Comparative Analysis of 2 Calcium Silicate–based Cements (Biodentine and Mineral Trioxide Aggregate) as Direct Pulp-capping Agent in Young Permanent Molars: A Split Mouth Study

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Abstract

Introduction: The purpose of this study was to compare Biodentine and mineral trioxide aggregate (MTA) for direct pulp capping in young permanent molars by clinical and radiographic evaluation in 7- to 9-year-old children. **Methods:** In 50 patients, 29 patients with bilateral asymptomatic first permanent molars with carious involvement were selected. According to split mouth design, these patients were then divided into 2 groups, Biodentine group (right side) and MTA group (left side). The pulp-capping procedure was performed by using Biodentine and MTA in 58 asymptomatic bilateral permanent molars with pulp exposure. At each recall (baseline, 6 and 12 months), treatment outcome was assessed clinically through pulpal sensitivity tests as well as radiographically to evaluate dentin bridge formation. **Results:** The study reported 100% success rate with both Biodentine and MTA at baseline and 6- and 12-month follow-up on the basis of clinical and radiographic parameters. These findings were statistically non-significant ($P < .05$) between both groups (Biodentine and MTA). Radiographically, dentin bridge formation was not evident with both groups at baseline, but it was evident after 6- and 12-month follow-up. These findings were statistically non-significant ($P < .05$) in both Biodentine and MTA groups. **Conclusions:** This study reported 100% success rate with both MTA and Biodentine when used as direct pulp-capping agent in first permanent molars in 7- to 9-year-old children. The major limitations of the study were smaller sample size and short follow-up period. *(J Endod 2017;■:1–7)*

Key Words

Biodentine, dentin bridge, direct pulp capping, MTA, permanent molars

Significance

Direct pulp-capping procedure involves the application of a medicament or dressing to the exposed pulp in an attempt to preserve its vitality. MTA and Biodentine act as perfect direct pulp-capping agents in young permanent molars.

The primary objective of pulp therapy is to maintain integrity and health of pulp tissue. It is desirable to maintain pulp vitality whenever possible (1, 2). The healing process of pulp occurs in the form of tertiary dentinogenesis. Vital pulp therapy techniques for permanent teeth are indirect pulp capping, direct pulp capping (DPC), and pulpotomy (3). The rationale behind vital pulp therapy is to maintain the vitality of the dental pulp and to stimulate the remaining pulp to regenerate the pulp-dentin complex (tertiary dentinogenesis). Tertiary dentinogenesis is particularly important in the young permanent tooth with incomplete apical root development (4, 5).

The definition of DPC is "treatment of an exposed vital pulp by sealing the pulpal wound with a dental material placed directly on mechanical or traumatic exposure to facilitate the formation of reparative dentin and maintenance of vital pulp" (3, 6).

In humans, success rate ranges from 30% to 85% in 2- to 10-year retrospective studies (7–9). The success rate of DPC is high in immature permanent teeth. The immature pulpal tissue after pulp-capping procedure allows a favorable tissue response followed by dentin bridge formation (10).

In 1756, Plaff described the first method of capping exposed pulp by using gold foil. In 1921, Dätwyler performed the first scientific clinical study to compare different capping materials (11). In the literature, various materials have been suggested for DPC such as calcium hydroxide, zinc oxide–eugenol cement, polycarboxylate cement, corticosteroids, inert materials (isobutyl cyanoacrylate and tricalcium phosphate ceramic), bonding agents, and glass ionomer cement. Mineral trioxide aggregate (MTA), Biodentine, stem cells, propolis, novel endodontic cement, Emdogain, and TheraCal are some of the newer materials used for pulp capping (12). Calcium hydroxide is a benchmark medicament for vital pulp therapy (3). Both clinically and histologically it has been found to produce satisfactory results in DPC (2). The presence of tunnels in dentin barrier, extensive dentin formation obliterating the pulp chamber, high solubility in oral fluids, and lack of adhesion and degradation after acid etching are some of the limitations reported with calcium hydroxide (3). Because of these disadvantages of calcium hydroxide, other materials have been proposed for DPC procedure during recent years such as MTA and Biodentine.

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MTA is a calcium silicate–based cement composed of tricalcium silicate, tricalcium aluminate, tricalcium oxide, silicate oxide, and other mineral oxides. MTA, like calcium hydroxide, induces dentin bridge formation. It has been used for pulp capping as a replacement for calcium hydroxide–based materials because it has demonstrated a promising clinical outcome (13, 14). The shortcomings of MTA such as difficult handling characteristics, long setting time, high cost, and potential of discoloration led to the development of new calcium silicate cement, namely Biodentine (Septodont, Saint-Maur-des-Fosses, France) (5, 15). Biodentine is a bioactive dentin substitute composed of powder components of tricalcium silicate, calcium carbonate, and zirconium oxide. The water-based liquid contains calcium chloride as the setting accelerator and water-reducing agent (16, 17).

The aim of this study was to compare Biodentine and MTA for DPC in young permanent molars by clinical and radiographic evaluation in 7- to 9-year-old children. The objective of this study was to determine dentin barrier formation with MTA and Biodentine by radiographic examination.

The null hypothesis (H0) considered for this study states that there was no difference in the success rate and dentin barrier formation with MTA and Biodentine when used as DPC agents in young permanent molars. Thus, if P1 and P2 are the proportion of patients with successful outcome and dentin barrier formation after 6 and 12 months with use of MTA and Biodentine as DPC agents, respectively, then

$$H0 : P1 = P2$$

Materials and Methods

Subject Enrollment

The institutional review board ethics committee gave ethical approval for this study (TDC/IRB-EC/26/2012). All procedures performed in this study involving human participants were in accordance with the ethical standards of the institutional review board ethics committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. A pilot study was carried out in the Department of Paedodontics and Preventive Dentistry with 5 patients who had decayed bilateral first permanent molars. In the pilot study, 3-month and 6-month follow-ups were done.

The sample size was determined by comparing the means of ordinal data when the samples are presumed to display relatively normal distributions. The minimum sample size was determined to be 100 (50 in each group) on the basis of 15% mean difference in outcomes between groups, power = 0.80, and P value < .05. In this study, 50 patients (100 molars) 7 to 9 years of age with bilateral involvement of first permanent molars in maxillary or mandibular arch were initially included. Before enrollment in the study, 1 of the parents or legal guardians was explained the purpose of the study and gave written consent for the same. The diagnostic instruments aided the conduction of dental examination. All first permanent molars were evaluated clinically and radiographically according to the inclusion and exclusion criteria. Intraoral periapical radiographs were standardized by using the paralleling technique. All teeth were examined to ensure an absence of periapical lesion or periapical pathology. The vitality of all teeth was tested and evaluated with a digital electrical pulp tester (Model DY310; Denjoy Dental Co, Ltd, Hunan, China) (18, 19).

Inclusion and Exclusion Criteria

The inclusion criteria were pinpoint inadvertent pulp exposure during caries excavation, bleeding controlled under pressure at exposure site, and vital pulp. Radiographically, the inclusion criterion was radiolucency involving enamel, dentin, and approaching the pulp. The exclusion criteria were unilateral carious first permanent molars, uncontrollable bleeding, non-vital pulp, large pulp exposure (more than 1 mm), presence of spontaneous pulpal pain, intraoral or extraoral swelling, sinus tract formation, and carious pulpal exposure. Radiographically, the exclusion criteria were pulp calcification, internal or external root resorption, and periapical radiolucency.

Bilateral asymptomatic first permanent molars with carious involvement were enrolled in the study and were assigned to DPC procedure. In this study, the treatment modalities were randomly assigned to 1 within-patient experimental unit. The DPC procedure was randomly allocated to half of each patient's dentition, divided by the mid-sagittal plane. The randomization procedure was performed before clinical procedure by using split mouth study design in which 29 patients with 58 carious involved molars were then divided into 2 groups, Biodentine group (right side) and MTA group (left side).

Treatment Procedure

A single operator performed all DPC procedures in a single sitting. After local anesthesia administration (Lignox 2% ADR; Warren Pharmaceutical Pvt Ltd, Mumbai, India), rubber dam (Hygienic; Coltene/Whaledent AG, Altstätten, Switzerland) isolation was done. Later the tooth was pumiced with a rubber cup at low speed (20). Carious lesion was removed by using a 3-step procedure (21, 22) (Fig. 1):

1. High-speed carious enamel removal with a round diamond bur–BR31 (Mani Inc, Utsunomiya, Japan)
2. Mechanical curettage of carious dentin with low speed powered no. 05 and no. 08 carbide burs (SS White, Lakewood, NJ)
3. Final dentin curettage by using sharp no. 130 spoon excavator (Dentsply Maillefer, Ballaigues, Switzerland)

Application of pressure to the exposure site with a cotton pellet moistened with saline controlled the bleeding (22–24). If bleeding persisted, it was controlled with a cotton pellet soaked in 3% sodium hypochlorite (Amdent AB, Mumbai, India), which is also a cavity disinfectant (24, 25). If bleeding persisted after this procedure, the tooth was not included in the study. In this study, Biodentine and grey MTA (Angelus Industria de Productos Odontologicos S/A, Londrina, Brazil) were used for DPC. In Biodentine group, Biodentine was applied to the pulp exposure site with a plastic filling instrument. According to the manufacturer's instructions, Biodentine was manipulated with CapMix (3M ESPE, Seefeld, Germany) and filled in the entire cavity. After 3 months, Biodentine was partially removed, leaving 1-mm layer of Biodentine intact. The permanent restoration was then done by using composite resin restorative material (25). In MTA group, a layer of MTA was placed with the help of plastic filling instrument over the pulp exposure. According to the manufacturer's instructions, MTA was manipulated. In the cavity, resin-modified glass ionomer restoration (Vitremer; 3M ESPE) was done over MTA layer. After 3 months, permanent restoration was done by using composite resin restorative material (Filtek Z350 XT Universal Restorative; 3M ESPE) (22).

Clinical and Radiographic Evaluation

Clinical and radiographic follow-ups were carried out for both groups at baseline and 6 and 12 months (Fig. 2 and Fig. 3).

The treatment was considered to be clinically successful when the tooth remained asymptomatic and vital with a standard response to electrical pulp vitality test. The treatment was considered to be