

# Effects of Two Dental Whitening Strips on Dental Sensitivity and Gingival Health

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## Abstract

**Aims:** The aim of this study was to evaluate the in-vivo effects of a novel whitening strip on tooth sensitivity and gingival irritation.

**Methods:** A total of 10 participants were simultaneously recruited to apply one brand of whitening strips to the upper left and lower right quadrant of the mouth and the other brand to the remaining teeth daily for a period of 30 mins over 10 consecutive days. Tooth sensitivity and gingival irritation were evaluated for each tooth at baseline, day 5 and day 10 by a blinded clinician, using a 3 sec air spray test on each isolated tooth to semi-quantify sensitivity (Likert scale, 0-4), and visual inspection to identify gingival irritation (0-3). Each participant completed a questionnaire daily after each whitening treatment and documented the following parameters: (1) dental sensitivity for each tooth (Yes/No) and (2) gingival irritation for each tooth (Yes/No). Data were analyzed using ANOVA techniques.

**Results:** For the office-based evaluations, significantly lower gingival irritation resulted from use of the test Oral EssentialsR whitening strips compared to the control 3D CrestR strips. Patient self-evaluations recorded lower gingival irritation, although not at a significant level, after the use of the test strips compared to the control strips. Dental sensitivity was comparable in the two treatment groups as evaluated in home and in the dental office.

**Conclusion:** Use of a novel tooth whitening strip resulted in less gingival irritation compared to a widely used control whitening strip.

**Keywords** Tooth whitening; Gingival irritation; Dental sensitivity; Whitening strips

## Introduction

Brightening discolored teeth is a very common procedure in dental offices, mainly for esthetic reasons [1]. Tooth staining can have many etiologies, including extrinsic factors such as the consumption of tea, coffee, and cigarettes, and intrinsic causes such as tetracycline, trauma, root resorption, enamel hypoplasia and ageing. Also, caries and ill-matched or deteriorated restorations may adversely affect tooth color. External pigments can either be adsorbed into the dental pellicle or remain on the surface of the tooth, resulting in color changes [2,3].

Tooth bleaching is considered routine treatment in 91% of dental offices, with a reported success rate of 79% [4]. Bleaching agents primarily contain hydrogen peroxide or carbamide peroxide, which breaks down to produce hydrogen peroxide [5,6]. Unstable free radicals are released when they contact a biological material such as saliva or enamel [7]. These free radicals oxidize large pigment or stain molecules, changing tooth color by altering the chemical structure of the organic substance of the enamel and dentine [8].

Currently, there are three commercially available categories of bleaching agents: in-office, in-home and over-the-counter formulations with different concentrations of the active ingredients [9]. Currently

10% carbamide peroxide is the only product approved by the American Dental Association (ADA), as a safe and efficient product for in-home bleaching procedures [10].

Over the counter bleaching agents are available in a wide range of formulations including whitening rinses, tray-based tooth whiteners, whitening strips and gels [10]. Hydrogen peroxide -based whitening strips have been commercially available since 2000. Their popularity is a result of their effectiveness, convenience of application, accessibility, ease of application and low cost [11,12]. However, safety and compatibility concerns have been raised due to the biotoxicity of the HO free radicals that are released to the target sites. Potential side effects include alteration of the enamel surface, gingival irritation, dental sensitivity and degeneration of the dental pulp [13]. The intensity of such side effects can vary depending on the concentration of the hydrogen peroxide used, treatment duration and the non-bleach composition of the product used [2]. In general, 50% of people may experience temporary tooth sensitivity as a result of tooth bleaching [13]. However, adverse effects increase with the greater concentration, duration and frequency of use of the bleaching agent [7]. Moreover, increased risk of adverse effects risk has been correlated with inappropriate or misuse of such bleaching products [12]. Although bleaching agent contact with the gingiva is undesirable, it can readily occur during home bleaching, especially when strips are applied [13].

Goal of this study was to evaluate in-vivo the effects of a novel tooth whitening strip on dental sensitivity and gingival irritation.

## Methods and Materials

### Overview

A total of 10 participants simultaneously applied one brand of whitening strip to the upper left and lower right quadrant of the mouth, and the other brand of whitening strip to the remaining teeth daily for a period of 30 mins for 10 consecutive days. Each participant filled out a questionnaire daily after each treatment and document (1) any sensitivity for each tooth (Yes/No: 1/0) and (2) gingival irritation for each tooth (Yes/No: 1/0). From this log, a cumulative score was calculated for sensitivity and gingival irritation for each tooth unit. Additionally, tooth sensitivity and gingival irritation were evaluated in-office for each tooth at baseline, day 5 and day 10 by a blinded, pre-standardized dentist with more than 25 years of clinical experience, using a 3 sec air spray test on each isolated tooth to semi-quantify sensitivity (Likert scale, 0-4), and visual inspection to identify gingival irritation (0-3 (none, mild, moderate, severe)). This study had only one leg. Subjects were provided with a new Oral BR (Procter & Gamble Company, Cincinnati, OH 45202) toothbrush and Crest Total CareR (Procter & Gamble Company, Cincinnati, OH 45202) toothpaste at the beginning of the study and were instructed not to use any other mouthwash or toothpaste during the study.

### Subjects

All subjects signed an informed consent form prior to enrollment in this study. Subjects consisted of 10 healthy volunteers age 18-45 (mean 29.4 years).

#### Inclusion Criteria

- <16 clinically and radiographically healthy teeth as defined by clinical examination by 1 dentist with >20 years clinical experience
- Löe and Silness Gingival Index <1
- all pocket depths ≤ 4 mm

#### Exclusion Criteria

- any known history of allergy to personal care/consumer products or their ingredients
- or any ingredients in the products used
- any medical condition which requires pre-medication prior to dental procedures
- diseases of the soft or hard oral tissues
- gingival recession >2 mm
- dental sensitivity to temperature change or pressure
- active or untreated caries lesions
- history of any systemic disease that could result in being immune compromised or delayed wound healing, and
- use of antibiotics within 3 months
- known history of hepatitis, HIV, ulcer forming diseases, abscesses, granulomas
- smokers and neither
- pregnant
- lactating

### Protocol

After enrollment in the study, each subject received 40 identically packaged, coded whitening strips, 20 of which were test whitening strips (Oral EssentialsR Whitening Strip, Beverly Hills, CA 90210) and 20 control whitening strips (Crest 3DR White Strip, Procter & Gamble Company, Cincinnati, OH 45202). During the study period, subjects brushed their teeth twice daily and abstained from all other oral hygiene measures. Subjects placed the whitening strips on the designated quadrants for 30 minutes per day followed by thorough rinsing with water to remove any residue. They were instructed to wait at least 22 hours before each subsequent application. After each daily application, subjects completed a standardized log that was provided and checked by the dental office at each visit to document tooth sensitivity and gingival irritation.

This was a routine double-blinded, randomized study, with neither subjects, nor clinicians, or any other members of the study aware of specific product allocation sites or treatment status of the samples.

### Primary endpoints

#### Data collection: *In office:*

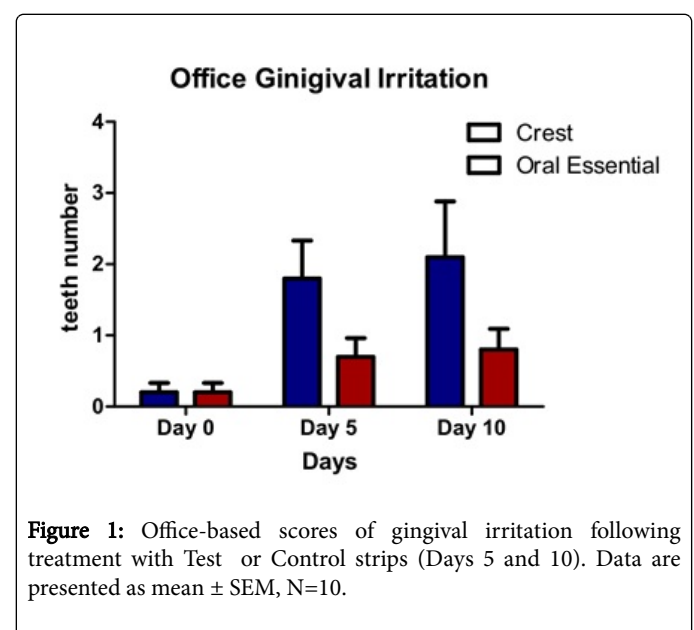
Day 5: photograph of teeth and gingiva, sensitivity testing with 3 sec blast of air for each tooth (0-4), documentation of gingival irritation status (0-3).

Day 10: photograph of teeth and gingiva, sensitivity testing with 3 sec blast of air for each tooth (0-4), documentation of gingival irritation status (0-3).

All testing was performed by the same blinded pre-standardized examiner, a dentist with more than 20 years of clinical experience.

**In home: Daily:** Sensitivity (Y/N per tooth); Gingival irritation (Y/N per tooth).

**Data analysis:** All data were analyzed using individual tooth units and two-way ANOVA with Bonferroni correction for multiple measures.



**Figure 1:** Office-based scores of gingival irritation following treatment with Test or Control strips (Days 5 and 10). Data are presented as mean ± SEM, N=10.

## Result

A total of 286 teeth were evaluated in 10 subjects. All subjects completed the study in full compliance with the protocol, as documented through in-home daily logs and in-office questionnaires at each visit.

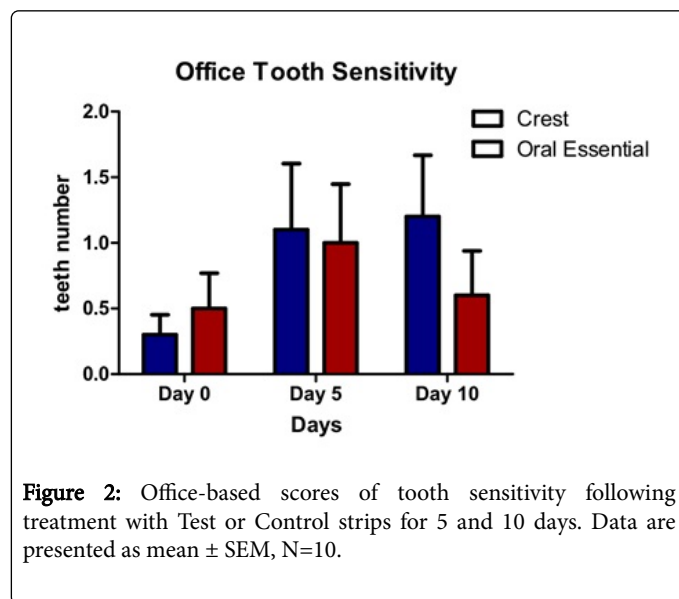
### Office-based evaluation

A significant overall difference was determined between the two treatment groups with regard to gingival irritation, (Figure 1) and between treatment effects on specific days of the treatment period ( $P < 0.05$ , Table 1).

	Day 0	Day 5	Day 10
<b>Crest</b>	0.2 ± 0.042	1.8 ± 0.170	2.1 ± 0.247
<b>Oral Essential</b>	0.2 ± 0.024	0.7 ± 0.082	0.8 ± 0.092

**Table 1:** Office-based mean scores of gingival irritation following treatment with Test or Control strips on Days 0, 5 and 10. Data are presented as mean ± S.D.

Our results show no significant difference in the effects of the two treatments on dental sensitivity overall (Figure 2) or on any specific treatment day (1,  $P > 0.05$ , Table 2).



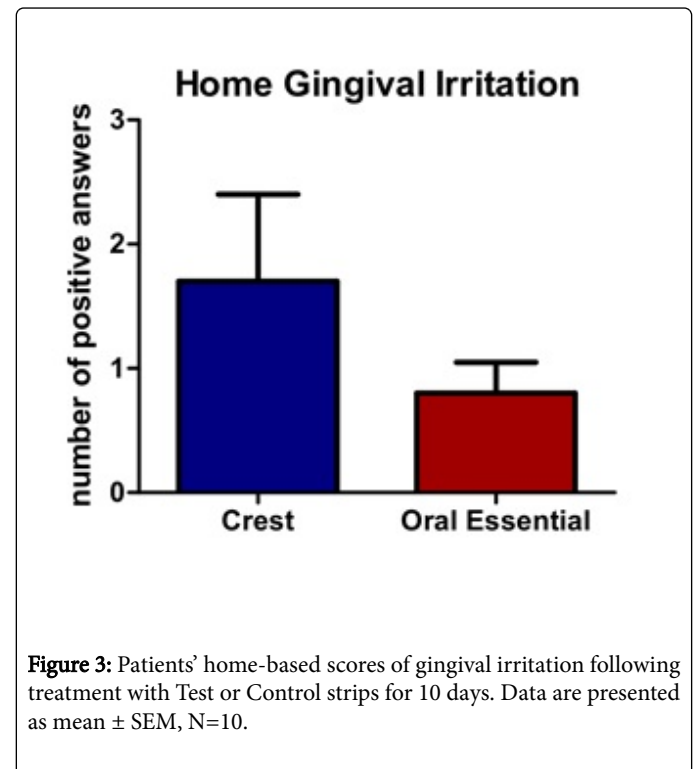
**Figure 2:** Office-based scores of tooth sensitivity following treatment with Test or Control strips for 5 and 10 days. Data are presented as mean ± SEM, N=10.

	Day 0	Day 5	Day 10
<b>Crest</b>	0.30 ± 0.048	1.10 ± 0.159	1.20 ± 0.150
<b>Oral Essential</b>	0.50 ± 0.085	1.00 ± 0.141	0.63 ± 0.108

**Table 2:** Office-based mean scores of tooth sensitivity following treatment with Test or Control strips on Days 0, 5 and 10. Data are presented as mean ± S.D.

### Patient self-evaluation

The home-based sensitivity (Figure 4) scores were lower for the test strip than the control, however the difference was not significant ( $P > 0.05$ , Table 4).

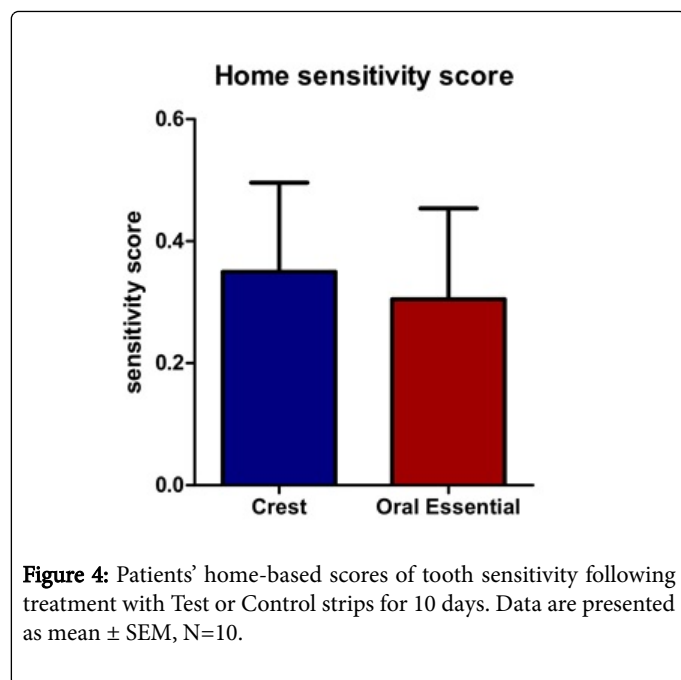


**Figure 3:** Patients' home-based scores of gingival irritation following treatment with Test or Control strips for 10 days. Data are presented as mean ± SEM, N=10.

	Crest	Oral Essential
<b>Mean</b>	1.70 ± 0.41	0.80 ± 0.29

**Table 3:** Mean self-assessed home-based scores of gingival irritation following treatment with Test or Control strips for 10 days.

The home-based sensitivity (Figure 4) scores were lower for the test strip than the control, however the difference was not significant ( $P > 0.05$ , Table 4).



**Figure 4:** Patients' home-based scores of tooth sensitivity following treatment with Test or Control strips for 10 days. Data are presented as mean  $\pm$  SEM, N=10.

	Crest	Oral Essential
Mean	0.35 + 0.16	0.30 + 0.17

**Table 4:** Mean self-assessed home-based scores of tooth sensitivity following treatment with Test or Control strips for 10 days.

## Discussion

Participants used the whitening strips for 30 minutes per day. Results were obtained in office at three time points: baseline, after 5 days and after 10 days. In addition, patients were asked to complete a questionnaire every day.

In this study, the adverse effects and symptoms often associated with tooth whitening were evaluated by a blinded in-office evaluator, and by the patients themselves. While the results differed somewhat between the 2 evaluation modalities, overall the test strips performed somewhat better than the control strips. In-office data documented significantly reduced gingival irritation, whereas self-evaluations determined somewhat lower (but not at a significant level) mean sensitivity resulting from use of the test strips as compared to the current gold standard treatment.

The side effects of bleaching agents on oral tissues have been studied extensively. Whitening strips have been widely used since their introduction in the year 2000. Typically, they contain a small layer of hydrogen peroxide on a plastic strip. These strips can whiten the teeth by 1 to 2 shades after twice daily applications for 14 days [2]. Their whitening effectiveness correlates with the concentration of H<sub>2</sub>O<sub>2</sub> that they contain [12].

A number of studies have evaluated the impact of different concentrations of hydrogen and carbamide peroxide on gingival health and tooth sensitivity. Generally, whitening effects of the 2 compounds are reported to be comparable at concentrations of 20% and 5.3% respectively [14]. A number of studies indicate that home-bleaching gel containing carbamide peroxide at a concentration level of 10% is

relatively safe [14-17]. However, other researchers have reported considerable concerns about the safety of using hydrogen peroxide products even at low concentrations [18-21]. A strong correlation between higher whitening performance and higher sensitivity from the use of whitening strips was postulated [22].

According to a study published in 2003, 7-23% of subjects developed gingival irritation and 12-19% developed dental sensitivity after the use of CrestR whitening strips [23]. Two other studies reported the development of dental sensitivity ranging from 20-40% and gingival irritation in 30-70% of subjects using the whitening strip [23-24]. In two additional studies, Karpinia et al reported 26% sensitivity and 14% gingival irritation in one study and 17% sensitivity and 31% irritation in another study after use of different whitening strips [25,26]. Thus, in order to minimize risks and maximize benefits, patients are well-advised to involve dental professionals as they establish their individual tooth bleaching plans [3].

It is interesting to note that some research has identified improved gingival and plaque indices after applying night guard bleaching formulations [27]. Other literature reports that 10% carbamide peroxide formulations from 3 different products inhibited select organisms from growing on the surface of the teeth [28]. This might be due to potential antibacterial effects of bleaching products, or perhaps patients might become motivated to take better care of their teeth and improve their oral hygiene as the appearance of their teeth improves from the bleaching process.

Over all, this study demonstrated that the use of a novel whitening strip can potentially mitigate the symptoms of dental sensitivity and gingival irritation that can result from applying bleaching products. However, additional and larger, controlled studies over longer periods of time are needed to more closely evaluate product effects after mid- and long-term clinical use.

## Conclusions

This in-vivo study determined that a novel whitening strip is very well tolerated after daily use over 10 days. Its side effects were minimal, with lower gingival irritation compared to a commonly used control product. Further studies are required to evaluate and characterize the mid- and long-term effects this novel whitening strips.

## Conflict of Interest Statement

No conflict of interest

## Author Contributions Statement

### Angel Emmanuel Rodriguez

Concept/Design, data collection, drafting article, final approval.

### Janet Ajdaharian

Concept/Design, data collection, drafting article.

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