Original Article

Journal of Iranian Medical Council, Volume 9, Issue no. 1
http://dx.doi.org/10.18502/jimc.v9i1.20492

Effectiveness of Using a Desensitizing Gel before Home Bleaching on Tooth Sensitivity and Color Change: A Clinical Trial

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Received: 20 May 2024
Accepted: 15 Mar 2025

Citation to this article
Elahifar R, Madani MR, Hosseini Tabatabaei S, Asadi MR. Effectiveness of Using a Desensitizing Gel before Home Bleaching on Tooth Sensitivity and Color Change: A Clinical Trial. *J Iran Med Counc.* 2026;9(1):182-89.

Abstract

Background: With the rise in living standards, the significance of a captivating smile in one's appearance has become more apparent. On the other hand, tooth bleaching is very popular as a conservative esthetic treatment. Investigating the effect of desensitizing gel before home bleaching on tooth sensitivity and color change.

Methods: This clinical trial study was conducted on 30 women assigned into two experimental groups: Control (CG) and Desensitizing (DG) Groups, who were treated with placebo gel and 2% KF desensitizing gel (2% sodium fluoride and 5% potassium nitrate), respectively. The primary color of the upper right central tooth was recorded using a ShadeStar digital colorimeter before bleaching. Tooth sensitivity was evaluated using the Visual Analog Scale on 1, 4, 7, 10, and 14 days. The tooth color was also tested on day 14 and at months 1, 3, and 6 intervals of bleaching.

The Friedman, Cochran's, Chi-Square, and Mann-Whitney U tests were used. A significance level of $p < 0.05$ was set.

Results: Tooth sensitivity was significantly higher in the CG than in the DG at all time points ($p<0.05$). There was no significant difference regarding the degree of color change in the DG and CG ($p>0.05$). Intragroup comparison at different time points showed that the difference in color stability at six months after bleaching was significant in the DG ($p=0.005$) but not substantial in the CG ($p=0.585$).

Conclusion: Desensitizing gel before home bleaching has been found to significantly reduce sensitivity. However, it does not affect color stability.

Keywords: Dentin sensitivity, Female, Potassium nitrate, Socio-economic factors, Sodium fluoride, Tooth bleaching, Visual analog scale

Introduction

As the quality of life improves, more individuals become aware of teeth' significant role in their overall appearance. This is particularly evident in the case of patients with discolored teeth, who often express a desire for whiter teeth and a more pleasing smile (1). Teeth discoloration is a prominent aesthetic concern, prompting the development of conservative approaches to address this issue (2). Bleaching is a safe approach to manage teeth discoloration with minimal destruction, among other treatments, including bleaching toothpaste, microabrasion, macroabrasion, resin-bonded composites, porcelain veneers, and crowns (1,3). The mechanism of tooth bleaching is based on the fact that hydrogen peroxide penetrates the tooth structure due to low molecular weight. Free radicals, such as hydroxyl, lead to oxidizing, breaking color molecules into smaller molecules, reflecting more light, and brightening the tooth (4). The most common ways of tooth bleaching include home, office, or over-the-counter product (4). Among the various approaches, at-home bleaching with custom trays is the most commonly used due to its clinical effectiveness, safety, and high patient and professional acceptance (5). At home bleaching, low concentrations of bleaching agents (*i.e.*, 10- to 30% carbamide peroxide) are placed in a special tray for each person and used daily for 2 to 4 weeks (depending on CP concentration) (5).

Adverse effects, however, were reported when CP was used in teeth bleaching, such as gingival irritation, morphological/chemical alterations in tooth structures, deteriorative effects on restorative materials, and Teeth Sensitivity (TS) (2). TS is the most common side effect of tooth-bleaching agents and usually causes mild and transient pain. Although tooth sensitivity can lead to severe discomfort in rare cases, one of the leading causes is incomplete bleaching treatment (6). Results of previous studies have shown that up to 66% of subjects experienced tooth sensitivity or gingival irritation after night bleaching (1).

The hydrodynamic theory has recently introduced a responsive mechanism for tooth sensitivity after bleaching. According to this theory, movement of intradentinal fluid leads to the stimulation of the receptors in the dentin-pulp area and subsequent pain. Others attribute the cause of pain to direct peroxide penetration into the dental structure and activation of the neuronal receptor, not to the hydrodynamic effects (7).

The bleaching may release factors, such as ATP and prostaglandins, that trigger pulpal nociceptors, as well as pulpal pain and irritation (1). Applying bleaching agents may reduce calcium, phosphate, and fluoride levels. It may also cause changes in the enamel surface, including porosity, abrasion, reduced microhardness and decalcification of enamel prisms, and possibly changes in the surface topography of enamel (8). In addition, some products lead to an increase in remineralization after bleaching (9,10).

Apart from teeth sensitivity, the long-term stability of the whitening effect is the most uncertain aspect of bleaching therapy. The reported recurrence rate of tooth discoloration after two years is 10%; after five years, it is 25%; and after eight years, it is 49%. Haywood reported regression of the whitening effect for home bleaching in 26% of cases at 18 months (11). According to some literature, potassium nitrate and sodium fluoride reduce tooth sensitivity, and these agents do not affect bleaching efficacy (12,13).

The mechanism of potassium nitrate and some types of desensitizing agents is unknown (1).

Grobler investigated the effects of desensitizing products, including potassium nitrate and sodium fluoride, as well as other products containing Amorphous Calcium Phosphate (APC) and fluoride. The level of tooth color stability after six months was higher in patients who used APC gel (14).

On the other hand, some studies showed no effect on tooth sensitivity in individuals treated with desensitizing agents, especially potassium nitrate (15-17). Considering the high incidence rate of tooth sensitivity during bleaching treatment, the different results of studies, and the various products available in the market, the present study intended to evaluate the use of a desensitizing gel for tooth sensitivity and color change before home bleaching.

Materials and Methods

This randomized, controlled, double-blind clinical trial was conducted after obtaining the approval of the Ethics Committee of Zahedan University of Medical Sciences, Zahedan, Iran, and registration

in the Iranian Registry of Clinical Trials (IRCT) with codes of IRCT2017021032484N1 and IRCT2017051332484N2. In this study, according to the inclusion and exclusion criteria, thirty women were selected from those subjects referring to the Department of Esthetic and Restorative Dentistry Faculty of Dentistry, Zahedan University of Medical Sciences for the tooth bleaching treatment criteria.

Inclusion and exclusion criteria

Inclusion criteria were as follows: women participants between the ages of 18-30 years, satisfaction without specific symptoms of COVID-19, having at least 24 teeth, anterior teeth with color shades of A2, B2, C2, D2, or darker, no anterior restorations, maintaining good oral hygiene, absence of calculus, gingivitis, and periodontal diseases, no root exposure, No bruxism, Non-Carious Cervical Lesions (NCCL), no orthodontic treatment during the study, no history of tooth sensitivity to cold or heat, or sensitivity expressed from an air blower, not pregnant or breastfeeding, no previous record of bleaching treatment, non-smokers, no discoloration caused by fluorosis or tetracycline, and absence of any systemic diseases.

Based on the exclusion criteria, the participants who expressed unwillingness to continue treatment or experienced severe sensitivity due to bleaching were excluded from the study.

Before commencing the treatment, the participants were provided with a detailed explanation of the procedure and required to sign a written consent form from the Ethics Committee.

Each participant received the same soft toothbrush and floss and was trained in the recommended bass brushing technique (thrice daily) and flossing method (once at night). The participants were asked to avoid using other oral hygiene products to standardize conditions.

During the bleaching period, the participants were instructed to refrain from consuming colored beverages.

Prophylaxis was performed for each participant one week before the treatment to eliminate any extrinsic stains.

Determining the tooth color

The molds (30×36 *mm*) were made on each participant's right upper central tooth using silicone impression material. Holes corresponding to the size of the color measurement device tip (ShadeStar DSI, DeguDent GmbH, Hanau-Wolfgang, Germany) were created in the molds. The extent of color was measured at the exact location in the middle third of the labial surface using the color measurement device with the Vitapan Classica (18).

Before each measurement, all teeth were dried with a blower for 3 seconds, and the device was calibrated; the readings were repeated twice and noted in the participant's medical record form. Two blinded operators conducted the measurements in a dark room under constant conditions.

Home bleaching process

A polyvinyl siloxane impression was obtained from each person. Immediately after the impression, a gypsum cast was made. The labial surfaces of the teeth were blocked out in the gypsum casts, leaving a distance of 0.5 *mm* from the gingival margin to the incisional surface. A special home tray with a vacuum device was custom-made for each participant. The tray was tested in the participant's mouth during the next session to ensure proper adaptation to the teeth and gingival margin. If necessary, the tray would be remade until it fits properly.

Each participant was given a 3-*g* tube of bleaching gel containing 16% carbamide peroxide (Whiteness Perfect, FGM Dental-Product, Joinville, Santa Catarina, Brazil) and instructed on how to use it. The bleaching gel was recommended to be applied after tooth brushing and flossing, at night, before going to bed, for at least 4 *hrs* every night for 14 days.

Selection of experimental groups

The participants were randomly assigned to one of the two groups by tossing a coin.

The participants were randomly assigned to the groups using the random allocation method. Forty balls numbered 1 to 40 were placed in a container; the first 20 balls were randomly removed, and their sequence was recorded. These participants were assigned to Group A, and the remaining 20 balls were assigned to Group B, ensuring a balanced number of people in each group at the end of the study.

Experimental gels consisted of placebo gel (control

group, A) and desensitizing gel of 2% KF (*i.e.*, 2% fluoride sodium and 5% potassium nitrate, B) (FGM Dental-Product, Joinville, Santa Catarina, Brazil) in identical 2-*g* tubes without any labels or identification symbols that were encoded by an observer (blind to therapist and patient) and kept confidential until up to the end of the study.

The placebo gel was similar in composition to the desensitizing gel but lacked its active components: potassium nitrate and sodium fluoride. The participants were explained orally and in writing how to maintain and clean the tray.

According to the instructions, the participants were required to apply the related experimental gels for half an hour into the anterior teeth in the special trays after using the toothbrush and dental floss and before using the bleaching agent. After half an hour, they brushed their teeth again, rinsed the special tray, and immediately used the bleaching gel of 16% carbamide peroxide (3-*g* tube) (Whiteness Perfect, FGM Dental-Product, Joinville, Santa Catarina, Brazil). In addition, the duration of use was 4 *hrs* per day in the tray for 14 days.

During the same meeting, the participants were instructed on correctly applying the tray and bleaching material for the study. Each participant received a tube of desensitizing toothpaste (Ultradent Products Inc., South Jordan, Utah, USA) along with the bleaching gel, as well as an Acetaminophen Codeine tablet (300 *mg*/10 *mg*) (pain relief medication) in case of intolerable pain.

Assessing the tooth sensitivity

The Visual Analog Scale (VAS) was used to evaluate tooth sensitivity. The VAS ranges from 0 to 9, with 0 indicating no pain, 1-3 indicating mild pain, 4-6 indicating moderate pain, and 7-9 indicating severe pain. The participants were asked to record their pain levels on days 1, 4, 7, 10, and 14 during the bleaching process according to the specifications in the questionnaire.

Finally, the individuals who used experimental agents at any time intervals after discontinuing bleaching were excluded from follow-up examinations regarding their use time.

Tooth color was re-evaluated at intervals of day 14 and months 1, 3, and 6 after bleaching, following the same order as previously mentioned for color determination.

Statistics

The data were analyzed using SPSS software (version 20). The Kolmogorov-Smirnov test was done to check the normality of the quantitative data. If the data did not follow a normal distribution, the non-parametric tests was applied to compare the means between the two groups.

The Friedman and Mann-Whitney U tests were utilized to compare tooth sensitivity between the groups in analytical statistics. In addition, the Chi-Square test was used to compare the percentage of color change at different time points between the groups. Moreover, Cochran's and Friedman's tests were applied to compare the rate of color change between other time points in each group. The significance level adopted in all analyses was 5%.

Results

In this clinical trial study, thirty participants with an average age of 25.92±3.61 years were included. It is worth noting that the age distribution of the two groups demonstrated no significant difference (p=0.178).

Tooth sensitivity in the placebo (*i.e.,* control) group showed that the median tooth sensitivity difference between days was not statistically significant (p=0.202).

The result of the Friedman test revealed that the difference in the median tooth sensitivity between different days in the desensitizing gel group was statistically significant (p=0.036)

The comparison of tooth sensitivity between the two groups proved that the level of tooth sensitivity on all days was significantly higher in the control group than in the desensitizing gel group (p<0.05)(Table 1).

According to table 2, 80% of the teeth in the desensitizing group were whitened within 14 days after bleaching. The same result was also repeated one month later. However, 73.3 and 46.7% of the teeth remained whiter 3 and 6 months after bleaching, respectively. Results of Cochran's test indicated that these changes were statistically significant (p=0.005).

In the control group, 93.3% of the teeth were whiter 14 days after bleaching. Moreover, 26% of the

Table 1. Comparison of intensity of tooth sensitivity between two groups during study days

Time	Group	Number	Median	IQR	Man-whitny test	
					Z	p-value
1 Days later	Control	15	2.733	3.034	1.89	0.017
	Case	15	0.6667	0.899		
4 Days later	Control	15	3.133	3.020	1.47	0.034
	Case	15	1.466	1.457		
7 Days later	Control	15	2.800	3.447	1.24	0.046
	Case	15	1.00	1.195		
10 Days later	Control	15	2.400	3.480	0.84	0.048
	Case	15	0.800	1.014		
14 Days later	Control	15	2.400	3.089	0.914	0.063
	Case	15	0.668	0.723		

Table 2. Frequency distribution and color percentage during four-time phases in terms of the evaluated group

	Time	14 Days later		1 Month later		3 Month later		6 Month later		p-value
Group	Color change	Number	Percent	Number	Percent	Number	Percent	Number	Percent	
Case	No change	3	20	3	20	4	26.7	8	53.3	0.005*
	Brighten	12	80	12	80	11	73.3	7	46.7	
	Darken	0	0	0	0	0	0	0	0	
	Total	15	100	15	100	15	100	15	100	
Control	No change	1	6.7	1	6.7	3	20	4	26.7	0.585**
	Brighten	14	93.3	14	93.3	12	80	9	60	
	Darken	0	0	0	0	0	0	2	13.3	
	Total	15	100	15	100	15	100	15	100	
Chi-square test		p=0.598		p=0.598		p=0.596		p=0.167		

*Cochran.

** Friedman test.

teeth returned to the first condition six months after bleaching, and 13% of the teeth were darker than the original color.

According to the results of the Friedman test, the reversibility of color change after six months was not statistically significant (p=0.585).

The changes between the two groups at 14 days, one month, and 3 and 6 months after applying the Chi-square test were compared, and the color change was not significant between the two groups (p>0.05).

Discussion

One of the most common complaints after bleaching is tooth sensitivity, and one of the biggest problems with bleached teeth is the color stability of bleaching (19).

The sensitivity results of the present study are similar

to those of the studies conducted by Thiesen *et al* (20), Bizreh and Milly (2), Parreiras *et al* (12), Tay *et al* (13), Reis *et al* (21), Nanjundasetty *et al* (22), Bernardon *et al* (23), and Po *et al* (24), and Martins *et al* (25).

Since tooth sensitivity is the most common complication of bleaching treatment, dentists have to reduce the frequency or duration of treatment or use desensitizing compounds 2 or 3 weeks before or during bleaching. According to the literature, potassium-containing desensitizing compounds in special trays also affect tooth sensitivity (23).

However, experimental desensitizing gels in some studies did not reduce tooth sensitivity (14-16), thus this study is inconsistent. Browning *et al* compared conventional bleaching agents and reported that the addition of 0.05% potassium nitrate to 10% carbamide peroxide reduces sensitivity level after bleaching higher than the addition of 3% potassium nitrate and does not affect the results of bleaching (26). The reason for this conclusion is probably related to the higher osmotic gradient of 3% potassium nitrate, compared to that of 0.05% concentration, leading to the increased movement of intradentinal fluid, stimulated mechanoreceptors, and pain (1). In a study by Singh (27), CPP-ACP with bleaching improved tooth sensitivity gels and increased the tooth color stability.

Through two mechanisms, the desensitizing agents decrease the sensitivity caused by bleaching treatment: 1) reducing the stimulation of intradentinal nerve terminals and 2) blocking dentin tubules (19).

The action mechanism of potassium nitrate is probably related to reducing the activity of sensory nerves in dentin due to K+ depolarization activity, not by blocking dentin tubules (1,13). Therefore, applying potassium nitrate gel before bleaching has no detrimental effect on color stability. However, the initial fluoride function leads to the blockage of dentin tubules or increased enamel hardness by calcium fluoride precipitation. Consequently, desensitizing gel before or during bleaching depends on factors such as the type of desensitizing agent that can affect bleaching quality (13). This is probably one of the reasons for no color change in 20% of our subjects within 14 days and one month after bleaching treatment in the present study.

The peroxide molecule is tiny and can cross into intertubular spaces, which is probably one reason for the lack of significant difference in color change between the desensitizing and control groups in the present study and other studies at different time points. In a study conducted by Tay *et al* (13) the findings of tooth color stability were similar to those of the present study; however, the rate of these changes was lower than that of the present study.

Despite the similarity of the desensitizing gel used, several factors attributed to different results: the type of bleaching agent in the present study was based on home bleaching of 16% carbamide *versus* the office bleaching of 35% hydrogen peroxide. Possibly, a higher percentage of peroxides penetrated the enamel and dentinal tubule. Furthermore, as mentioned above, the duration of use of the desensitizing agent in the study was 10 *min*; however, it was 30 *min* before bleaching in the present study. Therefore, the percentage of fluoride precipitation and blockage rate was probably higher. On the other hand, the duration of the color stability check was only up to 2 weeks after the treatment.

In a study by Browning *et al* (26), the contact time with the desensitizing gel was reported as 6 *hrs*. As mentioned earlier, there was no significant difference in color stability between the case and placebo groups in the study during 1, 2, 3, 4, 5, 6, and 7 weeks. This finding is similar to that of the present study.

On the other hand, according to the present study results, the color change (*i.e.,* no change or more darkening) was higher six months later in both groups. Thus, one reason for further changes over time is factors other than desensitizing gel, including different diets and habits and the teeth different morphological and structural properties. This is also probably one reason, in the present study, why 14% of the subjects in the control group had dark teeth after six months.

According to the ADA clinical guidelines, a noticeable discoloration should be maintained in at least half of the samples six months after bleaching as a standard measure of long-term bleaching treatment efficiency (28).

The similarities and differences between other studies and the present study were related to the differences in the desensitizing gels, duration of use, utilization before, during, or after bleaching, type of bleaching (*i.e.*, office or home), percentage of bleaching compounds, type of bleaching agent (*i.e.*, hydrogen peroxide - and carbamide peroxide), duration of examination and

follow-up of subjects, use of control group (*i.e.*, placebo and non-placebo), evaluation methods, selected teeth to be analyzed, and sample size.

Conclusion

Despite the limitations of the present study, the results showed that desensitizing gel (*i.e.,* 2% sodium fluoride and 5% potassium nitrate) before home bleaching decreased tooth sensitivity. However, no significant difference was observed in color stability compared to the non-use of the desensitizing gel.

Future studies examining different materials and techniques of tooth bleaching in terms of tooth color stability and sensitivity and the use of various desensitizing agents, especially plant varieties, are suggested.

Acknowledgement

The authors would like to thank Mr. Behrouz Lotfi for his help in data and statistical analysis.

This study was retrieved from two thesis and research projects (No:1912 and No: 2160). They were supported and funded by Zahedan University of Medical Sciences with the ethics codes of IR.ZAUMS.Rec.1395.82 and IR.ZAUMS.Rec.1396.246. This research registered in the Iranian Registry of Clinical Trials (IRCT) with codes of IRCT2017021032484N1 and IRCT2017051332484N2.

Conflict of Interest

There was no conflict of interest in this manuscript.

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