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CLINICAL AND RADIOGRAPHIC ASSESSMENT OF PULPOTOMY MATERIALS IN PRIMARY MOLARS

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ABSTRACT

Aim or purpose: Clinical and radiographic evaluation of four different materials utilized in vital pulpotomy in mandibular primary molars

Materials and methods: one hundred and sixty mandibular primary molars in forty children were included as split mouth design. Patients were medically free with an age range from 4-6 years. Inclusion criteria: patients presented with deep carious lesions including the first and second primary molars bilaterally, no evidence of any clinical pathology, mobility and had no tenderness to percussion. Pre-operative radiographs showed no evidence of external or internal root resorption, absence of furcal, periapical radiolucency or widened periodontal ligament space and no more than one-third root resorption detected. The included molars undergone vital pulp therapy and bilaterally randomly divided into four equal groups, group (1) formocresol, group (2) ferric sulphate, group (3) MTA (mineral trioxide aggregate) and group (4) Metapex (calcium hydroxide &iodoform). All treated molars were evaluated both clinically and radiographically for 12 months evaluation period. Data were collected and analysed statistically.

Results: It was shown that, at base line, there was no statistically significant difference between clinical as well as radiographic success rates among the four groups. After 3 as well as 6 months, there was a statistically significant difference between clinical and radiographic success rates among the four groups. FS, MTA and Metapex groups showed higher clinical and radiographic success rates than FC group.

Conclusions: Ferric sulphate, mineral trioxide aggregate (MTA) and Calcium hydroxide and iodoform paste (Metapex) provide clinically acceptable alternative to formocresol in vital pulp therapy in primary teeth.

INTRODUCTION

Dental caries is a continuous process especially in children till degradation of the dental hard tissues occur leading to infection of the dental pulp. Infected pulp tissue in primary teeth is usually treated with pulpotomy, which is defined as 'the amputation of infected coronal pulp, and treatment of the radicular uninflamed tissues with pulpotomy medicaments, pulpotomy rather than direct pulp capping that proved to have poor success is performed.[1,2]

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Ranly classified pulpotomy based on treatment objectives into devitalization (Mummification, Cauterization), preservation (minimal devitalization, noninductive) and regeneration (inductive, reparative). Non-chemical methods of pulpotomy include use of electro surgery and lasers [3].

The first pulpotomy treatment modality of primary teeth was **devitalisation** using formocresol that was introduced by Buckley in 1904. Since then various modifications have been tried and advocated regarding the techniques of FC pulpotomy and the concentrations [3]. Buckley's formula of formocresol includes formaldehyde 19%, Cresol 35%, glycerine 15%, and water with an approximate pH of 5.1. Currently 1:5 dilution of Buckley's formocresol is commonly used [4,5]. Formocresol prevents tissue autolysis by binding to peptide group of side chain of amino acid. It is a reversible process without changing of basic structure of protein molecules [6].

Despite the popularity of formocresol as a pulpotomy medicament in the primary dentition, concerns have been raised over its use in humans, mainly as a result of its toxicity and potential carcinogenicity [7]. A survey conducted in the United states reported that majority of dentists used FC as pulpotomy medicament and they were not concerned about adverse effects, while a survey conducted in the UK showed that 66.5%of pediatric dentists used FC for pulpotomy, 54.2% were concerned regarding their preferred medicament and were considering change of the chosen technique [8].

Preservative pulpotomy technique produce minimal insult to orifice tissue, thereby maintaining vitality and normal histological appearance of radicular pulp. Ferric sulphate is one of the materials included in this category which is a non-aldehyde chemical that has received attention recently as a pulpotomy agent. This haemostatic compound was proposed on the theory that it prevents the problem in clot formation thereby minimizing chances of inflammation and internal resorption. When ferric sulphate comes in contact with pulp tissue forms ferric ion-protein complex that mechanically occludes capillaries on amputation site forming barrier for irritants of sub-base [3,9].

Regenerative pulpotomy It is also called as inductive pulpotomy or reparative pulpotomy. This mechanism encourages the radicular pulp to heal and form a dentin bridge/hard tissue barrier. **Ranly** stated that "Ideal pulpotomy treatment should leave the radicular pulp vital and healthy and completely enclosed within an odontoblast-lined dentin chamber." In this situation, the tissue would be isolated from noxious restorative materials in the chamber, thereby diminishing the chances of internal resorption. Moreover, the odontoclasts of an uninflamed pulp could enter into the exfoliative process at the appropriate time and sustain it in a physiologic manner. On the opposite of the other two categories i.e devitalization and preservation, the rationale for developing regeneration is dependent upon on sound biologic principle [3].

Calcium hydroxide and mineral trioxide aggregate are two materials included in this category. Calcium hydroxide was the first agent used in pulpotomies that demonstrated any capacity to induce regeneration of dentin. The action of calcium hydroxide was attributed to a modification of the solubility product of Calcium, phosphate and a precipitation of salt into an organic matrix. Additionally, the high pH of calcium hydroxide stimulates the pulp to begin the intrinsic reparative cascade. Unfortunately, the stimulus evoked by this compound is delicately balanced between one of repair and one of resorption. It was claimed that the main disadvantage of this alternative intervention is internal resorption [10].

Mineral Trioxide Aggregate (MTA) was introduced by **Torabinejad** and has proven good success rates as pulpotomy agent [7]. MTA studies revealed

that it possesses not only good sealing ability, excellent long-term prognosis and good biocompatibility but also favours tissue regeneration. MTA has an alkaline pH of 10.2 immediately after mixing and increases to 12.5 after 3 hours of setting that induces dentin bridge formation by the pulp tissue. MTA on the histological level caused minimal pulpal inflammation [11].

Debates surrounding formocresol urged for further search for various safer and effective alternative medicaments as pulpotomy agents presented in this study.

SUBJESTS AND METHODS

This study was conducted at the Department of Pediatric Dentistry, Faculty of Dentistry, Cairo University. The study protocol was approved by the Ethical Committee of Faculty of Dentistry, Cairo University. The clinical procedure and associated risks and benefits were fully explained to the parents or legal guardian of the participants. Written informed consent was obtained from the parents or legal guardian of the participants prior to investigation. All participants were screened by taking a detailed history and performing a thorough clinical and radiographic examination.

One hundred and sixty mandibular primary molars in forty children were included as split mouth design. Patients were medically free with an age range from 4-6 years.

Sample size calculation

Sample size determination was based upon the results of Kusum B et al. Using alpha level of 0.05 (5%) and β level of 0.20 (20%) i.e. power = 80%; the estimated minimum required sample size (n) was 32 cases. Over-sampling was performed to compensate for 20% drop-out rate so the required sample size is a minimum of 38 cases.

Inclusion criteria

A) Clinical inclusion criteria:

- patients presented with deep carious lesions including the first and second primary molars bilaterally
- No evidence of any clinical pathology
- No mobility and had no tenderness to percussion.

B) Radiographic inclusion criteria:

- Pre-operative radiographs showed no evidence of external or internal root resorption.
- Absence of furcal radiolucency.
- Absence of periapical radiolucency or widened periodontal ligament space
- No more than one-third root resorption detected.

All the included molars undergone vital pulp therapy and were bilaterally randomly divided into four equal groups of 40 each, depending on the type of pulpotomy medicament used. Randomization of the pulpotomy medicament used was done by envelope draw method for all the selected molars in the same patient. After administering local anaesthesia, the molars were isolated with a rubber dam. All caries was removed and coronal access was gained using a sterile No. 330 high speed bur with water coolant to deroof the pulp chamber. A sterile spoon excavator was used for coronal pulp amputation. One or more sterile cotton pellets moistened with distilled water were placed over the pulp stumps, and light pressure was applied for 5 minutes for obtaining haemostasis. If bleeding did not stop after 5 minutes, the molar was excluded from the study. Depending on the type of pulp medicament, the molars were treated as follows:

Group I

Formocresol group (control group). The molars of this group were treated by applying formocresol (formocresol, Dentsply, Surrey, UK) using a sterile cotton pellet for 3–5 mins. After removal of the cotton pellet, a reinforced zinc oxide eugenol base covered the pulp stumps.

Group II

After the standardized technique, the molars assigned for group II were treated with 15.5% Ferric Sulphate solution (FS) (Astringedent, Ultradent products, USA). The FS was placed over amputated pulp stumps with the help of an applicator tip for 15 seconds and then the pulp chamber was flushed with water by an air-water syringe, dried by cotton pellet. A thick mix of zinc oxide eugenol (ZOE) cement was placed over the pulp stumps.

Group III

MTA paste (ProRoot MTA, Dentsply, Tulsa, OK, USA) (mineral trioxide aggregate) was prepared according to manufacturers' instructions to obtain a putty-like consistency. The mixture was delivered to the pulp stumps and condensed lightly with a moistened sterile cotton pellet to ensure a thickness of 2 to 3 mm. A thick mix of zinc oxide eugenol (ZOE) cement base was applied over the MTA followed by glass ionomer cement (GIC) restoration.

Group IV

After coronal pulp was amputated, haemostasis was achieved by dry cotton pellet. The remaining pulp tissue was dressed with metapex (Meta Biomed Co Ltda, Korea) (calcium hydroxide & iodoform). Care was taken to create a complete seal of the pulp tissue with metapex condensed lightly with a moistened sterile cotton pellet to ensure a thickness of 2 to 3 mm. A thick mix of zinc oxide eugenol (ZOE) cement base was applied followed by glass ionomer cement (GIC) restoration.

All the pulpotomized molars were covered with stainless steel crowns as a final restoration.

The patients were recalled for clinical and radiographic evaluations at 3, 6, 9 and 12 months intervals. The molars were evaluated clinically and radiographically by the second author who was blinded to the medicament used. Clinical and radiographic criteria for assessing molars were used according to **Zurn** and **Seale** [12]. Table (1) and (2).

TABLE (1): Clinical scoring

Clinical Score	Clinical Symptom	Definition
1	**Asymptomatic**	•Pathology: absent •Normal functioning •Mobility (physiological) ≤ 1 mm
2	**Slight Discomfort, Short-lived**	•Pathology: questionable •Percussion sensitivity •Gingival inflammation (due to poor oral hygiene) •Mobility (physiological) > 1 mm, but < 2 mm
3	**Minor Discomfort, Short- Lived**	•Pathology: initial changes present •Gingival swelling (not due to poor oral hygiene) •Mobility > 2 mm, but < 3 mm
4	**Major Discomfort, Long-lived Extract Immediately**	•Pathology: late changes present •Spontaneous pain •Gingival swelling (not due to poor oral hygiene) •Periodontal pocket formation (exudate) •Sinus tract present •Mobility ≥ 3 mm •Premature tooth loss, due to pathology

TABLE (2): Radiographic scoring

Radiographic score	Radiographic finding	Definition
1	**no changes present at 6 mon follow-up***	•internal root canal form tapering from chamber to the apex •periodontal ligament (pdl)/periapical regions; normal width and trabeculation
2	**pathological changes of questionable clinical significance at 3 mon follow-up***	•external changes are not allowed (widened pdl) widening, abnormal inter-radicular trabeculation or variation in radiodensity •internal resorption acceptable (not perforated) •calcific metamorphosis is acceptable and defined as: uniformly thin root canal; shape (non-tapering); variation in radiodensity between canals
3	**pathological changes present before 3 mon follow-up***	•external changes are present, but not large •mildly widened pdl •minor inter-radicular radiolucency with trabeculation still present •minor external root resorption; internal resorption changes are acceptable, but not if external change is also present (perforated form)
4	**pathological changes present extract immediately**	•frank osseous radiolucency present

Data were collected and analysed statistically.

Statistical Analysis

Data were presented as frequencies (n) and percentages (%). Since the study is a split-mouth design, so Friedman's test was used to compare between the four groups.

The significance level was set at $P \leq 0.05$. Statistical analysis was performed with IBM® SPSS® Statistics Version 20 for Windows.

RESULTS

Demographic data

The present study was conducted on 40 children; 22 boys (55.0%) and 18 girls (45.0%).

The mean ± standard deviation values of age were 5.1± 0.8 years with a minimum of 4.0 years and a maximum of 6.0 years old.

Clinical evaluation

At base line, there was no statistically significant difference between clinical scores of the four groups.

After 3 and 6 months, there was a statistically significant difference between clinical scores of the four groups. FS, MTA and Metapex groups showed the highest prevalence of Score 1. FC group showed the highest prevalence of Scores 2 and 3.

After 9 and 12 months, there was no statistically significant difference between clinical scores of the four groups Table (3).

Radiographic evaluation

Through all follow up periods**,** there was no statistically significant difference between radiographic scores of the four groups Table (4).

® IBM Corporation, NY, USA.
® SPSS, Inc., an IBM Company.

TABLE (3): Descriptive statistics and results of Friedman's test for comparison between clinical scores in the four groups

Time	Score	FC		FS		MTA		Metapex		*P*-value
		n	%	n	%	n	%	n	%	
Base line	1	40	100.0	40	100.0	40	100.0	40	100.0	1.000
3 months	1	34	85.0	40	100.0	40	100.0	40	100.0	<0.001*
	2	2	5.0	0	0.0	0	0.0	0	0.0	
	3	4	10.0	0	0.0	0	0.0	0	0.0	
6 months	1	33	82.5	37	92.5	39	97.5	38	95.0	0.009*
	2	2	5.0	2	5.0	0	0.0	1	2.5	
	4	4	10.0	0	0.0	0	0.0	0	0.0	
9 months	1	31	77.5	33	82.5	36	90.0	33	82.5	0.428
	2	1	2.5	4	10.0	2	5.0	1	2.5	
	3	0	0.0	1	2.5	0	0.0	4	10.0	
	4	2	5.0	0	0.0	0	0.0	0	0.0	
12 months	1	29	72.5	30	75.0	33	82.5	30	75.0	0.442
	2	0	0.0	5	12.5	3	7.5	0	0.0	
	3	1	2.5	0	0.0	0	0.0	2	5.0	
	4	0	0.0	0	0.0	0	0.0	2	5.0	

: Significant at P ≤ 0.05

TABLE (4): Descriptive statistics and results of Friedman's test for comparison between radiographic scores in the four groups

Time	Score	FC		FS		MTA		Metapex		*P*-value
		n	%	n	%	n	%	n	%	
Base line	1	40	100.0	40	100.0	40	100.0	40	100.0	1.000
3 months	1	34	85.0	39	79.5	38	95.0	35	87.5	0.076
	2	2	5.0	1	2.5	2	5.0	5	12.5	
	3	4	10.0	0	0.0	0	0.0	0	0.0	
6 months	1	33	82.5	36	90.0	36	90.0	33	82.5	0.347
	2	2	5.0	3	7.5	3	7.5	6	15.0	
	4	4	10.0	0	0.0	0	0.0	0	0.0	
9 months	1	31	77.5	33	82.5	36	90.0	32	80.0	0.488
	2	1	2.5	4	10.0	2	5.0	4	10.0	
	4	2	5.0	1	2.5	0	0.0	2	5.0	
12 months	1	29	72.5	31	77.5	34	85.0	30	75.0	0.479
	2	0	0.0	4	10.0	2	5.0	1	2.5	
	3	1	2.5	0	0.0	0	0.0	0	0.0	
	4	0	0.0	0	0.0	0	0.0	2	5.0	

: Significant at P ≤ 0.05

Success rate

Scores 1 and 2 were considered a success while Scores 3 and 4 were considered failure.

At base line, there was no statistically significant difference between clinical and radiographic success rates among the four groups.

After 3 and 6 months, there was a statistically significant difference between clinical and radiographic success rates among the four groups. FS, MTA and Metapex groups showed higher clinical and radiographic success rates than FC group.

After 9 and 12 months, there was no statistically significant difference between clinical and radiographic success rates among the four groups.

TABLE (5): Descriptive statistics and results of Friedman's test for comparison between clinical and radiographic success rates among the four groups

Time		FC		FS		MTA		Metapex		*P*-value
		n	%	n	%	n	%	n	%	
Clinical success	Base line	40	100.0	40	100.0	40	100.0	40	100.0	1.000
	3 months	36	90.0	40	100.0	40	100.0	40	100.0	0.007*
	6 months	35	87.5	39	97.5	39	97.5	39	97.5	0.007*
	9 months	32	80.0	37	92.5	38	95.0	34	85.0	0.145
	12 months	29	72.5	35	87.5	36	90.0	30	75.0	0.112
Radiographic success	Base line	40	100.0	40	100.0	40	100.0	40	100.0	1.000
	3 months	36	90.0	40	100.0	40	100.0	40	100.0	0.007*
	6 months	35	87.5	39	97.5	39	97.5	39	97.5	0.007*
	9 months	32	80.0	37	92.5	38	95.0	36	90.0	0.261
	12 months	29	72.5	35	87.5	36	90.0	31	77.5	0.392

: Significant at P ≤ 0.05

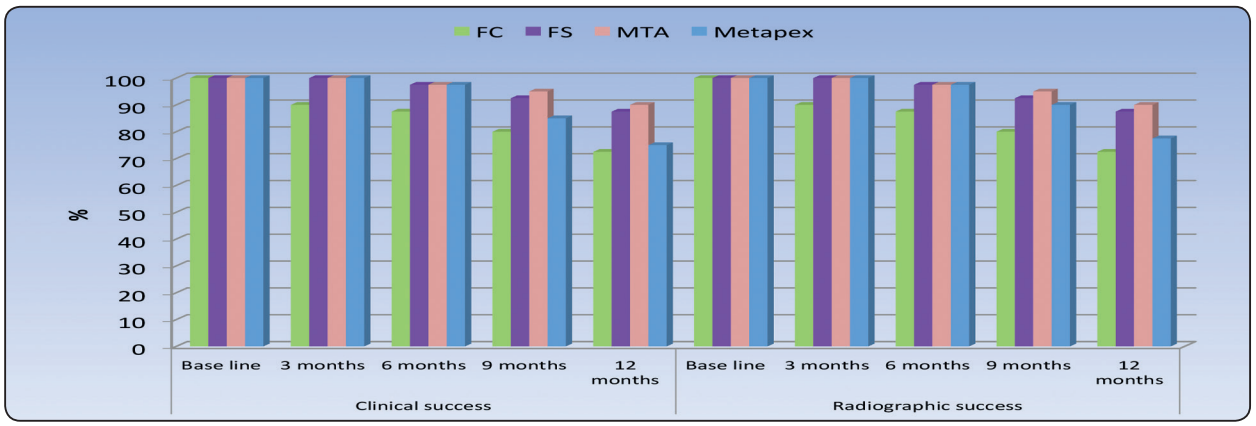


Fig. (1): Comparison between clinical and radiographic success rates among the four groups

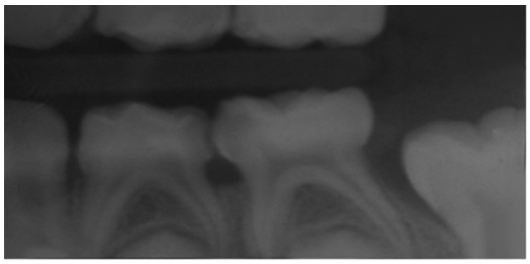
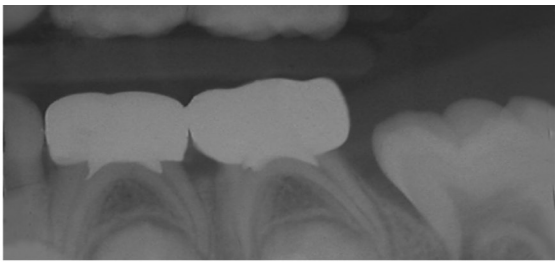
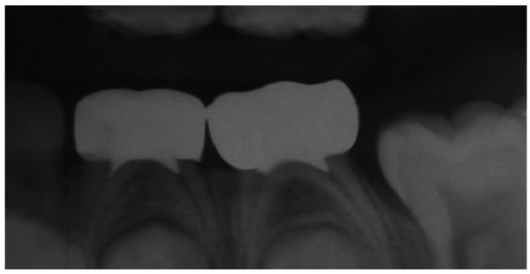
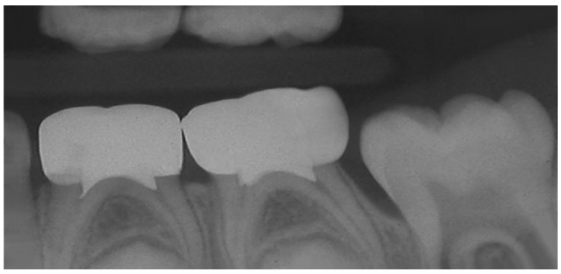
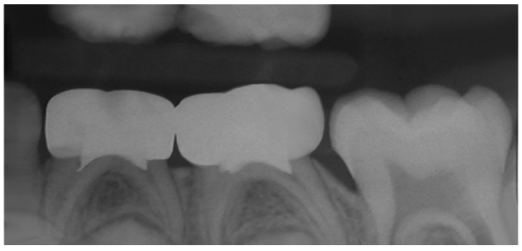
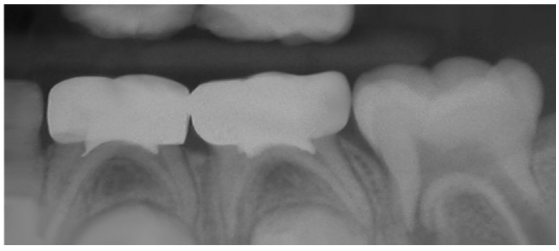
	
Pre-operative radiograph	At baseline, MTA pulpotomy in D & Metapex in E
	
At 3 months, MTA pulpotomy in D & Metapex in E	At 6 months, MTA pulpotomy in D & Metapex in E
	
At 9 months, MTA pulpotomy in D & Metapex in E	At 12 months, MTA pulpotomy in D & Metapex in E

Fig. (2): Radiographs of MTA and Metapex pulpotomy at different time intervals

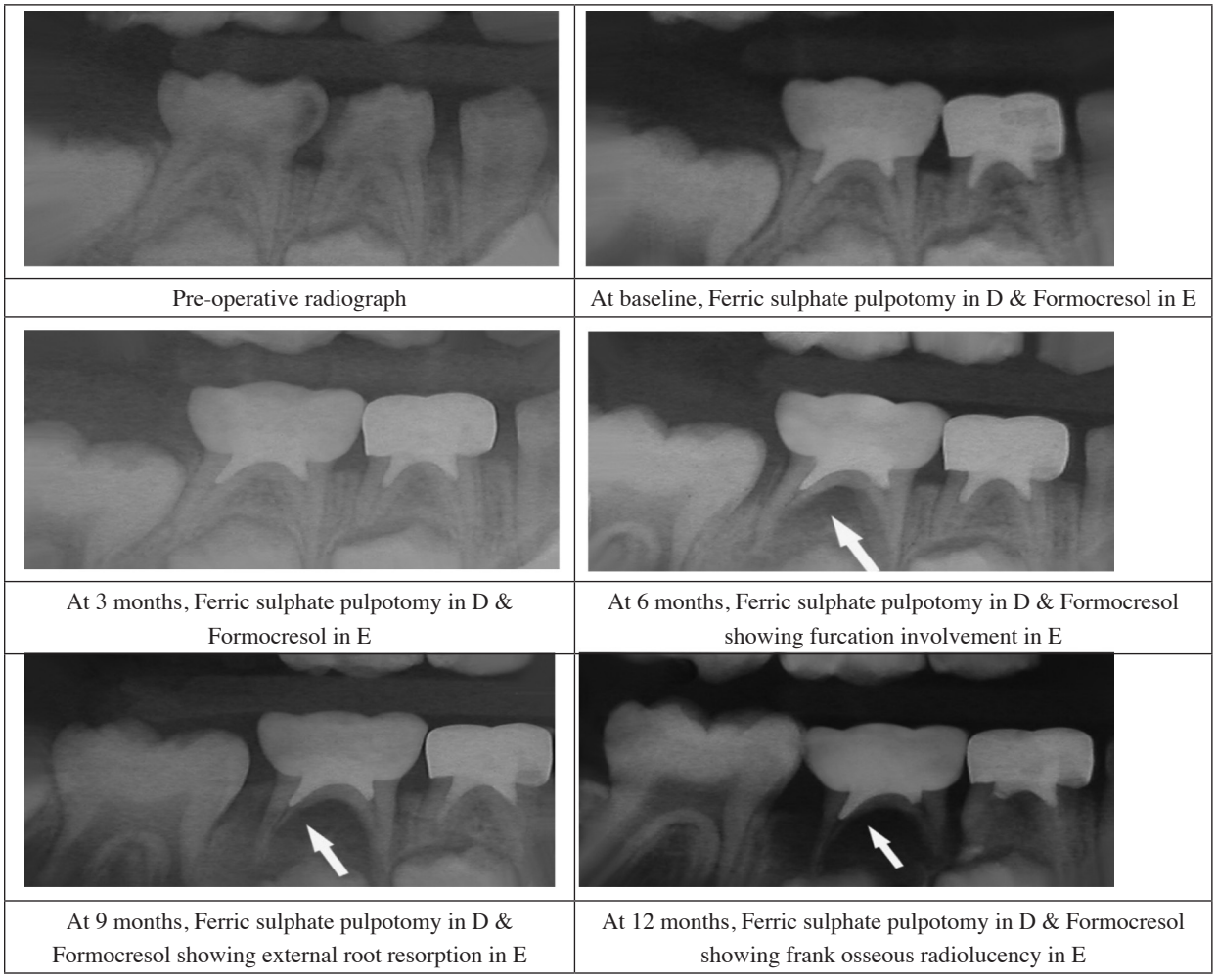


Fig. (3): Radiographs of Formocresol and ferric sulphate pulpotomy at different time intervals

DISCUSSION

The success of materials utilized in pulpotomy procedures is affected by a number of variables including potential of pulp healing, biocompatibility, dimensional stability, handling properties, antibacterial and mechanical properties. [13]

Formocresol has been the most commonly used pulpotomy medicament for many years. It was considered as "gold standard" in pediatric dentistry. However, concerns have been raised over its use in children that was attributed to its toxic and mutagenic effects in cell culture, dental crypts, and precancerous epithelial cells. Therefore, additional biocompatible treatment alternatives were required to replace formocresol pulpotomy. A wide range of alternatives such as ferric sulphate (FS), electrosurgery, laser, collagen, freeze dried bone, morphogenic bone proteins, and mineral trioxide aggregate (MTA) have been investigated for pulpotomy. [14]

This study examined the clinical and radiographic success rates of pulpotomies with formocresol, ferric sulphate (FS), mineral trioxide aggregate (MTA) and Metapex (calcium hydroxide and iodoform) as pulpotomy materials in primary molars.

Ferric sulphate is a nonaldehyde, haemostatic compound, which forms a metal-protein complex at the surface of the pulp stump that forms a barrier

to irritating components of the subbase. It was suggested that haemostasis of the remaining pulpal tissue leads to increased success of pulpotomy procedure. [15]

MTA was considered a promising pulpotomy medicament material and therefore was selected in this study owing to its properties. Recently, it was proven that it possesses not only biocompatible but also bio-inductive properties, pulp therapy medicaments have stepped from preservation to regeneration of the pulp tissue. Furthermore, MTA provides sealing ability better than that of amalgam or zinc oxide– eugenol. It was claimed that MTA stimulates cytokine release from bone cells, indicating that it actively promotes hard tissue formation [16].

Calcium hydroxide is a strong alkaline substance, which has a pH of approximately 12.5. In an aqueous solution, calcium hydroxide dissociates into calcium and hydroxyl ions. It provided various biological properties that included antimicrobial activity, high alkalinity, inhibition of tooth resorption and tissue dissolving ability. Several studies have investigated the mixture of other substances with calcium hydroxide aiming for improving some of its properties. Among these additional substances are vehicles that can speed up or slow down ionic dissociation, substances that aid the filling of pulpal cavity by means of their consistency, substances used as antimicrobial medium and media that enhance radiopacity. Metapex, is a silicone oil-based calcium hydroxide paste containing 38% iodoform [17,18].

The accurate diagnosis of pulp status and the prognosis of pulpotomy procedure depends on clinicians' experience, accuracy of data reported in dental history given. These confounding variables cannot determine the extent of bacterial penetration from carious lesion into the pulp. Therefore, in the current study, definitive selection for the primary molars was done intraoperatively on the basis of the time needed for haemostasis after coronal pulp amputation [19].

The patients in the study were monitored both clinically and radiographically at 3, 6, 9 and 12 months. The aim of scoring assessment was to reveal the severity of changes, molars were not counted as 'successful' or 'failed' based on clinical signs or symptoms. In this study, molars were considered 'successful 'when clinically and radiographically scored of 1 or 2. Similarly, **Zealand et al,** explained that, teeth scored (2) clinically and radiographically represented questionable pathological changes [20].

In the current study, clinical success scores rate evaluated for Formocresol, ferric sulphate, MTA, and Metapex groups were 72.5, 87.5, 90 and 75%, respectively, for 12 months evaluation period. Comparably, **Erdem et al**, and **Havale et al**, reported success rates of formocresol were 72% and 76.7% respectively [21,22].

Although ferric sulphate is not a new pulp medicament for pulpotomized primary molars, the number of clinical studies, especially high quality randomized clinical trials, was limited [23]. **Markovic et al**, reported a similar clinical success rate of 89 % regarding ferric sulphate in comparison with formocresol as a pulpotomy medicament [24].

Authors considered prevention of microleakage a major factor affecting the success of vital pulp therapy procedures. In the current study, the highest values of clinical success were reported in the MTA group that was in harmony with **Nowicka et al.,** who attributed the clinical success of MTA to its potential to prevent microleakage and excellent sealing properties [25].

However, in literature, there was no considerable supporting evidence for clinical success for Metapex as a pulpotomy agent as it was described as a pulpectomy filling material. The success rate of 75% Metapex group (calcium hydroxide and iodoform) could be referred to the synergistic effects of inductive calcium hydroxide and the antiseptic effect of added iodoform. Iodoform is soluble in fatty acids and composed of some powder

with bright hexagonal crystals of lemon yellow colour, with penetrating and persistent smell. On dissociation it releases nascent iodine (96,7% of iodine) [26,27].

Radiographic assessment of pulpotomized molars was conducted at 3, 6, 9 and 12 months intervals. Radiographic success rates for formocresol, ferric sulphate, MTA and Metapex groups were 72.5, 87.5, 90 and 77.5% respectively. During the follow-up period, when minor radiographic changes were noticed that included nonperforated internal resorption and/or pulp canal obliteration, cases were monitored and not counted as failure. Molars with certain radiographic pathological changes presented as periapical/ interradicular bone destruction, external root resorption and PDL widening were considered as failure.

Ferric sulphate, MTA and Metapex groups showed significant statistical difference than formocresol group regarding radiographic success observed at 3 and 6 months intervals. At 12 months evaluation period, all the study groups showed no significant statistical difference regarding radiographic success. Pulp Canal Obliteration was the most common radiographic finding in MTA group over a period of 12 months. **Erdem et al**. has attributed similar high rates of pulp canal obliteration with MTA as a result of odontoblastic activity [21].

Debates were evident about considering nonperforated internal resorption in pulpotomized primary molars criterion for determination of success or failure. **Holan et al**. and many other authors did not consider it as a sign of failure in the absence of clinical signs, symptoms, and advocated to be monitored at follow-up intervals as the pathology may cease and lead to the development of calcific metamorphosis [28]. External root resorption was reported as a radiographic failure in the current study. **Sonmez et al**, reported comparable radiographic rates to that of the present study [29].

All treated primary molars in the current study were restored with stainless steel crowns (SSCs) for standardization. The patients in the study were monitored clinically and radiographically at 3, 6, 9 and 12 months. The final restoration plays an important role over pulpotomized primary molars in preventing microleakage. **Croll** and **Killian** have advocated SSCs as a final restoration of molars undergone pulp therapy, that would ensure less leakage and more protection of the underlying pulp in crowned molars than those restored with amalgam for the success of pulp therapy [30,31].

CONCLUSIONS

Considering the results and according to the materials and methods of the current study, it could be concluded that the Ferric sulphate, mineral trioxide aggregate (MTA) and Calcium hydroxide and iodoform paste (Metapex) provide clinically and radiographically acceptable alternatives to formocresol in vital pulp therapy in primary teeth.

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