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ORIGINAL PAPER

Comparison of novel bioactive, bioceramic materials in vital pulp therapy in deciduous teeth – a clinical in vivo study

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ABSTRACT

Introduction and aim. The use of modern bioceramic materials has enhanced the predictability of vital pulp therapy. 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.

Material and methods. Indirect pulp treatment (IPT) was performed on 36 deciduous molars in 36 patients who were presented with deep carious lesions. The teeth were randomly assigned to three groups: Biodentine (12 teeth), modified NeoPuttyMTA (12 teeth), and $Ca(OH)_2$ (12 teeth).

Results. A statistical analysis was conducted using SPSS software version 21.0. Pearson's Chi-square test was employed to compare success and failure rates among Biodentine, modified Neoputty 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. In the statistical analysis, different pulp capping materials yielded varying success rates. The modified 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. IPT with calcium silicate-based materials, such as Biodentine and modified NeoPutty MTA, showed superior results when 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. calcium hydroxide, children, deciduous teeth, pulp capping

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 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]

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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 mild inflammatory response within the pulp. This subtle inflammation is considered beneficial, as it can contribute to the natural regeneration of pulp tissue. Therefore, the management of deep carious lesions is now geared towards achieving a different goal. Rather than solely focusing on complete eradication of all carious tissue, the primary objective is to resolve the inflammation within the pulp and, critically, to 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 own mechanisms for healing and repair. Indirect pulp therapy (IPT) is a valuable approach in pediatric dentistry, particularly for treating carious lesions in deciduous 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. Very few studies have reported on the clinical outcome of indirect pulp capping with Biodentine, CH, and MTA in deciduous teeth.[6] There are some drawbacks of MTA and to overcome this we used the newer MTA, namely NeoPutty MTA (Nusmile, USA). The objective of indirect IPT in primary teeth is to treat deep carious lesions while preserving the vitality of the dental pulp. This conservative approach aims to prevent the progression of caries, avoid pulpal exposure, and stimulate the formation of reparative dentin. Among the materials used for IPT, Mineral Trioxide Aggregate (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, and calcium hydroxide is valued for its long history of use and cost-effectiveness. NeoPutty MTA was launched in 2020 by NuSmile (Houston, Texas) to minimize most of MTA's drawbacks. This material was said to be premixed, bioceramic, nonstaining, resin-free, and it does not dry out when used. NeoPutty MTA has been shown to have similar physical and mechanical properties to traditional MTA materials, including good sealing ability, biocompatibility, and radiopacity. It has also been shown to have a shorter setting time than traditional MTA materials, which can reduce treatment time and improve patient comfort. This new material has antibacterial properties because of the alkaline pH of the material. Ideal endodontic cement should have bacteriostatic or bactericidal properties. MTA has the drawback of minimal antibacterial effect, especially against Enterococcus faecalis, which is the major microorganism responsible for the progression of pulpal and periradicular diseases and endodontic failures. E. faecalis forms a minor part of the microbial flora in uninstrumented canals, while it is a main etiologic factor for periradicular lesions that develop following the endodontic treatment. In various studies, adding certain additives, such as metallic silver, chlorhexidine, and calcium fluoride, has reduced the antibacterial counts. This comparison seeks to evaluate their effectiveness in achieving the primary objective of IPT – maintaining pulp vitality and promoting dentinogenesis in primary teeth.

Aim

This study reported the clinical success of three materials, Biodentine, CH, and modified NeoPutty MTA, used for indirect pulp capping of carious molars.

Material and methods

A clinical study was conducted, involving three experimental groups between March 2023 and August 2023. The trial received ethical approval and followed the guidelines outlined in CONSORT 2010. 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, as well as alternative treatment options. Signed Informed consent was obtained from all the parents of the children, before the procedure commenced. The inclusion and exclusion criteria were:

Inclusion criteria

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

Exclusion criteria

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, interradicular 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.

The Institutional Ethical Clearance (IHEC/SDC/Pedo/2204/22/004) was obtained and children's parents were informed about the procedure and a written consent was obtained both in English and 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 minimum 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 study. 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, 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/Whaledent, USA). Caries removal was performed manually with a spoon excavator, followed by the use of a sterile BR 31 ball round bur (Mani Inc., Japan) mounted to a handpiece. Caries was 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. To allocate each tooth after caries excavation to one of the three experimental groups, a simple randomization technique was employed.

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

Group 1: Dycal (Dentsply, 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, France) was manipulated following the manufacturer's guidelines. The prepared mixture was then placed in the base of the cavity.

Group 3: Modified NeoPuttyMTA (Nusmile, USA) was directly applied over the cavity base. Neoputty MTA was mixed with antibiotics (clindamycin 300 mg, ciprofloxacin 500 mg, and metronidazole 400 mg).

These distinct treatments were administered to the respective groups as part of the experimental procedure. The experimental materials were applied within the cavity floor with a thickness approximately ranging from 1 to 2 mm. Following this, the cavity was filled with direct glass-ionomer cement (GC Fuji IX, GC Japan). Occlusion was assessed during the one-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.

Statistical analysis

The statistical analysis was done using SPSS version 22.0 (IBM, Armonk, NY, USA) and the results have been given with each table below.

Results

A total of 36 children were included in this study, comprising 20 males and 16 females. The patient selection process and the treatment procedures performed are illustrated in Figure 1. 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.

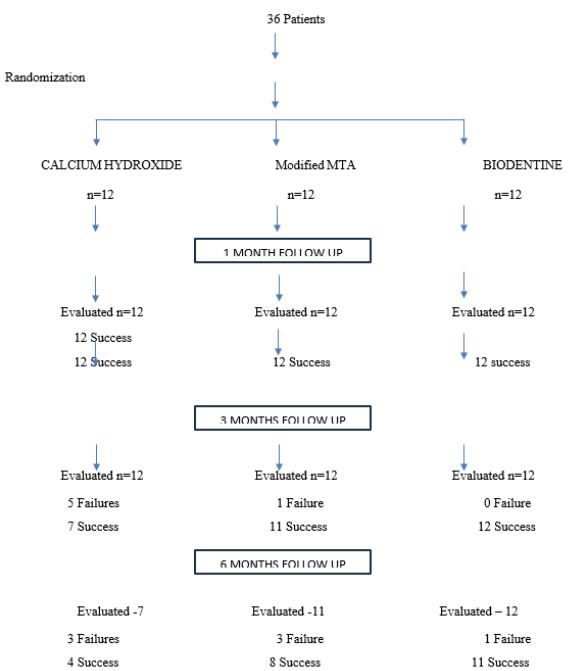

Fig. 1. Flowchart showing randomization of selected cases and review done

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.

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 months follow up	7/12 (58.33%)	11/12 (91.67%)	12/12 (100%)
6 months follow up	4/12 (33.33%)	8/12 (66.67%)	11/12 (91.67%)

* Chi square value=0.297; p=0.681

Table 2. Comparison between calcium hydroxide and Biodentine

	CH	Biodentine
1month	12	12
3 month	7	11
6 month	4	8
Chi square value; p	1.06; 0.585	

Table 3. Comparison between calcium hydroxide and modified NeoPutty MTA

	CH	Modified NeoPutty MTA
1 month	12	12
3 month	7	12
6 month	4	11
Chi square value; p	2.19; 0.33	

Table 4. Comparison between Biodentine and Modified NeoPutty MTA

	Biodentine	Modified NeoPutty MTA
1 month	12	12
3 month	11	12
6 month	8	11
Chi square value; p	0.275; 0.871	

The inter group comparisons between calcium hydroxide and Biodentine (Table 2), calcium hydroxide and modified Neoputty MTA (Table 3) and Biodentine and modified NeoPutty MTA (Table 4) 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 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 primary objective of this trial was to assess the effectiveness 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 six months. CH 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] 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] 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 the management of deep carious lesions. MTA 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 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] 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, USA), 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, 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 not only saves costs but also reduces chair time, making it an efficient and practical choice for dental procedures. There has not been much clinical studies on Neoputty MTA. The modified NeoPutty was made with triple antibiotics to enhance the efficacy.

Studies conducted by Aeinehchi et al. have reported that MTA demonstrates a superior dentinogenic in-

duction rate when compared to CH.[14] Two additional studies have conducted comparisons between 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. In another study conducted by George et al., 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 by Arora et al., 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 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 with a 6 month follow up. 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 modified NeoPutty MTA might be due to better washout resistance than CH and Biodentine and the antibiotics. In 2017, Saber, Meligy, and Alaki examined the use of Biodentine in the IPT (indirect pulp treatment) 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 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 too showed a better clinical success of Biodentine in comparison to calcium hydroxide. In another study comparing Biodentine and Theracal for indirect pulp treatment for young permanent teeth, by the end of 24 months, 54 teeth presented for follow up with overall success rate of 100% in Theracal, 94.44% in Biodentine, and 77.78% in Dycal. Overall success of Theracal was statistically significant in comparison to Biodentine and Dycal at 24 months follow up ($p=0.03$).[20]

Another factor that influences the success of IPT is the final restorative material. The bacterial leakage through the final restoration is considered to be highly detrimental. Neoputty MTA being a premixed material has the advantage of the placement of the final restoration immediately rather than waiting for the material to set. Neoputty MTA is a promising new material which has overcome many disadvantages of MTA. The modified NeoPutty we made with triple antibiotics is still better than NeoPuttyMTA.[21] This is one of the first studies to compare golden standard for IPT, CH with newer materials Biodentine and modified Neoputty MTA in primary teeth.

Study limitations

The sample size although small is appropriate as derived by appropriate statistical tools. Follow up is less. The follow up could have been more 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 modified NeoPutty MTA than CH group and Biodentine group. 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 provide robust support for these conclusions. In conclusion, while each material has its advantages and limitations, Biodentine and MTA generally provide better outcomes for IPC in primary teeth compared to CH. Biodentine's ease of use and quick setting time, combined with its 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. CH, 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 IPC in primary teeth.

Declarations

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Author contributions
Conceptualization, S.A.; Methodology, S.A.; Software, D.G.; Validation, S.A. and D.G.; Formal Analysis, SA.; Investigation, D.G.; Resources, D.G.; Data Curation, S.A.; Writing – Original Draft Preparation, S.A; Writing – Review & Editing, S.A.; Visualization, D.G.; Supervision, S.A.; Project Administration, S.A.

Conflicts of interest
The authors have no conflicts of interest to declare.

Data availability
The data presented in this study are available on request from the corresponding author.

Ethics approval
The Institutional Ethical Clearance (IHEC/SDC/Pedo/2204/22/004) was obtained.

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