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Comparison of Endoflas and Zinc Oxide Eugenol as Root Canal Filling Materials for Pulpectomy in Deciduous Teeth: a Systematic Review and Meta-Analysis

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Riham Awad ^{a,b,c,d,1}, Mazen Musa ^{e,f,g,1}, Mohamed Elhoumed ^{h,i}, Fei Liu ^{a,b,c}, Qingyu Guo ^{a,b,c,*}

^a Key Laboratory of Shaanxi Province for Craniofacial Precision Medicine Research, College of Stomatology, Xi'an Jiaotong University, Xi'an 710061, China

^b Laboratory Center of Stomatology, College of Stomatology, Xi'an Jiaotong University, Xi'an 710061, China

^c Department of Pediatric Dentistry, College of Stomatology, Xi'an Jiaotong University, Xi'an 710061, China

^d Department of Pediatric Dentistry, Faculty of Dentistry, International University of Africa, 11111 Khartoum, Sudan

^e Department of Stomatology, First Affiliated Hospital of Xi'an Jiaotong University, Xi'an 710061, China

^f Department of Orthodontics, College of Stomatology, Xi'an Jiaotong University, Xi'an 710061, China

^g Department of Orthodontics, Al Tegana Dental Teaching Hospital, Faculty of Dentistry, University of Since and Technology Omdurman, 11111 Khartoum, Sudan

^h Department of Epidemiology and Biostatistics, School of Public Health, Xi'an Jiaotong University, Xi'an 710061, China

ⁱ National Institute of Public Health Research (INRSP), BP. 695, Nouakchott, Mauritania

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ABSTRACT

Objectives: To evaluate and compare the effectiveness of Endoflas and Zinc Oxide Eugenol (ZOE) as root canal filling materials (RCFMs) for the pulpectomy of deciduous teeth by analyzing multiple clinical and radiographic success and failure follow-ups in previously published studies. *Data:* All clinical studies that investigated the pulpectomy of the deciduous teeth of children aged 3–9 years.

Sources: The databases used for source identification included MEDLINE (via PubMed), Scopus, Web of Science, and the Cochrane Library. No limitations were imposed on the publication year or language. The selection of studies and extraction of relevant study characteristics were conducted from December 26, 2021, to September 7, 2023. Additionally, the risk of bias (RoB) in the included studies was evaluated by using a RoB instrument (RoB 2). Eligible studies were then combined, and a random-effects model was applied by using the maximum like-lihood estimations of log risk ratios and their corresponding 95% confidence intervals.

Study selection: Of the 3913 records found in the abovementioned databases, nine were eligible for systematic review and eight were eligible for *meta*-analysis. The studies included 628 pulpectomies of deciduous molar teeth in children. The overall results showed that compared with Endoflas, ZOE was associated with a higher risk ratio for clinical evaluation (LOG[RR] = 0.06, CI 0.03–0.09, p-value 0.001) and radiographic evaluation (LOG[RR] = 0.68, CI 0.35–1.00, *p*-value 0.001). This association was highly significant at 6- and 9-month follow-ups. *Conclusion:* Compared with ZOE, Endoflas was associated with a lower risk of the clinical and radiographic failure of deciduous teeth pulpectomy and a 6%–6.8% higher risk ratio, especially at 6- and 9-month follow-ups. *Clinical significance:* This study suggests the superiority of Endoflas over ZOE as an RCFM for deciduous teeth.

1. Introduction

Globally, dental caries are a public concern; they primarily affect children and exert negative effects on their oral and overall health (Najjar and Alamoudi, 2019). Deciduous teeth serve as a crucial space maintainer among deciduous and mixed dentition. Additionally, they contribute to optimal mastication and support jaw growth. Therefore, preserving deciduous teeth until their natural exfoliation is essential for the appropriate development of permanent dentition (Brothwell, 1997).

The characteristics of ideal root canal filling materials (RCFMs) for deciduous teeth include radiopacity, antibacterial properties, absence of tooth discoloration, nontoxicity to the periapical area, and identical to

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Abbreviations: log (RR), Log risk ratio; CI, confidence interval; ZOE, Zinc Oxide Eugenol.

^{*} Corresponding author at: Department of Pediatric Dentistry, College of Stomatology, Xi'an Jiaotong University, Xi'an 710004, China.

E-mail addresses: guoqinyu@mail.xjtu.edu.cn, guoqinyu.xjtu.edu.cn@outlook.com (Q. Guo).

¹ Riham Awad and Mazen Musa should be considered joint first authors.

the tooth root in terms of resorption. Furthermore, these materials should efficiently fill canals and adhere to canal walls without shrinking as well as be rapidly resorbable and easily removable if needed if accidentally extruded beyond the apex. (Garcia-Godoy, 1987; Gupta and Das, 2011; Rifkin, 1980).

Zinc Oxide–Eugenol (ZOE) has been widely applied as an RCFM for a long time (Barja-Fidalgo et al., 2011; Primosch et al., 1997). Although ZOE has some limitations, such as not meeting all the criteria for an ideal RCFM (Rewal et al., 2014) due to its lack of antibacterial properties (Tchaou et al., 1996), it exhibits a slower resorption rate than deciduous tooth roots (Mortazavi and Mesbahi, 2004; Ozalp et al., 2005). ZOE has shown favorable outcomes over other filling materials for deciduous teeth. Its overall success rate based on clinical and radiographic evaluation (C&RE) in the 10–16-month follow-up period was 78.5 %. Furthermore, its overall success rate during the 12–48-month follow-up period and beyond was 65 % (Holan and Fuks, 1993; Mortazavi and Mesbahi, 2004).

While Endoflas contains components similar to those found in Vitapex (40 % iodoform and silicone oil), ZOE paste is prepared by mixing a liquid consisting of eugenol and paramonochlorophenol with a powder containing tri-iodomethane and iodine dibutilorthocresol (40.6 %), ZO (56.5 %), calcium hydroxide (1.07 %), and barium sulfate (1.63 %).

Hydrophilic materials provide a good seal by firmly sticking to the surface of root canals (RCs) and exhibit a wide range of antimicrobial action. The absorption rate of Endoflas is the closest to that of deciduous teeth (Subramaniam and Gilhotra, 2011), and Endoflas resorbs only extraradicularly, not intraradicularly. Tooth discoloration is the drawback of this material. Endoflas has a clinical success of 96.30 %, radio-graphical success of 88.90 % at 12 months (Goel et al., 2018), and C&RE success of 100 % at 9 months (Rewal et al., 2014).

Given the absence of an ideal RCFM for obturating RCs in the pulpectomy of deciduous teeth, utilizing the currently available clinical studies that compare the new emerging material Endoflas with the standard gold material ZOE is interesting.

We used ZOE as the control group because most studies compared new materials with ZOE. While ZOE demonstrates a remarakable rate of success, it does not fully meet all the requirements for an ideal RCFM.

A previous study compared Endoflas and ZOE as RCFMs and found no statistically significant difference between the two materials (Coll et al., 2020).

We propose the following null hypothesis: the use of Endoflas and ZOE as RCFMs in deciduous teeth lacks a significant difference.

The aim of this study is to summarize the existing evidence regarding the longitudinal evaluation of the C&RE success of Endoflas compared with that of ZOE for the pulpectomy of deciduous teeth. This aim was achieved through the implementation of a systematic review and *meta*analysis.

2. Materials and methods

2.1. Protocol and registration

The standards of Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) were followed in this study (Page et al., 2021). The protocol for this review was registered in the International Prospective Register of Systematic Reviews database and assigned the registration number CRD42021279593.

2.2. Review question

This review' main focus is the following research question: Is Endoflas more effective than conventional ZOE as an RCFM for deciduous teeth pulpectomy?

The following Population, Intervention, Control, and Outcome (PICO) scheme was used to determine the inclusion criteria for all the included papers that elaborated on the above research question: Population- Children with teeth needing pulpectomy. Intervention-Endoflas. Control- Conventional ZOE. Outcomes- C&R success rate.

2.3. Eligibility criteria

Clinical studies involving deciduous teeth and comparing Endoflas with ZOE were identified on the basis of their clinical and radiographic success.

Randomized clinical trials comparing the success of Endoflas as an RCFM with that of ZOE were included in consideration of all per operative interventions under the same condition for both groups. A trial must follow a specific clinical and radiographic success protocol to be considered related to postoperative care. Randomized clinical trials of children (aged 3–9 years) undergoing the pulpectomy of deciduous teeth and had completed at least 6 months of follow-up were classified as eligible.

The exclusion criteria encompassed the following categories: case reports; reviews; and cross-sectional, retrospective, in vitro, and animal studies. Additionally, works involving the pulpectomy of permanent teeth, deciduous teeth without succedaneous teeth, and traumatic teeth; laboratory studies; and studies specifically focusing on special needs cases were excluded.

2.4. Search strategy

The databases used in this study included MEDLINE (accessible via PubMed), Scopus, Web of Science, and the Cochrane Library (CEN-TRAL). A snowball search was also conducted to find additional studies by examining the bibliographies of publications eligible for full-text review on December 26, 2021. Ultimately, on September 7, 2023, the database search was upgraded, and the snowball search was used with the same search method. The selected studies were not limited in terms of language or year of publication. Relevant search terms were generated by examining these records' titles, abstracts, and topic indices. A draft search strategy was created by using these terms, and further search terms were determined on the basis of the strategy's results. Search terms were verified by examining if they could find the five previously determined related studies. The search strategies are described in Supplementary Information 1.

Electronic database searches were supplemented with manual searches of pediatric dentistry and endodontics journals related to the topic of interest, forwarding citation tracking via Google Scholar gray literature (via opengrey.eu).

Searches were customized to each database's syntax standards by employing a combination of MeSH keywords, synonyms, and free terms. Methods for searching were developed to find every study comparing the therapeutic outcomes (clinical and radiographic) of the pulpectomy of deciduous teeth using Endoflas with those of the pulpectomy of deciduous teeth using ZOE.

Before reaching an agreement on records and discussing discrepancies, two authors evaluated the titles and abstracts of the first 100 publications separately. Subsequently, the authors individually evaluated the titles and abstracts of all articles. In a disagreement, a discussion was held to determine which papers should be screened in full text. A third author was consulted to make the final judgment if necessary. Duplicate studies were pulled out after titles were checked for uniqueness. Next, two authors independently screened full-text articles to determine their eligibility for inclusion. In cases of disagreement, consensus was reached through discussion, and if needed, the third author was consulted.

2.5. Data extraction

Data were retrieved from each trial by using a data extraction sheet and then collected from the selected studies. The reviewers utilized a standardized predetermined form to enable straightforward extraction. The authors independently extracted data and supervised a third author to resolve discrepancies through consensus. When any of the above information was unclear, the study's author was contacted to provide further details.

Data were collected as follows: author name; year of publication; study setting, including study design; type of teeth; number of teeth /number of children; sample size; restoration/stainless steel crown SSC; number of visits; type of irrigation; follow-ups/months; ZOE; and Endoflas clinical and radiographic evaluation.

2.6. Risk of bias assessment of studies

Two authors used the risk of bias (RoB) 2 instrument to analyze the included studies independently. The RoB in the included studies was evaluated independently by two authors using the RoB 2 instrument (Sterne et al., 2019). For the evaluation of RoB in each included trial, five domains were assessed and assigned ratings: (D1) "randomization process," (D2) "deviations from intended interventions," (D3) "missing outcome data," (D4) "measurement of the outcomes," and (D5) "selection of the reported results".

Each domain was labeled as having a "low risk," "some concerns," or "high risk" of bias. When one domain was found to have some concerns of bias and when the study's authors provided no response, this situation was addressed in RoB assessment. If one or more domains were identified as having a high risk of bias, the study was classified as having a high level of bias.

2.7. Statistical analysis

Eligible studies were combined, and a random-effects model was fitted by using the maximum likelihood estimations of log risk ratios and their 95 % confidence intervals. Pooled data were analyzed in subgroups by study and follow-up. All of the study data were plotted in the form of L'Abbé plots to explore effect size and heterogeneity further. Funnel plots were also utilized to analyze minor-study effects and publication bias in *meta*-analyses, which included eight trials of varying sizes.

The statistical software Stata was utilized for data analysis and presentation purposes (SE 17.0, StataCorp, College Station, TX).

2.8. Certainty of the evidence assessment

Two authors independently assessed the certainty of the evidence of *meta*-analysis estimation through the Grading Recommendations, Assessments, Development, and Evaluations approach (GRADE) with the software GRADEpro GDT (GUYATT ET AL., 2008). The certainty of the evidence was rated accordingly as "high," "moderate," "low," or "very low".

3. Results

3.1. Study selection

A total of 3913 records were screened for inclusion, and 3835 records were retained after removing duplicates and managed systematically by using Mendeley Desktop 1.19.4. Another 3803 studies were excluded after being scanned on the basis of their titles and abstracts because they did not fit the inclusion criteria. Moreover, 30 articles qualified for full-text article analysis. Twenty-one studies were excluded as follows: studies comparing ZOE with other materials, three studies without a comparison group, one study comparing Endoflas with other materials, two studies without full texts, and one article that was found to be not a journal article after full-text analysis. Nine studies (Al-Ostwani et al., 2016; Goel et al., 2018; Gupta et al., 2019; Kiran N.K, 2020; Pandranki et al., 2018; Ramar and Mungara, 2010; Rewal et al., 2014; Saxena et al., 2017; Subramaniam and Gilhotra, 2011) were included for qualitative and quantitative analyses. The PRISMA flow diagram depicts the search

process, and the results are presented in Fig. 1.

3.2. Study characteristics

The selected nine hospital-based clinical trials included 628 pulpectomized primary molars (PMs) of children aged 3–9 years. Three studies had follow-up periods of 3, 6, and 9 months, (Ramar and Mungara, 2010; Rewal et al., 2014; Saxena et al., 2017); two had follow-up periods of 3 and 6 months (Gupta et al., 2019; Kiran N.K, 2020); one had follow-up periods of 6 and 12 months (Al-Ostwani et al., 2016); one had follow-up periods of 3, 6, 9, and 12 months (Goel et al., 2018); one had follow-up periods of 3, 6, 12, and 18 months (Subramaniam and Gilhotra, 2011); and one had follow-up periods of 3, 6, 9, 12, and 24 months (Pandranki et al., 2018).

Out of these studies, five specifically focused on PMs (Al-Ostwani et al., 2016; Goel et al., 2018; Gupta et al., 2019; Rewal et al., 2014; Saxena et al., 2017), and two included mandibular PMs (Kiran N.K, 2020; Ramar and Mungara, 2010). One study included maxillary and mandibular first and second PMs (Subramaniam and Gilhotra, 2011), and one did not mention the type of primary teeth (Pandranki et al., 2018).

The systematic review presented in this article provides information regarding the characteristics of the included clinical trials. These characteristics included details about their follow-up periods and rates of clinical and radiographic success. This information is displayed in Table 1.

3.3. RoB in studies

Among the nine included studies, one (Kiran N.K, 2020) was classified as having a high risk of bias for missing outcome data and insufficient outcome measurement. Given that only radiographic evaluation without any clinical evaluation was mentioned, follow-up periods of only 3 and 6 months were included. Ramar and Mungara, 2010, Rewal et al., 2014, and Saxena et al., 2017 mentioned follow-ups of 3, 6, and 9 months. Al-Ostwani et al., 2016 mentioned follow-ups of 6 and 12 months. Gupta et al., 2019 mentioned follow-ups of 3 and 6 months. These studies were then classified as having some concerns for missing outcome data. At the same time, three studies had a low risk of bias (Goel et al., 2018; Pandranki et al., 2018; Subramaniam and Gilhotra, 2011) (Fig. 2).

3.4. Meta-analysis

Eight studies were eligible for the *meta*-analysis, and one (Kiran N.K, 2020) out of nine studies was excluded because of missing data. Studies with follow-ups of 3, 6, 9, and 12 months were included. Studies with follow-ups exceeding these durations were excluded due to the absence of comparison: one study with a follow-up of 18 months and another with a follow-up of 24 months.

3.4.1. Clinical evaluation

In pooled analysis, the following studies showed statistical significance: Goel, H. et al., 2018 (*p*-value = 0.018, LOG[RR]: 0.08, and 95 % CI: [0.01–0.15]), Rewal, N. et al., 2014 (*p*-value = 0.001, LOG[RR]: 0.18, and 95 % CI: [0.07–0.29]), and Saxena, A. et al., 2017 (*p*-value = 0.000, LOG[RR]: 0.27, and 95 % CI: [0.15–0.39]).

Significance was found at 6-month follow-up (p-value = 0.014, LOG [RR]: 0.06, and 95 % CI: [0.01–0.11]) and 9-month follow-up (p-value = 0.001, LOG[RR]: 0.12, and 95 % CI: [0.05–0.19]).

The overall statistical significance was p-value = 0.000 with LOG (RR): 0.06 and 95 % CI: (0.03–0.09).

3.4.2. Radiographic evaluation

Pooled analysis showed that the following studies exhibited statistical significance: Goel, H. et al., 2018 (*p*-value = 0.001, LOG[RR]: 1.53,

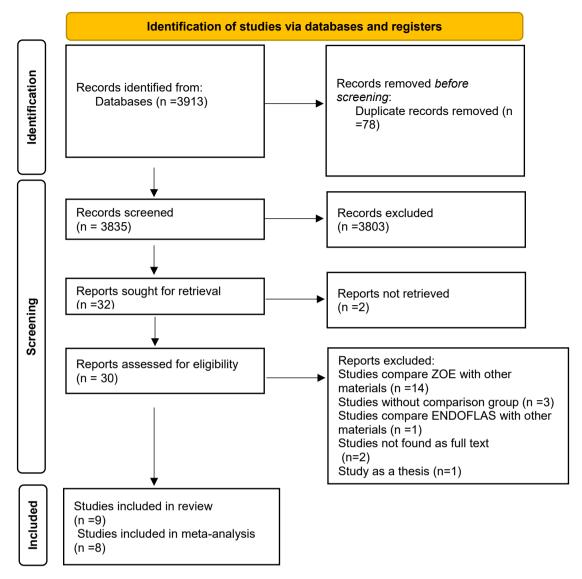


Fig. 1. Study selection criteria are represented in a flow diagram. ZOE stands for zinc oxide eugenol.

and 95 % CI: [0.66–2.40]), Ramar, K. & Mungara, J., 2010 (*p*-value = 0.014, LOG[RR]: 2.09, and 95 % CI: [0.42 –3.77]), and Rewal, N. et al., 2014 (*p*-value = 0.004, LOG[RR]: 2.40, and 95 % CI: [0.75–4.05]).

Significance was found at 6-month follow-up (p-value = 0.022, LOG [RR]: 0.72, and 95 % CI: [0.11–1.34]) and 9-month follow-up (p-value = 0.013, LOG[RR]: 1.12, and 95 % CI: [0.24–1.99]).

The overall statistical significance was p-value = 0.000 with LOG (RR): 0.68 and 95 % CI: [0.35–1.00]).

The forest plot of the pooled C&RE results by studies and follow-up time with the effect estimate as log relative risk with a 95 % confidence interval is shown in Figs. 3 and 4.

3.5. Heterogeneity

The heterogeneity among studies (I²) indicated that 16.62 % and 0.0 % of the variability in the effect-size estimates was due to the difference in C&RE between studies. However, the heterogenicity test statistic for the combined follow-ups of all studies was $X^2 = 29.51$ with *p*-value = 0.16 for clinical outcome data and $X^2 = 17.75$ with *p*-value = 0.77 for radiographic data. Therefore, no significant difference existed between the individual studies. L'Abbé plots were utilized to investigate outlier results and the potential source of heterogeneity. The outlier studies had small effect sizes (each circle represents a result, and the size of the circle

represents the effect size) (Supplementary Information 2).

3.6. Evaluation of minor study effects

Given that publication bias was low, the funnel plot for eight studies with four follow-ups appeared to be symmetrical around the intervention effect estimate for log risk LOG(RR) and standard error of LOG(RR) (Fig. 5).

Funnel plots were utilized to compare the success rates of Endoflas and ZOE in all investigations. A minor study effect was absent because the graphs had a funnel shape. The studies were almost symmetrical around the central line for clinical and radiographic success rates (Fig. 5).

3.7. Certainty of evidence

The quality of evidence for the outcome, in accordance with GRADE recommendations, was classified as "moderate" for the eight polled RCTs and stratified by studies and C&RE at follow-up (Supplementary Information 3). While the majority of the studies included in the analysis exhibited an uncertain RoB, bias was unlikely to reduce confidence in effect. Therefore, no serious limitations and downgraded level of evidence were found.

No	Author (year)	Age	No of children/ no of teeth	Type of teeth	Type of irrigation	Type of restoration/ SSC	Number of visits	Sample size ZOE n= / Endoflas n=	Follow- ups months	Comparison grou Clinical evaluation		ıp Radiographic evaluation		Endoflas Clinical evaluation		Radiographic evaluation	
	-	(y)	N				-	N		Ν	%	Ν	%	Ν	%	Ν	%
1	Subramaniam, P. & Gilhotra, K., 2011	5–9	NM/45	Maxillary and mandibular 1st,2nd primary molars	NaOCl + saline	Miracle mix/ SSC	Single	15 /15	3	14/ 15	93.3	14/ 15	93.3	14/ 15	93.3	14/ 15	93.3
									6	14/ 15	93.3	14/ 15	93.3	14/ 15	93.3	14/ 15	93.3
									12	14/ 15	93.3	14/ 15	93.3	14/ 15	93.3	14/ 15	93.3
									18	14/ 15	93.3	14/ 15	93.3	14/ 15	93.3	14/ 15	93.3
	Ramar, K. & Mungara, J., 2010	4–7	77/96	Primary mandibular molars	NaOCl + CHG	NM/SSC	Single	34 /32	3	34/ 34	100	32/ 34	94.11	32/ 32	100	32/ 32	100
2	5, 2010			monuro					6	33/	97	29/	85.2	32/	100	32/	100
									9	34 31/	01.1	34 207	85.2	32 31/	06.9	32 32/	100
									9	34	91.1	29/ 34	63.2	32	96.8	32/	100
3	Pandranki, J. et al., 2018	4–9	44/60	Primary teeth	NaOCl + saline	Composite/ SSC	NM	30/30	3	27/ 27	100	26/ 27	96.2	25/ 25	100	23/ 25	92
									6	26/	96.2	23/	85	25/	96	22/	85
									9	27 25/	92.5	27 21/	78	25 25/	96	25 21/	84
									12	27 24/	89	27 17/	63	25 23/	92	25 18/	72
									12	27	0,5	27	00	25	2	25	, _
									24	20/ 27	74	15/ 27	56	17/ 25	68	13/ 25	52
4	Rewal, N. et al., 2014	4_9	50/50	Primary molars	NaOCl + saline	NM/SSC	Single	24/26	3	20/ 24	83	18/ 24	90	26/ 26	100	26/ 26	100
					Summe				6	20/ 24	83	20/ 24	100	26/ 26	100	26/ 26	100
									9	20/ 24	83	20/ 24	100	26/ 26	100	26/ 26	100
5	Kiran, N.K. et al., 2020	4–9	NM/105	Mandibular primary molars	Saline + CHG	GIC/SSC	Single	36/34	3	NM	NM	24 36/ 36	100 %	NM	NM	20 34/ 34	100
				morars					6	NM	NM	36/	% 100 %	NM	NM	34/ 34/ 34	100
6	Goel, H. et al., 2018	4–9	120/120	Primary molars	NM	NM/SSC	Single	30/30	3	29/	96.70	36 29/	⁹⁰ 96.70	30/	100	34 30/	100
										30		30		30		30	
									6	27/ 30	89.70	25/ 30	82.80	29/ 30	96.60	29/ 30	96.60
									9	25/	82.80	22/	72.40	29/	96.30	29/	96.30
									12	30 22/	74.10	30 18/	60	30 29/	96.30	30 27/	88.90
									12	30	,	30	00	30	50100	30	00170
7	Gupta, B. et al., 2019	4–8	NM/48	Primary molars	NM	NM/ SSC	NM	12/12	3				-				
									6	10/ 12	79.25 %	6/ 12	47.3	11/ 12	92	9/ 12	77.6
8	Al-Ostwani, A. O. et al., 2015	3–9	39/64	Primary molars	NaOCl + Distilled	GIC/SSC	Single	16/16	6	15/ 16	93.80	13/ 16	81.25	16/ 16	100	13/ 16	81.30
					water				12	14/	87.50	13/	81.25	14/	87.50	13/	81.30
										16		16		16		16	
9	Saxena, A. et al., 2017	3–8	NM\40	Primary molars	Saline	NM\NM	NM	10/10	3	22/ 28	78.5	14/ 20	70	25/ 25	100	16/ 20	80
									6	27/	96.4	16/	80	25/	100	19/	95
									9	28 27/	96.4	20 17/	85	25 25/	100	20 19/	95
									-	28	2011	20		25	100	20	20

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Study	D1	D2	D3	D4	D5	Overall	D1	Randomization process
Subramaniam, P. & Gilhotra, K., 2011 [19]	+	+	+	+	+	+	D2	Deviations from the intended interventions
Ramar, K. & Mungara, J., 2010 [13]	+	+	!	+	+	1	D3	Missing outcome data
Pandranki, J. et al., 2018 [18]	+	+	+	+	+	+	D4	Measurement of the outcome
Rewal, N. et al., 2014 [12]	+	+		+	+		D5	Selection of the reported result
Kiran, N.K. et al., 2020 [22]	+	+			+		+	Low risk
Goel, H. et al., 2018 [20]	+	+	+	+	+	+	1	Some concerns
Gupta, B. et al., 2019 [21]	+	+		+	+	!		High risk
Al-Ostwani, A. O. et al., 2015 [17]	+	+		+	+	1		
Saxena, A. et al., 2017 [23]	+	+	!	+	+	!		

Fig. 2. Risk-of-bias summary of the included trials.

Study	к			Log risk-ratio with 95% Cl	p-value
Studies					<u>.</u>
Al-Ostwani, A. O. et al., 2015	2		•	0.04 [-0.10, 0.19]	0.544
Goel, H. et al., 2018	4	-		0.08 [0.01, 0.15]	0.018
Gupta, B. et al., 2019	2		•	0.10 [-0.12, 0.31]	0.387
Pandranki, J. et al., 2018	4	+•	<u> </u>	0.02 [-0.03, 0.08]	0.376
Ramar, K. & Mungara, J., 2010	3		_	0.02 [-0.03, 0.06]	0.484
Rewal, N. et al., 2014	3		•	0.18 [0.07, 0.29]	0.001
Saxena, A. et al., 2017	3			— 0.27 [0.15, 0.39]	0.000
Subramaniam, P. & Gilhotra, K., 2011	3			0.00 [-0.11, 0.11]	1.000
Test of group differences: $Q_b(7) = 22.67$	′, p = 0.00)			
followup					
3 months	7	+•	—	0.02 [-0.02, 0.06]	0.249
6 months	8	-	- •	0.06[0.01, 0.11]	0.014
9 months	5		•	0.12[0.05, 0.19]	0.001
12 months	4	-	•	0.07 [-0.03, 0.17]	0.186
Test of group differences: $Q_b(3) = 5.92$,	p = 0.12				
Overall			•	0.06 [0.03, 0.09]	0.000
Heterogeneity: $\tau^2 = 0.00$, $I^2 = 16.62\%$, H	$H^2 = 1.20$				
Test of $\theta_i = \theta_j$: Q(23) = 29.51, p = 0.16					
		2 0	.2	.4	
Random-effects ML model		Favour Endoflas	Favour ZOE*		

Fig. 3. Forest plot for clinical success by study and follow-up of Endoflas compared to ZOE. K: in the studies section: indicate the number of follow-ups per month for corresponding studies; in the follow-up section: indicate the number of studies for corresponding follow-ups. *: Favors ZOE means that the risk is for ZOE.

4. Discussion

Pulpectomy is an efficient therapeutic option for deciduous teeth presenting irreversible pulpitis or necrosis.

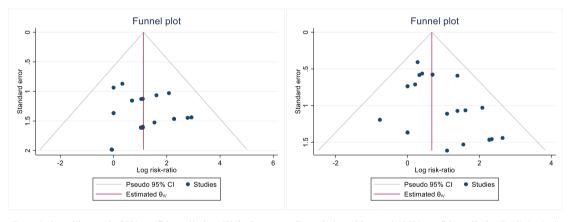
Mechanical and chemical preparations of RCs are equally essential in permanent and deciduous dentition. The success of the pulpectomy of deciduous teeth is influenced by the resorbable structure and antibacterial capabilities of filling materials (Ramar and Mungara, 2010; Subramaniam and Gilhotra, 2011). Despite adequate chemomechanical preparation and sufficient RCs irrigation, pulp therapy can fail due to trapped bacteria in the fins and isthmus of the tortuous, narrow, and ribbon-shaped RCs of deciduous teeth (Primosch et al., 1997; Rewal et al., 2014; Tchaou et al., 1996).

RCFM has two purposes: to prevent external infection from entering the RCs system and residual bacteria and necrotic tissue in the RCs system from being sealed in RCs without extravasation.

In the pooled analysis of studies, three studies were significantly different in terms of each C&RE likely due to differences among their

Study	к			Log risk-ratio with 95% CI	p-value
Studies					
Al-Ostwani, A. O. et al., 2015	2		•	0.00 [-1.02, 1.02]	1.000
Goel, H. et al., 2018	4			1.53 [0.66, 2.40]	0.001
Gupta, B. et al., 2019	2		•	0.69 [-0.11, 1.49]	0.090
Pandranki, J. et al., 2018	4	_	•	0.22 [-0.36, 0.79]	0.459
Ramar, K. & Mungara, J., 2010	3		•	- 2.09 [0.42, 3.77]	0.014
Rewal, N. et al., 2014	3		• • • • • • • • • • • • • • • • • • •		0.004
Saxena, A. et al., 2017	3	-	•	0.70 [-0.19, 1.59]	0.125
Subramaniam, P. & Gilhotra, K., 2011			0.00 [-1.55, 1.55]	1.000	
Test of group differences: $Q_b(7) = 15.55$	5, p = 0.03	3			
followup					
3 months	7			0.60 [-0.07, 1.26]	0.079
6 months	8		_	0.72 [0.11, 1.34]	0.022
9 months	5			1.12 [0.24, 1.99]	0.013
12 months	4			0.50 [-0.08, 1.08]	0.093
Test of group differences: $Q_b(3) = 1.39$,	p = 0.71				
Overall			•	0.68 [0.35, 1.00]	0.000
Heterogeneity: $\tau^2 = 0.00$, $I^2 = 0.00\%$, H^2	= 1.00				
Test of $\theta_i = \theta_j$: Q(23) = 17.75, p = 0.77					
		-2	0 2	4	
Random-effects ML model		Favour Endoflas	Favour ZOE*		

Fig. 4. Forest plot for radiographic success by study and follow-up of Endoflas compared to ZOE. K: in the studies section: indicate the number of follow-ups per month for corresponding studies; in the follow-up section: indicate the number of studies for corresponding follow-ups.*: Favors ZOE means that the risk is for ZOE.



Funnel plot with pseudo 95% confidante limits (Clinical)

Funnel plot with pseudo 95% confidante limits (Radiological)

Fig. 5. Funnel plot with lines indicate the triangular region within which 95% of studies are expected to lie in the absence of both publication biases and heterogeneity. The vertical line corresponds to no intervention effect.

settings, including sample size, follow-up times, tooth type, and study design.

In pooled analysis in accordance with follow-ups, significance was identified at only 6- and 9- month follow-ups, implying that significance was limited likely due to differences between the components, properties, and handling of the two filling materials. ZOE powder lacks antibacterial properties and ability for antibacterial agent release and has a low pH (Gupta et al., 2019). Its resorption rate is lower than the physiological root resorption rate, resulting in its retention in periapical tissue. ZOE is water soluble, releases eugenol, and stimulates periapical irritation. Furthermore, a study (Al-Ostwani et al., 2016) found that in 31.3 % of cases, ZOE was resorbed in roots. This finding corresponded to the results of Subramaniam and Gilhotra, 2011 and Trairatvorakul and Chunlasikaiwan, 2008, who clarified that high levels of eugenol produced from residual ZOE may have an adverse effect on adjacent tissue and impair healing because ZOE particles are resistant to giant cells.

Endoflas derives its properties from its components. ZOE resorption alone is slower than root resorption. The addition of iodoform increased the resorption rate of ZOE to the same level as that of root resorption. Iodoform is absorbable in the case of the over-obturation of root fillers. This quality can be a major disadvantage because absorption can extend within the canal, allowing infiltrators to be fixed by adding ZO to decelerate absorption. In addition, iodoform has a long history of use as an antimicrobial because it can release iodine. Paramonochlorophenol, which has antiseptic activity, is slowly released and effective at destroying bacteria. Precipitated barium sulfate is a white, crystalline powder that is used as a radiographic contrast material.

The addition of calcium hydroxide to Endoflas, which has excellent antibacterial ability due to its high pH caused by the release of hydroxyl ions in a humid setting, causes the denaturation of proteins and destruction of the bacterial cytoplasmic membrane (Mohammadi and Dummer, 2011).

Various other factors that can influence the success of RCFM treatment include the clinician's experience, manipulation, material proportion, mixing of material used, obturation technique, patient cooperation, and void volume (Orhan and Tatli, 2021). Furthermore, the pulpectomy of teeth with preoperative radiolucency is more susceptible to failure than that of teeth without pathology (Songvejkasem et al., 2021).

We found low heterogeneity among the papers included in our study despite the absence of a consistent protocol for the performance of pulpectomy on different types of teeth, type of irrigation materials, and type of restoration.

The greater heterogeneity of clinical evaluation (16.62 %) than that of radiographic evaluation (0.0 %) may be related to the subjectivity of clinical evaluation because it depends on the judgment of patients (children) and professionals.

In the pooled analysis, studies with the same direction of effect estimates suggest that using ZOE is related to a higher risk of failure than Endoflas in C&RE, implying the superiority of Endoflas over ZOE as an RCFM for deciduous teeth.

The evidence included in our systematic review and *meta*-analysis had the following limitations: inadequate sample size; different followup times; and differences in study design, including method randomization and blinding (non-blinded trials, blinded, and double-blinded trials) and operator number and experience; diversity in criteria applied for participants; and clinical and radiographic success.

The success of deciduous teeth pulpectomy is sensitive to the selection of a suitable RCFM. The findings of this *meta*-analysis provide evidence in favor of Endoflas as a filling material for the pulpectomy of deciduous teeth that is superior to ZOE. As a result, the null hypothesis was rejected.

Endoflas, when used as an RCFM for deciduous teeth, was associated with a low risk of treatment failure. Distinctions can be made between treatments and follow-ups (6 and 9 months) and evaluation type (clinical or radiographical) on the basis of our studies. GRADE suggested that the evidence had moderate quality. Before a conclusion can be formed regarding the optimal pulpectomy material for deciduous teeth, highquality randomized controlled clinical trials with large sample sizes and additional filling materials are required for outcomes with increased reliability.

5. Conclusion

- In C&RE, the use of ZOE is related to a 6 %–6.8 % higher risk of failure than that of Endoflas.
- The therapeutic outcomes (clinical and radiographic) of studies at short-term follow-up do not significantly differ.
- This study suggests the superiority of Endoflas over ZOE as an RCFM for deciduous teeth.

Citation

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Availability of data and materials

The datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

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Authors' contributions

R.A., M.M.. conceived the ideas; R.A., M.M., M.E., F.L., Software; R. A., M.M., M.E. Data curation and collection; R.A., M.M., M.E., and Q.G. Writing- Original draft preparation; R.A., M.M., M.E., Visualization, Investigation; M.M and Q.G. Supervision. All authors read and approved the final manuscript.

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Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

Declaration of competing interests

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.sdentj.2024.03.007.

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