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ORIGINAL ARTICLE

Randomized Clinical Study of the Use of MTA and Biodentine™ for Pulpotomy in Primary Teeth

Lídia Regina da Costa Hidalgo[1], Luciano Aparecido de Almeida-Junior[1], Marília Pacífico Lucisano Politi[1], Paulo Nelson-Filho[1], Raquel Assed Bezerra Segato[1], Francisco Wanderley Garcia Paula-Silva[1], Léa Assed Bezerra da Silva[1]

[1]Department of Pediatric Dentistry, School of Dentistry of Ribeirão Preto, University of São Paulo, Ribeirão Preto, SP, Brazil.

Correspondence: Francisco Wanderley Garcia Paula-Silva, School of Dentistry of Ribeirão Preto, University of São Paulo, Faculdade de Odontologia de Ribeirão Preto/Universidade de São Paulo. Av. do Cafe s/n, Monte Alegre, Ribeirao Preto, SP, Brazil. 14040-904. **E-mail:** franciscogarcia@usp.br

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ABSTRACT

Objective: To verify, through clinical and radiographic evaluations, the *in vivo* response of the dentin-pulpal complex of human primary teeth after pulpotomy with MTA and Biodentine™ in a follow-up period of 3, 6, and 12 months. **Material and Methods:** Thirty teeth were divided into MTA pulpotomy (n = 15) and Biodentine™ pulpotomy (n = 15) from children between 5 and 9 years of age, a randomized clinical trial with simple random sampling. The materials were inserted into the cavity after opening and removing the coronary pulp tissue. The cavity base consisted of glass ionomer cement and light-cured composite resin restoration. Clinical and radiographic analyses were performed after 3, 6, and 12 months. Statistical analysis by Fisher's exact test for dichotomous data at a 5% significance level was utilized. **Results:** Both materials caused color change after 12 months. However, MTA showed a higher percentage than Biodentine™ ($p<0.0001$). Pain was detected only with Biodentine™ at six months and mobility at 12 months ($p=0.0013$). Radiographically, after 12 months, periapical lesions, interradicular lesions, and internal resorption were evidenced in 13% of the cases for Biodentine™-treated teeth ($p<0.0013$). MTA induced pulp calcification in 13% of cases, unlike Biodentine™ ($p<0.0013$). **Conclusion:** Biodentine™ and MTA are suitable for clinical use in pulpotomy treatment, yet both materials lead to tooth discoloration.

Keywords: Pulpotomy; Tooth, Deciduous; Pediatric Dentistry; Dental Pulp Cavity.

Introduction

Pulpotomy is a therapy often performed on primary teeth and is defined as removing pulp tissue located in the coronal portion of the tooth, which may be inflamed or infected [1]. After removing this coronary pulp tissue, materials that preserve vitality and promote the repair of the remaining root pulp tissue, evidenced by the neoformation of mineralized tissue [2-3], can be applied. Regarding the materials used, the most common are mineral trioxide aggregate (MTA), Biodentine™ (BD), and calcium hydroxide (CH) [1].

MTA has calcium, aluminum, and selenium in its composition, present excellent properties such as biocompatibility, bioactivity, hydrophilicity, radiopacity, sealing ability, and low solubility [4]. It is indicated for pulp capping, pulpotomy, apexogenesis, apexification, regeneration of the pulp-dentin complex, root perforation, and endodontic treatment [4]. However, MTA has some disadvantages, such as tooth staining, long hardening time (more than 2 hours) [5], need for hydration during this period [6], difficulties in handling, and high cost [5,7]. Since the main active component of MTA is tricalcium silicate, researchers have sought to develop materials that present this component in its pure form, synthesized in the laboratory under controlled conditions from raw materials of unknown nature. Attempts to replace Portland cement resulted in the experimental development of dental materials containing pure tricalcium silicate with adequate physical properties [8,9], antimicrobial action comparable to calcium hydroxide, and good sealing capacity [10].

BD is a tricalcium silicate-based cement launched in Europe and has received favorable reviews in the literature due to its better handling and biocompatibility characteristics [11]. According to the manufacturer, BD is a biological material with good physical and chemical properties and high mechanical strength, acting as a substitute for dentin in restorative procedures without the need for surface acid etching. BD is presented in capsules containing the powder, which consists of tricalcium silicate, dicalcium silicate, calcium oxide and carbonate, and zirconium oxide (radiopacifier), and the liquid consisting of calcium chloride, the agent responsible for reducing the hardening time and a water-soluble polymer which maintains good flowability with a low water/solid ratio [12].

The main advantages of using BD over MTA include ease of handling, high viscosity, shorter hardening time (12 minutes), and better physical properties [13,14], in addition to having material of known purity in its composition [15]. Despite presenting differences with respect to MTA in composition and setting time, BD allows the deposition of hydroxyapatite on its surface when exposed to body fluid [16], has color stability [17], is non-genotoxic [18], and has low cytotoxicity [19], maintaining the viability of gingival fibroblasts [20]. *In vitro* studies with BD have shown compatibility with dental pulp cells and stimulated tertiary dentin formation [6,19,21-25]. The application of BD to pulp cells allowed their differentiation into odontoblast-like cells [21] and induced the formation of foci of mineralized tissue similar to MTA and calcium hydroxide [19,26]. Systematic reviews and meta-analyses comparing MTA and BD have not demonstrated differences in clinical and radiographic success between these materials [1,5]. Since BD was developed as a dentin replacement material, it becomes timely to investigate the use of this material for the conservative treatment of pulp tissue in primary teeth. The null hypothesis is that the response of the dentin-pulpal complex is similar in teeth treated with pulpotomy with MTA or BD material in primary teeth. Therefore, the objective of the present study was to verify, through clinical and radiographic evaluations, the *in vivo* response of the dentin-pulpal complex of human primary teeth after pulpotomy with MTA and BD in a follow-up period of 3, 6, and 12 months.

Material and Methods

Ethical Clearance

The present work was approved by the Human Research Ethics Committee of the Ribeirão Preto School of Dentistry (FORP) – University of São Paulo (process: 35908214.3.0000.5419).

Sample Selection

In the present study, pulpotomies were performed on the primary teeth of children aged 5 to 9. All the legal guardians of the selected children read and signed a Free and Informed Consent Form. Clinical and radiographic procedures were performed by a previously calibrated operator at the Pediatric Dentistry Clinic of FORP-USP.

A randomized clinical trial was carried out with simple random sampling to divide the groups, and the draw was done by tossing a coin. The selection of the sample was performed by clinical and radiographic analyses of the teeth according to the following inclusion criteria: (i) maxillary and mandibular first or second deciduous molars compromised by deep caries; (ii) absence of fistula or abscess; (iii) radiographic absence of internal and external resorption of more than 2/3 of the root; (iv) absence of lesions in the furcation region and the periapex; (v) possibility of tooth restoration. Individuals with systemic pathologies were excluded. The teeth were randomly divided into groups: Group 1 – Pulpotomy with MTA (n= 15) and Group 2 – Pulpotomy with BD (n= 15).

Clinical Procedures

All instruments used in the surgical procedures, including the gauze pads and cotton balls, were sterilized in an autoclave. The clinical technique steps included topical anesthesia and infiltrative anesthesia (upper teeth) or by blockade (lower teeth) (1 to 4% Mepivacaine with Epinephrine 1:100,000, DFL Indústria e Comércio S.A); after complete isolation with a rubber dam and clamps that fit the tooth correctly. Asepsis was performed with 2% chlorhexidine, and the carious lesion was removed with dentine curettes (#2, 3, 4 – S.S. White Artigos Dentários Ltda). The coronal opening, as well as the removal of the pulp chamber roof, were performed with spherical diamond burs (1014, 1015 - KG Sorensen), in high rotation under irrigation, and the removal of the coronal pulp was performed manually with dentine curettes.

After removing the pulp chamber roof and undergoing direct clinical examination, the pulp tissue, considered macroscopically vital, was submitted to pulpotomy and coated with different materials. In Group 1, the MTA powder was mixed with the distilled water accompanying the product in a 3:1 ratio. The cement handling was done to present a homogeneous mass of white color and a shiny surface at the end. The MTA was introduced into the tooth's pulp chamber with the aid of a padding foot and gently pressed against the tooth to adapt to the floor and cavity walls with at least 2 mm of thickness. In Group 2, the manipulation of BD was performed in an automated way in a mixing device (capsule amalgamator mixer), as recommended by the manufacturer. The capsule containing the powder was opened, and the liquid was introduced. Next, the capsule was closed and submitted to the mixing device for 30 seconds. The mixture was removed from the capsule and introduced into the pulp chamber with at least 2 mm of thickness with a padding foot and gently pressed against the tooth to adapt to the floor and cavity walls.

For both groups, a glass ionomer base (Vidrion R – S.S. White Artigos Dentários Ltda), approximately 2 mm thick, was made in the coronary chamber, and the definitive restoration was performed with Z250 light-curing composite resin (3M/ESPE) and radiographed after immediate treatment (Figure 1).

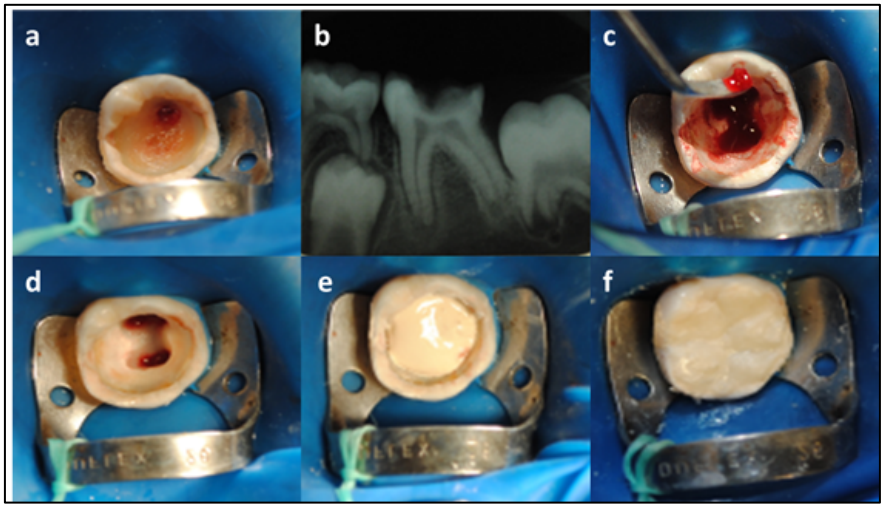

Figure 1. Representative photographs of the pulpotomy procedure with BD on element 75. (a) Coronary opening and access to pulp. (b) Initial radiograph demonstrating the depth of caries. (c) Removal of the coronary pulp and evaluation of the macroscopic aspects of the tissue (cut-resistant pulp, bright red color). (d) Hemostasis after irrigation with 0.9% saline and sterile cotton balls. (e) Insertion of the BD into the cavity, with at least 2 mm of material thickness. (f) Final restoration with composite resin.

Clinical and Radiographic Analysis

The pulpotomized teeth were evaluated clinically and radiographically at 3, 6, and 12 months for pulp response analysis as previously described [27,28]. All precautions regarding the risks related to the radiographic imaging were carefully controlled through the use of an apron and thyroid protector coated with lead rubber, child positioners for performing the technique, and ultrafast radiographic film (Kodak Insight EF Sensitivity Films, size no. 1), allowing a low exposure time to radiation. The focus/film distance of approximately 20 cm in a dental X-ray machine with 70kV and 10mA was maintained with an exposure time of 0.5 seconds. The development of radiographs was performed using automatic processing (A/T2000XR - Air Techniques).

Clinical success was considered when the teeth were presented with an absence of pain, mobility, and sensitivity to percussion, abscess/fistula, and color change. Radiographic success was considered when there was no internal root resorption, furcation, radiolucent interradicular area involvement, pulp calcification, periapical lesion, or formation of a dentinal barrier. The results obtained were analyzed using the GraphPad Prism 5.0 Software (Prism, Chicago, IL, USA), with statistical analysis using Fisher's exact test for dichotomous data at a significance level of 5%.

Results

Clinical Evaluation

Both BD and MTA led to tooth discoloration. Comparatively, the MTA led to tooth staining at six months (n= 6 - 40%), which was not observed in the BD ($p<0.0001$). At 12 months, a higher percentage of specimens in the MTA (n = 11 – 73%) group showed staining compared to the BD (n= 5 - 33%) ($p<0.0001$).

Painful symptoms were detected six months after using BD (n = 2 – 13%) ($p=0.0013$), however, it was not detected at 12 months. Teeth treated with MTA showed no painful symptoms.

Mobility was detected 12 months after using BD (n = 2 – 13%), but it was not detected in teeth treated with MTA ($p=0.0013$).

Fistula, foul odor, and increased sensitivity to percussion were not identified in any period, regardless of the material used (Table 1).

Table 1. Clinical evaluation of primary teeth submitted to pulpotomy and use of BD or MTA to protect the pulp remnant.

Evaluation	Color Change		Pain		Mobility		Percussion Sensitivity		Fistula		Odor	
	BD	MTA	BD	MTA	BD	MTA	BD	MTA	BD	MTA	BD	MTA
3 Months	0	0	0	0	0	0	0	0	0	0	0	0
6 Months	0	6 (40%)	2 (13%)	0	0	0	0	0	0	0	0	0
p-value	<0.0001		0.0013		>0.05		>0.05		>0.05		>0.05	
12 Months	5 (33%)	11 (73%)	0	0	2 (13%)	0	0	0	0	0	0	0
p-value	<0.0001		>0.05		0.0013		>0.05		>0.05		>0.05	

BD: Biodentine; MTA: Mineral Trioxide Aggregate.

Radiographic Evaluation

Radiographically, in teeth treated with BD, periapical lesions, inter-radicular lesions, and internal resorption were observed in 13% of cases (n = 2), unlike teeth that received MTA as a material for pulp protection (p<0.0013). On the other hand, the MTA induced pulp calcification in 13% of cases (n = 2), unlike the BD (p < 0.0013). All these radiographic changes were observed 12 months after the pulpotomy (Figure 2).

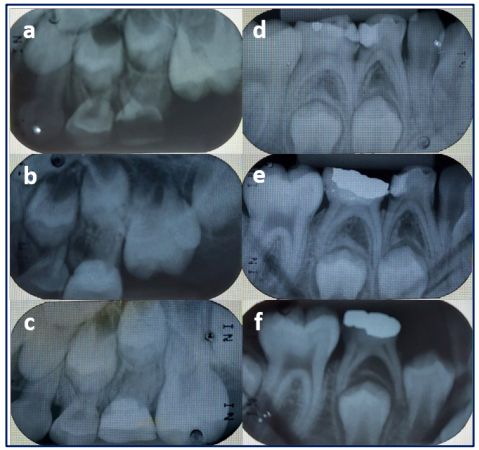

Figure 2. Representative radiographs of pulpotomies in primary teeth with MTA (a-c) or BD (d-f). Diagnostic X-ray (a and d). Radiograph after pulpotomy with MTA (b) or BD (e). Follow-up radiograph after one year of pulpotomy treatment with MTA (d) or BD (f).

Furcation resorption and mineralized tissue barrier in direct contact with the protective material were not observed in any period, regardless of the material used (Table 2). Thus, the MTA's clinical and radiographic success rate was 100%, although it presented a color change. However, BD presented a rate of 87%.

Table 2. Radiographic evaluation of primary teeth submitted to pulpotomy and use of BD or MTA to protect the pulp remnant.

Evaluation	Periapical Lesion		Interradicular Lesion		Furcation Resorption		Internal Resorption		Pulp Calcification		Dentin Barrier	
	BD	MTA	BD	MTA	BD	MTA	BD	MTA	BD	MTA	BD	MTA
3 Months	0	0	0	0	0	0	0	0	0	0	0	0
6 Months	0	0	0	0	0	0	0	0	0	0	0	0
12 Months	2 (13%)	0	2 (13%)	0	0	0	2 (13%)	0	0	2 (13%)	0	0
p-value	0.0013		0.0013		>0.05		0.0013		0.0013		>0.05	

BD: Biodentine; MTA: Mineral Trioxide Aggregate.

Discussion

Pulpotomy is defined as removing the coronal pulp from a living pulp to preserve the remaining root pulp for conservative treatments or temporary pain relief [29]. The application of biocompatible materials on the root pulp tissue can preserve vitality and stimulate the neoformation of mineralized tissue [2,3]. In the present study, we chose to compare MTA and BD since we can observe in the literature that they have similar clinical successes in approximately 100% of the cases [27,30-35]. Recent studies demonstrate the clinical and radiographic success of teeth that underwent pulpotomy with MTA or BD [36,37].

After 12 months, the success was 87% for the BD, while the MTA presented 100% with no statistical difference. Similar results occurred in the studies of Çelik et al. [36], who presented a success rate of 100% in the first six months, and from 12 months onwards, the BD presented 89.4% clinical and radiographic success, and in Cuadros-Fernández et al. [38] after 12 months of follow-up was 92% for the MTA and 97% for the BD. A randomized clinical trial followed the success rate over a more extended period of 24 months and found that the success rates of MTA and BD were 97.2% and 99.4%, respectively [39]. After the 12-month follow-up, the success rate showed no difference in the BD and MTA materials 88.46% of the cases [40].

In their study, Abuelniel et al. [37] clinically demonstrated that after 12 months, 16% of the BD group and 12% of the MTA group presented pain, mobility, and edema. Another critical factor is that in the present results, the MTA group presented pulp calcification in 13% of the teeth treated in 12 months, unlike Çelik et al. [36], where teeth showed pulpal obliteration in six months. Internal root resorption could be observed in 1 tooth in the MTA group, whereas in the BD, two molars had internal root resorption and periapical lesions [38]. A similar result was found in the present study, in which, after one year, two teeth had internal root resorption and periapical lesions in the BD group. However, two teeth had obliterated the root canal in the MTA group. In another study, 11.56% of the MTA and BD groups showed treatment failure after 12 months of follow-up, with the main response being internal root resorption [40].

A major disadvantage of MTA is its dental staining, which in the study presented a rate of 27% of the treated teeth in the period of six months, and no cases occurred with the BD in this period. After 12 months, tooth staining increased in the MTA group in 73% of the teeth and 33% in the BD group. The result below was found in the literature with Abuelniel et al. [37], where after six months, 60% of pulpotomies and after 12 months, 92% of pulpotomies performed with MTA presented staining. A systematic review and meta-analysis showed the periods analyzed after conservative treatment being 6, 12, and 18 months. They concluded that after examining the studies, there were no differences between the groups regarding clinical and radiographic success [5]. This corroborates the results of the present study in which the clinical and radiographic responses at 3, 6, and 12 months were evaluated.

Randomized clinical studies have their limitations in that each patient responds differently to the same treatment, in addition to the varied age groups and being able to influence the responses due to physiological resorption occurring at specific ages. Radiographically, the radiopacity demonstrated between the materials may differ, causing a qualified professional to distinguish which material was used even though it was a blind study. Studies comparing the BD with MTA mention that the materials have similar clinical and radiographic responses; however, the BD can be an alternative for conservative treatments due to its characteristics of shorter setting time, easier handling, and absence of tooth staining [5,36,37-40].

Conclusion

Overall, the results obtained for both the BD and MTA, based on clinical and radiographic manifestations after treatment, indicate that the materials are suitable for clinical use. There is a caveat regarding the staining of the teeth since both induced color change.

Authors' Contributions

LRCH	https://orcid.org/0000-0001-8615-4876	Conceptualization, Methodology, Software, Validation, Formal Analysis, Resources, Data Curation and Writing - Review and Editing.
LAAJ	https://orcid.org/0000-0002-4464-7506	Data Curation, Writing - Original Draft, Writing - Review and Editing, Visualization, Supervision and Funding Acquisition.
MPLP	https://orcid.org/0000-0002-6866-0561	Conceptualization, Methodology, Software, Validation, Formal Analysis, Resources, Data Curation and Writing - Review and Editing.
PNF	https://orcid.org/0000-0001-8802-6480	Data Curation, Writing - Review and Editing and Funding Acquisition.
RABS	https://orcid.org/0000-0002-0230-1347	Data Curation, Writing - Review and Editing and Funding Acquisition.
FWGPS	https://orcid.org/0000-0001-8559-532X	Data Curation, Writing - Original Draft, Writing - Review and Editing, Visualization, Supervision and Funding Acquisition.
LABS	https://orcid.org/0000-0001-7118-6859	Data Curation, Writing - Review and Editing and Funding Acquisition.

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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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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