A Randomized Controlled Study of the Use of ProRoot Mineral Trioxide Aggregate and Endocem as Direct Pulp Capping Materials: 3-month versus 1-year Outcomes

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Abstract

Introduction: The purpose of this study was to assess the long-term clinical outcomes of direct pulp capping (DPC) with ProRoot MTA (Dentsply, Tulsa, OK) and Endocem (Maruchi, Wonju, Korea) as pulp capping materials. To this end, the 1-year cumulative successes of both materials were evaluated and compared with those of the 3-month outcomes in a prospective, randomized controlled trial. **Methods:** Patients were recruited from the Department of Conservative Dentistry of the Yonsei University Dental Hospital, Seoul, South Korea, from January to May 2013. Of the 48 teeth that met the inclusion criteria, 46 teeth were randomly allocated to either ProRoot MTA or Endocem groups (n = 23). Direct pulp capping was performed, and clinical and radiographic examinations were conducted over 1 year after the treatment. Survival analyses were conducted to compare the cumulative successes between ProRoot MTA and Endocem and to evaluate other clinical variables. **Results:** Forty-one teeth were recalled 1 year after the treatments (recall rate = 89.13%). There were no significant differences between the cumulative successes of ProRoot MTA and Endocem in either log-rank or Cox proportional hazard regression analyses (P > .05). Among the other clinical variables, cavity type (class I, II, III vs class V) was determined to be significant in both the log-rank test (P = .001) and Cox regression analysis (P = .006). **Conclusions:** Both ProRoot MTA and Endocem exhibited similar cumulative successes as direct pulp capping materials up to 1 year. The teeth restored with class V cavities exhibited significantly lower cumulative success rates after direct pulp capping compared with the teeth restored with other types of cavities. *(J Endod 2015;41:1201–1206)*

Key Words

Direct pulp capping, Endocem, ProRoot MTA, randomized controlled trial, survival analysis

Direct pulp capping (DPC) is a procedure that treats exposed pulp by directly covering it with biocompatible materials (1). By separating the pulp from bacteria and noxious stimulus, DPC aims to maintain the vitality of the pulp rather than removing it. In this regard, the selection of appropriate pulp capping material that provides sufficient sealing and biocompatibility is an important prerequisite to achieving predictable DPC outcomes (2–4).

Calcium hydroxide (CH)-based materials were once widely used in DPC; however, because these materials do not sufficiently satisfy the requirements in terms of sealing and biocompatibility (1, 5–8), their success rates have exhibited wide fluctuations. Moreover, mineral trioxide aggregate (MTA), a calcium silicate–based cement, elicited remarkable improvements in DPC outcomes (1, 5, 8–10) because of its superior biocompatibility and sealing ability relative to other materials (11–13). However, several limitations remain regarding the use of conventional MTA (ProRoot MTA; Dentsply, Tulsa, OK) as capping material including poor manipulability and long setting times (14–16) that restrict the broader application of DPC. For these reasons, a recently introduced fast-setting pozzolan-based MTA (Endocem; Maruchi, Wonju, Korea) is gaining attention as an alternative capping material for its high manipulability, fast setting properties, and acceptable biologic responses (15–18).

However, it should be noted that there is still a lack of clinical evidence to guarantee the performance of Endocem as a capping material. Although our previous study confirmed the clinical outcome of Endocem up to 3 months (19), when considering that the cumulative success of DPC could experience alterations over time (1, 5), a 3-month follow-up period would not be sufficient to guarantee the long-term prognosis of the capping materials. Therefore, more reliable clinical evidence, particularly long-term results of at least 1 year, should be supplemented in the literature to support the clinical use of Endocem in DPC.

In addition, from the perspective of the levels of evidence, there are still few high-quality clinical trials that have investigated DPC in the current endodontic literature (20). Most studies have been conducted with nonrandomized controlled designs (ie, case-controlled studies or retrospective studies) or sample sizes that

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were too small to identify statistical significance (less than 20 subjects) or without consolidated standards (21, 22). Therefore, clinical studies with higher levels of evidence are strongly needed to promote a better understanding on the prognosis of DPC.

The purpose of this study was to assess the long-term clinical outcome of DPC with ProRoot MTA and Endocem as pulp capping materials in relation to the follow-up period after DPC. To accomplish this goal, the 1-year cumulative successes of both materials were evaluated and compared with the preceding 3-month outcomes (19) in a prospective, randomized controlled trial (RCT) based on the survival analysis.

Materials and Methods

This study was approved by Yonsei University Committee for Research on Human Subjects (2-2012-0052) and conducted in accordance with the CONSORT 2010 statement (23). Among the patients who attended the Department of Conservative Dentistry, Yonsei University Dental Hospital, Seoul, Korea, from January to May 2013, 37 patients (48 teeth) met the inclusion and exclusion criteria of this study and were initially assessed for eligibility in this study. The risks, benefits, and alternatives of the treatment were explained, and written informed consent was obtained from each patient with the exception of 2 patients (2 teeth) who declined involvement in this trial. Ultimately, 35 patients (46 teeth) were included and randomly assigned to either the ProRoot MTA or Endocem groups and received the allocated interventions.

Inclusion and Exclusion Criteria

The inclusion criteria were as follows:

1. Patients aged older than 19 years
2. Permanent teeth diagnosed with reversible pulpitis
3. Teeth exhibiting direct pulp exposure from trauma or dental caries

The exclusion criteria were as follows:

1. Patients aged younger than 19 years
2. Primary teeth
3. Teeth diagnosed with irreversible pulpitis or pulp necrosis
4. Teeth exhibiting clinical and/or radiographic signs of chronic periodontitis, cracked teeth, internal/external root resorption, or excessive pulp canal obliteration
5. Teeth showing persistent pulpal hemorrhage after receiving 10 minutes of sodium hypochlorite dressing

To discern the eligibility of each subject based on the previously described criteria, clinical and radiographic examinations were conducted including periapical radiographic assessment, mobility, percussion, bite tests, periodontal probing, and pulp sensibility tests with ice sticks and electric pulp testers (Digitest; Parkell Inc, Farmingdale, NY). The teeth were diagnosed with irreversible pulpitis or pulp necrosis when they exhibited relevant signs and symptoms, such as present or previous history of spontaneous pain, sinus tract, prolonged response or no response to the pulp sensibility test, or apical radiolucency on the periapical radiograph.

Sample Size Calculation

Before patient recruitment, the sample size was calculated by the method of Walters (24) with the assumption of the relatively normal distributions of the sample. With the expectation of a 15% mean difference between the control (ProRoot MTA) and experimental groups (Endocem), the minimum number of subjects needed to induce statistical significance ($P < .05$) was calculated as 38 with a power of 0.80. Considering a maximum of 20% follow-up loss, the sample size required in this study was ultimately estimated to be 46 subjects (23 subjects for each group).

Randomization, Allocation Concealment, and Blinding

By combining the 2 variables of patient age (>40 or ≤40 years) and exposure site (occlusal surface or axial surface), 4 strata (occlusal surface and age >40, occlusal surface and age ≤40, axial surface and age >40, and axial surface and age ≤40) were created for this study. Based on this stratification, an independent research coordinator randomly allocated each patient to either the ProRoot MTA or the Endocem group. Because the capping materials were different in terms of appearance and handling characteristics, allocation concealment and blinding to the clinical practitioners were not possible; therefore, the assignment was blinded only to the patients (single-blinded).

Treatment Protocol

After local anesthetic injection and rubber dam isolation, the tooth surfaces were disinfected by scrubbing with 2% chlorhexidine and 75% isopropyl alcohol before the excavation of the caries. Carious dentin was initially removed with round burs and low-speed handpieces under sterile water spray, and the remaining soft dentin was manually removed with a sterile spoon excavator. After complete caries excavation, the exposed pulp was disinfected with 2.5% sodium hypochlorite irrigation and a soaked cotton pellet. Teeth exhibiting adequate pulpal hemostasis after 10 minutes of sodium hypochlorite dressing were randomly allocated to each material group.

In the ProRoot MTA group, MTA was mixed according to the manufacturer's instructions (1:3 water/powder ratio) and applied on the pulp exposure site via a sterile amalgam carrier. Basically, the capping materials were placed with a thickness of 3 mm, but in several class II or V cavities, which did not provide sufficient cavity depth, every attempt was made to maintain the thicknesses of the capping materials as close as possible to 3 mm. Cotton pellets soaked with sterile saline were placed on top of the MTA, and the cavity was temporarily sealed with intermediate restorative material (IRM; Caulk Dentsply, Milford, DE). One or 2 days after DPC, the cavity was opened, and the setting status of MTA was confirmed. After the confirmation, the remaining cavity was restored with resin-modified glass ionomer (RMGI; GC Fuji II LC, GC Corp, Tokyo, Japan).

In the Endocem group, Endocem was mixed according to the manufacturer's instructions (1:2 water/powder ratio) and placed on the pulp exposure site using a Centrix syringe gun (Centrix, Shelton, CT) and a needle tip (Shinwoo Dental, Gyeonggi-do, Korea). After 5 minutes of Endocem hardening, the remaining cavity was immediately restored with RMGI.

In both groups, the teeth were finally restored with direct resin filling, an inlay/overlay, or a single crown when the pulp vitality was maintained without specific complications 3 months after DPC.

Outcome Assessment

The patients were recalled periodically at 1, 2, 4, and 12 weeks, 6 months, and 1 year after the treatments. To determine the successes and failures of the treatment, clinical and radiographic examinations were conducted at each appointment. Periapical radiographs were blindly evaluated by 2 independent examiners who were not involved in the clinical procedure.

Treatment success was defined by cases in which the tooth exhibited a positive response to the pulp sensibility test without any evidence of irreversible pulpitis or pulp necrosis in either the clinical or