



CLINICO – RADIOGRAPHIC COMPARISON OF ZINC OXIDE EUGENOL, ENDOFLAS AND METAPEX AS OBTURATING MATERIALS IN PRIMARY TEETH – AN IN VIVO STUDY

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Abstract

Preservation of primary dentition is important for orofacial development as it helps to maintain the space for eruption of permanent teeth, aids in masticatory functions, phonation and swallowing. The main objectives of endodontic treatment is removal of diseased pulp tissue, resolution of the periapical pathology and achieving physiological resorption of the primary roots so as to permit normal eruption of the succedaneous tooth. To avoid untoward changes when primary teeth are replaced by permanent teeth, resorption of the material used in primary teeth root canal filling should occur at the same rate as root resorption. An effective root canal material plays the major role in achieving the fluid impervious seal by defending against variant microflora and maintaining the tooth in function for longer duration. Various root canal filling materials are used to preserve a pulpally involved carious primary tooth. But there is no single material so far available to fulfill all the requirements of an ideal root canal filling material for a primary tooth. **Aim:** To compare and evaluate the postoperative (clinical and radiographical) success of three obturating materials in pulpectomies performed in primary molar teeth of children in the age group of 4 to 7 years at 1,3-,6- and 9-month intervals.

Method: The pulpectomy procedure was performed under rubber dam isolation after administration of local anaesthesia and Group I was obturated with ZOE, Group II with Endoflas and Group III with Metapex. Postoperative radiographs were taken immediately after obturation. All obturated teeth were restored with Type II GIC. Crown preparation was done and preformed stainlesssteel crown was luted using GICT ype I cement immediately. Postoperative radiograph was taken. The teeth were evaluated at 1, 3, 6 and 9 months postoperatively using clinical and radiographic criteria. The collected data was statistically analysed.

Results: The success of treatment was determined after a period of 9 months postoperatively. The overall success rate between the three groups was statistically significant ($p < 0.05$). Group II (Endoflas) showed 95 % overall success followed by Group I (ZOE) and Group III (Metapex) which showed 90% and 70% overall success.

Conclusion: The study concluded that Endoflas can be considered to be an effective obturating material in primary teeth due to its highest overall success, clinically and radiographically at a 9 month follow up period. Also, it possess most of the ideal requirements of an effective obturating material in primary teeth. However, Metapex possess the least success rate due to its fast resorptive process (Hollow - tube effect) than the physiological resorption of the root.

Keywords: Primary dentition, Zinc Oxide Eugenol, Endoflas and Metapex, Radiograph, GIC, Periapical pathology, Root resorption, Radiolucency, Obturating materials, Pulpectomy.

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1. Introduction

Primary dentition is important for orofacial development as it helps to maintain the space for eruption of permanent teeth, aids in masticatory functions, phonation and swallowing [1]. The main objectives of endodontic treatment are removal of diseased pulp tissue, resolution of the periapical pathology and achieving physiological resorption of the primary roots so as to permit normal eruption of the succedaneous tooth. This is achieved by biomechanical preparation, irrigation and followed by complete obturation of the root canal system. An ideal biomechanical preparation in primary root canals is hard to achieve due to their fenestrated and tortuous nature. Hence, obturating materials should have resorbable and long-lasting antibacterial properties.

The ideal requirements of obturating materials in primary teeth are as follows:

1. It should be bactericidal and should resorb at a similar rate as the primary tooth.
2. It should be non-irritating to the periapical tissues and to the permanent tooth germ.
3. If pressed beyond the apex it should readily resorb.
4. It should be inserted easily into the root canal and be removed easily if necessary.
5. It should adhere to the walls of the canal and should not shrink.
6. It should be water insoluble.
7. It should be radio opaque and not discolour the tooth [2].

Zinc oxide eugenol was introduced by Bonastre in 1837. Eugenol has anti-inflammatory and analgesic properties which are beneficial after a pulpectomy procedure. It is also radiopaque, easy to manipulate and insoluble in tissue fluids. It has certain disadvantages like slow resorption, less antimicrobial activity, irritation to the periapical tissues, necrosis of the bone and cementum and alters the path of eruption of succedaneous teeth [3].

Calcium hydroxide was introduced in 1930

by Herman as a pulp capping material. Calcium hydroxide, despite its antiseptic and osteoinductive properties has a tendency to get depleted from the canals earlier than the physiologic resorption of the roots Iodoform is a potent bactericidal, radiopaque, resorbable material and harmless to the permanent tooth germs as well as easy to remove [4]. Metapex is easy to use, resorbs at a slightly faster rate than that of the root and has no toxic effects on its permanent successor. Metapex contains a radiopaque component barium sulfate which guides the placement of material when seen radiographically [5]. Endoflas is available as powder and liquid. Powder consists of 40.6% triiodide and iodine dibutylorthocresol, 56.5% zinc oxide, 1.07% calcium hydroxide, and 1.63% barium sulfate and liquid consists of eugenol and paramonochlorophenol [6]. Endoflas is hydrophilic and can be used in mildly moist canals. It has a broad spectrum of antibacterial activity for disinfecting dentinal tubules and remotely located accessory canals which also cannot be cleansed mechanically [6]. Unlike other pastes, Endoflas only resorbs when extruded extraradically and does not wash out intra-radically. The disadvantages of this material are tooth discoloration and its eugenol content which can cause periapical irritation [7].

As such there is no ideal obturating material for primary teeth. There is ongoing research for the nearly ideal obturating material in primary teeth. The goal of this study was to evaluate the postoperative (clinical and radiographical) success rates of three different obturating materials i.e Zinc Oxide Eugenol, Endoflas and Metapex (Calcium hydroxide-Iodoform mixture) at 3,6 and 9 months follow up.

2. Materials And Method

After obtaining the clearance from the Institutional Ethics Committee, study was carried out in the Department of Paediatric

and Preventive Dentistry, Genesis Institute of Dental Sciences and Research Centre, Ferozepur, recognized by Baba Farid University of Health Sciences, Faridkot (Punjab).

Method: A total of 60 primary molars indicated for pulpectomy in children between the age of 4-7 years were selected for the study according to the criteria. Inclusion criteria included cooperative patients with no history of systemic illness/disease, tooth with carious pulp exposure, restorable teeth/coronal structure and tooth with at least two-third of intact root length. Exclusion criteria included tooth in preshedding stage, abnormal pathologic mobility, tooth with internal/external root resorption, acute or chronic periapical abscess, Intraoral swelling/sinus, tooth showing radiographic signs of furcal and/or periapical radiolucency and any known history of allergy to eugenol.

A diagnostic radiograph was taken. The procedures possible risks/discomforts and benefits were fully explained to the parents or guardian and the subject. Written and verbal informed consent was obtained from the parents of the children participating in the study.

The teeth were divided into three groups Group I, II and III with 20 teeth in each group. These groups were respectively treated with ZOE, Endoflas and Metapex. The pulpectomy was performed under rubber dam isolation after administration of local anaesthesia. Access opening was done after complete caries removal with slow speed no.4 and no 6-carbide bur and copious water supply. Overhanging dentin

was removed and a sharp spoon excavator was used to amputate the coronal pulp. H files were used for pulp extirpation. An IOPA radiograph was taken to establish the working length at 1 mm short of apex to avoid over obturation. The canals were prepared with reamers and K files with periodic irrigation. After appropriate irrigation the canals were dried using appropriately sized paper points and obturated with the respective material.

Group I was obturated with Zinc oxide Eugenol. Teeth in Group II received Endoflas and Group III received Metapex. Post operative radiographs were taken immediately after obturation. All obturated teeth were restored with type II GIC cement. Crown preparation was done and preformed Stainless-Steel crown (Kids Crown, Mumbai, India) were given immediately. Crowns were luted with GIC Type I cement. The teeth were evaluated at 1, 3, 6 and 9 months respectively using clinical and radiographical criteria.[Fig 1-3] Criteria for clinical evaluation at 1, 3, 6 and 9 months

1. Presence or absence of pain
2. Tenderness on percussion
3. Abscess
4. Mobility

Criteria for radiographical evaluation at 1, 3, 6 and 9 months

1. Periapical and or furcation radiolucency.
2. External/Internal root resorption.
3. Deviated eruption of succedaneous teeth.

The clinical and radiographical findings were tabulated and subjected to statistical evaluation (Chi-square test).

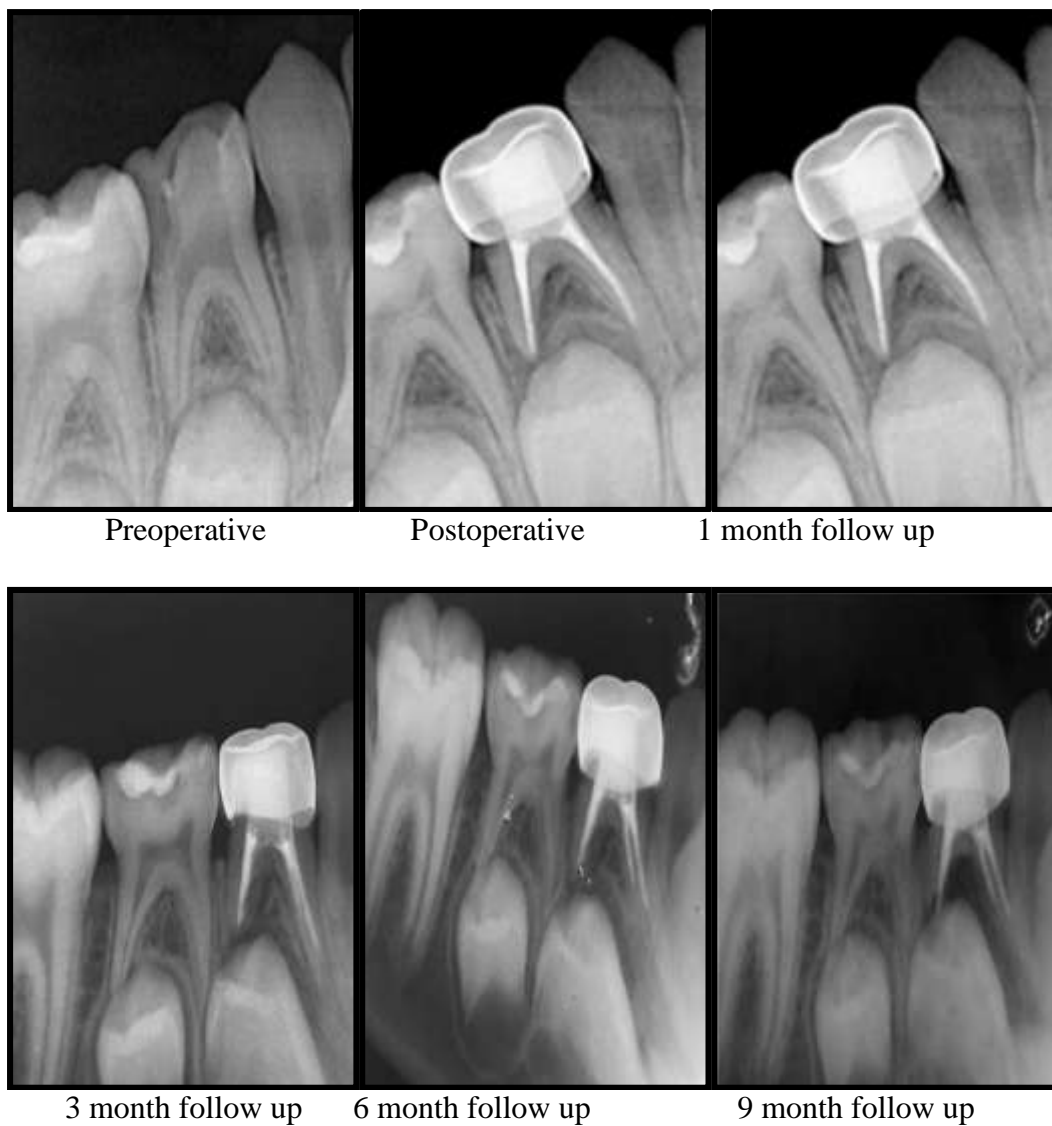
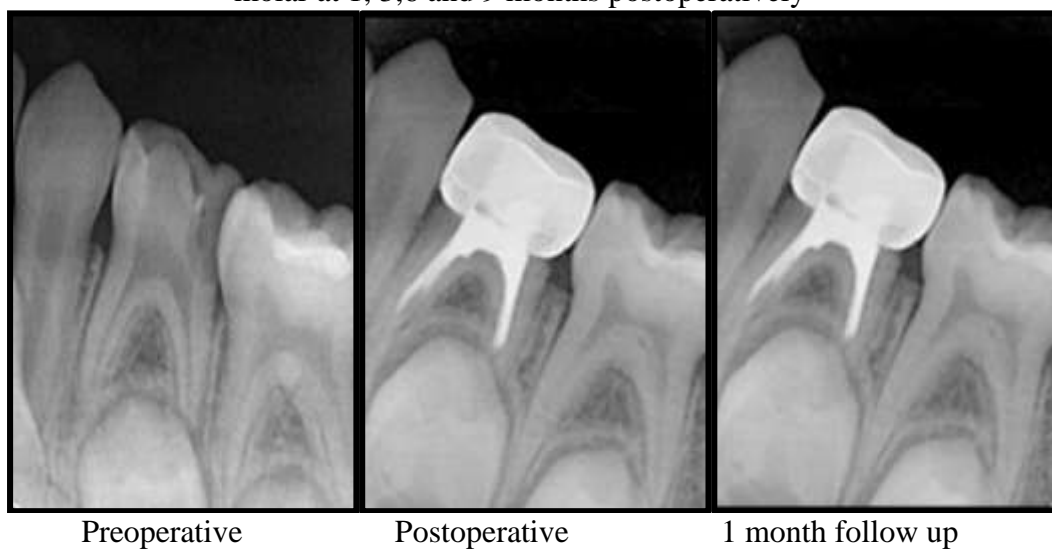


Figure 1. Radiographs showing zinc oxide eugenol obturation in mandibular left first primary molar at 1, 3, 6 and 9 months postoperatively



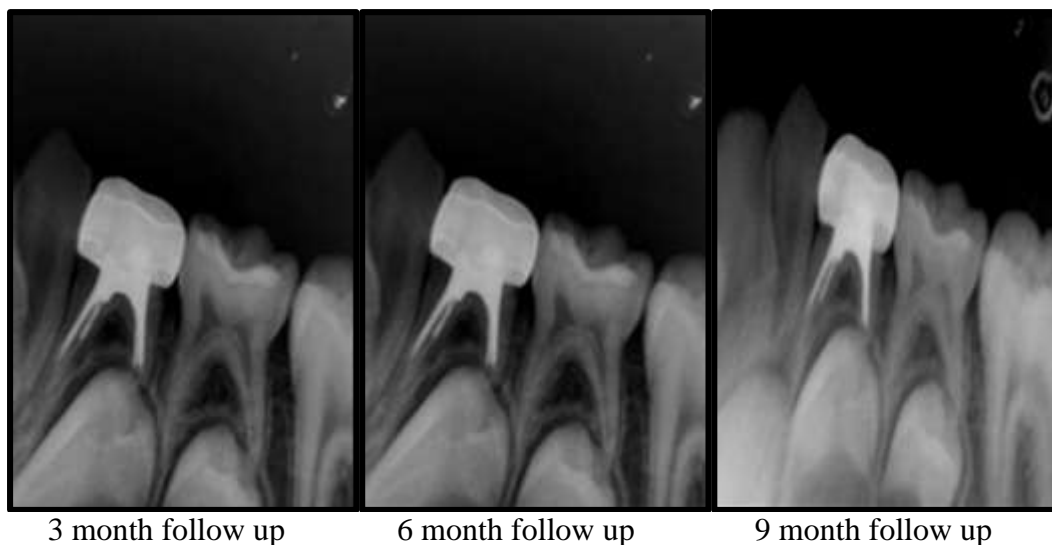


Figure 2. Radiographs showing Endoflas obturation in mandibular right first primary molar at 1, 3, 6 and 9 months postoperatively

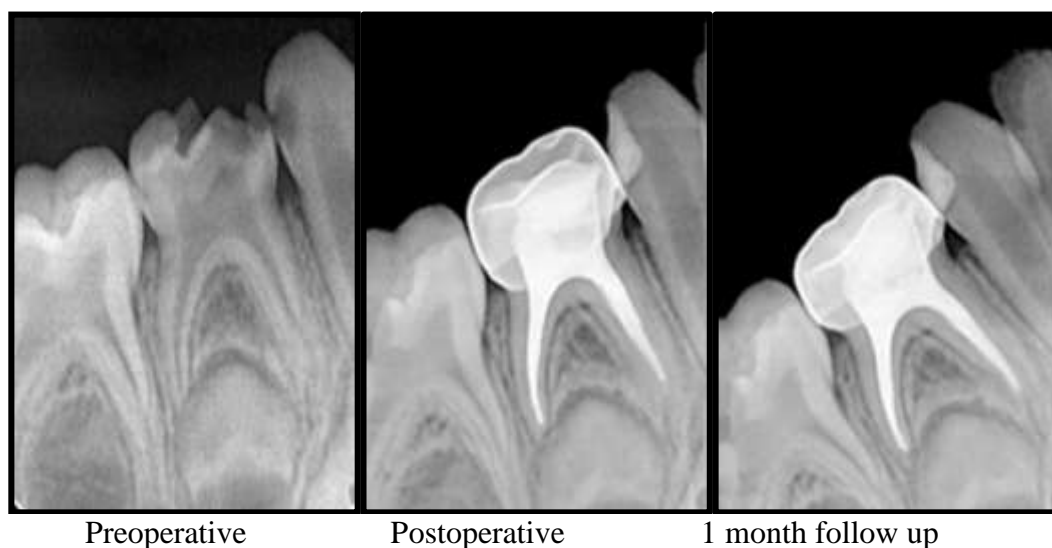


Figure 3. Radiographs showing Metapex obturation in mandibular left first primary molar at 1, 3, 6 and 9 months postoperatively

3. Results

Data was analysed using Statistical Package for Social Sciences (SPSS) version 21, IBM Inc. Descriptive data was reported for each

variable. The results are summed up in Tables 1 to 10 and Graphs 1 to 10. Chi square test was used for categorical variables. A level of $p < 0.05$ was considered statistically significant.

Table 1. Comparative clinical evaluation of pain in Group I (Zinc Oxide Eugenol), Group II (Endoflas) and Group III (Metapex) at 1, 3, 6 and 9 months postoperatively.

Duration	Total no. of teeth	Group I		Group II		Group III		p value
		Yes	No	Yes	No	Yes	No	
1 month	20	-	20	-	20	-	20	NA
3 months	20	-	20	-	20	-	20	NA
6 months	20	1	19	-	20	4	16	0.049*, Sig
9 months	20	1	19	-	20	5	15	0.005*, sig
p value		0.562, Ns		NA		0.016*, sig		

Chi square test, level of significance set at $p < 0.05$, Ns: Non-significant,*Sig: Statistically Significant

Table 2. Comparative clinical evaluation of Tenderness to Percussion in Group I (Zinc Oxide Eugenol), Group II (Endoflas) and Group III (Metapex) at 1,3,6 and 9 months postoperatively.

Duration	Total no. of teeth	Group I		Group II		Group III		p value
		Yes	No	Yes	No	Yes	No	
1 month	20	-	20	-	20	-	20	NA
3 months	20	-	20	-	20	-	20	NA
6 months	20	1	19	-	20	3	17	0.153, Ns
9 months	20	1	19	-	20	5	15	0.020*, Sig
p value		0.562, Ns		NA		0.019*, Sig		

Chi square test, level of significance set at $p < 0.05$, Ns:Non-significant , *Sig: Statistically Significant

Table3. Comparative clinical evaluation of abscess in Group I (Zinc Oxide Eugenol), Group II (Endoflas) and Group III (Metapex) at 1, 3, 6 and 9 months postoperatively.

Duration	Total no. of teeth	Group I		Group II		Group III		p value
		Yes	No	Yes	No	Yes	No	
1 month	20	-	20	-	20	-	20	NA
3 months	20	-	20	-	20	-	20	NA
6 months	20	-	20	-	20	3	17	0.043*, Sig
9 months	20	-	20	-	20	4	16	0.015*, Sig
p value		NA		NA		0.046*, Sig		

Chi square test, level of significance set at $p < 0.05$, Ns: Non-significant, *Sig: Statistically Significant

Table 4. Comparative clinical evaluation of mobility in Group I (Zinc Oxide Eugenol), Group II (Endoflas) and Group III (Metapex) at 1, 3, 6 and 9 months postoperatively.

Duration	Total no. of teeth	Group I		Group II		Group III		p value
		Yes	No	Yes	No	Yes	No	
1 month	20	-	20	-	20	-	20	NA
3 months	20	-	20	-	20	-	20	NA
6 months	20	-	20	-	20	3	17	0.043*, Sig
9 months	20	-	20	-	20	4	16	0.014*, Sig
p value		NA		NA		0.046*, Sig		

Chi square test, level of significance set at $p < 0.05$, Ns: Non significant, *Sig: Statistically Significant

Table 5. Comparative radiographic evaluation of Periapical and or Furcation radiolucency in Group I (Zinc Oxide Eugenol), Group II (Endoflas) and Group III (Metapex) at 1, 3, 6 and 9 months postoperatively.

Duration	Total no. of teeth	Group I		Group II		Group III		p value
		Yes	No	Yes	No	Yes	No	
1 month	20	-	20	-	20	-	20	NA
3 months	20	-	20	-	20	-	20	NA
6 months	20	1	19	-	20	5	15	0.020*, Sig
9 months	20	2	18	1	19	6	14	0.046*, Sig
p value		0.285, Ns		0.386, Ns		0.005*, Sig		

Chi square test, level of significance set at $p < 0.05$, Ns: Non significant, *Sig: Statistically Significant

Table 6. Comparative radiographic evaluation of External/Internal root resorption in Group I (Zinc Oxide Eugenol), Group II (Endoflas) and Group III (Metapex) at 1, 3, 6 and 9 months postoperatively.

Duration	Total no. of teeth	Group I		Group II		Group III		p value
		Yes	No	Yes	No	Yes	No	
1 month	20	-	20	-	20	-	20	NA
3 months	20	-	20	-	20	-	20	NA
6 months	20	1	19	-	20	5	15	0.023*, Sig
9 months	20	2	18	1	19	6	14	0.007*, Sig
p value		0.265, Ns		0.386, Ns		0.073, Ns		

Chi square test, level of significance set at $p < 0.05$, Ns: Non-significant, *Sig: Statistically Significant

Table 7. Comparative radiographic evaluation of Deviated eruption of succedaneous teeth in Group I (Zinc Oxide Eugenol), Group II (Endoflas) and Group III (Metapex) at 1, 3, 6 and 9 months postoperatively.

Duration	Total no. of teeth	Group I		Group II		Group III		p value
		Yes	No	Yes	No	Yes	No	
1 month	20	-	20	-	20	-	20	NA

3 months	20	- 20	- 20	- 20	NA
6 months	20	- 20	- 20	- 20	NA
9 months	20	- 20	- 20	- 20	NA
p value		NA	NA	NA	

Chi square test, level of significance set at $p < 0.05$, Ns: Non-significant, *Sig: Statistically Significant

Table 8. Overall success: Clinical evaluation of Group I (Zinc Oxide Eugenol), Group II (Endoflas) and Group III (Metapex) at 1, 3, 6 and 9 months postoperatively

Duration	Total no. of teeth	Group I		Group II		Group III		p value
		Yes	No	Yes	No	Yes	No	
1 month	20	-	20	-	20	-	20	NA
3 months	20	-	20	-	20	-	20	NA
6 months	20	1	19	-	20	4	16	0.049*, Sig
9 months	20	1	19	-	20	5	15	0.020*, Sig
p value		0.562, Ns		NA		0.016*, Sig		

Chi square test, level of significance set at $p < 0.05$, Ns: Non-significant, *Sig: Statistically Significant

Table 8 shows overall clinical success among the three groups. The comparison was done using chi square test across three

groups at 9 months postoperatively, the difference reached the level of significance. A maximum of 5 (25%) cases reported significantly higher failure in Group III as compared to other groups.



Graph 8: Comparison of overall clinical success among the groups Postoperatively.

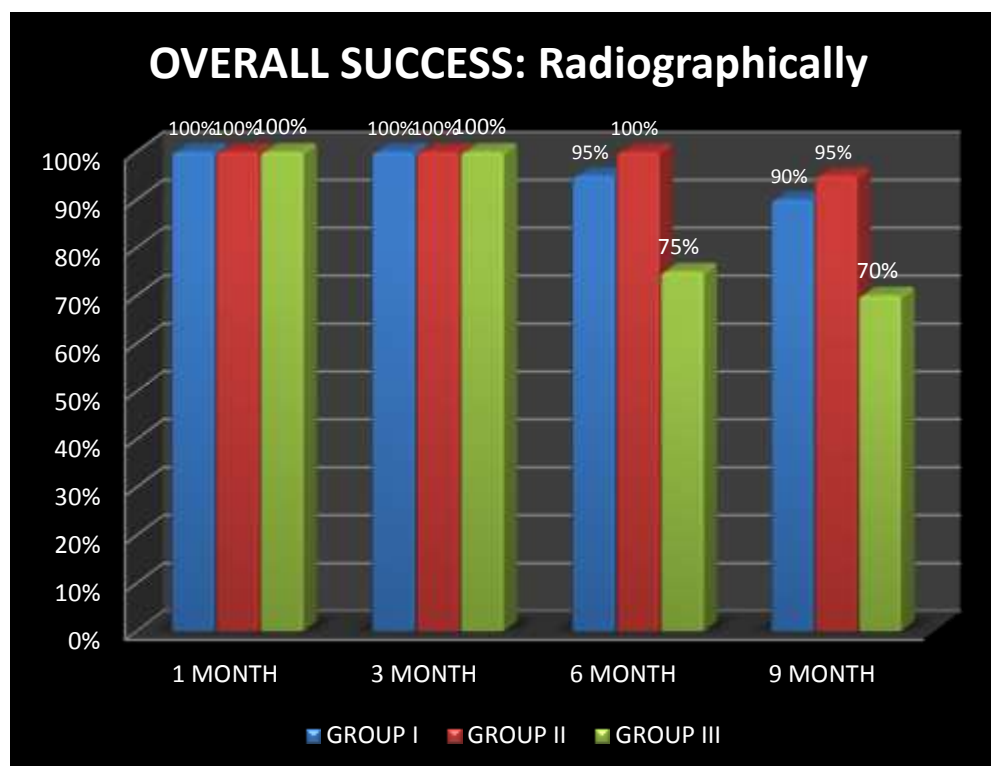
Table 9. Overall, Success: Radiographical evaluation of of Group I (Zinc Oxide Eugenol), Group II (Endoflas) and Group III (Metapex) at 1, 3,6 and 9 months postoperatively.

Duration	Total no. of teeth	Group I		Group II		Group III		p value
		Yes	No	Yes	No	Yes	No	
1 month	20	-	20	-	20	-	20	NA
3 months	20	-	20	-	20	-	20	NA
6 months	20	1	19	-	20	5	15	0.123*, Sig
9 months	20	2	18	1	19	6	14	0.007*, Sig
p value		0.265, Ns		0.386, Ns		0.073, Ns		

Chi square test, level of significance set at $p < 0.05$, Ns: Non-significant, *Sig: Statistically Significant

Table 9 shows overall success radiographically among the three groups. The comparison was done using chi square

test across three groups, at 9 months post operatively, the difference reached the level of significance. A maximum of 6 (30%) cases reported significantly higher failure in Group III as compared to other



Graph 9: Comparison of overall radiographical success among the groups postoperatively.

Table 10: Overall (Clinical and Radiographical) success of Group I (Zinc Oxide Eugenol), Group II (Endoflas) and Group III (Metapex) at 1, 3,6 and 9 months postoperatively.

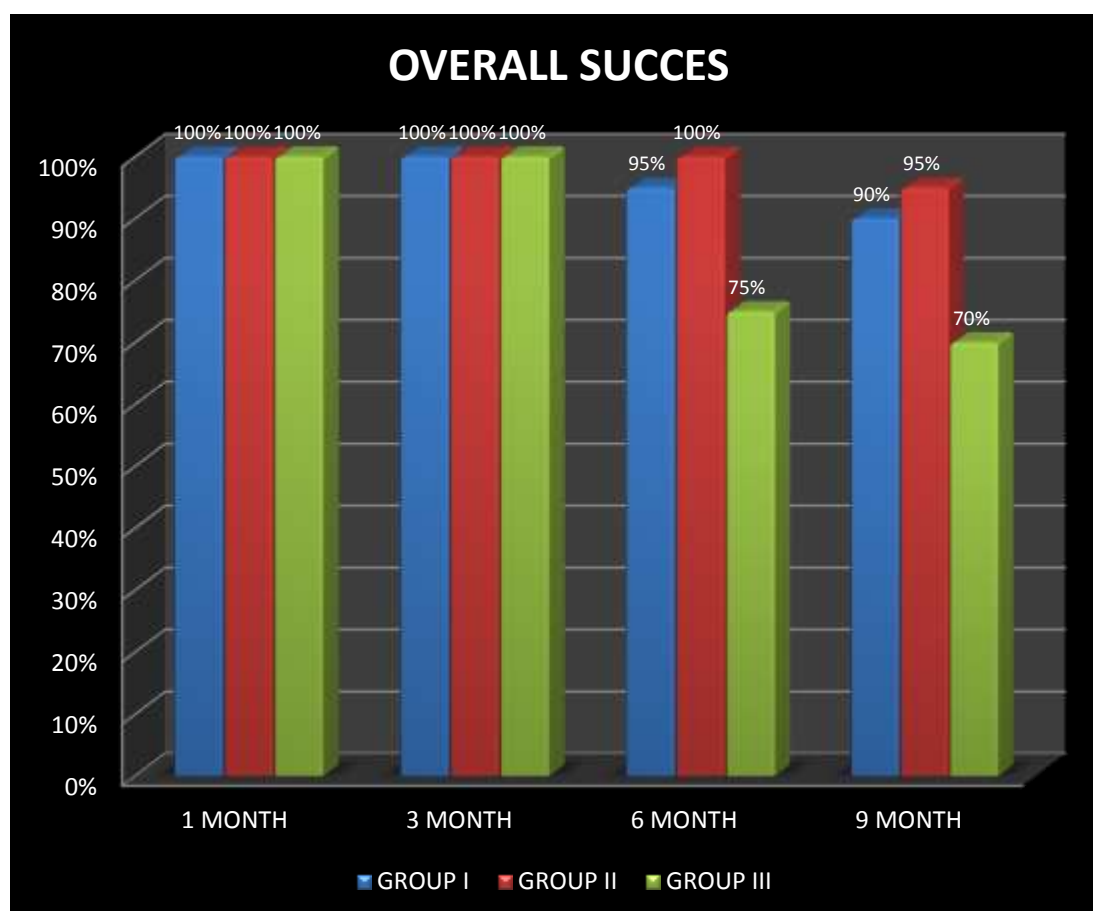
Duration	Total no. of teeth	Group I		Group II		Group III		p value
		Yes	No	Yes	No	Yes	No	
1 month	20	-	20	-	20	-	20	NA

3 months	20	- 20	- 20	- 20	NA
6 months	20	1 19	- 20	5 15	0.023*, Sig
9 months	20	2 18	1 19	6 14	0.007*, Sig
p value		0.265, Ns	0.386, Ns	0.073, Ns	

Chi square test, level of significance set at $p < 0.05$, Ns: Non-significant, *Sig: Statistically Significant

Table 10 shows overall (Clinical and Radiographical) success of three groups. At 9 months postoperatively, 2 (10%) cases were failure and 18 (90%) cases were successful for Group I, 1 (5%) cases was failure and 19 (95%) were successful for

Group II and 6 (30%) cases were failure and 14 (70%) cases were successful for Group III. The comparison was done using chi square test, across three groups, the difference reached the level of significance, a maximum of 6 (30%) cases reported significantly higher failure in Group III as compared to other groups.



Graph 10: Comparison of overall (clinical and radiographical) success among the groups postoperatively.

In the present study the success of treatment was determined after a period of 9 months

postoperatively. The overall success rate between the three groups was statistically

significant ($p < 0.05$ (Chi square test) but higher level of significance was seen in case of Group III (Metapex) at the end of 9 months follow up. Group II showed 95 % overall success followed by Group I (ZOE) and Group III (Metapex) which showed 90% and 70% overall success.

4. Discussion

Deciduous tooth pulpectomy has created a dilemma for the clinician owing to the tortuosity of the canals of a primary molar [8]. Preparation of the root canal in a primary tooth is based mainly on chemical means rather than mechanical debridement [9]. The presence of complex, tortuous root canals and danger of injury to the underlying tooth make it extremely difficult for a perfect biomechanical preparation. Hence, the prognosis after pulpectomy dependent on the qualities of the material that is used for obturation of the root canals [10].

An ideal pulpectomy material must possess properties like antibacterial effect, resorbability and should be harmless to periapical tissues and the developing tooth bud. In addition, it must be easy to fill the canals, adhere to the walls, must not shrink and should be easy to remove if required. It should be radiopaque and cause no discolouration of teeth (Rifkin 1980)[11]. Unfortunately, none of the obturating materials possess all these criteria.

The present study attempted to compare the clinical and radiographic success of three obturating materials in primary teeth namely Zinc Oxide Eugenol, Metapex and Endoflas over a 9 month follow up period, so as to identify an ideal or close to ideal obturation material that can be used effectively in primary teeth.

Traditionally, zinc oxide eugenol is the material of choice for obturating root canals in primary teeth [12]. Until 2008, it was the only material explicitly recommended in the clinical guidelines developed by the American Academy of Paediatric Dentistry (AAPD) [13]. In current study also, ZOE

gave an overall success rate of 90% at 9 months follow up post operatively. Dogra (2011) [14] also reported 90% success with 40 primary mandibular molars in children aged 4 to 9 years and showed that only partial resorption of excess material of zinc oxide eugenol took place. Delayed resorption of the material against the physiological root resorption was cited as the major disadvantage of zinc oxide eugenol [15]. In the current study no overfillings were recorded with zinc oxide eugenol and intraradicular resorption was slow.

Barcelos and Santos (2011) [16] in their systematic review showed that zinc oxide eugenol pulpectomies success rate varied from 85-100 %. Banerjee et al. (2019) [17], and Saxena, Koul and Grover (2017) [18] also reported an overall success rate of 83.33% and 85% with ZOE at 9 months follow up period. As the success rate was found to 90% in this study which is in contrast to Holan and Fucks (2002) [2] who reported the success rate of 65% with ZOE. In 2009, AAPD guidelines cited iodoform based pastes as suitable alternatives to zinc oxide eugenol [13]. Metapex is a combination of 30.3% calcium hydroxide, 40.4% iodoform and 22.4% silicone oil. The two most important reasons for using calcium hydroxide as a root canal filling material are stimulation of the periapical tissues to maintain health or promote healing and secondly for its antimicrobial effects [19]. One of the detrimental properties of calcium hydroxide is that it has a tendency to resorb earlier than the physiologic resorption of root. This creates a “hollow tube” effect leading to an unfilled root that eventually becomes a site for infection (Goldman & Pearson, 1965) [20]. Castagnola and Orlay (1952)[20] reported that iodoform paste is bactericidal to microorganisms in the root canal and loses only 20% of its potency over a 10-year period. Iodoform has a disadvantage that, it can produce a yellowish-brown discoloration of the tooth crowns, which

undermines esthetics [21].

Gupta and Das (2011) [10] showed an overall success rate of 85.71% in case of metapex pulpectomies over a 6 month follow up period where as in the current study metapex showed an overall success of 70% over a follow up period of 9 months.

Gonika et al. (2020) [22] also reported in their study the overall clinical and radiographical success of 100% and 68.75% success at the 12 month follow up. In the current study the overall clinical success and radiographical success was 75% and 70% at 9 months follow up. 5 (25%) clinical and 6 (30%) radiographical failures were reported at the end of the study.

Endoflas has the advantage of having the resorption limited to the excess material, which has been extruded periapically [23]. Resorption of the material does not occur within the canal. Thus, the material is neither resistant to resorption nor does it result in the hollow tube effect. **Aravind et al. (2006)** [24] reported on the antimicrobial efficacy of endoflas against *Enterococcus faecalis* and *Candida albicans* and found it to be even superior to amoxicillin and nystatin.

In current study also Endoflas gave the highest success rate of 95% at 9 month follow up. **Ramar and Mungra (2010)** [25] also compared the clinical and radiographic evaluation of Metapex, RC fill, and Endoflas for a duration of 9 months and showed that Endoflas gave an overall success rate of 95.1% followed by Metapex 90.5%, and RC Fill 84.7%. **Saxena, Koul and Grover (2017)** [18] reported an overall success of 95.7 % for Endoflas and considered it to be an effective root canal filling material in primary teeth due to its healing ability, bone regeneration characteristics, without depletion from the root canals.

An ideal root canal filling material for primary teeth should resorb at the same rate as the physiological root resorption. In this study at 9 months follow up, only 1(5%)

case in Group II (Endoflas) showed resorption of intracanal filling material at the same rate as the physiological root resorption, thus fulfilling the basic requirement of an ideal root canal filling material for primary teeth.

In current study the clinical and radiographic success rate of the ZOE group at 9 month follow up was 95%. Despite the high success rates, ZOE does not meet all criteria required for an ideal root canal filling material. It has certain disadvantages like less antimicrobial activity, delayed resorption of extruded material periapically [6], irritation to the periapical tissues [26].

Coll and Sadrian [3] also reported anterior crossbite, palatal eruption, necrosis of bone and cementum and deflected or ectopic eruption of the succedaneous tooth following ZOE pulpectomy.

In current study, Metapex showed the lowest success rate as its overall success rate declined from 100% at 3 months to 70% at 9 months. Metapex resorbed at a much faster rate than the physiological resorption of the root. Also periapical radiolucency was found to increase in 3 (15%) cases in metapex at the end of 9 months.

Brar et al. (2019) [27] also found highest success rate with Endoflas as it showed least incidence of resorption both outside and within the root canal whereas least success rate was observed with Metapex having the hollow tube effect in majority of the cases (70%) after the follow up of 12 months. **Kriplani et al. (2013)** [28] and **Harini priya et al. (2001)** [29] concluded that Metapex is having lowest antibacterial activity than ZOE.

In current study, at 6 months clinical and radiographic evaluation demonstrated that among the three groups Endoflas had success rate of 100% followed by ZOE (95%) and Metapex (75%) and at the end of 9 months success rate of Endoflas was 95% followed by ZOE(90%) and Metapex (70%).

5. Conclusion

Within the limitations of this *in vivo* study, it can be concluded that

1. Among all the three obturating materials, Endoflas showed the highest overall clinical and radiographical success rate whereas least success rate was observed in case of Metapex.

2. Endoflas - can be considered to be an effective obturating material in primary teeth due to its broadspectrum antibacterial activity, healing ability, bone regeneration characteristics and its resorption of excess material.

Hence, based on the observations from the current study, this knowledge can be applied to our daily clinical practice. More clinical trials with long term follow up should be conducted in the field of obturation materials in future so that data on large scale will be available, before a reliable conclusion can be drawn as to the best obturating material for endodontically treated primary teeth.

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