

ZOE Paste Pulpectomies Outcome in Primary Teeth: A Systematic Review

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Objective: To perform a systematic review in which the clinical research question for primary teeth with irreversible pulpal pathosis was “how pulpectomies with zinc oxide eugenol (ZOE) paste performed compared to other materials in their clinical and radiographic outcomes after twelve months or more follow-up period. **Study design:** A literature survey of the electronic database (1950-2010) used the Medical Subject Headings and free text terms. Forty three references were retrieved and inclusion criteria were applied; 15 articles remained for full-text evaluation. From these, two were selected for data extraction regarding quality characteristics and results. **Results:** Selected studies showed moderate or high risk of bias. The overall success of pulpectomy was 80.0% (Calcicur), 60.0% (Sealapex) and varied from 85.0% to 100.0% (ZOE) and 89.0% to 100.0% (Vitapex). Solely Calcicur presented success rate significantly lower when compared to ZOE and Vitapex. These pastes lead to overfilled canals and particles of extruded ZOE were still evident even after the evaluation period. Resorption of Vitapex, Calcicur and Sealapex within the root canal was also reported. **Conclusions:** In primary teeth with irreversible pulpal changes ZOE pulpectomies yielded similar outcome than Vitapex and Sealapex, although there was no agreement with regard to filling materials' resorption.

Keywords: Evidence-based Dentistry, Deciduous tooth, primary teeth, pulpectomy, Root Canal Filling Materials, Review.

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INTRODUCTION

Pulpectomy, is a treatment modality indicated for primary teeth with irreversible pulpitis, on the basis of reported symptoms and/or clinical findings, or

non-vital radicular pulp with or without associated infection.¹ The aim of this treatment is to retain teeth with irreversible pulp pathosis in a symptom free state until they are lost naturally during the transition from primary to permanent dentition, thus avoiding the extraction. The adequate treatment of pulpally involved teeth may preserve the arch length if normal function can be restored, prevent aberrant tongue habits and speech alterations and maintain normal masticatory function as well as esthetics. The rationale includes the removal of irreversibly inflamed or necrotic radicular pulp tissue by cleaning the root canal system, followed by root canal filling with a material that can resorb at the same rate as the primary tooth and be eliminated rapidly if accidentally extruded through the apex.^{1,2}

Despite the high success rates pointed out by previous studies³⁻¹⁶ pulp therapy of primary teeth still remain controversial¹⁷ for a number of reasons, such as root canal morphology, inherent physiological root resorption, the close proximity of the permanent successor tooth, complex diagnosis due to patients' immaturity to adequately relate their symptoms and the difficulty of obtaining good radiographic views of primary tooth apices, behavior management of pediatric patients, poor parents compliance and especially, the choice of technique and filling material. Many studies³⁻¹⁶ have been conducted to evaluate and compare the success rate of different root filling materials. To the present time, zinc oxide and eugenol paste, calcium hydroxide and

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iodoform paste are the most commonly used material.¹⁸ Considering the lack of evidence-based studies about root canal treatment, since the only systemic review found in the consulted literature about pulp therapy for primary teeth stated that there is no reliable evidence supporting the superiority of one type of treatment for pulp involved primary molars,¹⁹ the aim of this study was to use the principles of evidence-based dentistry to examine the relative efficacy of filling materials for pulpectomy in primary teeth. The clinical research question was how primary teeth with irreversible pulpal pathosis treated with zinc oxide eugenol paste compare to those treated with other materials in their clinical and radiographic outcomes after twelve or more months of follow-up.

METHODS

Search Strategy

The dental literature on the filling materials for root canal treatment was reviewed. The subject search used a combination of controlled vocabulary (Medical Subject Headings – MeSH) and free text terms as shown in Table 1. The following databases were used in order to conduct computerized searches: PubMed (from 1966 to week one of April 2010), OVID Medline (from 1950 to April week one of 2010) and Cochrane Library (from 1965 to April 2010). To identify studies included or considered for this review, detailed search strategies were developed for each database searched. This was based on the search strategy developed for OVID Medline, but revised appropriately for each database. In addition to electronic database searching, hand-search of

relevant journals was also performed. Language was restricted to English.

Selection Criteria

Eligibility of the studies was determined by reading the title and abstracts of the articles retrieved from each database and selecting for inclusion only those papers fulfilling the following criteria: prospective randomized clinical trials; root canal treatment and evaluation performed by clinical and radiographic criteria during at least twelve months. Studies that evaluated partial pulpectomy were excluded. All the abstracts that appeared to meet the inclusion criteria were selected and collected. Two researchers (RB and MS) performed the selection process independently, and afterwards the results were compared. In cases of discrepancies, a consensus decision was taken with a third evaluator (LM). Moreover, the reference lists of the selected articles were also searched manually for additional relevant publications that may have been missed in the database searches.

The same investigators independently evaluated the complete manuscripts of the selected abstracts. A consensus was reached with regard to which articles fulfilled the inclusion criteria, and these were finally included in the systematic review. No restrictions were placed on sample size, but case series without controls, retrospective studies, case reports, *in vitro* trials, text books, letters and review articles were not included.

Data Collection

Data were extracted on the following items: sample size,

Table 1. Sensitivity of Electronic Databases Searched

Database	Search strategy	Results	Abstracts selected	Full text selected	N° of articles selected and not included in PubM	Reasons of abstracts or articles rejection			
						Not related to comparisons between ZOE and other filling materials	Inadequate methodology	Follow-up less than 12 months	Absence of a control group
PubMed	((“root canal filling materials” AND “pulpectomy”) AND (“child” or “adolescent”) NOT (“pulpotomy”) NOT (“permanent teeth”))	27 (4, 7, 9, 10, 12-15, 21-31, 36-40, 43-45)	10 (4, 7, 9, 13-15, 39, 43-45)	02 (14, 15)	NA	11 (21-31)	10 (4, 7, 9, 10, 12, 36-40)	01 (45)	03 (13, 43, 44)
Ovid Medline	*pulpectomy AND **root canal filling materials” and *tooth, deciduous	09 (10, 12, 13, 15, 35, 38, 41, 43, 44)	05 (12, 13, 15, 43, 44)	01 (15)	0	0	05 (10, 12, 35, 38, 41)	0	03 (13, 43, 44)
Cochrane Library	“tooth, deciduous” and “pulpectomy” and “root canal filling materials” in The Cochrane Central Register of Controlled Trials	07 (15, 24, 32-34, 42, 46)	03 (15, 42, 46)	01 (15)	0	04 (24, 32-34)	01 (42)	01 (46)	0
Reference lists and hand-search	—	03 (16, 47, 48)	03 (16, 47, 48)	0	0	0	0	03 (16, 47, 48)	0

NA = not applicable

number of patients and age, inclusion and exclusion criteria, procedures and materials used for root canal treatment, type of teeth treated (anterior or posterior), pre-treatment pulp condition (necrosis or vital pulp), number of dropouts and withdrawals, overall success, statistical results and authors' conclusions. The data were extracted from each article by the same evaluators that had selected the articles. Inter-examiner conflicts were resolved by discussing each article to reach a consensus. In cases where relevant data were necessary, the authors, if available, were contacted to obtain the required extra information.

Quality assessment and risk of bias

Quality assessment was done independently and in duplicate by two reviewers (RB and MS), as part of the data collection process. Non agreement results were solved by consensus with the third evaluator (LM). The studies were classified according to slightly modified criteria proposed by Jadad *et al.*²⁰ The criteria were: the adequate definition of exclusion and inclusion criteria, the description of randomization method, allocation concealment and the blinding method of investigators or clinicians and other people involved in the clinical trial, the report withdrawals and drop outs during the period of follow-up with and the adequate definition of success and failure criteria. The quality assessment was made by answering yes, no or undetermined to each criterion previously described. When the answer was "yes" for all questions the study was classified as A (low risk of bias); when the answer was "no" for one or two question, or when there was "undetermined" answer a score B (mod-

erate risk of bias) was applied, and; when the answer was "no" for three or more questions it obtained a C (high risk of bias which seriously weakens confidence in the results). Again, this process was performed independently by the two researches previously cited and crossed to verify agreement.

RESULTS

The initial search identified 43 references in the electronic databases and many related citations were found in more than one search engine. Comparing the results between databases, PubMed obtained the greatest diversity of abstracts (n=27), but did not include the entire set of references retrieved in other databases. Seven references were not included in the retrieved citations from Pubmed, 5 from Cochrane Library and 2 from Ovid Medline. The total of different references found was 34 and additional 3 references were identified by hand searching, totalizing 37 references for evaluation. After collecting from different databases all the abstracts which appeared to fulfil the selection criteria (n=15), and verifying their eligibility by reading the full articles, only two well-designed studies remained (Figure 1). This represents 5.7% of total number of the retrieved references (n=37). The majority of articles were rejected either because they were not comparisons between ZOE and others filling materials,²¹⁻³⁴ the methodology used was not adequate (case reports, retrospective studies, pulpectomy outcome evaluated only by radiographic criteria, in vitro trials, and review articles),^{4,7,9,10,12,35-42} or due to lack of a control group to rule out clinical and radiographic findings^{13,43,44} as presented in Table 1. Another five studies^{16,45-48} were

Table 2. Description of sample (size, age, treated teeth and initial pulp condition) and sample collection

Author	No. of teeth	Age (years)	Follow-up (months)	Treated teeth	Initial pulp condition	Inclusion criteria	Exclusion criteria	Randomization Method	
Ozalp, Saroglu and Sonmez ¹⁵	ZOE: 20						<ul style="list-style-type: none"> Abnormal mobility Evidence of abscess or fistula Internal or pathological external root resorption Unhealthy patients 	• «NR	
	Vitapex: 20								
	Sealapex: 20	4-9	18	Posterior	Pulp degeneration changes	Spontaneous pain			
	CalciCur: 20								
Trairatvorakul and Chunlasikawaiwan ¹⁴	ZOE: 27					<ul style="list-style-type: none"> Presence of deep caries lesion with pulp exposure, where the bleeding could not be stopped following removal of the coronal pulp tissue Spontaneous pain Chronic apical abscess Abnormal mobility Radiographic pulp exposure in the crown Root and supportative structures with discontinuity of lamina dura or furcation involvement. 	<ul style="list-style-type: none"> Obliteration of root canal Internal resorption Physiologic root resorption more than a third of its length Unhealthy patients 	• Block randomization	
		3-7	12	Posterior (mandibular)	Infected				
	Vitapex: 27								

NR = Not reported

Table 3. Clinical procedures for root canal treatment, clinical and radiographic criteria for treatment assessment and drop-outs

Author	Irrigants	Files	Intracanal dressing	Interval evaluation	Clinical criteria	Radiographic criteria	Dropouts and withdrawals
Ozalp, Saroglu and Sonmez ¹⁵	5.0% sodium hypochlorite and 0.5% metronidazole solution (final irrigant)	H-files	Not applicable	2 months	<ul style="list-style-type: none"> Absence of: pain, gingival swelling, tenderness to percussion, abnormal mobility, fistula, or abscess 	<ul style="list-style-type: none"> Presence of furcation radiolucency Presence of periapical radiolucency Continuity of lamina dura Presence of pathologic root resorption 	Not reported
Trairatvorakul and Chunlasikaiwan ¹⁴	2.5% sodium hypochlorite	K-files	Not applicable	6 months	<ul style="list-style-type: none"> healthy tissue (absence of swelling, redness or sinus tract) Absence of: pain, or abnormal mobility, 	<ul style="list-style-type: none"> Continuity of lamina dura Reduction in the size of any pathologic inter-radicular and/or periapical radiolucencies Evidence of bony regeneration 	Not occurred

excluded because they had an evaluation period of less than twelve months (Table 1). A summary of the selected full articles is presented in Tables 2 and 3. The root canal filling materials evaluated in these articles were zinc oxide and eugenol (ZOE) paste,^{14,15} a premixed calcium hydroxide and iodoform paste (Vitapex),^{14,15} and two calcium hydroxide pastes (Calcicur and Sealapex).¹⁵

The two studies reported that the clinical signs and symptoms as pain, fistula and intraoral and extra-oral swelling had disappeared completely in all cases and clinical failures were just related to abnormal tooth mobility (Table 4).

All failed teeth were the once that had the most severe radiographic pathology. Ozalp, Saroglu and Sonmez¹⁵ described that two teeth (2/20) in the ZOE group showed a discrete increase in bone radiolucency at the 6-month follow-up, however because these teeth were clinically asymptomatic and the size of radiolucencies did not increase, these teeth continued under follow-up and the treatment was considered successful at 18 months. Conversely, at 6 months, two teeth in both the Calcicur (2/20) and the Sealapex (2/20) groups exhibited resorption of the material and pathological root resorption or periapical pathosis were considered failures and had to be extracted. In the Calcicur group, another two teeth (2/20) showed an increase in the size of radiolucency and mobility and were also extracted.¹⁵ Furthermore, Trairatvorakul and Chun-

lasikaiwan¹⁴ demonstrated that Vitapex appeared to resolve furcation pathology at a faster rate than zinc oxide-eugenol. The difference in success rates between materials at 6 months was statistically significant. Although, at 12 months both materials yielded similar results (Table 4).

When the the clinical and radiographic success taken together, it varies from 85.0%¹⁴ to 100.0%¹⁵ to ZOE group and from 89.0%¹⁴ to 100.0%¹⁵ in the Vitapex group. The overall success rate of ZOE and Vitapex groups was not statistically different on booth studies (Table 4). Solely Ozalp, Saroglu and Sonmez¹⁵ compared Calcicur and Sealapex that exhibited an overall success rate of 80.0% and 60.0%, respectively. Although these materials presented lower success rate when compared to ZOE and Vitapex groups its difference was statistically significant just between Calcicur and them.

Overfilled material was found postoperatively in ZOE and Vitapex group, although at the end of follow-up all cases in the Vitapex group showed complete resorption while only few teeth in the ZOE group exhibited the same result (Table 4). All teeth in the Calcicur and Sealapex groups were considered as adequately filled, and overfilled material resorptions problems were not found. Otherwise the resorption of Vitapex,^{14,15} Calcicur¹⁵ and Sealapex¹⁵ within the root canal was also reported (Table 4) and some teeth were considered to retreatment because of it.¹⁵ Deflection of the permanent

Table 4. Summary of the results drawn from selected studies at the 12 month follow up

Author	Material	Failure		Overall success		Overfilling material		Resorption of material within the canal (n)	Deflection of the permanent bud of normal path (n)
		Clinical (n)	Radiographic (n)	Rate (%)	Statistic results (test)	Absolute frequency (n)	Resorption of overfilled material (n)		
Ozalp, Saroglu and Sonmez ¹⁵	ZOE	0	0	100.0%	*p<0.05 (Z-test)	6	2	1	NR
	Vitapex	0	0	100.00%		8	7	6	NR
	Sealapex	2	2	90.0%		0	0	2	NR
	Calcicur	4	4	80.0%		0	0	2	NR
Trairatvorakul and Chunlasikaiwan ¹⁴	ZOE	2	4	85.0%	p=1 (Fisher s exact test)	10	2	0	4
	Vitapex	1	3	89.0%		NR	15	19	2

NR = not reported

* Statistical difference between Calcicur and ZOE and Vitapex groups

Table 5. Determination of the quality of the studies.

Study	Exclusion and inclusion criteria defined	Description of randomization method	Description of allocation concealment	Description of evaluator blinding method	Report of withdrawals and drop outs	Success and failure criteria defined	Risk of bias*
Ozalp, Saroglu and Sonmez ¹⁵	Yes	No	No	No	No	Yes	C
Trairatvorakul and Chunlasikaiwan ¹⁴	Yes	Yes	No	Yes	Yes	Yes	B

*A – low risk of bias, when the answer was “yes” for all questions; B – moderated risk of bias, when the answer was “no” for one or two question, or when one answer was undetermined; C – high risk of bias, when the answer was “no” for three or more questions.

successor tooth bud from the normal path of eruption was diagnosed both in ZOE and Vitapex treated teeth (Table 4).

In both studies some patients had more than one tooth treated. Regarding the quality assessment articles were classified as moderate¹⁴ or high¹⁵ risk of bias (Table 5). No meta-analysis could be undertaken due to the limited number of studies included. Subgroup and sensitivity analyses were also inappropriate.

DISCUSSION

Treatment success evaluation was undertaken in the studies by means of similar clinical and radiographic criteria and regular interval appointments. These characteristics are important, as they provide similarity between treatments studied. However, it is clear that there were differences in some aspects of clinical procedures, such as the type of treated teeth, files and irrigants used and initial pulp condition. According to the criteria used for the quality assessment of the studies, none was classified as A category. The selected studies showed moderate or high risk of bias as they failed to record some information considered essential for complete randomized clinical trial reports. In some cases this was simply due to incomplete reporting. Although the randomization method was adequate in the Trairatvorakul and Chunlasikaiwan¹⁴ study, attempts to conceal allocation were not reported. These aspects of trial designing and reporting need to be improved, since it has been shown that randomized controlled trials (RCT), in which randomization and allocation concealment procedures were inadequately conducted, tended to overestimate treatment effects.^{20,49} Therefore, in order for obtaining scientifically based evidence in clinical practice RCT should strictly follow the Consort Statement,⁵⁰ once it will be essential to judge the reliability or relevance of the findings. Regarding the method of blinding of assessors, it is recognized that it is not always possible to blind outcome assessors in RCT examining the effectiveness of pulp treatment, due to the differences between materials applied in the studies. However, the clinical assessments should be carried out by calibrated examiners who were not involved in the treatment procedures. Ideally they should be blinded to the treatment conditions.⁵¹ Blinding evaluation is necessary, because open outcome assessment has also been shown to overestimate treatment effects.^{20,49} Another studies limitation was due to clustering of teeth within individuals as one patient would have more than one tooth pulpectomized.

The literature differs about the number of appointments to perform the root canal treatment and some authors agree that one visit pulpectomy is more efficient for the professional as well as the patient.² Ozalp, Saroglu and Sonmez¹⁵ and Trairatvorakul and Chunlasikaiwan¹⁴ performed one-visit pulpectomy. Considering the treatment success described in the two studies one visit seems to be enough, even though when treating necrotic pulps like in Trairatvorakul and Chunlasikaiwan¹⁴ study. Although, it should be stressed that taking into account the age of the patients, a single visit may not be adequate for uncooperative patients. A two-visit procedure was necessary for some of the patients presenting behaviour management problems in the Ozalp, Saroglu and Sonmez¹⁵ trial.

Furthermore, considering the inclusion criteria, Ozalp, Saroglu and Sonmez¹⁵ selected primary molars, whereas Trairatvorakul and Chunlasikaiwan¹⁴ just included mandibular molars. The complex morphology of root canals in posterior teeth is well known, and therefore, root canal treatment of posterior teeth was not recommended for a number of years, as it presented the difficulties of adequate root canal cleaning and shaping.⁵²⁻⁵⁵ The present results confirmed that molars primary teeth pulpectomy are so effective as in anterior teeth. This procedure may be considered as a suitable alternative to extraction of pulpless molar tooth.

As regards root filling materials, ZOE was the first material used for filling root canals⁵⁶ and the success rates reported in literature varies from 53.0% to 100.0%.^{3,4,13-15,38,57} Iodoform based pastes were then proposed as a filler, due to their disinfectant and resorbability properties. The success rate with iodoform based pastes varies between 65.0% and 100.0%.^{38,55,58,59} and Calcium hydroxide from 86.7% to 100.0%.^{7,11,12,45,46} Other studies pointed out good results after using a combination of pure iodoform and calcium hydroxide powder.^{14-16,60} Although many clinical trials have been published about the subject, few studies with adequate methodology are available for comparing the results between different pastes. The articles selected for this review presented different results by comparing the success rate between studied pastes. In both, ZOE and Vitapex did not present statistical significant difference, which indicates that based on clinical and radiographic data, similar success rates for primary teeth can be expected with either ZOE or a calcium hydroxide and iodoform paste. However, the sample size of these studies were small, especially the second¹⁴ selected study. The difference between materials was not

statistically significant but is not clear if the treatments did not differ or it was due to insufficient power to detect the difference. Also, both studies do not meet the criteria to qualify for low risk of bias and one of them was limited by an evaluation period of a maximum of 12 months, which is considered a short term.⁵¹ Further long-term high quality randomized and controlled clinical trials are required to confirm the present findings with strong evidence.

It is important to stress out that the two studies reported that same cases were classified as requiring further observation at a first evaluation and later judged as radiographically successful. Even though the American Academy of Pediatric Dentistry's guideline on pulp therapy states that the radiograph infectious process of pulpectomized teeth should resolve in 6 months, the found results agreed with previous studies^{6,45} that, in some cases, more definitive assessments could be made at longer follow-up times. It is indicative of the progressive improvement in the treated teeth and that different results for the evaluated materials may be observed, according the evaluation period, as some materials appeared to yield faster resolutions than others. This observation emphasizes the statement that short periods of evaluation are not indicated to compare filling materials and the exclusion of short-term follow-ups in systematic review of this matter. Also, early evaluations were not able to detect evidence of deviation from the normal path of eruption, an important criterion for a root filling material selection.

Long term evaluation on the retention rate of ZOE filler after primary teeth as its relationship to exfoliation and succedaneous dentition are available,^{4,9,13,61} with many important findings to clinical practice. Although, these studies with evaluation period of over 24 months are based on retrospective evaluations that presents some disadvantages as the reliance on patient records, lack of randomization and their accuracy.⁶² Some systematic reviews are performed with retrospective studies, but considering the possibility of high biased interpretation of such data, the present review excluded studies designed as retrospective evaluation.

The oral health policies and clinical guidelines of the American Academy of Pediatric Dentistry stated several objectives of pulpectomy procedures in primary teeth, and the first one is that there should be radiographic evidence of successful filling without gross overextension or underfilling.¹ The selected studies^{14,15} reported that particles of extruded ZOE were still evident even the evaluation period. Regarding the retention of ZOE after pulpectomy, Sadrian and Coll¹³ demonstrated that none of the retained filler particles caused any observable pathology and were also not related to treatment failure. Therefore, as Vitapex can be rapidly eliminated from periapical tissues and does not set to a hard mass that may contribute to the deflection of permanent successors, it has been considered a suitable alternative to ZOE as primary tooth root filling.¹⁶ Besides, Vitapex presents two components, calcium hydroxide and iodoform, which are responsible for the antibacterial properties of its material, although its cytotoxic effects have not been established.³ Otherwise, Ozalp, Saroglu and Sonmez¹⁵ reported

the necessity of re-treatment of some teeth because of resorption of the material in the root canal in all three groups that used iodoform and/or calcium hydroxide pastes (Vitapex, Calciur and Sealapex), and Trairatvorakul and Chunlasikawan¹⁴ diagnosed deflection in the successor permanent from the normal path of eruption in both groups. Considering the differences of results regarding materials ability to resorb, long-term randomized and controlled clinical trials should be undertaken to ascertain the impact of the early resorption of Vitapex and on the eruption of succedaneous dentition.

CONCLUSIONS

Based on scientific information available at present, this evidence based assessment concluded that in primary teeth with irreversible pulp changes, pulpectomy is effective, and ZOE pulpectomies yielded similar outcome than Vitapex and Sealapex. There was no agreement with regard to resorption of the filling materials. Further long-term randomized controlled trials should address the effectiveness of currently used materials for pulpectomy in primary teeth.

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