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RESEARCH

Clinical outcomes of selective removal to soft dentin versus firm dentin for deep caries lesions: a randomized controlled trial up to 5 years

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Abstract

Objectives This study aimed to compare the success of selective removal to soft dentine (SRSD) with or without calcium silicate (CS) and selective removal to firm dentine (SRFD) in permanent dentition.

Materials and methods Between November 2018 and March 2020, 165 posterior deep caries lesions in 134 patients were included in the study and randomly assigned into test ($n=101$) and control ($n=64$) groups. The control group ($n=46$) received the treatment of SRFD with CS, while the test group was further randomized into two groups to receive SRSD with CS ($n=45$) and SRSD without CS ($n=45$). An additional group (PE) consisted of teeth with exposed pulps during caries removal ($n=29$). The primary outcome of the study was to assess the vitality of the teeth based on clinical and radiographic examination after five years. The secondary outcome of the study was to evaluate the influence of baseline variables and CS application on treatment outcome. The success rates of different treatment strategies were compared (Pearson chi-squared and Log-rank tests). The impact of baseline variables and treatment strategies on failure and dentin bridge formation was analyzed using binary logistic regression model.

Results The success rate for SRSD with or without CS (94.1–100%) was significantly higher compared to SRFD (75.8%) and PE (81.8%) after five years ($P=0.012$). Failure was less likely for premolars. Cavity type and depth had an influence on dentin bridge formation.

Conclusion A five-year follow-up in this study demonstrated better clinical outcome for SRSD with or without CS compared to SRFD technique, irrespective of age, pre-op sensitivity, cavity type, radiographic depth and activity of the caries. Application of CS after SRSD in deeper cavities provided better healing in terms of dentin bridge formation.

Clinical relevance SRSD might be more advantageous over SRFD for the management of deep caries lesions.

Keywords Selective caries removal · Clinical trial · Deep caries lesion · Dental materials · Permanent teeth

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Introduction

The total removal of deep caries lesions recently termed as selective removal to firm dentine (SRFD) is no longer considered as a conservative option with potential risk of pulp exposure [1]. Several techniques have been developed with the aim of preventing unintended pulp exposure. The stepwise caries removal technique (SW) is a method of caries excavation that is performed in two steps, with a time interval [1, 2]. The initial stage of the procedure involves leaving the soft carious tissue over the pulp and removal of peripheral carious tissue to firm dentin. The second step is the complete excavation of the caries [3]. The objective of the SW technique is to inhibit the progression of dental caries by removing microorganisms from the oral environment and reducing the probability of pulp exposure by stimulating reactions from the pulp-dentin complex [4]. However, pulp exposure during re-entry of the cavity, loss of temporary filling, and poor patient compliance are the shortcomings of this technique [5]. To overcome these shortcomings, the selective removal of soft dentin (SRSD) as a novel approach has been suggested whereby the caries is selectively removed with a technique similar to SW, but with the advantage of allowing the treatment to be completed in a single session [6]. The SRSD technique is the recently recommended technique for treatment of deep caries lesions extending ¾ of dentin [6].

Use of calcium hydroxide liner has been considered as gold standard for decades in management of deep caries lesions since 1920s [7, 8]. However, calcium hydroxide is no more recommended as the most efficient material in preserving pulp vitality of permanent teeth due to development of calcium-silicate based materials with enhanced bioactive properties and sealing abilities in the last 10–15 years [9]. Biodentine (Septodont, St Maur-des-Fosses, France) is one of these materials which was introduced as a bioactive dentin substitute. Some previous studies have shown that the success rate of Biodentine as a direct or indirect pulp capping material, was comparable to mineral trioxide aggregate (MTA), while higher than calcium hydroxide [7, 8]. Biodentine might be preferable due to its better handling properties, faster setting time and less discoloration potential compared to MTA.

To the best of our knowledge, studies in the literature evaluating long-term clinical outcome of SRSD in permanent teeth is scarce. Previous studies demonstrated high success rate of 91–98% for SRSD within the observation period of 1–3 years [10–12]. When compared to SRFD or SW techniques, SRSD showed superior efficacy in terms of preserving pulpal vitality [13]. Similarly, the 2-year results of the present study showed higher success rate for SRSD compared to SRFD in permanent teeth. Additionally, the use of calcium silicate (CS) was found to have no effect on the treatment results [14]. Since longer term observation might be better to provide more precise data, the primary outcome of the study was to assess the vitality of the teeth treated either with SRSD or SRFD based on clinical and radiographic examination after 5 years. The secondary outcome of the study was to investigate whether if baseline variables or CS application had an effect on success of treatment. The first null hypothesis of the study was that there would be no differences in success rates of different treatment strategies. The second null hypothesis of the study was that there would be no effect of the baseline variables, caries removal technique and CS application on 5-year clinal outcome in terms of preservation of tooth vitality and dentin bridge formation.

Materials and methods

Study design

This study was carried out as double blinded randomized clinical trial. The study approved by university ethical committee (Protocol number: E-10840098-202.3.02-1767; Approval No: 241; Date:04.03.2024) and registered at ClinicalTrials.gov (Registration No: NCT04052685). All participants provided written informed consent explaining the detailed descriptions, the risks and benefits of the study.

Eligibility criteria

The potential participants referred to the Restorative Dentistry Department of University Clinic with need of restoration were invited to study from both genders, aged between 13 and 65.

The inclusion criteria were as follows:

- Deep posterior primary caries lesion radiographically extending at least ¾ of dentin.
- Vital teeth with positive response to cold test (−50 C spray; Roeko Endo-Frost, Coltene, Whaledent GmbH, Langeneu, Germany) and negative response to percussion test.
- Teeth with absence of spontaneous pain and periradicular pathology.

The exclusion criteria as follow:

- Horizontal or vertical mobility of the teeth.
- Teeth with non-caries cervical lesions or attrition (might be related with bruxism or dentin hypersensitivity).
- Teeth with irreversible pulpitis symptoms.
- Subjects undergoing orthodontic treatment.
- Subjects classified as ASA III and ASA VI (according to the American Society of Anesthesiologist).
- Pregnancy or breastfeeding.

Sample size calculations

The sample size calculation was based on difference between the success rate of SRSD after 5 years follow-up period of %80 [15] and SRFD after same period of %46.3 [16], alfa = 5, with a power of 80%. This resulted the need for 31 restorations per group to be followed at 5 years.

Randomization

The eligible teeth meeting inclusion criteria were assigned to SRSD (test) and SRFD (control) groups by using 2:1 block randomization. The SRSD group was further divided into subgroups: SRSD with CS and SRSD without CS using sealed envelopes previously prepared by an independent researcher. The teeth with pulp exposure during caries removal were assigned to PE group. The study flow chart showing the allocation of eligible teeth to groups is given in Fig. 1.

Clinical procedures

Clinical procedures were conducted by the operator who had over 15 years of experience in restorative dentistry. All treatments were performed under local anesthesia and preoperative x-ray were made from each case. Firstly, round diamond bur operated at high speed under water cooling to remove unsupported enamel to access the carious dentin. Then, the carious tissue was removed to firm dentine at lateral walls of the cavities using round tungsten carbide bur at low speed in all groups. In SRSD group, caries tissue in close proximity to pulp was excavated by hand instrument to leave a thin layer of soft carious tissue above the leathery dentin. The residual caries was soft and dry at visual-tactile examination. Leaving a thick layer of soft carious tissue which was still moist and mushy after air-drying was avoided. In SRFD group, caries completely removed to firm dentine using tungsten carbide bur. After caries removal procedure, a cotton pellet soaked with 5% sodium hypochlorite was placed into each cavity for 3 min. Then, CS (Biodentine™, Septodont, St Maur-des-Fosses, France) was prepared according to manufacturer's instructions using

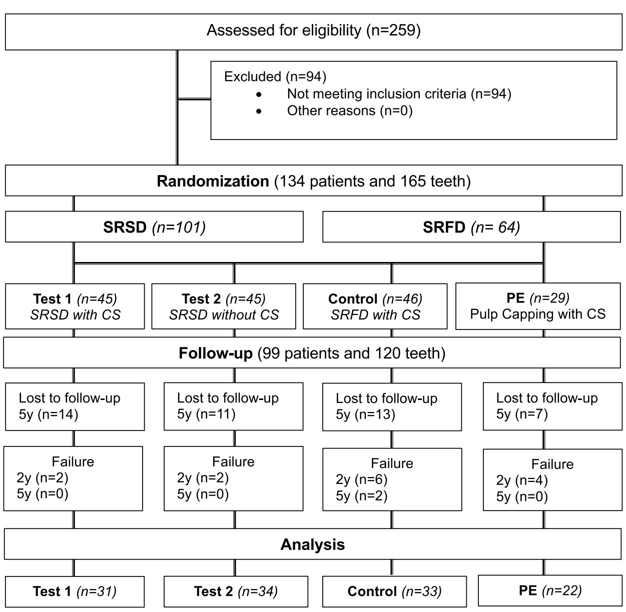

Fig. 1 Study flowchart showing allocation to treatment groups of selective removal to soft dentin (SRSD) with or without calcium silicate (CS) application, selective removal to firm dentin (SRFD) and unintentional pulp exposures (PE) during caries removal

a capsule mixing device (Silamat S6, Ivoclar Vivadent AG, Schaan, Liechtenstein) and applied on the pulpal floor in PE, SRSD with CS and SRFD with CS groups. CS was left to set for 12 min and immediately after covered with resin-based liner (Glass liner, Willmann & Pein GmbH, Barmstedt, Germany). Circumferential matrix band (Adapt Super Cap Matrix, KerrHave SA, Bioggio, Switzerland) was placed and fixed with wooden wedges prior to restorations of Class II cavities. A dry working field was obtained using cotton rolls and suction. Selective etching with 37% phosphoric acid (Total Etch—Ivoclar/Vivadent, Liechtenstein) for 10 s on enamel, followed by adhesive application (3 M Single Bond Universal Adhesive, 3 M ESPE St Paul, USA) for 20 s and light polymerization (LED.B, Guilin Woodpecker Medical Instrument, Guilin, Guangxi, China) for 10 s prior to resin composite placement (3 M Filtek Ultimate Universal, 3 M ESPE St Paul, USA). Fine grid diamond burs, discs and rubber caps were used for finishing and polishing.

Clinical and radiographic evaluation

Two observers blinded to interventions independently performed clinical and radiographic evaluations at 5-year recall. The primary success outcome, pulp vitality, was determined according to the following criteria: a positive response to the cold test (– 50 °C spray; Roeko Endo-Frost), a negative response to percussion, the absence of spontaneous pain, and the absence of periapical lesions. In the presence of at least one of these signs or symptoms, indicating pulp necrosis, was defined as a failure. The radiographic examinations were standardized using film-holding instruments for bitewing (Kwik-Bite, Kerr Corporation, Orange, CA, USA) and periapical (Super-Bite Senso, Kerr Corporation) radiography. Radiography was conducted using a digital radiography system (Kodak RVG CS 5200, Japan) and an intraoral X-ray unit (CareStream CS2100, Carestream Health), operating at 60 kVp, 7 mA and 0.25 s. The images were stored in a maximum-quality JPEG format. Dentin bridge formation was evaluated through a visual comparison of radiography at baseline and 5-year using a software (Keynote, Apple Inc., Cupertino, CA, USA) on a black background. Dentin bridge was indicated as a change in the shape of the pulp chamber. The integrity and quality of the restorations were evaluated according to FDI World Dental Federation criteria [17].

Statistical analysis

The success rates of groups according to treatment and baseline variables were compared using univariate Pearson chi-squared test and multivariate binary logistic regression model. Additionally, survival rates of the groups analyzed using Kaplan-Meier curves and log rank test. Baseline characteristics of unfollowed and followed teeth were compared (Pearson chi-squared test). With Fleiss multirater kappa statistic inter-examiner reliability was assessed. The level of statistical significance was set at $p<0.05$, and all calculations were performed using the SPSS Statistics version 23.0 (IBM, Chicago, IL, USA).

Results

Between November 2018 to March 2020, 165 teeth in 134 patients (77 female and 57 male; aged between 13 and 44 years) were included in the study. Figure 1 demonstrates the distribution of teeth according to test and control groups, additionally the unintentional pulp exposures during SRSD ($n=11$) and SRFD ($n=18$). None of the teeth excluded from the study due to prolonged bleeding as an indicator of irreversible pulpitis. Thus, SRSD with CS (Test 1), SRSD without CS (Test 2), SRFD (Control) and PE groups consisted of 45, 45, 46 and 29 teeth, respectively. There was no significant difference among groups regarding age, gender, tooth type, cavity type, radiographic depth, ICDAS scores and carious tissue characteristics ($P>0.05$), except higher moderate pre-op sensitivity in PE group ($P=0.001$), as previously published [11]. After 5 years of follow-up (mean ± SE follow-up period 1768.1 ± 23.7 days; 95% CI: 1721.6–1814.7), a total of 45 teeth from 35 patients were lost to follow-up mainly due to no show, followed by moving to another city and loss of contact phone number. Thus, 31 teeth in Test 1; 34 teeth in Test 2, 33 teeth in Control and 22 teeth in PE groups could be included in 5- year analysis. Baseline characteristics of followed teeth did not significantly differ from unfollowed teeth (Table 1; $P>0.05$), except higher proportion of moderate hypersensitivity of unfollowed in test groups compared to followed (Table 1; $P<0.05$). Five of these 9 unfollowed teeth with moderate hypersensitivity in test groups could be followed at 2-year follow-up without failure. Figure 2 shows the survival curves of groups. Overall observation time was found to be similar with respect to groups (Log rank test; $P=0.143$).

Based on the primary outcome of the study, success rate of SRSD with CS (100%) and SRSD without CS (94.1%) groups was significantly higher compared to SRFD (75.8%) and PE (81.8%) groups after 5 years (Table 2, $P=0.012$). Multivariate variate analysis also showed higher success for teeth received SRSD with CS or without CS compared to SRFD (Table 3, $P<0.05$).

Based on the secondary outcome of the study, univariate comparison of success rates with respect to baseline variables showed significantly higher success rates for premolars compared to molars; lesions extending ¾ radiographic depth compared to more than ¾ radiographic depth and teeth without pre-operative sensitivity compared to teeth with moderate or severe hypersensitivity (Table 2, $P<0.05$). Despite, multivariate analysis also showed similar results regarding the impact of tooth type on treatment outcome ($P=0.031$), no significant effect of the none of the other baseline variables was found (Table 3, $P>0.05$). Taken survived restorations into account, dentin bridge formation was most

Table 1 Comparisons of baseline variables between followed and unfollowed treatments according to test, control and pulp exposure (PE) groups

Variables (*n*)		Test 1			Test 2			Control			PE		
		F	UF	*P**	F	UF	*P**	F	UF	*P**	F	UF	*P**
Gender	Male	13	7	0.614	18	3	0.138	14	4	0.466	11	3	0.474
	Female	18	7		16	8		19	9		11	4	
Tooth Type	Molar	18	9	0.693	24	8	0.892	17	5	0.425	12	5	0.269
	Premolar	13	5		10	3		16	8		10	2	
Cavity Type	Cl I	5	3	0.667	3	0	0.308	3	3	0.205	3	2	0.495
	Cl II	26	11		31	11		30	10		19	5	
Radiographic Depth	3/4	8	2	0.389	12	4	0.949	15	3	0.161	5	2	0.947
	> 3/4	23	12		22	7		18	10		17	5	
Carious Tissue	LYAP	21	13	0.133	26	5	0.152	16	10	0.203	20	6	0.641
	LBSP	7	0		5	4		8	1		1	1	
	DBSP	3	1		3	2		9	2		1	0	
Pre-Op Sensitivity	No	29	10	**0.043**	31	6	**0.006**	30	11	0.505	10	4	0.210
	Moderate	2	4		3	5		2	2		12	3	
	Severe	0	0		0	0		1	0		0	1	

*Pearson chi-square test, *F*: Followed; *UF*: Unfollowed; *LYAP*: light yellow actively progressing; *LBSP*: light brown slowly progressing; *DBSP*: dark slowly progressing

Fig. 2 Survival curves of Test 1 (SRSD with CS), Test 2 (SRSD without CS), Control (SRFD with CS) and PE (Pulp exposure) groups up to 5-years

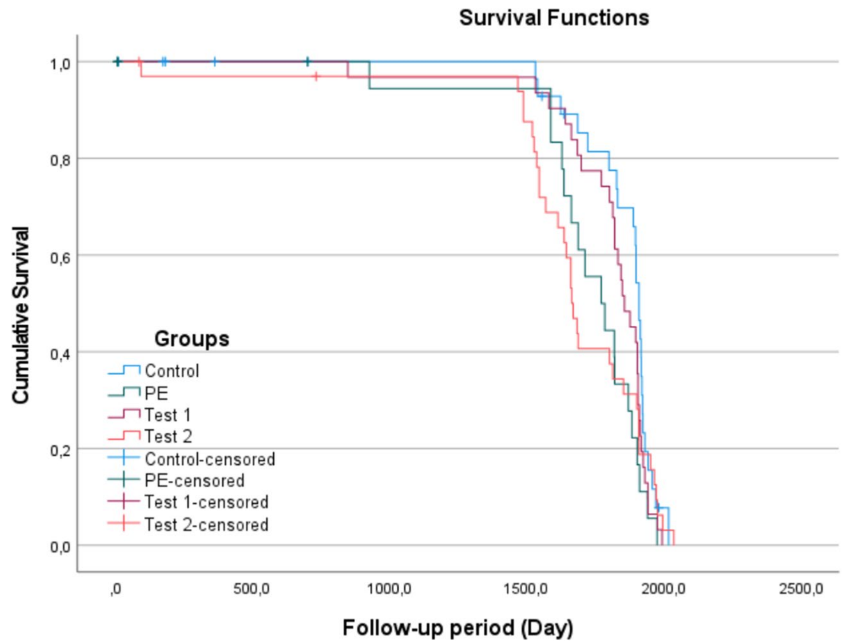

Table 2 Comparison of success and dentin formation rates according to baseline variables and treatments

Variables		Preservation of tooth vitality			Dentin bridge formation		
		Failure (*n*)	Success (*n*)	*P**	No (*n*)	Yes (*n*)	*P**
Treatments	SRSD + CS	0	31	**0.012**	7	24	**0.001**
	SRSD - CS	2	32		19	13	
	PE	4	18		1	17	
	SRFD + CS	8	25		16	9	
Gender	Male	7	49	0.945	18	31	0.425
	Female	7	57		24	33	
Cavity Type	Cl I	3	11	0.180	1	10	**0.027**
	Cl II	11	95		42	53	
ICDAS score	4	2	44	0.177	17	27	0.217
	5	11	58		26	32	
	6	1	4		0	4	
Radiographic depth	3/4	1	39	**0.036**	23	16	**0.002**
	> 3/4	13	67		20	47	
Tooth Type	Premolar	2	47	**0.045**	21	26	0.378
	Molar	12	59		22	37	
Caries tissue	LYAP	8	75	0.151	27	48	0.115
	DBSP	4	12		8	4	
	LBSP	2	19		8	11	
Pre-Op Sensitivity	No	10	90	**0.004**	40	50	**0.035**
	Moderate/ Severe	4	16		3	13	
		Total (*n*) = 120			**Total** (*n*) = 106		

*Pearson chi-square test, *LYAP*: light yellow actively progressing; *LBSP*: light brown slowly progressing; *DBSP*: dark slowly progressing

likely in PE group and SRSD with CS groups (Table 4). Univariate analysis of dentin bridge formation rates according to baseline variables showed higher rates for Cl I cavities compared to Cl II; lesions radiographically extending more than ¾ of dentin compared to lesions restricted to ¾ of dentin and teeth with moderate hypersensitivity compared to

Table 3 Influence of the baseline variables and treatment strategy on success rates of restorations

Variables		OR (95% CI)	P**
Treatments	SRSD + CS	16,461 (1,785 – 151,792)	**0,013**
	SRSD - CS	8,677 (1,510 – 49,874)	**0,015**
	PE	3,049 (0,627 – 14,837)	0,167
	SRFD + CS	Reference	
Tooth Type	Premolar	10,721 (1,236 – 92,982)	**0,031**
	Molar	Reference	
Radiographic depth	3/4	1.812 (1.072–3.065)	0,098
	More than 3/4	Reference	

**Multiple binary logistic regression analysis *OR*, odd ratio; *CI*, confidence interval

Table 4 Influence of baseline variables on dentin bridge formation at 5-year follow-up

Variables		OR (95% CI)	P **
Treatments	SRSD + CS	4.829 (1.329–17.5)	**0.017**
	SRSD - CS	0.902 (0.260–3.133)	0.871
	PE	68.15 (5.376–863.9)	**0.001**
	SRFD + CS	Reference	
Cavity Type	Cl I	12.13 (1.363–107.8)	**0.025**
	Cl II	Reference	
Radiographic depth	> 3/4	4.83 (1.566–14.9)	**0.006**
	3/4	Reference	

**Multiple binary logistic regression analysis *OR*, odd ratio; *CI*, confidence interval

teeth without hypersensitivity (Table 2, $P < 0.05$). Likewise, multivariate analysis showed the significant effect of cavity type ($P = 0.025$) and radiographic depth ($P = 0.006$) on dentin bridge formation, whereas no impact of pre-op operative sensitivity ($P > 0.05$) (Table 4). No effect of age was found neither on success ($P = 0.157$) nor dentin bridge formation ($P = 0.422$). Representative radiography for dentin bridge formation is given in Figs. 3 and 4.

Distribution of FDI scores of surviving restorations after 5 years of observation is given in Table 5. All the restorations were clinically acceptable according to FDI criteria, except one restoration failure due to loss of retention (FDI 5.5) together with irreversible pulpitis symptoms in control group at 5-year follow-up. Radiographic examination showed harmonious transition between tooth and restoration (FDI 9.1) for all restorations both at baseline and after 5 years without secondary caries or gap formation.

Inter-examiner agreement was found to be statistically significant for both FDI criteria and radiographic evaluation parameters ($p < 0.001$). The kappa values showed good or excellent agreement for FDI parameters (range between 0.64 and 1.00) and good agreement for dentin bridge formation (0.62).

Discussion

This study compared the 5-year clinical outcome of SRSD and SRFD caries removal techniques. Based on the primary outcome of the study, the success rate of SRSD was found to be higher compared to SRFD. Based on the secondary outcome of the study, tooth type showed an effect on overall success, while CS application, cavity type and radiographic depth on dentin bridge formation. Thus, both hypotheses of study were rejected.

To the best of our knowledge, this is the first prospective non-inferiority study comparing 5-year clinical outcome of SRSD and SRFD in permanent dentition. Previously, two studies showed no difference between two removal techniques within the observation period of 1.5–3 years [18, 19]. The first one was a retrospective study in which failures were mainly associated with restoration longevity rather than pulpal complications [18]. The second one was a prospective study favoring SRSD in terms of lower incidence of pulp exposure [19]. Taken the 5-year results of previous studies evaluating pulp vitality as the primary outcome measure into account, the success rate was 80% and 71.8–90.9% for permanent posterior teeth received SRSD with glass ionomer

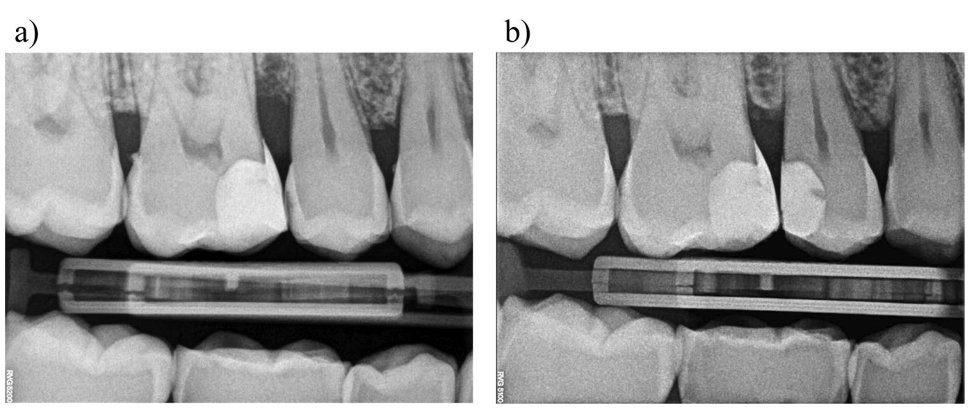

Fig. 3 Radiography of tooth #16 treated with SRSD without CS at **a**) baseline and **b**) 5-year follow-up with dentin bridge formation

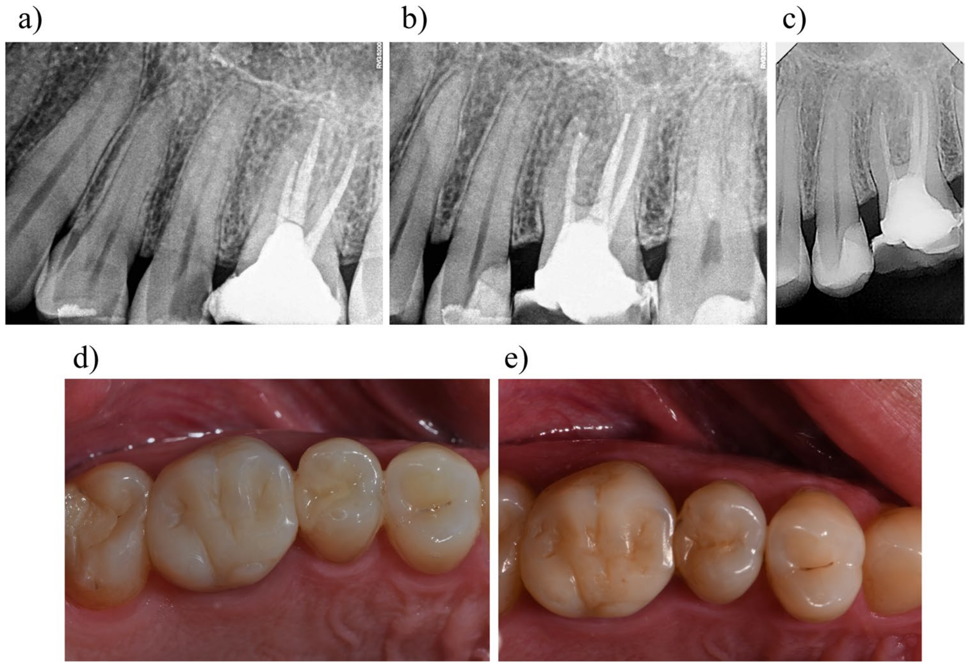

Fig. 4 Radiography of tooth #25 treated with SRSD with CS at **a**) baseline, **b**) immediately after treatment, **c**) at 5-year follow-up with dentin bridge formation; photography of restoration **d**) at baseline and **e**) 5-year follow-up with acceptable FDI scores

Table 5 Distribution of FDI scores of surviving restorations after 5 years

Criteria	Rating	Description of the Criteria	Baseline *n* (%)	5-year *n* (%)
FDI 1. Surface Luster	1	Luster comparable to enamel	86 (81.2)	64 (60.4)
	2	Slightly dull not noticeable from speaking distance	19 (17.9)	26 (24.5)
	3	Dull surface but acceptable if covered with film of saliva	1 (0.9)	16 (15.1)
FDI 2. Staining	1	No staining	106 (100)	63 (59.4)
	2	Minor staining, easily removable by polishing	0 (0)	26 (24.5)
	3	Moderate staining that may also present on other teeth, not esthetically unacceptable	0 (0)	17 (16.1)
FDI 3. Color match	1	Good color match	75 (70.8)	60 (56.6)
	2	Minor deviations	28 (26.4)	26 (24.5)
	3	Distinct deviation but acceptable	3 (2.8)	20 (9.7)
FDI 5. Fracture of material and retention	1	Restoration retained, no fractures/cracks	106 (100)	104 (98.1)
	3	Material chip not affecting marginal integrity or approximal contact	0 (0)	2 (1.9)
FDI 6. Marginal adaptation	1	Harmonious outline, no gaps or discolored lines	83 (78.3)	78 (73.6)
	3	Marginal gap (< 250 µm), not removable by polishing	23 (21.7)	28 (26.4)
FDI 12. Recurrence of caries	1	No secondary caries	106 (100)	101 (95.3)
	2	Very small demineralization, no need for intervention	0 (0)	5 (4.7)

[15] and SRFD with calcium hydroxide [16, 20], respectively. The higher success rates for SRSD with CS (100%) or without CS (94.1%) obtained in the present study within the same observation period might be promising to consider these treatment strategies as better options for the management of deep caries lesions.

In the present study, most of the pupal complications ($n = 12$) occurred within the 2 years of observation and no failures observed in any group except two failures in control group between 2- and 5-year follow-ups. Thus, the 5-year results of the present study were consistent with 2-year results [14]. However, in the study of Maltz et al.

[15], the increased incidence of pulp necrosis in SRSD group over time yielded to success rates of 99%, 91% and 80 at 1.5, 3 and 5-year follow-ups, respectively. This contradictory finding may be related to durability of restorations which were mostly scored as excellent in the present study whereas, some restorations needed repair with 5% annual failure rate in the study of Maltz et al. [15, 21]. From this point of view, the present study might be important to provide long-term evidence for pulpal reaction to different treatment options without concern of bacterial leakage due to deficiency of restorations over time.

Apart from carious removal technique, selection of liner material is another topic to be discussed in the context of management of deep carious lesions. Previously, high success rates observed for SRSD and neither the use of resin-modified glass ionomer nor calcium hydroxide influenced the treatment outcome within 1–1.5 years of observation time [10, 11]. Similarly, Torres et al. [22] showed no difference in 2-year clinical performance of restorations placed after caries removal to leathery dentin with and without resin-modified glass ionomer liner. However, Jardim et al. [21] suggested that increased fatigue of glass-ionomer cement liner in long-term (5-year) had a significant effect on the longevity of restorations. From the biological aspect, dentin barrier seems to be preserved with SRSD and no further liner application is required for pulp protection, whereas micro-exposures might occur during SRFD [23]. Dentin hardening, decrease in bacteria and dentin reorganization was previously shown to be possible with SRSD and good coronal sealing, irrespective of the lining material [24, 25]. Considering these facts, CS was applied after SRFD in the control group, while the test group divided into two subgroups to investigate the effect of CS with SRSD in the present study. Despite calcium hydroxide is the commonly used material for indirect pulp caping, CS was preferred in the present study due to its superior alkalizing potential and bioactive properties to induce hard tissue formation as an indirect pulp caping material compared to calcium hydroxide [26]. The results of the present were in accordance with results of the previous studies cited above favoring protection of natural dentin barrier rather than replacing it with a dentin substitute. However, application of CS seems to have provided beneficial effect on dentin bridge formation after SRSD. Nevertheless, further studies might be advisable to investigate whether if CS has the potential to provide better healing with SRSD or not.

Multivariate analysis of 2-year results of the present study revealed no significant effect of any of the baseline variables on treatment outcome in terms of preservation of pulpal vitality [14]. However, tooth type was found to have an effect on success at 5-year evaluation. Even though placement of CS was more challenging in premolars due to smaller cavities compared to molars, irreversible pulpitis symptoms observed in only two premolars treated with SRFD. Likewise, in the study of Oz et al. [20], the survival rate (90.3%) was high for premolars, but did not significantly differ from molars (81.9%) and anterior teeth (76%). Similar to findings of the present study, no significant effect of age, gender and cavity type was previously shown in short and long-term studies [11, 15]. Contrarily, Björndal et al. [16], found lower success for older patients and teeth with mild pre-operative sensitivity. This conflicting finding might be probably related to reduced pulp repair activity with increased age [27]. The immune response of the younger patients in the present study might have shown better defense against reversible inflammation of pulp. The result of the present study demonstrating no influence of lesion depth on success were in accordance with the findings of a recent study [11]. This result might be considered as encouraging to perform vital pulp treatment even in deep cavities with reversible pulpitis symptoms.

Tertiary dentin formation is the reaction of dento-pulpal complex against external stimulation. Reactive and reparative dentin have been defined as the types of tertiary dentin by Murray et al. [28] depending on the odontoblast survival. Reactive dentinogenesis occur when the vitality of odontoblasts is persevered whereas reparative dentin is formed by newly derived odontoblast-like cells from endogenous stem cells after a severe stimulus or injury. Murray et al. [28], suggested that cavity related factors such as remaining dentin thickness, cavity depth, cavity wall and floor area might have an influence on reactionary dentin repair. The results of the present study showing the impact of radiographic depth and cavity type on dentin bridge formation was in accordance with these findings. Lower rate of tertiary dentin formation observed in cavities involving ¾ of dentin compared to deeper ones might be related with decreased reactionary dentinogenesis due to increased distance of diffusion in these cavities. Since the diffusion of growth factors to stimulate the odontoblast cell body might be limited with the increased remaining dentin thickness [29].

The SRSD approach relies on stimulation of defense mechanisms of pulpo-dentinal complex and the belief that microorganisms entrapped within the soft carious tissue left behind. However a previous histological human study showed tertiary dentin formation after selective removal to leathery dentin, manifestation of chronic inflammatory cells was attributed to ongoing bacterial activity under the restoration [30]. In this prospective study, irreversible pulpitis with apical radiolucency which might be the result of chronical inflammation was observed in only one tooth treated with SRSD without CS after 2 years. The possible reason for failure was the location of the caries lesion at distal side of pulp arising from the horizontal position of the adjacent third mandibular molar. Notably, within the observation period of 5 years no clinical sign and symptom of pulpal inflammation observed in SRSD with CS. This finding of the present study may probably be related to antimicrobial effect of CS. Moreover, CS application seems to be able to stimulate the reactive and reparative dentinogenesis considering the higher rate of dentin bridge formation in SRSD with CS and PE groups compared to SRFD and SRSD without CS.

Considering the methodology of the present study, randomization resulted in equally distributed sample among groups. With prospective study design, a standard treatment protocol was followed, evaluations were performed by two blinded observers and descriptive baseline variables of the study sample could be recorded. Despite standardization could be achieved by an experienced single operator, variability among operators with different level of experience disregarded. Caries removal end point for SRSD technique might vary among operators depending on their knowledge of carious tissue characteristics and histology. Hence, external validity of the study might be questioned regarding the fact that the amount of the remaining soft tissue is a subjective parameter. The major limitation of the study was the drop-out rate of 27.3%. Since drop-out was an expected shortcoming in the long-term clinical trials, sample size was calculated accordingly in the beginning of the study. Additionally, the baseline variables of followed and unfollowed sample in each group were compared to make a predictive result for the scenario without any drop-out. The only variable that differed between followed and unfollowed teeth was higher ratio of moderate pre-operative sensitivity in test groups. Even though, the unfollowed teeth with moderate sensitivity were accepted as failure, the results would be still in favor of test groups. Nevertheless, further multi-center studies with larger sample size and multiple operators might be advisable to provide more precise data.

Conclusion

This study revealed that success rate was higher for SRSD compared to SRFD for the management of deep caries lesions in permanent teeth within the observation period of 5 years. Failure was found to be less likely in premolars and none of the other baseline variables nor use of CS had an effect on treatment outcome in terms of preserving tooth vitality. Dentin bridge formation was deemed to be more likely when one-surfaced cavities involving more than ¾ of dentin were treated with SRSD with CS compared to SRSD without CS or SRFD.

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Data availability No datasets were generated or analysed during the current study.

Declarations

Consent to participate Informed consent was obtained from all individual participants included in the study.

Ethics approval This study was approved by the University Ethics Committee with protocol no. Protocol No. E-10840098-202.3.02-1767; Approval No: 241; Date:04.03.2024.

Competing interests The authors declare no competing interests.

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