Impact of Packaging & Labeling on Whitening Strip Clinical Response

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ABSTRACT

Objectives: Clinical research often uses non-marketed (blinded) labeling. This research evaluated the effect of such labeling on clinical response with peroxide-containing whitening strips.

Methods: Healthy adults were randomly assigned 6% hydrogen peroxide whitening strips in experimental-labeled (blinded white pouches and boxes) or marketed (open-label) packaging. Maxillary teeth were treated twice daily for 30 minutes. All use was unsupervised over a 14-day period. Efficacy (ΔL*Δa*Δb*) color change was measured objectively by digital image analysis, and safety was assessed from clinical examination and subject report at baseline and end-of-treatment.

Results: A total of 20 adults completed the 14-day study and were evaluated. Mean (SD) age was 35.5 (9.80) years, most (95%) were female, and 25% used tobacco products. After 14-days treatment, all subjects (100%) had a measured two-parameter (ΔL* & Δb*) color improvement. Both groups showed statistically significant improvement from baseline (p < 0.001) in yellowness (Δa*) and brightness (ΔL*). After adjusting for age and baseline color, mean ΔL* (SE) for open-label strips was –2.47 (0.310) compared to –2.78 (0.347) for the experimental labeled strips. Treatments did not differ significantly (p > 0.546) on ΔL* at Day 15. Results were similar for Δa*, again, with no significant (p > 0.233) between-group differences based on labeling. Mild and transient tooth sensitivity (25%) and oral irritation (25%) represented the most common adverse events. Clinical examination was unremarkable. Both products were well tolerated with no subjects dropping out of the study due to adverse events.

RESULTS

Safety: Mild and transient tooth sensitivity (25%) and oral irritation (25%) represented the most common adverse events in both groups. Clinical examination was unremarkable. Both products were well tolerated with no subjects dropping out of the study due to adverse events.

MATERIALS AND METHODS

This was a single center, examiner-blinded, two treatment group clinical trial. Twenty healthy volunteers, between the ages of 22 and 44 years of age, with no current dentinal sensitivity were enrolled. At the Baseline visit, subjects were randomly assigned in approximately equal numbers to one of the two treatment groups. The randomization was balanced for age (low, middle, or high) and tobacco use (yes or no).

RESULTS (Cont.)

Efficacy: At the Day 15 visit, each treatment group provided statistically significant (p-values = 0.0003) mean color improvement from baseline as measured by ΔL*, Δa*, and Δb*.

Additionally at Day 15, the adjusted means and standard errors for changes in lightness (ΔL*) were 1.83 ± 0.276 for the Labeled Strip group and 2.36 ± 0.307 for the Blinded Strip group. The adjusted means and standard errors for changes in composite color (ΔW*) were –2.82 ± 0.375 for the Labeled Strip group and –3.61 ± 0.419 for the Blinded Strip group.

Adjusted mean for Δa*, ΔL*, and ΔW* for the Labeled Strip group was not statistically different (p > 0.199) from the Blinded Strip group.

RESULTS (Cont.)

CONCLUSION

In this clinical research, labeling and packaging conditions (experimental versus open-label) did not significantly impact on whitening effectiveness or safety.