Original Article

Tooth sensitivity and whitening effect of an in-office bleaching gel containing sodium hexametaphosphate: A randomized triple-blind clinical trial

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Abstract

Introduction: Dental sensitivity is one of the most prevalent clinical consequences among patients who receive in-office bleaching therapy. This study aimed to evaluate the effect of adding sodium hexametaphosphate (SHMP) to an in-office bleaching gel on tooth whitening and sensitivity after the treatment.

Methods: The right and left maxillary lateral incisors of 34 patients were randomly divided into intervention and control groups. In the control side, a bleaching gel containing 37.5% hydrogen peroxide was used, whereas in the intervention side, a combination of the same bleaching gel with 1% SHMP was applied for 30 minutes. Tooth sensitivity to cold, tactile sensitivity, and spontaneous sensitivity was measured before the treatment, and immediately, 24 hours, one week, and one month after therapy. Color changes were measured objectively by a spectrophotometer using the total variation in color (ΔE), and subjectively by a Vita Classical Shade Guide (ΔSGU).

Results: Immediately after bleaching, cold and tactile sensitivity was higher in the control group compared with the intervention group, but there was no significant difference between groups in any of the sensitivity parameters at different measurement intervals ($P>0.05$). Spontaneous and tactile sensitivity decreased significantly in both groups over one month ($P<0.05$). There was no significant difference in ΔE and ΔSGU between the intervention and control groups ($P>0.05$).

Conclusion: The addition of SHMP to the bleaching gel could not reduce sensitivity to cold, as well as tactile and spontaneous sensitivity; however, it showed no adverse effect on the bleaching effectiveness. (*J Dent Mater Tech 2023;12(1): 1-9)*

Keywords: *Hydrogen peroxide, sodium hexametaphosphate, tooth bleaching, tooth sensitivity, tooth whitening*

Introduction

Tooth discoloration has a substantial impact on smile esthetics. Continuous dentin formation, excessive fluoride absorption, and some food, medication, and cigarette may alter the natural and brilliant color of teeth over time. Undesirable colors may be caused by childhood disorders, trauma, and dental products used during root canal therapy, such as detergents or sealers.

Several therapeutic approaches have been offered to address tooth discoloration, according to the type and intensity of pigment as well as the vitality of discolored teeth (1). Bleaching procedures, micro and macro abrasions, direct composite or indirect ceramic veneers, and all ceramic crowns are among the treatment options available, ranging from conservative to aggressive approaches (2). The tooth bleaching methods are often preferred by both clinicians and patients due to their more conservative nature than the restorative modalities, lower

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Accepted: 28 August 2022. Submitted: 10 July 2022.

cost of treatment, and favorable outcomes (3). This esthetic treatment may be contemplated by home applied or in-office procedures or through over-the-counter whitening products. When tooth whitening should be achieved in a short period of time, a high concentration of hydrogen peroxide (HP) is administered under the supervision of a dentist; the so-called in-office bleaching therapy (4).

Tooth sensitivity (TS) is a typical side effect of bleaching treatments, particularly when a high proportion of hydrogen peroxide is utilized during the in-office treatment procedure (5). Although TS is usually mild and temporary, it may cause considerable pain in some people, particularly those who previously experienced dental hypersensitivity (6). In the literature, remineralizing agents such as fluoride, calcium phosphate-containing materials, and hydroxyapatite have shown promise in reducing TS. The possible mechanisms for minimizing TS are intratubular crystallization and dentinal tubule occlusion. Furthermore, certain compounds, such as potassium nitrate, may help in reducing TS by inhibiting neuronal activation (7, 8).

Sodium hexametaphosphate (SHMP) is a remineralizing and anti-staining compound that belongs to the polyphosphate family. It is a chemical whitening agent, and also has been utilized to prevent calculus formation. SHMP has a significant ability to absorb pigments with a positive charge, which results in pigment elimination and it also limits the absorption of new chromogens due to its very negative charge (9, 10). It possesses anti-inflammatory and anti-plaque effects, which help to reduce gingival bleeding caused by gingivitis and periodontitis (11). SHMP is also regarded as an anti-caries substance since it provides binding sites for the retention of CaF+ and Ca++ ions (12).

The use of SHMP during dental whitening treatments can give positive outcomes such as enamel remineralization, prevention of surface hardness loss, and removal of existing stains. Thus, the purpose of this triple-blind randomized controlled clinical trial was to determine whether adding 1% SHMP to a commercial in-office tooth bleaching gel containing 37.5% HP affects the TS and whitening performance of the gel.

Materials and methods

Study design

This research was carried out at the Department of Restorative Dentistry of Mashhad University of Medical Sciences from April 2019 to January 2020. The study was approved by the ethical committee of Mashhad University of Medical Sciences (IR. MUMS. DENTISTRY. REC). The identifying number for this randomized clinical trial was IRCT20180630040294N1 in the Iranian Registry of Clinical Trials (http://irct.ir). The Consolidated Standards of Reporting Trials (CONSORT) statement was used to construct this clinical experiment (13).

Inclusion and exclusion criteria

Healthy volunteers between the ages of 18 and 40 years, who needed tooth bleaching therapy met the inclusion criteria. The participants had excellent oral hygiene and no history of whitening treatment, and their lateral incisor teeth were free of any restorations, cavities, loss of vitality, or dental discomfort signs. In terms of periodontal status, the plaque and gingival indices (Silness and Loe) were both lower than 2 with no bleeding on probing (14).

Participants who were pregnant or breastfeeding, who were receiving fixed orthodontic treatment, or who had bruxism habits or any other condition that may induce sensitivity (such as recession or dentin exposure) were excluded from the sample. Patients with tetracycline-stained teeth, fluorosis, or pulpless teeth were also excluded from the study since they would not be eligible for bleaching therapy (15). At first, 46 participants were screened to see whether they were eligible. Following that, 12 patients were removed from the study because they did not match the inclusion criteria. Four individuals were dropped from the trial owing to a lack of participation during the evaluation sessions. The assessments were finally completed by 30 individuals.

Sample size calculation

The sample size was calculated according to a study by Vano et al (16) who evaluated the effect of nano-hydroxyapatite on bleaching efficacy and TS. A total of 26 patients were estimated to be required for this study using a 95% confidence interval. The sample size was raised to 34 patients to account for the possible dropout during follow-up visits.

Randomization

The split-mouth approach was used to construct this research in the left and right quadrants of the maxilla. The patients were given sealed envelopes to randomly choose the control and experimental sides. Computer-generated tables were used to execute the randomization process (www.random.org).

Blinding

The patients, statistician, and evaluator who recorded the color changes and TS were all blinded to the group assignment. The control and intervention bleaching gels were administered in identical syringes designated as 1 or 2, with the same consistency, taste, color, and odor. An operator, not engaged in the assessment, was in charge of the randomization process and the application of bleaching gels.

Bleaching procedure and Study intervention

A slurry of pumice powder and water was used to clean the labial surface of the teeth. A spectrophotometer (VITA Easyshade Advance 4.0; VITA Zahnfabrik, Germany) was used to record the initial color of both maxillary lateral incisors (T1). A silicon mold was made for each participant on lateral incisors to limit the confounding influence of ambient light on color measurements. This mold features a central hole that was sized to fit the tip of the spectrophotometer and was used for all color evaluations. The central incisors and canines were not examined owing to the likelihood of interference in the patient's sensitivity between the left and right quadrants, as well as their convex form, which makes color assessment with the spectrophotometer problematic. Lips and cheeks were protected from hydrogen peroxide burning, and gingival margins were coated and sealed with a light-polymerized resin substance (Opalescence Opaldam, Ultradent Products Inc, South Jordan, UT, USA).

The commercial bleaching gel containing 37.5% hydrogen peroxide (polaoffice+ SDI Co., Victoria, Australia) was applied according to the manufacturer's instructions in the control quadrant, and a mixture of the same bleaching gel with 1% SHMP was used in the intervention quadrant for 30 minutes.

Assessment

The degree of TS (sensitivity to cold stimuli, tactile sensitivity, and spontaneous sensitivity) was measured using the Visual Analogue Scale (VAS). Patients were asked to rate their sensitivity to these three stimuli on a scale from 0 to 10 (cm) depending on the degree of perceived pain. The 0 denoted "no discomfort," while a value of 10 indicated "extreme pain." Tactile, thermal, and spontaneous sensitivity was assessed in two lateral incisors per person, while neighboring teeth were separated using cotton rolls. The sensitivity to cold stimuli was assessed using air force for 3 seconds applied at a distance of one centimeter from the cervical third of the lateral incisor. For assessment of tactile sensitivity, a sharp dental explorer (EXD 11-12; Hu-Friedy, Chicago, IL, USA) was passed over the labial surface in the cervical region of the tooth at an estimated constant force, perpendicular to the long axis of the tooth. In each session, the participants were also prompted to report spontaneous sensitivity. The sensitivity test and color evaluation were performed before treatment (T1), immediately after treatment (T2), 24 hours (T3), one week (T4), and one month (T5) after treatment. Each patient was given a toothpaste containing 1450 ppm fluoride (pooneh, Iran) to use twice a day to keep regular oral health care.

Color evaluation

To remove any subjectively skewed judgments, color measurements were made objectively under the same conditions using a spectrophotometer (17, 18). The three color variables of L*, a*, and b* were recorded by the spectrophotometer. L* denotes the color lightness, which ranges from 0 (black) to 100 (white), whereas a* and b* denote the red-green and yellow-blue color axes, respectively. The following formula was used to compute the color difference (ΔE) between the two assessment sessions:

$$\Delta E = [\Delta L^2 + \Delta a^2 + \Delta b^2]^{1/2}$$

The color assessment was also done by ΔSGU (Shade Guide Units). For this purpose, the shade tabs of a VITA Classical Shade Guide were sorted from B1 to C4 (highest to lowest values), and the changes in the number of Vita shades were calculated.

Statistical analysis

The Kolmogorov–Smirnov test was used to determine the normality of the data. The Mann-Whitney U and Friedman tests were used to analyze differences in TS parameters between the intervention and control groups and throughout the assessment intervals, respectively. The Independent sample t-test was used to assess the color changes between the two groups. SPSS 16.0 (SPSS software; SPSS, Chicago, Il, USA) was used to analyze the data and the significance level was set at $P<0.05$.

Results

At the start of the treatment, 34 people enrolled, 18 men and 16 women, with an average age of 26.18 years (ranging from 18 to 40 years). Two patients in the fourth assessment and two additional patients in the final session did not engage in the assessment and were therefore eliminated from the study. Figure 1 presents the flowchart diagram showing enrollment, allocation, follow-up, and analysis during the study, based on the CONSORT statement (13).

In terms of the three sensitivity stimuli, there was no significant difference between the intervention and control groups at any of the measurement intervals (P>0.05; Table I). The tactile and spontaneous sensitivity in each of the study groups decreased significantly from the time of bleaching until one month later (P <0.05; Table 1), although the sensitivity to cold did not change significantly (P=0.32 in the control group and P=0.87 in the intervention group).

The color change data had a normal distribution (P>0.05). The independent sample t-test revealed no significant difference between the intervention and control groups either in overall color changes (ΔE) or in shade guide alterations (ΔSGU) at any of the measurement intervals (P>0.05; Tables 2 and 3).

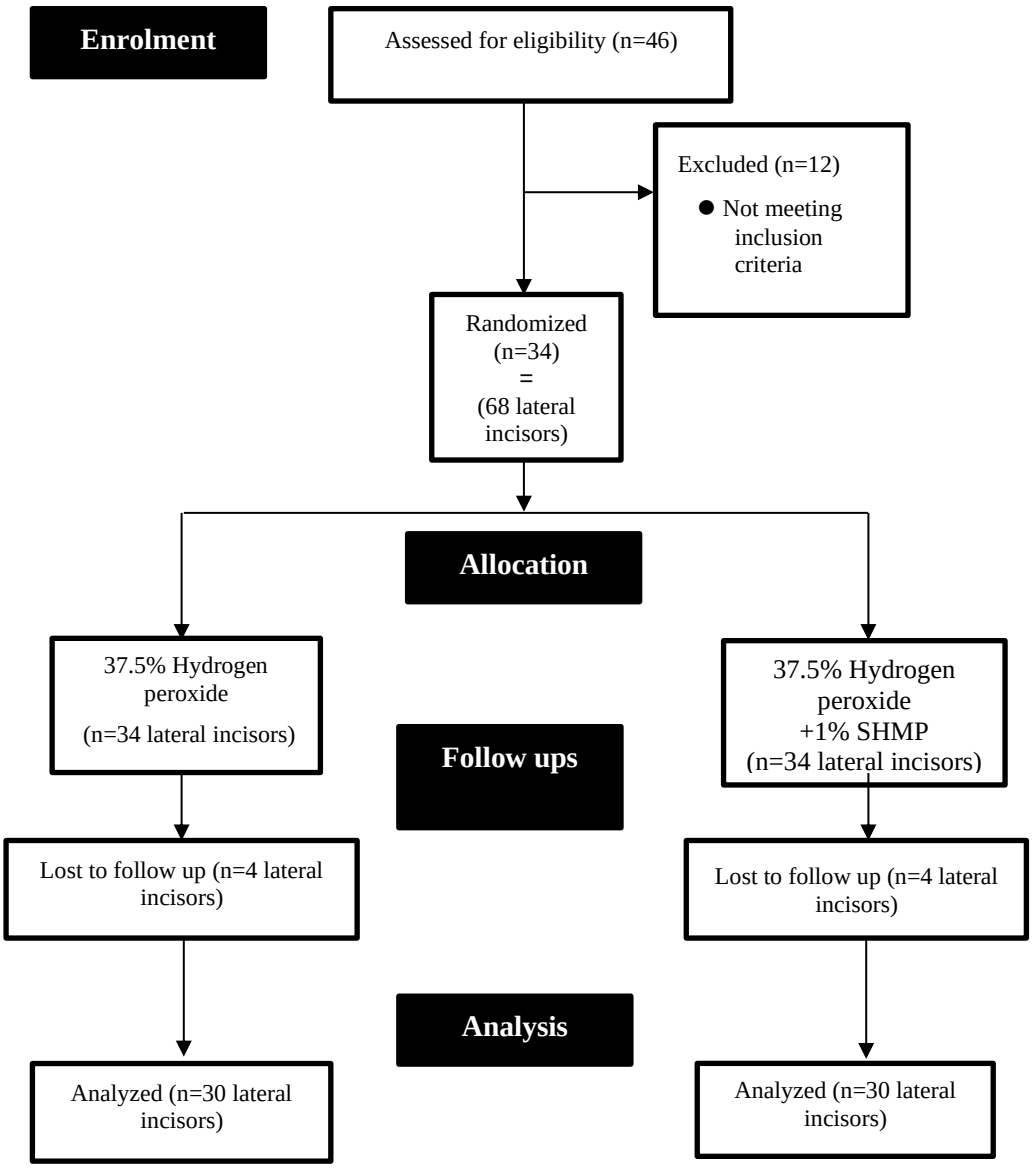

Figure 1: Flowchart diagram showing enrollment, allocation, follow-up, and analysis during the study, based on the CONSORT statement.

Table 1. Mean, standard deviation (SD), median, minimum (min), and maximum (max) values of Visual Analogue Scale (VAS) after exposure to three stimuli in each of the intervention and control groups over the experiment

Stimuli		Control group (37.5% HP)				Intervention group (37.5% HP + 1% SHMP)				
		(Mean ± SD)	median	min	max	(Mean ± SD)	median	min	max	P-value
Sensitivity to cold air flow	T1	.44±.96	0	0	4	.59±1.35	0	0	6	.921
	T2	.94±1.84	0	0	7	.56±1.39	0	0	7	.220
	T3	.61±1.17	0	0	4	.81±1.57	0	0	6	.534
	T4	.34±1.00	0	0	5	.59±1.29	0	0	5	.354
	T5	.57±1.10	0	0	5	.63±1.47	0	0	6	.653
	P-value	.328				.870				
Tactile sensitivity	T1	.24±.74	0	0	4	.24±.92	0	0	5	.504
	T2	.44±1.07	0	0	4	.38±1.10	0	0	5	.761
	T3	.32 ±.97	0	0	5	.42± 1.20	0	0	4	.783
	T4	.16± .51	0	0	2	.25 ±.88	0	0	4	.958
	T5	0.03 ±.18	0	0	1	0.03 ±.18	0	0	1	1.00
	P-value	0.006*				0.024*				
Spontaneous sensitivity	T1	.00±00	0	0	0	.00±00	0	0	0	1.00
	T2	.53±1.52	0	0	7	.65±1.68	0	0	7	.752
	T3	.19±.74	0	0	3	.13±.49	0	0	2	.947
	T4	.00±00	0	0	0	.00±00	0	0	0	1.00
	T5	.00±00	0	0	0	.00±00	0	0	0	1.00
	P-value	0.004*				0.001*				

* Statistically significant difference at P<0.05
T1: Before treatment; T2: Immediately after treatment; T3: After 24 hours; T4: One week after treatment; T5: One month after treatment

Discussion

Tooth bleaching is a popular and fairly conservative esthetic procedure. Although this therapy is safe and has minimal adverse effects, a significant number of people may experience tooth sensitivity (TS). The addition of SHMP to a commercial in-office bleaching gel containing 37.5% HP did not lessen sensitivity to cold, as well as tactile and spontaneous sensitivity, according to the findings of this investigation. However, it had no detrimental impact on the whitening efficacy of the bleaching gel.

The visual and instrumental approaches may be used to assess tooth color. Age, gender, eye strain, ambient light, and lighting aspect may all have a detrimental impact on visual color evaluation. Color assessment using a spectrophotometer, which was employed in this clinical experiment, is a reliable, accurate, and objective approach when compared to visual assessment, hence it is more often utilized by clinicians (15,16). The color change caused by the bleaching procedure was measured in this study by both objective and subjective methods: ΔSGU and ΔE. The results showed more than 6 unit changes in ΔE and 1 or 2 shade changes in ΔSGU values.

Table 2. The comparison of total color change (ΔE) in the intervention and control groups

Color change	Control group (37.5% HP) (Mean ± SD)	Intervention group (37.5% HP + 1% SHMP) (Mean ± SD)	P- value
ΔE T1-T2	7.24± 8.19	7.36 ± 7.58	.952
ΔE T1-T3	9.07± 6.74	6.75± 5.79	.150
ΔE T1-T4	7.00± 5.28	6.84± 4.44	.897
ΔE T1-T5	10.31± 20.74	10.80 ± 21.21	.929
ΔE T2-T3	7.93± 6.22	6.40 ±6.66	.356
ΔE T2-T4	8.27± 5.51	9.12± 6.94	.593
ΔE T2-T5	10.55± 20.51	11.86 ±21.63	.813
ΔE T3-T4	6.79 ±5.14	6.54 ±5.56	.855
ΔE T3-T5	10.36 ±20.65	9.51 ±21.32	.876
ΔE T4-T5	7.98 ±21.16	9.99 ±21.57	.716

T1: Before treatment; T2: Immediately after treatment; T3: After 24 hours; T4: One week after treatment; T5: One month after treatment

Table 3. The comparison of shade guide unit change (ΔSGU) in the intervention and control groups

Color change	Control group (37.5% HP)	Intervention group (37.5% HP + 1% SHMP)	P- value
	Mean ± SD	Mean ± SD	
ΔSGU12	1.59 ±3.84	.88± 3.97	.459
ΔSGU13	2.77± 4.50	1.13 ±3.33	.108
ΔSGU14	2.59± 3.51	1.59± 2.65	.204
ΔSGU15	2.50 ±3.59	1.93± 3.50	.539
ΔSGU23	1.03± 4.12	.61± 2.97	.648
ΔSGU24	.91 ±2.55	.66 ±3.87	.762
ΔSGU25	.63 ±2.71	.87 ±3.59	.778
ΔSGU 34	0.03± 3.32	.61±2.40	.432
ΔSGU 35	-0.30 ±3.32	0.77± 2.50	.165
ΔSGU 45	-.40 ±1.65	-0.23± 2.63	.770

T1: Before treatment; T2: Immediately after treatment; T3: After 24 hours; T4: One week after treatment; T5: One month after treatment

It is assumed that the effectiveness of the bleaching treatment is more related to ΔSGU than the overall color change (ΔE) (17). It's worth noting that the quantity of color change following bleaching in clinical investigations is lower than that of laboratory studies. This may be due to the use of pigments like tea and coffee in laboratory tests. However, when subjects are chosen based on inclusion criteria in clinical trials, usually teeth with light color in young patients with sufficient oral health are selected, and the efficacy of the bleaching chemicals may be less visible in such cases. ΔSGU comparison between one week and one month following the bleaching procedure indicated negative changes, suggesting that some part of the color alterations generated by bleaching had reverted to the original condition in both groups.

In the present study, the control group showed greater sensitivity to cold air flow and tactile sensitivity

immediately after treatment, but the difference between the control and intervention groups was not significant at any of the sensitivity tests. The highest level of sensitivity was seen up to 24 hours after the bleaching procedure and dropped dramatically after that. It has been demonstrated that the TS reduces and vanishes spontaneously in a short time after the in-office bleaching technique utilizing high concentrations of HP (18). Moosavi et al (19) found that the placebo group had the maximum sensitivity at 48 hours after treatment. Martin et al (20) reported the maximum TS shortly after the bleaching process.

SHMP powder was physically combined with bleaching gel and utilized in the intervention group under the same conditions as the control group. The inclusion of calcium-phosphate-containing compounds in bleaching gels may generate concerns about the negative effects on tooth whitening due to the possible inability of the bleaching gel to penetrate the interior regions of the teeth. In a previous study by Barbosa et al (21), adding MI Paste Plus to a bleaching gel containing 35% HP prevented the oxidative chemicals from penetrating the pulp, resulting in less inflammation and TS. In this study, the absence of significant differences in tooth color changes between the control and intervention groups validated the safety of including remineralizing agents into bleaching gels, a finding that has been supported by prior investigations (22, 23).

SHMP is a remineralizing agent capable of stain removal and pigment absorption prevention, making it a useful material for teeth bleaching (24,25). The combination of stannous fluoride and SHMP in a toothpaste exhibited esthetic (SHMP) and medicinal (fluoride) effects, according to Sensabaugh and Sagel (11). The current investigation was unable to demonstrate the efficacy of SHMP in the prevention of TS. The intervention group had lower sensitivity to cold and tactile sensitivity immediately after treatment than the control group, but this difference was not statistically significant. It should be noted that the in-office bleaching gel containing SHMP was applied only once in this study. Because of the potential beneficial features indicated above, further studies may be required to validate the therapeutic impact of SHMP during the bleaching process, and relying on just a few studies cannot rule out the material's advantages (26). It appears that incorporating SHMP into an at-home bleaching gel with many application times may be more beneficial in reducing TS and enhancing tooth whitening.

In the present study, the bleaching gel containing 37.5% HP (polaoffice+, SDI Co., Victoria, Australia) was utilized. It appears that this bleaching gel does not cause high TS similar to other in-office materials. At the same time, this gel did not perform as well as other bleaching gels in terms of whitening efficacy (1 or 2 shade alterations based on ΔSGU values). The decreased incidence of TS might be due to the inclusion of potassium nitrate in the formulation of polaoffice+, which helps lower TS levels in earlier investigations (7,8). Another factor contributing to tooth sensitivity after bleaching is the pH of the gel. The pH of most commercial bleaching chemicals is acidic, according to the findings of Price et al (27), while Polaoffice+ has a neutral pH. Because HP has a decomposition constant of roughly 11.5, the higher the pH, the quicker the bleaching gel decomposes, allowing less of it to reach the pulp and inducing pulpal sensitivity. Patients who used a neutral polaoffice+ bleaching gel (pH = 7.0) had a reduced incidence of TS and less severe TS than those who used acid products with the same whitening potential (28). Acidic gels, in addition to generating more TS, may also be damaging to the enamel.

Mineralizing chemicals used with bleaching gels may considerably lessen the detrimental effects of bleaching gels on enamel microhardness. A previous study found that adding MI Paste Plus to a gel containing 35% carbamide peroxide considerably increased the microhardness of enamel (29). Although the favorable impact of SHMP on lowering TS was not shown in this investigation, its possible benefits in preventing caries and reducing enamel microhardness cannot be overlooked.

One of the limitations of this study was that the bleaching gel was applied once for 30 minutes, although most manufacturers advocate utilizing in-office bleaching gels for 2-4 sessions with time intervals up to obtaining desired results. Furthermore, since the polaoffice+ bleaching gel did not cause severe TS, SHMP was unable to demonstrate its beneficial effects in lowering sensitivity. Because SHMP performed better when mixed with other remineralizing agents like fluoride (31), combining SHMP with other remineralizing materials may boost its beneficial qualities (26). Further studies are warranted to assess the effects of varying amounts of SHMP alone or in combination with fluoride in reducing TS and enhancing tooth whitening. Furthermore, it is suggested to establish the material's potential to eliminate stains, dental plaque, and gingivitis throughout the bleaching process (32, 33).

Conclusion

The incorporation of 1% SHMP into the commercial in-office bleaching gel containing 37.5% hydrogen peroxide showed no adverse effect on the bleaching effectiveness. However, it was not capable of significantly attenuating

bleaching-induced sensitivity to cold, as well as tactile and spontaneous sensitivity.

Conflict of Interest

The authors declare no conflict of interest.

Acknowledgments

This article was extracted from a thesis (Number = 3061) carried out in 2019 at the Dental School of Mashhad University of Medical Sciences, Iran, under the advisory guidance of Dr. Mohammadipour. The authors would like to extend their gratitude to the Vice-Chancellor for Research at Mashhad University of Medical Sciences for providing financial support of this project (Research Number = 970630).

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