

Clinical Investigation on 4.5% Hydrogen Peroxide (HP) Whitening Pen

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Objective: The aim of the clinical study was to investigate whitening efficacy of a pen-like applicator containing 4.5% HP gel (Test) compared to a matching placebo gel without HP (Negative Control) over a seven-day period.

Methods: The protocol was approved by an IRB. The study had a randomized, double-blind, parallel-group design.

Following baseline examinations of tooth color shade and soft tissue, qualified subjects were randomized into two groups (Test and Negative Control), which were balanced for Extended Bleachedguide scores. Subjects were instructed to apply gel (1-2 clicks each time) three times on day one and two times on day two through day seven, and leave gel on teeth for one hour and brush/remove after each application. Tooth shade guide and soft tissue examinations were conducted again after one day, three days and seven days of product use. All examinations were performed under the same lighting conditions and by the same examiner.

Results: Eighty subjects entered the study, of which seventy-nine subjects complied with the protocol and completed the study. The mean tooth shade scores in Test group at baseline, one day, three days and seven days were 19.68, 18.28, 17.15, 16.24, respectively, and likewise for Negative Control group at baseline, one day, three days and seven days were 19.76, 19.62, 19.55 and 19.52, respectively.

Compared to baseline, the Test group provided statistically significant whitening improvements at one day (1.40 shade change), three days (2.53), and seven days (3.43), and the Negative Control group at one day (0.13 shade change), three days (0.21), and seven days (0.24).

Compared to the Negative Control group, the Test group provided statistically significant ($p < 0.001$) whitening improvements at one day (1.27 shade change), three days (2.32), and seven days (3.19).

Conclusion: The clinical results supported the conclusions that after seven days of product use, the 4.5% HP Whitening Pen provided statistically significant more whitening efficacy than a matching placebo pen.

