



Efficacy
in vivo study

A Randomized, Parallel-Design Clinical Trial to Assess Tooth Bleaching Efficacy and Safety of Light versus non-Light Activated Chairside Whitening

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Objective

To characterize the extent to which the safety and efficacy profile of Philips Zoom WhiteSpeed (25% Hydrogen Peroxide) and Ultradent Opalescence Boost PF (40% Hydrogen Peroxide) cosmetic whitening regimens differ immediately following, and at seven and thirty days post bleaching application.

Methodology

One hundred thirty-five of 394 subjects screened completed an IRB-approved double-blind, randomized, parallel-design clinical trial in a population of healthy adults aged 18-75. Fifty-nine subjects were female, 76 were male; with a mean age of 50.0 years. Eligible subjects had a minimum of four maxillary anterior teeth with a tooth shade of A3 or darker assessed per VITA Classical (VC) shade guide. Sixty-eight subjects were randomized to Opalescence Boost and 69 to Philips Zoom. Efficacy was assessed by VITA EasyShade for ΔE characterization using a custom jig fabricated for a single anterior site in addition to VC and VITA Bleachedguide 3D-Master (BG) shade assessment. Safety was characterized by subject report of sensitivity, oral examination and subject use of sensitivity-reducing agents (Relief ACP or UltraEZ) applied and dispensed per manufacturer's instructions. Study endpoints were assessed pre- and post-whitening, at Day 7 and Day 30.

Results

Median ΔE values per Kruskal-Wallis analysis for instrumental color change immediately post-whitening were 5.12 for Zoom and 2.55 for Boost ($p < 0.0001$). At Day 7, ΔE outcomes were 6.34 for Zoom and 4.08 for Boost ($p = 0.0059$). At Day 30, ΔE outcomes were 6.03 for Zoom and 3.44 for Boost ($p = 0.0019$). The difference between treatments at each timepoint was statistically significant. For VC visual shade assessment, LS Mean (SE) based on analysis of variance immediately post-whitening values were 5.86 (0.18) for Zoom and 4.47 (0.18) for Boost ($p < 0.0001$). At Day 7, outcomes were 4.92 (0.20) for Zoom and 4.19 (0.20) for Boost ($p = 0.0106$). At Day 30, outcomes were 4.45 for Zoom and 4.11 for Boost ($p = 0.2648$).

For BG visual shade assessment, the median shade change per Kruskal-Wallis analysis immediately post-whitening was 3.17 for Zoom and 2.00 for Boost ($p < 0.0001$). At Day 7, outcomes were 2.33 for Zoom and 1.67 for Boost ($p = 0.0198$) and at Day 30, outcomes were 2.25 for Zoom and 1.83 for Boost ($p = 0.1195$).

The percentage of subjects who reported 'No Sensitivity' immediately post-whitening was 98.5% for Zoom and 98.6% for Boost. At Day 7, subject-reported values for 'No Sensitivity' were 82.1% for Zoom and 79.4% for Boost. Of those experiencing sensitivity, one subject rated sensitivity as 'Moderate.' All other reports were characterized as 'Mild' by subjects.

There were a total of 41 adverse events reported among 34 subjects. In general, these events were associated with sensitivity. Subject use of post-whitening sensitivity gel (Relief ACP and UltraEZ) was low. Four subjects (two per treatment group) used the products at Day 1 post-bleaching and one subject used the product on Day 2. There are no other reports of use from Day 3 to Day 7.

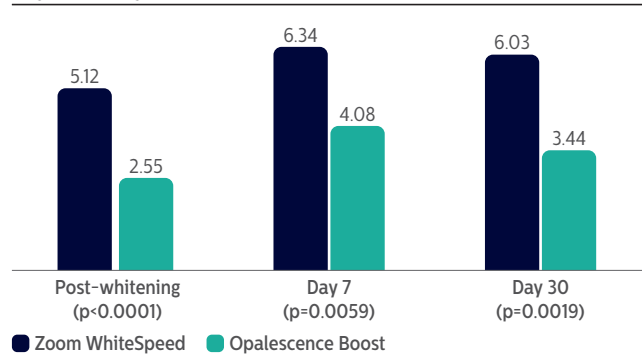
Conclusions

Philips Zoom WhiteSpeed whitens teeth significantly better than Opalescence Boost immediately following bleaching, and at seven and thirty days post application as measured by ΔE VITA EasyShade.

Philips Zoom WhiteSpeed whitens teeth significantly better than Opalescence Boost immediately following and seven days post application per VITA Classical Shade Guide and VITA Bleachedguide 3D-Master assessment.

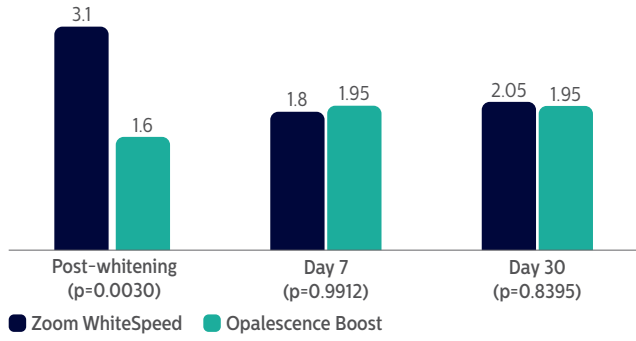
Philips Zoom WhiteSpeed and Ultradent Opalescence Boost are both well tolerated with low incidence of sensitivity and no significant differences in the safety profile between groups.

Median ΔE Post Whitening
Day 7 and Day 30



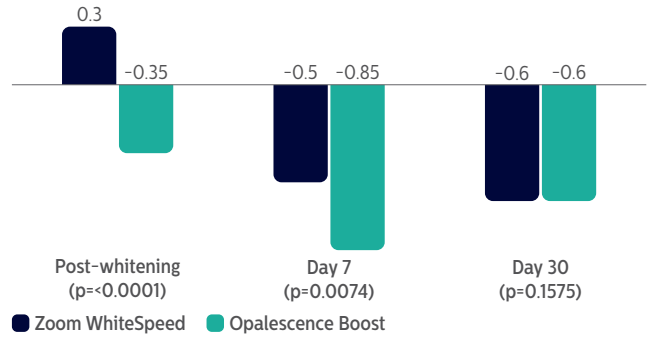
Median ΔL Post Whitening

Day 7 and Day 30



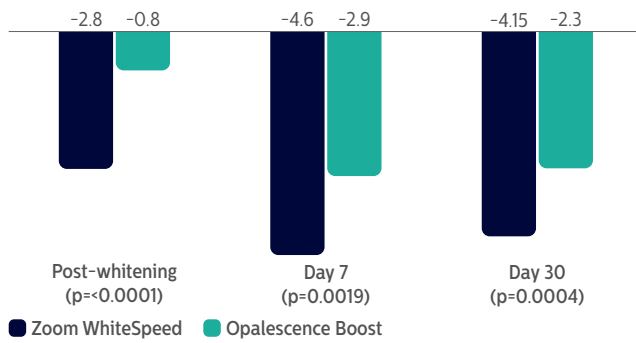
Median Δa Post Whitening

Day 7 and Day 30



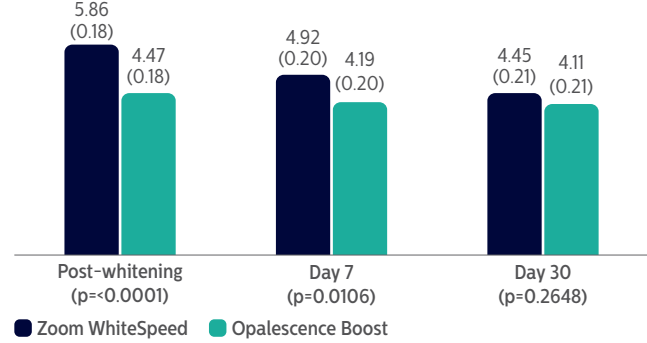
Median Δb Post Whitening

Day 7 and Day 30



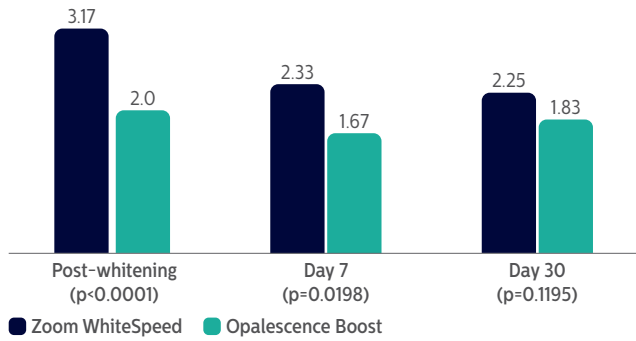
LSMeans VITA Classical Shade Reduction Post Whitening

Day 7 and Day 30



Median VITA Bleached Guide Shade Reduction Post Whitening

Day 7 and Day 30



Maximum Sensitivity Experienced from Whitening Treatment

%

