Endoflas, Zinc Oxide Eugenol and Metapex as Root Canal Filling Materials in Primary Molars—A Comparative Clinical Study

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Several materials have been used to fill root canals of primary teeth. Traditionally, zinc oxide eugenol was used for the purpose, until the introduction of calcium hydroxide and iodoform based materials. Another root canal filling material that contains zinc oxide eugenol, calcium hydroxide and iodoform is commercially available as Endoflas. The ***aim*** *of the study was to evaluate and compare the efficacy of Endoflas, zinc oxide eugenol and Metapex as root canal filling materials.* ***Method****: A total of forty-five primary molars from children aged 5-9 years were selected for a one stage pulpectomy procedure. Teeth were randomly divided into three groups of fifteen teeth each based on the type of root canal filling material used. All the molars were evaluated clinically and radiographically at regular intervals of 3, 6, 12 and 18 months. The observations were tabulated and statistically analyzed.* ***Results****: Endoflas and zinc oxide eugenol showed 93.3% success, whereas a higher percentage of success was observed with Metapex (100%). Overfilling and voids were more commonly seen in teeth filled with Metapex.* ***Conclusion****: There was no significant difference between the three root canal filling materials.*

Keywords*: Root canal filling, Endoflas, Metapex, zinc oxide eugenol, children.*
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INTRODUCTION

Pulpectomy is indicated for primary teeth with carious pulp exposures in which, following coronal pulpal amputation, the radicular pulp exhibits clinical signs of hyperemia or in cases where there is evidence of radicular pulpal necrosis, with or without caries involvement.[1]

The inherent difficulties in pulp therapy of primary teeth, more specifically related to instrumentation include molar root curvature, great number of collateral canals, complexity of the apical delta, process of physiological root resorption and the possibility of damage to the permanent successor. This has led to the search for an effective filling material which could overcome all instrumentation obstacles, leading to success of root canal treatment.[2, 3]

A major requirement for a successful root canal treatment of primary teeth is that the root canal filling material should resorb at the same rate as the physiologic resorption of the roots. In addition, the material should be radiopaque, non-toxic to the periapical tissue and tooth germ, easy to insert, non-shrinkable and should have disinfectant properties.[2-6] None of the materials currently available meet all these criteria.[4]

Since long zinc oxide eugenol has been routinely used for filling root canals of primary teeth with a success rate of 65% to 88.5%.[7-11] However this material is known to be irritating to the periapical tissues, does not resorb at the same pace as the roots and can cause necrosis of bone and cementum.[12,13]

The addition of iodoform to calcium hydroxide containing pastes has received attention in the past. In contrast to zinc oxide eugenol, these materials are known to easily resorb from the periapical area and cause no foreign body reaction.[14] They also have potent germicidal properties. Premixed calcium hydroxide and iodoform paste (Vitapex and Metapex) are presently available as premixed syringe in the market.

In the recent past a material containing zinc oxide eugenol, iodoform and calcium hydroxide was introduced in South America with the commercial name 'Endoflas.'[15] Endoflas is a material that encompasses the desirable properties of zinc oxide eugenol, calcium hydroxide and iodoform. It is hydrophilic, firmly adheres to the surface of the root canal walls, and has an ability to disinfect the dentinal tubules.

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Since the components are biocompatible, it can be removed by phagocytosis, hence making the material resorbable.[15]

Several studies have compared zinc oxide eugenol with iodoform based calcium hydroxide pastes, mainly Vitapex for root canal treatment in primary teeth.[14,16,17,18] In our country Metapex is more easily and widely available in the market. Metapex is less expensive than Vitapex (costing approximately 1/3rd the price of Vitapex) and is thus more commonly used. This study was undertaken to evaluate and compare Endoflas, zinc oxide eugenol and Metapex as primary root canal filling materials.

MATERIALS AND METHOD

Subjects for the study were normal and healthy children aged 5-9 years, attending the Department of Pedodontics and Preventive dentistry, The Oxford Dental College, Hospital and Research Centre, Bangalore. A detailed case history was recorded and oral examination was done. Standardized intraoral periapical radiographs showing all the roots and their apices were taken. Patients were selected according to the following criteria:

Inclusion criteria[19]

1. Young cooperative patients with no history of systemic illness/disease or recent hospitalization.
2. Tooth with carious pulp exposure.[16]
3. Tooth with carious pulp exposure, diagnosed as having irreversible pulpitis on basis of reported symptoms and/or clinical findings. (eg. profuse hemorrhage following pulpotomy procedure).[19]
4. Tooth which is restorable.[16]
5. Tooth with at least two-third of intact root length.[16,20]
6. Tooth showing radiographic signs of pulpal or interradicular involvement ranging from slight thinning of the trabeculae to furcal and/or periapical radiolucency.[14]

Exclusion criteria [21,22]

1. Tooth associated with the presence of a soft tissue/ dentoalveolar abscess and/or sinus, and not allowing for a single-visit pulpectomy procedure.
2. Tooth with presence of exudate requiring more than a one stage pulpectomy procedure.[19]
3. Tooth with preshedding and abnormal pathologic mobility.[23]
4. Tooth with internal/external root resorption involving permanent tooth follicle.[14,16]
5. Tooth showing perforation of pulpal floor.[14]

A total of 45 first and second primary molars (maxillary and mandibular) that were indicated for a one stage pulpectomy procedure were selected.[19] The parents and/or guardian were informed about the condition of the child's dentition. Explanation was then given regarding the treatment, the advantages and risks, if any. The nature and duration of the study was also briefly explained. Participation in the study was voluntary and prior written consent was obtained from the parents or guardians. Prior to the study, permission was also taken from the ethical committee of the institution.

Forty five primary molars were randomly divided into three groups of fifteen teeth each, based on the type of material used for root canal filling (Table 1). The materials used were: (1) Endoflas FS (Sanlor and Cia. S.en C.S., Cali, Colombia) which consists of a powder(tri-iodomethane and iodine di-butilorthocresol 40.6%, zinc oxide 56.5%, calcium hydroxide 1.07%, barium sulphate 1.63%) and a liquid(eugenol and para-monochlorophenol); (2) Metapex (Meta Biomed Company Ltd.) containing iodoform 30-40%, calcium hydroxide, silicon oil and; (3) zinc oxide eugenol.

TABLE 1. Distribution of Primary Molars According to Type of Filling Material

PRIMARY MOLARS	METAPEX n (%)	ENDOFLAS n (%)	ZINC OXIDE EUGENOL n (%)	TOTAL NO. OF TEETH
Maxillary 1st	1 (6.67%)	2 (13.33%)	0 (0.0%)	03
Maxillary 2nd	2 (13.33%)	0 (0.0%)	0 (0.0%)	02
Mandibular 1st	6 (40.0%)	5 (33.33%)	8 (53.33%)	19
Mandibular 2nd	6 (40.0%)	8 (53.33%)	7 (46.67%)	21
Total	**15**	**15**	**15**	**45**

Technique for Root Canal Treatment

Following local anesthetic administration, rubber dam isolation of the tooth was carried out. Dental caries and overhanging enamel were removed using a #330 bur at high speed with a water coolant. Access to the coronal pulp was obtained with # 8 round bur. Necrotic tissue from the pulp chamber was removed using a spoon excavator. Pulpal tissue was extirpated from the root canals using either smooth broaches or H files. A diagnostic radiograph with a K file placed in each canal was taken to ascertain the length of the root canal. The working length was kept 1mm short of the radiographic apex. The cleaning and shaping of the root canals was carried out with H file using a pullback motion.[24] Care was taken to selectively file the root canals. This maintained more pressure along the outer wall of the canal and not towards the generally thin interradicular area, thus minimizing the risk of perforation. Irrigation of the root canals was alternatively done with saline and 1% sodium hypochlorite solution. The canals were then dried with absorbent paper points and were ready for obturation.

With Metapex, the filling material was transported to the canals directly from its pre-packed polypropylene syringe. The syringe was inserted into the canals, near the apex. The paste was pressed down into the canals and when the paste flowed back from the canals into the pulp chamber the syringe was then slowly withdrawn.[15] The paste was not used to fill the pulp chamber.

With both Endoflas and zinc oxide eugenol, a homogenous thin mix was used to coat the root canal walls using reamers. Following this, a thick mix of the material was pushed into each root canal with a suitable root canal hand plugger and/or cotton pellets.[14]

An immediate post-operative radiograph was taken in order to determine the extent of root canal filling material in the canals. The filling was rated as 'flush', 'underfilled' and 'overfilled' according to Moskovitz *et al* [20] After the evaluation of quality of filling, additional material was added only in 8 teeth that were underfilled. A flush filling was confirmed by taking a second post operative radiograph. The pulp chamber was then filled with a thick paste of zinc oxide eugenol. All the teeth were restored with miracle mix, and stainless steel crown were given within one week of treatment.

Criteria for clinical success [14,15,21]

- No gingival swelling/inflammation/redness.
- No sinus opening in the oral mucosa or purulent exudate expressed from the gingival margin.
- No abnormal mobility other than mobility due to normal exfoliation.
- Absence of pain on percussion/tenderness.

Criteria for radiographic success [15,21]

- No evidence of extensive pathologic root resorption.
- Reduction or no change in pre-operative pathologic interradicular and/or periapical radiolucency.[14,20,25]
- No evidence of development of new post-operative pathologic radiolucency involving the succedaneous tooth germ.[14]

All patients were recalled at 3, 6, 12 and 18 months for clinical and radiographic evaluation of the treated teeth.

Data obtained was subjected to statistical analysis, using Freidman Anova and Chi square tests. Fisher exact test was used to find the significance of study parameters between the three groups. The statistical software namely SPSS 15.0, Stata 8.0, MedCalc 9.0.1 and Systat 11.0 were used for anaysis of the data. Significance was considered at $0.01<p\leq0.05$.

RESULTS

With regard to the quality of filling, a higher number of overfilled canals and voids were observed in teeth filled with Metapex. More number of under filled canals were seen with Endoflas and Zinc Oxide Eugenol. There was no significant difference between the 3 filling materials (Table 2).

At the third month of evaluation, all the teeth filled with Metapex showed no clinical signs and symptoms. Radiographically, none of them showed any signs of a developing pathosis. One tooth overfilled with zinc oxide eugenol presented with tenderness and severe mobility. Intraoral periapical radiograph showed pathological resorption of the roots. Also, gingival swelling together with pain was observed in relation to one tooth filled with Endoflas. Radiographically, the development of a new pathologic radiolucency involving the succedaneous tooth was also observed in relation to this tooth. Both these teeth were extracted. Another radiographic finding at the third month of evaluation was of a slight reduction observed in the pre-operative inter-radicular radiolucency associated with another tooth filled with Endoflas. This reduction was seen to continue at further evaluation. At 6, 12 and 18 months there were no clinical and radiographic findings in relation to any of the teeth. However, there was no significant difference between the three root canal filling materials (Table 3).

TABLE 2. Assessment of Quality of Root Canal Filling

QUALITY OF FILLING	METAPEX n (%)	ENDOFLAS n (%)	ZINC OXIDE EUGENOL n (%)	P VALUE	TOTAL
Flush	10 (66.7%)	10 (66.7%)	10 (66.7%)	1.000	30
Underfilling	02 (13.3%)	03 (20.0%)	03 (20.0%)	1.000	08
Overfilling	03 (20.0%)	02 (13.3%)	02 (13.3%)	1.000	07
Presence of voids	03 (20.0%)	02 (13.3%)	02 (13.3%)	1.000	07
Total	**18**	**17**	**17**		**52**

Chi square test, Fisher Exact test for significance

DISCUSSION

Several investigators agree that total removal of the pulp tissue from the root canals of primary teeth cannot be achieved because of their complex and variable morphology. It is also difficult to eliminate the wide range of organisms, which are often present in infected primary root canals.[9,26-28] In addition to irrigating root canals, quality of the paste used for root canal filling determines the prognosis of endodontically treated primary teeth.[5,29]

Materials used to fill root canals of primary teeth include zinc oxide eugenol, calcium hydroxide and iodoform based pastes such as Vitapex, Metapex, KRI paste, Maisto's paste and Endoflas. Success rates of these materials have been reported to range from 68.7% to 100%.[5,8,15,21,30,31]

TABLE 3. Percentage Of Success Of The Filling Materials

Evaluation period in months	Metapex (n=15)		Endoflas (n=15)		Zinc Oxide Eugenol (n=15)		P Value
	Clinical Success	Radiographic Success	Clinical Success	Radiographic Success	Clinical Success	Radiographic Success	
03	100%	100%	93.3%	93.3%	93.3%	93.3%	0.097+
06	100%	100%	93.3%	93.3%	93.3%	93.3%	0.097+
12	100%	100%	93.3%	93.3%	93.3%	93.3%	0.097+
18	100%	100%	93.3%	93.3%	93.3%	93.3%	0.097+

+Suggestive of significance ($0.05<p<0.10$)
Friedman ANOVA, Fisher Exact test for significance

Although Vitapex and Metapex are similar in their composition, almost all studies have evaluated Vitapex only.[14,25,32] (Vitapex contains 40.4% iodoform, 30.3% calcium hydroxide and 22.4% silicone). Also, there are very few reports on the use of Endoflas as a root canal filling material.[15,20,33] Most comparative studies have evaluated only two materials.[15,34,35] Hence this study compared three root canal filling materials, namely Endoflas, zinc oxide eugenol and Metapex.

In the present study, overfill of root canal filling material was seen in the periapical area and not in the interradicular area. This may be due to the filling technique followed as well as the absence of pre-operative bone pathology in the furcation area. The higher number of overfilled canals and presence of voids observed with Metapex is due to the thinner consistency of the premixed paste which may flow more easily into the narrow and tortuous canals of primary molars and reach the apex or even beyond.[14] It can also be due to the technique followed, wherein the filling material is pressed into the canal. Unlike zinc oxide eugenol, Metapex can be rapidly eliminated when extruded extraradicularly and does not set to a hard mass. However, there is a possibility of intraradicular resorption in the long term. An unfilled root canal can be permeated with tissue fluid that becomes stagnant and eventually a nidus for infection and is termed as 'hollow tube effect.'[36] In comparison to other iodoform based pastes, the resorption of Endoflas usually coincides with the physiologic root resorption. This is because it contains more than 50% zinc oxide eugenol that is slowly removed by giant cells.[20] A distinctive property of Endoflas is that it does not wash out from the canals and its resorption is limited only to the excess that is extruded without depleting the intraradicular material.[15]

Fuks *et al* [15] reported that 71% of teeth overfilled with Endoflas had pre-operative bone pathology. They suggested that pathological resorption of the bone and root apex can facilitate penetration of the paste resulting in an overfilling. In our study the tooth that had a pre-operative periapical radiolucency and was filled with Endoflas did not show any overfilling. The incremental technique that was followed could have reduced the chances of an overfill. In contrast, Fuks *et al* [15] did not find 29% of the teeth to be overfilled in spite of using a lentulo spiral to introduce the filling material.

According to Moskowitz *et al*,[20] rate of success did not significantly relate to the extent of root canal filling nor the presence of a pre-existing radiolucent area. They emphasized that success depended on prevention of microleakage and placement of a permanent restoration as soon as possible after completion of root canal treatment. In our study too, stainless steel crowns were given as they provide complete coverage and protect the tooth against leakage at the pulpal space-restoration interface.

In comparison to both zinc oxide eugenol and Endoflas, Metapex showed 100% success in our study. This is in accordance with earlier studies that have reported high success rates with the use of calcium hydroxide iodoform pastes.[25]

In the present study, pathologic root resorption of a tooth overfilled with zinc oxide eugenol could be primarily due to the presence of eugenol. Eugenol has been shown to irritate periapical tissues and thus cause a foreign body reaction.[12,37] The development of a new pathologic radiolucency involving the succedaneous tooth germ was observed in one tooth filled with Endoflas. There could have been some residual infection in the accessory canals causing perforation of the pulpal floor resulting in follicular involvement. A high success rate of 93.3% was observed with Endoflas in comparison to a study by Fuks *et al* [15] who reported 70% success. However, it is important to note that 62% of the teeth that they had selected presented with periapical lesions at baseline. In our study also, a pre-operative inter-radicular radiolucency associated with one primary molar filled with Endoflas showed a slight reduction in radiolucency, at the third month of evaluation. Healing may be related to the antibacterial properties of calcium hydroxide and iodoform present in Endoflas.

At the end of evaluation period, Metapex showed a higher success (100%) than both zinc oxide eugenol (93.3%) and Endoflas (93.3%). This difference was not statistically significant.

All the three root canal filling materials evaluated were successful. The choice of a root canal filling material can vary from tooth to tooth. The filling technique to be employed and the cost of the material must also be taken into consideration. All these factors contribute to the prognosis of root canal treatment.

CONCLUSION

Metapex showed higher success as a root canal filling material. However, there was no significant difference between the three root canal filling materials.

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