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Tooth whitening

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In vivo study

Tooth whitening gel with non-custom trays – a safety and efficacy clinical investigation

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Objective

To evaluate the effects of two at-home Philips Sonicare Teeth Whitening Gels on tooth shade as measured by the VITA Bleachedguide 3-D Master shade guide following 3, 6 and 9 applications.

Methodology

This was a randomized, single-blind, parallel-design clinical trial involving 98 participants (58 female, 40 male). 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 VITA Bleachedguide 3-D Master shade guide (VBG). Eligible subjects were randomized to one of two treatment groups: Philips Sonicare Gentle White Teeth Whitening Gel 6% hydrogen peroxide (PS6 group) or Philips Sonicare Premium White Teeth Whitening Gel 9.5% hydrogen peroxide (PS9.5 group). Both groups used non-custom boil and bite whitening trays. All subjects were provided with a standard manual toothbrush, string floss and dentifrice for use during the study. Subject VBG scores were recorded at baseline. Subjects returned to the clinic for VBG assessments after 3, 6 and 9 daily whitening gel applications (30-60 minutes each). 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, with overall shade calculated as the average of the designated 4-6 anterior teeth, with a positive shade change indicating a whitening effect. Tooth sensitivity and gingival irritation were assessed using subject questionnaires and logs. Gingival irritation was also assessed by the investigator using the Visual Scoring System for Gingival Irritation.

Results

At Baseline, the VBG Least Squares (LS) mean and 95% Confidence Interval (CI) tooth shade outcomes were 17.00 (15.98, 18.02) for the PS6 group and 16.60 (15.59, 17.61) for the PS9.5 group.

Following 3 applications of the assigned whitening gel, the LS mean and 95% CI tooth shade changes from baseline were 2.16 (1.68, 2.64) for the PS6 group and 3.03 (2.47, 3.59) for the PS9.5 group, with both changes being statistically significantly different from baseline, p-value < 0.0001.

Following 6 applications of the assigned whitening gel, the LS mean and 95% CI tooth shade changes from baseline were 3.58 (3.09, 4.06) for the PS6 group and 4.14 (3.58, 4.70) for the PS9.5 group, with both changes being statistically significantly different from baseline, p-value < 0.0001.

Following 9 applications of the assigned whitening gel, the LS mean and 95% CI tooth shade changes from baseline were 4.08 (3.59, 4.56) for the PS6 group and 4.91 (4.35, 5.48) for the PS9.5 group, with both changes being statistically significantly different from baseline, p-value < 0.0001.

One week following the 9th and last application of the assigned whitening gel, the LS mean and 95% CI shade changes from baseline were 4.06 (3.57, 4.55) for the PS6 group and 4.81 (4.24, 5.37) for the PS9.5 group, with both changes being statistically significantly different from baseline, p-value < 0.0001.

Safety

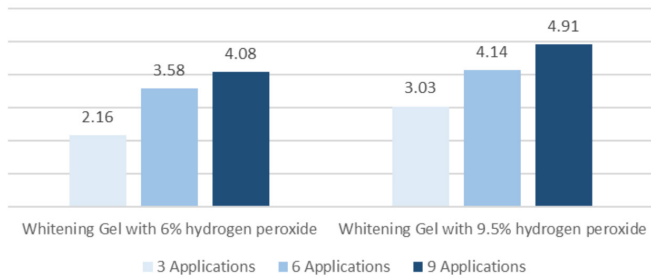
There were two adverse events reported in the study, one in each group. Both adverse events were related to COVID-19 and not related to the study or study products.

For the assessment of gingival irritation, the peak occurrence was after 6 applications of the tooth whitening gel, with 9.1% and 14.6% of subjects for PS6 and PS9.5 groups, respectively, reporting irritation. All reports were of mild to moderate irritation and were resolved after the 9th application of the whitening gel.

For the assessment of tooth sensitivity, the peak occurrence was after 6 applications of the tooth whitening gel, with 2.3% and 8.3% of subjects for PS6 and PS9.5 groups, respectively, reporting post-whitening tooth sensitivity. All reports were of mild to moderate sensitivity and were resolved after the 9th application of the whitening gel.

VITA Bleachedguide 3D-Master Shade (VBG)

Change in Shade from Baseline to after 3, 6 and 9 Applications of Tooth Whitening Gel



Conclusions

In home use of either the Philips Sonicare Gentle White Teeth Whitening Gel with 6% hydrogen peroxide or the Philips Sonicare Premium White Teeth Whitening Gel with 9.5% hydrogen peroxide, both used with non-custom trays, significantly whitened teeth after 3, 6 and 9 applications as measured by VITA Bleachedguide 3-D Master shade guide.

Both products tested were found to be safe for home use on teeth and gingival tissue.