

Bleaching Efficiency and Side Effects of Three Home Bleaching Systems

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Abstract. To compare the bleaching efficiency, side effects and patients' acceptance of two professional bleaching products and one over-the-counter home bleaching systems. Thirty females were randomly allocated to three equal home bleaching groups. Group I: Opalescence Trèswwhite, Group II: WHITEsmile®, and Group III: CleverWhite one over-the-counter. Teeth shade and gingival index were recorded at base line and after one week of product use. Teeth hypersensitivity, gingival irritation and patients' acceptance were recorded by the participants in questionnaires during and after one week of products use. Shade improvement was significantly higher in Group I and II compared to Group III ($p < 0.05$). There was no statistically significant difference between the three groups during and after the bleaching application regarding teeth hypersensitivity ($p > 0.05$). During products application, group I had the highest gingival irritation ($p < 0.05$). The mean gingival index was not statistically different between groups before and after bleaching. Patients' acceptance in Groups I, II and III represented as 100%, 60% and 33%, respectively with a statistically significant difference ($p < 0.05$). The two professional home bleaching products were significantly more efficient in bleaching the teeth than one over-the-counter product.

Keywords: Bleaching, Hydrogen Peroxide, Carbamide peroxide, Hypersensitivity, Gingival irritation.

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Introduction

Today, cosmetic dentistry is playing a very important role among other dental branches. Tooth whitening is one of the fastest growing areas in this branch. An increasing number of patients are demanding faster and easier way to bleach their teeth, while maintaining safety in procedure. Therefore, multiple professional and over-the-counter at home bleaching material have been developed to compensate for this continuous increase in patients' need. At home bleaching is available now with different concentrations of active ingredient, either carbamide peroxide (CP) or hydrogen peroxide (HP)^[1].

In general, there are many studies in the literature that compare between different home bleaching systems. Scientific data from researches conducted during the past decade have demonstrated the safety of the dentist-dispensed at-home whiteners containing 10% carbamide peroxide or 3.5% hydrogen peroxide^[1,2]. There has been no evidence of systemic adverse effects associated with the proper use of these whitening systems. Most commonly observed local adverse effects are mild-to-moderate tooth sensitivity and/or gingival irritation, which usually do not prevent the patient from completing the whitening treatment application. The sensitivity and irritation are transient in most cases, and they dissipate when the patient discontinues the use of the whitener. There is no evidence of any long-term consequences that have resulted from tooth sensitivity and/or gingival irritation^[1-3].

Studies conducted to compare bleaching efficiency of different professional home bleaching products, it was found that both carbamide peroxide and hydrogen peroxide products are effective at-home as bleaching agents^[2,4]. In addition to the professional at-home bleaching agents, over-the-counter (OTC) bleaching products are nowadays available and they are sold as cosmetics freely available through stores, pharmacies and the internet. They can be sold for example, as either strip or varnish systems. In 2005 Cronin *et al.* compared two OTC tooth whitening products where a 6% HP tooth bleaching gel delivered on polyethylene film and an 18% CP brush-applied liquid gel were compared. The results indicated that the bleaching efficiency was more significant for the hydrogen peroxide users^[5]. The efficacy and structural side effects of OTC products were not fully investigated or studied, and

they may cause patients problems, because dentists do not monitor the bleaching procedure.

Therefore, the aim of the present study was to evaluate and compare the bleaching efficiency, tooth hypersensitivity and gingival irritation of three home bleaching materials including two professional systems (Opalescence Trèswhite, WHITEsmile®) and one OTC bleaching system (CleverWhite). Patient's acceptance of each material was also evaluated and compared.

Materials and Methods

This study was carried out as a randomized double blinded experimental clinical trial, to compare the effectiveness and side effects of different bleaching agents

Sample Selection

Thirty females were recruited into the study and screened at the screening clinic at the Faculty of Dentistry, King Abdulaziz University, Jeddah, Saudi Arabia. The inclusion criteria were:

- Age from 22 to 35 years old.
- Presence of six maxillary anterior teeth which are free from any labial restorations.
- All subjects did not use tobacco products before and during the study period.
- All subjects signed a consent form and were able to return back for periodic examination.

Subjects with the following criteria were excluded from the study:

- Medical conditions that might interfere with the study or require attention.
- Pregnant or lactating women.
- A gingival index score greater than 1 or gross pathology in the mouth.
- Tetracycline-stained teeth or having undergone endodontic therapy in any of the maxillary anterior teeth.
- Use of professionally applied tooth whiteners within the past two years.

- Use of tobacco products during the past 30 days.

In the first visit of the study, the participants received a professional tooth cleaning and asked to brush their teeth twice daily with the allocated toothpaste (Colgate) and a medium hardness tooth brush in order to standardize tooth cleaning during the study. The baseline tooth color was assessed for each patient by two trained examiners using the VITA shade guide (VITAPAN classical, VITA Zahanfabriz, Bad Säckigen, Germany) on the facial surface of the right maxillary canine.

The tabs of the shade guide were arranged from B1 to C4, corresponding to a grade scale of whitening from 1 to 16 (Table 1), in which a smaller number means the tooth is lighter^[6,7].

Table 1. The Vita value-oriented shade guide with 16 shades ranked from the lightest color on the left to the darkest color on the right^[7].

B1	A1	B2	D2	A2	C1	C2	D4	A3	D3	B3	A3.5	B4	C3	A4	C4
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

Intra oral photographs of the six maxillary anterior teeth with the matching shade tab were taken in the same visit.

Gingival index of Löe^[8] was calculated to assess gingivitis for each subject at the baseline and were assessed for six index teeth.

In the second visit, the participants were randomly assigned to three groups of 10 participants each.

Group I

Treated with 9% hydrogen peroxide (Opalescence, Trèswhite, Ultradent, South Jordan, UT USA) and was assigned as a positive control group. The participants were instructed to use the material according to manufacturer instructions and apply the material 60 minutes every day for seven days.

Group II

Treated with 10% carbamide peroxide (WHITEsmile®, GmbH, Birkenau, Germany). The participants were instructed to use the material according to manufacturer instructions and apply the material 120 minutes every day for seven days.

Group III

Treated with 3.6% sodium carbonate peroxide (CleverWhite, Remedent, Deurle, Belgium). The participants were instructed to use the material according to manufacturer instructions and apply the material 30 minutes every day for seven days.

No special trays were constructed in this study as preloaded trays with their whitening gel were supplied with each material.

The participants were instructed to rinse their mouth with water after removing the trays in order to remove any remaining gel from the mouth, and refrained from consuming tea, coffee, coca cola, *etc.* for at least three hours after bleaching as this will reduce the effectiveness of the treatment.

Questionnaires were distributed to all the participants in order to indicate tooth hypersensitivity and gingival irritation during the gel application period and for seven days after using the whitening gel.

The degree of tooth sensitivity and gingival irritation were ranked as follows: 0 – none; 1-mild; 2-moderate and 3-severe. A question about their satisfaction was also included in the questionnaire after seven days of product use.

In the third visit immediately after the full regimen application of each material the shade change was recorded by the same examiners, gingival index was calculated for each participant and post treatment photographs were taken.

In the fourth visit after one week of no treatment application the shade was taken to check any color rebound and the questionnaires were collected from the participating subjects.

Statistical Analysis

Data were collected, statistically analyzed using SPSS program. ANOVA, Chi square, Kruskal-Wallis and paired sample *t*-tests were used at a significance level of 0.05.

Results

Twenty-nine participants completed the study since one participant in Group III used the material for two days only and did not complete the course.

Bleaching Efficiency

Bleaching efficiency was evaluated by comparing the mean values of the shade improvement between groups using ANOVA test (mean values = 4.4 ± 0.2 ; 3.4 ± 0.7 ; and 1.3 ± 0.5 for Groups I, II & III, respectively) and there was a statistically significant difference among the groups ($p = 0.005$) as shown in Table 2. Scheffe post-hoc test indicated that the significant difference was between Group I and III ($P = 0.006$) and between Group II and III ($p = 0.077$). While there was no significant difference between Group I and II ($p = 0.5$). Figures 1-3 show clinical pictures of one participant from each group at base line and after one week of product application.

Table 2. Analysis of variance results for the mean differences of bleaching efficiency between the three groups.

	Mean± SD	F	p	Scheffe
Group I	4.4 ± 0.2	6.4	0.005*	Group I vs. Group III* Group II vs. Group III*
Group II	3.4 ± 0.7			
Group III	1.3 ± 0.5			

*Significant at 5% level.

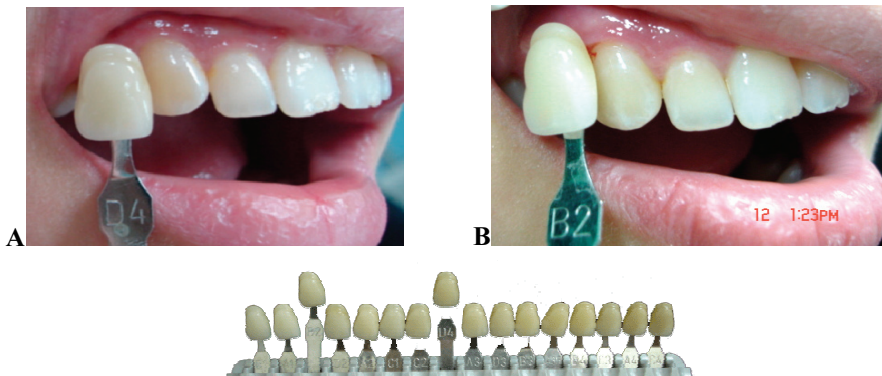


Fig.1. Results of tooth whitening in a patient in the control group, treated with 9% HP. (A) Baseline and (B) One week after treatment.

Evaluation of the shade in the fourth visit after one week of follow up without application of bleaching material revealed that, in Group I and II there were three cases in each group of color relapse (2-4 degrees) from the shade taken in the third visit immediately after bleaching application. However, there were two cases with further shade

improvement in Group I. In addition to that, one case of color relapse was recorded and four cases with no shade improvement from the base line observation were recorded in Group III. The differences between the mean values of shade improvement after one week and two weeks of product application were statistically insignificant for the three groups ($p > 0.05$) using paired sample *t*-test.

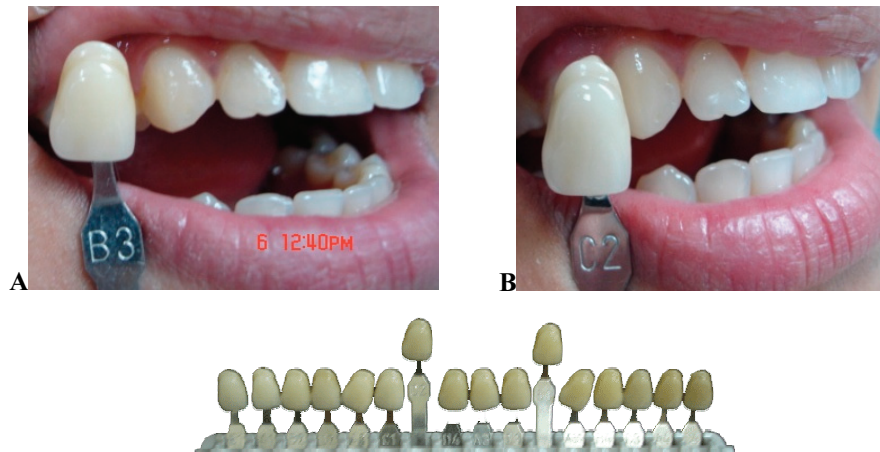


Fig. 2. Results of tooth whitening in a patient in group II, treated with 10% CP. (A) Baseline and (B) One week after treatment.

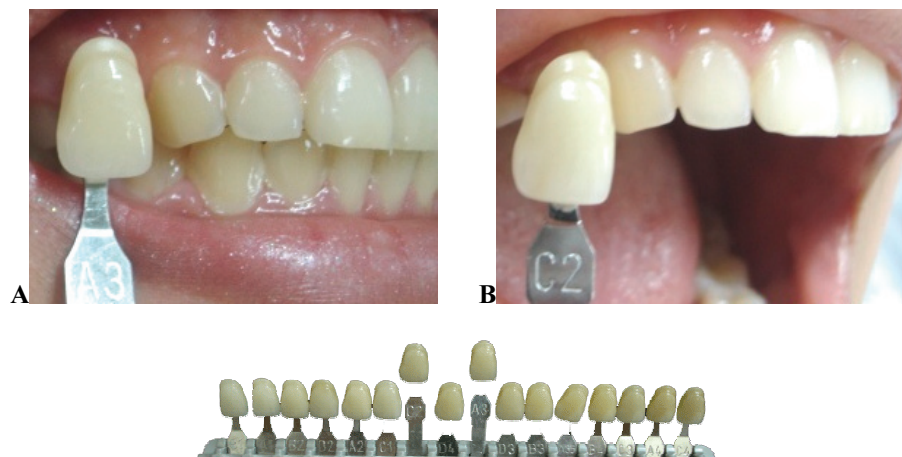


Fig. 3. Results of tooth whitening in a patient in group III, treated with 3.6% sodium carbonate peroxide. (A) Baseline and (B) One week after treatment.

Side Effects and Patient's Acceptance

Teeth Sensitivity

The results of teeth sensitivity for each group are presented in Table 3. There was no statistically significant difference between the studied groups, either during or after one week of bleaching application using chi-square test ($p > 0.05$).

Gingival Irritation

Table 4 represents the results of gingival irritation during application of the bleaching products and after one week of product use. The difference between groups during product application was statistically significant using Chi-square test ($p = 0.006$). Higher levels of gingival irritation were reported by participants using 9% HP (Group I), followed by Group III, while Group II participants using 10% CP experienced the least irritation. Meanwhile, there was no statistically significant difference of gingival irritation among the studied groups after one week of application ($p = 0.31$).

Table 3. Comparison of teeth sensitivity between the studied groups.

	Teeth Sensitivity							
	During application				After one week			
	Non	Mild	Moderate	Severe	Non	Mild	Moderate	Severe
Group I	5 50%	4 40%	0 0%	1 10%	9 90%	1 10%	0 0%	0 0%
Group II	8 80%	1 10%	1 10%	0 0%	10 100%	0 0%	0 0%	0 0%
Group III	4 44%	4 44.4%	0 0%	1 11.6%	8 88.9%	0 0%	1 11.1%	0 0%
Chi square	6.38				4.2			
p	0.38				0.38			

*Significant at 5% level

Table 4. Comparison of gingival irritation between the studied groups during and after one week of products application.

	Gingival Irritation							
	During application				After one week			
	Non	Mild	Moderate	Severe	Non	Mild	Moderate	Severe
Group I	1 10%	2 20%	4 40%	3 30%	10 100%	0 0%	0 0%	0 0%
Group II	8 80%	2 20%	0 0%	0 0%	10 100%	0 0%	0 0%	0 0%
Group III	2 22.2%	4 44.5%	3 33.3%	0 0%	8 88.9%	1 11.1%	0 0%	0 0%
Chi square	18.12				2.3			
p	0.006*				0.31			

*Significant at 5% level

Gingival Index

Table 5 represents the mean gingival index at the baseline and after one week of application of bleaching agent. Kruskal-Wallis test demonstrates a non significant difference of the mean gingival index between the studied groups either at the baseline or after one week of product application (KW = 1.13, 2.06 and $p = 0.5, 0.35$ respectively). However, a reduction of the mean gingival index was recorded in Group I and II after the application of the bleaching material (Fig. 4). The reduction was statistically significant in Group II ($p = 0.048$) using a paired sample t -test. While, the difference between the values was insignificant in Group I and III ($p > 0.05$).

Table 5. Gingival index of the studied groups.

	Gingival index (GI)		Reduction of (GI)
	At baseline	After one week	Paired Samples T- test P
	Mean \pm SD	Mean \pm SD	
Group I	0.37 \pm 0.43	0.22 \pm 0.27	0.209
Group II	0.22 \pm 0.21	0.07 \pm 0.05	0.048*
Group III	0.17 \pm 0.21	0.23 \pm 0.28	0.463
Kruskal-Wallis test	1.13	2.06	
p	0.5	0.35	

*Significant at 5% level

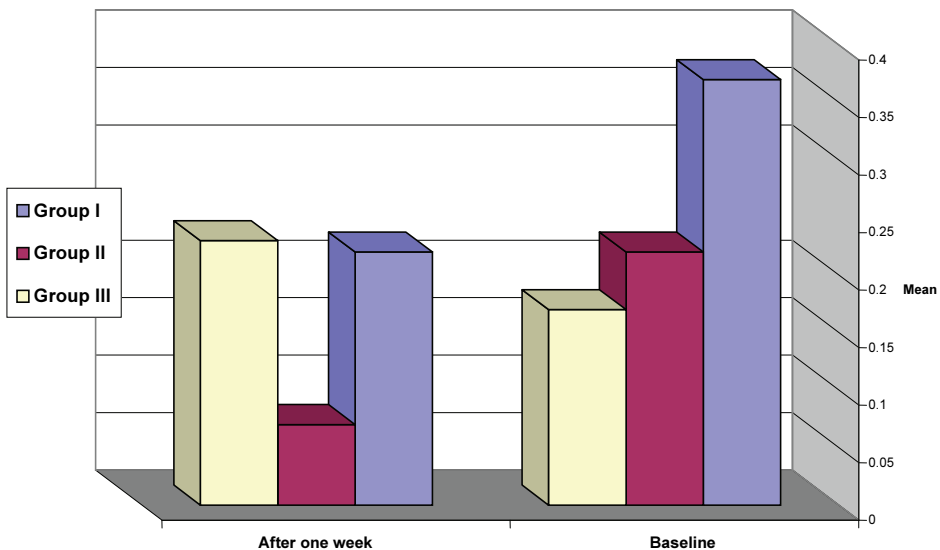


Fig. 4. Study groups according to Gingival Index.

Patient Satisfaction

Table 6 shows that all Group I patients were satisfied. On the other hand, only 60% and 33% of Group II and Group III patients, respectively, were satisfied. The difference between groups was statistically significant using Chi-square test ($p = 0.009$).

Table 6. Patients' satisfaction among the studied groups.

	Satisfied	Non-satisfied	Chi-Square Value	P
Group I	10 100%	0 0%	9.5	0.009*
Group II	6 60%	4 40%		
Group III	3 33.3%	6 66.7%		

*Significant at 5% level

Discussion

It can be observed that there are differences in efficacy between different bleaching products, mainly due to the different levels of active ingredients in these products. In addition to that, potential adverse effects from home bleaching products may occur from inappropriate applications, abuses, or the use of inappropriate products. The risks of using at-home whiteners without a dentist's involvement, or using formulations different from the recommended peroxide content, are yet to be determined. The present study compared the bleaching efficiency, patient acceptance and side effects of two professional products and one OTC home bleaching systems.

Vita shade guide system was used in this study for shade assessment as it is still the most widely used method for shade assessment clinically and is predictable when whitening the teeth^[9]. In addition to that, several studies found no difference between the subjective and objective methods regarding the assessment of color change, but with slightly different degrees of accuracy which is not the objective of the present study^[5,10]. Gingival index of all participants was calculated by only one examiner, while assessment of shade guide was assigned to another two examiners assisted by digital camera photographs. The intra and inter-examiner reliability of the examiners were assessed before the start of the study. Additionally, questions

regarding teeth hypersensitivity and gingival irritation were pre-tested before the onset of this work.

The mechanism of action of the bleaching material was explained in different literatures as follows: Carbamide peroxide solution ($\text{CH}_6\text{N}_2\text{O}_3$) breaks down into hydrogen peroxide (H_2O_2) and urea ($\text{Ca}[\text{NH}_2]_2$), after which the urea degrades into ammonia (NH_3) and carbon dioxide (CO_2). The active agent (H_2O_2) has to be in contact with the outer enamel surface for a period of time in order to develop its bleaching potential. Hydrogen peroxide breaks down into oxygen and water, which then penetrate the tooth and liberate the pigment molecules^[6].

In this study, 10% of carbamide peroxide was selected since in reviewing the biological aspect, it was recommended to avoid the use of concentrations more than 10%^[11]. Furthermore, it has been postulated that no further bleaching enhancement can be achieved if carbamide peroxide concentration exceeds 10% level^[10]. On the other hand, It has been found that 10% to 20% carbamide peroxide will result in release of 3.35-7% hydrogen peroxide^[6], that is to say that the 9% HP used in the present study is equivalent to 26% CP. This will explain the results of the present clinical trial where the 9% HP bleaching product (Opalescence Trèswhite) was more efficient in bleaching the teeth than the other tested materials. The difference was statistically significant when compared with the bleaching efficiency of 3.6% sodium carbonate peroxide bleaching product (CleverWhite), while the difference was statistically insignificant when compared with 10% CP (WHITEsmile®). This can be attributed to the low concentration of the bleaching agent in Group III and the short application time (30 min/day) as recommended by the manufacture in comparison to the other tested materials. The result of this study was in agreement with Alonso de la Peña and Balboa Cabrita^[2] and Braun *et al.* studies^[10]. However, it disagrees with the results of Cronin *et al.*^[5] study where shade improvement was better with 6% HP than 18% CP, and this was attributed to the different application techniques.

Shade relapse was recorded in some cases in Group I and II. However, further shade improvement was observed in two cases of Group I. This relapse pattern was recorded also in Zekonis *et al.*^[12] study. These results may indicate the need for a longer follow up period

to evaluate the long term stability of the bleaching techniques used in this study.

Penetration of bleaching agents into tooth hard tissue results in different changes in the vital tooth structure^[13,14]. Hypersensitivity is one of these changes which are usually mild and transient^[15]. In this study, only one subject in Group I and two subjects in Group III reported severe sensitivity during application period. This may be related to the high concentration of HP in group I and the sodium carbonate peroxide content in Group III. Further researches are needed to evaluate and study the safety of the latter material. This was in contrary with Auschill *et al.*, where the professionally applied home bleaching system caused slightly higher sensitivity than OTC one^[6]. This difference could be explained by the longer application time of professionally applied agent (8 hr) in Auschill *et al.* study, compared to short application time (1 - 2 hr) in the present study.

There was a statistically significant difference among the groups regarding gingival irritation during material application. Group I had the highest degree of irritation which also could be attributed to the acute exposure to the high concentration of HP in this group. However, the gingival irritation returned back to the pretreatment level in the second week of none treatment application. In addition to that, a reduction of the mean gingival index was observed in Group I and II after application of the bleaching material and the reduction was statistically significant in Group II. This observation could be attributed to the bacteriostatic anti-inflammatory and antiseptic action of hydrogen peroxide and carbamide peroxide in combination with the oral hygiene measures taken by the participants during the agents' application^[16]. This was in accordance with previous studies which reported a gingival improvement during bleaching application^[3,17-19]. Regarding patients acceptance, the highest patient's satisfaction in Group I compared to other groups was not unexpected. This is mostly due to highest shade improvement reported in this group which accounted for 100% satisfaction among participants.

Finally, to maximize benefits while minimizing potential risks, the authors recommend using at-home tooth whiteners under the supervision of a dental professional, and limit using OTC products to those materials that have been subjected to evidence based researches to prove their efficiency and safety. In addition to that, practitioners are

recommended to wait at least two weeks post-bleaching when making a good color match, if they are planning to place a tooth-colored restorative material in the anterior teeth.

Conclusion

The results of this study showed that the two professional home bleaching products were significantly more efficient in bleaching the teeth than OTC product. No significant difference was observed between the three products regarding hypersensitivity, while there was a moderate to severe gingival irritation during the application period of Opalescence Trèswwhite.

Significant reduction of the gingival index was recorded after the application of WHITESmile® product. However, Opalescence Trèswwhite home bleaching system showed the highest patient acceptance.

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مدى فعالية ثلاثة مبيضات أسنان منزلية والآثار الجانبية لاستعمالها

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المستخلص. تستهدف هذه الدراسة مقارنة مدى فعالية تبييض الأسنان والآثار الجانبية لها ومدى قبول المستهلك عند استخدام نوعين من مبيضات الأسنان المنزلية المحترفة مع منتج تبييض منزلي غير محترف. تم توزيع ثلاثين أنثى بشكل عشوائي ومتساوٍ على ثلاث مجموعات كالتالي: المجموعة الأولى: استعملت Opalescence Trèswhite، و المجموعة الثانية: WHITEsmile®، والمجموعة الثالثة: CleverWhite (مجموعة التبييض المنزلي الغير محترفة)، وقد تم تسجيل لون الأسنان والدليل اللثوي قبل البدء في الدراسة وبعد أسبوع واحد من استعمال المنتج، كما تم تسجيل فرط حساسية السن وتهيج اللثة ومدى قبول المنتج لدى المستهلك من قبل المشاركين أثناء الدراسة وبعد أسبوع واحد من استعمال المنتجات باستخدام الاستفتاءات. تحسن اللون بدا ملحوظاً بدرجة كبيرة في المجموعة الأولى والثانية بالمقارنة مع المجموعة الثالثة ($p < 0,05$). ولكن لم يكن هناك فرقا إحصائياً ملحوظاً بين

المجموعات الثلاث بخصوص فرط حساسية السن، والدليل اللثوي أثناء وبعد استخدام المنتج ($p > 0,05$). أما بخصوص تهيج اللثة فقد كان هناك فرقا إحصائيا ملحوظا بين المجموعات الثلاث، فمدى قبول المشتركين في المجموعة الأولى والثانية والثالثة كان ١٠٠٪، و٦٠٪، و٣٣٪ على التوالي، مع اختلاف إحصائي هام ($p < 0,05$). والخلاصة هي أن المجموعة الأولى والثانية سجلت تحسناً ملحوظاً في اللون أفضل من المجموعة الثالثة.