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Effect of BioMin-F and BioMin-C Pastes on At-home Bleaching Efficacy using 20% Carbamide Peroxide: A Randomized Controlled Trial

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ABSTRACT

This study aimed to evaluate the effect of modified bioactive glass (BioMin-F and BioMin-C) on at-home bleaching efficacy using 20% carbamide peroxide (CP) in terms of color change. A randomized double-blinded controlled clinical trial was conducted to measure the tooth color change of 30 patients after 1 week, 2 weeks, 1 month, 3 months, and 6 months of follow-up. The participants were instructed to apply 20% CP 4 hours a day for 14 days followed by applying either BioMin-F, BioMin-C, or a placebo paste 30 min a day for 14 days using a bleaching tray. Lightness (L*), redness (a*), and yellowness (b*) were measured using a digital spectrophotometer, and the overall color changes (ΔE) were calculated. ΔE values were statistically analyzed using the Kruskal-Wallis test. No significant differences were detected between BioMin-F, BioMin-C, and placebo groups regarding the ΔE (p-value >0.05). The modified BAG toothpaste (BioMin-F and BioMin-C) did not affect the color change induced by the at-home bleaching process.

1. Introduction

Enamel damage caused by cariogenic and non-cariogenic factors results in loss of the enamel layer and exposure of the underlying dentin, causing patients to feel the pain associated with dentine hypersensitivity (DH) [1].

DH pain is caused by the movement of dentin fluid when the dentinal tubule openings are exposed to the oral environment. This movement of dentin fluid stimulates nerve endings in the dentin tubules, causing sharp pain [1]. In the treatment of dentine hypersensitivity various techniques/materials are employed such as bioactive resins, desensitizers, dentin sealants, and iontophoresis intended to seal the dentin openings to reduce the painful symptoms of dentine hypersensitivity [1- 3].

The role of biomimetic materials such as bioactive glass (BAG) in treating DH has shown promising results [4]. BioMin-F is a bioactive glass enriched with fluoride to increase bioactivity, and BioMin-F has demonstrated the ability to release high doses of calcium and phosphate that deposit and form (interacting layers) in tooth structures [5]. This layer releases abundant calcium and phosphorus ions into the internal demineralized tooth structure, causing remineralization [6]. The effectiveness of bioactive glasses as remineralizing agents has led researchers to propose them as important dentin-desensitizing agents [7].

The addition of strontium and fluoride to HAP (hydroxyapatite crystals) increases the bioactivity and stability of the resulting HAP, which may help prevent dental caries [8]. Similar to fluorides, chlorides are believed to have a similar impact on the performance of BG by lowering the melting and glass transition temperature [9]. Chlorides are thought to play the same role in the glass structure, giving toothpaste glasses a great aspect for promoting remineralization [10].

The incorporation of chlorine into BG composites was shown to increase bioactivity. This is important for dental applications such as toothpaste [11]. Similarly, [12] developed a new chloride-containing BG that shows great promise for toothpaste remineralization and resorbable bone substitutes. Chloride-containing BG is expected to form chlorapatite (ClAP, $Ca_{10}(PO_4)_6C_{l2}$) glass ceramics. This is of great interest to biomedical applications.

Furthermore, ClAP is less stable and more absorbable than hydroxyl and fluoride ions. This is because chloride ions are larger than hydroxyl and fluoride ions. Previous use of BioMin-F and BioMin-C toothpaste has demonstrated efficacy as a short-term treatment (such as at-home bleaching) for hypersensitive dentin [13]. However, there are no controlled, randomized clinical trials on the effect of applying modified bioactive glass (BioMin-F and BioMin-C) to fluoro calcium phosphosilicate and chloro calcium phosphosilicate on the effectiveness of at-home bleaching. Therefore, this study was carried out.

2. Materials and Methods

2.1 Ethical considerations

The study protocol was approved by the Scientific Research and Postgraduate Board of Damascus University, Ethics Committee, Damascus University, Syria (IRB No. UDDS-494-22042021/SRC-1550). A detailed information sheet written in plain, non-technical language was provided in advance, and asked to sign an informed consent form.

2.2 Study population and inclusion criteria

A total of 30 patients were evaluated and invited to participate in the study according to following the inclusion criteria: The patient aged between 19 and 35 years old, has 10 caries-free maxillary and mandibular anterior teeth or restorations on the buccal surfaces, no tooth sensitivity or the use of anti-sensitive toothpaste in the past 3 months, color shade A2 or darker on the shade guide, and good oral hygiene. While exclusion was: a patient who has had their teeth bleached before, patients with systemic diseases, patients undergoing orthodontics treatment, patients with periodontal disease or active carious lesions, pregnant/lactating women, and smokers.

This randomized clinical trial has been written according to CONSORT statement guidelines and was randomly distributed into three groups using a lottery, as the patient was asked to draw from a box containing coded papers with A, B, and C. Each of the studied pastes was given one of the coded by a third party not involved in the research context (Fig. 1): Group A (Experiential, n=10): BioMin-F paste; Group

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B: (Experiential, n=10): BioMin-C paste; and Group C: (Control, n=10): Placebo paste. A double-blinded study was also adopted as the patients and examiners were masked to the group assignment.

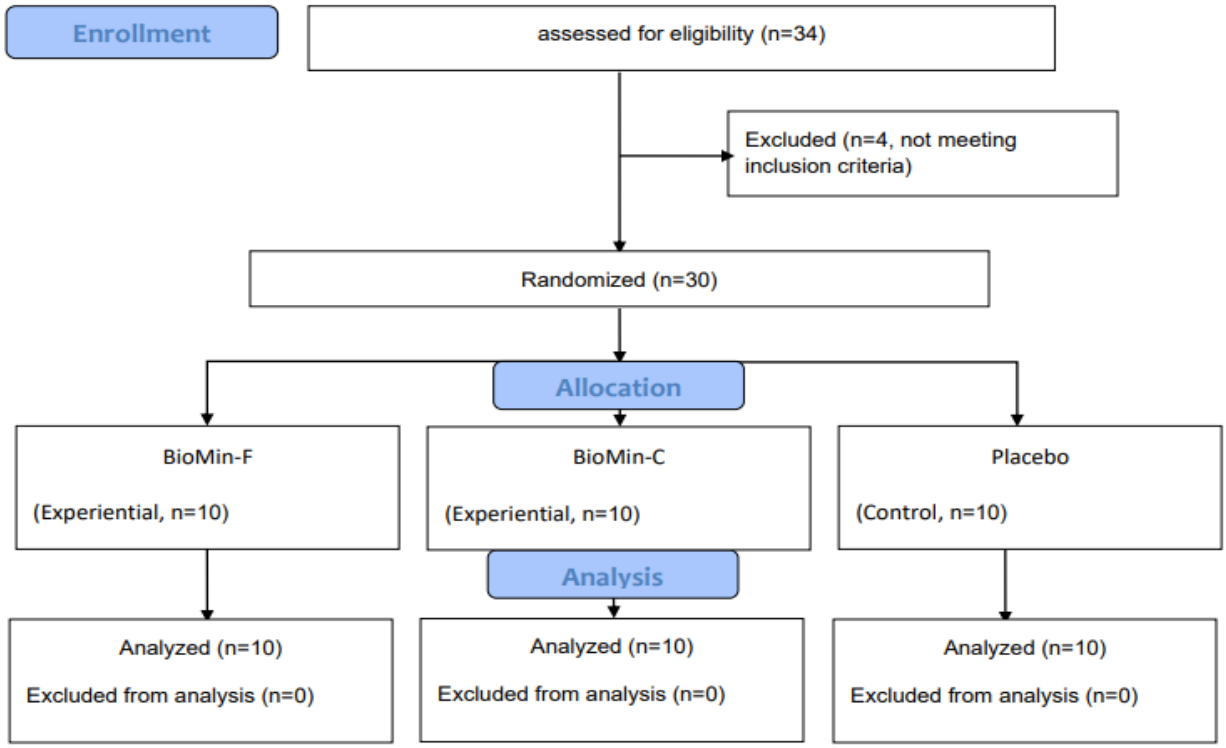

Figure 1. CONSORT flow diagram.

2.3 Intervention

All dental treatments were performed at Damascus University-Faculty of Dentistry-Department of Endodontics and operative dentistry. In the first session, the teeth were brushed with a fluoride-free non-pumice powder using a brush-tip on a low-speed handpiece to clean the dental surfaces and remove the plaque layer. Then an impression was taken using alginate (Hygedent® Alginate by Hygedent USA) to make two custom trays for each participant for the maxilla and mandible using soft vinyl sheets, 0.8 mm (Sof-Tray Classic, Ultradent, South Jordan, UT, USA) using a vacuum device, these custom trays have trimmed 1 mm beyond the gingival margins. The first custom trays were made to apply the bleaching gel, whilst the second one was equipped with holes in the middle of the buccal surface of the right maxillary incisors, right maxillary canines, left mandibular incisors, and left mandibular canines. The custom trays were designed to ensure color measurement at a fixed point during the follow-up sessions.

Each patient was provided with a kit containing: a bleaching tray, the bleaching gel syringe (Opalescence® PF™, Ultradent Products Inc. USA—20% carbamide peroxide), a coded container containing either modified bioactive glass pastes (BioMin-F® or BioMin-C®) or nonactive placebo paste and oral hygiene kit including toothbrush and non-whitening paste to standardize daily oral hygiene protocol for all participants.

All participants received a practical demonstration with instructions regarding the application of the bleaching gel and the experimental paste. They were asked to apply the bleaching gel for 4 h using the bleaching tray followed by rinsing the teeth and the tray to end with the application of the experimental paste in the same bleaching tray for 30 min daily for 14 days. Each patient was photographed using the

color guide from the VITA 3D-MASTER, during each follow-up period (Figures 2 and 3).

2.4 Outcome assessment

The colorimetric parameters (a, b, and L) were measured using Easy Shade Advance 4.0 spectrophotometer (VITA Zahnfabrik, Bad Säckingen, Germany) at six different time points (before bleaching, after one week, after two weeks, after one month, after three months, and after six months) for the right maxillary incisors, right maxillary canines, left mandibular incisors, and left mandibular canines. After calibration of the spectrophotometer, its tip was inserted in the holes of the positioning guide tray to obtain the shade based on the CIE L*a*b* color space system, measurements were repeated three times. The color change (ΔE) was calculated between the color of the studied tooth before bleaching (baseline) and the color of the studied tooth in each of the studied periods (T1 after one week, T2 after two weeks, T3 after one month, T4 after three months, and T5 after six months) according to the following equation:

$$\Delta E = [(\Delta a^*)^2+(\Delta b^*)^2+(\Delta L^*)^2]^{½}$$

(*$\Delta a=a_1-a_2$ / *$\Delta b=b_1-b_2$ / *$\Delta L=L_1-L_2$)

2.5 Statistical analysis

Statistical analysis was performed by using the SPSS 21.0 software (IBM, Armonk, NY, USA). Kolmogorov- distributed test was conducted to evaluate the normal distribution and the data were analyzed with the Kruskal-Wallis test. The testing was performed at $\alpha=0.05$ ($P<0.05$).

Figure 2. BioMin-C group: (a) before bleaching, (b) after 1 week, (c) after 2 weeks, (d) after 1 month, (e) after 3 months, (f) after 6 months.

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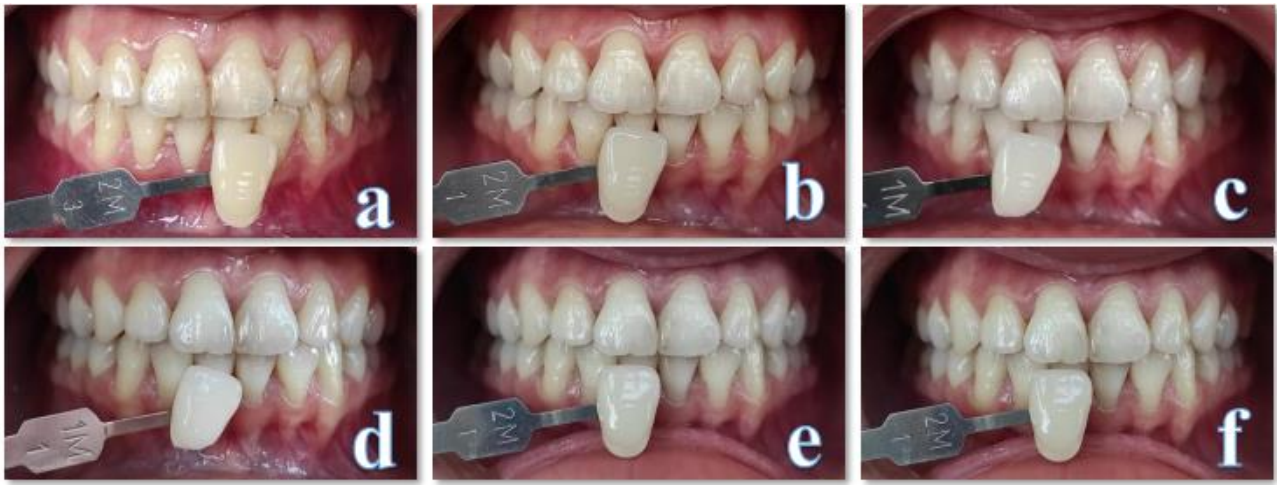

Figure 3. BioMin-F group: (a) before bleaching, (b) after 1 week, (c) after 2 weeks, (d) after 1 month, (e) after 3 months, (f) after 6 months.

3. Results

The studied sample consisted of 30 patients (23.3% male and 76.7% female patients), their ages ranged between 23 and 27 years (25.3±2 years), and they were divided into three equal main groups according to the toothpaste used (BioMin-F toothpaste, BioMin-C toothpaste, and placebo toothpaste) as seen in Table 1.

Table 1. Basic sample characters

Gender		Ages				Distribution according to the toothpaste		
Male	Female	Min	Max	Mean	SD	BioMin-F	BioMin-C	placebo
23.3%	76.7%	23.00	27.00	25.30	2.00	33.3%	33.3%	33.3%

The colorimetric parameters (a, b, and L) were measured at six different time points (before bleaching, after one week, after two weeks, after one month, after three months, and after six months). The color change (ΔE) was calculated between the color of the studied tooth before bleaching and the color of the studied tooth in each of the studied periods (T1 after one week, T2 after two weeks, T3 after one month, T4 after three months, and T5 after six months).

Kruskal-Wallis test was performed to study the significance of differences in color change (ΔE)between the three studied groups (Table 2). The test results showed that P-value at T1 (0.451), T2 (1.000), T3 (1.000), T4 (0.368), and T5 (0.359) as seen in Table 2 so there are no statistically significant differences in the frequencies of the color change (ΔE) between the toothpaste groups (BioMin-F, BioMin-C, and placebo).

Table 2. Teeth sensitivity reported by patients using VAS

	Criteria	Time interval					Rank means	Chi value	P-value
		Score 0	Score 1	Score 2	Score 3	Score 4			
T1	BioMin-F	0 (0%)	0 (0%)	0 (0%)	1 (2.5%)	39 (97.5%)	61.51	1.594	0.451
	BioMin-C	0 (0%)	0 (0%)	3 (7.5%)	3 (7.5%)	37 (92.5%)	58.54		
	Placebo	0 (0%)	1 (0%)	0 (0%)	0 (0%)	39 (97.5%)	61.45		
T2	BioMin-F	0 (0%)	0 (0%)	0 (0%)	0 (0%)	40 (100%)	60.50	0	1.000
	BioMin-C	0 (0%)	0 (0%)	0 (0%)	0 (0%)	40 (100%)	60.50		
	Placebo	0 (0%)	0 (0%)	0 (0%)	0 (0%)	40 (100%)	60.50		
T3	BioMin-F	0 (0%)	0 (0%)	0 (0%)	0 (0%)	40 (100%)	60.50	0	1.000
	BioMin-C	0 (0%)	0 (0%)	0 (0%)	0 (0%)	40 (100%)	60.50		

	Placebo	0 (0%)	0 (0%)	0 (0%)	0 (0%)	40 (100%)	60.50		
T4	BioMin-F	0 (0%)	0 (0%)	0 (0%)	0 (0%)	40 (100%)	61.00	2.000	0.368
	BioMin-C	0 (0%)	0 (0%)	0 (0%)	1 (2.5%)	39 (97.5%)	59.50		
	Placebo	0 (0%)	0 (0%)	0 (0%)	0 (0%)	40 (100%)	61.00		
T5	BioMin-F	0 (0%)	0 (0%)	0 (0%)	0 (0%)	40 (100%)	62.00	2.051	0.359
	BioMin-C	0 (0%)	0 (0%)	1 (2.5%)	1 (2.5%)	38 (95%)	58.99		
	Placebo	0 (0%)	0 (0%)	0 (0%)	1 (2.5%)	39 (97.5%)	60.51		

4. Discussion

At-home Vital teeth bleaching has become one of the most popular methods for bleaching discolored teeth after discovering the bleaching effect of carbamide peroxide, in addition to being a conservative aesthetic method [14], [15]. Nevertheless, several studies have reported dental sensitivity incidence with at-home bleaching which varies according to different factors such as the concentration of CP and the exposure time [16], [17].

Several studies have shown moderate to severe changes in the enamel surface after the use of carbamide peroxide, including demineralization [18], [19]. Different materials and pastes have been introduced to reduce dental sensitivity during teeth bleaching such as fluoride, arginine, CPP-ACP, and BAG [1], [20]. Several studies have confirmed that the application of BAG before, during, or after bleaching has an effect in preventing changes in the hardness and roughness of the surface of the bleached enamel, in addition to its contribution to the occurrence of remineralization and blocking of dentin canals [21], [22].

However, the effect of these toothpaste on teeth bleaching efficacy is still not clear, where one of the most important characteristics of the ideal desensitizing material is that it does not cause discoloration of the dental tissues and does not affect the effectiveness of bleaching [23].

In this study, custom trays were made with holes in the middle of the buccal surface of the right maxillary incisors, right maxillary canines, left mandibular incisors, and left mandibular canines, to ensure the color measurement at a repeatable fixed-point using the spectrophotometer during the follow-up sessions [24].

Spectrophotometers were used to determine the color of the teeth, being one of the most accurate devices in determining color, and it is not affected by different lighting conditions [25], while the optical method based on the shade guide is affected by many factors such as the examiner's, the degree of eye fatigue, the type of color guide used and the lighting conditions [26].

The bleaching gel was applied using custom trays while sleeping to achieve maximum benefit from the bleaching process [27]. Patients were also instructed to apply the studied paste within the custom trays for 30 min a day after at-home bleaching throughout the bleaching period, and this helps in achieving the maximum possible benefit from the modified BAG [28].

The results of the present study demonstrated that the use of modified BAG paste in both forms (BioMin-F and BioMin-C) does not significantly affect the color change resulting from at-home bleaching when compared with placebo paste, and therefore, the null hypothesis was accepted.

The result of this study agreed with Bizreh and Milly, [29] studies, which showed that the BAG toothpaste did not affect the bleaching efficacy [30]. The result of this study also agreed with [31] study, where it was shown that the use of ACP-CPP paste after bleaching with carbamide peroxide did not adversely affect the efficacy of bleaching.

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The result of this study agreed with [32] study, which showed that toothpaste containing potassium nitrate, conventional fluoride, arginine, and BAG toothpaste did not affect the bleaching efficacy. This study also agreed with [33] study that using BAG toothpaste for 7 days enhanced protection against negative effect on at-office dental bleaching without affecting the bleaching efficacy. Further investigations are still required to ascertain the effect of modified BAG on the bleaching efficacy when various concentrations of carbamide peroxide and hydrogen peroxide are used for both at-home and in-office bleaching procedures.

5. Conclusion

The application of the modified bioactive glass toothpaste in its two forms (BioMin-F and BioMin-C) did not have a negative effect on at-home bleaching efficacy and color change.

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