

ABSTRACT

Objective: While vital bleaching with a peroxide gel is generally recognized as both safe and effective, there is little comparative clinical evidence of the tolerability of combination whitening systems having multiple sources for peroxide delivery. This randomized 2-week clinical trial was conducted to compare the clinical response of a combination bleaching system relative to a marketed control. **Methods:** A total of 57 adults were randomized. One group received a combination peroxide bleaching system (dentifrice/bleaching gel/rinse), while the other received 6.0% hydrogen peroxide whitening strips. Both products were used according to manufacturers' instructions. Tooth sensitivity and oral irritation were assessed by subject report and oral examination. Bleaching Tolerability Severity-Days (BTSD) were calculated using onset, severity and duration data to compare treatments. **Results:** A total of 29 subjects (51% of the sample) reported either oral irritation or tooth sensitivity some time during the treatment period, while 10 subjects (18%) had treatment-related oral irritation observed by the examiner at one of the 2 post-treatment visits. BTSD means (SD) were 0.22 (0.39) and 0.43 (0.45) for the strip and combination groups respectively. Between-group comparisons using the non-parametric Wilcoxon rank-sum test showed the strip system to be significantly ($p=0.0458$) better tolerated than the combination system. **Conclusion:** The 6.0% whitening strip group exhibited a 34% reduction in tooth sensitivity and oral irritation, and statistically significant lower severity-days compared to the combination dentifrice/gel/rinse system.

OBJECTIVE

This study compares the clinical tolerability of a combination bleaching system relative to a marketed control.

MATERIALS AND METHODS

A two-week, randomized, parallel group, clinical trial was conducted involving two bleaching systems:

- 6.0% hydrogen peroxide whitening strips (Crest Whitestrips™ⁱ)
- 10% carbamide peroxide gel with stock tray/dentifrice/rinse combination system (Rembrandt® Plus™ Superior Bleaching Systemⁱⁱ).

The number of days to onset was computed for each adverse event (possibly or probably related to treatment) and summarized. Additionally, a bleaching tolerability severity-days score was computed for each subject by adding up the most severe (none=0, mild=1, moderate=2, severe=3) AE on a given day over the course of the study and then dividing by the number of days the subject received treatment. A bleaching tolerability severity-days score of 0.5 was indicative of a subject that had a mild AE for 50% of their treatment time (or 25% of their treatment time for a moderate AE). Due to the skewed nature of the endpoint, a non-parametric Wilcoxon Rank-Sum Test was used to compare treatment groups. An exact two-sided p -value was calculated and tested at a 5% level of significance.

RESULTS

A total of 29 subjects (51% of the sample) reported either oral irritation or tooth sensitivity some time during the treatment period. A total of 10 subjects (18% of the sample) had treatment-related oral irritation observed by the examiner. Transient tooth sensitivity or oral irritation (reported or observed) was more common in the combination group, affecting 68% of that population relative to 45% in the whitening strip group. Eighty-five percent of all events were "mild" in severity. The median number of days to onset of possible or probable treatment-related AEs was 1 day in the whitening strip group and 4 days in the combination group. With respect to severity and duration, the median BTSD score for the combination group was 0.21, while the median BTSD score for the whitening strip group was 0.00. Between-group comparisons showed that whitening strips were better tolerated overall. The bleaching tolerability severity-days scores for the two treatment groups were statistically different with a p -value of 0.0458.

Figure 1. Bleaching Tolerability Severity-Days Distribution

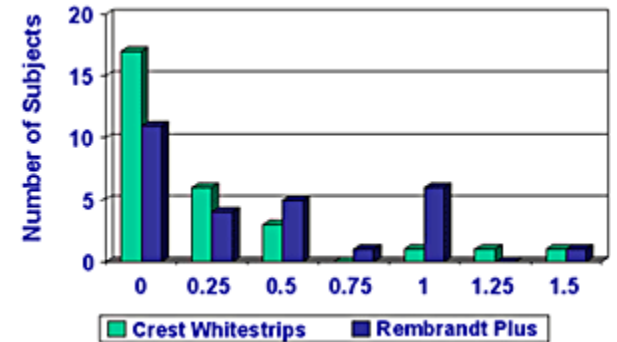


Table 1. Bleaching Tolerability Severity-Days Summary

Statistic	Crest Whitestrips	Rembrandt Plus
Number of Subjects	29	28
Mean (SD) BTSD	0.22 (0.39)	0.43 (0.45)
Min – Median – Max BTSD	0 – 0 – 1.57	0 – 0.21 – 1.57
Exact Two-sided p -value	0.0458	

CONCLUSION

The 6.0% whitening strip group exhibited a 34% reduction in tooth sensitivity and oral irritation, and statistically significant lower severity-days compared to the combination dentifrice/gel/rinse system.

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- ii. Den-Mat Corporation, Santa Maria, CA, USA.