

Subject-Level Meta-Analysis of Clinical Effectiveness for Direct-to-Consumer Vital Bleaching Products

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ABSTRACT

Objectives: Despite the growth in direct-to-consumer bleaching, only a few systems have been evaluated in well-controlled clinical trials. This research was conducted to systematically evaluate the clinical effectiveness of 10 peroxide-based, direct-to-consumer whitening systems. **Methods:** A meta-analysis was conducted using an inclusive dataset from 19 randomized clinical trials that had common entrance criteria and methods. Each study evaluated a direct-to-consumer, peroxide-based tooth whitening system, with common strip/paint-on systems as controls. Effectiveness was measured objectively as $L^*a^*b^*$ color change using digital image analysis. Comparative efficacy was evaluated using a mixed model that adjusted for study, age and baseline color. **Results:** The pooled sample included 724 subjects (18-75 years of age) who used direct-to-consumer products for periods up to 14 days. The two strip systems (6% strips for 2 weeks & 10% strips for 1 week) yielded the greatest color improvement. At the respective end-of-treatment periods, adjusted mean (SE) Δb^* was -2.22 (0.07) and -2.21 (0.21), and adjusted mean (SE) ΔL^* was 1.89 (0.08) and 1.90 (0.24) for the 6% & 10% strips, respectively. Response with the five stock tray systems was variable, with adjusted Δb^* means ranging from -0.02 (0.75% hydrogen peroxide) to -1.02 (12% carbamide peroxide). Response with the three paint-on systems was also variable, with adjusted Δb^* means ranging from -0.26 (hydrogen peroxide paint-on) to -0.99 (19% sodium percarbonate film). Both strip groups exhibited significantly ($p < 0.05$) greater whitening (Δb^* , ΔL^* , ΔE^* & ΔW^*) compared to the other self-directed products. **Conclusion: Whitening response with direct-to-consumer whitening products varied between products, with the two strip systems exhibiting superior and meaningful whitening relative to other tray and paint-on products.**

STATISTICAL METHODS

A meta-analysis was conducted using an inclusive dataset from 19 randomized clinical trials that had common entrance criteria and methods. Each study evaluated a direct-to-consumer, peroxide-based tooth whitening system, with common strip/paint-on systems as controls. Effectiveness was measured objectively as $L^*a^*b^*$ color change using digital image analysis. Comparative efficacy was evaluated using a mixed model with baseline color and age as fixed covariates and study as a random effect. Baseline tooth color and age were included because of the evidence showing these factors impact response. A study by treatment interaction was also tested to determine whether the treatment effect may be pooled across the studies. All testing used a two-sided 0.05 level of significance and did not adjust for multiple comparisons.

MATERIALS

Summary of the Products Tested in the Research				
Bleaching Ingredient	% HP*	Delivery	Daily Regimen	Duration
0.75% hydrogen peroxide	0.8	Stock Tray System †	10-15min QD	2 Weeks
9% hydrogen peroxide	9	Paint-on Gel	QD Overnight	2 Weeks
18% carbamide peroxide	6	Paint-on Gel	BID	2 Weeks
6% hydrogen peroxide	6	Foam Tray System †	5min BID	2 Weeks
10% carbamide peroxide	3	Stock DuoTray System ‡	10-20min QD or BID	1 Week
10% carbamide peroxide	3	Stock Tray System †	20-30min BID	2 Weeks
19% sodium percarbonate	5	Brush-on Film	QD Overnight	2 Weeks
12% carbamide peroxide	4	Stock Tray System †	≥ 30min BID	2 Weeks
10% hydrogen peroxide	10	Strips	30min BID	1 Week
6% hydrogen peroxide	6	Strips	30min BID	2 Weeks

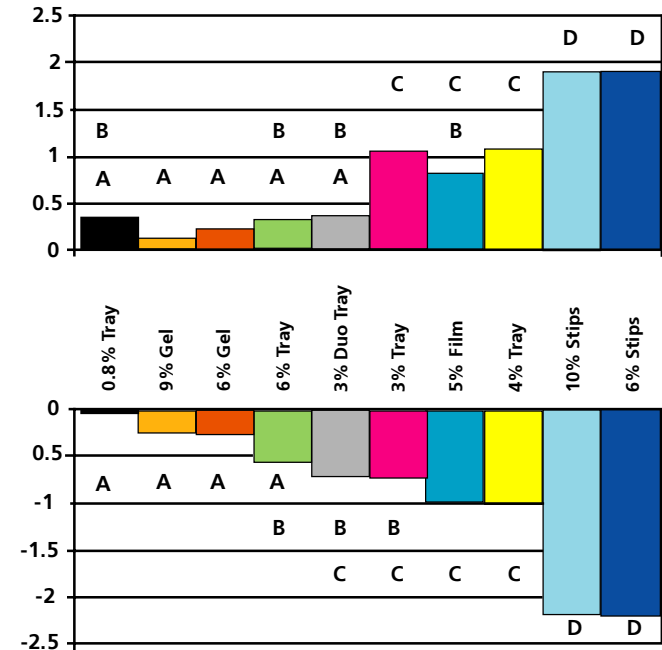
HP* = approximate % hydrogen peroxide equivalent. † = Rinse included. ‡ = Dentifrice and rinse included

RESULTS

The pooled sample included 724 subjects (Mean age was 36.9 ranging from 18-75 years and 68% were female) who used direct-to-consumer products for periods up to 14 days. Mean baseline b^* was 17.6 and baseline L^* was 73.5. Baseline color ($p < 0.0001$), age ($p < 0.0001$), and treatment ($p < 0.0001$) were included as fixed effects in each model and each were statistically significant. Since the study by treatment interaction was not statistically significant ($p > 0.2$), the treatment effect was estimated across the studies and the study effect was included as the only random effect.

The two strip systems (6% strips for 2 weeks & 10% strips for 1 week) yielded the greatest color improvement. At the respective end-of-treatment periods, adjusted mean Δb^* was -2.22 and -2.21 , and adjusted mean ΔL^* was 1.89 and 1.90 for the 6% & 10% strips, respectively. Response with the five stock tray systems was variable, with adjusted Δb^* means ranging from -0.02 (0.75% hydrogen peroxide) to -1.02 (12% carbamide peroxide) and adjusted ΔL^* means ranging from 0.33 (6% hydrogen peroxide) to 1.08 (12% carbamide peroxide). Response with the three paint-on systems was also variable, with adjusted Δb^* means ranging from -0.26 (9% hydrogen peroxide) to -0.99 (19% sodium percarbonate) and adjusted ΔL^* means ranging from 0.12 (9% hydrogen peroxide) to 0.79 (19% sodium percarbonate). Both strip groups exhibited significantly ($p < 0.05$) greater whitening (Δb^* , ΔL^* , ΔE^* & ΔW^*) compared to the other self-directed products.

Lightness Improvement (ΔL^*)



Yellowness Reduction (Δb^*)

Note: Treatments with the same letter were not statistically different ($p > 0.05$), Products sorted by adjusted mean Δb^* response.

CONCLUSION

Whitening response with direct-to-consumer whitening products varied between products, with the two strip systems exhibiting superior and meaningful whitening relative to other tray and paint-on products.