Clinical Comparison of Two Overnight Brush-Applied Tooth Whitening Products

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ABSTRACT

Objective: This research compared the clinical efficacy and safety of two different brush-applied whitening products used overnight for 2 weeks. **Methods:** A pooled, 2-study, subject-level analysis compared clinical response in 103 subjects who were randomized to Colgate® Simply White Night™ (a hydrogen peroxide paint-on gel) or Crest® Night Effects™ (a 19% sodium percarbonate film). Study participants were supplied with the manufacturers written instructions for use, treatment was at-home overnight, and all usage was unsupervised. Effectiveness was measured objectively as L*a*b* color change using digital image analysis. Comparative efficacy was evaluated using ANCOVA adjusting for study, age and baseline color. Subjects were interviewed for oral discomfort after 2 weeks use. **Results:** Study subjects ranged in age from 18 to 61 years. After 2 weeks use, adjusted means and standard errors for b* (yellowness reduction) were –1.02 ± 0.08 for the sodium percarbonate bleaching film compared to –0.17 ± 0.08 for the hydrogen peroxide paint-on with groups differing significantly with respect to b* and all other whitening color parameters ($p < 0.0005$). Efficacy results were consistent in the individual studies, and there were no significant ($p > 0.10$) study by treatment interactions. Oral irritation was the most common adverse event overall, reported by 16% of the paint-on users, and 2 of the film users. No one discontinued use early due to a product-related adverse event. **Conclusions: After 2 weeks overnight use, the 19% sodium percarbonate bleaching film provided significant whitening improvement relative to the hydrogen peroxide paint-on gel.**

OBJECTIVE

This research compared the clinical efficacy and safety of two different brush-applied whitening products used overnight for 2 weeks.

METHODS

A pooled, 2-study, subject-level analysis compared clinical response in 103 subjects who were randomized to Colgate® Simply White Night™ (a hydrogen peroxide paint-on gel) or Crest® Night Effects™ (a 19% sodium percarbonate film). Study participants were supplied with the manufacturers written instructions for use, treatment was at-home overnight, and all usage was unsupervised. Effectiveness was measured objectively as L*a*b* color change using digital image analysis. Comparative efficacy was evaluated using ANCOVA adjusting for study, age and baseline color. Subjects were interviewed for oral discomfort after 2 weeks use.

RESULTS

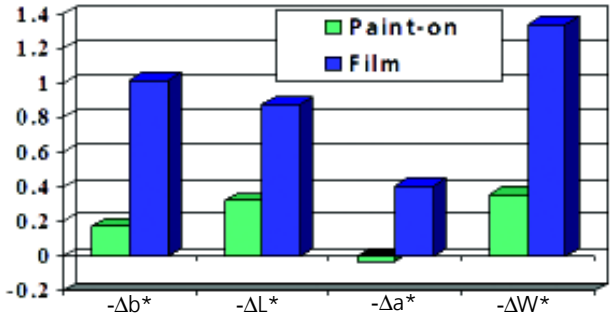
Study Population:

A total of 108 subjects (57 in study #1 and 51 in study #2) were randomized to treatment in the two studies with 103 of the subjects completing and evaluable for the entire 2 weeks of use. The age ranges (18-57 and 18-61) and gender distribution (55% and 65% female) of the two studies were comparable. Treatment groups in both studies were balanced with respect to baseline L* and b* scores and age. Pooled baseline mean b* (SE) values were 17.76 (0.20) for the sodium percarbonate bleaching film compared to 17.86 (0.21) for the hydrogen peroxide paint-on. Baseline mean L* (SE) values were 73.20 (0.28) for the film group compared to 72.84 (0.34) for the paint-on group.

Efficacy:

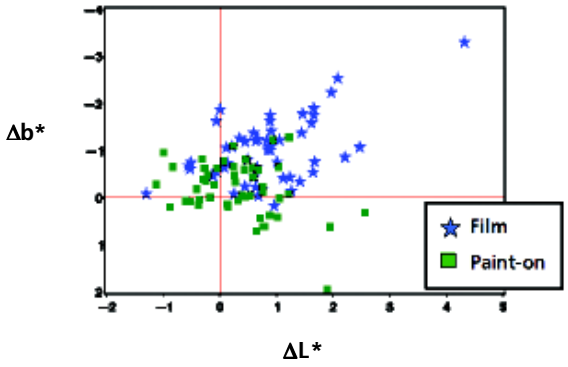
After 2 weeks use, the Δb* (yellowness reduction) were –1.02 ± 0.08 for the sodium percarbonate bleaching film compared to –0.17± 0.08 for the hydrogen peroxide paint-on, with these treatment groups differing significantly ($p \leq 0.0001$). Improvement in ΔL* (brightness) were 0.88 for the sodium percarbonate bleaching film compared to 0.32 for the hydrogen peroxide paint-on, the results again differing significantly ($p = 0.0003$). Similar results were achieved for both Δa* (redness reduction) and ΔW* (difference from white).

Pooled Mean Values at 2 Weeks



RESULTS (Cont.)

Pooled ΔL* and Δb* Scores at 2 Weeks



Safety:

Both treatments were generally well-tolerated. Minor oral irritation was the most common adverse event overall, reported by 16% (8) of the paint-on users and 4% (2) of film users.

CONCLUSION

After 2 weeks overnight use, the 19% sodium percarbonate bleaching film provided significant whitening improvement relative to the hydrogen peroxide paint-on gel.