



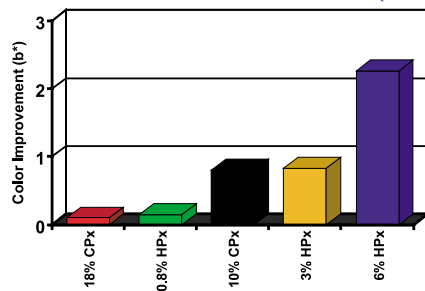
0034

Meta-analysis of the Clinical Effectiveness and Tolerability of Direct-to-Consumer Vital Bleaching Products

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Objective: The introduction of strips, trays and paint-on products has contributed to change and extraordinary growth in self-directed tooth whitening. This research was conducted to systematically evaluate the clinical effectiveness and tolerability of the most popular direct-to-consumer systems. **Methods:** A meta-analysis was conducted using an inclusive dataset from 5 randomized clinical trials having common entrance criteria and methods. Each study evaluated a direct-to-consumer, peroxide-based tooth whitening system under labeled use conditions, with 6.0% hydrogen peroxide strips as a reference control. Effectiveness was measured objectively as $L^*a^*b^*$ color change using digital image analysis, and tolerability was assessed by subject report. Comparative efficacy was evaluated using a mixed model that adjusted for study, age and baseline color. **Results:** The pooled sample included 160 subjects (18-60 years of age) who used direct-to-consumer products at concentrations from 0.75 to 6.0% hydrogen peroxide. Compared to the strip control, the self-directed tray/paint-on products exhibited only 4-36% of the adjusted mean Δb^* , and 2-57% of the adjusted ΔL^* . Adjusting for multiple comparisons, there were no significant ($p > 0.47$) differences in Δb^* between any of the tray/paint-on products. Outcomes were generally consistent across other color parameters (ΔL^* , Δa^* , ΔE^* , ΔW^*). In all instances, the strip group exhibited highly significant ($p < 0.001$) and superior whitening to the other self-directed products. While no subjects dropped “for cause”, there were directional or significant differences in tolerability usually favoring the strips. **Conclusion:** While there were few differences between the individual tray/paint-on products, 6.0% hydrogen peroxide strips exhibited superior and meaningful whitening relative to the other popular direct-to-consumer products.

**Comparative Whitening
Five Self Directed Products (N=160)**



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Safety and Tolerability of Vital Bleaching with Whitening Strips: Evidence from 32 Clinical Trials

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Objective: This research summarizes an extensive clinical trials database collected as part of the development of a strip-based tooth whitening system in order to ascertain factors that contribute to clinical safety and tolerability. **Methods:** Data from 32 different randomized clinical trials were included in the meta-analysis. This inclusive assessment involved study subjects who used flexible polyethylene, whitening strips coated with 5.3-6.5% hydrogen peroxide bleaching gel. Treatment was twice daily for 30 minutes over a 2-3 week period. Safety and tolerability were assessed from examination and interview. A logistic regression model was fitted to identify the risk factors for tooth sensitivity and oral irritation. **Results:** The analysis included 610 subjects (18-82 years of age) with complete safety and tolerability data. Mild and transient tooth sensitivity (17.9%) and oral irritation (19.7%) represented the most common adverse events associated with treatment. Tooth sensitivity was reported by 13.9% of subjects in the 5.3% group, 19.7% in the 6.0% group and 22.9% in the 6.5% group, with treatments differing significantly ($p < 0.05$) with respect to tooth sensitivity occurrence. Oral irritation was directionally ($p = 0.07$) more common among 5.3% strip users, the only group with pre-treatment tooth brushing. Age was a significant ($p = 0.0008$) effect in the tooth sensitivity model, with older subjects reporting less tooth pain during treatment. Race and gender were not significant contributors. Other adverse events were unremarkable. Only 7 subjects (1% of the population) discontinued treatment early due to adverse events. **Conclusion:** This meta-analysis further establishes the clinical safety and tolerability of whitening strip use.

**CWS is a safe method for tooth whitening
Evidence from 32 clinical trials (n=610)**

