G Oral Presentations

Wednesday, March 10



0046

## Impact of Smoking on Efficacy of Three Self-directed Bleaching Systems

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Vital-tooth whitening using peroxide-based bleaching systems represents one method of addressing tooth stain associated with smoking. **Objective:** The aim of this integrated research was to evaluate the impact of smoking on whitening response following treatment with three direct-to-consumer bleaching systems. **Methods:** A meta-analysis was performed using inclusive data from 5 randomized clinical trials having common entrance criteria and methods. Studies evaluated paint-on carbamide peroxide (Colgate® Simply White™) or hydrogen peroxide whitening gels (Colgate Simply® White Night™) under labeled-use conditions, with a self-directed 19% sodium percarbonate bleaching film (Crest® Night Effects™) as reference control. Whitening effects were measured objectively as L\*a\*b\* color change using digital image analysis. ANCOVA was utilized to estimate the whitening efficacy of smokers and non-smokers for each product group. **Results:** The analysis included 236 subjects from 5 studies, 65.3% female, 20.3% smokers and age ranged from 18 - 75. The adjusted mean reduction in tooth yellowness,  $\Delta b^*$  (p-value), for smokers and non-smokers is shown in the table below. Baseline tooth color, age and treatment had a significant ( $p < 0.001$ ) impact on whitening response. Smoking was associated with a directional smaller response (19-30%) across all groups although this was not statistically significant ( $p > 0.05$ ). Amongst smokers only subjects using the percarbonate bleaching film experienced significant and meaningful improvement in tooth color from baseline. **Conclusion: Irrespective of subjects' smoking status, the percarbonate bleaching film group experienced over 4-fold whitening efficacy relative to the other paint-on gel groups ( $p < 0.0001$ ).**

	18% carbamide peroxide paint-on gel	9% hydrogen peroxide paint-on gel	19% sodium percarbonate self-directed bleaching film
Smokers $\Delta b^*$ (p-value)	-0.22 (0.2561)	-0.24 (0.1689)	-1.17 (0.0001)
Non - smokers $\Delta b^*$ (p-value)	-0.31 (0.0017)	-0.32 (0.0009)	-1.44 (0.0001)

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## Clinical Trial of Two Whitening Systems: Strips Versus Overnight Paint-on

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**Objective:** Direct-to-consumer tooth whitening systems use various devices and treatment regimens to deliver peroxide to the tooth surface. This 14-day clinical trial was conducted to evaluate the clinical response of a new overnight paint-on gel relative to a marketed strip control. **Methods:** A total of 37 healthy adults were randomized to Colgate® Simply White™ Night, a hydrogen peroxide paint-on liquid in an applicator bottle, or Crest® Whitestrips®, a 6% hydrogen peroxide gel on a whitening strip. Study participants were supplied with the manufacturers written instructions for use. Both products were used unsupervised at-home over a 14-day period. The paint-on was applied overnight, while the strips were used twice daily for 30 minutes. Efficacy was measured as L\*a\*b\* color change using digital images of the anterior dentition on Day 2 & Day 15. **Results:** Adjusting for baseline and age, the Day 15 estimated means (SE) for  $\Delta b^*$  (yellowness) were -0.30 (0.14) for the paint-on group compared to -2.27 (0.15) for the strip group. Response was similar for lightness/brightness ( $\Delta L^*$ ), with the adjusted mean (SE) of -0.16 (0.15) and 1.77 (0.16) in the paint-on and strip groups, respectively. Between-group comparisons showed highly significant ( $p < 0.0001$ ) color improvement favoring the strip group at Day 15. Only the strip group exhibited significant ( $p < 0.01$ ) whitening at Day 2, as evidenced by the adjusted mean (SE)  $\Delta b^*$  of -0.79 (0.09). Strip whitening after 1 day ( $\Delta b^*$  &  $\Delta L^*$ ) differed significantly ( $p < 0.001$ ) from the paint-on used for two weeks. Both treatments were generally well tolerated, with only one subject in the paint-on group discontinuing treatment early due to an adverse event. **Conclusion: Use of 6% whitening strips resulted in 7-fold superior whitening versus the overnight hydrogen peroxide paint-on liquid.**