ORIGINAL ARTICLE

COMPARISON OF MINERAL TRIOXIDE AGGREGATE AND FORMOCRESOL AS PULPOTOMY AGENT IN PRIMARY MOLAR TEETH: A RANDOMIZED CLINICAL TRIAL

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ABSTRACT

Pulpotomy is a routine pulp therapy in primary molars with deep caries. For decades, Formocresol (FC) is considered as a gold standard for this procedure. However concerns have been raised regarding its safety. Mineral trioxide aggregate (MTA) has revolutionized modern endodontic procedures owing to its excellent biocompatibility and regenertive properties and is seen as a promising alternative to FC as a pulpotomy agent in primary teeth. The aim of the study was to compare the clinical and radiographic success of MTA and formocresol as pulpotomy agent for primary teeth. Patients aged between 4 to 8 years with carious primary molars, meeting the inclusion criteria were selected after thorough clinical and radiographic assessment. Sixty two teeth were randomly assigned to FC and MTA group comprising 31 teeth in each group. Conventional pulpotomy procedure was performed. In FC group, cotton pellet moistened with FC was placed on amputated pulp stumps for 5 minutes and then a base of zinc-oxide eugenol (ZOE) was placed. In the MTA group, MTA was placed an pulp stumps as pulp dressing material. The teeth were then restored with Glass Ionomer Cement (GIC). The patients were reviewed clinically and radiographically at 3, 6 and 12 months interval. The findings were documented and statistically analyzed. Both FC and MTA showed 100% clinical and radiographic results at 3 months follow-up. At 6 months, the clinical success rate of FC was 90.3% and that of MTA was 96.8% while the radiographic success rate was 77.4% and 83.9% respectively. At the end of 12 months, 82.1% and 86.7% clinical success rate was observed for FC and MTA respectively. The radiographic success for FC was found to be 70.8% while that of MTA was 88.5%. The results of this study show that MTA gives higher clinical and radiographic success rate compared to FC. Based on the results of this study, MTA has the potential to replace FC as pulpotomy agent.

Key Words: *Pulpotomy, formocresol, mineral trioxide aggregate, primary teeth*

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INTRODUCTION

The main focus in Pediatric Dentistry is to preserve the vitality of the deciduous tooth so it can continue to function normally until its natural exfoliation.[1] When carious lesion advances near the pulpal tissue, an inflammatory reaction is initiated. If this inflammation is confined to the pulp chamber and spares the root canals, pulpotomy is indicated.[2] Various medicaments have been used over the years to perform pulpotomy including glutaraldehyde, formocresol, ferric sulpahte, calcium hydroxide etc and the quest for the ideal agent continues.

Formocresol (FC) was first used for pulpotomy in primary teeth by Sweet in 1930 who reported a success rate of 97%.[3] Since then, FC has been in use and still remains a benchmark owing to its consistent success as a pulpotomy agent.[4] It mummifies the residual pulp stumps therefore preserving the vitality of the tooth.[5] Success rate of FC varies from 55% to 98%, as reported in different studies.[1] Although FC has a high success rate, it does not produce a favorable pulpal response at

histological level. It initiates chronic inflammation in the pulp tissue which possibly accounts for accelerated root resorption commonly observed in pulpotomized teeth.[6] Recently, concerns over the safety of FC have also been raised owing to its systemic distribution after dental procedures.[7] Formaldehyde, which is a major component of FC, is labeled by The International Agency for Research on Cancer (IARC) as a potential human carcinogen.[8, 9]

Mineral trioxide Aggregate (MTA) was developed by Torabinejad in 1993.[10] MTA has since become very popular in endodontics. Its excellent biocompatibility with the pulp-dentine complex, superior sealing properties and unique ability to cause tissue healing and regeneration has revolutionized modern endodontic approach.[11] MTA possesses all the properties of an ideal pulpotomy agent and is therefore the most promising substitute of FC for performing pulpotomy in primary teeth.[12]

Since it has been established that the existing gold standard, FC, is a potentially harmful material and does not produce favorable pulpal response, researchers continue to find its substitute. The Cochrane Review of Pulp Therapy 20142 concluded that there are inconsistent results regarding the success of pulpotomy using MTA and FC. The present study aims to compare the clinical and radiographic success of MTA and FC as pulpotomy agent in primary molars over a period of one year, therefore contributing to the literature in this regard.

METHODOLOGY

Institutional ethical clearance was obtained from the ethical committee, Pakistan Institute of Medical Sciences, Islamabad. Children aged between the 4-8 years meeting the inclusion criteria were selected.

Sample size was calculated to be 62 teeth (31 each in FC and MTA group) using WHO sample size calculator with 5% level of significance and 80% power of test. Informed written consent was obtained from the parents/guardians prior to clinical procedures. Teeth requiring pulpotomy were selected after thorough clinical and radiographic assessment. The following criteria were used:

Inclusion Criteria

1. Patients with good general health and no history of systemic illness
2. Teeth with deep carious lesions (radiographically caries approximating pulp chamber)
3. Vital primary teeth with healthy periodontium
4. Pain, if present, is neither spontaneous nor persists after removal of the stimulus
5. Tooth free of radicular pulpitis (Clinically: no evidence of pulpal degeneration such as TTP, history of swelling/abscess/ suppurating sinus or fistula in relation to the tooth or nocturnal pain. Radiographically: no signs of periapical or inter-radicular radiolucency, pathological root resorption)
6. Tooth with at least 2/3rd root length
7. Carious teeth with well defined margins which are restorable with GIC (Multi-surface carious teeth were excluded)

Exclusion Criteria

1. Presence of inter radicular bone loss or furcation involvement (periapical or inter-radicular radiolucency)
2. Internal root resorption
3. Radiographic sign of calcification in pulp chamber
4. Caries penetrating the floor of pulp chamber
5. Tooth close to natural exfoliation
6. Multi-surface carious teeth requiring stainless steel crowns as final restoration

The teeth were randomly divided into two groups using computerized randomization procedure to generate random number table. In FC group, formocresol (Produits Dentaires SA®, Switzerland) was used as the pulp dressing agent and in the other group, MTA (Angelus®, Brazil) was placed in the pulp chamber before restoration with Glass Ionomer Cement (Shofu® Inc. Japan) in all cases.

Study Design

Randomized clinical trial

All the clinical procedures were performed by a single operator. After administering local anesthesia, the tooth was isolated with rubber dam. Using No. 330 mounted on high-speed hand piece, caries was removed and de-roofing of the pulp chamber was done. Coronal pulp was amputated using a slowly revolving round bur and spoon excavator. Pulp chamber was irrigated with a light flow of normal saline. One or more moistened cotton pellets were placed over the pulp stumps for 5 minutes to achieve hemostasis. If hemorrhage continued, the tooth was excluded from the study. This ensured similar quality of the pulp tissue in all cases of the two groups. After achieving hemostasis, pulp dressing was applied.

In FC group, a sterile cotton pellet moistened with FC was placed in contact with the pulp orifices for 5 minutes. After pulp fixation, ZOE paste was applied on the pulpal tissue. The teeth were then filled using GIC. In MTA group, the pulp stumps were covered with MTA paste (formed as per manufacturer's guidelines by mixing the MTA powder with sterile water in a 3:1 powder/water ratio to obtain a thick, sandy consistency). A moistened cotton pellet was placed over MTA and the cavity was then filled with a temporary filling material (tgDent® tempfill, England). The patient was recalled the next day. Cotton pellet was removed and

the cavity was filled with GIC.

All teeth in the two groups were reviewed clinically and radiographically at 3, 6 and 12 months interval. The examiner who performed clinical and radiographic examination was blind to the treatment agent used for the procedure. The teeth were evaluated clinically for any apparent signs and symptoms. Tooth discoloration was also noted. A periapical radiograph was taken with a film holder using paralleling technique. Any sign of radicular pathology was evaluated from the radiograph. The findings were documented and statistically analyzed.

Success Criteria

Both clinical and radiographic outcome was determined. Teeth were scored as clinical success if they had no signs and symptoms such as spontaneous or nocturnal pain, tenderness to percussion or palpation, abscess, swelling, fistula and pathological mobility. Presence of any of these signs and symptoms was scored as clinical failure.

Radiographic assessment included evaluation of pathological external or internal root resorption, periapical or inter-radicular radiolucency and widening of the periodontal ligament (PDL). Presence of any of these signs on the periapical radiograph was recorded as a radiographic failure.

Data Analysis

Data was analyzed using Statistical Package for Social Sciences (SPSS v. 21) and descriptive statistics were calculated for all variables. Chi-square test was used to compare clinical and radiographic outcome at 3 months, 6 months and 12 months. p-value <0.05 was considered significant.

RESULTS

The mean age of the patients in the study sample was 5.69 years (SD+ 1.28) ranging from 4 to 8 years with 90% of the patients > 7 years. A total of 62 primary molars were assessed out of which 32 were primary first molars and 30 were primary second molars. The clinical and radiographic success of FC and MTA at 3, 6 and 12 months follow-up time is shown in Table 1 and 2 respectively.

3 months follow-up

The clinical and radiographic success for both FC and MTA at 3-months follow-up was 100%.

6 months follow-up

At 6 months follow-up, the clinical success rate for FC group was found to be 90.3% (n=28) while that of MTA was 96.8% (n=30). Chi-square test was performed and it showed that the difference was not statistically significant with the p-value of 0.301. Fisher's Exact test was applied and its value was calculated to be 0.612 which was also not significant. Figure 1 summarizes the clinical signs and symptoms observed at 6 months follow-up period.

Radiographically, the success rate of FC was 77.4% (n=24) and that of MTA was 83.9% (n=26). Chi-square test revealed that the difference was not statistically significant and p-value was calculated to be 0.520. All the four teeth (FC=3, MTA=1) which had clinical failure also failed radiographically. Pathological root resorption was the most common cause of radiographic failure observed in 10 of the 12 failed patients at 6 months. The results of the radiographic signs are summarized in Figure 2.

12 months follow-up

At 12 months, 28 patients in FC group and 30 in MTA group were included in the follow-up. A clinical success of 82.1% was reported in FC group (n=23) while 86.7% (n=26) in MTA group. The chi-square test was applied and the p-value was calculated to be 0.634 which was insignificant statistically. Fisher's Exact test was applied and its value was calculated to be 0.726 which was not significant. Figure 3 gives a brief summary of the clinical signs and symptoms observed in both the groups at 12-months follow-up. Tooth discoloration was only observed in the patients treated with MTA. At the end of 12 months, 19 of the 31 patients (61.3%) treated with MTA showed tooth discoloration.

Teeth which showed radiographic failure at 6 months were not included in the12 months follow-up so 24 teeth were included in the FC group and 26 teeth in the MTA group. Radiographically, success rate for FC was 70.8% and that of MTA was 88.5%. Although a marked difference was observed, the results were not statistically significant as the p-value was calculated to be 0.119. Figure 4 shows radiographic signs observed at 12 months follow-up. Root resorption was the most common cause of failure in FC group while furcation/periapical radiolucency was the most common cause in MTA group. At the end of 12 months, root resorption was observed in 35.5% (n=11/31) of FC treated teeth while only 19.3% (n=6/31) in MTA treated teeth.

DISCUSSION

The retention of the pulpally involved primary teeth in the oral cavity until their normal exfoliation poses a challenge to the pediatric dentists. Concerns regarding the toxicity, mutagenicty and carcinogenicity have raised an alarm at the use of FC as a pulpotomy agent.[12,13] As the search for a better pulpotomy agent continues, MTA owing to its superior biocompatibility, biological seal and dentinogenic potentials has emerged as a suitable replacement of FC.[14] The current study was conducted to evaluate the success of MTA and FC in terms of clinical and radiographic findings at 3, 6 and 12 months follow-up.

In this study, the age of the patients ranged between 4 to 8 years with a mean age of 5.69 years. Lack of chair-side co-operation shown by the children less than four years age was the major reason for not including

TABLE 1. COMPARISON OF CLINICAL ASSESSMENT OF FC AND MTA AT 3, 6 & 12 MONTHS FOLLOW-UP

Pulpotomy agent		3 months % (n)	6 months % (n)	12 months % (n)
FC	Success	100 (31)	90.3 (28)	82.1 (23)
	Failure	0	9.7 (3)	17.9 (5)
MTA	Success	100 (31)	96.8 (30)	86.7 (26)
	Failure	0	3.2 (1)	13.3 (4)

TABLE 2. COMPARISON OF RADIOGRAPHIC ASSESSMENT OF FC AND MTA AT 3, 6 & 12 MONTHS FOLLOW-UP

Pulpotomy agent		3 months % (n)	6 months % (n)	12 months % (n)
FC	Success	100 (31)	77.4 (24)	70.8 (17)
	Failure	0	22.6 (7)	29.2 (7)
MTA	Success	100 (31)	83.9 (26)	88.5 (23)
	Failure	0	16.1 (5)	11.5 (3)

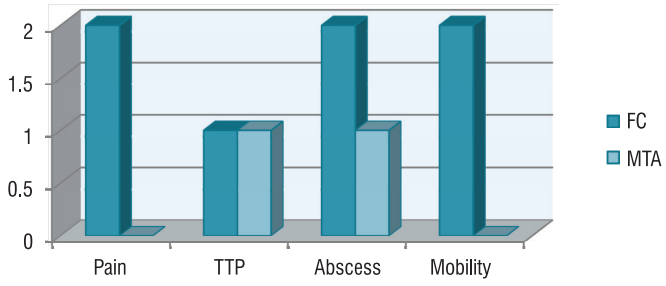

Fig 1: Clinical signs and symptoms at 6 months follow-up for FC and MTA

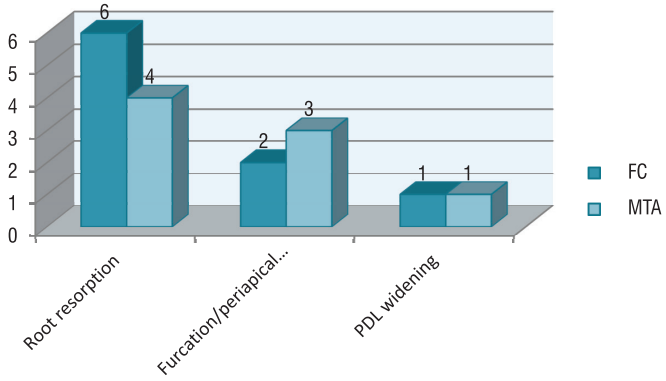

Fig 2: Radiographic signs and symptoms at 6 months follow-up for FC and MTA

them in the study.

The success rate of the study collaborates with the success rate reported in the literature with MTA showing better results compared to FC.[15, 16] In a study by Holan et al.[17] the success rate of MTA was found to be 14% higher than that of FC. In a meta-analysis performed by A. Shirvani in 2014, it was found that as many as 13 randomized control trials in the literature reported no statistical difference between FC and MTA.[18]

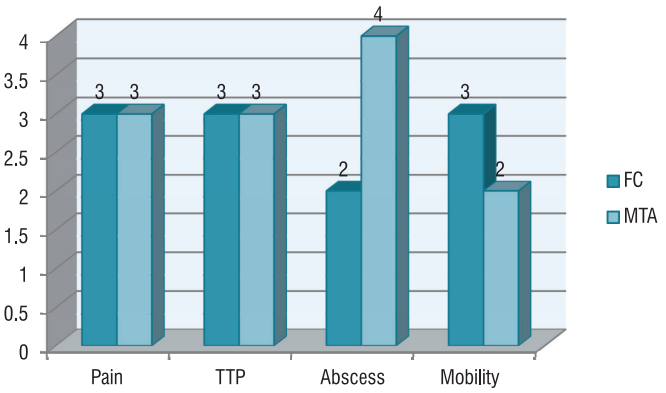

Fig 3: Clinical signs and symptoms at 12 months follow-up for FC and MTA

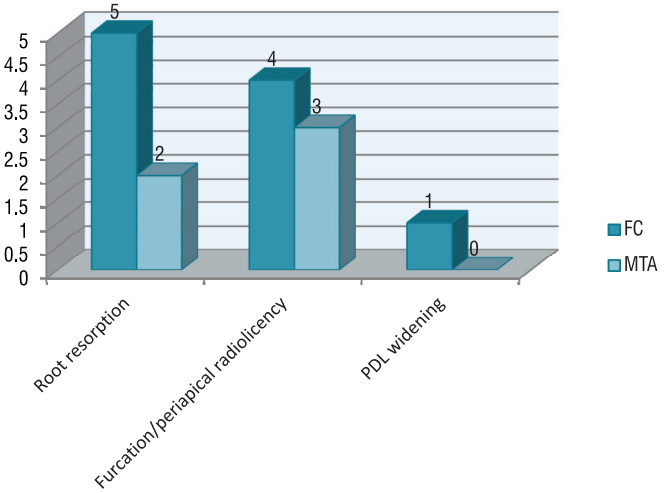

Fig 4: Radiographic signs at 12 months follow-up for FC and MTA

The main factors contributing to the failure of pulpotomy include undiagnosed radicular pulpitis, poor isolation during the procedure, incomplete removal of the pulpal tissue from the chamber and traumatic

amputation of the coronal pulp.[19] In the current study, since the teeth were randomly assigned to both the groups and similar protocol was followed by a single operator, these factors were overcome. The probable reason for the higher failure rate in FC group may be due to the reversible fixation of the pulp tissue by FC.[20, 21] The success of MTA could be considered due to its excellent biocompatibility, sealing properties and tissue regenerative properties.[14] MTA is said to heal the amputated pulp tissue by preserving its vitality and promoting hard tissue regeneration.[22]

In the current study, both FC and MTA showed a higher clinical success rate compared to radiographic success which is in conformity with various studies in the literature.[23, 20] It has been proposed that the radiographic changes in the teeth with vital pulp therapy are more sensitive to inflammatory reaction compared to the clinical changes.[5] This also explains the difference between clinical and radiographic outcomes at the follow-up visits as not all the radiographic failures were accompanied by the clinical symptoms and therefore did not require any treatment. In the current study, it was observed that the radiographic symptoms preceded the clinical symptoms. Six out of the eight clinically asymptomatic teeth which underwent radiographic failure at 6 months follow-up became clinically symptomatic at 12 months follow-up visit. This shows that the pathological changes continued in these teeth until the adjacent supporting tissues were involved and teeth became symptomatic leading to clinical failure.

Root resorption was the most common cause of radiographic failure in this study which was observed in 10 (16.1%) patients at 6 months follow-up and in 7 (14%) patients at 12 months follow-up. This is in accordance with the systematic review by A. Marghalani5, who found that root resorption was the most reported cause of radiographic failure and more patients in the FC group showed pathological root resorption when compared to MTA. G. Ansari24 also reported similar findings in their two years follow-up study where more cases of root resorption were observed with FC as compared to MTA. It is proposed that internal resorption is a result of chronic inflammation.[17] The reason for the pathological root resorption is believed to be due to the irritating effects of the pulpotomy agents used. Investigations have showed that the eugenol component in the zinc-oxide eugenol (ZOE) paste can cause inflammation thereby increasing the risk of internal resorption in the tooth. Another proposition is that the root resorption could be the result of undiagnosed chronic inflammation in the radicular pulpal tissue present at the time of performing pulpotomy. With time, this progresses leading to root resorption and therefore radiographic failures in these teeth. FC does not induce formation of new dentine[25] so the risk of root resorption due to existing undiagnosed pulpitis increases with its use. However, as MTA induces dentine formation and has reparative effect on the pulpal tissue, it heals the remaining pulp stumps, reducing the chances of progressive inflammation.

The success rate of the pulp therapy also depends on the type of restoration placed. In a recent meta-analysis of various randomized control trails, it was found that teeth restored with stainless steel crowns showed significantly greater success rate compared to other restorations.[26] An overall high failure rate in the study could be attributed to the use of GIC as it is not the restoration of choice for pulp-treated primary teeth.[27] Since the primary aim of the study was to compare two pulpotomy agents and both the groups were restored with the same restorative material, it is improbable to affect the outcome of the individual agents or the results of the comparison.

Tooth discoloration of the pulpotomized teeth was assessed at the end of 12 months follow-up period. None of the tooth treated with FC showed discoloration while it was present in 61.3% (19/31) of the patients in the MTA group. The crowns of the teeth showed grayish discoloration. These results are comparable to other studies. Naik et al.[28] reported tooth discoloration in 60% of the teeth treated with MTA. Since it does not affect the success of the treated teeth, it was noted as a separate entity.

CONCLUSION

The quest for newer, better materials in the field of dentistry is a never ending process. MTA has revolutionized modern endodontics and continues to replace the conventional materials. The results of the study add to the existing body of knowledge in this domain. Based on the results of the current study, it can be concluded that:

- Both the agents are suitable for pulpotomy in primary teeth as they demonstrated parallel clinical and radiographic success rates. However, MTA showed better success rate compared to FC which was not statistically significant.
- Fewer cases of root resorption were observed in teeth treated with MTA compared to FC.
- MTA is a safe alternative to FC as a pulpotomy agent which is known to be carcinogenic and mutagenic.

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3 Sadia Khalid	Helped in literature review and publication writing, Proof reading of the final draft and expert opinion
4 Dr. Shahab Ud Din	Helped in literature review and publication writing, Presented data in tables and figures, Refined the first draft written by first author, Helped in use of SPSS for data analysis
5 Dr. Abul Kher Zalan	Helped in literature review and publication writing, Helped to refine the first draft written by first author
6 Dr. Maleeha Ijaz	Helped in literature review and publication writing, Helped to refine the first draft written by first author