Clinical and radiographical evaluation of pulpotomy in primary molars treated with Pulpotec (PD), Formocresol and Mineral Trioxide Aggregate (MTA)

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ABSTRACT
Background: Pulpotomy is an accepted treatment for the management of cariously exposed pulps in symptom free primary molars to achieve one of the most important goals for Pedodontists, which is the retention of the pulpally involved deciduous teeth healthy until the time of normal exfoliation. The purpose of this study was to evaluate the relative success of pulpotec, formocresol and Mineral Trioxide Aggregate (MTA) in cariously exposed primary molar teeth, using clinical and radiographical examinations.

Materials and methods: Thirty nine children with 45 primary molars requiring pulpotomy were selected in this study, 15 teeth treated by each type of pulpotomy medicament. Clinical and radiographical follow up for the patients was performed after 1 month, 3 months and 6 months respectively.

Results: After six months, the clinical success rate of the Pulpotec group was (93.3%), formocresol group was (73.3%) and (100%) for the MTA group, although the success rate of the formocresol group was the least comparing to the other two groups, it was statistically not significant (P= 0.05). The highest and lowest radiographical success rates after six months, were encountered in the MTA (100%) and formocresol (66.7%) groups respectively, which showed a significant difference (P=0.04). The radiographical success rate of the pulpotec group was (86.7%).

Conclusion: This study suggests that Pulpotec and MTA can be used as a replacement for formocresol as a pulpotomy medicament in primary molar teeth.

Key words: Pulpotomy, Primary Molar, Formocresol, pulpotec, Mineral Trioxide Aggregate (MTA).

INTRODUCTION
Pulpotomy is the most common pulp treatment of the primary teeth in children before 6 years of age (1,2), it is indicated in primary molars when the radicular pulp tissue is healthy or is capable of healing after surgical amputation of the affected or infected coronal pulp (3). This treatment has attained wide acceptance clinically and radiologically when pulpal inflammation is confined to coronal pulp (4). The procedure involves coronal pulp amputation and the remaining vital radicular tissue surface is treated with long-term clinically evaluated medicaments to preserve the vitality and function of radicular pulp (5). For many years, formocresol was an acceptable and the most commonly used dressing material for the amputated pulp (7). Success rates of pulpotomy with formocresol in primary molars ranged between 70% to 97% (8-10) and declined with time 

Pulpotec (PD) is a radioopaque non resorbable material for simple rapid and long term treatment for pulpotomy of vital molar, the vitality of the residual radicular pulp after treatment with Pulpotec is undisputable and in many literatures, they confirm the fact that the components of Pulpotec, formaldehyde in particular, are not diffused beyond the pulp chamber, but only react at the level of the interface Pulpotec/pulp, maintaining the vitality of the underlying radicular pulp, that is the action of formaldehyde stops with the setting of the preparation. The setting time of PD being of about 7 hours, it allows the safeguarding of the vitality of the radicular pulp (11).

According to the clinical trials provided, the high efficiency of PD for treatment of odontitis in molars of temporary and permanent teeth by vital amputation method and absence of negative dynamics during 6 months of the observation were ascertained. Simplicity in use, absence of pain symptoms during the treatment, decreasing of terms of treatment to two visits, keeping of vital pulp will considered to be advantages of the preparation. Positive results of medical trials of PD preparation enable to recommend it for use in extensive clinical practice (14).

Mineral Trioxide Aggregate (MTA) is a new biocompatible material has been continuously investigated for its ability to seal the pathways of communication between the root canal system and external root surface (5, 15). It is a fine hydrophilic powder developed by Mahmoud Torabinejad in...
1993, it composed of tricalcium silicate, tricalcium aluminate, tricalcium oxide, silicate oxide and bismuth oxide (16). MTA has been proposed as a potential medicament for pulpotomy procedures as well as capping of the pulp with reversible pulpsitis, repair of root perforation and apexification (5), and one of its applications is using the material after coronal pulp amputation in primary molars with carious pulp exposure as a pulp dressing material (5,15-17,28). Furthermore, MTA has superior biocompatibility is less cytotoxic than other materials currently used in pulp therapy (16).

The present study is designed to compare the success rate of PD in comparison to conventional pulpotomy procedure (formocresol) and the use of Mineral Trioxide Aggregate MTA in pulpotomized primary molar teeth.

MATERIALS AND METHODS
Sample
Forty five primary molars with asymptomatic deep carious lesions selected from healthy children, attending Pedodontics and Prevention Department at College of Dentistry, University of Baghdad. The collection of the sample started from May 2009 and the follow up period end in May 2011. Their ages ranged from 4 to 8 years. Full detailed treatment plans were explained to the children's parents and written consents for treatment were obtained prior to the clinical procedures and any patient that could not return for follow up on call was excluded from the study. Preoperative periapical radiograph was taken and the selected teeth were assigned randomly to one of three treatment groups: Pulpotec (PD), Formocresol and Mineral Trioxide Aggregate (MTA). Fifteen primary molars were selected for each of the three groups.

Procedure
After performing local anesthesia, all teeth were isolated with a rubber dam and dental caries were removed and coronal access of the pulp were obtained by high speed bur with water spray. The entire roof of the pulp chamber was then removed. The coronal pulp was amputated using a slowly revolving round bur #6; the pulp tissue was removed by sharp spoon excavator. The amputated pulp stumps in the three groups were gently pressed by sterilized moistened cotton pellet that is to achieve hemostasis, if the bleeding not stopped, which is an indication of inflamed pulp canal tissue; the tooth was excluded from the study.

In the pulpotec group, the treatment was provided in two visits. In the first visit and according to the manufactures' instructions, pulpotomy was performed in the usual way, after removal of the coronal pulp tissue Pulpotec liquid was mixed with Pulpotec powder (PD, Switzerland) and blend to obtain required thick, creamy consistency of the paste, the paste was then inserted into the pulp-chamber with a large sized paste filler. The presence of small quantities of blood does not affect the efficiency of Pulpotec; the cavity was air-dried prior to the application of the paste, and then sealed with temporary cement. Place a cotton roll between the 2 dental arches and request the patient to bite progressively but firmly, so that the Pulpotec paste clings to the walls of the pulp-cavity as well as to the root-canal orifices. Setting time of Pulpotec is approximately 7 hours. During the second visit approximately 8-10 days later, the treatment was completed by setting the final tight obturation with amalgam, which placed on the Pulpotec, possibly leaving a thin intermediary layer of temporary cement to insulate Pulpotec from the final obturation material (14).

For the formocresol group, a cotton pellet dipped in Buckley’s formocresol (PD, Switzerland) and squeezed in a piece of cotton was placed in the pulp chamber for 5 minutes. The pulp chamber was then covered with the pulpotomy paste (1drop eugenol, 1 drop formocresol mixed with zinc oxide powder), covered with zinc phosphate cement base, and amalgam filling (15).

In the MTA group, white mineral trioxide aggregate powder (MTAANGELUS product) mixed with distilled water, according to the manufacture instructions, and by using amalgam carrier the material was applied over the pulp stumps and condensed by a condenser then covered by a layer of zinc oxide eugenol temporary filling material. After 24 hours, the teeth were restored by amalgam filling (16).

All the patients were recalled after 1 month, 3 months and 6 months (17) respectively and evaluated clinically and radio graphically.

Clinical evaluation: the presence of any signs such as swelling, pain, tenderness to percussion or palpation, sinus tract and pathological mobility was definitely of clinical failure (15).

Radiographical evaluation: the radiographs were examined carefully and compared with the preoperative radiographs (Fig. 1,2,3). Observation of any partial loss of the lamina dura, widening of the periodontal ligament, any sign of pathological external or internal root resorption as well as periapical or inter-radicular radiolucency was considered as radiographic failure (16,17).

All failed cases were treated by either pulpectomy or extraction of the tooth.
Statistical analysis was done using the Chi-square test at level of significance P<0.05 and Z-test (percentage test) to perform comparisons between the groups.

RESULTS

Thirty nine patients aged 4-8 years with mean age 6 years (19 males and 20 females) were included in the study from which 45 primary pulpotomies (11 upper and 34 lower) returned for definitive follow-up and followed up clinically and radio graphically. For each type of pulpotomy (Pulpotec, Formocresol and MTA), the treatment performed to 15 primary molars (Table 1).

Although the second primary molars were higher in number than the first primary molars 28, 17 respectively, no significant differences were observed between types of teeth treated (df =1, X²=3.592, P=0.166) which indicate that the three types of pulpotomy treatment had the same effect on the first as well as the second primary molars.

None of the patients in the MTA group showed any abnormal clinical findings, however, clinical failure symptoms of post operative swelling were reported with 1/15 in the formocresol group. Tenderness to percussion was seen in 1/15 for both Pulpotec and formocresol group, while sinus tract was reported only in formocresol group 2/15. Pain and pathological mobility were not reported in the entire follow up period.

At the end of 6 months, the follow up evaluations clinically revealed that MTA group had the highest (100%) and formocresol group had the lowest (73.3%) success rates. At the same time, an (93.3%) success rate was observed in the Pulpotec group, however, the differences between the clinical success rates of the three groups pulpotomy were statistically not significant (P=0.05), while by using Z-test a significant differences was found between MTA and formocresol group, Table 2.

Radiographical assessment of the treated sample is illustrated in Table 3. MTA group showed no evidence of radio graphic failure; while in Pulpotec group 2/15 showed internal resorption so it succeeded by a rate of 86.7%. On the other hand, the lowest success rate radio graphically was 66.7% for the formocresol group in which periapical and furcation radiolucency was seen in 3/15 and 2/15 of the treated teeth respectively. A significant difference was found statistically between the three groups (P= 0.04). Although the radiographic failures were higher than the clinical failures, they were statistically not significant.

DISCUSSION

During this study, the use of pulpotec was easy and simple and that was also mentioned by Tairov and Melekhov (18). Absence of pain at all patients without exception after use of pulpotec was seen. No complaints were lodged by patients either in the intervals between visits to clinic or during the dynamic observation. No swelling of gum in the area of the treated tooth was detected during the given period (6) months, no evidence of a fistula and no mobility of a tooth, this also was found in the results of the clinical trials provided by Dedeyan and Donkaya (14). Clinically, the success rate of pulpotec obtained in this study was 93.3%. Pulpotec (PD) composed of powder (polyoxyethylene, iodoform, and zinc) and liquid (dexamethasone acetate, formaldehyde, phenol, guaiacol, and subsidiary substances). The addition of pharmacological constituents ensures an aseptic treatment, induces cicatrization of the pulp stump at the chamber-canal interface, whilst maintaining the structure of the underlying pulp, and also avoids the numerous failures that have been noted with total pulpectomy (13).

Pulpotec showed antibacterial activity against S. aureus, E. faecalis, and E. coli, this result is probably due to the toxicogenic components in its composition (iodoform and formaldehyde) (19).

The clinical success rate in formocresol group was 73.3% which was near to that obtained by Zwain (20) who reported 75% success rate and Noorollahian (21) who reported 66% success rate. Formocresol is the most common material used in primary teeth with traumatic or mechanical exposure of coronal pulp (22) as the material has antiseptic and fixative qualities (23) but in the other hand, it is toxic and potentially carcinogenic material(24,25), while MTA was less cytotoxic, non mutagenic (26), prevent microleakage and it is a biocompatible dental material. Its biological properties may be due to its excellent sealing ability (27), high alkalinity (28), and induction of hard tissue formation (29), antibacterial effect (30), and stimulation of healing in the pulpal tissue (31,32). At the end of 6 months follow up, it was interested to note that the clinical success rate was 100% in the MTA group and this rate was obtained in other studies (5,17,33-35), while other studies showed this rate as 97% (15) and 86.7% (20).

In the present study, clinical failure symptoms were swelling, tender to percussion and sinus tract which were reported in the formocresol group. These symptoms were also noted in previous studies (4,26,22). While for pulpotec group, the only case failed was that showed tenderness to
success rate was 100%, so as in other studies (4,21,34). In the pulpotec group, it was 86.7% (two teeth showed internal resorption), which may be due to inflammatory cells attracted to the area as a result of placement of irritating capping material over the pulp tissue (presence of dexamethasone acetate, formaldehyde) which might well attract the osteoclastic cells and initiate the internal resorption. However, in the formocresol group, the success rate was 66.7% and compared to other studies this rate presented as: 68.75% (20), 67.75% (21) and 56.7% (4).

Failure of pulpotomy is normally detected radiographically, as the tooth may be asymptomatic clinically. The first sign of failure may be internal resorption of the root adjacent to the pulpal medicament. This may be accompanied by external root resorption, especially as the failure progresses. In primary molars, pathological interradicular radiolucency develops in the bifurcation or trifurcation area; in anterior teeth radiolucency may develop at the apex or laterals to the root. With more destruction, the tooth becomes mobile or a fistula may develop (37).

In the present study, after 6 months, in the formocresol group, three teeth showed periapical radiolucency and two other teeth showed furcal radiolucency. These findings of failure have also been reported in various previous studies (4,6,16,20,22,34,36,38). The pathological radiolucency in the formocresol group may have been due to the smaller molecular size of formocresol, which may cause seepage into the apical region through the pulpal canal(s) or into the furcation area via accessory canals or the pulpal floor, as it is thin, porous and permeable in nature, in deciduous molars (39,40). In addition formocresol even in reduced concentrations has the potential to result in negative immunologic, systemic, toxicological, and overt clinical consequences. More specifically formaldehyde employed during pulpotomy could evoke inflammation of surrounding non-target tissue and exert cytotoxic (41-44), genotoxic and mutagenic effects (45,46) leading to tissue damage ranging from vascular insult and inflammation (47,49) to necrotic (50,51) and osteolytic changes (52). It is also capable of damaging the enamel and the succedaneous teeth (53).

After 6 months, the MTA group was free from any pathological findings and its radiographic success rate was 100%, so as in other studies (15,32).

and this may be due to its excellent sealing ability, biocompatibility and ability to regenerate hard tissues (54-56).

Based on the data of the current study, although the clinical success rates varied between pulpotec, formocresol and MTA, it was statistically not significant, however, statistical significant differences was found concerning the radiographical success rates between the three groups. Pulpotec and MTA produce more favorable outcomes; it seems that the potential use of these materials could successfully eliminate side effects associated with formocresol in pulpotomy procedure for primary teeth.

REFERENCES
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Table 1: Distribution of the sample by type of teeth and type of treatment.

<table>
<thead>
<tr>
<th>Type of treatment</th>
<th>No. of children</th>
<th>No. of teeth</th>
<th>Maxillary 1st molars</th>
<th>Maxillary 2nd molars</th>
<th>Mandibular 1st molars</th>
<th>Mandibular 2nd molars</th>
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<tbody>
<tr>
<td></td>
<td>Males</td>
<td>Females</td>
<td>total</td>
<td>Right</td>
<td>Left</td>
<td>Right</td>
</tr>
<tr>
<td>Pulpotec group</td>
<td>6</td>
<td>7</td>
<td>13</td>
<td>15</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Formocresol group</td>
<td>3</td>
<td>10</td>
<td>13</td>
<td>15</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>MTA group</td>
<td>10</td>
<td>3</td>
<td>13</td>
<td>15</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>19</td>
<td>20</td>
<td>39</td>
<td>45</td>
<td>5</td>
<td>6</td>
</tr>
</tbody>
</table>

Table 2: Clinical assessment of the three groups pulpotomized teeth after 6-months follow up.

<table>
<thead>
<tr>
<th>Pulpotomy groups</th>
<th>Clinical findings</th>
<th>Total</th>
<th>Clinical success</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>P</td>
<td>Sw</td>
<td>T.P</td>
</tr>
<tr>
<td>Pulpotec</td>
<td>-</td>
<td>15</td>
<td>15</td>
</tr>
<tr>
<td>Formocresol</td>
<td>-</td>
<td>15</td>
<td>1</td>
</tr>
<tr>
<td>MTA</td>
<td>-</td>
<td>15</td>
<td>15</td>
</tr>
</tbody>
</table>

Pulpotec/FC/MTA
X²=5.85
P=0.05*

P: pain; Sw: swelling; T.P: tenderness to percussion; S.T: sinus tract; P.M: pathological mobility; F: failure;
S: success; FC: formocresol

Table 3: Radiographical findings of the three groups pulpotomized teeth after 6-months follow up.

<table>
<thead>
<tr>
<th>Pulpotomy groups</th>
<th>Radio graphical findings</th>
<th>Total</th>
<th>Radio Graphical success</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ER</td>
<td>IR</td>
<td>PLILD</td>
</tr>
<tr>
<td>Formocresol</td>
<td>-</td>
<td>15</td>
<td>-</td>
</tr>
</tbody>
</table>

Pulpotec/FC/MTA
X²=6.429
P=0.04**

ER: External resorption; IR: Internal resorption; PLILD: Partial Loss of Integrity of Lamina Dura; WPDL: Widening of Periodontal Ligament; PR: Periapical radiolucency; FR: Furcal radiolucency
F: failure; S: success; ** Statistically significant.

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Fig. 1: (A, B, C) illustrates the follow up of an 8 year old girl.

Fig. 2: (A, B, C) illustrates the follow up of a 6 year old boy.

Fig. 3: (A, B) illustrates the follow up of an 8 year old boy.