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Selective vs stepwise removal of deep carious lesions in primary molars: 12-Months results of a randomized controlled pilot trial

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ABSTRACT

Objectives: For deep carious lesions, selective or stepwise carious tissue removal (SE, SW) seem advantageous compared with non-selective removal. For primary molars, there is insufficient evidence comparing SE against SW. This randomized pilot trial compared SE and SW over 12 months.

Methods: A two-arm superiority trial was conducted comparing SE and SW in primary molars with deep lesions but without pulpal symptoms. We recruited 74 children (one molar/child) aged 3–9 years. In both groups, peripheral carious tissue removal was performed at T1 to hard dentin. In proximity to the pulp, leathery dentin was left followed by an adhesive compomer restoration. Blinded re-examination was performed after six months (T2). Molars allocated to SW were re-entered, removal to firm dentin carried out pulpo-proximally, and again restored. After another 6 months, all molars were re-examined (T3). Our primary outcome was success, defined as no restorative/endodontic complications (including pulp exposure) leading to reinterventions. Secondary outcomes included total treatment and opportunity costs. Patients', dentists' and parents' subjective assessments were recorded. This trial was registered (ClinicalTrials.gov/NCT02232828).

Results: After 12 months a total of 72 children (36 SE, 36 SW) were analyzed. Three failures occurred (2 exposures in SW, 1 pulpal complication leading to extraction in SE) ($p > 0.05$). The subjective evaluation by patients, parents or dentists did not differ significantly. Combined treatment and opportunity costs were significantly higher in SW (mean;SD: 186;61 Euro) than SE (100;59) ($p < 0.001$).

Conclusions: The significantly increased costs for performing SW instead of SE in deep carious lesions in primary molars may not be justified.

Clinical significance: For primary molars with deep lesions, but vital pulps, SE was less costly at similar efficacy compared with SW. Dentists' decision-making should consider this alongside further clinical aspects.

1. Introduction

Treating deep carious lesions comes with significant risks for the pulp, including pulpal exposure and post-operative pulpal complications, and the placed restoration. Managing these complications via endodontic therapy or restorative re-treatment is burdensome and costly [1–3].

In primary molars with deep lesions and vital pulps, a range of treatment options are available. Non-selective carious tissue removal aims at removing all bacterially contaminated and demineralized dentin, with only hard dentin remaining everywhere in the cavity. This treatment has been found to come with a high risk of pulp exposure and pulp complications; these are usually managed using direct capping (which has a poor prognosis) or pulpotomy (which is highly invasive) or extraction (which means loosing the tooth and, frequently, needing an orthodontic space maintainer) [4]. As an alternative, stepwise (SW, i.e. two-step) carious tissue removal has been recommended, where carious dentin is removed in the periphery of a cavity until only hard dentin remains, while in the proximity to the pulp, leathery or soft dentin is left and sealed beneath an interim restoration for some months. In a second step, the restoration is removed ('re-entry') and carious tissue removal to firm dentin performed in proximity to the pulp. This approach facilitates lesion arrest and remineralization; as tertiary dentin is laid down during the two treatment steps, the risk of

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pulpal exposure and post-operative complications is reduced compared with non-selective removal [5–7].

Several studies found sealed lesions to be clinically and microbiologically arrested, which is why the need to re-enter is increasingly questioned [8]. Selective (SE, i.e. one-step incomplete or partial) carious tissue removal involves only the first step of SW: Hard dentin is left in the periphery of the cavity, while leathery or soft dentin is remaining in proximity to the pulp. SE also reduces the risk of pulp exposure and post-operative complications compared with non-selective removal [9].

Hence, when choosing between these three strategies (non-selective, SW, SE), dentists should decide only between SW and SE. So far, only one three-arm study involving 63 primary teeth has compared SE and SW for managing deep lesions in primary molars [10]. It found both strategies to be not significantly different as to the risk of pulp exposures and pulp complications. Neither restorative complications, nor costs for initial or possible re-treatments, nor subjective evaluations of the treatments by patients, parents or dentists had been assessed.

It is thus unclear which of these strategies has superior efficacy, cost-effectiveness, or is preferred by those receiving or providing care in primary molars. For example, compared with SE, SW removal may lead to significantly more pulp exposures, as has been found in permanent teeth [11]. SW may also be more costly than SE, certainly initially (given the need for more treatment visits). On the other hand, restoration survival might be higher after SW than SE given that no soft dentin remains beneath the restoration [12,13]. The increased need for managing exposed pulps and the decreased need for managing restorative complications would, in turn, have long-term cost consequences.

The aim of this randomized pilot trial was to compare the success and survival, the initial and follow-up treatment costs and the subjective evaluation of patients, dentists and parents of SE and SW. Our primary hypothesis was that the success differs significantly between SE and SW. Secondary hypotheses were concerned with the differences in survival, costs and subjective evaluations.

2. Methods

2.1. Study design

The study is a prospective, two-arm, parallel-group, single-blinded, randomized controlled superiority pilot trial at Charité - Universitätsmedizin Berlin, Center for Dental and Craniofacial Sciences, in Germany. We enrolled 74 patients with one or more deeply carious, vital and non-symptomatic primary molar, where the tooth sensitivity was tested using thermal (cold) sensitivity testing. One molar per patient was randomly allocated to receive one of two treatments (SE or SW) and followed-up for 12 months. Success, survival, the initial and follow-up treatment costs and the subjective evaluation of patients, dentists and parents were recorded (Fig. 1). The study has been approved by the ethics committee of the Charité - Universitätsmedizin Berlin (EA4/057/14) and registered at ClinicalTrials.gov (NCT02232828). The study was originally planned as multi-center study, the respective protocol has been published [14]. Deviations from the protocol are noted below. Reporting of this trial follows the CONSORT criteria for parallel-arm trials [15] and the TIDieR checklist [16].

2.2. Setting and participants

The study took place at a publically funded teaching hospital. We included children aged 3–9 years with minimum one vital, clinically and radiographically non-symptomatic, retainable, deeply carious primary molar with a carious lesion involving either only the occlusal or the occlusal and one proximal (mesial or distal) surface (i.e. a one- or two-surfaced lesion). The lesion was required to radiographically extend into the inner third of the dentin (D3) and show signs of activity, e.g. plaque retention, papillary bleeding, softness of the surface etc. [17]. Parental consent was required from each patient for participation. In addition, patients' cooperation for treatment under no or only local anesthesia was expected. Patients with systemic diseases or disabilities, known allergies to the restoration material used as well as teeth which were expected to exfoliate within the next 18 months were also not included.

2.3. Sample size

Sample size calculation was planned for our primary outcome parameter, success, which is defined as not experiencing endodontic or restorative complications. Based on an existing trial on permanent teeth, we anticipated a Hazard Ratio of 1.3 [18] of SW compared with SE, with $\alpha = 0.05$ and $1\text{-}\beta = 0.9$. Originally, we also allowed for substantial drop-out and subgroup analyses in our sample size estimation, with 192 patients eventually to be included. This planned sample size was not realizable since a multi-center trial was not conducted due to limited funding, and recruitment was eventually terminated after 15 months. With the recruited 74 patients, we have to acknowledge that our trial might be under-powered to detect the originally assumed differences in our primary outcome, which is why we regard it as a pilot trial.

2.4. Recruitment

Both referred and in-house patients, who met the inclusion criteria, were consecutively recruited after routine clinical examination was performed. Patients who met the inclusion criteria and their parents received the study informations (one version for the parents and one for the children) and consent forms. The patient was officially enrolled in the study only after a written signed consent was given by both the parents/caregivers and the child.

2.5. Interventions

A full assessment and intraoral examination were performed in the first visit (T0). For patients who were possibly eligible, caries risk was estimated [19] and dental anxiety assessed [20]. Treatment was provided in the second visit (T1). In case that more than one primary molar met the inclusion criteria, the decision as to which tooth was included into the study was performed using random number tables prior to conducting the treatment. Removal of enamel and cavity preparation were performed using water-cooled diamond instruments. Carious tissue removal in the periphery including the enamel-dentinal junction was performed using low-speed rosehead burs until hard, dry dentin remained. This was justified as rosehead burs are by far the most frequently applied tool for carious tissue removal in Germany [21], but also as using rosehead burs is scientifically accepted standard [22]. The hardness of the dentin was intermittedly checked using straight dental probes. Pulpo-proximal carious tissue was removed until leathery, slightly moist dentin remained. The two operating dentists (KE, SR) were calibrated prior to study commencement regarding the endpoints of carious tissue removal by means of a hands-on training on extracted teeth under the supervision of an experienced dentist (FS). After this calibration, no discrepancies in what the different examiners would consider as hard, firm, soft etc. was noted. Note, however, that it is impossible to enumerate this and statistically quantify the agreement. Moisture control was performed using cotton rolls. Restorations were performed adhesively with a self-etching one-bottle adhesive (G-aenial bond, GC, Bad Homburg, Germany) and a compomer material, containing urethane dimethacrylate (UDMA), carboxylic acid modified dimethacrylate, camphorquinone, ethyl-4(dimethylamino)benzoate, butylated hydroxy toluene, a stabilizer, strontium-alumino-sodium-fluoro-phosphor-silicate glass, highly dispersed silicon dioxide, strontium fluoride, iron oxide pigments and titanium oxide pigments (Dyract, Dentsply, Konstanz, Germany). The adhesive was applied and