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Original Article

Clinical Evaluation of Silver Diamine Fluoride Combined with Potassium Iodide Versus Silver Diamine Fluoride in the Management of Class I Carious Lesions Over a Period of 12 Months Follow-up: A Randomized Controlled Clinical Trial

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ABSTRACT

Aim: This clinical trial was carried out to assess the clinical efficacy of silver diamine fluoride with or without potassium iodide before high-viscosity glass ionomer restoration compared to high-viscosity glass ionomer restoration for treating deep class I carious lesions over a one-year follow-up period.

Subjects and methods: After partial caries removal, 42 deep class I cavities in permanent molars were allocated to one of the following groups: group 1, SDF+KI (Riva Star) (n=14); group 2, SDF (SDF, Riva Star step 1 only) (n=14); and both groups were followed by HVGI restoration (EQUIA Fil). Group 3, HVGI restorations (EQUIA Fil) (n=14). The restorations were assessed over a 12-month follow-up period using the FDI criteria. (postoperative hypersensitivity, radiographic examination, and patient's view).

Results: There were no significant differences among the three materials regarding postoperative hypersensitivity or radiographic findings ($P > 0.016$). However, there were statistically significant differences in the patients' views ($P < 0.016$). There was a 13-fold greater risk of unacceptable score 4 (clinically unsatisfactory) for the patients' views with the SDF compared to HVGI after 12 months ($P = 0.0712$).

Conclusion: Applying HVGI alone or after SDF with or without KI could treat dentine hypersensitivity in deep class I cavities after partial caries removal. Dentine treated with either SDF, SDF+KI, or HVGI could obtain successful radiographic outcomes with no signs of pulpal pathology. KI could be applied immediately after SDF to prevent black staining of the teeth and increase patient satisfaction.

Keywords: High-viscosity glass ionomer, partial caries removal, silver diamine fluoride, silver diamine fluoride with potassium iodide.

INTRODUCTION

Traditional caries management often involves removing all softened dentine, but this may not always be necessary **(Hoefler et al., 2016)**. This can lead to larger cavities, excessive loss of tooth structure, and pulpal exposure **(Schwendicke et al., 2018)**. Preserving healthy and remineralizable tissue is crucial for maintaining tooth vitality and healing potential **(Jasim et al., 2023)**. Deep caries is radiographic evidence of caries reaching the inner third or inner quarter of dentine and posing a risk of pulp exposure **(Bjorndal et al., 2019)**. Minimally invasive treatments have revolutionized restorative dentistry, including partial or stepwise caries removal **(Alyahya, 2023)**. Several systematic reviews and meta-analyses support treating deep caries lesions with a partial caries removal technique, resulting in better outcomes **(Schwendicke et al., 2013; Li et al., 2018; Barros et al., 2020; Figundio et al., 2023)**. However, leaving carious dentine may compromise restoration longevity because of mechanical and adhesive reasons **(Ricucci et al., 2020)**. Therefore, there is a risk of hypersensitivity, secondary caries, or clinical failure due to reinfection **(Rinsathon et al., 2023)**.

A modern and effective method for arresting and remineralizing dental caries involves the topical application of silver diamine fluoride (SDF) **(Nguyen et al., 2017)**. Since 2014, the FDA has recognized it as a dentine hypersensitivity agent with off-label use for caries arrest and prevention **(Horst et al., 2016)**. The ADA officially supported the use of SDF for caries management in 2020 **(Zheng et al., 2022)**. SDF-treated dentine maintains a reservoir of silver and fluoride **(Nelson et al., 2016)**. The silver ions in SDF are believed to hinder and eliminate cariogenic bacteria. Additionally, fluoride through SDF promotes remineralization **(Rajendra et al., 2017)**.

Although SDF is widely supported for its effectiveness and applicability, obstacles prevent its integration into common practice **(Seifo et al., 2020)**. The main adverse effect of SDF is its pronounced black staining of dental tissues **(Crystal et al., 2017)**. To minimize this, researchers suggest applying a concentrated potassium iodide (KI) solution after SDF treatment **(Miller et al., 2016)**, which may reduce discoloration while preserving SDF's caries-arresting effects **(Zhao et al., 2019)**. Glass ionomer cement, known for its excellent adhesion and fluoride release, is often preferred for restorations following partial caries removal **(Eslami et al., 2021)**.

To our knowledge, there are limited available data on SDF with or without KI for treating deep carious lesions in permanent teeth. The null hypothesis was that in deep class I carious lesions, there would be no difference in the clinical efficacy of SDF with or without KI before HVGI restoration compared to that of HVGI restoration.

SUBJECTS AND METHODS

Study design and trial registration

This randomized controlled clinical trial with parallel groups, three arms, and an equivalence framework. The participants were randomly assigned to three groups (n=14) according to the tested materials. The protocol of this study was registered on clinicaltrials.gov (ID: NCT05485272) on 3/8/2022. This clinical trial followed the 2010 CONSORT guidelines **(Schulz et al., 2010)**. Written consent was obtained from all participants. This study was conducted by a single operator at the Conservative Dentistry Clinic, Faculty of Dentistry, Cairo University.

Sample size calculation

The sample size was calculated based on a previous study by **Hatirli et al., 2021**, in which percentage of postoperative hypersensitivity success of high viscosity glass ionomer occlusal restorations was 100% after 12 months. By implementing a two tailed Z test for difference

between two independent proportions with an alpha level of 5% and a power of 80%. The minimum sample size needed was 12 per group to detect a difference of 40%. Sample size was increased by 20% to compensate for possible dropouts to reach 14 teeth per group, resulting in a total of 42 patients. Sample size was performed using G*Power version 3.1.9.2 for windows.

The eligibility criteria

The inclusion criteria for patients were as follows: 1) patients with deep class I carious lesions in molars, according to the ICDAS, scores (4 or 5); 2) adults males or females; 3) age: 18-40 years old; 4) co-operative patients, approving to participate in the study; 5) teeth planned to be restored should be vital and sensible to cold pulp test; and 6) digital periapical radiograph with paralleling technique extending to the inner 1/3 of the dentine. Patients were excluded if they were presented with 1) severe systemic diseases, allergies, or adverse medical histories; 2) pregnant female patients; 3) lack of compliance; 4) teeth diagnosed with irreversible pulpitis, non-vital, or shallow class I; or 5) radiographic examination revealed interrupted or broken lamina dura, or periapical radiolucency.

Randomization, allocation, and blinding

Participants were randomly assigned to one of three groups using simple randomization (1:42) through (https://www.random.org/). Each column of generated numbers corresponded to one of the interventions: Riva Star (SDF+KI), Silver Diamine Fluoride (SDF, step 1), or the comparator, EQUIA Fil (High-Viscosity Glass Ionomer). Randomization was concealed in opaque envelopes, opened by the primary investigator only at the time of the restorative intervention. While the operator was not blinded, participants, assessors, and statisticians were blinded to the assigned treatments. Examiners were prohibited from sharing information during the study.

Clinical procedures

Pulp vitality was assessed using a refrigerant spray (HygenicEndo-Ice; Coltene, USA). Standardized intraoral digital periapical radiographs were taken using the parallel technique at the Oral and Maxillofacial Radiology Clinic, Faculty of Dentistry, Cairo University, using (TPC Dental X-ray Sensor Film Positioner, Digora Optime DXR-50 001 digital imaging system, and size 2 Dürr Dental sensor). Local anesthesia (Articaine HCL 4%, Art Pharma Dent, Egypt) was administered, and the tooth was isolated with a rubber dam (Sanctuary, Malaysia). A no. #245 bur (MANI, Japan) and high-speed handpiece (W&H, Austria) were used to access the lesion and prepare the cavity, followed by partial caries removal with a sharp excavator (Dentsply® Maillefer, Switzerland) following the guidelines published by the ICCC, to avoid pulp exposure **(Schwendicke et al., 2016)**. The tooth was then assigned to one of three groups.

In the SDF+KI intervention group, a drop of Riva Star step 1 (SDF) was applied to the cavity using a microbrush. Subsequently, two drops of Riva Star step 2 (KI) were applied using a new microbrush. Initially, the cavity appeared creamy white, and the Step 2 solution was applied until it became clear. The reaction products were washed off and the cavity dried with oil-free compressed air. As for the SDF intervention group, the procedure involved applying Riva Star step 1 (SDF) as previously mentioned, then it was left to stand for 1 minute, then rinsed with water and dried.

For the comparator and restorative material, the HVGI (EQUIA Fil) capsule was triturated, the mixture was extruded directly into the prepared cavity, excess material was removed, and the contour was formed with a gold-plated applicator (LASCOD ZEFFRIO, Italy). After the initial setting, an EQUIA Coat (GC Corporation, Tokyo, Japan) was applied to the restoration surface and light cured using an

LED light curing unit (1000mW/cm2) for 20 seconds. Occlusion was checked for prematurities using articulating papers and patient sensibility. The finishing was performed by a high-speed handpiece with air/water coolant (W&H high-speed handpiece, Bürmoos, Austria) using superfine yellow ringed finishing flame diamond stone (MANI, INC, Japan). Finally, the restoration was rinsed, dried, and a second layer of EQUIA Coat was applied and light cured.

Outcome assessment

The restorations were examined at baseline (one week after the restoration) and three-month, six-month, and one-year follow-ups. The primary outcome of this study was the evaluation of biological property (postoperative hypersensitivity), while secondary outcomes included functional properties (radiographic examination and patient's view). All are evaluated according to the FDI criteria. A detailed description of the FDI criteria and scoring system is in Table 1 **(Hickel et al., 2010)**. Two experienced, blinded assessors conducted the clinical evaluations. In instances of disagreement in their assessments, the assessors discussed their findings to reach a consensus. If disagreements persisted, a third clinical assessor was consulted to resolve the conflict.

Statistical analysis

Data were analyzed using MedCalc software, version 19 for Windows (MedCalc Software Ltd., Ostend, Belgium). Categorical data were described as frequencies and percentages. Intragroup comparisons between interventions were performed using the chi-square test. Intragroup comparisons within each intervention were conducted using Cochran's Q and Friedman's tests. The normality of the continuous data was explored using the Kolmogorov-Smirnov test and Shapiro-Wilk test. Continuous data with a normal distribution were described using means and standard deviations. Intergroup comparisons were performed using one-way ANOVA followed by Tukey's post-hoc test. Intragroup comparisons between follow-up periods were conducted using repeated measures ANOVA followed by Tukey's post-hoc test. Relative risk was used to assess the clinical significance.

RESULTS

Fifty-one (51) patients were examined of which 42 fulfilled the inclusion criteria and were enrolled in the study (Fig. 1). The outcomes were not significantly impacted by age, gender, or arch distribution (Table 2). There were no significant differences among the three groups regarding postoperative hypersensitivity or radiographic findings ($P > 0.016$). However, there were statistically significant differences in the patients' views ($P < 0.016$). There was a 13-fold greater risk of unacceptable score 4 for the patients' views with the SDF compared to HVGI (EQUIA Fil) after 12 months ($P = 0.0712$).

Regarding postoperative hypersensitivity, comparing the three groups revealed no statistically significant differences within various follow-up periods (baseline, 3, 6, or 12 months). However, there were statistically significant differences between the follow-up periods within each group. After 12 months, there was no risk of unacceptable scores (4 or 5) in the three groups. Regarding the radiographic examination, no significant differences were observed among the three groups at any follow-up period (baseline, 3, 6, or 12 months). Additionally, after 12 months, there was no risk of unacceptable scores (4 or 5) in the three groups.

The study found a statistically significant difference in patients' views across the three groups at various follow-up intervals (baseline, 3, 6, and 12 months). However, no significant intragroup differences were found between the Riva Star and HVGI groups. In contrast, the SDF group showed significant differences over time. After 12 months, Riva Star and HVGI had no risk of unacceptable scores (4 or 5), while SDF had a 13-fold higher risk of scoring 4. Frequencies and percentages for postoperative hypersensitivity, patients' views, and radiographic examinations for the intergroup and intragroup comparisons within different follow-up periods are presented in Table 3

Criterion	Scores	Descriptions	Measuring Method
Biological Property;			
Postoperative hypersensitivity	**1. Clinically excellent/very good**	No hypersensitivity, normal vitality.	Patient interviewing
	2. Clinically good	Minor hypersensitivity for a limited period, normal vitality.	
	3, Clinically sufficient/satisfactory	3.1. Moderate hypersensitivity. 3.2. Delayed/mild sensitivity; no subjective complaints, no treatment needed.	
	4. Clinically unsatisfactory	4.1. Intense hypersensitivity. 4.2. Delayed with minor subjective symptoms. 4.3. No clinically detectable sensitivity. Intervention is necessary but not replacement.	
	5. Clinically poor	Intense, acute pulpitis or non-vital tooth. Endodontic treatment is necessary, and restoration has to be replaced.	
Functional Properties;			
Radiographic examination	**1. Clinically excellent/very good**	No pathology, harmonious transition between restoration and tooth.	Standardized periapical digital radiographs taken by parallel technique
	2. Clinically good	2.1. Acceptable material excess present. 2.2. Positive/negative step present at margin <150 μm.	
	3. Clinically sufficient/satisfactory	3.1. Marginal gap < 250 μm. 3.2. Negative steps visible < 250 μm. No adverse effects noticed. 3.3. Poor radiopacity of filling material.	
	4. Clinically unsatisfactory	4.1. Marginal gap >250 μm. 4.2. Material excess accessible but not removable. 4.3. Negative steps >250μm and reparable.	
	5. Clinically poor	5.1. Secondary caries, large gaps, large overhangs. 5.2. Apical pathology. 5.3. Fracture/loss of restoration or tooth.	
Patient's view	**1. Clinically excellent/very good**	Entirely satisfied with esthetics and function.	Patient interviewing
	2. Clinically good	2. Satisfied. 2.1. Esthetics. 2.2. Function, e.g., minor roughness.	
	3. Clinically sufficient/satisfactory	3. Minor criticism but no adverse clinical effects. 3.1. Esthetic shortcomings. 3.2. Some lack of chewing comfort. 3.3. Unpleasant treatment procedure.	
	4. Clinically unsatisfactory	4. Desire for improvement. 4.1. Esthetics. 4.2. Function, e.g., tongue irritation. Reshaping of anatomic form or refurbishing is possible.	
	5. Clinically poor	Completely dissatisfied and/or adverse effects, incl. pain.	

Table 1 (FDI) criterion, scores, descriptions, and measuring method for assessing dental restorations.

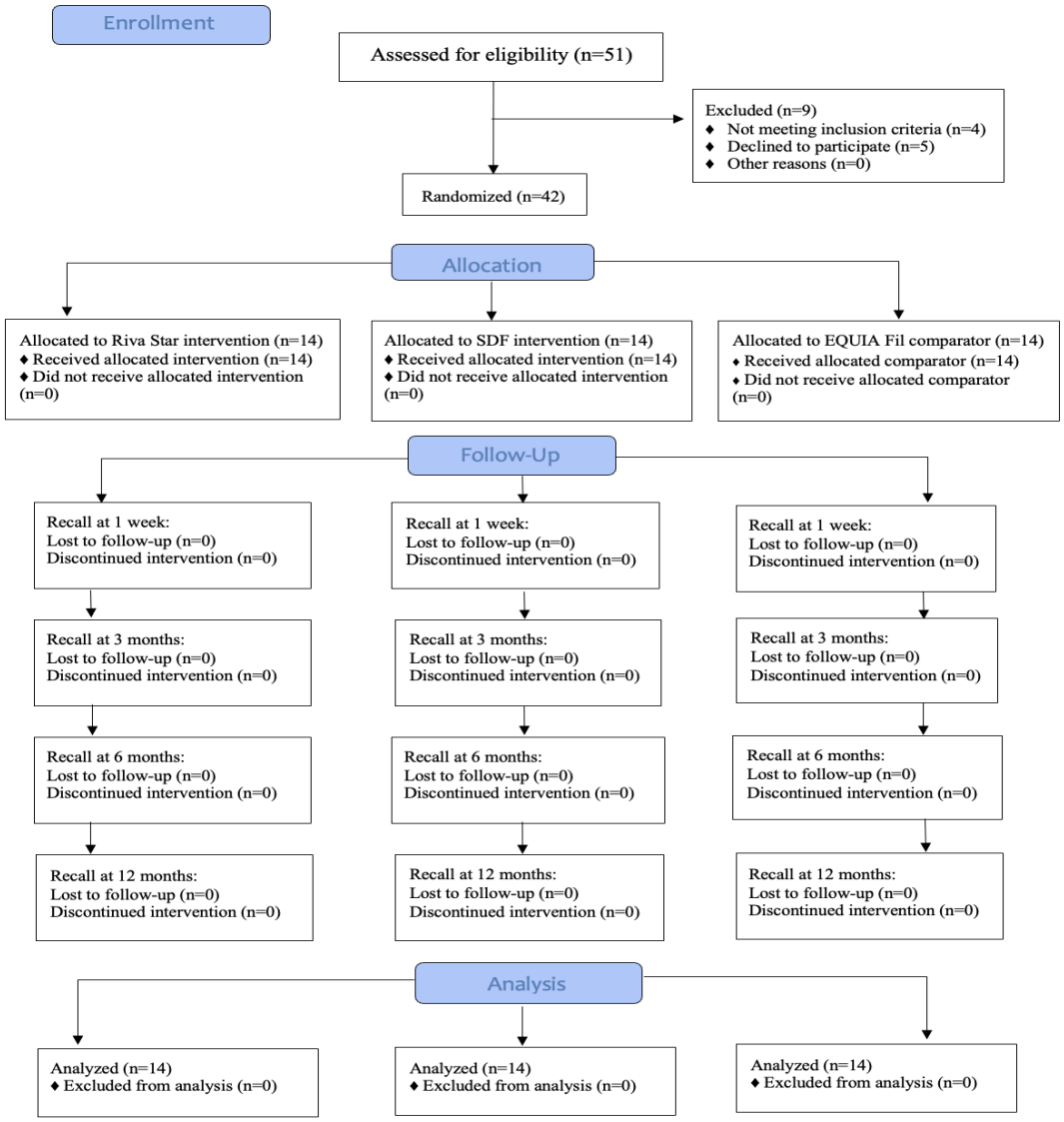

Figure 1 The flow chart of the study.

Table 2 Demographic distribution of study participants.

Group		Riva Star (n = 14)	SDF (n = 14)	HVGI (n = 14)	P value
Age Mean (SD)		25.85 (4.88)	28.4 (6.22)	27.92 (6.99)	0.503
Gender	**Males**	1 (7.1%)	1 (7.1%)	1 (7.1%)	1.0000
	Females	13 (92.9%)	13 (92.9%)	13 (92.9%)	
Arch	**Upper**	2 (14.3%)	1 (7.1%)	2 (14.3%)	0.9154
	Lower	12 (85.7%)	13 (92.9%)	12 (85.7%)	

Table 3 Frequencies and percentages for postoperative hypersensitivity, patients' views, and radiographic examinations for the intergroup comparisons within each follow-up and intragroup comparisons within each group between different follow-up periods

Postoperative hypersensitivity																
Follow-up	Riva star					SDF					HVGIC					P
	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
Baseline	3(21.4%)	8(57.2%)	3(21.4%)	0(0%)	0(0%)	4(28.6%)	7(50%)	3(21.4%)	0(0%)	0(0%)	3(21.4%)	8(57.2%)	3(21.4%)	0(0%)	0(0%)	0.99
3 months	7(50%)	7(50%)	0(0%)	0(0%)	0(0%)	10(71.4%)	4(28.6%)	0(0%)	0(0%)	0(0%)	6(42.9%)	6(42.9%)	2(14.3%)	0(0%)	0(0%)	0.20
6 months	13(92.9%)	1(7.1%)	0(0%)	0(0%)	0(0%)	13(92.9%)	1(7.1%)	0(0%)	0(0%)	0(0%)	10(71.4%)	3(21.4%)	1(7.1%)	0(0%)	0(0%)	0.39
12 months	11(78.6%)	3(21.4%)	0(0%)	0(0%)	0(0%)	12(85.7%)	2(14.3%)	0(0%)	0(0%)	0(0%)	`9(64.3%)	4(28.6%)	1(7.1%)	0(0%)	0(0%)	0.54
P value (friedman's)	P <0.00001					P <0.00001					P = 0.0002					
Patient's view																
Baseline	9(94.3%)	5(35.7%)	0(0%)	0(0%)	0(0%)	0(0%)	4(28.6%)	8(57.2%)	2(14.3%)	0(0%)	11(78.6%)	3(21.4%)	0(0%)	0(0%)	0(0%)	<0.0001
3 months	8(57.2%)	6(42.9%)	0(0%)	0(0%)	0(0%)	0(0%)	3(21.4%)	8(57.2%)	3(21.4%)	0(0%)	9(94.3%)	5(35.7%)	0(0%)	0(0%)	0(0%)	<0.0001
6 months	10(71.4%)	4(28.6%)	0(0%)	0(0%)	0(0%)	0(0%)	2(14.3%)	8(57.2%)	4(28.6%)	0(0%)	12(85.7%)	2(14.3%)	0(0%)	0(0%)	0(0%)	<0.0001
12 months	`9(64.3%)	4(28.6%)	1(7.1%)	0(0%)	0(0%)	0(0%)	0(0%)	8(57.2%)	6(42.9%)	0(0%)	10(71.4%)	4(28.6%)	0(0%)	0(0%)	0(0%)	<0.0001
P value (friedman's)	P = 0.30					P = 0.00025					P = 0.11					
Radiographic evaluation																
Baseline	14(100%)	0(0%)	0(0%)	0(0%)	0(0%)	14(100%)	0(0%)	0(0%)	0(0%)	0(0%)	14(100%)	0(0%)	0(0%)	0(0%)	0(0%)	1.00
3 months	13(92.9%)	1(7.1%)	0(0%)	0(0%)	0(0%)	12(85.7%)	2(14.3%)	0(0%)	0(0%)	0(0%)	13(92.9%)	1(7.1%)	0(0%)	0(0%)	0(0%)	0.76
6 months	11(78.6%)	3(21.4%)	0(0%)	0(0%)	0(0%)	10(71.4%)	4(28.6%)	0(0%)	0(0%)	0(0%)	12(85.7%)	2(14.3%)	0(0%)	0(0%)	0(0%)	0.65
12 months	10(71.4%)	4(28.6%)	0(0%)	0(0%)	0(0%)	10(71.4%)	3(21.4%)	1(7.1%)	0(0%)	0(0%)	11(78.6%)	3(21.4%)	0(0%)	0(0%)	0(0%)	0.69
P value (friedman's)	P = 0.03					P = 0.01					P = 0.11					

DISCUSSION

Based on the current study's findings, all restorations were evaluated after one year without any drop-outs, and the study participants (42) recorded a 100% retention rate. The outcomes were not significantly impacted by gender, age, or tooth distribution. The comparison of the three groups regarding postoperative hypersensitivity revealed no statistically significant differences among the various follow-up periods. However, we did observe statistically significant differences between the follow-up periods within each group. After 12 months, there was no risk of unacceptable scores of 4 or 5 in the three groups. These findings support those of **Abdulfattah et al., 2021**, who conducted a study to compare postoperative pain in primary molars following the application of 38% SDF before EQUIA Fil to EQUIA Fil restoration with partial caries removal. The patients were observed at 3 and 6 months; no pain was reported with either material. The efficacy of the EQUIA Fil was attributed to its antibacterial properties, which include the release of chemical components such as fluoride **(Craig et al., 2012)**.

Moreover, **(Permata et al., 2018)** concluded that using SDF+KI could treat dentine hypersensitivity. The efficacy of SDF was attributed to the product's constituents, such as silver and fluoride ions. Silver ions precipitate proteins in the dentinal tubules, while the fluoride ions react with free calcium ions to produce calcium fluoride deposits that effectively block the dentinal tubules **(Divyashree, 2021)**. Moreover, the reaction between SDF and KI may have led to the formation of silver iodide, which further reduced dentine tubule patency **(Zhao et al., 2017)**. However, the long-term effects of Riva Star or SDF were not evaluated in these studies.

Regarding the radiographic examination, there were no significant differences observed among the three groups at any time during the follow-up periods. Additionally, after 12 months, there was no risk of unacceptable scores of 4 or 5 in the three groups. These findings align with those of similar studies **(Patil et al., 2021; Baraka et al., 2022)**. They revealed that using SDF resulted in successful radiographic outcomes, arrested further caries progression, and did not cause adverse pulpal reactions when used for partial caries removal on dentine carious lesions. It is important to note that these studies were conducted on primary molars and had relatively short follow-up durations.

Furthermore**, (Shounia et al., 2017)** found no radiographic signs of pulpal pathology in permanent first molars among the SDF, SDF+KI, and RMGIC groups after a 12-month follow-up period. The efficacy of SDF in arresting dentine caries progression can be attributed to its mode of action **(Li et al., 2017)**. On the contrary, the results of this clinical trial disagree with those of **Zhao et al., 2018**, who reported that SDF and KI treatment inhibited the development of secondary root caries on GIC restorations but were less effective than SDF treatment alone. Also, **Li et al., 2016** reported that KI affected the efficacy of SDF in preventing secondary root caries. They claimed that applying KI decreased the amount of silver ions required for the antimicrobial properties of SDF in inhibiting caries progression. However, these studies specifically focused on root caries.

In terms of the patient's view, the study results showed a statistically significant difference among the three groups during different observation intervals. However, intragroup comparisons of the Riva Star and HVGI showed no significant differences between the different follow-up periods. In contrast, there was a statistically significant difference between the different follow-up periods in the SDF group. The study also revealed that after 12 months, Riva Star and HVGI did not pose a risk of unacceptable scores of 4 or 5. However, SDF had a significantly greater risk of scoring 4 than HVGI, with a 13-fold increase in risk

Patients tend to accept the shade provided by glass ionomers, particularly for nonobvious posterior teeth. Conversely, the risk of SDF causing dark staining of carious tissue and negatively impacting patients' views can be attributed to the reaction of silver with hydroxyapatite crystals that precipitate silver phosphate **(Kamble et al., 2021)**. However, KI can prevent discoloration by precipitating excess silver ions such as white silver iodide **(Patel et al., 2018)**. A study by **Aly et al., 2022** compared the efficacy of SDF and SDF/KI in terms of patient satisfaction and revealed that most patients were satisfied with both treatments due to their ease of application and lack of pain. This indicates that patients may be willing to compromise aesthetics for a less invasive approach.

After one year, the null hypothesis regarding postoperative hypersensitivity and radiographic examination could not be rejected, as there were no significant differences observed among the three groups. The only differences noted were in the patient's view, leading to the rejection of the null hypothesis for this outcome. The study had limitations, including a small sample size and a relatively short follow-up period. Additionally, we did not specifically consider confounding factors such as oral hygiene habits or snacking patterns. Despite these limitations, it provides a valuable foundation for further research. Notably, there were no instances of loss to follow-up or discontinuation of the intervention among the enrolled participants. This high level of participant retention enhances the study's internal validity and the credibility of its findings. To confirm the current results, further well-designed randomized controlled trials (RCTs) with larger sample sizes and extended follow-up periods are recommended. Additionally, using modified USPHS criteria in conjunction with FDI criteria is suggested to comprehensively compare material evaluation methods. Future clinical studies should also evaluate the effects of Riva Star (SDF+KI) or silver diamine fluoride (SDF) on resin composite restorations.

CONCLUSIONS

Under the limitations of this study, it could be concluded that applying HVGI alone or after SDF with or without KI could treat postoperative hypersensitivity in deep class I cavities after partial caries removal. Dentine treated with either SDF, SDF+KI, or HVGI could obtain successful radiographic outcomes with no signs of pulpal pathology. KI could be applied immediately after SDF to prevent black staining of the teeth and increase patient satisfaction.

Abbreviations

SDF+ KI: Silver diamine fluoride with potassium iodide.

SDF: Silver diamine fluoride.

HVGI: High-viscosity glass ionomer.

FDI: Fédération Dentaire Internationale.

FDA: Food and Drug Administration.

ADA: American Dental Association.

KI: Potassium iodide.

GIC: Glass ionomer cement.

CONSORT: Consolidated standards of reporting trials.

ICDAS: International caries detection and assessment system.

ICCC: International Caries Consensus Collaboration.

Conflict of interest

The authors declare no conflict of interest.

Funding

The authors declare that no funding was received for this study.

Data availability

Data are available from the authors upon reasonable request and with permission of the Faculty of Dentistry, Cairo University, Egypt.

Clinical trial registration

The protocol of this study was registered on clinicaltrials.gov (ID: NCT05485272) on 3/8/2022.

Ethics

The study was approved by the Research Ethics Committee (CREC), Faculty of Dentistry, Cairo University, with identification number: 10222 on 22/2/2022.

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