Spatial Whitening Response with 6.5% Hydrogen Peroxide Whitening Strips

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300

ABSTRACT

Objective: While effective overall, there is little *in vivo* evidence of the uniformity of vital bleaching across tooth surfaces. This research was conducted to evaluate the *in vivo* spatial whitening response profile following use of a hydrogen peroxide gel uniformly distributed across a flexible strip. **Methods:** Digital images from a randomized, placebo-controlled clinical trial (N = 29) were analyzed to assess the spatial whitening response on maxillary central and lateral incisors. Subjects dosed with 6.5% hydrogen peroxide whitening strips, which had a uniform 13 mg/cm^2 peroxide density, or placebo strips over a three week period. Color response (L*a*b*) was determined from the proximal edges to the central region of each target tooth by mapping spatial color change, and then, by comparing the proximal and midline changes following treatment. **Results:** The 6.5% whitening strip demonstrated highly significant improvement ($p < 0.001$) with respect to yellowness (Δb*), lightness (ΔL*), redness (Δa*), and overall whiteness (ΔW*) compared to placebo. This improvement was evident on both the proximal and central tooth regions. The adjusted mean ΔW* was –4.1 on proximal surfaces compared to –4.5 on central surfaces. Similarly, there were no meaningful between-region differences with respect to the individual color parameters. **Conclusion:** The application of a uniform 13 mg/cm^2 peroxide density gel to tooth surfaces via a whitening strip resulted in highly significant color improvement across proximal and midline tooth surfaces.

INTRODUCTION

Clinical trial tooth whitening data is typically reported at the subject or individual tooth level. The sparseness of tooth color data at more spatially specific levels is indicative of the crudeness of the color measurement technology generally implemented, e.g., subjective grading via shade tabs. Digital imaging technology permits objective color measurement as not only an average for the overall tooth, but also for specific regions of a tooth surface.

OBJECTIVE

The objective of this research was to evaluate the *in vivo* spatial whitening profile of a uniform density 6.5% hydrogen peroxide whitening strip. Of specific interest was the comparison of proximal versus central facial surfaces of the anterior central and lateral maxillary incisors.

MATERIALS AND METHODS

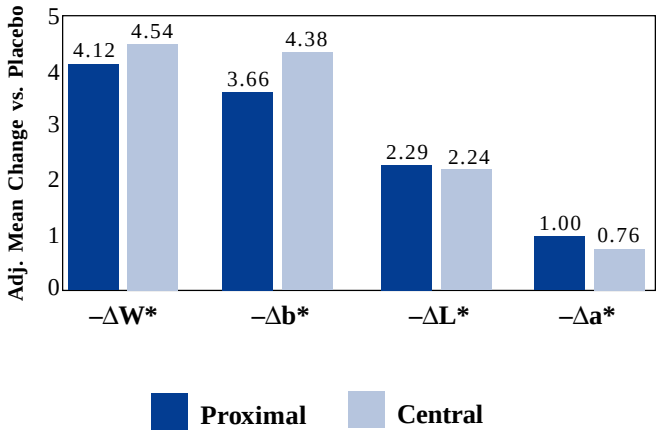
A randomized, parallel-groups clinical trial was conducted to assess the safety and efficacy of unsupervised use of a uniform 13 mg/cm^2 density hydrogen peroxide whitening strip relative to a matched placebo control. The maxillary anterior dentition of 30 generally healthy adults was treated for a period of three weeks. Digital image analysis was used to objectively measure pre- and post-treatment maxillary anterior tooth color in CIELAB color space as b* (yellow-blue), L* (lightness) and a* (green-red). Image pixels for the central incisors and the mesial half of lateral central incisors were classified as either *proximal* or *central* by their distance from their nearest proximal edge. Pixels less than 20% of the tooth width in distance from the nearest proximal edge were classified as proximal and all others were classified as central. A graphical representation of a typical proximal/central pixel classification is provided in the figure. A general linear mixed model was used to separately model the change from baseline in W*, b*, L* and a*. Each model included Treatment, Location, Treatment-by-Location, Baseline, and Treatment-by-Baseline fixed effects. The within-subject correlation structure was modeled as unstructured.

RESULTS

Following three weeks of use, the 6.5% H_2O_2 strip provided highly statistically significant overall whitening benefit relative to placebo ($p < 0.0001$) with respect to all color measures. The adjusted mean improvement in W*, b*, L*, and a* was 4.39, 4.12, 2.26, and 0.83 units greater, respectively, for the 6.5% H_2O_2 strip group than for the Placebo strip group. Proximal regions had 9% and 16% less improvement with respect to closeness to pure white (W*) and yellowness (b*), respectively, than central regions. Conversely, redness (a*) reduction was 24% smaller for central regions than for proximal regions. Central and proximal surfaces had approximately equal whitening benefit with respect to lightness or brightness (L*).

RESULTS (Cont.)

Mean Whitening Benefit by Tooth Region



Both treatments were generally well tolerated. The most common adverse events were minor tooth sensitivity and oral irritation, which were reported or observed for 40% of subjects in the 6.5% strip group compared to 13% of subjects in the placebo strip group. These results are similar to those reported for 6.0% hydrogen peroxide strips.

CONCLUSIONS

- Application of a uniform 13 mg/cm^2 peroxide density gel to tooth surfaces via a whitening strip resulted in highly significant color improvement across proximal and central maxillary tooth surfaces.
- No meaningful differences in whitening benefit were observed between proximal and central surfaces.
- Both treatments were generally well tolerated.

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