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Effect of Three Different Whitening Strips on Dental Sensitivity, Oral Tissues, Tooth Color and Luster: A Double-Blinded, Randomized, Controlled Clinical Study

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Abstract

Goal of this controlled, double-blinded, randomized in vivo study in 90 subjects was to compare the effects of 3different whitening strips over 7 and 14 days on gingival and mucosal tissues, dental sensitivity, tooth color and luster. Subjects were randomized to use 1 of 3 tooth whitening strips daily for 14 days. Formulations included non-peroxide-based Lemieux OE Whitening Strips (Group 1), Placebo Whitening Strips (Group 2), and peroxide-based Crest 3D Whitestrips Professional White At-home Teeth Whitening KitR (Group 3). On Days 0, 7 and 14, oral tissues were examined, Schiff Dental Sensitivity Test implemented, tooth color measured on 12

anterior teeth using a digital colorimeter, tooth luster recorded, and digital photographs acquired. Each participant completed a questionnaire daily and at study completion. Mean color change was calculated and analyzed for each timepoint using repeated measures analysis of variance models. Significantly more subjects in Group 3 developed dental sensitivity, oral burning, and soreness vs. those in Groups 1 and 2. In week 2, 4 subjects in Group 3 quit the study due to dental pain. There was no significant difference in the whitening effect observed in Groups 1 and 3 on Day 7 (4-5 digital "V" shades lighter) and Day 14 (8-9.5 digital "V" shades lighter). Teeth in Group 1 were significantly more lustrous than those in Group 3.

Keywords
Tooth; Whitening; Bleaching; Dental; Luster; Sensitivity

Introduction
Most individuals consider an attractive smile to be not only an esthetic and social necessity, but also a predicator of social confidence and acceptance [1-2]. According to Statists, approximately 37.0 million Americans used tooth whiteners in 2020 [3]. Many factors contribute to the perception of tooth color, and consequently tooth whiteness measurement is complex, especially given the many variables that are important, but difficult to standardize. These include tooth wetness, roughness, shine, the color of adjacent structures, and the properties and incidence angle of the external illumination used during the color evaluation process. Moreover, teeth are translucent, and their color is not constant over the entire tooth surface. Because of the challenges inherent to dental color quantification, there have been many different approaches, each with its own challenges [4]. In vivo measurement techniques have the advantage of direct measurements in situ but are time-consuming and require careful standardization of all variables. Digital photographic techniques have the advantage of convenience but are subject to the challenges to accurate color extraction posed by the impact of back-scattered light, which is contingent upon the tooth's level of luster and the angle and which photographs are recorded, as well as discrepancies caused by the RGB-aligned color-recording on the digital camera and the various non-RGB color assessments used in dental colorimetry.

Numerous clinical studies have been conducted to evaluate the efficacy and potential side-effects of in-home whitening treatments. These studies have generally shown effective tooth whitening after in-home treatment, with the most important reported side effects of gingival irritation and dentinal sensitivity occurring in between 6.7-27% and 10-42% of subjects respectively [5-12]. To date, most in-home whitening treatments have been based on hydrogen peroxide or its precursor, carbamide peroxide, as the active ingredient. They are used in concentrations ranging from 3% to 40% of hydrogen peroxide equivalent [3].

Recently there has been an upsurge in interest in non-peroxide-based OTC whitening formulations, because of concerns about some of the side effects of peroxide-based whitening agents. However, to date there is little information in the literature about these new formulations. Non-peroxide OTC formulations cite active components such as Dead Sea salt and essential oils of coconut, sage, orange, and lemon peel

[14-16]. The goals of this on vivo randomized, double-blinded, randomized, controlled study was to compare the effect over 14 days of three different whitening strip formulations on dental sensitivity, gingival and mucosal tissues, as well as tooth color and luster. The protocol was carefully designed to exclude confounding factors to the greatest extent possible, and to use the most accurate assessment tools that are available. One of the formulations evaluated is a very popular peroxide-based formulation; another formulation assessed in this study is based on essential oils and the final formulation served as negative placebo and has no active ingredients.

Materials and Methods

Overview

The goal of this single center, controlled, double-blinded, randomized in vivo study in 90 subjects was to compare the effects of 3 different whitening strip formulations over 7 and 14 days on gingival and mucosal tissues, dental sensitivity, as well as tooth color and luster. Subjects used the allocated whitening strips daily over a period of 14 days, in accordance with the product use directions. Thus, each day, 1 strip was used on the upper anterior teeth, and the other on the lower anterior teeth. 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. Tooth sensitivity was measured using the standard Schiff Cold Air Sensitivity Scale [17].Next, under standardized lighting, distance, and ambient conditions, digital tooth color "V" was measured on the 12 anterior teeth using a digital colorimeter (Vita Easy shade VR, Vita North America, Yorba Linda, CA 92887). Tooth luster was measured on a scale of 0-6 using the Sturzenberger gloss standards [18]. High-resolution digital camera images were recorded from the 12 anterior teeth at baseline and on days 7 and 14 of treatment using standard techniques. Finally, each participant completed a questionnaire daily to document perceived effects of the whitening treatment on the oral hard and soft tissues. On Days 7 and 14 subjects were asked to record their evaluation of tooth color and luster. Unstructured comments were also collected.

Subjects

90 subjects with 12 healthy anterior teeth without restorations, evident demineralization or decay were recruited. Subjects met the inclusion and exclusion criteria shown in (Table 1). In order to minimize the number of variables in this study, only subjects between age 18 to 30 were included in this study. In this age range, tooth colors, responsiveness to whitening agents, pulp chamber sizes and dentinal sensitivity are most uniform. Including a wider age range would introduce additional confounding variables to the study with regard to evaluating whitening efficacy, as teeth change color and altered susceptibility to whitening with age, and mouths become dryer [19-21].

Moreover, dental sensitivity is more difficult to measure in a meaningful manner in mixed age groups, due to the age-related reduction in pulp chamber dimensions, and radicular sensitivity from gingival recession and exposed root dentin [19-21].

Inclusion Criteria	
•	18 – 30 years of age
•	Minimum of 25 teeth present
•	Willing and able to provide written informed consent
•	Willing and able to comply with study visits as described in the protocol
•	Professional tooth cleaning 1-5 months prior to study begin
Exclusion Criteria	
•	Unable or unwilling to sign the informed consent form
•	History of tooth bleaching within 3 months of study begin
•	Current tooth sensitivity
•	Facial anterior restorations
•	Regular tobacco, tea, coffee, red wine and/or cola use (>1/week of any)
•	Tobacco use in any form
•	Need for dental treatment during the study duration.
•	History of significant adverse effects following use of oral hygiene products such as toothpastes, mouth rinses and whitening formulations.
•	Allergy to personal care/consumer products or their ingredients.
•	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.
•	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.

Table 1: Recruitment inclusion/exclusion criteria.

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. Subjects were randomized on a 1:1:1basis using randomizer.com to one of three test strip formulations. At the baseline visit, subjects were provided with sufficient de-identified test strips to last the entire duration of the study and were instructed on product application and removal. Subjects also received take-home de-identified manufacturer's instructions for use and a 24-hour contact number for use in case of an emergency. Test strips were provided in individual, silver pouches that were only marked with a code that connected to a masking sheet accessible only to the study administrator. All test products were stored under ambient conditions until they were given to the subjects. All subjects and researchers were blinded with regard to treatment allocations except the study administrator. All subjects were supplied with an anticavity toothpaste (Crest^{R} Cavity Protection Regular Paste, P&G, Cincinnati, OH, USA, 45202), and a soft toothbrush (Oral-B Pro Health^{R} Soft, P&G, Cincinnati, OH, USA, 45202) for use during the study.

Subjects maintained their regular dietary and oral hygiene routines throughout the study duration. None of the subjects used tobacco, tea, coffee, red wine, or cola more than once weekly.

Subjects applied 1 upper and 1 lower strip to their anterior teeth for 30 minutes each day over 14 days, according to package instructions. After removing the strips, subjects rinsed with water for 30s and did not consume food or beverages for thirty minutes thereafter. Subjects were contacted daily by text by study staff and questioned with regard to any perceived signs or symptoms according to the questionnaire shown in Figure 1, which includes all of the signs and symptoms recorded in clinical practice related to potential side effects of whitening treatments [22].

On Day 0, Day 7 and Day 14 of the study, subjects returned to the study site. Their soft and hard tissues were examined under standardized lighting conditions by the same dentist with more than 25 years of clinical experience. Any changes in the oral soft and hard tissues on Day 7 and Day 14 were recorded. Next, the dentist determined sensitivity using the standard Schiff Air scale, whereby a timed airblast was directed for 1 s from a distance of 1 cm at the exposed buccal surface of the tooth after its isolation from the adjacent teeth [17]. Directly after stimulation, the subject response was quantified by using a verbal rating of 0-3. All subjects registered a "0" on the Schiff scale on Day 0. Next, under standardized lighting, distance, and ambient conditions, digital tooth color "V" values were measured on the 12 anterior teeth using a digital colorimeter (Vita Easyshade VR, Vita North America, Yorba Linda, CA 92887). Standardized digital photographs were also collected. Tooth luster was measured on a scale of 0-6 using Sturzenberger gloss standards [18]. Finally, each participant completed by text message a daily questionnaire documenting the perceived effects of the whitening treatment on the oral hard and soft tissues. Unstructured comments were also collected at study completion.

Test Whitening Strip Formulations

Group 1. Non-peroxide-containing Lumineux OE Whitening Strips^{R} (Oral Essentials,Beverly Hills, CA 90210); Stated active ingredients: Coconut Oil, Dead Sea Salt, Sage Oil, Lemon Peel Oil

Group 2. Placebo Whitening Strips containing no active whitening agents (Oral Essentials, Beverly Hills, CA 90210); Stated active ingredients: None

Group 3. Peroxide-containing Crest 3D Whitestrips Professional White At-Home Teeth Whitening Kit^{R} (Procter & Gamble, Cincinnati, Ohio, 45202): Stated active ingredient: Hydrogen peroxide

Endpoints and Data Analysis

i. Effects on oral tissues: daily subject questionnaire

Subjects were contacted daily through text by study staff and questioned with regard to any perceived signs or symptoms according to the questionnaire shown in (Figure 1). Responses were scored on a scale of 0-3:

0- no symptoms; 1- mild symptoms; 2- moderate symptoms; 3-severe symptoms.

This daily log was included in the study protocol to obtain an ongoing record of any signs or symptoms in addition to the weekly professional assessments of oral and dental health.

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															

Figure 1: Daily subject questionnaire evaluating any side effects from whitening strips.

ii. 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 on a scale of 0-3 for each tissue type/location:

0- no symptoms; 1- mild symptoms; 2- moderate symptoms; 3- severe symptoms.

Sensitivity was measured by the same dentist using the same equipment at each visit on Days 0,7 and 14 using the standard Schiff scale of 0-3 [17].

iii. Color and luster

Digital tooth color "V" values were measured under standardized lighting conditions in the same room and position on the 12 anterior teeth using a digital colorimeter (Vita Easyshade VR, Vita North America, Yorba Linda, CA 92887). Tooth luster was measured under the same standardized conditions on a scale of 0-6 using the Sturzenberger gloss standards [18].

iv. Subject evaluation of treatment

Unstructured comments were collected from all participants at study completion.

v. Data analysis

All measures were described using means, SDs and SEs to obtain a single mean "V" color value for the facial surfaces of the 12 anterior teeth in each subject. Changes in tooth color were calculated by comparing each measurement with its baseline value. Mean change in tooth whiteness was calculated as percent change from baseline averaged across all teeth per patient and analyzed using repeated measures analysis of variance models. Measures of side effects and symptoms were also averaged across all teeth per patient and analyzed using repeated measures analysis of variance models.

Results

86/90 subjects completed the study in full compliance with the protocol. Four subjects in Group 3 requested to leave the study during week 2 because they had developed moderate to severe sensitivity. In these subjects, tooth color measurements were included for week 1, during which they had completed the protocol in full, but not for week 2 of the study. The mean subject age was 20.8 years; overall age ranged from 18-27 years. 51 subjects identified as female, 39 as male. 54 subjects identified as Asian, 31 as white (10 Hispanic), and 5 as multiracial (Table 2).

	Group 1 (n=30)	Group 2 (n=30)	Group 3 (n=30)	Total (n=90)
Age (Years)				
Mean	21.9	19.9	20.5	20.77
Range	18-25	18-26	19-27	18-27
Sex				
Female	18	16	17	51
Male	12	14	13	39
Race				
Asian	15	22	17	54
Caucasian (Hispanic)	13 (3)	8(6)	10 (1)	31 (10)
Multiracial	2	0	3	5

Table 2: Subject population demographics

Effects on Oral Tissues

i. Results of subject daily questionnaire (Table 3)

Overall, subjects tolerated the 14 days of whitening treatments well. There was 1 report of mild and transient dental sensitivity in Group 1. Two subjects in Group 2 (placebo) reported mild sensitivity, with each event lasting 2 days. In Group 3, 6 individuals reported mild to moderate sensitivity during week 1, and 8 reported mild to severe sensitivity during week 2, one of whom had progressed from mild sensitivity in week 1. In Group 3, 4 subjects asked to quit the study on days 8, 10, 10 and 11 of the study respectively due to dental sensitivity. 1 and 6 subjects in Group 3 complained of burning mouth in weeks 1 and 2 respectively. Subjects in Group 3 reported significantly greater sensitivity, burning mouth, and oral soreness than those in Groups 1 and 2 ($p<0.02$).

Symptoms	Group 1 (n=30)	Group 2 (n=30)	Group 3 (n=30 end of Week 1; n = 26 end of Week 2)
Sensitive teeth	1 mild (D3-5)	2 mild (D3-5, 7-9)	6 mild (D3-7, 4-7, 5-6, 6-7, 11-14, 13-14) 2 moderate (D6-8*, D5-10*) 4 severe (D8-10*, 8-11*, 9-14, 11-14)
Quit study due to sensitivity	0	0	4 (D8, 10, 10, and 11)
Burning mouth	0	0	1 (week 1) 6 (week 2)
Altered taste	0	0	0
Sore mouth, throat or gums	0	0	2 week 1 5 week 2
Change in gum color	0	0	0
Changes in fillings	0	0	0
Other	0	0	0

Table 3: Number of subjects reporting symptoms during 14 days of whitening strips usage. Asterisk* indicates subjects who did not complete the study because of dental sensitivity.

ii. Results of clinical examination by dentist (Table 4)

The dentist observed no adverse changes in the health or status of the oral gingiva, mucosa, and hard tissues in any treatment group after 14 days of bleaching strip use. The results of the Schiff sensitivity testing are shown in (Table 4). All subjects scored a “0” on the Schff test on Day 0, as this was an inclusion criterion for recruitment into the study to ensure identical sensitivity baselines in all groups. Subjects in Group 1 measured a “0” on the Schiff scale on each evaluation day (0,7,14). Subjects in Group 2 measured all “0”s except for 1 subject on Day 7, who measured a “1”. In Group 3, 5 subjects measured a “1” or “2” on Day 7, and 4 subjects measured a “1” or “3” on Day 14.

Schiff Score	Group 1 (n=30)	Group 2 (n=30)	Group 3 (n=30 end of Week 1; n = 26 end of Week 2)
Day 0	Score 0: 30 subjects	Score 0: 30 subjects	Score 0: 30 subjects
	Score 1: 0 subjects	Score 1: 0 subjects	Score 1: 0 subjects
	Score 2: 0 subjects	Score 2: 0 subjects	Score 2: 0 subjects
	Score 3: 0 subjects	Score 3: 0 subjects	Score 3: 0 subjects
Day 7	Score 0: 30 subjects	Score 0: 29 subjects	Score 0: 25 subjects
	Score 1: 0 subjects	Score 1: 1 subject	Score 1: 3 subjects
	Score 2: 0 subjects	Score 2: 0 subjects	Score 2: 2 subjects
	Score 3: 0 subjects	Score 3: 0 subjects	Score 3: 0 subjects
Day 14	Score 0: 30 subjects	Score 0: 30 subjects	Score 0: 22 subjects
	Score 1: 0 subjects	Score 1: 0 subjects	Score 1: 2 subjects
	Score 2: 0 subjects	Score 2: 0 subjects	Score 2: 0 subjects
	Score 3: 0 subjects	Score 3: 0 subjects	Score 3: 2 subjects

Table 4: Results of Schiff dental sensitivity testing on Days 0,7 and 14. Four subjects from Group 3 quit the study on Days 8, 10, 10 and 11 due to dental sensitivity.

Effects on Tooth Color and Luster

i. Effect on tooth color (Tables 5-6)

Teeth in Groups 1 and 3 were significantly ($p<0.05$) lighter on Days 7 and 14 vs. baseline and vs. Group 2. No significant ($p>0.05$) whitening effect was observed in Group 2 (placebo). On Day 0, baseline color between the groups did not differ significantly ($p>0.524$). On average, teeth in Groups 1 and 3 became 4-5 shades lighter after 7 days, and 8-9.5 shades lighter after 14 days of whitening strip use. On Day 7, there

was no significant difference (p>0.904) in the whitening effect observed in Groups 1 and 3, which performed significantly better (p<0.0001) than Group 2 (placebo). On Day 14, there was also no significant difference (p>0.5) in the whitening effect observed in Groups 1 and 3, which performed significantly better (p<0.0001) than Group 2 (placebo).

	Group 1 (OE)			Group 2 (Placebo)			Group 3 (Crest)		
	Day 0	Day 7	Day 14	Day 0	Day 7	Day 14	Day 0	Day 7	Day 14
Minimum	10	6	3	9	9	9	8	5	3
Maximum	18	14	9	19	19	19	19	14	7
Median	16	9	5	14	14	14	15	11	5
Mean	15.3	10.5	6	13.7	13.7	13.9	14.7	9.7	5.2
Mean Change vs Day 0		-4.8 (31.4%)	-9.3 (60.8%)		0	-0.2 (1.5%)		-5.0 (34%)	-9.5 (64.6%)

Table 5: Mean Digital Tooth Color and Color Change (%) after 7 and 14 Days of Whitening Strips Use.

	Mean Diff.	95.00% CI	Significance	Adj. P Value
Day 0				
Placebo (G2) vs. Crest (G3)	-1	-4.060 to 2.060	ns	0.829
Placebo (G2) vs. OE (G1)	-1.6	-4.660 to 1.460	ns	0.5243
Crest (G3) vs. OE (G1)	-0.6	-3.660 to 2.460	ns	0.9561
Day 7				
Placebo (G2) vs. Crest (G3)	4	0.9401 to 7.060	**	0.005
Placebo (G2) vs. OE (G1)	3.2	0.1401 to 6.260	*	0.0367
Crest (G3) vs. OE (G1)	-0.8	-3.860 to 2.260	ns	0.9036
Day 14				
Placebo (G2) vs. Crest (G3)	8.7	5.640 to 11.76	****	<0.0001
Placebo (G2) vs. OE (G1)	7.9	4.840 to 10.96	****	<0.0001
Crest (G3) vs. OE (G1)	-0.8	-3.860 to 2.260	ns	0.9036

Table 6: Statistical Analysis of Whitening Effect using Tukey's Multiple Comparisons Test.

ii. Effect on tooth luster (Tables7, 8)

On Day 0, baseline luster between the groups did not differ significantly (p>0.4015). On Days 7 and 14, teeth in Group 1 were significantly more lustrous than those in Group 3 (p<0.0059), and on Day 14 teeth in Group 2 were significantly more lustrous than those in Group 3 (p=0.0117).

	Group 1 (OE)			Group 2 (Placebo)			Group 3 (Crest)		
	Day 0	Day 7	Day 14	Day 0	Day 7	Day 14	Day 0	Day 7	Day 14
Minimum	2	3	5	3	3	3	4	2	2
Maximum	5	6	6	6	6	6	6	6	6
Median	4	6	6	4	4	4	4	4	3
Mean	4	5.1	5.8	4.3	4.3	4.4	4.7	3.6	3.5
Mean change vs Day 0		1.1	1.7		0	0.1		-1.1	-1.2

Table 7: Tooth Luster after 7 and 14 Days of Whitening Strip Use: Sturzenberger Scale (0-6).

	Mean Diff.	95.00% CI	Significance	Adj. P Value
Day 0				
Placebo(G2) vs. Crest (G3)	-0.4	-1.565 to 0.7654	ns	0.8071
Placebo (G2) vs. OE (G1)	0.3	-0.8654 to 1.465	ns	0.9075
Crest (G3) vs. OE (G1)	0.7	-0.4654 to 1.865	ns	0.4015
Day 7				
Placebo (G2) vs. Crest (G3)	0.7	-0.4654 to 1.865	ns	0.4015
Placebo (G2) vs. OE (G1)	-0.8	-1.965 to 0.3654	ns	0.2831
Crest (G3) vs. OE (G1)	-1.5	-2.665 to -0.3346	**	0.0059
Day 14				
Placebo (G2) vs. Crest (G3)	0.9	-0.2654 to 2.065	ns	0.1888
Placebo (G2) vs. OE (G1)	-1.4	-2.565 to -0.2346	*	0.0117
Crest (G3) vs. OE (G1)	-2.3	-3.465 to -1.135	****	<0.0001

Table 8: Statistical Analysis of Luster using Tukey's Multiple Comparisons Test.

Subject Satisfaction with Treatment Outcome (Tables9, 10)

Subjects were asked to record their satisfaction with tooth color and luster at study end, on Day 14 (Table 9). Satisfaction was significantly better for Group 1 vs Groups 2 and 3, and for Group 3 vs. Group 2. The results in Tables 9 and 10 show that whitening effectiveness was particularly appreciated by subjects in Groups 1 and 3, with bleaching speed cited as a particular benefit by participants in Group 3 and attractiveness of color and luster highlighted by individuals in Group 1.

	Group 1 (OE)	Group 2 (Placebo)	Group 3 (Crest)
	Day 14	Day 14	Day 14
Minimum	1	0	0
Maximum	1	0	1
Median	1	0	1
Mean	1	0	0.7

Table 9: Subject Satisfaction with Tooth Color and Luster (0-Dissatisfied; 1-Satisfied)

Group 1	Group 2	Group 3
POSITIVE COMMENTS		
(21x) Didn't develop any sensitivity	(20x) Didn't develop any sensitivity	(23x) Whitened fast
(20x) Liked shiny/glossy appearance of teeth and white rather than blue color	(11x) Strips easy to use, adhered well, no excessive residue	(14x) Teeth developed attractive bright white color
(11x) Didn't develop sore or burning throat		(11x) Strips easy to use, adhered well, no excessive residue, left teeth feeling smooth and clean
(10x) Strips easy to use, adhered well, left teeth feeling smooth and clean		(7x) Didn't develop any sensitivity
NEGATIVE COMMENTS		
(4x) Slower than Crest Whitestrips	(21x) Ineffective	(8x) Dental sensitivity, sore or burning throat

(3x) Teeth not as white as after Crest Whitestrips	(11x) Teeth not shiny	(5x) Teeth not shiny
	(1x) Left residue on teeth	(6x) Teeth blueish tinge

Table 10: Unstructured Comments from Subjects at Study End.

Discussion

Because patient age and dietary habits can affect tooth response to in-home whitening strips [19-21], the subjects enrolled in this study were all within the 18–30-year age range, non-tobacco users, and with restricted weekly tea, coffee, red wine, or cola use to no more than once weekly. By establishing these inclusion criteria, researchers were able to ensure that the tooth color attributes did not differ significantly between the three study groups at study begin.

As expected, the placebo formulation (Group 2) had no bleaching effect at either timepoint. On average, in this study, the teeth of subjects in Groups 1 and 3 were 4-5 digital "V" shades or 28-34% lighter after using whitening strips for 1 week, and 8-10 shades or 54-65% lighter after 2 weeks, which is similar to whitening effects reported for the product used by Group 3 in other studies [9-12-23].

One recent publication by Gurich et al describes a 14-day study comparing the whitening efficacy of the formulation used by Group 1 plus a plant-based whitening rinse and toothpaste vs hydrogen peroxide-based strips plus a non-whitening fluoride toothpaste [24]. The authors reported no significant whitening effect by the plant-based treatment, and a significant whitening effect from the peroxide strips. Perhaps one reason for this discrepancy is the greater age of subjects in that study compared to the current investigation. In older patients, teeth tend to have a more gradual and slower responsiveness to whitening treatments, especially by gentler non-peroxide whitening agents [19-21]. This concept is supported by the reduced levels of whitening also reported in the peroxide strip-treated group in the study by Gurich et al vs those reported in other studies [9-12,23]. Moreover, in the Gurich et al study, color determinations were performed indirectly, ex vivo and post-hoc using images of the teeth, whereas tooth color was measured directly on the in vivo teeth under standardized conditions in the current study. Color measurements using the photo-based image analysis approach employed by did not consider tooth luster, nor was luster measured in that study. Thus, the Gurich group may have registered inaccurately lower color readings than the actual in vivo tooth color in the non-peroxide group, because identical colors with higher levels of luster register as a darker shade than those with a lower luster level [25-28], and this effect is further magnified by the typically higher levels of backscattered light or luster in photographs recorded at 900 such as those used by the industry-recommended angles of 200, 400or 600[26]. Because the current study demonstrated that tooth luster increased significantly in the teeth treated with the non-peroxide formulations, butit decreased significantly in the teeth treated with the peroxide strips, it seems reasonable to assume that this unmeasured, but essential variable gave rise to misleading conclusions about whitening efficacy in the Gurich study.

Societally, tooth luster is seen as an important contributor to an attractive smile [20,29], yet there is a dearth of studies into the effects of tooth whitening procedures and formulations on tooth luster, and the perceived attractiveness of the bleaching outcome. The results of this study show that luster is indeed an important outcome for whitening studies, as subjects in Groups 1 preferred the bleaching outcome to those in Group 3, despite equal bleaching effectiveness of the strips. For this reason, as well as purposes of color measurement accuracy, future whitening studies should include tooth luster as an outcome in addition to the mere tooth color obtained at the study endpoints.

Surprisingly, there were 2 self-reported episodes of brief, transient dental sensitivity in the placebo group (Group 2), one of which coincided with a positive response to the Schiff Air test on Day 7. It remains unclear what the cause for these symptoms might have been, but it seems reasonable to assume that they were not related to the placebo whitening treatment. One subject in Group 1 reported transient dentinal sensitivity in their daily logs Days 3-5, which did not overlap with the clinical Schiff testing, when this subject did not exhibit any signs or symptoms of hypersensitivity. Subjects in Group 3 reported significantly greater sensitivity, burning mouth, and oral soreness than those in Groups 1 and 2. The level of these side effects in Group 3 was similar to those reported in other studies [5-12].

Conclusions

In this 14-day randomized, double-blinded, controlled clinical study, no significant difference was found between the whitening effect of a non-peroxide whitening strip vs that of a peroxide-based formulation. Tooth luster increased significantly after the non-peroxide treatments whereas it decreased significantly after treatment with the peroxide strips. The peroxide-based strip caused significantly more dental sensitivity, oral burning, and soreness than the other formulation. Whitening strips with non-peroxide formulations can provide an effective alternative to conventional peroxide-based formulations and may be associated with fewer side effects.

Author Contributions

Conceptualization, PWS, CW, and TT; Methodology, PWS, IV; Software, TT; Validation, TT and PWS; Formal Analysis, TT, Investigation, IV, SY, SK, CW, NP, TT, PWS.; Resources, PWS; Data Curation, SY, IV; Writing – Original Draft Preparation, PWS; Writing – Review & Editing, PWS, NP, TT, Visualization, TT and PW.; Supervision, PWS; Project Administration, IV, SY, SK; Funding Acquisition, PWS.

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Institutional Review Board Statement

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.

Informed consent statement

Informed consent was obtained from all subjects involved in the study.

Data Availability Statement

The data presented in this study are available on request from the corresponding author. The data are not publicly available due to privacy restrictions.

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Conflicts of Interest

The authors declare no conflict of interest.

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