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Treatment of deep caries lesions in adults: randomized clinical trials comparing stepwise vs. direct complete excavation, and direct pulp capping vs. partial pulpotomy

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Less invasive excavation methods have been suggested for deep caries lesions. We tested the effects of stepwise vs. direct complete excavation, 1 yr after the procedure had been carried out, in 314 adults (from six centres) who had received treatment of a tooth with deep caries. The teeth had caries lesions involving 75% or more of the dentin and were centrally randomized to stepwise or direct complete excavation. Stepwise excavation resulted in fewer pulp exposures compared with direct complete excavation [difference: 11.4%, 95% confidence interval (CI) (1.2; 21.3)]. At 1 yr of follow-up, there was a statistically significantly higher success rate with stepwise excavation, with success being defined as an unexposed pulp with sustained pulp vitality without apical radiolucency [difference: 11.7%, 95% CI (0.5; 22.5)]. In a subsequent nested trial, 58 patients with exposed pulps were randomized to direct capping or partial pulpotomy. We found no significant difference in pulp vitality without apical radiolucency between the two capping procedures after more than 1 yr [31.8% and 34.5%; difference: 2.7%, 95% CI (−22.7; 26.6)]. In conclusion, stepwise excavation decreases the risk of pulp exposure compared with direct complete excavation. In view of the poor prognosis of vital pulp treatment, a stepwise excavation approach for managing deep caries lesions is recommended.

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Deep caries induces severe inflammatory reactions in the pulp and may cause pulp necrosis. When deep caries lesions are excavated, the dentin barrier may be broken and the healing of the pulp impaired. It has been suggested that a stepwise approach to caries excavation, as opposed to a direct complete excavation, would decrease the number of pulp exposures and accordingly enhance the possibilities for the pulp to heal (1, 2). A Cochrane review (3) found only two trials that compared stepwise excavation vs. direct complete excavation with respect to pulp exposure. Magnusson & Sundell (1) found an advantage of stepwise excavation: only 15% of the pulps were exposed compared with 53% after complete excavation. Similar findings were reported by Leksell *et al.* (2) (18% vs. 40%). The teeth treated were either primary molars (1) or young permanent teeth in children (mean age 10 yr) (2). Whether these results are applicable to an adult population is unknown. Both trials used pulp exposure as the outcome measure and did not report on treatment of the exposed pulps or on sustained pulp vitality. Also, for a proper comparison between the outcomes of stepwise vs. complete caries excavation, randomized clinical trials are needed to improve the evidence concerning the treatment of deep caries (3–7).

The exposed pulp has been the subject of numerous studies, but well-designed clinical trials on the treatment of caries-exposed pulps in adult teeth are scarce (8). In a large cohort study with up to 12 yr of follow-up, Nyborg (9) reported 58% success in direct pulp capping with calcium hydroxide as the capping material in patients older than 15 yr of age. Shovelton *et al.* (10) showed that the 2-yr success rate following direct pulp capping varied between 50 and 80%, depending on the pulp condition and the materials used. Retrospective studies indicate that there is a difference in treatment success between the traumatically exposed pulp and the pulp exposed during caries excavation. For example, Al-Hiyasat *et al.* (11) found that direct capping of traumatically exposed pulps with calcium hydroxide was successful in 92% of treatments after a 3-yr follow-up period, while only 33% of the treatments of caries-exposed pulps were classified as successes. A potential reason for treatment failure in the latter situation might be the introduction of infected dentin chips into the pulp during caries excavation, acting as nuclei for irreversible inflammation (12). It has been suggested that removing a few millimetres of the pulp (partial pulpotomy) might increase the healing potential (13). However, partial pulpotomy of pulps exposed as a result of caries has only been studied using young permanent teeth (13, 14) and no randomized clinical trials of direct pulp capping vs. partial pulpotomy in adult teeth can be found in the literature.

The two randomized clinical trials presented here were designed to test the effect of: (i) stepwise excavation vs. direct complete excavation of deep caries lesions in adults, using pulp exposure, 1-yr pulp vitality without apical radiolucency, and pain as the outcome measures; and (ii) direct capping vs. partial pulpotomy of pulps exposed as a result of caries, using 1-yr pulp vitality without apical radiolucency, and pain, as the outcome measures.

Material and methods

The excavation trial (i) was conducted as a centrally randomized, patient-blinded, multicentre trial with two parallel groups (Fig. 1) comparing the effect of stepwise excavation vs. direct complete excavation. Sample size calculation showed that 134 patients were needed in each group to detect a 20% difference in the success rate between stepwise excavation and direct complete excavation at a two-sided alpha level of 5% (type I error) and 90% power (type II error of 10%), when expecting 50% in the direct complete excavation group to retain pulp vitality without apical radiolucency after 1 yr. With an anticipated patient drop-out of 15%, the trial was planned to include at least 308 patients. Consecutive patients referred to two Danish centres (the Dental Schools at the University of Copenhagen and Aarhus University) and four Swedish centres (Karolinska Institute, Stockholm; Faculty of Odontology, Malmö; Uppsala Public Dental Service; and Gothenburg Public Dental Service) participated. Inclusion criteria were: ≥ 18 yr of age; a primary caries lesion radiographically involving 75% or more of the dentin; and the presence of a well-defined radiodense zone between the caries lesion and the pulp (Fig. 2). In patients who reported pain, the pain was provoked and confirmed by stimulation with cold or compressed air (pretreatment pain). Exclusion criteria were: prolonged unbearable pain and/or pain disturbing night sleep; no response to cold and electrical pulp testing; attachment loss > 5 mm; apical radiolucency; pregnancy; any systemic disease preventing enrolment; or lack of informed consent. Written informed consent was obtained from all the patients participating in the study.

The clinicians were trained in identifying eligible caries lesions using 15 radiographs representing different lesion depths. During the enrolment procedure potentially eligible teeth were compared to a scoring chart (Fig. 2). The allocation sequences for stepwise excavation vs. direct complete excavation (1:1) were computer generated, stratified for pain (yes or no), age (18–49 yr or ≥ 50 yr), and centre in blocks of six. The block size was unknown to the investigators. Concealed allocation was achieved through central telephone randomization (Copenhagen Trial Unit). One tooth was treated in each randomized patient. Patients were unaware of the treatment assignment, and all were seen in at least two treatment visits.

If the excavation procedure led to pulp exposure the patient was assessed for eligibility for the pulp capping trial (ii). The inclusion criteria were: the patient had participated in the excavation trial described in the section above; the pulp was exposed as a result of the excavation of caries

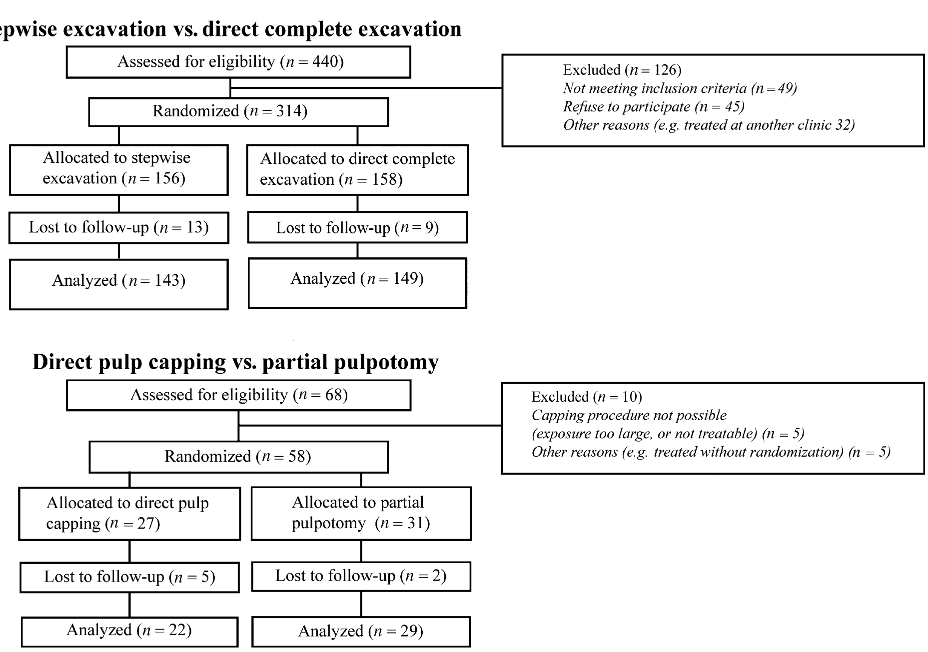

Fig. 1. Flow chart showing the number of patients according to enrolment, allocation, lost to followup, and final number of cases analyzed in the two trials.

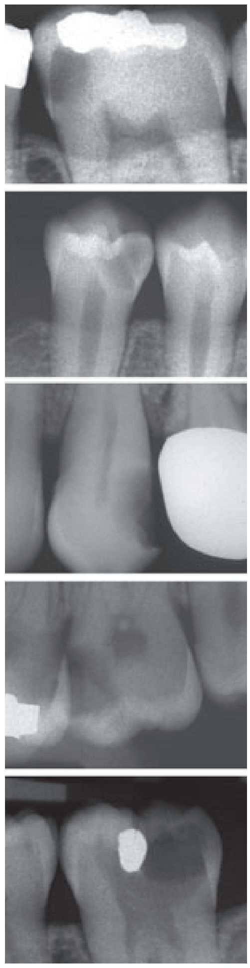

Fig. 2. The scoring chart used for the selection of cases is shown. Included teeth had caries lesions radiographically extending 75% or more into the dentin and walled off from the pulp by a well visible radiodense zone. A tooth was excluded if the caries lesion was either too small (as illustrated in the top) or too deep (bottom).

(mild pain could be present); and written informed consent had been given to take part. Exclusion criteria were: prolonged unacceptable pain or pain disturbing the night sleep; and pus draining from the exposed pulp. Eligible patients were centrally randomized to either direct pulp capping vs. partial pulpotomy using a similar randomization procedure as the one described for the excavation trial but only stratifying for pain (yes or no) (Fig. 1). The excavation trial (j.no: 03-004/03) and the pulp capping trial (j.no: 13-002/04) were approved by the joint Copenhagen and Frederiksberg ethics committees in Denmark and by the ethics committee at the Sahlgrenska Academy, University of Gothenburg, Sweden (j.no: 083-05), and was registered in the Danish Data Protection Agency (j.no: 2008-42-20329) and at http://www.ClinicalTrials.gov (NCT00187850 and NCT00187837). The trials were investigator initiated and investigator controlled.

Clinical procedures

The penetration depth of the lesion was assessed in bitewing radiographs (Insight IP22 film; Kodak, Stuttgart, Germany)

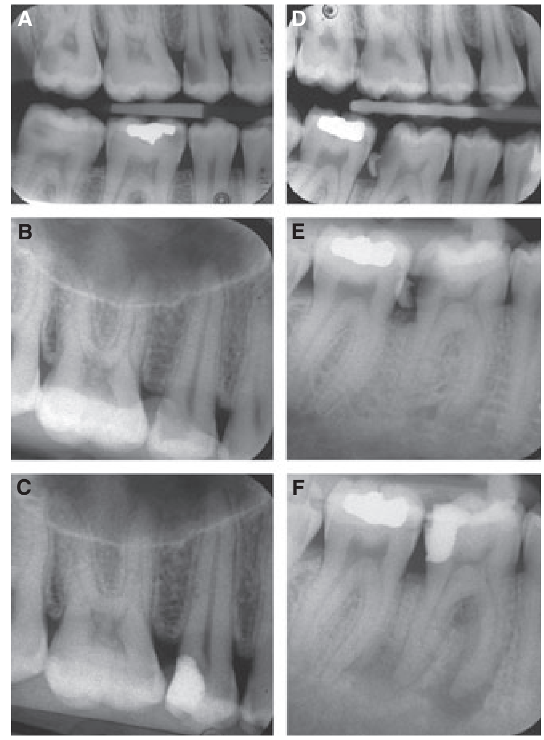

Fig. 3. A, B: Preoperative radiographs of a permanent upper right second premolar (stepwise excavation). At the 1-yr radiographical follow-up (C) the tooth was classified as a success (pulp vitality without apical radiolucency). D, E: Preoperative radiographs of a permanent lower right first molar (direct complete excavation). At the 1-yr follow-up (F) the tooth was classified as a failure (no pulp vitality with apical radiolucency).

(Fig. 3A,D). The penetration depth was expressed as the ratio between the maximum depth of the carious dentin (AB, Fig. 4) and the total dentin thickness (AC, Fig. 4), measured using computer software (PPX VIEW PRO version PRO 1.11.18; DeltaPix, Måløv, Denmark). The point A represented half the distance of the spread of the radiolucent carious dentin along the enamel–dentin junction. Point B was placed at the pulpal border of the radiolucent area, and C represented the border of the pulp. The difference between two repeated measurements [mean ± standard deviation (SD)] was 0.024 ± 0.601 mm for the distance AB and 0.001 ± 0.597 mm for the distance AC. To evaluate the periapical tissues (Fig. 3B,C,E,F) period-identical radiographs were obtained by means of a specific film holder (Super-Bite; KerrHawe, Bioggio, Switzerland). Pulp vitality was assessed using thermal methods (Green ENDO I.C.E; The Hygienic Corporation, Akron, OH, USA), or ethyl chloride (Rönnings Europa, Hässleholm, Sweden), and electrical pulp testing (Vitality Scanner Model 2006 or 2007; Analytic Technology, Redmond, VA, USA). The teeth were anaesthetized with Citanest Dental Octapressin (Dentsply, Weybridge, UK). The bulk of carious dentin was removed using a round bur followed by final excavation with hand instruments. The clinicians were calibrated before the trial was started. One of the investigators (L.B.) visited all centres and presented the guidelines for patient selection and clinical procedures.

In stepwise excavation the first excavation included removal of the superficial necrotic and demineralized dentin with complete excavation of the peripheral demineralized dentin (15), avoiding excavation close to the pulp. When a

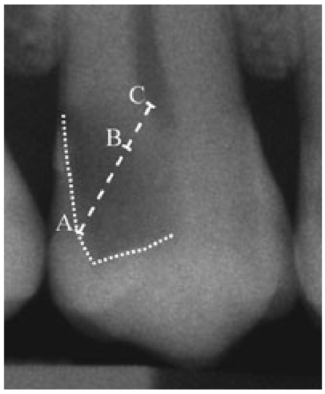

Fig. 4. The point A represents half the distance of the spread of the radiolucent carious dentin along the enamel-dentin junction (dotted line). Point B was placed at the pulpal border of the radiolucent area, and C at the border of the pulp. The ratio AB/AC defines the maximum penetration depth of the caries lesion.

temporary restoration could be properly placed no further excavation was carried out, leaving soft, wet, and discoloured dentin centrally on the pulpal wall. A calcium hydroxide base material (Dycal; DeTrey Dentsply, Skarpnäck, Sweden) was applied over the remaining carious dentin and the cavity was temporarily sealed with glass-ionomer (Ketac Molar; 3M ESPE, Glostrup, Denmark). After 8 to 12 wk, the cavity was re-entered and the final excavation was carried out leaving only central yellowish or greyish hard dentin (equal to the hardness of sound dentin, as judged by gentle probing). A calcium hydroxide base was applied and the cavities were restored with OptiBond Solo Plus (KerrHawe) and Herculite XRV (KerrHawe).

Direct complete excavation was completed during the first visit. Criteria for evaluating the remaining dentin were identical to those used at the second visit in the stepwise excavation group. Base material and a temporary restoration were placed as described above. At the second visit (8–12 wk later) the temporary restoration, but not the base material, was removed and replaced with a permanent restoration, as described above.

Direct pulp capping was performed after complete removal of carious dentin using hand excavation instruments (LM 533-534, LM 63-64, LM 631-641; LM-instruments, Parainen, Finland) in the final excavation, followed by isolation of the tooth with a rubber dam and cleaning with alcohol containing 5 mg ml^{-1} of chlorhexidine. The exposed pulp was irrigated with sterile saline. Following haemostasis (within 5 min) calcium hydroxide cement was applied (Dycal; DeTrey Dentsply, Sweden). The cement was covered with a temporary restoration (Ketac Molar; 3M ESPE). After 1 month the cavity was restored with OptiBond Solo Plus (KerrHawe) and Herculite XRV (KerrHawe). At the final restoration procedure a thin layer of the temporary restoration was left covering the pulp capping area to ensure that exposure to the oral environment was avoided.

The procedures and materials used for the partial pulpotomy were identical to those in the direct pulp capping group except that 1–1.5 mm of the pulp tissue (13) was removed using a high-speed round diamond bur under water spray coolant.

The treatment results were assessed after 1 yr. In the stepwise excavation trial the primary outcome measure was unexposed pulps with sustained pulp vitality without apical radiolucency (= success). Pulp vitality was defined as a positive response to thermal (cold) or electrical stimulation. Periapical radiolucency was diagnosed if the apical part of the periodontal ligament space was at least twice as wide as in other parts of the root and the lamina dura was absent. Two blinded observers independently examined the radiographs. Inter-examiner agreement in the determination of success or failure was judged as good (Kappa = 0.67). In 15 cases, the observers disagreed and they had to reach consensus. The consensus result was 12 successes and 3 failures. Patients who had to be treated with pulpectomy (because of unbearable pain) before the 1-yr follow-up were classified as failures.

Patients with mild-to-moderate pretreatment pain were included in the excavation trial, and the secondary outcome measure was the extent of pain relief on days 1 and 7 following excavation. The level of pretreatment pain was assessed just before treatment (Table 1) on the first visit using a 100 mm visual analogue scale (VAS) printed on paper ranging from 'no pain' to 'unbearable pain'. The patients were asked to make similar assessments at home on days 1 and 7 after excavation and to return the assessments by mail. Pain relief (secondary outcome measure) was defined as the difference in VAS scores (mm) between the pretreatment pain and pain on day 1 [median (mean)] and day 7 [median (mean)] after excavation. The tertiary outcome measure was pulp exposure during excavation.

In the pulp capping trial (Fig. 1), the primary outcome measure was pulp vitality without apical radiolucency.

Statistical analysis

The statistical investigator was unaware of the allocation codes. The non-Gaussian distributions of the VAS scorings were compared between the intervention groups using a non-parametric test (Mann–Whitney *U*-test). The mean ratio of the caries lesion depth was presented with 95% confidence interval (CI). The binary outcomes were analyzed by comparing the probability of success (Chi-square test) and by reporting the difference between intervention groups along with the 95% CI. In addition, binary logistic regression analysis (16) was performed to assess the effect of treatment, while adjusting for age, pretreatment pain, and treatment centre. Odds ratio (OR) estimates were presented with 95% CI. The level of significance (two-sided) was set to 0.05.

Results

We evaluated 440 patients for eligibility to participate in this study between February 2005 and April 2007. Of these patients, 126 were excluded because they did not meet the inclusion criteria, refused to participate, or underwent treatment at other clinics. Thus, 314 patients were randomized to stepwise excavation vs. direct complete excavation (Fig. 1). The baseline values of the demographic variables and VAS scorings of pretreatment pain are shown in Table 1, including the mean depth ratio of the caries lesions. The median number of days of the observation period was 476 (interquartile range 442–559) in the stepwise excavation group and 477 (interquartile range 434–524) in the direct complete excavation group.

Table 1

Demographic variables and pretreatment pain assessments on a 100-mm visual analogue scale (VAS) at baseline

Variables	Stepwise excavation (n = 156)	Direct complete excavation (n = 158)
Men n (%)	63 (39.9)	69 (44.2)
Median age (yr) (IQR)*	29.0 (25.3–38.0)	29.0 (26.0–37.8)
Age < 50 yr n (%)	141 (89.2)	146 (93.6)
Type of tooth		
Incisor/canine n (%)	5 (3.2)	7 (4.4)
Premolar n (%)	70 (44.9)	58 (36.7)
Molar n (%)	81 (51.9)	93 (58.9)
Lesion site		
Approximal n (%)	151 (96.8)	151 (95.6)
Mean depth ratio of caries lesion (95% CI)	0.77 (0.75; 0.79)	0.77 (0.76; 0.78)
Median pretreatment pain (VAS) (IQR)	3.0 (0.0–26.0)	5.0 (0.0–30.0)
Centre		
Centre 1 n (%)	15 (9.6)	17 (10.8)
Centre 2 n (%)	29 (18.6)	26 (16.5)
Centre 3 n (%)	12 (7.7)	10 (6.3)
Centre 4 n (%)	3 (1.9)	6 (3.8)
Centre 5 n (%)	12 (7.7)	14 (8.9)
Centre 6 n (%)	85 (54.5)	85 (53.8)

CI, confidence interval; IQR, interquartile range.

Table 2

Primary outcome analysis of teeth at 1 yr of follow-up

Randomized (n = analyzed teeth)	Stepwise excavation (n = 143)	Direct complete excavation (n = 149)	Difference between groups (95% CI)	P-value
Success				
Pulp vitality without apical radiolucency n (%)	106 (74.1)	93 (62.4)	11.7 (0.5; 22.5)	0.044
Failures				
Pulp exposure n (%)	25 (17.5)	43 (28.9)	−11.4 (−21.3; −1.2)	0.030
Pulp vitality with apical radiolucency n (%)	2 (1.4)	2 (1.3)	0.1 (−3.5; 3.8)	0.665
No pulp vitality with apical radiolucency n (%)	2 (1.4)	4 (2.7)	−1.3 (−5.5; 2.8)	0.712
Unbearable pain* n (%)	8 (5.6)	7 (4.7)	0.9 (−4.8; 6.8)	0.934

*Resulting in pulpectomy.
CI, confidence interval.

The results from the excavation trial are summarized in Table 2. The stepwise excavation group had a significantly higher proportion of success (74.1%) at follow-up compared with the direct complete excavation group (62.4%) (P = 0.044). The difference was still significant when adjusted for the effect of age, pain, and centre (Table 3). The pulp was exposed in 25 teeth (17.5%) after the stepwise excavation procedure. In four of these teeth the pulp had already been unintentionally exposed at the first visit. In the direct complete excavation group the pulp was exposed in 43 teeth (28.9%). The estimated difference was 11.4% with a 95% CI of 1.2–21.3 (P = 0.030) (Table 2). This difference was also statistically significant when the analysis was adjusted for the effect of age, pain, and centre (Table 3). Considering only teeth remaining with unexposed pulps, 89.8% of these teeth retained pulp vitality without apical radiolucency following stepwise excavation vs. 87.7% after direct complete excavation (P = not significant).

Among patients with pretreatment pain in the excavation trial, we found no significant difference in pain relief [median (mean)] on day 1 (P = 0.41, Mann–Whitney U-test) between the stepwise excavation group [0.0 (−0.01)] and the direct complete excavation group [0.0 (−0.88)]. The level of pain relief on day 7 was similarly low and not significant (P = 0.88, Mann–Whitney U-test) between the stepwise excavation group [0.0 (−1.91)] and the direct complete excavation group [0.0 (−4.12)].

Patients with pretreatment pain were significantly less likely to show a successful treatment result at follow-up compared to those without pain, when adjusting for the effect of treatment, age, and centre (Table 3). Treatments of patients younger than 50 yr of age (median for the group 28 yr) were more likely to result in sustained pulp vitality without apical radiolucency than treatments of older patients (median for the group 58 yr); however, only borderline significance was noted (Table 3).

The ORs of pulp exposure differed among the centres, with centres 1 and 2 avoiding pulp exposure significantly

Table 3

Logistic regression analysis of the outcomes 'unexposed pulps with sustained vitality without apical radiolucency' at 1 yr of follow-up and 'pulp exposure' after excavation (n = 292)

	Unexposed pulps with sustained vitality without apical radiolucency		Pulp exposure	
Independent variables	OR (95% CI)	*P*-value	OR (95% CI)	*P*-value
Intervention	1.74 (1.03–2.94)	0.038	0.50 (0.27–0.90)	0.021
Ref: 'Direct com- plete excavation'				
Age < 50 yr	3.34 (0.98–6.22)	0.054	0.44 (0.15–1.30)	0.137
Ref: 'age ≥ 50 yr'				
Pretreatment pain	0.48 (0.28–0.82)	0.007	2.38 (1.31–4.34)	0.005
Ref: 'no pain'				
Centre		0.076*		0.016*
Ref: 'Centre 6'				
Centre 6	1.00		1.00	
Centre 1	3.25 (1.12–9.46)	0.031	0.15 (0.03–0.71)	0.016
Centre 2	2.82 (1.25–6.36)	0.012	0.17 (0.05–0.53)	0.002
Centre 3	1.37 (0.50–3.71)	0.539	0.68 (0.23–2.07)	0.499
Centre 4	1.17 (0.29–5.30)	0.841	0.74 (0.13–4.23)	0.733
Centre 5	2.05 (0.71–5.97)	0.186	0.55 (0.17–1.75)	0.307

*Comparing all centres.
CI, confidence interval; OR, odds ratio; Reference.

Table 4

Primary outcome analysis of the pulp capping trial at 1 yr of follow-up

Randomized (*n* = analyzed teeth)	Direct pulp capping (*n* = 22)	Partial pulpotomy (*n* = 29)	Difference between proportions (95% CI)	*P*-value
Success				
Pulp vitality without apical radiolucency *n* (%)	7 (31.8)	10 (34.5)	−2.7 (−26.6; 22.7)	0.923
Failures				
No pulp vitality and apical radiolucency *n* (%)	1 (4.5)	2 (6.9)	−2.4 (−17.9; 15.5)	0.810
Unbearable pain* *n* (%)	14 (63.6)	15 (51.7)	11.9 (−14.8; 35.9)	0.573
No haemostasis* *n* (%)	0 (0)	2 (6.9)	−6.9 (−22.0; 8.8)	0.597

*Primary outcome assessment was no pulp vitality at follow-up as a result of pulpectomy.
CI, confidence interval.

more often (adjusted for the effect of treatment, age, and pain) (Table 3).

Of the 68 patients with exposed pulps it was possible to randomize 58 to direct pulp capping vs. partial pulpotomy (the pulp capping trial). Ten patients were excluded because it was not possible to perform either the randomization or the capping procedure (Fig. 1). The median number of days of the observation period was 416 (interquartile range 407 – 531) in the direct pulp capping group vs. 426 (interquartile range 390–530) in the partial pulpotomy group. The results from the pulp capping trial are summarized in Table 4.

The total proportion of teeth retaining pulp vitality without apical radiolucency at the 1-yr follow-up did not differ significantly between the direct pulp capping group and the partial pulpotomy group (31.8% vs. 34.5%) (Table 4). It should be noted that the majority of failed pulp treatments occurred as a result of pain (Table 4) because a number of patients received endodontic emergency treatment (pulpectomy) before the scheduled follow-up appointment.

Discussion

We observed significantly fewer pulp exposures after stepwise excavation (17.5%) than after direct complete excavation (28.9%) in adult teeth. Moreover, a significantly better success rate (74.1%) was found for stepwise excavation at 1 yr of follow-up vs. direct complete excavation (62.4%), when considering unexposed pulps with sustained vitality without apical radiolucency (Table 2). These results are similar to findings in studies on primary teeth and young permanent teeth (1, 2). The biological rationale for this difference could be that the first phase of stepwise excavation inactivates caries progression (15) and stimulates the formation of tertiary dentin (17), which over time makes carious dentin easier to remove without exposing the pulp at the final excavation. Such reactions might also be enhanced by placing a calcium hydroxide compound on the remaining carious dentin (1, 18). In our excavation trial we used 8–12 weeks as the treatment interval for the stepwise excavation and it could be speculated that a prolonged treatment interval might have induced more tertiary dentin and reduced the number of pulp exposures. However, Leksell *et al.* (2) found no difference in the frequency of pulp exposure between a group of patients treated within a shorter time interval (8–10 wk) and one treated within a longer time interval (11–24 wk). It might also be considered to avoid re-entry of the cavity (6). However, the recently recommended procedure of permanently leaving a small amount of carious dentin to arrest lesion progression and to prevent pulp exposure (19) has not been systematically evaluated in a randomized clinical trial, and merits further study (20).

In our excavation trial fewer pulp exposures were noted after direct complete excavation than previously reported: 40% by Leksell *et al.* (2) and 53% by Magnusson & Sundell (1). Trials with inadequate allocation concealment may exaggerate the treatment effect (21, 22). Therefore, as concealment of allocation in both of the above studies was unclear (3), the treatment effects may have been overestimated. Another explanation might be that the operators in the present study performed a less invasive caries-excavation procedure than that carried out by Leksell *et al.* (2).

The statistically significant difference in pulp exposures between the centres may be caused by differences in depths or progression rates of the caries lesions. However, our analysis of lesion depths indicated that proper depths had been selected at all centres according to the scoring chart (Fig. 2). Other plausible reasons could be differences in technical skills, or random error.

Amongst the teeth with exposed pulps we found a low overall pulp survival (32.8%) at the 1-yr follow-up, which differs from the results reported by Nyborg (9) and Shovelton *et al.* (10) but is in accordance with the results reported by Al-Hiyasat *et al.* (11). It should be noted that the present study was carried out using teeth with deep caries lesions and that the actual health status of the pulps was unknown. In a majority of the failed cases the patient, within a few months, developed intensely painful symptoms that had to be treated by pulpectomy. This indicates that a deleterious pretreatment condition of the pulp, rather than micro-organisms entering the wound area via marginal leakage, caused the unsuccessful outcome.

At 1 yr of follow-up we found no statistically significant difference in the number of patients with pulp vitality without apical radiolucency between partial pulpotomy and direct pulp capping (Table 4). However, the relatively small number of pulp exposures makes the CIs wide, and definite conclusions concerning the choice of capping procedure cannot be made from our data. Further trials are required.

A calcium hydroxide material was used as wound dressing in both pulp capping interventions. High outcome rates for teeth with pulp exposures treated by partial pulpotomy (23), as well as direct pulp capping (24), have been reported in small observational studies using mineral trioxide aggregate (MTA). However, no significant difference was found in two randomized clinical trials comparing calcium hydroxide vs. MTA in young permanent molars with deep caries treated with partial pulpotomy (14) and in carious primary molars treated with direct pulp capping (25). Therefore, we do not expect our choice of calcium hydroxide cement as a wound dressing to have influenced the results negatively.

Pulp survival at follow-up amongst teeth with unexposed pulps was much higher than amongst teeth with exposed pulps (Table 4). This observation emphasizes the importance of maintaining an unbroken dentin barrier against the pulp. Leksell *et al.* (2) reported 1-yr pulp survival to be 100% in teeth with unexposed pulps. The lower frequency of pulp survival found in our study might indicate that we included patients with more severe caries and pulp inflammation by including patients with pretreatment pain. In our study the presence of pretreatment pain was significantly associated with treatment failure (Table 3).

Age of the patient tended to influence the treatment results. We observed that younger patients were associated with a higher proportion of vital pulps without apical radiolucency at follow-up than older patients. This is in accordance with an earlier observational study on stepwise excavation of deep caries lesions in a mixed population of children and adults (median age 24 yr), where a relatively high pulp survival (89%) was noted 3½–4½ yr later (26). A similar influence of the age of the patients on the treatment outcome is known from direct pulp capping. Hørsted *et al.* (27) showed a higher pulp survival amongst younger patients compared with older patients in a long-term retrospective study of direct pulp capping.

In conclusion, the stepwise excavation group had a significantly higher proportion of unexposed pulps with sustained vitality without apical radiolucency compared with direct complete excavation of deep caries lesions in adult teeth. As the treatment of teeth with caries exposures had a lower pulp survival than teeth with unexposed pulps, a stepwise excavation procedure is preferable for the management of deep caries lesions.

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