

2821. Oral Tolerability of Hydrogen Peroxide Whitening Gel Formulations

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Introduction

This experimental tooth-whitening system, consisting of a prefabricated tray predosed with hydrogen peroxide gel (Figure 1) applied to teeth once daily for 45 minutes over 7 days, provided significant reductions in tooth shade, as assessed using the VITA Shade Guide. Several clinical studies have already shown the efficacy of this experimental tooth-whitening system^{1,2}. Irrespective of the delivery systems and concentrations, tooth sensitivity and gingival irritation are widely recognized as the most common side-effects of tooth whitening, with up to two-thirds of individuals affected sometime during the treatment course. These events are typically mild in severity and transient in nature, and often resolve during active treatment³. This study is intended to provide information on the tolerability and tooth-whitening efficacy of an experimental tooth-whitening system containing Carbopol/silica 11.2% w/w hydrogen peroxide gel compared with two Carbopol hydrogen peroxide (10.5% w/w and 11.2% w/w) reference gel formulations.

Objective

To evaluate the oral tolerability and efficacy of three hydrogen peroxide whitening gel formulations after seven days of treatment.

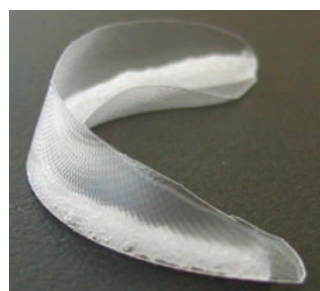


Figure 1. Experimental tooth whitening system.

Methods

This was a randomized, parallel-group, longitudinal, examiner-blinded study to evaluate the efficacy and safety of three experimental hydrogen peroxide gels (approximately 10% w/w) predosed in a flexible tray.

A total of 157 subjects with a VITA shade of A1 or greater (value-oriented scale) on two of the four maxillary incisors were randomized to one of three treatments to be used once daily for 45 minutes.

Subjects were evaluated for VITA shade rank and tooth sensitivity, and had an oral soft tissue examination prior to the first treatment and after 7 days of treatment, on Day 8 (+1 day). Subjects were also asked to complete a tooth-whitening efficacy questionnaire on Day 3.

Test products were as follows:

- experimental product 1: Carbopol/silica 11.2% w/w hydrogen peroxide gel
- experimental product 2: Carbopol 11.2% w/w hydrogen peroxide gel
- experimental product 3: Carbopol 10.5% w/w hydrogen peroxide gel.

Results

- For all three treatment groups, the number and type of oral findings were similar to those reported with the use of marketed whitening products.
- The number of subjects with oral findings in the Carbopol/silica 11.2% w/w hydrogen peroxide gel treatment group was directionally lower than in the two other groups after 7 days of treatment (Table 1).
- Reductions in VITA shade after 7 days of treatment were statistically significant for all three formulations (Table 2).

Table 1. Treatment-Emergent Adverse Events (AEs): Safety Population

	Carbopol/silica 11.2% w/w hydrogen peroxide (n = 52) n (%), nAE	Carbopol 11.2% w/w hydrogen peroxide (n = 51) n (%), nAE	Carbopol 10.5% w/w hydrogen peroxide (n = 54) n (%), nAE
Subjects with AEs	5 (9.6), 11	10 (19.6), 16	10 (18.5), 15
Non-oral AEs	0	0	0
Oral AEs	5 (9.6), 11	10 (19.6), 16	10 (18.5), 15
Oral reactions			
Erythema	5 (9.6), 5	7 (13.7), 7	5 (9.3), 5
Gingival sensitivity	3 (5.8), 3	6 (11.8), 6	4 (7.4), 4
Gingival soreness	1 (1.9), 1	0	0
Oral ulceration	1 (1.9), 1	0	0
Tooth sensitivity	1 (1.9), 1	3 (5.9), 3	6 (11.1), 6
95% CI for oral AEs	1.6%, 17.63%	8.71%, 30.5%	8.18%, 28.88%

Table 2. Whitening Efficacy of Experimental Tooth Whitening Gels – VITA Shade Change from Baseline

	Carbopol/silica 11.2% w/w hydrogen peroxide (n = 50) Mean ± SD	Carbopol 11.2% w/w hydrogen peroxide (n = 49) Mean ± SD	Carbopol 10.5% w/w hydrogen peroxide (n = 54) Mean ± SD
Baseline	9.7 ± 4.2	9.4 ± 4.2	9.3 ± 4.1
Day 7	6.4 ± 4.0	5.9 ± 3.8	5.9 ± 3.3
Change from baseline	-3.3 ± 2.6*	-3.5 ± 2.4*	-3.3 ± 2.6*

p values for all pair-wise comparisons were not statistically significant.

*Indicates highly statistically significant within treatment mean VITA shade change from baseline (p < 0.0001).

Table 3. Self-Perceived Tooth Whitening on Day 3 Compared with Baseline

Are your teeth whiter?	Carbopol/silica 11.2% w/w hydrogen peroxide (n = 50) n (%)	Carbopol 11.2% w/w hydrogen peroxide (n = 49) n (%)	Carbopol 10.5% w/w hydrogen peroxide (n = 54) n (%)
Yes	36 (72.0)	35 (71.4)	42 (77.8)
No	14 (28.0)	14 (28.6)	12 (22.2)

p values for all within-treatment comparisons to baseline were statistically significant (p < 0.05).

- Table 3 shows the feedback obtained from subjects on Day 3, regarding improvement in self-perceived tooth whitening. The percentage of positive responses compared with baseline is statistically significant.
- No differences between treatments could be elicited for either VITA shade reductions or self-perceived tooth whitening.

Conclusions

- The Carbopol/silica formulation demonstrated a similar safety profile to the two other experimental products and had a lower incidence of oral findings.
- The majority of subjects reported that their teeth were whiter, compared with baseline, after 3 days.
- Whitening efficacy, compared with baseline, was statistically significant after 7 days (examiner assessment), and there were no statistically significant differences between treatments.

References

1. Stockert LA, Barouth K, Bosma ML, Selmani A. Safety and efficacy of a 10% hydrogen peroxide whitening gel. Presented at the 85th International Association for Dental Research Congress, 21–24 March 2007. New Orleans, LA, USA. Abstract 2825.
2. Stockert LA, Bosma ML, Proskin HM, Kleber CJ, Milleman KR. Safety and efficacy results of whole mouth tooth whitening treatments. Presented at the 85th International Association for Dental Research Congress, 21–24 March 2007. New Orleans, LA, USA. Abstract 2670.
3. Gerlach RW, Zhou X, 2001. Vital bleaching with whitening strips: summary of clinical research on effectiveness and tolerability. *J Contemp Dent Pract* 2:1–16.

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