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ASSESSMENT OF THE POSTOPERATIVE HYPERSENSITIVITY FOLLOWING PARTIAL CARIES REMOVAL WITH APPLICATION OF NANOSILVER FLUORIDE IN DEEP CARIOUS LESIONS - A RANDOMIZED CONTROLLED CLINICAL TRIAL

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KEYWORDS

Deep caries, Hypersensitivity, Nanosilver, Partial caries removal, Silver diamine fluoride.

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ABSTRACT

Introduction: Postoperative sensitivity after a composite restoration is a common concern in dental procedures that causes discomfort in the patient and inconvenience to the professional, especially when dealing with deep caries lesions**. Aim:** The aim of the study was to prepare and synthesize a fluoride varnish containing silver nanoparticles, and to evaluate the postoperative hypersensitivity after partial caries removal with application of nanosilver fluoride, and silver diamine fluoride in deep caries. **Materials and methods:** Active deep carious dentinal lesions in permanent teeth from thirty-six participants were included in the study and randomly allocated according to the material used into three groups; nanosilver fluoride, silver diamine fluoride and control. Teeth were isolated by rubber dam, access was done followed by partial caries removal. For the pulpal floor, soft dentine was left to prevent pulp exposure. Silver diamine fluoride or nanosilver fluoride were applied, and all teeth were restored using composite resin restoration. Patients were recalled after 1 week, 3 and 6 months for follow up. Postoperative hypersensitivity was measured using a visual analog scale. **Results:** The results showed that there was no statistically significant difference in the reported hypersensitivity between the three study groups at the three measured time points. **Conclusion:** It may be concluded within the scope of this study the postoperative hypersensitivity was not affected by placement of different lining material used in the study after partial removal of caries.

INTRODUCTION

Short, acute pain is a hallmark of dental hypersensitivity to heat and chemical stimulation. Brannstrom's hydrodynamic theory is the main mechanism explaining the dentinal hypersensitivity, according to this notion, stimulation like cold or friction on open dentinal tubules causes a fluid flow that might lead to pain [(1)]. Post-operative hypersensitivity is influenced by numerous factors including the cavity depth, remaining dentin thickness, caries removal technique and whether or not a cavity liner was used [(2)]. Pulpal injury can result from desiccation and overheating[(3)]. Additionally, pathogens that were left behind or that entered the dentin as a result of microleakage may infiltrate and affect the pulpal tissues beneath restorations[(4)].

Postoperative hypersensitivity is characterized as discomfort in a tooth that is related to chewing or that is sensitive to hot, cold, and sweet stimuli one week or more following the removal of caries and restoration of the tooth[5]. While pain on mastication is thought to be a type of postoperative sensitivity caused by shrinkage due to polymerization, gaps between the restoration and dentin that fill with fluid, during mastication the restoration and tooth deform causing the built-up fluid to be released into the dentin tubules, thus resulting in hypersensitivity[6]. Pain with clenching only typically indicates a restoration in hyper occlusion[7]. Measurement strategies for postoperative hypersensitivity have not all been consistent as it is frequently considered a secondary topic of research, initially assessing restorative material and placement techniques [6].

Silver nanoparticles have withdrawn attention in the latest years due to their antibacterial potential. Nanoparticles can be synthesized utilizing physical, chemical, or biological processes. Chemical synthesis of nanoparticles offers advantages like simplicity of manufacture, cheap cost, and high yield. Particle characterization is crucial after synthesis since its physicochemical qualities might greatly affect biological properties.

The aim of the study was to prepare and synthesize a fluoride varnish containing silver nanoparticles and evaluate the postoperative hypersensitivity after partial caries removal and application of nanosilver fluoride and silver diamine fluoride in management of deep carious lesions.

MATERIALS AND METHODS

Silver nanoparticles synthesis in powder form

Drop by drop, 25ml of transparent silver nitrate solution was added to a freshly produced aqueous solution of Sodium Hypoboride at 60 °C for 30 minutes in the dark. The pH of the mixed solution was set at 11 along with increasing the temperature to 90 °C and continuous stirring was performed for 30 minutes. It was set aside to cool to room temperature. The nanoparticle solution was centrifuged before drying at 50 °C to generate a dark greyish powder with very small particles [8].

Characterization of silver nanoparticles

Ultraviolet-visible absorption spectroscopy and a transmission electron microscope (TEM) were used to characterize the silver nanoparticles generated. Images were captured on the microscope using a Gatan (DualVision 600t CCD) camera and analyzed with Gatan (Digital Micrograph Version 3.11.1) [9].

Preparation of 5% silver nanoparticles in fluoride varnish (nanosilver fluoride)

In a brown light proof container, 0.5 grammes of silver nano-particle powder were combined with ten milliliters of slow release (22,600 ppm) sodium fluoride varnish (FLUORITOPTM-SR) and forcefully agitated by vortex at low speed for 30 seconds to obtain uniform particle dispersion[8].

Sample size calculation and trial design

Power analysis was used to calculate the total sample size for a Chi-square test comparing three groups. The effect size (w) was 0.75, with an alpha level of 0.05 (5%) and a beta level of 0.10 (10%), resulting in a power of 90%; the minimum projected sample size was 30 participants. To account for a 20% dropout rate, the number of individuals was raised to 36, resulting in 12 subjects in each group. G*Power Version 3.1.9.2 was used to calculate sample size.

Ethical approval

This trial was conducted on 36 participants ranging in age from 18 to 50 years, with the agreement of the Research Ethical Committee (REC) of the Faculty of Dentistry Suez Canal University (approved number 226/2019). Subjects were chosen from outpatient clinics at Suez Canal University's Faculty of Dentistry. The study protocol was submitted to the US National Institute of Health protocol registry (ClinicalTrials.gov NCT05231330). The Consolidated Standards of Reporting Trials (CONSORT) were used to report this study.

Inclusion and exclusion criteria

Medically free patients between 18-50 years old having vital lower first and second molars with class I primary deep carious lesions, no widening in the periodontal ligaments, pain, mobility, or sensitivity to percussion. Medically compromised participants, recalcitrant patients or pregnant women, and allergic people were also excluded. Teeth with irreversible pulpitis, pulp necrosis, periapical or periodontal diseases were excluded.

Grouping and randomization of patients

Thirty-six participants were equally and randomly allocated into three groups according to the tested material; nanosilver fluoride , silver diamine fluoride and a control group (no material used). A co-investigator utilized computer software to construct a random sequence. The operator set up opaque envelopes holding folded numbered sheets to be dragged by the participants. The patients were unaware of their therapy group. The research groups remained anonymous at the end of the study through the statistician's evaluation.

Diagnostic procedures

A thorough medical as well as dental history was taken from each patient and then recorded. Digital periapical and bitewing radiographs (EzSensor Classic, Vatec, Korea) were taken for each tooth by the same X-ray machine (Xgenus®, De Götzen, Italy). Included teeth were dried then tested with a cold test using EndoIce (Hygenic Endo-Ice, Coltene Whaledent, Cuyahoga Falls, OH) and electric pulp tester (Denjoy DY310, Denjoy, Henan, China).

Tooth isolation was performed, access through the cavitated enamel were obtained when necessary. Following the International Caries Consensus Collaboration latest guidelines[10], selective caries removal to soft dentine strategy was performed using hardness criteria. A sterile tungsten carbide bur (#245 bur, 0.8 mm in diameter and 0.8 mm in length) was used to remove all caries from hard dentine on the cavity's periphery walls. Soft dentine was removed using hand excavator from the pulpal floor until it reached a level that would expose the pulp.

The cavity was cleaned with abundant water spray to remove any debris before drying with compressed air stream. For the nanosilver fluoride group; the micro brush bending and dipping into nanosilver fluoride solution and pressing against the wall of the plastic dappen dish to remove excess liquid before application. Excess material was removed using gauze, followed by a moderate flow of compressed air until the medication was dry, and then allowed to dry for two minutes. For the silver diamine fluoride group, the cavity was cleansed thoroughly with water spray, dried gently with compressed air, and silver diamine fluoride was applied directly to the carious tooth surface with a microbrush according to the instructions provided by the manufacturer. Excess silver diamine fluoride was removed with gauze before applying a mild flow of compressed air until the medicine was

dry, which might take up to three minutes. For the control group, final restoration was directly carried out without placing any lining material.

For all subjects, selective etching of the enamel was carried out using a 35% phosphoric acid gel. A single coating of universal glue was then applied to the entire cavity preparation. Resin composite restorative was used to restore the cavities, the material was then incrementally packed, and light cured. Occlusion was checked and polishing was achieved. All of the participants were given postoperative instructions as well as oral hygiene suggestions to follow during the follow-up phase. Participants were encouraged to contact the lead investigator if they had any discomfort or had any complaints regarding the restoration**. Figure (1)** describes an illustration for the clinical steps.

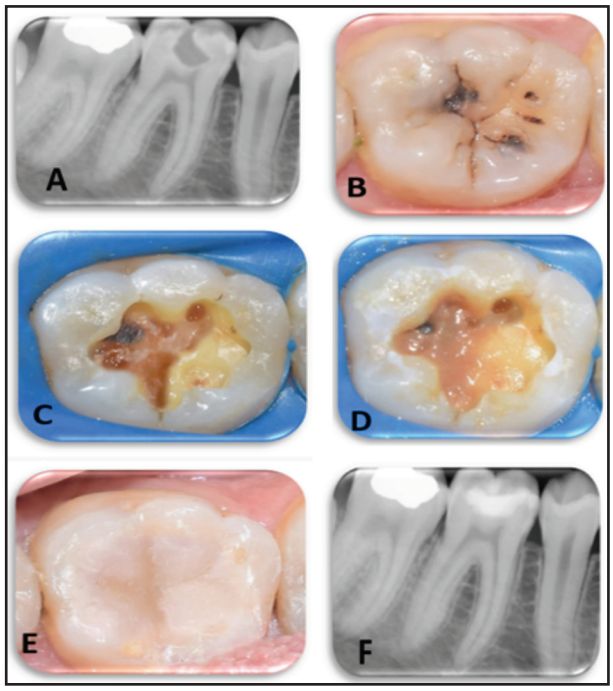

Fig. (1) Clinical procedures; preoperative radiograph (A), preoperative clinical photo (B), cavity preparation (C), application of nanosilver fluoride (D), composite restoration (E), postoperative radiograph (F).

Postoperative hypersensitivity assessment was done after 1 week, 3 and 6 months by asking the patient to score the pain on 11- point visual analog (VAS) scale. Recorded scores of 3 or higher was considered troublesome to the patient and reported as (present postoperative hypersensitivity) [7].

Statistical analysis

The categorical data were provided as frequency and percentage values and analysed using the chi-square test. The mean and standard deviation values of numerical data were analysed for normalcy using the Shapiro-Wilk test. The data were parametric, and one-way ANOVA was used to analyze them. Within all tests, the significance threshold was set at $p \leq 0.05$. R statistical analysis software version 4.1.1 for windows was used for the statistical analysis.

RESULTS

UV-visible absorption (UV-Vis) spectroscopy was utilized to assess the optical characteristics of silver nanoparticles. The absorption curve revealed that the peak was at 401.5 nm, and the greatest absorption peak was at twenty-four hours, due to silver particles surface plasmon resonance, confirming silver nanoparticles synthesis. TEM revealed that the silver particles were 45± 5 nm in size, spherical in form, with a smooth surface . ***Figure 2***

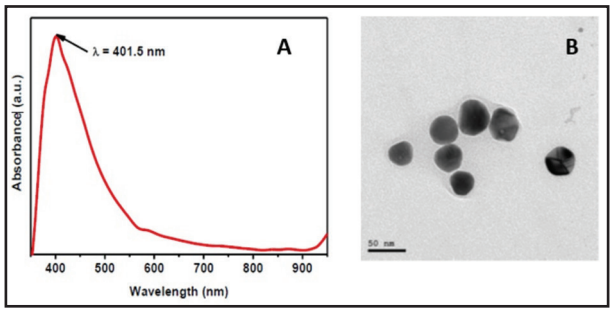

Fig. (2) The absorption rate curve of silver (A), TEM of silver nanoparticles. (B)

The study was conducted on 36 cases that were equally and randomly allocated to one of the three studied groups. There was no statistically significant difference between the baseline characteristics. **Table 1** .

Frequency and percentage values for reported postoperative hypersensitivity were presented in **table 2 and figure 3**. Regarding the effect of material (nanosilver fluoride, silver diamine fluoride or no material used), there was no statistically significant difference between the three groups at the three measured time points (1 week, 3 and 6 months).

Regarding the effect of time within each group, there was a decrease in the recorded postoperative hypersensitivity with time for the nanosilver fluoride and control group However this difference was not statistically significant. For the silver diamine fluoride group no change was recorded.

Table (1) *Summary of statistics of demographic data*.

Parameter			Control	Silver diamine fluoride	Nanosilver Fluoride	p-value
Sex	Male	N	5	8	7	0.589ns
		%	41.7%	66.7%	58.3%	
	Female	n	7	4	5	
		%	58.3%	33.3%	41.7%	
Age	Mean±SD		32.50±11.55	28.42±10.47	31.25±13.30	0.690ns

Table (2) *Frequency and percentage values for postoperative hypersensitivity for different groups*.

Group	1 week			3 months	6 months
Control	Present	N	4	3	3
		%	33%	25%	25%
	Absent	N	8	9	9
		%	66%	75%	75%
Silver diamine fluoride	Present	N	3	3	3
		%	25%	25%	25%
	Absent	N	9	9	9
		%	75%	75%	75%
Nanosilver fluoride	Present	N	2	2	1
		%	16%	16%	18%
	Absent	N	10	10	11
		%	83%	83%	92%
P-Value	0 .64118 Ns			0.85153 Ns	0.491959 Ns

Significant ($p \leq 0.05$), ns; non-significant ($p>0.05$)

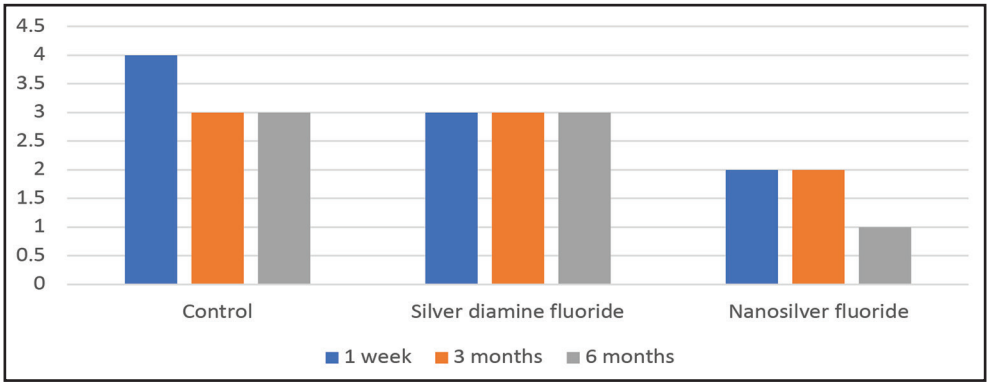

Fig. (3) Bar chart showing percentage values for postoperative hypersensitivity for different groups.

DISCUSSION

This study was designed to evaluate the postoperative hypersensitivity after partial caries removal of deep carious lesions with nanosilver fluoride in comparison to silver diamine fluoride . Silver diamine fluoride has an established history of clinical efficacy as a caries arresting medication for up to ten years of follow-up [11,12]. The concentration of silver diamine fluoride in the current research was 38%. Although silver diamine fluoride is available in different concentrations, the 38% solution appears to be the most effective in remineralization and caries preventio [13,14].

In recent years, silver nanoparticles have gotten a lot of interest in the disciplines of biological systems, living things, and medicine[15]. In the current investigation, nanosilver fluoride was the experimentally generated material for treating deep carious lesions[16,17] . The substance contained nanosilver for antibacterial properties and fluoride to improve remineralization[18]. In addition, to create a material with a similar composition as ready-made silver diamine fluoride but on a nanoscale in the hopes of improving its cariostatic function and eliminating the downsides of black staining produced by silver in its molecular form and without ammonia in order to avoid the unpleasant taste[19].

Characterization is a key phase in the development of Silver nanoparticles -containing materials (20). UV visible spectroscopy was used to characterize the synthesized Silver nanoparticles, which has been demonstrated to be a good and substantial approach for metal nanoparticles examination. The UV absorption spectral measurement was performed to monitor and validate the reduction of silver ions to Silver nanoparticles. The particle size and shape were visualized using TEM. The weight dilution procedure published by **Haghgoo *et al***. in 2014 was used to prepare 5% nanosilver fluoride[18].

While dyes can reduce visual and tactile subjective sensations, they are less specific to caries, causing excessive loss of perfectly healthy tooth structure and increasing the risk of mechanical pulp exposures[20,21].

To provide mechanical strength, wear resistance, and enhanced aesthetics and function, definitive restoration is essential. Furthermore, dental pulp healing is directly related to the ability of both the dressing and the definitive restorative material to provide a biological seal against both immediate and

long-term microleakage along the entire restoration interface, rather than just the alleged stimulatory effect of a specific type of medication[23].

Despite the fact that post restoration hypersensitivity and tooth vitality have been listed among the FDI biological properties of ranking restorations, controversially postoperative hypersensitivity is frequently a secondary topic of research primarily assessing restorative materials and implantation procedures, this resulted in lack of uniform assessment approaches[24] .

The result of this study showed that for the nanosilver fluoride and control group there was a decrease in the hypersensitivity over time, while for the silver diamine fluoride group there was no difference in the recorded hypersensitivity at the measured time points, however, this was not statistically significant. There are few studies with which to compare the present investigation, which focuses on short-term postoperative hypersensitivity[25]. However, the findings of this study are consistent with the findings of several studies that have shown that postoperative hypersensitivity can be linked to a variety of factors such as the size of the cavities, the specific type of occlusion of the patient, and the minor variation in the pulp response. It was determined that the type of restoration or the use of a lining material had no effect on postoperative hypersensitivity and pulpal response. The caries removal procedure might be a key element in preserving pulp vitality[26-28].

There are many causes for the higher incidence of postoperative sensitivity in deep cavities. One factor contributing to polymerization shrinkage and shrinkage stress is the big cavity design in posterior teeth, which calls for a larger bulk of composite for restoration[28,29]. Additionally, the decreasing thickness of the remnant dentin exacerbates the postoperative sensitivity since the dentin tubules density and permeability increase with cavity depth[30].

Previous research indicated that postoperative hypersensitivity following deep caries removal in posterior teeth treated with resin composite restorations intensified with cavity depth and was unaffected by the addition of lining layers underneath the restoration. Furthermore, Wegehaupt et colleagues discovered that the presence of discomfort or hypersensitivity is unrelated to the residual dentin thickness, the use of a lining, or the restorative system[27]. Their findings are consistent with previous research that found that even a thin layer of residual dentin can shield the pulp from both material and bonding system toxicity, allowing diverse restorative materials or adhesives to have little effect on the pulp tissue[31,32].

It could be concluded that the postoperative hypersensitivity was not affected by placement of a lining material after partial removal of caries. Visual Analog Scale can still be considered reliable, simple and fast method for assessment of hypersensitivity[33] .

The current investigation was done over a 6-month period, which was limited by the availability of subjects for recalls. A longer clinical trial would have offered a broader viewpoint and more relevant results. Furthermore, it would have enabled for a longer-term assessment of the destiny of residual caries. However, regardless of the clinical indications and symptoms suggesting the pulp's vitality, there is no absolute dependable relationship between the clinical signs and symptoms and the pulp's real histological condition. Furthermore, there is a dearth of convincing information demonstrating the fate of left-over caries left at the cavity's depth after partial caries removal[34]. Further studies are needed to evaluate the long-term stability and the long-term effects of silver nanoparticles.

CONCLUSION

It may be concluded within the scope of the study the postoperative hypersensitivity was not affected by placement of different lining material used in the study after partial removal of caries.

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