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## Evaluating the Clinical Efficacy of a Non-Peroxide Dental Whitening Strip

Guy Miller\*, Megan Walker, Lora Bardin, Brianna Baiz, Katelyn Malone, Emily Morrison, Jerica Block

Department of Dental Hygiene, San Joaquin Valley College, Ontario, CA, USA

\*Corresponding author: Guy Miller, School of Dental Hygiene, San Joaquin Valley College, Ontario, CA, USA

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### Abstract

**Background:** While in-home tooth whitening with peroxide-based strips has been practiced for many years, concerns over adverse effects on the teeth and soft tissues have driven the search for alternative formulations.

**Objectives:** To evaluate the usability and 30-minute whitening effects of a non-peroxide whitening strip.

**Methods:** In thirty subjects aged 20-70, tooth color was measured using a colorimeter (VITA Easyshade) before and after 30-minute application of a test whitening strip (Lumineux Oral Essentials) to the 12 anterior teeth. Strip fit, retention and durability were also evaluated.

**Results:** The mean 30-minute whitening effect ( $\Delta E$ ) measured 4.73, was robustly significant ( $p < 0.0001$ ), and exceeded the threshold for perceptibility to the naked eye by more than twofold. Strip usability and durability were excellent.

**Conclusion:** This clinical study demonstrated significant tooth whitening ( $p < 0.0001$ ) at more than twice the level of perception by the naked eye after 1 one single 30-minute application of a novel non-peroxide whitening strip.

### Keywords

Non-Peroxide; Tooth whitening; Dental Whitening Strip; clinical study

## Introduction

Numerous over the counter (OTC) tooth whitening products are available, including dentifrices, mouth rinses, strips, whitening dental floss, and oil pulling. Whitening strips, which are among the most commonly used in-home whitening products, were developed to avoid the need for customized trays and in-office treatments and to allow direct in-home utilization by the public. These products originally were based on hydrogen peroxide or its precursor, carbamide peroxide, as the active ingredient, delivering concentrations ranging from 3% to 40% of hydrogen peroxide [1]. However, concerns about potential enamel damage and sensitivity as well as gingival irritation have accelerated the search for alternative active ingredients [2-9].

Recently, various formulations of whitening strips have become available that contain peroxide alternatives such as blends of antioxidants and essential oils. The results from an initial clinical study using one formulation that contains lemon peel and coconut oil have been encouraging, both with regard to whitening efficacy as well as the avoidance of dental sensitivity and gingival irritation [10]. Moreover, in a recent controlled, double-blinded, randomized in vivo study in 90 subjects using the same active ingredients, investigators found no significant difference between the whitening effect over 7 and 14 days of the non-peroxide strips vs. a commonly used peroxide-based strip, while significantly more subjects developed dental sensitivity, oral burning, and soreness in the group using the peroxide strips [11].

Unfortunately, there is still a dearth of published studies on the efficacy and potential side effects of non-peroxide whitening options. As the search for effective and biocompatible whitening formulations continues, further studies are urgently needed to establish the efficacy and safety of novel formulations. The goal of this in vivo study was to determine the effects of a one-time application of a non-peroxide Lumineux Oral Essentials Whitening Strip (Oral Essentials, Beverly Hills, CA 90210) on tooth color after 30 minutes of intra-oral wear. Strip fit, retention, and durability were also evaluated.

## Materials and Methods

### Subjects

Thirty individuals were recruited through word of mouth from San Joaquin Valley College (SJVC) and its vicinity. Prior to participation, all subjects provided written informed consent. The demographic profile of the participant cohort closely reflected that of the general population, encompassing similar distributions in gender and age, alongside comparable patterns of consumption for coffee, tea, wine, soda, and tobacco.

All participants were recruited according to the following inclusion and exclusion criteria:

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### Inclusion criteria

- Male or female.
- 18–70 years old.
- Able to provide written informed consent.
- Minimum of 12 healthy anterior teeth without restorations as defined by clinical examination.

### Exclusion Criteria

- Any pathological symptoms, gum recession, tooth sensitivity and obvious periodontal disease in the anterior teeth at study begin.
- Medication which alters the natural tooth color or appearance.
- History of allergy or significant adverse effects following use of oral hygiene products such as toothpastes, mouth rinses, and whitening formulas.

### Protocol

This research was conducted in accordance with the Allendale Institutional Review Board protocol SJVC-WP-1, adhering to the principles outlined in the Declaration of Helsinki (1975, revised 2013). No significant alterations to the study design were implemented following its initiation.

The study was performed in the clinics of SJVC Department of Dental Hygiene. Subjects received one pouch of Lumineux Oral Essentials Whitening Strips (Oral Essentials, Beverly Hills, CA 90210), which included a peel-off strip designed for the upper teeth and a smaller strip for the lower teeth. Subjects were all provided with the following usage instructions in accordance with package instructions:

1. Remove top and bottom strip from backer.
2. With both hands apply upper strip to the top teeth.
3. With both hands apply lower strip to the bottom teeth.
4. Leave for 30 minutes.
5. Remove, rinse with water for 30 seconds.

Immediately after application of the strips by study participants, a clinician with over 25 years of experience assessed the fit of the test strips, categorizing them as “adequate” or “inadequate”. Following a 30-minute retention period, the same clinician evaluated the strips for adhesion, retention, and integrity, again classifying the outcomes as “adequate” or “inadequate”.

Tooth color was measured at the midline of the mid-cervical third of each of the 12 anterior teeth before and after whitening. L\*a\*b\* color measurements were obtained for each location and timepoint by a pre-standardized, experienced clinician under controlled lighting, distance, and ambient conditions, using the VITA Easyshade V digital spectrophotometer (VITA North America, Yorba Linda, CA 92887).

The following measures served as primary measures of study outcomes:

- a.  $\Delta E$  (E tooth color change as measured using L\* a\* and b\* color measurement)
- b. Adequacy of strip adhesion, retention, and integrity

Changes in tooth color were assessed by comparing L\*, a\*, and b\* measurements at the 30-minute timepoint to baseline values, utilizing the standard  $\Delta E$  metric [12, 13], a metric designed specifically to inform on how the human eye perceives color, color change, and color differences. It is calculated using the formula  $\Delta E_{ab}^* = \sqrt{(L_2^* - L_1^*)^2 + (a_2^* - a_1^*)^2 + (b_2^* - b_1^*)^2}$  where L\* represents the darkness-lightness coordinate or value from the Munsell's Dimensions of Color, a\* represents the chromaticity between green (negative a\*) and red (positive a\*), and b\* represents the chromaticity between blue (negative b\*) and yellow (positive b\*) [12]. Furthermore, the fit, adhesion, retention, and durability of the strips were evaluated both at baseline and after 30 minutes. Data were analyzed using repeated measures analysis of variance, with significance defined at  $p < 0.05$ .

## Results

The study population closely resembled that of the overall US population in terms of habits that may contribute to tooth staining (Table 1).

	Tobacco Use	Daily Tea	Daily Coffee	$\geq 1$ Glass Red Wine weekly	Staining Soda
Study population (n) (%)	4 (13%)	4 (13%)	21 (70%)	6 (20%)	18 (60%)
US population (%)	11.5% <sup>14</sup>	23% <sup>15</sup>	75% <sup>16</sup>	18% drink wine (color unknown) weekly <sup>17</sup>	63% <sup>17</sup>

**Table 1.** Demographics and habits that might lead to tooth staining of the study population vs the US population at large.

All whitening strips were correctly applied, positioned, and secured to the twelve anterior teeth, as assessed by a single clinician (Table 2).

	Correct strip placement	Effective initial strip adherence	Did strips tear?	Did strips wrinkle?	Complete strip retention over 30 mins.	Strip slippage over 30 mins.
Yes (n)	30	27	0	0	30	0
No (n)	0	3	30	30	0	30

**Table 2:** Clinician observations regarding fit, adherence, wear ability, and durability of whitening strips.

Each strip remained in situ throughout the 30-minute study duration. There were no incidents of slipping, tearing, and wrinkling (Table 2, Figure 1). The majority of participants reported that the strips were easy to place and comfortable to wear, maintaining their position without tearing and offering a pleasant taste. However, a minority commented that the mandibular strip should be a little larger.

Whitening data are presented in (Table 3), and the results of the statistical analysis of the data are presented in Table 4. With a mean  $\Delta E$  value for all teeth of 4.73, tooth color was significantly whiter ( $p < 0.0001$ ) after 30 minutes of whitening strip application. This high level of statistical significance underlines the consistency and efficacy of the strips' whitening effects. Moreover, as a mean  $\Delta E$  of 2 or more is considered to be a color change "perceptible at a glance by the naked eye" [13], the  $\Delta E$  of 4.73 evidenced in this study greatly exceeds the threshold of visible perception of color change. Representative clinical photographs are shown in (Figure 1).



**Figure 1:** Representative standardized photographs of subjects before (a,c,e,g) and after (b,d,f,h) 30-minute whitening strip use.

Patient #	Mean $\Delta E$
1.	5.52
2.	3.35
3.	3.83
4.	4.60
5.	2.83
6.	7.71
7.	4.75
8.	3.66
9.	3.62
10.	4.07
11.	5.67
12.	6.97
13.	5.28
14.	5.91
15.	2.78

16.	4.76
17.	3.50
18.	8.71
19.	5.84
20.	3.03
21.	5.88
22.	5.20
23.	4.67
24.	3.51
25.	3.94
26.	3.13
27.	4.91
28.	5.63
29.	4.90
30.	3.72
<b>Mean</b>	<b>4.73</b>

**Table 3.** Mean  $\Delta$  E after 30 minutes of whitening strip use. Mean total  $\Delta$ E measured 4.73.

<b>P value</b>	<b>&lt;0.0001</b>
P value summary	****
Significantly different (P < 0.05)?	Yes
One- or two-tailed P value?	Two-tailed
t, df	t=18.06, df=29
Number of pairs	30
Mean of differences (B - A)	4.729
SD of differences	1.434
SEM of differences	0.2618
95% confidence interval	4.194 to 5.265
R squared (partial eta squared)	0.9184

**Table 4:** Statistical analysis results: teeth were significantly whiter after 30 minutes of whitening strip use with a very high level of significance ( $p < 0.0001$ ).

## Discussion

The overall goal of this study was to evaluate the efficacy and usability of a non-peroxide whitening strip whose active ingredients include Dead Sea salt and essential oils of coconut, sage and lemon peel [18]. The participants in this clinical trial resembled the general US population with regard to age, demographics, and use of staining agents such as colored beverages and tobacco [14-18]. This is important, as teeth become darker and less responsive to whitening with age [19]. Moreover, different stains exhibit varying degrees of responsiveness to whitening treatments [20]. Nevertheless, all participants in this study, regardless of age and habits associated with tooth staining, evidenced quick and significant whitening that was readily apparent to the naked eye after only one 30-minute bleaching event. These findings are in agreement with previous studies [10,11]. Additionally, larger studies are underway to explore the effects of additional variables, and longer use periods on whitening strip performance, and to provide a direct comparison between various whitening formulations.

## Conclusion

In this clinical study involving 30 participants, a single thirty-minute application of non-peroxide Lumineux Oral Essentials Tooth Whitening Strips yielded highly significant and consistent tooth whitening. The mean change in whiteness ( $\Delta E$ ) measured 4.73, exceeding the threshold for perceptibility to the naked eye by more than twofold. The significance of this change was robust, with a p-value of  $<0.0001$ . Furthermore, there were only very minimal issues related to strip fit and handling during the 30-minute application period.

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