A Randomized Controlled Study of the Use of ProRoot Mineral Trioxide Aggregate and Endocem as Direct Pulp Capping Materials

Minju Song, DDS, MSD, PbD, Minji Kang, DDS, Hyeon-Cheol Kim, DDS, MSD, PbD, and Euiseong Kim, DDS, MSD, PbD

Abstract
Introduction: The purpose of the present study was to evaluate and compare the short-term clinical outcomes of direct pulp capping using ProRoot MTA (Dentsply, Tulsa, OK) or Endocem (Maruchi, Wonju, Korea) as capping materials in a prospective randomized controlled study. Materials and Methods: This study was conducted with subjects who were recruited from the pool of patients from the Department of Conservative Dentistry at the Dental College of Yonsei University, Seoul, Korea, between January and May 2013. Of the 48 teeth confirmed to be eligible for direct pulp capping, a total of 46 teeth were randomly assigned to either the ProRoot MTA or the Endocem group (23 teeth per group). Direct pulp capping was performed using these 2 materials, and clinical and radiographic evaluations were performed at 1, 2, 4, and 12 weeks after the treatments. Teeth with no response to pulp vitality test and those exhibiting clinical or radiographic signs and/or symptoms of irreversible pulpitis or pulp necrosis were considered to be failures. Results: Thirty-two patients (43 teeth) were examined at the 3-month follow-up (patient recall rate = 91.4%); 22 of these teeth were in the ProRoot MTA group, and 21 were in the Endocem group. The overall success rate was 93%, and the success rates in the ProRoot MTA and Endocem groups were 95.5% (21/22 teeth) and 90.5% (19/21 teeth), respectively. Statistical analyses of these success rates did not reveal any significant difference between the groups (P = .522). Conclusions: In this randomized controlled study, no significant difference in the short-term clinical outcomes of direct pulp capping using ProRoot MTA or Endocem as the capping material was found. Furthermore, the favorable short-term outcome success rate of 93% indicates that direct pulp capping may be a reliable treatment for pulp exposure in adult teeth. (J Endod 2014;■:1−5)

Key Words
Clinical outcome, direct pulp capping, Endocem, ProRoot MTA, randomized controlled study

Direct pulp capping is a procedure in which a medicament is placed directly over exposed dental pulp with the specific aim of maintaining pulp vitality and health (1−3). Compared with conventional endodontic therapy, direct pulp capping is a minimally invasive procedure that has numerous advantages, including the avoidance of more extensive treatment. However, the rates of successful outcomes that have been reported range from 13%−95% (4−7); hence, the treatment of pulp exposure via direct pulp capping remains controversial. Calcium hydroxide was once considered the standard for pulp capping materials and provides an option for reparative dentin formation with antibacterial properties (8, 9). However, the disadvantages of calcium hydroxide, which include dissolution over time and reparative dentin bridges containing multiple tunnel defects, might be responsible for the variable and somewhat unpredictable results that have been reported in relation to the use of this material (2, 10).

Mineral trioxide aggregate (MTA) was developed in the 1990s by Torabinejad and his coworkers at Loma Linda University (Loma Linda, CA); MTA is a bioactive silicate cement that is currently used for pulp therapy. Some studies have compared the clinical and histologic outcomes of direct pulp capping with MTA (ProRoot MTA; Dentsply, Tulsa, OK) with those of calcium hydroxide (3, 11−14). Most of these trials have reported that the clinical and histologic responses achieved through the use of MTA are similar or superior to those achieved with calcium hydroxide (3, 13, 14). MTA is hygroscopic, and its ability to set is not affected by the presence of blood or serum fluid (15). The close physiochemical seal formed between dentin and MTA provides an insoluble barrier against microleakage (16, 17). These properties of MTA may contribute to the success of direct pulp capping and the decreases in pulpal irritation, dystrophic calcification, and potential degenerative changes in the pulp that are associated with the use of calcium hydroxide (9).

Endocem (Maruchi, Wonju, Korea) is an MTA-derived pozzolan cement that was recently introduced for pulp therapy and was approved in 2012 by the US Food and Drug Administration. The chemical composition of Endocem is similar to that of MTA, and Endocem has some advantages over MTA that include rapid setting and favorable manipulation properties (18, 19). Although, like MTA, the use of Endocem has been suggested for a variety of clinical applications, Endocem was initially developed...
Consort Randomized Clinical Trial

for vital pulp therapies such as pulp capping and was designed to prevent irritation of the pulp and secondary infections (20). However, to date, only a few studies have investigated the biocompatibility and physical properties of Endocem in vitro (18, 21, 22), and no clinical studies have evaluated Endocem as a pulp capping material. Therefore, the purpose of the present study was to evaluate and compare the short-term clinical outcomes of direct pulp capping with ProRoot MTA and Endocem in a prospective randomized controlled study.

Materials and Methods

This was a preliminary prospective, randomized controlled study that was conducted with subjects who were recruited from the pool of patients from the Department of Conservative Dentistry at the Dental College, Yonsei University, Seoul, Korea, between January and May 2013. Approval for the project was obtained from the Yonsei University Committee for Research on Human Subjects (2-2012-0052), and informed consent was acquired from all participants.

Subject Enrollment and Inclusion/Exclusion Criteria

All patients who were 19 years of age or older and exhibited pulp exposure (carious or traumatic) were eligible. The teeth were subjected to periapical radiographs, periodontal probing, percussion testing, and vitality assessment with ice sticks and an electric pulp tester (Digitest; Parkell Inc, Farmingdale, NY); the teeth determined to have reversible pulpsitis were included. Teeth exhibiting signs and/or symptoms of irreversible pulpsitis or pulp necrosis, such as a history of spontaneous unprovoked toothache, a sinus tract, periodontal inflammation, excessive mobility, a crack, furcation/apical radiolucency, radiographic evidence of internal/external resorption, or calcification of the pulp chamber or canals, were excluded from the study. Teeth found to have unexposed pulp during the procedure and those that exhibited uncontrolled pulpal hemorrhage during the procedure lasting more than 10 minutes were also excluded.

Sample Size and Randomization Method

The sample size was determined using the method described by Walters (23) for comparing the means of ordinal data when the samples are presumed to display relatively normal distributions. The minimum sample size was determined to be 38 on the basis of a 15% mean difference in outcomes between the groups, a power = 0.80, and a P value <.05. To ensure minimum sample sizes of at least 19 subjects in each group at the 3-month follow-up examination, the initial goal was to enroll a total of 46 subjects based on the assumption that 20% of the patients may fail to attend the follow-up.

Of the 37 patients (48 teeth) who were confirmed to be eligible for direct pulp capping, 2 patients (2 teeth) chose not to participate. After written and verbal informed consent was obtained, a total of 46 teeth were included in the randomized controlled trial and randomly assigned to either the ProRoot MTA group or the Endocem group (23 teeth per group). Randomization was stratified based on the age of patients (≤40 or >40 years) and the site of exposure (occlusal or axial). With the 4 strata (age ≤40 and occlusal exposure, age ≤40 and axial exposure, age >40 and occlusal exposure, and age >40 and axial exposure), the clinical research coordinator assigned the material in the order registered for each patient. It was not feasible to blind the practitioners to the materials because their handling characteristics are dissimilar.

Treatment Procedure

Under local anesthesia, the tooth was scratched with 2% chlorhexidine and 75% isopropyl alcohol after rubber dam isolation and rough removal of caries via mechanical excavation with a low-speed round bur and sterile water spray. The remaining decay was scooped out with a sterile spoon excavator. When the pulp was exposed, the cavity was disinfected with 2.5% sodium hypochlorite using a syringe and a cotton pellet, the latter of which was left at the cavity. Teeth with excessive uncontrolled bleeding that lasted over 10 minutes were excluded from the study. After the bleeding was controlled, the tooth was rinsed with saline and dried with a cotton pellet. The direct pulp capping material used was either ProRoot MTA or Endocem and was selected according to the randomization.

In the ProRoot MTA group, MTA was mixed according to the manufacturer’s directions (in a 3:1 powder-to-water ratio using sterile water) and incrementally placed in a 3-mm-thick layer directly over the exposure site. A cotton pellet moistened with sterile saline was laid over the MTA to provide the moisture required for a proper set. Next, the cavity was restored provisionally with IRM Intermediate Restorative Material (Caulk Dentsply, Milford, DE). The patients returned after 1 or 2 days for the assessment of MTA hardness, and the IRM Intermediate Restorative Material was subsequently replaced with a resin-modified glass ionomer (RMGI; GC Fuji II LC, GC Corp, Tokyo, Japan).

In the Endocem group, Endocem was mixed with distilled water or saline (in a 2:1 powder-to-liquid ratio) and applied over the exposure site in a 3-mm-thick layer using the metal tip (Needle Tip; Shinwoo Dental, Gyeonggi-do, Korea) of a Centrix syringe gun (Centrix, Shelton, CT). After allowing 5 minutes for hardening, RMGI was placed over the Endocem and light cured.

Clinical and Radiographic Evaluations

Clinical and radiographic evaluations were performed at 1, 2, 4, and 12 weeks after direct pulp capping. At each appointment, the teeth were clinically assessed for pulp vitality, and periapical radiographs were taken at 4 and 12 weeks. Two investigators who did not participate in the clinical procedure blindly evaluated the radiographs of the teeth, and consensus was reached for all teeth. The teeth that exhibited pulpal vitality and did not show any clinical or radiographic signs and/or symptoms of irreversible pulpsitis and pulp necrosis were considered successes. The teeth with no response to pulp vitality test and those that exhibited clinical or radiographic signs and/or symptoms of irreversible pulpsitis or pulp necrosis were considered failures. The patients were informed to return to the office immediately if they experienced spontaneous pain that was not ameliorated with analgesics. These teeth were also considered failures, and the patients were advised to undergo endodontic treatment. When a tooth was judged to have normal pulp at 12 weeks, the tooth received a direct filling (using a bonded composite resin), an inlay/onlay (using resin or gold), or a full-veneer crown depending on the shape and the size of the cavity.

Statistical Analyses

To analyze and compare the success rates according to the pulp capping material used (ProRoot MTA vs Endocem), the Pearson chi-square test was conducted with a significance level of 0.05 using SPSS v19.0 software (IBM Corp, Somers, NY).

Results

Thirty-five patients (46 teeth) were initially included in this randomized controlled trial, and 32 patients (43 teeth) were examined...
at the 3-month follow-up (patient recall rate = 91.4%). The ages of the patients ranged from 19–79 years with a median age of 43 years (inter-quartile range = 31). Among the 43 teeth, a total of 22 teeth in the ProRoot MTA group and 21 teeth in the Endocem group were examined. A flow diagram of the subjects’ path through the phases of this randomized trial is shown in Figure 1. Table 1 lists the distributions of the analyzed cases according to the capping material used.

The overall success rate was 93%, and the success rates in the ProRoot MTA and Endocem groups were 95.5% (21/22 teeth) and 90.5% (19/21 teeth), respectively. Statistical analysis of these success rates did not reveal any significant difference between the groups ($P = .522$).

The failed cases included 1 in the ProRoot MTA group and 2 in the Endocem group. All 3 of these teeth were in patients over the age of 40 years, and all exposure sites were axial (Table 2). Of these 3 cases, root canal treatments were performed in 2 cases (cases A and C), and additional treatment was not provided for the other tooth (case B) despite the presence of periapical radiolucency on radiography and no response to pulp vitality test because the patient did not want any further treatment for this asymptomatic tooth.

### Discussion

The present study sought to evaluate and compare the short-term clinical outcomes of direct pulp capping of permanent teeth with ProRoot MTA and Endocem. This study was designed as a prospective randomized controlled trial of adult direct pulp capping that included a 3-month follow-up for the tentative evaluation of the prognoses.

In recent years, many clinical studies that have examined direct pulp capping using MTA have reported favorable results (3, 9, 13, 24). In some of these studies, the success rates of direct pulp capping of permanent teeth have been reported to exceed 90% (9, 24). However, these studies included both mature teeth and also immature permanent teeth that have high regenerative capacities. Rates of pulpal repair and pulp capping success appear to be higher for teeth with larger apical foramina and greater vascularization of the pulp in which active immune cell surveillance may increase the chance of repair and enhance the potential for vital pulpal maintenance (25). The present study showed favorable short-term outcomes with a 93% success rate in a study population that was limited to patients over 19 years of age in which the median age was 43. Therefore, our results suggested that MTA and Endocem could be successfully used for pulp capping in mature permanent teeth with further follow-up outcomes.

One of the major drawbacks of MTA is its long setting time, which might delay the completion of the treatment. Many clinical studies that have used MTA have followed a 1-visit pulp capping protocol in which permanent restorations are performed immediately after the application of MTA when proper setting of the MTA is doubted (3, 26, 27). Although adhesive dentistry has improved greatly over the last decade, there is still no clear evidence about the durability and efficiencies of bonding systems in the prevention of the microleakage of bacteria around the restoration (28). Therefore, it is imperative that the materials used to protect the pulp should form an enhanced seal to compensate for potential marginal leakage in the restoration (24).

In the present study, we followed a 2-visit pulp capping protocol for the MTA group, and 21 of 22 teeth exhibited successful outcomes. The setting time of Endocem is short (4–5 minutes), which allowed for the use of a 1-visit pulp capping procedure. The results obtained with Endocem were similar to those obtained with MTA in the present study.

In the present study, all teeth received temporary restorations (RGMI) and were followed up for 12 weeks to evaluate the short-term clinical outcomes of direct pulp capping. Temporary restorations are inferior to permanent restorations in terms of peripheral seals and resistance to occlusal pressure. However, the application of permanent restorations immediately after direct pulp capping makes subsequent procedures complicated when the teeth show signs of failure of the direct pulp capping and need root canal treatment. Therefore, short-term clinical outcomes at specific points in time should be evaluated to determine the next step in treatment. Matsuo et al (29) suggested that 3 months was adequate for tentative prognoses and the determination of the need for final restorations because the success rates of groups who received postoperative follow-ups over periods of 3–18 months are similar (range, 80%–83.3%). Moreover, Mente et al (3) showed that the late placement of permanent restorations after tooth capping with MTA does not conspicuously influence success rates; these authors observed no time-dependent decline in the success rate after capping with MTA. Therefore, the short-term clinical outcomes observed at the 3-month follow-ups were sufficient to make tentative prognoses and determinations of the final restorations in the present study.

In the present study, all 3 failed teeth were in patients over the age of 40 years (Table 2). To varying extents, older pulps exhibit degenerative changes that may be physiological and/or caused by previous operative experiences, and, therefore, the healing potential of these pulps may be reduced (30). Some studies have also

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**Figure 1.** A flow diagram of a subject’s progress through the phases of this randomized trial.

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**Table 1.** Distribution of Analyzed Cases per Filling Material Used

<table>
<thead>
<tr>
<th></th>
<th>ProRoot MTA (n = 22)</th>
<th>Endocem (n = 21)</th>
<th>Total (N = 43)</th>
</tr>
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<tbody>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>11</td>
<td>12</td>
<td>23</td>
</tr>
<tr>
<td>Female</td>
<td>11</td>
<td>9</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>$\leq 40$</td>
<td>11</td>
<td>8</td>
<td>19</td>
</tr>
<tr>
<td>$&gt; 40$</td>
<td>11</td>
<td>13</td>
<td>24</td>
</tr>
<tr>
<td>Tooth type</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anterior</td>
<td>1</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Premolar</td>
<td>8</td>
<td>9</td>
<td>17</td>
</tr>
<tr>
<td>Molar</td>
<td>13</td>
<td>8</td>
<td>21</td>
</tr>
<tr>
<td>Type of exposure</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carious</td>
<td>21</td>
<td>20</td>
<td>41</td>
</tr>
<tr>
<td>Traumatic</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Site of exposure</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
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<td>7</td>
<td>5</td>
<td>12</td>
</tr>
<tr>
<td>Axial</td>
<td>15</td>
<td>16</td>
<td>31</td>
</tr>
</tbody>
</table>

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**Table 2.** Distribution of Analyzed Cases per Filling Material Used

<table>
<thead>
<tr>
<th>Type of exposure</th>
<th>ProRoot MTA (n = 22)</th>
<th>Endocem (n = 21)</th>
<th>Total (N = 43)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carious</td>
<td>21</td>
<td>20</td>
<td>41</td>
</tr>
<tr>
<td>Traumatic</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Site of exposure</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Occlusal</td>
<td>7</td>
<td>5</td>
<td>12</td>
</tr>
<tr>
<td>Axial</td>
<td>15</td>
<td>16</td>
<td>31</td>
</tr>
</tbody>
</table>
shown that patients younger than 40 years of age have significantly better outcomes than older patients (7, 13, 31). However, these studies included immature permanent teeth, and this study was conducted exclusively on mature permanent teeth. Further studies may be required to evaluate whether age affects the clinical outcomes of direct pulp capping in mature teeth with these materials. In the 3 failed cases observed in the present study, all of the exposure sites were on the axial side and involved 2 root caries (cases A and B in Fig. 2) and 1 proximal caries (case C in Fig. 2). These results are consistent with those of some previous studies that have shown that axial exposure appears to be more unfavorable than occlusal exposure in terms of the prognoses of direct pulp capping (6, 13). Axial dentin is more permeable than the pulpal floors of class II cavities (32). Furthermore, it may be more difficult to isolate and seal axial exposures from contaminants than occlusal exposures. Moreover, class II restorations may be more vulnerable to fracture than class I restorations. In 1 case in this study (the failed case C in Fig. 2), pulp vitality was maintained after pulp capping; however, 10 weeks after direct pulp capping, the patient experienced spontaneous pain and was diagnosed with irreversible pulpitis that likely resulted from leakage from a fracture in the restoration.

Within the limited sample size of the present study, there was no significant difference in the short-term clinical outcomes of direct pulp capping with ProRoot MTA and Endocem ($P = .522$). Endocem is a newly developed material that is based on pozzolan cement, and its chemical composition is similar to that of ProRoot (CaO [46.7%], SiO$_2$ [12.8%], Al$_2$O$_3$ [5.4%], other metallic oxides, and Bi$_2$O$_3$ [11%]), which is used as a radiopacifier. Although the number of studies on the subject is limited, the biocompatibility and osteogenicity of Endocem have also been shown to be similar to those of ProRoot (18, 22). Additionally, the reduced setting time of Endocem might be associated with increases in early strength and washout resistance (18, 33).

The strength of the present study is that the use of the pulp capping materials was randomized; therefore, the clinical variables

<table>
<thead>
<tr>
<th>Case</th>
<th>Age</th>
<th>Tooth number</th>
<th>Exposure site</th>
<th>Capping material</th>
<th>Decision of failure</th>
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</thead>
<tbody>
<tr>
<td>A</td>
<td>66</td>
<td>12</td>
<td>Axial</td>
<td>ProRoot MTA</td>
<td>4 weeks</td>
</tr>
<tr>
<td>B</td>
<td>58</td>
<td>5</td>
<td>Axial</td>
<td>Endocem</td>
<td>12 weeks</td>
</tr>
<tr>
<td>C</td>
<td>67</td>
<td>19</td>
<td>Axial</td>
<td>Endocem</td>
<td>10 weeks</td>
</tr>
</tbody>
</table>

Figure 2. Failed cases A, B, and C. (A1) The preoperative radiograph of tooth #12. (A2) A radiograph showing periapical radiolucency (arrow) 4 weeks after pulp capping. This tooth was diagnosed with pulp necrosis. (B1) The preoperative radiographs of tooth #5 (star). (B2) A radiograph taken 4 weeks after the capping procedure. The pulp was vital. (B3) A radiograph showing periapical radiolucency (arrow) 12 weeks after pulp capping. (C1) The preoperative radiograph of tooth #19. (C2) A radiograph taken 4 weeks after the capping procedure. Hypersensitivity was sustained for 1 week after treatment and subsequently disappeared. (C3) At 10 weeks after treatment, the patient experienced spontaneous pain in tooth #19. A fracture of the restoration (arrow) was observed, and a diagnosis of irreversible pulpitis was made.
that may have affected healing were equally distributed between the 2 groups. In the present study, the numbers of teeth in each group were reasonably evenly distributed in terms of age and site of exposure, which may have limited a significant source of bias (Table 1). Furthermore, even if the 3-month follow-up period was sufficient, which may have limited a significant source of bias (Table 1). The numbers of teeth in each group that may have affected healing were equally distributed between the 2 groups. In the present study, the numbers of teeth in each group were reasonably evenly distributed in terms of age and site of exposure, which may have limited a significant source of bias (Table 1). Furthermore, even if the 3-month follow-up period was sufficient, which may have limited a significant source of bias (Table 1).

In conclusion, this randomized controlled study found no significant difference in short-term clinical outcomes after direct pulp capping with ProRoot MTA or Endocem materials and found the favorable short-term outcome of a 93% success rate, which indicates that direct pulp capping may be a reliable treatment for pulp exposure in adult teeth.

Acknowledgments

Supported by Basic Science Research Program through the National Research Foundation of Korea funded by the Ministry of Education, Science and Technology (2010-0021281).

The authors deny any conflicts of interest related to this study.

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