

Comparative Effectiveness of Two Self-directed Whitening Systems: Outcomes from Three Randomized Clinical Trials

R.W. Gerlach, M.L. Barker, X. Zhou, P.A. Sagel, S.F. McClanahan*
Procter & Gamble, Mason, OH, USA



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ABSTRACT

Objective: This integrated research was conducted to establish the comparative efficacy of 6% hydrogen peroxide whitening strips (Crest® Whitestrips®) versus 18% carbamide peroxide paint-on gel (Colgate® Simply White™). **Methods:** Three separate clinical trials were conducted, each at a different research center under the direction of a different investigator. Study participants were supplied with the manufacturers' written instructions for use, treatment was twice daily for 30 minutes, and all usage was unsupervised over a 14-day period. Whitening was measured objectively on the maxillary teeth via digital image analysis using well-established and standard methods for L*a*b* color change. **Results:** A total of 97 healthy adults were randomized to whitening strips or the paint-on gel in these three trials. Outcomes from each of the three clinical trials were consistent, showing highly significant ($p < 0.0001$) greater color improvement for the strip group for individual (Δb^* , ΔL^*) color parameters compared to the paint-on gel. The 3-study mean improvement in Δb^* was 2.57 for whitening strips compared to 0.39 for the paint-on gel. Similar findings were noted for ΔL^* , with the strips exhibiting a 3-study mean improvement of 2.13 compared to 0.30 for the paint-on product. For these primary and secondary color outcomes, whitening strip users experienced approximately a 6.7-fold reduction in yellowness (Δb^*) and a 7.2-fold increase in brightness (ΔL^*) relative to the paint-on gel. Both treatments were well tolerated over the 14-day treatment period. **Conclusion:** Outcomes from three randomized clinical trials demonstrate a highly significant, more than six-fold superior whitening benefit for 6% hydrogen peroxide whitening strips compared to the 18% carbamide peroxide paint-on gel.

OBJECTIVE

The primary objective of this research was to compare the effectiveness of two self-directed tooth whitening systems following the recommended label usage.

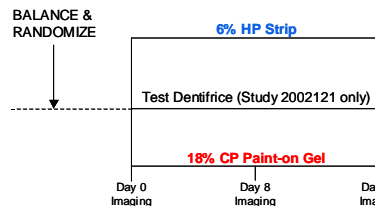
Paint-on Gel Label Usage Instructions

- Use this product twice a day for 14 days.
- Step 1**
- Brush your teeth as you normally would. Dry the surface of your teeth.
 - Try not to let your lips or tongue touch your dried teeth to avoid rewetting.
 - Unscrew the cap to remove the applicator brush from the bottle.
- Step 2**
- Apply a thin layer of gel one tooth at a time to your upper teeth using an up and down motion.
 - Re dip the brush as needed.
- Step 3**
- Try not to let your lips or tongue touch your teeth for 30 seconds.
 - For best results, do not eat or drink for 30 minutes so that the gel remains on your teeth and has time to work.
 - Make sure cap is replaced promptly and closed tightly to prevent the gel from drying out.

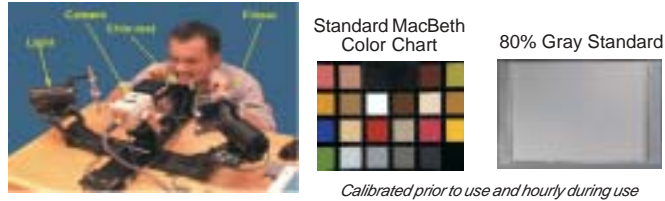
Strip Label Usage Instructions

Wear a tooth whitening strip on your upper teeth for 30 minutes two times per day (once in the morning and once in the evening). Do not brush before applying strip. Wear two whitening strips every day during the study period. Do not eat, drink, smoke, or sleep while wearing the strips on your teeth.

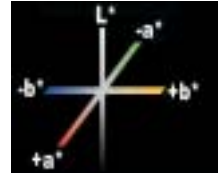
STUDY DESIGNS



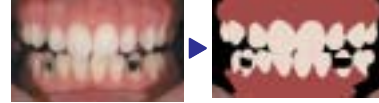
CONTROLLED IMAGE ACQUISITION



3-D COLOR SPACE OF L*, a*, b*



DIGITAL IMAGE ANALYSIS



L*, a*, b* values of teeth
calculated by computer

BASELINE COLOR VALUES

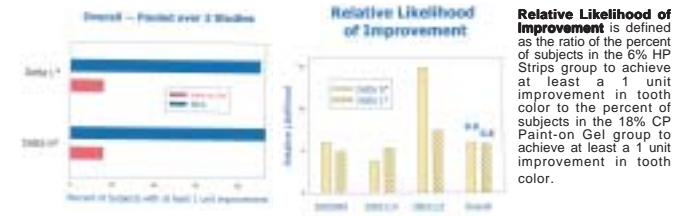
STUDY NUMBER	TREATMENT GROUP	b*
2002099	Paint-on Gel	15.52
	Strip	15.57
2002114	Paint-on Gel	16.78
	Strip	16.80
2002121	Paint-on Gel	16.82
	Strip	17.52
	Test Dentifrice	17.48

No statistically significant differences between treatment group

BASELINE COLOR VALUES



POOLED/OVERALL RESULTS



DEMOGRAPHIC CHARACTERISTICS

STUDY NUMBER	TREATMENT GROUP	NUMBER OF PATIENTS	SEX M	SEX F	ETHNICITY								AGE MEAN	SMOKER YES	SMOKER NO	COFFEE/TEA/COLA YES		COFFEE/TEA/COLA NO	
					WHITE	BLACK	ASIAN	HISPANIC	MULTI RACIAL	YES	NO	YES				NO			
2002099 Ohio	Paint-on Gel	15	4	11	13	1	0	1	0	35.9	2	13	12	3					
	Strip	15	4	11	12	3	0	0	0	34.9	0	15	11	4					
2002114 Gainesville, FL	Paint-on Gel	16	5	11	16	0	0	0	0	38.4	4	12	15	1					
	Strip	16	5	11	13	2	1	0	0	36.8	2	14	15	1					
2002121 West Palm Beach, FL	Paint-on Gel	19	10	9	15	4	0	0	0	32.6	0	19	16	3					
	Strip	14	5	9	7	3	0	4	0	30.1	0	14	12	2					
	Test Dentifrice	18	7	11	14	3	0	0	1	31.6	0	18	15	3					

No statistically significant differences between treatment groups except where noted (*)
* 2-sided p-value = 0.045

SUBJECT ACCOUNTABILITY

STUDY NUMBER	TREATMENT GROUP	NUMBER OF PATIENTS	SEX M	SEX F	ETHNICITY	AGE MEAN	SMOKER YES	SMOKER NO	COFFEE/TEA/COLA YES	COFFEE/TEA/COLA NO				
											WHITE	BLACK	ASIAN	HISPANIC
2002099	Paint-on Gel	15	4	11	13	1	0	1	0	35.9	2	13	12	3
	Strip	15	4	11	12	3	0	0	0	34.9	0	15	11	4
	Test Dentifrice	18	7	11	14	3	0	0	1	31.6	0	18	15	3
2002114	Paint-on Gel	16	5	11	16	0	0	0	0	38.4	4	12	15	1
	Strip	16	5	11	13	2	1	0	0	36.8	2	14	15	1
	Test Dentifrice	18	7	11	14	3	0	0	1	31.6	0	18	15	3
2002121	Paint-on Gel	19	10	9	15	4	0	0	0	32.6	0	19	16	3
	Strip	14	5	9	7	3	0	4	0	30.1	0	14	12	2
	Test Dentifrice	18	7	11	14	3	0	0	1	31.6	0	18	15	3

LTFU = Lost To Follow Up MV = Missed Visit
PV = Protocol Violation VW = Voluntary Withdrawal

*Four subjects were randomized to treatment (one each in the Paint-on Gel and Strip groups and two in the Dentifrice group) but failed to present for product distribution.

CONCLUSION

- A 6% hydrogen peroxide controlled dose whitening strip is approximately 7-fold more effective in tooth whitening than a 18% carbamide peroxide paint-on gel over a 2-week period.
- Subjects using the strip are approximately 6x as likely to experience at least a one unit improvement in tooth color as subjects using the paint-on gel.