

Clinical Efficacy and Safety of Two Marketed Whitening Treatments

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ABSTRACT

Objectives: This clinical study compared efficacy and safety of two marketed whitening treatments.

Methods: 26 subjects were randomized and received one of two whitening regimens: Rembrandt® 2 Hour Whitening kit (2-hour kit) with four applications to be completed in one day or Crest® Whitestrips® Premium containing 10% hydrogen peroxide and worn 30 minutes twice a day for 7 days (7-day strips). Each treatment followed the manufacturers written instructions. Tolerability was assessed from subject interviews and oral examination, and efficacy was measured objectively from CIELAB digital measurements. Whitening response was compared at Day 2, Day 5, Day 8 and at the end-of-treatment (Day 2 for the 2-hour kit and Day 8 for the 7-day Strip) using the analysis of covariance method.

Results: The study population was healthy adults averaging 41.3 years of age. At the end-of-treatment, use of 2-hour kit resulted in adjusted means of -0.39 for Δb^* and 0.68 for ΔL^* , while the use of 7-day strips resulted in adjusted means of -2.14 for Δb^* and 1.58 for ΔL^* . Groups differed significantly ($p \leq 0.006$) on Δb^* and ΔL^* favoring the 7-day strip group. In addition, the 7-day strip group demonstrated significantly greater improvement of b^* and L^* ($p \leq 0.05$) relative to the 2-hour kit at Days 5 and 8. Both treatments were generally well-tolerated, and there were no adverse event dropouts in the study.

Conclusions: Use of a marketed 10% hydrogen peroxide, 7-day whitening strip resulted in a significantly greater tooth whitening response relative to that of a marketed 2-hour whitening kit.

MATERIALS AND METHODS

Twenty-six subjects were randomized and received one of the whitening products.

- Rembrandt® 2 Hour Whitening Kit consisting of four 20 minute H_2O_2 containing tray applications completed in one day (2-hour kit)
- Crest Whitestrips® Premium consisting of a total of fourteen 10% H_2O_2 strips worn 30 minutes, twice daily for 7 days (7-day strips)

Tooth color ($L^*a^*b^*$) was measured objectively from standard digital images of the maxillary anterior teeth at Days 2, 5, and 8. Analysis of covariance was used for color change comparisons between treatments with baseline color and age as covariates. Safety was assessed from clinical examination and subject interviews.

RESULTS

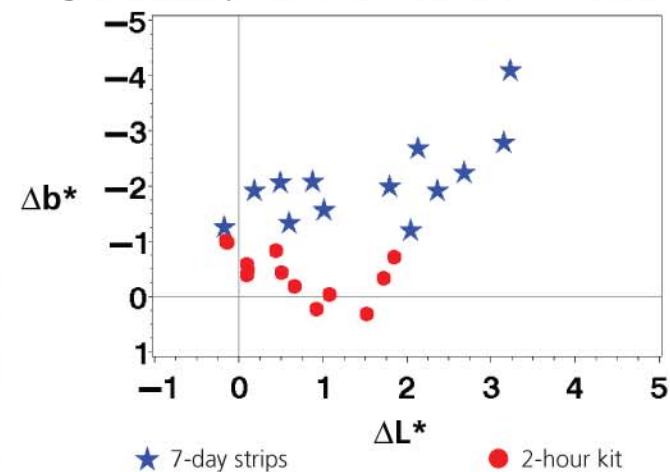
Visit** / Treatment	Cumulative Exposure Time	Δb^*		ΔL^*	
		Adj. Mean Change from Baseline (SE)	2-sided p-values	Adj. Mean Change from Baseline (SE)	2-sided p-values
Day 2					
7-day strips	1 hour	-0.74 (0.127)	0.077	0.56 (0.145)	0.563
2-hour kit	2 hours	-0.41 (0.127)		0.68 (0.145)	
Day 5					
7-day strips	4 hours	-1.70 (0.150)	< 0.001	1.46 (0.172)	0.040
2-hour kit	2 hours	-0.20 (0.150)		0.93 (0.172)	
Day 8					
7-day strips	7 hours	-2.13 (0.158)	< 0.001	1.58 (0.221)	0.050
2-hour kit	2 hours	-0.33 (0.158)		0.93 (0.221)	
End-of-treatment					
7-day strips at Day 8	7 hours	-2.14 (0.163)	< 0.001	1.58 (0.211)	0.006
2-hour kit at Day 2	2 hours	-0.39 (0.163)		0.68 (0.211)	

** Measurement taken the day after treatment.

RESULTS

Efficacy: Subjects ranged in age from 25 to 58 with an average of 41 years and 62% were female. Groups were balanced with respect to demographic characteristics and baseline tooth color ($p > 0.54$). At Day 5, Day 8 and end-of-treatment, the 7-day strips provided statistically significant color improvement relative to the 2-hour kit for both Δb^* and ΔL^* ($p \leq 0.05$).

Figure 1: Scatterplot of Δb^* versus ΔL^* at End-of-treatment



Safety: 31% of subjects in each treatment reported oral irritation, and 8% in each group reported tooth sensitivity. No subjects in either group had examiner observed oral irritation or dropped out due to treatment related adverse events.

CONCLUSIONS

Use of a marketed 10% hydrogen peroxide, 7-day whitening strip resulted in a significantly greater tooth whitening response relative to that of a marketed 2-hour whitening kit.