# Systematic Review

# The clinical and radiographic success of Endoflas compared with other root canal obturating materials in primary teeth: A systematic review

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#### ABSTRACT

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Address for correspondence: Dr. Sujatha Bandi, Department of Paediatric and Preventive Dentistry, Narayana Dental College and Hospital, Nellore, Andhra Pradesh, India. E-mail: elicherlasai@gmail. com Pulpectomy aims at retaining the tooth in the asymptomatic state until exfoliation. Root canal obturating materials should resorb in synchronization with the primary root and get eliminated rapidly upon accidental extrusion. This systematic review aims at appraising the clinical and radiographic outcomes of Endoflas as an obturating material for primary teeth. An extensive literature search on obturating materials used for primary teeth using MeSH terms in PubMed, Cochrane library, and Ovid® from September 2002 to March 2020. Studies evaluating the clinical and radiographic success of Endoflas as an obturating material in children were included. From 45 retrieved articles, eight qualified for the systematic review. Moderate quality of evidence was elicited in this review. There was a dramatic reduction of inter radicular radiolucency in Endoflas obturated teeth compared to other root canal filling materials. Even for resorption of the extruded material beyond the apex too, Endoflas has depicted a faster clearance rate. Hence, it was concluded that, Endoflas can be a potential root canal obturating material for treating the primary teeth, even with furcal radiolucency. We recommend randomized clinical trials satisfying all the norms of CONSORT guidelines to provide a high quality of evidence.

Key Words: Clinical outcomes, Endoflas, Obturating material, Primary teeth, Pulpectomy

# **INTRODUCTION**

The prime motive of pulp therapy lies in conserving the integrity and health of the teeth, along with its supporting tissues.<sup>[1]</sup> The pulpectomy is a viable treatment option available for repairable primary teeth with irreversible pulpitis,<sup>[2]</sup> which aims for complete removal of the inflamed or necrotic pulp tissue. Hence, the rationale of pulpectomy is to sanitize the root canal system that is associated with/ without infection and to fill the root canal with an

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appropriate paste that resorbs at the same rate as the primary root and should get eliminated rapidly upon accidental extrusion through the apex.<sup>[2,3]</sup> Due to the complex root canal morphology of primary molars, it is hard for flawless scavenging of the infected root canal system. Hence, some authors recommended the use of root canal filling materials with antibacterial properties for optimal success of pulpectomy.<sup>[4]</sup>

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The root canal material for primary teeth should easily fade away along with the root, radiopaque and should not irritate the periapical tissues or readily resorbed if extruded beyond the apex. Furthermore, it should be quickly introduced and removed from the root canal if necessary and should not discolor the tooth.<sup>[5,6]</sup>

Zinc oxide and eugenol (ZOE) paste described by Sweet in 1930 was the first recommended root canal filling material for primary teeth.<sup>[7]</sup> Slow resorption of the extruded ZOE,<sup>[8]</sup> deviated path of its successor permanent tooth,<sup>[9]</sup> irritation to the periapical tissue, and necrosis of bone<sup>[10]</sup> are the potential disadvantages of ZOE. Calcium hydroxide [Ca(OH)<sub>2</sub>] was introduced by Hermann as a silicone oil-based paste and is widely used. Iodoform has been added to Ca(OH)<sub>2</sub> due to its antibacterial effect,<sup>[11]</sup> healing properties, and ability to get resorbed upon apical extrusion.<sup>[12]</sup>

Success rates of the combined  $Ca(OH)_2/iodoform$  paste range from 84% to 100%.<sup>[13]</sup> The potential drawback of  $Ca(OH)_2/iodoform$  paste is an inherent risk of intracanal resorption, which results in a hollow-tube effect.<sup>[14]</sup>

Endoflas is a resorbable paste with properties that are analogous to Vitapex, along with an addition of ZOE. Endoflas has the property of resorption of extruded material by phagocytosis without intracanal resorption of the material.<sup>[15,16]</sup> It has antibacterial properties due to its high pH, and also promotes healing and periapical bone formation. Even though currently available obturating materials have marked clinical and radiographic success rates, none of these materials meet the requirements of an ideal root canal filling materials due to their drawbacks and lack of parallelism with the physiological root resorption of primary teeth. Hence, the objective of the present systematic review was to evaluate the clinical and radiographic success of Endoflas due to its advantageous properties.

To our data, this is the first evidence-based systematic approach to the available literature regarding the clinical and radiographic success of Endoflas. The clinical research question is "clinical and radiographic success of Endoflas compared with other root canal filling agents in primary teeth: An evidence-based systematic approach."

### **METHODOLOGY**

The present systematic review protocol has been registered with the PROSPERO, the Prospective International Register of Systematic Reviews (CRD42019127615).

#### Search strategy and information sources:

The dental literature on the obturating materials for primary root canal treatment was reviewed to identify all the studies regarding the clinical and radiographic success of Endoflas. The search was confined to PubMed, Cochrane Library, and Ovid® to segregate the published studies appropriate for this review from September 2002 to March 2020, limited to the English language. The key terms used in the literature search included Medical Subject Heading terms (MeSH) or free text words and their synonyms with multiple combinations using Boolean operators ("OR" and "AND") and truncations to expand and taper the search were children, primary teeth, Endoflas, zinc oxide eugenol, Metapex, Vitapex, antibacterial efficacy, and quality of obturation. A supplementary search was performed in Google Scholar and hand search on cross-references of the relevant studies to find out additional citations.

Two researchers independently evaluated the titles of the studies that were retrieved initially from the databases and hand search. Abstracts of the studies were assessed after removing the duplicates and irrelevant titles. All the abstracts that appeared to meet the inclusion criteria were included in the review. A further full-text review was accessed for the included studies if the abstract of a study did not provide enough information. If there were any unresolved issues regarding the inclusion of a study for the review after the full-text phase, a consensus judgment was arrived by employing a third evaluator.

#### **Eligibility criteria**

The Population, Intervention, Comparison, Outcomes, and Study design (PICO-S) method was applied to establish the inclusion and exclusion criteria for this systematic search [Table 1]. The population comprises healthy children who required pulp therapy; intervention was Endoflas, used to obturate the root canals of the primary teeth. Other obturating materials such as Metapex, Vitapex, calcium hydroxide, zinc oxide–eugenol, iodoform, Pulpotec, and zinc-oxide ozonated oil used to obturate primary teeth were included for comparison. Outcomes were assessed based on the success rate of Endoflas against that of other obturating materials.

Randomized clinical trials, prospective clinical trials, where Endoflas was used as the obturating material in one of the groups of the performed study, and studies published in the English language were included.

PICO	Population	Intervention	Comparison	Outcome	Study design
Characteristics	s children, dentition	Endoflas, "Endoflas-chlorophenol - free"	Zinc oxide eugenol, calcium hydroxide, Metapex, Vitapex, Pulpotec, zinc-oxide ozonated oil	Success rate	Randomized clinical trials
MeSH terms	Child, tooth	Endoflas, "Endoflas-chlorophenol - free"	Zinc oxide eugenol, calcium hydroxide, Metapex, Vitapex, Pulpotec, zinc-oxide ozonated oil	Success rate, quality of obturation, antibacterial efficacy, physiologic root resorption, inter-radicular radiolucency	Randomized clinical trials
Alternative terms	Pedodontic, pedodontic, primary teeth, primary tooth, deciduous dentition, primary dentition	Endoflas-FS	Calcium hydroxide/ iodoform, calcium hydroxide combinations		

# Table 1: Population, Intervention, Comparison, Outcomes, and Study design format used for the extraction of data in the review

PICO: Population, Intervention, Comparison, and Outcomes

#### **Exclusion criteria**

*In vitro* studies, case reports, case series, narrative reviews, systematic reviews, and letters if mentioned in the title were excluded earlier in the abstract phase.

#### Data extraction and quality assessment

The data extraction was performed independently for all the studies that met the inclusion criteria, using piloted electronic Excel spreadsheets.

The quality of analysis and risk of bias for the included studies were evaluated independently utilizing "The Cochrane Collaboration's risk of bias assessment tool."<sup>[17]</sup>

#### RESULTS

A flow diagram of studies included in the review was presented adhering to the Preferred Reporting Items for Systematic Review and Meta-Analysis. A total of 45 studies were retrieved from all three databases (PubMed, Cochrane library, and Ovid®) and Google Scholar. After eliminating duplicates, 35 studies were eligible for the title phase, of which 23 were excluded after screening the titles with reasons being irrelevant studies (22) and systematic review (1). Subsequently, 12 studies were available for the abstract phase; after screening them, nine were included for full-text review, excluding three studies with cross-sectional study design. Out of 9, one study was excluded after full-text screening because of improper reporting of sample number for the outcomes assessed [Figure 1].

Finally, eight studies were included for quality appraisal. The substantial inter-examiner agreement corresponding to kappa statistics for the methodological quality assessments was over 0.93 for all the categories.<sup>[18]</sup> The

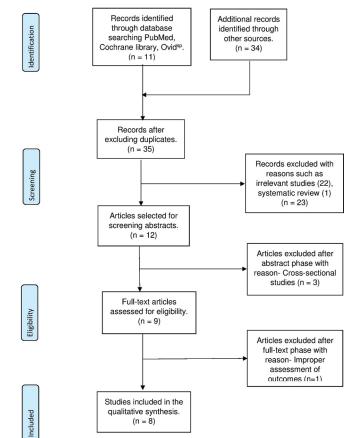


Figure 1: PRISMA flow diagram. PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-analyses.

studies included in this systematic review had follow-up periods ranging between 3 and 24 months.

The demographic data of the included studies containing details of the authors, age of children, sample size, and clinical and radiographic outcomes of the eight evaluated studies were given in Tables 2 and 3.

#### **Quality assessment**

The study by Pandranki et al.[19] was the only study

with good quality and the rest of the seven studies<sup>[20-26]</sup> elicited moderate quality of evidence [Figure 2].

For random sequence generation, the risk of selection bias was low in three studies (Ramar and Mungara,<sup>[20]</sup> Goel *et al.*,<sup>[24]</sup> and Pandranki *et al.*,<sup>[19]</sup>), whereas in the remaining five studies, there was insufficient information to make a clear judgment. Sample size calculation was determined

by using a formula, only in the study reported by Goel *et al.*<sup>[24]</sup>

No single study included in the review had clearly explained the process of allocation concealment. All the eight studies were ranked as low risk for selective reporting. Only two studies reported by Al-Ostwani and associates,<sup>[23]</sup> Pandranki *et al.*<sup>[19]</sup> have been rated as low regarding blinding of participants and

#### Table 2: Demographic data including characteristics of the selected studies in the systematic review

Age	Sample size	Outcomes assessed	
(years)	(number)	Clinical outcomes	Radiographic outcomes
4-7	96 teeth	Pain, redness, SA, DF, mobility, SC	FR, ARR, IRR, ERR, CM, DE, EFR
5-9	45 teeth	TP, redness, ST, swelling, mobility	ERR, RNP, DNP
4-9	50 teeth	Pain, redness, mobility, TP, ST, swelling	EFR, RR, IR
3-9	64 teeth	NM, pain, TP	DNP, RNP, BR, RR
4-9	120 teeth	Pain, TP, SA, ST, mobility	RE, RR
4-9	60 teeth	Pain, TP, SA, mobility	RR, RE, EF, PP
4-9	30 teeth	Pain, mobility, SA, ST, TP	DE, IRR, DNP, RNP, RE, RR
4-10	30 teeth	Pain, SA, TP mobility	DE, RNP, RE, RR
	(years) 4-7 5-9 4-9 3-9 4-9 4-9 4-9 4-9	(years)(number)4-796 teeth5-945 teeth4-950 teeth3-964 teeth4-9120 teeth4-960 teeth4-930 teeth	(years)(number)Clinical outcomes4-796 teethPain, redness, SA, DF, mobility, SC5-945 teethTP, redness, ST, swelling, mobility4-950 teethPain, redness, mobility, TP, ST, swelling3-964 teethNM, pain, TP4-9120 teethPain, TP, SA, ST, mobility4-960 teethPain, TP, SA, ST, mobility4-930 teethPain, mobility, SA, ST, TP

TP: Tendemess on percussion; FR: Furcation radiolucency; SC: Soft tissue changes; SA: Swelling or abscess; ARR: Abnormal root resorption; IRR: Internal root resorption; CM: Calcific metamorphosis; DE: Deviated eruption of succedaneous teeth; EFR: Excess filling and its resorption rate; DF: Draining fistula; DNP: Development of new postoperative pathologic radiolucency; RNP: Reduction/no change in preoperative pathologic inter-radicular/periapical radiolucency; PRR Pathologic root resorption; RR: Relative resorption of filling material with respect to root resorption; NM: Normal mucosa without abnormality; BR: Bone regeneration; IR: Inter-radicular/periapical fill; RE: Resorption of excess material; PP: Periradicular pathosis; ST: Sinus tract

#### Author Materials 3 months 6 months 9 months 12 months 18 months 24 months Р and year used **Clinical Radio Clinical** Clinical Radio Clinical Radio Radio Clinical Radio Clinical Radio Clinical Radio graphic graphic graphic graphic graphic graphic graphic Ramar & RC Fill 100% 81.10% >0.05 0.047 Mungara Metapex 96.80% 72.50% (2010) Endoflas 100% 90.32% Subrama 100% 100% 100% 100% 100% 100% 100% 100% 0.097 0.097 Metapex niam & Endoflas 93.30% 93.30% 93.30% 93.30% 93.30% 93.30% 93.30% 93.30% -Gilhotra ZOE 93.30% 93.30% 93.30% 93.30% 93.30% 93.30% 93.30% 93.30% (2011)Endoflas 100% 100% 100% 100% 100% 100% >0.05 Rewal < 0.05 et al. ZOE 83% 90% 83% 100% 83% 100% -(2014)ZOE 93.80% 56.30% 87.50% 56.30% 0.2 Ostwani 1 et al. Endoflas 100% 81.30% 87.50% 81.30% (2016)ZnO + Pro 93.80% 100% 75% 62.50% 87.50% Metapex 93.80% 75% 75% Goel ZOE 96.70% 96.70% 89.70% 82.80% 82.80% 72.40% 74.10% 63% >0.05 >0.05 et al. ZnO + Aloe 100% 100% 92.60% 88.90% 88.90% 85.20% 83.30% 79.20% (2018) ZnO-NaF 100% 96.60% 100% 96.60% 96.40% 89.30% 92.90% 85.70% Endoflas 100% 100% 96.60% 96.60% 96.30% 96.30% 96.30% 88.90% Pandranki ZOE 100% 96.20% 96.20% 85% 92.50% 78% 89% 63% 74% 56% 0.629 0.797 et al. Endoflas 100% 92% 96% 85% 96% 84% 92% 72% 68% 52% (2018) Divya Endoflas 100% 80% 100% 93% 100% 100% 0.0001 < 0.05 \_ + Pro et al. (2019) 3Mix 93% 93% 80% 100% 86.60% 86.60% Kottapalli 7nO +100% 74% 100% 66.66% 100% 66.66% >0.05 < 0.05 et al. Hydroxya (2019) patite Endoflas 100% 100% 100% 100% 100% 100%

#### Table 3: Clinical and radiographic outcome of the included studies in percentage (%)

ZOE-Zinc oxide eugenol; ZnO- Zinc oxide powder; Pro- Propolis; NaF- Sodium Fluoride

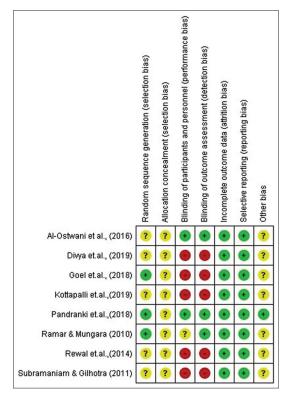


Figure 2: Risk of bias of included studies according to "The Cochrane Collaboration's tool for assessing the risk of bias."

outcome assessors. In the study reported by Ramar and Mungara,<sup>[20]</sup> there was insufficient information regarding the blinding of the outcome assessor, which was judged as unclear. The risk of bias for inadequate outcome data was low for all the studies assessed in the review [Figure 3].

Clinical and radiographic outcomes of the included studies were summarized as follows.

### **Clinical outcomes**

A trial reported by Ramar and Mungara on three obturating materials – RC FILL, Metapex, and Endoflas – with a follow-up of 9 months revealed a marked reduction in the preoperative clinical features in terms of pain or tenderness to percussion. Only one tooth obturated with RC FILL was extracted at 6 months review as the patient reported with severe pain concerning to it. No significant difference was reported regarding clinical outcomes among the groups (P > 0.05).<sup>[20]</sup>

Subramaniam and Gilhotra after 18 months of the review suggested that there was no significant difference (P = 0.097) between the three materials (Metapex, Endoflas, and ZOE). Two teeth over-obturated with ZOE and Endoflas were extracted as they exhibited tenderness, severe mobility, and gingival swelling coupled with pain, respectively.<sup>[21]</sup>

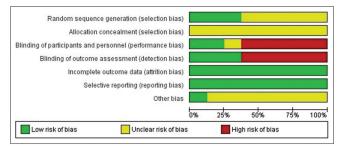


Figure 3: Risk of bias of each item presented as percentages across all included studies.

Rewal *et al.* compared and reviewed Endoflas and ZOE in primary molar pulpectomy for 9 months. At the end of 3-month follow-up, four teeth obturated with ZOE were extracted, restricting its success rate to 83% at the end of the trial. In contrast, no extractions or failures were observed with Endoflas (100% clinical success; P < 0.05).<sup>[22]</sup>

Al-Ostwani *et al.* reported a trial, in which they compared ZOE, Endoflas-CF, zinc oxide powder (ZO) + propolis (ZOP), and Metapex as primary root canal filling materials and suggested that no significant difference (clinical success rates; P > 0.05) lies between them. The clinical success rate for ZOP was 93.8%, and for ZOE, Endoflas-CF, and Metapex was 87.5% at 12 months of the follow-up period.<sup>[23]</sup>

Goel *et al.* utilized ZOE and its combinations (ZO + *Aloe vera*, ZO + 10% NaF, Endoflas) in their trial for obturating primary teeth. Clinical evaluation (in terms of pain, mobility, swelling, presence of sinus tract, and tenderness on percussion) done at 3, 6, 9, and 12 month intervals revealed regression of postoperative symptoms but without significant (P > 0.05) difference among the materials used.<sup>[24]</sup>

In a study reported by Pandranki *et al.*, both the materials (Endoflas and ZOE) used for obturation exhibited a reduction in clinical symptoms such as pain and tenderness on percussion, except for sinus/ abscess and mobility. Seven teeth obturated with ZOE and eight obturated with Endoflas showed signs of periradicular infections at the end of 2-year follow-up. Overall, the clinical success rate was 92% for Endoflas and 89% for ZOE (P = 0.629).<sup>[19]</sup>

Divya *et al.* treated infected primary molars with periapical lesions using propolis liquid mixed with Endoflas powder and 3Mix. They suggested that a significant difference (P = 0.0001) exists among pre and post clinical signs and symptoms at 3-, 6-, and 12-month follow-up between propolis liquid-mixed

Endoflas powder and 3Mix. One tooth obturated with 3Mix was extracted at 12-month follow-up, whereas no extractions/failures were observed in the counterpart, which yielded 100% clinical success for propolis liquid-mixed Endoflas powder.<sup>[25]</sup>

Kottapalli *et al.* reported a clinical trial comparing a mixture of ZO + hydroxyapatite with Endoflas as an obturating material. There were no extraction/failures of teeth obturated with both the materials owing to the 100% clinical success rate till the end of 9-month follow-up (P > 0.05).<sup>[26]</sup>

### **Radiographic outcomes**

At the end of 9-month follow-up trial by Ramar and Mungara, the radiographic assessment showed progressive regression of radiolucencies where Endoflas exhibited the highest (90.32%) radiographic success rate followed by RC FILL (81.1%) and Metapex (72.5%). Statistically, a significant difference was observed between them (P = 0.047).<sup>[20]</sup>

Subramaniam and Gilhotra in their trial witnessed overfilled canals and voids in teeth obturated with Metapex (because of its thin consistency), whereas underfilled canals were appreciated with Endoflas and ZOE. Gradual reduction of inter-radicular radiolucency with Endoflas-obturated teeth was attributed to its antibacterial property. Regarding the radiographic success, no significant difference was depicted among them (P = 0.097).<sup>[21]</sup>

In a trial reported by Rewal *et al.*, the radiographic success rate for teeth overfilled with Endoflas and ZOE was 100% and 60%, respectively. In terms of resorption of material analogous to physiologic resorption of the root, it was 100% for Endoflas and 41.7% for ZOE. At the end of the trial (9-month follow-up), a 100% reduction in the size of inter-radicular radiolucency was evident with Endoflas, whereas it was 45% with ZOE and a significant difference exists between them (P < 0.01). Whereas for overall radiographic success, no significant difference exists (P > 0.05) at 3, 6, and 9 months.<sup>[22]</sup>

Al-Ostwani *et al.* revealed the highest radiographic success rate for Endoflas-CF (81.3%) obturated teeth, followed by Metapex (75%), ZOP (62.5%), and ZOE (56.3%) at the end of 12-month follow-up. Regarding resorption of filling material in correspondence with physiological root resorption, it was 62.5% for ZOP and 43.8% for Endoflas-CF. Resorption of filling material earlier than root was

observed in 56.3% and 31.3% cases obturated with Endoflas-CF and Metapex, respectively. In contrast, cases obturated with ZOE lagged the resorption (i.e., slower resorption than root). These filling materials achieved convergent radiographic success rates within the follow-up period without significant differences between them (P > 0.05).<sup>[23]</sup>

Radiographic assessment by Goel *et al.* exhibited progressive healing of preoperative radiolucency; in contrast, one tooth each filled with ZOE, ZO-NaF, and Endoflas displayed an enlargement. Expect a single tooth with an increase in radiolucency, no other tooth filled with Endoflas reported postoperative pain and swelling until the end of the trial. Overall, the radiographic assessment was highest for Endoflas (88.90%) followed by ZO-NaF (85.70%), ZO-*Aloe vera* (79.20%), and ZOE (63%) at the end of 12-month follow-up.<sup>[24]</sup>

Overall, the radiographic success rate for Endoflas (72%) was superior to that of ZOE (63%) at the end of the trial by Pandranki et al.[19] There was an aggregate regression of periradicular infection in both groups. Optimal filled with Endoflas and underfilled with ZOE displayed better results compared to overfilled concerning to either of the materials. Retention of the extruded material was evident in 92.3% of cases obturated with ZOE, whereas no retained material was present in counterpart. In 88% of the teeth obturated with Endoflas, there was synchronization with the physiologic root resorption. Conversely, 63% of teeth filled with ZOE displayed resorption at a slower pace. No significant difference was elicited for both materials at the end of 24 months (P = 0.797) between them.

Propolis-mixed Endoflas powder and 3Mix used for treating periapical lesions in primary molars exhibited 100% and 60% radiographic success rates at the end of the 12-month follow-up by Divya *et al.*<sup>[25]</sup> One of the teeth obturated with 3Mix was extracted as it exhibited internal resorption and deviation in the path of eruption of its permanent tooth. In 93.3% of the teeth obturated with propolis-mixed Endoflas powder, resorption of the material was identical to physiologic root resorption.

Teeth obturated with ZO + hydroxyapatite exhibited 66.66% of radiographic success; in contrast, it is 100% for Endoflas obturated teeth in a trial reported by Kottapalli *et al.*<sup>[26]</sup> In terms of the correlation between the resorption of material and physiological root resorption of the tooth, it was 100% for Endoflas and 80% for

ZO + hydroxyapatite combination, and statistically significant difference (P < 0.05) exists among them.

# DISCUSSION

Pulp therapy aims in preserving the restorable tooth with infected and/or necrotic pulp until their normal exfoliation process, helps in maintaining the function, upholds the space for their succeeding tooth, and prevents their premature eruption.<sup>[16,27-29]</sup>

Several investigators suggested that it is challenging to eradicate the wide range of microbes that resides in infected primary root canals because of their complex and variable morphology.<sup>[30-32]</sup> Hence, the preparation of primary root canal is based usually on chemical means rather than mechanical debridement.<sup>[33]</sup>

The success of pulp therapy in primary teeth necessitates a resorbable material (similar to that of physiological resorption of the primary root) that provides an airtight seal with antimicrobial properties, which hinders the growth of the resident bacteria and stimulates periapical healing.<sup>[34,35]</sup>

The composition of Endoflas incorporates three materials ZOE,  $Ca(OH)_{2}$ , and iodoform. The rationale behind this combination was to compensate the disadvantages of one individual component with the advantages of others.

Most of the studies reported that the resorption of Endoflas was analogous to physiological resorption of root, which is the essential requirement of an ideal obturating material for primary teeth.[19-22,25,26] In terms of reduction of inter-radicular radiolucency, Endoflas is superior compared to other materials that were used in the studies included in this systematic review. This reduction can be attributed to its excellent healing capabilities and broad antibacterial activity because of the presence of Ca(OH), and iodoform.<sup>[24]</sup> Moreover, resorption of the extruded material without its intracanal resorption is evident by maintaining an airtight seal.<sup>[16]</sup> It assists in the complete regeneration of bone with 100% regression of furcal radiolucency, which can be attributed to its antibacterial properties. It can also be advocated as an obturating material even in mild, moist canals because of its hydrophilic nature.<sup>[15]</sup>

From the findings of the studies included in the current review, Endoflas can be considered a suitable obturating material as it has antibacterial properties to sterilize the dentinal tubules and accessory canals that are difficult to access.<sup>[15]</sup>

At the end of the follow-up period, only one of the eight studies included in this review demonstrated a statistically significant difference between studied materials both clinically and radiographically.<sup>[25]</sup> In contrast, two studies showed significant differences only in radiographic outcomes.<sup>[20,26]</sup>

Radiographic criteria taken for success were not uniform so that cases mentioned as success in some studies<sup>[23]</sup> would be considered a failure by other studies.<sup>[19,20,22,24,25]</sup> Furthermore, it is not possible to follow complete blinding in trials comparing obturating materials of primary teeth due to the radiographic appearance of a faster rate of resorption of iodoform-based pastes.

Three out of eight studies had <1 year of the follow-up period, which is considered a short term.<sup>[19,22,26]</sup> Furthermore, the sample size was small in some studies, which may have led to lower power to find meaningful results.<sup>[25,26]</sup> There is no much difference in the procedure followed in the included studies, i.e., BMP, obturation, irrigation solutions, and type of definite restoration of the teeth. Sample selection might not be homogenous due to different pathologic conditions of primary teeth.

Except one,<sup>[19]</sup> the remaining studies<sup>[20-26]</sup> showed a moderate risk of bias as they fail to record or report the required information, which is essential for randomized clinical trials. Aspects such as trial designing and reporting should be improved as inadequate randomization, and allocation concealment tends to overestimate treatment outcomes. Furthermore, adequate blinding is needed since open outcome assessment has also been shown to overestimate the treatment results.<sup>[36,37]</sup>

Apart from the admirable features of Endoflas, a few disadvantages such as irritation to apical tissues,<sup>[38]</sup> external root resorption because of extruded material,<sup>[39]</sup> cemental necrosis, and discoloration<sup>[24]</sup> were documented in studies because of eugenol, chlorophenol, and iodoform, respectively. Extruded Endoflas can irritate the follicle upon entering the dental follicle and results in an immense inflammatory reaction, which, in turn, exacerbates the root resorption.<sup>[40]</sup>

For overcoming the side effects, few amendments were done and tested in clinical trials. Better results were evident when the Endoflas powder was combined with propolis,<sup>[25]</sup> while chlorophenol-free Endoflas reported 87.5% clinical success, which is

less than Endoflas-FS (92%).<sup>[23]</sup> The Endoflas powder upon the combination with Curcumin gel showed a decrease in inter-radicular radiolucency after 1 month and enhanced resorption of the extruded material within 1 week.<sup>[41]</sup> A better success rate was reported for optimal filled (83.3%) teeth when compared to underfilled (67%) and overfilled (60%).<sup>[19]</sup>

### CONCLUSION

Endoflas can be advocated as a potential root canal filling material in treating the primary tooth with furcal radiolucency upon optimal filling of the root canals. Although moderate quality of evidence was obtained in this systematic review, the documented clinical and radiographic success rates of Endoflas are superior to other obturating materials in primary teeth. Randomized clinical trials satisfying all the norms of CONSORT guidelines will yield a high quality of evidence.

#### Why this paper is important

- The success of pulpectomy in primary teeth relies on the appropriate choice of an ideal root canal filling material, which is a challenging aspect
- Endoflas emerges as a potential root canal filling material due to its outstanding antimicrobial efficacy, resorption of periapically extruded material without resulting in a hollow tube effect, and also can be advocated for mild moist canals because of its hydrophilic nature
- More randomized controlled trials satisfying all the norms of CONSORT guidelines with a longterm follow-up period will provide a high quality of evidence.

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#### **Conflicts of interest**

The authors of this manuscript declare that they have no conflicts of interest, real or perceived, financial or nonfinancial in this article.

#### REFERENCES

- American Association of Endodontists. Glossary of Endodontic Terms. 7<sup>th</sup> ed. Chicago, Ill: American Association of Endodontists; 2003.
- American Academy on Pediatric Dentistry Clinical Affairs Committee-Pulp Therapy Subcommittee; American Academy on Pediatric Dentistry Council on Clinical Affairs. Guideline on pulp therapy for primary and young permanent teeth. Pediatr Dent 2008;30:170-4.
- 3. Rodd HD, Waterhouse PJ, Fuks AB, Fayle SA, Moffat MA;

British Society of Paediatric Dentistry. Pulp therapy for primary molars. Int J Paediatr Dent 2006;16 Suppl 1:15-23.

- Navit S, Jaiswal N, Khan SA, Malhotra S, Sharma A, Mukesh, et al. Antimicrobial efficacy of contemporary obturating materials used in primary teeth – An *in-vitro* study. J Clin Diagn Res 2016;10:C09-12.
- Garcia-Godoy F. Evaluation of an iodoform paste in root canal therapy for infected primary teeth. ASDC J Dent Child 1987;54:30-4.
- Rifkin A. The root canal treatment of abscessed primary teeth A three to four year follow-up. ASDC J Dent Child 1982;49:428-31.
- 7. Mass E, Zilberman UL. Endodontic treatment of infected primary teeth using Maistois paste. J Dent Child 1989;56:117-20.
- Barker BC, Lockett BC. Endodontic experiments with resorbable paste. Aust Dent J 1971;16:364-73.
- Coll JA, Sadrian R. Predicting pulpectomy success and its relationship to exfoliation and succedaneous dentition. Pediatr Dent 1996;18:57-63.
- Erausquin J, Muruzábal M. Root canal fillings with zinc oxide-eugenol cement in the rat molar. Oral Surg Oral Med Oral Pathol 1967;24:547-58.
- Estrela C, Estrela CR, Hollanda AC, Decurcio Dde A, Pécora JD. Influence of iodoform on antimicrobial potential of calcium hydroxide. J Appl Oral Sci 2006;14:33-7.
- Nurko C, Ranly DM, García-Godoy F, Lakshmyya KN. Resorption of a calcium hydroxide/iodoform paste (Vitapex) in root canal therapy for primary teeth: A case report. Pediatr Dent 2000;22:517-20.
- Reddy VV, Fernandes. Clinical and radiological evaluation of zinc oxide-eugenol and Maisto's paste as obturating materials in infected primary teeth – Nine months study. J Indian Soc Pedod Prev Dent 1996;14:39-44.
- Goldman M, Pearson AH. A preliminary investigation of the "Hollow Tube" theory in endodontics. J Oral Therap Pharmacol 1965;6:618-26.
- 15. Moskovitz M, Sammara E, Holan G. Success rate of root canal treatment in primary molars. J Dent 2005;33:41-7.
- Fuks AB, Eidelman E, Pauker N. Root fillings with Endoflas in primary teeth: A retrospective study. J Clin Pediatr Dent 2002;27:41-5.
- Higgins JP, Green S. Cochrane Handbook for Systematic Reviews of Interventions. Ver. 5.1.0. London, UK: The Cochrane Collaboration; 2011.
- Sim J, Wright CC. The kappa statistic in reliability studies: Use, interpretation, and sample size requirements. Phys Ther 2005;85:257-68.
- Pandranki J, Vanga NR, Chandrabhatla SK. Zinc oxide eugenol and Endoflas pulpectomy in primary molars: 24-month clinical and radiographic evaluation. J Indian Soc Pedod Prev Dent 2018;36:173-80.
- Ramar K, Mungara J. Clinical and radiographic evaluation of pulpectomies using three root canal filling materials: An *in-vivo* study. J Indian Soc Pedod Prev Dent 2010;28:25-9.
- Subramaniam P, Gilhotra K. Endoflas, zinc oxide eugenol and metapex as root canal filling materials in primary molars – A comparative clinical study. J Clin Pediatr Dent 2011;35:365-9.
- 22. Rewal N, Thakur AS, Sachdev V, Mahajan N. Comparison of

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endoflas and zinc oxide eugenol as root canal filling materials in primary dentition. J Indian Soc Pedod Prev Dent 2014;32:317-21.

- Al-Ostwani AO, Al-Monaqel BM, Al-Tinawi MK. A clinical and radiographic study of four different root canal fillings in primary molars. J Indian Soc Pedod Prev Dent 2016;34:55-9.
- Goel H, Mathur S, Sachdev V. Clinical and radiographic evaluation of four different zinc-oxide integrated root canal obturating materials used in primary teeth. Pediatr Dent J 2018;28:73-86.
- 25. Divya DV, Prasad MG, Radhakrishna AN, Sandeep RV, Reddy SP, Santosh Kumar KV. Triple antibiotic paste versus propolis: A clinical quest for the reliable treatment of periapical lesions in primary molars. Saudi Endod J 2019;9:34-9.
- 26. Kottapalli P, Madu GP, Ambati NR, Bolla D, Rayala VS, Narra R. Clinical and radiographic evaluation of mixture of zinc oxide powder and nanohydroxyapatite as an obturating material in primary molars. Braz Dent Sci 2019;31:63-9.
- 27. Goerig AC, Camp JH. Root canal treatment in primary teeth: A review. Pediatr Dent 1983;5:33-7.
- Barr ES, Flatiz CM, Hicks MJ. A retrospective radiographic evaluation of primary molar pulpectomies. Pediatr Dent 1991;13:4-9.
- Dummett CO Jr., Kopel HM. Pediatric endodontics. In: Ingle J, editor. Endodontics. Philadelphia: Lea and Febiger; 2002. p. 861-902.
- 30. Gould JM. Root canal therapy for infected primary molar teeth Preliminary report. ASDC J Dent Child 1972;39:269-73.
- 31. Saltzman B, Sigal M, Clokie C, Rukavina J, Titley K, Kulkarni GV. Assessment of a novel alternative to conventional formocresol-zinc oxide eugenol pulpotomy for the treatment of pulpally involved human primary teeth: Diode laser-mineral trioxide aggregate pulpotomy. Int J Paediatr Dent 2005;15:437-47.
- 32. Bodrumlu E, Semiz M. Antibacterial activity of a new endodontic

sealer against *Enterococcus faecalis*. J Can Dent Assoc 2006;72:637.

- Rosendahl R, Weinert-Grodd A. Root canal treatment of primary molars with infected pulps using calcium hydroxide as a root canal filling. J Clin Pediatr Dent 1995;19:255-8.
- American Academy of Pediatric Dentistry. Guideline on pulp therapy for primary and immature permanent teeth. Pediatr Dent 2016;38:280-8.
- Pabla T, Gulati MS, Mohan U. Evaluation of antimicrobial efficacy of various root canal filling materials for primary teeth. J Indian Soc Pedod Prev Dent 1997;15:134-40.
- Jadad AR, Moore RA, Carroll D, Jenkinson C, Reynolds DJ, Gavaghan DJ, *et al.* Assessing the quality of reports of randomized clinical trials: Is blinding necessary? Control Clin Trials 1996;17:1-12.
- Jüni P, Witschi A, Bloch R, Egger M. The hazards of scoring the quality of clinical trials for meta-analysis. JAMA 1999;282:1054-60.
- Chawla HS, Setia S, Gupta N, Gauba K, Goyal A. Evaluation of a mixture of zinc oxide, calcium hydroxide, and sodium fluoride as a new root canal filling material for primary teeth. J Indian Soc Pedod Prev Dent 2008;26:53-8.
- Moskovitz M, Tickotsky N, Ashkar H, Holan G. Degree of root resorption after root canal treatment with iodoform-containing filling material in primary molars. Quintessence Int 2012;43:361-8.
- Coser RM, Gondim JO, Aparecida Giro EM. Evaluation of endodontic techniques used to treat human primary molars with furcation radiolucency area: A 48-month radiographic study. Quintessence Int 2008;39:549-57.
- Radhakrishna AM, Menni AC, Prasad MG, Chandrasekhar S. The success rate of Endoflas powder mixed with Curcumin gel as obturating material in Primary Molars: Case-series. J Biomed Pharma Res 2018;6:100-6.