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Evaluation of desensitizing efficacy of nanohydroxyapatite on the treatment of dentine hypersensitivity following ultrasonic scaling: a randomized controlled trial

Avaliação da eficácia dessensibilizante da nanoidroxiapatita no tratamento da hipersensibilidade dentinária após raspagem ultrassônica: um ensaio clínico randomizado

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ABSTRACT

Objective: This randomized controlled trial aimed to compare nanohydroxyapatite with fluoride on managing post ultrasonic scaling Dentine hypersensitivity (DH). **Material and Methods:** Thirty patients (aged 20-50 years) with post ultrasonic-scaling DH were included in this study. The sample was randomly divided into three equal groups of 60 teeth each: the first group received nanohydroxyapatite material, the second group received fluoride material and the third group received sterile water as a placebo (controls). The materials were applied once for each patient. All patients were instructed to rate the level of pain before treatment, and after 1 hour, 24 hours, 2 weeks and 1 month on the numerical rating scale (NRS). The Kruskal-Wallis test, Mann-Whitney tests, linear regression analysis were used for the statistical analysis. Significance level was set at 0.05. **Results:** Both nanohydroxyapatite and fluoride were successful in reducing pain associated with DH when compared with the placebo in subsequent follow-ups ($p < 0.05$). However, one-hour and one-day post application, nanohydroxyapatite could reduce hypersensitivity pain more effectively than fluoride ($p < 0.05$). **Conclusion:** Nanohydroxyapatite material was found to be significantly more effective in reducing the DH that followed ultrasonic scaling one-hour and one-day post application as compared to fluoride and sterile water. Both fluoride and nanohydroxyapatite had similar effect on DH after two-weeks and one-month after application.

KEYWORDS

Dentine hypersensitivity; Desensitizing agent; Fluoride; Nanohydroxyapatite; Ultrasonic scaling.

RESUMO

Objetivo: Este ensaio clínico randomizado teve como objetivo comparar a nano-hidroxiapatita com o flúor no manejo da hipersensibilidade dentinária (HD) pós-raspagem ultrassônica. **Material e Métodos:** Trinta pacientes (com idades entre 20-50 anos) com HD pós-raspagem ultrassônica foram incluídos neste estudo. A amostra foi dividida aleatoriamente em três grupos iguais com 60 dentes cada: o primeiro grupo recebeu material de nano-hidroxiapatita, o segundo grupo recebeu material de flúor e o terceiro grupo recebeu água esterilizada como placebo (controle). Os materiais foram aplicados uma vez para cada paciente. Todos os pacientes foram instruídos a avaliar o nível de dor antes do tratamento, e após 1 hora, 24 horas, 2 semanas e 1 mês na escala de avaliação numérica (NRS). Os testes de Kruskal-Wallis, Mann-Whitney e análise de regressão linear foram usados para a análise estatística. O nível de significância foi estabelecido em 0,05. **Resultados:** Tanto a nano-hidroxiapatita quanto o flúor foram bem-sucedidos na redução da dor associada à HD quando comparados ao placebo em acompanhamentos subsequentes ($p < 0,05$). No entanto, 1 hora e 1 dia após a aplicação, a nano-

hidroxiapatita pode reduzir a dor de hipersensibilidade de forma mais eficaz do que o flúor ($p < 0,05$). **Conclusão:** O material da nano-hidroxiapatita foi significativamente mais eficaz na redução da HD que se seguiu à raspagem ultrassônica, 1 hora e 1 dia após a aplicação, em comparação com o flúor e a água estéril. Tanto o flúor, quanto a nano-hidroxiapatita apresentou efeito semelhante na HD após 2 semanas e 1 mês após a aplicação.

PALAVRAS-CHAVE

Hipersensibilidade dentinária; Agente dessensibilizante; Fluoreto; Nano-hidroxiapatita; Raspagem ultrassônica.

INTRODUCTION

The treatment results of periodontal disease depends on the effective removal of calculus and bacterial deposits from tooth surfaces [1]. This can be achieved through different home-based and professional-based methods [1]. The mechanical treatment, which is performed by a dentist, can be performed with hand instruments, power-driven instruments (known as sonic and ultrasonic instruments) or both. Power-driven instruments, especially ultrasonic ones, are characterized by effectiveness and time saving in performing the mechanical treatment when compared with hand instruments [2]. Nevertheless, gingival recession is a common sequel for the mechanical treatment, as a result of diminishing the inflammatory edema. This leads to the exposure of root surfaces to the oral environment causing, in many instances, dentine hypersensitivity (DH) [1]. Thus, DH is one of the most common side effects of the mechanical treatment [3].

According to the international workshop on the design and conduct of clinical trials, DH is defined as a short and sharp pain happening from exposed dentin in response to evaporative thermal, chemical and, physical stimuli [4]. The prevalence of DH varied from 8-57% according to the studied population. It mostly affects 20- to 40-year-old individuals, with the peak at the end of the third decade [3]. In general, DH was reported more in females than in males, though the oral hygiene among females is better. This was attributed partially to the resultant gingival recession due to incorrect use of oral hygiene products. On the other hand, it is more common in people who frequently consume acidic foods and drinks due to dentinal exposure after the erosion of the enamel in such cases. Subsequently, the erosive acids open and enlarge the dentinal tubules, leading to DH [5]. The cervical region of the vestibular face of teeth is the most affected region [6], especially the canines and premolars in both dental arches [7]. The exposed dentine is affected by different stimuli that cause fluids in the dentinal tubules to move rapidly in different directions which result in activation of sensory nerves in the pulp. This process, known as the hydrodynamic theory, is the most accepted explanation of etiology of DH [8].

Many materials are used to treat DH, with different mechanisms of action. Some of these materials, such as Fluoride and oxalate, depend on closing the dentinal tubules and diminishing the movement of fluids inside the tubules resulting in decreased DH [7,9,10]. Other materials, such as potassium containing compounds, depend on tubular closure and blockage of nerve activity, increasing the concentration of potassium ions acting on the pulpal nerve sensorial activity [7,11].

The application of fluoride forms a barrier by precipitation of the calcium fluoride crystals that are created at the entrance of the dentinal tubules, the sediments is slowly soluble in saliva. This effect, however, depends on fluoride type [12]. It remains for a short period of time in the oral environment before it gradually dissolves. These sediments disappear by mechanical factors such as brushing [13]. Thus, only a relatively short and limited effect is produced with this treatment modality. A previous study reported diminishes of DH in 26.6% of fluoride treated group after scaling and root planning, and in 86,6% of patients treated with laser [14].

Recent studies have suggested the use of nanohydroxyapatite particles in the treatment of DH. Hydroxyapatite, which is the basic component in bone and teeth, is very important in the remineralization of enamel [15]. Nanohydroxyapatite is a biologically active material, biocompatible, nontoxic. Its high ability to retain and not being irritant to close tissues are advantages over other materials in this field. Therefore, materials containing calcium phosphate were found to be the best biomaterial for medical

applications. Other uses of nanohydroxyapatite include remineralization of initial enamel lesions [16], anti-sensitive agent during active bleaching [17], reconstructing bone defects with or without the loss of dental implants, and as a material for alveolar bone augmentation [18].

Although several studies recommended nanohydroxyapatite for DH, there is no study that evaluated the effectiveness of nanohydroxyapatite after ultrasonic scaling, which is more rigor than hand-instrumentation scaling, i.e. post ultrasonic scaling is more likely to produce DH with higher severity. On the other hand, nanohydroxyapatite was shown to be effective after single application. Accordingly, the aim of this randomized controlled trial was to evaluate the effectiveness of nanohydroxyapatite and fluoride application as treatment options for DH following ultrasonic scaling.

MATERIALS AND METHODS

Ethical approval and informed consent: The ethical Approval of this study was obtained from the Local Ethic Research Committee at the University of Damascus Dental School. Patients were given verbal and written information about the randomized allocation in this study, and informed consent was obtained from all participants. The research was conducted in full accordance with ethical principles including the World Medical Association Declaration of Helsinki.

Sample size calculation: Minitab® version 17 (Minitab Inc., Pennsylvania, USA) was used for sample size calculation. Significance level (α) and power (1-β) were set at 0.05, and 80%; respectively. The minimum difference in numeric rating scale (NRS) between groups was set at 3, as determined from a previous study on DH [19]. Although sample size calculation software indicated the need for 90 teeth, we aimed to enroll 180 teeth; this number was chosen for any potential drop-out after the commencement of the trial.

Study Design: This is a randomized controlled study conducted at the Department of Periodontology, School of Dentistry, University of Damascus, following the CONSORT criteria. Among 60 candidates who had DH, only 30 patients with 180 teeth met the inclusion criteria and were included in this study (Figure 1). Fifteen patients were excluded because they did not match

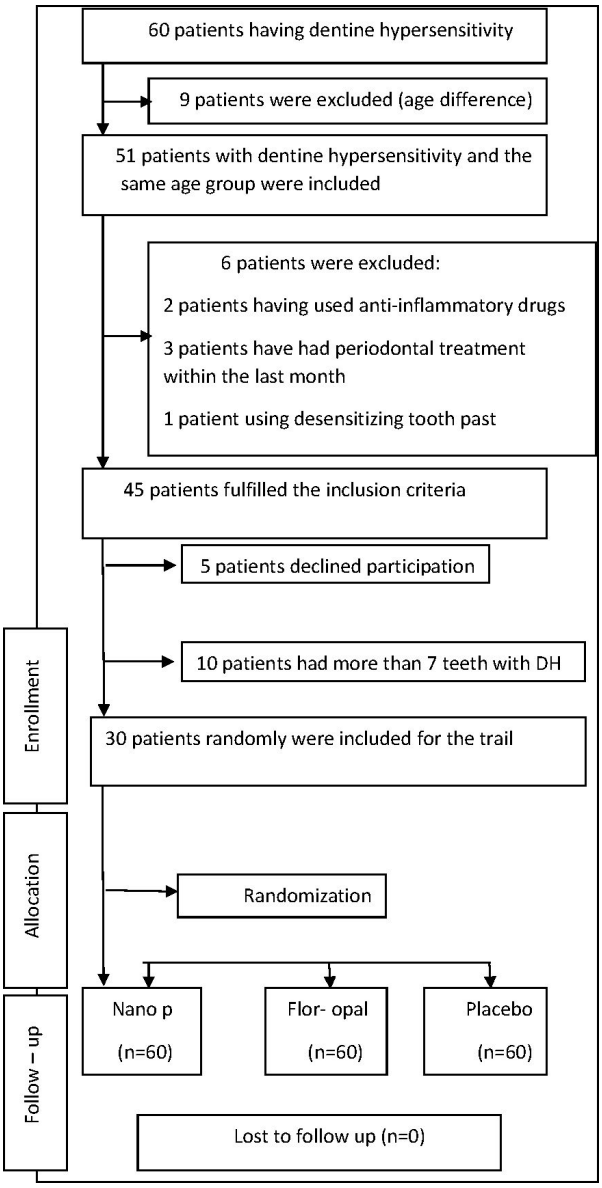

Figure 1 - Flow diagram of patients' recruitment and follow-up.

the inclusion criteria (out of the determined age range, using non-steroid anti-inflammatory drugs, using desensitizing toothpaste, having periodontal treatment in the previous 3 months from the day of attendance). In addition, five patients declined to participate. Patients who had 8 or more teeth with DH were excluded to avoid bias (10 patients). Three treatment options were applied in this study; nanohydroxyapatite, fluoride, and sterile water. Each patient received only one type of treatment options.

Selection criteria

Inclusion criteria

- Healthy patients with no signs or symptoms of any systemic disease.

- Patients from 20 to 50 years old.
- Patients with good oral hygiene suffering from DH caused by gingival recession after ultrasonic scaling.
- Patients that had calculus with gingival recession (class I of Miller classification for gingival recession; gingival recession with intact interproximal gingiva), inflamed gingiva due to the presence of calculus, where ultrasonic scaling might be a therapeutic option.

Exclusion criteria

- Patients on non-steroids anti- inflammatory drugs within the previous 3 months.
- Patients who have had periodontal treatment within the last three months.
- Patients with chronic or acute pulpal dental pain.
- Sensitive teeth due to reasons other than DH; such as improper restorations, caries or fractures.
- Patients who have used desensitizing tooth pastes, mouth rinses or any other material within the past 6 weeks.
- Pregnant and lactating women.
- Patients with 8 or more teeth with HD.

Study groups: The first group (n = 60 teeth) received nanohydroxyapatite material (Nano P, FGM, Joinvile, Brazil), which contained 9000 ppm fluoride and 5% potassium nitrate as active materials. The second group (n = 60 teeth) received fluoride material (Flor-opal, Ultradent, products Inc, USA), with an active components of 0.5% fluoride ion and 3% potassium nitrate. The third group (the control group; n = 60 teeth) received sterile water. The assessment of DH after applying the materials were scheduled to be (1) after 1 hour (2) after 24 hours (3) after two weeks (4) after one month.

Methods of Application

Enrolled patients were examined and the number of teeth with DH was assessed in each patient. Then, patients were allocated to one of the three treatment groups based on drawing a card from a black box containing three labelled cards with A (nanohydroxyapatite), B (fluoride), or C (sterile water). The principal investigator was never involved in randomization process. From each patient, the principal investigator chose sensitive teeth starting from the anterior teeth, but no adjacent teeth were selected. If the last patient in any group had teeth with DH that would cause exceeding the number above 60, only the required number of teeth were chosen, because the maximum number in each group was set at 60 teeth.

Using an ultrasonic scaler (Suprasson P5 Booster, Satelec, France), the mechanical treatment was performed to all recruited patients to remove debris and calculus. Patients were informed then to rinse with chlorhexidine (0.12%) solution for 30 seconds. The Application of the material on the cervical surface for 5 minutes with the aid of a disposable micro applicator was done after isolating the teeth with cotton rolls and suction. Excess, if any, was removed with a cotton pellet. Patients were instructed to refrain food and drink for 30 minutes. The medications and sterile water were applied once only for each patient. One dentist (W.E) who was helped by one assistant performed the treatments. To follow the correct protocol of applying each material, it was not possible to blind the principal investigator during the application of the materials.

Post-treatment evaluation

The evaluation of DH after application of the materials was performed by applying an air stimulus to the teeth under evaluation. Air blast was applied with an air syringe for 1 sec at a distance of 1 cm of the tooth buccal surface, the adjacent teeth were protected by the examiner's fingers. All patients were instructed to rate their pain level on a Numeric Rating scale (NRS). A line of 10 cm length was used, with the left side representing (0 = no pain) and the right side representing (10 = the worst pain). Patients were instructed not to take any analgesic during pain assessment period. Pain assessment was conducted before applying the medication, after 1 hour, 24 hours, 2 weeks, and 1 month of the ultrasonic scaling.

The numbers (1, 2, 3), (4, 5, 6), and (7, 8, 9, 10) on the NRS were considered to representing a mild, moderate, and severe pain; respectively.

Statistical analysis

For data collection Microsoft Excel Software (2016) was used. Statistical analysis was performed using SPSS version 13 (SPSS, Chicago,

IL, USA). The Kruskal-Wallis test was used to compare the difference between the treatment and control groups. The post-hoc test that showed the least significant difference (LSD) was chosen as the post-hoc tests for binary comparisons. Finally, linear regression analysis was used to adjust for any potential confounding factor.

RESULTS

A total of 180 teeth in 30 patients (11 men and 19 women; mean age was 32 (SD = 9) years), with DH following ultrasonic scaling, were evaluated in the current study. Table I shows the distribution of the sample by types of teeth. Incisors were the most common teeth affected by DH, followed by pre-molars, canines and molars; respectively.

Table II shows the distribution of NRS at the baseline and subsequent follow-ups. In nanohydroxyapatite group, the number of teeth with severe pain was reduced from 26 (43.3%) to zero (P = 0,001), and nine teeth were asymptomatic at the last follow up appointment (P-value = 0,001).

In Fluoride group, all teeth were either with severe or moderate pain at baseline, but at the last follow-up appointment, 56 teeth (93.3%) became with mild or moderate pain, and just one tooth expressed severe pain. Reduction in the number of teeth with severe and increments in the number of teeth with mild pain were statistically significant (P-value = 0.001 and P-values = 0.001; respectively).

In the placebo group, although the number of teeth with severe pain decreased after one month follow up with statistical significance (P-value=0.001), the number of asymptomatic teeth at baseline and at the last follow up appointment was roughly equal.

Nevertheless, there were statistically significant differences in the number of teeth with any degree of pain between two follow-ups at least (out of the four follow up appointments) in all groups.

Table III shows the mean and standard deviation of pain scores as measured with NRS in all treatment groups. Apart from the 24-hour-follow-up scores, Kruskal-Wallis revealed statistical significances between the three groups in all follow-ups.

Table IV shows post-hoc comparisons in all treatment groups and all follow-ups. Although the result of nanohydroxyapatite did not differ

Table I - Distribution of types of teeth affected with dentine hypersensitivity

Treatment group	Incisors (n)	Canines (n)	Pre-molar (n)	Molar (n)	Total (n)
Nanohydroxyapatite	27	14	17	2	60
Fluoride	24	13	20	3	60
Sterile water	28	14	14	4	60
Total	79	41	51	9	180

Table II - Numeric rating scale (NRS) distribution of each group at baseline and subsequent follow-ups

Group	Severity	Baseline Score (%)	After 1 hour (%)	After 24 hours (%)	After 2 weeks (%)	After 1 month (%)	p- value
Nanohydroxy-apatite	No pain	0(0%)	1(1.7%)	1(1.7%)	8(13.3%)	9(15%)	<0,001*
	Mild	6(10%)	11(18.3%)	20(33.3%)	33(55%)	39(65%)	
	Moderate	28(46.7%)	34(56.7%)	34(56.7%)	18(30%)	12(20%)	
	Severe	26(43.3%)	14(23.3%)	5(8.3%)	1(1.7%)	0(0%)	
Fluoride	No pain	0(0%)	0(0%)	1(1.7%)	3(5%)	3(5%)	<0,001*
	Mild	0(0%)	4(6.7%)	23(38.3%)	35(58.3%)	36(60%)	
	Moderate	23(38.3%)	42(70%)	30(50%)	22(36.7%)	20(33,3%)	
	Severe	37(61.7%)	14(23.3%)	6(10%)	0(0%)	1(1.7%)	
Sterile water	No pain	0(0%)	0(0%)	0(0%)	1(1.7%)	1(1.7%)	<0.001*
	Mild	3(5%)	12(20%)	10(16.7%)	12(20%)	14(23.3%)	
	Moderate	40(66%)	43(71.7%)	47(78.3%)	44(73.3%)	41(68.3%)	
	Severe	17(28.3%)	5(8.3%)	3(5%)	3(5%)	4(6.7%)	

*Significant difference at p<0.05.

Table III - Descriptive statistics of pain level in three groups of patients at the different assessment times. *Significant difference at p < 0.05

Time	Material	N	Mean (difference from baseline)	SD	P-Value*
Before Treatment	Nanohydroxyapatite	60	6.15 (0)	1.89	0.000*
	Fluoride	60	7.15 (0)	1.49	
	Sterile water	60	5.88 (0)	1.3	
After 1 hour	Nanohydroxyapatite	60	5.28 (-0.87)	2	0.007*
	Fluoride	60	5.58 (-1.57)	1.51	
	Sterile water	60	4.70 (-1.18)	1.23	
After 24 hours	Nanohydroxyapatite	60	4.17 (-1.98)	1.84	0.18
	Fluoride	60	4.18 (-2.97)	1.83	
	Sterile water	60	4.58 (-1.3)	1.17	
After 2 weeks	Nanohydroxyapatite	60	2.72 (-3.43)	1.71	0.000*
	Fluoride	60	3.15 (-4)	1.53	
	Sterile water	60	4.45 (-1.43)	1.45	
After 1 month	Nanohydroxyapatite	60	2.28 (-3.87)	1.54	0.000*
	Fluoride	60	3.12 (-4.03)	1.61	
	Sterile water	60	4.38 (-1.5)	1.53	

*Kruskal-Wallis test.

from that of fluoride after one hour and two-weeks, there were statistical differences after one month follow up (Table IV). There were statistically significant differences between (nanohydroxyapatite–placebo) after 2 weeks, 1 month and between (fluoride- placebo) at all assessment times (Table IV). Fluoride showed that it was better than placebo in all follow ups, however, nanohydroxyapatite was better than placebo only at 2-weeks, and one -month follow up appointments.

Due to the fact that the pain at baseline was higher in fluoride group than the other groups according to the Kruskal-Wallis test (table III), linear regression analysis was performed to test whether the improvement in the intervention groups was significant or not. First, the results of the linear regression analysis emphasized that intervention groups (fluoride and nanohydroxyapatite) were effective in treatment DH after adjusting the pain degree at baseline in comparison to the control group (table V). Then, linear regression analysis was done again to compare between nanohydroxyapatite and fluoride in treating DH. Pain at baseline was also adjusted (table V). Nanohydroxyapatite was more effective in reducing DH than fluoride after one hour and one day only (P-value = 0.003 and 0.006; respectively). However, no differences were found between them after two weeks and one month (P-value = 0.979 and 0.097; respectively).

Table IV - Post-hoc binary comparisons using Mann-Whitney U test in each assessment point

Time	A	A-B	P-value
Before treatment	Nanohydroxyapatite	-1	0.003*
		0.27	0.427
	Fluoride	1.27	0.000*
After 1hour	Nanohydroxyapatite	-0.3	0.333
		0.58	0.055
	Fluoride	0.88	0.001*
After2 weeks	Nanohydroxyapatite	-0.43	0.138
		-1.73	0.000*
	Fluoride	-1.3	0.000*
After 1 month	Nanohydroxyapatite	-0.83	0.007*
		-2.1	0.000*
	Fluoride	-1.27	0.000*

*Statistically significant difference (p<0.05).

Table V - Results of linear regression analysis after adjusting the pain at baseline

Dependent variable	P-value considering all treatment groups	P-value for fluoride vs. nanohydroxyapatite
Pain after one hour	0.027	0.003
Pain after one day	0.014	0.006
Pain after two weeks	<0.001	0.979
Pain after one month	<0.001	0.097

DISCUSSION

This randomized controlled study found superiority to nanohydroxyapatite in reducing

the DH that follows the ultrasonic scaling than the conventional treatment (Fluoride) instantly after the application.

In this study, an air stimulus was used to assess pain, because it is one of the most accurate stimuli to induce pain caused by hypersensitivity, and it mimics the stimulation of DH in the real life. Furthermore, it spreads over the exposed surface of dentine [20]. This method is considered as remarkably effective, with a fixed and repeatable stimulus [20]. The blast of air has been successfully used in previous studies [21].

Pain realization depends on several variables such as social factors, the degree of apprehension, individual personality, the significance and anticipation of pain [21]. For these reason in the present study the assessment of pain was based on the NRS. NRS was used because it is easier to explain to the patient and its accuracy is similar to the accuracy of visual rating scale [22,23].

The hydrodynamic theory has been widely accepted to explain the etiology of DH and the mechanism of action of materials used for its treatment. According to this theory, any material that has the ability to reduce the flow of dentinal fluid through the dentinal tubules by closing the openings of these tubules is able to decrease the clinical symptom of DH [24]. In this study, nanohydroxyapatite was introduced as a treatment option to DH. Similar to fluoride, nanohydroxyapatite also closes the dentinal tubules, which explains its mechanism of work. Nanohydroxyapatite had longer duration effect than that of fluoride, however.

In the current study, nanohydroxyapatite group completely relieved from severe pain, and the majority of patient had either mild or no pain at the end of the study. As it resembles the composition of dental tissues; it is a biocompatible material [24]. The statistical significances between nanohydroxyapatite and fluoride and between nanohydroxyapatite and placebo after one month of treatment, illuminate the effectiveness of nanohydroxyapatite in treating DH.

Our findings are in consistent with that of Wang et al. [25], where the efficiency of nanohydroxyapatite material was effective in reducing DH after one month of treatment. However, Allen et al. [26] reported better improvement with nanohydroxyapatite than that of the current study. This may be attributed to the different form of the material used in their study. Allen et al. used toothpaste several times a day, whereas we used gel one time.

Fluoride was first proposed as desensitizing agent by Lukomsky, who suggested that it forms an effective barrier and results in desensitization of dentine when applied to sensitive teeth [27].

In this study, the majority of patients in fluoride group who had either moderate or severe pain at the beginning of the study, had mild to moderate pain at the end of the study. Fewer patients were free of pain in the end of the study in this group in comparison to the nanohydroxyapatite group. This may be explained by the short-term effect of fluoride in comparison to nanohydroxyapatite. Fluoride binds with calcium from saliva to form calcium fluoride, which in turn precipitates in the inlet of dentine tubules. Nevertheless, this precipitation slowly dissolves in saliva [7]. Ipic et al, kielbassa et al, and Yilmaz et al. reported that fluoride had a positive effect on controlling DH, but its effect stays a short time [21,28,29]. Corona et al. compared the efficacy of 5% sodium fluoride and the low-level laser therapy in the reduction of DH, they followed up the patients for 30 days after treatment and the found that both treatments were effective [30].

Anyhow, both nanohydroxyapatite and fluoride provided effective treatment for DH, as they resulted in better results than that of sterile water. The reduction of DH with sterile water, which was used as a negative control in this study, may be attributed to the psychological impact and placebo effect, and that DH may be regress gradually with time.

Among different treatment options available for DH, nanohydroxyapatite material was used in this study. Other options require repeated application, or they are expensive, such as laser. Nano hydroxyapatite has similar composition to that of hard components of natural teeth. In addition, it penetrates the enamel and forms a matrix that attracts calcium and phosphate ions to surface of teeth which in turn closes dentine tubules and reduces the disturbance caused by DH after ultrasonic scaling. Furthermore, it is not an expensive option.

One of the strength points in this study is that the materials were applied one time only by the investigator. Nanohydroxyapatite was

more effective than fluoride in this regard, which require multiple applications. This means that patients are not required to use medications at home, especially that high-concentrated fluoride materials are considered toxic if swallowed; for example, by children.

On the other hand, one of the limitations of this study was the difference between groups in the baseline despite random allocation; however, the difference was about 1 unit as per the NRS, and was adjusted throughout regression analysis. Furthermore, the principal investigator applied the materials and evaluated DH before and after applying the different materials used in this study; therefore, it was not possible to blind the principal investigator from applying the application or collecting the DH data.

CONCLUSION

This randomized controlled trial showed that nanohydroxyapatite was more effective than fluoride, the commonly used material in this field, in reducing DH instantly after its application, though both materials had similar effects two-weeks and one-month post application.

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Conflict of Interest

The authors have no proprietary, financial, or other personal interest of any nature or kind in any product, service, and/or company that is presented in this article.

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Regulatory Statement

This study was conducted in accordance with all the provisions of the local human subjects oversight committee guidelines and policies of Declaration of Helsinki (The seven version; 2013). The approval code for this study is: 403-18/2016.

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