Final Report: Human Enamel Whitening Study
Study EWS 10-242

Title

Determination of the whitening potential of products designed to change the color of teeth.

Study Number

Dental Product Testing Study Number 10-242

Study Sponsor

Vista Dental
2200 Northwestern Ave.
Racine, WI 53404

Attention: Brett Rhodes
877-418-4782

Conducting Agency

Dental Product Testing
Therametric Technologies, Inc.
9880 Douglas Floyd Parkway
Noblesville, IN 46060-7900

Principal Investigator: Bruce R. Schemehorn MS
(317) 565-8070

Objectives

The purpose of the study was to determine if a whitening effect could be observed with an H_2O_2 gel.

Procedure

Human permanent incisors or canines were used in this study. The lingual surface was flattened and the root was removed from the tooth and discarded. The tip of the cusp and proximal surfaces were cut to obtain a relatively rectangular specimen at least 6 mm on a side. The specimens were then embedded in auto polymerizing methyl methacrylate so that only the buccal enamel surface was exposed. The enamel surface was as horizontal as possible. The specimens were then gently buffed with a 3:2 flour of pumice water slurry to remove any exogenous stains. They were then rinsed, placed in plastic containers under humid conditions and refrigerated until used.

The color of each specimen was determined photometrically using a Minolta CM-2600d Chromameter. The area examined was the center of the specimen. Four readings per specimen were obtained turning the specimen 90^{O} for each reading. All values (L a* and b*) were determined and an average L, a* and b* was calculated. All specimens

had an average L value <60 to be eligible for inclusion into the study. On the basis of the average baseline scores, the specimens were divided up into groups of 12 specimens each balanced on their baseline L value scores.

The treatments were performed mimicking clinical instructions for application. For this study, the treatment time was 2 hours. The two gels and the water control were applied for ten, 120-minute intervals with 60 minute immersions in deionized water between treatments. Any residual gel was rinsed off before going into the water. Overnight, they were kept in a humid environment under refrigerated conditions. Controls were treated in a similar manner with tap water.

The specimens were examined for color after one-half (5) of the treatments and again after all the treatments using the methodology outlined above. The individual changes in color were determined as Δ L, Δ a* and Δ b* as well as Δ E.

Treatment Groups

1 DI Water (control)
2 Opalescence (20% Carbamide Peroxide)
3 Fluorescent (22% Carbamide Peroxide)

Calculations

The mean and SEM of the baseline, each post scoring and each change in L, a* and b* as well as the Δ E were calculated and reported. The L value is the dark to light shift (the higher the value the whiter the specimen). The a value is a red to green color shift (increase in a is shift to red). The b values is a yellow to blue color shift (increase in b is a shift to yellow). Delta E is the overall color shift.

Statistical Analyses

Statistical analyses were performed within groups to determine changes over time and among groups to determine relative effectiveness. The within groups analyses were with t-tests. The among groups analyses were with a one-way analysis of variance model. If the ANOVA indicated significant differences, the individual means were analyzed by the Student Newman Keuls (SNK) test. All analyses were performed using the Sigma Stat (2.0) software.

Record Maintained

DPT will be responsible for the storage, expiration and destruction of all specimens, raw data and final report in accordance with the standard operating procedures or as requested by the sponsor.

Final Report: Human Enamel Whitening Study

Results

The results are summarized in the attached tables. The L values (indicating the lightness shift) are similar and significantly higher for both whitening gels compared to the negative control water after both five and 10 treatments. This indicates that both will significantly lighten enamel. The largest increase is after five treatments and then they both seem to plateau off somewhat (ie no significant difference between five and 10 treatments) although they continue to numerically higher.

The a values are similar and significantly lower with the use of both whitening gels after 10 treatments. After five treatments they are numerically but not significantly lower. This would indicate a slight shift from a reddish color to a greenish color.

Similarly, the b values are similar and significantly lower with the use of both whitening gels after 10 treatments. After five treatments they are numerically but not significantly lower. This would indicate a slight shift from a yellowish color to a bluish color. A blue color is normally associated with a whiter looking tooth.

The delta E values indicate that the Fluorescent Gel caused a significantly greater overall color change than the Opalescence Gel.

Conclusion

Both whitening gels, (Opalescence and Fluorescent) significantly whitened the appearance of the human teeth over and above a negative control. They were not significantly different. This was primarily determined by a shift in the L value, and to a lesser extent the b value, of the Lab color spectrum. In addition, although not quantified, the specimens in the two whitening gel treated groups were visually whiter.

Bruce R. Schemehorn

2/2/11

This study has been conducted and reviewed according to the FDA Monograph on Anticaries Drug Products for Over the Counter Human Use and the FDA Good Laboratory Practices to the best of our knowledge.

2/2/11

Bruce R. Schemehorn
Director

Date

Final Report: Human Enamel Whitening Study

Summary of Changes in L Values Over the Study Period

Treatment	L Values					
	Baseline	Interim	Final	Significant (p)		
				Ba→In	In→Fi	Ba→Fi
DI Water	59.5 ± 0.6* **	58.9 ± 0.4	59.4 ± 0.8	0.414**	0.574	0.920
Opalescence (20%)	59.8 ± 0.4	61.2 ± 0.4	62.3 ± 0.4	**0.022**	0.065	**<0.001**
Fluorescent (22%)	59.7 ± 0.8	62.3 ± 0.8	63.2 ± 0.8	**0.031**	0.435	**0.005**

* - Mean ± SEM (N=12)
** - All comparisons connected by lines (among groups) and with $p \geq 0.05$ (within groups) are not significantly different.
Bold values are significant.

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Final Report: Human Enamel Whitening Study

Summary of Changes in a* Values Over the Study Period

Treatment	a* Values					
	Baseline	Interim	Final	Significant (p)		
				Ba→In	In→Fi	Ba→Fi
DI Water	3.6 ± 0.3* **	3.5 ± 0.3	3.4 ± 0.3	0.816**	0.816	0.646
Opalescence (20%)	3.8 ± 0.2	2.9 ± 0.2	2.6 ± 0.2	**0.004**	0.300	**<0.001**
Fluorescent (22%)	4.0 ± 0.5	3.0 ± 0.3	2.6 ± 0.3	0.100	0.356	**0.025**

* - Mean ± SEM (N=12)
** - All comparisons connected by lines (among groups) and with $p \geq 0.05$ (within groups) are not significantly different.
Bold values are significant.

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Final Report: Human Enamel Whitening Study

Summary of Changes in b* Values Over the Study Period

Treatment	b* Values					
	Baseline	Interim	Final	Significant (p)		
				Ba→In	In→Fi	Ba→Fi
DI Water	9.9 ± 1.0* **	9.0 ± 1.0	10.2 ± 1.0	0.531	0.405	0.834
Opalescence (20%)	10.7 ± 0.7	7.3 ± 0.7	7.2 ± 0.6	**0.002**	0.915	**<0.001**
Fluorescent (22%)	9.4 ± 0.9	6.6 ± 0.9	5.2 ± 0.5	**0.039**	0.188	**<0.001**

* - Mean ± SEM (N=12)
** - All comparisons connected by lines (among groups) and with $p \geq 0.05$ (within groups) are not significantly different.
Bold values are significant.

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Final Report: Human Enamel Whitening Study

Summary of Changes in ΔE Values Over the Study Period

Treatment	ΔE Values			Significant (p) In→Fi
	Interim		Final	
DI Water	2.84 ± 0.43*	**	2.90 ± 0.67	0.941
Opalescence (20%)	4.00 ± 0.38		4.65 ± 0.49	0.306
Fluorescent (22%)	4.47 ± 0.67		5.84 ± 0.90	0.235

* - Mean ± SEM (N=12)
** - All comparisons connected by lines (among groups) and with $p \geq 0.05$ (within groups) are not significantly different.
Bold values are significant.

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