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RESEARCH

Selective removal to soft dentine or selective removal to firm dentine for deep caries lesions ın permanent posterior teeth: a randomized controlled clinical trial up to 2 years

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Abstract

Objectives The aim of this randomized clinical trial was to compare selective removal to soft dentin (SRSD) and selective removal to firm dentin (SRFD) in permanent teeth. The primary outcome of the study was to compare the success rates of the two caries removal techniques. The secondary outcome of the study was to investigate whether or not calcium silicate-based material (CS) had an effect on the success rate of the treatment.

Materials and methods Between November 2018 and March 2020, patients with deep caries lesions were invited to participate in the study. Posterior teeth ($N=165$) with primary caries lesion radiographically extending ¾ of dentin and positive response to cold test were randomly selected. A total of 134 participants meeting the inclusion criteria were randomized to SRSD and SRFD (control) groups. After the caries removal procedure, teeth with exposed pulps were assigned to the pulp exposure (PE) group, and the SRSD group was further divided into test 1 (with CS) and test 2 groups (without CS). Success was defined as a positive response to the cold test, a negative response to percussion, the absence of pain, an abscess, a fistula, and periapical alterations. Fisher–Freeman–Halton exact tests, Kaplan–Meier survival analysis, and the log-rank tests were performed for comparisons between groups.

Results No statistically significant difference was found between the success rates of test 1 (100%) and test 2 (93.5%) groups, whereas the proportion of success in control (82.4%) and PE (84%) groups were significantly lower when compared with test groups ($p=0.024$; $p<0.05$) at the end of 2-year follow-up.

Conclusions SRSD had a higher success rate when compared to SRFD to treat deep carious lesions after 2 years of follow-up. The use of CS material after SRSD as a liner had no effect on the treatment outcome.

Clinical relevance SRSD with good coronal sealing might be recommended without CS application for the treatment of deep caries lesions in permanent teeth.

Trial registration Clinical trial registration number NCT04052685 (08/09/2019).

Keywords Selective caries removal · Dental materials · Permanent dentition · Calcium silicate cements · Clinical trial

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Introduction

In recent years, there has been a growing number of studies questioning conventional caries tissue removal, especially for deep caries lesions [1]. In the concept of conventional caries removal, "affected dentin" and "infected dentine" are widely used terms [2]. According to this concept, the removal of infected dentin contaminated with bacteria and remaining affected dentin detected as firm dictated the management of cavitated caries lesions. Recently, this removal technique has been termed "SRFD" and seems to increase the potential risk for loss of pulp vitality for deep caries lesions radiographically extending ¾ of dentin tissue [3].

The first treatment option proposed as an alternative to SRFD for deep caries lesions to reduce pulp exposure and preserve pulp vitality was the stepwise excavation method [4]. Stepwise removal is a 2-stage procedure in which incomplete removal of caries tissue is carried out in the first stage, and then the cavity is sealed with a temporary filling to promote tertiary dentin formation. In the second stage, the cavity is reopened, and the remaining demineralized dentin is removed [5]. Regarding the disadvantages of stepwise removal, including the requirement of two sessions for treatment completion and the probability of pulp exposure during the second procedure, partial caries removal in 1-stage was proposed later on [6]. Higher success rates were observed for partial caries removal in 1-stage versus stepwise excavation in a long-term randomized clinical trial [7]. Reduced frequency of pulp exposure has also been shown with partial caries excavation when compared with SRFD [8]. Recently, the used term for this 1-stage partial caries removal is SRSD which refers to the removal of peripheral carious tissue to hard dentin to provide hermetic sealing of the restoration and leaving behind a layer of soft carious tissue over the pulp to avoid pulpal exposure [9]. According to the report of the International Caries Consensus Collaboration (ICCC) group, SRSD is strongly recommended in deep cavitated lesions extending into ¾ of dentin tissue [1].

In the case of pulp exposure, direct pulp capping is the treatment of choice for a tooth with vital pulp and without any inflammation predictor. However, according to the results of a retrospective study evaluating the treatment outcome of direct pulp capping with calcium hydroxide, 44.5% in the 5-year group and 79.9% in the 10-year group had a postoperative root canal treatment or an extraction [10]. Similarly, another retrospective study showed that over the 1st year after direct pulp capping with calcium hydroxide, almost 10% and, after 5 years, nearly 20% of the teeth had an unfavorable treatment outcome [11]. Recently, Biodentine™ (Septodont, St Maur-des-Fosses, France), which is a calcium silicate-based material, has gained popularity for pulp capping treatment. The success rate of Biodentine™ was reported to be 91.7% after 3 years in a recent prospective longitudinal randomized controlled study of vital permanent teeth with deep caries [12].

In the literature, there are very few studies concerned with the clinical success of SRSD. In a recently published review, it has been reported that SRSD seems to be the best option for the treatment of deep caries lesions, and the remaining caries tissue close to the pulp seems not to interfere with the longevity of the restorations [13]. However, information on the clinical advantages or disadvantages of SRSD and SRFD excavation methods mostly relies on studies conducted for primary teeth [8, 14–16]. In the currently available literature, not much scientific evidence on the clinical success of SRSD and SRFD excavation methods for deep carious lesions in permanent teeth could be found. Moreover, clinical trials are needed to demonstrate the combined effect of various removal strategies and CS.

The aim of this study was to compare clinical success rates of SRSD and SRFD techniques in posterior deep caries lesions of permanent teeth. The primary outcome of the study was a comparison of the clinical success of SRSD and SRFD techniques by clinical and radiographic evaluation after 3 months, 6 months, 1 year, and 2 years. The secondary outcome of the study was to investigate whether or not CS had an effect on the success rate of the treatment. The hypothesis tested in this study was that SRSD preserves tooth vitality better than SRFD.

Materials and methods

Study design

The study was approved by the University Ethics Committee (the protocol number is given in the "Declarations" part of the manuscript). All participants provided written informed consent. Written information was given to each patient regarding the alternative treatment options. This study was carried out as a prospective randomized clinical trial and registered at clinicaltrials.gov (the registration no. was given on the "Abstract" part of the manuscript). Teeth ($N=259$) were evaluated for eligibility to participate in this study between November 2018 and March 2020. Of these teeth, 94 were excluded because they did not meet the inclusion criteria. Thus, 165 teeth were included. The study had a double-blind design, as the observers who assessed outcomes and the patients were blinded to the interventions performed. Details of the study design can be seen in Fig. 1.

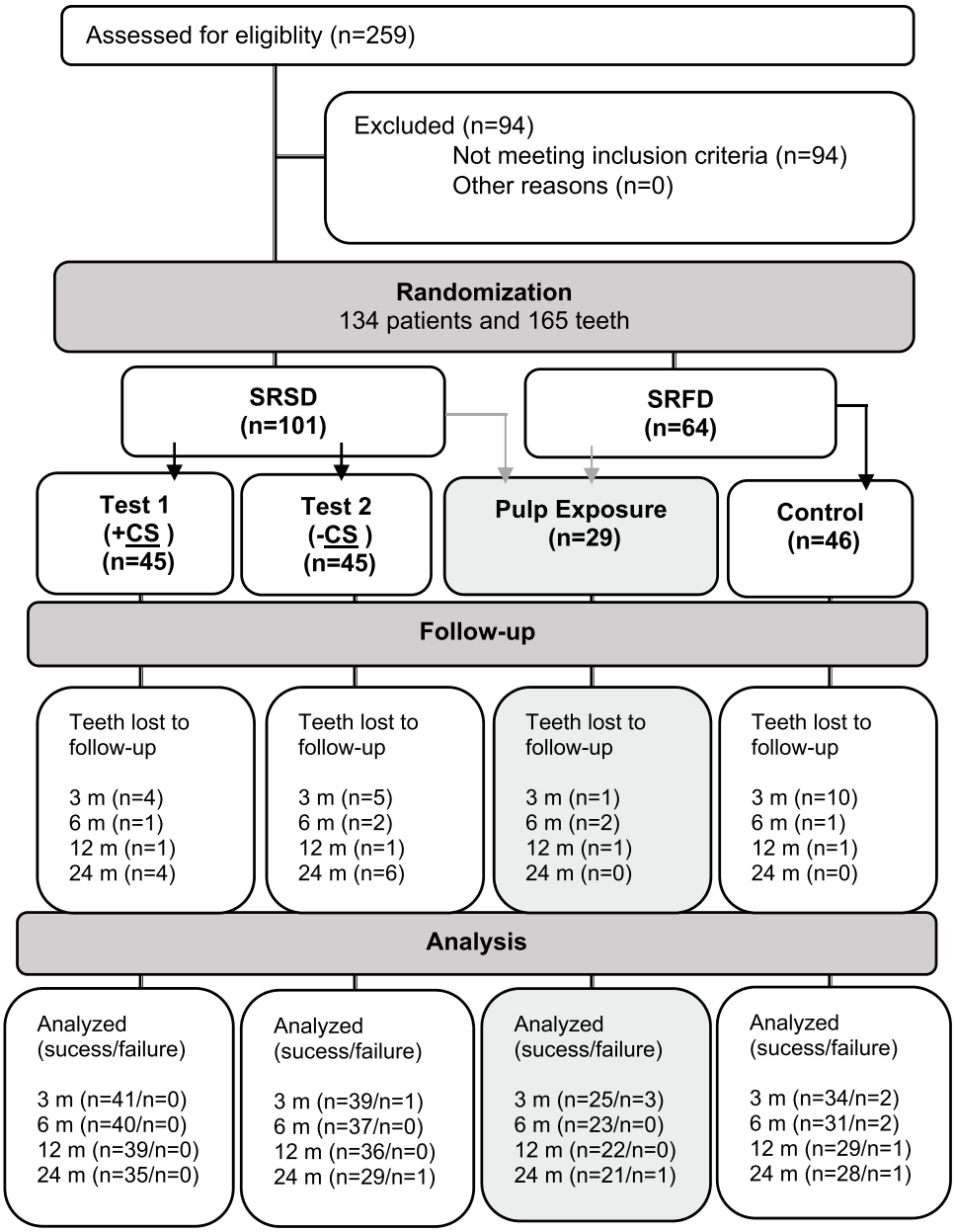

Fig. 1 Study flowchart

The sample size calculation was based on the difference between success rates of partial caries removal after a 3-year period of 91% [6] and direct complete excavation after a 1-year follow-up period of 62.4% [17], at $\alpha = 5\%$ with a power of 90%. This indicated the need for 33 restorations per treatment group. Taking into account a dropout rate of 50% after 2 years, the trial was planned to include at least 66 restorations. Unexpectedly, due to COVID-19 pandemic-related restrictions, a total number of 198 restorations could not be completed. Thus, enrollment in the study had to be finished by March 2020.

Potential patients attending the University Dental Clinics from both genders, with ages ranging from 13 to 65, in good general health, were invited to the study. To be included in the study patients were required to have at least one deep posterior primary caries lesion radiographically extending ¾ of dentin. Eligible lesions detected on panoramic X-ray radiography were further evaluated by measurement of the extent of the lesion on periapical and bite-wing radiography using the software (Kodak RVG 5200, Carestream Health, New York, USA). Additionally, teeth were required to present the absence of spontaneous pain, periradicular pathology, or non-carious lesions (attrition, abrasion, erosion, or abfraction). Teeth with untreated periodontal disease, positive response to percussion, and negative response to electrical and cold vitality tests were excluded. Patients were not included in the study in case of pregnancy, orthodontic

treatment, prosthetic rehabilitation, and allergy to the ingredients of the study materials.

Study groups

The unit of randomization was the tooth. A randomization software (Excel, Microsoft Office 2016) was used for 2:1 block randomization of the teeth into SRSD and SRFD (control) groups. In the case of pulp exposure, pulp capping was performed for these teeth, and they were assigned to the "PE" group. The SRSD group was further divided into two subgroups: (1) SRSD with CS (test 1) and (2) SRSD without CS (test 2). In order to ensure allocation concealment, the operator was unaware of the subgroup until SRSD was completed. The operator received a sealed envelope for each tooth, previously prepared by an independent research coordinator who was responsible for block randomization of teeth in the SRSD group.

Clinical procedures

Clinical treatments were carried out by the operator (BGÇ), who has experience in restorative dentistry for more than 15 years since graduation. The operator was trained in all clinical procedures before the beginning of the study. All procedures were carried out under local anesthesia. The treatments were performed as follows:

- The level of preoperative sensitivity, tooth type, age and gender of the patient, ICDAS score, and radiographic depth of the lesions were assessed just before treatment. The patient's description of sensitivity to thermal stimulus lasting up to 15–20 s was considered moderate, while increased pain for more than several minutes and needing painkillers was considered severe [18].
- Dentinal carious lesions were accessed by the removal of surrounding unsupported enamel with a round diamond bur operated at high speed under water cooling.
- Carious tissue was examined by the operator and the characteristics of the caries tissue were categorized as light yellow actively progressing (LYAP), light brown slowly progressing (LBSP), or dark brown slowly progressing (DBSP) and recorded [19].
- Carious tissue at the lateral walls of cavities was removed to hard dentin using round tungsten carbide burs operated at low speed in all groups.
- In SRSD groups, carious tissue in the pulpal aspect of the cavity was excavated by hand instruments to soft dentin. Only disorganized dentine was removed. A reasonable amount of soft carious tissue was left over the pulp.
- In the SRFD group, carious tissue was completely removed to firm dentin using round tungsten carbide burs.
- Following caries removal, a cotton pellet moistened with 5% sodium hypochlorite was placed into each cavity in all groups for 3 min [12].
- In test 1 and control groups, after caries removal, CS was applied on the pulpal floor following the instructions of the manufacturer. CS (Biodentine™) was covered by resin-based lining material (Glass liner, Willmann & Pein GmbH, Barmstedt, Germany) after 12 min setting time.
- In test 2 group, resin composite application procedure was followed after caries removal without CS placement.
- If the excavations led to pulp exposure, the teeth were assessed for eligibility for pulp capping. Pulp-capping with CS was performed for teeth with normal bleeding. None of the teeth included in the study were referred for endodontic treatment due to prolonged bleeding for more than 3 min.
- Matrix band (Adapt Super Cap Matrix, KerrHave SA, Bioggio, Switzerland) was used prior to restoration for ClI cavities.
- Selective etching with 37% phosphoric acid (Total Etch—Ivoclar/Vivadent, Liechtenstein) was applied for 10 s in enamel. Cavities were rinsed for 10 s, and adhesive material (3 M Single Bond Universal Adhesive, 3M ESPE St Paul, USA) was applied with a micro brush in cavity walls rubbing for 20 s. After gentle air drying for approximately 5 s, a 1200 W/cm^2 intensity LED light device (LED.B, Guilin Woodpecker Medical Instrument, Guilin, Guangxi, China) was used for 10 s light curing.

Clinical and radiographic evaluation

The patients were asked to make pain assessments at home daily for the 1st week after the treatments using a visual analog scale (VAS) printed on paper ranging from no pain to unbearable pain (1–10) and return the assessments by phone call.

The primary outcome was pulp vitality without apical radiolucency. Two blinded observers to the study who have experience in endodontics and oral diagnosis more than 10 years since graduation independently evaluated the following parameters for overall success:

- Positive response to cold test (– 50 °C spray; Roeko Endo-Frost, Coltene, Whaledent GmbH, Langeneu, Germany).
- A negative response to percussion.
- Absence of pain on palpation, abscess, or fistula.
- Radiographically, absence of periapical pathology or alterations (absence of lamina dura, periodontal ligament space widening at least twice, root canal obliteration, internal and external resorption).

The radiographic examinations were performed before treatment, immediately after the treatment, and then during control visits. The examinations were standardized using film-holding instruments for bite-wing (Kwik-Bite, Kerr Corporation, Orange, CA, USA) and periapical (Super-Bite Senso, Kerr Corporation) radiography. All periapical radiographic procedures were based on the parallel capturing technique. Radiography was taken using Kodak RVG CS 5200 digital radiography system and intraoral x-ray unit CareStream CS2100 (Carestream Health) operating at 60 kVp, 7 mA, and 0.25 s. The object-to-focus distance was 30 cm. The images were stored in maximum-quality JPEG format. All the images of the same tooth were placed side by side on a black screen using software (Keynote, Apple Inc., Cupertino, CA, USA) for comparative evaluation of the radiographic changes through follow-ups according to baseline. Radiographically, interruption of the white line of the lamina dura, darkening around the roots, and abnormal radiolucency or radiopacity at the pulpal or root surfaces were considered a failure of the treatment.

Clinical performance of the resin composite restorations was evaluated at baseline and designated follow-ups according to FDI World Dental Federation criteria for surface luster, surface and marginal staining, color match and translucency, esthetic anatomical form, fracture and retention of the material, marginal adaptation, occlusal wear, approximal anatomic form, radiographic examination, and patient's view [20].

Statistical analysis

Number Cruncher Statistical Systems (NCSS 2007, Kaysville, UT, USA) was used for statistical analysis. Distribution of quantitative data (age and postoperative pain scores) was rejected as being normally distributed (Shapiro–Wilk test), hence Mann–Whitney *U* and Kruskal–Wallis with Dunn–Bonferroni tests for inter-group comparisons were used. Qualitative data was compared with Pearson chi-square and Fisher–Freeman–Halton exact tests. Cox proportional hazard regression analyses were used to evaluate the univariate and multivariate influences of baseline variables on treatment success. Kaplan–Meier analysis was used to determine survival rates, and the log-rank test to find out the differences between the survival rates of the groups was used. The significance level was set at 5%, and the unit of analysis was the tooth.

Results

Out of 134 (77 female and 57 male) patients included in the study, approximately 80% received 1 treatment, 17% received 2 treatments, and 3% received 3 or more treatments. The participants were mainly young adults; the mean age was 24.14 (with a minimum age of 13 and a maximum age of 44 years), with a standard deviation of 8.30 years. All baseline characteristics are listed in Table 1. There was no statistically significant difference between the control and test groups with respect to age, gender, tooth, cavity type, radiographic depth, ICDAS scores, carious tissue characteristics, and preop sensitivity. In the PE group, the teeth with moderate preoperative sensitivity scores were higher and the teeth with no preoperative sensitivity were lower when compared to the control and test groups ($p = 0.001$; $p < 0.01$).

Postoperative pain within the 1st week following the interventions was evaluated. The change in the VAS scorings of the postoperative pain according to groups was given in Fig. 2. Postoperative pain was found to be significantly higher in the PE group when compared to test groups ($p < 0.05$). No significant difference was found between PE and control group ($p > 0.05$) except for the higher pain scores on day 1 in the PE group ($p < 0.05$).

At the end of 2 years of follow-up, 125 restorations in 100 patients (76%) could be followed, and 40 restorations in 33 patients (24%) were lost to follow-up. The study flow is summarized in Fig. 1. Among the lost cases, 2 patients moved to another city, 10 patients could not be reached, and the remaining 21 patients could be reached but did not show up. No differences were observed between followed and unfollowed cases regarding age, gender, radiographic depth, ICDAS score, caries tissue, preoperative sensitivity, and tooth and cavity type (Table 2; $p > 0.05$).

Success and failure rates according to groups after 2 years are given in Table 3. No statistically significant difference was found between the success rates of test 1 (100%) and test 2 (93.5%) groups, whereas the proportion of success in control (82.4%) and PE (84%) groups were significantly lower when compared to the test groups ($p = 0.024$; $p < 0.05$). No statistically significant difference was found for the incidence of vitality loss with apical radiolucency ($p = 0.79$; $p > 0.05$). The presence of irreversible pulpitis with pain at percussion and palpation was significantly lower in test 1 (0%) and test 2 (3.2%) groups when compared to the control (14.7%) and PE (12%) groups ($p = 0.038$; $p < 0.05$).

Figure 3 shows the survival curves for the groups. Statistically significant difference was found in favor test groups versus control and PE groups using the log rank test (p=0.45; p<0.05). When all lost cases were considered as success the difference between the survival curves was still statistically significant (p=0.038; p<0.05). Representative radiography of the teeth in test 1 and test 2 groups assessed as having normal periapical structures at 2-year follow-up is presented in Figs. 4 and 5. One failure due to loss of vitality was observed in each group except the test 1 group ($p = 0.709$; $p > 0.05$). Representative radiography of these

Table 1 Description of baseline characteristics by type of treatment assigned

Variables	Test 1 ($n_{restotarion}=45$) ($n_{patient}=38$)	Test 2 ($n_{restotarion}=45$) ($n_{patient}=33$)	Control ($n_{restotarion}=46$) ($n_{patient}=36$)	PE ($n_{restotarion}=29$) ($n_{patient}=27$)	*p*
Gender					
Female *n* (%)	21 (55.3)	20 (60.6)	21 (58.3)	15 (55.6)	[a]0.970
Male *n* (%)	17 (44.7)	13 (39.4)	15 (41.7)	12 (44.4)	
Age					
Mean (SD)	23.95 (8.38)	23.42 (8.25)	25.64 (8.62)	23.30 (8.00)	[b]0.641
Median (min–max)	23.5 (13–44)	22 (13–42)	25.5 (13–41)	23 (13–41)	
Tooth type					
Molar *n* (%)	28 (62.2)	31 (68.9)	22 (47.8)	17 (58.6)	[a]0.225
Premolar *n* (%)	17 (37.8)	14 (31.1)	24 (52.2)	12 (41.4)	
Cavity type					
Cl I *n* (%)	8 (17.8)	3 (6.7)	6 (13.0)	5 (17.2)	[a]0.384
Cl II *n* (%)	37 (82.2)	42 (93.3)	40 (87.0)	24 (82.8)	
Radyographic depth					
> 3/4 *n* (%)	35 (77.8)	29 (64.4)	28 (62.2)	22 (75.9)	[a]0.309
3/4 *n* (%)	10 (22.79	16 (35.6)	18 (37.8)	7 (24.1)	
ICDAS score					
4 *n* (%)	16 (35.6)	18 (40.0)	19 (41.3)	5 (17.2)	[a]0.051
5 *n* (%)	28 (62.2)	27 (60.0)	26 (56.5)	20 (69.0)	
6 *n* (%)	1 (2.2)	0 (0.0)	1 (2.2)	4 (13.8)	
Caries tissue					
LYAP *n* (%)	34 (75.6)	31 (68.9)	26 (56.5)	26 (89.7)	[a]0.068
LBSP *n* (%)	7 (15.6)	9 (20.0)	9 (19.6)	2 (6.9)	
DBSP *n* (%)	4 (8.9)	5 (11.1)	11 (23.9)	1 (3.4)	
Preop sensitivity					
No *n* (%)	39 (86.7)	37 (82.2)	41 (89.1)	13 (44.8)	[a]0.001**
Moderate *n* (%)	6 (13.3)	8 (17.8)	4 (8.7)	15 (51.7)	
Severe *n* (%)	0 (0.0)	0 (0.0)	1 (2.2)	1 (3.4)	

[a]Fisher Freeman Halton test; [b]Kruskal–Wallis test; $^{**}p<0.01$

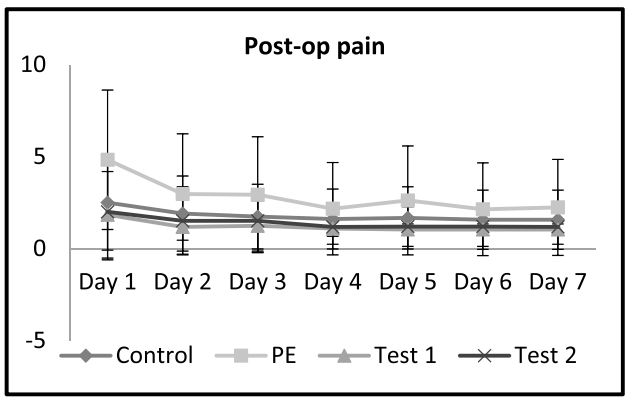

Fig. 2 The change in the VAS scorings of the postoperative pain within the 1st week

failures with apical radiolucency is given in Fig. 6 (a, b, e, and f). In total, 9 failures were detected due to irreversible pulpitis symptoms: 6 failures within 3 months, 2 failures at 6 months, and one at 1-year follow-up. Representative radiography of one of these failures can be seen in Fig. 6 c, d.

The Cox proportional hazard regression analyses are displayed in Table 4. Borderline significance was obtained for univariate analysis of tooth type, radiographic depth, carious tissue, and preoperative sensitivity (Table 4; $p<0.200$). Multivariate analyses with the backward elimination method were performed for these variables. Tooth type and radiographic depth showed some effect in this model, whereas carious tissue and preop sensitivity had no effect on the treatment outcome. No variable exhibited a statistically significant influence on the outcome of the interventions (Table 4; $p<0.05$).

The pulp was exposed unintentionally in 11 and 18 teeth after SRSD and SRFD techniques, respectively (Fig. 1, Table 5). Pulp exposure rates according to groups and characteristics of the carious tissue were given in Table 5. Representative radiography of one of the teeth with unintentional pulp exposure in the SRSD group was given in Fig. 7. The

Table 2 Comparisons of baseline variables between followed and unfollowed treatments

Variables		Followed	Unfollowed	*P*
Age	Mean (SD)	24.44 (8.58)	23.26 (7.46)	[c]0.566
	Median (min–max)	23 (13–44)	23 (13–42)	
Gender	Female	59	18	[d]0.537
	Male	41	16	
Tooth type	Molar	74	24	[d]0.929
	Premolar	51	16	
Cavity type	Cl I	18	4	[d]0.476
	Cl II	107	36	
Radiographic depth	3/4	37	13	[d]0.751
	More than 3/4	88	27	
ICDAS score	4	39	19	[d]0.088
	5	80	21	
	6	6	0	
Caries tissue	LYAP	86	31	[a]0.554
	LBSP	21	6	
	DBSP	18	3	
Preop sensitivity	No	100	30	[a]0.448
	Moderate	24	9	
	Severe	1	1	

[a]Fisher Freeman Halton test; [c]Mann–Whitney *U* test; [d]Pearson chi-square test

Table 3 Primary outcome analysis of teeth at 2 years of follow-up

Analyzed ($n=125$)	*Test 1 SRSD + CS ($n=35$)*	*Test 2 SRSD − CS ($n=31$)*	*Control SRFD ($n=34$)*	*PE ($n=25$)*	*P*
Overall success					
Pulp vitality without apical radiolucency *n* (%)	35 (100)	29 (93.5)	28 (82.4)	21 (84.0)	[a]0.024*
Overall failure					
No pulp vitality with apical radiolucency *n* (%)	0 (0.0)	1 (3.2)	1 (2.9)	1 (4.0)	[a]0.709
Irreversible pulpitis with pain at percussion and palpation *n* (%)	0 (0.0)	1 (3.2)	5 (14.7)	3 (12.0)	[a]0.038*

[a]Fisher Freeman Halton Test; *$p<0.05$

risk of pulp exposure in the SRFD group was approximately 3 times higher than in the SRSD group, with a 95% CI of 1.396–7.342 ($p=0.005$; $p<0.01$).

Representative radiography for tertiary dentin formation in the PE group is given in Figs. 7 and 8. The highest rate of tertiary dentin formation was observed in the PE group (84%), when compared to the control (41.2%) and test groups after 2 years ($p<0.01$). Tertiary dentin formation was also higher in the test 1 group (77.1%) when compared to the test 2 (22.6%) group after 2 years ($p<0.01$).

Discussion

In the present study, different treatment strategies for deep carious lesions were tested. After 2 years of follow-up, the results demonstrated that SRSD was more effective than SRFD in preserving pulp vitality in permanent teeth. A higher proportion of teeth with unexposed pulps (17.6%) in the SRFD group experienced pulp inflammation, whereas only 3.1% of teeth in the SRSD groups were referred to endodontic treatment. Moreover, significantly less pulp exposure was observed after SRSD (10.9%) than after SRFD (28.1%).

To our knowledge, the present study is the first longitudinal randomized clinical trial on permanent teeth compared to the clinical outcomes of the SRSD and SRFD techniques. In permanent teeth, uncompleted caries removal in combination with different base materials and resin composite restorations has previously been studied in two clinical trials [7, 21]. The first one was a single-arm clinical trial that evaluated SRSD in combination with calcium hydroxide cement [22]. The second one compared SRSD in combination with glass ionomer cement with stepwise

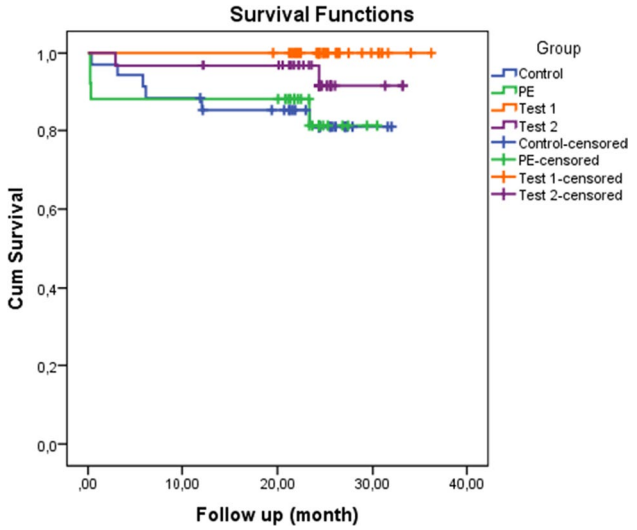

Fig. 3 Survival curves of clinical and radiographic success over 2 years of Test 1 (SRSD with calcium silicate-based material), Test 2 (SRSD without calcium silicate-based material), Control (SRFD with calcium silicate-based material) and PE (Pulp exposure) groups

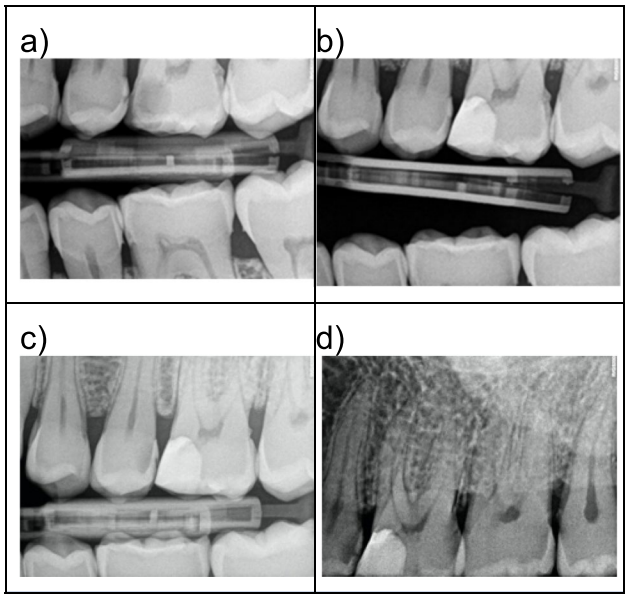

Fig. 4 Representative photo and radiography of one of the cases in Test 2 group (SRSD without calcium silicate-based material) group with vital pulp **a)** pre-op **b)** immediately after treatment **c-d)** after 2 years follow-up without any apical radiolucencyc

caries removal [7]. High rates of overall success (90–91%) for SRSD were found in these clinical trials at 36 months after treatment [7, 21]. The observed success of SRSD with (100%) or without (93.5%) calcium silicate-based material in the present study corroborates the findings of these previous studies.

A longitudinal randomized clinical trial on primary teeth comparing SRSD and SRFD in combination with calcium hydroxide cement has also found high rates of success (92 and 96%, respectively) at 24 months after treatment [8]. In this study, no significant difference was observed between the success rates of the two caries removal techniques. This result was in accordance with the findings in clinical trials on primary teeth and young permanent teeth [23, 24]. However, in the present study, the success rate of SRSD was higher than the SRFD. Similarly, a recent systematic review and meta-analysis of clinical trials on permanent teeth demonstrated a statistically significant difference, favoring SRSD for the overall success of maintaining pulp vitality compared with the control group that was composed of stepwise caries removal, or SRFD [9]. Obviously, different results were obtained from permanent and primary teeth for the comparison of two caries removal techniques. It seems that the results of the studies conducted on primary dentition could not be extrapolated to permanent dentition, as suggested by Barros et al. [9], taking into account the difference in regeneration potential between the two different types of dentition.

The risk of pulp exposure in the present study was found to be approximately 3 times higher in SRFD when compared to SRSD. This was in accordance with the findings reported by Orhan et al. [25] in mixed dentition that pulp exposure was reduced with SRSD when compared with SRFD (6 and 22%, respectively). However, Franzon et al. [8] reported a lower risk ratio of pulp exposure for SRSD (2%) compared to SRFD (27.5%) on primary teeth. When interpreting these results, the depth of carious lesions should be taken into consideration. Notably, lesions radiographically extending ¾ of dentin were evaluated by Orhan et al. [25], which was similar to the depth of lesions in the present study, whereas the radiographic depth of the caries lesions was not clearly defined by Franzon et al. [8]. Additionally, the characteristics of the caries lesions might also have an influence on the frequency of pulp exposure. In the present study, 89.7% of the lesions were defined as LYAP according to the classification of Bjørndal et al. in the PE group [19]. The overall pulp exposure rate was higher during the removal of LYAP carious tissue (22%) when compared to LBSP (7%) and DBSP (4.7%), irrespective of the caries removal technique. Taking only the LYAP lesions into account, it seems that pulp exposure was still less likely with SRSD (12.1%) compared with SRFD (39.5%), whereas no difference for LBSP and DBSP lesions (Table 5).

The degree of excavation and excavation technique can also be argued that perhaps less pulp exposure would have been observed if more amount of soft caries tissue was left over the pulp. The use of a hand excavator for SRSD might have increased the risk of pulp exposure [26]. However, it is still unclear whether leaving more carious tissue is beneficial or harmful [9]. In the present study, carious removal was performed following the principles recommended by Schwendicke and Innes [27]. Understanding the terms soft,

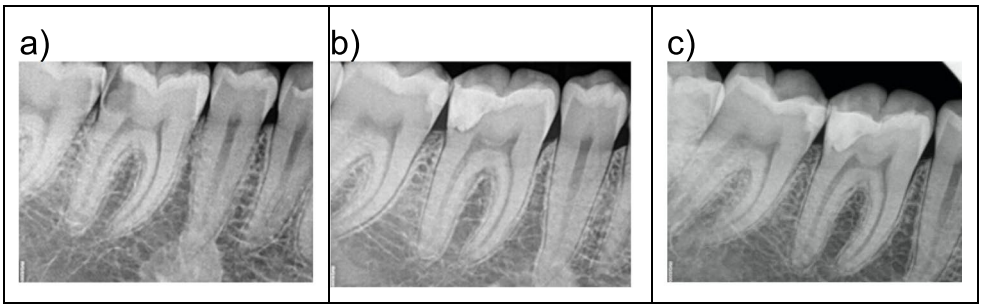

Fig. 5 Radiography of one case in Test 1 (SRSD with calcium silicate-based material) group with vital pulp and without apical radiolucency a) Pre-op b) immediately after treatment c) 2 years follow-up

Table 4 The Cox proportional hazard regression analyses of the influence of the baseline variables on the failure outcomes at 2 year follow-up

Variables	*Success*	*Failure*	*Univariate*		*Multivariable*	
	n	*n*	*HR (95% CI)*	*P*	*HR (95% CI)*	*P*
Tooth type						
Molar	64	10	Reference			
Premolar	49	2	3.679 (0.806–16.795)	0.093	3.339 (0.729–15.292)	0.120
Radiographic depth						
3/4	36	1	Reference			
More than 3/4	77	11	5.041 (0.650–39.073)	0.122	4.416 (0.567–34.376)	0.156
Caries tissue						
LYAP	80	6	Reference	0.152		
LBSP	19	2	1.214 (0.245–6.030)	0.812		
DBSP	14	4	3.417 (0.963–12.119)	0.057		
Preop sensitivity						
No	92	8	Reference			
Modarete	20	4	2.347 (0.706–7.805)	0.164		

CI, confidence interval; *HR*, hazard ratio

Table 5 Pulp exposure rates according to groups and characteristics of the carious tissue

		Group SRSD ($n=101$)			Group SRFD ($n=64$)		
Pulp exposure	*No n (%)*	*90 (89.1)*			*46 (71.9)*		
		LYAP	LBSP	DBSP	LYAP	LBSP	DBSP
		65 (87.8)	16 (94.1)	9 (90)	26 (60.5)	9 (90)	11 (100)
	Yes n (%)	*11 (10.9)*			*18 (28.1)*		
		LYAP	LBSP	DBSP	LYAP	LBSP	DBSP
		9 (12.1)	1 (5.9)	1 (10)	17 (39.5)	1 (10)	0 (0)

LYAP, light yellow actively progressing; *LBSP*, light brown slowly progressing; *DBSP*, dark slowly progressing

leathery, firm, and hard dentine was helpful for the standardization of the carious removal degree. The endpoint for caries excavation was in close proximity to the leathery dentin, and residual soft tissue was very thin and appeared dry after air drying. Leaving a thicker layer of carious tissue can be challenged in further randomized clinical trials.

Pulp exposure was not accepted as a failure in this clinical trial. Teeth with exposed pulps were assigned to the PE group, and 84% of the teeth that received pulp capping treatment had successfully sustained pulp vitality, with tertiary dentin formation and without apical radiolucency or unbearable pain at a 2-year follow-up. The overall survival rate of the teeth with exposed pulps at the 12-month follow-up (89%) in the current study was significantly different from the survival rate of teeth treated with calcium hydroxide cement (32.8%) but in accordance with the survival rate of the teeth treated with CS (96%) at the same follow-up period in permanent teeth [12, 17]. However, Brizuela et al. [28] reported higher success rates and no significant difference between calcium hydroxide cement (86.4%) and CS (100%)

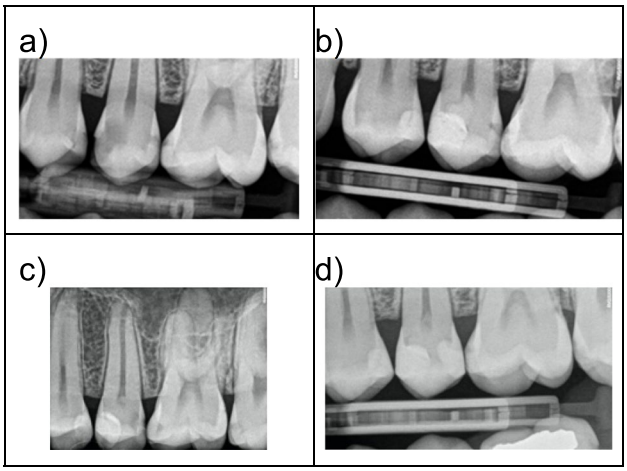

Fig. 6 **a**–**d** Radiography of one PE (pulp exposure) case with vital pulp and dentin bridge formation **a** preop **b** immediately after treatment **c** 2 years follow-up periapical radiography (cavity formation at distal side) **d** 2 years follow-up bite-wing radiography after the restoration of the cavitation

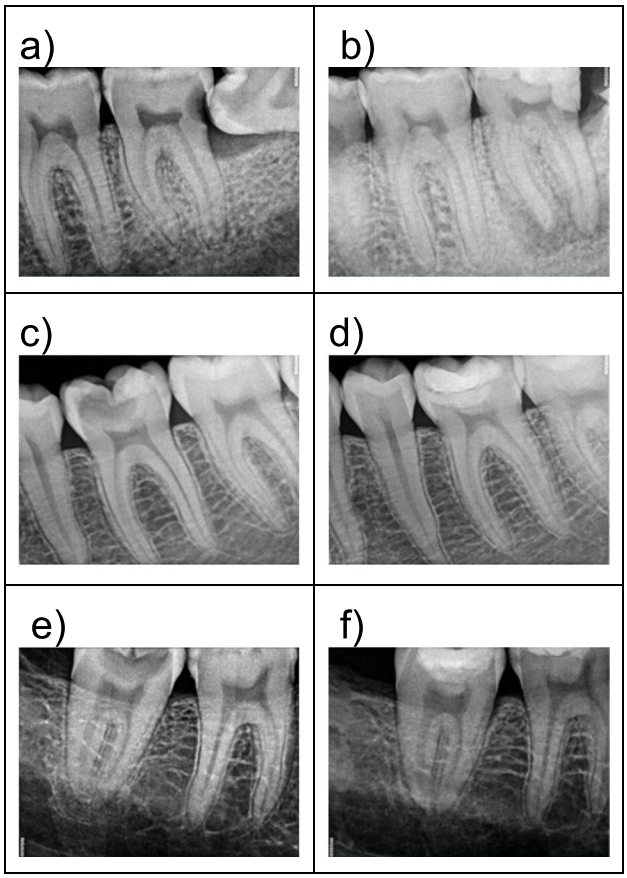

Fig. 7 **a**–**f** Representative radiography of failed cases: **a**, **b** preop and 2 years follow-up with apical radiolucency in test 2 (SRSD without calcium silicate-based material) group **c**, **d** preop and immediately after treatment (failure after 1 week with unbearable pain and positive percussion) in PE (pulp exposure) group **e**, **f** preop and 2 years follow-up with a negative response to the cold test, absence of lamina dura and dentin bridge formation in PE group

in young permanent teeth. The treatment outcome of pulp capping relies on the factors such as age, the capping material, preoperative condition of the pulp, use of rubber dam, and size of the pulp exposure [29, 30]. In the present study, one of the possible reasons for failures might be not using a rubber dam to provide asepsis. No prolonged bleeding, which is an indicator of pulp inflammation, was observed in any failed case. When the radiography of success (Fig. 7 and Fig. 8) and failure cases (Fig. 7.2 and 7.3) are compared, it can be underlined that the contact area between pulp tissue and CS is smaller in failed cases. One possible explanation can be offered concerning the bioactive effect of CS is that presence of a hard tissue barrier at the pulpal surface may prevent the healing potential of the material. Even though the lower success rate (77.8%) of indirect pulp capping with CS in permanent teeth after 2 years [18] when compared with the results obtained from previous direct pulp capping studies [12, 28] supports this view, no significant difference between SRFD and PE groups was found in the present study.

Age, gender, tooth, cavity type, radiographic depth, ICDAS scores, carious tissue characteristics, and preoperative sensitivity were not correlated with treatment success. These findings corroborate previous studies showing no significant influence of gender, tooth, and cavity type on treatment outcome [4, 6, 8]. However, Björndal et al. [30] compared stepwise caries removal with SRFD and found higher success rates for teeth without preoperative pain and lower success rates for patients older than 50 years old. These contradictory findings may be related to the difference in the precondition of the pulp and age of the population. In the present study, the study population consisted of younger patients, and the preoperative pain could be defined as moderate sensitivity. To the best of our knowledge, this is the first clinical study to assess whether radiographic depth, ICDAS scores, and carious tissue characteristics are associated with clinical and radiographic success or not.

Based on the clinical and radiographic observations reported from the present study, CS might be proposed to be a choice of base material for deep carious lesions with or without pulp exposure. CS seemed to have a positive influence on tertiary dentin formation and preservation of pulp vitality. However, long setting time and difficult handling properties were the main drawbacks to the application of CS in this clinical trial. It should also be noted that the application of a lining material was required to cover the CS prior to placement of the restoration. Otherwise, CS was easily removed during air drying, or the walls of the cavity were contaminated during the application of the adhesive system with a micro brush, despite the 12 min setting time

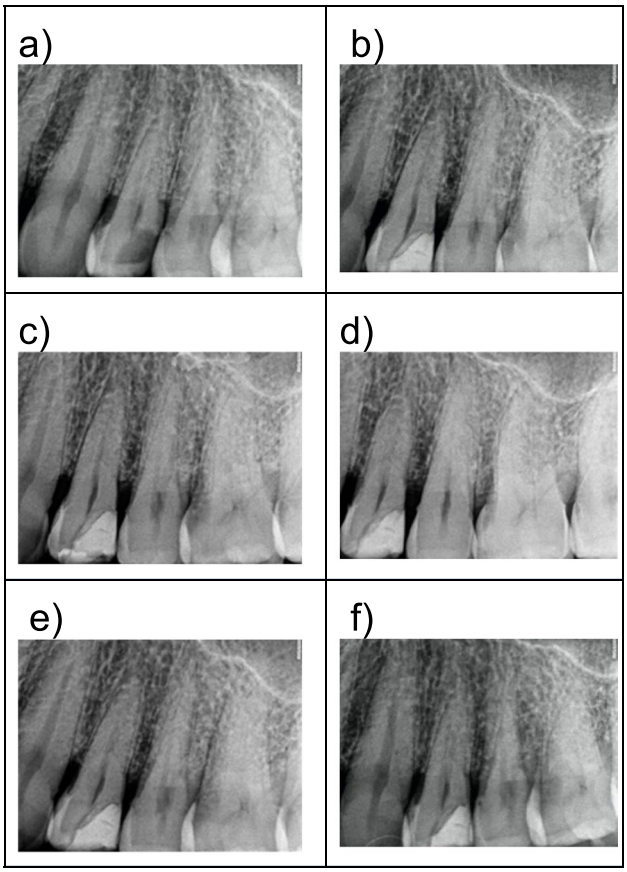

Fig. 8 **a**–**f** Radiography of the tooth (#24) with preop severe sensitivity, dark brown slowly progressing carious tissue characteristics and pulp exposure during SRSD **a** preop **b** immediately after treatment **c** 3 months, **d** 6 months, **e** 1 year, and **f** 2 years follow-up with vital pulp, dentin bridge formation and without apical radiolucency

recommended by the manufacturer being completed. Alternatively, the use of novel resin-based composite materials with self-adhesive properties might be preferred instead of conventional resin composites to eliminate these difficulties. However, there is a lack of long-term evidence on the clinical outcome of this simplified restoration concept.

In the case of pulp exposure, despite all of the disadvantages such as long chairside time and high cost, CS still might be the material of choice with its potential to prevent endodontic treatment procedures and related complications. However, the role of lining material in treatment success with SRSD can be questioned. Coralo and Maltz [31] compared the effects of calcium hydroxide, glass ionomer cement, and wax (inert material) on carious dentin after SRSD. In this randomized clinical trial, after a sealing period of 3–4 months, dentin hardening detected by clinical assessment and partial or total obliteration of tubules revealed by ultrastructural analysis indicated that liner itself did not play a role in the arrestment process of the remaining carious tissue [31]. It was emphasized that SRSD with good cavity sealing played a major role to the promote defense mechanisms of the pulpo-dentinal organ [31]. The effect of various lining materials on treatment outcomes with SRSD was also investigated in long-term clinical trials [4, 26]. Sign et al. [4] reported no significant difference between the success rates of calcium hydroxide (96.6%), resin-modified glass ionomer cement (96.5%), and direct composite (94.6%) in permanent teeth after 1 year. Falster et al. [26] reported a 96% success rate without placement of calcium hydroxide prior to direct composite in primary teeth after 2 years. Similar to the results of the abovementioned studies, no significant effect of CS on treatment success after SRSD was found in the present study. This is an important finding that further adds to the clinical evidence that only SRSD with good coronal sealing may be recommended without any liner application for the treatment of deep caries lesions. Nevertheless, longer-term evidence is required for a strong recommendation.

The high success rates in the present study may also be attributed to good coronal sealing, and all of the restorations were 100% acceptable according to FDI criteria. No restoration failure, such as fracture, secondary caries, or marginal gap that may promote detrimental effects of bacteria in the remaining caries tissue, was observed.

Randomization, single operator, standardized treatment, well-defined lesions, and no difference between the control and test groups with respect to the baseline characteristics were strengths of this study. One of the limitations of this study was that not all patients attended the follow-up appointments, which might affect the reported success rates. As a precaution against loss of contact, the phone number of the one to be called in an emergency situation, e-mail, and social media accounts of the patients were noted at the first session. Most of the patients reached out but did not want to show up, declaring any pain and disturbance. Additionally, the unbalanced distribution of sample size according to lesion characteristics could not be predicted at the beginning of the study. Thus, the stratified randomization technique was not used. This is one of the other limitations of the present study that no firm evidence could be provided for the influence of this parameter on pulp exposure. Therefore, future studies with a large sample permitting subgroup analysis of teeth with well-defined radiographic depths and carious tissue characteristics are required to find out whether or not these parameters have an effect on the incidence of pulp exposure.

Conclusions

From this study, it can be concluded that SRSD had a high success rate when compared to SRFD to treat deep carious lesions in permanent teeth after 2 years of follow-up. The

use of calcium silicate-based material after SRSD had no effect on the treatment outcome.

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Author contribution BGÇ and MÖ contributed to the conceptualization and methodology of the study. AT, YEH, and BGÇ performed the data curation. BGÇ performed the project administration, funding acquisition, literature research, interpretation of the data, and draft writing. The study and manuscript writing were supervised by MÖ. All authors revised, validated, and edited the work. All authors agree to be accountable for all aspects of the study design and its content. All authors approved the final submitted version.

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Declarations

Ethics approval The study was approved by the University Ethics Committee with protocol no. 10840098–604.01.01-E.53565.

Consent to participate All participants provided written informed consent.

Conflict of interest The authors declare no competing interests.

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