

**Comparison of Clinical and Radiographic Success of  
Three Obturation Materials in Primary Teeth -  
A Randomized Controlled Clinical Trial**

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## **KSR INSTITUTE OF DENTAL SCIENCE AND RESEARCH**

**DEPARTMENT OF PEDODONTICS AND PREVENTIVE DENTISTRY**

### **Certificate**

This is to certify that the dissertation titled **“Comparison of Clinical and Radiographic Success of Three Obturation Materials in Primary Teeth - A Randomized Controlled Clinical Trial”** is a bonafide work done by **Dr.K.Saravana Kumar**, Postgraduate Student, during the course of the study for the degree of **“Master of Dental Surgery”** in Department of Pedodontics and Preventive Dentistry, KSR Institute of Dental Science and Research, Tiruchengode during the period of 2013-2016.

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**COMPARISON OF CLINICAL AND RADIOGRAPHIC SUCCESS OF THREE  
OBTURATION MATERIALS IN PRIMARY TEETH- A RANDOMIZED  
CONTROLLED CLINICAL TRIAL”**

**Abstract:**

**Aim**

To evaluate and compare the clinical and radiographic success of zinc oxide eugenol, metapex and endoflas as obturating materials in pulpectomy of primary teeth at 3 and 6 months follow up.

**Methodology**

A total of 60 carious primary molars with clinical signs and symptoms indicative of irreversible pulpitis were selected from 36 children, aged 4 to 9 years and free from any systemic disease who visited the outpatient ward of Department of Pedodontics, KSRIDSR, Tiruchengode between January 2015 till April, 2015. The teeth were selected on specific inclusion and exclusion criteria randomly divided into three groups A, B and C. The pulpectomy procedure was performed under rubber dam isolation after administration of local anaesthesia. The selected teeth were randomly obturated with zinc oxide eugenol in group A, metapex in group B and zinc oxide eugenol and endoflas as Group C. Post operative radiographs were taken immediately after obturation. All obturated teeth received an entrance restoration, followed by preformed stainless steel crown. The teeth were evaluated at 3 and 6 months respectively using clinical and radiographic criteria cited by Gupta and Das (2011). Clinical and radiographic success was scored by two well-trained pediatric dentists. Inter examiner reliability was correlated by using Cohen's Kappa coefficient ( $k = 0.8$ ).

**Statistics:** Statistical analysis was done using SPSS version 17.0 (Chicago: SPSS Inc) with statistical significance set at  $p \leq 0.05$ . Chi square test was employed for the statistical analysis.

**Results and Conclusion:** Zinc oxide eugenol had 100 % overall success rate, followed by endoflas with 98.6% and metapex with 92.1%. Intergroup comparison of overall success was statistically significant ( $p = 0.0027$ ). Both zinc oxide eugenol and endoflas showed 100% clinical success rate at 3 and 6 months interval. Metapex showed 100 % clinical success at the 3<sup>rd</sup> month, but it declined to 89.4 % in the 6<sup>th</sup> month follow up. Similarly, inter group comparisons of clinical success between the three groups was highly statistically significant at the 6<sup>th</sup> month interval ( $p < 0.001$ ). Intra group comparison of radiographic success was highly statistically significant for metapex ( $p < 0.001$ ) and statistically significant for the endoflas ( $p = 0.045$ ). Inter group comparison between the three groups was statistically significant at the 3<sup>rd</sup> and 6<sup>th</sup> month interval with  $p = 0.004$  and  $p < 0.001$  respectively.

**Key words:** Zinc oxide eugenol, Metapex, Endoflas, Clinical, Radiographical

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## Introduction

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.<sup>1</sup> In the past, extraction was the only solution to treat any pulpal injury for relieving pain and preventing complications.<sup>2</sup> In 1879, Witzel's pulpotomy technique advocated amputation of infected tissue and retention of devitalized pulp tissue in the canals which was sealed with strong antiseptic cement. The treatment of non vital pulps with pulpectomy was initially questioned due to fear of damage to the erupting successors and the clinical difficulty of the procedure.<sup>3</sup> The approach to invasive pulpal therapy became popular with the invention of local anaesthetics in the 1920's.<sup>4</sup> Practitioners gradually started accepting the rationale behind the extirpation of the entire pulpal tissue and obturation of the root canals with appropriate sealer cements.<sup>3</sup>

Understanding the pulp morphology, root genesis and physiologic resorptive processes of primary teeth is essential to re-establish healthy periodontal tissues, prevent pathologic root resorption and maintain the primary tooth in a healthy state to space maintenance.<sup>5</sup> Child cooperation and parent consent are critical to the success of endodontic procedures.<sup>6</sup>

The main objectives of endodontic treatment is removal of diseased pulp tissue, resolution of the radiographic infectious process within 6 months and physiological resorption of the primary roots and filling material so as to permit normal eruption of the succedaneous tooth.<sup>7</sup> This is achieved by careful cleaning and shaping followed by the complete obturation of the canal space. Hence, the ultimate goal of endodontic obturation is creating a fluid-tight seal along the length of the root canal system, from the coronal opening to the apical termination.<sup>8</sup> 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 root canal filling materials in primary teeth are as follows: 1. It should resorb at a similar rate as the primary tooth. 2. It should be harmless to the periapical tissues and to the permanent tooth germ; if pressed beyond the apex it should resorb readily. 3. It should have a stable disinfecting power. 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 not be soluble in water. 7. It should be radio opaque and not discolour the tooth.<sup>9</sup> The most commonly used obturation materials in pulpectomy procedures are zinc oxide eugenol, calcium hydroxide, and iodoform paste. Many studies have been carried for evaluation and comparison of success rates of various root canal filling materials used in pulpectomy procedures.<sup>10</sup>

Zinc oxide eugenol, introduced by Bonastre in 1837 is one of the most widely used root canal filling material in primary teeth. Eugenol has anti-inflammatory and analgesic properties which are very useful after a pulpectomy procedure.<sup>11</sup> It has a disadvantage in that excess material forced through the apex can remain in the apical tissue during the process of physiologic root resorption, taking months or years to resorb.<sup>12</sup>

Calcium hydroxide was introduced in 1930 by Herman as a pulp capping material. In 1966, Frank described the clinical method to use calcium hydroxide paste for stimulating root closure. Pure calcium hydroxide paste has a high pH (approximately 12.5-12.8) and is mildly irritating to vital pulp tissue. It has bacteriostatic properties and its mechanism of actions are achieved through the ionic dissociation of Ca (2+) and OH (-) ions and their effect on vital tissues, the induction of hard-tissue deposition and the antibacterial properties. Calcium

hydroxide is used solely or in combination with iodoform. Calcium hydroxide - iodoform mixture is commercially available as Metapex which resorbs if inadvertently pushed beyond the apex. The pH gradient of the cytoplasmic membrane is altered by the high concentration of hydroxyl ions of calcium hydroxide resulting in protein denaturation. Iodoform, a known bactericide suppresses residual bacteria in the canal or periapical region. This material is easy to use and it resorbs at a slightly faster rate than that of the root.<sup>13</sup> It has no toxic effects on its permanent successor and is radio opaque. Metapex contains a radiopaque component barium sulfate which guides the placement of material when seen radiographically.<sup>14</sup>

Endoflas is a resorbable paste manufactured in South America. It contains components similar to that of Vitapex (40% iodoform along with silicone oil), with the addition of zinc oxide and eugenol. This paste is obtained by mixing a powder containing tri-iodomethane and iodine dibutylorthocresol (40.6%), zinc oxide (56.5%), calcium hydroxide (1.07%), barium sulphate (1.63%) and with a liquid consisting of eugenol and paramonochlorophenol. The material is hydrophilic and can be used in mildly humid canals. It firmly adheres to the surface of the root canals to provide a good seal. It has a broad spectrum of antibacterial activity for disinfecting dentinal tubules and remotely located accessory canals which also cannot be cleansed mechanically. The components of Endoflas are biocompatible and are removed by phagocytosis, which makes it resorbable. Unlike other pastes, Endoflas only resorbs when extruded extra-radicularly and does not wash out intra-radicularly. The disadvantages of this material are tooth discoloration and its eugenol content which can cause periapical irritation.<sup>15</sup>

In the present study, the clinical and radiographic success rates of three different obturation materials Zinc oxide eugenol, Metapex and Endoflas has been evaluated. Zinc oxide eugenol and Metapex though commonly used do not fulfill all the requirements of an ideal



obturation material. Ramar and Mungara (2010) report a 95.1% success rate with Endoflas with good healing ability, bone regeneration and absence of an intraradicular washout.<sup>15</sup> Fuks et al (2003) reported 70% success clinical success rate with endoflas with a 100% decrease in periapical radiolucency.<sup>16</sup> Studies by Chawla et al indicate a 100 % radiographic success with 54.8% complete bone regeneration.<sup>17</sup> Very little literature exists on the use of Endoflas as an effective obturation material alternative to Zinc oxide eugenol and Metapex. Hence the study attempts to compare the clinical and radiographic success of these three materials to identify the ideal obturation material in primary teeth.

**Aim**

To evaluate and compare the clinical and radiographic success of zinc oxide eugenol, metapex and endoflas as obturating materials in pulpectomy of primary teeth at 3 and 6 months follow up.

**Objectives**

1. To evaluate and compare the clinical and radiographic success of three obturation materials in pulpectomies performed in primary molar teeth of children in the age group of 4 to 9 years at 3 and 6 month intervals.
2. Intra group comparison of the three obturation materials both clinically and radiographically at 3 and 6 month intervals.
3. To evaluate the overall success of these three obturation materials at 3 and 6 months follow up.
4. To determine the cause for clinical and radiographic failures at 3 and 6 months in pulp therapies using these three obturation materials.

## Review of literature

**Coll JA, Casper JS (1985)<sup>18</sup>** studied root resorption in non-vital primary teeth after a single appointment formocresol pulpectomy. Forty one pulpectomies were done in non vital primary molars from 37 subjects in the age group of (2 years, 10 months to 8 years, 10 months). At an initial follow-up examination at 21 months, 80.5% of the pulpectomies were successful clinically and radiographically. The study showed that age of the patient, the time interval, and the type of tooth, had no significant effect on the success of the procedure. Pulpectomies tended to have root resorption similar to contralateral pulpotomies. There were no overretention and succedaneous premolars showed few cases of hypoplasia. In almost 50% of the cases, zinc-oxide eugenol retention in the gingival sulcus was reported after exfoliation.

**Aylard SR, Johnson R (1987)<sup>19</sup>** in their study evaluated and compared five different techniques of obturation using zinc oxide eugenol cement in both straight and curved simulated root canals and their depth- of-fill capabilities was assessed. The techniques included endodontic pressure syringe, the mechanical syringe, the lentulo spiral, the Jiffy TM tube, and the tuberculin syringe. Statistical analysis revealed that the instruments of choice for filling straight canals were the endodontic pressure syringe and the lentulo spiral ( $P= 0.05$ ). Also, the lentulo spiral was found be the instrument of choice when filling curved canals ( $P = 0.05$ ). When considering the depth-of-fill properties, it was concluded that the lentulo spiral was the best overall zinc oxide eugenol filling tool.

**Coll JA, Sadrian (1996)**<sup>20</sup> evaluated factors that affected zinc oxide eugenol pulpectomy success rate and the effect on its successor tooth eruption and enamel formation. Eighty one zinc oxide eugenol pulpectomies (30 incisors, 51 molars) from 65 patients were followed and overall pulpectomy success was 77.7% with no difference between molars and incisors ( $p = 0.53$ ). Enamel defects were observed in 18.7% of succedaneous teeth which is statistically significant. It was mainly caused by pre existing infection which resulted in excess root resorption but was not related to the over retention of ZOE filler. They reported a 20% incidence of anterior cross-bite or palatal eruption following incisor pulpectomy and a 21.6% ectopic eruption of premolars following primary molar pulpectomy. Approximately 95.9 % of the pulpectomized teeth were lost at their normal exfoliation time or earlier, while 35.8% required extraction due to prolonged retention by soft tissue. Pulpectomy success rates were predominantly dependent on the amount of primary tooth root resorption ( $P = 0.001$ ) Short filled or up to the apex filled pulpectomies showed significantly greater success ( $P = 0.011$ ) than long filled teeth.

**Randall RC (2002)**<sup>21</sup> in their review on the efficiency and usage of preformed metal crowns (PMCs) from eighty three research papers searched on Medline for primary and permanent molar teeth. The papers addressed various regarding preformed metal crowns like indications for usage, placement techniques, risks, longevity, cost effectiveness and so on. The study reported results of a systematic review and a meta-analysis done on 105 studies and compared preformed metal crowns with amalgam restorations in primary molars. The preformed crowns were indicated for restoring large carious lesions and amalgam for the less involved teeth. A 2 year retrospective evaluation by Papathanasiou et al carried out a 2-year retrospective on 604 restorations that included amalgam, composite and glass ionomer cements in patients between 3 to 10 years of age revealed that failure rates for glass ionomer cements was 73% ,

while composite had 43% and amalgam 30 % in terms of longevity. Preformed metal crowns showed the least 20 % failure rate. Moreover, the extra time and cost incurred for the dental practitioner in replacing restorations were discussed. The authors concluded that a well fitting pre formed metal crown can permit the tooth its full lifetime.

**Bawazir OA, Salama FS (2003)<sup>22</sup>** suggested administration of local anesthesia for primary teeth with necrosed pulps and also during the second visit as it will anesthetize the gingiva for rubber dam placement. Over instrumentation should be avoided in primary teeth as the objective is to clean and not to shape the canals. Single visit pulpectomy can be done when acute conditions are present. The authors state that materials like calcium hydroxide and iodoform should be used for obturation in primary teeth.

**Bawazir OA, Salama FS (2006)<sup>10</sup>** in their study appraised two different obturation techniques, one using a lentulo spiral mounted in a slow-speed handpiece and the other a hand-held technique in primary teeth of 24 children who were in the mean age of 6.71 years. The children received 50 single-visit zinc oxide eugenol pulpectomies in primary molars. Obturation was done either by a lentulo spiral mounted in a slow-speed hand piece or by a hand-held lentulo spiral. Evaluation was done independently by two examiners immediately following treatment and as 6 months follows up. According to the quality of the root canal filling it was defined as an underfilling if all the canals were filled more than 2mm short of the apex; An optimal filling is if one or more of the canals having ZOE ending at the radiographic apex or up to 2 mm short of the apex; and as an overfilling if any canals showed zinc oxide eugenol outside the root .The results showed 64% (16/25) optimal fillings with the lentulo spiral mounted in the slow-speed hand piece technique and a 96% (21/22) clinical success rate. There was 48% (12/25) optimal fillings and a 92% (23/25) clinical success rate in the hand-held lentulo spiral group. The radiographic

success for over- and optimally filled canals, when combining both lentulo groups, was significantly greater than under-filled root canals ( $p = .009$ ). No statistically significant difference was observed between the two techniques based on the quality of obturation or the success rate.

**Pascon FM, Kantovitz KR, Puppin-Rontan RM (2006)**<sup>23</sup> The paper attempted to research on the topic of endodontic techniques and root dentin permeability in both primary and permanent teeth using Bireme and Medline databases. The efficacy of various root canal cleansers and irrigation systems that work on manual and ultrasonic activation was discussed. According to the literature, instrumentation and irrigation of the root canals is accomplished by conventional endodontic files or by endodontic ultrasonic-vibration-generator system which induce changes in the root dentin permeability. Ultrasonically activation of a file and passive placement results in acoustic streaming which provides superior debridement. According to this paper, the endosonic system with 2.5% sodium hypochlorite solution provided the most effective irrigation technique to remove debris was the ultrasonic system.

**Trairatvorakul C, Chunlasikaiwan S (2008)**<sup>12</sup> evaluated the clinical and radiographic success rates of zinc oxide eugenol and calcium hydroxide with iodoform paste (vitapex) as obturation materials in primary molar pulpectomies. The appraisal was done at 6 and 12 months by another examiner and the trial was blinded. Fifty four mandibular primary molars were selected from 42 children in the age group of  $5.6 \pm 1.2$  years. A single visit pulpectomy with a stainless steel crown was performed and block randomization was used to select the obturation material. Zinc oxide eugenol showed 48 % and 64 % success rate at 6 and 12 months respectively. Vitapex showed 78% and 89 % success rate at 6 and 12 months respectively. At the 6 month time interval, vitapex showed a statistically significant difference over zinc oxide eugenol.

**Barja-Fidalgo F, Moutinho-Ribeiro M, Oliveira MAA, Oliveira BH (2010)**<sup>24</sup> conducted a systematic review to determine an alternative obturation material that was equally or more effective than zinc oxide-eugenol cement. Six clinical trials selected for inclusion were independently reviewed by two researchers. Only two clinical trials showed statistically significant different success rates between the test and the control groups. One clinical trial reported that calcium hydroxide iodoform paste was better than zinc oxide eugenol, while the other found that zinc oxide eugenol and calcium hydroxide - iodoform were similar. The other four studies compared zinc oxide eugenol with an iodoform paste, a calcium hydroxide cement, and calcium hydroxide/ iodoform cement. Zinc oxide eugenol success rates were lesser compared to the other groups. Zinc oxide eugenol with iodoform and calcium hydroxide /iodoform mixture were equally effective as root canal fillings in primary teeth.

**Ramar K, Mungara J (2010)**<sup>15</sup> evaluated clinically and radiographically the efficacy of three obturating materials namely calcium hydroxide with iodoform (Metapex), zinc oxide eugenol with iodoform (RCFill) and zinc oxide eugenol and calcium hydroxide with iodoform (Endoflas) in primary teeth. 96 carious primary mandibular molars showing signs of pulpal/periapical/interradicular radiolucency showing no abnormal mobility were selected from 77 children in the age group of 4 to 7 years. They were randomly divided into 3 groups and obturated with the respective cements. Follow up was done for a 9 month period. The results showed that metapex and endoflas groups had a 100% clinical success rate while RCFill showed 96.8% success ; Similarly, endoflas had a 90.32% success, metapex showed 81.1% success while RCFill had 72.5% radiographic success.

**Barcelos R, Santos MPA, Primo LG, Luiz RR, Maia LC (2011)**<sup>25</sup> in their systematic review compared the performance of zinc oxide eugenol as an obturating material in primary

teeth with other obturating materials over a 12 month follow up period or greater. A literature survey of the electronic database between 1950 and 2010 was done. Forty three references were retrieved and inclusion criteria were applied .The search revealed that overall success of pulpectomy was 80.0% for radio opaque calcium hydroxide paste (Calcicur), 60.0% for non eugenol calcium hydroxide sealer (Sealapex) and varied from 85.0% to 100.0% for zinc oxide eugenol and 89.0% to 100.0% for calcium hydroxide iodorm mixture (Vitapex). The authors concluded that in primary molar pulpectomes zinc oxide eugenol had similar success rates with Vitapex and Sealapex.

**Bhatia R, Naik S, Singh S, Gupta N, Naik S (2012)**<sup>26</sup> reported on the periapical and intraradicular resorption of endoflas (calcium hydroxide, zinc oxide eugenol and iodoform) when used as an obturating material in primary teeth. The material did not cause any periapical irritation as seen with zinc oxide eugenol. Endoflas did not dissolve within the canals. The authors conclude that endoflas fulfilled most of the criteria for an ideal obturation material like it resorbs at a similar rate as the root, resorbs only periradicularly and no intraradicular washouts are evident. The material is biocompatible, hydrophilic and has the property of disinfecting the dentinal tubules as well.

**Gupta S, Das G (2011)**<sup>27</sup> compared and evaluated the clinical and radiographic success of zinc oxide eugenol and metapex as obturating materials in primary teeth. For the study, 42 necrotic primary teeth from children in the age group of 4–7 years were randomly divided into two groups and obturated with zinc oxide eugenol and metapex. Clinical and radiographic follow up was done at 6 months postoperatively. The overall success rates of zinc oxide eugenol and Metapex were 85.71% and 90.48%, respectively. The results concluded that both are effective obturating materials with metapex having an edge. There was greater reduction in



preoperative signs /symptoms and a quicker resorption of extruded/overfilled material with metapex. The findings suggest that metapex is an effective alternative to zinc oxide eugenol as a root canal obturating material.

**Neena IE, Ananthraj A, Praveen P, Karthik V, Rani (2011)<sup>28</sup>** compared working length determination in primary dentition using intra oral digital radiovisiography and apex locator with conventional method .The study was done invivo on 30 primary teeth indicated for pulpectomy in the patients between 5-11years of age. A standardized intraoral periapical radiograph (IOPA) using paralleling technique was taken. During pulpectomy, the working length was determined by digital radiograph and apex locator. The results showed that working length determined in primary molars using digital radiography and apex locator were not superior to the conventional IOPA radiographic method.

**Praveen P, Anantharaj A,Venkataramahavan K,Prathibha Rani S, Sudhir R, Jaya JR (2011)<sup>11</sup>** reviewed the obturating materials (zinc oxide eugenol, calcium hydroxide, iodoform paste and endoflas) used for primary teeth. The drawbacks associated with zinc oxide eugenol cement have led to the introduction of newer obturating materials. The addition of components like formocresol, formaldehyde and paraformaldehyde to zinc oxide eugenol did not improve its success rate or the resorbability. The study reported that calcium hydroxide and iodoform paste combination (vitapex) is considered more effective than zinc oxide eugenol cement because it finds easier apply, resorbs at a greater rate than physiological root reorption and has no toxic effects on the succedaneous teeth. The study also reported on endoflas a resorbable paste which contains calcium hydroxide iodoform mixture with zinc oxide eugenol. The material is hydrophilic, biocompatible and resorbs only when extruded outside the root canal

**Subramaniam P, Gilhotra K (2011)**<sup>29</sup> in their randomized controlled trial compared the clinical efficacy of zinc oxide eugenol, metapex and endoflas as obturation materials in primary molar pulpectomies. Forty five primary molars were selected randomly from children in the age group of 5 to 9 years of age and a single sitting pulpectomy procedure was done with the allocated obturating material. They were evaluated radiographically and clinically at 3, 6, 9, 12 and 18 months interval. Metapex showed a 100 percent success rate, but overfilling and voids were reported with metapex obturation. Obturation with zinc oxide eugenol and endoflas showed only 93.3% success.

**Musale PK, Mujawar S (2013)**<sup>30</sup> The study attempted to evaluate the shaping ability, cleaning efficacy, working time and distortion of instrument of rotary ProFile, ProTaper, Hero Shaper and K-files in pulpectomy procedures of primary teeth. The invitro study involved sixty extracted primary mandibular second molars which were divided into 4 groups and were treated for pulpectomy procedures using K-file, ProFile, ProTaper file and Hero Shaper file. NiTi instruments show 2-3 times greater flexibility than stainless steel files due to its low modulus of elasticity and greater ductility. The shaping ability of the files was evaluated using CBCT scanning and instrumentation time was recorded for each group. The cleaning efficacy was assessed by evaluating the degree of ink removed from the root canal walls using stereomicroscopy. The results showed a more conical for rotary files as compared to K-files with Chi-square test ( $p < 0.05$ ). The Cleaning efficacy of rotary files for various groups (Groups II- 0.68, III- 0.48 and IV- 0.58) was greater than K-files (Group I- 0.93) with statistically significant p value.. Mean instrumentation time with K-file was 20.7 minutes which is much higher than rotary files (Groups II 8.9, III 5.6, and IV 8.1 min). Instrument distortion was observed in Group (4.3 %) distortion was seen with K files, while none of the rotary files were distorted. The study

concluded that rotary files were clinically more efficient for pulp therapy procedures in primary teeth as working time and shaping ability were significantly greater than normal K files.

**Ahmed HMA (2014)<sup>4</sup>** recommended that an adequate knowledge on the root anatomical variations in primary teeth, radiographic limitations, instrumentation, techniques, action of endodontic irrigants are essential before proceeding to pulpectomy procedures in exfoliating or retained primary molars. This article provided an overview of partial and total pulpectomy in primary molar teeth along with the recommended guidelines. Partial, partial/total and total pulpectomy procedures are reasonable treatment options for primary molars having radicular canals with inflamed or necrotic pulps to ensure either normal shedding or a long-term survival in instances of retention. Despite being a more conservative treatment option than extraction, efficient pulpectomy of bizarre and tortuous root canals especially that are resorbing and close to developing dentition is considered an endodontic challenge.

**Bhandari SK, Anita, Prajapati U (2015)<sup>31</sup>** The study attempted to sketch out a simple, cost-effective technique for obturating root canals in primary tooth. A total of 52 patients involving 75 primary teeth, between 3½ to 9 years of age were involved in the study. The criterion for selection was outlined by Camp (1994) and Milledge (2008) and it essentially included a pulpally involved tooth without internal resorption. pulpal perforation, resorption not involving more than 1/3rd of root and adequate bone support. Teeth were obturated using reinforced zinc oxide eugenol cement into the root canals after adequate biomechanical preparation, using a disposable needle and syringe. The needle was inserted into the canal 1 mm short of the apex and the material was pressed gently until the canal orifice was filled and later the needle was gradually withdrawn. The cases were reviewed for 3 years and 6 months. No clinical or radiographic failures were seen except for one case which caused prolonged retention

of primary incisors and had to be extracted. The disposable injection technique provided a homogenous stereo type fill up of the material without any voids upto the desired working length. Moreover the procedure can be repeated if require and can be easily mastered. Various restorative materials could be effectively used and the disposable injection technique is cost effective and requires fewer inventories.

**Armamentarium:**

- Rubber Dam Kit
- Cotton rolls/ Suction tips/ paper points
- Diagnostic instruments
- Plastic instruments
- Spoon excavators
- Aerotar hand piece (NSK hand piece, Japan)
- Micromotar with Hand piece (Rocket SK-ST-105, India)
- Burs /Diamond points – straight carbide no.4, round burs no.2, 169 L bur, flame shaped bur.
- K files (premier dental products company, USA)
- H files (premier dental products company, USA)
- Cartridge
- Metapex (Meta Biomed, Korea)
- Endoflas (Sanlor Laboratories, Colombia)
- Zinc oxide Eugenol cement (Prodent, Deccan Dental Depot pvt ltd, Hyderabad, India)
- Type IX, I, Glass ionomer cements (GC corporation, Tokyo, Japan)
- Stainless steel crowns (Kids crown, Mumbai)
- Sodium chloride solution; Chlorhexidine gluconate; Metrogyl solution
- Lignocaine (Lignox, Warren, Mumbai)
- Precaine gel (Pascal Company Inc, USA)
- Portable x-ray machine; IOPA radiographs – adult (size 2 - 31× 41mm); pediatric radiographs (size 0 - 22 ×35 mm)

## Methodology

A randomized controlled clinical trial was planned and the protocol was approved by the Institutional review board and institutional ethics committee of KSRIDSR, Tiruchengode. The study was carried out in the Department of Pedodontics and Preventive Dentistry. Sample size estimation was done with the power of test at 80% ( $\alpha = 0.05$ ). A total of 60 carious primary molars with clinical signs and symptoms indicative of irreversible pulpitis were selected from 36 children, aged 4-9 years and free from any systemic disease who visited the outpatient ward of Department of Pedodontics between January 2015 till April, 2015. Teeth showing internal resorption, pathologic root resorption, pathologic mobility and extensive bone loss were excluded.<sup>15</sup> A diagnostic radiograph was taken, assessed and the treatment plan was approved by the staff members. 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 randomly divided into three groups A, B and C using a computer generated sequence of 1:1:1. The selected teeth were randomly obturated with zinc oxide eugenol - Prodent (Deccan Dental Depot Pvt Ltd, Hyderabad, India) as group A, calcium hydroxide with iodoform mixture - Metapex (Meta Biomed, Korea) as group B and zinc oxide eugenol and calcium hydroxide with iodoform mixture - Endoflas (Sanlor Laboratories, Colombia) as Group C.

The pulpectomy procedure was performed under rubber dam isolation after administration of local anaesthesia. Access opening was done after complete caries removal with a straight fissure no.4 carbide bur with copious water supply. Removal of overhanging dentin was done. A sharp spoon excavator was used to amputate the coronal pulp. Fine H Files were

gently inserted into the canals; pulp was extirpated and an IOPA radiograph was taken to establish the working length which was maintained 1 mm short of apex to avoid over obturation. The canals were debrided and enlarged upto 30 size H file size which was used in a pull-back motion with periodic irrigation. A mixture of sodium chloride (1.5 ml) and 0.12% chlorhexidine gluconate (1.5 ml) was used for irrigation.<sup>15</sup> The canals were dried and filled with the respective material as per randomization.

Teeth in Group A received zinc oxide eugenol and the material was obturated using finger pressure technique. Teeth in group B received calcium hydroxide with iodoform (Metapex) which is available in preformed syringes. The material was extruded directly into the canal using by simple pressure after placing the syringe tip inside the canal close to the apex. The paste was pressed down into the canals, and when the paste flowed back from the canal into the pulp chamber the syringe was then slowly withdrawn. Group C received zinc oxide eugenol and calcium hydroxide with iodoform (Endoflas) available in a powder liquid form. The cement was mixed to thick creamy consistency using a metal spatula and glass slab and introduced into the canal using H files and was obturated using finger pressure technique. Post operative radiographs were taken immediately after obturation. All obturated teeth received an entrance restoration with type IX GIC cement. Crown preparation was done and preformed Stainless Steel crown (Kids Crown, Mumbai, India) was luted using GIC Type I cement (GC Corporation, Tokyo, Japan) on the same day. Post treatment antibiotics and analgesics were prescribed for the patient.

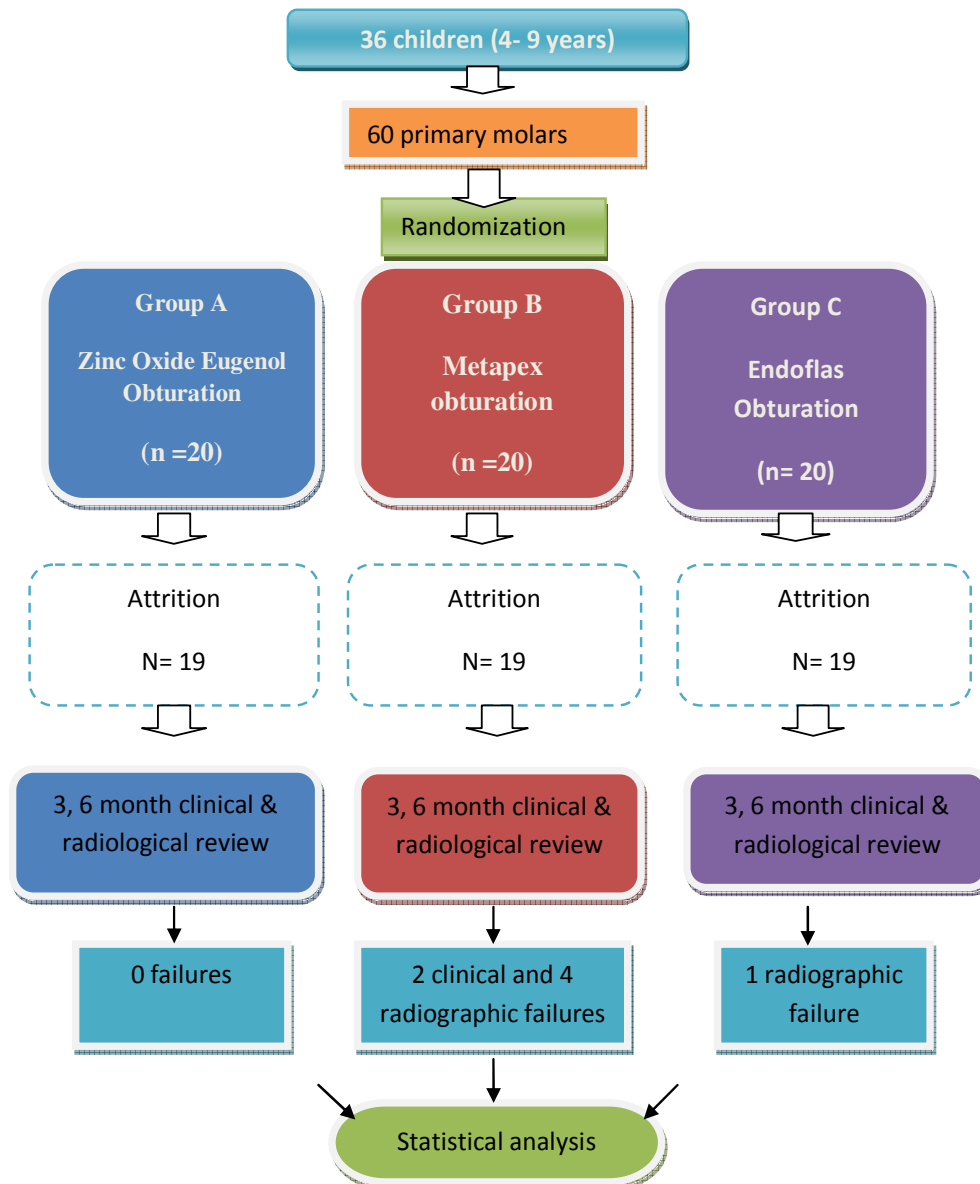
The teeth were evaluated at 3 and 6 months respectively using clinical and radiographic criteria cited by Gupta and Das (2011)<sup>27</sup>. The clinical criteria for evaluation included 1. Presence or absence of Pain 2. Tenderness on percussion 2. Abscess 3. Draining fistula 4. Mobility 5. Soft tissue pathology. The radiographic criteria included 1. Presence or absence of furcation

radiolucency 2. Abnormal root resorption 3. Internal root resorption 4. External root resorption 5. Calcifications 6. Deviated eruption of succedaneous teeth 7. Resolution or increase in size of the radiolucency.<sup>27</sup> Clinical and radiographic success was scored by two well-trained pediatric dentists. Inter examiner reliability was correlated by using Cohen's Kappa coefficient ( $k = 0.8$ ).

**Statistics:** Statistical analysis was done using SPSS version 17.0 (Chicago: SPSS Inc) with statistical significance set at  $p \leq 0.05$ . Chi square test was employed for the statistical analysis.



### Flow chart representing the randomization





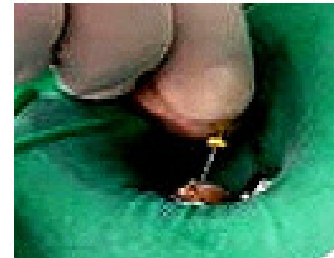
**Figure 2. Pulpectomy procedure**



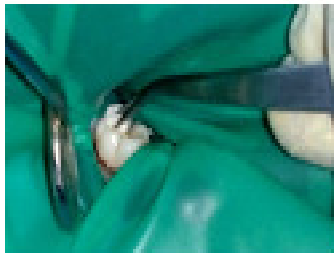
**a. Caries removal**



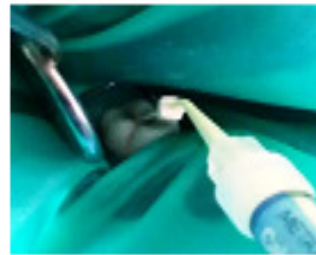
**b. Access cavity**



**c. Biomechanical preparation**



**d. Simple pressure obturation  
(endoflas , zinc oxide eugenol)**



**e. Metapex syringe obturation**

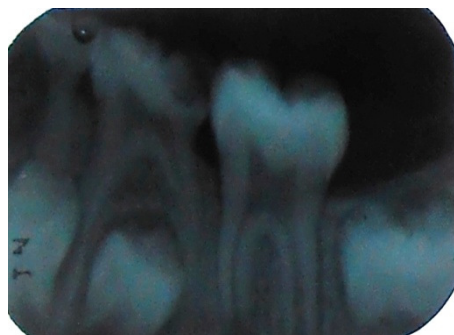


**f. Entrance restoration**

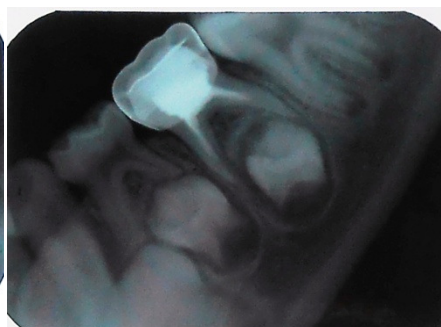


**g. Stainless steel crown**

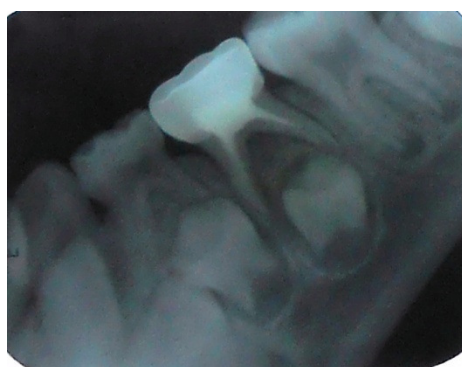
**Figure 3. Radiographs showing zinc oxide eugenol obturation in left lower second primary molar at 3 and 6 months**



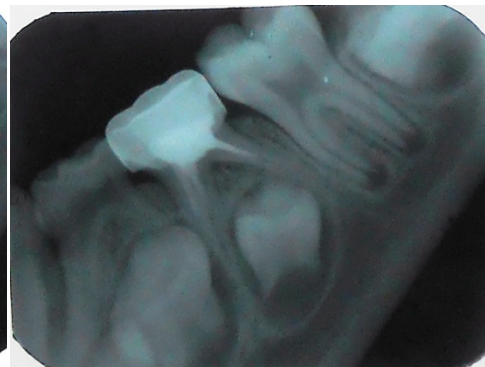
**Pre-operative**



**Post-operative**



**3<sup>rd</sup> month**

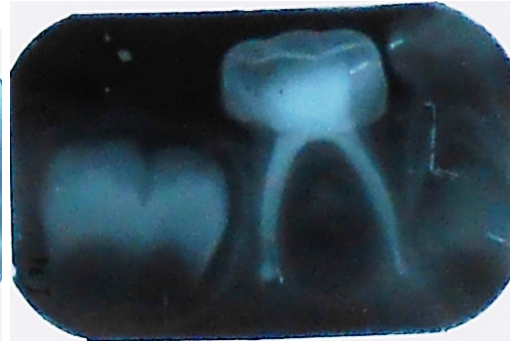


**6<sup>th</sup> month**

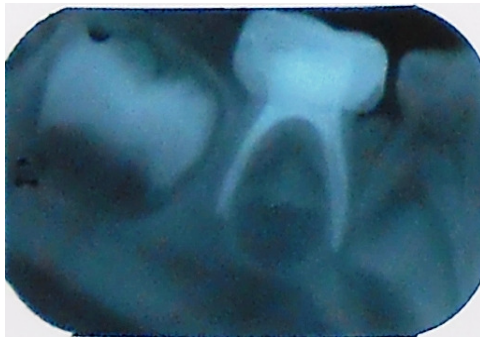
**Figure 4. Radiographs showing metapex obturation in right lower second primary molar at 3 and 6 months**



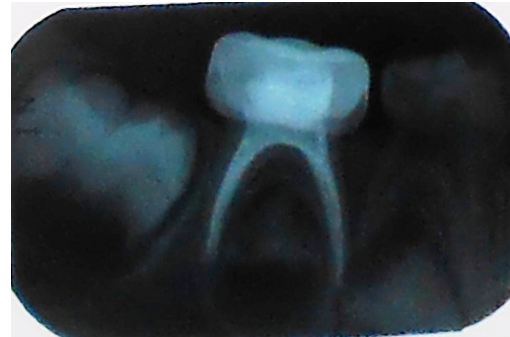
**Pre-operative**



**Post-operative**

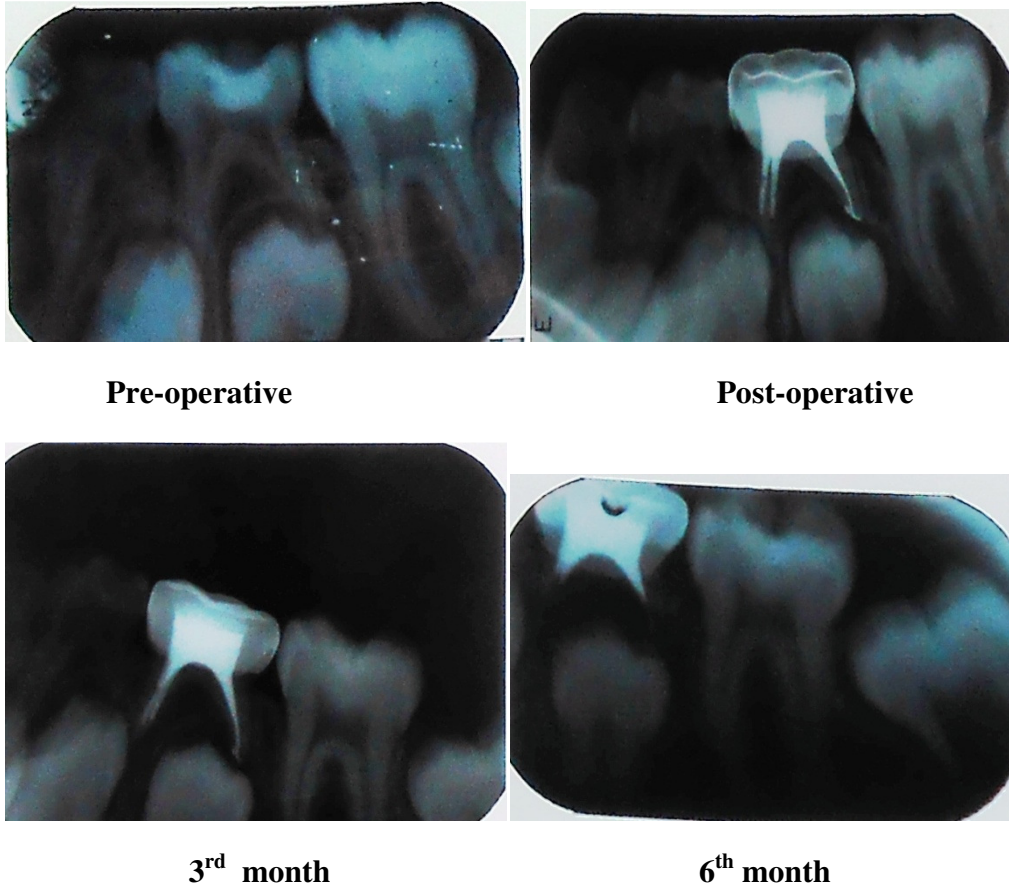


**3<sup>rd</sup> month**

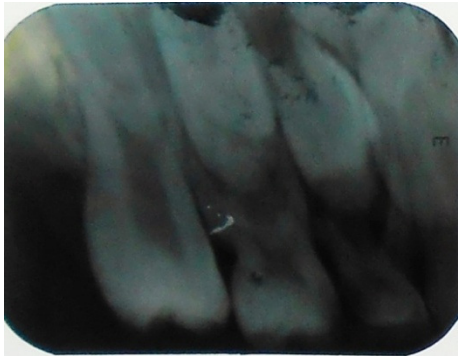


**6<sup>th</sup> month**

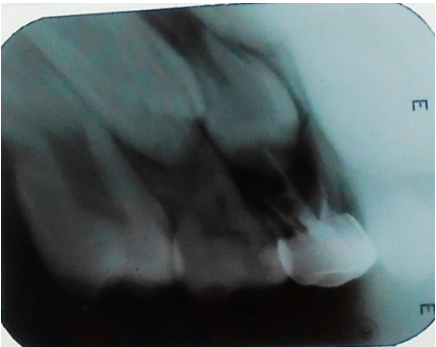
**Figure 5. Radiographs showing endoflas obturation in left lower second primary molar at 3 and 6 months**



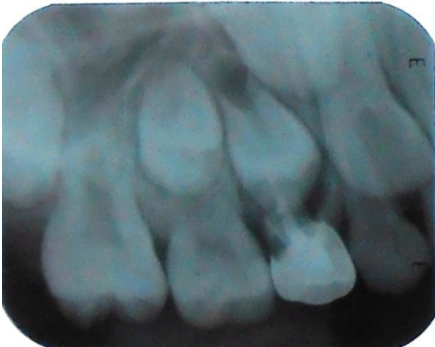
**Fig 6. Radiographs showing metapex obturation of upper right first primary molar with internal resorption at 6<sup>th</sup> month**



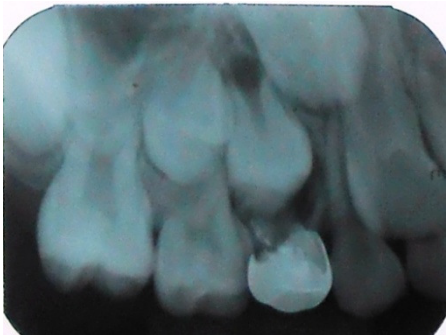
**Pre-operative**



**Post-operative**



**3<sup>rd</sup> month**



**6<sup>th</sup> month**

**Table 1. Sample distribution based on number of children and number of teeth treated**

Obturation material	Number of children	Number of teeth treated
Zinc oxide eugenol (Group A)	14	20
Metapex (Group B)	12	20
Endoflas (Group C)	10	20
Total	36	60

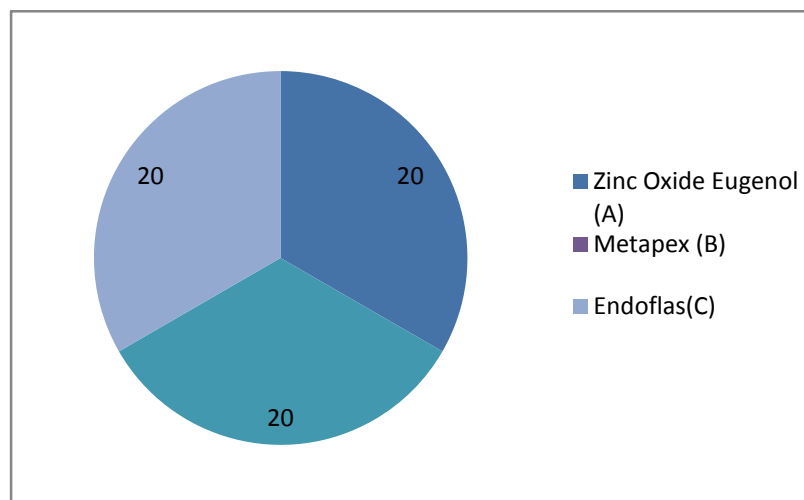


Fig a. Pie chart showing sample distribution based on number of children and number of teeth treated.



**Table 2. Sample distribution of teeth based on age group**

<b>Obturation material</b>	<b>Age (4-6 years)</b>	<b>Age (7-9 years)</b>
Zinc oxide eugenol (Group A)	6	14
Metapex (Group B)	8	12
Endoflas (Group C)	3	17
<b>Total</b>	<b>17</b>	<b>43</b>

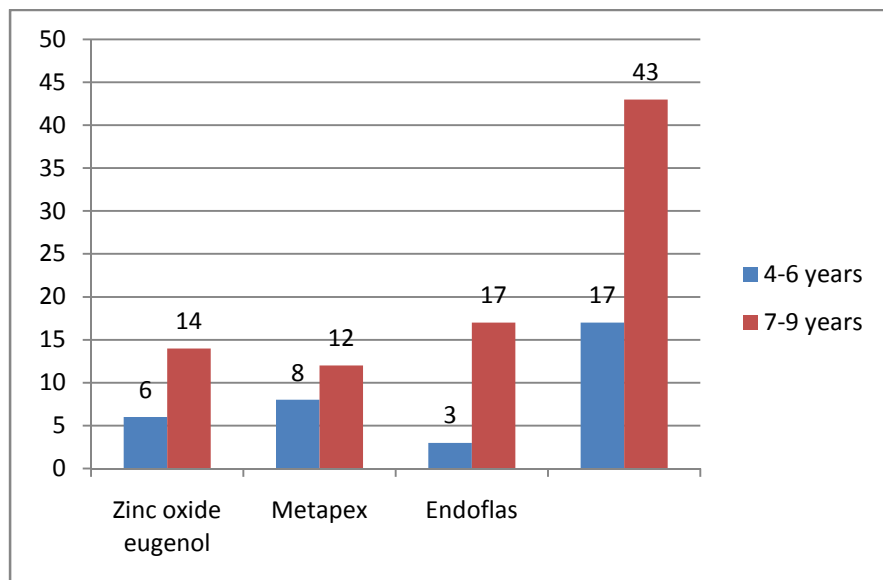


Fig b. Bar diagram showing sample distribution of teeth based on age group

**Table 3. Sample distribution of teeth based on the dental arch**

Obturation material	Maxillary arch	Mandibular arch
Zinc oxide eugenol (Group A)	4	16
Metapex (Group B)	7	13
Endoflas (Group C)	9	11
Total	20	40

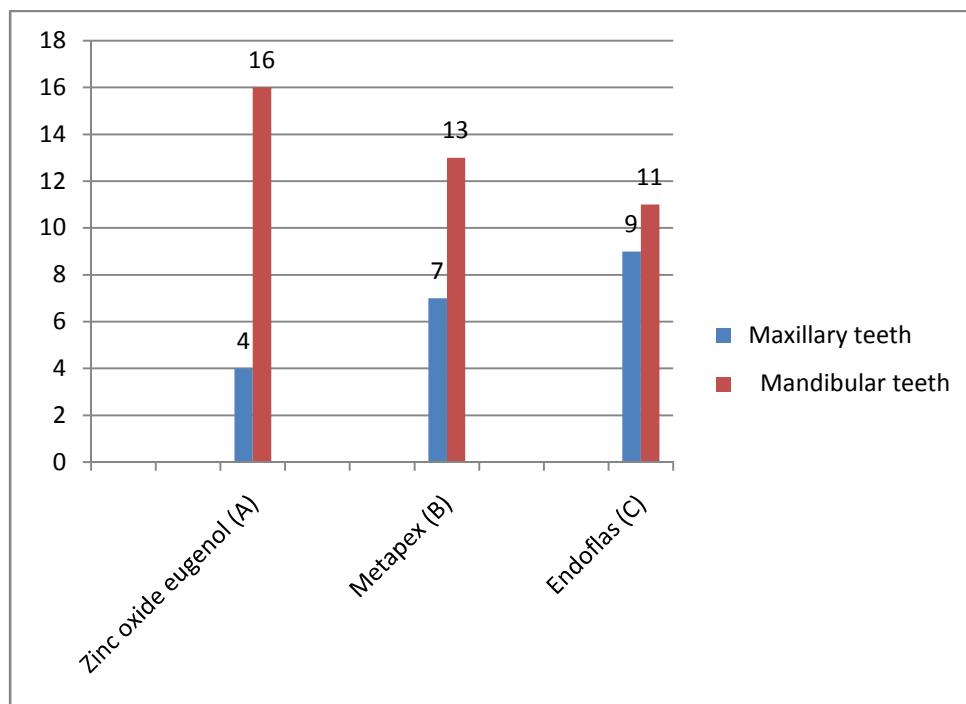


Fig c. Bar diagram showing sample distribution of teeth based on the arch

**Table 4. Sample distribution based on root resorption of teeth**

<b>Obturation material</b>	<b>Teeth showing initial resorption</b>	<b>Teeth showing 1/3<sup>rd</sup> resorption</b>
Zinc oxide eugenol (Group A)	14	6
Metapex (Group B)	14	6
Endoflas (Group C)	18	2
<b>Total</b>	<b>46</b>	<b>14</b>

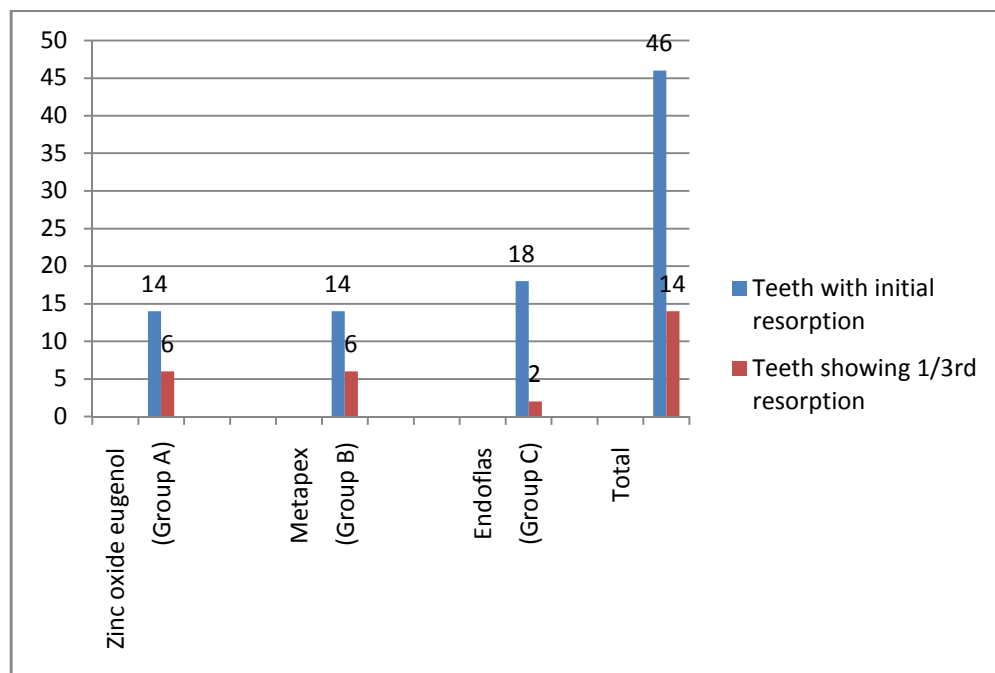


Fig d. Bar diagram showing sample distribution based on root resorption of teeth

**Table 5. Sample distribution of teeth based on attrition at 3 and 6 months interval**

Obturation material	Number of teeth treated (n)	Attrition	
		(3 months)	(6 months)
Zinc oxide eugenol (Group A)	20	1 (n=19)	0 (n=19)
Metapex (Group B)	20	1 (n=19)	0 (n=19)
Endoflas (Group C)	20	1 (n=19)	0 (n=19)

**Table 6. Comparison of clinical success in the three groups at 3 and 6 months interval**

Obturation material	Clinical success rate (%)		p value*
	3 months	6 months	
Zinc oxide eugenol (Group A)	100	100	1.00
Metapex (Group B)	100	89.4	<b>0.008</b>
Endoflas (Group C)	100	100	1.00
p value*	1.00	<b>&lt;0.001</b>	

\* Chi square test

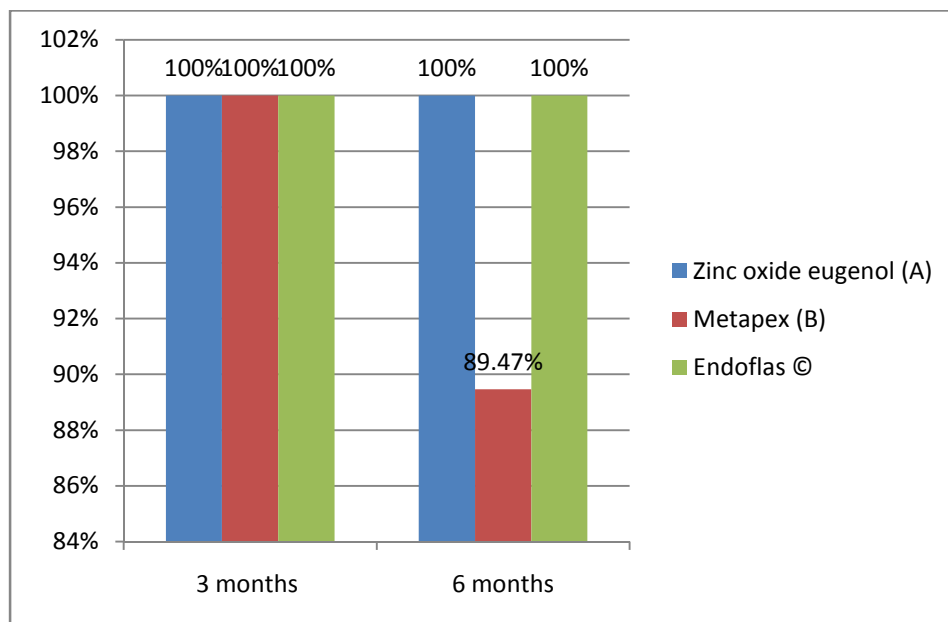
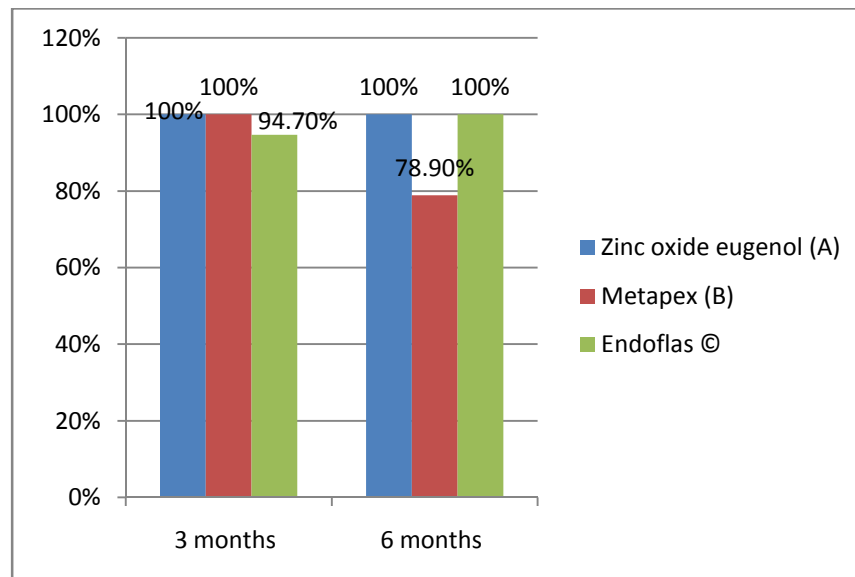


Fig e. Bar diagram showing comparison of clinical success between the three groups at 3 and 6 months interval

**Table 7. Comparison of radiographic success in the three groups at 3 and 6 months interval**

Obturation material	Radiographic Success rate (%)		p value*
	3 months	6 months	
Zinc oxide eugenol ( Group A)	100	100	1.00
Metapex ( Group B)	100	78.9	<b>&lt;0.001</b>
Endoflas ( Group C)	94.7	100	<b>0.045</b>
p value*	<b>0.004</b>	<b>&lt;0.001</b>	

\* Chi square test



**Fig f. Bar diagram showing comparison of radiographic success in the three groups at 3 and 6 months interval**

**Table 8. Comparison of clinical failures between the three groups at 3 and 6 months interval**

Obturation material	Follow up			
	3 months		6 months	
	Total teeth (N)	Failures (N)	Total teeth (N)	Failures (N)
Zinc oxide eugenol (Group A)	19	0	19	0
Metapex (Group B)	19	0	19	2
Endoflas (Group C)	19	0	19	0
p value*	NA		0.1258	

\* Chi square test

NA- not available

**Table 9. Comparison of radiographic failures between the three groups at 3 and 6 months interval**

Obturation material	Follow up			
	3 months		6 months	
	Total teeth (N)	Failures (N)	Total teeth (N)	Failures (N)
Zinc Oxide Eugenol (Group A)	19	0	19	0
Metapex (Group B)	19	0	19	4
Endoflas (Group C)	19	1	18	0
p value*	0.361		<b>0.013</b>	

\* Chi square test



**Table 10. Distribution of the overall success rates of teeth according to the type of molar, age and degree of root resorption**

Parameters	Teeth		Success		Failures		p value*
	Total	Attrition	N	%	N	%	
<b>Age</b>							
4-6 years	18	1	17	97.7	0	2.3	<b>&lt;0.001</b>
7-9 years	42	2	35	66.6	5	33.3	
<b>Type of molar</b>							
Maxillary molar	20	0	18	90	2	10	0.639
Mandibular molar	40	3	34	91.9	3	8.1	
<b>Root resorption</b>							
Initial root resorption	46	1	44	95.6	1	2.2	<b>0.007</b>
1/3 <sup>rd</sup> root resorption	14	2	8	57.1	4	28.5	

\* Chi square test

**Table. 11 Comparison of overall success between the 3 groups**

Obturation material	Overall success (%)
Zinc oxide eugenol (Group A)	100
Metapex (Group B)	92.1
Endoflas (Group C)	98.6
p value*	<b>0.0027</b>

\* Chi square test

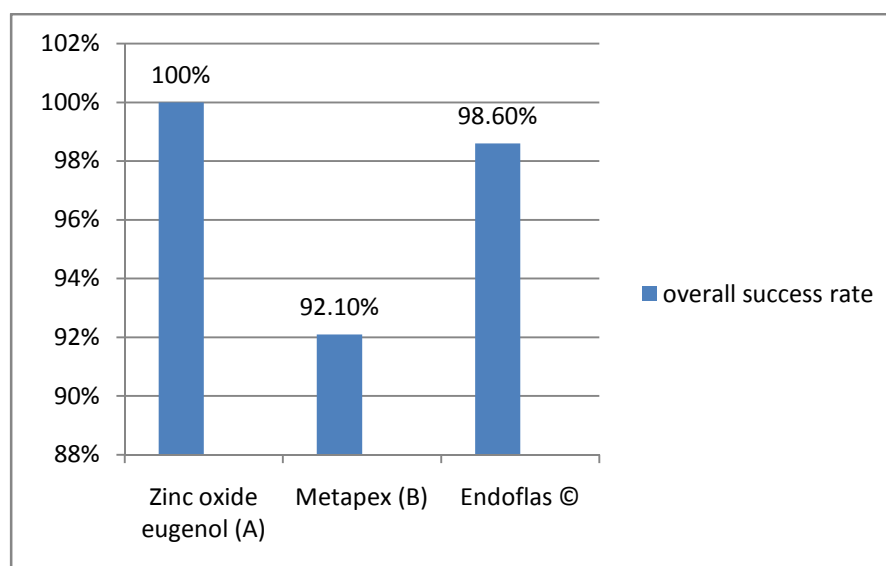


Fig g. Bar diagram showing comparison of overall success between the 3 groups

## Results:

Table 1 represents sample distribution based on number of children and number of teeth treated. A total of 60 primary molars from 36 children were randomly divided into the three groups; zinc oxide eugenol (group A), metapex (group B) and endoflas (group C). Each group received 20 teeth for the pulpectomy procedure. Sample distribution of teeth based on age group is shown in table 2 Of the 60 primary molars, 43 belonged to the 7-9 years age group; while only 17 molars belonged to the 4-6 year age group. Within the 43 primary molars, 14 were allocated to receive zinc oxide eugenol, 12 for metapex and 17 for endoflas. Similarly of the 17 primary molars, 6 received zinc oxide eugenol, 8 received metapex and 3 endoflas.

Table 3 showed sample distribution of teeth based on the dental arch. Of the total 60 teeth, 40 were mandibular and 20 were maxillary teeth. In the zinc oxide group, only 4 were maxillary teeth, while 16 were mandibular teeth. In the metapex group, 7 were maxillary teeth and 13 were mandibular teeth. In the endoflas group, 9 were maxillary and 11 were mandibular teeth. Table 4 showed sample distribution based on root resorption of teeth. Of the total teeth, 46 teeth showed initial root resorption and 14 teeth showed 1/3<sup>rd</sup> root resorption. Of the 46 teeth showing initial resorption, 14 teeth belonged to the zinc oxide eugenol group, 14 metapex and 18 endoflas group. Similarly of the 14 teeth showing 1/3<sup>rd</sup> root resorption, 6 belonged to zinc oxide eugenol, 6 metapex and only 2 teeth belonged to endoflas group.

There was attrition of sample size by 1 dropout in each group at the 3<sup>rd</sup> month interval alone as evident in Table 5. In Table 6 comparison of clinical success between the three groups at 3 and 6 months interval is seen. Both zinc oxide eugenol and endoflas showed 100% clinical success rate at 3 and 6 months interval. Metapex showed 100 % clinical success at the 3<sup>rd</sup> month, but it declined to 89.4 % in the 6<sup>th</sup> month follow up. Intragroup comparison of clinical success

was statistically significant for the metapex with  $p = 0.008$ . Similarly, Inter group comparisons of clinical success between the three groups was highly statistically significant at the 6<sup>th</sup> month interval ( $p < 0.001$ ).

Comparison of radiographic success between the three groups at 3<sup>rd</sup> and 6<sup>th</sup> month interval is shown in table 7. Zinc oxide eugenol showed 100 % radiographic success at 3<sup>rd</sup> and 6<sup>th</sup> month interval. Metapex showed 100 % success at 3<sup>rd</sup> month, but it declined to 78.9% at the 6<sup>th</sup> month follow up. Endoflas had one radiographic failure in the third month review and hence the success rate was 94.7 %; but at the 6<sup>th</sup> month interval none of the other teeth showed any radiographic failures, thereby 100 % success rate. Intra group comparison was highly statistically significant for metapex ( $p < 0.001$ ) and statistically significant for the endoflas ( $p = 0.045$ ). Inter group comparison between the three groups was statistically significant at the 3<sup>rd</sup> and 6<sup>th</sup> month interval with  $p = 0.004$  and  $p < 0.001$  respectively.

Table 8 showed comparison of clinical failures between the three groups at 3 and 6 months interval. Only two clinical failures were recorded at the 6th month interval for the metapex group and there was no statistically significant difference ( $p =$  not available;  $p = 0.1258$ ).

Table 9 showed that comparison of radiographic failures between the three groups at 3<sup>rd</sup> and 6<sup>th</sup> month. Four radiographic failures were recorded for the metapex group at the 6<sup>th</sup> month interval, while one for endoflas at the 3<sup>rd</sup> month interval. Hence, it was not statistically significant at 3<sup>rd</sup> month ( $p = 0.361$ ), but at the 6<sup>th</sup> month interval, a statistically significant difference was observed ( $p = 0.0134$ ).

Distribution of overall success and failure rates of teeth according to the age, type of molar, and degree of root resorption is shown in table 10. The overall success based on age

group between 4-6 years and 7-9 years was highly statistically significant ( $p < 0.001$ ). There was no statistical significance based on the type of molar (maxillary or mandibular arch). Overall success based on comparison between teeth with initial root resorption and 1/3<sup>rd</sup> root resorption was statistically significant ( $p = 0.007$ ). Table 11 showed the comparison of overall success between the 3 groups. Zinc oxide eugenol had 100 % overall success rate, followed by endoflas with 98.6% and metapex with 92.1%. Intergroup comparison of overall success was statistically significant ( $p = 0.0027$ ). Inter examiner reliability was correlated by using Cohen's Kappa coefficient ( $k = 0.8$ ).

## Discussion

Preservation of primary teeth in a functional state is an integral component of the dentition, until its natural exfoliation.<sup>32</sup>This is of great importance in pediatric dentistry. However, if a primary tooth with irreversible pulpitis or pulpal necrosis is not treated, it can affect the underlying tooth. It can also produce negative impacts on the child's oral health related quality of life through pain, difficulty in mastication and absentia from school.<sup>24</sup>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 of a pulpectomized tooth is dependent on the qualities of the material that is used for obturation of the root canals.<sup>27</sup>

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, be radiopaque and cause no discolouration of teeth. Unfortunately, none of the obturating materials possess all these criteria.<sup>33</sup>

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 in primary teeth over a 6 month follow up period, so as to identify an ideal or close to ideal obturation material that can be used effectively in primary teeth. 60 primary molars needing pulpectomy procedures were selected from children in the age group of 4 to 9 years, based on specific inclusion and exclusion criteria. The age range of the children was set wide between 4 to 9 years to assess the role of factors like age of the patient, the stage of root resorption on the success rate of the pulpectomy procedures.

## Zinc oxide eugenol

Zinc oxide eugenol was discovered by Bonastre in 1837 and Chisolm (1876) subsequently used it in dentistry.<sup>11</sup> Traditionally, zinc oxide eugenol is the material of choice for filling root canals in primary teeth. Until 2008, it was the only material explicitly recommended in the clinical guidelines developed by the American Academy of Pediatric Dentistry (AAPD).<sup>24</sup> According to Hashieh cited in Praveen et al (2011), the amount of eugenol released in the periapical zone immediately post obturation was  $10^{-4}$  and falls to  $10^{-6}$  after 24 hours, reaching zero after one month, which is responsible for its anti-inflammatory and analgesic properties.<sup>11</sup>

Zinc oxide eugenol though commonly used and is the most preferred obturating material has many side effects cited in the literature.<sup>32</sup> According to Jeeva and Ratnakumari (2014), zinc oxide eugenol is considered genotoxic, cytotoxic and kills macrophages, thereby capable of causing chronic and fibrous inflammatory reactions, ulcerations, and osteosclerosis.<sup>34</sup> Various defects like delayed resorption of extruded material, deflected or ectopic eruption of succedaneous tooth, anterior crossbite, and palatal eruption have also been reported with zinc oxide eugenol.<sup>35</sup>

Literature review on zinc oxide eugenol as an obturation material showed varying success rates. Barr et al (1991) showed 82.3 % overall success rate with zinc oxide eugenol in 62 primary molar pulpectomies followed up for 40.2 months.<sup>36</sup> Gould (1972) showed 68.7% success with 29 primary molar pulpectomies using zinc oxide eugenol over a 26 month follow up. Coll et al (1985) showed 86.1% success with 29 primary molar pulpectomies with zinc oxide eugenol over a 82 month follow up.<sup>37</sup> Nadkarni and Damle (2000) reported an 88.5% success rate with zinc oxide eugenol in a study involving 70 primary molars from 60 children aged 4 to 8 years over a 9 month follow up.<sup>38</sup> Dogra (2011) showed 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.<sup>39</sup> In the present study no overfillings were recorded with zinc oxide eugenol and intraradicular resorption was slow. Coll and Sadrian (1996) observed 77% overall success rate with zinc oxide eugenol in 81 primary molar/incisor pulpectomies followed up for 90.8 months.<sup>20</sup>

Barcelos and Santos (2011) in their systematic review showed that zinc oxide eugenol pulpectomies success rate varied from 85 -100 %.<sup>25</sup> Bahrololoomi and Zamaninejad (2015) showed that a two visit pulpectomy in 76 primary molars with zinc oxide eugenol had an overall success rate of 93.4 % in a follow up study ranging from 6 to 59 months.<sup>40</sup> Interestingly in the present study, clinical and radiographic success of zinc oxide eugenol was highest at 100 %. The high percentage of success for zinc oxide eugenol was independent of variables like age of the patient, resorption stage of the root and type of molar as more than 2/3<sup>rd</sup> of zinc oxide eugenol pulpectomies were done in the higher age group of 7-9 years and in teeth with considerable amount of root resorption.

### **Metapex**

In 2009, AAPD guidelines cited iodoform based pastes as suitable alternatives to zinc oxide eugenol.<sup>24</sup> Metapex is a combination of 30.3% calcium hydroxide, 40.4% iodoform and 22.4% silicone oil. The mixture can be dispensed into the root canals by using disposable tips. The silicone oil content of metapex neutralizes the alkalinity of the paste to a certain extent, thereby causing lesser injury to the periapical tissues.<sup>11</sup> Machida (1983) cited in Gupta and Das (2011) considered calcium hydroxide - iodoform mixture (Metapex) to be an ideal pulpal filling



material for primary teeth, but reported that it resorbs a little faster than the rate of normal physiologic root resorption.<sup>27</sup>

Gupta and Das (2011) showed overall success rates of 85.71% and 90.48% for zinc oxide eugenol and metapex pulpectomies respectively in children aged 4-7 years of age over a 6 month follow up.<sup>27</sup> Subramaniam and Gilhotra (2011) compared endoflas, zinc oxide eugenol and metapex pulpectomies in children aged 5-9 years over a period of 18 months and showed no statistically significant difference between the three materials. However, metapex showed 100 % overall success, while endoflas and zinc oxide eugenol had only 93.3% success.<sup>29</sup>

Ramar and Mungara (2010) evaluated the clinical and radiographic efficacy of metapex, endoflas and RCFill for 9 months and reported overall success rate of 90.5% for metapex, 95.1% for endoflas, and 84.7% for RCFill. Clinical success rate of 96.8% and radiographic success rate of 72.5% was reported for metapex.<sup>15</sup> In the present study, metapex showed 94.7% clinical success and 89.4% radiographic success and overall success was 92.1 %. In the present study, 2 clinical failures (mobility) and 4 radiographic failures (internal resorption) were reported with metapex at the end of the study. Only 12 teeth out of the total 20 belonged to the higher age group of 7 to 9 years and only 6 teeth showed 1/3<sup>rd</sup> root resorption in the metapex obturated group. The clinical success declined from 100% at 3 months to 89.4% at 6 months which was statistically significant ( $p = 0.008$ ). Similarly, the radiographic success declined from 100 % at 3 months to 78.9% at 6 months which is highly statistically significant ( $p < 0.001$ ). Extrusion of material was seen in 6 teeth obturated with metapex. Though it was beyond the scope of the study, it was observed that metapex resorbed both intradicularly and also when it extruded beyond the apex.

## Endoflas

Endofloss is a resorbable paste manufactured in South America available in powder-liquid form with powder containing tri-iodomethane and iodine dibutylorthocresol (40.6%), zinc oxide (56.5%), calcium hydroxide (1.07%), barium sulphate (1.63%) and liquid containing eugenol and para-monochlorophenol.<sup>11</sup> Though the material was introduced in the 1960's and in spite of various advantages, it has not found profound use with clinicians and the reason is unknown.

Praveen et al (2011) cited that the hydrophilic property of endoflas made obturation compatible in even mildly humid canals. Owing to its broad spectrum of antibacterial activity, it can disinfect dentinal tubules and difficult to reach accessory canals which cannot be cleansed mechanically.<sup>11</sup> Fuks et al (2002) observed that endoflas material resorbed when over-extended periapically, but no intraradicular resorption was seen. Dissolution of overextruded material that occurred in seven days was considered due to macrophagic activity.<sup>41</sup> However, Bhatia et al (2011) reported on the intraradicular resorption of endoflas material.<sup>26</sup> In the present study, no overfills were observed with endoflas obturation and no intraradicular resorption of material was observed. Arvind et al (2006) reported on the antimicrobial efficacy of endoflas against *Enterococcus faecalis* and *Candida albicans* and found it to be even superior to amoxicillin and nystatin. The antimicrobial property was attributed to the presence of eugenol and iodoform which caused protein denaturation in microorganisms and this could be the reason for its high clinical success.<sup>42</sup>

In the present study, endoflas had an overall success of 98.6 % with 100% clinical success and 97.3% radiographic success. There was only one radiographic failure in the endoflas group at the 3<sup>rd</sup> month follow up showing internal resorption. Out of the total 20 teeth, 17

obtreated with endoflas fell in the higher age group of 7-9 years. With regard to root resorption only 2 of them showed 1/3<sup>rd</sup> root resorption and remaining 18 showed only initial resorption. This could also be a reason for the high clinical success of endoflas in the present study. The results for endoflas are comparable to studies by Rewal et al (2014) who reported 100 % overall success for endoflas and only 83 % success zinc oxide eugenol with 50 primary molars in children aged 4 to 9 years over a 9 month follow up. They observed that endoflas unlike any other material employed for pulpectomy resorbed at the same pace as the physiological resorption of root.<sup>43</sup> But in the present study, zinc oxide eugenol had absolute success, relatively better than endoflas which was not the case in the other studies. Ramar and Mungara (2011) showed an overall success of 95.1% for endoflas. Moreover, they reported a complete decrease in furcation radiolucency (100%) and complete bone generation in 54.8% of pulpectomized teeth with endoflas.<sup>15</sup> But there are some studies with lesser success rates. Fuks (2003) showed only 70 % success with endoflas pulpectomies in a retrospective study of 55 teeth comprising of 27 maxillary incisors and 28 molars of 47 children with a follow up ranging from 6 to 52 months.<sup>16</sup>

### **Distribution of the success and failure rates of teeth according to the age, type of molar, and degree of root resorption**

Bahrololoomi and Zamaninejad (2015) found no significant relationship between failures and the age of children at the time of the treatment. The failures occurred at 4, 5, 6 and 8 years old children.<sup>40</sup> Whereas Coll et al (1985) noted that more failures were expected in older patients because of greater secondary dentin deposition in older root canals which made debridement difficult.<sup>18</sup> In the present study, all five failures were reported in patients aged 7 to 9 years of age. The difference in success rates between pulpectomies done in 4-6 year old children (97.7%) success and in 7-9 year old children (66.6 %) was statistically significant ( $p < 0.001$ ).

In the present study, of the 57 treated teeth post attrition, 20 were maxillary and 37 were mandibular teeth. Of the five failures reported, there were 3 mandibular teeth and 2 maxillary teeth involved. There was no significant relation between the type of teeth involved and the overall success rate. Bahrololoomi and Zamaninejad (2015) reported that more failures were recorded in mandibular teeth than maxillary teeth and attributed this partly to difficulties in detecting small radiolucencies in the maxilla because of the overlapping of the permanent tooth germ and the palatal root of the primary molar on the interradicular bone.<sup>40</sup> Similarly, Coll and Sadrian (1996) compared 31 incisors and 50 molar teeth pulpectomies obturated with zinc oxide eugenol and found no statistically significant difference between them.<sup>20</sup>

Coll and Sadrian (1996) showed that pulpectomy success rate was related to the amount of preoperative root resorption. Teeth with excess resorption greater than 1 mm had a success rate (23.1%) which was significantly lower than teeth without any or minimal preoperative root resorption (44.4%).<sup>20</sup> In the present study, there was only one failure in teeth with initial root resorption whereas 4 failures were observed in teeth with 1/3<sup>rd</sup> root resorption. Comparison between success rates of teeth with initial resorption and 1/3<sup>rd</sup> resorption was statistically significant ( $p = 0.007$ ). Teeth with initial root resorption had 95.6 % success while teeth with 1/3<sup>rd</sup> root resorption had only 57.1% success at 6 months follow up.

The results of the present study show that zinc oxide eugenol was the most effective obturating material both clinically and radiographically, Metapex though is easier to dispense into the root canal had least success rate with 2 clinical and 4 radiographic failures. Though zinc oxide eugenol success rate is very high, various disadvantages like cytogenicity, mutagenicity, soft tissue irritation and deflection of succedaneous teeth in overfilled teeth should be kept in mind Endoflas with 100% clinical success and with just one radiographic failure has various

advantageous properties like extrarardicular resorption of extruded material, potential bactericidal effect and resorption comparable to the physiological resorption of tooth which looks promising to be close to an ideal obturation material.

**Limitations:**

A longer follow up period ranging from 12 - 18 months is necessary to confirm the clinical and radiological success of the three obturating materials.

## Summary and Conclusion

The study was carried out in the Department of Pedodontics and Preventive Dentistry, KSRIDSR, Tiruchengode. The aim of the study was to determine the clinical and radiographic success of zinc oxide eugenol, metapex and endoflas as obturating materials in pulpectomy of primary teeth of children aged 4 to 9 years at 3 and 6 months follow up. The objectives of the study were to make intra group comparisons of the three obturation materials both clinically and radiographically at 3 and 6 month intervals ; to evaluate the overall success of these three obturation materials at 3 and 6 months follow up; to evaluate the effect of age, root resorption and location of teeth based on arch on the success of pulp therapy and to determine the cause of clinical and radiographic failures at 3 and 6 months in pulp therapies using these three obturation materials.

A total of 60 carious primary molars with clinical signs and symptoms indicative of irreversible pulpitis were selected from 36 children, aged 4-9 years and free from any systemic disease who visited the outpatient ward of Department of Pedodontics, between January 2015 and April, 2015. The teeth were randomly divided into three groups A, B and C using a computer generated sequence of 1:1:1 to receive zinc oxide eugenol, metapex and endoflas respectively. The pulpectomy procedure was performed under rubber dam isolation after administration of local anaesthesia and the teeth were obturated with the respective material as per randomization. Post operative radiographs were taken immediately after obturation. All obturated teeth received an entrance restoration. Crown preparation was done and preformed stainless steel crown was luted using GIC Type I cement on the same day. The teeth were evaluated at 3 and 6 months respectively using clinical and radiographic criteria cited by Gupta and Das (2011).

**The findings of the study can be summarized as follows:**

1. The overall success of the 3 groups were, zinc oxide eugenol had 100 % overall success rate, followed by endoflas with 98.6% and metapex with 92.1% respectively. Intergroup comparison of overall success was statistically significant ( $p = 0.0027$ ).
2. Comparison of clinical success between the three groups at 3 and 6 months interval showed showed 100% clinical success rate for both zinc oxide eugenol and endoflas. Metapex showed 100 % clinical success at the 3<sup>rd</sup> month, but it declined to 89.4 % in the 6<sup>th</sup> month follow up.
3. Intragroup comparison of clinical success was statistically significant for the metapex group ( $p = 0.008$ ).
4. Inter group comparisons of clinical success between the three groups was highly statistically significant at the 6<sup>th</sup> month interval ( $p < 0.001$ ).
5. Comparison of radiographic success between the three groups at 3<sup>rd</sup> and 6<sup>th</sup> month interval showed 100 % radiographic success for zinc oxide eugenol at 3<sup>rd</sup> and 6<sup>th</sup> month interval. Metapex showed 100 % success at 3<sup>rd</sup> month, but it declined to 78.9% at the 6<sup>th</sup> month follow up. Endoflas showed 94.7% success at 3<sup>rd</sup> month and 100% success at 6<sup>th</sup> month.
6. Intra group comparison of radiographic success was highly statistically significant for metapex ( $p < 0.001$ ) and statistically significant for the endoflas ( $p = 0.045$ ).
7. Inter group comparison of radiographic success between the three groups was statistically significant at the 3<sup>rd</sup> month and highly statistically significant at the 6th month interval with  $p = 0.004$  and  $p < 0.001$  respectively.
8. The overall success based on age group between 4-6 years and 7-9 years was highly statistically significant ( $p < 0.001$ ).

9. There was no statistical significance based on the type of molar (maxillary or mandibular arch).
10. Overall success based on comparison between teeth with initial root resorption and 1/3<sup>rd</sup> root resorption was statistically significant ( $p = 0.007$ ).
11. Comparison of clinical failures between the three groups at 3 and 6 months interval showed two clinical failures at the 6th month interval for the metapex group and there was no statistically significant difference ( $p = \text{not available}$ ;  $p = 0.1258$ ).
12. Comparison of radiographic failures between the three groups at 3<sup>rd</sup> and 6<sup>th</sup> month showed four radiographic failures for the metapex group at the 6<sup>th</sup> month interval, while one for endoflas at the 3<sup>rd</sup> month interval. It was not statistically significant at 3<sup>rd</sup> month ( $p = 0.361$ ), but at the 6<sup>th</sup> month interval, a statistically significant difference was observed ( $p = 0.0134$ ).



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Appendix - I



## INSTITUTIONAL ETHICAL COMMITTEE

### KSR INSTITUTE OF DENTAL SCIENCE & RESEARCH

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Chairman

**Dr. P. PONMURUGAN, Ph.D.,**

Prof. & Head Dept. of Biotechnology  
KSR College of Technology,  
KSR Kalvi Nagar, Tiruchengode.

Member Secretary

**Dr. G. S. KUMAR, MDS.,**

Principal,  
KSR Institute of Dental Science & Research,  
KSR Kalvi Nagar, Tiruchengode.

Members

**Dr.G.Ayppadasan, Ph.D.,**  
Biotechnologist

**Mr.A.Thirumoorthi, M.A.B.L.,**  
Human Activist

**Dr.R.Renuka, M.D.S., (Perio), M.Sc.,**  
Family Counsellor

**Dr.K.Sivakumar, MDS., (Cons.Dent.)**

**Dr.Suman, M.D.S., (OMDR)**

**Dr.Sharath Ashokan, MDS., (Pedo)**

**Dr.G.Rajeswari, Ph.D., (Biochemistry)**

**Dr.K.Karthick, MDS., (Cons.Dent.)**

**Mr.V.Mohan, M.Sc., M.Phil., (Physicist)**

**Mr.A.P.S.Raja, B.A.,**  
(Layperson)

Ref.: 055 /KSRIDSR/EC/2014

Date : 09.01.2014

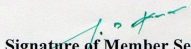
To

Dr.K.Saravana Kumar,  
Postgraduate Student,  
Dept. of Paedodontics,  
KSR Institute of Dental Science & Research,

\*\*\*\*\*

Your dissertational study titled "COMPARISON OF CLINICAL AND RADIOGRAPHIC SUCCESS OF THREE OBTURATING MATERIALS IN PRIMARY TEETH A RANDOMIZED CONTROLLED CLINICAL TRIAL" presented before the ethical committee on 7<sup>th</sup> Jan. 2014 has been discussed by the committee members and has been approved.

You are requested to adhere to the ICMR guidelines on Biomedical Research and follow good clinical practice. You are requested to inform the progress of work from time to time and submit a final report on the completion of study.

  
Signature of Member Secretary,  
(Dr.G.S.Kumar)

கே.எஸ்.ஆர்.பல் மருத்துவம் மற்றும் ஆராய்ச்சி மையம்  
குழந்தைகள் பல் நலப் பிரிவு  
முறையான ஒப்புதல் - நோயாளியின் தாய்மொழியில்

\_\_\_\_\_ ஆகிய நான் என்னுடைய மகன்/மகள்  
\_\_\_\_\_ என்பவருக்கு தற்சமயம் கே.எஸ்.ஆர். பல்  
மருத்துவமனையில் வேர் சிகிச்சை செய்து கொள்ள அழைத்து  
வந்துள்ளேன். இந்த சிகிச்சை பற்றி அனைத்து தகவல்கள்,  
பலன்கள், பக்கவிளைவுகள் பற்றியும் பல் மருத்துவர் எனக்கு  
நன்றாக விளக்கினார்.

இதை நன்கு அறிந்து கொண்டு என் மகன்/மகள்  
\_\_\_\_\_ என்பவருக்கு வேர் சிகிச்சை செய்ய நான்  
சம்மதிக்கிறேன். நான் எடுத்த முடிவினால் எந்த ஒரு அசம்பாவிதம்  
ஏற்பட்டாலும் அதற்கு இந்த மருத்துவமனையோ அல்லது  
மருத்துவமனையில் பணிபுரியும் எந்த ஒரு நபருக்கும் பொறுப்பு  
இல்லை என்று நான் உறுதியளிக்கிறேன்.

தேதி:

இடம்:

கையொப்பம்

**Appendix - III**

**INFORMED CONSENT FORM:**

**Comparison of Clinical and Radiographic success of three obturating materials in primary teeth – A randomized controlled clinical trial**

**Chief Investigator:** Dr .K.Saravana Kumar

**Guide:** Dr. Sharath Asokan

**Name of the patient:**

**Address:**

**Age:            Sex:**

**Name of Parent / Guardian:**

**O P No:**

I \_\_\_\_\_ Parent / Guardian of \_\_\_\_\_ aged \_\_\_\_\_ have been explained in understandable language by Dr. K.Saravana Kumar about the pulpectomy procedure which will be used for my child's treatment. I have also been informed about the advantages, disadvantages and potential risks involved in the treatment procedure. I understand that the information gained will be kept confidential and will be used for academic purposes only. I willingly consent to allow my child to be a part of the above mentioned study and I am aware that I can at any point of time withdraw from the study with no retribution of any kind. I hereby voluntarily give my consent for the procedure and have no objection in the use of and collection of information for the study.

Signature of Doctor

Signature of Parent/Guardian



## Appendix - IV

<b>Criteria for clinical evaluation at 3 and 6 months (Gupta and Das, 2011)</b>	
<b>1</b>	Presence or absence of Pain
<b>2</b>	Tenderness on percussion
<b>3</b>	Redness, Swelling or abscess,
<b>4</b>	Draining fistula
<b>5</b>	Mobility
<b>6</b>	Any remarkable soft tissue changes

<b>Criteria for radiographic evaluation at 3 and 6 months (Gupta and Das, 2011)</b>	
1	Presence or absence of Furcation radiolucency
2	Abnormal root resorption
3	Internal root resorption
4	External root resorption
5	Calcific metamorphosis
6	Deviated eruption of succedaneous teeth
7	Signs of resolution or arrest or increase in size of radiolucency