

# Fate of Pulpotomized Teeth in Pediatric Patients: A 3-year Case Series in a Malaysian Dental Teaching Hospital

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## ABSTRACT

**Aim:** This 3-year retrospective case series evaluated the clinical and radiographic outcome of ferric sulfate and formocresol pulpotomy in primary molar teeth in a dental teaching hospital in Malaysia.

**Materials and methods:** Clinical and radiographic records of all pediatric patients who had pulpotomy of primary molar teeth between July 2005 and October 2008 were evaluated. A total of 55 pulpotomized primary molars were observed. Clinical assessments were carried out during the second visit to assess the presence of sinus tract, gingival swelling, excessive tooth mobility, tenderness to percussion, and abnormal exfoliation of the treated teeth. Periapical radiographs were reviewed for evidence of pathologic root resorption, radicular and/or periapical radiolucency, and abnormal pulp canal calcification. Treatments were regarded as failure in the presence of one or more of the above clinical and/or radiographic signs and symptoms.

**Results:** Of 55 pulpotomized teeth, 26 (47.3%) remained free from any clinical signs and symptoms and 48 (87.3%) showed no pathological radiographic findings. The clinical success rates of ferric sulfate and formocresol pulpotomy were 44.4% and 60.0%, respectively, whereas the radiographic success rates of ferric sulfate and formocresol pulpotomy were 86.7% and 90.0%, respectively. Although teeth treated with formocresol had higher both clinical and radiographic success rates compared with those treated with ferric sulfate, it was not statistically significant.

**Conclusion:** The clinical success rates of pulpotomy were lower compared with radiographic success rates. Ferric sulfate is an alternative to formocresol; however, the use of both agents in the dental undergraduate teaching at Universiti Sains Malaysia can still be recommended.

**Clinical significance:** Formocresol and ferric sulfate are advocated as pulpotomy agents in primary molar teeth since both agents showed comparable clinical and radiographic success rates.

**Keywords:** Ferric sulfate, Formocresol, Primary molar, Pulpotomy, Success rate.

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## INTRODUCTION

Pulpotomy is a type of conservative pulp therapy commonly employed in a primary or permanent tooth with reversible inflamed pulp. It involves the amputation of the affected or infected coronal pulp and the placement of a dressing over the radicular pulp to maintain its vitality and function. Thus, pulpotomy provides an alternative to extraction and preserves a primary tooth in the dental arch for natural exfoliation.<sup>1</sup>

Over the years, various pharmacotherapeutic agents and techniques have been employed in pulpotomy. These include glutaraldehyde, calcium hydroxide, formocresol, ferric sulfate, bone morphogenetic protein, enamel matrix derivative, electrosurgery, sodium hypochlorite, and mineral trioxide aggregate (MTA). Formocresol has been a popular pulpotomy agent in the primary dentition for the past 70 years<sup>2</sup> due to its ease of use and excellent success rates.<sup>3-6</sup> It was once considered the most universally taught and preferred pulp therapy for primary teeth.<sup>7-9</sup> However, its popularity has decreased in the recent years.<sup>10,11</sup> Formocresol has been scrutinized due to its systemic distribution and its potential toxicity, allergenicity, carcinogenicity, and mutagenicity.<sup>12-14</sup> Nevertheless, literature has shown that the typical dose of formocresol used in pulpotomy is unlikely to pose any risk to children.<sup>15</sup> In addition, there is inconsequential risk of carcinogenesis associated with formaldehyde use in pediatric pulp therapy.<sup>16</sup> Results from animal studies exposed to high concentration of formaldehyde gas which resulted in nasal cancers cannot be extrapolated to humans because the experimental

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conditions differed from those carried out in formocresol pulpotomy.<sup>17,18</sup>

Alternatives such as ferric sulfate were advocated in an attempt to minimize concerns regarding the use of formocresol.<sup>19-23</sup> Earlier studies on ferric sulfate and formocresol pulpotomy in primary molars have shown that at 1-year recall, the ferric sulfate group showed higher combined clinical and radiographic success rates

compared with the formocresol group.<sup>19</sup> Nevertheless, long-term follow-up studies showed that ferric sulfate has similar clinical and radiographic success rates compared with formocresol.<sup>3,6,20,21,24</sup> Thus, some dental schools still have the preference to use formocresol as a pulpotomy agent. However, studies on ferric sulfate and formocresol pulpotomy are still ongoing.

To our knowledge, there has been no published data investigating the fate of pulpotomized teeth in pediatric patients in Malaysia. Therefore, the aim of this study was to evaluate the clinical and radiographic outcome of ferric sulfate and formocresol pulpotomy in primary molars at a dental teaching hospital—the School of Dental Sciences, Hospital Universiti Sains Malaysia (USM).

## MATERIALS AND METHODS

This retrospective case series study was carried out at the School of Dental Sciences undergraduate dental clinic, Hospital USM. Following the approval from the USM Human Ethics Committee with the study protocol code USM/JEPeM/17090409, the treatment folders of all pediatric patients who have had ferric sulfate or formocresol pulpotomy of the primary molars at the Hospital USM undergraduate dental clinic between July 2005 and October 2008 were retrieved from the Record Unit, Hospital USM. The clinical and radiographic records of pulpotomized primary molars of these patients were evaluated. After obtaining consent from parents/guardian, these patients were recalled for clinical and radiographic assessment of the pulpotomized teeth. The follow-up period ranged from 8 months to 46 months.

The inclusion criteria were patients aged 3–12 years who have completed the pediatric dentistry examination and diagnosis, had preoperative radiograph, and had received either ferric sulfate or formocresol pulpotomy of the primary molars by the undergraduate dental students at the School of Dental Sciences Dental Clinic, Hospital USM. Patients who did not complete examination and diagnosis and those without preoperative radiographs were excluded in this study.

The clinical assessment was carried out using a straight dental probe, a periodontal probe, and a dental mirror to detect the presence of sinus tract, gingival swelling, excessive tooth mobility, tenderness to percussion, and abnormal (early or delayed) exfoliation. The radiographic evaluation was carried out by taking a periapical radiograph of the pulpotomized tooth to check for evidence of pathologic root resorption, radicular and/or periapical radiolucency, and abnormal pulp canal calcification. Radiographic interpretation was done by the operator. Treatment was regarded as failure by the presence of one or more of the above clinical and/or radiographic signs and symptoms.

The collected data were statistically analyzed using the IBM SPSS software version 22.0. Descriptive statistics were used to calculate frequency and percentage. Fisher's exact test was used to assess the association between treatment outcome and the type of pulpotomy agent. The statistical significance level was established at  $p$  value  $<0.05$  with 95% confidence interval.

## RESULTS

Table 1 shows the distribution of study sample which consisted of 55 children (32 males and 23 females) ranging from 3 years to 12 years old. The number of patients who had ferric sulfate pulpotomy was higher (81.8%) than the formocresol group (18.2%). The mean age ( $\pm$ standard deviation) of male and female patients who had ferric sulfate pulpotomy (male =  $6.9 \pm 1.4$ ; female =  $6.1 \pm 1.3$ ) was

lower compared with the formocresol group (male =  $7.6 \pm 0.9$ ; female =  $7.8 \pm 1.5$ ).

The frequency of ferric sulfate and formocresol pulpotomy according to the tooth type is also shown in Table 1. A total of 77.3% (17/22) and 22.7% (5/22) of maxillary molars were treated with ferric sulfate and formocresol, respectively, whereas 84.8% (28/33) and 15.2% (5/33) of mandibular molars were treated with ferric sulfate and formocresol, respectively.

## Clinical Findings

Table 2 shows that the clinical success rates of ferric sulfate pulpotomy were lower than formocresol pulpotomy (44.4% vs 60.0%). Gingival swelling, excessive tooth mobility, and abnormal exfoliation were present in both groups, whereas sinus tract and tenderness to percussion were present only in the ferric sulfate group. A total of 20.0% of females in the formocresol group showed evidence of abnormal exfoliation only but free of other clinical findings indicative of pulpotomy failure. Both male and female subjects in the ferric sulfate group demonstrated all positive clinical findings except for the presence of sinus tract and gingival swelling.

## Radiographic Findings

The radiographic success rates of ferric sulfate pulpotomy (86.7%) were slightly lower than formocresol pulpotomy (90.0%) (Table 3). In addition, both groups exhibited higher radiographic success rates (ferric sulfate = 86.7%, formocresol = 90.0%) compared with clinical success rates (ferric sulfate = 44.4%, formocresol = 60.0%). Pathologic root resorption was observed in both groups, whereas radicular and/or periapical radiolucency and abnormal pulp canal calcification were observed in the ferric sulfate group only.

Only 7.4% of males in the ferric sulfate group showed evidence of radicular and/or periapical radiolucency but free from other radiographic signs of pulpotomy failure, whereas in the formocresol group, 20.0% of males showed evidence of pathologic root resorption and free of other radiographic signs of treatment failure. All female subjects in the formocresol group did not exhibit any radiographic findings indicative of treatment failure. To the contrary, all females in the ferric sulfate group exhibited positive radiographic findings. Tables 2 and 3 show that the clinical and radiographic success rates of ferric sulfate and formocresol are not significantly different ( $p > 0.05$ ).

## DISCUSSION

Although extensive works have been conducted on new pulpotomy agents such as MTA, this study evaluated the treatment outcome of two agents that have been equally well researched. Formocresol and ferric sulfate were selected because the former was once and is still regarded as the gold standard for pulpotomy in primary molars,<sup>2,7,9,25</sup> whereas the latter has been widely compared with it as an alternative medicament.<sup>3,19–21,26</sup>

## Clinical Findings

This study found that the overall clinical and radiographic success rates for formocresol pulpotomy were higher than those of ferric sulfate. The results of this study are consistent with preceding studies;<sup>21,27</sup> however, other studies have shown different findings.<sup>3,5,19</sup> Despite disparities in these studies, there was no statistical significance observed between both pulpotomy agents and has been confirmed by extensive research.<sup>3,21,23,24,26,28</sup>

**Table 1:** Distribution of age, tooth type, and gender of pediatric patients who have had ferric sulfate or formocresol pulpotomy

Variables	n	Ferric sulfate			Formocresol		
		Male	Female	Total	Male	Female	Total
Sample		27	18	45	5	5	10
Age		6.9 (1.4)	6.1 (1.3)	–	7.6 (0.9)	7.8 (1.5)	–
Maxillary first primary molar	6	3/6 (50.0%)	2/6 (33.3%)	5/6 (83.3%)	1/6 (16.7%)	0 (0.0%)	1/6 (16.7%)
Maxillary second primary molar	16	6/16 (37.5%)	6/16 (37.5%)	12/16 (75.0%)	2/16 (12.5%)	2/16 (12.5%)	4/16 (25.0%)
Mandibular first primary molar	16	11/16 (68.8%)	3/16 (18.7%)	14/16 (87.5%)	0 (0%)	2/16 (12.5%)	2/16 (12.5%)
Mandibular second primary molar	17	7/17 (41.2%)	7/17 (41.2%)	14/17 (82.4%)	2/17 (22.2%)	1/17 (12.5%)	3/17 (17.6%)

**Table 2:** Distribution of clinical findings of ferric sulfate and formocresol pulpotomy

Clinical findings	Ferric sulfate			Formocresol			p value <sup>a</sup>	
	Male	Female	Total	Male	Female	Total		
Positive								
Sinus tract	1 (3.7%)	0 (0.0%)	1 (2.2%)	25 (55.6%)	0 (0.0%)	0 (0.0%)	4 (40.0%)	0.490
Gingival swelling	0 (0.0%)	1 (5.6%)	1 (2.2%)		1 (20.0%)	0 (0.0%)	1 (10.0%)	
Excessive tooth mobility	2 (7.4%)	3 (16.7%)	5 (11.1%)		1 (20.0%)	0 (0.0%)	1 (10.0%)	
Tender to percussion	6 (22.2%)	4 (22.2%)	10 (22.2%)		0 (0.0%)	0 (0.0%)	0 (0.0%)	
Abnormal exfoliation	6 (22.2%)	2 (11.1%)	8 (17.8%)		1 (20.0%)	1 (20.0%)	2 (20.0%)	
Negative	12 (44.4%)	8 (44.4%)	20 (44.4%)	20 (44.4%)	2 (40.0%)	4 (80.0%)	6 (60.0%)	6 (60.0%)
Total	27	18	45	45	5	5	10	10

<sup>a</sup>Fisher's exact test 2 × 2 clinical findings vs type of treatment

**Table 3:** Distribution of radiographic findings of ferric sulfate and formocresol pulpotomy

Radiographic findings	Ferric sulfate			Formocresol			p value <sup>a</sup>		
	Male	Female	Total	Male	Female	Total			
Positive									
Pathologic root resorption	0 (0.0%)	2 (11.1%)	2 (4.4%)	6 (13.3%)	1 (20.0%)	0 (0.0%)	1 (10.0%)	1 (10.0%)	1.000
Radicular/periapical radiolucency	2 (7.4%)	1 (5.6%)	3 (6.7%)		0 (0.0%)	0 (0.0%)	0 (0.0%)		
Abnormal pulp canal calcification	0 (0.0%)	1 (5.6%)	1 (2.2%)		0 (0.0%)	0 (0.0%)	0 (0.0%)		
Negative	25 (92.6%)	14 (77.8%)	39 (86.7%)	39 (86.7%)	4 (80.0%)	5 (100%)	9 (90.0%)	9 (90.0%)	
Total	27	18	45	45	5	5	10	10	

<sup>a</sup>Fisher's exact test 2 × 2 radiographic findings vs type of treatment

This study involved a review of 55 primary molars (ferric sulfate = 45 teeth, formocresol = 10 teeth), 8–46 months after treatment. Hence, the sample size was small compared with other pulpotomy studies. Fei et al.<sup>19</sup> studied the clinical and radiographic success rates of 83 primary molars for 3-, 6-, and 12-month periods. Even though the follow-up period was between 3 months and 12 months and shorter compared with this study, the authors had a considerable sample size.<sup>19</sup> Similarly, in a long-term clinical and radiographic follow-up of 6–34 months, Fuks et al.<sup>3</sup> reviewed 96 pulpotomized primary molars which were treated by either ferric sulfate (58 teeth) or diluted formocresol (38 teeth). The small number of pediatric patients requiring pulpotomy of primary molars at the Hospital USM's dental clinic has limited the sample size of this study. In addition, the operator factors which comprised undergraduate dental students in this study may contribute to inconsistencies while performing pulpotomy technique, as well as the quality of the final restorations. The outcome of pulpotomy is dependent on accurate diagnosis<sup>1,29</sup> and adequate coronal seal to prevent leakage of the restoration.<sup>30–32</sup>

In comparison with this study, some studies reported higher success rates for both ferric sulfate and formocresol.<sup>20,21</sup> When compared with studies that have comparable follow-up periods of 6–34 months<sup>3</sup> and 42–48 months,<sup>21</sup> this study (8–46 months) showed that the clinical success rates of ferric sulfate and formocresol pulpotomy were lower than Fuks et al.<sup>3</sup> and Ibricevic and Al-Jame<sup>21</sup> (Table 4). In a 12-month follow-up study, Fei et al.<sup>19</sup> reported a clinical success rate of 100% and 96.0% for ferric sulfate and formocresol, respectively, which was higher compared with a study by Fuks et al.<sup>3</sup> who reported a clinical success rate of 92.7% and 83.8% for ferric sulfate and formocresol, respectively. The authors reported no statistical differences between ferric sulfate and formocresol groups.<sup>3</sup> In addition, the different follow-up periods in both studies showed lower success rates with longer follow-up periods.<sup>3,21</sup> These findings were supported by Ibricevic and Al-Jame.<sup>20,21</sup> In the earlier study, a shorter follow-up period of 20 months exhibited higher success rate for both ferric sulfate (100%) and formocresol (100%) groups,<sup>20</sup> whereas in the later study of 42–48 months follow-up period, the clinical success rate was slightly

lower for ferric sulfate (96.0%) and formocresol (97.0%) groups.<sup>21</sup> In contrast, a shorter follow-up period of 12 months<sup>19</sup> showed lower clinical success rate in the formocresol group (96.0%) compared with studies of 20 months follow-up period (100%).<sup>20</sup> Nevertheless, the clinical success rates for ferric sulfate groups were similar in both studies (100%).<sup>19,20</sup>

In addition, previous studies comparing ferric sulfate and formocresol pulpotomy showed higher clinical success rates for both agents compared with this study.<sup>3,5,19–21,24</sup> This could be due to several variables such as age, gender, tooth type, arch type, case selection, diagnosis, coronal restorations, pulpotomy techniques, and recall period. In a retrospective study of emergency formocresol pulpotomy restored with temporary zinc oxide eugenol, variables such as gender, type of tooth, or arch did not show any statistically significant differences for the treatment outcome.<sup>33</sup> Patients younger than 6 years old showed statistically significant higher chances for success when compared with older children.<sup>33</sup> A short-term low success rate may be due to undiagnosed, subclinical inflamed pulp, whereas a long-term treatment failure could be related to microleakage of a temporary zinc oxide eugenol restorative material.<sup>33</sup> In addition, a high clinical success rate post emergency pulpotomies in primary molars was associated with the immediate placement of stainless steel crowns when compared with zinc oxide eugenol-based temporary restoration [intermediate restorative material (IRM)] or IRM and Ketac Molar.<sup>34</sup> The time interval between emergency and definitive treatment, age, gender, tooth type, and arch did not show any statistically significant differences on the outcome of treatment.<sup>34</sup>

This study also demonstrated that the two most common occurrences in the ferric sulfate group were tenderness to percussion (22.2%) and abnormal exfoliation (17.8%). Similarly, abnormal exfoliation (20.0%) accounted for most teeth in the formocresol group; however, there was no tooth exhibiting tenderness to percussion. Early exfoliation associated with pulpotomy was demonstrated with the use of ferric sulfate or formocresol.<sup>35,36</sup> When full-strength Buckley's formocresol pulpotomy group was compared with contralateral non-pulpotomized tooth, approximately 29% of the former exfoliated earlier.<sup>36</sup> Despite these findings, it was clinically insignificant and did not affect clinical management.

### Radiographic Findings

Unlike the findings of the clinical success rates, the radiographic success rates for the ferric sulfate (86.7%) and formocresol (90.0%) groups in this study were comparable with other clinical trials.<sup>5,21,24</sup> Two studies<sup>5,24</sup> with identical follow-up periods of 6–24 months showed equal radiographic success rate of 88.0% for ferric sulfate and formocresol groups<sup>24</sup> and 86.0% for ferric sulfate and 90.0% for formocresol.<sup>5</sup> The closest match in the follow-up period of this study is 6–34 months by Fuks et al.<sup>3</sup> The radiographic success rates for both studies are different in the formocresol groups [90.0%

(this study) vs 80.0% (Fuks et al.<sup>3</sup>)], but comparable in the ferric sulfate groups [86.7% (this study) vs 93.0% (Fuks et al.<sup>3</sup>)]. However, Ibricevic and Al-Jame<sup>21</sup> observed that radiographic success rates are comparable with this study in both groups. They reported radiographic success rates of 92.0% for the ferric sulfate group and 94.0% for the formocresol group with a follow-up period of 42–48 months.

In contrast to higher clinical success rates observed in both ferric sulfate and formocresol pulpotomy with a shorter duration of follow-up period,<sup>20</sup> the radiographic success rates for the formocresol groups (81.0%) in the 12 months follow-up period<sup>19</sup> were lower compared with studies with longer follow-up periods of 20 months (97.2%)<sup>20</sup> and between 42 months and 48 months (94.0%)<sup>21</sup> (Table 4). However, the radiographic success rates in the ferric sulfate groups did not show any significant differences in these studies.<sup>20,21</sup> Although the duration of the follow-up periods could be a factor in determining the success rates of pulpotomy, the evidence have shown that the differences in both clinical and radiographic success rates were not significant.<sup>5,20,21,24</sup>

In a retrospective study involving 202 pulpotomized primary molars, Burnett and Walker<sup>26</sup> found no statistical difference in radiographic failure rates between formocresol, ferric sulfate, or a combination procedure of formocresol and ferric sulfate regardless of postoperative period. The postoperative period ranged from 1 month to 36+ months. Nevertheless, when postoperative periods were considered, formocresol pulpotomies performed better at >36 months, and the combination procedure showed significantly more failures at >36 months.<sup>26</sup> This study showed no differences in both clinical ( $p = 0.490$ ) and radiographic ( $p = 1.000$ ) findings between ferric sulfate and formocresol groups. Although there was conflicting evidence regarding the effect of postoperative period, follow-up period is an important contributing factor in determining the success rates of pulpotomy.

Unlike other studies where clinical and radiographic success rates were comparable, this study showed higher radiographic success rates of the same treatment group (ferric sulfate = 86.7%, formocresol = 90.0%) compared with the clinical success rates (ferric sulfate = 44.4%, formocresol = 60.0%). This highlights the importance of incorporating radiographs at recall visits of pulpotomy.<sup>35</sup> Internal root resorption was the main reason for premature exfoliation regardless of whether ferric sulfate or formocresol was used.<sup>35</sup> Kurji et al.<sup>37</sup> found that the most common radiographic failures were internal root resorption and pulp canal obliteration. Hence, a review of radiographic criteria is important during follow-up visits of pulpotomy to monitor treatment failure associated with root pathology such as internal root resorption leading to premature tooth loss.<sup>35</sup> Smith et al.<sup>38</sup> also reported similar findings in the retrospective study of ferric sulfate pulpotomy. Besides calcific metamorphosis (6–33%), internal resorption (7–18%) was observed frequently.

**Table 4:** Comparison of clinical and radiographic success rates of this study

Authors	Follow-up period (months)	Clinical success rate		Radiographic success rate	
		Ferric sulfate (%)	Formocresol (%)	Ferric sulfate (%)	Formocresol (%)
This study	8–46	44.4	60.0	86.7	90.0
Fei et al. <sup>19</sup>	3–12	100	96.0	–	–
Fuks et al. <sup>3</sup>	6–34	92.7	83.8	93.0	80.0
Ibricevic and Al-Jame <sup>20</sup>	20	100	100	–	–
Ibricevic and Al-Jame <sup>21</sup>	42–48	96.0	97.0	92.0	94.0

Pathologic root resorption was observed in both ferric sulfate and formocresol pulpotomy. This resorption could be initiated by zinc oxide and eugenol (ZOE) which was used as the base material in all pulpotomized teeth in this study. The effect of eugenol is determined on its concentration in tissues. When ZOE comes in contact with the pulp tissue, zinc eugenolate undergoes hydrolysis and yields free eugenol.<sup>39</sup> Eugenol release from ZOE is much greater when there is pulp exposure due to the availability of water from tissue fluid. Thus, the amount of eugenol released exceeds the level required to cause pulp necrosis.<sup>39</sup> In addition, a direct contact of eugenol with the pulp tissue results in extensive tissue damage.<sup>40</sup> The inflammatory response was observed in all teeth that were pulp-capped with zinc oxide eugenol.<sup>41</sup> Direct placement of eugenol over vital pulp tissue has caused localized and extensive inflammation and necrosis of the pulp.<sup>41</sup> This, in turn, may give rise to internal root resorption.

The limitations in this study include small sample size particularly formocresol-treated teeth and inconsistency of pulpotomy techniques due to the involvement of many operators performing the treatment. Larger sample size could also investigate the association between tooth type and treatment outcome, as well as to assess possible contributing factors such as the size of the tooth, the anatomy of pulp chamber, the proximity of pulp horns to the occlusal surface, and the location of the root canals.

## CONCLUSION

The clinical success rates of pulpotomy were lower compared with the radiographic success rates. The overall clinical and radiographic success rates of formocresol pulpotomy were higher than those of ferric sulfate; however, the differences were insignificant. Thus, the use of both ferric sulfate and formocresol in the dental undergraduate teaching at USM can still be recommended.

## CLINICAL SIGNIFICANCE

Formocresol and ferric sulfate are advocated as pulpotomy agents in primary molar teeth since both agents showed comparable clinical and radiographic success rates.

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