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Review

Treatment of pulps in teeth affected by deep caries – A systematic review of the literature

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ABSTRACT

Background: This systematic review assesses the effect of methods commonly used to manage the pulp in cases of deep caries lesions, and the extent the pulp chamber remains uninfected and does not cause pulpal or periapical inflammatory lesions and associated tooth-ache over time.

Study design: An electronic literature search included the databases PubMed, EMBASE, The Cochrane Central Register of Controlled Trials and Cochrane Reviews from January 1950 to March 2013. In addition, hand searches were carried out. Two reviewers independently evaluated abstracts and full-text articles. An article was read in full if at least one of the two reviewers considered the abstract potentially relevant. Altogether, 161 articles were read in full text. Of these, 24 studies fulfilled established inclusion criteria. Based on studies of at least moderate quality, the quality of evidence of each procedure was rated in four levels according to GRADE.

Results: No study reached the high quality level. Twelve were of moderate quality. The overall evidence was insufficient to assess which of indirect pulp capping, stepwise excavation, direct excavation and pulp capping/partial pulpotomy, pulpotomy or pulpectomy is the most effective treatment approach for teeth with deep caries.

Conclusions: Because of the lack of good studies it is not possible to determine whether an injured pulp by deep caries can be maintained or whether it should be removed and replaced with a root canal filling. Both randomized studies and prospective observational studies are needed to investigate whether a pulp exposed to deep caries is best treated by measures intended to preserve it or by pulpectomy and root filling.

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Introduction

Pulpal inflammation, caused by deep caries infection, can be clinically managed either by an attempt to preserve the tissue, or remove it and root-fill the tooth. Considerable controversy exists on the issue and it is frequently maintained that pulp capping/pulpotomy procedures should be considered for minimally affected teeth where the exposure occurred through healthy and non-cariou dentine (for review see e.g. [1-3]). The advantage of preserving the pulp is nevertheless obvious in cases with large pulp chambers and underdeveloped roots because pulpectomy arrests root development. The dentinal walls in the root canal will then be thin and increase the risk of root fracture. Thus, from a biological, patient and cost perspective, especially in young teeth, the route of retaining all or some of the pulp can be seen preferable.

There are several modes to preserve pulpal vitality in teeth with deep caries. In recent years indirect pulp capping has been advocated in several reports (e.g. [4,5]). By leaving the deepest layer of carious dentine undisturbed, the aim of this method is to avoid exposure of the pulp and thus enhance what is believed to be a better long-term outcome. Favourable outcome studies have been reported [4-6]. Carious tissue may also be completely removed, either at the same appointment (complete caries excavation) or in one or more treatment steps (stepwise excavation). In the latter case the objective is to allow the pulp an opportunity to recover, at the same time as a potentially unnecessary pulpal exposure may be prevented. If the pulp happens to be exposed, the wound can then be treated with a conservative procedure (direct pulp capping or partial or complete pulpotomy). The most radical approach is to remove the entire pulp (pulpectomy) and replace it with a root filling. In this report we examine the scientific support for the effect of these procedures, i.e. that the pulp chamber remains uninfected and does not give rise to pulpal or periapical inflammatory lesion and associated toothache.

Systematic review reports have recently addressed the area [7-9]. One propose is that the pulp capping has a reasonably good outcome in a short-term perspective [7], while others see advantages of step excavation or one-step

incomplete excavation in comparison to two-step incomplete or complete caries removal [8,9].

The present review is part of a more comprehensive systematic review first published in Swedish by the Swedish Council on Health Technology Assessment (SBU) covering methods of diagnosis and treatment in endodontics [10]. In 2012 an English translation was made available. SBU is an independent national authority for the critical evaluation of methods for preventing, diagnosing and treating health care problems.

The specific questions addressed in this report were

- How effective are the different methods for preserving the pulp in a vital, asymptomatic condition in teeth with deep caries?
- How effective is pulpectomy in comparison?
- What factors may influence healing after a pulpectomy procedure?

Material and methods

Electronic literature search included the databases PubMed, Embase and CENTRAL. All languages were accepted provided there was an abstract in English. Articles published between 1950 and 2010 were sought in the first series of searches. Considered were articles in all languages having at least a summary in English or Swedish. For this review, articles published between 2010 and 2013 were pursued by March 2013 and added. Also searches by hand were carried out. Table 1 describes the inclusion criteria and Table 2 the exclusion criteria for the selected studies.

The review process

Two assessors (GB and IM) examined independently the abstracts of the acquired studies. The objective was to identify studies, which were relevant to the three questions. The results were compared and full-text versions were ordered of all articles judged as relevant or "possibly relevant". The same

Table 1 – Inclusion criteria.

Population	Deciduous or permanent teeth of all ages. While the response of the pulp of a deciduous tooth might be different from that of the permanent tooth, studies on deciduous teeth were accepted with respect to stepwise excavation and direct or indirect pulp capping to avoid losing important information. Studies calculating the cost effectiveness and cost benefit. Study type: randomisation controlled studies (RCT) quasi-RCT, controlled clinical studies (CCT) or prospective cohort studies with reference groups. Observation time ≥ 1 year, Attrition $\leq 30\%$ of included individuals
Intervention	Indirect pulp capping, direct pulp capping, partial pulpotomy, pulpotomy and pulpectomy. Pulp capping using various wound dressings. Pulp exposure after stepwise and immediate complete caries excavation.
Control	RCT, quasi-RCT, (CCT) or prospective cohort with reference group. Acceptable reference groups are groups within the cohort, e.g. age, size of pulp exposure, degree of root closure.
Outcome	Survival of the pulp, verified by absence of symptoms, sensibility testing, radiographic examination or closure of the roots in young teeth. With reference to studies on pulpectomy: the minimum allowable unit for effect measure is the individual tooth.

Table 2 – Exclusion criteria.

Population	Animal studies. Human experimental studies employing teeth with healthy pulps. Retrospective studies, observational studies (cohorts without comparison groups). Studies with undefined populations or small samples.
Intervention	Studies with traumatic lesions, pulpotomy in deciduous teeth, pulp dressings which devitalize pulpal tissue, apexification (closure of the root).
Control	Retrospective studies, prospective observational studies without reference groups.
Outcome	Studies with undefined outcome measures.

Table 3 – Criteria of high, moderate and low quality study.

High: small risk of bias	RCT with adequate (generalizable) patient spectrum, consecutive inclusion, number of eligible patients reported, adequate randomization method, power calculation, one tooth/patient; outcome measures defined and validated with clinical and radiological data with at least two blinded investigators to outcome, reliability test reported; follow-up time: ≥ 2 years for primary teeth; ≥ 5 years for permanent teeth; attrition analyzed if $< 30\%$; precision of results reported; data presented in four-fold tables, adequate data analysis.
Moderate: moderate risk of bias	RCT or CCT (cohort study with comparator group) not fulfilling all requirements for high quality but adequate patient spectrum; outcome measures defined and validated against clinical and radiographic data at least one blinded investigator to outcome; follow-up time: ≥ 1 year for primary and permanent teeth; attrition analyzed if $> 30\%$; adequate data analysis; if CCT: important (known) confounders at baseline controlled for.
Low	Studies not fulfilling criteria for moderate quality, e.g. high risk of bias, retrospective study.

two assessors then examined independently the full-text versions. In order to determine whether a study warranted inclusion in the third phase of the review process, predetermined inclusion and exclusion criteria were applied. The reasons for exclusion of a study were noted. Studies judged by at least one of the assessors to fulfil, or possibly fulfil the inclusion criteria were selected for inclusion in the final review.

The review evaluated the relevance and the methodological quality such as study design, internal validity (reasonable guarantee against systematic errors), analysis of the results, statistical power and generalizability. In order to ensure uniform, transparent and reproducible assessment

with limited subjectivity, appraisal sheets were used, specifically structured for various study designs and research question. After appraisal, each study was rated for methodological quality (high, moderate, or low; Table 3). When there was lack of consensus about the quality of a study, the articles were appraised by the entire project group. In cases where the appraisal concerned a paper in which a member of the project group was an author, or had any other kind of association with the content of the study, the entire expert committee participated in the final evaluation. Finally, important facts from the included studies were summarized and tabulated.

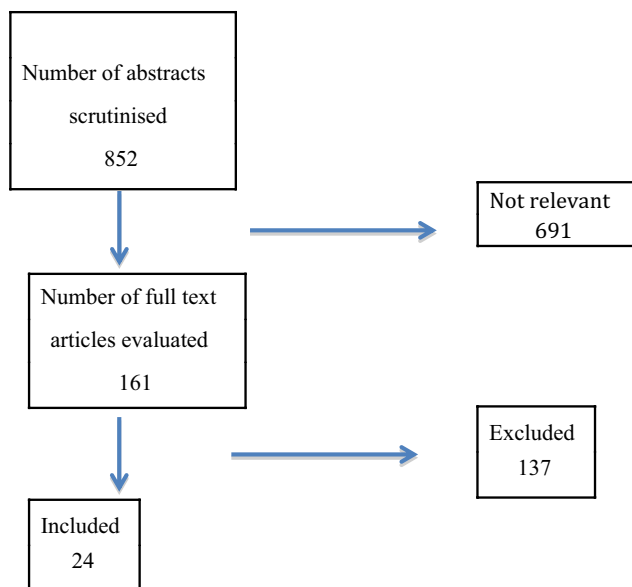


Fig. 1 – Flow diagram of literature search.

The result of treatment (the effect measure) was ascertained by determining that healing of either pulp or periapical tissue had occurred. For stepwise excavation and pulp capping or partial pulpotomy, these criteria were applied:

- asymptomatic tooth;
- positive response to sensitivity testing;
- radiographically normal periapical conditions; and
- continued root development in immature teeth.

Criteria for lack of healing included:

- pain and tenderness in the tooth and
- necrotic pulp as indicated by clinical and radiographic observations.

For teeth treated by pulpotomy or pulpectomy, the outcome was evaluated primarily on the basis of radiographic examination. Subjective symptoms were noted in addition, as well as other clinical findings, which indicated the development of a root canal infection.

Selection of studies

The literature search yielded 852 abstracts, of which 691 were considered irrelevant. In all the 161 full-text articles were assessed according to the predetermined criteria for inclusion/exclusion described above. Articles, which met the inclusion criteria, were scrutinized and assessed with the aid of the appraisal form and rated. Twenty-four studies were finally included (Fig. 1). Yet only those, which were rated, at least of moderate quality, were used for assessment of the overall quality of evidence (see below). With the main reason for exclusion the excluded studies were listed in an Appendix (can be requested from SBU, E-mail address: <http://www.sbu.se>). The same apply to included studies given a rate of low quality.

Rating quality of evidence

The quality of evidence of the accuracy of each methodological procedure was rated in four levels according to GRADE [11,12]:

- High (++++): based on high- or moderate-quality studies containing no factors that weaken the overall judgement.
- Moderate (+++o): based on high- or moderate-quality studies containing isolated factors that weaken the overall judgement.
- Limited (++oo): based on high- or moderate-quality studies containing factors that weaken the overall judgement.
- Insufficient (+ooo): the evidence base is insufficient when scientific evidence is lacking, the quality of available studies is low or studies of similar quality are contradictory.

GRADE amounts to asking how much confidence one can have in a particular estimate of effect. Is it built on solid ground, or is it likely that new research findings will change the evidence in the foreseeable future? The rating starts at high, but confidence in the evidence may be lowered for several reasons, including limitations in study design and/or quality, inconsistency or indirectness of results, imprecision of estimates and probability of publication bias. Any disagreements about inclusion/exclusion criteria, rating quality of individual studies or quality of evidence of test methods were solved by consensus.

Results

Exposure and healing of pulps on various caries excavation procedures

Four randomized controlled studies of moderate quality found that the risk of pulp exposure increased with immediate complete excavation of caries compared with stepwise excavation (relative risk=2.2 (95% CI=1.6;3.0)) or indirect pulp capping [5,13–15]. A very recent multi-centre RCT of moderate quality [4] observed better success rate for indirect pulp capping than stepwise excavation after an observation period of 3 years, 91% versus 69%. This report included 22 operators and a total of 299 teeth. Selection was based on caries to or deeper than half the distance to the pulp. A single centre RCT of 94 primary and 60 permanent mandibular molars of 4–15 year old individuals observed no difference in pulpal exposure between indirect pulp capping and stepwise excavation, while more pulpal exposures occurred after direct caries excavation [5]. Pulpal healing rate in the study varied from 95% (direct caries excavation) to 100% (indirect pulp capping). Table 4 gives details on the studies evaluated moderate quality for vital pulp treatment.

Direct pulp capping

Two randomized controlled studies [13,16] and a prospective cohort study [17], all of moderate quality, investigated healing of pulps in teeth with either asymptomatic or symptomatic

Table 4 – Study details of vital pulp treatment of deep caries lesions. Effect (pulp exposure and/or healing) of one-visit treatment (incomplete or complete excavation) or two visit treatment (stepwise excavation). IPC= 1-visit indirect pulp capping leaving caries behind permanently, SWE= 2-visit stepwise excavation, DCE = 1-visit direct complete excavation, NS = not statistically significant, CI = confidence interval.

First author, Year, Country, Reference	Study design Setting Sample size Tooth types	Inclusion criteria	Intervention Outcomes Blinding Follow-up Drop-out rate	Main findings *Calculations not reported, by the author(s). CI=95%	Study quality Comments
Björndal, 2010, Denmark [13]	RCT, multi-centre. Operators: not reported. Sample size: 292. Incisors, premolars and molars.	Age: > 18 years, lesion depth: radiographically, $\geq 3/4$ of the dentin, mild to moderate pre-treatment pain accepted.	SWE or DCE. Outcome 1: pulp exposure/ no pulp exposure. Outcome 2: healing/ no healing. Blinding: observers of radiographs blinded to treatment. Follow-up: 1 year. Drop-out rate: 7%.	Pulp exposure: SWE: 25/143=17.5%; DCE: 43/149=28.9%; difference: 11.4% (CI: 1.2; 21.3). Healing: SWE: 106/143=74.1%; DCE: 93/149=62.4%; difference: 11.7%; ($p < .04$). Pre-treatment pain: less healing.	Moderate. Short follow-up time.
Leksell, 1996, Sweden [14]	RCT, single-centre. Operators: $n=6$. Sample size: 134 teeth/116 subjects. Posterior permanent teeth.	Age: 6–16 years (mean=10.2), lesion depth: pulp exposure expected with DCE. Provoked or transient pain before treatment accepted ($n=14$).	SWE or DCE. Outcome 1: pulp exposure/ no pulp exposure. Outcome 2: healing/ no healing. Blinding: observers of radiographs blinded to treatment. Follow-up: > 1 year (mean 3.6 years). Drop-out rate: 5–15%.	Pulp exposure: SWE: 10/57=17.5%; DCE: 28/70=40%. *Relative risk: DCE/SWE=2.3 (CI: 1.65; 2.91). Healing: SWE, unexposed pulps: 40/40, exposed pulps: not reported. DCE: not reported.	Moderate. Randomization procedure not reported.
Magnusson, 1977, Sweden [15]	RCT, single-centre. Operators: not reported. Sample size: 55 teeth/55 children. Primary molars.	Age: 5–10 years. Lesion depth: Supposedly thin layer of softened carious dentin remaining on the pulpal floor. Transient pain before treatment accepted.	SWE or DCE. Outcome: pulp exposure/ no pulp exposure. Drop-out rate: not reported.	Pulp exposure: SWE: 8/55=15%; DCE: 29/55=53%. *Relative risk: DCE/SWE=3.6 (CI: 2.9; 4.3).	Moderate. Quasi-randomized. No follow-up of the two interventions.

Table 4 (continued)

First author, Year, Country, Reference	Study design Setting Sample size Tooth types	Inclusion criteria	Intervention Outcomes Blinding Follow-up Drop-out rate	Main findings *Calculations not reported, by the author(s). CI=95%	Study quality Comments
Maltz, 2012, Brazil [4]	RCT, multi-centre. Operators: n=22. Sample size: 299 teeth/233 subjects. Permanent molars: 62% 1st, 33% 2nd, 5% 3rd molars.	Age: 6–53 years (median 14 years). Lesion depth: radiographically $\geq 1/2$ of dentin thickness. Absence of clinical/radiographic symptoms.	IPC, 1visit, SWE (2-visit). Outcome: healing/no healing. Follow-up: 3 years. Blinding: evaluator of results blinded to treatment not reported. Drop-out rate: 29%.	Healing: IPC: 102/112=91%; SWE: 70/101=69%; Difference stat sign ($p=.004$). SWE completing treatment: 74/84=88%. SWE not completing treatment: 2/17=13%. One surface restorations higher success rate (OR=5.2).	Moderate. Subjects in SWE group not completing treatment (2nd visit) included in the main analysis.
Orhan, 2010, Turkey [5]	RCT, single-centre. Operators: n=1. Consecutive enrolment not reported. Sample size: 154 teeth/123 subjects. 94 primary 2nd molars, 60 permanent mandibular 1st molars.	Age: 4–15 years. Lesion depth: radiographically $\geq 3/4$ of dentin thickness. Absence of clinical/radiographic symptoms.	IPC (1visit), SWE (2 visit):DCE (1visit). Outcome1: pulp exposure/ no pulp exposure. Outcome 2: healing/no healing. Follow-up: 1 year. Blinding: 2 observers of radiographs blinded to treatment. Drop-out rate: not reported.	Pulp exposure: IPC: 3/50=6%; SWE: 4/49=8%; DCE: 12/55=22%. *Relative risk: DCE/SWE=2.7 (CI: .9:7.7); IPC vs. SWE: NS; IPC vs. DCE: $p < .02$; IPC+SWE and DCE: $p=.008$. Healing: IPC: 100%; SWE: 98%; DCE: 95%.	Moderate. Short follow-up time. Randomization procedure suboptimal.

pulps. In one of the studies, circa a third of the teeth were extracted for histological examination [17]. Two of the studies reported a lower frequency of successful pulp capping in permanent teeth with clinical and/or radiographic signs of pulpitis at the time of treatment compared with teeth without such signs [16,17]. Most of the patients with symptoms had persistent toothache. For permanent teeth without preoperative symptoms of pulpitis, the clinically assessed healing rate was around 80% and for symptomatic teeth, around 60% (relative risk=2.07). In one of the studies the failure rate for pulp capping in the group with preoperative symptoms of pulpitis was in fact greater than that reported in Table 2 because 17.5% (24/137) of the teeth were assessed as failures only 3 days posttreatment on the grounds of persistent toothache [16]. Because of subsequent loss to follow-up, these teeth were not included in the analysis. The difference in healing rate between teeth with and without preoperative symptoms was thus greater than reported in the study.

Another randomized controlled study compared the outcomes of pulp capping and partial pulpotomy in adults after an observation period of 1 year. The healing rates were the same for both treatment approaches and much lower than the one reported in the two studies described above (33%) [13]. Only teeth with very deep carious lesions were included in the study. The study also found a higher risk of failure in cases of preoperative toothache. The number of patients with and without toothache was not reported.

Partial pulpotomy

A randomized controlled study of moderate quality [18] and a cohort study of low quality [19] reported healing rates of 91–94% for young permanent teeth without preoperative signs or symptoms. The follow-up period in both studies was 2 years. No studies investigating long-term healing frequency were identified. The previously cited study [13] reported much lower (33%) pulpal survival after 1 year of follow-up. Table 5 presents details on the studies assessing moderate quality for pulp capping and partial pulpotomy.

Pulpotomy

Few studies were carried out on pulpotomy. Very recently, March 2013, a 12-month prospective clinical follow-up examination of moderate quality was published on molars showing a high outcome rate and similar to pulpectomy [33]. It is a multicentre study comprising subjects recruited in 23 health care centres of five Medical Universities in Iran. Treatments were conducted in 407 patients and only 16% were lost to follow-up. While being a study on general dentists, it failed to indicate procedures for pain assessment, patients age distribution in the two study arms, and the quality of the root fillings. Blinding of assessors to treatment outcome was not stated.

Wound dressings

The effect of different wound dressings for treatment of exposed pulps was compared in six randomized controlled studies [16,18,20–23]. One study of moderate quality

investigated the effect of Ledermix, an anti-inflammatory non-steroidal compound, calcium hydroxide and zinc oxide eugenol in direct pulp capping [16]. After an observation period of 2 years, there were no significant differences between the four dressings. Two studies of moderate quality compared calcium hydroxide paste with “mineral trioxide aggregate” (MTA) as dressings after direct pulp capping and partial pulpotomy, respectively [18,22]. After observation periods of 2–3 years, no difference was disclosed with respect to healing. Thus, there is limited scientific evidence that MTA has equal effect as calcium hydroxide paste. Two studies of low quality compared different calcium hydroxide containing compounds for indirect pulp capping and found no differences after a 1-year observation period [21,23]. A randomized controlled study of low quality compared adhesive resin with calcium hydroxide paste as a dressing for indirect pulp capping in deciduous teeth with deep carious lesions [20]. The observation period was 1.5 years. The results disclosed no differences between the materials.

Pulpectomy

A randomized controlled study of moderate quality compared the outcome of pulpectomy in one or two treatment sessions (calcium hydroxide was used as a root canal dressing between the appointments) [24]. A majority of the teeth in the study were affected by caries and had symptoms because of pulpitis. The healing rate was 93% and similar in both treatment groups with a follow-up time up to 3 years. A single dentist specialized in endodontics carried out the treatments and this limits the extrapolation of the results.

A controlled clinical study of low quality found that at 1 year follow-up, teeth with positive bacterial samples at the time of root filling had a poorer, statistically non-significant treatment outcome than teeth with negative bacterial samples [25]. After an observation period of 3.5–4 years, it was noted that the outcome for teeth with positive bacterial samples was significantly lower than that for teeth with negative samples. Dental students under supervision carried out the treatments in this study. Significantly more treatment failures were noted after 3.5–4 years than after 1 year of observation.

Comparison of methods

Except for the recent study on pulpotomy from Iran it was not possible to identify randomized or non-randomized controlled studies of at least moderate quality, comparing different methods aimed at preserving the vitality and functional capacity of the whole or part of the pulp. This means that there is room for well-planned, well-conducted studies comparing the outcomes of indirect pulp capping, direct pulp capping, partial pulpotomy and pulpotomy. There is also need for more studies comparing these methods with pulpectomy.

Comparison of immature and mature permanent teeth and between tooth types

One study of moderate quality observed no statistically significant difference in healing rate after direct pulp capping

Table 5 – Study details of vital pulp treatment of deep caries lesions. Healing after pulp capping and partial pulpotomy.

First author, year, Country, Reference	Study design	Inclusion criteria	Intervention (I)	Main findings	Study quality/comments
	Setting		Outcomes	*Calculations not reported by the author. CI=95%	
	Sample size		Blinding		
	Tooth types		Follow-up		
			Drop-out rate		
Björndal, 2010, Denmark [13]	Multicentre (n=6) RCT. Consecutive enrolment. Operators: n not reported.	Age: ≥ 18 years (mean=30 years). Depth of primary lesion: radiographically ≥ 3/4 of the dentin; pulps exposed after stepwise (n=25) or direct complete excavation (n=43). Mild to moderate pre-treatment pain was accepted.	I1. Direct pulp capping; I2. Partial pulpotomy. Outcome: healing/no healing.	I1: 7/22=31.8%; I2: 10/29=34.5%; Difference NS. Presence of pre-treatment pain significantly associated with treatment failure.	Moderate Short follow-up time. Small sample.
	Sample size: 51 teeth/51 subjects.		Blinding: 2 observers of radiographs blinded to treatment.		
	Premolars and molars.		Follow-up: 1 year. Drop-out rate: 12%. Pre-operative lesion depth: Repeated measurements by one observer.		
Nyborg, 1958, Sweden [17]	Single-centre cohort study with two comparison groups. Consecutive enrolment. Operators: n=1.	Age: < 15 years (n=124), adults (n=101). Deep caries lesions.	I: Direct pulp capping; I1: no sign of pulpitis; I2: signs of pulpitis. Outcome: healing/no healing: (a) clinical and (b) histological.	Clinical vs. histologic findings: difference NS. Healing clinical/radiographic: I1: 106/124=86%; I2 (prolonged pain, pain at night): 9/20=45%. *Relative risk: I2/I1=3.79 (CI: 3.21; 4.37).	Moderate Small sample in one subgroup Unclear exclusion criteria for I2.
	Sample size: 225.		Blinding: clinical/radiographical: yes. Histological: not reported.		
	Permanent teeth: incisors (n=48), premolars (n=61), molars (n=116). Clinical study (n=144).		Follow-up: (a): > 3 years: 82%, (b): > 2 years: 72%.	Healing histologic: I1: 55/69=80%; I2: 0/5=none (uncertain assessment, n=1).	Limited external validity (one operator).
	Clinical and histologic study (n=81).		Drop-out rates: (a) 4% and (b) 6%.		
Shovelton, 1971, England [16]	Multi-centre (n=8) RCT.	Age: 15–44 years. Premolars and molars with exposed vital pulps due to caries.	I: Direct pulp capping with different dressing materials.	Healing: no difference between dressing materials.	Moderate
	Operators: n not stated.		I1. No preoperative pain. One step procedure.	1 Year follow-up. I1: 164/200=82%; I2: 48/67=72%.	Possible confounding (age, type of pulp exposure: caries or accidental).

	Sample size: 412 subjects/412 teeth.		I2. Preoperative pain. Two step procedure. Teeth with unsuccessful temporary treatment (no pain relief) considered unsuccessful. Outcome: healing/no healing.	*Relative risk: I2/I1: 1.58 (CI: 1.09; 2.06).	High drop-out rate at 2 year- follow-up.
	Premolars and molars.		Blinding: independent, blinded outcome examiner. Follow-up: 1 and 2 years. Drop-out rates:1 year: 31%, 2 years: 47%.	2 Year follow-up. I1: 115/154=75%; I2:33/51=65%.	
Qudeimat, 2007, Jordan [18]	Single-centre RCT.	Age: 6.8–13.3 years (mean 10.3 years).	Partial pulpotomy. I1: capping with MTA; I2: capping with calcium hydroxide. Outcome: Healing/no healing.	Healing: No difference between dressing materials.	Moderate
	Operator: n=1.	Carious pulp exposures with no history of pain.	Blinding: independent outcome examiners. Follow-up: 25–46 months (mean 35 months). Drop-out rate: 19–21%.	I1: 26/28=93%. I2: 21/23=91%.	Limited external validity (one operator).
	Sample size: 43 subjects/63 permanent 1st molars.				
Tuna, 2008, Turkey [22]	RCT (quasi-randomised; split mouth model), consecutive enrolment.	Age: 5–8 years.	Direct pulp capping. I1: capping with MTA; I2: capping with calcium hydroxide. Outcome: Healing/no healing.	Healing: no difference between dressing materials.	Moderate
	Operators: not reported.	Pulp exposure from deep dentin caries, exposure less than 1 mm, red colour, haemostasis evident in 2–3 min, no other clinical or radiographic pathology (no spontaneous pain).	Blinding: outcome examiners blinded to materials. Follow-up: 2 years. Drop-out rate: 8/50=16%.	I1: 22/22. I2: 20/20.	Randomization procedure not described. Power analysis unclear.
	Sample size: 50.				External validity unclear.
	Primary molars.				

in permanent teeth of young (<15 years) and older individuals (≥ 15 years) [17]. Nor did the study find any statistically significant difference in healing rate with respect to tooth type: molars versus premolars versus incisors. There were however, numerical differences and incisors had the highest healing rate and premolars the lowest. The study of Björndal et al. [13] noted that teeth with unexposed pulps after stepwise excavation had a greater healing rate in individuals <50 years than in those >50 years of age [13]. Statistically the difference was of borderline significance. Because of the insufficient scientific support, it is not possible to conclude with respect to the influence of patient age or type of tooth on the outcome of direct pulp capping. One study of low quality showed no differences in healing rates between deciduous and permanent teeth following direct or indirect pulp capping [23].

Systematic reviews

A systematic review of low quality compared the effect of various wound dressings [26]. The authors' concluded that the results did not support proposals to change currently accepted practice. Another systematic review [27] had included four studies, two of which investigated the survival of restorations after complete or incomplete removal of dentinal caries [28,29]. These studies did not specifically investigate teeth with deep carious lesions and did not meet our inclusion criteria. The other two studies were included and are tabulated in the report [14,15].

Cost-analysis

A modelling study of moderate quality investigated the costs and benefits of direct pulp capping compared with pulpectomy [30]. With the support of the decision analysis, the authors concluded that if the healing rate for pulp capping is greater than 56%, then this and not pulpectomy should be chosen. The analysis considered only direct costs for the procedures. The long-term effects of the treatment (e.g. risk of toothache) and the patients' preferences were not assessed.

Discussion

The result of this systematic review shows that there are substantial gaps in our knowledge base with respect to treatment of the vital pulp exposed to deep caries. Hence, the report is unable to offer a clear answer to the question of whether indirect pulp capping, stepwise excavation, direct pulp capping/partial pulpotomy, pulpotomy or pulpectomy is the most effective treatment for this kind of cases. Indirect pulp capping and stepwise excavation certainly lead to fewer pulp exposures than direct complete caries excavation. Whether this results in a higher survival rate for the pulp over time has not been thoroughly investigated.

The studies reporting the outcomes of direct pulp capping upon deep caries in general have short follow-up times. While retrospective studies have indicated a poorer outcome over time [31], the long-term survival of the pulp is not well confirmed. It is furthermore not well known whether pulp

capping or pulpectomy offers a greater potential to attain non-infectious conditions and thus the health of the periapical tissues and asymptomatic teeth long-term. There are almost no studies at all of health economic aspects of different treatment options. Such studies should consider both patient satisfaction and direct and indirect costs.

The presence of preoperative pain (toothache), particularly over a longer period and if it has caused sleep disturbance, appears negative for the outcome of pulp capping. Yet, pain is difficult to properly assess. The experience is subjective and is modified by both physical and psychological factors. Thus, measurement of pain can easily be erroneous. The three studies, which evaluated the result of pulp capping in relation to preoperative toothache, have differing and in part imprecise definitions of toothache, which makes it difficult to compare the results. It has been proposed that dichotomizing toothache/no toothache is the most relevant and this was the basis for the current report [32]. Data shows that the healing rate after pulp capping is lower in cases of preoperative toothache. The evidence is limited and better-designed studies evaluating the importance of preoperative toothache are required. An important further question is how data such as the patient's age, tooth type, a combination of preoperative symptoms and clinical observations e.g. presence, persistence and character of toothache, the extent and depth of the carious lesion, the location of the pulp exposure, its size and the tendency of the pulp to bleed can be applied to make a well-informed choice between pulp preservation procedure and pulpectomy.

If the pulp tissue is directly exposed, some type of wound dressing is usually applied. Even restorative materials (e.g. resin composite) have been used to cover the wound. Over the years calcium hydroxide has been the most commonly employed wound dressing. Despite its high pH, it creates conditions conducive to healing of the pulp tissue. Other wound dressings contain steroids, with or without antibiotics, but were not accounted as these agents are not routinely used in Sweden. In recent years promising results have been reported for "mineral trioxide aggregate", MTA. Studies comparing different types of dressings for the exposed pulp (calcium hydroxide paste, cement containing calcium hydroxide, MTA, Ledermix and zinc oxide eugenol), disclose no clear difference in treatment outcome. MTA and calcium hydroxide paste were comparable in two studies [18,22]. Yet patients in these studies were of very young ages. Our review found no support for other materials.

The outcome of treatment of a deep caries lesion, with or without pulpal exposure, depends largely on how extensively the pulp is infected at the time of treatment. The outcome may also depend on the age of the patient, the treatment approach (indirect pulp capping, direct pulp capping, etc) and the choice of material applied to the exposed pulp tissue. The capacity of the restorative material to prevent leakage of bacteria is yet another important factor.

The primary aims of pulpectomy are to prevent infection of the pulp chamber, to maintain the health of the periapical tissues and to ensure asymptomatic conditions. In order to achieve these results, proper asepsis during treatment, effective removal of the pulp tissue and dense fill of the instrumented root canal are regarded critical measures in order to

prevent the development of root canal infection. Complicated root canal anatomy and the skill of the operator may also influence the outcome. The impact of these and other treatment variables on the outcome including the length of the follow-up period has not been satisfactorily explained and were not possible to investigate in this systematic review.

Calcium hydroxide has also been considered to provide a beneficial treatment effect after pulpectomy. The material is then used as an intermediate dressing in the instrumented canal between appointments. Whether this measure improves the treatment result is still the subject of debate.

On the basis of this analysis the following conclusions on the evidence-graded results can be drawn:

- Limited scientific support exists for the claim that pulpal exposure occurs twice as frequently during direct complete caries excavation as in stepwise excavation (⊕⊕□□).
- Insufficient scientific basis endures to allow an evaluation of whether there are differences in pulpal survival rates following immediate complete caries excavation and stepwise excavation (⊕□□□).
- The scientific basis is contradictory with respect to healing following direct pulp capping when the pulp is exposed during excavation of deep caries. In two studies, the short-term (1-3 year) healing rate was 80-85% in asymptomatic teeth. Another study on adults with very deep carious lesions, including patients with preoperative toothache, reported a much lower healing rate after 1 year (33%) (⊕□□□).
- Limited scientific support exists for preoperative toothache to be associated with increased risk of failure after direct pulp capping (⊕⊕□□).
- Insufficient scientific basis endures to allow an evaluation of the effect of indirect pulp capping, i.e. when the innermost layer of carious dentine is permanently left in situ (⊕□□□).
- There is no scientific basis for assessment of whether indirect pulp capping, stepwise excavation, direct pulp capping, partial pulpotomy, or pulpotomy offers the best potential for maintaining the pulp in a vital and asymptomatic condition.
- Limited scientific evidence exists that there is no difference in treatment effect between “mineral trioxide aggregate” (MTA) and calcium hydroxide as wound dressings on an exposed vital pulp (⊕⊕□□).
- There is insufficient scientific evidence to determine the influence of age and type of tooth on survival of the pulp following direct pulp capping (⊕□□□).
- There is insufficient scientific basis on which to assess whether it is more advantageous to preserve all or some of the pulp in teeth with deep caries than to undertake a pulpectomy and root filling (⊕□□□).
- There is a no scientific basis on which to assess the treatment outcome after pulpectomy and root filling.
- There is insufficient scientific evidence to determine whether the number of treatment sessions is of importance for the outcome of pulpectomy and root filling (⊕□□□).
- There is no scientific basis on which to assess which other factors might be of importance for the treatment outcome of pulpectomy and root filling.
- Insufficient evidence exists for the cost effectiveness and cost benefit of the various procedures (⊕□□□).

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