

PHILIPS ZOOM!

Tooth Whitening
In vivo study

Safety and efficacy of Philips take-home teeth whitening gel in custom whitening trays

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Objectives

The primary objective was to assess changes in tooth shade after use of Philips tooth whitening products containing hydrogen peroxide (HP) or carbamide peroxide (CP). Safety and user experience associated with the whitening products were also assessed during the study.

Methodology

This was a randomized, single-blind, parallel-design clinical trial with subjects undergoing 14 days of tooth whitening. Subjects were generally healthy adults aged 18-75 years who exhibited an average tooth shade of 2M2 (13) or darker on the facial surface of a minimum of 4 out of 6 maxillary anterior teeth, per a VITA Bleachedguide 3D Master shade guide (VBG). At the screening visit, eligible subjects were randomized to one of six treatment groups per [Table 1 \(page 2\)](#) and provided with a standard manual toothbrush, string floss and dentifrice for use during the study. All groups used custom whitening trays created after enrollment. At the baseline visit, VBG scores were recorded and subjects received their whitening product. Subjects returned to the clinic for VBG assessments after 3-day, 9-day, and 14-day use periods. A final study visit to confirm efficacy and safety was conducted one week following the last application. For analysis, tooth shade was converted to a numeric value (1 to 29) for each tooth assessed. Overall shade was calculated as the average of the designated 4-6 anterior teeth, with a positive shade change indicating a whitening effect. To assess safety, each subject self-reported tooth sensitivity, whereas the investigator recorded gingival irritation using incidences of gingival erythema, edema and sloughing.

Safety

Adverse events (AEs) were reported by 24 participants, with 22 participants experiencing AEs related to the study products. All AEs were mild to moderate in severity. Subject-reported moderate tooth sensitivity included 2 subjects after 3 days use, 6 subjects after 9 days use, and 1 subject after 14 days use. Gingival irritation included 6 reports after 3 days use, 3 reports after 9 days use, and 2 reports after 14 days use. Examiner-reported erythema included 6 reports after 3 days use, 2 reports after 9 days use, and 2 reports after 14 days use. There were no reports of edema or sloughing at any visit.

User Experience

Subjects' user experience results are presented in [Table 3 \(page 2\)](#). The results show a clear positive rating for ease of use, ease of following instructions, satisfaction with results, and perceived lasting results. Additionally, over 90% of the subjects were willing to recommend the whitening products.

Results

Of 309 subjects enrolled, 293 were dispensed treatment at baseline and 279 subjects completed the study. Sixteen discontinued before treatment, and 14 discontinued after treatment. The data analysis included all randomized subjects with a baseline and at least one post-baseline efficacy observation. [See Table 2 \(page 2\)](#)

VITA Bleachedguide 3D-Master Shade (VBG)

Average change in shade from baseline after use of tooth whitening gel. A greater change represents more whitening.

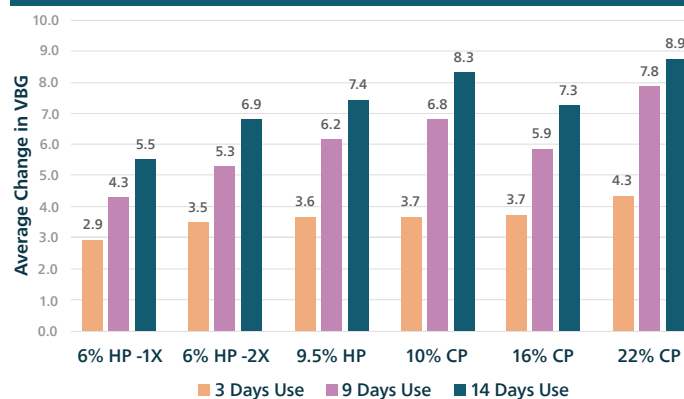


Figure 1. Tooth whitening after 3-, 9-, and 14-days use of the six study products.

The VBG score (least squares mean and standard error) for each group is presented in [Table 2 \(page 2\)](#) at baseline and after 3-, 9- and 14-days use of the whitening gel as well as for the 1 week post-use evaluation. The change in VBG score after 3-, 9- and 14-days use is graphically presented in Figure 1, with a greater change representing more whitening.

Conclusions

In home use of Philips Whitening products significantly whitened teeth as measured by VITA Bleachedguide 3D Master shade guide. The efficacy was significantly improved for all whitening products after 3-, 9- and 14-days use.

The take-home whitening products were safe to use and associated with little to no sensitivity.

Across all products and dosing regimens, participants consistently rated the Philips Zoom! take-home whitening products positively for ease of use, easy to follow instructions, satisfaction with results, and perceived lasting effects.

TABLE 1

Group ^a	Whitening Product ^a	Application
6% HP -1X	Philips Zoom! DayWhite 6% HP	Once daily, 60 min.
6% HP -2X	Philips Zoom! DayWhite 6% HP	Twice daily, 45 min. each
9.5% HP	Philips Zoom! DayWhite 9.5% HP	Once daily, 60 min.
10% CP	Philips Zoom! NiteWhite 10% CP	Once daily, 4 hr.
16% CP	Philips Zoom! NiteWhite 16% CP	Once daily, 4 hr.
22% CP	Philips Zoom! NiteWhite 22% CP	Once daily, 4 hr.

^a HP = hydrogen peroxide, CP = carbamide peroxide.

TABLE 2 VBG Score^a: mean (standard error)

Group ^b	N ^c	Baseline	After 3 days ^d	After 9 days ^d	After 14 days ^d	1 week post ^d
6% HP -1X	49/46	16.76 (0.50)	13.70 (0.26)	12.31 (0.26)	11.12 (0.27)	11.51 (0.27)
6% HP -2X	48/45	15.18 (0.39)	11.52 (0.29)	9.77 (0.29)	8.19 (0.29)	8.72 (0.29)
9.5% HP	50/50	15.81 (0.53)	12.17 (0.30)	9.58 (0.30)	8.38 (0.30)	8.82 (0.30)
10% CP	49/48	16.36 (0.49)	12.69 (0.26)	9.55 (0.26)	8.09 (0.26)	8.84 (0.26)
16% CP	49/48	15.65 (0.40)	11.94 (0.29)	9.78 (0.29)	8.41 (0.29)	9.20 (0.29)
22% CP	48/42	16.37 (0.54)	12.10 (0.40)	8.66 (0.41)	7.58 (0.42)	8.25 (0.42)

^a A lower VBG score indicates a whiter tooth surface.

^b HP = hydrogen peroxide, CP = carbamide peroxide.

^c Number of subjects dispensed treatment at baseline / Number of subjects completing the study.

^d The change in VBG score from Baseline was statistically significant ($p < 0.0001$) for all groups.

TABLE 3 Top Ratings^a across All Products

	Range of Users Reporting	Range of Scores
Easy to use	88.9% - 100%	4.38 – 4.82 (out of 5)
Easy to follow instructions	93.3% - 100%	4.58 – 4.84 (out of 5)
Satisfaction with results	80.4% - 91.1%	6.17 – 6.46 (out of 7)
Perceived lasting results	82.0% - 95.6%	4.10 – 4.51 (out of 5)
Willingness to recommend	91.3% - 97.9%	

^a Top Ratings include top 2 responses on either a 5-point scale or a 7-point scale.

