Comparative study of the clinical and radiographic effects of pulpotec and mineral trioxide aggregate on the pulp of the primary molars

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Objective
The aim was to evaluate clinically and radiographically the effectiveness of pulpotec and mineral trioxide aggregate (MTA) on the radicular pulp tissue of the primary molars after pulpotomy procedure and compare the results of the tested materials with that of formocresol (FC).

Materials and methods
Pulpotomy was performed on 90 lower primary molars in 30 children aged 4–8 years then were randomly divided into three treatment groups of 30 molars for each group. Group I: the pulp was treated with Pulpotec. Group II: the pulp was treated with MTA. Group III: the pulp was treated with FC. All treated molars were covered with stainless steel crowns. Clinical evaluation and standardized periapical radiographs were done after 3, 6, and 9 months.

Results
The three groups were clinically successful as Pulpotec showed (100%) success rate, MTA showed (100%) and FC showed (92.9%) success rate. There was no statistically significant difference ($P > 0.05$) between the three groups regarding to their clinical performance. While the radiographic examinations showed that Pulpotec had the highest radiographic success rate (100%) in comparison to MTA and FC (92.9, 78.6%, respectively) with statistically significant difference between the three tested materials ($P > 0.05$).

Conclusion
Pulpotec and MTA may be promising materials as pulpotomy agents in primary molars.

Keywords:
mineral trioxide aggregate, primary molars, pulpotec, pulpotomy

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Introduction

Adequate treatment of pulpally involved primary teeth is one of the most valuable services of pediatric dentistry that can be provided for the child patient. Different principles and techniques for the treatment and preservation of primary teeth has been suggested [1]. The primary objectives of these therapies are to maintain the integrity and health of the teeth and their supporting tissues also to maintain the vitality of the pulp of a tooth affected by caries, traumatic injury, or other causes [2].

Several materials have been introduced as pulpotomy agents, the gold standard pulp dressing material is formocresol (FC), it has been a popular pulpotomy medicament for many years and many clinicians continue to perform the FC pulpotomy because it produces predictable outcomes [3]. Although many studies have reported the clinical success of FC pulpotomies, concerns have been expressed about it because of observed pulpal responses with inflammation and necrosis [4], cytotoxicity [5], systemic disturbances [6], and mutagenic and carcinogenic potential [7].

Quest for newer materials are never ending especially in the field of dental science. Various materials have been formulated, tested and standardized to obtain maximum benefit for good clinical performance. One such new material is mineral trioxide aggregate (MTA) [8]. Recently Pulpotec, a filling paste which is composed of powder (polyoxymethylene, iodoform, and zinc oxide) and liquid (dexamethasone acetate, formaldehyde, phenol, guiacol, and subsidiary substances) has been introduced for simple, rapid, long-term treatment of primary molars [1,9]. Therefore, the purpose of this study was to evaluate the pulpal response to Pulpotec and to compare the outcomes to different pulpotomy materials including FC, MTA in cariously exposed primary molars.

Materials and methods

Study setting

The study was carried out at the Clinic of Pediatric Dentistry Department, Faculty of Dentistry, Tanta University.

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Patient selection

This study was performed on 90 lower primary molars of 30 healthy children of both sexes, aged from 4 to 8 years with mean age 8 years. Through clinical as well as radiographic examinations, each child had at least three primary molars with deep carious lesions. The molars were divided into three treatment groups of 30 molars for each group. Group I: the molars were treated with Pulpotec (Produits Dentaires SA, Vevey, Switzerland). Group II: the molars were treated with MTA (Angelus Solucoes Odotologicas, Londorina, Brazil). Group III: the molars were treated with FC (Sultan Health Care, Eenglewood, New Jersey, USA).

Criteria for teeth selection

(1) Clinical criteria:
  (a) Inclusion criteria:
    (i) Bilateral carious lower primary molars (three molars).
    (ii) Teeth that could be restored with proper restorations.
    (iii) Apparently healthy children free from any systemic diseases.
  (b) Exclusion criteria:
    (i) Abnormal tooth mobility.
    (ii) Pain or tenderness on percussion.
    (iii) History of swelling or sinus tract.
(2) Radiographic criteria:
  (a) Inclusion criteria:
    (i) No bifurcation involvement or periapical radiolucency.
    (ii) No internal or external root resorption.
    (iii) No more than one-third of root with physiologic resorption.
  (b) Exclusion criteria:
    (i) Pulp calcification.
    (ii) Periodontally involved teeth.
    (iii) Abnormal position of permanent tooth germ.

Procedure

Preoperative periapical films were taken for each patient. After application of topical and local anesthesia, complete isolation was done using rubber dam. Caries and the roof of the pulp chamber had been removed using high-speed bur No. 330 under water spray. The coronal pulp tissue was amputated by a sharp spoon excavator then the cavity was irrigated with sterile normal saline. Bleeding was stopped by gentle application of small piece of wet cotton pellets. All the materials were mixed and applied according to the manufacturer's instructions.

All treated molars were sealed with IRM (DENTSPLY, GmbH, Germany) then prepared to receive appropriate stainless steel crowns (3M, Neuss, Germany). Occlusion and adaptation were checked and crowns had been cemented with glass ionomer cement (KetacCem; 3M ESPE) then postoperative radiographs were taken.

Patients follow up

All patients were instructed to maintain good oral hygiene and recalled for clinical and radiographic evaluation at 3, 6, and 9 months intervals and the results were recorded. Evaluation had been done by the pedodontist and blinding done by the two supervisors.

Criteria of success and failure

The clinical criteria of success:
(1) Absence of tooth mobility.
(2) Absence of spontaneous pain or pain on percussion.
(3) Absence of swelling, abscess or fistula.

The clinical criteria of failure:
(1) Clinical evidence of pain.
(2) Tooth mobility.
(3) Swelling and fistula formation.

The radiographic criteria of success:
(1) Absence of periapical radiolucency.
(2) Absence of internal or external root resorption.
(3) Absence of furcation radiolucency.
(4) Normal periodontal ligament.
(5) Absence of pulp calcification.

The radiographic criteria of failure:
(1) Periapical or inter-radicular bone loss.
(2) Presence of internal or external root resorption.
(3) Presence of furcation radiolucency.
(4) Presence of pulp calcification.

Statistical analysis

Clinical evaluation and standardized periapical radiographs were done after 3, 6, and 9 months. The data were collected, tabulated, and statistically analyzed using the $\chi 2$-test (SPSS version 16; IBM Corporation, Armonk, New York, USA). Descriptive statistics and $\chi 2$-test were used at a significance level of P less than or equal to 0.05.

Results

Group I: Pulpotec

The clinical and radiographic success rate was 100%. There was no statistically significant difference between the clinical and radiographic findings of pulpotec group at different follow-up periods ($P = 1.00$) (Table 1).

Group II: MTA

Clinical results

The treated teeth were symptom-free with no pathological signs at all follow-up periods There was no statistically significant difference between the clinical findings of MTA group at different follow-up periods ($P = 1.00$) (Table 2).

Radiographic results

At three months only one (3.3%) molar showed furcation radiolucency while at 6 months another one showed pulp canal calcification. At the end of follow up both molars showed the same radiographic changes and two patients were lost so the radiographic success rate decreased to 92.9%. There was no statistically significant difference between the radiographic findings of MTA group at different follow-up periods ($P = 0.78$) (Table 3).

Group III: FC

Clinical results

At 3 and 6 months the treated molars were clinically asymptomatic and the clinical success rate was 100%, while at 9 months the success rate was decreased to 92.9% as two molars showed spontaneous pain, pain on percussion and swelling. There was no statistically significant difference between the clinical findings of FC group at different follow-up periods ($P = 0.116$) (Table 4).

Radiographic results

At 3 months only three (10%) molars showed furcation radiolucency with a radiographic success rate of 90% while at 6 months, two molars showed furcation radiolucency, one molar showed internal root resorption and three molars showed pulp canal calcification with a failure rate of 20.7% with a success rate of 79.3%. At 9 months six (21.4%) molars with those radiographic changes and two patients were lost so the radiographic success rate was decreased to 78.6%. There was no statistically significant difference between the radiographic findings of FC group at different follow-up periods ($P = 0.28$) (Table 5).

Comparison between clinical success and failure rates of the three groups at different follow-up periods

MTA and Pulpotec groups showed the highest clinical success rates at different follow-up periods 100%, while the FC group showed 100% success rate at 3 and 6 months and decreased to 92.9% at 9 months but the difference was not significant between them. Also the differences were nonsignificant when comparing (Pulpotec and FC) and (MTA and FC) (Table 6).

Comparison between radiographic success and failure rates of the three groups at different follow-up periods

Pulpotec group showed the highest radiographic success rate100% among the tested materials during follow-up periods while, MTA group showed 96.7% at 3 months, 93.1% at 6 months and 92.9% at 9 months. The FC group showed 90, 79.3, and 78.6%, respectively, success during 3, 6, and 9 months. While the difference between the 3 groups was not significant (0.1) at 3 months, it was significant (0.02) at 6 and 9 months. The differences were significant between Pulpotec and FC at 6 and 9 months, while the differences were not significant between MTA and FC at different follow-up periods (Table 7).

Discussion

Pulpotomy is the accepted treatment for the management of cariously exposed pulp in 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 [10].

Unfortunately, the ideal pulp dressing material has not yet been identified and the continuous search for

Table 1 Clinical and radiographic evaluation of group I during the study periods

Materials	3 months (*n*=30) [*n* (%)]		6 months (*n*=29) [*n* (%)]		9 months (*n*=28) [*n* (%)]	
	Success	Failure	Success	Failure	Success	Failure
Pulpotec	30 (100.0)	0	29 (100.0)	0	28 (100.0)	0
P			1.00			

Table 2 Clinical evaluation of group II during the study periods

Materials	3 months (*n*=30) [*n* (%)]		6 months (*n*=29) [*n* (%)]		9 months (*n*=28) [*n* (%)]	
	Success	Failure	Success	Failure	Success	Failure
MTA	30 (100.0)	0	29 (100.0)	0	28 (100.0)	0
P			1.00			

MTA, mineral trioxide aggregate.

alternatives to FC as a pulp dressing in primary tooth pulpotomy has yet to reveal an agent or technique that has long-term success rates better than those of FC [11].

Although, Pulpotec used in this study containing formaldehyde, it is less harmful than FC. It is available in powder/liquid preparation and mixing of its ingredients results in a paste that hardens quickly thus eliminates the presence of volatile fraction which may penetrate the underlying pulp tissue and produce undesirable systemic effect [9]. In addition it lacks the presence of cresol which potentiate the effect of formaldehyde on tissue protein [12]. Thus to obtain the benefits and eliminate unwanted side effects associated with FC in pulpotomy procedure of primary teeth.

Table 3 Radiographic evaluation of group II during the study periods

Materials	3 months (*n*=30) [*n* (%)]		6 months (*n*=29) [*n* (%)]		9 months (*n*=28) [*n* (%)]	
	Success	Failure	Success	Failure	Success	Failure
MTA	29 (96.7)	1 (3.3)	27 (93.1)	2 (6.9)	26 (92.9)	2 (7.1)
P	0.781					

MTA, mineral trioxide aggregate.

Table 4 Clinical evaluation of group III during the study periods

Materials	3 months (*n*=30) [*n* (%)]		6 months (*n*=29) [*n* (%)]		9 months (*n*=28) [*n* (%)]	
	Success	Failure	Success	Failure	Success	Failure
FC	30 (100.0)	0	29 (100.0)	0	26 (92.9)	2 (7.1)
P	0.116					

FC, formocresol.

Table 5 Radiographic evaluation of group III during the study periods

Materials	3 months (*n*=30) [*n* (%)]		6 months (*n*=29) [*n* (%)]		9 months (*n*=28) [*n* (%)]	
	Success	Failure	Success	Failure	Success	Failure
FC	27 (90)	3 (10)	23 (79.3)	6 (20.7)	22 (78.6)	6 (21.4)
P	0.286					

FC, formocresol.

At the end of the study, the three groups were clinically successful. The Pulpotec and MTA groups showed 100% success rate while the FC group showed 92.9%. In the Pulpotec group, there were absence of pain, swelling, fistula and mobility at all patient without exception after use of pulpotec. These results are in agreement with the results of the clinical trials provided by Dedeyan and Donkaya [13]. These results were also agree with the result of the study done by Moaanes *et al*. [14] that compared pulpotec and FC and showed 100% clinical and radiographic success for pulpotec group.

While these results are comparable with the results of Al-Dahan *et al*. [10] who demonstrated clinical and radiographic success of 93.3 and 86.7% for Pulpotec, respectively, and 100% for MTA.

The high clinical success rate of Pulpotec in this study may be due to the fact that the components of Pulpotec, formaldehyde in particular, are not diffused beyond the pulp chamber, but only react at the level

Table 6 Comparison between clinical success and failure rates of the three groups at different follow-up periods

Study groups	Follow-up period [*n* (%)]					
	3 months (*n*=30)		6 months (*n*=29)		9 months (*n*=28)	
	Success	Failure	Success	Failure	Success	Failure
Pulpotec	30 (100)	0	29 (100)	0	28 (100)	0
MTA	30 (100)	0	29 (100)	0	28 (100)	0
Formocresol	30 (100)	0	29 (100)	0	26 (92.9)	2 (7.1)
P					0.116	
Pulpotec and MTA						
Pulpotec and Formocresol					0.149	
MTA and Formocresol					0.149	

MTA, mineral trioxide aggregate.

Table 7 Comparison between radiographic success and failure rates of the three groups at different follow up periods

Study groups	Follow-up period [*n* (%)]					
	3 months (*n*=30)		6 months (*n*=29)		9 months (*n*=28)	
	Success	Failure	Success	Failure	Success	Failure
Pulpotec	30 (100)	0 (0)	29 (100)	0 (0)	28 (100)	0 (0)
MTA	29 (96.7)	1 (3.3)	27 (93.1)	2 (6.9)	26 (92.9)	2 (7.1)
Formocresol	27 (90)	3 (10)	23 (79.3)	6 (20.7)	22 (78.6)	6 (21.4)
P	0.160		0.021*		0.020*	
Pulpotec and MTA	0.313		0.150		0.150	
Pulpotec and Formocresol	0.076		0.010*		0.010*	
MTA and Formocresol	0.301		0.128		0.127	

MTA, mineral trioxide aggregate. *Significant at $P \leq 0.05$.

of the Pulpotec/pulp interface 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 Pulpotec being of about 7 h, it allows the safeguarding of the vitality of the radicular pulp [15].

Also the synergetic action of other ingredients in the Pulpotec cement like dexamethasone, a potent synthetic member of the glucocorticoid class of steroid drugs has an anti-inflammatory and immunosuppressant property [16]. Phenol has anti-inflammatory, antiviral, antibacterial, and anticarcinogenic properties [17]. In addition to the disinfectant effect of Iodoform [18].

It has been found that despite removal of the pulp chamber, a root pulp may be partly viable. At first glance this occurrence may be considered doubtful because of the mummification properties of the components, but we suggest a mummification process refers to the pulp mouth part which closely adjoins the Pulpotec layer while the apical portion remains viable [15].

The clinical success rate of MTA in this study was 100%, this agree with the studies of Farsi *et al.* [19] and Godhi *et al.* [20] who reported 100% success rate. The high clinical success rate of MTA has been due to its ability to seal off the pathways of communication between the root canal system and the external surface of the tooth, which prevents the bacterial leakage and has a high level of biocompatibility [8].

The clinical success rate in FC group was 92.9% which was agree with the results of Cuisia and colleagues who reported 93% success rate. This may be due to fixation of affected and infected radicular tissue, so that a chronic inflammation replaces an acute inflammation so that the pulp remains in a metastable condition [3].

Although the clinical success rates varied between pulpotec, FC and MTA, it was statistically not significant, however, statistical significant differences was found radiographically concerning the three groups.

In this study MTA group showed 92.9% radiographic success rate that was agree with the results obtained by Cuisia *et al.* [21] and Jabbarifar *et al.* [22], but disagree with the results obtained by Holan *et al.* [23] and Naik *et al.* [24] who recorded 97 and 100% radiographic success rate, respectively.

FC group showed 78.6% radiographic success rate comparable with that obtained by Cuisia *et al.* [21], Holan *et al.* [23], Agamy *et al.* [25], and Naik *et al.* [24] who showed radiographic success of 83, 90, and 100%, respectively.

The radiographic failure in the FC group may have been due to the smaller molecular size of FC, which may cause seepage into the apical region through the pulpal canals or into the furcation area via accessory canals or the pulpal floor, as it is thin, porous and permeable in nature, in deciduous molars [26].

Conclusion

(1) Pulpotec and MTA showed high clinical and radiographic success rate compared to FC.
(2) Pulpotec and MTA could be a promising pulpotomy materials.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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