

# A Randomized Trial of Mineral Trioxide Aggregate Cements in Primary Tooth Pulpotomies

**Berna Celik, DDS, PhD      Atila S. Ataç, DDS, PhD**  
**Zafer C. Cehreli, DDS, PhD      Serdar Uysal, DDS, PhD**

## ABSTRACT

**Purpose:** The purpose of this study was to compare the outcome of primary tooth pulpotomies using two different white mineral trioxide aggregate (MTA) cements and calcium hydroxide (CH).

**Methods:** Primary molars (N=139) from three- to nine-year-old children were randomly assigned to be treated using either ProRoot MTA (N=46), MTA Angelus (N=45), or CH paste (N=48) as pulpotomy medicaments. All pulpotomized teeth received a Class I amalgam as a final restoration. Recall examinations were carried out at one, three, six, 12, 18, and 24 months.

**Results:** The 24-month cumulative clinical success rates for ProRoot MTA, MTA Angelus, and CH were approximately 98 percent, 96 percent, and 77 percent, respectively. The cumulative radiographic success rates for ProRoot MTA, MTA Angelus, and CH were approximately 98 percent, 91 percent, and 45 percent, respectively. For all parameters evaluated, the MTA cements showed similar clinical and radiographic outcomes ( $P>.05$ ), which were significantly better than those of CH ( $P<.05$ ). The two-year clinical and radiographic survival probabilities for ProRoot MTA and MTA Angelus were comparable ( $P=.62$  and  $P=.20$ , respectively) and superior to calcium hydroxide (all  $P>.05$ ).

**Conclusions:** ProRoot MTA and MTA Angelus showed similar and favorable success rates as pulpotomy materials in primary molars. (J Dent Child 2013;80(3):126-32)

Received January 25, 2012; Last Revision May 5, 2012; Revision Accepted June 4, 2012.

**KEYWORDS:** MINERAL TRIOXIDE AGGREGATE, CALCIUM HYDROXIDE, PRIMARY TOOTH, PULPOTOMY, RANDOMIZED CONTROLLED TRIAL

A primary tooth pulpotomy is a widely accepted clinical procedure, consisting of complete removal of the inflamed coronal pulp tissue and healing the radicular pulp with a suitable medicament.<sup>1</sup> Pulpotomized teeth can remain asymptomatic until exfoliation and, thus, help maintain the integrity of the dental arch.<sup>2,3</sup> The pulpotomy procedure is also recommended in young permanent teeth with open apices.<sup>4,5</sup>

Formocresol has been used as a pulpotomy medicament for decades, although concerns of toxicity and car-

cinogenicity of formaldehyde,<sup>6</sup> one of its primary components, has stimulated investigations of alternative approaches. These include glutaraldehyde<sup>7</sup> and ferric sulphate<sup>8</sup>, and techniques such as laser<sup>9</sup> and electrosurgery.<sup>10</sup> Mineral trioxide aggregate (MTA) is a relatively new agent that can be used in pulpotomies of primary molar teeth.<sup>11,12</sup> Originally developed as a root-end filling material, the main components of MTA include tricalcium silicate, tricalcium aluminate, tricalcium oxide, and silicate oxide.<sup>13</sup> Its popularity can be attributed to several factors, including biocompatibility,<sup>14-16</sup> good sealing properties,<sup>17</sup> antimicrobial activity,<sup>18</sup> and ability to set in the presence of moisture and blood.<sup>19</sup> An increasing number of reports have documented the favorable clinical outcome of primary tooth pulpotomies utilizing MTA.<sup>1,20-23</sup>

*Dr. Celik is a research assistant and Drs. Ataç and Cehreli are professors, Department of Pediatric Dentistry, and Dr. Uysal is an assistant professor, Department of Oral Diagnosis and Radiology, all in the school of Dentistry, Hacettepe University, Ankara, Turkey. Correspond with Dr. Cehreli at zcehrel@gmail.com*

Despite several clinical reports that evaluated MTA cements against commonly used pulpotomy agents, only two studies have compared different MTA cements (gray and white MTA) in a single trial.<sup>24,25</sup>

The purpose of this randomized, controlled trial is to evaluate and compare two different white MTA cements as pulpotomy medicaments in human primary teeth, ProRoot MTA and MTA Angelus. They were chosen due to their similar composition and because the latter is a less expensive substitute.

## METHODS

### SELECTION OF PARTICIPANTS

The study subjects were healthy three- to nine-year-old children who attended the pediatric dental clinic at the School of Dentistry, Hacettepe University, Ankara, Turkey. In order to participate, they had to have a pulpally healthy primary molar with a deep occlusal carious lesion, which presented potential risk of pulp exposure during complete removal of carious dentin, as determined by clinical and radiographic assessment.

Teeth that had the following clinical or radiographic signs and symptoms were excluded: spontaneous pain, sensitivity to percussion, pathologic mobility, carious pulp exposure, presence of swelling or fistulae, proximal caries, internal/external resorption, inter-radicular bone destruction, calcific metamorphosis, and uneven/pathologic root resorption. Informed written consent for participation in the study was obtained from parents after explaining the possible outcomes of treatment. Both the consent form and the research protocol were approved by the Institutional Human Subject Review Committee of Hacettepe University, Ankara, Turkey.

### STUDY DESIGN

This was a randomized, controlled, single-blinded (patient) clinical trial. Operator blinding was not possible due to the color and consistency of the control medicament (calcium hydroxide paste), which did not match those of the MTA cements. The operator, however, was blinded to the MTA cements, since both materials had similar color and handling properties.

Eligible primary maxillary and mandibular first and second molars were assigned to one of the following treatment groups:

**Group 1:** White MTA (ProRoot, Dentsply/Tulsa Dental, Tulsa, Okla) was mixed according to the manufacturer's instructions to produce a homogeneous paste. The material was placed in the pulp chamber with a plastic carrier. Light pressure was applied with moist cotton pellets to enhance adaptation of the material.

**Group 2:** Angelus MTA (Angelus, Londrina, Paraná, Brazil) paste was prepared according to the manufacturer's recommendations and applied over the pulpotomy sites as in Group 1.

**Group 3:** Calcium hydroxide powder (Merck, Darmstadt, Germany) was mixed with sterile water in a 3:1 ratio to produce a homogeneous paste. The material was placed in the pulp chamber as described for groups 1 and 2.

Allocation of patients was made randomly using sequentially numbered opaque-sealed envelopes prepared with unrestricted (simple) randomization.<sup>26,27</sup> The envelopes were opened by a dental auxiliary blinded to treatment.

### CLINICAL PROCEDURES

Treatment was provided by a pediatric dentist resident in the Department of Pediatric Dentistry at the School of Dentistry, Hacettepe University, Ankara Turkey, under supervision of a faculty member. Following local anesthesia with 4% articaine hydrochloride with 1:100,000 adrenaline and rubber dam isolation, the undermined enamel was removed with a no. 330 carbide bur at high speed and copious air/water spray, followed by complete removal of carious dentin at the cavosurface margins and lateral walls. Caries removal at the site of "risk for pulp exposure"<sup>28</sup> was performed with low-speed ISO 016 or 018 carbide burs under sterile saline irrigation. Additional teeth were excluded from the study if: (1) there was pulp exposure during caries removal, thus enabling the operator to perform indirect pulp therapy and (2) complete caries removal resulted in a class II restoration or stainless steel crown.

In teeth with mechanical pulp exposure and light red pupal bleeding, the pulp chamber was opened with a high-speed water-cooled carbide bur, followed by removal of the entire coronal pulp tissue with a sharp excavator. Thereafter, the pulp chamber was copiously irrigated with sterile saline to clear the debris. To control hemorrhage, light pressure was applied on the entrance of the canals with saline-moistened sterile cotton pellets for two to four minutes. Once hemostasis was obtained, a pulpotomy agent was applied according to treatment group.

In all groups, a layer of conventional glass ionomer cement (Ketac Fil Plus, 3M/ESPE, Seefeld, Germany) was placed before the final restoration with a non-gamma II type amalgam (Permite, SDI, Victoria, Australia). The amalgam was placed in small increments with special care not to damage the glass ionomer cement during condensation. After occlusal adjustments and burnishing, the tooth-restoration margins were etched with phosphoric acid for 30 seconds, rinsed with water for 15 seconds, dried and sealed with a thin layer of fissure sealant (Helioseal, Ivoclar/Vivadent, Schaan, Liechtenstein) to prevent short-term microleakage.<sup>29,30</sup>

**FOLLOW-UP**

Follow-up examinations were carried out by two pediatric dentistry faculty members one, three, six, 12, 18, and 24 months after treatment. The following criteria were used for the determination of clinical and radiographic success<sup>28</sup>: (1) absence of spontaneous pain and/or sensitivity to palpation/percussion; (2) absence of fistula, swelling, and/or abnormal mobility; (3) absence of radiolucencies at the inter-radicular and/or periapical regions, as determined by conventional periapical radiographs taken at all control appointments; (4) absence of pulp canal obliteration (fully obliterated canals); and (5) absence of internal or external (pathologic) resorption that was not compatible with a normal exfoliation process. To evaluate a possible correlation between indirect evidence of clinical microleakage<sup>31</sup> and clinical/radiographic failure, the marginal quality of the amalgam restorations were evaluated according to the modified United States Public Health Service (USPHS) clinical rating system.<sup>32</sup> Discoloration possibly caused by the tested MTA cements was not recorded.

Two calibrated operators, blinded to group assignment and treatment, performed all clinical and radiographic recall examinations and restoration margin assessments. A consensus was reached when disagreement arose.

**STATISTICAL ANALYSIS**

Comparative evaluations between groups regarding clinical and radiographic findings were done using the log-rank test, followed by multiple comparison tests. The cumulative survival rate was calculated using

the Kaplan-Meier method. Descriptive statistics and statistical analysis were performed using SPSS 11.5 (SPSS Inc, Chicago, Ill.) The results were considered statistically significant at  $P<.05$ .

**RESULTS**

A CONSORT diagram showing the flow of patients and pulpotomized teeth up to 24 months of follow-up is presented in Figure 1. A total of 139 molars were pulpotomized in 75 children (female to male ratio:1.25). There were dropouts (3 ProRoot MTA, 1 MTA Angelus, and 1 calcium hydroxide) throughout the follow-up period.

At 24 months, clinical evaluations using the USPHS criteria showed that approximately two percent of the teeth in the ProRoot MTA group, two percent in the MTA Angelus group and four percent in the calcium hydroxide group had amalgam restorations with ditched margins and had at least one sign of radiographic failure. No significant relationship was found, however, between marginal integrity failure and radiographic pathologies ( $P<.12$ ).

Kaplan-Meier analysis showed that the 24-month cumulative clinical survival probabilities of the ProRoot MTA, MTA Angelus, and calcium hydroxide groups were 0.973, 0.953, and 0.752, respectively (Figure 2A). Comparisons using the log-rank test showed that the clinical survival probabilities of ProRoot MTA and MTA Angelus were similar ( $P>.62$ ), and were significantly greater than that of the calcium hydroxide group ( $P=.008$  and  $P=.004$ , respectively). Throughout the follow-up period, 1 tooth in the ProRoot MTA group, two teeth in the MTA Angelus group, and seven teeth in the calcium hydroxide group presented with a fistula and were extracted (Table 1).

The 24-month cumulative radiographic survival probabilities of the ProRoot MTA, MTA Angelus, and calcium hydroxide groups were 0.974, 0.908, and 0.446, respectively (Figure 2B). The survival probabilities of ProRoot MTA and MTA Angelus were similar

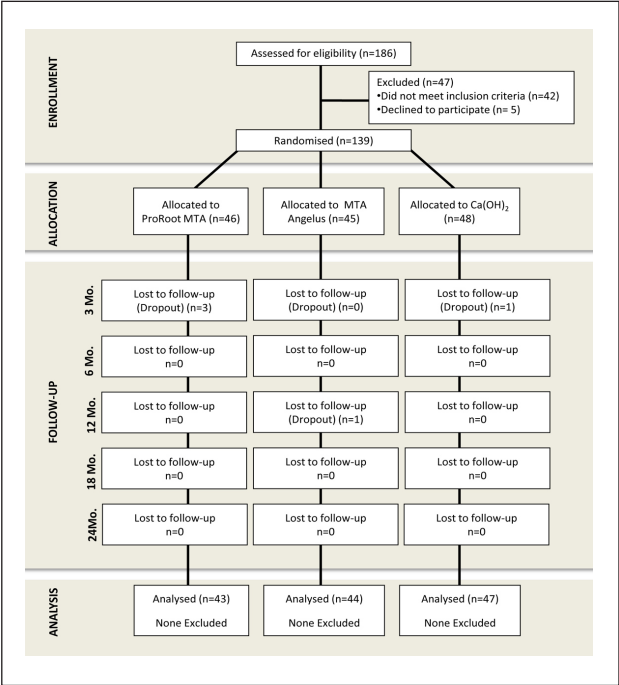


Figure 1. Flow of participants and pulpotomized teeth up to 24 months.

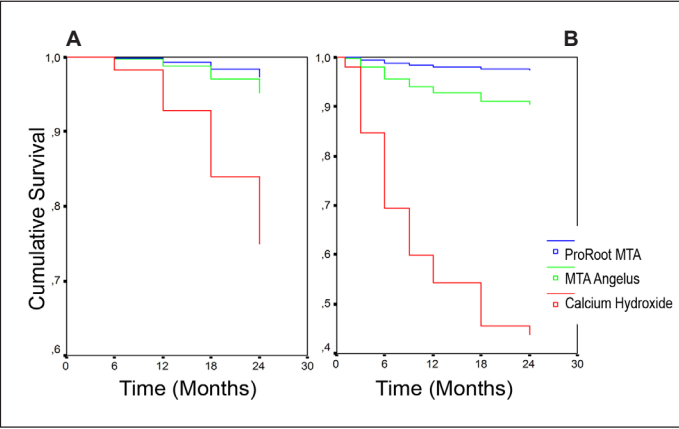


Figure 2. (A) Clinical and (B) radiographic survival probabilities of the treatment groups (Kaplan-Meier analysis).

( $P>.20$ , log-rank test), and were significantly greater than that of the calcium hydroxide group (both  $P<.001$ , log-rank test). Most radiographic failures were associated with internal resorption, which was observed in 23 teeth in the calcium hydroxide group, compared to none in the ProRoot MTA and three in the MTA Angelus groups ( $P<.001$ ). Pulp canal obliteration was observed in two mandibular molars, one in each of the MTA groups. Typical examples of radiographic findings are presented in Figure 3.

## DISCUSSION

This study evaluated the clinical and radiographic success rates of primary molar pulpotomies using 2 white MTA cements. Calcium hydroxide was selected as the control medicament both for its capability of promoting pulp repair and healing,<sup>9</sup> and because it is believed that MTA has an action similar to that of calcium hydroxide, since after hardening, the calcium oxide within MTA reacts with tissue fluids to form calcium hydroxide.<sup>33</sup> Furthermore, calcium hydroxide is a safe alternative to formocresol, which has been traditionally utilized in clinical studies as both the test and control medicament.<sup>1,23</sup> Both calcium hydroxide and formocresol have produced less favorable responses than MTA in pulpotomized primary molars.<sup>11,20,21</sup> Although better clinical and radiographic outcomes might be expected with formocresol than with calcium hydroxide as a control medicament,<sup>21</sup> a decision was made in favor of the latter, since the concerns of toxicity and mutagenicity associated with formocresol in children outweighed its potential clinical efficacy.<sup>6</sup>

In randomized clinical trials (RCTs), both the researchers and participants should ideally be blinded to the treatment group assignment. When the double-blind study model is applied to endodontic or restorative interventions, however, it quickly becomes apparent that the clinician, who is inevitably familiar with one or more the medicaments/materials being used, will not be able to adhere to a strict double-blind model.<sup>34</sup> For this reason, RCTs designed to evaluate the efficacy of such treatments are often single-blind, with only the subjects being unaware of their assignment to the study or control group.<sup>34</sup> To preserve the credibility of such trials, blinded evaluation protocols appear to be a valid and well-accepted approach, especially when different medicaments/materials are administered with the same type of intervention (ie, pulpotomy).

In the present study, the operator was blinded to the type of MTA cement, but could not be blinded to calcium hydroxide (control), since it differed from the near-identical MTA cements in color and consistency. Since calcium hydroxide had a similar radiographic appearance as the MTA cements, however, the radiographic assessments could be easily carried out in a strictly blinded fashion. Likewise, the existence of Class I amalgam restorations over the pulpotomy medicaments enabled treatment concealment during clinical evaluations.

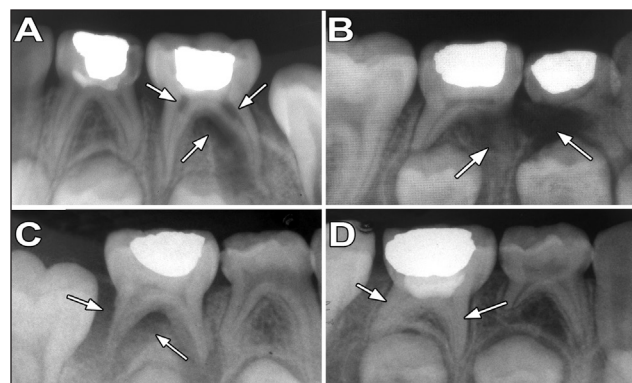
To our knowledge, no previous study has compared different white MTA cements in a RCT of primary tooth pulpotomies. There was no significant difference between the clinical and radiographic outcome of pulpotomies done with the MTA cements. Both materials showed high and similar clinical and radiographic success rates, with only two teeth from the Angelus MTA group and one tooth from the ProRoot MTA group showing clinical failure at 24 months.

There was no significant difference between the clinical and radiographic outcome of pulpotomies done with the MTA cements. Both materials showed high and similar clinical and radiographic success rates, with only two teeth from the Angelus MTA group and one tooth from the ProRoot MTA group showing clinical failure at 24 months.

**Table 1. Treatment Outcomes According to the Material Used for Pulpotomy\***

Treatment outcomes	ProRoot MTA (N=43) n (%)	MTA Angelus (N=44) n (%)	CH (N=47) n (%)
<b>Clinical</b>			
Spontaneous pain	0 (0)	1 (2)	1 (2)
Sensitivity to percussion	0 (0)	2 (5)	3 (6)
Fistula	1 (2)	2 (5)	7 (15)
Swelling	0 (0)	0 (0)	1 (2)
Abnormal mobility	0 (0)	0 (0)	0 (0)
Teeth with $\geq 1$ signs of failure	1 (2)	2 (5)	11 (23)
<b>Radiographic</b>			
Periradicular RL	0 (0)	0 (0)	11 (23)
Inter-radicular RL	0 (0)	1 (2)	16 (34)
Loss of lamina dura	0 (0)	0 (0)	14 (30)
Pathologic root resorption	0 (0)	0 (0)	1 (2)
PCO	1 (2)	1 (2)	0 (0)
Internal/external RR	0 (0)	3 (7)	23 (49)
Teeth with $\geq 1$ signs of failure	1 (2)	4 (9)	26 (55)

\* CH=calcium hydroxide; RL=radiolucency; PCO= pulp canal obliteration; RR=root resorption.



**Figure 3. Examples of radiographic failures: (A) internal resorption and inter-radicular radiolucency (calcium hydroxide/24 months); (B) external and pathologic root resorption (calcium hydroxide/24 months); (C) external root resorption and inter-radicular radiolucency (calcium hydroxide/24 months); (D) pulp canal obliteration (ProRoot MTA/24 months).**



Pulp canal obliteration (PCO) has been reported at varying degrees and frequencies in primary teeth pulpotomized with formocresol, ferric sulphate, and MTA.<sup>1,24,25,35,36</sup> According to previous reports, PCO is less frequently seen in pulpotomized teeth treated with white MTA than those treated with gray MTA.<sup>24,25</sup> In the present study, the frequency of PCO was approximately two percent in both MTA groups. This finding agrees with Agamy et al.,<sup>24</sup> who demonstrated a PCO rate of only five percent with white MTA compared to 58 percent with gray MTA, which is no longer available. Cardoso-Silva et al.<sup>25</sup> also reported that gray MTA induced a higher percentage of pulp canal stenosis, without a statistically significant difference. In their study, grey MTA induced a higher percentage of PCO with statistically significant differences ( $P<.05$ ). PCO indicates that the presence of pulp vitality increases over time and does not affect the clinical and radiographic outcome of MTA pulpotomies in the long term.<sup>1, 22,25,35</sup>

In the present study, calcium hydroxide performed significantly worse than the MTA cements, but not primarily due to internal resorption, as had been suggested.<sup>9,37</sup> The clinical evidence of fistula was regarded as a true failure, and three out of seven teeth extracted for that reason had no radiographic sign of internal resorption. As with the present study, internal resorption has been regarded as a sign of radiographic failure,<sup>9</sup> since it occurs as a consequence of osteoclastic activity in inflamed pulp.<sup>9,38,39</sup> Although a considerable number of internal resorption lesions become arrested and remain unchanged over time without interfering with physiologic root resorption, they may be accepted as failure if accompanied by other clinical signs of failure. Finally, the clinical failure rate of calcium hydroxide pulpotomies observed herein appear to be lower than those reported previously.<sup>9,40</sup> In line with the present results, other studies have reported favorable clinical outcomes in more than 80 percent of cases.<sup>41,42</sup>

In the present study, the pulpotomized teeth were restored with 1-surface (occlusal) amalgam. Although pulpally treated primary teeth should be ideally restored with stainless steel crowns to ensure an adequate coronal seal, placement of amalgam as a final restoration may be necessary in pediatric patients. The American Academy of Pediatric Dentistry guideline on pulp therapy states that a tooth receiving a pulpotomy should be restored to minimize microleakage.<sup>43</sup> An occlusal amalgam that is sealed will accomplish such results.

Holan et al.<sup>44</sup> showed that pulpotomized primary molars restored with one-surface amalgam had similar success rates to those restored with stainless steel crowns. In an attempt to delay the effects of inevitable postoperative microleakage, especially during the critical period of pulpal healing,<sup>45</sup> the study protocol stipulated confinement of the cavities to the occlusal

surface (Class I). Furthermore, all margins were surrounded by sound enamel and sealed with a fissure sealant due to the inferior resistance of amalgam to microleakage in the short term.<sup>46</sup> Guelmann et al.<sup>29</sup> showed that new amalgam restorations sealed with an unfilled sealant demonstrated significantly less microleakage than those that were not sealed after storage in an acid environment, which conformed to our primary aim of preventing microleakage in the short term. Marginal integrity assessments of sealed-over amalgam restorations were done to evaluate a possible correlation between indirect evidence of clinical microleakage and clinical/radiographic failure. Based on our results, the loss of marginal integrity—characterized by either loss of the sealant alone or loss of the sealant and ditched amalgam margins—did not correlate with the clinical and/or radiographic outcome over 24 months.

In line with these results, a recent 24-month clinical trial of MTA and Portland cements as pulpotomy medicaments failed to establish a correlation between restoration failure and treatment outcome.<sup>22</sup> Interestingly, that study utilized resin-modified glass ionomer cement as a final restoration (including proximally involved molars), which may not be expected to offer better sealing efficiency than full-crown coverage in primary teeth.

## CONCLUSIONS

Based on the results of this study, the following conclusions can be made:

1. ProRoot MTA and MTA Angelus showed high clinical and radiographic success rates as pulpotomy agents in primary molars.
2. Calcium hydroxide showed considerably less clinical and radiographic success than the MTA cements.

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