ORIGINAL RESEARCH

Comparison of Modified NeoPutty MTA®, Biodentine, and Calcium Hydroxide in Indirect Pulp Therapy in Deciduous Teeth: An *In Vivo* Clinical Study

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Abstract

Background: Pulp capping is a vital dental procedure used to preserve the vitality of teeth affected by deep caries lesions without irreversible pulpitis. The use of modern bioceramic materials has enhanced the predictability of vital pulp therapy (VPT).

Aim: This study aimed to assess the clinical success of Biodentine, modified NeoPutty mineral trioxide aggregate (MTA), and calcium hydroxide (Ca(OH)2) as pulp capping materials for indirect pulp capping in carious primary teeth.

Materials and methods: Indirect pulp treatment (IPT) was performed on 36 deciduous molars in 36 patients presenting with deep carious lesions. The teeth were randomly assigned to three groups: Biodentine (12 teeth), NeoPutty MTA (12 teeth), and Ca(OH)2 (12 teeth). Patients were monitored at 1, 3, and 6 months post-treatment to evaluate the clinical success of the procedures.

Statistical analysis: Statistical analysis was conducted using Statistical Package for the Social Sciences (SPSS) software version 21.0. Pearson's Chi-squared test was employed to compare success and failure rates among Biodentine, MTA, and Ca(OH)2 at three different time intervals (30, 90, and 180 days) and overall success and failure rates regardless of the time intervals.

Results: In the statistical analysis, different pulp capping materials yielded varying success rates. The NeoPutty MTA group demonstrated a success rate of 91.67%, the Biodentine group 83.33%, and the Ca(OH)2 group 58.33% after 6 months. However, these differences were not statistically significant.

Conclusion: Indirect pulp treatment with calcium silicate-based materials, such as Biodentine and modified NeoPutty MTA, showed superior results compared to the use of calcium hydroxide (Ca(OH)2). Although differences in success rates were observed among the materials, they did not reach statistical significance.

Keywords: Biodentine, Calcium hydroxide, Deciduous teeth, Indirect pulp capping, NeoPutty mineral trioxide aggregate.

International Journal of Clinical Pediatric Dentistry (2024): 10.5005/jp-journals-10005-2953

Introduction

Essential pulpal treatment represents a minimally invasive and patient-friendly method to address teeth with impaired pulpal tissue, often resulting from tooth decay, injury, or restoration methods.[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 is now recognized that complete dentin removal may not always be necessary to halt the progression of caries effectively. In fact, striving to entirely excavate carious lesions carries the risk of inadvertently exposing the pulp, which can lead to the direct infiltration of harmful microorganisms into the pulp chamber, potentially compromising the treatment's success.[3]

Recent studies have shed light on the fact that even after superficial caries removal, some residual microorganisms may persist within the dentin.[4] Surprisingly, this isn't necessarily detrimental; in fact, it can trigger a minimal inflammatory response within the pulp. This slight inflammation is advantageous, as it can contribute to the natural regeneration of pulp tissue. Therefore, the management of deep carious lesions is now geared toward achieving a different goal. Rather than solely focusing on the complete eradication of all carious tissue, the primary objective is to resolve the inflammation within the pulp and, critically, to preserve

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How to cite this article: Acharya S, Gurunathan D, Assiry AA, *et al.* Comparison of Modified NeoPutty MTA®, Biodentine, and Calcium Hydroxide in Indirect Pulp Therapy in Deciduous Teeth: An *In Vivo* Clinical Study. Int J Clin Pediatr Dent 2024;17(9):1025–1029.

Source of support: Nil

Conflict of interest: None

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 toward preserving pulp vitality and harnessing the body's own mechanisms for healing and repair. Indirect pulp therapy (IPT) is a valuable approach in pediatric dentistry, particularly for alleviating decayed portions in milk teeth. This conservative procedure involves selectively removing 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 aims to halt the progression of caries, eliminate microbial activity, and encourage the natural healing processes within the pulp, ultimately preserving the vitality of the deciduous tooth. This approach is especially crucial in pediatric dentistry to maintain primary teeth's function, space for permanent teeth, and overall oral health in young patients. The choice of material plays a crucial role in the success of this procedure. Little research has been done in IPT with different materials, namely CH, MTA, and Biodentine in primary teeth.[6] There are some drawbacks of MTA, and to overcome these, we used the newer MTA, namely NeoPutty MTA (NuSmile, United States of America). This study reported the outcomes in favor of three materials: Biodentine, CH, and modified NeoPutty MTA, used for indirect pulp capping of carious molars.

Materials and Methods

A clinical study was conducted, involving three experimental groups, between March 2023 and August 2023. The trial received ethical approval (IHEC/SDC/PEDO/2204/22-004). The study included child 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, as well as alternative treatment options. Written informed consent was obtained from all the guardians of the children before the procedure started.

Inclusion Criteria

- Mild discomfort experienced in response to chemical and thermal stimuli.
- The presence of active carious lesions affecting either the occlusal or proximal surfaces of primary molars.
- Extent of carious lesion such that complete removal of caries would pose a risk of exposing the pulp.
- Cooperative children and parents who are willing to adhere to instructions and attend scheduled follow-up appointments.

Exclusion Criteria

- History of spontaneous sharp, penetrating pain, or tenderness upon percussion.
- Presence of abnormal tooth mobility, fistula formation, interrupted lamina dura, internal or external root resorption, interradicular or periapical pathosis, or an enlarged periodontal ligament space.
- Presence of chronic systemic illnesses such as congenital or rheumatic heart disease, hepatitis, or leukemia.
- Patients currently undergoing long-term medication regimens, particularly corticosteroid therapy.
- Patients who are physically or mentally challenged.

The institutional ethical clearance (IHEC/SDC/Pedo/2204/22/004) was obtained, and the children's mother or father was informed about the procedure. Written consent was obtained in both English and the local language. The sample size for this study was determined to be 12 participants per group, following the guidelines outlined by Steven A Julious, who recommends a sample size of 12 for a pilot design. In total, 36 participants were enrolled in the study.[7]

In this clinical procedure, a total of 40 children initially diagnosed with deep dental caries were assessed, and 36 of them were selected to participate in the trial. The assessment of pulp vitality included tooth sensitivity tests such as thermal tests and pulse oximetry. Preoperative radiographs were taken to assess the condition of the periodontium and hard tissues. Local anesthesia was administered using 2% lidocaine hydrochloride with epinephrine 1:80,000 (Lignospan, Septodont, France). For maxillary teeth, anesthesia was delivered buccally *via* infiltration, while mandibular teeth received anesthesia through the infra-alveolar nerve block technique. To isolate the area, a rubber dam (Hygienic; Coltene/Whaledent, United States of America) was used.

Caries removal was performed manually with a spoon excavator and then with a sterile BR 31 ball round bur (Mani Inc., Japan) mounted on a handpiece. Carious tissue was removed until resistance was met, either through hand excavation or with the bur. If pulp exposure occurred and resulted in bleeding, the affected tooth was excluded from the trial.

Following caries excavation, each tooth was randomly assigned to one of three experimental groups using a simple randomization technique.

The study involved three experimental groups, each with a distinct treatment approach:

Group I: Dycal (Dentsply, United States) was prepared by mixing it on a paper pad supplied by the manufacturer. The mixture was then applied to the base of the prepared cavity using a plastic filling instrument.

Group II: Biodentine (Septodont, France) was prepared according to the manufacturer's instructions. Once mixed, the material was placed in the base of the cavity.

Group III: Modified NeoPutty MTA was directly applied over the cavity base. NeoPutty MTA was mixed with antibiotics (clindamycin 300 mg and metronidazole 400 mg), one by one, and tested. NeoPutty was mixed with 1 mg/mL concentrations of the antibiotics.

These distinct treatments were administered to the respective groups as part of the experimental procedure. The experimental materials were applied to the cavity floor with a thickness of approximately 1–2 mm. Following this, the cavity was filled with direct glass-ionomer cement (GC Fuji IX, GC Japan). Occlusion was assessed during the 1-month recall visit. Children were scheduled for follow-up appointments at 1, 3, and 6 months after the initial procedure. 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. For a tooth to be considered clinically successful in this study, it had to exhibit no symptoms of disease and respond within normal limits to sensitivity tests.

Results

A total of 36 children participated in this study, including 20 males and 16 females. Among the treated teeth, 28 were mandibular molars and 8 were maxillary molars. The patient selection process and the treatment procedures performed are illustrated in Figure 1.

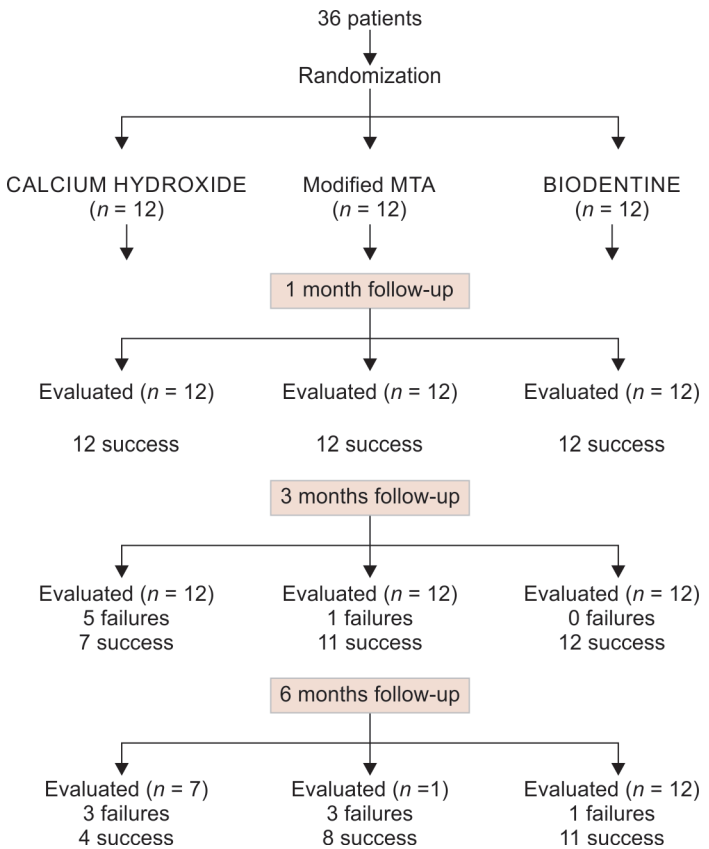

Fig. 1: Flowchart showing randomization of selected cases and review done

Table 1: Clinical success of materials at different time periods

	CH (n = 12)	*Biodentine (n = 12)*	*Modified NeoPutty MTA (n = 12)*
1-month follow-up	12/12 (100%)	12/12 (100%)	12/12 (100%)
3-month follow-up	7/12 (58.33%)	11/12 (91.67%)	12/12 (100%)
6-month follow-up	4/12 (33.33%)	8/12 (66.67%)	11/12 (91.67%)

Chi-square value—0.297; *p*-value—0.681

Table 2: Comparison between CH and Biodentine

	CH	*Biodentine*
1 month	12	12
3 months	7	11
6 months	4	8

Chi-square value—1.06; *p*-value—0.585

Table 3: Comparison between CH and modified NeoPutty MTA

	CH	*NeoPutty MTA*
1 month	12	12
3 months	7	12
6 months	4	11

Chi-square value—2.19; *p*-value—0.33

Table 4: Comparison between Biodentine and modified NeoPutty MTA

	Biodentine	*NeoPutty MTA*
1 month	12	12
3 months	11	12
6 months	8	11

Chi-square value—0.275; *p*-value—0.871

Specifically, 12 molar teeth were subjected to indirect pulp capping with CH, another 12 with modified NeoPutty MTA, and 12 with Biodentine. 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. Modified NeoPutty MTA had a success rate of 100% at 3 months and 91.67% at 6 months, while CH showed a success rate of 58.33% at 3 months and 33.33% at 6 months.

The intergroup comparisons between CH and Biodentine (Table 2), CH and modified NeoPutty MTA (Table 3), and Biodentine and modified NeoPutty MTA (Table 4) did not show any statistically significant results.

Discussion

The goal of conservative dental treatment is to preserve the vitality of the pulp and ensure it continues to function normally. This approach recognizes that only a pulp that is both vital and functional has the capacity to naturally heal itself by stimulating the formation of reparative dentin and resolving any inflammation.[8] Our study focused on implementing a conservative approach for the treatment of carious molar teeth by employing novel materials for indirect pulp capping. The major goal of this trial was to see the advantages of three different materials—CH, modified NeoPutty MTA, and Biodentine—in the context of indirect pulp capping for primary molars. This assessment was conducted through a comprehensive evaluation of pulp vitality and clinical observations over a period of 6 months. CH was chosen as one of the materials in the trial due to its historically recognized status as

the benchmark for pulp capping procedures over nearly a century. However, it is essential to note that CH is associated with several limitations, including inadequate bonding to dentin, vulnerability to dissolution, and the development of tunnel-like flaws in the formed dentin bridge.[9] However, there has been a noticeable shift in the preferences of clinicians when it comes to choosing pulp capping materials, transitioning from CH to MTA due to the more reliable and consistent outcomes associated with MTA.[10] Mineral trioxide aggregate 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 the treatment of deep cavities. Mineral trioxide aggregate is composed of 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 initiating the formation of 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 increased setting time, brackishness of teeth, and challenges associated with its handling, all of which can present obstacles to its ideal utilization in dental procedures.[12] To overcome these drawbacks, NeoPutty MTA (NuSmile) was produced. The manufacturers claim that this material has better properties than traditional MTA, even better than the newer MTA available, like ProRoot MTA (Dentsply, Tulsa, United States of America) and MTA Angelus (Angelus, Brazil). NuSmile NeoPutty® is a premixed bioactive, bioceramic MTA that triggers hydroxyapatite and supports healing. NeoPutty is the preferable choice among pediatric dentists recently due to its firm, nontacky 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 not only saves costs but also reduces chair time, making it an efficient and practical choice for dental procedures. There have not been many clinical studies on NeoPutty MTA.

Studies conducted by Aeinehchi et al. have reported that MTA demonstrates a superior dentinogenic induction rate when compared to CH.[14] Two additional studies have conducted comparisons between CH 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 CH group achieved a 93.5% success rate, and the glass ionomer cement (GIC) group achieved a 97% success rate. In another study conducted which included a total sample size of 40, a notable difference was observed between MTA and Dycal in terms of their ability to promote reparative dentin formation. These findings highlight the distinct outcomes associated with different pulp capping materials.[15] 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. In a study, it was noted that Biodentine's sealing ability closely resembled that of apatite crystals when observed under a scanning electron microscope.[17] This characteristic positions Biodentine as a promising agent for vital pulp therapy (VPT) applications. Biodentine has the drawback of poor washout resistance and poor radiopacity, two properties which are essential for an indirect pulp therapy procedure.[18] NeoPutty MTA has better radiopacity and washout resistance than Biodentine.

A clinical trial was conducted to assess the efficacy of indirect pulp therapy (IPT) using CH, MTA, and Biodentine in primary molars. The study comprised a sample size of 45 primary molars, distributed evenly into three groups, with each group consisting of 15 teeth. The clinical outcomes revealed a 100% success rate across all three groups. However, on radiographic evaluation, Biodentine demonstrated superiority compared to the other materials.[6]

In our trial, the modified NeoPutty MTA 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 MTA compared to the other materials tested in the study. The better results for NeoPutty MTA might be due to better washout resistance than CH and Biodentine. In 2017, an article in the Pediatric Dentistry Journal examined the use of Biodentine in the indirect pulp treatment (IPT) of primary molars.[19] The study included 60 patients, and a split-mouth design was employed, with one side receiving IPT using Biodentine and the other side treated with CH. 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 in comparison to CH. Another element that affects the success of IPT is the choice of final restorative material. Bacterial leakage through the final restoration is regarded as highly harmful.[20] NeoPutty MTA, being a premixed material, has the advantage of allowing the placement of the final restoration immediately rather than waiting for the material to set. NeoPutty MTA is a promising new material that has overcome many disadvantages of MTA. This is one of the first studies to compare the gold standard for IPT, CH, with newer materials like Biodentine and a modified NeoPutty MTA in primary teeth.

Drawbacks of the Study

- The sample size is small and can lead to bias, limited variability, and reduced statistical power of our study.
- Follow-up is less. The follow-up could have been longer to obtain 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 modified NeoPutty MTA than with the CH group and Biodentine group. Nonetheless, it is imperative to emphasize the need for further studies with larger sample sizes and longer follow-up periods. Moreover, additional histological investigations are essential to provide robust support for these conclusions.

Data Availability Statement

The data presented in this study are available upon request from the corresponding author.

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