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Randomized controlled trial of mineral trioxide aggregate and formocresol for pulpotomy in primary molar teeth

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Abstract

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Aim To compare the outcome after 6 months of the application of formocresol (FC) or mineral trioxide aggregate (MTA) during pulpotomy in primary molar teeth.

Methodology A maximum of 126 children (aged 5–9 years) with carious primary teeth that required pulpotomy were selected. Following randomization, a standard pulpotomy preparation was undertaken, and the coronal pulp removed and bleeding arrested. In the FC group, cotton balls, soaked in FC, were placed for 5 min, and then the pulp chamber was filled with Zonalin, a pulpotomy agent. In the MTA group, a 1-mm-thick paste of MTA was used as a pulpotomy agent. The crowns in both groups were restored with amalgam or glass ionomer. The teeth of 100 patients were evaluated and compared clinically and radiographically after 3 and 6 months.

Results No signs of clinical failure were observed at the 3- and 6-month follow-up appointments in either group. There were no significant differences in the radiographic findings of the teeth and surrounding tissue at the 3-month follow-up. However, at the 6-month follow-up, significantly more cases ($P = 0.036$) with root resorption were seen in the FC group; no cases of resorption occurred amongst the MTA cases. The surrounding tissue showed radiographic signs of post-treatment disease in four FC cases; none was seen in the MTA cases.

Conclusion After 6 months, pulpotomy with MTA was associated with fewer cases of root resorption and post-treatment disease. MTA appears to be a reliable alternative material for pulpotomy in primary molar teeth.

Keywords: formocresol, mineral trioxide aggregate, pulpotomy.

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Introduction

A high proportion of deep carious lesions in primary teeth is associated with pulpal exposure. The removal of the infected coronal pulp tissue (pulpotomy) is one of the treatment methods employed. In order to enhance treatment, to fix the pulp tissue and to preserve its vitality, the surface of the pulp is covered with a therapeutic agent (Alacam 1984). This method is recommended for use not only in primary teeth with inflamed pulps but also in permanent teeth with open apices (Cohen & Burn 2002).

A wide range of materials such as formocresol, glutaraldehyde, ferric sulphate, zinc oxide eugenol, polycarboxylate cement and calcium hydroxide have been used over the years in pulpotomy (Alacam 1984). In primary molar pulpotomy, however, the most common materials are formocresol and ferric sulphate. In a study, which followed up the clinical outcome of

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pulpotomy with formocresol for 3 years, the success rate was estimated to be approximately 70% (Vij *et al.* 2004). However, premature exfoliation in multi-visit pulpotomy techniques has been reported (Hunter 2003). Likewise, it is documented that both ferric sulphate and formocresol pulpotomies can lead to premature exfoliation of primary teeth, with the subsequent need for orthodontic space maintenance (Vargas & Packham 2005).

Nadin *et al.* (2003) systematically reviewed 82 randomized or quasi-randomized controlled trials comparing different pulp treatment techniques for extensive decay in primary molar teeth. These trials investigated pulpotomy with formocresol, ferric sulphate and electrosurgery. Nadin *et al.* (2003) could not identify any, yet they revealed no reliable evidence supporting the superiority of one method and material.

Moreover, the International Agency for Research on Cancer (IARC) Working Group, following an evaluation of the available documents, concluded that there was sufficient evidence in both experimental animals and humans for formaldehyde to be classed as carcinogenic. The IARC statement strongly recommended the substitution of formaldehyde-containing materials with other safe alternatives.

New materials such as bioactive glass (BAG) and mineral trioxide aggregate (MTA) have been introduced for pulpotomy (Eidelman *et al.* 2001, Stanley *et al.* 2001).

Evaluation of the pulpal reaction to MTA in the teeth of monkeys showed that MTA was a suitable material for capping pulps (Torabinejad *et al.* 1996). In another study, Aeinehchi *et al.* (2003) compared MTA with calcium hydroxide when used as a pulp capping material in human teeth. Histological evaluation demonstrated less inflammation, hyperaemia and necrosis plus thicker dentinal bridge and more frequent odontoblastic layer formation with MTA than with calcium hydroxide (Aeinehchi *et al.* 2003).

Likewise, the evaluation of dentine bridge formation after MTA pulpotomy in primary tooth indicated that, after 6 months, 55% of the molars and 100% of the canines treated showed radiographic signs of the dental bridge formation (Farsi *et al.* 2005).

Eidelman *et al.* (2001) compared MTA and formocresol as pulp-dressing agents during pulpotomy in primary molar teeth. The follow-up evaluations revealed one failure in a molar treated with formocresol, whilst none of the teeth with MTA showed any clinical and radiographic pathology (Eidelman *et al.* 2001).

Long-term evaluation of pulpotomy in primary molar teeth of children using MTA or formocresol has confirmed the greater clinical and radiographic success rate of the former (Holan *et al.* 2005). Besides, the Maroto *et al.* investigation also reported the success of MTA in pulpotomized primary teeth. Their results revealed that none of the MTA group had any clinical or radiographic pathology, whilst the formocresol group showed a success rate of 86.8% radiographically and 98.6% clinically (Maroto *et al.* 2005).

Finally, as there have been a few studies on the clinical success of MTA in primary teeth reported (Farsi *et al.* 2005, Maroto *et al.* 2005), the present study sought to assess the effects of MTA as a pulp dressing material following pulpotomy in primary molars and compare it with FC.

Materials and methods

This study was conducted at the dental clinic of Azad University, Tehran, Iran in January and February 2001. It included 126 children aged 5–9 years who required pulpotomy according to clinical and radiographic evaluations. The baseline characteristics of patients assigned into the two study groups are summarized in Table 1.

Written informed consent was obtained from the parents of the patients. The protocol was approved by the Ethics Committee of Azad University of Medical Sciences. The patients who met the inclusion criteria (Table 2) were assigned by a random number producing system to either the formocresol or MTA group. Altogether, 75 patients were allocated to the formocresol group compared with 51 in the MTA group. The flow of participants through the study is shown in Fig. 1.

According to the questionnaire completed by the parents, none of the children had systemic problems, drug use, spontaneous pain or pain during the night. The children were cooperative and could receive dental treatment. The selected teeth and surrounding tissues

Table 1 Demographic and baseline characteristics of patients

Characteristic	MTA group ($n = 43$)	FC group ($n = 57$)
Age (years), mean ± SD	6.29 ± 1.23	6.67 ± 1.08
Male	21 (48.8)	32 (56.1)
Maxillary		
First primary molar (D)	13 (30.2)	14 (24.6)
Second primary molar (E)	0 (0.00)	5 (8.8)
Mandibular		
First primary molar (D)	19 (44.18)	15 (26.31)
Second primary molar (E)	11 (25.58)	23 (40.35)
Symptomatic teeth	8 (18.60)	14 (24.56)

Values in parentheses are in percentages.
MTA, mineral trioxide aggregate; FC, formocresol.

Table 2 The inclusion and exclusion criteria of the teeth

Inclusion criteria
Presence of deep caries
Formation of at least 2/3 of the root
Exclusion criteria
History of any systemic disease
Having spontaneous tooth pain or pain on percussion
Presence of any internal resorption, apical or furcal radiolucency
Presence of a sinus tract
Presence of external fistulae
Presence of primary teeth with no sign of substitute teeth
Existence of periodontal pocket more than 3 mm deep
Haemostasis takes more than 3 min

showed no sign of swelling, sinus tract, periodontal pocket, root resorption, spontaneous pain or regional lymphadenopathy.

All pulpotomies were carried out by a dentist under the supervision of an endodontist. Following pulpotomy, the teeth were restored with amalgam or glass ionomer as indicated. The pulpotomy procedure was carried out after anaesthetizing the teeth with 2% lidocaine and 1/100 000 adrenaline.

Upon the accomplishment of anaesthesia and isolation with the rubber dam, coronal access was made using a no. 245 bur (Dentsply Maillefer, Tulsa, OK, USA) in a high-speed handpiece, and the coronal pulp was removed to the canal orifices with a round, spoon-shaped excavator. Finally, the pulp chamber was rinsed with normal saline and the orifices were covered with a small cotton pellet soaked in normal saline until blood clots had formed.

In patients randomized to the formocresol group, after controlling bleeding, small cotton ball pellets soaked in formocresol (Tricresol formalina; Dispensatory Veneno, Brasileria) were inserted over the orifices of the canals. Where pulpal haemorrhage could not be arrested within 3 min, the teeth were excluded, on the account that prolonged bleeding is a sign of irreversible pulpitis (McDonald *et al.* 2004, Guelmann *et al.* 2005a). The orifices and the rest of the pulp chamber were filled respectively with a reinforced 2-mm-thick layer of Zonalin (MFG Associated Dental Products, Kemdent, Purton, UK) and amalgam or glass ionomer.

In patients randomized to the MTA group, Pro Root MTA (Dentsply Maillefer) was mixed according to the manufacturer's recommendations. One gram of powder was mixed with distilled water contained in a vial and a smooth mix of MTA was obtained and then applied over the pulp and into the base of the cavity. After the setting of MTA, the rest of the cavity was filled with amalgam.

After initial clinical and radiographic examinations, the teeth were evaluated after 3 and 6 months for

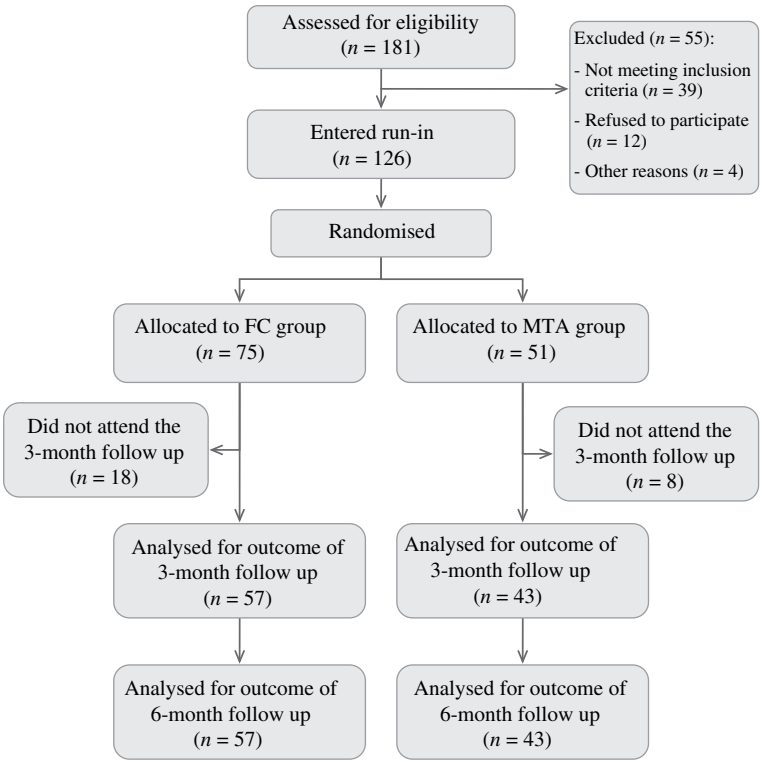

Figure 1 The flow of participants through the study.

clinical signs (spontaneous pain, swelling, pain on palpation or percussion and sinus tract formation) or radiological signs of failure (root resorption, periodontal ligament widening and apical, lateral or furcal radiolucency) (Kalaskar & Damle 2004, Guelmann *et al.* 2005a,b).

E films (Kodak Ektaspeed film; Kodak, Chalons sur Saone, France) were positioned with a straight haemostat using parallel technique and exposed by a radiologist. A Kodak RP X-omat processor was used for film processing with RD-omat developing and fixing solutions (Kodak). After calibration training, the radiographs were evaluated independently by four examiners. In daylight, a magnifying viewer (type Dental X-ray 2× magnification) (Kentzler & K Schner-Dental, Germany) on a light box was used for assessment. When disagreement arose, a consensus approach was adopted.

Statistical analysis of the results of the clinical and radiographic evaluation between the two groups was completed using SPSS software (SPSS Inc., Chicago, IL, USA) and the chi-square test with Yates correction.

Results

The questionnaire revealed that, whilst 87% of the cases had no symptoms, the remaining 13% experienced some pain after eating, suffered from localized or transient pain or had sensitivity to sweet stimuli.

Of the 126 patients enrolled for the study, 26 did not attend the follow-up visits (18 of the formocresol group and eight of the MTA group) resulting in 100 cases for outcome analysis.

Overall, 92.5% of 100 pulpotomized teeth were restored with amalgam and 7.5% with glass ionomer.

In 5% of the radiograph assessments, three of the four examiners agreed on the diagnosis, and their opinion was considered as the result outcome. In 8.5% of the assessments, only two examiners agreed and the final diagnosis was obtained when they reached a 3 : 1 agreement ratio following discussion on the radiograph. In 86.5% of the radiograph assessments, all examiners agreed on the diagnosis.

At the 3-month follow-up, no sign of clinical failure in the two groups was observed. A radiographic evaluation of the teeth showed root resorption in one out of 57 in the formocresol group (1.7%, 95%CI : 0.3–9.3%). The same phenomenon was not detected in the MTA group (0%, 95%CI : 0–8.2%). This difference was not statistically significant.

At the 6-month follow-up, no clinical failure was noted. However, in six out of 57 cases treated in the formocresol group, root resorption was detected radiographically (10.5%, 95%CI : 4.9–21.2%) (Figs 2 and 3). In the MTA group, no such features were observed (0%, 95%CI : 0–8.2%). The differences between the groups were statistically significant ($P = 0.036$) (Fig. 4). The differences in the condition of the

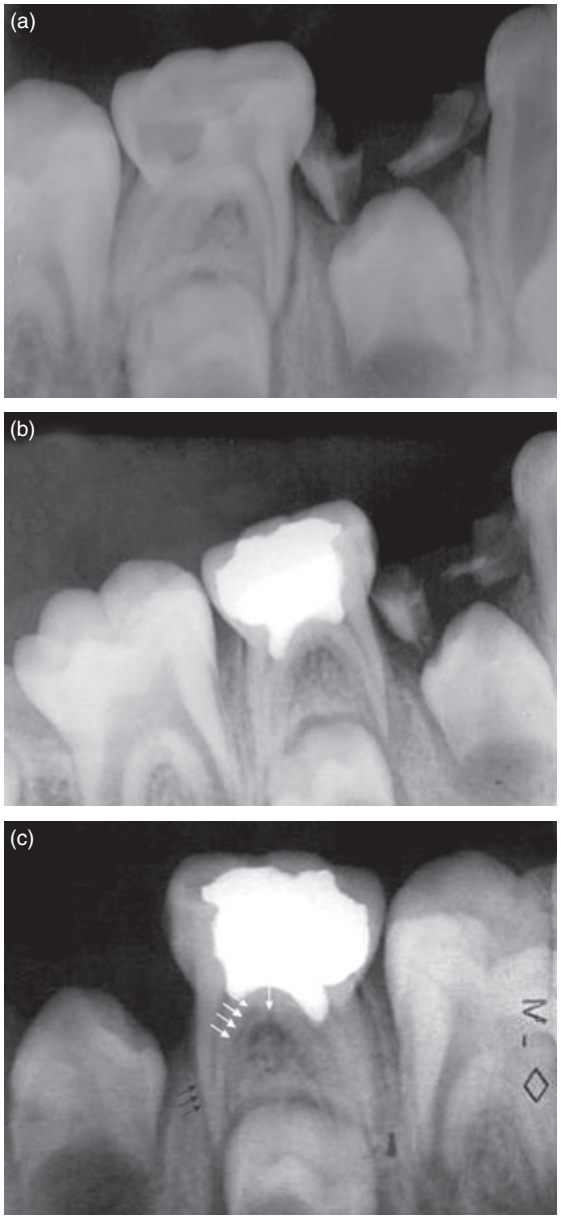

Figure 2 (a) Initial radiographic feature of failure in pulpotomy with formocresol. (b) Radiographic feature of failure in pulpotomy with formocresol after 3 months. (c) Radiographic feature of failure in pulpotomy with formocresol after 6 months. Note the resorption in dentine (white arrows) and thinning of the mesial root of the teeth (black arrows).

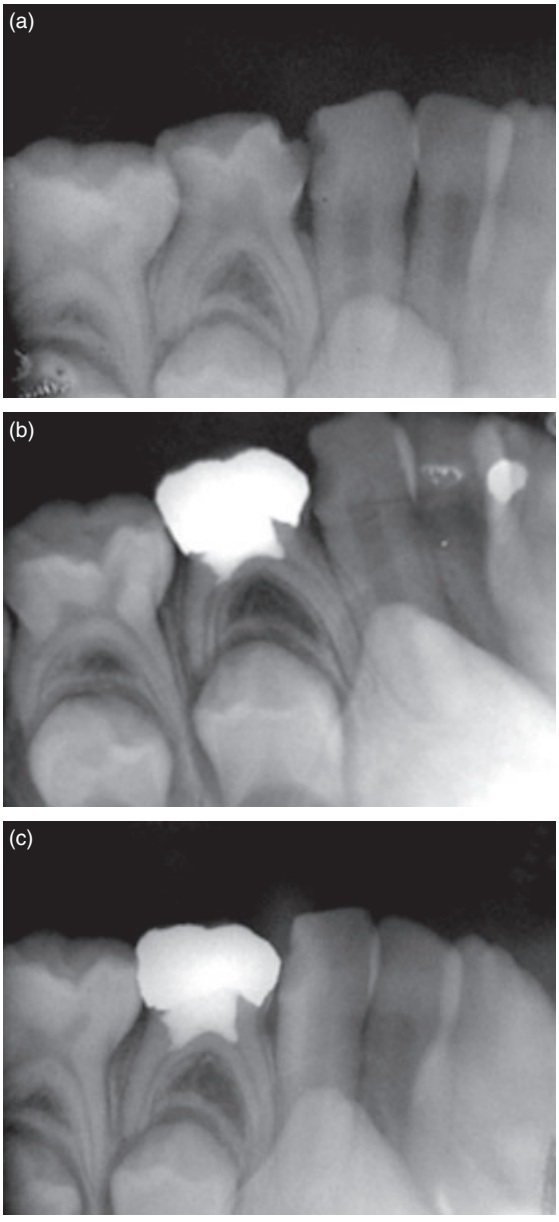

Figure 3 (a) Initial radiographic feature of successful pulpotomy with formocresol. (b) Radiographic feature after successful pulpotomy with formocresol after 3 months. (c) Radiographic feature after successful pulpotomy with formocresol after 6 months.

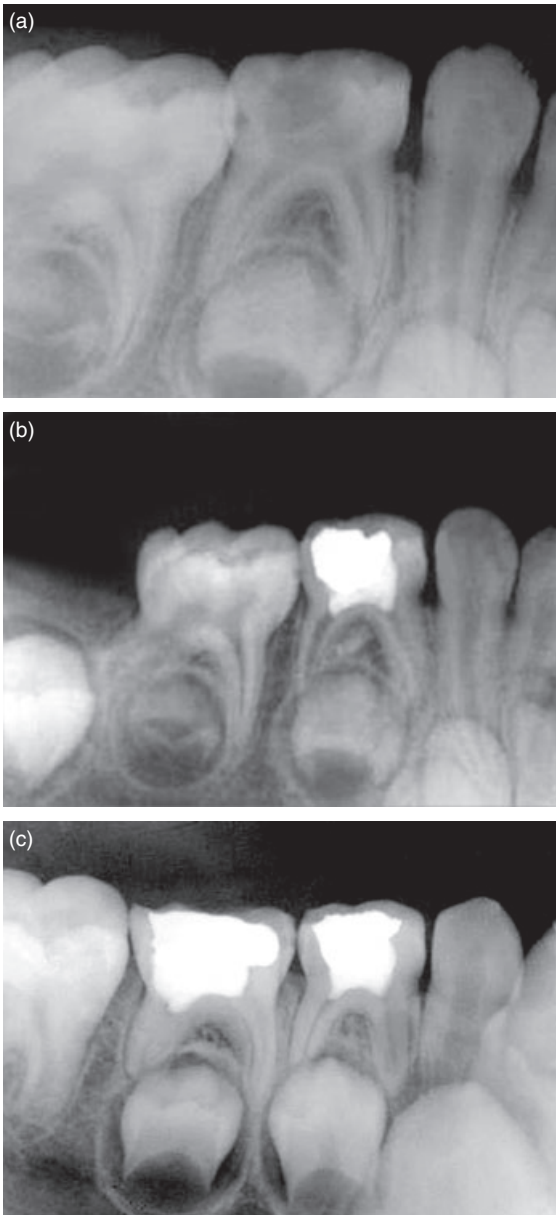

Figure 4 (a) Initial radiographic feature of successful pulpotomy with MTA. (b) Radiographic feature of successful pulpotomy with MTA after 3 months. (c) Radiographic feature of successful pulpotomy with MTA after 6 months.

supporting tissue, such as periodontal ligament widening, apical and furcal radiolucency, when assessed radiographically, after 3 and 6 months of pulpotomy were not significant ($P > 0.05$) (Table 3). The teeth with root resorption were referred to a paediatric dentist for further treatment.

Discussion

Mineral trioxide aggregate is a relatively new agent in endodontics that can be used in the place of formocresol in the pulpotomy of primary molar teeth. Experimental studies on laboratory animals have shown that MTA is biocompatible (Mitchell *et al.* 1999), and

Table 3 Comparison of pulpotomy with mineral trioxide aggregate (MTA) and formocresol (FC) on 3- and 6-month follow-up by investigated variants

Follow-up	MTA group ($n = 43$)	FC group ($n = 57$)	*P*-value
3 months			
Clinical symptom and sign	0 (0)	0 (0)	–
Radiological symptom and sign			
Supporting tissue	0 (0)	0 (0)	–
Root resorption	0 (0)	1 (1.7)	0.88
6 months			
Clinical symptom and sign	0 (0)	0 (0)	–
Radiological symptom and sign			
Supporting tissue	0 (0)	4 (7.0)	0.132
Root resorption	0 (0)	6 (10.5)	0.036

Values in parentheses are in percentages.

capable of dentine bridge formation (Pitt Ford *et al.* 1996), periodontal regeneration, cementum formation (Beak *et al.* 2005) and sealing furcal perforation (Pitt Ford *et al.* 1995, Nakata *et al.* 1998). MTA has recently been considered not only as a root end filling material and perforation sealing material, but also as a pulp cap or apexification agent (Torabinejad & Chivian 1999).

In a study by Salako *et al.* (2003), pulpotomy was performed on 80 molar teeth in Sprague–Dawley rats using either MTA, formocresol, ferric sulphate or BAG. The histological analysis, performed 2 and 4 weeks after pulpotomy, demonstrated that inflammatory changes were seen within 2 weeks. After 4 weeks, normal histology with vasodilation was observed in some cases. Likewise, in the MTA cases, some acute inflammatory cells around the substance material with some macrophages were detected in the pulp of the root. Dentine bridge formation with normal pulp histology was a constant finding in the MTA group after 2 and 4 weeks. In the ferric sulphate group, a moderate inflammation with some areas of necrosis was noted in the coronal pulp after 4 weeks. However, in the formocresol group, some areas of fibrosis, inflammation and tissue atrophy were also observed. Fibrosis extended in the fourth week with some evidence of calcification in some cases (Salako *et al.* 2003).

Holland *et al.* (2001), investigating pulpotomy and pulp capping, performed pulpotomy with MTA or formocresol on 26 pulps in the teeth of dogs. After 60 days, the animals were killed and the teeth and pulps were evaluated histopathologically. The detection of a hard tissue as a complete dentine bridge in most cases led to the conclusion that MTA and formocresol had similar results when used as a direct pulp protection agent after pulpotomy (Holland *et al.* 2001).

Eidelman *et al.* (2001) compared two methods of pulpotomy with formocresol and/or MTA in 45 primary molar teeth in 26 children. Their study differed from those of others in that they used crowns for restoration in both groups so as to provide the best seal against microleakage. Altogether, 32 molar teeth of 18 children were followed up for 6–30 months. It was noted that, whilst one case failed because of root resorption in the formocresol group at the 17-month follow-up, no failure was detected in the MTA group following clinical and radiographic evaluation. This study provided evidence that MTA could be a substitute for FC in pulpotomy (Eidelman *et al.* 2001).

The present study is particularly important in that it appears to be the first time that MTA has ever been applied in the primary molar tooth pulpotomy in children. However, unfortunately, the demerit of this study was the paucity of cases that were available for evaluation, which compromised and rendered the conclusions inauthentic. It is noteworthy that the method and results of this study are similar to the above-mentioned studies and those of others who observed an increase in the incidence of root resorption with formocresol compared with MTA. However, the 6-month follow-up of our patients is rather short for evaluating the outcome of pulpotomy and success rate, and further studies are needed to judge the preference of MTA to formocresol in the long term. This study might provide a basis for further studies in this field with a long-term follow-up and more participants.

Conclusion

After 6 months, pulpotomy with MTA was associated with fewer cases of root resorption and post-treatment disease, and MTA appears to be a reliable alternative material for pulpotomy in primary molar teeth.

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