Comparative Clinical Effectiveness of Two Dual-Phase Whitening Dentifrices

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ABSTRACT

Objectives: Clinical research was conducted to compare the effectiveness of two dual-phase whitening dentifrices.
Methods: Two clinical trials were conducted at different centers under the direction of different investigators, in order to compare the clinical response seen with dual phase whitening dentifrices. Subjects were randomized to Colgate® Simply White® Advanced Whitening Toothpaste, a dual phase dentifrice with 1% hydrogen peroxide and manganese gluconate as an activator, or Crest® Vivid White™, a dual phase dentifrice without peroxide or manganese gluconate. Subjects were provided the manufacturers' instructions for use. In each trial, whitening was measured objectively on the maxillary teeth via digital image analysis using well-established and standard methods for L*a*b* color change. A meta-analysis was conducted using the pooled raw data from the two clinical trials.
Results: A total of 56 healthy adults were randomized to peroxide or no-peroxide dentifrices. After 2 weeks, the adjusted mean (SE) for Δb* (yellowness) was –0.13 (0.078) for the peroxide group, and –0.20 (0.075) for the no-peroxide group. Only the no-peroxide group differed significantly (p = 0.011) from baseline. Results were generally similar for ΔL*, with adjusted means (SE) of 0.04 (0.094) and 0.14 (0.090) in the peroxide and no-peroxide groups, respectively. While the no-peroxide group showed directionally better whitening, groups did not differ significantly. Both dentifrices were well tolerated over the 14-day treatment period.
Conclusion: In this meta-analysis of two dual phase whitening dentifrices, only the whitening dentifrice without peroxide showed a significant reduction in yellowness after 14 days use.

METHODS

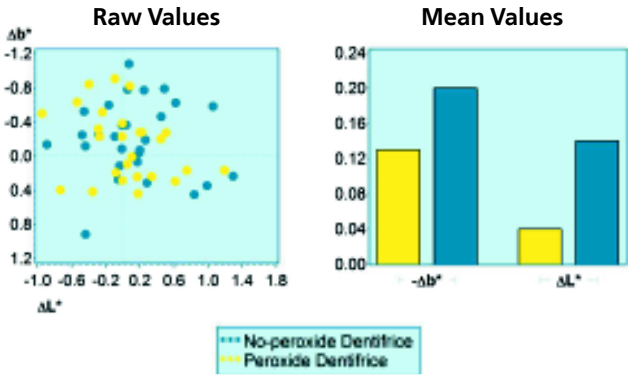
Two randomized, double-blind clinical trials were conducted in order to compare the response seen with two dual phase whitening dentifrices: Colgate Simply White Advanced Whitening Toothpaste (peroxide + activator) and Crest Vivid White (no-peroxide, no-activator). Subjects used the products following the manufacturers' instructions, for 2 weeks. Whitening was measured objectively on the maxillary teeth via digital image analysis using well-established and standard methods for L*a*b* color change. A meta-analysis was conducted using the pooled raw data from the two clinical trials.

METHODS (Cont.)

The primary efficacy endpoints in this meta-analysis were b*, a measure of yellowness, and L*, a measure of lightness or brightness. A decrease in b* from Baseline to Week 2 indicated decreased yellowness. An increase in L* indicated increased brightness. The effect of treatment on Δb* and ΔL* was evaluated using separate general linear models. Baseline color (b* or L*, respectively) was included as a continuous covariate and Study and Treatment were included as fixed effects. All testing used a two-sided 0.05 level of significance.

RESULTS

A total of 56 healthy adults were randomized to peroxide or no-peroxide dentifrices. Mean age ± SD was 37 ± 9.3 ranging from 22 to 61 years. Sixty-eight percent of subjects were female. Mean ± SD baseline b* was 18.5 ± 1.5 and L* was 73.9 ± 2.3. Treatment groups were well balanced with respect to demographic characteristics and baseline color parameters.



RESULTS (Cont.)

EFFICACY ANALYSIS RESULTS

Color Measure/ Treatment	Adj. Mean (SE)	Vs. Baseline *P*-value	Treatment Comparison *P*-value
Δb *			
Peroxide	-0.13 (0.078)	0.011	
No-peroxide	-0.20 (0.075)	0.093	0.545
ΔL *			
Peroxide	0.04 (0.094)	0.127	
No-peroxide	0.14 (0.090)	0.685	0.438

Following 2 weeks of use, the adjusted mean ± SE for Δb* was –0.13 ± 0.078 for the peroxide group, and –0.20 ± 0.075 for the no-peroxide group. Only the no-peroxide group provided a statistically significant ($p<0.05$) reduction in yellowness versus baseline. Results were similar for ΔL*, with adjusted means ± SE of 0.04 ± 0.094 and 0.14 ± 0.090 in the peroxide and no-peroxide groups, respectively. While the no-peroxide group showed directionally better whitening, the groups did not differ significantly. Ninety-five percent confidence intervals for the Δb* and ΔL* treatment differences (peroxide minus no-peroxide) were (-0.15, 0.28) and (-0.36, 0.16), respectively. Both dentifrices were well tolerated over the 14-day treatment period.

CONCLUSION

In this meta-analysis, only the no-peroxide dentifrice showed a statistically significant benefit versus baseline with respect to Δb*.