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ORIGINAL ARTICLE

Ferric Sulfate Versus Calcium-Enriched Mixture Cement in Pulpotomy of Primary Molars: A Randomized Clinical Trial

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ABSTRACT

Objective: To evaluate the postoperative pain and clinical and radiographic success of pulpotomized primary molars using two materials, Ferric Sulfate (FS) and Calcium-Enriched Mixture (CEM) cement, over a period of 3 and 6 months. **Material and Methods:** This randomized clinical trial was conducted on a total of 38 teeth selected from 19 patients aged 3-9 years. FS 15.5% and CEM cement were used as pulpotomy agents. Permanent restorations were Stainless Steel Crowns (SSCs) in both groups. Patients were recalled for follow-up at 3 and 6 months intervals for clinical and radiographic assessment. Postoperative pain was recorded by using Visual Analogue Scale up to ten days following the treatment. The data were statistically analyzed using chi-square test and repeated measures ANOVA. **Results:** At 6 months, a 100% clinical success rate was observed in the FS and CEM cement groups. The radiographic success rate in the FS group was 94.7%, whereas 100% in the CEM cement group at 6 months. No statistically significant difference was found between the two groups ($p>0.05$). There was no significant difference in postoperative pain between the teeth that received either FS or CEM cement as pulpotomy agents following the procedure ($p>0.05$). **Conclusion:** There were favorable outcomes of FS and CEM cement in pulpotomy of primary molar teeth.

Keywords: Child; Tooth, Deciduous; Pulpotomy; Pain.

Introduction

The maintenance of primary dentition is essential for aesthetic enhancement and development of jaws in children. In populations with extensive caries in primary teeth, pulp therapy is significantly important to maintain teeth [1]. In recent years, there have been many challenges in presenting the best treatment for primary molar teeth with deep caries lesions. According to a recent systematic review and a new AAPD (The American Academy of Pediatric Dentistry) guideline for vital pulp therapy in primary teeth, indirect pulp therapy, direct pulp cap, and pulpotomy are introduced as suitable treatments of choice [2,3].

A pulpotomy is the removal of the inflamed coronal pulp tissue, and the vital radicular pulp tissue is covered with a suitable covering material [4]. The pulpotomy is done in cases where pulp exposure occurs after caries removal in a primary tooth with normal pulp or reversible pulpitis. The pulpotomy is only indicated when there is a pulp exposure in the presence of caries tissue, in which selective caries removal is being conducted [5]. This method needs a bactericidal medicament that has no side effects, improves the healing process, and has no interference in physiologic root resorption [6].

In this regard, researchers have introduced various medicaments, such as formocresol, Ferric Sulfate (FS), calcium hydroxide, sodium hypochlorite, Mineral Trioxide Aggregate (MTA), and, recently, Calcium-Enriched Mixture (CEM), for vital pulp therapy in primary teeth [7]. For decades, formocresol has been a popular pulpotomy medicament owing to its simple use and suitable prognosis [8,9]. Nevertheless, the potential of systemic distribution of formocresol molecules through the root canals, which results in toxicity, hypersensitivity and teratogenicity, has necessitates the replacement of this medicament with a safer material [10,11]. Clinical and histological studies have shown that most residual pulp treated with this medicament develops chronic inflammation and even partial necrosis [12].

On the other hand, Ferric Sulfate (FS) is used as a pulpotomy medicament due to its hemostatic function. In fact, FS acts as a barrier to inflammation-initiating factors by forming a protein clot at the surface of pulp. Even though high clinical success rates have been found by using Ferric Sulfate (FS), studies have shown that it might produce moderate to severe inflammatory responses histologically [13]. Nevertheless, no concerns about toxic or harmful effects have been reported in the dental literature to date [14].

One of the medicaments that has attracted much attention in the last decade due to its biocompatibility properties and good clinical results is MTA. The use of MTA has caused problems for users, especially in primary teeth, due to its disadvantages such as technique sensitivity, staining and high cost [13]. CEM cement is a medicament recently added to dental materials, that has clinical applications similar to MTA. In fact, these two materials have a similar sealing ability, biocompatibility, and pH. However, CEM cement has more efficient antibacterial properties, as well as lower setting time, film thickness, cost and tooth discoloration compared to MTA [15]. The main compounds of this medicament include calcium oxide (CaO), sulfur trioxide (SO_3), phosphorus pentoxide (P_2O_5), and silicon dioxide (SiO_2), and the proportion of these compounds in CEM cement is different from that of MTA [16].

Pain is an unpleasant experience or feeling that can be associated with real or unrealistic tissue injury. Prevention of pain during treatment, especially in pediatric dentistry, can make a positive relationship between the dentist and child, build trust, and change the attitude of children to dental clinic [17]. In pediatric dentistry, the level of pain experienced by children after dental treatment is important [18,19].

It has previously been demonstrated that there was no significant difference between formocresol, ferric sulfate, CEM and CEM combined with lasers in pulpotomy of primary molars [10]. Also, other authors compared the success rate of pulpotomized primary molars with formocresol and ferric sulfate, that they were

observed a higher success rate for ferric sulfate compared to formocresol [20]. There was no significant difference in the radiographic and clinical success rate of Biodentine and FS in pulpotomy of primary molars [13].

Previous authors evaluated pain after use of CEM cement and MTA in pulpotomy of primary molars and observed that no significant difference between the two types of medicaments [21]. In another study, Poureslami et al. compared the pain after the use of formocresol and Elaegnus Angustifolia fruit powder in pulpotomy of primary molars. In this study, pain significantly decreased in both groups 10 days after the treatment [22].

Several studies have shown the high success rate of pulpotomy with FS [10,14] and CEM cement [10,16,23] separately. However, very few researches have compared the Ferric Sulfate and CEM cement in regarding their success rate and the level of pain experienced after pulpotomy of primary molars. Therefore, given the constant introduction of new medicaments for pulp treatment of primary molars, it is important to evaluate and compare the success rate of various materials. The aim of this study was to evaluate the postoperative pain and clinical and radiographic success rate of CEM cement and Ferric Sulfate in pulpotomy of primary molars.

Material and Methods

Study Design and Ethics

This double-blind clinical trial was confirmed by the ethics committee of the Kerman University of Medical Sciences with the code of IR.KMU.REC.1393.538. Also, it has been registered in Iranian Registry of Clinical Trials (IRCT20171020036896N8).

Sample

In total, 24 children aged three-nine years were investigated that had at least two bilateral primary molars in the maxilla or mandible with the caries lesions on occlusal-proximal surfaces that need pulpotomy treatment, who were referred to the pediatric department of Kerman Dental School participated. Inclusion criteria were deep decay of bilateral primary molars, no tooth sensitivity to percussion, no history of spontaneous pain other than pain induced by eating, no radiographic and clinical signs caused by pulp degeneration, no sinus tract, and grade 4 and 3 Frankel [21,24]. On the other hand, exclusion criteria were catching any systemic disease (e.g., leukemia) that would prevent pulp treatment, presence any radiographic signs, such as internal resorption, external resorption, periodontal ligament (PDL) widening, existence of radiolucency surrounding the root or furcation, pulp canal obliteration, and physiologic resorption of more than two-thirds of the root length [21].

At first, research objectives were explained to the parents of children and informed consent was obtained prior to the study. The primary molar on one side was randomly based on the flip the coin method, treated with Ferric Sulfate (FS) (Astringent, Ultradent Products Inc., UT, USA) and the other molar was treated with CEM cement (Bionique Dent, Tehran, Iran) in the next session (10 days later). After local anesthesia by 2% lidocaine and epinephrine 1/80000 (Darou Pakhsh Pharma Chem. Co., Tehran, Iran) and isolation with a rubber dam, the teeth were treated. After removing dental caries with a low-speed handpiece, the roof of the pulp chamber was removed with a diamond bur (Tizkavan Co., Tehran, Iran) with a high-speed handpiece.

Pulp tissue was removed with a sharp spoon excavator and a cotton pellet impregnated with normal saline for five minutes to stop the bleeding [21]. In the first group, CEM cement was prepared according to the manufacturer's instructions and placed in the pulp chamber. Then, light-curing glass ionomer (GC Corporation, Tokyo, Japan) was placed on CEM cement [21]. In another group, after stop of bleeding, a cotton pellet impregnated with 15.5% Ferric Sulfate was placed on orifice of pulp canals for 15 seconds. After pulp tissue homeostasis, the entire access cavity was filled with Zonalin® (Kemdent, Associated Dental Products Ltd., Purton, UK) [10,14]. If the bleeding not stop, the teeth were excluded from the study. Finally, in the both groups the teeth were restored with Stainless Steel Crown (SSCs) (3M Dental Products, St Paul, MN, USA) and cemented by Glass Ionomer cement [21].

Evaluation

In the next stage, Visual Analogue Scales (VAS) tool was provided to parents, demanding them to complete it 10 days after the treatment. This tool encompasses of six faces with different moods, each showing a level of pain, from no pain to severe pain. In this study, the pain after treatment was classified as mild, moderate and severe. Pain severity ratings in patients were scored, as follows: (0) no pain, (one-three) mild pain, (four-six) moderate pain, (seven-nine) severe pain [21]. All treatments were performed by a trained and experienced postgrad-resident.

The next follow-ups for each tooth were in the third and six months after the treatment. The assessment of clinical and radiographic success was performed by two pediatric dentists who were blinded to the type of treatment of teeth. In case of disagreement between them, a single result was obtained by discussing the disputed samples. Clinical success included the absence of symptoms such as pain, swelling, fistula, mobility and tenderness, whereas radiographic success included the absence of internal and external resorption, radiolucency in the periapical and furcation area, and widening of PDL [10]. CEM cement is radiopaque but the SSC edges cover any radiopacity of the CEM cement. The information obtained was recorded in separate forms for each group.

Data Analysis

Data analysis was performed in SPSS version 20 using Chi-square (to compare clinical and radiographic signs, as well as the frequency of post-treatment pain intensity) and repeated measured ANOVA (for comparison of mean pain score from the first day until 10 days after the treatment). Moreover, a P-value of 0.05 was considered statistically significant.

Results

From 24 patients, five subjects were not referred for the third and sixth-month follow-ups. Therefore, statistical analyses were performed on 19 patients, nine of whom were male and 10 were female. In this study, pulpotomy treatment was performed on 16-second primary molars and 22 first primary molars in both jaws (Table 1). In the radiographic assessment after third-month in the FS group showed external root resorption and periapical radiolucency in a first primary molar and widening of PDL in a second primary molar. Both of these cases considered as radiographic failure in FS group, while there was no radiographic failure related to teeth treated with CEM cement. Furthermore, no radiographic failure was detected after sixth-month in two groups.

In third and six-month clinical assessments, none of the teeth treated with CEM cement and FS, showed clinical failure. In this regard, statistical analysis demonstrated no significant difference between the two medicaments regarding the success rate of pulpotomy treatment (p=0.31) (Table 2).

Table 1. Characterization of participants.

Variables	Categories	N	%
Gender	Male	9	47.4
	Female	10	52.6
Tooth Type	Second Primary Molar	16	42.1
	First Primary Molar	22	57.9
Material	CEM Cement	19	50.0
	Ferric Sulfate	19	50.0

In third and six-month clinical assessments, none of the teeth treated with CEM cement and FS, showed clinical failure. In this regard, statistical analysis demonstrated no significant difference between the two medicaments regarding the success rate of pulpotomy treatment (p=0.31) (Table 2).

Table 2. Comparison of radiographic and clinical success in two groups after third and six-month.

Variables	CEM Cement		Ferric Sulfate		p-value
	Success N (%)	Failure N (%)	Success N (%)	Failure N (%)	
Radiographic Signs					
Internal Resorption (3 Months)	19 (100.0)	0 (0.0)	19 (100.0)	0 (0.0)	
Internal Resorption (6 Months)	19 (100.0)	0 (0.0)	19 (100.0)	0 (0.0)	
External Root Resorption (3 Months)	19 (100.0)	0 (0.0)	18 (94.7)	1 (5.3)	0.31
External Root Resorption (6 Months)	19 (100.0)	0 (0.0)	18 (94.7)	1 (5.3)	0.31
Periapical Radiolucency (3 Months)	19 (100.0)	0 (0.0)	18 (94.7)	1 (5.3)	0.31
Periapical Radiolucency (6 Months)	19 (100.0)	0 (0.0)	18 (94.7)	1 (5.3)	0.31
Furcation Radiolucency (3 Months)	19 (100.0)	0 (0.0)	19 (100.0)	0 (0.0)	
Furcation Radiolucency (6 Months)	19 (100.0)	0 (0.0)	19 (100.0)	0 (0.0)	
PDL Widening (3 Months)	19 (100.0)	0 (0.0)	18 (94.7)	1 (5.3)	0.31
PDL Widening (6 Months)	19 (100.0)	0 (0.0)	18 (94.7)	1 (5.3)	0.31
Clinical Signs					
Clinical Pain (3 and 6 Months)	19 (100.0)	0 (0.0)	19 (100.0)	0 (0.0)	
Swelling (3 and 6 Months)	19 (100.0)	0 (0.0)	19 (100.0)	0 (0.0)	
Fistula (3 and 6 Months)	19 (100.0)	0 (0.0)	19 (100.0)	0 (0.0)	
Mobility (3 and 6 Months)	19 (100.0)	0 (0.0)	19 (100.0)	0 (0.0)	
Percussion (3 and 6 Months)	19 (100.0)	0 (0.0)	19 (100.0)	0 (0.0)	

Regarding pain score, 68.4% of the children in both CEM and FS groups experienced post-treatment pain. In general, 68.4% of the patients experienced pain after the treatment regardless of the type of medicament applied in the process.

According to VAS, the highest score of pain was reported on the first day of treatment in two groups, which had a descending trend until 10 days after the treatment. In this respect, no significant difference was observed between two agents regarding the mean pain score (p=0.47) (Tables 3 and 4 and Figure 1).

Table 3. Comparison of mean and standard deviation of pain level after treatment.

Days	CEM Cement		Ferric Sulfate		p-value
	Mean	SD	Mean	SD	0.47
Day 1	2.8	2.4	2.5	2.4	
Day 2	1.3	1.6	1.2	1.7	
Day 3	0.7	1.1	0.3	0.6	
Day 4	0.4	0.6	0.3	0.6	

Day 5	0.4	0.7	0.3	0.5
Day 6	0.3	0.6	0.2	0.4
Day 7	0.3	0.6	0.2	0.4
Day 8	0.2	0.5	0.1	0.3
Day 9	0.2	0.5	0.3	0.7
Day 10	0.2	0.5	0.1	0.3

Table 4. Comparison of pain level during 10 days after treatment.

Days	CEM Cement				Ferric Sulfate				p-value
	Pain				Pain				
	No	Mild	Moderate	Severe	No	Mild	Moderate	Severe	
Day 1	6	6	5	2	6	8	4	1	0.86
Day 2	10	6	3		10	6	3		1.00
Day 3	13	6			14	5			0.72
Day 4	13	6			14	5			0.72
Day 5	14	5			14	5			0.72
Day 6	15	4			16	3			1.00
Day 7	15	4			16	3			0.67
Day 8	16	3			17	2			0.63
Day 9	16	3			16	3			1.00
Day 10	16	3			17	2			0.63

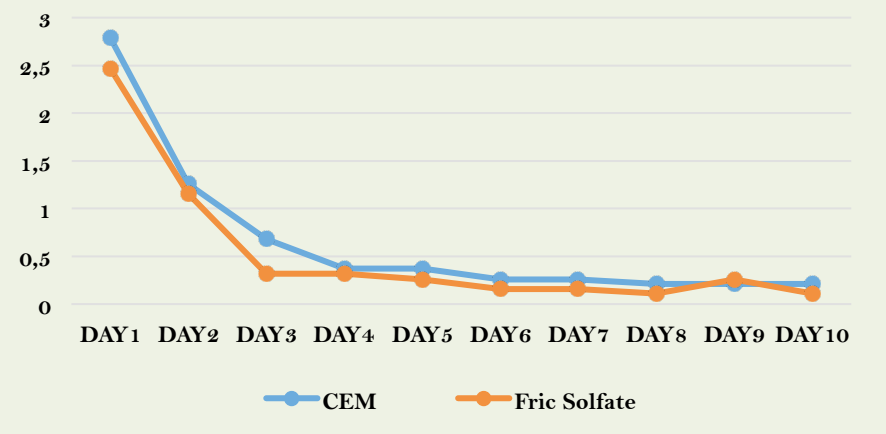

Figure 1. Comparison of descending trend of pain during 10 days after the treatment.

Discussion

Despite many reports of the use of different types of medicaments in the pulpotomy of primary teeth, there is still a lack of consensus in this area. In the present study, we compared the success rate of pulpotomy treatment of primary molars with CEM cement and FS. In this study, both the first and the second primary molars in both jaws were included in order to compare the effect of the mentioned medicaments on teeth with different pulp shapes and various nervous vascular nutrition resources. In a systematic review and meta-analysis of randomized clinical trials was shown that a lack of relationship between the success rate of treatment and variables such as, first/second molar, upper/lower jaw, gender, and various follow-up times. Also, this study has recommended SSC restoration after pulpotomy treatment of the primary molars since this method is reliable and have long-term survival [25].

In this research, the clinical success rate of pulpotomy with FS and CEM was 100% in both follow-ups, whereas the radiographic success rate was reported 94.7% and 100%, respectively. In dental treatments,

inaccurate case selection can fail after a short period. Two radiographic failure cases in the FS group might be due to this reason. Moreover, the leakage of microorganisms around the edges of SSC might have led to radiographic failure of the treatment. In terms of replacing formocresol with FS, it is generally believed that FS can induce homeostasis without exerting a harmful effect on the pulp tissue [6,26]. The higher number of radiographic failures might be due to different mechanisms of FS, which has a higher inflammation risk in the long-term [27]. Previous authors reported the overall success rate of FS to be higher, compared to formocresol, during 12 months [28].

Pulp treatment of decayed primary molars was developed by introducing more modern medicaments, such as MTA since this biocompatible substance lacks the risks associated with formocresol use. While MTA has been introduced as a safe replacement for formocresol, more research is required to confirm this claim [29]. However, a new agent known as CEM cement was introduced due to MTA's disadvantages, such as being technique sensitive, having the potential to change the color of teeth, and high cost [30,31]. Recent evidence shows that close contact with a vital pulp tissue can enable CEM cement to reproduce hard tissue in teeth [32]. According to the results of the present study, no significant difference was observed between FS and CEM cement medicaments. Histologic studies appear to be necessary to determine any possible histologic difference in pulp response of the two medicaments.

In one study it was shown that there is significant difference in clinical and radiographic success rate of formocresol and MTA after 12 months. In fact, widening of PDL and interradicular radiolucency were observed in the formocresol group, which might be due to the impacts of formocresol fixative and ability to release vapor through the apical foramen [33]. In another study, there was no significant difference between the success rate of formocresol and FS in pulpotomy treatments of primary teeth [20]. In the present study, widening of PDL in one molar and external root resorption and interradicular radiolucency in another molar were observed after third-month in FS group, that this failure might be due to improper case selection before treatment. Nevertheless, the difference was statistically insignificant.

Previous authors evaluated the clinical, radiographic and histological success rates of MTA and FS in pulpotomy of primary molars at three, six, 12 and 18-month intervals. No significant difference between the two medicaments in terms of success rate. In this study, MTA, which has compounds similar to CEM cement, was compared to FS, and the results are in line with our findings [34]. So, it could be concluded that both CEM cement and FS are effective for pulpotomies of primary teeth, with this difference that CEM cement is not as expensive as MTA.

In the present research, the pain was observed in 68.4% of the children after pulpotomy and SSC with the two medicaments. However, no significant difference was observed between the groups. Furthermore, the pain had a descending trend in both groups 10 days after pulpotomy treatments. More recently, studies focusing mainly on pain after dental treatment has received increasing attention. Despite many advances in dentistry, postoperative pain is still one of the complaints of patients. Therefore, it is important to assess the causes of pain and find appropriate solutions to reduce pain [35]. Dental pain is common after tooth extraction, crown placement and root canal treatment. The pain after placement of SSC can be related to pressure the edge of crown on the marginal gingiva and cause pain [36].

The results of this study showed that, 68.4% of the children in both CEM and FS groups experienced post-treatment pain. the highest score of pain was reported on the first day of treatment in two groups, which had a descending trend until 10 days after the treatment. This result was confirmed by Ashkenazi et al. According to their results, 38% of the subjects had postoperative pain. The highest level of pain was related to

crown placement [18]. The reasons for the high frequency of post-treatment pain could be related to the pressure from the crown margin into the gingival sulcus and to possible trauma to the gingiva during crown preparation.

In a previous study, a significantly higher level of pain was reported after pulpotomy and SSC placement in children, compared to other dental treatments [19]. That this result was similar to the present study, as most patients had pain after pulpotomy and SSC placement. Poureslami et al. evaluated pain following pulpotomy with formocresol during 10 days after treatment. Similar to our findings, pain significantly decreased 10 days after the treatment. The researchers reported that gingival injury caused by SSC can contribute to pain in the first days after treatment [22]. The results of a previous study reported that 90% of patients had different levels of pain immediately after pulpotomy treatment. Another cause of pain after treatment can be related tothis factor that cutting any tissue in the body can cause pain, and pulpotomy can also cause pain due to cutting the pulp tissue that contains nerves and vessels [37].

In general, it is best to evaluate the success of dental treatments over long periods to identify the failure. One of the limitations of the present study was the follow-up duration. In addition, evaluation of the success of treatment at the histologic level is also important due to showing the minor effects of the medicaments used on pulp tissue, which was another limitation of the present study. Also comparison to a control/gold-standard group (calcium hydroxide, for example) It is recommended that pain be assessed after pulpotomy with amalgam restoration to determine whether the main cause of pain is pulpotomy treatment or type of dental restoration. Also, comparison these materials to a control/gold-standard group like calcium hydroxide is recommended.

Conclusion

There was no significant difference between pulpotomy of primary molars with CEM cement and FS at three and six-month follow-ups, in terms of clinical and radiographic success rates and postoperative pain.

Authors' Contributions

FSS	https://orcid.org/0000-0002-5855-6533	Formal Analysis, Data Curation, Funding Acquisition, Project Administration and Supervision.
FJ	https://orcid.org/0000-0002-4868-1285	Methodology, Investigation, Formal Analysis, Writing – Original Draft Preparation, Writing – Review and Editing and Project Administration.
MK	https://orcid.org/0000-0003-0150-7199	Data Curation.

All authors declare that they contributed to critical review of intellectual content and approval of the final version to be published.

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Conflict of Interest

The authors declare no conflicts of interest.

Data Availability

The data used to support the findings of this study can be made available upon request to the corresponding author.

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