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Effect of One 30-Minute Application of a Non-Peroxide Dental Whitening Strip: A Clinical Study in 50 Subjects

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Abstract

Background: Due to the reported adverse side effects of peroxide whitening strips, the whitening efficacy of non-peroxide strips requires evaluation.

Objectives: The goal of this single center, *in vivo* study in 50 subjects was to determine the effects of a one-time application of a non-peroxide dental whitening strip on tooth color after 30 minutes of intra-oral wear. Strip fit, retention, and durability were also evaluated.

Methods: In 50 subjects aged 18-70 with similar demographics and risk factors for tooth staining as the general population, tooth color was recorded on 12 anterior teeth under standardized conditions. Next, subjects applied one test whitening strip (Lumineux Oral Essentials, Beverley Hills, CA) to the upper and lower anterior teeth respectively. The fit of the strip was checked by a dentist. After 30 minutes, the fit, adhesion, retention, and integrity of the strip were checked again, the strips were removed, and tooth color was measured again using a VITA Easy shade V for color measurements.

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Study endpoints were change in tooth color, and strip fit and wear ability. Finally, participants completed a brief questionnaire evaluating the performance of the strips.

Results: One-time application of the test strip significantly whitened the teeth ($p < 0.0001$). Strips fitted well and adhered to the teeth without tearing or becoming dislodged over the 30-minute whitening duration.

Conclusion: A one-time, 30-minute application of a non-peroxide strip whitened the teeth with a high level of significance while maintaining structural and adhesive integrity of the strip.

Keywords

Tooth; Whitening; Bleaching; Dental; Non-peroxide; Peroxide; Strips

Introduction

Approximately 37 million Americans used tooth whiteners in 2020 [1]. A bright, white smile is considered to be a great esthetic and social asset that communicates success and confidence [2-3]. Peroxide-based tooth strips for in-home application have been used to whiten the teeth for many years. These treatments are typically based on hydrogen peroxide or its precursor, carbamide peroxide, as the active ingredient. They deliver concentrations ranging from 3% to 40% of hydrogen peroxide equivalent [1]. Although many studies have confirmed their effectiveness in lightening the teeth, the side effects of these formulations have provided a strong impetus to find alternatives. The most important side effects are gingival irritation and dentinal sensitivity, which are reported to occur in 6.7-27% and 10-42% of subjects respectively [4-11].

In a recent controlled, double-blinded, randomized *in vivo* study in 90 subjects comparing the effects of a non-peroxide-based vs a peroxide-based strip, investigators found no significant difference between the whitening effect of the 2 types of strips over 7 and 14 days, while significantly more subjects developed dental sensitivity, oral burning, and soreness in the group using the peroxide strips [12]. That study confirms the need for and the potential of non-peroxide-based approaches to in-home tooth whitening. It also raises the question of how effectively the non-peroxide strips whiten over shorter periods of time than the 7 and 14 days that were evaluated in that investigation [12].

The goal of this single center, *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.

Material and Method

A. Overview

In 50 subjects aged 18-70, tooth color was recorded on 12 anterior teeth under standardized conditions, then subjects applied one test whitening strip respectively to the upper and lower anterior teeth. The fit of the strip was checked by a dentist. After 30 minutes, the fit, adhesion, retention, and integrity of the strip were checked again by the same dentist, then the strips were removed, and the tooth color measurements were repeated. The VITA Easy shade V (VITA North America, Yorba Linda, CA 92887) was used for color measurements under standardized ambient and lighting conditions. Finally, participants completed a brief questionnaire evaluating the performance of the strips.

B. Participants

50 individuals who met inclusion/exclusion criteria were recruited by word of mouth on and around the University of California Irvine campus. Participants provided written, informed consent before study begin. This research was performed in full compliance with University of California Irvine IRB protocol 2013-9778, and all clinical procedures were conducted in accordance with the Helsinki Declaration of 1975, as updated in 2013. No significant changes were made in the study design after commencement of the study.

Participants met the following inclusion and exclusion criteria:

Inclusion criteria

- Male or female aged 18–70
- Able to provide written informed consent
- Able to attend study visit
- 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 formulations.

Additionally, subjects were broadly balanced to represent the general population in terms of gender and age distribution, as well as coffee, tea, wine, and tobacco use.

C. Protocol

Test product

Subjects were provided with 1 pouch of Lumineux Oral Essentials Whitening Strips(Oral Essentials, Beverly Hills, CA 90210) containing 1 peel-off strip for the upper teeth, and a smaller one for the lower teeth.

Instructions for using the strips were as follows:

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 30s.

Measurements

Directly after the strips had been applied by the study participants, the fit of the test strips was evaluated as being “adequate” or “inadequate” by the same clinical dentist with >25 years of experience. After 30 minutes in the mouth, immediately prior to their removal, the test strips were again evaluated by same dentist for adhesion, retention, and integrity. The outcomes for these variables were again characterized as “adequate” or “inadequate”.

Tooth color was measured midline in the mid-cervical third of each of the 12 anterior teeth before and after whitening. L*a*b* color measurements were collected 3 times for each location and time point by 1 pre-standardized, experienced clinician under standardized lighting, distance, and ambient conditions, using the VITA Easy shade V (VITA North America, Yorba Linda, CA 92887) digital spectrophotometer. L* represents lightness from black to white on a scale of zero to 100, while a* and b* represent chromaticity with no specific numeric limits. Negative a* corresponds with green, positive a* corresponds with red, negative b* corresponds with blue and positive b* corresponds with yellow.

Finally, subjects evaluated the strips’ performance by means of a written questionnaire that included the following questions:

- a. Was the strip easy to apply? (Y/N)
- b. Did it wrinkle or tear during application? (Y/N)
- c. Did it stay in place during the entire 30-minute wear period? (Y/N)
- d. Was it comfortable to wear? (Y/N)
- e. Did it wrinkle or tear during the 30 minutes while it was on your teeth? (Y/N)
- f. Were you aware of any leakage of strip contents during the 30 minutes while the strip was on your teeth? (Y/N)
- g. Other comments

Primary end points

- Mean change in tooth color after 30 minutes of whitening strip wear
- Strip fit, adhesion, retention, and durability (integrity).

Data Analysis

Changes in tooth color were calculated by comparing each L* a* and b* color measurement at the 30-minute timepoint with its baseline value. Mean change in color was calculated as percent change from baseline averaged across all teeth per patient and analyzed using repeated measures analysis of variance

models. Additionally, fit, adhesion, retention and durability of the strip were evaluated at baseline and after 30 minutes, and analyzed using repeated measures analysis of variance models. Significance was set at $p < 0.05$.

Results

All 50 subjects completed the study in full compliance with the study protocol.

Study population demographics and habits.

The study population closely resembled that of the US population overall (Table 1).

| | Female | Male | Tobacco Use | Daily Tea | Daily Coffee | >1 glass red wine weekly |
|--------------------------|-------------------|-------------------|---------------------|-------------------|-------------------|---|
| Study population (n) (%) | 27 (54%) | 23 (46%) | 4 (8%) | 9 (18%) | 36 (72%) | 6 (12%) |
| US population (%) | 51% ¹³ | 49% ¹³ | 11.5% ¹⁴ | 23% ¹⁵ | 75% ¹⁶ | 18% drink wine (color unknown) weekly ¹⁷ |

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

Ease of application, wear ability, fit, durability of test strips.

All whitening strips were applied, placed, and attached correctly and effectively to the 12 anterior teeth, as evaluated by 1 clinician (Table 2). All whitening strips remained in situ over the 30-minute study duration, without slipping, tearing, or appearing to leak (Table 2, Figure 1).

| | Were strips placed correctly by subject at study begin? | Did strips adhere fully to teeth at study begin? | Did strips remain in place for 30 mins? | Did strips slip over 30 mins? | Did strips tear over 30 mins? | Did strips wrinkle over 30 mins. |
|---------|---|--|---|-------------------------------|-------------------------------|----------------------------------|
| Yes (n) | 50 | 50 | 50 | 0 | 0 | 0 |
| No (n) | 0 | 0 | 0 | 50 | 50 | 50 |

Table 2. Clinician observations regarding fit, adherence, wearability, and durability of whitening strips.



Figure 1. Representative photographs (Subjects 2, 36 and 48) of strip fit and integrity before (left-hand side) and after (right-hand side) 30 minutes of wear.

Evaluation of whitening strips by study participants. Subjects reported no problems of any sort with strip application, adherence, retention, discomfort, leakage, tearing, or wrinkling. They provided no additional comments beyond the feedback requested in the above-cited questionnaire (Table 3).

| | Was strip easy to apply? | Did it wrinkle/tear during application? | Did it stay in place for 30 mins? | Was it comfortable? | Did it wrinkle/tear over 30 mins? | Perceived leakage of strip contents | Other |
|------------|--------------------------|---|-----------------------------------|---------------------|-----------------------------------|-------------------------------------|-------|
| Yes (n/50) | 50 | 0 | 50 | 50 | 0 | 0 | NONE |
| No (n/50) | 0 | 50 | 0 | 0 | 50 | 50 | NONE |

Table 3: Study participants' observations regarding wear ability, fit, durability of whitening strips.

Whitening effects after 30 minutes. Teeth were significantly whiter after 30 minutes of whitening strip application (Tables 4 – 7). On average, L^* values increased (became lighter) by 4.81 (sig. $p < 0.001$); a^* values decreased by 0.0216 (sig. $p < 0.001$), and b^* values decreased by 1.24 (sig. $p < 0.001$), resulting in a mean ΔE of 5.03. Briefly, Delta E is a metric for understanding how the human eye perceives color

difference. It is calculated using the formula $\Delta E_{ab}^* = \sqrt{(L_2^* - L_1^*)^2 + (a_2^* - a_1^*)^2 + (b_2^* - b_1^*)^2}$ [18]. A mean ΔE of 2 or more is considered as a color change “perceptible at a glance by the naked eye [18].

| Baseline | | | 30 minutes whitening | | | Delta E |
|----------|------|-------|----------------------|------|-------|------------|
| L* | a* | b* | L* | a* | b* | ΔE |
| 68 | 7.23 | 18.71 | 75.31 | 7.13 | 18.14 | 7.33 |
| 68.43 | 7.14 | 17.28 | 74.62 | 6.94 | 17.54 | 6.20 |
| 67.05 | 7.98 | 17.51 | 73.39 | 7.59 | 16.43 | 6.44 |
| 66.09 | 7.17 | 17.62 | 72.24 | 6.84 | 16.85 | 6.21 |
| 69.71 | 6.84 | 18.51 | 72.25 | 6.63 | 16.94 | 2.99 |
| 69.94 | 7.02 | 18.76 | 74.63 | 6.73 | 17.23 | 4.94 |
| 68.58 | 6.99 | 17.94 | 72.21 | 6.64 | 17.33 | 3.70 |
| 67.42 | 8.12 | 18.62 | 71.89 | 7.75 | 17.13 | 4.73 |
| 68.05 | 7.14 | 19.36 | 73.27 | 6.59 | 17.74 | 5.49 |
| 66.29 | 6.97 | 19.04 | 70.62 | 6.66 | 18.42 | 4.39 |
| 67.21 | 7.21 | 18.23 | 68.23 | 6.82 | 17.92 | 1.14 |
| 67.27 | 7.94 | 17.94 | 70.56 | 7.24 | 16.88 | 3.53 |
| 60.17 | 7.53 | 18.27 | 74.42 | 7.18 | 16.94 | 14.32 |
| 67.21 | 7.76 | 17.98 | 73.86 | 7.29 | 16.21 | 6.90 |
| 70.01 | 7.92 | 18.26 | 75.22 | 7.64 | 17.02 | 5.36 |
| 66.23 | 7.35 | 17.95 | 70.73 | 7.06 | 16.79 | 4.66 |
| 71.31 | 7.21 | 18.27 | 74.68 | 7.03 | 16.89 | 3.65 |
| 68.76 | 7.44 | 18.84 | 73.35 | 7.19 | 16.75 | 5.05 |
| 65.64 | 7.98 | 18.27 | 69.96 | 7.34 | 17.13 | 4.51 |
| 64.12 | 7.62 | 18.88 | 68.24 | 7.3 | 16.99 | 4.54 |
| 62.15 | 7.55 | 18.81 | 64.37 | 7.11 | 17.08 | 2.85 |
| 65.25 | 7.79 | 17.94 | 68.93 | 7.31 | 17.06 | 3.81 |
| 65.99 | 7.69 | 17.67 | 69.34 | 7.22 | 17.24 | 3.41 |
| 70.13 | 7.39 | 17.91 | 76.27 | 6.99 | 17.67 | 6.16 |
| 65.47 | 7.44 | 19.24 | 69.75 | 7.85 | 17.96 | 4.49 |
| 68.21 | 7.98 | 17.96 | 74.5 | 7.54 | 16.79 | 6.41 |
| 66.48 | 8.01 | 18.64 | 70.75 | 7.66 | 18.2 | 4.31 |
| 69.11 | 7.75 | 18.91 | 76.27 | 7.47 | 17.35 | 7.33 |
| 68.73 | 7.35 | 18.63 | 74.58 | 6.94 | 16.44 | 6.26 |
| 67.78 | 7.44 | 18.81 | 74.34 | 7.15 | 16.74 | 6.88 |
| 66.93 | 7.68 | 18.33 | 69.63 | 7.57 | 16.96 | 3.03 |
| 69.72 | 7.31 | 19.03 | 73.69 | 6.89 | 17.98 | 4.13 |
| 68.68 | 7.02 | 17.61 | 75.04 | 6.97 | 16.99 | 6.39 |
| 66.24 | 7.91 | 18.01 | 69.01 | 7.44 | 17.43 | 2.87 |

| | | | | | | |
|-----------------|----------------|-----------------|-----------------|----------------|-----------------|--------------|
| 67.69 | 7.76 | 18.61 | 73.23 | 7.4 | 16.07 | 6.11 |
| 67.93 | 7.64 | 18.71 | 73.88 | 7.22 | 17.72 | 6.05 |
| 69.01 | 7.45 | 19.28 | 74.26 | 6.93 | 17.25 | 5.65 |
| 65.56 | 7.49 | 18.69 | 69.08 | 7.18 | 16.22 | 4.31 |
| 64.05 | 7.87 | 18.2 | 67.41 | 7.36 | 16.87 | 3.65 |
| 65.79 | 7.72 | 18.94 | 70.34 | 7.44 | 16.72 | 5.07 |
| 66.23 | 8.03 | 18.89 | 70.22 | 7.69 | 16.59 | 4.62 |
| 70.22 | 7.94 | 19.18 | 74.83 | 7.58 | 17.33 | 4.98 |
| 75.21 | 7.43 | 18.49 | 79.02 | 6.94 | 17.04 | 4.11 |
| 69.17 | 7.32 | 17.69 | 74.89 | 6.97 | 16.1 | 5.95 |
| 64.31 | 7.67 | 17.51 | 69.53 | 7.22 | 17.23 | 5.25 |
| 66.85 | 7.79 | 18.63 | 70.07 | 7.3 | 17.52 | 3.44 |
| 67.71 | 7.84 | 18.77 | 72.43 | 7.26 | 17.76 | 4.86 |
| 68.42 | 7.62 | 19.04 | 73.79 | 7.34 | 17.8 | 5.52 |
| 67.48 | 7.76 | 17.31 | 71.42 | 7.42 | 16.98 | 3.97 |
| 66.72 | 7.89 | 18.28 | 70.22 | 7.33 | 17.72 | 3.59 |
| MEAN 67.4142 | MEAN 7.5618 | MEAN 18.3992 | MEAN 72.2154 | MEAN 7.2056 | MEAN 17.1616 | MEAN 5.03 |

Table 4: Mean tooth color (L^* , a^* , b^*) in each of 50 subjects before and after 30 minutes of whitening strip application and ΔE .

| | L^* | | | a^* | | | b^* | | |
|-------------|-------|-------|--------|-------|--------|---------|-------|--------|---------|
| | Mean | SD | SEM | Mean | SD | SEM | Mean | SD | SEM |
| Baseline | 67.41 | 2.369 | 0.335 | 7.562 | 0.3315 | 0.04688 | 18.4 | 0.5468 | 0.07733 |
| 30 Mins. | 72.22 | 2.799 | 0.3958 | 7.206 | 0.3099 | 0.04383 | 17.16 | 0.551 | 0.07792 |

Table 5: Mean tooth color (L^* , a^* , b^*), SDs and SEMs before and after 30 minutes of whitening strip application.

| | $T_{30} - T_0$ | | |
|-------------|----------------|---------|---------|
| | L^* | a^* | b^* |
| Mean change | 4.81 | -0.0216 | -1.24 |
| P value | <0.0001 | <0.0001 | <0.0001 |
| Significant | Yes | Yes | Yes |

Table 6: Mean change in tooth color (L^* , a^* , b^*) before and after 30 minutes of whitening strip application.

| | ΔE | | |
|--------------------|------------|-------|--------|
| | Mean | SD | SEM |
| ΔE 30 Mins | 5.031 | 1.884 | 0.2664 |

Table 7: Mean ΔE after 30 minutes of whitening strip application.

Discussion

Because patient age and dietary habits can affect tooth response to in-home whitening strips [19-21], the demographics and potentially tooth-staining habits of the subjects enrolled in this study were matched closely to those of the US population at large [13-17]. By conducting the study in this representative population, researchers were able to ensure that the study findings were relevant within the larger context of the demographics and habits of the entire US population.

Non-peroxide OTC formulations cite active components such as Dead Sea salt and essential oils of coconut, sage, orange, and lemon peel [22-24]. The impetus behind such formulations is primarily to avoid the side effects of peroxide-based formulations. However, more information is needed regarding the effectiveness of these strips, with regard to user-friendliness, efficacy, and outcomes. To be accepted by users, strips need to be easy to apply, to remain adhered to the teeth, and to avoid tearing or breakdown throughout use. This study demonstrated that non-peroxide strips can indeed meet all of these requirements very effectively. In addition, the whitening outcomes should be comparable to – or better than – those of existing peroxide-based strips. The results of a recent large *in vivo* study confirmed a comparable whitening effect from non-peroxide and peroxide-based strips over 7 and 14 days [12]. Moreover, subjects rated their teeth as being significantly more attractive after bleaching with the non-peroxide vs the peroxide strips, because their teeth were significantly shinier or more lustrous. Finally, the current study demonstrated that the non-peroxide strips whiten quickly and effectively, achieving significant lightening after only one 30-minute bleaching event in individuals of all ages manifesting a wide range of habits that are associated with tooth staining.

Conclusion

This clinical study in 50 subjects demonstrated highly significant and consistent tooth whitening after a one-time thirty- minute application of the non-peroxide Lumineux Oral Essentials Tooth Whitening Strips. There was no evidence of any deficiencies or problems regarding accuracy of fit, adequacy of adhesion, strip retention and integrity over 30 minutes.

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