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ASSESSMENT OF CALCIUM HYDROXIDE-FORMOCRESOL MIX, ZINC OXIDE AND CALCIUM HYDROXIDE-IODOFORM PASTES AS A ROOT FILLING IN PRIMARY TEETH: A CLINICAL AND RADIOGRAPHIC STUDY

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ABSTRACT

Objective. The objective of this study is to clinically and radiographically evaluate the calcium–hydroxide formocresol mix as a root filling material in primary teeth. **Materials and Methods**. The study was performed on 75 primary molars of patients aged from 4-8 years that were indicated for pulpectomy. Teeth were divided randomly into 3 main equal groups. Each group formed of 25 primary molars. Group A: 25 children teeth in which zinc oxide and eugenol (ZO/E) was used as filling material. Group B: 25 children teeth in which calcium hydroxide formocresol mix was used as a filling material. Group C: 25 children teeth in which Metapex was used as a filling material. Teeth were assessed clinically and radiographically at 5 different intervals (preoperative, 24 hours, 6 weeks , 3 months and 6 month postoperative), using standard clinical and radiographic criteria. **Results.** It was found that Maetapex offers best clinical and radiographical results when compared with ZO/E and calcium hydroxide fromocresol mix . ZO/E (group A) showed (84%) success rate, while the Calcuim hydroxide fromocresol mix (group B) showed a higher success rate (88%) than (ZO/E) . Metapex (group C) showed the best success rate of all groups (94%). Failure rates were (16%), (12%) and (6%) for the three groups, respectively. **Conclusion**. Metapex is the best material as root filling material with a high success rate and showing competitive properties to ZO/E and Calcium hydroxide formocresol mix. Calcium hydroxide formocresol mix shows better result than ZO/E .Both of Metapex & Calcium hydroxide formocresol mix have the power to be an alternative for ZO/E in primary molars treated by pulpectomy.

KEYWORDS. Primary Teeth, Pulpectomy, ZO/E, Calcium Hydroxide Formocresol, Metapex.

INTRODUCTION

Dental caries is still the number one disease affecting children all over the world. It is not only the most common dental problem, but also the most common chronic childhood disease affecting the general health of children. Moreover, it does not seem to be diminishing especially in developing countries. It is a multifactorial disease which results of a complex interplay of multiple determinants that may change overtime. It is continues to be a major problem in dentistry and should receive significant attention in every day practice not only from the

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standard point of restorative procedures, but also in terms of preventive practices designed to reduce the problem [1-4] .

Pulpotomy is the most common technique to treat curiously exposed pulp and symptom-free primary teeth. The rational is based on the healing ability of the radicular pulp tissue following amputation of the infected pulp chamber. Formocresol is the material of choice and the most commonly used pulp dressing in primary teeth showing high success rate of pulpotomy [5-7]. However, many concerns have been expressed about formocresol toxicity and mutagenicity. Several studies have reported its potential for the local/systemic side effects , such as local effect on the enamel structure of the permanent successors, pulpal inflammation/necrosis, general cytotoxicity, mutagenic/carcinogenic effect, systemic disturbances and immunologic responses[8]

Zinc oxide-eugenol was the first popular obtunding agent to use for preservation. But earlier studies revealed some negative aspects that eugenol possesses destructive properties, and cannot be placed directly on pulp tissue, showing low success rate in case of traumatized teeth and failure of root resorption in case of overfilling [9].

Several materials have been used instead of formocresol and Zinc oxide-eugenol. Calcium hydroxide is one of these materials since it is able to induce the formation tissue barrier. In addition, calcium hydroxide is also capable of stimulating pulp tissue repair and presents the best pulp capping outcomes [10].Some investigators asserted that alternatives to calcium hydroxide should be considered because of dissolution of calcium hydroxide, recurrence of pulp inflammation and necrosis, and the presence of tunnel defects in dentin bridges formed against calcium hydroxide that increases its permeability [11].

A viscous paste mixture of calcium hydroxide and iodoform (Metapex) was used as a root canal filling material in primary teeth. It contains iodoform (40.4%), calcium hydroxide (30.3%), and silicone oil (22.4%) [12]. Calcium hydroxide formocresol mix showed high success rates as a capping material in pulpotomized young permanent teeth of dogs and humans[13]. Moreover it showed superior properties as a capping materials in human primary molars[14-15]. According to the available literatures, it appears that there is no data about this mix as root canal filling in primary teeth. Accordingly, to the present study will be directed to evaluate this mix as a root canal filing in primary teeth.

MATERIALS AND METHODS

Study setting and population

Patients selected from the Pedodontics Outpatient Clinic, Faculty of Dental Medicine, Boys, Cairo, Al-Azhar University. Patient's aged ranged from 4 -8 years old, who had badly decayed primary molars indicated for pulpectomy. A total of 75 primary teeth were included.

Sample size

A sample size of 25 in each group that has a 80% power has been selected to detect a difference between means of 4.60 with a significance level (alpha) of 0.05 (two-tailed).

Pulpectomy was performed in 75 badly decayed primary molars that divided into three equal groups according to material used in pulpectomy:

Group A: 25 primary molars received ZO/E as root filling material

Group B: 25 primary molars received Calcuim hydroxide mix as root filling material.

Group C: 25 primary molars received Metapex as a root filling material.

Eligibility criteria of population

Inclusion criteria:

1. A Cooperative child with clinical characteristics showing one sign or more to require partial pulpectomy.

2. Tooth with deep carious and a pulp exposure.
3. Tooth with carious pulp exposure, diagnosed as having irreversible pulpitis on basis of reported symptoms and/or clinical findings (Profuse hemorrhage following pulpotomy procedure).
4. Tooth should be restorable.
5. Uncontrolled hemorrhage after coronal pulp removal.
6. Tooth showing radiographic signs of pulpal or inter-radicular involvement ranging from slight thinning of the trabeculae to furcal and/or periapical radiolucency.

Exclusion criteria:

1. Tooth associated with dentigerous cyst.
2. Uncooperative child or any child with systemic disease.
3. Tooth in preshedding and abnormal pathologic mobility.
4. Tooth with internal/external root resorption involving permanent tooth follicle.
5. Tooth showing perforation of pulpal floor.
6. Non restorable tooth.

Preparation of Calcuim hydroxide formocresol mix:

It was made from mixing of 1.5gm pure calcium hydroxide powder with 1ml of Buckley's formocresol (full thickness). The resulted paste (pH is about 9.5) was used as a pulp capping materials in Calcium hydroxide-Formocresol pulpectomy

Intervention

Following local anesthetic administration, rubber dam isolation of the tooth was carried out. Dental caries and overhanging enamel were removed using at high speed contra-angled handpiece with a water coolant. Access to the coronal pulp was obtained with a round bur and flaring with fissure diamond stone was made. A sharp excavator was used if there were any remnants of necrotic tissue inside the canal pulp chamber. Pulpal tissue was extirpated from the root canals using H files.

A diagnostic radiograph with a K file placed in each canal was taken to ascertain the length of the root canal. The working length was kept 1.5mm short of the radiographic apex to avoid over instrumentation and over obturation. The cleaning and shaping of the root canals was carried out using k file (20, 25, 30, and 35). Care was taken to selectively file the root canals. This maintained more pressure along the outer wall of the canal and not towards the generally thin inter-radicular area, thus minimizing the risk of perforation. Irrigation of the root canals was alternatively done using saline and 2.5% sodium hypochlorite solution. Canals were then dried with absorbent Paper points and were ready for obturation. After placement of the root filling material (each group received the root canal filling material it was assigned to), the tooth was restored by glass ionomer cement as temporary restoration then amalgam as a final restoration (Figure 1).

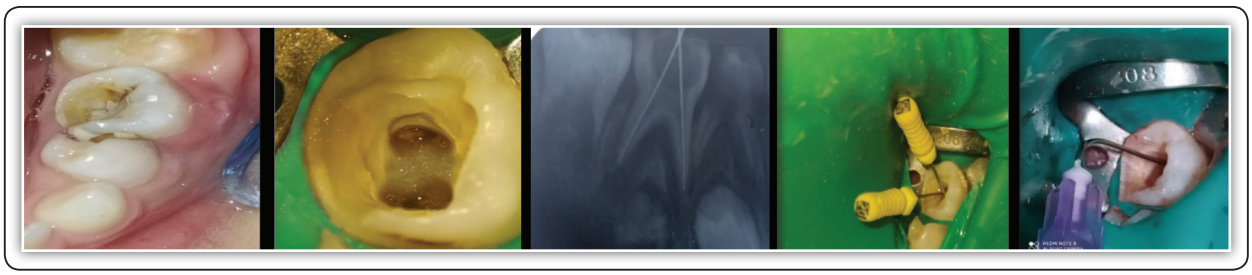

FIG (1) A photograph of the pulpectomy procedure in a badly decayed lower right second primary molar treated with Calcium Hydroxide Formocresol mix as a root filling material. (From left to right; preoperative, access cavity, working length determination, canal preparation using hand files, and canal irrigation).

Ethical consideration

The study was approved by the Pedodontics Scientific Committee and Department council, Faculty of Dental Medicine, Boys, Cairo, Al-Azhar University. A signed informed consent was taken from the parents of each child prior to beginning of the procedure.

Statistical Analysis:

Data were statistically analyzed using SPSS statistical program (Statistical Package for Social Sciences) version 21 for windows. A value of $P \leq 0.05$ was considered statistically significant. Chi square test and odd ratio were performed for data analysis. Sample size (n=25/group) was large enough to detect large effect sizes for main effects and pair-wise comparisons, with the satisfactory level of power set at 80% and 95% confidence level.

RESULTS

Clinical and radiographic examinations were done preoperative, 24 hours, 6 weeks, 3 months, and 6 months post-treatment. Patients' assessment were done on every visit and the success rate was regularly calculated. The final outcome was taken after the final evaluation on the last visit. The evaluation criteria included presence of acute pain, tooth mobility, apical periodontitis (acute or chronic), radiographic evidence of internal or external resorption, widening of periodontal membrane space, apical or bifurcation radiolucent areas.

Clinical and radiographic evaluation:

The cases treated were considered successful clinically if there was no pain, tenderness on percussion, periapical pathology, absence of swelling or fistula, and absence of mobility. The cases were considered successful radiographically when no evidence of internal or external resorption, widening of periodontal membrane space, apical or bifurcation radiolucent areas were present (Figure 2). All cases were examined for clinical and radiographic symptoms prior to the procedure that was recorded. Results of the pre-operative and follow-up clinical factors are summarized in the table (1).

After a 6 months follow up period in calcium hydroxide fromocresol mix group, only 2 teeth caused of pain, 1 tooth was tender to percussion. Meanwhile, in the ZO/E group, 4 teeth caused pain, 2 teeth were tender to percussion, and 2 teeth showed mobility and gingival swelling. In the Metapex group, only 1 tooth caused pain and was tender to percussion. Clinically, postoperative evaluation revealed that there was reduction in clinical signs and symptoms, which was statistically significant but the difference between the three groups ($P = 0.045 < 0.5$) was significant statistically.

The success of the treatment was determined after a follow up period of 6 months. In the group treated with Metapex, the success rate clinically and radiographically was 94% (24 out of 25 teeth were successfully treated) while in CaOH/FC mix group it was 88% (22 out of 25 teeth). In ZO/E the success rate clinically and radiographically was 84% (21 out of 25 teeth) were considered successful as these teeth were asymptomatic and clinical as well as radiographical signs of pathology were absent.

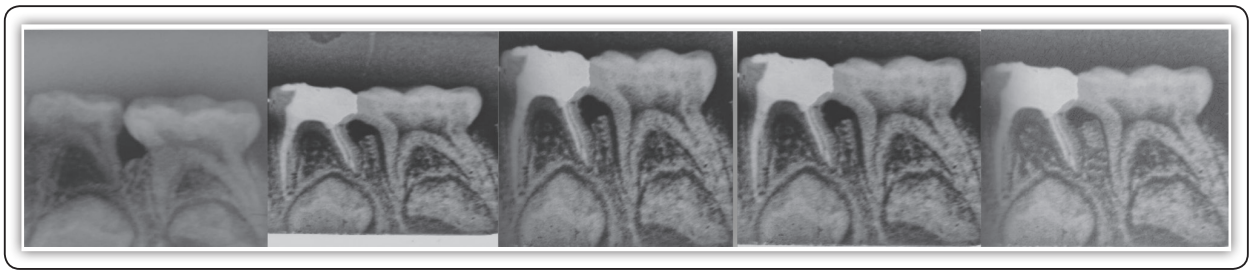

FIG (2) A photograph of the radiographic assessment of a tooth from group (A) treated with pulpectomy using ZO/E (From left to right; pre-operative, 24 hours, 6 weeks, 3 months, and 6 months post-operative, respectively).

TABLE (1): Comparative clinical evaluation between the 3 groups, preoperatively, 24 hours, 6 weeks, 3 months, and 6 months postoperatively.

Variables		Material group					
		ZO/E		CaOH/FC mix		Metapex	
		Yes	No	Yes	No	Yes	No
Follow up time	Pre-operative	14 (56%)	11 (44%)	16 (64%)	9 (36%)	18 (72%)	7 (28%)
	After 24 hours	14 (56%)	11 (44%)	16 (64%)	9 (36%)	18 (72%)	7 (28%)
	After 6 weeks	5 (20%)	20 (80%)	4 (16%)	21 (84%)	4 (16%)	21 (84%)
	After 3 months	4 (16%)	21 (84%)	3 (12%)	22 (88%)	1 (6%)	24 (94%)
	After 6 months	4 (16%)	21 (84%)	3 (12%)	22 (88%)	1 (6%)	24 (94%)
Chi square Test	P value	<0.0001*		<0.0001*		<0.0001*	
		0.5921 ns					

**: significant ($p < 0.05$)* *ns: non-significant ($p > 0.05$)*

DISCUSSION

The lack of treatment of a deciduous tooth with irreversible pulpitis or pulpal necrosis can cause damage to the permanent successor tooth, such as enamel hypomineralization or enamel hypoplasia, having negative impacts on the child's oral health and related quality of life (such as pain, missed school days, and difficulty in chewing). Therefore, teeth presenting these conditions should be extracted or subjected to root canal treatment. Various techniques for the endodontic treatment of deciduous teeth have been described [16].

Dental caries still the number one disease affecting children in Egypt and all over the world .It is one of the most common conditions affecting the general health of children. Pulpectomy is considered the last option for keeping a primary tooth that has an irreversibly-affected pulp tissue due to caries in a child. The aim of pulpectomy is to preserve teeth in a symptom free state until they are replaced by their successor naturally during the transition from primary to permanent dentition, thus avoiding extraction [17].

ZOE is the most commonly used substance that was recommended in 2008 by the American Academy of Pediatric Dentistry (AAPD) for treatment in primary teeth [18]. The success rate reported for ZOE varies from 65% to 100%, with an average of 83%, and there is no significant difference between the success rates of ZOE and calcium hydroxide or iodoform formulations [19]. Despite several advantages of ZOE that made it the material of choice for intra-canal filling, it is not an ideal one. ZOE has some disadvantages such as low resorption rate, irritation of periapical tissues, and changing the path of eruption of permanent successor [20]. It may also cause necrosis of bone and cementum when be extruded beyond the apex of teeth. A lot of controversial studies have been done about success rate of different intra-canal filling material, especially ZOE that almost none of them

were only on necrotic teeth, For example, Holan and Fuks [7] gave an overall success rate of 65% to ZOE as an intra-canal filling material, after a 12-48 month follow up. Whereas, Coll et al. [21] reported a success rate of 86.1% after at least a 5-year follow up of 41 pulpectomized teeth with ZOE.

So in this study, the investigators tried to increase the success rate of calcium hydroxide and decrease the toxicity of formocresol, and avoid the disadvantage of ZO/E reaching to a more successful, available, and cheaper filling material. The new mix results were compared to that of ZO/E and Metapex.

In Group A (ZO/E Group)**,** it was found that the success rate is (84%), which is nearly the same as the results of Mani SA and Chawla HS 2000 who reported 83.3% success rate in follow up period of 6 months. Also the current study results are compatible with many other results as Nadkarni U, Damle SG. 2000 who reported 88.6% success rate in follow up period of 9 months [22,23]. However, the study results are contradicted with the results of Zahra B and Shiva Z Who reported 93.4% success rate in the follow up period of one year. This contradiction may be due to incorrect case selection or individual variations [24].

In Group B (CaOH/FC mix group) the study results (88% success rate) came compatible with the results of Alaa et al (who reported 100% success rate of calcium hydroxide-Formocresol mix after 3 months of clinical and radiographic follow up in young permanent molars). In addition, the results of this study are in agreement with the study of Alaa et al [25] who also reported 100% clinical and radiographic success of the same mix after 3 years of follow up of recently exposed young permanent teeth. This slight difference may be referred to difference in teeth tissues reaction and individual variations [16].

This higher success rate of the mixture than calcium hydroxide and formocresol may be due to, firstly, the milder pH (9.5) of the calcium hydroxide-formocresol mix (slightly alkaline) i.e. it is less irritable than calcium hydroxide pH (11) and formocresol pH (4.5). However this irritation is recommended and enough to stimulate the undifferentiated mesenchymal cells to differentiate into odontoblasts cells that laying the reparative dentine layer and thus forming the calcific dentine barrier. This newly formed dentin bridge isolate & protect the injured pulp from the external infection and irritation and subsequent inflammation and complication[26]. Secondly, the low diffusion ability of formocresol in the new mix that has two effects, the first one is the antiseptic (bactericidal) effect against invaded bacteria. The second effect is decreasing the toxic effects of formocresol on pulp cells, thus providing more favorable conditions for healing and success [26].

In Group C (Metapex Group)**,** it was found that the success rate of this study (94 %) is in agreement with Swati et al [16] who reported a success rate (100%) clinically and radiographically. The slight difference may be due to individual variations and difference in teeth tissue.

CONCLUSIONS

Based on the results of the present study, the following conclusions could be drawn:

1. Calcium hydroxide-Formocresol mix proved a better clinical and radiographic result. So it can be used as a successful filling material in treatment of badly decayed deciduous teeth that indicated for pulpectomy techniques.
2. Calcium hydroxide-Formocresol mix could be used in the future in treatment of recently exposed traumatized deciduous teeth.

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