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ORIGINAL ARTICLE

Comparison of Novel Bioactive Materials in Indirect Pulp Therapy in Deciduous Teeth: An *in Vivo* Study

Sonu Acharya[1], Deepa Gurunathan[2]

[1]Department of Pediatric and Preventive Dentistry, Institute of Dental Sciences, Siksha O Anusandhan (Deemed to be) University, Bhubaneswar, Odisha, India.
[2]Department of Pedodontics and Preventive Dentistry, Saveetha Dental College, Saveetha Institute of Medical and Technical Sciences, Chennai, India

Corresponding author: Deepa Gurunathan **E-mail:** deepag@saveetha.com

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ABSTRACT

Objective: To assess the clinical success of Biodentine, NeoPutty, and calcium hydroxide as pulp capping materials for indirect pulp capping in carious primary teeth. **Material and Methods:** Indirect pulp treatment was performed on 36 deciduous molars in patients with deep carious lesions. The teeth were randomly assigned to three groups (n=12): Biodentine, NeoPutty, and calcium hydroxide. Statistical analysis was conducted using SPSS software version 21.0. Pearson's Chi-square test was employed to compare success and failure rates of the materials at three different time intervals (30, 90, and 180 days) and overall success and failure rates regardless of the time intervals. **Results:** Different pulp capping materials yielded varying success rates. The NeoPutty demonstrated a success rate of 91.67%, the Biodentine 83.33%, and the calcium hydroxide 58.33% after 6 months. However, these differences were not statistically significant ($p>0.05$). **Conclusion:** Indirect pulp treatment with calcium silicate-based materials, such as Biodentine and NeoPutty, showed superior results compared to calcium hydroxide. Although differences in success rates were observed among the materials, they did not reach statistical significance.

Keywords: Endodontics; Dental Pulp Capping; Child; Tooth, Deciduous;

Introduction

Vital pulp therapy represents a conservative and patient-friendly approach to addressing teeth with compromised pulp tissue, often resulting from dental caries, trauma, or restorative procedures [1]. In recent times, there has been ongoing debate among dentists regarding the best course of action for treating deep carious lesions, challenging the conventional belief in complete caries removal [2]. Traditionally, the emphasis was on completely removing all caries-affected dentin. However, current thinking advocates for a more conservative approach. It's now recognized that complete dentin removal may not always be necessary to halt the progression of caries effectively. Striving to entirely excavate carious lesions carries the risk of inadvertently exposing the pulp, which can directly infiltrate harmful microorganisms into the pulp chamber, potentially compromising the treatment's success [3].

Recent studies have highlighted that even after superficial caries removal, some residual microorganisms may persist within the dentin [4]. Surprisingly, this isn't necessarily detrimental; it can trigger a mild inflammatory response within the pulp. This subtle inflammation is considered beneficial, as it can contribute to the natural regeneration of pulp tissue. Therefore, managing deep carious lesions is now geared towards achieving a different goal. Rather than solely focusing on eradicating all carious tissue, the primary objective is to resolve the pulp's inflammation and preserve its vitality. This approach recognizes the potential for the pulp's inherent healing mechanisms to repair and regenerate tissue when given the opportunity, without unnecessary intervention [5]. The focus has shifted towards preserving pulp vitality and harnessing the body's mechanisms for healing and repair.

Indirect pulp therapy (IPT) is valuable in pediatric dentistry, particularly for treating carious lesions in deciduous teeth. This conservative procedure selectively removes infected dentin while preserving a thin layer of affected dentin to avoid pulp exposure. After careful excavation, a biocompatible material, often mineral trioxide aggregate (MTA) or calcium hydroxide (CH), is placed over the remaining affected dentin to create a protective barrier and promote healing. IPT focuses on slowing caries progression, reducing bacterial activity, and promoting pulp healing, helping to sustain the health of primary teeth. In pediatric dentistry, this method plays a key role in preserving primary teeth, ensuring proper spacing for permanent teeth, and supporting overall oral development in children.

The choice of material plays a crucial role in the success of this procedure. Very few studies have reported on the clinical outcome of indirect pulp capping with Biodentine, CH, and MTA in deciduous teeth [6]. Among the materials used for indirect pulp therapy, MTA, Biodentine, and calcium hydroxide are commonly compared due to their distinctive properties and clinical outcomes. MTA is renowned for its excellent sealing ability and biocompatibility. Biodentine is appreciated for its quick setting time and bioactivity, while calcium hydroxide is valued for its long history of use and cost-effectiveness. This comparison seeks to evaluate their effectiveness in achieving the primary objective of IPT — maintaining pulp vitality and promoting dentinogenesis in primary teeth. This study evaluated the clinical success of three materials used for indirect pulp capping of carious molars.

Material and Methods

Study Design and Ethical Clearance

A randomized clinical trial involved three experimental groups between March 2023 and August 2023. The trial received ethical approval and followed the guidelines outlined in CONSORT 2010. The Institutional Ethical Clearance (IHEC/SDC/Pedo/2204/22/004) was obtained, the children's parents were informed about

the procedure, and written consent was obtained in English and the local language. Signed Informed consent was obtained from all the parents of the children before the procedure commenced.

Sampling

The sample size for this study was determined to be 12 participants per group, following the guidelines outlined by Julious and Zariffa [7], who recommend a minimum sample size of 12 for a pilot design. In total, 36 participants were enrolled in the study.

Participants

The study included participants aged between 4 and 7 years. Prior to enrollment, all parents were provided with detailed information about the treatment procedure, its potential benefits and drawbacks, and alternative treatment options. The following inclusion criteria were adopted: 1. Mild discomfort experienced in response to chemical and thermal stimuli; 2. Presence of active carious lesions affecting the occlusal or proximal surfaces of primary molars; 3. Extent of a carious lesion such that complete removal of caries would pose a risk of exposing the pulp; and 4. Cooperative children and parents willing to follow instructions and attend scheduled follow-up appointments.

Children who presented the following conditions were excluded: 1. History of spontaneous sharp, penetrating pain or tenderness upon percussion; 2. Presence of abnormal tooth mobility, fistula formation, interrupted lamina dura, internal or external root resorption, inter radicular or periapical pathosis, or an enlarged periodontal ligament space; 3. Presence of chronic systemic illnesses such as congenital or rheumatic heart disease, hepatitis, or leukemia; 4. Patients currently undergoing long-term medication regimens, particularly corticosteroid therapy; 5. Patients who are physically or mentally challenged.

Clinical Procedures

Forty children initially diagnosed with deep dental caries were assessed, and 36 were selected, comprising 20 males and 16 females. The assessment of pulp vitality included tooth sensitivity tests like thermal tests and pulse oximetry. Preoperative radiographs were taken to evaluate the condition of the periodontium and hard tissues. Local anesthesia, specifically 2% lidocaine hydrochloride with epinephrine 1:80,000 (Lignospan, Septodont, Saint-Maur-des-Fossés, France), was administered either buccally via infiltration for maxillary teeth or by the infra-alveolar nerve block technique for mandibular teeth selected for the experiment. Isolation was achieved using a rubber dam (Hygienic; Coltene Inc., Cuyahoga Falls, OH, USA). Caries removal was performed manually with a spoon excavator, followed by a sterile BR 31 ball round bur (Mani Inc., Takenzawa, Japan) mounted to a handpiece. Caries were removed until resistance was encountered during hand excavation or with the bur. If bleeding occurred during this process due to pulp exposure, the tooth with pulp exposure was excluded from the trial. A simple randomization technique was employed to allocate each tooth after caries excavation to one of the three groups:

- Group 1: Dycal (Dentsply Sirona Inc., Charlotte, NC, USA) was prepared by mixing it on a manufacturer-provided paper pad. The resulting mixture was then placed in the base of the prepared cavity using a plastic filling instrument.
- Group 2: Biodentine (Septodont, Saint-Maur-des-Fossés, France) was manipulated following the manufacturer's guidelines. The prepared mixture was then placed in the base of the cavity.

- Group 3: NeoPutty (NuSmile Manufacturing, Houston, TX, USA) was applied over the cavity base.

These distinct treatments were administered to the respective groups. The materials were applied within the cavity floor with approximately 1 to 2 mm thickness. The cavity was filled with direct glass-ionomer cement (GC Fuji IX, GC Corp., Tokyo, Japan). Occlusion was assessed during the one-month recall visit. Children were scheduled for follow-up appointments 1, 3, and 6 months after the initial procedure (Figure 1). During these follow-up visits, the pulp-capped tooth was carefully examined and assessed using pulp sensitivity tests, which included cold and electrical tests. Clinical evaluation was also conducted to determine if there were any symptoms or signs of disease. To be considered clinically successful in this study, a tooth exhibited no disease symptoms and responded within normal limits to sensitivity tests.

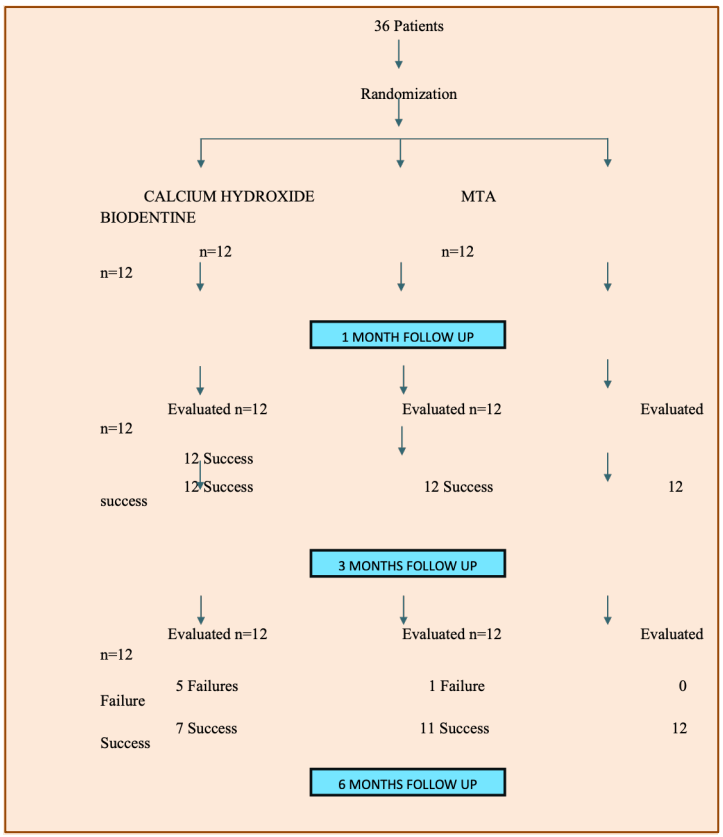

Figure 1. The flowchart shows the randomization of selected cases.

Data Analysis

The results were descriptively analyzed using the Statistical Package for Social Sciences (IBM Corp. Armonk, NY, USA), version 24.0. Pearson's Chi-Square was used with a significance of 5% ($p<0.05$).

Results

Among the 36 molars included in the trial, 8 were maxillary molars, and 28 were mandibular molars. The success rates of the experimental materials at different intervals are outlined in Table 1. Biodentine exhibited a success rate of 91.67% at 3 months and 66.67% at 6 months. NeoPutty had a success rate of 100% at 3 months and 91.67 % at 6 months, while calcium hydroxide showed a success rate of 58.33 % at 3 months and 33.33% at 6 months.

Table 1. Clinical success of materials at different periods.

Follow-up Time	Clinical Success Rate			p-value
	Calcium Hydroxide	Biodentine	NeoPutty	
1 Month	12/12 (100.0)	12/12 (100.0)	12/12 (100.0)	0.681
3 Months	7/12 (58.33)	11/12 (91.67)	12/12 (100.0)	
6 Months	4/12 (33.33)	8/12 (66.67)	11/12 (91.67)	

The inter-group comparisons between calcium hydroxide and Biodentine (p=0.585), calcium hydroxide and NeoPutty (p=0.33), and Biodentine and NeoPutty (p=0.871) did not show any statistically significant result.

Discussion

The objective of conservative dental treatment is to maintain the vitality of the pulp while ensuring its normal functions. This approach recognizes that only a vital and functional pulp can naturally heal itself by stimulating the formation of reparative dentin and resolving any inflammation [8].

Our study focused on implementing a conservative approach to treating carious molar teeth by employing novel materials for indirect pulp capping. The primary objective of this trial was to assess the effectiveness of three different materials - calcium hydroxide (CH), NeoPutty, and Biodentine - in the context of indirect pulp capping for primary molars. This assessment was conducted through a six-month comprehensive pulp vitality evaluation and clinical observations.

Calcium hydroxide was chosen as one of the materials in the trial due to its historical use as the gold standard for pulp capping procedures over nearly a century. However, it is essential to note that CH is associated with several limitations, such as poor adhesion to dentin, susceptibility to dissolution, and the formation of tunnel-like defects in the resulting dentin bridge [9]. There has been a noticeable shift in the preferences of clinicians when it comes to choosing pulp capping materials and transitioning from CH to MTA due to the more reliable and consistent outcomes associated with MTA [10].

Mineral Trioxide Aggregate (MTA) is a material that was developed by modifying Portland cement and was introduced to the field in 1993 [11]. Over time, it has gained significant recognition in managing deep carious lesions. MTA comprises several key components, including tricalcium silicate, tricalcium oxide, tricalcium aluminate, bismuth oxide, and silicate oxide. This calcium silicate-based pulp capping material plays a crucial role in forming reparative dentin by promoting the release of growth factors and cytokines. However, it is essential to acknowledge that MTA does have certain limitations. These limitations include an extended setting time, the potential for tooth discoloration, and challenges associated with its handling, all of which can present obstacles to its ideal utilization in dental procedures [12].

NeoPutty was produced to overcome these drawbacks. The manufacturers claim that this material has better properties than traditional MTA, even better than the newer MTA available, like ProRoot MTA (Dentsply Sirona Inc., Charlotte, NC, USA) and MTA Angelus (Angelus Odontologia, Londrina, PR, Brazil). NeoPutty is a premixed bioactive, bioceramic MTA that triggers hydroxyapatite and supports healing. This product has recently become the preferred choice among pediatric dentists due to its firm, non-tacky consistency, resistance to washout, and notable bioactivity [13]. This versatile material meets various pulp-related needs in pediatric dentistry. Moreover, NeoPutty offers the advantage of being ready-to-use, requiring no additional preparation, thus minimizing wastage. This saves costs and reduces chair time, making it an efficient and practical choice for dental procedures. There have not been many clinical studies on NeoPutty.

Aeinehchi et al. [14] reported that MTA demonstrates a superior dentinogenic induction rate when compared to CH. Two additional studies have compared calcium hydroxide and MTA, revealing significant findings. In one study involving a sample of 109 teeth, it was observed that the MTA group achieved a 100% success rate, the calcium hydroxide group achieved a 93.5% success rate, and the Glass Ionomer Cement (GIC) group achieved a 97% success rate. Selvendran et al. [15] reported that indirect pulp capping with calcium silicate materials provided better results compared to that of calcium hydroxide. Biodentine, introduced in 2009, represents a significant advancement in dental materials. It offers enhanced biocompatibility, a clinically acceptable setting time, improved mechanical strength, better bonding with dentin surfaces, and greater ease of handling [16]. Biodentine offers several distinct advantages compared to other products, including a shorter setting time of approximately 12 minutes, superior mechanical properties, and excellent sealing capabilities. When comparing the shear bond strength of Biodentine, ProRoot MTA, glass ionomer cement and resin composite on dentin, it was found that the adhesion of Biodentine to dentine surface seams was superior compared to that of MTA [17]. This characteristic positions Biodentine as a promising vital pulp therapy (VPT) application agent. Biodentine has the drawbacks of poor washout resistance and poor radiopacity, which are essential for an indirect pulp therapy procedure [18]. NeoPutty has better radiopacity and washout resistance than Biodentine.

A clinical trial assessed the efficacy of indirect pulp therapy using calcium hydroxide, MTA, and Biodentine in primary molars. The study comprised a sample size of 45 primary molars, distributed evenly into three groups, each comprising 15 teeth. The clinical outcomes revealed a 100% success rate across all three groups with a 6-month follow-up. However, on radiographic evaluation, Biodentine demonstrated superiority compared to the other materials [6].

In our trial, the NeoPutty group demonstrated a remarkable success rate of 91.67%, while the CH group achieved a success rate of 58.33%, and the Biodentine group achieved an 83.33% success rate. These findings underscore the favorable attributes and clinical performance of NeoPutty compared to the other materials tested in the study. The better results for NeoPutty might be due to better washout resistance than CH and Biodentine. In 2017, Saber et al. [19] examined the use of Biodentine in primary molars' indirect pulp treatment. The study included 60 patients, and a split-mouth design was employed, with one side receiving indirect pulp treatment using Biodentine and the other side treated with calcium hydroxide. The 12-month follow-up results revealed no statistically significant difference in success rates between the two groups. Notably, Biodentine's reduced cost compared to MTA has increased its accessibility for clinical use. Our study also showed a better clinical success of Biodentine compared to calcium hydroxide. Another factor that influences the success of indirect pulp treatment is the final restorative material. The bacterial leakage through the final restoration is considered to be highly detrimental [20]. NeoPutty, being a premixed material, has the advantage of placing the final restoration immediately rather than waiting for the material to set. NeoPutty is a promising new material that has overcome many disadvantages of MTA. This is one of the first studies to compare the golden standard for indirect pulp treatment, calcium hydroxide, with newer materials, Biodentine and NeoPutty in primary teeth.

The study has some limitations. First, the small sample size can lead to bias, limited variability, and reduced statistical power of our research. Second, the follow-up could have been more extensive to get better results in the study for a new material being tested.

Conclusion

According to the outcomes of our study, a better clinical success rate was observed with NeoPutty than with the calcium hydroxide and the Biodentine. Nonetheless, it is imperative to emphasize the need for subsequent research involving larger sample sizes and extended follow-up periods. Moreover, additional histological investigations are essential to support these conclusions robustly. While each material has advantages and limitations, Biodentine and MTA generally provide better outcomes for indirect pulp treatment in primary teeth than calcium hydroxide. Biodentine's ease of use, quick setting time, and biological properties make it a favorable option. MTA's superior sealing and biocompatibility make it an excellent choice, albeit with higher cost and handling challenges. Calcium hydroxide, while still effective, is often outperformed by the newer materials in terms of long-term success and pulp vitality preservation. Clinicians should consider these factors alongside patient-specific needs to choose the most appropriate material for indirect pulp treatment in primary teeth.

Authors' Contributions

SA	https://orcid.org/0000-0003-1006-1993	Conceptualization, Methodology, Formal Analysis, and Writing - Original Draft.
DG	https://orcid.org/0000-0002-6014-946X	Investigation, Writing - Original Draft and Writing - Review and Editing.

All authors declare that they contributed to a critical review of intellectual content and approval of the final version to be published.

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None.

Conflict of Interest

The authors declare no conflicts of interest.

Data Availability

The data used to support the findings of this study can be made available upon request to the corresponding author.

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