Comparison of clinical and radiographic success rates of pulpotomy in primary molars using Formocresol, Ferric Sulfate and Mineral Trioxide Aggregate (MTA)

H. Neamatollahi 1✉, A. Tajik 2

1Assistant Professor, Department of Pediatric Dentistry, Faculty of Dentistry, Mashhad University of Medical Sciences, Mashhad, Iran
2Assistant Professor, Department of Pediatric Dentistry, Faculty of Dentistry, Zahedan University of Medical Sciences, Zahedan, Iran

Abstract:
Statement of Problem: Pulpotomy is the most common pulp treatment of primary molars. Formocresol pulpotomy has enjoyed long-term clinical use and success, but concerns over its toxicity and mutagenicity have prompted research into other pulpotomy techniques.

Purpose: The aim of the present study was to compare the relative success of formocresol, ferric sulfate and MTA pulpotomy methods in primary molars, using clinical and radiographic examinations.

Materials and Methods: 135 second primary molars requiring pulpotomy treatment were selected from children between 3 and 6 years of age. They were randomly assigned to three groups according to the pulpal therapy technique: pulpotomy with formocresol, ferric sulfate, and MTA. All pulpotomized teeth were restored with amalgam. The subjects selected for clinical and radiographic evaluations were monitored periodically for 3 and 12 months.

Results: The clinical success rate of the MTA group was 82.1% after one year which was significantly less than the 100% observed in the other groups (P=0.005). The highest and lowest radiographic success rates after one year, were encountered in the formocresol (92.5%) and MTA (69.2%) groups respectively, which showed a significant difference (P=0.01). The success rate of the ferric sulfate group was 80.50%.

Conclusion: MTA is not recommended as a pulpotomy medicament in primary teeth, but ferric sulfate may be acceptable as an alternative to formocresol.

Key Words: Pulpotomy; Primary Molar; Formocresol; Ferric Sulfate; Mineral Trioxide Aggregate (MTA)

INTRODUCTION
Pulpotomy is the most common pulp treatment of the primary teeth in children before 6 years of age [1] and formocresol pulpotomy is the most widely accepted technique [2]. Formocresol applied to radicular pulp stumps has been shown to distribute systemically. Moreover, formocresol and one of its constituents, formaldehyde, have demonstrated mutagenic and carcinogenic potential in animal studies [3]. It has also been reported that formocresol has toxic and mutagenic effects in cell culture, dental crypts and precancerous epithelial cells. Therefore, additional biocompatible treatment alternatives have been sought to replace formocresol pulpotomy [4]. After amputation of the inflamed coronal pulp...
(pulpotomy), recovery of the noninflamed radicular pulp can develop along one of three lines:

- **Devitalization**: by using drugs or other methods, the pulp in the orifice becomes non-vital and nonfunctional, for example the formocresol technique is classified in this category.
- **Preservation**: the function of the remaining pulp demonstrates minimal changes which are reversible. Preservation is exemplified by the ferric sulfate technique.
- **Regeneration**: The remaining pulp is not only vital and functional but is also stimulated to form a dentin bridge. In addition regeneration causes odontoblasts to surround the pulp. The Mineral Trioxide Aggregate technique is considered a typical example of regeneration [5,6].

Mineral trioxide aggregate (MTA) is a fine hydrophilic powder [7] developed by Mahmoud Torabinejad in Loma Linda University [8]. It consists of tricalcium silicate, tricalcium aluminate, tricalcium oxide, silicate oxide and bismuth oxide and is supplied as a grey powder [9].

MTA is currently being used in pulp therapy and has been shown to provide an enhanced seal over the vital pulp and is nonresorbable [10,11]. Furthermore, MTA has superior biocompatibility and is less cytotoxic than other materials currently used in pulp therapy [8]. The present study aimed to compare these three methods (formocresol, ferric sulfate and Mineral Trioxide Aggregate) and an alternative technique for formocresol pulpotomy will be introduced.

**MATERIALS AND METHODS**

135 children of both sexes were selected from patients who were referred to the pediatric department, School of Dentistry, Mashhad University of Medical Sciences, Mashhad, Iran. Their ages ranged from 3 to 6 years and all of them were healthy and cooperative. Full detailed treatment plans were explained to the children's parents and written consents for treatment were obtained prior to clinical procedures. The criteria for tooth selection in this study were:

1. Second primary molars with vital carious pulp exposures that bled upon entering the pulp chambers.
2. Lack of clinical or radiographic evidence of pulpal degeneration such as pain on percussion, history of swelling or sinus tracts.
3. Absence of radiographic signs of internal or external resorption and no furcation radiolucency.
4. Teeth that could be restored with proper restorations.

All 135 patients were assigned randomly to one of three treatment groups: Formocresol, Ferric Sulfate and Mineral Trioxide Aggregate (MTA). 45 second primary molars were selected for each of the 3 groups. When subjects had more than one 2nd primary molar requiring pulpotomy, only one of them were included in the study. Clinical and recent radiographic examinations were considered in the selection of teeth for vital pulpotomy, but final case selection was based on a direct evaluation of pulp tissue after coronal amputation. If the nature of the bleeding from the amputation site was normal (red color and homeostasis evident in less than 5 minutes with mild cotton pellet pressure), the pulp tissue in the canals were assumed to be normal. This ensured similar quality of the pulp tissue in all cases of the three groups.

After performing local anesthesia, all teeth were isolated with a rubber dam and dental caries were removed with a large slow-speed round bur before pulpal exposure. The entire roof of the pulp chamber was then removed. This procedure was accomplished using a No.330 bur mounted in a water-cooled high-speed turbine. The coronal pulp was amputated using a slowly revolving round bur and the pulp chamber was irrigated with a light
flow of normal saline. One or more moistened cotton pellets were placed over the pulp stumps, and high pressure was applied for a few minutes. When the cotton pellets were removed homeostasis was apparent.

In the formocresol group, a blotted cotton pellet moistened with Veneno Formocresol (S.S. White, USA) was placed in contact with the pulp orifices for 5 minutes. After fixation, Zinc Oxide Eugenol paste was applied on the pulp tissue and the floor of the pulp chamber. The teeth were subsequently filled, using amalgam with reinforced ZOE cement (IRM) base (DENTSPLY, USA).

In the ferric sulfate group, a cotton pellet was moistened with Astringedent ferric sulfate (Ultradent, USA) and was placed in contact with the radicular pulp for 15 seconds. After irrigation with normal saline and observation of homeostasis, Zinc Oxide Eugenol paste was applied on the pulp tissue. Amalgam with IRM cement base was used as the filling material.

In the MTA group, according to the direction for pulpotomy treatments with MTA (Proroot™, DENTSPLY, TULSA, USA) the coronal pulp was removed, and the cavity was rinsed with a light flow of normal saline and bleeding was controlled with one or more cotton pellets moistened with normal saline. The pulp stumps were then covered with MTA paste was formed by mixing the MTA powder with sterile water in a 3:1 powder/water ratio to obtain a thick, creamy consistency. The MTA base was placed on the floor of the pulp chamber and padded against the pulp orifices with a moist cotton pellet. The cavity was filled with IRM cement followed by amalgam filling after 7 days.

At the end of the treatment session, the data were recorded on a form for each patient. All teeth in the three groups were followed up clinically and radiographically at 3 and 12 months. The outcome of success or failure was determined by the following clinical and radiographic criteria:

- The presence of any signs such as spontaneous or nocturnal pain, tenderness to percussion or palpation, abscess, swelling, fistula and pathologic mobility was definitively indicative of clinical failure.
- The lamina dura of the pulpotomized teeth, examined on high quality periapical radiographs were compared with their radiographs before treatment. Observation of partial loss of the lamina dura or widening of the periodontal ligament (PDL) was recorded as a radiographic failure.
- The presence of any sign of pathologic external or internal root resorption as well as periapical or inter-radicular radiolucency was definitively demonstrative of radiographic failure.

Clinical treatment outcomes and radiographic findings were submitted for statistical analysis by the Statistical Package for Social Science (SPSS). The differences were statistically analyzed using the Fisher's exact and McNemar tests. The level of significance was set at P <0.05.

**RESULTS**

At the end of the 3rd month, only 103 out of 135 subjects were available for follow-up. None of the patients in the formocresol and ferric sulfate groups showed any abnormal clinical findings however alveolar abscess with luxation was seen in 5.7% of the MTA subjects. No significant difference was found between the 3 groups. Furthermore, radiographic evaluation revealed the formocresol and ferric sulfate groups to have the highest (100%) and lowest (80.6%) success rates, respectively. At the same time, an 82.9% success rate was observed in the MTA group. The differences between radiographic success rates of the formocresol group with both the MTA and ferric sulfate groups were statistically significant (P= 0.025 and P= 0.012 respectively).

After one year, follow-up was available for
120 of 135 primary subjects. None of the patients in the formocresol and ferric sulfate groups showed any abnormal clinical findings, but %17.9 of the MTA subjects revealed at least one of the pathologic clinical findings. Statistical analysis revealed a significant difference between these groups (P-value = 0.005).

Radiographic success rate for all pulpotomized teeth during the 12 month follow up period is illustrated in Figure 1. The formocresol group had the highest (92.5%), while the MTA group showed the lowest (69.2%) success rates (Fig. 2). The ferric sulfate group displayed success rate of 80.5%. The difference between the formocresol and MTA groups was significant (P=0.01), while significant difference between the formocresol/ferric sulfate and the MTA/ferric sulfate groups was not observed (P= 0.19 and P= 0.01 respectively).

The highest rate of treatment failure was detected in the MTA pulpotomized teeth and the mean age of the patients with MTA treatment failure was 4 years and 2 months. The teeth with both clinical and radiographic failures underwent pulpectomy (Fig. 3A & B). Pathologic radiographic findings for all pulpotomized teeth during the 12 month follow up period is shown in Table I. The most common radiographic finding was pulp canal obliteration (PCO), which developed in 64.17% (77/120) of all teeth. PCO was found in

Fig. 2: Normal appearance of the pulp 12 months after pulpotomy using MTA.

65% (26/40), 64.1% (25/39) and 56.1% (23/41) of the formocresol, MTA and ferric sulfate patients, respectively (Fig. 4A&B). The most common pathologic radiographic finding was internal resorption, which developed in 14.6% of the ferric sulfate patients. External resorption was seen in 10.3% of the MTA subjects.

After one year, 96 samples with previous follow-ups in the 3rd and 12th months were available for reevaluation. Comparing the radiographic findings in two follow up visits, it is possible to assess the response to pulpotomy treatment within the selected control periods. Therefore the subjects were classified into two groups: Teeth with new pathological findings or progression of the former lesions at the second follow up visit were considered as failure and classified as such. Samples that did not show any kind of pathological defect or progression of the previous lesions or cases that demonstrated healing of the former defects were categorizes as the “successful group”.

As illustrated in Figure 1, the long-term yearly follow-up in the ferric sulfate study group revealed a higher success rate (91.1%) as compared to the 3 month examinations (80.5%), which was found to be statistically significant (P = 0.02).
**Table I:** Pathological radiographic findings in the pulpotomized second primary molars after 12 month follow up.

<table>
<thead>
<tr>
<th>Medicaments</th>
<th>ER</th>
<th>IR</th>
<th>PLILD</th>
<th>WPDL</th>
<th>PR</th>
<th>FR</th>
<th>RR</th>
</tr>
</thead>
<tbody>
<tr>
<td>MTA</td>
<td>N</td>
<td>%</td>
<td>N</td>
<td>%</td>
<td>N</td>
<td>%</td>
<td>N</td>
</tr>
<tr>
<td>Ferric Sulfate</td>
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<td>6</td>
<td>14.6</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Formocresol</td>
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<td>0</td>
<td>0</td>
<td>1</td>
<td>2.5</td>
<td>1</td>
</tr>
<tr>
<td>MTA/FS</td>
<td>* 0.19</td>
<td>* 0.027</td>
<td>* 0.11</td>
<td>* 0.11</td>
<td>* 0.32</td>
<td>* 0.11</td>
<td>0.61</td>
</tr>
<tr>
<td>P-Value</td>
<td>MTA/F</td>
<td>* 0.20</td>
<td>0.35</td>
<td>* 0.35</td>
<td>1</td>
<td>* 0.11</td>
<td>0.61</td>
</tr>
<tr>
<td>FS/F</td>
<td>1</td>
<td>* 0.029</td>
<td>0.49</td>
<td>0.49</td>
<td>0.61</td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>

ER: External resorption; IR: Internal resorption; PLILD: Partial Loss of Integrity of Lamina Dura; WPDL: Widening of the periodontal ligament; PR: Periapical radiolucency; FR: Furcal radiolucency; RR: Replacement resorption.

DISCUSSION

In this study, the higher clinical and radiographic success rates in the formocresol group can be related to its antiseptic and fixative qualities. The rate of success in the ferric sulfate subjects was less than the formocresol group, in which no change occurred in pulpal tissue. Internal resorption could be observed as a sign of vitality of the pulp. In a recent study, Eidelman et al [12] compared the clinical and radiographic success rates between formocresol and MTA pulpotomy in primary teeth. Clinical and radiographic success rates of 100% were demonstrated for MTA pulpotomy, at 35 months follow up. These results differ from the findings of the present study, possibly because of a smaller sample size (15 cases) or the wider age range of the patients (5 to 12 years) which can reduce the validity and reliability of the results.

Furthermore, Agamy et al [13] reported that the clinical and radiographic success rate of pulpotomy was 100% for gray MTA and 90% for formocresol, 12-months postoperatively. The age range of their subjects was between 4 to 8 years, with a mean of 6.1 years. One tooth exfoliated normally between the 3 and 6-month evaluations.

Additionally, according to the results of Holan et al [14], the success rate of pulpotomy was 97% for MTA and 83% for formocresol. The mean age of their subjects at the time of treatment was 6 years, 7 months; ranging from 4½ years to 10 years, in the MTA group.

A higher radiographic failure rate of MTA pulpotomy (30.8%) was obtained in the present study as compared to previous investigations [14,15].

One of the differences between the current study and other reports is the age of the subjects. Our study groups consisted of children aged from 3 to 6 years with the mean age of 4 years and 5 months, which was lower than previous investigations [14, 15]. The findings of Salzmann et al [16] on diode laser-MTA pulpotomy in primary molars were the closest to the results obtained from the present study. They reported a radiographic failure rate of 28.6% and the mean (standard deviation) age of their patients was 5.1 (1.2) years with a range of 3.5 to 7.5 years. Due to the design of laser pulpotomy it would be difficult to tell whether the diode laser or the MTA was having the primary affect on treatment outcomes. Younger patients and high radiographic failure rates after 12 months are important similarities between this
investigation and the present study. A possible explanation for the high failure rates observed in these studies, shown by a considerable amount of external bone and root resorption, could be because of the wider pulp canals (as compared to narrower ones) in younger teeth which can facilitate the transfer of stimulatory factors.

Pulpotomy failures in primary teeth with caries exposure can be attributed to misdiagnosis of inflammation in the radicular pulp prior to treatment or pulp contamination due to microleakage of an amalgam filling [14]. These arguments, however, can not explain the differences in success rates between the MTA, formocresol and ferric sulfate groups in the present study. Considering that the teeth were randomly assigned to one of the three groups, it would not seem logical to assume that most of the teeth with undiagnosed, inflamed, radicular pulps were accidentally assigned to the MTA group.

Pulp canal obliteration (PCO) was the most common radiographic finding in all three groups, with no significant difference; 65%, 56.1% and 66.1% for formocresol, ferric sulfate and MTA, respectively. Our results are in contrast to the findings of Hollan et al [14], who reported a 52% PCO after application of MTA and 38% PCO after formocresol pulpotomy in human primary molars. PCO was not considered as a pathologic finding because it showed that the pulp was vital and active and therefore, was not regarded as failure. PCO is a common radiographic finding in pulpotomized teeth, and has been reported

Fig. 3: Periapical radiograph of Primary mandibular second molar; A: external resorption appeared 12 months after pulpotomy using MTA, B: calcified tissue replacing the inter-radicular region, 3 months after pulpectomy.

Fig. 4: Periapical radiograph of Primary mandibular second molar with pulp canal obliteration 12 months after pulpotomy; A: MTA and B: ferric sulfate.
in teeth treated with formocresol [14,17], ferric sulfate [18] and MTA [14]. The most common radiographic finding in the formocresol group was pulp canal obliteration in the present investigation that is in accordance with a study conducted by Willard [19] and Hicks et al [20].

According to the results of the current study, the ferric sulfate group showed a higher radiographic success rate in long-term follow-ups (one year) as compared to 3 month reevaluations. These findings are similar to the results obtained by Fuks et al [2] who reported a success rate of 93% in ferric sulfate pulpotomies, and demonstrated a higher success rate after 35 months as compared to 6 month follow-ups. This shows a higher percentage of unchanged previous lesions (the lesions remained static) or a larger amount of improvement in preexisting pathologic defects, in this group. Some of the areas listed initially as internal resorption of the preliminary follow up period remained unchanged or improved after 12 months. This finding was not detected in the formocresol and MTA groups. However Holan et al [14] reported internal root resorption in 20.7% and 6.1% (2/33) of the teeth treated with formocresol and MTA pulpotomy, respectively. They found cessation of internal root resorption in two of the teeth in each group, and the pulp was replaced by calcified tissue.

Our data showed that the most common pathologic radiographic finding in the MTA group was external resorption which can be related to the stimulating effect of MTA. Studies by Torabinejad et al [21-26] have shown that MTA prevents microleakage, is biocompatible and promotes regeneration of the original tissues when it is placed in contact with the dental pulp or periradicular tissues. Furthermore, Koh et al [13] believe that MTA stimulates the release of cytokines that, in turn, promote hard tissue genesis. They concluded that MTA is not an inert dental material, but is rather active in promoting hard tissue formation.

Considering that MTA induces cytokine release and consequently stimulates bone matrix apposition; the bone resorption encountered in our MTA samples, would be questionable. This may be explained by the fact that the proximity of dental follicles to the periradicular bone of primary teeth causes a major difference in this bone as compared to bone found in other sites. Dental follicles may change the response of the periradicular osteocytes to the released cytokines, especially in comparison to osteocytes present in other locations [27]. In addition regarding the fact that the function of cytokines depends on the type of receptors present in the tissue, it can be postulated that dental follicles may also affect these receptors [28].

Therefore, the external bone resorption observed in the MTA group of the present study may be due to the conducting action of sub base material (MTA), and not because of the failure of the technique. Radiographic evidence of internal resorption occurring within the pulp canal after pulpotomy of primary teeth is the most frequently seen evidence of an abnormal response but internal resorption was not observed in any of the failed MTA-treated cases [5].

CONCLUSION
Based on the findings of the present study, MTA pulpotomy demonstrates a lower success rate in preschool children, as compared to pulpotomy using formocresol and ferric sulfate. Further investigation is suggested for comparison of MTA in young versus older children.

Preservation techniques by use of Ferric Sulfate can be suggested to replace the formocresol method but sterile conditions should be adopted and cases should be selected carefully. In addition, investigations that compare other regeneration techniques
with preservation methods are recommended.

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REFERENCES