

# Comparative Study of Pulpotomy between Formocresol and Various Materials and Techniques used in Primary Molar: A Meta-Analysis

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## ABSTRACT

**Introduction:** Pulpotomy is a common therapeutic procedure to treat reversible pulpitis in primary molars by using various materials and techniques. Pulpotomy method via formocresol has raised concern about the toxicity and potential carcinogenicity and alternative materials have been proposed to maintain the partial pulp vitality, however to date no material have been accepted as an ideal pulpotomy agent. This evidence-based study of the literature assessed the relative efficacy of non-aldehyde medicaments as opposed to formocresol in vital pulpotomy to treat primary teeth with extensive carious lesions involving the pulp.

**Objective:** This study is to undertaken a systemic review and meta-analysis to compare the clinical and radiographic outcomes of various medicaments and techniques like calcium hydroxide, ferric sulfate, electrosurgery, laser, and MTA that can act as an alternative to formocresol pulpotomy in primary molars.

**Materials and Method:** Electronic literature search of scientific papers from 2000 to 2010 was carried out on the PubMed, EMBASE, Science Citation Index (SCI), Google Scholar, the Springer, John Wiley & Sons, Elsevier, and Scopus databases using specific key words. Medications for pulpotomy including ferric sulfate, calcium hydroxide, mineral trioxide aggregate (MTA), electrosurgery and laser pulpotomy are compared with formocresol in the meta-analyses. The outcome is the odds ratio for clinical and radiographic failure including premature tooth loss at 6 months to 74 months after treatments amongst different treatment procedures. The search yielded 448 papers, out of which 100 were identified as conforming to the applied criteria from which 41 full text were used for this study by a series of validity criteria. Jadad's score was done and it came to be 3/5. Mantel-Haenszel method<sup>1</sup> was used to calculate odd pool ratio assuming a fixed-effects model, and the DerSimonian-Laird method that assumes a random-effects model. Cochran Q test was used to evaluate whether the results were homogenous.<sup>3</sup> All tests were two tailed and  $p < 0.05$  was considered significant. Stata 10 (Stata Corp, College Station, TX, USA) software was used for analysis.

**Result:** After 6-74 months, in terms of treatment failure, the odds ratio for calcium hydroxide vs. formocresol clinically was 4.08 [95% credible interval (CI): 2.69, 6.20] and radiographic 4.9 [95% credible interval (CI): 2.82, 8.85] ; clinically 3.1 (95% CI: 0.3, 30.7) and radiographic 2.24 (95% CI 0.72, 7.00) for electrosurgery vs. formocresol; clinically 1.01 (95% CI: 0.62, 1.66) and radiographic 1.14 (95% CI 0.76, 1.70) for ferric sulfate vs. formocresol; clinically 0.66 (95% CI: 0.35, 1.26) and radiographic 0.47 (95% CI 0.23, 0.93) for lasers vs. formocresol; and clinically 0.7 (95% CI: 0.46, 1.05) and radiographic 1.06 (95% CI 0.62, 1.80) for MTA vs. formocresol.

**Conclusion:** This study showed that Laser, MTA and ferric sulfate showed significantly better clinical and radiographic outcomes than calcium hydroxide and electrosurgery therapies in primary molar pulpotomies. Laser can be the first choice for primary molar pulpotomies. Due to treatment cost as an issue, and primary molars are

going to be replaced by permanent teeth, MTA and ferric sulfate may be the choice. However, there is insufficient long term, clinical evidence to make a strong recommendation regarding an alternative material and techniques to formocresol as a medicament for pulpotomy in primary teeth.

**Keywords:** Calcium hydroxide; electrosurgery; ferric sulphate; formocresol; lasers; mineral trioxide aggregate; primary teeth, pulpotomy.

## INTRODUCTION

The dental pulp is an innervated and vascularized tissue that is able to react to physical, chemical and biological stimuli and promote an adequate healing, with the formation of hard tissue barrier.<sup>1</sup> If the stimulus or damage is severe to the pulp, it may exceed the pulp healing capacity and progress to an irreversibly inflamed condition leading to necrosis. However, if pulp exposure is discrete in primary or young permanent teeth, some procedures may be performed in an attempt to re-establish pulpal health and maintain its vitality.<sup>1,2</sup> The treatment of pulp exposure should aim at its complete repair with the formation of a mineralised barrier that covers the exposed area completely.<sup>3</sup>

Pulpotomy, a therapeutic procedure, is done in reversible inflammation of pulp of primary teeth, when the radicular pulp tissue has remained healthy and is capable of serving healthy dentition for long term until normal exfoliation.<sup>4</sup> Pulpotomy comprises coronal pulp amputation and placement of a protective agent over the remaining viable pulp in order to preserve its vitality and function.<sup>2,5</sup> Pulpotomy for the primary dentition can be classified according to the treatment objectives as devitalization, preservation and regeneration.<sup>6</sup> Of the three categories, remineralisation is expected to develop most rapidly in the coming years.<sup>6</sup> It is indicated for primary or young permanent teeth with inflamed and/or infected coronal pulp and to keep the remaining pulp healthy without adverse clinical signs or symptoms or radiographic evidence of internal or external root resorption. The goal of vital pulpotomy is to preserve the radicular pulp, avoiding pain and swelling, preserving arch integrity and to retain the functions of esthetics, speech and mastication until exfoliation.<sup>7</sup> New approaches have been based on the understanding

of the molecular and cellular mechanisms regulating dentinogenesis during dental tissue repair and their potential for clinical exploitation.<sup>8</sup>

Although many techniques have been suggested,<sup>9</sup> a recent Cochrane Review found that evidence is lacking as to which is the most appropriate technique.<sup>10</sup> Several materials have been used as pulp capping agents in pulpotomized teeth, among which formocresol (FC), calcium hydroxide (Ca(OH)<sup>2</sup>), ferric sulfate (FS) and more recently mineral trioxide aggregate (MTA)-<sup>3,11,12</sup> are being used. Additionally, electrosurgery (ES),<sup>13</sup> Erbium:Yttrium-Aluminum Garnet laser have been used to treat the remaining pulp tissue as an option to chemical therapy. Hydroxyapatite and bone morphogenic protein are also being used recently. All these medicaments and techniques are used as parallel intervention methods.

Our objective was to evaluate clinical and radiographic effects of various alternative medicaments like calcium hydroxide, ferric sulfate, electrosurgery, laser, and MTA, and compare the results with formocresol pulpotomy, to find out which of these materials and techniques are more superior or similar to formocresol and can be used as an alternative material in due course of time in carious primary molars and young permanent teeth in children.

## MATERIALS AND METHOD

The study list was obtained by using PubMed, EMBASE, Scopus, Science Citation Index (SCI), Google Scholar, the Springer, John Wiley and Sons, Elsevier all from the year 2000 to 2010 and also hand searches through dental journals approved by the Indian Ministry of Health. Only articles in English were included. The search ended in February 2010 (Table 1).

**Table 1: Search history.**

Search History	Articla Number
Total no. of articles found with key words in Pubmed	207
Articles rejected at title stage	96
Articles at abstract stage	39
Articles rejected at abstract stage	22
Articles at full copy stage	53
Articles found by related searches	11
Total no. of articles at full copy stage	47
Articles rejected at full copy stage	6
Total no. of articles selected	41

The search results yielded total 41 articles that have been presented in tabulated form for formocresol, calcium hydroxide, MTA, lasers, ferric sulfate and electro-surgery. Only the papers which met the inclusion criteria were included (Table 2,3). Each study was separately assessed by at least two reviewers.

**Table 2: Inclusion and exclusion criteria.**

Inclusion criteria:	
	Randomized and Quasi randomized clinical trials were used to compare pulpotomies using FC and other medicaments like MTA, Ca(OH) <sup>2</sup> , FS, glutaraldehyde, lyophilized freeze dried platelet, bone morphologic protein and techniques like electro-surgery and lasers.
	Human studies were only considered.
	All selected teeth were pulpally exposed primary and young permanent teeth only by caries or trauma.
	All selected teeth have a 6 months follow-up time at least.
	The outcome was evaluated by clinical symptoms and radiographic evidence. All selected teeth had no clinical or radiographic sign or symptoms such as internal root resorption, inter radicular or periapical bone destruction, periodontium involvement, swelling or sinus tract.
Exclusion criteria:	
	All selected teeth would be restorable with posterior stainless steel crowns.
	The outcome comparison followed a standard definition of success/failure as shown by the number of teeth.
	Animal studies.
	Pulpotomies involving permanent teeth in adults.
	Studies carried in vitro or on retreatment cases.
	The selected teeth were treated by the medicaments mentioned above with other additional methods.
	Other pulp therapies like Indirect/Direct Pulp capping and Pulpectomy.
	The article could not be located.

All the studies were assessed separately and the quality of studies was evaluated by a series of validity criteria according to Jadad's scale.<sup>14</sup> Over all clinical and radiographic success rates were assessed as outcome variables. The criteria for quality were based on the following:

1. Was the study randomized clinic trial ?
2. Was the study described double-blind ?
3. Was there a description of withdrawals and dropouts ?

The scores for the first 2 questions ranged from 0 to 2 and for last question 0 to 1. The studies with the higher scores were weighed more when the meta-analysis was performed.

Odds ratios (OR) were calculated to assess the association between FC and other medicaments and techniques ie. Ca(OH)<sup>2</sup>, ES, FS, laser and MTA. The techniques used to calculate pooled OR were the Mantel-Haenszel method 1 assuming a fixed-effects

model, and the DerSimonian-Laird method that assumes a random-effects model.<sup>2</sup> Cochran Q test was used to evaluate whether the results were homogenous.<sup>3</sup> This analysis evaluated the influence of individual studies by estimating the weighted average OR in the absence of each study. All tests were two tailed and  $p < 0.05$  was considered significant. Stata 10 (Stata Corp, College Station, TX, USA) software was used for analysis.

## RESULT

The age range considered in the 41 studies<sup>2,13,15-52</sup> was 2 to 13 years, that comprised of boys and girls in random ratios. Sample size ranged from 13 to 354 primary carious molars. Formocresol (control group) was used in the strength of 1:5 dilution as the pulpotomy agent in all studies and other materials were used for the comparative study. The studies range from 6 months to 74 months for the clinical and radiographic results. Jadad's score was 3/5.

**Table 3: Included studies.**

Study	Time (months)	Total no. of teeth	Material used in Pulpotomy	Individual teeth	Clinical Failure		Radiographic Failure		Clinical Success N(%)	Radiographic success N(%)
					N	%				
1. Deniz Sonmez 2008	12	84	Calcium hydroxide	84	17	20.2	14	16.7	67 (79.8)	70 (83.3)
2. Noorollahian H 2008	24	60	Formocresol	30	3	10	0	0	27 (90)	30 (100)
			MTA	30	1	3.3	2	6.7	29 (96.7)	28 (93.3)
3. Deniz Sonmez 2008	56	56	Formocresol	13	3	23	2	15.4	10 (77)	11 (84.6)
			Ferric sulfate	15	4	26.7	4	26.7	11 (77.3)	11 (77.3)
			Calcium Hydroxide	13	7	53.8	6	46.2	6 (46.2)	7 (53.8)
			MTA	15	5	33.3	3	20	10 (66.7)	9 (60)
4. Waterhouse PJ 2000	12	84	Formocresol	46	9	19.6	9	19.6	37 (80.4)	37(80.4)
			Calcium hydroxide	38	11	29	11	29	27 (71)	27 (71)
5. Alev Alacam 2009	12	105	Formocresol	35	9	26	3	8.6	26 (74)	32(91.4)
			Calcium hydroxide	70	54	77	50	71.4	16 (23)	20 (28.6)
6. John F. Roberts 2000		175	Formocresol	175	6	3.42	5	3	169(96.6)	170 (97)
7. John David Roberts 2009	12	26	Formocresol	26	6	23	6	23	20 (77)	20 (77)
8. Dean J. A 2002	6	50	Formocresol	25	0	0	2	8	25 (100)	23 (92)
			Electrosurgery	25	1	4	4	16	24 (96)	21 (84)
9. Ay-Luen Fei 2000	12	56	Formocresol	27	6	22	6	22	21 (78)	21 (78)
			Ferric sulfate	29	1	3.4	1	3.4	28 (96.6)	28 (96.6)
10. Zurn D 2008	24	76	Formocresol	38	1	3	1	3	37 (97)	37 (97)
			Calcium hydroxide	38	6	16	11	29	32 (84)	
11. Farsi N 2005	6	74	Formocresol	36	1	3	5	14	34 (97)	31 (86)
			MTA	38	0	0	0	0	38 (100)	38 (100)
12. Mesut Enes 2007	12	42	Formocresol	21	2	9.5	2	9.52	19 (90.5)	19 (90.5)
			Laser	21	3	14.3	6	28.6	18 (85.7)	15 (71.4)
13. Neamatollahi H 2005	12	135	Formocresol	45	0	0	4	9	45 (100)	41 (91)
			Ferric sulfate	45	0	0	9	20	45 (100)	36 (80)
			MTA	45	8	18	14	31	37 (82)	31 (69.0)
14.Zurn D 2008	24	76	Formocresol	38	1	3	1	3	37 (97)	37 (97)
			Calcium hydroxide	38	6	16	11	29	32 (84)	27 (71)
15. Noorollahian H 2007	24	60	Formocresol	30	0	0	0	0	30 (100)	30 (100)
			MTA	30	0	0	2	7	30 (100)	28 (93)
16. Agamy HA 2004	12	48	Formocresol	24	2	8.3	2	9.3	22 (91.7)	22 (90.7)
			MTA	24	5	21	5	21	19 (79)	19 (79)
17. Jabbarifar SE 2004	12	64	Formocresol	32	3	9.4	3	9.4	29 (90.6)	29 (90.6)
			MTA	32	2	6.3	2	6.3	30 (93.7)	32 (93.7)
18. Holan G 2005	74	62	Formocresol	29	16	55	11	38	13 (45)	18 (62)
			MTA	33	4	12	3	9.1	29 (88)	30 (90.9)

19. Jengfen Liu 2003	48	115	Formocresol	51	6	12	9	18	45(88)	42(82)
			Laser	64	2	3	4	6.3	62(97)	58(93.7)
20. Kalaskar RR 2004	6	56	Calcium hydroxide	28	1	3.6	1	3.6	27 (96.4)	27 (96.4)
			Lyophilized freeze dried platelet	28	0	0	0	0	28(100)	28 (100)
21. Ibricevic H 2003	48	164	Formocresol	80	2	2.5	4	5	78 (97.5)	76 (95)
			Ferric sulfate	84	7	8.3	4	5	81 (91.7)	77 (95)
22. Aktoren O 2000	24	48	Formocresol	24	3	12.5	5	21	21 (87.5)	19 (79)
			Ferric sulfate	24	3	12.5	4	17	21 (87.5)	20 (83)
23. Papagiannoulis L 2002	36	133	Formocresol	60	2	3.3	13	22	58 (96.70)	47 (78)
			Ferric sulfate	73	7	9.6	19	26	66 (90.4)	54 (74)
24. Markovic D 2005	18	104	Formocresol	33	3	9	5	15	30 (91)	28 (85)
			Ferric sulfate	37	4	11	7	19	33 (89)	30 (81)
			Calcium hydroxide	34	6	18	8	23.5	28 (82)	26 (76.5)
25. Jeng-fen Liu 2006	12	137	Laser	68	2	3	4	6	66 (97)	64 (94)
			Formocresol	69	10	14.5	15	22	59 (85.5)	54 (78)
26. Sahza Hatibovic-Kofman 2006	12	354	Formocresol	250	4	1.6	19	7.6	246(98.4)	231 (92.4)
			Ferric sulfate	104	2	2	7	7	102 (98)	97 (93)
27. Waterhouse PJ 2000	12	79	Formocresol	44	2	4.5		42		95.5
			Calcium hydroxide	35	4	11.43		31		88.6
28. Bahrololoomi Z 2008	9	70	Formocresol	35	0	0		35		100
			Electrosurgery	35	1	3		34		97
29. Huth K.C 2005	24	200	Formocresol	50	7	14		43		86
			Ferric sulfate	50	7	14		43		86
			Calcium hydroxide	50	23	46		27		54
			Laser	50	11	22		39		78
30. Ibricevic H 2000	20	70	Formocresol	35	1	3		34		97
			Ferric sulfate	35	0	0		35		100
31. Sonmez D 2008	24	80	Formocresol	20	5	25		15		75
			Ferric sulfate	20	5	25		15		75
			Calcium hydroxide	20	11	44		9		56
			MTA	20	7	35		13		65
32. Moretti ABS 2008	24	24	Formocresol	15	5	33.3		10		66.7
			Calcium hydroxide	15	5	33.3		10		66.7
			MTA	15	6	40		9		60
33. Eidelman E 2001	30	32	Formocresol	15	1	7		14		93
34. Naik S 2005	6	50	Formocresol	25	0	0		25		100
			MTA	25	0	0		25		100
35. Aeinehchi M 2007	6	100	Formocresol	57	10	17.5		47		82.5
			MTA	43	0	0		43		100
36. Kowsari A 2007	12	30	Formocresol	15	1	7		14		93
			MTA	15	2	13.3		13		86.7
37. Holan G 2005	38	62	Formocresol	29	5	17.2		24		82.8
			MTA	33	1	3		32		97
38. Subramaniam P 2009	24	40	Formocresol	20	3	15		17		85
			MTA	20	1	5		19		95
39. Barrieshi-Nusair 2006	24	31	MTA	31	2	6.4		29		93.6
40. Caicedo R 2006	6	11	MTA	11	1	9		10		91
41. Sakai V. T 2009	12	15	MTA	15	1	7		14		93

N – No. of teeth, % - Percentage of teeth

The clinical pooled OR of calcium-hydroxide being higher likely to be failure, was 4.08(Figure 1) and at an individual study it was as less as 1.67<sup>15</sup> and as high as 9.75<sup>27</sup> than formocresol (Table 4). The Cochran Q test was  $p > 0.05$  ( $Q=7.72$  on 8 degree of freedom) indicating not significant heterogeneity. There was no evidence of bias using the Egger (weighted regression) method ( $p=0.624$ ). The radiographic pooled OR of calcium hydroxide being higher likely to be failure, was 4.9 (95% CI 2.8 and 8.8), and at an individual study it was as less as 1.67 (95% CI 0.6 and 4.60) and as high as 26.6 (95% CI 7.3 and 97.07) than formocresol (Figure 7). The Cochran Q test was  $p < 0.05$  ( $Q=14.84$  on 3 degree of freedom) indicating significant heterogeneity. There was no evidence of bias using the Egger (weighted regression) method ( $p=0.43$ ).

The clinical pooled OR of electrosurgery being higher, likely to be failure was 3.1 (Figure 2), and at an individual study it was as less as 3<sup>30</sup> and as high as 3.12<sup>13</sup> than formocresol (Figure 6) and radiographic pooled OR of electrosurgery likely to be higher was 2.24 (95% CI 0.7 and 7) than formocresol (Table 4, Figure 7). There was no evidence of bias using the Egger (weighted regression) method ( $p=0.48$ ) clinically and radiographically where  $p=0.52$ .

The clinical pooled OR of ferric sulfate being higher, likely to be failure was 1.01 (Figure 3), and at an individual study it was as less as 0.13<sup>32</sup> and as high as 351 than formocresol. The Cochran Q test was  $p > 0.05$  ( $Q= 6.09$  on 9 degree of freedom) indicating not significant heterogeneity. There was no evidence of bias using the Egger (weighted regression) method ( $p=0.45$ ). Radiographic pooled OR of ferric sulfate being higher, likely to be failure was 1.13 (95% CI 0.75 and 1.7), and at an individual study it was as less as 0.12 (95% CI 0.013 and 1.1) and as high as 2.5 (95% CI 0.72 and 9) than formocresol (Table 4, Figure 7). The Cochran Q test was  $p > 0.05$  ( $Q=6.99$  on 7 degree of freedom) indicating not significant heterogeneity. There was no evidence of

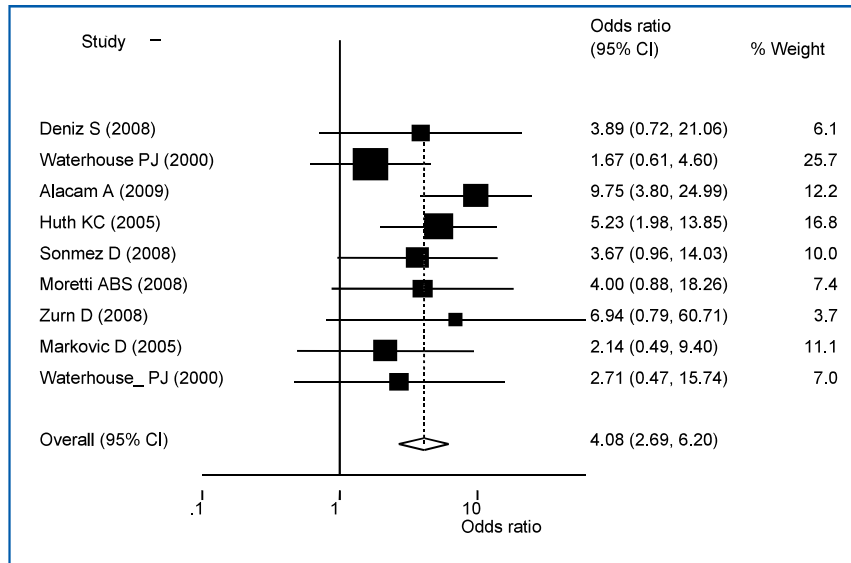
bias using the Egger (weighted regression) method ( $p=0.52$ ).

Laser and formocresol results were quite similar (Figure 4). The clinical pooled OR of laser was just 0.66 higher than formocresol which was very much insignificant, and at an individual study it was as less as 0.146 and as high as 1.7.2 The Cochran Q test was  $p > 0.05$  ( $Q=8.23$  on 3 degree of freedom) indicating not significant heterogeneity. There was no evidence of bias using the Egger (weighted regression) method ( $p=0.9$ ). Studies showed radiological failure rate of laser is 0.4 in comparison to formocresol which shows that there is no significant difference in between them. This study's radiological pooled OR of laser is 0.4 (95% CI 0.23 and 0.93), and at an individual study it was as less as 0.2 (95% CI 0.07 and 0.7) and as high as 3.8 (95% CI 0.6 and 21.5). The Cochran Q test was  $p > 0.05$  ( $Q=7.46$  on 2 degree of freedom) indicating not significant heterogeneity. There was evidence of publication bias using the Egger (weighted regression) method ( $p=0.01$ ).

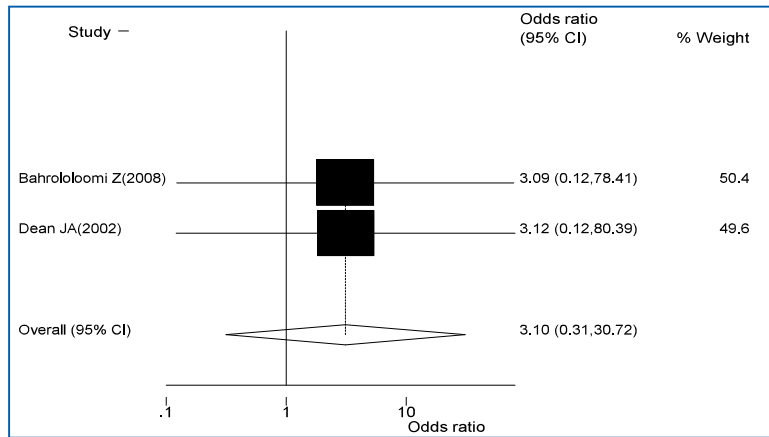
MTA and formocresol had very small failure difference clinically and radiographically. The clinical pooled OR of MTA had failure of 0.7 only when compared with formocresol (Figure 5), and at an individual study it was as less as 0.1<sup>20</sup> and as high as 10.89.<sup>31</sup> The Cochran Q test was  $p > 0.05$  ( $Q=26.21$  on 13 degree of freedom) indicating not significant heterogeneity. There was no evidence of bias using the Egger (weighted regression) method ( $p=0.85$ ). This study shows the radiologic pooled OR of MTA compared with formocresol as 1.06 (95% CI 0.6 and 1.8), and at an individual study it was as less as 0.16 (95% CI 0.04 and 0.6) and as high as 4.6 (95% CI 1.3 and 15.44) ( Table 4, Figure 7). The Cochran Q test was  $p > 0.05$  ( $Q=17.57$  on 7 degree of freedom) indicating not significant heterogeneity. There was no evidence of bias using the Egger (weighted regression) method ( $p=0.7$ ).

**Table 4:** Clinical and Radiological failure rates of various materials and techniques compared to Formocresol.

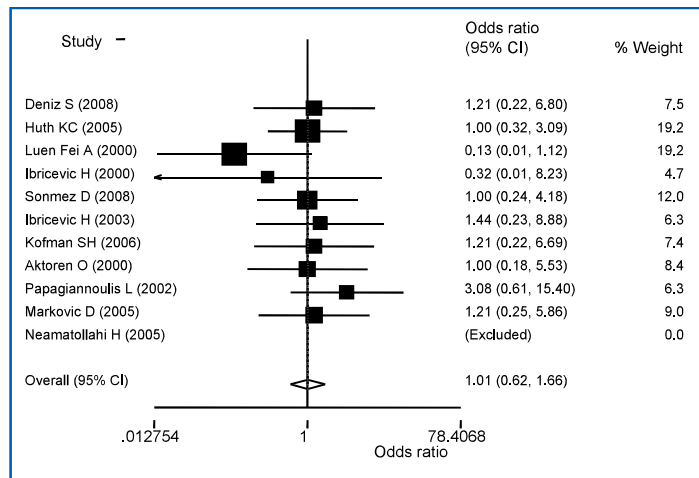
S.N.		Clinical Pooled OR of material at 95% CI when compared to Formocresol	Less as	High	Radiographic OR at 95% CI of material when compared to Formocresol	Less as	High as	Clinical Egger (weighted regression)	Radiographical Egger (weighted regression)
1.	Calcium hydroxide	4.08	1.67	9.45	4.9	1.67	26.6	$p=0.624$	$p=0.43$
2.	Electrosurgery	3.1	3	3.1	2	2.2	4	$p=0.48$	$p=0.52$
3.	Ferric sulfate	1.01	0.12	3	1.13	0.12	2.5	$p=0.45$	$p=0.52$
4.	Laser	0.66	0.1	1.7	0.46	0.2	3.8	$p=0.9$	$p=0.01$
5.	MTA	0.7	0.1	10.89	1.06	0.16	4.6	$p=0.85$	$p=0.7$



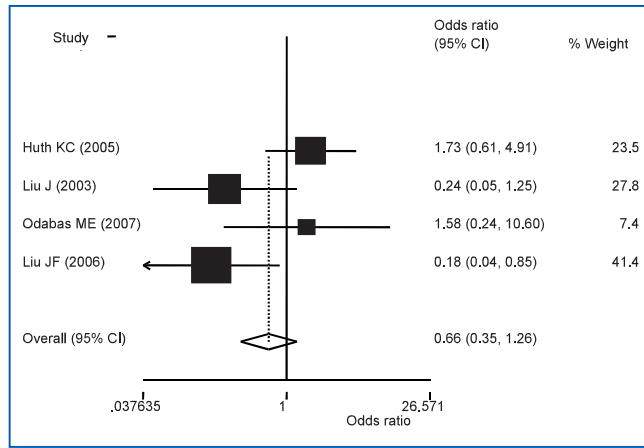
**Figure 1:** Forest plot of meta-analysis of 9 studies indicating excess of failure rate in calcium hydroxide compared to formocresol.



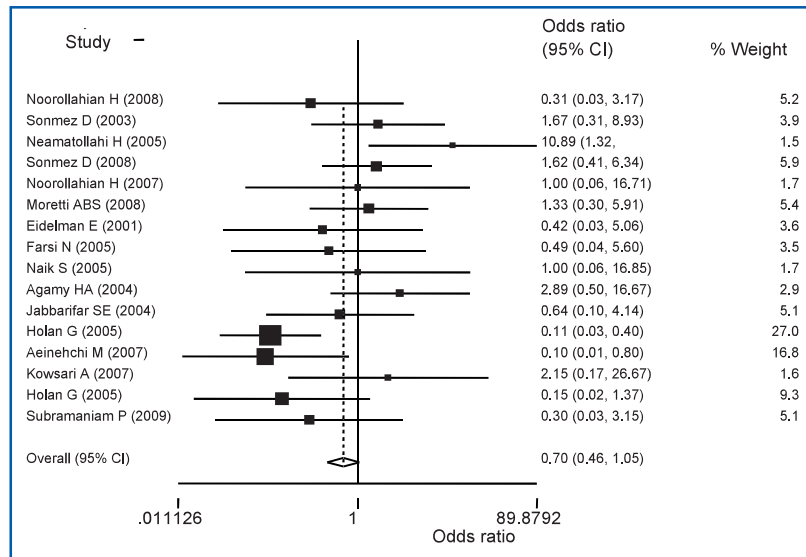
**Figure 2:** Forest plot of meta-analysis of 2 studies indicating excess of failure rate in electrosurgery compared to formocresol.



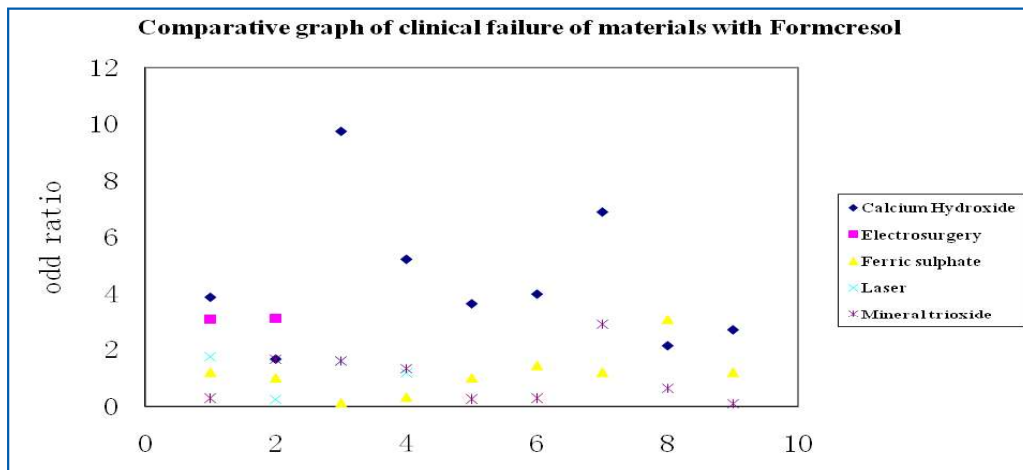
**Figure 3:** Forest plot of meta-analysis of 11 studies indicating similar success rate in ferric sulfate compared to formocresol.



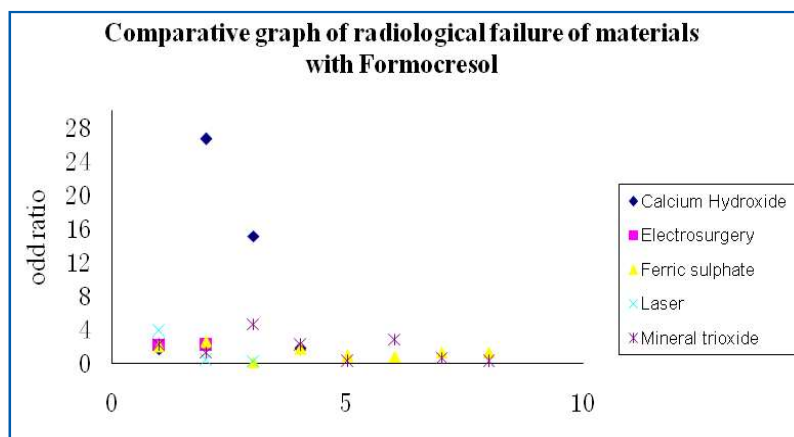
**Figure 4:** Forest plot of meta-analysis of 4 studies indicating similar success rate in laser compared to formocresol.



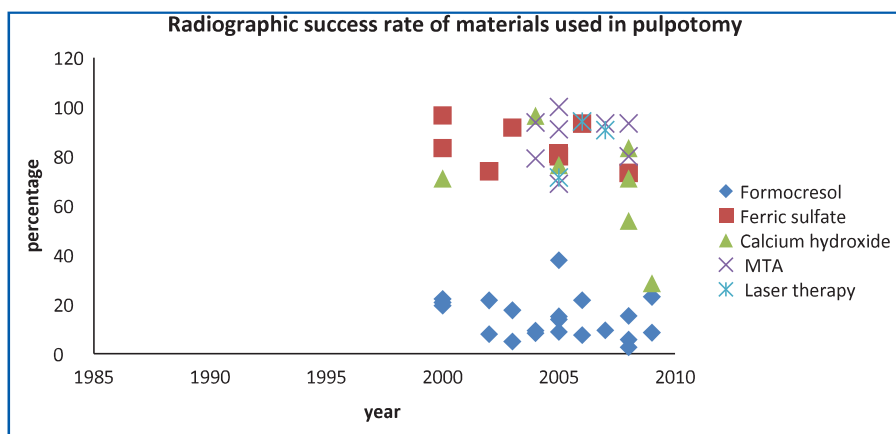
**Figure 5:** Forest plot of meta-analysis of 16 studies indicating similar success rate in mineral trioxide aggregate compared to formocresol.



**Figure 6:** Scattered graph was plotted by taking the clinical odds ratio and 95% CI from individual studies.



**Figure 7:** Scattered graph was plotted by taking the radiographic odds ratio and 95% CI from individual studies.



**Figure 8:** Success rate of materials like formocresol, electrosurgery, ferric sulfate, MTA and laser is higher and improving in due course of time whereas Calcium hydroxide has less success rate.

## DISCUSSION

The analysis of this meta-analysis reveals that there are possible alternative medicaments to Formocresol, which may be considered equally efficacious like MTA and ferric sulfate. This meta-analysis brought together evidence from 41 studies, collected in between 2000-2010. Because the alternatives to formocresol pulpotomy have moderate advantages, pulpotomy techniques or agents still have a questionable advantage in 21<sup>st</sup> century pediatric dentistry. In this meta-analysis, the prognosis of pulpotomy in primary and young permanent teeth with various materials and techniques as listed was evaluated clinically and radiographically. The success and failure rate was taken into consideration for the study.

The results of various studies need to be interpreted with caution due to certain shortcomings inherent in each study. In a few of the studies, the restorative materials employed were different in the treatment and

control groups. Some of these studies lacked an ethical approval, while some were not blinded, which could amount to a certain degree of bias. Also there is need for further studies with a greater number of teeth treated with various medicaments to determine the long-term effects on primary and young permanent teeth. With lasers, the need for specialization to carry out treatment and the equipment cost also comes into consideration, while determining its efficacy.

This meta-analysis showed the failure rate of calcium hydroxide was higher than formocresol. The clinical pooled OR of calcium hydroxide being higher likely to be failure, was 4.08 [95% CI 2.69 and 6.20], and at an individual study it was as less as 1.67 [95% CI 0.61 and 4.60] and as high as 9.45 [95% CI 3.80 and 24.99] than formocresol. In this clinical study, Moretti<sup>34</sup> and Sonmez<sup>25</sup> odd ratio was 4, 3.8 and 3.6 respectively and it was quite near to our meta-analysis result which showed, that the calcium hydroxide's failure rate in

comparison to formocresol is higher around four times and these authors had also come to that result. Alacam,<sup>27</sup> Zurn,<sup>16</sup> and Huth<sup>2</sup> results odd ratio were 9.7, 6.9 and 5.2 which showed that the failure rate of calcium hydroxide is way higher than formocresol which is taken as a standard agent. Calcium hydroxide performed significantly worse than other medicaments in a few studies, while its greater success in some other studies may be due to strict selection criteria like Waterhouse,<sup>15</sup> Markovic,<sup>52</sup> and Waterhouse,<sup>26</sup> where the odd ratio were 1.6, 2.1 and 2.7 respectively, this result reported a statistically insignificant difference in treatment outcomes between formocresol and calcium hydroxide pulpotomy. Thus, calcium hydroxide in its pure powder form can be a clinically acceptable alternative to formocresol but recommended further research is needed.

On average, the radiographic failure rate of calcium hydroxide was higher than formocresol (Figure 1). The radiographic pooled OR of calcium hydroxide being higher likely to be failure, was 4.9 (95% CI 2.8 and 8.8), and at an individual study it was as less as 1.67 (95% CI 0.6 and 4.60) and as high as 26.6 (95% CI 7.3 and 97.07) than formocresol. In this study only Waterhouse<sup>15</sup> and Markovic<sup>52</sup> showed a low odd ratio of 0.6 and 1.7 respectively. Via,<sup>53</sup> Schröder,<sup>54</sup> Schröder et al,<sup>55</sup> and Doyle et al<sup>56</sup> concluded that the calcium hydroxide treatment was associated with dentine bridge formation and when this happens success rate is higher. Alacam<sup>27</sup> and Zurn<sup>16</sup> radiographic results of calcium hydroxide compared with formocresol showed an odd ratio of 26.6 and 15.07 respectively which is very much higher when compared with other studies. This shows that calcium hydroxide is not a compatible medicament that can be used in long term and high incidence of failure rate is due to internal resorption.

This meta-analysis showed on average, the failure rate of electrosurgery was higher than formocresol (Figure 2). The use of electrosurgery as a nonpharmacological pulpotomy technique has been well-documented and has proven to have merit.<sup>57</sup> The clinical pooled OR of electrosurgery being higher, likely to be failure was 3.1 (95% CI 0.3 and 30.72), and at an individual study it was as less as 3 (95% CI 0.12 and 78.4) and as high as 3.12 (95% CI 0.12 and 80.39) than formocresol and radiographic pooled OR of electrosurgery likely to be higher was 2.2 (95% CI 0.7 and 7) than formocresol. In the study of Bahrololoomi et al<sup>30</sup> and Dean<sup>13</sup> clinical ratio of 3.08 and 3.12 and radiographic odd ratio of 2.2 and 2.1 are similar to the meta-analysis odd ratio of 3.1 and 2.2 respectively. Dean et al<sup>13</sup> also demonstrated

the clinical and radiographic success rates for electrosurgical pulpotomy to be comparable to those for formocresol pulpotomy. This can be due to less histopathological reaction as said by El-Meligy et al.<sup>58</sup> But still further studies with longer evaluation periods are warranted.

This meta-analysis showed the failure rate of ferric sulfate was higher than formocresol (Figure 3). The clinical pooled OR of ferric sulfate being higher, likely to be failure was 1.01 (95% CI 0.61 and 1.6), and at an individual study it was as less as 0.12 (95% CI 0.01 and 1.1) and as high as 3 (95% CI 0.61 and 15.39) than formocresol. In most of the studies, ferric sulfate showed good results regarding their clinical and radiographic outcomes. In this study Deniz,<sup>25</sup> Huth,<sup>2</sup> Sonmez,<sup>25</sup> Ibricevic,<sup>42</sup> Kofman,<sup>48</sup> Aktoren,<sup>50</sup> and Markovic<sup>52</sup> have shown the clinical odd ratio of 1.2, 1, 1, 1.4, 1.2, 1 and 1.2 respectively and it has come to be quite similar to the result of meta-analysis. Only Papagiannoulis<sup>51</sup> showed a clinical odd ratio of 3 which showed that it had 3 times more failure rate than formocresol. Similarly, in a retrospective study, Smith et al<sup>59</sup> showed lower success rates for ferric sulfate than those previously reported in the dental literature. Similarly in this study, Fei<sup>32</sup> and Ibricevic et al<sup>17</sup> clinical odd ratios were 0.1 and 0.32 which showed that it is a better alternative to formocresol. Ibricevic et al<sup>17</sup> (Level 1 Grade B recommendation) study and Neamatollahi<sup>31</sup> recommends the use of ferric sulfate as a pulpotomy agent on the basis of their 100 % clinical success results. An evidence-based assessment of clinical trials of ferric sulfate and formocresol with meta-analysis by Loh et al<sup>60</sup> concluded that, in human carious primary molars with reversible coronal pulpitis, pulpotomies performed with either formocresol or ferric sulfate are likely to have similar clinical/radiographic success.

In this study the radiographic pooled OR of ferric sulfate being higher, likely to be failure was 1.13 (95% CI 0.75 and 1.7), and at an individual study it was as less as 0.12 (95% CI 0.013 and 1.1) and as high as 2.5 (95% CI 0.72 and 9) than formocresol. The comparative radiographic odd ratio of ferric sulfate to formocresol in Sonmez,<sup>25</sup> Neamatollahi,<sup>31</sup> Papagiannoulis,<sup>51</sup> and Ibricevic<sup>42</sup> were 2, 2.5, 1.2 and 1.7 which was higher than our study result of 1.1. The radiographic odd ration in Fei,<sup>32</sup> Kofman<sup>48</sup> and Aktoren<sup>50</sup> were 0.12, 0.8 and 0.7 respectively and these groups showed a higher radiographic success as compared to our meta-analysis report. Clinical studies have reported similar Eidelman,<sup>19</sup> Cleaton-Jones<sup>61</sup> or higher Huth<sup>2</sup> clinical

and radiographic success rates of ferric sulfate as compared to 1:5 dilute formocresol. Success rates of FS, and DFC were not significantly different in Fuks et al<sup>7</sup> and success rates were similar to those from Fuks and her co-workers when Ibricevic and Al-Jame<sup>42</sup> reported the combined clinical and radiographic success results, first at the end of 20 months and later at 48 months. Based on the available evidence so far, ferric sulfate and formocresol produce equivalent outcomes.

In this meta-analysis study the laser and formocresol results were quite similar (Figure 4). The clinical pooled OR of laser was just 0.66 higher than formocresol which was very much insignificant (95% CI 0.3 and 1.2), and at an individual study it was as less as 0.1 (95% CI 0.03 and 0.8) and as high as 1.7 (95% CI 0.6 and 4.9). In this clinical study Huth<sup>2</sup> and Odabas<sup>36</sup> showed an OR of 1.7 and 1.5 respectively. Other studies of Liu<sup>46</sup> and Liu<sup>38</sup> showed an OR of 0.17 and 0.2 which was significantly lower than meta-analysis result of 0.6 when compared with formocresol which shows that laser is better than formocresol and it can be used as an alternative technique for pulpotomy. Nd:YAG Laser did not cause any damage to the permanent successors and they erupted without any complications. Therefore, the Nd:YAG laser pulpotomy can be considered for use as a pulpotomy technique in clinical practice.

This study's radiological failure rate of laser is 0.4 in comparison to formocresol which shows that there is no significant difference in between them. This study's radiological pooled OR of laser is 0.4 (95% CI 0.23 and 0.93), and at an individual study it was as less as 0.2 (95% CI 0.07 and 0.7) and as high as 3.8 (95% CI 0.6 and 21.5). In this radiographic study Liu<sup>38</sup> and Liu<sup>46</sup> showed an OR of 0.3 and 0.2 which was significantly lower than meta-analysis result of 0.4 which shows that it can be used as an alternative technique for pulpotomy. This meta-analysis showed that the MTA and formocresol had very small failure difference clinically and radiographically. The clinical pooled OR of MTA had failure of 0.7 only when compared with formocresol (95% CI 0.4 and 1.05), and at an individual study it was as less as 0.1 (95% CI 0.03 and 0.4) and as high as 10.89 (95% CI 1.32 and 89.88). This study shows the radiologic pooled OR of MTA compared with formocresol as 1.06 (95% CI 0.6 and 1.8), and at an individual study it was as less as 0.16 (95% CI 0.04 and 0.6) and as high as 4.6 (95% CI 1.3 and 15.44). The clinical studies by Sonmez,<sup>25</sup> Neamatollahi,<sup>31</sup> Noorollahian,<sup>33</sup> Moretti,<sup>34</sup> Naik,<sup>18</sup> Agamy<sup>21</sup> and Kowsari<sup>40</sup> had the OR of MTA compared with formocresol 1.67,10.89,1.62,1.1,1.3,1.2,8

and 2.1 respectively which was higher than our study result. The radiographic studies by Noorollahian,<sup>24</sup> Sonmez,<sup>25</sup> Naematollahi,<sup>31</sup> Noorollahian,<sup>33</sup> and Agamy<sup>21</sup> showed their radiographic OR as 2.1, 1.3, 4.6, 2.1 and 2.8 respectively which showed that they were higher than our result OR and this states that the radiographic failure was a bit higher of MTA when compared with formocresol. Other studies Noorollahian,<sup>24</sup> Eidelman,<sup>19</sup> Farsi,<sup>35</sup> Jabbarifar,<sup>37</sup> Holan,<sup>20</sup> Subramaniam,<sup>43</sup> and Holan<sup>41</sup> had OR 0.3, 0.42, 0.4, 0.6, 0.11, 0.1, 0.3 and 0.15 respectively which was lower than the result OR of MTA compared with formocresol. In other studies Farsi,<sup>35</sup> Jabbarifar,<sup>37</sup> and Holan<sup>41</sup> showed OR of 0.1, 0.6 and 0.16 which was similar or lesser than our meta-analysis result. This shows that MTA is a better alternative than formocresol radiographically also.

Similarly Aeinehchi et al<sup>62</sup> compared MTA and formocresol as pulpotomy agents during 6 and 18 months in 2 separate clinical studies. They reported more favorable results after pulpotomy with MTA in comparison with FC. Another meta-analysis Ng<sup>63</sup> of the results of current studies evaluating MTA, Ca(OH)<sub>2</sub>, and FC reported a more favorable success rate for MTA in terms of clinical and radiographic signs before tooth exfoliation. The results of Peng<sup>64</sup> meta-analysis comparing success rates of pulpotomies using FC or MTA showed that MTA has significantly fewer failures compared with FC. Maroto et al<sup>65</sup> investigation also reported the success of MTA in pulpotomized primary teeth clinically and radiographically. Torabinejad and Chivian<sup>66</sup> proposed MTA as a potential medicament for pulpotomy procedures. MTA showed higher long-term clinical and radiographic success when used as a pulpotomy material in primary molars with exposed vital pulps when compared with the outcomes of teeth treated with formocresol.

Eidelman et al<sup>19</sup> reported no significant difference between MTA and FC. Radiographically MTA was better than formocresol. Although the sample sizes were small, MTA was proposed as a suitable alternative to formocresol in primary teeth. Similarly in a clinical investigation, Naik et al<sup>18</sup> showed no clinical and/or radiographic failures at 1, 3, and 6 months after pulpotomy with either FC or MTA.

This shows that MTA is a biocompatible material which showed high success rates and all the studies showed no conflicting evidence regarding the clinical and radiographic success so it can be used as an

alternative material. MTA successfully induced a thick dentine bridge at the amputation sites, while formocresol induced thin, poorly calcified dentine. The studies demonstrated new matrix deposition with cellular inclusions in a 2-week period and tubular type dentin-like barrier at 3 weeks.<sup>67</sup> It has been speculated that hard tissue stimulation may occur because of the biocompatibility, sealing properties and the alkalinity of MTA.

### Limitation of the study

There were 2 major limitations of this study:

1. The most significant of which is the short observation time. Investigations of vital pulp therapy on primary teeth would benefit from survival analysis with longer periods of follow-up. This sample will be followed for an additional year to allow assessment of 18 and 24 month outcomes. Only some articles had longer observation time.
2. Another limitation is the small sample size. Prospective randomized trials in humans are difficult and time consuming to conduct.

### CONCLUSION

Controversy persists as to the best way to perform vital pulp therapy and additional research is needed to see whether formocresol, MTA, ferric sulfate, electrosurgery, laser or calcium hydroxide are best suited for pulpotomy. From our meta-analysis and the present review of the literature the following conclusions can be made.

1. In primary molar teeth with vital pulp exposure by caries or trauma, a pulpotomy performed with MTA appear to result in better clinical and radiographic observed outcome due to lack of internal resorption

in addition to the biocompatibility, sealing ability and promotion of hard tissue formation. MTA performs equal to or better than formocresol or ferric sulfate and may be the preferred pulpotomy agent in the future but more clinical research is needed before it can be used as an alternative material. Manipulation consideration and cost may limit widespread use of MTA.

2. Calcium hydroxide appears to be clinically less appropriate than FC, FS and MTA so it might not be the optimal choice for pulpotomy material, because of high failure rate and the presence of adverse outcomes more prevalent than other materials. It has less favourable outcome over a period of time which leads to failure of treatment.
3. Ferric sulfate is a non-toxic medicament and the success rate is more and it could be a better alternative to Formocresol. It can become the medicament of choice in future because of its equal or higher success rate clinically and radiographically. In addition it requires less manipulation time, has haemostatic effect and has affordable cost. But more studies are required to evaluate its systemic effects as well as its effects on permanent teeth.
4. Lasers success rate is better than formocresol so it can also be considered as an alternative medicament technique in pulpotomies of primary teeth but longer follow-ups are required for these results to be confirmed. When considering lasers as an alternative, cost and a need for specialization to carry out treatment, also comes into play.
5. Although electrosurgical pulpotomy is a non-pharmacological and easy technique with favorable results, it is still a preservative technique and the cost of electrosurgical equipment is a drawback.

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