Outcomes of Direct Pulp Capping by Using Either ProRoot Mineral Trioxide Aggregate or Biodentine in Permanent Teeth with Carious Pulp Exposure in 6- to 18-Year-Old Patients: A Randomized Controlled Trial

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Abstract

Introduction: This study aimed to compare the success rates of direct pulp capping (DPC) by using either ProRoot Mineral Trioxide Aggregate (MTA) or Biodentine in the cariously exposed permanent teeth of 6- to 18-year-old patients. Gray discoloration was also evaluated. **Methods:** Fifty-nine cariously exposed permanent teeth, including teeth with diagnosis of normal pulp, reversible pulpitis, or irreversible pulpitis, early periapical involvement, and exposure size of up to 2.5 mm, were included. Each patient with only 1 cariously exposed tooth was randomly allocated to DPC with either ProRoot MTA ($n = 30$) or Biodentine ($n = 29$). Patients were recalled every 6 months. Clinical and radiographic examinations were used to determine success. **Results:** Fifty-five patients (mean age, 10 $\pm$ 2 years), 27 treated with ProRoot MTA and 28 with Biodentine, were included in the analysis. At mean follow-up of 18.9 $\pm$ 12.9 months, the success rate was 92.6% with ProRoot MTA and 96.4% with Biodentine ($P > .05$; difference, 4%; 95% confidence interval [CI], –8% to 16%). Biodentine was non-inferior to ProRoot MTA. Failures were distributed equally in all categories of pulpal diagnosis and occurred in teeth with no periapical involvement and small exposures (0.5 mm). The survival probabilities of DPC with ProRoot MTA and Biodentine were 0.92 (95% CI, 0.73–0.98) and 0.96 (95% CI, 0.80–0.99). No significant difference was observed between them ($P > .05$). Gray discoloration was observed only with ProRoot MTA (55%). **Conclusions:** Biodentine was non-inferior to ProRoot MTA when used as a DPC material for cariously exposed permanent teeth of 6- to 18-year-old patients. However, Biodentine did not cause any gray discoloration in this study. *(J Endod 2017;■:1–8)*

Key Words

Biodentine, cariously exposed, direct pulp capping, permanent teeth, ProRoot MTA

Significance

ProRoot MTA and Biodentine can be used as a DPC material. Biodentine did not cause discoloration. Teeth with carious exposure, irreversible pulpitis, or early periapical involvement or exposures up to 2.5 mm should not be absolute contraindications for DPC.

Promising evidence of the success of direct pulp capping (DPC) has increased tremendously during the past few decades. One of the reasons behind this increased success is the introduction of the first calcium silicate cement (CSC), gray mineral trioxide aggregate (MTA), by Torabinejad and Chivian (1) in the 1990s. MTA appears to be more effective than calcium hydroxide (CH) in maintaining long-term pulp vitality (2). Favorable properties of MTA include significant reduction in pulpal inflammation and improved dentin bridge quality (2). However, MTA has many disadvantages, including long setting time, poor handling properties, high cost, and the potential for tooth discoloration (3, 4). Although white MTA was later developed to overcome the severe discoloration caused by the original gray MTA, one study found tooth discoloration in 13.6% of cases after DPC (5). Tooth discoloration can be problematic, especially in the esthetic region, resulting in more complicated procedures such as internal bleaching, which can jeopardize the vitality of the tooth (6). Moreover, the discolored tooth may be incorrectly recognized as a necrotic tooth.

Continued searching for alternatives has been ongoing for some time. In 2009, Biodentine, a new CSC with the same active by-product (CH) to that of MTA, was

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0099-2399/$ - see front matter

https://doi.org/10.1016/j.joen.2017.10.012

introduced. Biodentine has shorter setting time, and the manufacturer of Biodentine claims that it has better handling properties (7). In *in vitro* studies, Biodentine caused less discoloration than did white MTA (8, 9); however, the evidence from clinical studies in humans is limited. Previous *ex vivo* histologic studies in animals (10, 11) as well as histologic and radiographic studies in humans have demonstrated favorable results of Biodentine used as a DPC agent (12, 13). However, there has been only one recently published randomized controlled trial aimed to compare DPC by using either MTA or Biodentine in young permanent teeth of 7- to 9-year-old patients (14). In that study, only teeth with inadvertent mechanical exposure, no spontaneous pain indicating irreversible pulpitis, no periapical radiolucency, and exposure size of not more than 1 mm were included. However, variation exists regarding the indications for DPC in different studies.

Although the American Association of Endodontists has defined DPC as a procedure that should be performed only on a tooth with mechanical or traumatic exposure (15), several studies have reported success of DPC of between 67% and 100% in teeth with carious exposure (5, 16–19). In addition, the commonly recommended diagnoses for DPC in previous studies were normal pulp or reversible pulpitis with no periapical involvement (16, 19). Nevertheless, 1 case series reported high success (96.4%) of DPC in teeth with irreversible pulpitis with widened periodontal ligament (PDL) space and periapical radiolucency (17). Moreover, the recommended exposure sizes for DPC in previous studies varied greatly from pinpoint to 2.5 mm in diameter (16, 18, 20). Currently, evidence on the outcome of DPC on teeth with more challenging clinical criteria, as well as on newer CSC capping materials, is still limited.

Therefore, this randomized controlled trial aimed to compare the outcomes of DPC by using either ProRoot MTA or Biodentine in the cariously exposed permanent teeth of 6- to 18-year-old patients, including teeth with diagnoses of normal pulp, reversible pulpitis, or irreversible pulpitis, teeth with diagnoses of normal pulp, reversible pulpitis, or irreversible pulpitis, and teeth with exposure size of up to 2.5 mm. In addition, gray discoloration was evaluated.

Materials and Methods

Study Design

A non-inferiority randomized controlled trial was conducted to compare DPC by using ProRoot MTA (control group) and Biodentine (test group) in cariously exposed permanent teeth. Teeth were randomly assigned to the groups by using a randomization table with a block size of 4.

Participants

Participants were recruited from 6- to 18-year-old American Society of Anesthesiologists I or II patients who attended the Pediatric Dentistry Clinic, Faculty of Dentistry, Chiang Mai University between October 2012 and November 2016. One permanent tooth with deep caries per patient was included in the study. Clinical inclusion criteria were the following:

1. The tooth responded positively to cold test with Green Endo-Ice (Coltene/Whaledent, Cuyahoga Falls, OH), leading to a preoperative diagnosis of normal pulp, reversible pulpitis, or irreversible pulpitis;
2. The tooth had no associated swelling, pus exudate, fistula, or abnormal mobility;
3. The tooth had a pulp exposure that was not larger than 2.5 mm in diameter, as measured by a sterilized preformed wire;
4. The tooth had vital pulp, judged by its appearance, including its color and texture;
5. The tooth could have any pulpal bleeding controlled within 10 minutes; and
6. The tooth could be restored with resin composite, amalgam, or stainless steel crown (SSC).

Radiographic inclusion criteria were the following:

1. Presence of caries radiolucency penetrating into three fourths or more of the entire dentin thickness and
2. No prominent radiolucency in the furcation or periapical regions, internal or pathologic external root resorption, or calcification/or pulp canal obliteration.

It must be noted that the presence of early periapical lesions such as widened PDL space or condensing osteitis was not considered an exclusion criterion for this study.

Ethics

This study was approved by the Human Experimentation Committee of the Faculty of Dentistry, Chiang Mai University, Chiang Mai, Thailand and registered in the Thai Clinical Trials Registry. The study was explained to both the patients and their legal guardians, and the legal guardians signed assent and informed consent forms after they agreed to participate.

Sample Size

Sample size was estimated following the formula proposed by Bouman et al (21). According to the study of Bogen et al (16), the success rate for DPC using MTA was 98%. Because of the lack of success rate evidence for DPC with Biodentine, the success rate for Biodentine was assumed not to be less than that of MTA. With 15% non-inferiority limit, 80% precision of test, and 5% type I error, the required sample size was 22 teeth per material group. Twenty percent of the required sample size was added to compensate for dropout, resulting in a sample size of 28 teeth for each group.

Intervention

Patients were blinded to the material group. The teeth were treated by 8 unblinded postgraduate students following the same strict protocol under supervision of 1 instructor. Topical anesthesia (One Touch; Hager Worldwide, Concord, Ontario, Canada) was applied at the injection site. Four percent articaine with 1:100,000 epinephrine (Septanest SP; Septodont, Saint-Maur-des-Fossés, France) was administered, and the tooth was isolated with rubber dam. In each tooth, a cavity was prepared by using a high-speed round diamond bur, and caries was removed by using a low-speed round steel bur and a spoon excavator. When the pulp exposure met the inclusion criteria, pulp tissue was irrigated with 2.5% sodium hypochlorite (NaOCl). Bleeding was then controlled with 2.5% NaOCl-moistened cotton pellets and evaluated every 2 minutes. The time used to control bleeding was recorded for each tooth.

Then the materials were mixed according to the manufacturer's instructions. In the ProRoot MTA (Dentsply, Tulsa, OK) group, a 1.5-mm thickness of ProRoot MTA was placed on the pulp exposure site and surrounding dentin. Then resin-modified glass ionomer cement (Vitrebond; 3M ESPE, St Paul, MN) was placed immediately over the ProRoot MTA as a base material.

In the Biodentine (Septodont, Saint-Maur-des-Fossés, France) group, Biodentine was placed as a pulp dressing as well as a base material and allowed to set, usually in 12 minutes. All teeth were restored with resin composite, amalgam, or an SSC, depending on the amount of