Treatment outcomes of pulpotomy in primary molars using two endodontic biomaterials. A 2-year randomised clinical trial

Aim To compare the treatment outcomes of calcium-enriched mixture (CEM) cement and mineral trioxide aggregate (MTA) as pulp dressing biomaterials in vital pulpotomy of carious primary molars. Study design: split-mouth randomised clinical trial.

Materials and methods Forty children aged 4-8 years with 2 carious teeth requiring pulpotomy were selected and randomly assigned to MTA (n=40) or CEM (n=40) groups. After coronal pulp removal, the remaining radicular pulp was covered with an appropriate biomaterial; the teeth were then permanently restored. Clinical/radiographic success/failures were blindly evaluated at 6-, 12- and 24-month follow-ups. Statistics: the recorded data were analyzed with McNemar test and GEE.

Results A total of 36, 33 and 35 patients were available for 6-, 12- and 24-month follow-ups, respectively. At the 12-month follow-up only one and three teeth in the CEM and MTA groups had pathologic external root resorption, respectively. The resorbed teeth were then missed due to extraction/exfoliation at the 24-month follow-up; all other treated teeth were symptom-free. Overall, clinical and radiographic outcomes in both MTA/CEM groups were comparable at the three follow-ups without significant differences. Time had no significant effect on the success.

Conclusion MTA and CEM demonstrated favourable treatment outcomes for pulpotomy of carious primary molars; CEM may be an effective pulp dressing biomaterial.

Keywords: Calcium enriched mixture; CEM cement; Dental cements; Mineral trioxide aggregate; Pulpotomy; Primary tooth.

Introduction

The aim of pulpotomy is to treat reversible pulpal injuries; this procedure can be performed when the coronal pulp has been exposed by caries removal, restorative procedures, or from trauma to the primary tooth [Fuks, 2002]. The infected and/or inflamed coronal pulp is surgically amputated, leaving the vital radicular pulp tissue intact.

The rationale for pulpotomy of primary molars is based on the assumption that inflammation is limited to the coronal portion of the dental pulp and that the radicular pulp has the potential to heal. It is difficult, if not impossible, to determine the histopathological status of the pulp clinically. Therefore, the operator relies on subjective criteria to determine whether the remaining pulp is or is not affected, such as the bleeding time of the radicular pulp stump after amputation, colour of haemorrhage, and consistency of the tissue. These are all subjective criteria that may lead to diagnostic error [Holan et al., 2005]. A chronically inflamed radicular pulp that is misdiagnosed as reversibly inflamed can be a cause of failure.

Since 1950, formocresol (FC) has been widely used as a pulp dressing material for pulpotomy of primary molars. However, formaldehyde, the major component of FC, spreads systemically after pulpotomy [Block et al., 1978]. Recently, many concerns have been raised about the potential mutagenicity and carcinogenicity of FC in humans [Lewis, 1998], and therefore alternative pulpotomy agents/techniques have been proposed. For example, electrosurgery, laser, glutaraldehyde, ferric sulphate, hydroxyapatite, freeze-dried bone, bioactive glass, bone morphogenic protein (BMP), and mineral trioxide aggregate (MTA) have all been investigated.

MTA has been approved by the FDA as a therapeutic endodontic material for humans in 1998. It is a powder composed of Portland cement, calcium sulphate and bismuth oxide. The cement's setting time is ~4 hours, and its compressive strength after setting is comparable to that of IRM; it also has an alkaline pH [Torabinejad et al., 1995]. MTA has been introduced as an alternative pulp dressing material for pulpotomy of primary molars, with advantages such as inducing hard tissue formation, i.e. having dentinogenic effect on the dental pulp [Holan et al., 2005]. Its sealing ability is superior to that of amalgam or reinforced zinc-oxide eugenol [Torabinejad & Pariorkh, 2010]. Though MTA has favorable biocompatibility, it has delayed setting time, poor handling characteristics, off-white color, and is comparably an expensive material [Parirokh and Torabinejad, 2010].

A new endodontic biomaterial has been introduced [calcium enriched mixture cement] (CEM) [Asgary et al., 2008a], which combines characteristics such as appropriate setting time, handling characteristics, and chemical properties with the favorable biocompatibility of MTA. Moreover, CEM cement has a similar pH, increased flow, decreased working time and film thickness, and different components compared with MTA [Asgary et al., 2008c; Asgary et al., 2009b]. Sealing ability of CEM and MTA is superior to that of IRM [Asgary et al., 2008a]. CEM cement has demonstrated similar results to MTA when used as pulp capping agents [Tabarsi et al., 2008a].
Asgary et al., 2008b;[30] furcal perforation repair [Samiee et al., 2010], and root-end filling materials [Asgary et al., 2010]. It has also shown favourable results in pulpotomy of permanent molars with established irreversible pulpitis and management of internal root resorption [Asgary and Ehsani, 2009]. This cement has antibacterial effects superior to MTA and comparable with calcium hydroxide [Asgary and Kamrani, 2008]. It also has low cytotoxicity on different cell lines, similar to MTA [Mozayeni et al., 2010; Ghoddusi et al., 2008].

This split-mouth randomised clinical trial was designed to compare treatment outcomes of MTA and CEM cement pulpotomy in human primary molars with carious pulp exposure at 6-, 12- and 24-month follow-up.

Materials and methods

The outline of this prospective randomised clinical trial was assessed and approved by the Iranian Center for Endodontic Research (ICER) and the Ethics Committee of the Dental Research Center of Shahid Beheshti Medical University, Tehran, Iran. The trial was conducted in compliance with the ethical principles of the Declaration of Helsinki. The patients were recruited from a pool of healthy 4-8 year-old children of both genders, referred to the Paediatric Dental Clinic of Shahid Beheshti Dental School, Tehran, Iran. The procedure and its possible benefits, as well as possible risk or discomfort were explained to the child’s parent(s) or legal guardian(s). Informed consent was then obtained prior to trial participation. The inclusion criteria were as follows: symptom-free primary molars with a deep caries lesion; presence of at least two teeth with carious exposure; presence of a vital pulp; restorable crowns; and readiness to appear for follow-up. Patients who did not have carious exposures after treatment were excluded from the study.

Exclusion criteria were as follows: clinical and/or radiographic sign or symptoms of pulp degeneration (i.e. spontaneous pain, excessive bleeding from the root canal, internal root resorption, inter-radicular and/or periapical bone destruction, tenderness to percussion, swelling or acute/chronic apical abscess, pathological mobility); active systemic disease; and physical or mental disability.

Statistically, if the effect size was taken to be 5% with \( \alpha=0.05 \) and 80% power, 25 teeth per treatment group would be considered sufficient. With an estimate of 20% drop-out per year for the two-year follow up, approximately 40 patients would be required.

For each patient, teeth were assigned randomly, to either the CEM cement group or the MTA group (split-mouth design). After the application of local anaesthesia (2% lidocaine and 1:80000 epinephrine; Darou Pakhsh, Tehran, Iran), isolation with rubber dam, caries removal, and then pulp exposure, the pulp chamber was unroofed using a 008 high-speed fissure bur with copious water spray. Following the coronal pulp removal with round bur in a low-speed handpiece and copious irrigation with normal saline solution, heemostasis was achieved by application of small pieces of sterile cotton pellets wetted with normal saline solution.

The blood clot-free pulpal wounds were covered with either mineral trioxide aggregate (tooth-coloured ProRoot MTA, Dentsply, Tulsa, OK, USA) or CEM cement (BioniqueDent, Tehran, Iran). The teeth were restored with a stainless steel crown or amalgam depending on the cavity size.

The patients were asked to return for 6, 12-months clinical/radiographic examinations. When a child did not attend an appointment, further attempts were made to call the parents and a follow-up examination was rescheduled. The children were then examined clinically by a blinded paediatric dentist. The treatment outcome was classified as a failure when one or more of the following signs were present: swelling/abscess, sinus tract, spontaneous pain, and/or pathological mobility.

Radiographic evaluations were performed by a blinded oral radiologist and paedodontist. All investigators independently evaluated the radiographs to detect signs of furcation radiolucency, periapical bone destruction, internal root resorption, and pathological external root resorption. Arrested internal resorption with calcific metamorphosis of the pulp and pulp canal obliteration (PCO) were not regarded as failures.

The data were analysed using the McNemar test and generalised estimating equation (GEE). Statistical analysis was performed using the SPSS software, version 15.0 (SPSS Inc., Chicago, IL). The significance level was set at 0.05.

Results

In total, 80 primary molars in 40 children (23 boys and 17 girls) were treated in this trial. The patient age at the time of treatment ranged between 4-8 years with an average of 6 ± 0.75 years. The most frequently treated teeth were the mandibular second molars (38.75% of total) (Fig. 1). Thirty

![FIG. 1 - A) Preoperative radiograph of the second lower right primary molar showing deep carious lesion treated with (MTA) pulpotomy; B) favorable outcomes at 6-month follow-up; the first primary molar was treated at this session; C) Preoperative radiograph of the second lower left primary molar treated with CEM pulpotomy; D) 6-month follow-up radiograph showing favorable outcomes.](image-url)
six and 44 teeth were restored with stainless steel crown and amalgams, respectively. In the MTA group 19 (47%), 6 (15%), 15 (37%) teeth and in CEM group, 17 (42%), 4 (10%), 19 (47%) teeth received SSC, Class I and Class II amalgam restorations, respectively. The distribution of pulpotomised primary molars in the two experimental groups is shown in Table 1.

First follow-up times ranged between 6-9 months with a mean of 6 months and 27 days. For the 12- and 24-month follow ups, the mean was 13 months and 5 days and 25 months and 14 days, respectively. Overall, a total of 36, 33, and 35 children attended 6-, 12-, and 24-month follow-ups, respectively. Hence, 72 (90%), 66 (82.5%), and 69 (-4 missed teeth (82.5%)) teeth were available for 6-, 12-, and 24-month clinical and radiographic analysis, respectively.

Sign or symptoms of failure were not clinically observed at the 6-month follow-up as well as the 1- and 2-year follow ups (100% clinical success rate for both groups). Both groups showed 100% radiographic success at 6-month follow-up. One and three cases of pathologic root resorption were observed in CEM and MTA groups at 12-month follow-up, respectively, without significant difference (P=0.625). These teeth were then extracted/exfoliated and therefore were missing at the 24-month follow-up. In the last follow-up MTA and CEM achieved 100% radiographic success (Table 2).

Based on the results of GEE analysis for effects of material and time interval on radiographic success in 6-, 12-, and 24-month, there were no statistical differences between materials (P=0.398) and time intervals (P=0.352) and time intervals (P=0.398).

**Discussion**

The present study is the first clinical trial on vital pulpotomy with CEM cement on human primary molar teeth. Standardisation was achieved by randomly distributing the treated teeth among the treatment groups; based on the split-mouth design each patient received pulpotomy with the two biomaterials. Moreover, the treatment procedure, 6-, 12-, and 24-month follow ups were performed blindly. As the type of the two biomaterials was water-based, the clinician was unaware of the pulp capping agent used, therefore eliminating researcher's cognitive bias in this trial.

Formocresol is still considered the most popular devitalizing material in primary tooth pulpotomy. However, toxicity, mutagenicity and carcinogenicity are still problematic features of FC, and an alternative would be desirable [Lewis, 1998]. Formocresol is a devitalising agent whereas MTA and CEM maintain pulp vitality. The results of a meta-analysis revealed that treatment outcomes of MTA versus FC pulpotomy suggested that MTA was superior to FC and had a lower failure rate [Peng et al., 2006]. Therefore, highest level of evidence supports the use of MTA instead of FC when performing pulpotomy on primary molars.

MTA prevents microleakage, is biocompatible, and promotes regeneration of the original tissues when it is placed in contact with the dental pulp [Parirokh & Torabinejad, 2010]. Several in vivo studies have reported excellent results when using MTA as pulp dressing agent for human permanent [Eghbal et al., 2009] or primary dentition [Holan et al., 2005; Innes, 2007; Zealand et al., 2010] as well as animals [Asgary et al., 2006]. A recent long-term study on primary molars demonstrated favourable biologic response after pulpotomy with both gray and white MTA during 7 year follow-ups [Cardoso-Silva et al., 2011]. Therefore, white MTA was selected in this trial as the control/gold standard.

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This trial is designed to compare the clinical/radiographic success of pulpotomy with CEM cement to MTA, in order to determine the effectiveness of this novel endodontic biomaterial for pulpotomy of human primary molars. The results revealed 100% clinical success rates for both
bimaterials during the trial. Interestingly, the radiographic interpretation demonstrated 100% success for 6-months follow up for both groups. However, 91% and 97% success rates were achieved for MTA and CEM at one-year, respectively; this was not statistically significant. When the failed teeth had been extracted/exfoliated during the second year of the trial, all remaining treated teeth were radiographically successful at 24-month follow-up.

Several properties are necessary when choosing a pulp capping agent including sealing ability, antibacterial activity, and more importantly, dentinogenesis [Tziafas et al., 2000]. The favourable treatment outcomes for CEM cement in comparison with MTA in the present trial can be due to a compound of factors. This includes possible general factors, i.e. complete caries/bacteria removal as well as prevention of bacterial recontamination and specific factors, i.e. good sealing ability [Asgary et al., 2008a], antibacterial activity [Asgary & Kamrani, 2008], hydroxyapatite formation [Asgary et al., 2009a], low cytotoxicity [Mozayeni et al., 2010], and induction of hard tissue formation [Tabarsi et al., 2010; Samiee et al., 2010; Asgary, 2010] by this novel cement.

MTA pulpotomy has had favourable success rates; it does not induce internal root resorption, which has been observed in teeth treated with calcium hydroxide and FC [Fucks, 2002; Peng et al., 2006]. However, MTA is prohibitively expensive for routine use in clinical paediatric dentistry [Fucks, 2002; Parirohk and Torabinejad, 2010]. CEM cement has been introduced as an endodontic biomaterial that has similar biological features to MTA but reasonable price. There are as yet no reports of the arrest of internal resorption after vital pulp therapy. Recent reports showed that internal resorption had ceased, dentin formation had occurred and condensing apical periodontitis had healed as a result of pulpotomy with CEM cement [Asgary and Ehsani, 2009; Asgary, 2011]. Besides, CEM cement can be used as a pulp-capping agent in apoxogenesis of immature teeth [Nosrat and Asgary, 2010a,b] as well as management of external root resorption and regenerative endodontic treatment [Nosrat et al., 2011; Asgary et al., 2011]. Surprisingly, recent randomised multicenter non-inferiority trials revealed that CEM cement pulpotomy in comparison to root canal therapy by human permanent molars with established irreversible pulpitis had significantly greater pain relieving effect initially, as well as higher radiographic success rates after 6-month follow-up [Asgary and Eghbal, 2010a,b].

In the present trial, periods of 6 to 24 months were used to evaluate the treatment outcome of pulpotomy with the two bimaterials. While many studies used the 6-month time interval [Ainehrchi et al., 2007], several other studies evaluated treatment outcomes at different time intervals, including up to 42 months [Maroto et al., 2007]. Matsuo et al. [1996] found that success rates were similar at 3- and 18- month follow-ups; they suggested that 3 months was adequate. It therefore seems that >18-month follow-ups would be sufficient for evaluating the success of pulpotomy with CEM/MTA.

It is well established that healing of the dental pulp is directly related to the capacity of both the pulp dressing and definitive restorative material which should provide a biological seal against microleakage along the entire restoration interface. Overall, the teeth in the MTA group had more restorations with SSC and Class I amalgams, while the dominant restoration in CEM group was Class II amalgam. Despite this difference, the radiographic success in CEM at 1-year follow up was higher than the MTA group. The good sealing ability of CEM may be responsible for this favourable result [Asgary et al., 2008a].

Conclusion

This split-mouth randomised clinical trial demonstrated favorable treatment outcomes of CEM/MTA pulpotomy in human primary molar teeth. CEM as a new endodontic cement is a promising biomaterial.

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References


MALEKAFZALI B., SHEKARCHI F. AND ASGARY S.
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The title of the book is very appropriate since many Dental disciplines, including Paediatric Dentistry, are changing both their philosophy and techniques, as all chapters of this book demonstrate: some illustrate current changes in dental epidemiology and their influence on clinical practice. Also, sealant techniques should be modified, emphasizing proximal sealing, and thus filling of primary teeth could be avoided, by implementing prevention techniques or by means of protective steel crowns.

A solution to the problems connected to the use of rotating instrument is suggested: microinvasive treatment and increased preventive measures.

Nowadays the new prevalent problem in Paediatric Dentistry is malocclusion and not only caries, limited to ECC. All these aspects are well presented and documented in the book.

Some topics are personally written by the editor; while others with the contribution of many other authors not only from Germany, but also from Denmark, Syria, Switzerland, Turkey, UK, and overseas from Canada and the USA. This is a very interesting and useful book to read and study.

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