Vital Bleaching Clinical Response Comparing Stock and Custom Trays

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ABSTRACT

Objective: This research was designed to evaluate the effects of a customized tray on vital bleaching clinical effectiveness and tolerability. **Methods:** A total of 23 healthy adult volunteers were enrolled in a parallel group clinical study using a direct-to-consumer 10% carbamide peroxide bleaching gel. Study subjects randomly received either a "boil and bite" tray or a custom tray with gingival scalloping. Only the maxillary arch was treated, twice daily for up to 30 minutes, and all treatment was unsupervised. L*a*b* color change was measured from digital images of the anterior dentition, and tolerability was assessed by interview and clinical examination. **Results:** Both treatments exhibited modest color improvement. Adjusting for baseline, the estimated means and standard errors for Δb* (yellowness) were –0.55 ± 0.198 for the stock tray compared to –0.63 ± 0.177 for the custom tray. Between-group comparisons demonstrated no significant ($p > 0.36$) color differences between the "boil and bite" or custom trays for Δb*, ΔL*, Δa* or ΔE*. While there were no differences in effectiveness, there were apparent differences in tolerability based on tray type, with 91% of stock tray users having oral irritation and/or tooth sensitivity, compared to 42% of the custom tray group ($p = 0.027$). **Conclusion:** While use of a custom bleaching tray did not contribute to any significant whitening benefits beyond that seen with a stock bleaching tray, bleaching with a custom tray was better tolerated overall, with approximately one-half the occurrence of oral irritation and tooth sensitivity.

OBJECTIVE

This research was designed to evaluate the effects of a customized tray on vital bleaching clinical effectiveness and tolerability.

METHODS

A total of 23 healthy adult volunteers were enrolled in a parallel group clinical study using a direct-to-consumer 10% carbamide peroxide bleaching gel. Study subjects randomly received either a "boil and bite" tray or a custom tray with gingival scalloping. Only the maxillary arch was treated, twice daily for up to 30 minutes, and all treatment was unsupervised. L*a*b* color change was measured from digital images of the anterior dentition, and tolerability was assessed by interview and clinical examination.

The Day 15 tooth color was compared to Baseline by calculating the color change from Baseline within each treatment group and then performing one-sample *t*-tests. Treatment groups were compared via analysis of covariance methods for Δb*, ΔL*, Δa* and ΔE*. The response was color change from Baseline and the covariate was the Baseline color. Additionally, Fisher's exact test was used to compare treatment groups with respect to the percent of subjects in each group having adverse events.

RESULTS

Study Population:
Twenty-three subjects were randomized and received product in this study. Subjects ranged in age from 26 to 52 years with an average of 39.3 years. Seventeen (74%) of the subjects were female. Treatment groups were relatively well balanced with respect to demographic characteristics and behavioral parameters.

Efficacy:
Compared to Baseline, both treatment groups were effective in whitening teeth at Day 15. For all color parameters in this study (Δb*, ΔL*, Δa*, and ΔE*), both groups exhibited statistically significant improvements as measured by the mean color change from Baseline (p-value < 0.05).

Between-group comparisons showed no statistically significant difference (p-value > 0.3) between the custom tray and the stock tray for any of the color parameters (Δb*, ΔL*, Δa*, and ΔE*) at Day 15. Table 1 displays the adjusted means, standard errors for each color measurement in addition to p-values and 95% confidence intervals for treatment differences. Average color benefit for the two tray groups was quite similar at Day 15.

Table 1: Color Changes at Day 15

Outcome/ Treatment	Baseline Mean (SE)	Adjusted Mean Change (SE)	p-value for Treatment Difference	95% CI for Treatment Difference
Δb*				
Stock Tray	17.87 (0.655)	-0.55 (0.198)	0.757	(-0.65, 0.48)
Custom Tray	17.44 (0.526)	-0.63 (0.177)		
ΔL*				
Stock Tray	73.78 (0.766)	1.03 (0.129)	0.761	(-0.32, 0.43)
Custom Tray	75.16 (0.704)	1.08 (0.115)		
Δa*				
Stock Tray	8.28 (0.446)	-0.65 (0.110)	0.366	(-0.18, 0.45)
Custom Tray	8.37 (0.198)	-0.51 (0.098)		
ΔE*				
Stock Tray		1.48 (0.169)	0.943	(-0.51, 0.48)
Custom Tray		1.46 (0.151)		

RESULTS (Cont.)

Safety:
Overall, there were a total of 20 adverse events (10 in each group) involving 17 study subjects. No subject in either group withdrew from the study as the result of an AE.

Most subjects assigned to the stock tray regimen (90.9%) experienced either possibly/probably treatment-associated oral irritation or tooth sensitivity as compared with 41.7% of those using the custom tray regimen; this difference was statistically significant ($p = 0.0272$). This represents an increased risk of 2.2 with a 95% confidence interval of (1.1, 4.4).

The majority of treatment-related events consisted of observed and/or self-reported oral irritation, where 81.8% and 33.3% of stock tray and custom tray users, respectively, were affected during the course of the trial (between-group difference significant at $p = 0.0361$). This represents an increased risk of oral irritation of 2.5 with a 95% confidence interval of (1.1, 5.7).

Treatment-associated tooth sensitivity was reported by 16.7% of subjects using the custom tray and 9.1% of subjects using the stock tray; this difference was not statistically significant. The average number of days to onset of a possibly/probably treatment related adverse events was 8.7 for the custom tray group and 6.2 for the stock tray group.

CONCLUSIONS

- Use of a custom bleaching tray did not contribute to any significant whitening benefits beyond that seen with a stock bleaching tray.
- Bleaching with a custom tray was better tolerated overall, with approximately one-half the occurrence of oral irritation and tooth sensitivity.

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