Clinical Trial Comparing Whitening Strips to a Carbamide Peroxide Potassium Nitrate Tray System
R.W. Gerlach, H. Shahidi*, X. Zhou
P&G, Mason, OH, USA

ABSTRACT

Objective: Several factors may impact on bleaching-related sensitivity, including peroxide concentration, contact time, delivery system, use of desensitizing agents and others. This randomized clinical trial was conducted to evaluate the clinical response of a low peroxide bleaching system with a desensitizing agent relative to a marketed control.

Methods: Balancing for baseline color and age, 34 healthy adult volunteers were randomized to one of two marketed bleaching systems. Subjects received either 5% carbamide peroxide bleaching gel + potassium nitrate in a custom tray or 6.0% hydrogen peroxide bleaching strips. Daily contact time was 6-8 hours for the tray system compared to 1 hour for the strip system, following manufacturers instructions. Whitening was measured objectively using digital image analysis to assess L*a*b* after 7 days.

Results: The predominantly female (85%) and non-smoking (91%) study population ranged from 20-47 years of age. Both treatments yielded a statistically significant (p<0.01) whitening benefit with respect to reduction in yellowness (Δb*), as well as secondary endpoints (ΔL* and ΔE*). The strip group experienced greater color improvement on average for all color parameters in the study. After 7 days treatment, mean Δb* was –1.20 in the strip group and –0.68 in the tray group, with these groups differing significantly (p=0.03). Tooth sensitivity was reported by 13% of subjects in the Strip group compared to 22% in the Tray group.

Conclusion: The 6.0% hydrogen peroxide whitening strip system had greater whitening and less tooth sensitivity compared to the 5% carbamide peroxide potassium nitrate tray system.

MATERIALS AND METHODS

Study Design: Balancing for baseline color and age, 34 healthy adult volunteers were randomized to one of following two marketed bleaching systems.

- Crest Whiestrips™*: 30 minutes BID (7 hours total use).
- Colgate® Platinum™ Gentle Plus™†: 6-8 hours per day (42-56 hours total use).

Efficacy and Safety Assessment: The color of six maxillary anterior teeth was measured objectively at baseline and Day 7 visits using digital image analysis. Tooth color change from baseline in b* (yellowness) was of primary interest. Safety evaluations included the examination of oral soft and hard tissue and adverse events at each study visit.

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

RESULTS

Baseline, tooth color, behavioral parameters and demographic characteristics:†

<table>
<thead>
<tr>
<th>Sample Size</th>
<th>34</th>
</tr>
</thead>
<tbody>
<tr>
<td>Starting tooth color in b*</td>
<td>17 (1.6)</td>
</tr>
<tr>
<td>Age</td>
<td>34.1 (8.8)</td>
</tr>
<tr>
<td>Gender (Female)</td>
<td>29 (85.3%)</td>
</tr>
<tr>
<td>Ethnicity (Non-white)</td>
<td>5 (14.7%)</td>
</tr>
<tr>
<td>Tobacco Use</td>
<td>3 (8.8%)</td>
</tr>
<tr>
<td>Coffee/Tea/Cola Use</td>
<td>25 (73.5%)</td>
</tr>
</tbody>
</table>

†Treatment groups were balanced with respect to these demographic characteristics, behavioral parameters and baseline tooth colors.

CONCLUSION

The 6.0% hydrogen peroxide whitening strip system had greater whitening and less tooth sensitivity compared to the 5% carbamide peroxide potassium nitrate tray system.