ISSN: 0976-3031

Available Online at http://www.recentscientific.com

CODEN: IJRSFP (USA)

International Journal of Recent Scientific Research
Vol. 10, Issue, 09(E), pp. 34859-34865, September, 2019

International Journal of Recent Scientific Research

DOI: 10.24327/IJRSR

Research Article

CLINICAL & RADIOLOGICAL EVALUATION OF THREE ROOT CANAL FILLING MATERIALS FOR PRIMARY MOLARS –AN IN VIVO STUDY

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DOI: http://dx.doi.org/10.24327/ijrsr.2019.1009.3987

ARTICLE INFO

Article History:

Received 06th June, 2019
Received in revised form 14th July, 2019
Accepted 23rd August, 2019
Published online 28th September, 2019

Key Words:

Pulpectomy, Endoflas, Metapex, ZnOE

ABSTRACT

Pulpectomy is preferable treatment to maintain the primary teeth in the oral cavity in a healthy and functional state until natural exfoliation occurs. However, none of the currently available material can fulfill all of the criteria of an ideal root canal filling material for primary teeth.

Endoflas is a good root canal filling material with high success rate but the main disadvantage of Endoflas is that its liquid component contains Paramonochlorophenol which is highly Cytototoxic and possible carcinogenic.

Chlorhexidine (CHX) has a wide range of activity against both Gram positive and Gram negative bacteria including E, faecalis and fungus like C.albicans.

So, a newer root canal filling material (Paste formed by mixing Powder part of Endoflas with 1% Chlorhexidine gel) has been tried and compared with two traditional filling materials (METAPEX & ZnOE) in this in vivo study.

In this study 45 selected teeth were divided randomly into 3 groups with 15 teeth in each group, treated with three different root canal filling materials and studied clinically & radiologically for 9 months.

At the end of the study, "Promising" results were found with the Newer filling material with 100% success rate both clinically & radiologically.

INTRODUCTION

"Natural tooth is the Best Space Maintainer"

for both the primary and mixed dentition period. So, every effort should be made to preserve the primary tooth in the oral cavity in a healthy and functional state until its natural exfoliation.[1]

Pulpectomy of primary teeth involves the removal of the necrotic pulp tissue, elimination of micro-organisms followed by filling the root canals with a resorbable material.[2]

But due to the anatomical complexities & physiologic root resorption, proper biomechanical preparation and total elimination of bacteria from infected primary root canals is not possible. Thus, the particular properties of the root canal filling material play an important role in the success of endodontic treatment of infected primary teeth.

According to Rifkin (1980) [3], an ideal Root canal filling material for primary teeth should have – (1) Resorbability (2) Antiseptic property (3) Non-inflammatory and non-irritating to the underlying permanent tooth germ, (4) Radiopacity for visualization on radiographs, (5) Ease of insertion and (6) Ease of Removal.

The materials most commonly used for filling the root canals of primary molars are Zinc Oxide Eugenol, Calcium Hydroxide, Iodoform and their combinations.

Zinc Oxide Eugenol is one of the most widely used material for root canal filling of primary teeth but it has certain disadvantages like-limited antibacterial activity, slower rate of resorption than the root, irritation to the periapical tissue, necrosis of bone and cementum and alteration of path of eruption of succedaneous tooth.[4, 5, 6]

Calcium hydroxide alone or in combination with Iodoform (Vitapex or Metapex) has been widely used as primary root canal filling material with good success rates.

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But the main disadvantage is the rate of resorption of the intra-canal material is faster than the rate of physiologic root resorption making "Hollow tube" for bacteria to induce re-infection.[7]

Endoflas is now used as root canal filling material for primary teeth and its powder part composed of Zinc oxide, Calcium Hydroxide, Iodoform, Barium Sulphate and liquid part contains Eugenol and Paramonochlorophenol.

Endoflas is hydrophilic and can be used in mildly humid canals, firmly adheres to the surface of the root canals to provide a good seal, due to its broad spectrum of antibacterial activity, Endoflas has the ability to disinfect dentinal tubules and accessory canals which are difficult to reach. The main advantage of Endoflas is that it only resorbs when extruded extra-radicularly, but does not wash out intra-radicularly and resorbs at the same pace as that of physiological resorption of roots.[8, 9]

The main disadvantage of Endoflas is that its liquid component contains Eugenol and Paramonochlorophenol. Studies have shown that these compounds are highly Cyototoxic, Mutagenic and Carcinogenic. The International Agency for Research on Cancer (IARC) has determined that the Chlorophenols are possibly carcinogenic to man.[10, 11]

Liquid part also contains Eugenol which can cause periapical irritation.

Chlorhexidine (CHX) is used widely as a root canal irrigant and intracanal medicament. Chlorhexidine (CHX) has a wide range of antimicrobial activity against both Gram positive and Gram negative bacteria including E. faecalis. Chlorhexidine (CHX) is an effective antifungal agent especially against C.albicans Chlorhexidine (CHX) has antibacterial substantivity in dentine and the biocompatibility of Chlorhexidine (CHX) is acceptable.[12]

Schafer & Bossmann (2005)[14] and Ercan *et al*. (2006)[15]showed that in human dentine, 2% CHX gel had greater activity against E. faecalis, followed by CHX and Ca(OH)2 mix and then Ca(OH)2 used alone.

In an in vivo study in primary teeth, Oncag *et al*. (2006)[16] showed that 1% CHX-gluconate gel, both with and without Ca(OH)2, was more effective against E. faecalis than Ca(OH)2 alone over a 48-h period. So, a newer root canal filling material (Paste formed by mixing Powder part of Endoflas with 1% Chlorhexidine gel) has been tried and compared with two traditional filling materials (METAPEX & ZnOE) in this in vivo study. Here an attempt has been made to modify Endoflas by replacing the liquid part with another substance with broad spectrum of antimicrobial activity and lower cytotoxicity (Chlorhexidine gel).

MATERIALS AND METHODS

Consent was obtained from the ethical committee constituted by the college and from the parents or guardian of the child prior to start of the study.

Total numbers of 45 primary mandibular molars (both first and second molars) from 45 patients were selected from the outpatient clinic of the Department of Pedodontics and Preventive Dentistry, Guru Nanak Institute of Dental science & Research, Kolkata according to following Inclusion & Exclusion criteria presented in Table 1.

45 selected teeth were divided randomly into 3 groups with 15 teeth in each group and treated with three different root canal filling materials:

Group 1 with Powder part of Endoflas mixed with 1% Chlorhexidine gel (ENDOFLAS+CHX)

Group 2 with Metapex and Group 3 with Zinc Oxide and Eugenol (ZnOE)

Study Procedure

The clinical procedure was performed in a "**Single sitting**" by a single operator and the clinical and radiological evaluation was done by the same operator.

Step by step procedure:

1. ***Clinical examination & pre-operative radiographic assessment*** Was done to ascertain the status of the tooth, root length and its relation to the succedaneous tooth by Intra-oral periapical radiograph and Radiovisiography (RVG).
2. ***Anaesthesia -*** Optimum local anesthesia was achieved by Inferior alveolar nerve block using 2% Lignocaine with 1:80000 Adrenaline.
3. ***Isolation-***Was achieved with the help of Rubber dam and sterile plastic suction tip attached with high volume saliva ejector and sterile cotton roll.
4. ***Removal of caries and previous restorations -*** All carious lesions and previous restorations were removed with a slow speed stainless steel bur on a micromotor handpiece or a sharp spoon excavator to ensure a clean operating field.
5. ***Access cavity preparation -*** Access opening was done with No. 4 or No. 6 round burs and copious water supply slowly and judiciously to avoid perforation owing to the short crown of primary molars. All overhanging dentin was removed from the roof of the pulp chamber to gain a straight line access.
6. ***Pulp extirpation -*** Complete amputation of coronal pulp was done by using spoon excavator to gain entrance into the root canal identified at the floor of pulp chamber. Extirpation of pulp from the root canals was done by fine barbed broaches.
7. ***Determination of working length -***The working length was determined by inserting no.15 /no.20 sized K file [21 mm**]** with the help of Radiovisiography. The working length was maintained 1 mm short of the radiographic apex to minimize the chance of over instrumentation apically and periapical damage.
8. ***Root canal debridement and drying –*** The cleaning and shaping of the canals was carried out up to a maximum K file size no.35 [21 mm] sequentially in a pull- back motion in a judicial manner. The root canals were periodically irrigated to remove debris by using 2.5% sodium hypochlorite alternatively with normal saline. The canals were dried using appropriate sized paper points as per the size of the last used K-file).
9. ***Filling of the root canals –*** After proper drying, the canals were filled with a paste formed by mixing powder part of Endoflas mixed with 1% Chlorhexidine gel

[Hexigel, ICPA] (Group 1) or with Metapex (Group 2) or with Zinc oxide and Eugenol (Group 3).

10. ***Filling of root canals***

In Group 1 (Powder part of Endoflas mixed with 1% Chlorhexidine gel)

Powder part of Endoflas was mixed with 1% Chlorhexidine gel in glass slab (5:1 by volume or 4:1 by weight) with the help of cement spatula to obtain a homogenous and medium consistency mix. First K reamer (of appropriate size**)** covered with the aforesaid mix is used to coat the walls of the canals. Then the rest of the canal was filled incrementally with the help of Endodontic plugger and moistened cotton pellets till the complete filling of canals was achieved.

In Group 2 (Metapex)

Metapex is supplied in a pre-packed polypropylene syringe and was transported directly to the canals. The tip of the syringe was inserted into the canals. The paste was pressed down into the canals and when the paste flowed back from the canals into the pulp chamber, the syringe was slowly withdrawn. The material was condensed into the canals with the help of endodontic plugger and moistened cotton pellets till the complete filling of canals was achieve

In Group 3 (Zinc oxide with Eugenol)

ZnOE paste was made by mixing Zinc Oxide powder with Eugenol (0.36gm powder, 0.28 gm liquid) to make mixture of adequate consistency with the help of glass slab and cement spatula.

First the walls of the canals were coated with paper points covered with the thin mix of ZnOE paste. Following this, a thick mix of the ZnOE paste was prepared and condensed into the root canals with the help of suitable endodontic plugger and moistened cotton pellets till the complete filling of the canals was achieved.

In each case, the excess filling material was removed from the pulp chamber. Treated teeth were restored with Glass Ionomer Cement. An immediate post-operative Radiovisiograph was taken.

First follow up done after 7 days and asymptomatic teeth were restored with Stainless Steel Crown with luting Glass Ionomer Cement

Table 1 Inclusion & Exclusion criteria

Inclusion criteria	Exclusion criteria
Patients of 4-9 years of age	Unrestorable tooth
Restorable tooth with clinical and/or radiological signs of irreversible pulpitis or necrotic pulp	Peri-apical or inter-radicular lesion involving the crypt of the developing permanent successor
Non-vital tooth with prolonged history of pain, swelling, mobility, radiolucency involving the furcation area	Pathological external root resorption involving > 1/3 root or excessive internal root resorption or perforation of the floor of the pulp chamber
Tooth having minimal root resorption	Excessive pathological loss of bone support with loss of normal periodontal attachment and excessive mobility
Cooperative parent and clinically manageable patient	Uncooperative patient / parent
	Congenital cardiac disease, Immuno-suppressed patients, children with poor healing potential and any other serious systemic illness

***Follow up*-**Patients were recalled at 1 month, 3 months, 6 months and 9 months intervals and treated teeth were evaluated both clinically and radiologically.

RESULT

The success of the treatment procedure was assessed according to the criteria described in table 2.

Table 2 Clinical& Radiological Criteria for Success

Clinical criteria	*Radiological criteria*
Absence of pain Absence of tenderness on percussion Absence of abnormal mobility Absence of gingival swelling	Absence / decease of furcal radiolucency Absence of abnormal root resorption

All the data were recorded and statistical analysis was done. The data and the results were tabulated in the following tables.

All the data were recorded and statistical analysis was done. Table 3 shows distribution of teeth in three obturation groups according to age and sex. Presence of different clinical symptoms and signs (pain, tenderness on percussion, abnormal mobility, gingival swelling) and presence of different radiological findings (furcal radiolucency, abnormal root resorption) at preoperatve period in each group is shown in Table 4 and Table 5.

Table 3 distribution of teeth according to age and sex of children and group

Age Group (in years)	Group1 (ENDOFLAS+CHX)			Group-2 (METAPEX)			Group-3 (ZnOE)		
	Male	Female	Total	Male	Female	Total	Male	Female	Total
4-5 years	4 26.67%	4 26.67%	8 53.3%	5 33.33%	2 13.33%	7 46.6%	5 33.33%	4 26.67%	9 60.0%
6-7 years	2 13.33%	3 20.00%	5 33.3%	3 20.00%	3 20.00%	6 40.0%	4 26.67%	2 13.33%	6 40.0%
8-9 years	2 13.33%	0 0.00%	2 13.3%	0 0.00%	2 13.33%	2 13.3%	0 0.00%	0 0.00%	0 0.0%
Total	8 53.3%	7 46.6%	15 100%	8 53.3%	7 46.6%	15 100%	 60.0%	6 40.0%	15 100%

Table 4 Presence of different clinical symptoms and signs (pain, tenderness on percussion, abnormal mobility, gingival swelling) at pre-operative period

Group	Pain	Tender on Percussion	Abnormal Mobility	Gingival Swelling	Total no. of Patients
Group 1	15 100%	8 53.3%	4 26.6%	2 13.3%	15 100.00%
Group 2	14 93.3%	11 73.3%	3 20.0%	4 26.6%	15 100.00%
Group 3	15 100%	8 53.3%	4 26.6%	4 26.6%	15 100.00%

* Group 1(Endoflas+CHX), Group 2(Metapex) and Group 3 (ZnOE)

Table 5 Presence of different radiological findings (furcal radiolucency, abnormal root resorption) at preoperatve period

GROUP	Furcal Radiolucency	Abnormal Root Resorption	Total no. of patients
Group 1	9 60.0%	0 0.0%	15 100.00%
Group 2	11 73.3%	0 0.0%	15 100.00%
Group 3	10 66.6%	0 0.0%	15 100.00%

Majority (93.3%-100%) of the patients presented with pain or tenderness on percussion preoperatively in every group. In Group 2 (METAPEX) one patient had no pain but complaining of abnormal mobility of tooth and also had tender on percussion. Table no.5 showed that majority of the teeth

represented radiologically with furcal radiolucency (60% - 73.3%) but no tooth had abnormal root resorption.

At 3 months post-operative period (Table 6A), both Group1(Endoflas+CHX) and Group 2(Metapex) showed 100% clinical success rate as in all the 15 teeth in both groups there was absence of pain, tender on percussion, mobility and gingival swelling. But in group 3(ZnOE), 2 patients were complaining of persisting pain along with other clinical signs and symptoms. So, extraction of these 2 teeth was done at 3 months follow up visit. So, in Group 3(ZnOE), the clinical success rate at 3 months post-operative period was 86.66%. Test of proportion showed that there was no significant difference in clinical success rate at 3 month of Group1 (100%) and Group2 (100%) ($Z=0$; $p>0.05$). But the success rate of Group-1 and Group-2 were significantly higher than that of Group-3 (86.66%) ($Z=3.78$; $p<0.01$).

Table 6A Presence of Different Clinical Symptoms And Signs (Pain, Tenderness on Percussion, Abnormal Mobility, Gingival Swelling) At 3 Months Post-Operative Period

Group	Pain	Tender on percussion	Abnormal mobility	Gingival swelling	No. Of symptomatic cases	No. Asymptomatic cases	Clinical success rate
Group 1	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	15	100%
Group 2	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	15	100%
Group 3	2 13.3%	1 6.67%	2 13.3%	2 13.3%	2 13.3%	13	86.66%

Table-6A: Test of proportion showed that there was no significant difference in clinical success rate at 3 month of Group1 (100%) and Group2 (100%) ($Z=0$; $p>0.05$). But the success rate of Group-1 and Group-2 were significantly higher than that of Group-3 (86.66%) ($Z=3.78$; $p<0.01$).

Table no.6B showed that all the 15 teeth in Group 1 (Endoflas+CHX), were free of radiological signs at 3 months post-operative period. But 3 teeth in Group 2 (Metapex) and 4 teeth in Group 3 showed presence of furcal radiolucency even at 3 months post-operative period. The results was significantly higher in Group 1(Endoflas+CHX), (100%) than Group 2(Metapex) (80%) and Group 3 (73.33%) ($Z=4.71$; $p<0.01$) but there was no significant difference between Group 2(Metapex) (80%) and Group 3(ZnOE) (73.33%) ($Z=1.12$; $p>0.05$).

Table 6B presence of different radiological findings Furcal radiolucency, abnormal root resorption) At 3 months post-operative period

Group	Furcal radiolucency	Abnormal root resorption	No. Of symptomatic Teeth	No. Of asymptomatic Teeth	Radiological Success rate
Group 1	0 0.00%	0 0.00%	0 0.0%	15	100%
Group 2	3 20.0%	0 0.00%	3 20.0%	12	80%
Group 3	4 26.6%	0 0.00%	4 26.6%	11	73.33%

Table-6B: Test of proportion showed that radiological success rate at 3 month of Group1 (100%) was significantly higher than that of Group-2 (80%) and Group-3 (73.33%) ($Z=4.71$; $p<0.01$). But there was no significant difference in success rate of Group2 (80%) and Group-3 (73.33%) ($Z=1.12$; $p>0.05$)

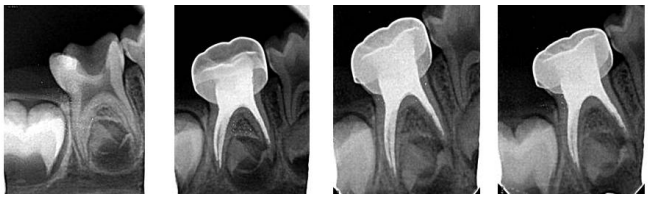

Figure 1 Preoperative, 1 month post operative 3 months post operative and 6 months post operative (right to left) RVG of a case obturated with CHX

Figure 2 Preoperative, 1 month post operative 3 months post operative and 6 months post operative (right to left) RVG of a case obturated with metapex

Figure 3 Preoperative, 1 month post operative 3 months post operative and 6 months post operative (right to left) RVG of a case obturated with ZOE

Table no.7A represents that both Group 1(Endoflas+CHX), and Group 2(Metapex) showed 100% clinical success rate which were significantly higher than Group 3 (znoe) i.e. (86.66%).

Table 7A presence of different clinical symptoms and signs (pain, tenderness on percussion, abnormal mobility, gingival Swelling) at 6 months & 9 months post-operative period [as same results were found at 6 months & 9 months post-operative period, so tabulated in one table)

Group	Pain	Tender on percussion	Mobility	Gingival swelling	Failure as extracted	No. of success	Clinical success rate
Group 1	0 0.00%	0 0.00%	0 0.00%	0 0.00%	0 0.00%	15	100%
Group 2	0 0.00%	0 0.00%	0 0.00%	0 0.00%	0 0.00%	15	100%
Group 3	0 0.00%	0 0.00%	0 0.00%	0 0.00%	2 13.3%	13	86.66%

Table-21: Test of proportion showed that there was no significant difference in clinical success rate at 6 & 9 month of Group1 (100%) and Group2 (100%) ($Z=0$;$p>0.05$). But the success rate of Group-1 and Group-2 were significantly higher than that of Group-3 (86.66%) ($Z=3.78$;$p<0.01$).

Table no.7B showed 100 % radiological success in Group 1(Endoflas+CHX), as all the 15 teeth in Group 1 were free of radiological signs. In Group 2(Metapex), 2 teeth showed presence of furcal radiolucency even at 9 months post operative period, so the radiological success rate was 86.66%. In Group 3(ZnOE), total number of radiological failure was 3(as the 2 extracted cases were considered as both clinical and radiological failure and one tooth had persistent furcal radiolucency) and the radiological success rate was 80%.

Table 8A represented the rate of resorption of three intra-canal materials at 6 months post-operative period. Group1 (Endoflas+CHX), showed resorption of the intra-canal material in 3 cases (20%) and among them 2 cases (13.3%) were at the same rate with the root and 1 case (6.6%) had resorption more than the root. Group 2(Metapex) showed resorption in 3 cases(20%) and among them 2 cases(13.3%) showed resorption

rate more than the root and 1 case(6.6%) showed resorption at the same rate with the root. But Group 3(ZnOE) showed resorption of 2 cases (13.3%) and among them 1 case (6.6%) showed resorption as same rate at that of the root and other 1 case (6.6%) showed resorption rate slower than the root.

Table 7 B Presence of Different Radiological Findings (Furcal Radiolucency, Abnormal Root Resorption) At 6 months and 9 Months Post-Operative Period

Group	Furcal radiolucency	Abnormal root resorption	Failure As extracted	No. Of failure	No. Of successs	Radiological Success rate
Group 1	0 0.00%	0 0.00%	0 0.00%	0 0.00%	15	100%
Group 2	2 13.3%	0 0.00%	0 0.00%	2 13.3%	13	86.66%
Group 3	1 6.67%	0 0.00%	2 13.3%	3 20.00%	12	80%

Table-20: Test of proportion showed that radiological success rate at 6 month of Group1 (100%) was significantly higher than that of Group-2 (86.66%) and Group-3 (80%) ($Z=3.78; p<0.01$). But there was no significant difference in success rate of Group2 (86.66%) and Group-3 (80.0%) ($Z=1.26; p>0.05$)

Table 8A comparative radiographic evaluation of resorption of Intracanal material with respect to tooth at 6 months post-operative period

Group	No resorption	Same as root	More than root	Less than root	Extracted as failure	Total no. Of cases
GROUP-1	12 80%	2 13.3%	1 6.6%	0 0.0%	0 0.0%	15 100.00%
GROUP-2	12 80%	1 6.6%	2 13,3%	0 0.0%	0 0.0%	15 100.00%
GROUP-3	11 73.3%	1 6.6%	0 0.0%	1 6.6%	2 13.3%	15 100.00%

Table 8B Comparative Radiographic Evaluation of Resorption of Intracanal Material With Respect To Tooth at 9 Months Post-Operative Period

Group	No resorption	Same as root	More than root	Less than root	Extracted As failure	Total on. Of cases
GROUP-1	9 60%	5 33.33%	1 6.6%	0 0.0%	0 0.0%	15 100.00%
GROUP-2	9 60%	2 13.3%	4 26.6%	0 0.0%	0 0.0%	15 100.00%
GROUP-3	9 60%	1 6.6%	0 0.0%	3 20%	2 13.3%	15 100.00%

Table 9 A Number of Teeth Where Presence of Extruded Materials occurs In Immediate Post-operative Period

Group	No. of Cases Where Extrusion Occured	Total no. of Cases
Group 1	3 20%	15 100.00%
Group 2	4 26.6%	15 100.00%
Group 3	4 26.6%	15 100.00%

Table 9 B Number Of Tooth Where Resorption Of Extruded Materials Occurs In 1 Month, 3 Months, 6 Months And 9 Months Intervals

Group	1 Month	3 Months	6 Months	9 Months	Total No.of Extruded Case
GROUP 1	3 (100%)	3 (100%)	3 (100%)	3 (100%)	3 (100%)
GROUP 2	1 (25%)	4 (100%)	4 (100%)	4 (100%)	4 (100%)
GROUP 3	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (25%)	4 (100%)

Table 10 Overall Success Rate At The End Of The Study (9 Months)

Group	Clinical Success Rate	Radiological Success Rate	Overall Success Rate
Group1	100%	100%	100%
Group 2	100%	86.66%	93.33%
Group 3	86.66%	80%	83.33%

Table 8B represented the rate of resorption of three intra-canal materials at 9 months post-operative period. In Group1 (Endoflas+CHX) resorption of intra-canal material occurred in 6 cases (40%) and among them in 5 cases (33.33%) showed resoption at the same rate with the root. Group 2(Metapex) showed 6 cases (40%) of intra-canal resorption and among them 4 cases (26.6%) had resorption more than that of the root. In Group 3(ZnOE), 3 (20%) cases represented with resorption rate lower than that of root.

Table 9A shows Group 1 (Endoflas+CHX) showed 3 cases (20%) of extrusion where as there was 4 cases (26.6%) of extrusion in both Group 2 (Metapex) and Group 3(ZnOE).

Table no.9B showed that in Group (Endoflas+CHX), complete resorption of the extruded material occurred in all the 3 cases in one month i.e. 100% resorption of the extruded material occurred in one month post-operative period. In Group 2(Metapex), only 1 case out of 4 extruded case showed resorption of the material i.e. 25% resorption of extruded material at one month post-operative period. But at 3 months post operative period, all the 4 cases (100%) showed resorption of the extruded material. Group 3 (ZnOE) showed no resorption (0%) of the extruded material till 6 months post operative period. But at 9 months post-operative period, only 1 out of 4 cases (25%) showed resorption of extruded material.

Overall clinical success at 9 months of study was 100% for group 1, 93.33% for group 2 and 83.33% for group3 (Table 10)

DISCUSSION

The primary goal of endodontic treatment of primary teeth is to eliminate infection and retain the tooth in a functional state until it is normally exfoliated. Different materials had been tried by different researchers, but till today, there is no such material which meets all the desired criteria.

As till date no study has been attempted to modify Endoflas by replacing Para- monochlorophenol with another substance (Chlorhexidine gel), a pilot study was performed to obtain the proper mixing ratio with a final product which have properties of ease of application and efficacy. Study was also perfomed in the department of Pharmacy to taste any untoward reaction in between the above mentioned material.

Thus the paste was formed by mixing powder part of Endoflas with 1% Chlorhexidine gel in glass slab (5:1 by volume or 4:1 by weight) by a cement spatula.

3 months post-operative clinical evaluation revealed all the 15 teeth (100%) in both Group1 (Endoflas+CHX) and Group 2(METAPEX) were clinically asymptomatic. (Table-6A)

But in Group 3 (ZnOE), 2 patients were complaining of persisting pain along with other clinical signs and symptoms. Among these 2 patients, one had pain, tender on percussion, mobility and gingival swelling and one had pain, mobility and

gingival swelling. So, these 2 teeth were extracted at 3 months post-operative visit.

Radiographic evaluation at 3 months post-operative period showed that all the 15 teeth (100%) in Group1 ((Endoflas+CHX) were free of radiological signs. This may be due to bone healing capacity of Endoflas. (Table-6B)

But 3 teeth (20%) in Group 2 (Metapex) and 4 teeth (26.6%) in Group 3 showed presence of furcal radiolucency even at 3 months post-operative period.

The result was significantly higher in Group 1(Endoflas+CHX), (100%) than Group 2(Metapex) (80%) and Group 3(ZnOE)(73.33%).

At the end of 9 months, Group1 (Endoflas+CHX) showed 100% clinical and radiological success rate. (Table-10)

The high success rate may be attributed to the fact that both Endoflas[17, 18] and Chlorhexidine [12] have strong antimicrobial properties and Endoflas has bone healing and bone regeneration capacity.[19]

Nivedita Rewal *et al*. (2014) [9] found complete clinical and radiological success of 100% with the Endoflas group at 9 months follow up which was similar with present study.

Moskovitz *et al*. (2010) [20] described 96.7% (234/242) clinical and radiographic success rate and Ramar K, Mungara J (2010) [19] found Clinical success rate of Endoflas was 100%and Radiographic success rate was 90.32% with an overall success rate of 95.1%.

These results were also in accordance with present study.
But in contrary, Fuks AB.*et al*. (2002) [21]found approximately 70 % of the cases were successful and Moskovitz *et al*. (2005) [22] reported a clinical and radiographic success rate of 82%.
The authors attributed their low success to that fact the teeth included in the study had periapical lesions at baseline.

The high clinical and radiological success rates with Group1 (Endoflas+CHX) in the study may also be due to absence of periapical lesions and abnormal root resorption pre-operatively. Ramar K, Mungara J (2010) [19] found Clinical success rate of Metapex was 96.8%, Radiographic success rate of 72.5% and the overall success rate of 84.7%.

They said that its use in acute infections is uncertain. A similar report was done by Tchaou *et al*. (1995) [23] and they were uncertain how effective METAPEX would be in cases of acute infection, as it was reported to have minimal or no anti-bacterial properties.

However, Gupta S, Das G (2011) [24] concluded that Metapex was successful in 90.48% cases and this result was almost similar with our study.

In this study Group 3(ZnOE) showed clinical success of 86.66%, radiological success of 80%with an overall success of 83.33%at the end of 9 months.

Present study results were in accordance with Yacobi *et al*. (1991) [25] who reported an 84% success rate with ZOE primary molar root canal therapy after a follow up time of 12 months.

Zahra Bahrololoomi, Shiva Zamaninejad (2015) [26] showed 93.4% Clinical and Radiological success by using ZnOE and formocresol.

The relatively low success of present study may be explained due to the fact that Zinc oxide eugenol alone has limited antimicrobial activity [W.S. Tchaou *et al*. (1996)][27] and no additional antimicrobial substance has been added to Zinc oxide eugenol in this study.

An ideal root canal filling material for primary teeth should resorb at the same rate with that of the root. Endoflas have the advantage of resorption limited to the excess extruded extra-radicularly; without washing out intra-radicularly.[16, 20]

In this study at 9 months follow up- 5 cases (33.33%) in Group 1((Endoflas+CHX) showed resorption of intra-canal material at the same rate of the root, thus fulfilling the basic requirement of an ideal root canal filling material for primary teeth. (Table-8B)

Ramar K, Mungara J (2010) [19] and Nivedita Rewal *et al*. (2014) [9] also found that Endoflas resorbs at the same rate with that of root.

But in Group 2 (Metapex), 4 cases (26.6%) showed resorption of the intra-canal material faster than that of root where as in Group 3 (ZnOE), 3 cases (20%) showed resorption of the intra-canal material slower than that of root-thus not fulfilling the basic criteria.

Another criterion of an ideal root canal filling material is that the extruded material should resorb at earliest period.

When discussing about the resorption of the extruded material it was found that

Group 1(Endoflas+CHX) showed complete resorption of the extruded material in all the 3 cases(100% resorption) in one month .This result was similar with that of Nivedita Rewal *et al*.(2014) [9] who also found complete resorption of extruded material with Endoflas.

In Group 2(Metapex), only 1 case out of 4 extruded cases (25%) showed resorption of the at one month post-operative period. But at 3 months post operative period, all the 4 cases (100%) showed resorption of the extruded material.

Group 3 (ZnOE) showed no resorption (0%) of the extruded material till 6 months post operative period. But at 9 months post-operative period, only 1 out of 4 cases (25%) showed resorption of extruded material. (Table-9B)

So, Group1 (Endoflas+CHX) showed more favourable properties than Group 2 (Metapex) and Group 3 (ZnOE) in 9 months follow up period.

SUMMARY AND CONCLUSION

So, to summarize the whole study, the present study clearly indicates that though the success rates of Group 2 and Group 3 in terms of clinical and radiological evaluation were satisfactory, Group 1 showed absolute success rates and proved to be an ideal root canal filling material.

In accordance with the methodology used and the results obtained, it can be concluded that the replacement of liquid part (Paramonochlorophenol and Eugenol) with Chlorhexidine gel in Endoflas did not negatively affect the properties of the root canal filling paste and the combined mix can be regarded as "Promising" root canal filling material for primary molars.

Further study with longer duration and larger sample size is needed to establish its long term effectiveness.

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How to cite this article:

Supriya Banerjee *et al*., 2019, Clinical & Radiological Evaluation of three root Canal Filling Materials for Primary Molars –an in Vivo Study. *Int J Recent Sci Res.* 10(09), pp. 34859-34865. DOI: http://dx.doi.org/10.24327/ijrsr.2019.1009.3987