Research Square

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Selective versus Complete Caries Removal in Primary Molars: A 24 Month Randomized Controlled Trial Conducted in a Practise-Based Research Network

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Abstract

Purpose

Selective caries removal (SCR) is increasingly recommended to preserve pulp vitality in primary molars, yet evidence from practice-based settings is limited. The aim of this study was to compare SCR to complete caries removal (CCR) in terms of restoration failure and tooth survival over 24 months.

Methods

A 2-arm practice-based randomized controlled trial was conducted in public and private dental clinics. Children aged 3–8 years with moderately deep carious lesions in primary molars were randomly allocated to SCR or CCR, with follow-up based on dental records at 12 and 24 months post-treatment. Primary outcomes were restoration failure, tooth extraction, and composite restoration failure defined as either event occurring. Secondary outcomes included pulpitis, abscess, secondary caries and emergency visits.

Results

A total of 262 restorations in 147 children were included (SCR n=126; CCR n=136). At 24 months, treatment groups showed no significant difference in the composite restoration failure rate (SCR 23.8% vs CCR 19.9%, p=0.545). Multi-surface restorations and younger age were associated with higher failure rates. Lack of anesthesia was associated with early restoration failure.

Conclusion

SCR and CCR showed similar clinical outcomes at 24 months when performed in routine clinical practice. Hence, operator- and case-related factors appear to be more important for restoration survival than choice of excavation method.

Registry: ClinicalTrials.gov, TRN: NCT04614285, Registration date: 25 November 2020

Introduction

Dental caries remains one of the most prevalent non-communicable diseases worldwide and is particularly common in young children. Despite preventive efforts, the global prevalence of untreated caries in primary teeth has remained high, contributing significantly to the burden of disease in early childhood (Peres et al. 2019; Bernabé et al. 2025). In Sweden, as in many other high-income countries, overall caries prevalence in children has declined, but the disease is increasingly concentrated in socioeconomically disadvantaged groups, where affected children are at increased risk of rapidly progressing disease and development of deep carious lesions (Koch et al. 2017; Östberg et al. 2017; Blomma et al. 2024). Deep carious lesions can cause pain, infection, impaired eating and sleeping, and reduced oral-health-related quality of life for both the child and their family (Finucane 2012; Mota-Veloso et al. 2016; Zaror et al. 2022).

In managing deep carious lesions in primary teeth, the traditional approach has been complete caries excavation. However, this method increases the risk of pulp exposure and can necessitate more invasive treatment, including pulpotomy or extraction (Bjørndal and Kidd 2005; Ricketts et al. 2006). Restorative treatment in young children often presents additional challenges due to limited cooperation, dental fear, and the child's physical and emotional immaturity. From a clinical perspective, achieving adequate moisture control, isolation, and precision during caries removal and restoration can be technically demanding, increasing the risk of procedural complications and restoration failure (Chisini et al. 2018). In turn, this may result in repeated treatment episodes, which can place additional emotional and physical burden on the child and their family (Klingberg and Broberg 2007; Twetman and Dhar 2015; Alshoraim et al. 2018). These factors highlight the importance of minimally invasive strategies that reduce the complexity of the procedure, shorten treatment time, and improve the likelihood of successful outcomes (Dahlander et al. 2019).

In recent years, minimally invasive (MI) strategies such as selective caries removal (SCR) have gained attention. These techniques aim to preserve tooth vitality, reduce the need for pulp therapy, minimize treatment discomfort, and maintain function until natural exfoliation (Schwendicke et al. 2016). Clinical trials and systematic reviews have suggested that SCR can achieve comparable or superior outcomes in terms of pulp health and restoration survival when compared to complete caries removal (CCR) (Maltz et al. 2012; Ricketts et al. 2013; BaniHani et al. 2022; Ramezanzade et al. 2025).

However, despite the growing number of clinical studies, most investigations have been conducted under controlled conditions with calibrated operators, which may not fully reflect routine clinical practice. There is limited evidence regarding the effectiveness of these approaches in real-world settings, as studies conducted within practice-based research networks involving general dental practitioners and routine patient populations appears to be limited. Further research is therefore needed to strengthen the evidence base for the management of deep carious lesions.

The aim of this practice-based randomized controlled trial was to compare selective caries removal (SCR) to complete caries removal (CCR) in primary molars carious lesions of moderate depth in terms of (1) restoration failure and (2) tooth survival over 24 months. Our primary hypothesis was that SCR is non-inferior to CCR in terms of restoration failure and tooth survival at both 12 and 24 months post-treatment.

Materials and methods

Study design and setting

This is a prospective, two-arm, randomized controlled clinical trial conducted in general dental practice settings, with planned follow-up at 12 and 24 months after restoration treatment. Patients were recruited from four Public Dental Service (PDS) clinics in the Stockholm region, one PDS clinic in the Östergötland

region, and one private dental clinic in the Stockholm region. Patients were recruited between 2019-2021 during routine dental examinations. The study was approved by the Regional Ethics Committee in Stockholm (Daybook no. [Dnr] 2018/743-31-1). An amendment concerning a change of principal investigator was approved by the Swedish Ethical Review Authority (Dnr 2019-02164) (Daybook no. [Dnr] 2019/021-64) and an updated study protocol (Daybook no. [Dnr] 2022/01185-02). The study was also registered in ClinicalTrials.gov (NCT04614285).

The intervention group received SCR, however total caries removal was performed in the periphery including the dentino-enamel junction. In the inner part of the lesion, the caries removal was limited to reach leathery or slightly soft dentin by probing. The control group received the same treatment procedure as the intervention group, but the restorative treatment included total removal of the carious tissue (CCR). In both groups, restorations were placed according to evidence-based protocols and using the operator's material of choice.

Procedure

Recruitment and Training of Participating Dentists

Before study initiation, one of the authors informed participating clinics about the study objectives and procedures. Dentists who expressed interest registered via the website of the practice-based research network (PBRN), reviewed written study information, and provided written consent to participate.

To familiarize themselves with the electronic study platform, participating dentists entered test cases before enrolling study participants. No formal operator calibration was conducted, as the study was designed as a pragmatic trial embedded in routine clinical practice. Operators were instructed to follow their usual clinical routines except for adherence to the allocated excavation protocol (SCR or CCR).

ELIGIBILITY CRITERIA AND SCREENING

Inclusion and exclusion criteria were communicated to participating dentists before study start.

Inclusion criteria:

a. Children aged 3–8 years
b. At least one primary molar requiring restoration due to a moderately deep carious lesion defined as:

    a. Radiographic dentine involvement not exceeding the inner third, and/or
    b. A visually cavitated lesion extending into dentine

The lower age limit was chosen because children younger than three years were considered unlikely to cooperate with restorative treatment. The upper age limit was chosen because primary molars in children older than eight years were more likely to exfoliate before completion of follow-up.

Exclusion criteria:

a. Inability to cooperate sufficiently to undergo restorative treatment
b. Clinical signs or symptoms of pulpal involvement
c. Tooth expected to exfoliate within 18 months

ENROLMENT AND BASELINE ASSESSMENT

Between 2019 and 2021, children attending routine dental examinations were screened for eligibility. Children meeting the inclusion criteria were invited to participate. Written informed consent was obtained from parents or legal guardians prior to enrolment.

At the beginning of the treatment visit and before allocation, baseline data were recorded in the electronic study database (PBRN platform), including:

a. Child characteristics (age, sex)
b. Tooth position
c. Surfaces to be restored
d. Radiographic diagnosis
e. Clinical findings

Randomisation

Sequence Generation

Randomisation was performed in a 1:1 ratio to selective caries removal (SCR) or complete caries removal (CCR). During the initial phase of the study, the first 12 eligible teeth were randomized using sealed, opaque envelopes prepared prior to study start. For the remaining participants, allocation was generated

using the computerized randomization module integrated in the PBRN platform. The system automatically generated the allocation sequence.

Allocation Concealment

Allocation was concealed until baseline data had been entered into the electronic database. The treatment assignment was revealed only after registration of eligibility and baseline variables.

Implementation

Participating dentists screened and enrolled patients and entered baseline data into the study platform. The allocation sequence was generated automatically by the electronic system.

Blinding

Due to the nature of the intervention, operators could not be blinded after allocation.

Outcome assessment was performed retrospectively using dental records and radiographs. Outcome assessors were not blinded to treatment allocation.

Treatment Documentation

Immediately after completion of the treatment visit, the following procedural variables were entered into the electronic database:

a. Adjacent tooth restored at the same visit
b. Use of local anaesthesia
c. Use of sedation
d. Restorative material used
e. Intraoperative complications
f. Operator-rated quality of treatment result

Participants were anonymized within the study database. The linkage key and signed consent forms were securely stored at each participating clinic.

Outcome Assessment

Outcomes were assessed retrospectively through review of dental records and radiographs.

Records covering the preceding 12 months were reviewed at:

a. 12 months post-treatment
b. 24 months post-treatment

Primary outcomes:

a. Restoration failure
b. Tooth extraction

A composite restoration failure outcome was defined as restoration failure and/or tooth extraction.

Secondary outcomes:

a. Referral to paediatric specialist
b. Pulpitis
c. Fistula or abscess
d. Radiographic pathology
e. Secondary caries
f. Food impaction
g. Emergency visit

All outcomes were recorded as dichotomous variables (yes/no).

Participants continued to receive routine dental care during the study period. Information on dental treatment unrelated to the study tooth, such as preventive care, treatment of other teeth, trauma management, or other routine dental procedures, was not systematically collected.

Harms were not predefined as study outcomes and were therefore not systematically assessed. No data on adverse events or treatment-related harms were collected. No interim analyses were planned or performed, and no formal stopping guidelines were specified.

Statistical analysis

The à priori sample size calculation based on estimates from previous research had determined that with 90% power and significance level = .05, a total sample size of 250, randomized 1:1 to 125 patients per treatment group, was needed to detect a clinically relevant difference in restoration failure proportions between treatment groups. However, this power calculation was not tailored to a non-inferiority design corresponding to the aim of the present study.

To address the hypothesis of SCR non-inferiority to CCR in terms of restoration failure rates at 12 and 24 months post-treatment, we set a non-inferiority margin of 10% for 12 months post-treatment and 15% for 24 months post-treatment, as informed by the literature (Amend et al. 2022). The observed restoration failure proportions were tested against the inferiority margins by calculating the difference in composite restoration failure proportions between treatment groups at each time point ($prop.fail_{CCR} - prop.fail_{SCR}$), along with one-sided 95% confidence limits for the difference in failure proportions. As the rule of thumb assumption for sufficiently large sample size (n*p >10) did not hold for either time point, confidence intervals were calculated using the continuity-corrected method presented by Miettinen & Nurminen (1985). In order to pass the test for non-inferiority, the one-sided 95% confidence limit for the difference in failure proportions must not be smaller than -0.10 at 12 months post-treatment and not smaller than -0.15 at 24 months post-treatment.

Baseline characteristics of the child, the treated tooth and surface, and the treatment visit are presented as mean and standard deviation (SD) or count and percentage, as appropriate. Outcome variables were dichotomous, coded as yes/no and presented as count and percentage. Missing data were not imputed and are reported in Tables 1 and 2.

Analyses were conducted per-protocol, i.e. only restorations completed as randomized were included. Differences in the distribution of outcome variables between treatment groups were tested using Fisher's exact test. Differences in participant, tooth and treatment visit characteristics between composite outcome groups were tested using t-test or Fisher's exact test.

Predictors of the composite outcome were explored for each follow-up period. To account for children contributing more than one restoration to the study (i.e. restorations being clustered within children), associations were estimated using generalized estimating equations (GEE) specifying binomial family and logit link function with an exchangeable working correlation matrix.

Results

Of the 269 treatment events eligible for study inclusion, five treatments were terminated prior to completion due to complications (three of which were randomized to CCR and terminated to reduce the risk of pulp exposure), one received CCR despite being randomized to undergo SCR, and one parent withdrew consent. The resulting study sample consisted of 262 restorations in 147 children: 136 restorations (52%) were randomized to the CCR treatment group, and 126 (48%) to the SCR group.

Figure 1 illustrates the flow of restorations through the 24 months of follow-up. Three restorations in each treatment group were lost to follow-up prior to the 12month record review, leaving 256 restorations for outcome analyses. At the 24-month record review, 13 restorations had been lost to follow-up and 17 experienced an event during the first 12 months, leaving 226 restorations (86.3% of the original sample) for analyses of the 12- to 24-months follow-up period.

Table 1 presents the characteristics of participants, treated teeth and treatment conditions at the time of treatment. One clinic located in an area with lower socioeconomic status contributed more than half of the study sample (56%), suggesting a relatively higher caries burden in their uptake area. Less than one third of restorations were performed in children aged four to five years, just over half were in boys, and 86% were completed without complications. Nearly half of the restorations involved both occlusal and approximal surfaces, and 97% were performed using glass ionomer cement. Local anaesthesia was administered in 35% of treatments.

Treatment groups did not differ significantly in outcomes (Table 2), except for a higher incidence of secondary caries in the CCR group (7.4% vs 1.6%, p-value 0.034) and of emergency visits in the SCR group (12.1% vs 4.1%, p-value 0.037) 24 months post-treatment.

At dental record review 12 months post-treatment, restoration failure or tooth extraction had occurred in 6.77% (95% binomial confidence interval [CI] 3.14 – 12.46%) of restorations in the CCR group and 6.50% (95% binomial CI 2.85 – 12.41%) in the SCR group. At 24 months post-treatment, the proportion of composite restoration failure among restorations that were not censored during follow-up was 21.60% (95% binomial CI 14.74 – 29.85%) in the CCR group and 23.44% (95% binomial CI 16.41 – 31.74%) in the SCR group. The difference in composite restoration failure proportions at 12 months was 0.27% favouring SCR with one-sided 95% confidence limit -0.0606. At 24 months, the difference was -1.84% favouring CCR with one-sided 95% confidence limit -0.1326. Hence, SCR was demonstrated as non-inferior to CCR at both 12 and 24 months post-restoration in terms of composite restoration failure.

Restoration failure rates were higher at 24 months post treatment in children aged 4-5 years compared to children 6-8 years (45% aged 4-5 years vs 26%, p-value 0.026, Table 3). Restorations involving both approximal and occlusal surfaces had significantly higher failure rates compared with only occlusal restorations at both 12 and 24 months ($p \leq 0.020$).

When regressing the composite outcome on potential predictors, the non-use of anaesthesia was significantly associated with the outcome during the first year post-treatment (odds ratio [OR] 5.23, 95% CI 1.07 – 25.57, p-value 0.041, Table 4) when controlling for treatment group, the child's age, adjacent tooth being treated at the same time, tooth position and surface treated. In the same model, having an adjacent tooth treated at the same time was also associated with the composite outcome, increasing odds almost threefold (OR 3.78, 95% CI 1.47 – 10.16). At 24 months post-treatment, odds of experiencing the composite event were higher for younger children (OR 3.15, 95% CI 1.37 – 7.21) and lower for treatments of occlusal surfaces compared to treatments of both approximal and occlusal surfaces (OR 0.23, 95% CI 0.06 – 0.79).

Treatments that did not use anaesthesia constituted 86-100% of incidences of emergency visits, restoration failure, and extracted teeth during the first-year post-treatment, and 63-69% of incidences during the second-year post-treatment. Absence of anaesthesia was significantly associated with the composite failure outcome during the first year of follow-up (OR 5.23, 95% CI 1.07–25.57, Table 5).

Discussion

In this pragmatic practice-based randomized trial, selective caries removal (SCR) resulted in clinical outcomes comparable to complete caries removal (CCR) over 24 months. The observed differences in composite restoration failure were small and remained within the predefined non-inferiority margins. These findings are consistent with current minimally invasive principles in the management of deep carious lesions in primary teeth.

MI treatment of dental caries, including SCR, manages caries lesions with conservative techniques to maximise the preserved tooth structure. SCR is recommended in the Swedish national guidelines for the treatment of deep carious lesions in both children and adults (Nationella riktlinjer för tandvård, 2022) and is supported by strong evidence to avoid pulp exposure (Ricketts et al. 2013). Most previous randomized trials comparing excavation strategies have been conducted under highly controlled university conditions with calibrated operators. In contrast, the present study reflects routine clinical practice within a practice-based research network, thereby enhancing external validity and generalizability to everyday paediatric dental care (Maltz et al. 2012; Franzon et al. 2014; Ricketts et al. 2013; Elhennawy et al. 2021; Vaghasiya et al. 2024). Further, the absence of a difference in restoration failure rates between excavation strategies supports the contemporary biological concept that, once a sound peripheral seal is achieved, residual affected dentine does not necessarily compromise pulp health. This reinforces the principle that restoration quality and the marginal integrity may be more decisive for clinical success than complete removal of demineralized dentine.

The overall composite restoration success rate was 93.4% at 12 months post-treatment and 76.5% at 24 months post-treatment when excluding restorations censored during follow-up. Regression analysis accounting for clustering of restorations in children also showed significant associations of composite restoration failure at 12 months post-treatment with having two adjacent teeth restored at the same time, as well as without using local anesthesia. In addition, restoration failure was consistently associated with increased cavity complexity. A significant association was found between failure and number of surfaces restored, where more multiple surfaces restorations failed compared to one-surface fillings during the second-year post-treatment. Similar associations with cavity complexity have been reported in previous survival studies of primary molars (van Nieuwenhuysen 2003; Franzon et al. 2014; Pedrotti et al. 2019), indicating that technical and behavioural factors should be considered when selecting treatment strategies in children. Ultimately, these findings suggest that technical demands and procedural complexity may outweigh choice of excavation technique in terms of effect on medium-term outcomes in primary dentition.

The treatment success of carious primary molars with marginal breakdown have been studied by Basta et al. (2023) in a real-world clinical setting. The mean patients age was 6.8 ± 1.8 years. After a follow-up period of 12 months the authors reported a success rate of only 69% for Class II restorations with compomer. In the present study, most of the cavities (97%) were restored with glass ionomer cement. This material has several advantages which makes it suitable for use on children regarding restauration in primary teeth. The GIC-based materials adhere chemically to the dentin, release fluoride ions, promote remineralization and inhibit secondary caries formation.

In this real-world clinical setting, we also found a significant association between failure and not using local anesthesia in the treatment of carious lesions in primary molars. The strong association between failure and the absence of local anesthesia was unexpected and suggests that behavioral or procedural factors may influence restoration longevity in primary molars. Possible explanations include compromised moisture control, incomplete caries removal, or reduced cooperation in non-anesthetized children. These findings merit further investigation.

The use of local anesthesia is crucial to create a positive experience of dental care for the patient. In this study, the mean (SD) age of the participating children was 6.19 (1.23) years. The results showed that local anesthesia in this Practice-based Research Network has been avoided in 65% of the treatments, even though it was deep carious lesions that had to be treated and thus, local anesthesia was not used to the same extent as it is taught among students during their undergraduate education as a dentist. Our findings indicate that several dentists change the way they work when they are practice in a real-world clinical setting. Why they do this could have many reasons such as lack of time, a perception that it won't hurt but also a fear of giving young children local anesthesia. Considering the conclusion of previous studies, a current reason why dentists are reluctant to apply anesthesia in primary molars in the lower jaw may be due to the fear of placing a mandibular block on a child (Wondimu and Dahllof, 2005; Ghanei et al. 2018). This highlights the complexity of children, given that injections have been reported to be the most common cause of discomfort during dental treatment and then avoiding this affecting the overall quality of care.

The idea behind performing studies in practice-based research networks is to engage dentists in studies that are directly related to daily clinical practice, and to reduce the substantial delay between generation of new knowledge and its application in clinical practice (Mjör, 2007). The PBRN's overall goals are to conduct scientific research that is immediately applicable to clinical practice, and to foster knowledge transfer into everyday clinical practice, thereby improving population health. However, studies that are directly related to daily clinical practice are prone to operator and patient-related variability, which is

not controlled for and may negatively affect outcomes. The lack of operator calibration in our study likely increased procedural heterogeneity. While this may introduce operator-related variability, it reflects real-world practice and thus increases external validity.

All participating dentists were informed prior to study start that they were expected to perform their restorations according to routine clinical procedures. As no procedure protocol was provided to the operators, clinical procedures including rubber dam, local anesthesia and restoration material were used at operator preference. The only training provided was a theoretical instruction on the procedural differences between SCR and CCR, along with clinical photos of a) deep caries lesion, b) after selective caries removal with a leathery appearance, and c) after complete caries removal.

In this PBRN, five general dental practices and one private dental practice were involved. The clinics were situated in areas with different socioeconomic profile; high, medium and low, although one clinic in a socioeconomically disadvantaged area accounted for just over half of all restorations (55.7%). The uneven clinic distribution likely reflects the higher caries burden in socioeconomically disadvantaged areas, which is well documented in both Swedish and international epidemiological data. While no socioeconomic variables were directly collected at the participant level, clinic-level clustering should be considered when interpreting external validity.

To summarise, this study has several limitations that should be considered when interpreting the findings. The original sample size calculation assumed independence of observations, with one tooth contributed per participant. In the final study population, however, several children contributed more than one restoration. Clustering of restorations within children was accounted for using generalized estimating equations. Although such clustering may reduce the effective sample size compared with the nominal number of restorations analysed, the total number of participants exceeded the number required by the original power calculation, supporting adequate statistical precision.

Outcome assessment was not blinded to treatment allocation, which may have introduced detection bias, particularly for outcomes based on clinical judgement documented in routine dental records. Furthermore, no operator calibration was performed. While this reflects the pragmatic design within a practice-based research network and enhances external validity, it likely introduced heterogeneity in clinical technique. In addition, uneven treatment volume across participating clinics may have resulted in clinic-level clustering effects that were not explicitly modelled and could potentially influence the estimates.

Loss to follow-up of 14% at 24 months may have introduced attrition bias, and missing outcome data were not imputed. Finally, as the vast majority of restorations were placed using glass ionomer cement, the findings primarily reflect outcomes associated with this material and may not be directly generalisable to other restorative materials.

Conclusion

In conclusion, SCR performed in routine dental practice showed non-inferiority to CCR in terms of restoration failure at 12- and 24-months post-restoration treatment. These results support current recommendations of MI treatment, highlighting that technical execution and behavioural management may be more critical determinants of success than the extent of dentine removal itself.

Declarations

Conflict of interest:

The authors have no competing interests to declare that are relevant to the content of this article

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Data availability statement

The data that supports the findings of this study are available within this paper.

Author Contribution

AJ, AA, JT, MA, and GT contributed to the design, and conduct of the study and AL conducted the statistical analyses. All authors contributed to the interpretation of the data and the preparation of the manuscript. All authors reviewed and approved the final version.

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Tables

Tabell 1. Characteristics of children, teeth, surfaces, and the treatment procedure at baseline, by treatment group

		Treatment group	
	Total	**CCR**	**SCR**
	N = 262	n = 136 (51.9%)	n = 126 (48.1%)
	n (%)	n (%)	n (%)
Clinic			
Väsby FTV	6 (2.3%)	3 (2.2%)	3 (2.4%)
Brotandläkarna (Praktikertjänst)	17 (6.5%)	10 (7.4%)	7 (5.6%)
Östergötland FTV	4 (1.5%)	1 (0.7%)	3 (2.4%)
Södertälje FTV	146 (55.7%)	73 (53.7%)	73 (57.9%)
Sollentuna FTV	47 (17.9%)	28 (20.6%)	19 (15.1%)
Täby FTV	42 (16.0%)	21 (15.4%)	21 (16.7%)
Age of child			
4-5 years	76 (29.0%)	23 (27.2%)	23 (31.0%)
6-8 years	186 (71.0%)	49 (72.8%)	43 (69.0%)
Sex of child			
Girl	129 (49.2%)	67 (49.3%)	62 (49.2%)
Boy	133 (50.8%)	69 (50.7%)	64 (50.8%)
Tooth treated			
54	23 (8.8%)	12 (8.8%)	11 (8.7%)
55	37 (14.1%)	18 (13.2%)	19 (15.1%)
64	29 (11.1%)	17 (12.5%)	12 (9.5%)
65	36 (13.7%)	22 (16.2%)	14 (11.1%)
74	46 (17.6%)	22 (16.2%)	24 (19.0%)
75	34 (13.0%)	14 (10.3%)	20 (15.9%)
84	30 (11.5%)	13 (9.6%)	17 (13.5%)
85	27 (10.3%)	18 (13.2%)	9 (7.1%)
Surface treated			
Occlusal	63 (24.0%)	33 (24.3%)	30 (23.8%)
Approximal	72 (27.5%)	37 (27.2%)	35 (27.8%)
Approximal + occlusal	127 (48.5%)	66 (48.5%)	61 (48.4%)
Diagnosis by x-ray			
Outer half of the dentin	85 (32.4%)	47 (34.6%)	38 (30.2%)
Inner half of the dentin	96 (36.6%)	48 (35.3%)	48 (38.1%)
No x-ray available	81 (30.9%)	41 (30.1%)	40 (31.7%)
Visual inspection			
No cavity, no shadow	14 (5.3%)	11 (8.1%)	3 (2.4%)
No cavity, visual shadow	58 (22.1%)	35 (25.7%)	23 (18.3%)
Cavity	190 (72.5%)	90 (66.2%)	100 (79.4%)
Anaesthesia			
Yes	92 (35.1%)	47 (34.6%)	45 (35.7%)
No	170 (64.9%)	89 (65.4%)	81 (64.3%)
Sedation			
Midazolam	31 (11.8%)	20 (14.7%)	11 (8.7%)
Nitrous oxide	2 (0.8%)	2 (1.5%)	0 (0%)

No sedation	229 (87.4%)	114 (83.8%)	115 (91.3%)
Filling material used			
Composite	3 (1.1%)	0 (0%)	3 (2.4%)
Compomer	5 (1.9%)	2 (1.5%)	3 (2.4%)
Glass ionomer cement	254 (96.9%)	134 (98.5%)	120 (95.2%)
Quality of treatment result			
Excellent	67 (25.6%)	36 (26.5%)	31 (24.6%)
Acceptable	194 (74.0%)	100 (73.5%)	94 (74.6%)
Inadequate	1 (0.4%)	0 (0%)	1 (0.8%)
Complications during treatment			
Yes	36 (13.7%)	20 (14.7%)	16 (12.7%)
No	225 (85.9%)	115 (84.6%)	110 (87.3%)
N/A	1 (0.4%)	1 (0.7%)	0 (0%)
Adjacent tooth treated at the same time			
Yes	79 (30.2%)	42 (30.9%)	37 (29.4%)
No	177 (67.6%)	91 (66.9%)	86 (68.3%)
N/A	6 (2.3%)	3 (2.2%)	3 (2.4%)

Note: CCR: complete caries removal; N/A: data not available; SCR: selective caries removal. Percentages are column percentages.

Tabell 2. Outcomes during follow-up, by treatment group and follow-up period.

	0-12 months post-treatment			12-24 months post-treatment			0-24 months post-treatment		
Treatment group	CCR	SCR	**p-value**	CCR	SCR	**p-value**	CCR	SCR	**p-value**
	n (%)	**n (%)**		**n (%)**	**n (%)**		**n (%)**	**n (%)**	
Restoration failure			1			1			1
Yes	7 (5.1%)	7 (5.6%)		15 (11%)	14 (11.1%)		22 (16.2%)	21 (16.7%)	
No	126 (92.6%)	116 (92.1%)		101 (74.3%)	96 (76.2%)		101 (74.3%)	96 (76.2%)	
N/A	3 (2.2%)	3 (2.4%)		20 (14.7%)	16 (12.7%)		13 (9.6%)	9 (7.1%)	
Tooth extracted			1			.127			.273
Yes	2 (1.5%)	1 (0.8%)		3 (2.2%)	8 (6.3%)		5 (3.7%)	9 (7.1%)	
No	124 (91.2%)	115 (91.3%)		98 (72.1%)	88 (69.8%)		98 (72.1%)	88 (69.8%)	
N/A	10 (7.4%)	10 (7.9%)		35 (25.7%)	30 (23.8%)		33 (24.3%)	29 (23%)	
Composite restoration failure			1			.390			.545
Yes	9 (6.6%)	8 (6.3%)		18 (13.2%)	22 (17.5%)		27 (19.9%)	30 (23.8%)	
No	124 (91.2%)	115 (91.3%)		98 (72.1%)	88 (69.8%)		98 (72.1%)	88 (69.8%)	
N/A	3 (2.2%)	3 (2.4%)		20 (14.7%)	16 (12.7%)		11 (8.1%)	8 (6.3%)	
Referral to paediatric specialist			1						
Yes	0 (0%)	1 (0.8%)		-	-	-	-	-	-
No	133 (97.8%)	122 (96.8%)		-	-		-	-	
N/A	3 (2.2%)	3 (2.4%)		-	-		-	-	
Pulpitis			1			.487			.614
Yes	1 (0.7%)	1 (0.8%)		0 (0%)	1 (0.8%)		1 (0.7%)	2 (1.6%)	
No	132 (97.1%)	122 (96.8%)		116 (85.3%)	109 (86.5%)		116 (85.3%)	109 (86.5%)	
N/A	3 (2.2%)	3 (2.4%)		20 (14.7%)	16 (12.7%)		19 (14%)	15 (11.9%)	
Pathology on x-ray			.685			.650			.422
Yes	4 (2.9%)	2 (1.6%)		12 (8.8%)	9 (7.1%)		16 (11.8%)	11 (8.7%)	
No	129 (94.9%)	121 (96%)		104 (76.5%)	101 (80.2%)		103 (75.7%)	100 (79.4%)	
N/A	3 (2.2%)	3 (2.4%)		20 (14.7%)	16 (12.7%)		17 (12.5%)	15 (11.9%)	
Secondary caries			.787			.034			.137
Yes	8 (5.9%)	6 (4.8%)		10 (7.4%)	2 (1.6%)		17 (12.5%)	8 (6.3%)	
No	125 (91.9%)	117 (92.9%)		106 (77.9%)	108 (85.7%)		103 (75.7%)	102 (81%)	
N/A	3 (2.2%)	3 (2.4%)		20 (14.7%)	16 (12.7%)		16 (11.8%)	16 (12.7%)	
Food impaction			1			.716			1
Yes	3 (2.2%)	2 (1.6%)		3 (2.2%)	4 (3.2%)		6 (4.4%)	6 (4.8%)	
No	130 (95.6%)	121 (96%)		113 (83.1%)	106 (84.1%)		112 (82.4%)	105 (83.3%)	
N/A	3 (2.2%)	3 (2.4%)		20 (14.7%)	16 (12.7%)		18 (13.2%)	15 (11.9%)	
Emergency visit			.601			.037			.165
Yes	9 (6.6%)	6 (4.8%)		4 (2.9%)	12 (9.5%)		11 (8.1%)	17 (13.5%)	
No	124 (91.2%)	117 (92.9%)		112 (82.4%)	98 (77.8%)		112 (82.4%)	97 (77%)	
N/A	3 (2.2%)	3 (2.4%)		20 (14.7%)	16 (12.7%)		13 (9.6%)	12 (9.5%)	

Note. CCR: complete caries removal, n= 136; N/A: data not available; SCR: selective caries removal, n= 126. Percentages are column percentages.

Tabell 3. Comparison of composite outcome groups, by follow-up period

	0-12 months post-treatment			12-24 months post-treatment			0-24 months post-treatment		
Composite restoration failure	**Yes** n = 17	**No** n = 239	**Total** n = 256	**Yes** n = 40	**No** n = 186	**Total** n = 226	**Yes** n = 57	**No** n = 186	**Total** n = 243
	n (%)	**n (%)**	**p-value**	**n (%)**	**n (%)**	**p-value**	**n (%)**	**n (%)**	**p-value**
Treatment group			1			.479			.581
CCR	9 (52.9%)	124 (51.9%)		18 (45%)	98 (52.7%)		27 (47.4%)	98 (52.7%)	
SCR	8 (47.1%)	115 (48.1%)		22 (55%)	88 (47.3%)		30 (52.6%)	88 (47.3%)	
Referral to paediatric specialist			1			1			1
Yes	0 (0%)	1 (0.4%)		0 (0%)	1 (0.5%)		0 (0%)	1 (0.5%)	
No	17 (100%)	238 (99.6%)		40 (100%)	185 (99.5%)		57 (100%)	185 (99.5%)	
Clinic			.113			.300			.060
Väsby FTV	0 (0%)	6 (2.5%)		0 (0%)	4 (2.2%)		0 (0%)	4 (2.2%)	
Brotandl. (Praktikertjänst)	0 (0%)	17 (7.1%)		0 (0%)	17 (9.1%)		0 (0%)	17 (9.1%)	
Östergötland FTV	0 (0%)	4 (1.7%)		0 (0%)	4 (2.2%)		0 (0%)	4 (2.2%)	
Södertälje FTV	15 (88.2%)	126 (52.7%)		23 (57.5%)	98 (52.7%)		38 (66.7%)	98 (52.7%)	
Sollentuna FTV	2 (11.8%)	45 (18.8%)		10 (25%)	33 (17.7%)		12 (21.1%)	33 (17.7%)	
Täby FTV	0 (0%)	41 (17.2%)		7 (17.5%)	30 (16.1%)		7 (12.3%)	30 (16.1%)	
Age of child			.746			.026			.028
4-5 years	6 (35.3%)	68 (28.5%)		18 (45%)	48 (25.8%)		24 (42.1%)	48 (25.8%)	
6-8 years	11 (64.7%)	171 (71.5%)		22 (55%)	138 (74.2%)		33 (57.9%)	138 (74.2%)	
Sex of child			.349			.766			1
Girl	6 (35.3%)	120 (50.2%)		21 (52.5%)	90 (48.4%)		27 (47.4%)	90 (48.4%)	
Boy	11 (64.7%)	119 (49.8%)		19 (47.5%)	96 (51.6%)		30 (52.6%)	96 (51.6%)	
Tooth position			.525			.405			.247
4	10 (58.8%)	114 (47.7%)		22 (55%)	86 (46.2%)		32 (56.1%)	86 (46.2%)	
5	7 (41.2%)	125 (52.3%)		18 (45%)	100 (53.8%)		25 (43.9%)	100 (53.8%)	
Surface treated			.008			.020			<.001
Occlusal	0 (0%)	62 (25.9%)		4 (10%)	51 (27.4%)		4 (7%)	51 (27.4%)	
Approximal	3 (17.6%)	68 (28.5%)		11 (27.5%)	56 (30.1%)		14 (24.6%)	56 (30.1%)	
Approximal + occlusal	14 (82.4%)	109 (45.6%)		25 (62.5%)	79 (42.5%)		39 (68.4%)	79 (42.5%)	
Diagnosis by x-ray			.066			.352			.054
Outer half of the dentin	2 (11.8%)	81 (33.9%)		11 (27.5%)	68 (36.6%)		13 (22.8%)	68 (36.6%)	
Inner half of the dentin	6 (35.3%)	89 (37.2%)		14 (35%)	68 (36.6%)		20 (35.1%)	68 (36.6%)	
No x-ray available	9 (52.9%)	69 (28.9%)		15 (37.5%)	50 (26.9%)		24 (42.1%)	50 (26.9%)	

Visual inspection			.281			.100		.100
No cavity, no shadow	0 (0%)	14 (5.9%)		2 (5%)	12 (6.5%)		2 (3.5%)	12 (6.5%)
No cavity, but shadow	2 (11.8%)	55 (23.0%)		5 (12.5%)	50 (26.9%)		7 (12.3%)	50 (26.9%)
Cavity	15 (88.2%)	170 (71.1%)		33 (82.5%)	124 (66.7%)		48 (84.2%)	124 (66.7%)
Anaesthesia use			.059			.578		.121
Yes	2 (11.8%)	90 (37.7%)		13 (32.5%)	72 (38.7%)		15 (26.3%)	72 (38.7%)
No	15 (88.2%)	149 (62.3%)		27 (67.5%)	114 (61.3%)		42 (73.7%)	114 (61.3%)
Sedation use			.661			.400		.600
Midazolam	1 (5.9%)	30 (12.6%)		5 (12.5%)	22 (11.8%)		6 (10.5%)	22 (11.8%)
Nitrous oxide	0 (0%)	2 (0.8%)		1 (2.5%)	1 (0.5%)		1 (1.8%)	1 (0.5%)
No sedation	16 (94.1%)	207 (86.6%)		34 (85%)	163 (87.6%)		50 (87.7%)	163 (87.6%)
Filling material used			.746			.511		.500
Composite	0 (0%)	3 (1.3%)		1 (2.5%)	2 (1.1%)		1 (1.8%)	2 (1.1%)
Compomer	0 (0%)	5 (2.1%)		0 (0%)	4 (2.2%)		0 (0%)	4 (2.2%)
Glass ionomer cement	17 (100%)	231 (96.7%)		39 (97.5%)	180 (96.8%)		56 (98.2%)	180 (96.8%)
Quality of treatment result			.136			.400		.060
Excellent	1 (5.9%)	66 (27.6%)		8 (20%)	56 (30.1%)		9 (15.8%)	56 (30.1%)
Acceptable	16 (94.1%)	172 (72.0%)		32 (80%)	129 (69.4%)		48 (84.2%)	129 (69.4%)
Inadequate	0 (0%)	1 (0.4%)		0 (0%)	1 (0.5%)		0 (0%)	1 (0.5%)
Complications during treatment			1			.308		.437
Yes	2 (11.8%)	32 (13.4%)		8 (20%)	23 (12.4%)		10 (17.5%)	23 (12.4%)
No	15 (88.2%)	207 (86.6%)		32 (80%)	163 (87.6%)		47 (82.5%)	163 (87.6%)
Adjacent tooth treated at the same time			.021			.065		.005
Yes	10 (58.8%)	69 (28.9%)		17 (42.5%)	49 (26.3%)		27 (47.4%)	49 (26.3%)
No	7 (41.2%)	170 (71.1%)		23 (57.5%)	137 (73.7%)		30 (52.6%)	137 (73.7%)

Note. CCR: complete caries removal; SCR: selective caries removal. Percentages are column percentages.

Tabell 4. GEE regression of composite restoration failure, by follow-up period

	0-12 months post-treatment			12-24 months post-treatment			0-24 months post-treatment		
	n= 256 restorations, 143 clusters			n= 226 restorations, 132 clusters			n= 243 restorations, 136 clusters		
	OR	**95% CI**	**p-value**	**OR**	**95% CI**	**p-value**	**OR**	**95% CI**	**p-value**
Treatment group									
SCR vs CCR	0.96	0.28 – 3.25	0.946	1.23	0.61 – 2.50	0.559	1.21	0.63 - 2.30	0.566
Age of child									
4-5 years vs 6-8 years	1.41	0.39 – 5.10	0.599	3.15	1.37 – 7.21	0.007	2.99	1.36 - 6.57	0.006
Anaesthesia									
No vs Yes	5.23	1.07 – 25.57	0.041	1.33	0.61 – 2.92	0.470	1.84	0.88 - 3.84	0.106
Adjacent tooth treated at the same time									
Yes vs No	3.87	1.47 – 10.16	0.006	1.80	0.84 – 3.86	0.132	2.07	1.07 - 4.00	0.031
Tooth position									
4 vs 5	1.72	0.84 – 3.53	0.140	0.98	0.51 – 1.90	0.956	1.01	0.55 - 1.83	0.981
Surface treated, ref = *both**									
Approximal	-	-	-	0.76	0.30 – 1.91	0.551	0.73	0.32 - 1.67	0.455
Occlusal	-	-	-	0.23	0.06 – 0.79	0.020	0.16	0.05 - 0.53	0.003

Note. *: not used in model for first 12 months post-treatment due to zero cell count, please refer to Table 3 for details

CCR: complete caries removal; CI: confidence interval; OR: odds ratio, ref: reference category; SCR: selective caries removal

Tabell 5. Outcome variables by strata of anaesthesia used during treatment or not

Follow-up period		**Emergency visit**		**Restoration failure**		**Tooth extracted***		**Composite restoration failure**	
0-12 months	**Anaesthesia**	Yes	No	Yes	No	Yes	No	Yes	No
n = 256	Yes	2 (13%)	90 (37%)	2 (14%)	90 (37%)	0 (0%)	90 (38%)	2 (12%)	90 (38%)
	No	13 (87%)	151 (63%)	12 (86%)	152 (63%)	3 (100%)	149 (62%)	15 (88%)	149 (62%)
12-24 months	**Anaesthesia**	Yes	No	Yes	No	Yes	No	Yes	No
n = 226	Yes	6 (37%)	79 (38%)	9 (31%)	76 (39%)	4 (36%)	72 (39%)	13 (32%)	72 (39%)
	No	10 (63%)	131 (62%)	20 (69%)	121 (61%)	7 (64%)	114 (61%)	27 (68%)	114 (61%)

Note. *: total count is the number of restorations that did not fail during the same follow-up period. Percentages are column percentages

Figures

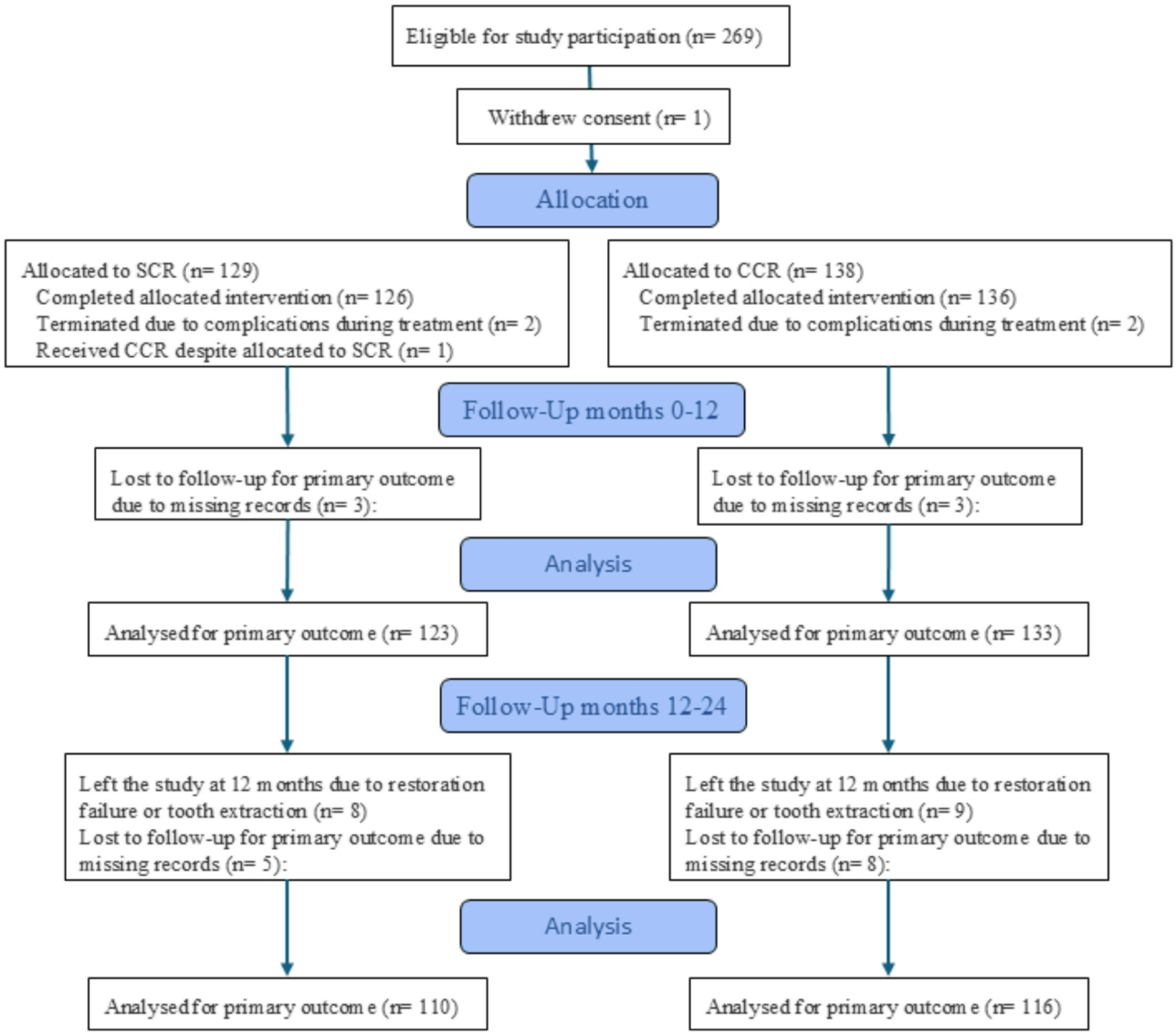


Figure 1

Flowchart illustrating the flow of restorations through the study