Clinical and Radiographic Evaluation of the Effectiveness of Formocresol, Mineral Trioxide Aggregate, Portland Cement, and Enamel Matrix Derivative in Primary Teeth Pulpotomies: A Two Year Follow-Up

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Objective: *The aim of this study was to evaluate and to compare clinical and radiographic outcomes of 4 materials (formocresol, mineral trioxide aggregate (MTA), Portland cement and enamel matrix derivative) using in primary teeth pulpotomies.* ***Study Design:*** *Sixty-five patients aged 5–9 years (32 female, 33 male) were included in this study. A total of 140 primary first and second molars with deep caries were treated with pulpotomy. All teeth were then restored with stainless steel crowns. The treated teeth were evaluated clinically and radiographically at 3, 6, 12, 18 and 24 months.* ***Results:*** *At 24 months, the clinical success rates of formocresol, MTA, Portland cement, and enamel matrix derivative were 96.9%, 100%, 93.9%, and 93.3%, respectively. The corresponding radiographic success rates were 84.4%, 93.9%, 86.7% and 78.1%, respectively.* ***Conclusion:*** *Although there were no statistically significant differences in clinical and radiographic success rates among the 4 groups, MTA appears to be superior to formocresol, Portland cement, and enamel matrix derivative as a pulpotomy agent in primary teeth.*

Key words: *Pulpotomy, Formocresol, Mineral trioxide aggregate, Portland cement, Enamel matrix derivative*

INTRODUCTION

Caries and perforation result in microorganism infection of the coronal pulp, which leads to inflammation and degenerative changes in the pulp. When the abnormal tissue is removed, healthy pulp with healing potential remains.[1] Pulpotomy treatment is used when the remaining root pulp is clinically and radiographically vital and no other pathological changes are observed.[2] Procedures and materials used in pulpotomy treatment have evolved to include devitalizing treatment, preventive treatment, and regenerative treatment.

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The ideal material used in pulpotomy should be bactericidal, should not damage the pulp or surrounding tissue, should close the root pulp with a limited dentin barrier, should promote healing of the root pulp, and should not affect the physiological root resorption process of the primary tooth.[3,4] Because no such ideal material containing all these features is available, research to produce new materials continues. Procedures and materials used in pulpotomy treatment have evolved as follows: devitalizing treatment (formocresol, glutaraldehyde, and electrosurgery), preventive treatment (calcium hydroxide, ferric sulfate, mineral trioxide aggregate, bioaggregate, biodentine, and lasers), and regenerative treatment (bone morphogenetic protein, collagen, and freeze-dried bone).[5,6]

Formocresol, a potent germicide used to fixate viable tissues, was first used by Sweet in 1930 as a multisession technique in the pulpotomy treatment of primary teeth. The aim of this technique was complete tissue mummification.[5] It has been postulated that complete fixation of tissues theoretically devitalizes and sterilizes the radicular pulp, thus preventing infection and internal resorption.[6] However, due to cooperation difficulties over time and for financial reasons, the number of sessions has been reduced.

Mineral trioxide aggregate (MTA) was first used in dentistry in 1993 to repair canal perforations.[6] Many in vivo and in vitro studies have shown that MTA prevents microleakage, is biocompatible, and enables the regeneration of original tissues upon contact with the pulp and periradicular tissues.[7] It has been reported that MTA can be used as a pulp coating material as well as a pulpotomy material.

MTA has two forms—white and gray.[8] White MTA, used in frontal teeth to correct the esthetic features of the original material, consists of tricalcium silicate, dicalcium silicate, tricalcium aluminate, calcium sulfate dihydrate, and bismuth oxide. Bismuth oxide powder is added to the aggregate to gain radiopacity.[6]

Portland cement consists of tricalcium silicate, dicalcium silicate, tetracalcium aluminoferrite, and dehydrated calcium sulfate. It is used in dentistry for pulpotomy treatment, root perforation repair, coating of the pulp, and radicular tip filling.[9] Studies have revealed that Portland cement is not cytotoxic, stimulates reparative dentin formation, and allows cell growth.[10] Portland cement differs from MTA by the presence of potassium ions and the absence of bismuth ions.[11,12] Taking into account the low cost and apparently similar properties of Portland cement in comparison to MTA, it is reasonable to consider Portland cement as a possible substitute for MTA in endodontic applications.[11-13]

Enamel matrix derivative is a bioactive material that stimulates the regeneration of periodontal tissues such as matrix protein, periodontal ligament, cement, and alveolar bone. During odontogenesis, enamel matrix derivative is replaced by pre-ameloblasts, including amelogenins.[14] The proliferation of periodontal ligament cells is stimulated more quickly than that of fibroblasts and bone cells. In vitro studies have shown that enamel matrix derivative stimulates aggregation of immature osteoblasts in the early period.[15]

The aim of this study was to compare the clinical and radiographic outcomes of formocresol, MTA, Portland cement, and enamel matrix derivative in primary teeth pulpotomy treatment. While many studies have evaluated the clinical and radiographic success of different pulpotomy agents[16-18], no studies thus far have compared the success of the four agents used in this study.

MATERIALS AND METHOD

Patients who presented to the Gülhane Military Medical Academy (GMMA) Pediatric Dentistry Clinic were recruited for this study; the aim was to evaluate the success rates of four different materials—formocresol, Portland cement, mineral trioxide aggregate, and enamel matrix protein—used in primary teeth pulpotomies. Sixty-five patients (32 female and 33 male patients aged 5–9 years) with a total of 140 deep primary tooth caries of the first and second molar teeth and without any systemic disease were included in the study. Approval from the GMMA Health Sciences Institute Ethics Committee was obtained (30.11.2010). Prior to the treatment, the patients and their parents were informed about the benefits and possible risks, and written consent was obtained.

In our study, 4 different materials were used: formocresol (Sultan Chemists, Englewood, USA), Portland cement (Vicat Prompt Çimento, Baştaş Çimento, Ankara Turkey), mineral trioxide aggregate (Dentsply, DeTrey, Konstanz, Germany), and enamel matrix protein (Emdogain, Straumann, Peter-Merian-Weg 12 Basel, Switzerland). The selection criteria for the patients and teeth are as follows.

Patient selection criteria[1,13]

1. Absence of systemic disease such as bacterial endocarditis, kidney disease, leukemia, diabetes, neutropenia, and bleeding problems
2. Absence of any type of medical treatment or continuous use of any medication
3. Absence of drug allergies, anesthetics, and environmental allergies
4. Patient and parent compliance with the treatment

Teeth selection criterion[18]

Teeth with no clinical or radiographic pulpal degeneration

Clinical selection criteria

1. Teeth with deep decay lesions and no symptoms
2. Teeth with vital pulp exposed by decay; no spontaneous pain; and absence of edema, pain, and fistula
3. Absence of sensitivity on percussion
4. Absence of pathological mobility
5. Teeth with manageable pulpal hemorrhage

Radiographic selection criteria

1. Teeth with code 3 decay (radiolucency spread to 1/3 of the dentine) and code 4 decay (radiolucency spread to 1/3 of the pulp) according to the codes for decay lesion grade and severity used by Ekstrand *et al*.[19]
2. Teeth with no pathological root resorption
3. Teeth with no periradicular or furcal radiolucency
4. Teeth with healthy periodontal space
5. Teeth with less than 1/3 physiological root resorption (no resorption or 1/4 resorption of the root)[20]

To anesthetize the teeth and local tissues prior to the pulpotomy treatment, the patients received local infiltration anesthesia of the maxilla and inferior alveolar nerve block of the mandible. A topical anesthetic solution (Xylocaine Spray 10%, AstraZeneca AB, Sodertalje, Sweden) was applied to the dry mucosal surface for 2 min with a cotton swab prior to instilling the local anesthesia (Maxicaine, VEM İlaç, Ankara, Turkey).

After local anesthesia was achieved, the teeth were isolated with a rubber dam and suction was set up. All pulpotomy treatments were performed by the same dentist (C.Y.). All carious tissue was removed before preparing the coronal access cavity. Then, the interproximal cavities were prepared, the ceiling of the pulp chamber was removed under water cooling, the entrance cavity was prepared, and the coronal pulp was removed under water cooling. Complete removal was ensured by checking the coronal pulp; pulpal residues under dentin spurs continue to bleed and prevent visualization of the canal apertures. Any remaining coronal pulp tissue was completely removed with a sharp excavator. A sterile cotton pellet soaked in sterile saline was then placed in the pulp canal; hemorrhage control was obtained with 3–5 min of mild pressure. After the hemorrhage ceased, one of the materials—formocresol, mineral trioxide aggregate, Portland cement, or enamel matrix protein—was randomly selected and applied.

Formocresol group

The formocresol pulpotomy group was designated as the control group. In this group, the pulpotomy treatment was carried out using formocresol solution (Sultan Chemists, Englewood, USA). The excess amount of formocresol from the cotton palettes was impregnated into a sterile cotton roll that was then placed in the canals; leakage was prevented by placing a sterile cotton pellet onto the formocresol-impregnated cotton pellet. The formocresol pellet remained in the canals for 3–4 min, after which the cotton pellet was removed from the cavity and it was confirmed that the bleeding had stopped and the pulp tissue had turned brown. Zinc oxide eugenol (Cavex Zinc Oxide Eugenol Cement, Haarlem, Holland) was then placed on the root pulp, the cavity was closed with glass ionomer cement (Ionobond, Voco, Cuxhaven, Germany), and the tooth was restored with a stainless steel crown (3M ESPE, St. Paul, USA).

Mineral trioxide aggregate group (MTA)

In this group, after the bleeding was controlled, the MTA powder (Pro Root MTA, Dentsply, DeTrey, Konstanz, Germany) was mixed with distilled water in a 3:1 ratio, according to the manufacturer's instructions, and placed onto the pulp tissue. The MTA surface was smoothed with a slightly moist cotton swab, the cavity was closed with glass ionomer cement, and the tooth was restored with a stainless steel crown (3M ESPE, St. Paul, USA).

Portland cement group

The Portland cement (Vicat Prompt Çimento, Baştaş Çimento, Ankara Turkey) used in this group was sterilized with ethylene oxide prior to use, and 0.16 g of the cement were mixed with distilled water until a homogeneous pat was obtained The pulp was then closed. After the cement was smoothed with a slightly moist cotton swab, zinc oxide eugenol was applied, the cavity was filled with glass ionomer cement, and a stainless steel crown was applied (3M ESPE, St. Paul, USA).

Enamel matrix derivative group

In this group, after bleeding was controlled in the pulpotomy field, 0.7 mL of enamel matrix derivative (Emdogain, Straumann, Peter-Merian-Weg 12 Basel, Switzerland) was injected to fill the pulp tissue. It was then covered with zinc oxide eugenol and the cavity was filled with glass ionomer cement. Surface restorations were performed in the same session, after the pulpotomy treatment. After the 6 min required for hardening of the glass ionomer cement had elapsed, the tooth as restored with a stainless steel crown (3M ESPE, St. Paul, USA).

Evaluation of pulpotomy treatment and use of stainless steel crowns

Periapical radiographs were obtained immediately after the pulpotomy treatments and application of the stainless steel crowns. The teeth subjected to the pulpotomy treatments were also followed up clinically and radiographically at 3, 6, 12, 18, and 24 months. Clinical and radiographic controls of the pulpotomy treatments and stainless steel crowns were evaluated according to the following criteria.

Clinical evaluation criteria

1. Spontaneous pain
2. Sensitivity on percussion and palpation
3. Change of color, edema, or fistula of the soft tissue
4. Pathological mobility
5. Lymphadenopathy of the related region

Radiographic evaluation criteria

1. Radiolucency of the periapical or furcation
2. Pathological internal or external root resorption
3. Widening of the periodontal space
4. Calcification of the pulp canal

Restoration evaluation criteria

1. Marginal adaptation of the crown
2. Crushing or deformities of the crown
3. Changes in occlusion

Failure status of pulpotomy treatment

The teeth were evaluated as successful or unsuccessful according to the above criteria. Spontaneous pain, swelling, fistula, radiolucency of the periapical or furcation, and pathological external root resorption were indications for tooth removal. Teeth with radiographic pulp canal obliteration and internal root resorption, but with no clinical symptoms, were monitored but not removed.

Data evaluation was performed using the SPSS 15.0 program. Number and percentage values were used for data identification, and comparisons among groups were performed with Pearson's chi-square test and Fisher's exact test. Values of $p<0.005$ were considered statistically significant.

RESULTS

Sixty-five patients (32 female and 33 male patients between the ages of 5 and 9 years) with a total of 140 deep primary tooth caries on the first and second molar teeth and without any systemic disease were included in the study. Eight patients did not continue with the study and 13 teeth were unable to be checked, so 127 teeth were followed up for 24 months (Table 1). Distribution of number of patients according to treated teeth is given in Table 2. More than one pulpotomy was performed on some of the patients.

The correlations between clinical and radiographic success and failure rates and age, sex, root resorption, and teeth, without taking into account the material, were evaluated with Pearson's chi-square test and/or Fisher's exact test. No statistically significant differences were found between these factors and clinical or radiographic success rates ($p>0.05$).

Clinical and radiographic success rates of the four materials at 3, 6, 12, 18, and 24 months are presented in Table 3. There were no significant differences in success rates among the four materials at 3, 6, 12, 18, or 24 months. After the 24-month follow-up, one tooth in the formocresol group, two teeth in the Portland cement group, and three teeth in the enamel matrix protein group were found to be unsuccessful.

Table 1. The distribution of the teeth that can be followed at the beginning of the study and 24th months.(MTA: Mineral Trioxide Aggregate, PC: Portland Cement, EMD: Enamel Matrix Derivative)

	Beginning of the study	24th months
Formocresol	35	32
MTA	35	33
PC	35	30
EMD	35	32
Total	140	127

Table 2. Distribution of number of patients according to treated teeth. (MTA: Mineral Trioxide Aggregate, PC: Portland Cement, EMD: Enamel Matrix Derivative)

	Formocresol n=35	MTA n=35	PC n=35	EMD n=35	TOTAL n=140
Mandible	19	17	17	16	69
Maxilla	16	18	18	19	71
Primary 1st molar	17	16	17	15	65
Primary 2nd molar	18	19	18	20	75

In the formocresol group, spontaneous pain, sensitivity on percussion, and fistula were detected at 6 months in one tooth, which was extracted. After 24 months of follow-up, 31 teeth were considered clinically successful. In the Portland cement group, fistula formation and pathological mobility were detected at three months in one tooth and spontaneous pain and fistula formation were detected at six months in another tooth. Both teeth were extracted. After 24 months of follow-up, 28 teeth were considered clinically successful. In the enamel matrix protein group, spontaneous pain and sensitivity on percussion developed in one tooth at three months, and pathological mobility and fistula formation were detected in two teeth at six months. The teeth were considered to have indications for extraction. After 24 months of follow-up, 29 teeth were accepted as clinically successful; space maintainers were made for the teeth planned for extraction.

Findings consistent with radiographic failure were as follows: internal resorption, widening of the periodontal space, radiolucency of the furcation, and radiolucency of the periapical region. In the formocresol group, two teeth had internal resorption, one tooth had widening of the periodontal space, and two teeth had radiolucency of the furcation (Table 4). The probable reason for the internal resorption could be the irritative pH of the formocresol and its reversible fixative effect. It is also possible that the pulp was inflamed prior to treatment without clinical signs of inflammation. In the MTA

Table 3.Success-failure rates of materials at 3rd, 6th, 12nd , 18th and 24th months. (MTA: Mineral Trioxide Aggregate, PC: Portland Cement, EMD: Enamel Matrix Derivative)

	n %	Formocresol n=35		MTA n=35		PC n=35		EMD n=35		*p**
		(+)	(-)	(+)	(-)	(+)	(-)	(+)	(-)	
Beginning	n	35	0	35	0	35	0	35	0	
	%	100%		100%		100%		100%		
3rd month	n	35	0	34	0	34	1	33	1	0.566
	%	100%		100%		97.1%		97.1%		
6th month	n	32	1	34	0	31	2	31	3	0.327
	%	97%		100%		93.9%		91.2%		
12nd month	n	31	1	33	0	29	2	29	3	0.310
	%	96.9%		100%		93.5%		90.6%		
18th month	n	31	1	33	0	28	2	29	3	0.307
	%	96.9%		100%		93.3%		90.6%		
24th month	n	31	1	33	0	28	2	29	3	0.307
	%	96.9%		100%		93.3%		90.6%		

* Pearson's chi-square test

Table 4. Distribution of materials according to radiographic failure after 24-months follow up period. (MTA: Mineral Trioxide Aggregate, PC: Portland Cement, EMD: Enamel Matrix Derivative)

	Radiographic Failure				
Materials	Internal Resorption	Widening of the periodontal space	Radiolucency of the periapical or furcal part	Periapical Radiolucency	Total (n=127)
Formocresol (n=32)	2	1	2	0	5 3.9%
MTA (n=33)	0	1	1	0	2 1.6%
PC (n=30)	1	1	2		4 3.1%
EMD (n=32)	2	2	3	0	7 5.5%

group, one tooth had widening of the periodontal space and one had radiolucency of the furcation. In the Portland cement group, one tooth had internal resorption, one tooth had widening of the periodontal space, and two teeth had radiolucency of the furcation. In the enamel matrix protein group, two teeth had internal resorption, two teeth had widening of the periodontal space, and three teeth had radiolucency of the furcation (Table 4).

Clinical evaluation of upper restorations

In the teeth that underwent pulpotomy treatment and received stainless steel crowns, seven showed a change in occlusion and six had crushed crowns or perforation deformities. No problems were detected in the marginal adaptation of the stainless steel crowns.

DISCUSSION

Treatment options for vital pulp in primary teeth have been a debated topic for years in pedodontics.[20] A precise and accurate diagnosis followed by appropriate treatment is crucial in primary teeth caries.[21] Treatment choices include the use of many different methods and various dental materials.[22] In this study, we aimed to compare the radiographic and clinical success rates of formocresol, MTA, Portland cement, and enamel matrix derivative. The radiographic and clinical success and failure rates at 3, 6, 12, 18, and 24 months after the pulpotomy treatments were evaluated using Pearson's chi-square test. No statistically significant differences in clinical or radiographic results were found among the four groups. The clinical success rates were 96.9% in the formocresol group, 100% in the MTA group, 93.3% in the Portland cement group, and 90.6% in the enamel matrix protein group. The radiographic success rates were 84.4% in the formocresol group, 93.9% in the MTA group, 86.7% in the Portland cement group, and 78.1% in the enamel matrix protein group.

Similar to the clinical success rate of 96.9% in the formocresol group in our study, Huth *et al* [20] and Agamy *et al* [17] reported success rates of 96% (follow up duration, 24 months) and 90% (12 months), respectively. Unlike those studies, the clinical success rate of Farooq *et al* [23] was 74% (24 months), and that of Waterhouse *et al* [24] was 84%. The higher success rate in our study might be due to the use of stainless steel crowns for upper restoration; Farooq et al. [23] and Waterhouse et al. [24] used amalgam, compomer, and IRM.

In our study, the radiographic success rate in the formocresol group was 84.4%. Similar to our results, Waterhouse [24] reported 84% and Holan *et al* [19] reported 83% (16 months) radiographic success. In contrast to these findings, the radiographic success rate of Ibricevic *et al* [25] was 97% (20 months) and that of Ansari *et al* [26] was 90% (24 months).

Similar to the 100% success rate in the MTA group in our study, Agamy [17] (12 months) and Mortazavi [27] (24 months) both reported success rates of 100%. Similar to the 93.9% radiographic success rate in the MTA group in our study, Ansari [26] reported a 95% (24 months) radiographic success rate.

Portland cement and enamel matrix protein studies have generally been performed on animal models; clinical research studies are new and limited in number. In the Portland cement group in our study, the clinical success rate was 93% and the radiographic success rate was 86.7%. Conti *et al* [28] reported no significant difference between Portland cement and MTA in the formation of dentin bridges in primary molar teeth. Sakai *et al* [29] performed pulpotomies, using Portland cement and MTA, of 30 lower primary molar teeth in children aged 5–9 years. No clinical or radiographic failures were reported in any of the groups during their two-year follow up.

Sabbarini *et al* [21] used formocresol and enamel matrix protein in pulpotomies of primary teeth, and they reported clinical and radiographic success rates of 93.3% and 60%, respectively, for enamel matrix protein after six months of follow up. The clinical and radiographic success rates of enamel matrix protein in our study were 90.6% and 78.1%, respectively. Our higher radiographic success rate might be due to the stainless steel crowns used for the upper restoration. In contrast, Sabbarini [21] used enamel matrix protein and glass ionomer cement hardened by light for the restoration.

In our study, among the teeth subjected to pulpotomy treatment, the highest clinical success rate was obtained in the MTA group (100%). However, no statistically significant differences were found between this success rate and the success rates of the other groups. The highest radiographic success rate was also found in the MTA group (93.9%), and no significant differences were found between this success rate and those of the other groups.

Certain studies consider internal resorption as an indicator of failure.[18] Internal resorption is believed to occur as a result of chronic pulpitis, and in teeth with necrotic pulp, internal resorption develops. Therefore, the pulpotomy treatment should not be considered successful if any pathological change occurs because of the treatment, even if the pathology does not affect the tooth beneath or the course of the tooth position.[28] In our study, internal resorption was considered a radiographic criterion of failure. However, because the teeth with internal resorption were symptom-free and no clinical failure was detected, they were followed up.

Researchers have reported that clinical symptoms have weak relationships with histological pulpal conditions.[2] Therefore, if inflammation has affected the radicular pulp, asymptomatic primary teeth can be treated by pulpotomy according to clinical and radiographic results. Because of the fixative feature of formocresol, the remaining pulpal tissue is mummified and the tooth remains in the oral cavity without any symptoms. Formocresol pulpotomy is clinically oriented, meaning that the tooth is kept until exfoliation. However, it is important nowadays to promote stem cell healing in the pulp and to maintain its viability in addition to keeping the tooth until exfoliation.

Enamel matrix derivative is a bioactive material that stimulates regeneration in pulpal tissue. However, its use as a gel, its high price, and the required storage conditions are disadvantages.

No significant difference was shown between formocresol, glutaraldehyde, and ferric sulphate as medicaments for use following pulpotomy.[30] Glutaraldehyde exhibits very low tissue binding and is readily metabolised.[31] Unfortunately, a buffered solution of glutaraldehyde is unstable due to short shelf life and it has to be freshly prepared. That is why we chose to evaluate formocresol instead of glutaraldehyde.

Shorter time of use is one of the advantages of MTA and Portland cement. While formocresol needs to be applied for 3–5 min before removing the cotton pellet, base material can be filled after MTA and Portland cement are placed in the pulp canal. In addition, hemorrhage can reoccur after the formocresol cotton pellet is removed, while MTA and Portland cement can be used directly,

without the need for a cotton pellet. Furthermore, while formocresol has potentially toxic, mutagenic, and carcinogenic effects, MTA exhibits a high degree of biocompatibility. However, there are concerns regarding the ingredients of Portland cement, and further clinical studies should be performed. The routine clinical use of MTA is limited because of its high price; another factor limiting its use is the problem of storage once it is opened.

CONCLUSION

This study has demonstrated that MTA has long-term clinical success rates that are better than those of formocresol, Portland cement, and enamel matrix derivative. MTA is an appropriate material for pulpotomy procedures in primary teeth, and it has the potential to replace formocresol, which is still used extensively in pulpotomies.

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