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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SELECTIVE REMOVAL TO SOFT DENTINE OR SELECTIVE REMOVAL TO FIRM DENTINE FOR DEEP CARIES LESIONS IN PERMANENT POSTERIOR TEETH?: A RANDOMIZED CONTROLLED CLINICAL TRIAL UP TO 2 YEARS

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Short Title: *SRSD vs SRFD for deep posterior caries lesions of permanent teeth*

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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 success rates of the two caries removal techniques. The secondary outcome of the study was to investigate whether or not calcium silicate-based materials (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 study. 165 deep posterior teeth with primary caries lesion radiographically extending ¾ of dentin and positive response to cold test were randomly selected. 134 participants meeting the inclusion criteria were randomized to SRSD and SRFD (Control) groups. After caries removal procedure, teeth with exposed pulps were assigned to pulp exposure (PE) group and SRSD group was further divided into Test 1 (with CS) and Test 2 groups (without CS . Success was defined as positive response to cold test, negative response to percussion, absence of pain, abscess, fistula and periapical alterations. Fisher-Freeman-Halton exact tests, Kaplan-Meier 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 y follow-up.

Conclusions: SRSD had a higher success rate when compared to SRFD to treat deep carious lesions after 2 y of follow-up. Use of CS material after SRSD as 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 NCT04052685 (08/09/2019)

Keywords

Selective caries removal, dentin caries, permanent dentition, calcium silicate cements, clinical trial

Introduction

In recent years, there has been 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, removal of infected dentin contaminated with bacteria and remaining affected dentin detected as firm suggested for the management of cavitated caries lesions. Recently, this removal technique is termed as selective removal to firm dentin (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 stepwise excavation method [4]. The stepwise removal is a 2-stage procedure that incomplete removal of caries tissue is carried out in the first stage and then cavity is sealed with a temporary filling to promote tertiary dentin formation. At the second stage cavity is re-opened, and the remaining demineralized dentin is removed [5]. Regarding the disadvantages of stepwise removal including requirement of two sessions for treatment completion and 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 selective removal to soft dentin (SRSD) that refers to 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 International Caries Consensus Collaboration (ICCC) group SRSD is strongly recommended in deep cavitated lesions extending into ¾ of dentin tissue [1].

In case of pulp exposure, direct pulp capping is the treatment of choice for a tooth with a vital pulp and without any inflammation predictor. However, according to results of a retrospective study evaluating the treatment outcome of direct pulp capping with calcium hydroxide, 44.5% in the 5-yr group and 79.9% in the 10-yr group had a post-operative root canal treatment or an extraction [10]. Similarly, another retrospective study showed that over the first 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 the longevity of the restorations [13]. However, information on clinical advantages or disadvantages of SRSD and SRFD excavation methods mostly rely on studies conducted for primary teeth [8,14-16]. In the currently available literature, not much scientific evidence on 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 carious removal strategies and calcium silicate-based materials (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 comparison of 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 University Ethics Committee (protocol number is given in '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 (Registration No. was given in 'Tittle page' and also 'Abstract' parts of the manuscript). 259 teeth 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 (Study flow chart).

The sample size calculation was based on the difference between success rates of partial caries removal after 3-year period of 91% [6] and direct complete excavation after 1year 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, total number of 198 restorations could not be completed. The enrollment of the study had to be finished in March 2020.

Potential patients attending to University Dental Clinics (mentioned in title page) 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 extend 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 absence of spontaneous pain, periradicular pathology or non-carious lesions (attrition, abrasion, erosion or abfraction). Teeth with untreated periodontal disease, positive response to percussion, 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 case of pulp exposure, pulp-capping was performed for these teeth and they were assigned to 'Pulp Exposure (PE)' group. SRSD group was further divided to 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 SRSD group.

Clinical Procedures

Clinical treatments were carried out by the operator (BGÇ) who have experience in restorative dentistry 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 pre-operative sensitivity, tooth type, age and gender of the patient, ICDAS score and radiographic depth of the lesions were assessed just before treatment. Patients' 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 pain killers 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. Reasonable amount of soft carious tissue was left over the pulp.
- In SRFD group, carious tissue 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 minutes [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^{TM}) was covered by resin-based lining material (Glass liner, Willmann & Pein GmbH, Barmstedt, Germany) after 12 minutes 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 the 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 more than 3 minutes.
- 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 10s and adhesive material (3M Single Bond Universal Adhesive, 3M ESPE St Paul, USA) was applied with a micro brush in cavity walls rubbing for 20s. After gentle air-drying for approximately 5s, 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 assessment at home daily for the first week after the treatments using visual analogue scale (VAS) printed on a 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 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)
- 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 radiological 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 were 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 placed side by side on a black screen using a software (Keynote, Apple Inc., Cupertino, California, 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, abnormal radiolucency or radiopacity at the pulpal or root surfaces were considered as 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, patient's view [20].

2.5 Statistical analysis

Number Cruncher Statistical Systems (NCSS, 2007, Kaysville, Utah, USA) was used for statistical analysis. Distribution of quantitative data (age and post-operative 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 was used to evaluate the uni- and multivariate influences of baseline variables on treatment success. Kaplan-Meier Analysis to determine survival rates and the log-rank test to find out the differences between the survival rates of the groups were used. The significance level was set at 5%, and the unit of analysis was the tooth.

Results

From the 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; mean age was 24.14 (minimum 13 and maximum 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 pre-op sensitivity . In the PE group, the teeth with moderate pre-operative sensitivity scores were higher and the teeth with no pre-operative sensitivity were lower when compared to control and test groups ($p=0.001$; $p<0.01$)

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

At the end of 2 y 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 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, pre-operative sensitivity, tooth and cavity type (Table 2; $p> 0.05$).

Success and failure rates according to groups after 2 y 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 was significantly lower when compared with test groups ($p=0.024$; $p<0.05$). No statistically significant difference for incidence of vitality loss with apical radiolucency was found ($p=0.79$; $p>0.05$). 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 with Control (14.7%) and PE (12%) groups ($p=0.038$; $p<0.05$).

Representative radiography of the teeth in Test 1 and Test 2 groups assessed as having normal periapical structures at 2 y follow-up are presented in Fig. 4 and Fig. 5. One failure due to loss of vitality was observed in each group except Test 1 group ($p=0.709$; $p>0.05$). Representative radiography of these failures with apical radiolucency are given in Fig. 7 (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 m and one at 1 y follow-up. A representative radiography of one of these failures can be seen in Fig.7 (c and d).

Fig. 3 shows the survival curves for the groups. Statistically significant difference in favor test groups versus control and PE groups was found using the log rank test ($p=0.45$; $p<0.05$). When all lost cases were simulated as success the difference between the survival curves was still statistically significant ($p=0.038$; $p<0.05$).

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 pre-operative sensitivity (Table 4; $p<0.200$). Multivariate analyses with backward elimination method was performed for these variables. Tooth type and radiographic depth showed some effect in this model whereas carious tissue and pre-op 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 SRSD group were given Fig. 8. The risk of pulp exposure in SRFD group was approximately 3 times higher than in SRSD group with a 95% CI of 1.396-7.342 ($p=0.005$; $p<0.<01$).

Reresentative radiography for tertiary dentin formation in PE group are given in Fig. 6 and Fig.8. The highest rate of tertiary dentin formation was observed in PE group (84%) when compared to control (41.2%) and test groups after 2 years ($p<0.01$). Tertiary dentin formation was also higher in Test 1 group (77.1%) when compared to Test 2 (22.6%) group after 2 y ($p<0.01$).

Discussion

In the present study, different treatment strategies for deep carious lesions were tested. After 2 y of follow-up, the results demonstrated that SRSD was more effective than SRFD in preserving pulp vitality in permanent teeth. 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 fewer 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 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 evaluated SRSD in combination with calcium hydroxide cement [22]. The second one compared SRSD in combination with glass ionomer cement with stepwise 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 between the success rates of two caries removal techniques was observed. 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] taken 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 depth of lesions in the present study, whereas the radiographic depth of the caries lesions were not clearly defined by Franzon et al [8]. Additionally, the characteristics of the caries lesions might also have an influence on frequency of pulp exposure. In the present study, 89.7% of the lesions was defined as LYAP according to classification of Bjørndal et al in 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).

Degree of excavation and excavation technique can also be argued that perhaps fewer pulp exposure would have been observed if more amount of soft caries tissue was left over the pulp. Use of 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 of the terms soft, leathery, firm, and hard dentine was helpful for standardization of carious removal degree. The end point for caries excavation was in close proximity with the leathery dentin and residual soft tissue was very thin that appeared dry after air drying. Leaving thicker layer of carious tissue can be challenged in further randomized clinical trials.

Pulp exposure was not accepted as failure in this clinical trial. Teeth with exposed pulps were assigned to PE group and 84% of the teeth received pulp capping treatment had successfully sustained pulp vitality, with tertiary dentin formation and without apical radiolucency or unbearable pain at 2 y follow-up. Overall survival rate of the teeth with exposed pulps at the 12 m 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%) in young permanent teeth. Treatment outcome of pulp capping rely on the factors such as age, the capping material, pre-operative condition of 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 rubber dam to provide asepsis. No prolonged bleeding that is an indicator for pulp inflammation was observed in any failed case. When the radiography of success (Fig. 6 and Fig. 8) and failure cases (Fig.7.2 and 7.3) are compared, it can be underlined that contact area between pulp tissue and CS is smaller in failed cases. One possible explanation can be offered concerning bioactive effect of CS is that presence of a hard tissue barrier at the pulpal surface may prevent healing potential of the material. Even tough lower success rate (77.8%) of indirect pulp capping with CS in permanent teeth after 2 y [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 pre-operative sensitivity were not correlated with treatment success. These finding 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 found higher success rates for teeth without pre-operative pain and lower success rates for patients older than 50 years old. These contradictory findings may related with

the difference in precondition of the pulp and age of the population. In the present study, the study population consisted of younger patients and the pre-operative pain could be defined as moderate sensitivity. To our knowledge, this is the first study to assess whether radiographic depth, ICDAS scores, carious tissue characteristics, are associated with clinical and radiographic success.

Based on the clinical and radiographic observations reported from the present study, CS might be proposed to be choice of base material for deep carious lesions with or without pulp exposure. CS seemed to have positive influence on tertiary dentin formation and preservation of pulp vitality. However, long setting time and difficult handling properties were main drawbacks for the application of CS in this clinical trial. It should also be noted that 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 micro brush, despite the 12 min setting time recommended by the manufacturer was completed. Alternatively, 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 lack of long-term evidence on clinical outcome of this simplified restoration concept.

In case of pulp exposure, despite the 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 procedure 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 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 promote defense mechanisms of pulpo-dentinal organ [31]. The effect of various lining materials on treatment outcome 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 y. Falster et al [26] reported 96% success rate without placement of calcium hydroxide prior to direct composite in primary teeth after 2 y. Similar to results of abovementioned studies, no significant effect of CS on treatment success after SRSD was found in the present study. This is an important finding further add 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 strong recommendation.

The high success rates in the present study may also be attributed to good coronal sealing that 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, 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 to loss of contact the phone number of the one to be called in emergency situation, e-mail and social media accounts of the patients were noted at the first session. Most of the patients reached but did not want to show up declared no pain and disturbance. Additionally, unbalanced distribution of sample size according to lesion characteristics could not be predicted at the beginning of the study. Thus, 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 incidence of pulp exposure.

Conclusions

Within the limits of the 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 y of follow-up.. Use of calcium silicate-based material after SRSD had no effect on the treatment outcome. Nevertheless, future studies with large sample and longer follow-up time are required to evaluate long-lasting rate of success.

Author contributions

BGÇ and MÖ made contribution to conceptualization and methodology of the study. AT, YEH and BGÇ performed the data curation. BGÇ performed the project administration, funding acquisition, the 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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Conflict of interest

The authors did not have any commercial interest in any of the materials used in this study.

Ethics Approval

The study was approved by University Ethics Committee with protocol No.10840098-604.01.01-E.53565.

Consent to participate

All participants provided written informed consent.

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

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

Tables:

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)	
Pre-Op 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

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-Maks)	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	87	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	
Pre-op 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 y 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

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

	Success	*Failure*	*Univariate*		*Multivariable*	
Variables	*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		
Pre-op 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

Legends:

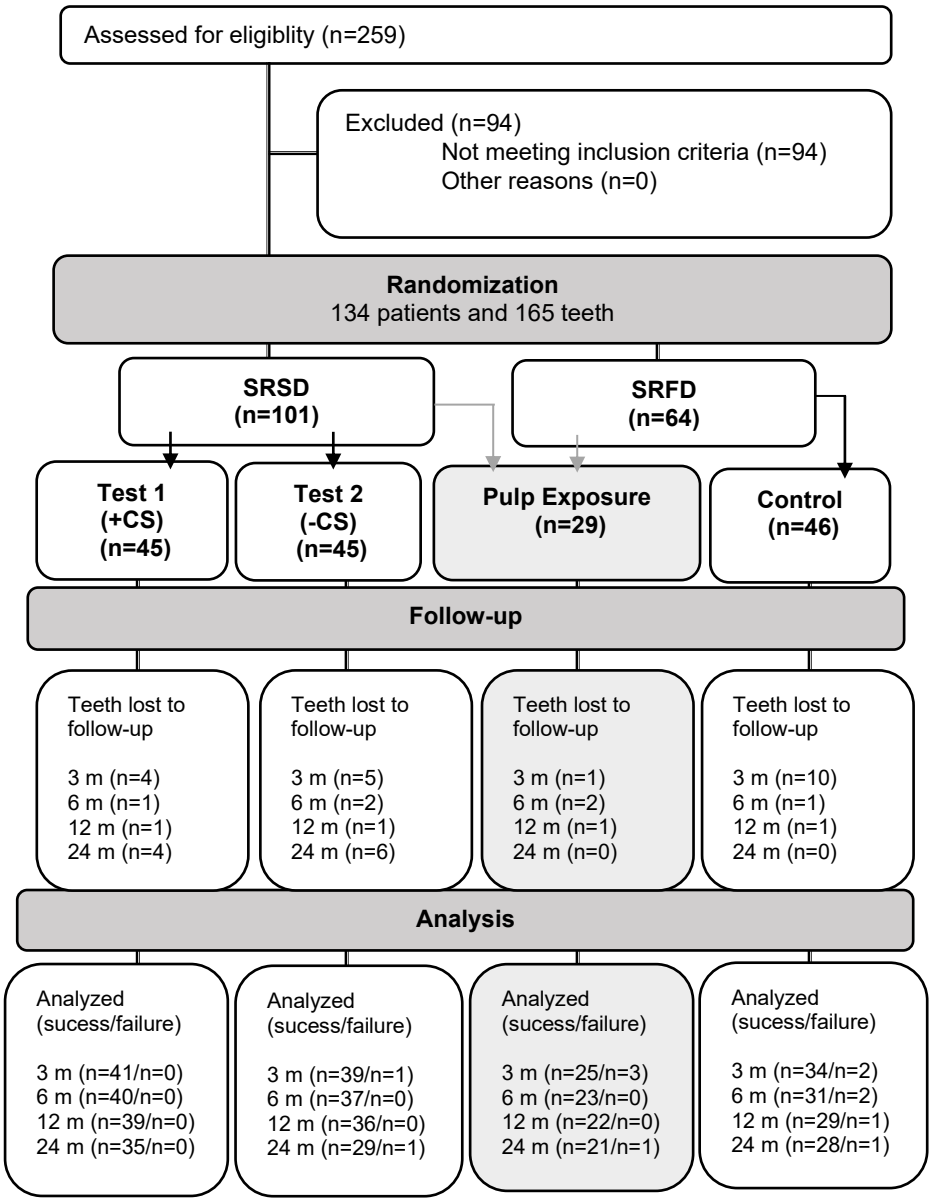


Fig. 1 Study flow chart

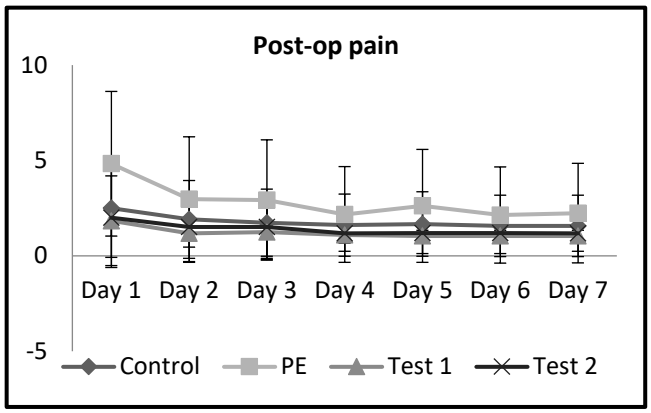


Fig. 2 The change in the VAS scorings of the post-operative pain within the first week

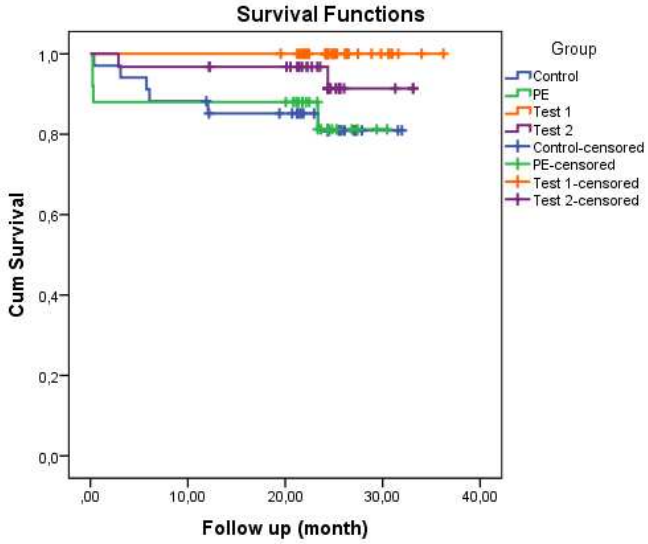
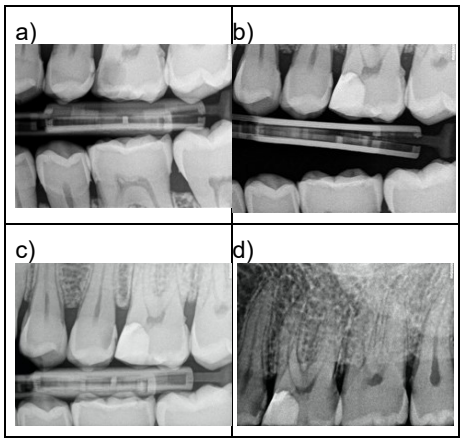


Fig.3 Survival curves of clinical and radiographic success over 2 y of Test 1 (SRSD with calcium silicate-based material), Test 2 (SRSD without calcium silicate-based material), Control (SRFD with calcium silicate-based material) and PE (Pulp exposure) groups



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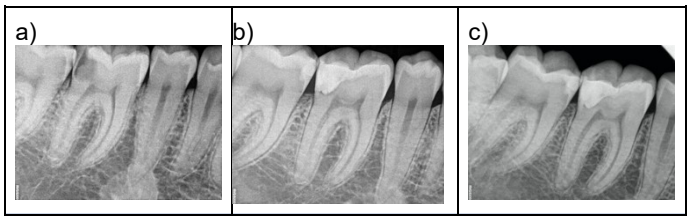


Fig. 5a-c Radiography of one case in Test 1 (SRSD with calcium silicate-based material) group with vital pulp and without apical radiolucency a) Pre-op b) immediately after treatment c) 2 y follow-upa)

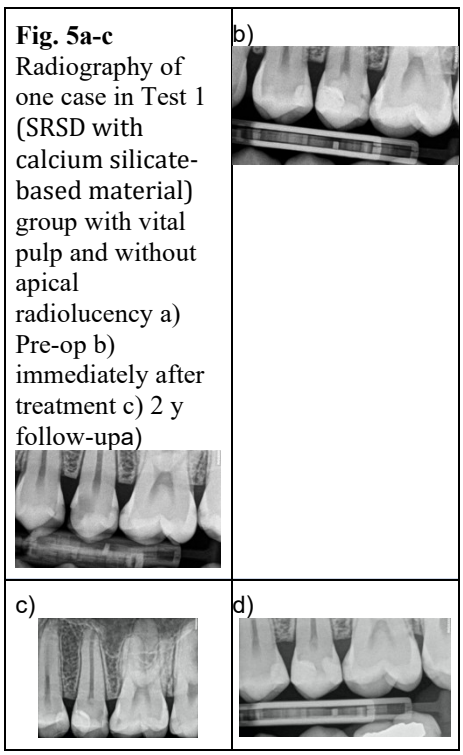
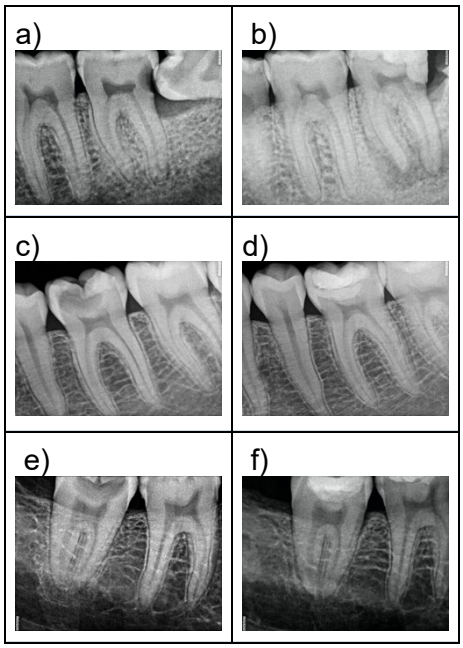


Fig. 6a-d Radiography of one PE (Pulp exposure) case with vital pulp and dentin bridge formation a) Pre-op b) immediately after treatment c) 2 y follow-up periapical radiography (cavity formation at distal side) d) 2 y follow-up bite-wing radiography after restoration of the cavitation



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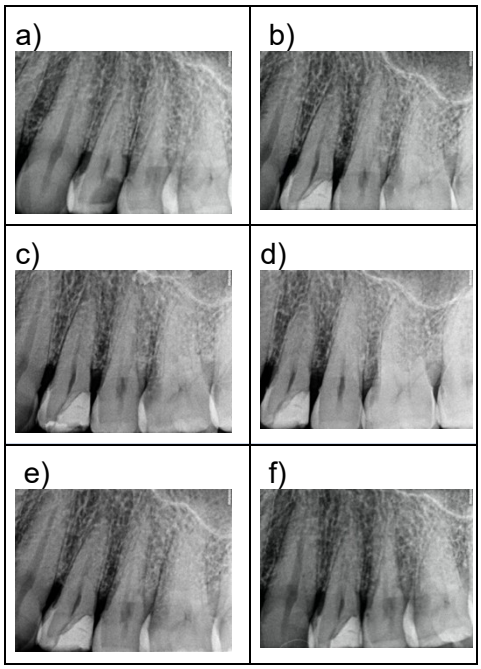

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