

## ABSTRACT

Although the safety and efficacy of vital tooth bleaching with peroxides is well-established, up to two-thirds of custom tray users may experience mild-to-moderate tooth sensitivity or gingival irritation (Haywood, J Am Dent Assoc 1994). Compared to tray-based systems, 14 day BID use of a low peroxide dose, flexible strip system (Crest Whitestrips™) is reported to facilitate whitening and limit tooth sensitivity (Gerlach, Comp Contin Educ Dent 2000). Because tooth brushing may contribute to the efficacy/safety profiles, a randomized clinical trial was conducted to evaluate clinical response to 5.3% H<sub>2</sub>O<sub>2</sub> strips with 2 brushing regimens. 41 adults were randomized to: immediate pre-bleaching tooth brushing or no immediate pre-brushing (ad lib brushing only). Both groups were assigned a marketed anticavity dentifrice, and both used the whitening strips 30 minutes BID for 14 days. All pre-brushing and bleaching treatments were supervised. Efficacy was measured objectively in CIELab color space using digital image analysis. Both treatments were effective, with overall Δb\* averaging -1.8 units. While immediate pre-bleaching tooth brushing contributed to a 14% reduction in b\* relative to the ad lib brushing group, regimen did not significantly impact on ΔL\*. In contrast, ad lib brushing contributed to improved tolerability, with that group experiencing a 58% reduction in oral irritation reports. For individuals who may experience oral irritation during bleaching, **elimination of pre-bleaching brushing may improve oral soft tissue tolerability and compliance without meaningfully impacting on overall whitening.**

## INTRODUCTION

Most peroxide based whitening products recommend brushing prior to applying the bleaching agent to the tooth surfaces. Therefore, the efficacy and tolerability of these products have historically been evaluated in conjunction with a pre-brushing regimen. The untested assumption is brushing cleans the tooth surfaces and allows the peroxide to be more efficiently delivered to the tooth surface without interference from salivary components, dental plaque and other oral debris. Assuming the peroxide is more efficiently delivered to the tooth surface, better efficacy would be expected in a pre-brushing regimen. Similarly, the tolerability of the whitening products has mostly

been established with a pre-brushing regimen. Thus, the tolerability impact of the whitening product and the brushing regimen are confounded.

## OBJECTIVE

The purpose of the present clinical investigation is to estimate the impact of brushing prior to Whitestrips application on whitening efficacy and product tolerability. The hypothesis is brushing prior to applying Whitestrips will improve efficacy vs. no pre-brushing yet tolerability will be decreased with pre-brushing.

## MATERIALS AND METHODS

Forty-one (41) adults were randomized across two whitening regimens using the flexible strip delivery system Crest Whitestrips. Both groups used Crest Whitestrips twice daily for 30 minutes for 14 days. One group brushed ad-lib with a marketed anti-cavity dentifrice prior to strip application while the other group refrained from pre-brushing. At baseline, tooth color, hypersensitivity and oral soft tissue were assessed. In addition an oral status interview was also conducted with each patient to obtain patient perceived tolerability. All treatments were supervised in the clinic. After day 14, tooth color, hypersensitivity and oral soft tissue were assessed again along with a final oral status interview. Soft tissue and oral status interviews were conducted immediately after removing the Whitestrips. Tooth color was assessed 24 hours after product removal to avoid dehydration impact on tooth color. Tooth color assessments were made with digital imaging under calibrated lighting conditions. After image acquisition, the image pixels of the central 4 incisors of each subject were averaged to yield a single set of red, green and blue values for the tooth surfaces of interest. The set of red, green and blue values were then mapped into L a b color space using a standard Macbeth color chart with pre-assigned L a b values. The L a b values of the mapping chart were determined by measurement with a Spectrascan PR650 in L\*a\*b\* mode under the same lighting conditions as the images were captured.

## RESULTS

### Efficacy

#### Average starting tooth color

	No Pre-brushing	Pre-brushing
L	75.3	75.2
a	8.0	8.0
b	17.4	17.3

#### Changes in tooth color after day 14

	No Pre-brushing	Pre-brushing
ΔL	0.81*	0.74*
Δa	<i>-0.01*</i>	<i>-0.24</i>
Δb	<i>-1.72*</i>	<i>-1.97*</i>

\* denotes significant change from baseline, italics denote significant differences between regimens

1-sided (p<0.1)

### Symptoms

	No Pre-brushing (N=21)	Pre-brushing (N=20)
Tooth Sensitivity	5 (24%)	6 (30%)
Oral Irritation	8 (38%)	13 (65%)

## DISCUSSION

### Efficacy

Brushing prior to applying Whitestrips significantly improved the reduction of yellowness ( $\Delta b$ ) from the teeth. The increase in brightness ( $\Delta L$ ) and reduction of redness ( $\Delta a$ ) were not meaningfully impacted via pre-brushing. The increase in efficacy due to pre-brushing may be due to many factors such as removal of oxidizable substances and dilution of salivary enzymes which degrade peroxide rapidly. Thus, by brushing away agents which decrease peroxide concentration, efficacy of the Whitestrips is significantly increased.

### Tolerability

Pre-brushing may contribute to product tolerability. 65% of patients who pre-brushed experienced some degree of soft tissue discomfort. When patients did not brush prior to applying Whitestrips, only 38% experienced soft tissue irritation a significant reduction in soft tissue irritation. Clinically, the majority of the irritation observed is mild in nature (81%) and only observed immediately after product removal. All irritation subsides within a few hours after product removal. Similar to the self reported irritation, clinical observations also indicate improved product tolerability for subjects refraining from brushing prior to strip application.

## CONCLUSION

Pre-brushing prior to applying Crest Whitestrips significantly improves product efficacy in terms of reduction of the yellowness from the teeth measured. Elimination of the pre-brushing step may improve soft tissue tolerability with only a modest reduction in product efficacy.