Comparative Effectiveness of Two Self-directed Whitening Systems: Outcomes from Three Randomized Clinical Trials
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ABSTRACT
Objective: This integrated research was conducted to establish the comparative efficacy of 6% hydrogen peroxide whitening strips (Crest® Whitestrips®) versus 18% carbamide peroxide paint-on gel (Colgate® Simply White®). Methods: Three separate clinical trials were conducted, each at a different research center under the direction of a different investigator. Study participants were supplied with the manufacturers’ written instructions for use, treatment was twice daily for 30 minutes, and all usage was unsupervised over a 14-day period. Whitening was measured objectively on the maxillary teeth via digital image analysis using well-established and standard methods for L*a*b* color change. Results: A total of 97 healthy adults were randomized to whitening strips or the paint-on gel in these three trials. Outcomes from each of the three clinical trials were consistent, showing highly significant (p < 0.0001) greater color improvement for the strip group for individual (Δb*) color parameters compared to the paint-on gel. The 3-study mean improvement in Δb* was 2.57 for whitening strips compared to 0.39 for the paint-on gel. Similar findings were noted for ΔL*, with the strips exhibiting a 3-study mean improvement of 2.13 compared to 0.30 for the paint-on product. For these primary and secondary color outcomes, whitening strip users experienced approximately a 6.7-fold reduction in yellowness (Δb*) and a 7.2-fold increase in brightness (ΔL*) relative to the paint-on gel. Both treatments were well tolerated over the 14-day treatment period. Conclusion: Outcomes from three randomized clinical trials demonstrate a highly significant, more than six-fold superior whitening benefit for 6% hydrogen peroxide whitening strips compared to the 18% carbamide peroxide paint-on gel.

OBJECTIVE
The primary objective of this research was to compare the effectiveness of two self-directed tooth whitening systems following the recommended label usage.

STUDY DESIGNS

CONTROLLED IMAGE ACQUISITION

DIGITAL IMAGE ANALYSIS

BASELINE COLOR VALUES

POOLED/OVERALL RESULTS

DEMOGRAPHIC CHARACTERISTICS

SUBJECT ACCOUNTABILITY

CONCLUSION
➤ A 6% hydrogen peroxide controlled dose whitening strip is approximately 7-fold more effective in tooth whitening than a 18% carbamide peroxide paint-on gel over a 2-week period.
➤ Subjects using the strip are approximately 6x as likely to experience at least a one unit improvement in tooth color as subjects using the paint-on gel.