

REVIEW ARTICLE

Outcomes reporting in systematic reviews on vital pulp treatment: A scoping review for the development of a core outcome set

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Abstract

Background: A large number of research reports on vital pulp treatment (VPT) has been published over the last two decades. However, heterogeneity in reporting outcomes of VPT is a significant challenge for evidence synthesis and clinical decision-making.

Objectives: To identify outcomes assessed in VPT studies and to evaluate how and when outcomes are measured. A subsidiary aim was to assess evidence for selective reporting bias in the included studies. The results of this review will be used to inform the development of a core outcome set (COS) for endodontic treatments.

Methods: Multiple healthcare bibliographic databases, including PubMed/MEDLINE, Ovid EMBASE, Scopus, Cochrane Database of Systematic Reviews and Web of Science were searched for systematic reviews published between 1990 and 2020, reporting on VPT. Screening, data extraction and risk of bias assessment were completed independently by two reviewers. Outcomes' information was extracted and aligned with a healthcare taxonomy into five core areas: survival, clinical/physiological changes, life impact, resource use and adverse events.

Results: Thirty-six systematic reviews were included, 10 reporting on indirect pulp capping or selective caries removal, nine on direct pulp capping, eight on pulpotomy and nine on combined VPTs. There was considerable variation in the outcomes reported in these reviews and their included studies. Clinician-reported outcomes were used considerably more often than patient-reported outcomes. A range of instruments and time points were used for measuring outcomes. Several of the reviews were assessed as having low risk of selective reporting bias, but many did not specifically report this domain, whilst others did not provide risk of bias assessment at all.

Discussion: Considerable variation in selection of outcomes and how and when they are measured and reported was evident, and this heterogeneity has implications for evidence synthesis and clinical decision-making.

Conclusions: Whilst there is a lack of consistency, several potentially important outcomes for VPT, including pulp survival, incidence of post-operative pain and

need for further intervention, have been identified which could inform the development of a COS for endodontic treatment.

Registration: Core Outcome Measures in Effectiveness Trials (COMET) (No. 1879).

KEYWORDS

direct pulp capping, endodontics, outcomes, pulpotomy, selective caries removal, vital pulp treatment

INTRODUCTION

Vital pulp treatments (VPTs) represent a group of minimally invasive endodontic treatments intended to preserve the health of all or part of the dental pulp (Duncan, Galler, et al., 2019). These treatments include a spectrum of modalities including indirect pulp capping, direct pulp capping and pulpotomy (partial or complete). Although not novel, VPT has recently emerged as a promising biologically based treatment due, in part, to advances made in the scientific field, including the introduction of bioactive hydraulic calcium silicate cements (Nair et al., 2008; Parirokh et al., 2018) as well as advances in pulp biology that have improved clinicians' understanding of the biological and reparative processes occurring in the injured dental pulp (Duncan, Cooper, & Smith, 2019; El Karim, Cooper, et al., 2021). Consequently, a plethora of clinical studies reporting on the outcome of VPT have been published over the last two decades and have demonstrated high success rates (Asgary et al., 2017; Bjørndal et al., 2017; Taha & Abdulkhader, 2018). Many systematic reviews have also been conducted summarizing the evidence from these studies (Cushley et al., 2019, 2020; Elmsmari et al., 2019). However, these systematic reviews are limited not only by methodological shortcomings, but also by the considerable heterogeneity and lack of standardization in the reporting of outcomes within the included studies.

A treatment outcome is generally defined as a clinical measure used to judge the efficacy or effectiveness of a treatment, but it can also represent the suffering or loss of health experienced by an individual because of the disease process (Boers et al., 2014). With this background, the outcomes of all endodontic treatment, including VPT, are often evaluated through detailed history-taking accompanied by clinical and radiographic examination. The reporting of these clinical findings, however, is heterogeneous with no clear consensus amongst researchers and clinicians on the most important and relevant outcomes to be reported for each respective treatment. For instance, tooth survival is an important outcome for patients, but is generally not reported, and even when reported, different terminologies and descriptions are used.

This makes evidence synthesis and meta-analysis unnecessarily difficult, if not impossible (Saldanha et al., 2020). In addition, many of the reported outcomes tend to be clinician-reported and not patient-reported (Duncan, Chong, et al., 2021). There is also a lack of consensus on the methods and timing used to measure outcomes. Such heterogeneity negatively impacts evidence synthesis, pooling of primary studies, clinical guidelines development and provision of clinical care (Rosenbaum et al., 2010). Therefore, a need exists to develop a minimum core outcome set (COS) for VPT, which would be used in all future studies of these treatments.

A COS is defined as an agreed, standardized set of outcomes that should be measured and reported as a minimum in all clinical trials and clinical outcome studies in a particular field (Williamson et al., 2012). It is not intended to be a restrictive list but rather it allows researchers to also include additional outcomes that support their study aims whilst ensuring better clarity of available evidence. Adopting a COS approach in clinical research increases the likelihood that important outcomes are measured, improves evidence synthesis by reducing heterogeneity between studies and reduces outcome-reporting bias, thereby, improving the validity of the studies (Clarke, 2008). The process of COS development as described in the Core Outcome Set-Standard for Development (COS-STAD) statement, involves identification of outcomes and how they are measured through systematic review of the literature, followed by a structured consensus process to agree the most important outcomes and how and when they should be measured (Kirkham et al., 2016; Kirkham et al., 2017).

This scoping review reports on the outcomes of existing VPT studies and serves to inform the development of a COS outcome set for endodontic treatment modalities (COSET) project (El Karim, Duncan, et al., 2021). The objectives of this scoping review are to: (1) Identify what outcome domains are assessed in studies evaluating VPT, (2) Report on how the outcomes are measured (that is, what validated or nonvalidated instruments are used) and (3) Assess any selective reporting bias in the included studies.

METHODS

This scoping review is reported in line with the PRISMA-ScR guidance (Tricco et al., 2018). The protocol for this review and the COSET project has previously been published (El Karim, Duncan, et al., 2021). The project is registered in the Core Outcome Measures in Effectiveness Trials (COMET) database (registration No. 1879).

Selection criteria

Population: Humans undergoing VPT in a permanent tooth.

Treatment procedures carried out: direct pulp capping (DPC); indirect pulp capping (INDPC)/ selective caries removal (one and two visits); partial pulpotomy and full/complete coronal pulpotomy.

Follow up: No restriction on follow up period.

Studies: Systematic reviews published in the English language which included clinical studies reporting clinical and or radiographic outcomes of VPT.

Information sources

A comprehensive structured literature search was performed using PubMed/MEDLINE, Ovid EMBASE, Scopus, Cochrane Database of Systematic Reviews, Web of Science databases and grey literature to identify systematic reviews published in English between January 1990 and December 2020 covering the outcomes of VPT.

Search process

A detailed search strategy was developed in MEDLINE and adapted for other bibliographic databases (Table S1). An electronic library of all references was uploaded to EndNote 20 and duplicates were removed. Two reviewers (SC, IEK) independently assessed the title and abstracts of all systematic reviews identified. Any disagreement about article inclusion was resolved by arbitration from a third reviewer (HD) if required.

Outcome measures

The main outcomes of this scoping review were: (1) Identification and list all outcomes reported in the studies included in the reviews (clinician- and patient-reported outcomes), (2) Methods used to measure these outcomes, and (3) Duration of follow up of the reported outcomes.

Data extraction

Data extraction from the full text of eligible reviews was completed independently by one reviewer (SC) and verified by another (IEK). A data extraction proforma was piloted based on the outcomes reported in three of the included studies. Extracted data included all clinician and patient-reported outcomes in eligible studies. Histological and microbiological outcomes were also extracted if they were provided in conjunction with a clinical or radiographic outcome. Data were also collected on the range of instruments (radiographs, questionnaires, pulp testers, etc.) used for outcome measurement and the duration of the follow up. Instruments included pain measurement scales, unspecified pain questionnaires, radiography, cone-beam computer tomography, histopathological as well as clinical and photographic assessments. In addition, demographic and other data to facilitate description of the included studies was collected including, country of study and the method of data synthesis.

Categorization into domains

Outcomes data collected was aligned with a healthcare taxonomy (Dodd et al., 2018). The taxonomy involves grouping outcomes into five core areas: survival, clinical/physiological changes, life impact, resource use and adverse events. Each core area has both disease and treatment-specific domains for outcomes. The outcomes in each domain were collated and presented in table forms.

RESULTS

Literature search

The initial search of the data bases using the search strategy shown in Table S1 yielded 433 articles. After removal of duplicates, 367 abstracts and titles were available for screening, of which 320 were excluded for reasons summarized in Figure 1. The remaining 47 full text articles were then assessed for eligibility, and 11 that did not meet the review criteria were excluded (Table S2). Finally, 36 systematic reviews were included in this scoping review.

Characteristics of included studies

The characteristics of the included systematic reviews are shown in Table 1. Of these, 10 reported on INDPC/ selective or stepwise caries removal (Table 1A), nine

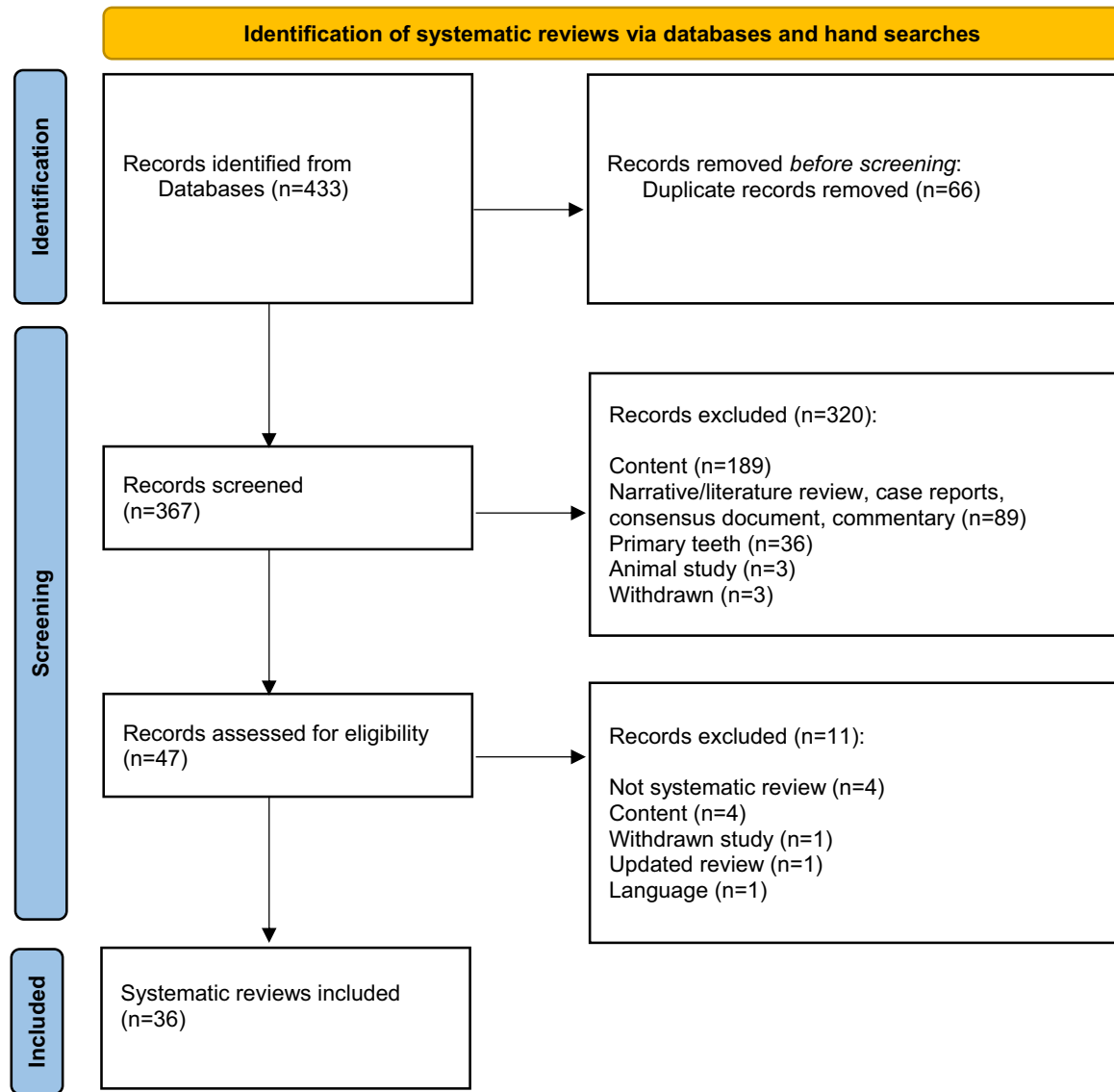


FIGURE 1 PRISMA flow diagram.

on DPC (Table 1B), eight on pulpotomy (Table 1C) and nine on a combination of VPTs (Table 1D). There was a wide geographical distribution of authors across Asia, Europe, North and South America. The number of studies included in each review varied (range: 2 to 37). The type of included studies within the reviews also varied and included randomized controlled trials (RCT) ($n = 85$), controlled clinical trial (CCT) (where it was not explicit that the trial was randomized) ($n = 14$), cohort studies ($n = 47$) and case series ($n = 15$) out of a total of 161 studies. A list of these studies and an additional 10 studies identified from the reference lists of the included systematic reviews are available in Tables S3 and S4. A meta-analysis was conducted in 22 of the systematic reviews included in this scoping review (Table S4).

Synthesis of results

Outcome domains for pulpotomy, DPC and INDPC were shown in Tables 2–4, respectively, and described in detail as follows.

Survival

In the survival core area, the outcome domain was ‘tooth survival’ and ‘pulp survival’. Tooth survival was reported in 2 INDPC studies, 4 DPC studies and 1 pulpotomy study. Pulp survival was reported only in DPC studies ($n = 5$). Several studies (4 INDPC, 7 DPC, 4 pulpotomy) did not define the type of ‘survival’ being measured.

Clinical and physiological changes

Most of the outcome domains were reported in this core area. Whilst there was some commonality with the reported outcomes, slight differences existed between different VPT modalities (Tables 2–4). ‘Pain’, maintenance of ‘tooth vitality’ and ‘radiographic assessment’ were frequently reported outcomes across all three VPT methods. ‘Pain’ was reported in 21 INDPC studies, 45 DPC studies and 45 pulpotomy studies. The ‘tooth vitality’ domain was reported in 28 INDPC, 48 DPC and 23 pulpotomy studies. Radiographic assessment was also reported for all three treatments. This assessment was carried out for a variety of indications including radiographic evidence of apical periodontitis in 19 INDPC, 44 DPC and 47 pulpotomy studies. ‘Continued root development’ in cases of immature teeth was reported for 2 INDPC, 4 DPC and 17 pulpotomy studies. Other outcome domains within this core area reported across all treatment types include ‘evidence of infection’, ‘tertiary dentine formation’, ‘tooth mobility’ and ‘integrity or quality of the tooth restoration’. Treatment-specific outcomes included ‘pulp exposure during caries excavation’, which was reported only in the INDPC studies, and ‘change in carious lesion depth’ which was reported in both the DPC and INDPC studies.

Life impact

The most commonly reported outcome domain in this area across all treatment types was success/healing following the intervention assessed clinically and radiographically ($n = 16, 30, 24$) for INDPC, DPC and pulpotomy studies, respectively. The definition of success differed between studies and between treatment modalities. ‘Presence of a functional tooth’ was occasionally reported as was ‘discolouration’, and ‘satisfaction with treatment’ (Tables 2–4).

Use of resources

The ‘need for further intervention’ was the most commonly reported outcome being reported in 13 IDPC, 22 DPC and 14 pulpotomy studies. ‘Use of analgesics’ during the postoperative period and ‘time to complete the procedure’ were also reported across all treatment types, whilst ‘cost-effectiveness’ was reported in one pulpotomy study only.

Adverse effects

Outcomes were rarely reported in this core area but included, ‘intra-chamber or pulpal calcification’ ($n = 10,$

9) and ‘pathological narrowing of the pulp chamber’ ($n = 3, 11$) reported in DPC and pulpotomy, respectively. Resorption was reported across all three treatment types ($n = 3, 11, 20$), whilst development of the carious lesion was reported only in INDPC and DPC studies ($n = 13, 3$).

How were the outcomes measured?

Different methods have been used to measure the reported outcomes. Pain for example, was measured using VAS ($n = 11$) and NRS ($n = 3$). Some studies used unspecified questionnaires ($n = 2$), but in most of the studies ($n = 94$) pain was reported from patient history using no measurement instrument. Several studies reported presence of symptoms that were not specified ($n = 9, 36, 20$) for IDPC, DPC and pulpotomy, respectively. Clinical examination was used in most studies to assess outcomes such as pain on percussion and palpation, and presence of signs of infection such as swelling and sinus tract. Radiographic assessment was carried out for various indications but mainly for evidence of periapical changes indicative of disease or healing ($n = 110$). Other studies reported on root resorption, pathological and physiological narrowing of the pulp chamber, pulpal calcifications, and root development. Assessment of pulpal status was measured using multiple methods including singular or combinations of thermal, electric and Doppler flowmetry tests. Cold only tests were employed in 33 studies, hot and cold tests combined ($n = 2$), electric only ($n = 12$), cold and heat tests combined with electric ($n = 3$). Doppler flowmetry was employed in two studies. In many studies the type of thermal test used was not specified ($n = 6$) whereas in others the method used for assessing vitality/sensibility was not specified ($n = 21$). One pulpotomy study involved probing the calcific barrier for evidence of vitality whilst a further 21 studies did not specify the method of measurement in reporting this outcome. Although the level of pulpal inflammation can be assessed objectively by measurement of selected biomarker levels, none of the included studies reported adoption of this measure. Outcomes related to life impact such as functionality of the tooth were reported from the patient history. No study reported global quality-of-life measures.

When are the outcomes measured?

The minimum and maximum follow up time for outcomes depended largely on the nature of the outcome and treatment modality. Pain and symptoms of pulpal disease were usually reported for short-, as well as long-term (range: 1 day to 29 years). Histological outcomes were frequently

TABLE 1 Characteristics of systematic reviews on (A) indirect pulp capping /selective caries removal ($n = 10$); (B) direct pulp capping (DPC) ($n = 9$); (C) pulptomy ($n = 8$); (D) combining different VPTs ($n = 9$)

Author	Year	Country	Journal name	VPT modality reported	Outcomes reported in review
(A)					
Barros et al., 2020	2020	Brazil	<i>Clinical Oral Investigations</i>	INDPC	Maintenance of pulp health (clinically and radiographically) pulp exposure, dentin deposition, microbiological examination, quality of the restoration
da Rosa et al., 2019	2019	Brazil	<i>International Endodontic Journal</i>	INDPC	Dentine hardening and thickness
Hayashi et al., 2011	2011	Japan	<i>Journal of Dentistry</i>	INDPC	Pulp exposure, postoperative pain or discomfort, amounts of cariogenic bacteria in a cavity, colour and hardness of carious dentin, remineralization of softened dentin, regeneration of tertiary dentin, and retention of sealing material, vitality
Hoefler et al., 2016	2016	USA	<i>Journal of Dentistry</i>	INDPC	Restorative failures and loss of pulp vitality
Kiranmayi et al., 2019	2019	India	<i>Journal of International Oral Health</i>	INDPC	Success or failure of pulp capping [≠]
Li et al., 2018	2018	China	<i>Acta Odontologica Scandinavica</i>	INDPC	Risk of pulp exposure, risk of pulpal symptoms. (clinical or radiological pulp symptoms such as pain, irreversible pulpitis and loss of vitality), and failure (technical or biological complications demanding intervention)
Ricketts et al., 2013	2013	United Kingdom	<i>Cochrane Systematic Reviews</i>	INDPC	Pulpal exposure, signs and symptoms pulpal disease, progression caries, restoration failure, health economics, OHQoL, patient/carer and dentist perception of treatment, patient discomfort during treatment
Ricketts et al., 2007	2007	United Kingdom	<i>Cochrane Systematic reviews</i>	INDPC	Exposure of the pulp during caries removal. Patient experience of symptoms of pulpal inflammation or necrosis. Progression of caries under the filling. Time until the filling is lost or replaced
Schwendicke, Dorfer, & Paris, 2013	2013	Germany	<i>Journal of Dental Research</i>	INDPC	Pulpal exposure during treatment; postoperative pulpal symptoms (clinical or radiological pulp symptoms requiring treatment and failure (technical or biological complications demanding intervention)
Schwendicke, Meyer-Lueckel, et al., 2013	2013	Germany	<i>Journal of Dentistry</i>	INDPC	Clinical or radiological failure. Events or conditions associated with previous treatment of deep caries, which require re-treatment. Pulpal failures included pain, clinical or radiological signs of loss of vitality, or abscess or sinus formation leading to re-treatment. Nonpulpal failures included fracture of the tooth or the restoration, loss of the restoration or its integrity, or secondary as well as progressing residual caries leading to re-treatment
(B)					
Cushley et al., 2020	2020	United Kingdom	<i>International Endodontic Journal</i>	DPC	Clinical and radiographic success of DPC
Deng et al., 2016	2016	China	<i>Journal of American Dental Association</i>	DPC	Success or failure treatment
Edwards et al., 2020	2020	United Kingdom	<i>Endodontic Practice Today</i>	DPC	Tooth survival, pulp survival, clinical success, cost effectiveness
Javed et al., 2017	2017	United States of America	<i>Lasers in Medical Science</i>	DPC	Pulp vitality and healing response to laser therapy
Li et al., 2015	2015	China	<i>Journal of Endodontics</i>	DPC	Success rate, inflammatory response, and dentin bridge formation
Mahmoud et al., 2018	2018	Egypt	<i>Journal of Conservative Dentistry</i>	DPC	Clinical symptoms and/or radiographic evidence
Matsuura et al., 2019	2019	Japan	<i>Journal of Oral Science</i>	DPC	Clinical and radiographic success
Schwendicke et al., 2016	2016	Germany	<i>Clinical Oral Investigations</i>	DPC	Clinical and radiographic success (no pain or signs of irreversible pulpitis or lost vitality, no abscess/sinus, no radiographic pathologies). Costs/time required for capping and subjective handling of different capping materials
Zhu et al., 2015	2015	China	<i>International Journal of Clinical Medicine</i>	DPC	Clinical success and dentine bridge formation radiographically
(C)					
Alqaderi et al., 2016	2016	United States of America	<i>Journal of Dentistry</i>	CP	Success rate ^c

Number and type of eligible studies						
No.	RCT	CCT	CS	Case series	Meta-analysis	Follow up
10	9		1		Yes	3 months–5 years
2	2	—	—	—	Yes ^b	3–71 months
7	1	1	—	5	No	4 months–11 years ^a
5	2	—	—	3	No	2–10 years
6	6	—	—	—	Yes	2–24 months
2	2	—	—	—	Yes	6–24 months
4	4	—	—	—	Yes	3 months–11 years ^a
2	2	—	—	—	Yes	12 months–11 years ^a
4	4	—	—	—	Yes	6 months–10 years
14	7		1	6	Yes	6 months–10 years
14	5	—	9	—	Y	6–120 months
5	5	—	—	—	Y	6 months–4 years
4	4	—	—	—	N	7 days–36 months
6	5	—	—1	—	Y	0.5–54 months
9	4	2	3	—	Y	1 day–123 months ^a
6	—	—	6	—	N	8–540 days
7	7	—	—	—	N	6–36 months
5	4	1	—	—	Y	3–24 months
3	3	—	—	—	Y	1 week–2 years ^a
6	1	—	5	—	Y	1–88 months

(Continues)

TABLE 1 (Continued)

Author	Year	Country	Journal name	VPT modality reported	Outcomes reported in review
Chen et al., 2019	2019	China	<i>BMC Oral Health</i>	CP	Clinical and radiographic success ^d
Cushley et al., 2019	2019	United Kingdom	<i>Journal of Dentistry</i>	CP	Long-term success of pulpotomy ^e
Elmsmari et al., 2019	2019	United Arab Emirates	<i>Journal of Endodontics</i>	PP	Success rate
Li et al., 2019	2019	China	<i>Journal of Dentistry</i>	CP	Clinical or radiographic success at 12 months ^f
Taylor et al., 2020	2020	United Kingdom	<i>International Journal of Paediatric Dentistry</i>	CP & PP	Clinical success defined as the tooth being in situ at the end of the study. Assumption that for the tooth to remain in situ it was symptom free and showed no signs of new or progressive infection
Zafar et al., 2020	2020	Pakistan	<i>Journal of Conservative Dentistry</i>	CP	Lack of clinical and radiographic signs of failure. Healing or resolution of periapical rarefaction
Zanini et al., 2019	2019	France	<i>Acta Odontologica Scandinavica</i>	CP	Clinical and histological success
(D)					
Aguilar & Linsuwanont, 2011	2011	Thailand	<i>Journal of Endodontics</i>	DPC CP	Clinical and radiographic success of treatment
Bergenholtz et al., 2013	2013	Sweden	<i>Singapore Dental Journal</i>	INDPC, DPC, CP	Survival of the pulp, verified by absence of symptoms, sensibility testing, radiographic examination or closure of the roots in young teeth
Brodén et al., 2016	2016	Sweden	<i>American Journal of Dentistry</i>	DPC, CP	Treatment outcome was based on radiographic examination and/or sensitivity testing for teeth treated by pulp capping procedures and radiographic examination and the presence/absence of clinical symptoms for the root filled teeth
Didilescu et al., 2018	2018	Romania	<i>Journal of American Dental Association</i>	DPC, PP	Hard tissue formation
Fransson et al., 2016	2016	Sweden	<i>International Endodontic Journal</i>	DPC, CP	Formation hard tissue barrier
Mahgoub et al., 2019	2019	China	<i>Journal of International Society of Preventive & Community Dentistry</i>	DPC, CP	Dentine bridge formation, treatment success, mineralization, and the presence of inflammatory cells
Miyashita et al., 2007	2007	Japan	<i>Cochrane systematic reviews</i>	DPC, INDPC	Clinical success, extraction, patient satisfaction, adverse events
Munir et al., 2020	2020	Switzerland	<i>Journal of Clinical Medicine</i>	DPC, CP	Pulp survival after intervention
Paula et al., 2018	2018	Portugal	<i>Journal of Evidence Based Dental Practice</i>	DPC, CP	Preservation of pulp vitality (success rate, absence of inflammatory response, and dental bridge formation)

Note: (A) ≠Secondary outcomes included: (1) overall, clinical, or radiographic success at longer follow up periods; and (2) root growth or apical closure (for immature permanent teeth only). Clinical success was described as devoid of clinical manifestations such as pain on percussion/palpation and spontaneous pain, and devoid of need for further root canal treatment. Radiographic success was defined as healing or resolution of radiographic periapical lesions, and devoid of need for further root canal treatment. Overall success was defined as achievement of both clinical and radiographic success. Abbreviations: CCT, Case control studies; CP, Complete pulpotomy; CS, Cohort studies; DPC, Direct Pulp Capping; INDPC, Indirect pulp capping; OHQoL, Oral health quality of life; PP, Partial Pulpotomy; RCT, Randomized control trials; VPT, Vital pulp treatment.

^aData not stated in review and collated from included studies.

^bThe eligible studies for this review were not included in the meta-analysis.

^cSuccess was defined as no radiographic abnormality or clinical symptoms, such as spontaneous pain, tenderness to percussion or palpation, resolution (decrease in size or elimination) of an existing radiographic periapical lesion, and no need for further pulpectomy and RCT of the treated teeth.

^dSuccess was defined as no pain, no abscess or fistulation, no excessive tooth mobility and no swelling. Radiographic success was considered if the teeth showed no evidence of apical and furcal radiolucency, internal or external root resorption, periodontal ligament widening, or periapical bone destruction.

^eSuccess was defined as; (1) radiographic success in which there was no abnormality suggestive of apical periodontitis as well as resolution (decrease in size or elimination) of an existing radiographic periapical lesion, and (2) clinical success where there were no clinical symptoms of spontaneous pain, tenderness to percussion and/or no swelling or sinus tract. Long-term success is also defined by minimum 12-month follow up period.

^fFailures were considered when there were clinical symptoms such as pain, tenderness and radiolucency in the periapical region including the widening of periodontal ligament. All the six studies evaluated the thickness of tertiary dentin formed after INDPC by tooth sensibility tests, pain evaluation by visual analogue scale, percussion test, and radiographically assessed the presence or absence of periapical radiolucency and thickness of tertiary dentin after INDPC procedure.

Number and type of eligible studies

No.	RCT	CCT	CS	Case series	Meta-analysis	Follow up
5	5	—	—	—	Y	6–24 months
8	3	—	5	—	N	12–60 months
9	5	—	—	4	Y	3–154 months
16	16	—	—	—	Y	1–60 months
9	3	—	5	1	N	1 day–140 months
6	2	—	4	—	N	1–10 years
32	10	1	20	1	N	1 day–96 months ^a
22	4	—	5	1	Y	>6 months–>3 years
10	8	1	—	1	N	1–3.6 years
10	2	—	—	8	N	12–140 months
18	7	11	—	—	Y	5–136 days
15	10	5	—	—	N	1 day–6 months
2	1	—	1	—	N	3 weeks–3 years
4	3	—	1	—	Y	6 months–3 years
26	25	1	—	—	N	1 day–5 years ^a
37	25	4	8	—	Y	30–2400 days

TABLE 2 Outcomes of INDPC/selective/stepwise caries removal

Core area	Outcome domain	How it is measured	Number of articles reporting outcome	Minimum/maximum follow up	
Survival	Tooth survival	Tooth present	2	1.5–10 years	
		NS	4	6–62 months	
Physiological/ clinical changes	Pain	Patient report	19	1 week–5 years	
		VAS	2		
	Symptoms	Patient report	9	1 day–62 month	
	Infection-swelling, sinus, fistula or abscess	Clinical assessment	6	3 months–3 years	
	Radiographic evidence disease progression	Radiographic assessment	19	2–62 months	
	Vitality/sensibility		Cold test only	15	1 week–10 years
			Heat and cold test	1	
			Cold test and EPT	6	
			Heat and cold test and EPT	1	
			Cold test or EPT	2	
			Thermal unspecified and EPT	1	
			NS	2	
	Tenderness to percussion /palpation		Clinical assessment	4	1 week–5 years
			TTP and palpation	6	
			TTP only	—	
			Palpation only	—	
	Mobility		NS	6	3 months–3 years
	Continued root development or apexogenesis		Radiographic assessment	2	2 months–11 years
	Remineralisation/ hard tissue/dentine barrier formation		Radiographic assessment	10	3 months–10 years
Clinical assessment			11		
Radiographic and CBCT			1		
Histological assessment			2		
Histological evidence of carious process in dentine		Microbiology	10	3–12 months	
Integrity /quality of restoration		NS	5	2 months–10 years	
Exposure during caries excavation or temporary restoration removal		Clinical assessment	12	Baseline–6 months	
Life impact	Success	Clinical and radiographic assessment	12	1 week–11 years	
		Clinical assessment	—	—	
		Radiographic assessment	—	—	
		NS	4	6–62 months	
	Aesthetics- discolouration	Clinical assessment- photographic comparison	1	6 months	
Resources use	Need for further intervention	Clinical and radiographic assessment	13	1 week–10 years	
	Time to complete procedure	CROM- timed procedure	1	18 months	
	Use of analgesics after procedure	Patient report	1	1 week–1 year	
Adverse effects	Resorption	Radiographic assessment	3	2 months–3 years	
		Change in lesion depth/ secondary caries	Radiographic assessment	7	3 months–10 years
		NS	5		
		Radiographic and CBCT	1		

Abbreviations: CBCT, Cone-beam computed tomography; CROM, Clinician reported outcome measures; EPT, Electric pulp test; NS, not specified; TTP, tender to percussion; VAS, visual analogue scale.

reported in the short- to medium-term (range: 1 week to 20 months) whilst evidence of tissue healing usually requires a long-term follow up. There is inconsistency in the timing of reporting, even within the early and late outcome categories.

Outcome reporting bias

An assessment of selective reporting bias within the included reviews is outlined in [Tables 5](#). The outcomes reported in this review covered all the five core healthcare areas, albeit with a high level of heterogeneity ([Tables 2–4](#)). All the reviews assessing risk of selective reporting bias for RCT followed by Cochrane's Risk of Bias tool. Several reporting methodologies were used for other study designs including Newcastle-Ottawa Scale ($n = 4$), modified Downs & Black ($n = 3$), Methodological Index for Non-Randomized Studies MINORS ($n = 2$), Risk of Bias in Non-Randomized Studies-of Interventions ROBINS-I ($n = 3$) and Critical Appraisal Skills Programme CASP ($n = 1$).

Of the included reviews, 10 failed to completely report on the risk of selective reporting bias. Due to the measurement scale adopted, selective reporting bias was not specified in four reviews. Lack of reporting of selective reporting bias seemed to be a problem with the systematic reviews that reported on a combination of VPTs ([Table 5D](#)).

DISCUSSION

Summary of evidence

This scoping review has identified outcomes of VPT reported in clinical studies and how and when these outcomes were measured. A large number of systemic reviews representing a variable number of clinical studies were eligible for inclusion. The outcomes reported in these studies fell within the five core areas defined in the taxonomy developed for health interventions (Dodd et al., 2018). There is evidence of heterogeneity in the outcome definitions and reporting across the three VPT modalities investigated. The same was also noted for the instruments and timing used for measuring the reported outcomes.

The results of the current review will be used to identify outcomes for the development of a COS for endodontic treatments (El Karim, Duncan, et al., 2021). The findings of the review demonstrated clear lack of consensus and standardization in outcomes reporting in the included studies, highlighting the need for a COS for VPT. The review has also shown that the majority of the outcomes reported are

clinician-reported outcomes with fewer reports focussing on patient-reported outcomes. For instance, tooth survival is one of the most important patient-reported outcomes (Ng et al., 2011), but was reported by few studies. In some studies where "survival" was mentioned, there was no specific reference to whether it was tooth or pulp survival. The most important patient-reported outcome is oral health-related quality of life (OHRQoL), which is a significant contributor to overall health-related quality of life (John, 2020). Surprisingly, none of the clinical studies assessed the global quality of life of patients after undergoing VPT whilst a small number did report on tooth function, tooth discolouration and treatment satisfaction postintervention.

A range of different instruments have been used for the measurement of outcomes. In most of the studies, pain experience was only obtained through patient history. Some studies used a numerical rating scale (NRS) and nonspecified questionnaires, whilst the visual analogue scale (VAS), which is more sensitive than other pain scales (Price et al., 1994), was used in few studies. This lack of standardization in reporting pain is a major problem for meta-analysis in systematic reviews reporting on endodontic pain (Vishwanathaiah et al., 2021). There are many other patient-reported outcomes such as cost effectiveness of treatment and satisfaction with treatment which are not reported in most of the studies. It is also not clear whether all outcomes are accounted for in these studies because assessment for selective reporting bias revealed many of the reviews did not report this and many others found high selective reporting bias.

The optimal time for measuring a specific outcome or end point is important for patient-reported outcomes (Browne et al., 2013), but it is evident from this review that a range of timings and follow ups have been used in research. Whilst there is no clear indication of the optimal time to measure long-term vs short-term outcomes, a recent publication has identified time points appropriate for VPT follow up (Duncan, Nagendrababu, et al., 2021).

Although a recent scoping review reported on the outcomes of endodontic treatments (Azarpazhooh et al., 2022), the review reported here is the first to adopt the health intervention taxonomy to summarize outcomes into a format compatible with COS development covering the breadth of VPTs.

Strengths of review

The review design was appropriately based on the need to conduct a preliminary assessment of the available literature and capture data from a wide range of study designs, adopting a range of methodologies. A robust, transparent

TABLE 3 Outcomes for DPC

Core area	Outcome domain	How it is measured	Number of articles reporting outcome	Min/max follow up (day; week; month; year)	
Survival	Tooth survival	Pulp	5	6 months–9 years	
		Tooth	4	0.4–22 years	
		NS	7	1–3 years	
Physiological/ Clinical changes	Pain	VAS	4	1–7 days	
		Questionnaire	1	8–30 days	
		Patient report	39	1 day–16.6 years	
		Verbal pain scale	1	1–6 weeks	
		Symptoms	Patient report	36	1 week–7.4 years
	Infection-swelling, sinus, fistula or abscess	Clinical examination	16	1 week–123 months	
	Radiographic evidence of disease progression	Radiographic assessment	44	3 weeks–22 years	
	Vitality/sensibility		Cold test only	16	1 week–22 years
			EPT only	7	
			Cold test and EPT	4	
			Cold test or EPT	3	
			Thermal unspecified and EPT	3	
			Heat and cold test and EPT	2	
			EPT &/or heat or cold	1	
			Thermal unspecified and Doppler flowmetry	1	
			Cold test and Doppler flowmetry	1	
			NS	10	
	Tenderness to percussion/palpation		TTP and palpation	8	1 week–16.6 years
			TTP only	14	
			Palpation only	1	
Mobility		Clinical examination/NS	7	3–123 months	
Periodontal probing depths/attachment loss		Clinical examination	5	1–22 years	
Continued root development or apexogenesis		Radiographic assessment	4	6 months–22 years	
Evidence of inflammatory response		Histology	28	1–300 days	
		Clinical	2		
Hard tissue/dentine barrier formation/remineralisation		Radiographic assessment	8	30 days–22 years	
		Radiographic and clinical	1		2 months
		Histological assessment	24		7 days–6 months
Integrity /quality of restoration		Histological and CBCT	2	2 weeks	
		Clinical and radiographic	4	12–123 months	
		Clinical only	5	1 week–8 months	

TABLE 3 (Continued)

Core area	Outcome domain	How it is measured	Number of articles reporting outcome	Min/max follow up (day; week; month; year)
Life impact	Presence of a functional tooth	NS	2	12–123 months
		Clinical/ radiographic assessment	18	1 week–6 years
	Aesthetics- discolouration	Clinical only	4	0.4–16.6 years
		Radiographic only	1	3 years
		NS	7	1 month–5 years
		Clinical assessment	9	1 month–7 years
		Visual comparison, photographs		
Satisfaction with treatment	History and questionnaire	1	8–30 days	
Resource use	Need for further intervention	Clinical or radiographic assessment	22	1 month–22.2 years
	Time to complete procedure	Timed by clinician	1	Baseline
	Patient comfort	Questionnaire	1	Baseline
	Emergency attendance for any treatment related to tooth	CROM	1	6–36 months
	Need for analgesic medication in postop period	History	4	1 week–1 year
Adverse effects	Calcification	Radiographic assessment	10	6–72 months
	Resorption	Radiographic assessment	10	6 month–22 years
		Histological assessment	1	7–65 days
	Pathological narrowing pulp chamber or canals/ obliteration	Radiographic assessment	3	6 months–3 years
	Secondary caries	Clinical and radiographic assessment	3	1–123 months

Abbreviations: CBCT, Cone-beam computed tomography; CROM, Clinician reported outcome measure; EPT, electric pulp test; NS, Not specified; TTP, tender to percussion; VAS, Visual analogue Scale.

and reproducible methodology was employed throughout the review process. Thorough database searches combined with the screening of the reference lists of the 36 included reviews and use of an electronic library minimized the risk of missing studies. Finally, including the full range of study designs more closely mimics clinical practice optimizing the likelihood of inclusion of any study which reported clinical and/or radiographic outcomes as a minimum.

Limitations of review

Whilst systematic reviews bring together the findings of primary research, the applicability and reliability of their conclusions is only as accurate as the included studies.

Having based our search strategy on existing systematic reviews, the accuracy of this review is reliant on the original review authors' development of a focussed and comprehensive search strategy. However, these authors did employ inclusive and appropriate search terms across the breadth of health-related databases minimizing the likelihood of missing literature. Language restrictions were applied in several of the systematic reviews, and in this review, which was limited to reviews published in English. Although often done for practical reasons, this does exclude research in this area that was published in other languages. Restricting inclusion to published reviews only also risks the introduction of publication bias. Heterogeneity in the terminology used within studies to describe seemingly similar constructs was apparent. Criteria of success of treatment for example, when reported, differed across

TABLE 4 Outcomes of pulpotomy

Core area	Outcome domain	How it is measured	Number of articles reporting outcome	Min/max follow up (day; week; month; year)			
Survival	Tooth survival	Tooth present	1	1–29 years			
		NS	4	1–2 years			
Physiological/ Clinical changes	Pain	Standardized questionnaire	1	1 day–29 years			
		VAS	5				
		Numeric rating scale	3				
		Patient report	36				
	Symptoms	Patient report	20	1 day–88 months			
	Infection- swelling, sinus, fistula or abscess	Clinical examination	35	1 day–96 months			
	Radiographic evidence of disease progression	Radiographic assessment	47	1 month–29 years			
	Vitality/sensibility		Probing dentine barrier to elicit pain	1	6 months		
			NS	9	2 days–29 years		
			Cold test only	2	6–154 months		
			Heat and cold test	1	45–60 days		
			EPT only	5	1–140 months		
			Thermal unspecified	1	3–53 months		
			Cold test or EPT	2	12–60 months		
			Cold test and EPT	2	3–24 months		
			Periapical tests- (tenderness to percussion, palpation)		Clinical examination	8	1 month–29 years
					TTP and palpation	24	
	TTP only	—					
	Palpation only	—					
	Mobility	Clinical examination	18	1–154 months			
Periodontal probing depths/ attachment loss	Clinical examination	6	2 weeks–88 months				
Continued root development or apexogenesis	Radiographic assessment	17	3–154 months				
Physiological narrowing of chamber/canals	Radiographic assessment	2	3–48 months				
Hard tissue/dentine barrier formation		Radiographic assessment	31	1 month–29 years			
		Clinical assessment- probing	5	45 days–9 months			
		Histological assessment	9	5 weeks–20 months			
		Histological and radiographic assessment	1	5–24 weeks			
Integrity /quality of restoration		Clinical assessment (2/12 use USPHS criteria)	12	1–88 months			
		Radiographic assessment	2	2 weeks–62 months			
Histological evidence of pulpal inflammation		Histopathology	5	4 weeks–6 months			

TABLE 4 (Continued)

Core area	Outcome domain	How it is measured	Number of articles reporting outcome	Min/max follow up (day; week; month; year)
Life impact	Functional tooth	NS	4	6–12 months
	Success	Clinical and radiographic assessment	23	6 weeks–73.6 months
		Radiographic and histological assessment	1	6 months
	Aesthetics- discolouration	Clinical assessment Visual comparison, photographs	5	6 months–3 years
Resource use	Need for further intervention	Clinical or radiographic assessment	14	1–96 months
	Time to complete procedure	CROM	1	Baseline
	Analgesic use in postoperative period	Patient report	7	1 day–3 months
	Cost-effectiveness	Questionnaires	1	2 years
Adverse effects	Calcification	Radiographic assessment	9	3–154 months
	Resorption	Radiographic assessment	20	1 month–29 years
	Pathological narrowing pulp chamber or canals/ obliteration	Radiographic assessment	11	5 weeks–154 months

Abbreviations: CBCT, Cone-beam computed tomography systems; CROM, Clinician reported outcome measures; EPT, Electric pulp test; NS, Not specified; TTP, tender to percussion; USPHS, United States Public Health Service; VAS, Visual analogue Scale.

studies and between mature and immature teeth. Finally, one author extracted the data which increases the risk of misclassification within the taxonomy. This was mitigated by having a second author verify the results, and repeated checks during the piloting of the extraction form and the classification process.

Future directions

This review clearly demonstrates large heterogeneity and a lack of standardization in reporting outcome of VPTs. The number of included studies in the included reviews highlights the increasing interest in VPTs. Therefore, improvements in the reporting of future clinical studies and evidence synthesis and the quality of clinical decision making, will require the development of an agreed set of patient- and clinician-reported outcomes for VPT.

CONCLUSION

The evidence in this review suggests that there is considerable heterogeneity in the outcomes reported in VPT research, with only minimal commonality across methods and timing of measurement. Moreover, aside from pain measurement, there is a general paucity of patient-reported outcomes reflecting the need to ensure the valuable addition of patient experience is not missed when designing, conducting and reporting clinical trials. Within the limitations of this review, however, there is the opportunity to seek consensus and develop a COS to improve healthcare provision in VPT and the wider discipline of endodontics.

AUTHOR CONTRIBUTIONS

All the authors have made relevant contributions to the manuscript. All the authors have read and approved the final version of the manuscript.

TABLE 5 Selective reporting bias in (A) indirect pulp capping studies; (B) direct pulp capping studies; (C) pulpotomy studies; (D) combined vital pulp treatment studies

Systematic review	Method for assessing risk of bias (RCT/CCT)	Selective reporting bias risk
(A)		
Barros 2020	Cochrane RoB and NOS	All low
da Rosa 2019	Cochrane's Collaboration	All low
Hayashi 2011		Not reported
Hoeffler 2016	Cochrane's Collaboration & NOS	1 high, 1 low
Kiranmayi 2019	Cochrane RoB	5 low, 1 not specified
Li 2018	Cochrane RoB	All low
Ricketts 2013	Cochrane RoB	All low
Ricketts 2006	Cochrane guidelines	Not reported
Schwendicke 2013	Cochrane RoB	2 Low, 9 unclear, 3 high
Schwendicke 2013	Cochrane RoB	1 Low, 3 unclear
(B)		
Cushley 2020	Cochrane RoB, Modified Downs & Black	All low for RCT
Deng 2016	Cochrane RoB	All low
Edwards 2020	Cochrane RoB	All low
Javed 2017	CASP	Not specified
Li 2015	Cochrane RoB	All low
Mahmoud 2018	Cochrane's Collaboration ^a	Not specified
Matsuura 2019	Cochrane RoB	All low
Schwendicke 2016	Cochrane RoB	1 unclear, 4 low
Zhu 2015		Not reported
(C)		
Alqaderi 2016	Cochrane RoB and NOS	All low
Chen 2019	Cochrane RoB	All low
Cushley 2019	Cochrane RoB	Unclear
Elmsmari 2019	Cochrane RoB NOS	All low
Li 2019	Cochrane RoB	All low
Taylor 2020	Cochrane RoB	All high
Zafar 2020	Cochrane RoB	All low
Zanini 2019		Not reported
(D)		
Aguilar 2011		Not reported
Bergenholtz 2013		Not reported
Broden 2016		Not reported
Didilescu 2018	Cochrane RoB	All low ^b
Fransson 2016		Not reported
Maghoub 2019	Modified Downs & Black	Not specified
Miyashita 2007		Not reported
Munir 2020	Cochrane RoB-2	All low
Paula 2018	Cochrane RoB	28 low, 1 high

Abbreviations: CASP, Critical Appraisal Skills Programme; CCT, controlled clinical trial; NOS, Newcastle Ottawa Scale; RCT, randomized controlled trials; RoB, Risk of bias.

^aNo RCT was included.

^bRoB not completed for all included RCT and CCTs.

CONFLICT OF INTEREST

The authors have stated explicitly that there are no conflicts of interest in connection with this article.






DATA AVAILABILITY STATEMENT

Data sharing not applicable to this article as no datasets were generated or analysed during the current study

ETHICAL STATEMENT

Ethical approval was not necessary as this article is secondary research involving review of the literature.

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REFERENCES

- Aguilar, P. & Linsuwanont, P. (2011) Vital pulp therapy in vital permanent teeth with cariously exposed pulp: a systematic review. *Journal of Endodontics*, 37, 581–587.
- Alqaderi, H., Lee, C.T., Borzangy, S. & Pagonis, T.C. (2016) Coronal pulpotomy for cariously exposed permanent posterior teeth with closed apices: a systematic review and meta-analysis. *Journal of Dentistry*, 44, 1–7.
- Asgary, S., Eghbal, M.J. & Bagheban, A.A. (2017) Long-term outcomes of pulpotomy in permanent teeth with irreversible pulpitis: a multi-center randomized controlled trial. *American Journal of Dentistry*, 30, 151–155.
- Azarpazhooh, A., Sgro, A., Cardoso, E., Elbarbary, M., Laghapour Lighvan, N., Badewy, R. et al. (2022) A scoping review of 4 decades of outcomes in nonsurgical root canal treatment, nonsurgical retreatment, and apexification studies-part 2: outcome measures. *Journal of Endodontics*, 48, 29–39.
- Barros, M.M.A.F., De Queiroz Rodrigues, M.I., Muniz, F.W.M.G. & Rodrigues, L.K.A. (2020) Selective, stepwise, or nonselective removal of carious tissue: which technique offers lower risk for the treatment of dental caries in permanent teeth? A systematic review and meta-analysis. *Clinical Oral Investigations*, 24, 521–532.
- Bergenholtz, G., Axelsson, S., Davidson, T., Frisk, F., Hakeberg, M., Kvist, T. et al. (2013) Treatment of pulps in teeth affected by deep caries – a systematic review of the literature. [review]. *Singapore Dental Journal*, 34, 1–12.
- Bjørndal, L., Fransson, H., Bruun, G., Markvart, M., Kjældgaard, M., Näsman, P. et al. (2017) Randomized clinical trials on deep carious lesions: 5-year follow-up. *Journal of Dental Research*, 96, 747–753.
- Boers, M., Kirwan, J.R., Wells, G., Beaton, D., Gossec, L., D'Agostino, M.A. et al. (2014) Developing core outcome measurement sets for clinical trials: OMERACT filter 2.0. *Journal of Clinical Epidemiology*, 67, 745–753.
- Brodén, J., Heimdal, H., Josephsson, O. & Fransson, H. (2016) Direct pulp capping versus root canal treatment in young permanent vital teeth with pulp exposure due to caries. A systematic review. *American Journal of Dentistry*, 29, 201–207.
- Browne, J., Bastaki, H. & Dawson, J. (2013) What is the optimal time point to assess patient-reported recovery after hip and knee replacement? A systematic review and analysis of routinely reported outcome data from the English patient-reported outcome measures programme. *Health and Quality of Life Outcomes*, 11, 128.
- Chen, Y., Chen, X., Zhang, Y., Zhou, F., Deng, J., Zou, J. et al. (2019) Materials for pulpotomy in immature permanent teeth: a systematic review and meta-analysis. *BMC Oral Health*, 19, 227.
- Clarke, M. (2008) Standardising outcomes in Paediatric clinical trials. *PLoS Medicine*, 5, e102.
- Cushley, S., Duncan, H.F., Lappin, M.J., Chua, P., Elamin, A.D., Clarke, M. et al. (2019) Pulpotomy for mature carious teeth with symptoms of irreversible pulpitis: a systematic review. *Journal of Dentistry*, 88, 103158.
- Cushley, S., Duncan, H.F., Lappin, M.J., Chua, P., Elamin, A.D., Clarke, M. et al. (2020) Efficacy of direct pulp capping for management of cariously exposed pulps in permanent teeth: a systematic review and meta-analysis. *International Endodontic Journal*, 54, 556–571.
- Da Rosa, W.L.O., Lima, V.P., Moraes, R.R., Piva, E. & Da Silva, A.F. (2019) Is a calcium hydroxide liner necessary in the treatment of deep caries lesions? A systematic review and meta-analysis. *International Endodontic Journal*, 52, 588–603.
- Deng, Y., Zhu, X., Zheng, D., Yan, P. & Jiang, H. (2016) Laser use in direct pulp capping: a meta-analysis. *Journal of the American Dental Association*, 147, 935–942.
- Didilescu, A.C., Cristache, C.M., Andrei, M., Voicu, G. & Perlea, P. (2018) The effect of dental pulp-capping materials on hard-tissue barrier formation: a systematic review and meta-analysis. *Journal of the American Dental Association*, 149, 903–917.e4.
- Dodd, S., Clarke, M., Becker, L., Mavergames, C., Fish, R. & Williamson, P.R. (2018) A taxonomy has been developed for outcomes in medical research to help improve knowledge discovery. *Journal of Clinical Epidemiology*, 96, 84–92.
- Duncan, H.F., Chong, B.S., Del Fabbro, M., El-Karim, I., Galler, K., Kirkevang, L.L. et al. (2021) The development of European society of endodontology S3-level guidelines for the treatment of pulpal and apical disease. *International Endodontic Journal*, 54, 643–645.
- Duncan, H.F., Cooper, P.R. & Smith, A.J. (2019) Dissecting dentine-pulp injury and wound healing responses: consequences for regenerative endodontics. *International Endodontic Journal*, 52, 261–266.
- Duncan, H.F., Galler, K.M., Tomson, P.L., Simon, S., El-Karim, I., Kundzina, R. et al. (2019) European Society of Endodontology position statement: management of deep caries and the exposed pulp. *International Endodontic Journal*, 52, 923–934.
- Duncan, H.F., Nagendrababu, V., El-Karim, I. & Dummer, P.M.H. (2021) Outcome measures to assess the effectiveness of endodontic treatment for pulpitis and apical periodontitis for use in the development of European society of endodontology S3-level clinical practice guidelines: a consensus-based development. *International Endodontic Journal*, 54, 2184–2194.

- Edwards, D.C., Burns, L., Witton, R. & Tredwin, C. (2020) MTA or calcium hydroxide for direct pulp capping in fully developed permanent teeth: a systematic review. *Endo-Endodontic Practice Today*, 14, 91–102.
- El Karim, I.A., Cooper, P.R., About, I., Tomson, P.L., Lundy, F.T. & Duncan, H.F. (2021) Deciphering reparative processes in the inflamed dental pulp. *Frontiers in Dental Medicine*, 2, 1–10.
- El Karim, I.A., Duncan, H.F., Cushley, S., Nagendrababu, V., Kirkevang, L.L., Kruse, C. et al. (2021) A protocol for the development of Core outcome sets for endodontic treatment modalities (COSET): an international consensus process. *Trials*, 22, 812.
- Elmsmari, F., Ruiz, X.F., Miro, Q., Feijoo-Pato, N., Duran-Sindreu, F. & Olivieri, J.G. (2019) Outcome of partial pulpotomy in cariously exposed posterior permanent teeth: a systematic review and meta-analysis. *Journal of Endodontics*, 45, 1296–1306.
- Fransson, H., Wolf, E. & Petersson, K. (2016) Formation of a hard tissue barrier after experimental pulp capping or partial pulpotomy in humans: an updated systematic review. *International Endodontic Journal*, 49, 533–542.
- Hayashi, M., Fujitani, M., Yamaki, C. & Momoi, Y. (2011) Ways of enhancing pulp preservation by stepwise excavation--a systematic review. *Journal of Dentistry*, 39, 95–107.
- Hoefler, V., Nagaoka, H. & Miller, C.S. (2016) Long-term survival and vitality outcomes of permanent teeth following deep caries treatment with step-wise and partial-caries-removal: a systematic review. *Journal of Dentistry*, 54, 25–32.
- Javed, F., Kellesarian, S.V., Abduljabbar, T., Gholamiazizi, E., Feng, C., Aldosary, K. et al. (2017) Role of laser irradiation in direct pulp capping procedures: a systematic review and meta-analysis. *Lasers in Medical Science*, 32, 439–448.
- John, M.T. (2020) Foundations of oral health-related quality of life. *Journal of Oral Rehabilitation*, 48, 355–359.
- Kiranmayi, G., Hussainy, N., Lavanya, A. & Swapna, S. (2019) Clinical performance of mineral trioxide aggregate versus calcium hydroxide as indirect pulp-capping agents in permanent teeth: a systematic review and meta-analysis. *Journal of International Oral Health*, 11, 235–243.
- Kirkham, J.J., Davis, K., Altman, D.G., Blazeby, J.M., Clarke, M., Tunis, S. et al. (2017) Core outcome set-STAndards for development: the COS-STAD recommendations. *PLoS Medicine*, 14, e1002447.
- Kirkham, J.J., Gorst, S., Altman, D.G., Blazeby, J.M., Clarke, M., Devane, D. et al. (2016) Core outcome set-STAndards for reporting: the COS-STAR statement. *PLoS Medicine*, 13, e1002148.
- Li, Z.F., Cao, L.H., Fan, M.W. & Xu, Q.G. (2015) Direct pulp capping with calcium hydroxide or mineral trioxide aggregate: a meta-analysis. *Journal of Endodontics*, 41, 1412–1417.
- Li, Y.Y., Sui, B.D., Dahl, C., Bergeron, B., Shipman, P., Niu, L. et al. (2019) Pulpotomy for carious pulp exposures in permanent teeth: a systematic review and meta-analysis. *Journal of Dentistry*, 84, 1–8.
- Li, T., Zhai, X., Song, F. & Zhu, H. (2018) Selective versus non-selective removal for dental caries: a systematic review and meta-analysis. [review]. *Acta Odontologica Scandinavica*, 76, 135–140.
- Mahgoub, N., Alqadasi, B., Aldhorae, K., Assiry, A., Altawili, Z.M. & Hong, T. (2019) Comparison between iRoot BP plus (EndoSequence root repair material) and mineral trioxide aggregate as pulp-capping agents: a systematic review. *Journal of International Society of Preventive and Community Dentistry*, 9, 542–552.
- Mahmoud, S.H., El-Negoly, S.A., Zaen El-Din, A.M., El-Zekrid, M.H., Grawish, L.M., Grawish, H.M. et al. (2018) Biodentine versus mineral trioxide aggregate as a direct pulp capping material for human mature permanent teeth – a systematic review. *Journal of Conservative Dentistry*, 21, 466–473.
- Matsuura, T., Kawata-Matsuura, V.K.S. & Yamada, S. (2019) Long-term clinical and radiographic evaluation of the effectiveness of direct pulp-capping materials. *Journal of Oral Science*, 61, 1–12.
- Miyashita, H., Worthington, H.V., Qualtrough, A. & Plasschaert, A. (2007) Pulp management for caries in adults: maintaining pulp vitality. *Cochrane Database of Systematic Reviews*, 11, CD004484.
- Munir, A., Zehnder, M. & Rechenberg, D.K. (2020) Wound lavage in studies on vital pulp therapy of permanent teeth with carious exposures: a qualitative systematic review. *Journal of Clinical Medicine*, 9, 989.
- Nair, P.N., Duncan, H.F., Pitt Ford, T.R. & Luder, H.U. (2008) Histological, ultrastructural and quantitative investigations on the response of healthy human pulps to experimental capping with mineral trioxide aggregate: a randomized controlled trial. *International Endodontic Journal*, 41, 128–150.
- Ng, Y.L., Mann, V. & Gulabivala, K. (2011) A prospective study of the factors affecting outcomes of nonsurgical root canal treatment: part 1: periapical health. *International Endodontic Journal*, 44, 583–609.
- Parirokh, M., Torabinejad, M. & Dummer, P.M.H. (2018) Mineral trioxide aggregate and other bioactive endodontic cements: an updated overview - part I: vital pulp therapy. *International Endodontic Journal*, 51, 177–205.
- Paula, A.B., Laranjo, M., Marto, C.M., Paulo, S., Abrantes, A.M., Casalta-Lopes, J. et al. (2018) Direct pulp capping: what is the MOST effective therapy?-Systematic review and META-analysis. *The Journal of Evidence-Based Dental Practice*, 18, 298–314.
- Price, D.D., Bush, F.M., Long, S. & Harkins, S.W. (1994) A comparison of pain measurement characteristics of mechanical visual analogue and simple numerical rating scales. *Pain*, 56, 217–226.
- Ricketts, D.N., Kidd, E.A., Innes, N. & Clarkson, J. (2007) Complete or ultraconservative removal of decayed tissue in unfilled teeth. *Cochrane Database of Systematic Reviews*, 3, CD003808.
- Ricketts, D., Lamont, T., Innes, N.P.T., Kidd, E. & Clarkson, J.E. (2013) Operative caries management in adults and children. *Cochrane Database of Systematic Reviews*, 3, CD003808.
- Rosenbaum, S.E., Glenton, C. & Oxman, A.D. (2010) Summary-of-findings tables in Cochrane reviews improved understanding and rapid retrieval of key information. *Journal of Clinical Epidemiology*, 63, 620–626.
- Saldanha, I.J., Lindsley, K.B., Money, S., Kimmel, H.J., Smith, B.T. & Dickersin, K. (2020) Outcome choice and definition in systematic reviews leads to few eligible studies included in meta-analyses: a case study. *BMC Medical Research Methodology*, 20, 30.
- Schwendicke, F., Brouwer, F., Schwendicke, A. & Paris, S. (2016) Different materials for direct pulp capping: systematic review and meta-analysis and trial sequential analysis. *Clinical Oral Investigations*, 20, 1121–1132.
- Schwendicke, F., Dorfer, C.E. & Paris, S. (2013) Incomplete caries removal: a systematic review and meta-analysis. *Journal of Dental Research*, 92, 306–314.
- Schwendicke, F., Meyer-Lueckel, H., Dorfer, C. & Paris, S. (2013) Failure of incompletely excavated teeth-A systematic review. *Journal of Dentistry*, 41, 569–580.

- Taha, N.A. & Abdulkhader, S.Z. (2018) Full pulpotomy with biodentine in symptomatic young permanent teeth with carious exposure. *Journal of Endodontics*, 44, 932–937.
- Taylor, G.D., Vernazza, C.R. & Abdulmohsen, B. (2020) Success of endodontic management of compromised first permanent molars in children: a systematic review. *International Journal of Paediatric Dentistry*, 30, 370–380.
- Tricco, A.C., Lillie, E., Zarin, W., O'Brien, K.K., Colquhoun, H., Levac, D. et al. (2018) PRISMA extension for scoping reviews (PRISMA-ScR): checklist and explanation. *Annals of Internal Medicine*, 169, 467–473.
- Vishwanathaiah, S., Maganur, P.C., Khanagar, S.B., Chohan, H., Testarelli, L., Mazzoni, A. et al. (2021) The incidence and intensity of Postendodontic pain and flareup in single and multiple visit root canal treatments: a systematic review and meta-analysis. *Applied Sciences*, 11, 3358.
- Williamson, P.R., Altman, D.G., Blazeby, J.M., Clarke, M., Devane, D., Gargon, E. et al. (2012) Developing core outcome sets for clinical trials: issues to consider. *Trials*, 13, 132.
- Zafar, K., Nazeer, M.R., Ghafoor, R. & Khan, F.R. (2020) Success of pulpotomy in mature permanent teeth with irreversible pulpitis: a systematic review. *Journal of Conservative Dentistry*, 23, 121–125.
- Zanini, M., Hennequin, M. & Cousson, P.Y. (2019) Which procedures and materials could be applied for full pulpotomy in permanent mature teeth? A systematic review. *Acta Odontologica Scandinavica*, 77, 541–551.
- Zhu, C.X., Ju, B. & Ni, R. (2015) Clinical outcome of direct pulp capping with MTA or calcium hydroxide: a systematic review and meta-analysis. *International Journal of Clinical and Experimental Medicine*, 8, 17055–17060.

SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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