

Clinical Effects of Prolonged Application Time of an In-office Bleaching Gel

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Clinical Relevance

By refreshing the in-office bleaching gel at each clinical appointment, clinicians can improve the bleaching speed and reduce tooth sensitivity rates.

SUMMARY

Objective: The aim of this study was to evaluate whether the use of a gel applied for 1×45 minutes would have the same bleaching rate and tooth sensitivity levels when compared with 3×15 -minute applications.

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Methods: In-office bleaching was performed in 30 participants with 35% hydrogen peroxide gel. In one group ($n=15$; 3×15 minutes), the bleaching agent was refreshed every 15 minutes, three times at each bleaching appointment. In the other group ($n=15$; 1×45 minutes) the gel was left undisturbed on the buccal surfaces of all teeth for 45 minutes at each bleaching appointment. This protocol was repeated after one week. The bleaching evaluation was completed by two blinded, calibrated evaluators who compared the baseline color of the maxillary anterior teeth with a value-oriented shade guide after each period. The patients recorded the tooth sensitivity on a 0–4 scale. The color changes were evaluated by appropriate tests ($\alpha=0.05$). The percentage of patients with tooth sensitivity and its intensity were also statistically analyzed ($\alpha=0.05$), respectively.

Results: The use of gel for a single 45-minute period (1×45 minutes) decreased the bleaching efficacy ($p<0.05$) 86.7%, and 100% of patients from the 3×15 -minute and 1×45 -minute groups, respectively, experienced tooth sensi-

tivity ($p=0.22$). The intensity of sensitivity was lower for the 3×15 -minute applications ($p=0.04$).

Conclusions: A 35% hydrogen peroxide gel for in-office bleaching preferably should be applied in three 15-minute applications because 1×45 minutes reduces the bleaching speed and slightly increases the intensity of tooth sensitivity.

INTRODUCTION

Since the introduction of carbamide peroxide for at-home bleaching,¹ this technique has been considered the most conservative treatment for vital discolored teeth when compared with other treatment modalities, such as veneers, crowns, or composite bonding.² High levels of satisfaction and effectiveness of at-home bleaching have been reported,³⁻⁵ making this therapy the first choice for vital tooth bleaching. Perdigão and others⁶ reported that the popularity of tooth whitening has increased with the advent of patient-applied, peroxide-based whitening agents, as well as increased media influence.

Although at-home bleaching has increased dramatically in popularity, in-office bleaching products are still in demand⁷ for several reasons. First, some patients do not adapt well to the at-home protocol because they prefer not to use a bleaching tray; second, patients sometimes require faster results and cannot wait for two to three weeks to see the results of their treatment; and finally, some patients need to be closely monitored due to the presence of extensive tissue recession or deep, unrestored abfraction lesions.²

The use of hydrogen peroxide in high concentrations (35%-38%) applied by a dental professional allows the patient to obtain visible results even after only one clinical appointment. This has been responsible for the increase of in-office bleaching treatment in the last few years. The results of a published survey of general practitioners showed that 33% of dentists in the United States use in-office bleaching.⁸

Usually the hydrogen peroxide is applied and left undisturbed on tooth surfaces for five to 15 minutes and this procedure is repeated three to five times at each clinical appointment, depending on the bleaching gel brand. The reason for the gel being refreshed every five to 15 minutes is the fast degradation rate of hydrogen peroxide. However, an earlier study⁹ evaluating a hydrogen peroxide gel with low concentration demonstrated that after one hour in contact with the tooth structures, the average of the total

remaining active hydrogen peroxide was 32.23%. Given that the degradation kinetics of bleaching gels seems to be independent of the initial concentration, one may suppose that a 35% hydrogen peroxide gel might have a similar degradation rate.¹⁰

Thus, considering that the gel retains substantial activity after one hour, one may speculate that a single application of the gel for a prolonged period might yield similar bleaching outcomes. This approach would lead to less chair-time and would reduce the costs associated with in-office bleaching because less material would be spent per patient. Moreover, the risk of occasional soft tissue burns would be reduced because the material would be handled only once.

Recently, two clinical studies compared the bleaching efficacy of a single 45-minute versus three 15-minute applications.^{11,12} Whereas Marson and others¹¹ reported good results in terms of bleaching efficacy, comfort, sensitivity, and patient satisfaction, Matis and others¹² demonstrated that three 15-minute applications were more effective than a single 40-minute application.

Because there is ongoing controversy on this topic, the aim of this randomized clinical study was to evaluate the bleaching outcomes and tooth sensitivity of a 35% hydrogen peroxide gel applied in three 15-minute or one 45-minute applications.

MATERIALS AND METHODS

This clinical investigation was approved by the scientific review committee and by the committee for the protection of human subjects of the university's institutional review board. A total of 30 undergraduate students who had anterior teeth with a shade of C2 or darker as judged by comparison with a value-oriented shade guide (Vita Lumin, Vita Zahnfabrik, Bad Säckingen, Germany) were enrolled in a double-blind, controlled clinical trial. All participants received dental screening and dental prophylaxis two weeks before bleaching started and signed an informed consent form before the study began.

Inclusion and Exclusion Criteria

Patients included in this clinical trial were at least 18 years old and had good general and oral health. Participants were required to have six caries-free maxillary anterior teeth without restorations on the labial surfaces, be willing to sign a consent form, and have central incisors determined to be shade C2 or darker. Patients were excluded from the study if

they had undergone tooth-whitening procedures, had labial anterior restorations, were pregnant or lactating women, had severe internal tooth discoloration (tetracycline stains, fluorosis, pulpless teeth), bruxism habits, or any severe pathology in the mouth. Patients with noncarious cervical lesions, incisal anterior teeth with exposed dentin, or spontaneous tooth pain were also excluded. Those interested in participating were asked to record whether they experienced sensitivity the week before the beginning of the bleaching therapy using the following criteria: 0 = *none*, 1 = *mild*, 2 = *moderate*, 3 = *considerable* and 4 = *severe*.^{13,14} Patients with sensitivity equal to or greater than mild were also excluded from the study.

Study Design

Participants were randomly divided into the two groups according to the application time of bleaching gel by tossing a coin. Neither the patient nor the evaluator knew to which group the patient was assigned. The gingival tissue of the teeth to be bleached was then isolated using a light-polymerized resin dam (Top Dam, FGM Dental Products, Joinville, SC, Brasil). A 35% hydrogen peroxide gel (Whiteness HP Maxx, FGM Dental Products) was applied for a total of 45 minutes.

In one group (3×15 minutes), the bleaching agent was refreshed every 15 minutes, three times at each bleaching appointment. In the other group (1×45 minutes) the gel was left undisturbed on the buccal surfaces of all teeth for 45 minutes at each bleaching appointment. Participants repeated the in-office bleaching treatment one week later. All participants were instructed to brush their teeth regularly using fluoridated toothpaste (Sorriso Fresh, Colgate-Palmolive, SP, Brazil).

Shade Evaluation

The 16 tabs of the shade guide are arranged from highest (B1) to lowest (C4) value (Table 1). Although

this scale is not linear in the truest sense, the changes were treated as though they represented a continuous and approximately linear ranking for the purpose of analysis. Shade changes were calculated from the start of the active phase to the individual recall times by calculating the change in the number of shade guide units (Δ SGU) that occurred toward the lighter end of the value-oriented list of shade tabs.

Two calibrated evaluators (L.Y.T. and D.H.) recorded the shade of each participant’s teeth at baseline and weekly intervals. The measurement area of interest for shade matching was the middle third of the facial surface of maxillary anterior teeth, according to American Dental Association (ADA) guidelines.¹⁵ Five participants who were not included in the sample because they were used in the pilot study participated in the training phase of this study. The two examiners scheduled these patients for bleaching and evaluated their teeth against the shade guide weekly. Before beginning the study evaluation the two examiners were required to agree on the shade to the extent of at least 85% (κ statistic).

Tooth Sensitivity Evaluation

Participants were asked to record whether they experienced sensitivity immediately after the bleaching and on the days after it, using the following criteria: 0 = *none*, 1 = *mild*, 2 = *moderate*, 3 = *considerable*, and 4 = *severe*.^{13,14} The worst score given by each patient after the first bleaching session was taken into the statistical analysis. The scores were arranged into two categories: overall percentage of patients with tooth sensitivity and overall intensity of tooth sensitivity for each group.

Statistical Analysis

Agreement between examiners was checked by using κ statistics. The means and standard deviations for Δ SGU were calculated at each weekly recall for each

Table 1: Arrangement of Vita Classic Shade Guide (Adapted From Browning and Others ¹⁷)															
Vita Shade Guide															
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
Brightest shade												Darkest shade			

Table 2: Tooth Shade at Assessment Points for the Two Treatment Groups

Clinical Sessions	Treatment Modality			
	1 × 45 min		3 × 15 min	
	Median/Mean (SD)	Statistical Analysis	Median/Mean (SD)	Statistical Analysis
Baseline	9/8.3 (1.3)	aA*	9/8.2 (1.5)	aA
After 1st bleaching session	5/5.0 (1.4)	bB	4/4.1 (1.3)	cB
After 2nd bleaching session	2/2.5 (1.3)	dC	1/1.2 (1.2)	eC
Final color change (Δ SGUs)	5.8 (1.3)		6.9 (1.3)	
Abbreviation: Δ SGUs, change in shade guide units. * Similar lowercase letters indicate statistically similar means within columns. Similar uppercase letter indicate statistically similar means within rows ($p < 0.05$).				

group. The data were subjected to two different statistical analyses. First, the differences in the ratings of the two treatment modalities after baseline and first and second bleaching sessions were tested with the Student *t*-test ($\alpha=0.05$); second, the performance of the each treatment modality at baseline and after each bleaching session (first and second session) was evaluated using the McNemar's test ($\alpha=0.05$). The different percentages of patients with tooth sensitivity were analyzed between groups by using the Fisher exact test ($\alpha=0.05$), whereas the intensity of tooth sensitivity was analyzed using the Student *t*-test for independent samples ($\alpha=0.05$).

RESULTS

Of the 30 participants who began the study, all completed the study. The level of agreement between the two evaluators by means of κ statistics was 92%. The statistical analyses revealed that significant differences were observed for the treatment modality (Student *t*-test, $p < 0.05$) and clinical sessions (McNemar's test, $p < 0.005$).

The means and standard deviations of Δ SGU are shown in Table 2. The mean tooth color at baseline was similar for the two groups (Student *t*-test, $p > 0.05$). However, a significantly faster bleaching occurred for the 3 × 15-minute group after the first and second bleaching sessions (McNemar's test, $p < 0.05$). After the bleaching sessions, the participants from the 1 × 45-minute group showed a final color change of 5.8 SGUs, whereas participants from the 3 × 15-minute group showed a final color change of 6.9 SGUs (Student *t*-test, $p < 0.05$) (Table 2).

With regard to the prevalence of tooth sensitivity, only two participants from the 3 × 15-minute group did not experience tooth sensitivity after the bleaching treatment (Table 3). Most of the participants reported tooth sensitivity immediately and up to 24 hours after the bleaching protocol. In a small percentage of patients (17%) this sensitivity persisted on the second day after treatment. Figure 1 depicts the percentage of participants according to the level of reported sensitivity for both groups. It was observed that no severe sensitivity was reported by any of the participants. A similar report of considerable intensity was observed for both treatment modalities (40%). Moderate sensitivity was reported by 46.7% of the participants from the 1 × 45-minute group, whereas this figure was lower for the 3 × 15-minute group (26.7%).

The intensity of sensitivity was significantly higher in the 1 × 45-minute group when compared with the 3 × 15-minute group ($p=0.04$). In terms of means and standard deviations, the intensity of tooth sensitivity was significantly higher in the

Table 3: Comparison of the Number and Percentage (%) of Patients Who Experienced Tooth Sensitivity During the Bleaching Regimen

	1 × 45 min	3 × 15 min	<i>p</i> -value
Yes	15 (100.0)	13 (86.7)	0.22
No	0 (0.0)	2 (13.3)	
Fisher exact test ($\alpha=0.05$).			

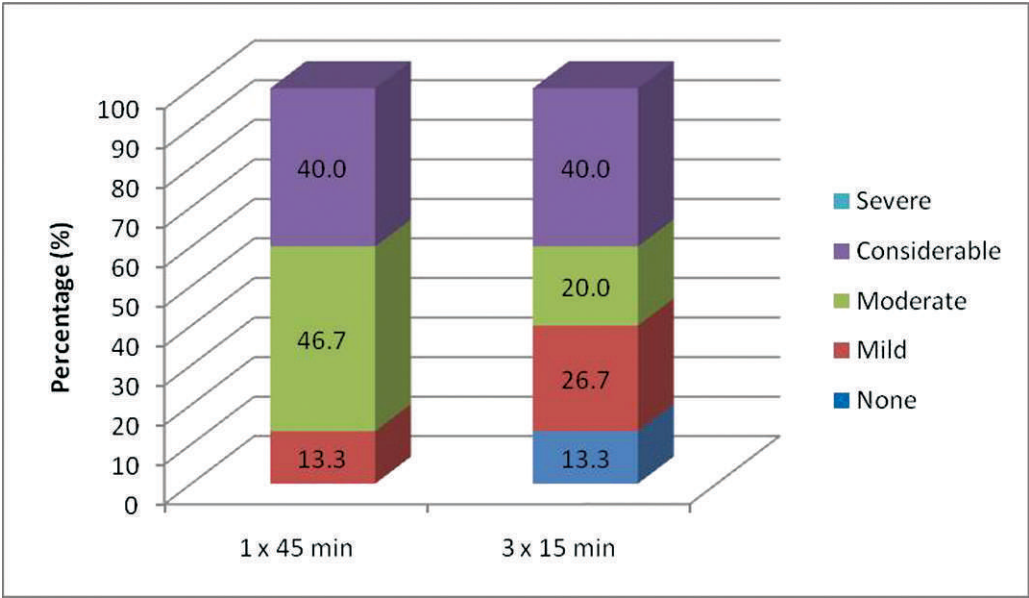


Figure 1. Levels of sensitivity (%) perceived by the participants in the two groups of the study.

group receiving the 1 × 45-minute (2.43 ± 1.1) application than that observed in patients receiving the 3 × 15-minute application (1.86 ± 0.9 ; $p=0.04$) (Table 4).

DISCUSSION

A value-oriented shade guide was used for visual identification of the color change throughout the study period. The selection of this method was based on the fact that it is an easy, fast, and satisfactory method that has been used in several investigations.^{16–18} The validity and reliability of this color evaluation method was confirmed by a recent study.¹⁹ The authors reported that despite the subjectivity of the method, visual assessment of tooth color using the Vitapan Classical shade guide is a valid method, with good reliability for differentiating between dark and light colors.¹⁹

The results of this study indicated that the application of a 35% hydrogen peroxide gel for 45 minutes decreased the bleaching efficacy and slightly increased overall patient sensitivity when compared with three 15-minute applications. Three studies that evaluated the degradation kinetics of hydrogen peroxide and carbamide peroxide gels for at-home bleaching under clinical conditions were found in the literature.^{9,10,20} They demonstrated that both bleaching agents have similar overall degradation kinetics, although hydrogen peroxide was shown to have a faster degradation rate. Although there is still 50% of the active ingredient

after two hours when carbamide peroxide is used, this is the amount available after 20 minutes for at-home hydrogen peroxide gels.^{9,10,20} Although a significant amount of active ingredient can be retrieved from the tooth surfaces, this may not be sufficient to sustain the same degree of bleaching obtained in the first 15 minutes, and therefore, this might well be the reason why the participants in the 1 × 45-minute group showed less color change after two appointments.

However, different results were obtained when the degradation of 35%-38% hydrogen peroxide gels for in-office bleaching was assayed by a potassium permanganate titration method under *in vitro* conditions.^{21,22} The concentration of active hydrogen peroxide measured after 45 minutes of mixing showed that 91%-93% of active hydrogen peroxide

Table 4: Means and Standard Deviations of the Intensity of Tooth Sensitivity During the Bleaching Regimen as Well as the Respective Medians and the Minimum (Min) and Maximum (Max) Scores			
	Mean ± Standard Deviation	Median (min/max)	p-value
1 × 45 min	2.43 ± 1.1	2 (1/3)	0.04
3 × 15 min	1.86 ± 0.9	2 (0/3)	
Student t-test (α = 0.05).			

was still available for the bleaching procedure. It was speculated that the differences between the *in vivo* at-home^{9,10,20} and *in vitro* in-office studies^{21,22} may depend on the different experimental conditions. Contrary to *in vitro* conditions,^{21,22} the bleaching gel can be washed out by saliva during use before being collected under clinical conditions,^{9,10,20} which could decrease the total amount of hydrogen peroxide available for bleaching. Therefore, attempts should be made to evaluate the degradation kinetics of in-office bleaching gels under *in vivo* conditions.

Although both treatment modalities showed different bleaching rates, both procedures allowed a significant whitening effect. The 1 × 45-minute and the 3 × 15-minute groups allowed bleaching of 5.8 and 6.9 SGUs, respectively, after the two bleaching sessions. These bleaching rates are very close to those that were recently demonstrated in a literature review.²³ Matis and others²³ reported that after two weeks of bleaching with 35% hydrogen peroxide, a change of 4.5 to 9.6 SGUs is expected.

Tooth sensitivity is the most common adverse side effect of bleaching treatment. Although the etiology of this side effect has not yet been fully established, it seems that it results from the peroxide penetrating through enamel and dentin and into the pulp during tooth whitening.^{24,25} Within five to 15 minutes after application of a bleaching gel, peroxide penetrates to the pulp, where it irritates nerves and essentially produces a reversible pulpitis.^{26–28} Further proof of this passage of peroxide is found in the research that showed color changes in dentin next to the pulp as fast as it occurs next to the dentin-enamel junction.²⁹ This may account for the common occurrence of tooth sensitivity in patients with no gingival recession or other sites of exposed dentin. Moreover, several studies have reported morphologic alterations, reductions in enamel microhardness, and increase in enamel permeability after bleaching,^{30–32} factors that may enhance bleaching agent penetration into pulp.

As previously demonstrated, it seems that the pH of the bleaching gel has an impact on enamel microhardness after bleaching therapy. Recently, Borges and others³³ evaluated the influence of two bleaching gels with different pH (acid 3.5 and neutral 6.6) on enamel microhardness. The authors concluded that the enamel microhardness decreased significantly when the most acidic bleaching agent was compared with the neutral formulation.

The hydrogen peroxide gel used in the present investigation has a pH of 7 immediately after

mixture. However, after a single 45-minute application, the pH of the gel²² decreases to approximately 5, which can explain the slightly higher tooth sensitivity of the 1 × 45-minute group. A bleaching gel with more acidic features may induce more pulp alterations than a neutral solution does. However, this hypothesis should be further evaluated in detail under clinical conditions.

Similar results in terms of bleaching speed and tooth sensitivity were reported by Matis and others.¹² The authors compared a single 40-minute application and three 15-minute applications of a 36% hydrogen peroxide gel. However, Marson and others¹¹ did not find any difference between 1 × 45-minute and 3 × 15-minute applications. Unfortunately the latter is an abstract and several details of the method, such as the commercial brand name of the bleaching product used and inclusion and exclusion criteria, are not available for the purposes of comparison.

CONCLUSION

Within the limitations of the present investigation it could be concluded that the in-office 35% hydrogen peroxide gel (Whiteness HP Maxx, FGM Dental Products) should be used in three 15-minute applications because this approach favors fast bleaching and reduces the intensity of tooth sensitivity when compared with a single 45-minute application.

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