Clinical Comparison of Whitening with 6.0% and 5.3% Hydrogen Peroxide Whitening Strips

P.A. Sagel, M.L. Barker, C.R. Mayer*, R.W. Gerlach
P&G, Mason, OH, USA

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ABSTRACT

This research was conducted to compare the clinical response of two different peroxide-containing gel formulations delivered using self-applied whitening strips. **Methods:** A meta-analysis was conducted to assess the effectiveness of two different whitening gel formulations: a low water 5.3% hydrogen peroxide gel and a high water 6.0% hydrogen peroxide gel. Both studies were randomized, double blind trials. The maxillary teeth were treated twice daily over a 2-week period with whitening strips. Efficacy (L*a*b* color change) was measured objectively by digital image analysis. **Results:** A total of 60 adults ranging from 19-85 years of age participated in the research. Both treatments were effective in whitening teeth, as evidenced by a statistically significant improvement from baseline ($p<0.05$). After adjusting for study effects and baseline, mean Δb^* (SE) for the high water content 6.0% hydrogen peroxide gel strip was –1.85 (0.151) compared to –1.41 (0.164) for the low water content 5.3% strip, with these treatments differing significantly ($p=0.023$). For the primary response variable Δb^*, this represented a 31.4% improvement in whitening for the higher water/higher concentration gel compared to the lower water/lower concentration gel. Outcomes for the other color parameters favored the 6.0% formulation. Both treatments were well-tolerated, and no subjects discontinued treatment due to adverse events related to bleaching. **Conclusion: For whitening strips, this research demonstrates that a high water 6.0% hydrogen peroxide gel provides superior whitening clinical response compared to a low water 5.3% hydrogen peroxide formula.**

OBJECTIVE

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

MATERIALS AND METHODS

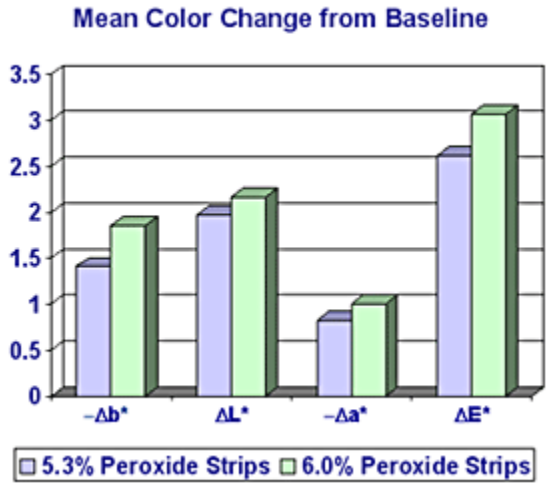
A meta-analysis was conducted to assess the effectiveness of two different whitening gel formulations: a low water 5.3% hydrogen peroxide gel and a high water 6.0% hydrogen peroxide gel. Both studies were randomized, double blind trials. The maxillary teeth were treated twice daily over a 2-week period with whitening strips. Tooth color was measured objectively from standardized digital images of the anterior dentition. After positioning and aligning subjects in the chin rest, digital images of the anterior facial tooth surfaces were captured using a high resolution digital camera and motorized zoom lens, under standard polarized lighting conditions. Red-green-blue values for the six maxillary teeth were determined for each tooth pixel in the image with reference to a calibration standard, and these values were averaged to determine an overall red-green-blue score for each visit. Using a standard method, these data were transformed to derive numerical values for tooth color in terms of L*a*b*, which represents standard three-dimensional color space. Oral examinations were performed along with subject interviews to determine the adverse effects of treatment.

RESULTS

Study Population: A total of 60 adults ranging from 19-85 years of age participated in the research. Sixty-seven percent of these subjects were female. Of the 60 subjects randomized to treatment, 55 subjects received treatment (27 and 28 subjects using the 5.3% and 6.0% formulations, respectively). Five subjects voluntarily withdrew from the studies before product distribution. A total of 48 subjects completed the studies (23 and 25 subjects using the 5.3% and 6.0% formulations, respectively). Treatment groups were well balanced with respect to demographic characteristics and behavioral parameters.

Efficacy: The treatment groups were well balanced on b* (yellowness), L* (lightness), and a* (redness) at baseline. Both treatments were effective in whitening teeth, as evidenced by a statistically significant improvement from baseline ($p<0.05$) for each color measurement.

After adjusting for study and baseline effects using analysis of covariance methods, mean Δb^* (SE) for the high water content 6.0% hydrogen peroxide gel strip was –1.85 (0.151) compared to –1.41 (0.164) for the low water content 5.3% strip, with these treatments differing significantly ($p=0.023$). For the primary response variable Δb^*, this represented a 31% improvement in whitening for the higher water/higher concentration gel compared to the lower water/lower concentration gel. Outcomes for the other color parameters favored the 6.0% formulation with 10% greater improvement in lightness, 22% greater redness reduction and 17% greater overall color change relative to the 5.3% formulation.



Safety: Both treatments were generally well-tolerated. Minor oral irritation or transient tooth sensitivity represented the most common adverse events. These events were reported by 22% of the subjects treated by the 5.3% formulation and 29% of the subjects treated by the 6.0% formulation. No subjects discontinued treatment due to bleaching-related adverse events.

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After 14 Days Product Use				
Outcome / Treatment	**Baseline Mean (SE)**	**Adjusted Mean (SE)**	**% Improvement**	**p-value**
Δb*				
5.3% H_2O_2 strips	18.43 (0.340)	-1.41 (0.164)	31.38	0.0229
6.0% H_2O_2 strips	18.31 (0.364)	-1.85 (0.151)		
ΔL*				
5.3% H_2O_2 strips	71.71 (0.800)	1.97 (0.211)	9.84	0.2336
6.0% H_2O_2 strips	71.71 (0.835)	2.17 (0.189)		
Δa*				
5.3% H_2O_2 strips	9.36 (0.298)	-0.82 (0.106)	22.43	0.0890
6.0% H_2O_2 strips	9.29 (0.358)	-1.00 (0.097)		
ΔE*				
5.3% H_2O_2 strips		2.62 (0.222)	17.43	0.0619
6.0% H_2O_2 strips		3.07 (0.205)		

CONCLUSION

For whitening strips, this research demonstrates that a high water 6.0% hydrogen peroxide gel provides superior whitening clinical response compared to a low water 5.3% hydrogen peroxide formula.

Both strip treatments were well-tolerated with similar occurrence of oral irritation and tooth sensitivity.

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