



Study Report – PWS-OEH-TWP02-05212

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

Study Goal:

To determine the effect over 14 days of Lumineux OE Ultra-Brite Pen^R on gingival and mucosal tissues, dental hard tissues, and tooth color.

Study Overview:

Thirty subjects used the Lumineux OE Ultra-Brite Pen^R daily over a period of 14 days, in accordance with the product use directions. Thus, two thin coats of the gel were applied to the anterior teeth once daily, then subjects waited at least 30 minutes before eating or drinking. 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 pen use. On average, teeth became 6.49 digital Colormaster V shades lighter after using the whitening pen for 7 days, and 15.23 digital Colormaster V shades lighter after using the whitening pen 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.**

Submitted by:

A handwritten signature in black ink, which appears to read "Petra Wilder-Smith". The signature is written over a faint, circular watermark of the University of California, Irvine logo.

Petra Wilder-Smith, DDS, DMD, PhD
Professor and Director of Dentistry

Date Submitted

2/7/2022

1. PURPOSE

Goal of this single center, in vivo study was to determine the effect of Lumineux OE Ultra-Brite Pen^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 December 2021 and all the study visits were completed by one examiner by end January 2022.

Subjects maintained their regular dietary and oral hygiene routines throughout the study duration. They were provided OTC Lumineux OE Ultra-Brite Pens^R for the study duration. Subjects applied the pen to the upper and lower anteriors each day for 14 days, according to package instructions. Briefly, subjects smiled wide, keeping lips away from teeth. Then they applied two thin coats by brushing over the teeth with the pen. Subjects then avoided eating and drinking for 30 minutes. Subjects were contacted daily by study staff and questioned regarding 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 Pen

OTC Lumineux OE Ultra-Brite Pen^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 pen 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, no positive questionnaire responses were reported by any study participants. (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 Pen

Many subjects also provided unsolicited feedback regarding the whitening pens. 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 pen 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 pen 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 Pens Use

No adverse changes of any sort were observed in the dental hard and soft tissues by the dentist during 14 days of whitening pen 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 Pen (see also Exhibit A of Appendix)

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

	Day 0	Day 7	Day 14
Mean tooth color (Digital Vita V)	20.47 ±5	13.98 ±6	5.24 ±3
Median tooth color (Digital Vita V)	19.26	12.47	5.88
Lightest tooth color (Digital Vita V)	15.37	9.42	2.02
Darkest tooth color (Digital Vita V)	23.46	16.41	9.26
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 (1.0)
Mean Change vs Day 0 (Digital Vita V/% change)		6.49/31.7%	15.23/74.4%
Mean Change vs Day 7 (Digital Vita V/% change)			8.74/62.52%
Median Change vs Day 0 (Digital Vita V/% change)		6.79/35.25%	13.38/69.47%
Median Change vs Day 7 (Digital Vita V/% change)			6.59/52.84%

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

On average, teeth became 6.49 digital Colormaster V shades lighter after using the whitening pen for 7 days, and 15.23 digital Colormaster V shades lighter after using the

whitening pen 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 the Lumineux OE Ultra-Brite Pen^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 pen whitened the teeth significantly between each time point. Mean improvement in tooth color measured 6.49 digital Colormaster V shades on Day 7 and 15.23 on Day 14.

5. APPENDIX

5.1. Exhibit A: Sample Photos of Subjects Using the Lumineux OE Ultra-Brite Pen[®] at 0, 7 and 14 days.

Day 0

Day 7

Day 14



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															

5.3. Subject Comments

- Pens were easy to use: 30x
- My teeth and gums usually get sore after whitening- with these pens I had no soreness or sensitivity of any kind: 28x
- The bleached teeth have a very natural color: 16x
- Love how bright and white my teeth look: 30x
- The white is bright, shiny, and natural, no blueish tinge (or similar): 23x
- I will keep using these pens- I love them (or similar): 24x
- Love that I didn't have to use strips and there were no residual deposits after bleaching: x14
- The pens don't leave a burning sensation in my mouth/throat like the market leader: 16x
- Love them- where can I buy them?: 25

5.4. Researcher Comments

- It was a pleasure to conduct this study. The test product received some of the most positive and enthusiastic feedback we have ever obtained from subjects in 30+ years of research.
- Subjects seemed most excited about the shiny result and natural color of the whitened teeth- no blue tinge. They told us that “shiny” is at least as important as “white”.