

Scientific Article

Success Rates of Mineral Trioxide Aggregate, Ferric Sulfate, and Formocresol Pulpotomies: A 24-month Study

Arzu Pinar Erdem, DDS, PhD¹ • Yeliz Guven, DDS, PhD² • Beyza Balli, DDS, PhD³ • Banu Ilhan, DDS, PhD⁴ • Elif Sepet, DDS, PhD⁵ • Isin Ulukapi, DDS, PhD⁶ • Oya Aktoren, DDS, PhD⁷

Abstract: ***Purpose:** The purpose of this study was to evaluate the total success rates of mineral trioxide aggregate (MTA), ferric sulfate (FS), and formocresol (FC) as pulpotomy agents in primary molars. **Methods:** A randomized, split-mouth study design was used in 32 healthy 5- to 7-year-old children with 128 carious primary molars without clinical or radiographic evidence of pulp degeneration. The pulpotomy agents were assigned as follows: Group 1=MTA; Group 2=FS; Group 3=1:5 diluted Buckley's FC; and Group 4=zinc oxide eugenol (ZOE) base. Clinical and radiographic follow-up at 6, 12, and 24 months used the following criteria: pain; swelling; sinus tract; mobility; internal root resorption; and furcation and/or periapical bone destruction. The data were analyzed using chi-square. **Results:** No significant differences in success rates were found among the groups at 6 and 12 months. Success rates in groups 1 to 4 at 24 months were 96%, 88%, 88%, and 68% respectively. There was a significant difference ($P<.001$) between the MTA and ZOE groups at 24 months. **Conclusions:** ZOE, as the only pulpotomy medicament, had a significantly lower success rate than MTA. No significant differences were observed, among the 3 experimental materials (MTA, FC, and FS) at 2 years follow-up. (Pediatr Dent 2011;33:165-70) Received October 24, 2009 | Last Revision April 4, 2010 | Accepted April 25, 2010*

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Pulpotomy in a primary tooth is defined as a procedure performed when the coronal pulp tissue is exposed by caries during caries removal or trauma.¹ The inflamed and infected coronal pulp is amputated, leaving vital and uninfected radicular pulp tissue. The pulp stumps can be treated by electrosurgery, Er:YAG laser, or with a dressing such as formocresol (FC), calcium hydroxide (CH), glutaraldehyde, enriched collagen solution, ferric sulfate (FS), or mineral trioxide aggregate (MTA), which can protect the remaining pulp tissue and promote healing.²

The diagnosis and subsequent management of pulp pathology in carious primary molars remain challenging, and clinical guidelines written by various bodies can assist dentists. The UK National Clinical Guidelines in Paediatric Dentistry recommend FC, FS, CH, or MTA for direct application to vital radicular pulp.³ The American Academy of Pediatric Dentistry states that Buckley's formocresol, ferric sulfate, electrocautery, and MTA have shown long-term success in pulpotomies.⁴ Waterhouse⁵ supports the need to move away from formaldehyde-containing preparations in the dental care of children. She stated that such a move should be made not just because of concerns relating to the possible toxicity of

formaldehyde but to reflect a more contemporary, biologic approach to pulp therapy in the primary dentition.⁵ The British Society of Paediatric Dentistry has produced a range of clinical guidelines. The update reflects a shift in treatment modalities away from formocresol and discusses pulp therapy, vital pulpotomy, desensitizing pulpotomy, and pulpectomy.⁶ Although many techniques have been suggested,⁷ a recent Cochrane review has stated that evidence is lacking as to which is the most appropriate technique.⁸

Finally, there are few studies on the clinical success of mineral trioxide aggregate in primary teeth,⁹⁻¹¹ the purpose of this study was to determine the clinical and radiographic success rates of the following pulpotomy agents: MTA, ferric sulfate, one-fifth dilution of Buckley's formocresol, and no pulpotomy medicament except zinc oxide eugenol in primary molars during a 2-year follow-up period.

Methods

The procedure and its possible discomfort and benefits were explained fully to the parents of the children involved and their written consent was obtained prior to the investigation. In addition, the ethical approval was obtained from the Ethics Committee of the Medical Faculty of Istanbul University, Istanbul, Turkey. A randomized, single-blind, and split-mouth study design was used in a sample of 32 healthy 5- to 7-year-old children (18 females and 14 males). Each child had at least 4 primary molars (first or second), each of which was in

Drs. ¹Erdem, ²Guven, ³Balli, and ⁴Ilhan are research assistants and Drs. ⁵Sepet, ⁶Ulukapi, and ⁷Aktoren are professors, all in the Department of Pedodontics, Faculty of Dentistry, Istanbul University, Istanbul, Turkey.

Correspond with Dr. Guven at yelizgn@yahoo.com

a different quadrant and similarly cariously involved so as to require a pulpotomy.

A total of 128 primary molars in 32 patients were selected (1 tooth from each quadrant) based on clinical and radiographic criteria. The inclusion criteria were: cooperative children; presence of deep caries; no more than two-thirds root resorption; and the tooth was restorable. The exclusion criteria were: history of systemic disease; spontaneous tooth pain or tenderness to percussion; pathological mobility; presence of any internal resorption; apical or furcal radiolucency; presence of widened periodontal ligament space; presence of sinus tract; presence of primary teeth without permanent successor; and haemostasis requiring more than 5 minutes. Four primary molars in different quadrants in each patient were randomly assigned to receive MTA, FS, FC, or zinc oxide eugenol (ZOE) pulpotomies. Twenty-five children were examined at the end of a 2-year follow-up; 7 children were not available after 2 years (Table 1).

Table 1. DISTRIBUTION OF THE PRIMARY TEETH ACCORDING TO THE PULPOTOMY MATERIAL*

	MTA	FS	FC	ZOE	Total
Maxillary					
Primary first molar	6	6	9	6	27
Primary second molar	5	7	7	4	23
Mandibular					
Primary first molar	7	6	3	10	26
Primary second molar	7	6	6	5	24
Total	25	25	25	25	100

* MTA=mineral trioxide aggregate; FS=ferric sulfate; FC=formocresol; ZOE=zinc oxide eugenol.

A 1-session conventional pulpotomy technique was undertaken by 3 pediatric dentists after the administration of a local anesthetic. Caries removal was obtained with a slow-speed turbine after rubber dam isolation. The coronal pulp tissue was removed with a spoon excavator and irrigated with saline; the hemostasis was obtained with moistened sterile cotton pellets.

Table 2. TOTAL SUCCESS RATES OF THE GROUPS AT 6-, 12-, AND 24-MONTH FOLLOW-UPS

Materials*	Result	Follow-up times (mos)			McNemar's test (6/12 M) P-value	McNemar's test (6/24) P-value
		6 N (%)	12 N (%)	24 N (%)		
MTA	Success	25 (100)	25 (100)	24 (96)	-	>.96
FS	Success	25 (100)	25 (100)	22 (88)	-	<.88
FC	Success	25 (100)	25 (100)	22 (88)	-	<.88
ZOE	Success	24 (96)	23 (92)	17 (68)	>.95	.003
P-value		<.39	<.11	<.001		

* MTA=mineral trioxide aggregate; FS=ferric sulfate; FC=formocresol; ZOE=zinc oxide eugenol.

The teeth were treated as follows depending on the group to which they were assigned:

1. Group 1—MTA paste (ProRoot, Dentsply, Tulsa, OK, USA) was obtained by mixing 3 parts of powder with 1 part of water to obtain a putty consistency. This mixture was placed on the radicular pulp stumps and condensed lightly with a moistened cotton pellet. A ZOE base was applied over the MTA.
2. Group 2—15.5 % FS solution (Astringent, Ultra-dent Products Inc, South Jordan, Utah) was applied to the pulp stumps for 15 seconds; after irrigation, a ZOE base was placed.
3. Group 3—a cotton pellet was dipped in a 1:5 dilution of Buckley's FC (Sultan Chemists Inc, Englewood, NJ) and squeezed dry and placed on the pulp tissues for 5 minutes and removed; a ZOE base was placed.
4. Group 4—ZOE (Kalzinol, Dentsply) was directly applied to the radicular pulp tissues after the coronal pulp tissue was removed.

Following the pulpotomies, all teeth were restored with amalgam. The children were recalled for clinical and radiographic examinations after 6 months, 1 year, and 2 years. When a patient did not respond or broke an appointment, a follow-up examination was rescheduled. The children were examined clinically and radiographically by 3 experienced pediatric dentists (not the operators) blinded to the technique, and in cases of disagreement, consensus was forced. The inter- and intra-examiner reproducibility were calculated by Cohen's unweighted kappa statistic (Cohen's $\kappa=0.80$, $\kappa=1$). Pulpotomy was considered a failure clinically and/or radiographically if 1 or more of the following signs was present: pain; swelling; mobility; percussion pain; internal root resorption; and furcation and/or periapical bone destruction. Pulp canal obliteration (PCO) was not regarded as a failure.

The data were analyzed to assess the clinical, radiographic, and total success rates of the pulpotomies at each follow-up period. The statistical analysis was completed using PASS 2007 software (NCSS, Kaysville, Utah) and the chi-square test; the level of significance was set at $P<.05$.

Results

Thirty-two children, each with at least 4 cariously exposed primary molars, were enrolled in this study. Three children with failed restorations (a restoration failed when it was missing either partially or wholly) and 4 children not available at 1 of the follow-ups were completely excluded from the study; a total of 100 pulpotomized primary molars in 25 children (12 males, 13 females; mean age at the time of treatment= 6.16 ± 0.69 years; range=5-7 years) were evaluated statistically. Flow of participants and pulpotomized teeth up to 24 months is shown in Figure 1. The total success rates at the 6-, 12- and 24-month follow-ups are shown in Table 2.

The clinical and radiographic evaluation at 6 months revealed total success rates of 100% in the MTA, FS, and FC groups and 96% in the ZOE group. In the ZOE group, internal resorption was detected in 1 tooth. At the 12-month follow-up, no clinical and radiographic failures were noted in the MTA, FS, and FC groups. One additional tooth demonstrated internal resorption in the ZOE group. PCO was observed in 1 tooth treated with MTA and 2 teeth treated with FC. Total success rates at 12 months were similar to 6-month results except for the ZOE group, which had a success rate of 92%. No statistically significant differences in total success rates were determined between the groups at 6 and 12 months.

At the 24-month follow-ups, the total success rates in the MTA, FS, FC, and ZOE groups were 96%, 88%, 88%, and 68%, respectively (Figure 1). One tooth in the MTA group failed due to a furcation defect and pain on percussion. The teeth that exfoliated were considered successes. Three teeth in the FS group, 1 tooth in the FC group and 2 teeth in the ZOE group with advanced physiological root resorption were regarded as clinically successful due to no signs of clinical failure. Physiological root resorption was evaluated using radiographs, tooth type, jaw (mandibular or maxillary), and chronological age. The most common radiographic failure at the 24-month follow-up period was noted as internal resorption in approximately 9% (8/88) of all teeth. Internal resorption was observed in approximately 27% (6/22) in the ZOE, 5% (1/21) in the FS, and 5% (1/21) of the FC groups.

A statistically significant difference ($P < .001$) between the MTA and ZOE groups at 24 months was noted. FS and FC success rates were not statistically different from MTA success. No statistically significant differences were found between the other groups. The ZOE group showed a significantly higher rate of internal resorption than the other groups. PCO, which was not considered a pathological finding, was observed in approximately 20% (5/25), 5% (1/21), and 10% (2/21) of the MTA, FS, and FC groups, respectively. When the groups were compared according to the time intervals, no significant differences were observed between the 6- to 12-month values. A statistically significant difference was observed only in the ZOE group between 6- and 24-month time intervals ($P = .003$). The success rates of the materials decreased over time.

Discussion

This study intended to examine and compare the success rates of 4 different pulpotomy techniques. The MTA group's success rates in this study are promising. At the 2-year follow-up, MTA showed the highest success rate (96%). FS and FC had the same success rates (88%), and ZOE exhibited the lowest success rate (68%).

MTA is a biocompatible material with numerous exciting clinical applications in endodontics. Several studies have shown that MTA is a biocompatible material which promotes regeneration of the original tissues when placed in

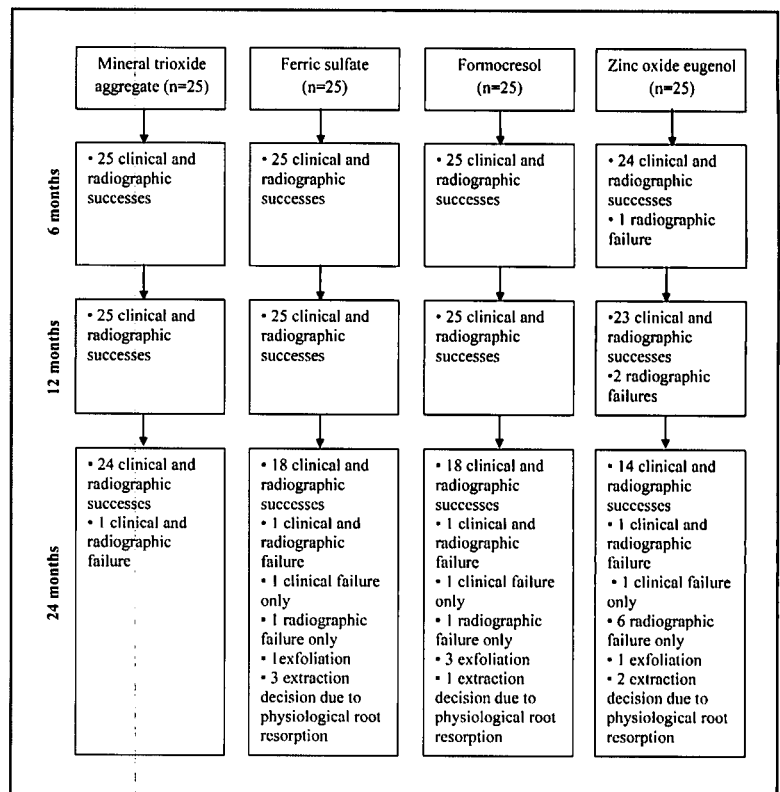


Figure 1. Flow of participants and pulpotomized teeth up to 24 months.

contact with the dental pulp or periradicular tissues and also prevents microleakage.^{12,13} The clinical and radiographic success rates of MTA of 94% to 100% at 12 to 74 months follow-up have been reported.¹⁴ Eidelman et al.,¹⁵ compared MTA's effects to those of FC in 32 pulpotomized primary molars during a follow-up evaluation of 6 to 30 months and reported the clinical success rate in the MTA group to be 100%, while internal resorption was found in 1 molar treated with FC. Agamy et al.¹⁶ demonstrated significantly better results for the MTA group than the FC group in a 12-month clinical study. Aeinehchi et al.,¹¹ observed an increase in the incidence of internal resorption with FC compared with MTA in a 6-month clinical study.

Results of a meta-analysis conducted by Ng and Messer¹⁴ comparing the outcomes of FC and MTA primary molar pulpotomies have shown MTA to be a superior pulpotomy dressing to FC with higher clinical and radiographic success rates and a lower rate of internal root resorption. Farsi et al.,⁹ compared the pulpotomy medicaments MTA to FC clinically and radiographically. At the end of the 24-month evaluation period, they found 100% success with MTA and 87% FC success, and those success rates were significantly different. Saltzman et al.¹⁷ investigated the use of a diode laser pulpotomy sealed with MTA as an alternative to the conventional formocresol pulpotomy sealed with ZOE in human primary teeth. They found 73% MTA success and 88% FC success after 16 months; however, these results were not significantly different. Most of the aforementioned studies, however, indicated that MTA could be considered a superior pulpo-

tomy medicament when compared with FC. In this study, MTA and FC success rates at 24-month follow-up were 96% and 88%, respectively, and these results were not significantly different.

One of the outcomes for a successful pulpotomy is the presence of a "dentin bridge" on the site of pulp amputation.¹⁸ MTA appears to encourage a successful dentin bridge formation in exposed pulps, which could be due to a combination of its sealing ability, biocompatibility, alkalinity, and other properties.¹⁹ Caicedo et al.,²⁰ reported that the presence of a dentin bridge could not be determined radiographically, although the teeth were observed to have dentin bridges histologically. On the basis of these findings, formation of a dentin bridge in the MTA group was not evaluated radiographically in this study.

FS, a nonaldehyde chemical, has been proposed as a pulpotomy agent. It acts as a hemostatic agent by agglutination of blood protein without the presence of a blood clot.²¹ Papagiannoulis²² and Ibricevic and Al-Jame²³ reported the clinical success rates as 97% and radiographic success rates as 78% to 94% at 36 to 48 months. Smith et al.,²⁴ investigated the clinical and radiographic data from a retrospective chart review of patients receiving ferric sulfate pulpotomies. They reported that radiographic success rates ranged from 74% to 80% and the clinical success rate was 99% after 19 months. Casas et al.²⁵ examined long-term outcomes of ferric sulfate pulpotomy and found a 67% success rate after 47 months. In this study, the clinical and radiographic success rates of FS were approximately 92% and 91% at the 24-month follow-up. The overall clinical success rates of FS in the aforementioned studies were found to be higher than the radiographic success rates. In the present study, clinical and radiographic success rates were similar. Since the frequency of normal appearing pulps could decrease over time, the present study would have benefitted from a larger sample size and long-term follow-up to appropriately compare the treatment modalities.

In human carious primary molars, pulpotomies performed with either FS or FC are likely to have similar clinical and radiographic success rates.²⁴⁻²⁷ In the meta-analysis conducted by Ng and Messer,¹³ MTA pulpotomies were found to be significantly more successful radiographically than FS pulpotomies. In the current study, the success rate of the MTA (96%) pulpotomies at 24 months was also found to be higher than the rates of FC (88%) and FS (88%) pulpotomies; furthermore, it was noted that similar clinical and radiological findings were found in the FC and FS pulpotomies.

Despite the reported toxic, mutagenic, and carcinogenic properties, FC is still used in pulp therapy of primary teeth due to its high clinical success rates.²⁸ Although a decline in the success rates of pulpotomies could occur as follow-up time increases, relatively higher rates were reported in the FC pulpotomies at 1- and 2-year follow-ups.^{24,27,29,31} In the review by Ng and Messer²⁹, the clinical and radiographic success rates of FC pulpotomies were stated as 97% and 78% to 94% at 36 to 48 months, respectively. In this study, FC pulpotomies had a 100% radiographic success rate at 1 year and approximately 91% at 2 years.

In the present study, ZOE constituted one of the treatment groups. Its treatment objective was classified as preservation, which implies maintaining the maximum vital tissue with no induction of reparative dentin.³² In studies, clinical and radiographic success rates of ZOE were found to be less successful than the experimental medicaments.²⁴ The investigations of ZOE as a pulpotomy agent or base for pulpotomies suggest that ZOE can cause pulp inflammation with a risk of subsequent internal resorption.^{33,34} The placement of ZOE directly over the pulp tissue has been suggested as the cause of the internal resorption that has previously been reported in FS pulpotomies.^{24,33} In this study, internal resorption was noted in approximately 27% of the ZOE group and in 5% of both the FS and FC groups at the 24-month follow-up. ZOE was chosen as one of the experimental materials, despite its known internal resorption effect and the fact that it is still used as a base material in pulpotomy procedures. Lack of internal resorption in MTA-treated teeth could be explained by the presence of a layer of MTA that separates the pulp from the irritating ZOE. One cannot preclude, however, the development of internal resorption with longer follow-up periods as a response to MTA.

The ZOE group showed internal root resorption in all follow-up visits at an increasing rate over time. FS and FC, however, showed internal root resorption only at the 24-month follow-up, with similar resorption rates (~5%). Internal root resorption was identified as a failure result in most studies.^{2,35} Some of the authors argued, however, that internal root resorption should be regarded as a failure only if the process reached the root's outer surface, thereby inducing an inflammatory process in the periodontal ligament and surrounding bone. Arrest of internal root resorption with calcifying metamorphosis of the pulp was not regarded as a failure.^{22,24,36} In this study, internal root resorption was identified as a sign of failure in all instances.

PCO was the most common radiographic finding in the MTA (20%), FC (~10%), and FS (~5%) groups at the 2-year follow-up. At the 1-year follow-up, PCO was observed only in the MTA (4%) and FC (8%) groups. PCO, however, has not been regarded as a failure^{9,10,22,37,38} since it is the result of extensive activity of odontoblast-like cells, demonstrating that the tooth has retained some degree of vitality. Agamy et al.,¹⁶ found a high rate of PCO (58%) with gray MTA, but only a 5% rate of PCO with white MTA and no obliteration in teeth treated with FC. Farsi et al.,⁹ also reported a higher rate of PCO in pulpotomies with MTA than FC. Sonmez et al.,³⁹ observed PCO in approximately 27% of teeth treated with MTA, 20% of teeth treated with FS, and none of the teeth treated with FC.

Premature exfoliations have been reported in multivisit pulpotomies⁴⁰ and FC pulpotomies.⁴¹ Likewise, it is documented that both FS and FC pulpotomies could lead to premature exfoliation of primary teeth.⁴² In this study, premature exfoliations of 3 teeth in the FS, FC, and ZOE groups were also noted in the 24 month follow-ups. In the current study, FS, FC, and ZOE pulpotomies led to premature exfoliation of primary teeth, with no need for orthodontic space maintenance. In the radiographic examination

of these primary molars, it was seen that the roots of the teeth were all resorbed. This excessive root resorption could be due to the ZOE sub-base, since this same effect was not seen in the MTA group where ZOE was not directly in contact with the pulp tissue. Although only the crowns of the primary molars were seen in the radiographs, these radiographic images were accepted as successful.

The restorations of pulpally treated teeth have been shown to have an impact on the prognosis of the pulp therapies. Stainless steel crowns (SSCs) were highly recommended for treating pulpotomized teeth, based on the assumption that there is less leakage in crowned teeth than those restored with amalgam.⁴³ In this study, the unavailability of SSCs because of financial constraints dictated the treatment using amalgam restorations in all the pulpotomized molars. Failed restorations were excluded to provide a standard evaluation of the success rates of the materials.

Holan et al.⁴⁴ reported that FC pulpotomy failure rates were 23% with a 2-surface amalgam restoration and 13% with a SSC restoration, which was significantly different. In the present study, MTA pulpotomies were significantly better than ZOE used alone. Since ZOE is very poor at preventing microleakage and amalgam does not corrode and seal its margins from microleakage for up to 6 months, ZOE-based pulpotomies possibly were significantly worse than MTA. MTA hardens after 1 hour and likely seals the remaining pulp from microleakage.

To define the success rates of any medicament, long-term studies should be planned. Further investigations are suggested to compare pulpotomy medicaments.

Conclusions

1. Mineral trioxide aggregate pulpotomies were significantly more successful ($P < .001$) than ZOE when used as the pulpotomy medicament alone.
2. While not significant, differences were observed among the 3 experimental materials (MTA, ferric sulfate, and formocresol), with MTA pulpotomies resulting in higher radiographic success rates than FS and FC pulpotomies at the 2-year follow-up.

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