Abstract

Introduction: Pulpotomy is a regular procedure in the management of inflamed primary teeth. Diverse materials have been reviewed for the pulpotomy, some of them being formocresol, glutaraldehyde, ferric sulfate, and mineral trioxide aggregate (MTA). Aims: The aim was to evaluate and compare clinically and radiographically the effects of MTA as a pulp dressing after coronal pulp amputation (pulpotomy) in primary molars. Settings and Design: Sixty primary molars of thirty healthy children using split mouth design aged between 4 and 6 years were treated by pulpotomy technique. Subjects and Methods: Sixty primary mandibular molars of thirty healthy children aged between 4 and 6 years were treated by pulpotomy technique. The teeth on the right side were assigned to MTA (Group A) and the left side for the formocresol (Group B). The children were then examined clinically and radiographically every 6 months. Statistical analysis used: Chi-square test using the SPSS version 19.0 was used to compare between the two groups. Results: Results showed that both MTA and formocresol have the same outcome on the primary molars, with Chi-square value being 1.1483 (P ≥ 0.05). None of the teeth in any children in the study showed any clinical pathology. Conclusion: The principle conclusions of this study are that there are no significant differences in MTA and formocresol. The success rate of MTA and formocresol pulpotomy can be considered comparable till this therapy influences the development and growth of the permanent teeth.

Keywords: Children, formocresol, mineral trioxide aggregate, pulpotomy

Introduction

Treatment of pulpally involved teeth in primary and immature permanent teeth presents unique challenges. As the carious process exposes the pulp, it reacts through inflammation limiting to the area in proximity to the carious lesion; it is generally agreed that the young dental pulp particularly pulp in the primary teeth, has a high potential for the repair. There is a very little doubt that the pulp is incapable of healing, however, there are questions concerning the techniques and materials which offers the highest percentage of success.¹

Pulpotomy is one of the most commonly used procedures in the pediatric endodontic which will help us to retain primary teeth in the arch. From years formocresol has been a popular pulpotomy agent. Concerns have been raised about the potential toxicity and carcinogenicity of formocresol in humans. Formocresol, a formaldehyde compound has evolved as the preferred medicament for pulpotomy since many years. It is the agent of choice for pulpotomy in the primary molars despite its disadvantages such as cytotoxicity, systemic disturbances, mutagenicity, and carcinogenicity.²

Mineral trioxide aggregate (MTA) has rigorously been investigated for its capability to seal the pathways of communiqué between the root canal system and external tooth surface. MTA is compositionally prepared to possess properties and requirements necessary for an ideal repair and medicament materials. Previous research has shown that pulp responds favorably to the layered protection provided by MTA in the form of forming reparative dentine that is constantly homogeneous and thicker. The ability of the pulp to tolerate this dental material and offer the protection against the microleakage has also been compared, and thus MTA has been projected as a prospective medicament for pulpotomy procedures as well as medicament for pulpotomy since many years. It is the agent of choice for pulpotomy in the primary molars despite its disadvantages such as cytotoxicity, systemic disturbances, mutagenicity, and carcinogenicity.²

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capping of pulp with reversible pulpitis, apexification, and repair of root perforation.\[^{[3]}\]

Various studies have compared MTA’s effects to that of formocresol as pulpotomy agent in primary teeth and compared clinical and radiographic evaluation. Thus, the study was conducted to evaluate and compare the clinical/ radiographic and histopathological success of MTA and formocresol pulpotomy in primary molars over a period of 60 months.

### Subjects and Methods

The study was carried out in the Department of Pedodontics and Preventive Dentistry after obtaining the permission from the ethical committee of the institutional review board and written informed consent, and assent form from the parents was obtained.

#### Sample size

The estimated sample size was 60 which was divided into two groups of 30 each

\[
\sqrt{\frac{S^2}{2} \left( \frac{2\alpha}{2 + z(1-\beta)} \right)^2} = d^2
\]

Where \(\alpha = 5\%\), \(z\alpha = 1.96\) and \(\beta = 80\%\), \(z(1-\beta) = 0.824\), where \(\alpha = \) type 1 error, \(1-\beta = \) power of the study, \(S = \) standard deviation, \(d = \) mean difference.

Thus, sixty primary molars of thirty healthy children aged between 4 and 6 years attending the outpatient clinics in the Department of Pedodontics and Preventive Dentistry were selected for the study and treated by pulpotomy technique using split mouth design.

The teeth indicated for pulpotomy were assessed by a single clinician who was blinded to material who then performed the procedures/techniques and evaluated the teeth periodically. In the study, samples were assigned to one of the groups by lottery method.

#### Inclusion and exclusion criteria

The criterions for the choice of teeth to be included in the study are according to the criteria laid down by Waterhouse et al.\[^{[5]}\] [Figure 1].

#### Clinical procedure

Sixty largely intact first or second primary mandibular molars were selected for the study with the above-mentioned inclusion criteria. Using split-mouth technique, the teeth are assigned to the MTA (Group A) and the formocresol (Group B) respectively by lottery method. The pulpotomy procedure was then performed on the selected teeth as follows:

- The tooth was anesthetized
- Achieve rubber dam isolation
- Caries removal and coronal access was obtained with high-speed bur with water spray to expose the pulp chamber
- Coronal pulp was removed with a spoon excavator
- Hemostasis was obtained with a moistened cotton pellet gently pressed against the amputated pulp stumps in both groups [Figure 2].

After the standardized technique, in MTA (Group A), all the teeth first or second primary molars were treated by MTA (Proroot, Dentsply, Tulsa Dental, Okla, USA). Using a taut metal spatula, MTA powder mixed with distilled water provided by the manufacturer in 3:1 (powder: liquid) ratio and then positioned over the exposure site with a plastic instrument. Then the mixture was compressed against the exposure site with a damp cotton pellet and a thick mix of zinc oxide eugenol cement was placed into the coronal pulp chamber. A layer of intermediate restorative material (IRM) was placed at the same appointment as the pulpotomy.\[^{[5]}\] In formocresol group (Group B), all the first or second primary molars under study were treated with cotton pellet moistened with formocresol (Pharmadent Remedies Pvt. Ltd., Gundlav, India) duly blotted and virtually dry, was placed above the radicular pulp for 5 min and then removed and thick mix of zinc oxide eugenol cement was then placed into the coronal pulp chamber. IRM cement base was placed above the zinc oxide layer at the same appointment as the pulpotomy. After 1 day, the teeth belonging to Group A and B were restored with a preformed stainless steel crown after placement of Glass Ionomer Cement as a definitive restoration [Figure 3].

The children were examined clinically at regular intervals of 24 h, 1 month, 3 months, 6 months, 1 year, 2nd year, 3rd year, 4th year, and at 5 years or at the exfoliation of the teeth by single investigator who was blinded to which the subject group belonged [Figure 4a and b]. The children were looked for the following signs and symptoms such as pain, swelling, sinus/fistula, periapical changes, furcation radiolucency, and internal resorption.

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**Figure 1**: Preoperative radiograph
The treatment was considered as a failure when one or more of the above-mentioned signs and symptoms were evident, but pulp canal obliteration (PCO) was not regarded as a failure. The absence of dentinal bridge was not regarded as a failure in case of MTA (Group A).

The teeth under the study were followed up clinically and radiographically [Tables 1-4] for 60 months with follow-up intervals being 24 h, 1 month, 3 months, 6 months, 1 year, and then every yearly till the exfoliation of the tooth occurred (5 years) [Figure 5a and b]. Dropout was not observed in this study. After the teeth exfoliated, the teeth were then subject to a histopathologic examination which showed that in Group A (MTA) there were calcospherites of dentin and below this calcospherites there was thin layer of calcified structure but the Group B (formocresol) showed no evidence of predentin or dentoid like structure adjacent to pulp core [Figure 6a and b].

Results

The data were entered into a standardized format and analyzed statistically analyzed by Chi-square test and test of proportion Z-test to weigh up the success rate of the treatment with MTA (Group A) and formocresol (Group B) after 6 months.

A total of 38 first primary molars and 22 s primary molars were treated by the above method. Children in both groups were evaluated for 60 months postoperatively. The follow-up evaluations revealed 100% success with regard to the clinical signs, namely, pain, swelling and sinus/fistula for both groups. Not a single of the teeth in either of the group showed any clinical pathology at the end of 6 months when observed by the same observer.

Z-test was not necessary for the clinical signs as all the sample size showed no clinical evidence of failure, giving 100% success. In the present study, MTA (Group A n = 30), at the end of 6 months and 60-month evaluation showed eighteen pulpotomized teeth with dentin bridge formation, two samples with PCO and ten samples did not reveal any calcific bridge.

With regard to the methodology, the treatment was taken as a failure when one or more following signs were present internal resorption, furcation radiolucency, and periapical bone destruction though PCO was not considered as failure.

Out of thirty pulpotomy carried on primary molars, with MTA (Group A), none of them showed signs of failure such as internal resorption, furcation involvement, and periapical radiolucency with the 100% success radiographically.

However, out of thirty teeth treated with formocresol (Group B), twenty-nine teeth did not show any internal resorption while one case showed internal resorption but with no considerable difference between MTA-treated and formocresol-treated teeth.

Discussion

Pulpotomy is a general procedure in the treatment of acutely inflamed primary teeth. When the curious

| Table 1: Clinical assessment for mineral trioxide aggregate group |
|---------------------------------------------------------------|
| Observed period | Total number of teeth evaluated | Number of primary molars without pain | Number of primary molars without mobility | Number of primary molars without swelling | Number of primary molars without sinus |
|-----------------|---------------------------------|--------------------------------------|------------------------------------------|------------------------------------------|----------------------------------------|
| 24 h            | 30                              | 30                                   | 30                                       | 30                                       | 30                                     |
| 1 month         | 30                              | 30                                   | 30                                       | 30                                       | 30                                     |
| 3 months        | 30                              | 30                                   | 30                                       | 30                                       | 30                                     |
| 6 months        | 30                              | 30                                   | 30                                       | 30                                       | 30                                     |
| 1 year          | 30                              | 30                                   | 30                                       | 30                                       | 30                                     |
| 2 years         | 30                              | 30                                   | 30                                       | 30                                       | 30                                     |
| 3 years         | 30                              | 30                                   | 30                                       | 30                                       | 30                                     |
| 4 years         | 30                              | 30                                   | 30                                       | 30                                       | 30                                     |
| 5 years         | 30                              | 30                                   | 30                                       | 30                                       | 30                                     |

| Table 2: Clinical assessment for formocresol group |
|---------------------------------------------------|
| Observed period | Total number of teeth evaluated | Number of primary molars without pain | Number of primary molars without mobility | Number of primary molars without swelling | Number of primary molars without sinus |
|-----------------|---------------------------------|--------------------------------------|------------------------------------------|------------------------------------------|----------------------------------------|
| 24 h            | 30                              | 30                                   | 30                                       | 30                                       | 30                                     |
| 1 month         | 30                              | 30                                   | 30                                       | 30                                       | 30                                     |
| 3 months        | 30                              | 30                                   | 30                                       | 30                                       | 30                                     |
| 6 months        | 30                              | 30                                   | 30                                       | 30                                       | 30                                     |
| 1 year          | 30                              | 30                                   | 30                                       | 30                                       | 30                                     |
| 2 years         | 30                              | 30                                   | 30                                       | 30                                       | 30                                     |
| 3 years         | 30                              | 30                                   | 30                                       | 30                                       | 30                                     |
| 4 years         | 30                              | 30                                   | 30                                       | 30                                       | 30                                     |
| 5 years         | 30                              | 30                                   | 30                                       | 30                                       | 30                                     |
process exposes the pulp, it reacts through inflammation restricted to the area close to the carious injury. If the pulp in the root canal seems to be unaffected pulpotomy is the treatment of choice. The success or failure of the procedure lies not only with the choice of the procedure but also with the different pharmacotherapeutic agent, which have been by now used for the above procedure of the primary teeth.\textsuperscript{[6,7]}

Formocresol has been the pick of material for the pulpotomy procedure. It has otherwise proved as “gold standard” in pediatric dentistry may be mainly due to its ease in use and exceptional clinical success, but this clinical success rate has been always in close observation due to its safety considerations and to the availability of the newer materials in the market.\textsuperscript{[8]}

MTA is relatively a new material that has now become the material of choice for definite endodontic applications. The USA Food and Drug Administration in 1998 approved MTA as an beneficial endodontic material in humans.\textsuperscript{[9]} MTA has proved as not only an inert material but one which actively promotes hard tissue formation.\textsuperscript{[10]} In the present study as per criterion first and second primary molars were considered to receive pulpotomy materials, for example, MTA (Group A) and Formocresol (Group B), \( (n = 30 \text{ each}) \) respectively [Table 5].

Ever since its introduction, MTA has been used in pulpotomy procedures in both primary and permanent teeth. Comparative studies have made known MTA to be equal to or better than other medicaments and materials used for primary tooth pulpotomies the majority of the reports are comparative in character employing clinical signs and symptoms with radiographic analysis to resolve success or failure. Continuing clinical trials have shown MTA to generate better results than formocresol when used for pulpotomy in primary teeth. Even though radiopaque calcified tissue leading to canal obliteration can be seen
In greater than half of the cases using both materials, MTA demonstrates dentin bridge formation enhancing the superiority of the material.\(^\text{[11-13]}\)

In the present study, there was no significant difference between first and second primary molars during our observation period using these materials (\(P \geq 0.05\)). In this study, no difference was found in clinical outcomes for both the medicaments [Tables 1 and 2]. The success rate of MTA in this study with all the molars showing the absence of adverse clinical signs such as pain, swelling, and sinus/fistula can be considered due to its exceptional sealing ability, biocompatibility, and gift to regenerate the hard tissues.\(^\text{[14]}\)

Although success rate in this study is promising with eighteen teeth showing calcific bridge and two teeth with PCO, ten cases without calcific bridge can be attributable to the observation period being <1 year [Table 2]. The present data indicate that under standardized and optimal clinical conditions and defined period of observation MTA has shown very promising success with all thirty samples not showing any adverse effects of clinical sign.

MTA’s effect on amputated pulpal tissue gives the impression to suggest that the material preserves the pulp tissue and promotes the rebirth of hard tissues. The nearly normal pulpal architecture, intact and continuous odontoblastic layer and reparative dentin bridging observed indicate about the material’s biocompatibility and regeneration ability. MTA stimulates dentin formation neighboring the dental pulp, dentinogenesis of MTA can be due to its superior sealing ability, biocompatibility, and alkalinity.\(^\text{[15]}\)

The 100% clinical success rate of formocresol pulpotomy (Group B) in our study was attributable to its germicidal action. The chemical bonding with the proteins of microorganisms is the foundation of bactericidal feat of formocresol and also to its fixative qualities. Although the study is imperative to suggest the clinical and radiographic success, it is difficult to forego the actions which are present due to the chemical action of the formaldehyde with reference to fixation with the protein.\(^\text{[16,17]}\)

Formocresol also has also been reported to show a greater quantity of root resorption than MTA. One tooth from formocresol (Group B) radiographically showed internal resorption which was considered as failure in
the posttreatment evaluation period as per methodology. In this study, there appears a very little difference in the clinical and radiographical outcomes in both the medicaments.

**Conclusion**

The principle conclusions of this study are that there are no significant differences in MTA and formocresol. Clinical and radiographic evaluation revealed that formocresol pulpotomy can be considered as successful as MTA till this therapy influences the development and growth of the permanent teeth.

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**Conflicts of interest**

There are no conflicts of interest.

**References**

1. Dominguez MS, Witherspoon DE, Gutmann JL, Opperman LA. Histological and scanning electron microscopy assessment of various vital pulp-therapy materials. J Endod 2003;29:324-33.
2. Ranly DM. Pulpotomy therapy in primary teeth: New modalities for old rationales. Pediatr Dent 1994;16:403-9.
3. Bodem O, Blumenshine S, Zeh D, Koch MJ. Direct pulp capping with mineral trioxide aggregate in a primary molar: A case report. Int J of Pediat Dent 2004;14:376-79.
4. Waterhouse PJ, Nunn JH, Whitworth JM. An investigation of the relative efficacy of Buckley’s Formocresol and calcium hydroxide in primary molar vital pulp therapy. Br Dent J 2000;188:32-6.
5. Agamy HA, Bakry NS, Mounir MM, Avery DR. Comparison of mineral trioxide aggregate and formocresol as pulp-capping agents in pulpotomized primary teeth. Pediatr Dent 2004;26:302-9.
6. Berger JE. Pulp tissue reaction to formocresol and zinc oxide-eugenol. J Dent Child (Chic) 1965;32:13-28.
7. Naik S, Hegde AH. Mineral trioxide aggregate as a pulpotomy agent in primary molars: An in vivo study. J Indian Soc Pedod Prev Dent 2005;23:13-6.
8. Ranly DM, Lazzari EP. The formocresol pulpotomy – The past, the present, and the future. J Pedod 1978;2:115-27.
9. Schwartz RS, Mauger M, Clement DJ, Walker WA 3rd. Mineral trioxide aggregate: A new material for endodontics. J Am Dent Assoc 1999;130:967-75.
10. Torabinejad M, Chivian N. Clinical applications of mineral trioxide aggregate. J Endod 1999;25:197-205.
11. de Menezes JV, Takamori ER, Bijella MF, Granjeiro JM. In vitro toxicity of MTA compared with other primary teeth pulpotomy agents. J Clin Pediatr Dent 2009;33:217-21.
12. Yildirim C, Basak F, Akgun OM, Polat GG, Altun C. Clinical and radiographic evaluation of the effectiveness of formocresol, mineral trioxide aggregate, Portland cement, and enamel matrix derivative in primary teeth pulpotomies: A two year follow-up. J Clin Pediatr Dent 2016;40:14-20.
13. Asgary S, Shirvani A, Fazlyab M. MTA and ferric sulfate in pulpotomy outcomes of primary molars: A systematic review and meta analysis. J Clin Pediatr Dent 2014;38:1-8.
14. Economides N, Pantelidou O, Kokkas A, Tziafas D. Short term periradicular tissue response to mineral trioxide aggregate (MTA) as root end filling material. Int Endod J 2003;36:44-8.
15. Vij R, Coll JA, Shelton P, Farooq NS. Caries control and other variables associated with success of primary molar vital pulp therapy. Pediatr Dent 2004;26:214-20.
16. Macwan C, Deshpande A. Mineral trioxide aggregate (MTA) in dentistry: A review of literature. J Oral Res Rev 2014;6:71-4.
17. Roberts HW, Toth JM, Berzins DW, Charlton DG. Mineral trioxide aggregate material use in endodontic treatment: A review of the literature. Dent Mater 2008;24:149-64.