



**COMPARATIVE EVALUATION OF CLINICAL SUCCESS BETWEEN TWO
DIFFERENT PULP CAPPING MATERIALS USED FOR INDIRECT PULP
CAPPING IN PERMANENT MOLARS- AN IN VIVO STUDY**

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ABSTRACT

Aim:

To evaluate the clinical efficacy of Biodentine and Mineral trioxide aggregate as pulp capping materials for indirect pulp capping in carious permanent teeth.

Materials and Methods:

Twenty-four molars of twenty-four patients with deep caries lesions, diagnosed with reversible pulpitis were subjected to indirect pulp capping treatment. They were randomly divided into two groups, Biodentine group (12 teeth) or MTA group (12 teeth). Lot randomization of two was employed to allocate the treatment materials. Patients were

recalled at one, three and six months to evaluate the clinical success of the treatment outcome.

Results:

In statistical trial/study, the pulp capping materials gave different success rate, 100% success in the Biodentine group and 91.67% success in MTA group.

Conclusion:

In our study in the materials tested at 1 month, 3 month and 6-month follow-up, - Biodentine is better than MTA.

Clinical Significance:

The findings of this study could promote the reliable pulp capping material for treatment of deep carious lesions by conservative approach rather than opting endodontic management.

Keywords: Indirect pulp capping, MTA, Biodentine

INTRODUCTION

Concepts and treatment principles of deep carious lesions are an area of debate and constant change because the traditional concept of complete caries removal in very deep preparation has been challenged. Complete carious dentin removal may not be a prerequisite to arrest caries progression. Inadvertent exposure of the pulp in an attempt to completely remove caries would result in direct ingress of microorganisms into the pulp which could substantially reduce the successful outcome. Studies reveal that residual microorganisms in dentin after superficial caries removal could evoke a mild inflammatory response in the pulp which is considered beneficial for pulp regeneration.¹ Management of the deep carious lesion should be aimed at resolution

of the inflammation and preservation of pulp vitality.²

Indirect pulp capping is a procedure in which only infected dentin is removed, leaving a thin layer of affected dentin as complete caries removal could result in pulp exposure and lining the cavity floor with a suitable capping material and maintenance of a patent seal against microleakage by an intact restoration ensuring complete lesion sterilization and tissue regeneration.³ Indirect pulp capping is performed in one step or two step procedures decided by case selection and clinical requirement.⁴

The search for an ideal pulp capping material has led researchers to investigate a plethora of dental materials. These include calcium hydroxide (CH), zinc oxide, calcium phosphate, zinc phosphate and

polycarboxylate cement, calcium tetracycline chelate, antibiotic and growth factor combination, calcium phosphate ceramics, emdogain, bioglass, cyanoacrylate, hydrophilic resins, hydroxyapatite, resin modified glass ionomer and mineral trioxide aggregate (MTA).⁵

Numerous materials have been used throughout the years for pulp capping. Calcium hydroxide is considered to be traditional and regarded as the evidence based universal standard material for the vital pulp therapy. Desirable characteristics of Calcium Hydroxide include initial high alkaline pH, which is responsible for stimulating fibroblasts and enzyme systems. Calcium Hydroxide acts by promoting the pulp tissue defence mechanism and repair by initial matrix formation by newly differentiating odontoblast type cells, the proliferation of extracellular matrix vesicles, and subsequent calcification followed by mineralization process.^{6,7} The drawbacks of Calcium Hydroxide comprise weak marginal adaptation to dentin, degradation and dissolution over time. Dentin formation subjacent to Calcium Hydroxide can also characterize tunnel defects. Histologically Calcium Hydroxide demonstrates cytotoxicity in cell cultures and induces cell apoptosis. However, long-term clinical

studies have shown that Calcium Hydroxide products are resorbable over time and dimensionally unstable.⁸⁻¹⁰

MTA is a calcium silicate-based cement that was developed in 1993. It is composed of tricalcium silicate, tricalcium aluminate, tricalcium oxide, silicate oxide, and other mineral oxides.¹¹ Mineral trioxide aggregate (MTA) is a calcium silicate material-based pulp capping agent. MTA stimulates hard tissue formation by sequestering growth factors and cytokines embedded in the surrounding dentin matrix. MTA demonstrates excellent marginal adaptation to dentin.¹² However, its long setting time, poor handling properties, high material cost, and the discoloration potential remain a challenge for using as an ideal pulp capping material.¹³

Biodentine is an improved calcium silicate-based cement that was introduced in 2009. The powder components include tricalcium silicate, calcium carbonate, and zirconium oxide. The liquid contains calcium chloride, which is used as a setting accelerator and water-reducing agent. It sets in approximately 12 min and causes significantly less tooth discoloration.¹⁴ Biodentine promoted a significantly higher amount of reparative dentin formation without any pulpal inflammation.¹⁵⁻¹⁷

However, there is a lack in studies that evaluate the clinical outcome of indirect

pulp capping with Biodentine and MTA. The study reported herein comprised a clinical trial to evaluate the clinical efficacy of Biodentine and MTA as pulp capping materials for indirect pulp capping in permanent teeth.

MATERIALS AND METHODS

Study Design and Participants

This was a randomized clinical trial with 2 parallel experimental groups. The project was evaluated and approved by the ethics committee of the Karpaga Vinayaga Institute of dental sciences. The selected patients were adults with age between 19 to 40 years. All patients were informed of the benefits, risks, and alternative treatment choices before enrolment in the trial. All participants signed to give their assent, and signed the informed consent form. All the procedures were performed in the Department of conservative Dentistry and Endodontics of Karpaga Vinayaga Institute of dental sciences, located in Chengalpet district, Tamilnadu, India.

Inclusion and Exclusion Criteria

The inclusion criteria were patients between 19 and 40 years of age with deep carious lesion not exposing pulp in a permanent molar, with complete radicular growth, and with pulpal testing that was compatible with normal pulp or reversible pulpitis. The exclusion criteria were patients with Irreversible pulpitis, Apical

Periodontitis, systemic and/or neurologic pathology, teeth with radiologic signs of internal resorption or pulpal calcifications, no restorable teeth, and pulpal bleeding on carious exposure.

Determination of the Sample Size

The sample size was determined 12 per group as described by Steven A. Julious, the minimum sample size required for a pilot design is estimated to be 12. Overall, 24 participants were enrolled.

Clinical Procedure

30 patients with deep caries were diagnosed with deep dental caries and 24 patients were selected for the trial. Tooth sensitivity was assessed by means of thermal (Endo Ice, Hygienic; Coltene/Whaledent AG, Altstfatten, Switzerland) and electrical stimuli (Digitest II, Parkell, USA). Preoperative radiograph, RVG was taken to assess periodontium and hard tissue, Local anesthetic (2% lidocaine hydrochloride with epinephrine 1:80,000; Lignospan, Septodont, France) was administered by buccal infiltration (Maxillary teeth) or by Infra alveolar nerve block (Mandibular teeth) to the teeth selected for the experiment. A rubber dam was used for isolation in all cases (Hygienic; Coltene/Whaledent, USA). Complete removal of the caries was achieved mechanically by means of a sterile BR 31 ball round bur (Mani Inc, Japan) that was

mounted in a slow speed handpiece and manually with a sterile caries removal spoon (GDC, INDIA). Caries removal continued until the dentin offered resistance to hand excavation with the dental spoon or the bur. If bleeding occurred in this procedure due to pulp exposure, the tooth was not included in the study. At this point, the tooth was allocated by lot method to one of the experimental groups by using a Microsoft Excel (Microsoft Corp) table.

Experimental Groups

In group 1, MTA (White MTA, Angelus, Brazil) was mixed in accordance with the manufacturer's instructions. The mixture was placed with a MTA carrier in the floor of cavity.

In group 2, Biodentine (Septodont, France) was mixed in accordance with the manufacturer's instructions. The mixture was applied in the prepared cavity with the technique as used in group 1.

The layer of the different experimental materials placed in the cavity prepared measured 2 * 2 mm approximately. Provisional restoration with IRM was completed over the experimental materials. Final restoration was done with direct Glass ionomer cement (GC gold label IX, GC corporation, Japan), and occlusion was checked at one month recall visit.

Clinical follow-up examinations were performed at baseline, 1 month, 3 months

and 6 months. In each clinical follow-up examination, sensitivity tests (thermal and electrical) and a percussion test were performed. Radiographic follow-up examinations were performed at baseline, 3 months and 6 months.

Clinical success was defined as a tooth with no pain, normal sensitivity tests, no facial edema, no internal or external resorption, no periradicular disease, periodontal ligaments of normal width, and no fistula.

Statistical Analysis

The data was compiled in Microsoft excel sheet and subjected to statistical analysis using SPSS (Statistical package for the social sciences software) version 21. Chi-Square test was applied. The level of significance was kept as < 0.05.

Results

A total of 30 patients were included. Eighteen male patients and six female patients were included. 19 Mandibular molars and 5 maxillary molars. Twelve molar teeth underwent indirect pulp capping with MTA, and twelve molar teeth with Biodentine.

At the 1 month and 3 months follow-up, there was 100% clinical success. At 6 months, there was 1 failure (1 in the MTA group).

Discussion

Preservation of the pulp is extremely important for various reasons; to allow

odontoblasts to deposit reparative dentin between the pulp and the dressing material, and to maintain pulp function. This study was focused on the use of dental materials to preserve the vitality of the dental pulp in permanent molars. This trial was conducted to evaluate the efficacy of MTA, Biodentine and Calcium Hydroxide in indirect pulp capping of permanent molars by clinical and radiographic assessment during six months follow up. Calcium hydroxide was used because it has been the gold standard material for pulp preservation treatments (indirect pulp capping, direct pulp capping, and pulpotomy) for many years. Calcium Hydroxide has several disadvantages, unsatisfactory adherence to dentin, dissolution over time, and multiple tunnel defects in the dentin bridges.^{18,19}

However there is a paradigm shift in the preference of clinicians for pulp capping materials from calcium hydroxide to MTA because of its predictable effects.²⁰ Min et al demonstrated that MTA is superior to CH in terms of inducing the dentinogenic process in human pulp capping.²¹ Some other authors have reported that MTA forms dentinal bridges more frequently and of greater thickness than those formed by CH.²²⁻²⁴ However, MTA also has some drawbacks; it has a long setting time that prevents completion of the treatment in 1 visit; it includes bismuth oxide as its

radiopacifier, which seems to cause tooth discoloration, so it is no longer indicated in esthetic treatments; and it is difficult to manipulate.^{13,25,26}

Recently, different calcium silicate-based materials have been developed to counter the limitations of MTA. Among them, Biodentine stands out for its biocompatibility, rapid setting, mechanical strength, ability to bond to dentin, and easy manipulation.²⁷⁻²⁹ In our study, we found 100% success in the Biodentine group and 91.67% success in the MTA group. Nowicka et al also reported similar clinical results for both MTA and Biodentine in premolars extracted for orthodontic reasons after 6 weeks of follow-up.³⁰ However, their teeth were caries free, and the literature shows that bacteria are the main cause of pulpal infection.³¹ In our study we have attempted to assess the efficacy of two different pulp capping materials in a more challenging clinical scenario where the outcome is unpredictable because of variability in the bacterial load, virulence and diversity.

It is very important that researchers attempt to identify the prognostic factors that favour a better outcome for carious teeth after pulp capping procedures rather than after artificial exposures in sound dentin.³²

The exact mechanisms by which Calcium Silicate materials induce formation of a

dentin bridge are not fully understood.³³ It is known that they release calcium hydroxide as a by-product, but unlike pure Calcium Hydroxide, which dissolves over time, Calcium Silicate materials are relatively stable, promote dentin bridging, and are probably able to seal the injured pulpal tissue.^{34,35} The inflammation that is induced by these materials is only short-term, less severe, and less extensive than that induced by Calcium Hydroxide.³⁶ The major limitations of the research described herein were the small sample size and the short length of the evaluation period, but it is a clinical study, indirect pulp capping in carious permanent molars to compare MTA and Biodentine. Our results showed statistically significant difference among the materials tested at 3- and 6-month follow-up. Biodentine is better than MTA for indirect pulp capping.

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