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## Original Research Article

# Clinical and radiographic evaluation of deep occlusal carious molars treated with partial caries removal with and without using silver diamine fluoride (SDF) + Potassium iodide (KI) prior to resin composite restoration: A randomized clinical trial

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## ABSTRACT

**Background:** Dental caries is considered the most widespread human disease. Caries arrest therapy is now being marketed as a component of the essential dental care regimen. Researchers and dental clinicians are paying close attention to silver diamine fluoride (SDF), one of the antibacterial agents, for its ability to stop active caries.

**Aim and Objective:** This study aimed to evaluate the effect of SDF+KI in maintaining pulp health, dentin bridge formation and remineralization after partial caries removal in permanent teeth that were evaluated clinically and radiographically after different follow-up periods.

**Materials and Methods:** Eighty teeth having deep occlusal carious lesions from 70 participants between the age 18-50 years were randomly divided into two groups: Group 1 (n= 40) using 38 %SDF+KI, while Group 2 (n= 40) using Resin Modified Glass Ionomer Cement (RMGIC). Soft deep caries was removed by low-speed handpiece and spoon excavators, then the teeth were evaluated radiographically. The teeth were evaluated at baseline and were compared at 6,12 months after the application to assess the vitality of the pulp, postoperative pain, dentin bridge formation and remineralization by using intraoral periapical radiograph using Diagora TM Optime and pixel grey values were measured using Diagora for window software.

**Result:** There was no statistically significant difference between the two groups in success rate and remineralization after a 6,12-month follow-up period ( $P \leq 0.05$ ). Regarding the dentin bridge formation, the SDF +KI showed better results, but there wasn't a significant difference between the two groups.

**Conclusion:** With or without 38% SDF+ KI application, the glass ionomer had remineralization potentials on the carious dentine and tertiary dentine formation. SDF gave better dentin bridge formation, indicating a good future in caries arrest.

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## 1. Introduction

The biological caries management philosophy has changed from the traditional surgical approach to a minimally invasive technique. A minimally invasive procedure

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involves Partial caries removal (PCR) and stepwise removal techniques that reduce the pulp exposure risk where permanent teeth with deep dentin caries treated with either method (Partial caries removal or stepwise removal) have a high likelihood of survival beyond two years.<sup>1</sup> Moreover, partial caries removal to the soft dentin has demonstrated effectiveness in microbiological, histological, biochemical and clinical outcomes.<sup>2</sup>

The superficial soft and demineralized dentin typically needs to be removed since it cannot be remineralized and collagen is exposed because of the action of acids produced by bacteria. On the other hand, the affected layer, deeper dentin, still maintains its structural integrity.<sup>2</sup>

In clinical situations, it is challenging to differentiate between affected dentin and infected dentin. Therefore, some infected dentin may remain after cavity preparation and residual bacteria may increase in the smear layer and dentinal tubules of the cavity-causing pulp irritation, secondary caries and restoration failure over time. Continuing efforts are being made to improve remineralization and find other preventive or reparative strategies for non-cavitated and cavitated carious lesions.<sup>3</sup> Most currently available direct restorative materials neither provide adequate seals nor prevent leakage for a sufficiently long period.<sup>4</sup>

Glass-ionomer cement (GIC) materials can bond chemically to tooth tissues in addition to having acceptable biocompatibility, antibacterial properties and fluoride release making it a preferred lining material in cases of incomplete caries removal technique. However, some studies showed that the fluoride released by GIC would only be effective in preventing the progression of incipient carious lesions, which does not apply to lesions involving dentin.<sup>5</sup>

To solve this issue, there were recommendations to use cavity disinfectants such as chlorhexidine and sodium hypochlorite solutions, dental bonding agents with antimicrobial activity, antibiotics, laser and ozone on the defective dentin before the restoration. There is a lot of debate regarding the use of silver-containing strategies for caries control, concentrating on the role of silver either alone (nanoparticles) or in combination with fluoride (e.g., silver diamine fluoride) as antibacterial and remineralizing agents helping in dentin caries arrest.<sup>4</sup>

SDF at a concentration of 38%, contains 44,800 ppm fluoride. It has been shown that SDF ( $\text{Ag}(\text{NH}_3)_2\text{F}$ ) reacts with hydroxyapatite (HA) of the tooth to release calcium fluoride ( $\text{CaF}_2$ ) and silver phosphate ( $\text{Ag}_3\text{PO}_4$ ), resulting in the hardening of affected dentin. However, a significant disadvantage of SDF is black staining of teeth which can cause aesthetic concerns. A way that has been suggested for managing this problem is to apply a saturated solution of potassium iodide (KI) immediately after SDF application.<sup>6</sup> It was recommended that discoloration of the carious lesion

could be avoided while the caries arresting effect of SDF is not changed.<sup>7</sup>

Riva Star (SDI, Bayswater, Australia) is the only commercial product of 38% SDF + KI. It has two colored capsules; a silver capsule containing 38% SDF and a green capsule with saturated potassium iodide (KI) solution, which is claimed to mitigate the black staining of arrested carious lesions.<sup>6,7</sup>

The literature supports 38% SDF as the optimal concentration to arrest carious lesions. Riva Star SDF is compatible with glass-ionomer cement (GIC) and may increase the resistance of GIC and composite restorations to secondary caries.<sup>8</sup>

The purpose of the study was to evaluate the effect of SDF+ KI in maintaining pulp health, dentin bridge formation and caries remineralization (Mineral density) after partial caries removal in permanent teeth with deep occlusal carious lesions clinically and radiographically. The null hypothesis of this study was that there is no difference clinically and radiographically in occlusal carious molars treated with partial caries removal with or without using silver diamine fluoride (SDF+ KI) prior to resin composite restoration.

## 2. Materials and Methods

The current study protocol was registered in the ([www.clinicaltrials.gov](http://www.clinicaltrials.gov)) database with the unique identification number NCT04561934. All procedures performed in this study involving human participants followed the ethical standards of the Research Ethics Committee. The study was conducted out of clinical patients in the conservative department, Faculty of Dentistry, Future University. The researcher was responsible for all activities associated with conducting a research project, including explaining and performing the procedures to them. After explaining all the steps and hazards to the recruited participants they signed the consent form.

### 2.1. Study design and sample size calculation

The study design in this investigation was a randomized controlled clinical trial design; with parallel, two arms, superiority trial and allocation ratio of 1:1.

A power analysis was designed to have adequate power to apply a 2-sided statistical test of the research hypothesis (null hypothesis) that the application of sodium diamine fluoride will have the same clinical performance as the resin composite restoration in the preservation of pulp vitality of permanent molars undergoing partial caries removal. According to the results of Labib et al.<sup>1</sup> the probability of success of resin composite (comparator) was (0.894). If the estimated 45 probability of success of PRF was (0.60) with a 29% clinical difference. By adopting an alpha ( $\alpha$ ) level of 0.05 (5%), power=80%. The predicted sample size (n) was

a total of 68 (34 per group) sample size was increased by (40) for each group. Sample size calculation was performed using G\*Power 3.1.9.2 using the Z test.

## 2.2. Eligibility criteria

Participants between the ages of 18-50 years were chosen for this study. The participants who had any systemic disease or severe medical complications and periodontal problems were excluded.

Teeth with active occlusal carious lesions at risk of pulp exposure during complete excavation according to ICDAS II in upper or lower molars were included. Eligible scores were codes 4, 5 and 6 (permanent carious lesion involving more than half of the entire dentin thickness as determined radiographically) with signs and symptoms indicative of pulp vitality. Teeth with spontaneous pain or sensitivity to percussion, periodontal lesions, sinus opening, mobility and internal or external root resorption were excluded. Also, teeth were excluded if the radiographic examination revealed interrupted or broken lamina dura widened periodontal ligament space or periapical radiolucency.

## 2.3. Randomization and blinding

Eighty carious lesions in 70 participants were chosen in this study by using computer-generated randomization (www.randomization.com), the participants who fulfilled the eligibility criteria were allocated randomly into two groups with a 1:1 allocation ratio. The sequentially generated numbers were placed in opaque envelopes until the time of intervention when each participant was asked to select an envelope that determined his/her group for future intervention. Participants with more than one tooth assigned for this study chose two envelopes to assign each tooth to the randomized group to have the same fair chance for each tooth, either both the same treatment or different treatments. The patients and assessors who carried out the radiographic assessment were blinded to the treatment group. Finally, the treatment results were assessed blindly by a statistician.

## 2.4. Cavity preparation

All operative procedures were performed with rubber dam isolation. A high-speed handpiece under water coolant and No. #245 0.8 mm in diameter and 1.6 mm in length (Komet Dental Gebr brasseler GmbH & Co lemgo, Germany) were used to remove the occlusal enamel, allowing access to restricted carious lesions beyond the dentin-enamel junction and obtaining outline form. Then complete caries excavation was performed in the cavity except at the cavity pulpal floor where partial caries removal was performed.<sup>1</sup> The partial caries removal was performed using a sharp sterile excavator carefully, the softer friable necrotic superficial carious dentin on the cavity floor was removed with the excavator without exerting force or

pressure on the floor of the cavity until a slightly moist and reasonably leathery dentin was reached which showed slight resistance to excavation after that the wall of the cavity were finished using yellow coated finishing stone.<sup>9</sup>

## 2.5. Restorative procedures

In group 1, Riva star SDF was applied over the entire dentin floor in two steps. In the first step, the silver capsule solution was applied using the silver brush provided. Then the second step; the green capsule solution was applied in a generous amount immediately after applying the silver capsule solution at the same treated site until the treated surface color changed from creamy white to clear. Then, after one minute, Riva star SDF was blotted and dried with a brush.

Then, the cavity was lined with a liquid paste, RMGIC liner (Fuji Lining LC Paste Pak; GC, Tokyo, Japan) was applied at 0.5–1 mm thickness over the entire dentin floor. First, we inserted the paste pak into the dispenser then twisted it into the position, later the desired amount of material was dispensed into the cavity. Mixed with a spatula for 10 seconds. The paste pak dispensing system gave a 1.0:1.1 mix ratio which was constant in all the applications followed by light-curing for 20 seconds using an LED light-curing device (Elipar™ Deep Cure, 3M ESPE) of 1470 mw/cm<sup>2</sup> light intensity 15 seconds.

Bonding procedure selective enamel etching was done with phosphoric acid for 15 sec rinsed for 30 seconds and gently air dried, then the self-etching adhesive (Clearfil SE Bond; Kuraray Medical, Okayama, Japan) was applied according to manufacturer instruction. First, the primer application was done and left for 20 sec with no rinsing and dried with mild airflow only. Then the bond was applied and evenly distributed with mild airflow and light cured for 10 seconds using the same LED curing light. Application of composite 3M filtek Z350 (Filtek Z350 XT, 3M ESPE) was then done in increments by (Nova Instrument Gold plated Composite Plastic HF-PFI179), then light curing for every increment was done for 20 sec and finally finished and polished using the finishing and polishing instruments.<sup>10</sup>

For group 2, the same procedure was performed without the application of 38% SDF+KI.

## 2.6. Occlusal adjustment

The occlusal contacts were adjusted using an articulating paper (Blue Red Combo 0.0028"/71 μm, Crosstex® International, USA). Finally, Finishing was done using fine grit yellow coded tapered with round and flame diamond stones (#368EF, #852EF, Komet, USA) while polishing was done by rubber points (Kerr Corp., Orange, CA, USA) operated at low-speed contra-angle handpiece (NAC-EC, NSK, Japan) with a maximum speed 20,000 rpm under water coolant and minimal pressure.<sup>11</sup>

### 2.7. Radiographic examination

Digital periapical radiographs were taken at the Oral and Maxillofacial Radiology Clinic, Faculty of Dentistry, Future University. Standardized radiographs were performed immediately after the restoration (baseline) after 6 months and 12 months follow-up using a posterior parallel kit film holder (FPS 3000 film positioning system).

The customized acrylic bite block and the imaging plate were stabilized onto the film holder and all were inserted in the patient's mouth. The plastic aiming ring was fixed flush with the round end of the long cone then, the image plate was exposed.

Radiographic exposure was performed using the Dentsply Sirona Heliodent Plus with the following parameters: 70kVp, 7mA and exposure time 0.12sec. The exposure parameters were fixed for all patients at the baseline and during the follow-up. After radiographing the patient, the image plate was scanned by a digital scanner. Images were displayed on the computer monitor and analyzed using the Digora for Windows (DFW) 2.5 software program (Soredex-Finland).

### 2.8. Image analysis

For the assessment of the tertiary dentin formation 2 parallel lines were drawn, one connecting the pulp horns and one bypassing the deepest point of excavation and a vertical line between them was drawn to represent the dentine bridge thickness. After 6 and 12 months the same lines and distance were drawn again and the measurements of each follow-up were subtracted from the baseline measurement which indicated the length of dentin bridge that was formed along the follow-up periods. To standardize the same measured point in each tooth a line was drawn from the measuring point and cemento-enamel junction as a reference point.

While for assessment the remineralization. The density profile of the software was opened and the radiographic density was assessed in the form of a gray value ranging from 0-255. In the image, three short horizontal lines were placed along the remaining carious dentin (at its mesial, middle and distal ends). The density along each of these lines was recorded and the average density was calculated.

These procedures were done at the baseline and then repeated after six months and 12 months. To make sure that changes that occurred in the carious lesion were due to changes in mineral density and not due to any other condition a line of 2 mm length running parallel to the dentin-enamel junction and 0.5 mm away from it reaching the cemento-enamel junction was drawn and density along this line was measured at baseline, after 6 months and 12 months too. This acted as a control line; changes in density along this line were calculated, the follow-up value was divided by the baseline value and the resultant factor was multiplied by the density of the dentin in the cavity at

the follow-up period density along each of these lines was recorded.

### 2.9. Outcomes and outcome measures

The primary outcome of this clinical trial was success, expressed as a binary variable indicating whether the restored tooth maintained its pulp vitality and restoration integrity after 6 and 12 months, without the need for endodontic or restorative treatment or extraction. Success was evaluated by a positive response to cold pulp testing using refrigerant spray (Hygenic Endo-Ice; Coltene, Ohio, USA), absence of spontaneous pain, no tenderness to percussion, absence of sinus tracts or swelling and absence of periapical radiolucency as determined by periapical radiographs.<sup>1</sup> If at least one of these signs/symptoms was detected, indicating irreversible pulpitis or pulp necrosis, failure was defined. Teeth that had been endodontically or restoratively treated by another healthcare facility or by another dentist were considered a failure too.

If failures occurred, patients were referred for in-house retreatment. Endodontic retreatment was performed by manual instrumentation and lateral condensation obturation.<sup>1</sup>

The secondary (dentin bridge formation) and tertiary outcomes (remineralization) were evaluated by digital radiographs taken with standardized exposure parameters by a single operator.<sup>11</sup>

Assessment of clinical and radiographic criteria was performed by two blinded, calibrated outcome assessors for each tooth.

Statistical analysis Data was analyzed using IBM SPSS advanced statistics (Statistical Package for Social Sciences), version 21 (SPSS Inc., Chicago, IL). Numerical data was described as mean and standard deviation or median and range. Categorical data was explored for normality using the Kolmogorov-Smirnov test and the Shapiro-Wilk test. Comparison between two groups for normally distributed numeric variables was done by the Mann-Whitney test. Comparison between categorical variables was performed using the chi-square test. A p-value less than or equal to 0.05 was considered statistically significant. All tests were two-tailed.

## 3. Results

This study was conducted on (70) patients; 60 patients had 1 deep carious lesion and 10 patients had 2 deep carious lesions, resulting in 80 teeth that were randomly assigned to either the intervention or the comparator groups (n=40). After 12 months 65 participants completed the follow-up with a 96 % retention rate.

Results of the current study revealed that for the clinical success of the teeth, Kaplan-Meier analysis was used to obtain survival curves, a comparison of success curves

was performed using the Logrank test and there was no statistically significant difference at baseline and 12 months between group 1 and group 2 ( $P = 1.0000$  and  $P = 0.6942$ ) respectively. (Table 1)

The results of dentin bridge formation in radiographic assessment revealed that there was no statistically significant difference between group 1 and group 2 at baseline, 6 months and 12 months. Dentin bridge increased after 12 months within group 1 ( $0.06 \pm 0.68$  mm), while within group 2 dentin bridge decreased after 12 months ( $-0.1 \pm 0.46$  mm) (Table 2).

The results for Caries remineralization in radiographic assessment revealed that there was no statistically significant difference at baseline. In 6 and 12 months in the caries remineralization between group 1 and group 2 ( $P = 0.7184$ ,  $P = 0.9257$  and  $P = 0.8108$ ) respectively. Intragroup comparisons within group 1 have shown statistically significant differences between different follow-up periods ( $P < 0.001$ ). Caries remineralization increased after 12 months within group 1 ( $6.76 \pm 12.55$  gray value), also within group 2 caries remineralization increased after 12 months ( $6.56 \pm 12.95$  gray value). The mean difference between both groups was  $0.82 \pm 12.83$  gray value after 12 months. (Table 3).

#### 4. Discussion

From a biological and cost perspective, preserving a healthy pulp is essential for maintaining its healing ability.<sup>12</sup> In dentistry, silver has been used for over a century as an antimicrobial agent because of its broad spectrum, low toxicity and absence of cross-spectrum bacterial resistance.<sup>13</sup>

The current study was conducted to explore the clinical success, ability of tertiary dentin formation and remineralization of silver diamine fluoride when applied to carious dentin treated with partial caries removal.

To standardize the cavity depth, all the selected carious lesions extending to the middle two-thirds of the dentin were detected by pre-operative radiograph using a digital X-ray machine with an imaging plate (digital sensor size 2; Dürr Dental, Bietigheim- Bissingen, Germany).<sup>11</sup>

To improve bonding quality and reduce post-operative hypersensitivity, rubber dam isolation was used. To facilitate cleaning and cavity disinfection prior to adhesion procedures as well as improve the operator's vision throughout the entire procedure, a rubber dam was applied during cavity preparation to improve vision and decrease as much as possible of bacterial invasion into the prepared cavity. Along with shielding the entire mouth cavity from any cutting objects and tool aspiration.<sup>14</sup>

After caries removal, the cavity was assessed by visual and tactile methods. Caries detector dyes weren't used due to their low specificity and ability to stain sound and circum-pulpal dentin leading to over-excavation and the

possibility of pulp exposure.<sup>15</sup>

In the present study, we used RMGIC liner (Fuji Lining LC Paste Pak; GC, Tokyo, Japan) in 0.5–1 mm thickness over the entire dentin floor; it is light-cured Glass Ionomer lining material used as a liner under composite resin owing to its strong bond to the tooth structure and composite resin that leads to reduce the marginal fractures and optimized marginal seal of the final restoration. It is a Paste-Paste formulation that bonds chemically to the tooth structure, creating a durable bacterium-proof seal for long-term protection of the dentin. According to the manufacturer, Fuji Lining LC paste has improved mechanical properties. It adheres chemically to dentin in moisture without conditioning and exhibits greater tensile bond strength than traditional glass ionomers.<sup>16</sup>

The final restoration was done with composite resin material by using a self-etching adhesive, which is a two-component, self-etch, light-cured bonding agent, that is intended for universal use for both direct and indirect restorations. Clearfil SE Bond® is one of the most frequently used adhesives in laboratory studies and is considered the gold standard in terms of bonding capability.<sup>17</sup>

There are several ways to calculate the remineralization of dentin. One of the methods is digital radiography which was used in the present study. Digital radiography is the most widely used method for detecting carious lesions and for evaluating measurable treatments<sup>18</sup> Radiographic analysis of a tooth subjected to partial dentin caries removal reveals a radiolucent area below the restoration. over time if remineralization occurs this was apparent radiographically as increased radio-opacity.

A study by Anani. H et al.,<sup>19</sup> reported that the average pixel grey value can be used to quantitatively monitor caries remineralization, this is based on remineralization being a slower process than demineralization.

Quantifying gray values can be done with the help of software like Adobe photoshop®, Digora, Image Tool® and VixWin®. Digora® radiography system was used to measure density with a sufficient degree of sensitivity. In the present study, Digora™ Optime PSP radiography system and Digora for Windows 2.5 (DFW 2.5) software were used for image acquisition and analysis respectively.<sup>11,19</sup>

To standardize the radiographic images obtained at baseline and after the follow-up period, a periapical paralleling technique with a film holder and custom-made bite block were used. Also, the exposure parameters were constant throughout the study. The customized bite block acted as an occlusal index which was placed on the film holder. With the help of this occlusal index, the PSP was relocated in the same position at baseline and follow-up period, eliminating the need to predetermine and position the patient's head therefore the same angle can be duplicated at subsequent visits as well.<sup>20</sup>

**Table 1:** Frequency and percentage of success rate for the intergroup comparison between materials for each follow-up and intragroup comparison within each material between different follow-up periods.

Follow-up	SDF		RMGIC		P value
	Yes	No	Yes	No	
Baseline	40 (100%)	0 (0%)	40 (100%)	0 (0%)	P = 1.0000
12 months	36 (90%)	4 (10%)	37 (92.5%)	3 (7.5%)	P = 0.6942
P value	P < 0.0001*		P < 0.0001*		RR = 1.3333

**Table 2:** Mean and standard deviation for dentin bridge formation for the intergroup comparison between materials within each follow-up and intragroup comparison within each material between different follow-up periods.

Follow-up	SDF		RMGIC		P value
	Mean	SD	Mean	SD	
Baseline	2.12	0.53	2.12a	0.46	P = 0.9489
6 months	2.11	0.45	2.03b	0.42	P = 0.4799
12 months	2.18	0.81	2.02b	0.46	P = 0.3529
P value	P = 0.252		P < 0.001*		Difference = -0.16±0.65

**Table 3:** Mean and standard deviation for caries remineralization for the intergroup comparison between materials within each follow-up and intragroup comparison within each material between different follow-up periods.

Follow-up	SDF		RMGIC		P value
	Mean	SD	Mean	SD	
Baseline	137.88 <sup>a</sup>	12.95	138.91 <sup>a</sup>	12.40	P = 0.7184
6 months	142.70 <sup>b</sup>	11.67	142.99 <sup>b</sup>	13.13	P = 0.9257
12 months	144.64 <sup>c</sup>	12.13	145.47 <sup>c</sup>	13.49	P = 0.8108
P value	P < 0.001*		P < 0.001*		Difference = 0.82±12.83

Regarding the results of the clinical survival of teeth, there was no statistically significant difference at baseline and 12 months between SDF and RMGIC materials (P = 1.0000 and P = 0.6942) respectively. The overall survival of both materials was assessed after 12 months, 4 teeth in the SDF group and 3 teeth in the RMGIC group failed after 12 months. There was 33% more risk for failure of SDF when compared to RMGIC after 12 months. This failure may be attributed to several factors; sometimes early periapical lesions are present that couldn't be detected radiographically and during restoration, there might be poor adaption of the restoration. In addition, the host factors may play a role in the process of secondary dentin formation. This result agreed with that found by previous studies.

On the other hand, Cleary et al.,<sup>21</sup> showed that SDF-treated lesions had more clinical failure compared to restorative treatment at 12 months. This disagreement can be explained as this study was done on primary teeth which had pulp horns of higher levels than in permanent teeth, which can cause more chances of clinical failure.

Regarding the remaining dentin thickness which accounts for the tertiary dentin formation, the results of the present study revealed no statistically significant in the remaining dentin bridge thickness after 12 months in both groups. The formed tertiary dentin was thicker in the SDF+KI group without a significant difference from the control. Dentin bridge increased after 12 months within SDF (0.06±0.68 mm), while within RMGIC dentin bridge

decreased after 12 months (-0.1±0.46 mm).

Results obtained with SDF can be explained by the fact that Silver Diamine Fluoride has significant antibacterial and gets precipitated in the biofilm. The reason can be a hardening of the tooth surface and/or inhibition of bacterial adherence. Microhardness of the carious dentin significantly increases the application of SDF.<sup>6</sup>

A highly mineralized dense layer forms on application of SDF and it is around 150 microns thick and mineral content is more when compared to affected dentin which is attributed to increased microhardness.

The SDF penetration throughout the entire thickness of carious lesions allows the antimicrobial effect, which is mainly derived from the silver element, to occur thoroughly. The exposure of reversible denatured collagen results in the precipitation of silver particles within demineralized carious dentin due to the presence of functional groups with a high affinity for silver ions, such as sulfur and nitrogen groups.<sup>14</sup> Silver phosphate (Ag<sub>3</sub>PO<sub>4</sub>), silver chloride (AgCl) and silver protein complexes have been identified as the reaction products of SDF with tooth tissue. Ag<sub>3</sub>PO<sub>4</sub> was a significant reaction product that could turn into other compounds and release phosphate ions to initiate apatite formation. The formation of silver salts increased the hardness of dentin and blocked dentinal tubules, thus reducing the irritation of the pulp-dentin complex.<sup>7,8</sup> This result agreed with that found by previous studies.<sup>7,20,22</sup>

Results obtained with RMGIC lining might be explained as RMGIC was developed to improve the physical, chemical and mechanical properties of GICs. The most common resin monomer is 2-hydroxyethyl methacrylate (HEMA), to which a photo-initiator, such as camphoroquinone, is added to allow a light-mediated setting. These materials undergo a dual-setting reaction consisting of the typical acid-base reaction of GICs and photopolymerization. However, the presence of resin monomers may affect the biological properties of RMGIC, especially their biocompatibility. This property decreases due to the cytotoxic effect of the resin component especially during the first 24 hours.<sup>23</sup>

The results of the caries remineralization in radiographic assessment revealed that there was no significant difference between the two groups. Caries remineralization increased after 12 months within SDF and RMGIC ( $6.76 \pm 12.55$  gray value and  $6.56 \pm 12.95$  gray value).

Results obtained with SDF can be explained by the fact that SDF at a concentration of 38% contains 44,800 p.p.m. fluoride. Its fluoride concentration is the highest among the fluoride agents available for dental use. Fluoride promotes the remineralization of hydroxyapatite in enamel and dentin. Also, the presence of fluoride increases the resistance of the dentin to the action of acid resulting in reduced penetration of acid into inner dentin. The remineralization action of SDF on dental caries could be attributed to its high concentration of fluoride.<sup>7</sup>

SDF contains diamine groups, which might enable the formation of  $\text{NH}_4\text{OH}$  (Ammonium-hydroxide), which has potentially promoted the optimum required pH and conditions for the mineral formation, enhanced antibacterial action and stabilizing silver ions in  $\text{AgNO}_3$  (Silver nitrate) solution, forming Silver diamine nitrate (SDN), which is expected to enhance the mineral precipitation. SDF [ $\text{Ag}(\text{NH}_3)_2\text{F}$ ] reacts with hydroxyapatite (HA) to release Calcium fluoride ( $\text{CaF}_2$ ) and Silver phosphate ( $\text{Ag}_3\text{PO}_4$ ), which arrest carious lesions.<sup>6,7</sup>

Fluoridated apatite has a lower solubility than fluoride-free apatite. Therefore, it promotes remineralization by precipitating calcium and phosphate ions as well as by increasing the precipitation of fluoride apatite above the critical pH. In addition, it can protect the organic matrix of dentin in two different ways. First, mineral crystals can protect collagen molecules by binding to calcium binding sites, resulting in less depleted collagen fibers. Second, fluoride ion is a powerful inhibitor of matrix metalloproteinases 2, 8 and 9. Fluoride has also been shown to inhibit cathepsins B and K which are required for MMP activation. Apart from the fluoride ion mechanism of action, SDF is an alkaline solution with PH 8,9. This circumstance promotes the association of covalent bonds between phosphorus ions and collagen molecules, which are required for collagen protection. This result agreed with that found by previous studies.<sup>19,22,24</sup>

Results obtained with RMGIC only, without any treatment, showed very close remineralization potentials. This could be due to the fluoride released by GIC restoration. Fluoride ions can promote remineralization, inhibit cariogenic bacterial growth and enhance the calcification of demineralized dentin after curettage.

The significant results of the increased dentin density after 12 months obtained with glass-ionomer in this study can be attributed to the superior and innovative formula of RMGIC liner (Fuji Lining LC Paste Pak, GC, Tokyo, Japan) as it releases high levels of fluoride.

This came in agreement with Pereira et al.,<sup>25</sup> who found resin-modified glass ionomer restoration as being sufficient with partial caries removal and no additional benefit from calcium hydroxide liner application.

Finally, it should be mentioned that many limitations were faced in this clinical study longer follow-up period is advised to evaluate the clinical performance of the used materials on restoration, also using multiple commercial types of Resin Modified Glass Ionomer to confirm their remineralization potentials.

Further randomized clinical trials are needed to show the clinically reasonable effect of SDF +KI in caries arrest in human subjects with longer follow-up periods and weigh its benefit versus cost.

## 5. Conclusions

Partial caries removal and Resin Modified Glass Ionomer with and without application of SDF+KI proved remineralization of the remaining carious dentin and tertiary dentin formation. RMGIC had a positive impact on the percentage of clinical success. Moreover, the addition of SDF+KI promoted supplementary remineralization and seems to be a promising agent helping in caries arrest.

## 6. Ethical Approval

This study was conducted after taking ethical approval with reference number 30-9-2020 from the Faculty of Dentistry, Cairo University (CREC).

## 7. Source of Funding

None.

## 8. Conflict of Interest

None.

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