

SUCCESS OF PULPECTOMY IN PRIMARY MOLARS USING A MODIFIED OBTURATING MATERIALS (A COMPARATIVE STUDY BETWEEN METAPEX AND ENDOFLAS)

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ABSTRACT

Metapex a material used widely today in pulpectomy treatment of deciduous teeth. A comparison between Metapex and Endoflas as root canal obturating material was presented. Sixty children with age range from four to seven years were participating in the research, selected from the pediatric dentistry department in Delta hospital, Delta university. Restorable non-vital deeply decayed primary first mandibular molars indicated for pulpectomy with previous spontaneous pain and pulp exposure were selected. Radiographically, the teeth selected were presented with inter-radicular and peri-radicular radiolucency's. The selected teeth were separated into two groups each of them consists of 30 teeth:

Group 1, the canals filled with Metapex.

Group 2, the canals filled with endoflas.

Endoflas showed the higher percentage of Flush-filled obturated roots (93.3%), with no cases of overfilled roots. Additionally, 80% of Metapex treated teeth were flush filled in comparison to 10% with overfilling. No statistically significant difference is detected between studied groups as regard flush-filled, underfilled, and overfilled materials. Non statistically significant difference is detected between the two groups Metapex and endoflas regarding clinical and radiographic rate of success which is higher in group Metapex than endoflas (90% versus 80%, respectively). Clinical and radiographic finding were evaluated among studied groups at each follow up period.

Metapex appears to be an effective treatment more than endoflas in pulpectomy procedures. Other studies may be needed in the future to compare Metapex with the other obturating materials in deciduous teeth.

KEYWORDS: Endoflas, pulpectomy, Metapex.

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INTRODUCTION

Extraction or pulpectomy are the treatment of choice for Carious primary molars with infected and/or necrotic pulp. The primary teeth, represent a proper guidance of permanent dentition preserving arch length and function so pulpectomy treatment is preferable⁽¹⁾. Only teeth with severe tooth structure loss, gross internal or external resorption, or periapical infection affect the succedaneous tooth crypt may subjected to extraction⁽²⁾.

The selected material for primary teeth root canal filling must be, with a wide range of antimicrobial properties, harmless to the developing tooth bud and periapical tissues structures, cause no discoloration of the tooth. It must fill the canals easily with radiopaque appearance, adhere to the walls with no voids or shrinkage, resorb if penetrate the apex and removed easily if necessary^(3,4).

Zinc oxide eugenol and Calcium hydroxide pastes are the most popular substances in pulpectomy treatment of deciduous teeth. Zinc Oxide Eugenol has been reported to irritate the periapical tissues although it has exhibited high success rates, may cause bone and Cementum necrosis, sometimes alter the succedaneous tooth path during eruption^(5,6). Endoflas which composed of zinc oxide eugenol, calcium hydroxide, and iodoform, are manufactured to be an effective root canal filling material in primary teeth as compared with zinc oxide eugenol.

Primary teeth pulpotomies with calcium hydroxide resulted in internal resorption in many attempts, which proved to be due to either the presence of an extra pulpal blood clot or faulty technique with the result sustained bacterial infection in the dentinal tubules⁽⁷⁾. Calcium hydroxide became used for obturating the root canals of primary tooth. Premixed paste called Metapex which modify calcium hydroxide with addition of iodoform is a root canal filling material with excellent radiopacity and antibacterial properties

This study compares between Metapex and endoflas obturating materials regarding clinical and radiographic outcome in pulpectomy of deciduous teeth.

MATERIALS AND METHODS

Study design and location:

This randomized controlled clinical trial was conducted between April 2022 and May 2023 at The Pediatric Dental Clinic in Delta Hospital, Delta University (DU).

Sample size, participants' gender, and age:

About sixty children of both genders with ages 4-to-7 years participated in the study.

Inclusion criteria

The children were selected according to the following inclusion criteria; they should be free from any systemic diseases and refrained from taking any antibiotics one week before the study. Additionally, they should have restorable non-vital primary first mandibular molars indicated for pulpectomy. The children could have symptoms of pain, tenderness on percussion, or mobility of the selected teeth. Radiographically, the selected teeth were presented with inter-radicular and/or peri-radicular radiolucency. There should be adequate bone support with no internal or external root resorption.

Groups allocation

The selected participants were allocated randomly into two groups each consisting of 30 children. In group I, the canals were filled with Metapex (Meta biomed. Korea), which is composed of Calcium hydroxide with Iodoform. While in group II, the canals were treated with Endoflas (Sanlor and Cia.S. en C.S.), which is a mixture of zinc oxide eugenol, Calcium hydroxide, and Iodoform.

Ethical approval and parent's consents

The proposal for this study was approved by the Ethics Committee of the Faculty of Dentistry at DU (LFODMRC/DU-2022-00113). Legal guardians of the study participants were informed about the aim and specific objectives of the research and the value of their children's participation. Furthermore, they were informed that participation was voluntary and that the children's identities would be kept anonymous and confidential. Written informed consents were collected from parents/legal guardians prior to data collection stage.

Data collection

Periapical radiographs were taken for all children prior to the study to evaluate the teeth roots, periapical and inter-radicular areas. Pulpectomy was performed in one visit for all cases, by the same clinician for standardization. The teeth were anesthetized and isolated with cotton rolls then access was obtained, and the orifices were enlarged using Gates Glidden drills.

Barbed broaches were used to extirpate the pulp from the canals, it was necessary to be loosen within the canal to engage soft tissues, followed by irrigation with 2.5% sodium hypochlorite. Depending on the pre-operative radiographs, Fine reamers were used by half turn twist and pull action were inserted into the full length of the canal then other radiographs were taken to confirm the length.

The canals were enlarged using Hedstrom files size 5-35 at 1 mm shorter length from the apex. The canals were irrigated with 2.5% sodium hypochlorite with each change in file size. After completing instrumentation, the root canals were irrigated with physiologic saline and dried using paper points.

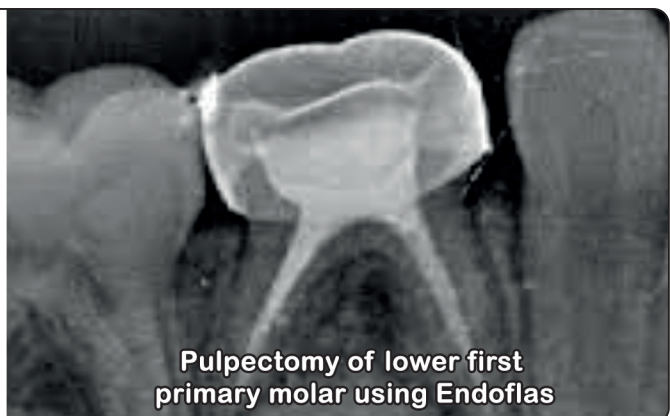
In group I, Metapex was introduced into the root canals using a lentulo spiral in a low-speed handpiece. While, in group II, Endoflas was introduced into the root canals by the same technique.

The extent of root canal filling material was determined by a postoperative radiograph. The obturation was classified into; "flush filled" If the filling reached the apex of the roots without extending beyond it, "underfilled" If the filling material did not reach the apex, and "overfilled" if the filling material extended beyond the apex. All the teeth were restored with glass ionomer cement (GIC) and stainless-steel crown (3M. ESPE) during the same visit.

Follow-up periods and evaluation:

Treatment was considered successful when the following clinical and radiographic criteria were fulfilled.

1. No pain, mobility, or swelling.
2. No sensitivity to percussion.
3. No pathologic internal or external resorption.
4. Decreased or arrested periapical or inter-radicular radiolucency.



Clinical and Radiographic evaluation of the treated teeth were carried out at three, six, nine and twelve months. Radiographic examination included evaluation of increasing, decreasing, or arresting of radiolucency. The fate of extruded material observed in some cases. Clinical evaluation included presence of pain, tenderness to percussion, mobility, and signs of pathosis.

Statistical analysis:

Data analysis was performed by SPSS software, version 25 (SPSS Inc., PASW statistics for windows version 25. Chicago: SPSS Inc.). Standard descriptive statistics such as frequencies were calculated to determine characteristics of the sample. The Chi-Square test was used to compare qualitative data between groups as appropriate. A P-value ≤ 0.05 was considered statistically significant.

RESULTS

Endoflas showed the higher percentage of Flush-filled obturated roots (93.3%), with no cases of overfilled roots. Additionally, 80% of Metapex treated teeth were flush filled in comparison to 10% with overfilling. No statistically significant difference is detected between studied groups as regard flush-filled, underfilled, and overfilled materials as shown in table 1.

TABLE (1) Comparison Between Root Canal Filling Material States among Study Groups.

	Group 1 (Metapex) n=30	Group 2 (Endoflas) n=30	Test of significance
Flush-filled	24(80%)	28(93.3%)	$\chi^2=2.256$ P=0.133
Underfilled	0	2(6.6%)	$\chi^2=2.013$ P=0.156
Overfilled	6(10%)	0	$\chi^2=3.105$ P=0.078

χ^2 : Chi-square test for comparison between group I & II

Regarding success rate in group I, 29 teeth showed no signs or symptoms of pain, tenderness, mobility, or radiolucency after three months. While in group II, 26 teeth were free from the previous outcomes. Three months later (6 months from baseline), there was no extra failure in both groups. However, another two teeth were showing signs of failure in group I in comparison to one tooth in group II after nine months from baseline. By the end of follow up period, there was no change in group I, while in group II an extra tooth showed signs of failure. Significant differences were found between group I and II at three, six, and 12 months (P= 0.009, 0.009, and 0.048; respectively) (Table 2).

TABLE (2) Distribution of success and failure during follow up periods among study groups (30 teeth each)

Follow up periods	Group I		Group II		Test of significance
	Success n (%)	Failure n (%)	Success n (%)	Failure n (%)	
3 months	29 (96.7)	1(3.3%)	26 (86.7%)	4(13.3%)	$\chi^2_1=6.765$ P=0.009*
6 months	29 (96.7)	1(3.3%)	26 (86.7%)	4(13.3%)	$\chi^2_1=6.765$ P=0.009*
9 months	27 (90%)	3(10%)	25 (83.3)	5(16.7%)	$\chi^2_1=1.654$ P=0.198
12 months	27 (90%)	3(10%)	24 (80%)	6(20%)	$\chi^2_1=3.902$ P=0.048*

χ^2 : Chi-square test for comparison of success and failure rates in group I & II

*: Statistically significant difference at $p \leq 0.05$

About 27 out of 30 teeth in Metapex group showed no symptoms of pain, tenderness on percussion, mobility, or radiographic radiolucency after 12 months of follow up. Concerning Endoflas group, a little difference was noticed than Metapex group, as 24 teeth out of 30 were free from the same clinical and radiographic symptoms. No significant difference was reported between both groups (P=0.278). (Table 3)

As shown in table 4, complain of dental pain was reported in 100% of cases in both groups pre-eruptively. Three months after treatment, only one case in group I and 4 cases in group II were suffering from dental pain. By the end of follow up period (at 12 months), only one case was presented with dental pain in group II, with no cases in group I. This reduction in pain was statistically significant in both groups across the follow up periods (P<0.0001). With regards to tenderness on percussion, 80% of group I and 73.3% of group II presented tenderness on percussion pre-operatively. The same results

TABLE (3) Clinical and Radiographic Success After 12 Months Follow Up among Study Groups

Study groups	Total No. of teeth	Clinical and radiographic success N (%)	Test of significance
Group I (Metapex)	30	27 (90%)	$\chi^2=1.18$ p=0.278
Group II (Endoflas)	30	24 (80%)	

$\chi^2=Chi\text{-Square test}$

were the same as found in pain detection at different follow up periods. About 13.3% vs 6.6% of cases shown teeth mobility pre-eruptively in both groups. Later, after three months, this number was reduced to two in group I, while in group II it was increased to four. After six months, there was no cases with tooth mobility in both groups. Despite this, a new two cases in group I and one case in group II were

TABLE (4) Comparison of Clinical Findings at Each Follow Up Period Among Study Groups. (30 Teeth Each).

	Follow up periods	Pre-operative	After 3 months	After 6 months	After 9 months	After 12 months	Test of significance
Presence of pain	Group I	30(100%)	1(3.3%)	0	2(6.7)	0	$\chi^2=351.7798$ p* < 0.0001
	Group II	30(100%)	4(13.3%)	0	1(3.3)	1(3.3%)	$\chi^2=309.0252$ p* < 0.0001
	Test of significance	-	$\chi^2= 1.938$ P=0.164	-	$\chi^2= 0.359$ P=0.549	$\chi^2 = 0.990$ P=0.320	
Presence of tenderness	Group I	24(80%)	1(3.3%)	0	2(6.7)	0	$\chi^2=273.0787$ p* < 0.0001
	Group II	22(73.3%)	4(13.3%)	0	1(3.3)	1(3.3%)	$\chi^2=207.7826$ p* < 0.0001
	Test of significance	$\chi^2= 0.370$ P=0.5430	$\chi^2= 1.938$ P=0.164	-	$\chi^2= 0.359$ P=0.549	$\chi^2 = 0.990$ P=0.320	
Presence of mobility	Group I	4(13.3%)	2(6.6%)	0	2(6.7)	0	$\chi^2=23.200$ p* < 0.0001
	Group II	2(6.6%)	4(13.3%)	0	1(3.3)	1(3.3%)	$\chi^2=19.600$ p* < 0.0006
	Test of significance	$\chi^2= 0.739$ P=0.390	$\chi^2= 0.739$ P=0.390	-	$\chi^2= 0.359$ P=0.549	$\chi^2 = 0.990$ P=0.320	

χ^2 : Chi-square test for comparison between group I & II at different follow up periods, as well as between different follow up periods in each group.
*: Statistical significant difference at p≤ 0.05

reported after nine months of follow up. By the end of follow up period, the same case in group II had tooth mobility, with no mobile teeth in group I. Statistically significant differences were detected between different follow up periods in group I ($P < 0.0001$) and group II ($P < 0.0006$).

As seen in table 5, 100% of cases showed radiographic radiolucency pre-operatively in both groups. Three months later, there was 33.4% reduction in radiolucency in group I and 46.7% in group II. Further reduction was noticed after six and nine months; 14 then seven teeth were reported in group I vs 15 then 11 teeth in group II; respectively. Finally, by the end of the year, only four teeth in group I and seven teeth in group II were still having radiographic radiolucency. Statistically significant differences were found between different follow up periods in both groups ($P < 0.0001$)

TABLE (5) Comparison of Radiographic Radiolucency Distribution Among Study Groups (30 Teeth Each).

Duration in months	Group I n (%)	Group II n (%)	Test of significance
Pre-operative	30(100%)	30(100%)	-
After 3 months	20(66.6%)	16(53.3%)	$\chi^2=1.087$ $P=0.297$
After 6 months	14(46.6%)	15(50%)	$\chi^2=0.068$ $P=0.794$
After 9 months	7(23.3%)	11(36.6%)	$\chi^2= 1.244$ $P=0.265$
After 12 months	4(13.3%)	7(23.3%)	$\chi^2 = 0.987$ $P=0.321$
Test of significance	$\chi^2=98.1694$ $p^* < 0.0001$	$\chi^2=64.9847$ $p^* < 0.0001$	

χ^2 : Chi-square test for comparison between group I & II at different follow up periods, as well as between different follow up periods in each group.

*: Statistical significant difference at $p \leq 0.05$

DISCUSSION

Primary teeth may severely damage by decay or trauma, there are important for reserving a space for the permanent tooth. This is representing a valid reason for pulpectomy⁽⁸⁾. The treatment consists of extirpation of the pulp tissue, removal of organic debris with filing, and obturation of the canals with a suitable material.

Metapex incorporates two ingredients, calcium hydroxide and Iodoform, is a biocompatible root canal sealer. As a result of the induction effect of these two ingredients, Metapex stimulates healing process⁽⁹⁾. The accidental extrusion of Metapex did not have any detrimental effect on periapical healing according to several studies^(10,11,12). However, the presence of BaSO₄ and iodoform may be additional cause to healing of the periapical tissues as well as delayed resorption of Metapex as compared to Calcium hydroxide alone⁽¹³⁾.

Endoflas incorporates three materials zinc oxide eugenol, Calcium hydroxide, and iodoform is another root canal sealer. This combination was to compensate the drawback of one component with the advantages of others. The resorption of Endoflas was analogous to physiological resorption of root as proved by many studies,^(14,15) which is of great value of an ideal obturating material for primary teeth. When compared with zinc oxide eugenol alone, Endoflas can be considered to be an effective root canal filling material in primary teeth. The comparison between Metapex and Endoflas is mandatory in understanding the properties of both sealers and effects of both on success of pulpectomy as a last option in treatment of primary teeth.

In the present study, selection of teeth was done with a clear clinical and radiographic criterion. Restorable primary first mandibular molars with carious exposures of the pulp and history of spontaneous pain, with evident inter-radicular and peri-radicular radiolucency's with adequate bone support with no internal or external root resorption. All criteria were represented to assure that the teeth indicated for pulpectomy.

First mandibular molars were selected due to the ease of visualization and direct access to the root canals. After taking of a periapical radiograph, the pulpectomy was performed in one visit for each case, by the same clinician for standardization, The access to the canals was obtained after the tooth anesthetized and isolated with cotton rolls and gates glidden system was used to enlarge the orifice of the canals.

The pulp was extirpated from the canals using barbed broaches, as they allow to remove tissue from much smaller root canals. Followed by irrigation with 2.5% sodium hypochlorite. Many studies revealed that 2.5% sodium hypochlorite, completely remove pulpal remnants and pre dentin from the uninstrumented surfaces ^(16,17).

Depend on preoperative radiograph, Fine K reamers were inserted into the full length of the canal as it is more flexible than other files, then another radiograph was taken to confirm the length. The canal was enlarged using hedstrom files 15-35 not k files to avoid wide danger areas ⁽¹⁸⁾, to 1 mm short of the apex and irrigated with 2.5% sodium hypochlorite with each change in file size for clear access to another size. After completing instrumentation, the root canal was irrigated with physiologic saline to ensure adequate antibacterial effect and complete removal of organic debris, and dried using paper points.

In the first and second groups, Metapex and endoflas respectively was introduced into the root canal using a lentulo spiral in a low-speed handpiece as the lowest over filling rate in the clinical studies was related to lentulo spiral techniques either for calcium hydroxide or zinc oxide eugenol ⁽¹⁹⁾.

No statistically significant difference is detected between studied groups as regard flush-filled, underfilled, and overfilled materials as shown in table 1. This may be attributed to that the root canal filling techniques were the same for both groups. However, Endoflas showed the higher percentage of Flush-filled obturated roots (93.3%), with no cases

of overfilled roots. Additionally, 80% of Metapex treated teeth were flush filled in comparison to 10% with overfilling. These variations may be attributed to many factors that increase the chance of over filling. The existence of radicular pathological lesions, thin dentinal tubules in the inter radicular area, physiologic or pathologic bone and root apex resorption, Wide and straight canals, extensive preparation of canals, thin consistency of the filling material ⁽²⁰⁾.

Regarding success rate the treatment was considered success if the case became asymptomatic and clinical signs of pathology were absent after 3, 6, 9 months follow up period and finally after 12 months. In group I, 29 teeth showed no signs or symptoms of pain, tenderness, mobility, or radiolucency after three months. While in group II, 26 teeth were free from the previous outcomes. Three months later (6 months from baseline), there was no extra failure in both groups. However, another two teeth were showing signs of failure in group I in comparison to one tooth in group II after nine months from baseline. By the end of follow up period, there was no change in group I, while in group II an extra tooth showed signs of failure. Significant differences were found between group I and II at three, six, and 12 months ($P= 0.009, 0.009, \text{ and } 0.048$; respectively), (Table,2). The success rate in group 1 Metapex was higher than group 2 endoflas (90% versus 80%, respectively), (Table, 3). These may be attributed to zinc oxide eugenol which is present in endoflas and not present in Metapex. Many studies revealed that ZOE was potentially irritating to periapical tissues; may produce necrosis of bone and cementum, and extruded particles may develop a fibrous capsule that prevents resorption of the paste ^(21,22). which explain the results of the study.

In Comparison of Clinical Findings (Pain, Tenderness and mobility) at Each Follow Up Period Among Study Groups, Table 4, (30 Teeth Each). A statistically significant differences were detected between different follow up periods in group I ($P<0.0001$) and group II ($P< 0.0006$). Complain of

dental pain was reported in 100% of cases in both groups pre-eruptively. Three months after treatment, only one case in group I and 4 cases in group II were suffering from dental pain. By the end of follow up period (at 12 months), only one case was presented with dental pain in group II, with no cases in group I. With regards to tenderness on percussion, 80% of group I and 73.3% of group II presented tenderness on percussion pre-operatively. The same results were the same as found in pain detection at different follow up periods. About 13.3% vs 6.6% of cases shown teeth mobility pre-eruptively in both groups. Later, after three months, this number was reduced to two in group I, while in group II it was increased to four. After six months, there was no cases with tooth mobility in both groups. Despite this, a new two cases in group I and one case in group II were reported after nine months of follow up. By the end of follow up period, the same case in group II had tooth mobility, with no mobile teeth in group I.

The same, in Comparison of Radiographic Radiolucency Distribution Among Study Groups (30 Teeth Each) Table 5. A statistically significant differences were found between different follow up periods in both groups ($P < 0.0001$). 100% of cases showed radiographic radiolucency pre-operatively in both groups. Three months later, there was 33.4% reduction in radiolucency in group I and 46.7% in group II. Further reduction was noticed after six and nine months; 14 then seven teeth were reported in group I vs 15 then 11 teeth in group II; respectively. Finally, by the end of the year, only four teeth in group I and seven teeth in group II were still having radiographic radiolucency.

All of these results were attributed to the high success rate of pulpectomy procedures for both groups 1 and 2 respectively. Another study revealed success rate 93.3% with endoflas while the success rate was 100% with Metapex, the voids and over filling was seen in teeth filled with Metapex⁽²³⁾ which agree with the results of this study while in another study the success rate of endoflas was 95.1% while was 90.5% with Metapex⁽²⁴⁾ which

not in accordance with our study. However, a study compares between Endoflas and ZOE material in pulpectomy of primary molars revealed that endoflas could be a potential alternative to ZOE for preserving infected primary molars⁽²⁵⁾.

CONCLUSIONS

Metapex appears to be an effective treatment more than endoflas in pulpectomy of deciduous teeth. Other studies may be needed in the future to compare Metapex with the other root canal obturating materials in primary teeth.

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