



Mineral Trioxide Aggregate vs Calcium-Enriched Mixture Pulpotomy in Young Permanent Molars with a Diagnosis of Irreversible Pulpitis: A Randomized Clinical Trial

Marwa Sharaan^{a*} , Asmaa Ali^b 

^a Department of Endodontics, College of Dentistry, Suez Canal University, Egypt; ^b Department of Pedodontics and Oral Public Health, College of Dentistry, Suez Canal University, Egypt

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*Corresponding author: Marwa Sharaan,
Department of Endodontics, College of
Dentistry, Suez Canal University, Egypt.

E-mail: marwaelsayedsharaan@gmail.com

Introduction: The aim of this blind randomized clinical study was to prospectively compare the clinical and radiographic success outcomes of calcium-enriched mixture (CEM) pulpotomy versus white mineral trioxide aggregate (WMTA) pulpotomy in permanent molars diagnosed with irreversible pulpitis. **Materials and Methods:** Forty patients met the inclusion criteria and agreed to join. The patients were randomly assigned into two groups: CEM pulpotomy ($n=20$) and WMTA pulpotomy ($n=20$). Clinical success was reviewed at 7 days and 3, 6 and 12 months after treatment. We organized radiographic assessment at 6 and 12 months. The data was analyzed using Chi-square, Independent t-test, and Mann-Whitney for the baseline and post-operative characteristics of the patients. **Results:** None of the patients were lost during recalls. Twenty-one females and 19 males participated in the study ranging between 7-14 years of age. The follow up period was extended in some of the cases for more than 1 year (12-23 month). Regarding the baseline and post-operative characteristics of the patients, there was no significant difference between the groups ($P>0.05$). All the cases showed clinical and radiographic success outcomes for both groups at/after 12-month recall periods. There was no significant difference between the two groups clinically and radiographically ($P=1$). **Conclusions:** Based on this randomized clinical trial study, CEM and WMTA as pulpotomy agents expressed excellent clinical and radiographic outcomes with no significant difference in the treatment of permanent molars with irreversible pulpitis over a 12-month period.

Keywords: Calcium-enriched Mixture; Irreversible Pulpitis; Pulpotomy; Randomized Clinical Trial; White Mineral Trioxide Aggregate

Introduction

Endodontist generally opt for vital pulpotomy as the treatment of choice for immature teeth with exposed pulp tissues; being considered a part of the regenerative pulp therapy [1]. Currently, there is a paradigm shift towards vital pulp therapy (VPT), specifically pulpotomy, as a final treatment in permanent teeth with exposed pulp tissues [2-4]. The idea is based upon removal of the inflamed coronal pulp tissues followed by placement of a bioactive material that affords a biological seal to initiate the formation of dentin like tissue [5-8]. Pulpotomy is a simple, fast,

and non-costly procedure in comparison to the traditional root canal treatment (RCT) [9-11]. Additionally, the benefits of pulpotomy in comparison to RCT are not only tooth structure conservation but also the preservation of the regenerative ability of having all the functions of a vital pulp such as proprioceptive mechanism and mechanoreceptors of the pulp [10-16].

The successful use of mineral trioxide aggregate (MTA) has been investigated for pulpotomy of carious exposure in immature permanent teeth with irreversible pulpitis [11, 13, 16-19]. MTA has many advantages such as biocompatibility, sealing ability, and antibacterial effect. All these merits aid to promote



the healing response of the pulp [3, 4, 7]. On the other hand, MTA possess some disadvantages such as the prolonged setting time, discoloration and cost [7, 17].

Calcium-enriched mixture (CEM) is a bioactive and biocompatible water-based tooth colored cement. It discharges calcium and phosphate ions to develop hydroxyapatite stimulating the formation of a dentinal bridge. The product is alkaline (pH>10.5) and releases calcium hydroxide during and after setting [20]. Clinically, using CEM is like to MTA because of the comparable characteristics of this cement to MTA. Comparing CEM to MTA showed shorter setting and working time as well as a lower film thickness [18]. CEM also showed a superior antibacterial effect, sealing ability and improved handling [21]. The stated advantages of CEM and its potential effect on healing of the remaining pulp and induction of dentinal bridge formation have led researchers to recommend its use in pulp treatment procedures in permanent teeth such as indirect and direct pulp cap, pulpotomy permanent teeth associated with irreversible pulpitis [19, 22-24].

According to recent meta- analysis studies, the results of some clinical trials suggested VPT as an alternative treatment to root canal therapy in cases with irreversible pulpitis [2, 8, 25, 26].

To date, few studies have compared CEM to MTA as capping materials for pulpotomy in young permanent molar teeth diagnosed by irreversible pulpitis. The four studies used only ProRoot MTA either the white or grey [9, 15, 24, 27]. None of the previous studies compared White MTA Angelus (WMTA) to CEM. The purpose of this present clinical trial was to assess the clinical and radiographic outcomes of CEM in comparison to WMTA as pulpotomy agents in young permanent molar teeth with irreversible pulpitis.

The null hypothesis was that the clinical and radiographic outcomes of pulpotomy using CEM in young permanent molars diagnosed with irreversible pulpitis are not significant in comparison to WMTA.

Materials and Methods

Ethical consideration

The study was approved by the Human Ethics Review Committee (REC) at the College of Dentistry, Suez Canal University (registered No. 110/2018). Additionally, the study was registered at the ClinicalTrials.gov (NCT04243733). The study had been performed in accordance with the "Declaration of Helsinki". To start the study, the clinician explained the procedure and any risks to the patients' guardians as they signed the informed consent.

Study design

It was a double-blind (patient and clinician), randomized, and controlled clinical trial to compare between the two experimental materials: CEM (Bionique Dent, Tehran, Iran), White MTA Angelus (WMTA; Angelus, Londrina, Brazil). For this clinical study, permanent mature/immature molars in male or female patients aged 7-14 years had been selected from the Endodontics and Pedodontics Clinics in the College. Randomization was accomplished using a table of computerized generated random numbers equivalent for each case. Block randomization was adopted to ensure an equal number of patients assigned to each group. Later, blind allocation concealment was conducted using the closed envelop method, it was generated by a researcher who was not involved in the trial.

Sample size determination

The sample size was obtained by using the G* power software (Heinrich-Heine-Universität Düsseldorf, Düsseldorf, Germany) according to a previous study [28, 29]. Thirty-six patients were enough to detect the effect size of 0.39 and a power (1- β) of 80% at a significant level of (α) level of 0.05. Accordingly, a total sample size of 40 patients was required to compensate for any loss during the follow up period.

Inclusion criteria

Clinical examination disclosed extensive carious lesion on maxillary or mandibular molar's surface not reaching the root. The patients should experience a history of either asymptomatic irreversible pulpitis (AIP) or symptomatic irreversible pulpitis (SIP). Patients diagnosed by SIP might have spontaneous or lingering pain persisting for a few seconds to several hours in the days before the dental visit. This excruciating pain was provoked by hot and cold fluids necessitating analgesia for pain relief [30]. The pain could be also intermittent, dull or sharp, localized, diffuse, or referred pain. All of the parents were willing to join the study. All teeth were believed to be vital and the vitality of all the subjected molar teeth was checked by the endodontist during the pulpotomy procedure through visual inspection of pulpal hemorrhage. In addition, teeth which exhibited symptomatic or asymptomatic apical periodontitis were included in the study where the diagnosis was confirmed by percussion [30]. Whether there was a periapical change or not was also involved in the trial, providing that the periapical change is confined to either widening of the periodontal ligament space or a periapical index (PAI)<3 of the related radiolucency accompanied by vital pulp during the pulpotomy procedure [30].

Exclusion criteria

Patients with systemic disease or physical or mental disability, extremely poor oral hygiene, periodontal problems, signs of abscess or fistula or non-physiological tooth mobility and non-restorable teeth were excluded from the study. Teeth with external or internal root canal resorption, or root canal calcification in pre-operative radiographs were also excluded.

Pulpotomy procedure

One clinician completed the medical and dental history, clinical examination and pulpotomy procedure for all patients. Thermal test with refrigerant spray (Endo ICE-Coltene/Whaledent Inc., OH, USA) and electrical pulp test (Analytic Technology Pulp tester, Redmond, WA, USA) were used to prove the irreversible pulpitis diagnosis [31]. Rinn® XCP holder (Dentsply/Rinn, Elgin, IL, USA) was used to standardize the pre- and post-operative radiographs.

Table 1. Baseline characteristics of the trial patients

	CEM Group	WMTA Group	Test value	P-values
Gender, n(%) chi square				
Male	8 (40%)	11 (55%)	0.401	0.526
Female	12 (60%)	9 (45%)		
Age (year), Mann-Whitney test				
Minimum-Maximum	7-14	8-13	1.255	0.209
Mean (SD)	11.09 (2.16)	10.35 (1.84)		
Tooth position, Mann-Whitney test				
Lower molars	14 (70%)	12 (60%)	0.434	0.507
Upper molars	6 (30%)	8 (40%)		
Pulpal diagnosis, n (%) chi square test				
SIP	15 (75%)	5 (25%)	0.476	0.490
AIP	13 (65%)	7 (35%)		
Apical diagnosis, n (%) chi square test				
AAP	8 (40%)	14 (70%)	3.64	0.056
SAP	12 (60%)	6 (30%)		
Periapical radiographic change, n (%) chi square test				
Yes	10 (50%)	5 (25%)	2.66	0.102
No	10 (50%)	15 (75%)		
Root maturation, n (%) chi square test				
Mature	12 (60%)	13 (65%)	0.1067	0.743
Immature	8 (40%)	7 (35%)		

AIP, asymptomatic irreversible pulpitis; AAP, Asymptomatic apical periodontitis; SAP, symptomatic apical periodontitis; SIP, symptomatic irreversible pulpitis

Table 2. Post-operative characteristics of the trial patients

	CEM Group	WMTA Group	Test value	P-values
Partial canal obliteration, n (%) chi square test				
Yes	5 (25%)	4 (20%)	0.143	0.703
No	15 (75%)	16 (80%)		
Bleeding control (Min) (Independent t-test)				
Min-Max	1-12	1-12		
Mean (SD)	4.60 (3.77)	5.15 (3.49)	0.478	0.335
Follow-up (Months) (Independent t-test)				
Min-Max	12-23	12-23		
Mean (SD)	16.70 (2.34)	16.45 (2.96)	0.296	0.769



Figure 1. A tooth #46 radiographic evaluation, A) The preoperative periapical radiograph with periapical radiolucency represented in grey arrows; B) The postoperative immediate periapical radiograph after WMTA Pulpotomy; C) The 6-month follow-up with healing of the periapical radiolucency; D) The 18-month follow-up showing healing of preoperative periapical radiolucency and partial canal obliteration in the mesial and distal roots

The treatment procedure was performed after obtaining adequate local anesthesia with 4 % Articaine HCL and 1:200,000 epinephrine (Septocaine; Septodont Novocol, Ontario, Canada). The surface of the tooth was rinsed with normal saline and cleaned by swab wetted by a 2% chlorhexidine oral rinse (Consepsis V; Ultradent Products, South Jordan, UT, USA). Rubber dam was then applied followed by complete removal of caries using fissure diamond burs and round stainless-steel burs. Coronal pulpotomy was performed with a sterile round diamond bur on a high-speed handpiece with copious water to remove all of the inflamed pulpal tissue. Following pulp amputation, the pulp chamber was irrigated using 5% sodium hypochlorite (Clorox; Household Cleaning Products of Egypt, Cairo, Egypt) until hemostasis is obtained. An assistant used a stopwatch to assess the time for hemostasis not to exceed 12 min [31, 32]. The CEM powder and liquid or WMTA powder were mixed according to the manufacturer's instructions and a base of approximately 2 mm of the tested material was placed over the amputation site [31]. All teeth were temporarized with glass ionomer filling (Equia Forte Fil, GC America, IL, USA). After 1 week the patient was recalled for final restoration of the tooth with a stainless steel crown. Prior to tooth restoration, the operator checked that the patient had no pain or clinical problems (*i.e.*; tenderness to percussion, swelling, fistula or mobility due to disease). Placement of the stainless-steel crown (SSC) (3M/ ESPE, St. Paul, MN, USA) was done by the same pedodontist who cemented the crown by Spofa Dental Kavitan Pro glass ionomer cement (SpofaDental; Zhengzhou Shengxin Medical Instrument, Henan, China). Guardians were taught to replace the stainless-steel crown by a permanent crown by the age of 16. A recall program was arranged for all patients and all of the teeth were evaluated clinically and radiographically.

Clinical assessment

Clinical success was reviewed at 7 days and 3, 6 and 12 months after treatment. The teeth were tested for severe and continuous

pain, mobility, tenderness to percussion, soft tissue redness, oral swelling, abscess and fistula indicating any extension of inflammation toward the root canals. If the patients experienced one of the previously mentioned signs and symptoms, the case was recorded as a clinical failure. The parents were given a telephone number so that they can call the clinicians if there was any inquires.

Radiographic assessment

No internal or external root resorption, no loss of lamina dura integrity, no periodontal ligament space widening, and no alveolar bone resorption in the periapical region were considered indicative of successful treatment. Moreover, root development in case of immature roots, healing of a preoperative periapical radiolucency including decrease in the size and disappearing of the radiolucency were also considered as successful cases, like a case described in [Figure 1](#). Assessments were done at 2 recall times, at 6 and 12 months. The clinical and radiographic assessments were all performed by the same two calibrated dentists. The examiners were adjusted for radiographic interpretation of the radiographs, while each of them repeated the assessment 2 times within a week to check the intra-examiner reliability. Furthermore, if there was a disagreement between the examiners, it gave rise to a discussion that led at the end to an agreement (inter-examiner reliability).

Statistical analysis

All collected data were calculated, tabulated, and statistically analyzed. Qualitative data were presented as frequencies (n) and percentages (%). Chi-square test was used to test significance of association between categorical variables, Mann-Whitney test was used to compare between non-parametric variables and independent t-test for continuous outcomes. P -value<0.05 was considered to be statistically significant. Statistical analysis was performed using the computer program SPSS software for windows version 22.0 (Statistical Package for Social Science, Armonk, NY: IBM Corp, NY, USA).

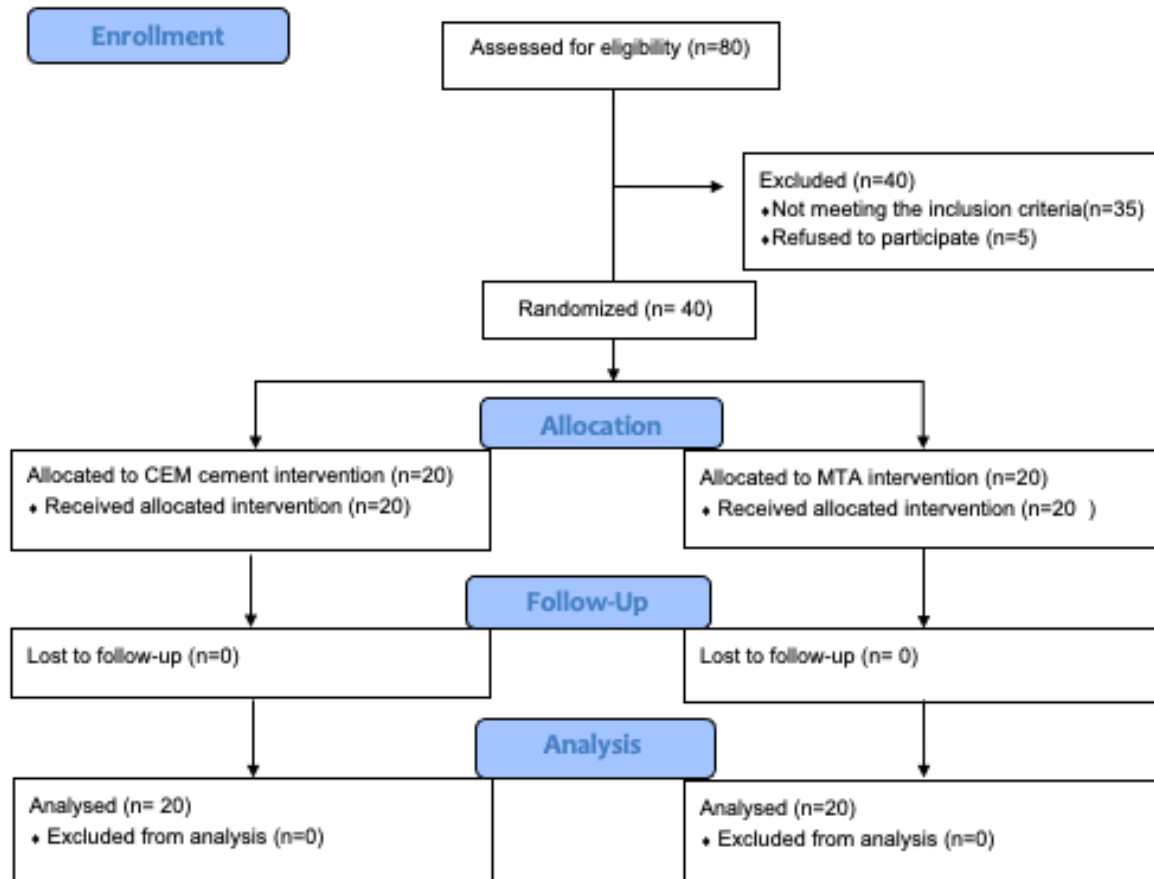


Figure 2. Consolidated Standards of Reporting Trials flowchart of the eligible patients up to the 1-year follow-up



Figure 3. A tooth #36 radiographic evaluation, A) The preoperative periapical radiograph of immature roots represented in gray arrows with periapical radiolucency represented in white arrows; B) The immediate postoperative periapical radiograph after CEM pulpotomy; C) The 6-month follow-up with healing of the periapical radiolucency and maturation of the mesial root; D) The 12-month follow-up, healing of periapical radiolucency and maturation of both roots

Results

Baseline characteristics of the study participants and eligible patients' flowchart are shown in Table 1 and Figure 2. Totally, the range of the patients' age was from 7-14 years (10.72 ± 2.02). Twenty-one females and 19 males participated in the study. As

displayed in Table 1, no statistical significant difference between the two groups was observed regarding the preoperative baseline characteristics of the studied patients. None of the cases were excluded due to unsuccessful hemostasis. As shown in Figure 1, none of the patients were lost during the recall periods.

The follow up period was extended in some of the cases for

more than 1 year (12-23 month). Both CEM and MTA pulpotomy were successful in 100% of the cases (clinical and radiographic success). All molars that were diagnosed immature at the beginning of the trial, started to have closed apices by the end of the recall periods (100%), like one of the cases described in Figure 3. Similarly, all cases with radiographic periapical radiolucency showed healing (100%) with neither internal nor external resorption. All the pre- and post-operative characteristics of the study patients in both groups were summarized in Tables 1 and 2.

Discussion

Previous histopathological and histo-bacteriological studies showed that teeth with carious exposure of the pulp can have both healthy and inflamed tissues in variable parts of the pulp [2, 4]^{2,4}. Removal of the damaged pulpal tissues and preservation of the healthy ones is considered as a conservative and optimum treatment at the same time [2]. Currently, it is well accepted that either symptomatic or asymptomatic irreversible pulpitis whether with or without symptomatic apical periodontitis could be treated with coronal pulpotomy rather than traditional RCT [10, 13, 16, 23, 27, 31, 32]. Coronal pulpotomy is defined according to the American Association of Endodontists (AAE) as “the removal of the coronal portion of a vital pulp as a means of preserving the vitality of the remaining radicular portion” [33]. A recent systematic review and meta-analysis displayed successful clinical and radiographic outcomes in cases treated by coronal than partial pulpotomy [26]. Besides, we have adopted coronal pulpotomy to standardize all the cases.

In the current trial, we have chosen CEM in comparison to WMTA as pulpotomy agents in the treatment of molars with irreversible pulpitis. Few studies compared both bioactive materials but none of them investigated White MTA Angelus (WMTA) [9, 16, 24, 27]. Recently, in one study, White MTA Angelus was compared to Biodentine and showed 100% successful outcome [17]. Although it was insignificant, a systematic review and meta-analysis showed superior outcome of CEM pulpotomy than MTA pulpotomy [34]. In the present study, all the 40 included cases in both groups demonstrated clinical and radiographic success (100%) during the recall periods. 5% NaOCl was used to control bleeding, which showed potent antibacterial and hemostatic action [17]. Most of the studies recommended the time of hemostasis for pulpotomy procedure not to exceed 10 mins, using less concentration of NaOCl [1, 13, 16, 27, 30, 35]. On the other hand, previous studies

demonstrated clinical and radiographic success for some cases where bleeding control was achieved at 12 min using 5% NaOCl [31, 32]. Literature showed that the direct correlation between the duration of bleeding control and the successful outcome is not evident, as some cases failed and the bleeding control time was 1 min, while some cases had successful results and the bleeding control time was almost 12 min [3, 31, 32]. It is already known that the normal time range for the clotting of a healthy tissue is 8-15 min [2]. All the cases that revealed radiographic periapical radiolucency at the beginning of the study in both groups healed completely by the end of the follow up recalls. Whenever there is a periapical radiolucency, it is not mandatory to find necrosis [30]. Neurogenic inflammation can give rise to periapical radiolucency due to the release of the substance P from the nerve fibers innervating the pulp and periapical tissues [36]. So, when the inflamed tissues were removed as in the present study, the periapical radiolucency resolved. The same idea could be applied for the symptomatic apical periodontitis, in both groups, all cases were asymptomatic by the end of the recall periods.

We have accepted the null hypothesis as there was no significant difference between CEM and WMTA regarding clinical and radiographic success. This result was consistent with previous studies [9, 15, 24, 27]. Both CEM and MTA pulpotomy showed 100 % success rates clinically and radiographically. This excellent outcome was in accordance with a similar study expressed 100% clinical and radiographic success [12]. Likewise, the 100% successful outcome for MTA was in agreement with earlier studies [30, 31, 35, 37]. For CEM cement, the 100% successful outcome was in accordance with former trials [32, 38]. Other researchers demonstrated successful outcome ranged from 75-98% [9, 10, 12, 13, 23, 24]. In the current trial, the follow-up recalls extended from 12 to 23 month in some cases. The age factor might have a major role in the successful outcome as the patients' age was from 7-14 years (10.72±2.02). All immature molars had closed apices by the end of the study which affirmed the fact of the potent healing capacity of young pulp [24]. Partial canal obliteration was found in 22% of the cases in both groups with significant difference between CEM and WMTA. This finding was observed in a previous study, where they explained its occurrence because of the action of the odontoblasts that led to canal narrowing [37]. Partial canal obliteration is not considered as failure as far as the tooth is functioning clinical and radiographically.

The mechanism of CEM or MTA that encourages healing promoting dentinogenesis and cementogenesis in this trial could be attributed to many characteristic features such as

their: antibacterial action, sealing ability, biocompatibility, bioactivity and high alkalinity [5, 6, 8, 19]. Besides, the coronal seal offered by the stainless steel crown could attribute to the successful outcome [26]. Interestingly, the preoperative pulp and periapical status, time for hemostasis and stage of root maturation did not affect the successful outcome.

Under the limitations of this trial, CEM and WMTA pulpotomy presented efficacious clinical and radiographic outcomes. However, further investigations should be conducted using cryotherapy to control bleeding. Moreover, larger sample of patients should be included in additional studies over a longer period of recalls studying the long-term outcome.

Conclusion

CEM and WMTA as pulpotomy agents expressed good clinical and radiographic outcomes with no significant difference in the treatment of permanent molars with irreversible pulpitis.

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Conflict of Interest: 'None declared'.

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