

Use of a Chromameter to Compare the Shade Change for Two Professional Tooth Whitening Systems

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ABSTRACT

Objective: Although common, use of shade guides to measure bleaching effectiveness carries risk for bias, particularly in comparative trials involving dissimilar products. This randomized clinical trial evaluated an objective method for shade measurement to compare shade changes for two professional vital bleaching systems.

Methods: Twenty healthy adults were randomized to either a whitening strip containing 6.5% hydrogen peroxide or a custom tray-based, hydrogen + carbamide peroxide bleaching system. Shade change was measured objectively over a 14-day period using a portable chromameter (Shofu® ShadeEye-Ex). Shade measurements were collected in triplicate from the facial cervical one-third of the maxillary right central and lateral incisors. Effectiveness was determined by comparing ranked (1-16) shade scores using standard methods. **Results:** In the 6.5% whitening strip group, individual improvement averaged 4.1 shades compared to 1.4 shades for the hydrogen + carbamide peroxide tray group. Both the strip group ($p < 0.0001$) and tray group ($p = 0.013$) differed significantly from baseline with respect to objectively measured tooth shade. Between-group comparisons showed that the 6.5% whitening strip averaged an additional 2.7 shades improvement over the hydrogen + carbamide peroxide tray system, with these groups differing statistically ($p = 0.0011$). **Conclusion:** When shade change is measured objectively using a chromameter, the 6.5% hydrogen peroxide strip system yielded a nearly three-fold shade change compared to the hydrogen peroxide + carbamide peroxide, custom tray-based system. Such methods may help limit examiner bias in bleaching clinical trials.

OBJECTIVE

This randomized clinical trial compares shade changes from baseline for two professional vital bleaching systems using an objective shade measurement.

MATERIALS AND METHODS

Study Design: A total of 20 healthy adults who desired to have their teeth whitened were enrolled into the study. Subjects were randomly assigned to one of the following two treatment groups and were treated for two weeks.

- Crest Professional Whitestrips™ *: 30 minutes, BID.
- Nite White® Excel2™†: 2 hours, QD.

* The Procter & Gamble Company, Cincinnati, OH, USA
† Discus Dental, Inc. Culver City, CA, USA

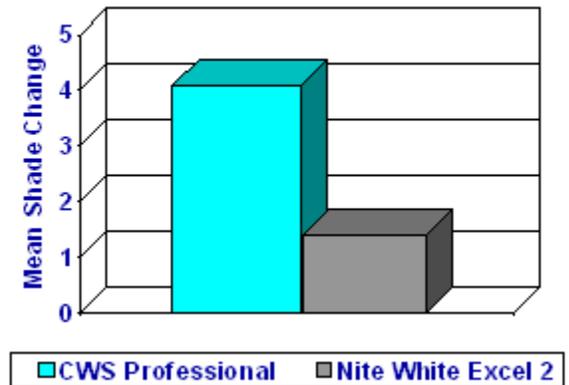
Efficacy Assessment: Tooth color was measured at baseline and Day 14 visits using a portable chromameter (Shofu ShadeEye-Ex). Shade measurements were collected in triplicate from the facial cervical one-third of the maxillary right central and lateral incisors. Effectiveness was determined by comparing ranked (1-16) shade scores in the order specified by the manufacturer.

Statistical Analyses: Analysis of covariance method was conducted to determine the mean shade change from baseline and treatment difference. Baseline shade score was used as the covariate in the model.

RESULTS

Baseline and demographic characteristics: Among the 20 subjects enrolled, forty-five percent were female. Age ranged from 22 to 59, with an average of 38.3 years. The average baseline shade score was approximately A3. Treatment groups were balanced with respect to these demographic characteristics, safety parameters, and average baseline shade score, as determined by the Shofu chromameter.

Shade Improvement



Efficacy:

- The mean color improvements from baseline in shade scores at day 14 were statistically significant ($p < 0.013$) for both treatment groups.
- Between-group comparisons showed that the 6.5% whitening strip averaged an additional 193% shade improvement over the hydrogen + carbamide peroxide tray system, with these groups differing statistically ($p = 0.0011$).

CONCLUSION

When shade change is measured objectively using a chromameter, the 6.5% hydrogen peroxide strip system yielded a nearly three-fold shade change compared to the hydrogen peroxide + carbamide peroxide, custom tray-based system.

Such methods may help limit examiner bias in bleaching clinical trials.