Objectives: Direct-to-consumer tooth whitening systems use various devices and treatment regimens to deliver peroxide to the tooth surface. This 7-day clinical trial was conducted to evaluate the clinical response of a two marketed strip systems.

Methods: A total of 52 healthy adults were randomized to either Oral-B® Rembrandt Whitening Strips (tabs strips worn once daily for 5 days) or Crest® Whitestrips® Premium (10% hydrogen peroxide whitening strips applied twice daily for 7 days), following manufacturers written instructions. The maxillary arch was treated for 30 minutes per application, and all treatment was unsupervised. Efficacy was measured at baseline and Day 8 using L*a*b* color change collected from digital images of the anterior dentition. Tooth color change was compared between the treatment groups using analysis of covariance adjusting for baseline and age.

Results: Age ranged from 18 to 81 with a mean of 36 years. Tobacco users accounted for 29% of the subjects. Groups were balanced for demographic and baseline tooth color. Day 8 adjusted means ± SE for Δb* (yellowness) were –0.96 ± 0.19 for the once daily group compared to –1.64 ± 0.21 for the twice daily group. Similarly for ΔL* (lightness), the Day 8 adjusted means ± SE were 1.03 ± 0.15 for the once daily group compared to 1.75 ± 0.16 for the twice daily group. Between-group comparisons showed significant (p < 0.05) improvement favoring the twice daily strips for Δb* and ΔL*. Both products were well tolerated.

Conclusion: Head-to-head testing of the 10% hydrogen peroxide twice daily strips resulted in significantly whitening improvement relative to the once daily tab strips.

Poster Presentations - Research Supported by P&G

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Clinical Trial Comparing Two Direct-to-Consumer Tooth Whitening Systems
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Objectives: A randomized, double-blind clinical trial was conducted to evaluate the clinical effectiveness and tolerability of 6% hydrogen peroxide whitening strips relative to placebo. Methods: 30 healthy adults with no history of vital bleaching or hypersensitivity were randomized to Crest® Whitestrips® (6% hydrogen peroxide) or placebo. Maxillary teeth were treated unsupervised twice daily for 30 minutes over a 14-day period, and clinical response was measured from digital images (CIELAB), examination and interview at baseline and end-of-treatment. Results: The study population ranged from 22-56 years, 63% were female, and 17% used tobacco. Groups were well-balanced (p > 0.46) on pertinent demographic and behavioral characteristics and starting L*a*b* tooth color. Relative to baseline, the 6% strip group experienced significant (p < 0.0001) reduction in yellowness (Δb*) and increased brightness (ΔL*) with treatment, with Day 15 means (SD) of –1.8 (0.51) and 1.4 (0.80) for Δb* and ΔL*, respectively. All (100%) subjects in the 6% strip group had measured two parameter (b* & L*) color improvement. There was no evidence of a significant (p > 0.18) placebo response, with the 6% strip differing significantly from placebo (p < 0.0001) for Δb* and ΔL*. Minor tooth sensitivity was the most common adverse event, reported by 20% of subjects in the 6% strip group and 0% in placebo. No subjects discontinued strip use early because of a treatment-related adverse event. Conclusion: In this double blind, placebo-controlled clinical trial, twice daily use of a 6% hydrogen peroxide strip yielded significant tooth whitening without meaningful side effects.