

Comparative Clinical Responses of Two Peroxide Tooth-whitening Gels

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ABSTRACT

Objective: This research compared the clinical response of two different peroxide-containing gel formulations delivered using self-applied whitening strips. **Methods:** A randomized, double-blind clinical trial was conducted to compare a modified hydrogen peroxide bleaching gel with 0.075% sodium saccharin to matched control without saccharin. The bleaching gels were applied to the maxillary anterior dentition twice daily using thin polyethylene strips. Efficacy ($L^*a^*b^*$ color change) was measured objectively by digital image analysis. **Results:** A total of 23 adults ranging from 23-57 years of age participated in the research. Both treatments were effective in whitening teeth, as evidenced by a statistically significant improvement from baseline ($p < 0.0005$). After adjusting for age and baseline color, mean Δb^* (SE) for the modified formula was -2.37 (0.180) compared to -1.95 (0.200) for the matched formula. While the modified formula had 21% greater whitening (Δb^*), the treatments did not differ significantly (two-sided p -value = 0.147). Outcomes for the other color parameters directionally favored the modified formula. Both treatments were well tolerated. Both tooth sensitivity and oral irritation (reported by 27%-33% of subjects) were mild in severity, and no subjects discontinued treatment due to bleaching-related adverse events. **Conclusion:** For whitening strips, this research demonstrates that the clinical response was similar between a modified 6% hydrogen peroxide bleaching gel with sodium saccharin and the matched control without saccharin.

OBJECTIVE

This research compared the clinical response of two different peroxide-containing gel formulations delivered using self-applied whitening strips.

METHODS

A randomized, double-blind clinical trial was conducted to compare a modified 6% hydrogen peroxide (12mg) bleaching gel with 0.075% sodium saccharin to matched control without saccharin. These low dose bleaching gels were applied to the maxillary anterior dentition twice daily using thin polyethylene strips. Efficacy ($L^*a^*b^*$ color

METHODS (Cont.)

change) was measured objectively by digital image analysis. Analysis of covariance methods were used to compare treatments. The response was color change from baseline and the covariates were the color at baseline as well as age.

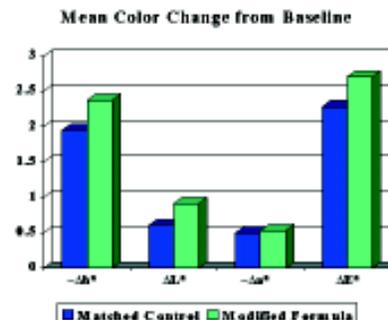
RESULTS

Study Population:

Twenty-three randomized subjects received product and completed the study (11 subjects assigned to the control group and 12 subjects assigned to the modified formula). Subjects ranged in age from 23-57 years with an average of 37.9 years. Treatment groups were well balanced with respect to demographic characteristics and behavioral parameters.

Efficacy:

Both treatments were effective in whitening teeth, as evidenced by a statistically significant improvement from baseline ($p < 0.0005$). After adjusting for age and baseline color, mean Δb^* (SE) for the modified formula was -2.37 (0.180) compared to -1.95 (0.200) for the matched control. With respect to reduction of yellowness (Δb^*), the treatment groups did not differ significantly ($p = 0.147$) with a difference of -0.42 favoring the modified formula with a 95% confidence interval of $(-0.99, 0.16)$. The table and figure display the adjusted mean response for each of the color measurements including ΔE^* . The treatment groups did not differ significantly ($p = 0.237$) for ΔE^* with a difference of 0.42 favoring the modified formula with a 95% confidence interval of $(-0.31, 1.16)$. The 95% confidence intervals indicate that the modified 6% hydrogen peroxide (12 mg) bleaching gel with sodium saccharin was at least as good as the matched control without saccharin.



RESULTS (Cont'd)

After 14 Days Product Use				
Outcome/ Treatment	Baseline Mean (SE)	Adjusted Mean (SE)	% Improvement Vs. Control	Two-sided p -value
Δb^*				
Matched Control	16.60 (0.708)	-1.95 (0.200)		
Modified Formula	17.05 (0.554)	-2.37 (0.180)	21%	0.1474
ΔL^*				
Matched Control	77.65 (0.767)	0.60 (0.302)		
Modified Formula	76.44 (1.032)	0.91 (0.273)	53%	0.4589
Δa^*				
Matched Control	5.80 (0.337)	-0.50 (0.153)		
Modified Formula	6.29 (0.333)	-0.53 (0.138)	6%	0.8863
ΔE^*				
Matched Control		2.28 (0.251)		
Modified Formula		2.70 (0.226)	19%	0.2371

Safety:

Both treatments were generally well-tolerated. Both tooth sensitivity and oral irritation (reported by 27%-33% of subjects) were mild in severity, and no subjects discontinued treatment due to bleaching-related adverse events.

CONCLUSION

For whitening strips, this research demonstrates that the clinical response of the modified 6% hydrogen peroxide (12 mg) bleaching gel with sodium saccharin was at least as good as the matched control without saccharin.