



Study Report – PWS-OEH-TW14-1121

A Fourteen-Day Clinical Study in 30 Subjects to Determine the Effect on Oral Tissues and Tooth Color of Lumineux OE Whitening Strips^R

Study Goal:

To determine the effect over 14 days of Lumineux OE Whitening Strips^R on gingival and mucosal tissues, dental hard tissues, and tooth color.

Study Overview:

Thirty subjects used the Lumineux OE Whitening Strips^R daily over a period of 14 days, in accordance with the product use directions. Thus, 1 strip was allocated to be used on the upper anterior teeth, and the other on the lower anterior teeth each day. On Days 0, 7 and 14, the oral soft and hard tissues were examined carefully by a dentist, and tooth color was measured on the 12 anterior teeth using a digital colorimeter under standard, calibrated lighting conditions. Each participant completed a questionnaire daily to document perceived effects on the oral hard and soft tissues. **No whitening-related adverse effects or symptoms were reported by subjects or observed by the dentist during 14 days of whitening strip use. On average, teeth became 5.5 digital Colormaster V shades lighter after using the whitening strips for 7 days, and 13.3 digital Colormaster V shades lighter after 14 days. Mean improvement in tooth color was statistically significant for Day 7 vs. Day 0, Day 14 vs. Day 7, and Day 14 vs. Day 0 (P < 0.01).**

Submitted by:

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1. PURPOSE

Goal of this single center, in vivo study was to determine the effect of Lumineux OE Whitening Strips^R on gingival and mucosal tissues, dental hard tissues, and tooth color over 14 days. A dentist with more than 25 years of clinical experience examined the oral soft and hard tissues on Day 0, Day 7 and Day 14 under standardized lighting conditions and documented any changes in these tissues at each time point. Additionally, the color of the 12 anterior teeth was measured on Day 0, Day 7 and Day 14 under standard, calibrated lighting conditions using the state-of-the-art Vita Easyshade V^R digital colorimeter *(Vita North America, Yorba Linda, CA 92887). Each participant completed a questionnaire daily to document perceived hard and soft tissue effects, and any other signs or symptoms. Unstructured comments were also recorded.

2. MATERIALS AND METHODS

2.1. Subjects

30 subjects with 12 healthy anterior teeth without restorations, evident demineralization or decay were recruited, and provided written, informed consent under University of California, Irvine IRB-approved protocol # 2013-9778.

Subjects additionally met the following inclusion and exclusion criteria:

Inclusion Criteria

1. Male or non-pregnant female, 18 years of age and above.
2. Minimum of 25 teeth present.
3. Willing and able to provide written informed consent.
4. Willing and able to comply with study visits as described in the protocol.
5. Available for follow up on the telephone.

Exclusion Criteria

1. Unable or unwilling to sign the informed consent form.
2. Participation in any other clinical study within 30 days prior to enrollment into this study.
3. Subjects who must receive dental treatment during the study duration.
4. History of significant adverse effects following use of oral hygiene products such as toothpastes, mouth rinses and whitening formulations.
5. Allergy to personal care/consumer products or their ingredients.
6. Diagnosed with Sjögren's disease, or immune deficiency diseases (i.e., HIV or AIDS, poorly controlled diabetes), or anti TNF-alpha medication for rheumatoid arthritis, systemic antibiotics in the last 3 months, anti-inflammatory drugs, or immune suppressants.
7. Presence of any condition, abnormality, or situation at Baseline that in the opinion of the Principal Investigator may affect the patient's ability to comply with study requirements

2.2. Protocol

This study 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. The rolling recruitment through advertisements was initiated in October 2021 and all the study visits were completed by one examiner by mid-November 2021.

Subjects maintained their regular dietary and oral hygiene routines throughout the study duration. They were provided OTC Lumineux OE Whitening Strips^R for the study duration. Subjects applied 1 upper and 1 lower strip for 30 minutes each day for 14 days, according to package instructions. After removing the strips, subjects rinsed with water for 30s. Subjects were contacted daily by study staff and questioned with regard to any perceived signs or symptoms according to the questionnaire included in the Appendix. Comments were also collected and are presented in the Appendix.

On Day 0, Day 7 and Day 14 of the study, the subjects' soft and hard tissues were examined under standardized lighting conditions by a dentist with more than 25 years of clinical experience. Any changes in these tissues on Day 7 and Day 14 were recorded. Additionally, the color of the 12 anterior teeth was measured on Day 0, Day 7 and Day 14 under standard, calibrated lighting conditions using the state-of -the-art Vita Easyshade V^R digital colorimeter.

2.3. Test Whitening Strips

OTC Lumineux OE Whitening Strips^R (Beverly Hills, CA 90210)

2.4. Endpoints and Data Analysis

2.4.1. Effects on Oral Tissues: Daily Subject Questionnaire

Subjects were contacted daily by study staff and questioned with regard to any perceived signs or symptoms according to the questionnaire included in the Appendix. Responses were scored as "yes" or "no". Any unsolicited comments were also noted.

2.4.2. Effects on Oral Tissues: Examination by Dentist

Observed effects of the whitening strips on the oral hard and soft tissues were scored by an experienced dentist using 4 semi-quantitative measures for each tissue type:

Effect: None (score 0), Mild (score 1), Moderate (score 2), Severe (score 3)
Tissue Type: Gingiva, Mucosa, Dental hard tissues.

Each change observed was recorded as 1 "observation".
Thus, for example,

A mouth with no observed changes received a breakdown score of “Gingiva 0, Mucosa 0, Hard tissues 0” and a total score of 0.

A mouth with 1 gingival lesion received a breakdown score of “Gingiva 1, Mucosa 0, Hard tissues 0” and a total score of 1.

2.4.3. Whitening Effects

Tooth color was recorded as the numerical output from the digital Vita Easyshade V^R colorimeter.

2.4.4. Data Analysis

All measures were described using means and SDs. Change over time was estimated using repeated measures analysis of variance models. Measures were also dichotomized to describe presence vs absence of symptoms. Mean pre- and post- treatment measures (and SDs) from the colorimeter were estimated. Mean change in tooth whitening was estimated as percent change from baseline averaged across all teeth per patient.

3. RESULTS

All subjects completed the study in full compliance with the protocol. No adverse events were reported or observed.

3.1. Effects on Oral Tissues

3.1.1. Subject Daily Questionnaire Results

During the entire study duration, one positive questionnaire response was reported by one subject. Reportedly the subject developed a lesion on the palate lasting from Day 1 through Day 5. He attributed it to consuming an overly hot slice of pizza very quickly. The lesion had healed and was no longer discernible at clinical examination by the Dentist on Day 7. No other changes were reported by any of the subjects on any days throughout the study duration (Table 1).

| | Day 0 | Day 1 | Day 2 | Day 3 | Day 4 | Day 5 | Day 6 | Day 7 | TOTAL |
|----------------------------------------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| Burning mouth | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Altered taste | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Mouth soreness | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Mouth ulcers | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Change in gum color | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Tooth sensitivity | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Changes in fillings like increased roughness | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Other | 0 | 0* | 0* | 0* | 0* | 0* | 0 | 0 | 0* |

| | Day 8 | Day 9 | Day 10 | Day 11 | Day 12 | Day 13 | Day 14 | TOTAL |
|----------------------------------------------|-------|-------|--------|--------|--------|--------|--------|-------|
| Burning mouth | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Altered taste | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Mouth soreness | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Mouth ulcers | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Change in gum color | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Tooth sensitivity | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Changes in fillings like increased roughness | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Other | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0* |

Table 1: Subject-Reported Oral Signs and Symptoms During 14 Days of Using Whitening Strips

* Minor trauma on palate- attributed by subject to, and consistent with, consuming very hot pizza too quickly

Many subjects also provided unsolicited feedback regarding the whitening strips. All comments are presented in the Appendix.

No whitening-related oral lesions, signs or symptoms such as sensitivity or soreness were reported by the 30 subjects during 14 days of whitening strip use. Thus, mean change is 0; S.D. is also zero. Median and range values are also 0.

3.1.2. Dentist Clinical Examination Results

The dentist observed no adverse changes in the health or status of the oral gingiva, mucosa, and hard tissues of 30 subjects after 14 Days of bleaching strip use (Table 2).

| | Day 7 | Day 14 | TOTAL |
|------------------------------------------------|-------|--------|-------|
| Gingival changes vs Day 0 | 0 | 0 | 0 |
| Mucosal changes vs Day 0 | 0 | 0 | 0 |
| Hard tissue changes (excluding color) vs Day 0 | 0 | 0 | 0 |
| Total | 0 | 0 | 0 |

Table 2: Changes in Gingival, Mucosal and Dental Health after 7, 14 Days of Whitening Strips Use

No adverse changes of any sort were observed in the dental hard and soft tissues by the dentist during 14 days of whitening strip use. Thus, mean change in gingival, mucosal and hard tissues is 0; S.D. is also 0. Median and range values are also 0.

3.1.3. Whitening Effect of the Test Strips (see also Exhibit A of Appendix)

All teeth showed progressive whitening after 1 and 2 weeks of whitening strips use (Table 3).

| | Day 0 | Day 7 | Day 14 |
|--------------------------------------------------------|---------------|---------------|--------------|
| Mean tooth color (Digital Vita V) | 19.36 \pm 4 | 13.88 \pm 3 | 6.03 \pm 4 |
| Median tooth color (Digital Vita V) | 18.88 | 14.13 | 5.88 |
| Lightest tooth color (Digital Vita V) | 15.50 | 11.63 | 2.14 |
| Darkest tooth color (Digital Vita V) | 24.00 | 17.75 | 10.33 |
| Mean tooth color (Vita 3-D Master Bleaching Guide) | M2 (3.5) | M2 (2) | M1 (1) |
| Lightest tooth color (Vita 3-D Master Bleaching Guide) | M2 (2.5) | M2 (1.5) | M1 (0.5) |
| Darkest tooth color (Vita 3-D Master Bleaching Guide) | M2 (4.5) | M2 (3.0) | M2 (1.5) |
| Mean Change vs Day 0 (Digital Vita V/% change) | | 5.48/28.3% | 13.33/68.85% |
| Mean Change vs Day 7 (Digital Vita V/% change) | | | 7.85/56.56% |
| Median Change vs Day 0 (Digital Vita V/% change) | | 4.75/25.2% | 13.00/68.86% |
| Median Change vs Day 7 (Digital Vita V/% change) | | | 8.25/58.39% |

Table 3: Change in Tooth Color After 7 and 14 Days of Using Whitening Strips

On average, teeth became 5.48 digital Colormaster V shades lighter after using the whitening strips for 7 days, and 13.33 digital Colormaster V shades lighter after using the whitening strips for 14 days. Mean improvement in tooth color was significant (P < 0.01) between Day 7 vs. Day 0, Day 14 vs. Day 0 and Day 14 vs. Day 7.

4. CONCLUSION

Daily use of Lumineux OE Whitening Strips^R over a period of 14 days did not cause any adverse effects in the oral soft and hard tissues. Neither the gums, nor the oral mucosa or the teeth showed any signs or symptoms of any adverse effects. The strips whitened the teeth significantly, between each time point. Mean improvement in tooth color measured 5.48 digital Colormaster V shades on Day 7 and 13.33 on Day 14.

5. APPENDIX

5.1. Exhibit A: Sample Photos of Subjects Going through Whitening at 0, 7 and 14 days.

Subject 1



Baseline



After 1 week



After 2 weeks

Subject 2



Baseline



After 1 week



After 2 weeks

Subject 3



Baseline



After 1 week



After 2 weeks

Subject 4



Baseline

After 1 week

After 2 weeks

5.2. Subject Evaluation form: subjects were contacted daily and asked whether they experienced any of the signs and symptoms listed below. Daily responses were documented for each category as: “none”, “mild”, “moderate” or severe”.

Subject Initials

Please Complete This Evaluation Form Daily on Day 0 through Day 14

| | DAY0 | DAY1 | DAY2 | DAY3 | DAY4 | DAY5 | DAY6 | DAY7 | DAY8 | DAY9 | DAY10 | DAY11 | DAY12 | DAY13 | DAY14 |
|----------------------------------------------|------|------|------|------|------|------|------|------|------|------|-------|-------|-------|-------|-------|
| Burning mouth | | | | | | | | | | | | | | | |
| Altered taste | | | | | | | | | | | | | | | |
| Tooth sensitivity | | | | | | | | | | | | | | | |
| Mouth soreness | | | | | | | | | | | | | | | |
| Mouth ulcers | | | | | | | | | | | | | | | |
| Change in gum color | | | | | | | | | | | | | | | |
| Changes in fillings like increased roughness | | | | | | | | | | | | | | | |
| Any other changes/ observations/comments | | | | | | | | | | | | | | | |
| What did you like about the strips? | | | | | | | | | | | | | | | |
| What did you dislike about the strips | | | | | | | | | | | | | | | |

5.3. Subject Comments

- Strips were easy to use: 27x
- Strips tasted (much) better than market leader: 26x
- My teeth and gums usually get sore after whitening- with these strips I had no soreness or sensitivity of any kind: 22x
- The bleached teeth have a very natural color/love the way they look: 21x
- I will keep using these strips- I love them (or similar): 21x
- Strips stayed on better than leading competitor: 18x
- Residual bleaching material came off teeth (very) easily after removing the strips: 13x
- The strips don't leave a burning residue in my moth/throat like the market leader: 8x

- Bottom strip tore during use: 1x