

Short-term treatment outcome of pulpotomies in primary molars using mineral trioxide aggregate and Biodentine: a randomized clinical trial

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Abstract

Introduction An ideal pulpotomy agent for primary molars has been sought for many years. Recently, new materials that allow regeneration of residual pulp tissue have been developed. In this study, we compared the preliminary clinical results obtained using Biodentine and mineral trioxide aggregate (MTA) as pulp-dressing agents in pulpotomies of primary molars.

Methods A randomized clinical study was performed in children aged 4–9 years with at least one primary tooth with decay or caries requiring pulp treatment. A total of 90 primary molars requiring pulpotomy were randomly allocated to the MTA or Biodentine group, and 84 pulpotomies were performed. Clinical and radiographic evaluations were undertaken 6 and 12 months after treatment. All teeth were restored with a reinforced zinc oxide–eugenol base and stainless steel crowns. Statistical analysis using Fisher's exact test was performed to determine the significant differences between the groups.

Results A total of four clinical failures were observed; all involved gingival inflammation. The clinical success rate in the MTA Group after 12 months was 92 % (36/39), whereas the Biodentine Group obtained 97 % (38/39) ($p = 0.346$). All radiographic failures were observed at the 12-month follow-up evaluation. One molar from MTA Group showed internal resorption obtaining a radiographic success rate of 97 % (38/

39). Two molars from the Biodentine Group showed radiographic failure (1 internal resorption and 1 periradicular radiolucency) obtaining a radiographic success rate of 95 % (37/39).

Conclusions Biodentine showed similar clinical results as MTA with comparable success rates when used for pulpotomies of primary molars. However, longer follow-up studies are required to confirm our findings.

Clinical relevance This article demonstrates the effectiveness of Biodentine as a primary teeth pulpotomy material, performing similar results as MTA at 12-months evaluation.

Keywords Biodentine · Mineral trioxide aggregate · Primary molar · Pulpotomy

Introduction

Pulpotomy remains the most common treatment for pulp cavities exposed by caries in symptom-free primary molars [1]. During pulpotomy, the coronal pulp is amputated, and the remaining vital radicular pulp tissue surface is treated with a pulp-dressing agent [2]. Although Formocresol (FC) has long been considered the gold standard, researchers are questioning its use in this procedure due to its possible mutagenic and toxic effects [3]. Different materials such as calcium hydroxide, ferric sulfate, and glutaraldehyde have been studied to identify an alternative to the use of FC [4]. With the development of materials that are both biocompatible and bioinductive, the emphasis has shifted from preservation to regeneration of residual pulp tissue [5, 6]. Mineral trioxide aggregate (MTA; Dentsply, Tulsa, OK, USA) has gained popularity among pediatric dentists for use in pulpotomy because of its excellent sealing ability, biocompatibility, and ability to stimulate hard tissue formation [7]. Indeed, when applied directly onto the pulp, MTA has

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been found to induce reparative dentin bridge formation [8]. This effect seems to be partially due to the fact that MTA induces release of bioactive molecules such as transforming growth factor- β 1 (TGF- β 1) from powdered human dentin and pulp cells [9, 10] and this growth factor has been shown to be involved in odontoblastic differentiation [11]. This is why several authors advocate the use of MTA over FC because of its excellent clinical and radiographic results [12, 13]. A recent meta-analysis comparing MTA to FC in 30 clinical articles from 7 databases reported superior clinical success with MTA (95 %) than FC (success rate 87 %) [14].

The notable biological properties of Portland cement have led to the development of Biodentine (Septodont, St. Maurice-Fosses, France). This new calcium silicate-based cement is packaged as powder and liquid. According to the manufacturer, the powder consists mainly of tricalcium silicate, calcium carbonate, and zirconium oxide. The aqueous component is made up of water, calcium chloride (to accelerate setting), and a modified polycarboxylate (as a superplasticizer). A single measure of liquid is dispensed into a disposable capsule containing the Biodentine powder and mixed with a mixing device for 30 s [10]. Biodentine was developed to combine the high biocompatibility and bioactivity of calcium silicates with enhanced properties such as rapid setting time (conferred by the calcium chloride) and high strength (conferred by the low water-to-cement ratio, made possible by the water-soluble superplasticizing agent) [15]. An in vitro study has evaluated the use of Biodentine in pulpotomies of primary pig teeth. Hard tissue formation was observed after 90 days in all samples [16]. Another in vitro investigation in human molars demonstrated by tomographic evaluation that Biodentine showed the highest thickness of dentin bridges in comparison with MTA and other materials [17]. These properties make Biodentine a possible choice for use as a pulp-dressing agent for pulpotomies in primary molars.

In this study, we aimed to clinically and radiographically evaluate and compare the performance of MTA and Biodentine as pulp-dressing materials following pulpotomy in human primary molars in a 12-month follow-up.

Materials and methods

Study design and participants

This is a randomized open label clinical trial. This study was conducted between February 2012 and April 2013. The project was evaluated and approved by the Ethics Committee of the Universitat Internacional de Catalunya, Sant Cugat del Valles, Barcelona, Spain (Approval Reference: D-34-LBD-09). The study was designed in accordance with the 2010 Consolidated Standards of Reporting Trials statement, *Updated Guidelines for Reporting Parallel Group Randomized*

Trials [18]. This report is part of a larger study, which has been registered at ClinicalTrials.gov (Identifier: NCT01591278).

The participants were selected from patients attending the Department of Paediatric Dentistry at the Universitat Internacional de Catalunya. The procedures, possible discomfort or risks, and possible benefits were explained to the participants and their parents/guardians. Informed consent was obtained from the parents/guardians before participation.

Patients eligible to participate were healthy individuals aged 4–9 years requiring pulpotomy in one or two primary molars. The criteria for the selection of teeth to be included in the study comprised the following:

- Carious pulp exposure in symptom-free vital primary molars found during the removal of caries
- No clinical or radiographic evidence of pulp degeneration (excessive bleeding from the root canal, internal root resorption, or inter-radicular and/or furcal bone destruction)
- The potential for proper restoration of the tooth with a minimum of three walls present
- Physiologic resorption of less than one third of the root

The exclusion criteria included the presence of systemic pathology and any history of allergic reaction to local anesthetics or to the constituents of the test pulp-dressing agents.

Sample size calculation

Sample size was performed under the assumption of non-inferiority study. Pulpotomy with MTA have a 95 % of clinical success. Similar results can be achieved with Biodentine (maximum difference of 10 % in clinical success between groups). Accepting an alpha risk of 0.05 and a beta risk of 0.2 in a one-sided test, a total of 78 subjects are necessary (36 in MTA group and 36 in Biodentine group). It has anticipated a drop-out rate of 10 %.

Study procedures and outcomes

A single postgraduate student in pediatric dentistry performed the procedures, and one investigator checked to ensure that the pulp was exposed during preparation and that the teeth were suitable for pulpotomy. The molars were randomly assigned to either the Control (MTA) or Experimental (Biodentine) Groups using a random number table.

The primary molars were anesthetized using 4 % articaine with 1:100,000 epinephrine (Ultracain®; Normon S. A., Madrid, Spain) administered by inferior alveolar nerve block for mandibular primary molars and by buccal infiltration for maxillary primary molars [19] using a maximum of one carpule. Rubber dam isolation was used in all cases. Following the removal of caries and exposure of the vital pulp, access to the pulp chamber was obtained using a #330 high-speed bur

with a water spray. The access was refined with round burs in a slow-speed handpiece. Subsequently, the coronal pulp tissue was removed using a sterile slow-speed round bur (#6 or #8) [20, 21]. Complete removal of the pulp tissue down to the canal orifices was ensured by visual inspection and corroborated by a second investigator. Bleeding from the remaining pulp tissue was controlled by the application of slight pressure for 5 min [20, 22] with a sterile cotton pellet moistened with saline solution. If bleeding started again at this point, the tooth was eliminated from the study. The remaining radicular pulp tissue was treated with either MTA or Biodentine, as described below.

Mineral trioxide aggregate (control group)

The radicular tissue was covered with MTA paste obtained by mixing MTA powder with sterile saline in a ratio of 3:1 in accordance with the manufacturer's instructions.

Biodentine (experimental group)

The radicular tissue was covered with Biodentine obtained by mixing Biodentine powder with a single dose of liquid in accordance with the manufacturer's instructions.

Restoration

The pulp chambers of the molars in both groups were filled with a polymer-reinforced zinc-oxide–eugenol restorative material (Intermediate Restorative Material [IRM]; Dentsply Caulk, Milford, DE, USA). Periapical radiographs were taken immediately after the procedure to ensure that the dressing agents had been placed correctly. All molars were restored with stainless steel crowns (3M ESPE, St. Paul, MN, USA) cemented with glass ionomer cement (Ketac-Cem; 3M ESPE, St. Paul, MN, USA).

Recall visits

At the 6-months and 1-year recall visits, clinical and radiographic examinations were performed. Teeth were evaluated clinically by a single investigator and scored as a clinical success if the patient had no symptoms of pain, and there was no swelling or gingival inflammation, fistulation, or pathologic mobility. Postoperative radiographs were taken using digital radiography (VistaScan; Durr Dental Medics Iberica S. A., Barbera del Valles, Barcelona). For each patient, the radiographs were evaluated independently by two observers experienced in pedodontics. An HP Compaq LA2205 screen was used for the evaluation of the radiographs [23]. Teeth were scored as a radiographic success if they showed no evidence of internal or external resorption or periradicular radiolucency.

Statistical analysis

The Kappa index was measured to assess inter-observer agreement. A tooth-level analysis was performed. Results are presented as valid % or mean (SD). The comparisons between groups at 6 and 12 months were performed using the Chi-square test (exact Fisher test with observed frequencies <5) for categorical variables. *P* value <0.05 was considered to be statistically significant. All statistical analyses were performed using a statistical software package (IBM Corp. Released 2013. IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp.).

Results

The final study population comprised 68 children (35 boys, 33 girls) with a mean age (\pm standard deviation) at the time of treatment of 6.6 (\pm 1.3) years.

A total of 90 primary molars were initially included in the study, but six were excluded because of uncontrollable bleeding during treatment (a flow chart of molars included in the study is shown in Fig. 1). In total, 84 pulpotomies were performed on teeth randomly assigned to either the MTA or Biodentine Groups. Twenty-five patients had one pulpotomy with Biodentine, 27 patients had one pulpotomy with MTA, and 16 patients had two pulpotomies (one with MTA and one with Biodentine). This makes a total of 41 pulpotomies with Biodentine and 43 pulpotomies with MTA. The types of teeth were as follows: 24 mandibular first primary molars, 18 mandibular second primary molars, 24 maxillary first primary molars, and 18 maxillary second primary molars. After 6 months of follow-up, all molars were clinically and radiographically evaluated without any drop-out; whereas, at the 12-month follow-up evaluation, which had a recall rate of 93 % (78/84), six molars could not be checked as a result of four drop-outs from the MTA Group and two drop-outs from the Biodentine Group (Fig. 1). The Kappa index obtained was 0.8.

Clinical findings

After 6 months of follow-up, three clinical failures had occurred. All involved gingival inflammation (two molars from the MTA Group and one from the Biodentine Group). One molar from the MTA Group showed gingival inflammation at the 12-month follow-up visit. These molars were re-evaluated after educating the patient on oral hygiene, and the gingival inflammation was resolved. No clinical failures were observed in the Biodentine Group at the 12-month follow-up evaluation. Therefore, the clinical success rate in the MTA Group after 12 months was 92 % (36/39), whereas the clinical success rate in the Biodentine Group after 12 months was 97 %

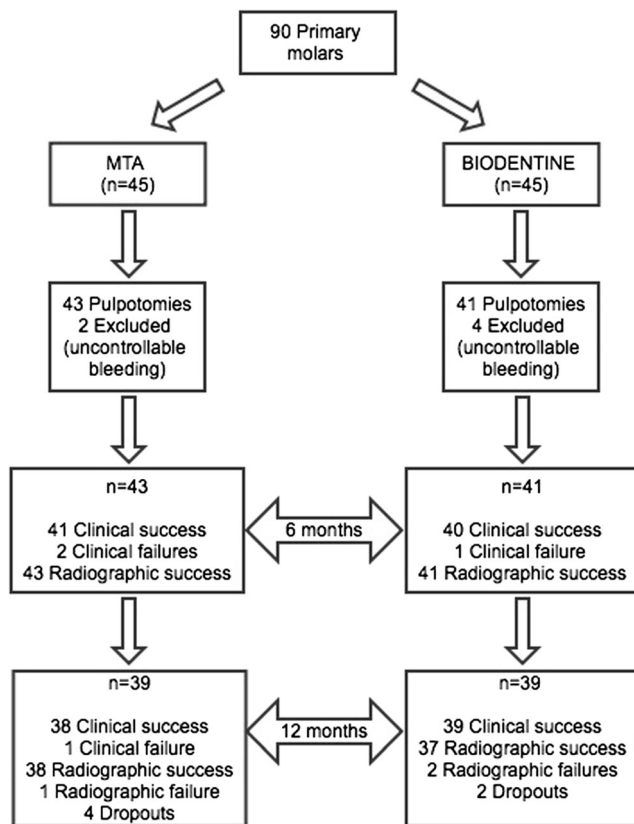


Fig. 1 Flow chart of molars included in this study

(38/39; Table 1) ($p = 0.346$). No patients showed signs of pain, tooth mobility, fistula, or swelling.

Radiographic findings

No evidence of internal or external resorption or periradicular radiolucency was observed in any molar in either group at the 6-month recall (Fig. 2). All radiographic failures were observed at the 12-month follow-up evaluation. One molar from the MTA Group showed internal resorption; therefore, use of MTA yielded a radiographic success of 97 % (38/39). Use of Biodentine yielded a radiographic success of 95 % (37/39). One molar showed internal resorption and a second exhibited periradicular radiolucency (Table 1; $p = 0.635$).

Discussion

This randomized clinical trial was conducted to evaluate the preliminary effects of the use of Biodentine and MTA as pulp-dressing agents during pulpotomies of primary molars. We observed similar clinical and radiologic success rates in both groups (97 % total success for Biodentine and 96 % for MTA).

With the development of materials that are both biocompatible and bioinductive, the search for alternative pulpotomy agents has shifted from preservation to regeneration of the

Table 1 Clinical success (S) and failure (F) rates for mineral trioxide aggregate and Biodentine™ pulpotomies at 6 and 12 months of follow-up

	MTA	Biodentine	p value ^a
Baseline ($n = 90$)	$n = 45$	$n = 45$	
6 months of follow up ($n = 84$)	$n = 43$	$n = 41$	
Clinical findings			0.600
Success	41 (95.3 %)	40 (97.5 %)	
Failure	2 (4.7 %)	1 (2.5 %)	
Radiographic findings			NA
Success	43 (100 %)	41 (100 %)	
Failure	0	0	
12 months of follow up ($n = 78$)	$n = 39$	$n = 39$	
Clinical findings			0.346
Success	38 (97.4 %)	39 (100 %)	
Failure	1 (2.6 %)	0	
Radiographic findings			0.635
Success	38 (97.4 %)	37 (94.9 %)	
Failure	1 (2.6 %)	2 (5.1 %)	

NA not applicable

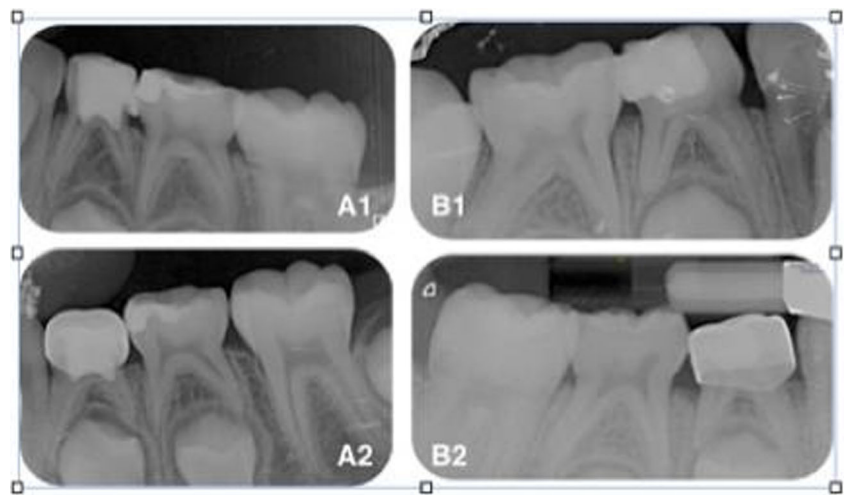
^a Fisher test

remaining pulp tissue [6]. One material that has demonstrated potential for pulp regeneration is MTA [24]. In this study, MTA was considered the control treatment, because good results obtained with MTA in previous studies are comparable to those obtained with FC [25–29]. Despite these high rates of success of MTA in the use of pulpotomies, there is still little evidence of its superiority to other materials [4]. We obtained 94 % total success rate for MTA, and this finding is comparable to those obtained in other studies [26, 30].

Both MTA and Biodentine are primarily composed of tricalcium silicate. The biocompatibility of both materials has been established [24, 31, 32]. Indeed, a comparison of pulp response to pulpotomy in dog teeth demonstrated that both MTA and Biodentine induced dentin bridge formation in all investigated samples [33]. MTA has a long setting time of 3–4 h [34], whereas Biodentine sets in just 12 min as a result of the addition of calcium chloride to the mixing liquid [10]. Another difference between these materials is the superior compressive strength of Biodentine compared with MTA and its possible application as an enamel replacement material for up to 6 months [15, 35]. Here, we used IRM as a temporary restorative material for comparison with MTA. However, one major advantage of Biodentine is that it can be placed as a permanent dentin substitute under the crown in a single session.

We experienced a high degree of clinical and radiographic success using both Biodentine and MTA as pulp-dressing agents during pulpotomies of primary molars. This success rate, which was high whatever the tooth type, indicates that both materials seem to be suitable for pulpotomy of all

Fig. 2 Radiographic findings in two molars included in the study. *A1* Immediate radiograph of a first mandibular primary molar after pulpotomy with mineral trioxide aggregate. *B1* Immediate radiograph of a first mandibular primary molar after pulpotomy with Biodentine. *A2* and *B2* Radiographic findings for *A1* and *B1*, respectively, at the 12-month follow-up



primary molar teeth. Such clinical success may be due to the fact that both materials lead to a non-porous dentin bridge formation as demonstrated *in vivo* and *in clinic* [17, 36]. While our clinical protocol cannot bring a scientific explanation to the obtained results, experimental works performed on fibroblast cell cultures and on entire human tooth cultures demonstrated that this dentin regeneration seems to be due to the fact that when these materials are applied to pulp fibroblasts, the later release TGF- β 1 and this growth factor recruits pulp stem cells which regenerate the missing dentin in the form of reparative dentin bridge [10, 37]. Also, recent data reported an anti-bacterial activity of both MTA and Biodentine which have been shown to inhibit the growth of oral bacterial strains including *Streptococcus* mutants and *Enterococcus faecalis* [38, 39]. This antibacterial property is very significant to the restoration clinical success. Indeed, a retrospective work on factors influencing the pulp response to cavity restorations reported that the presence of bacteria on the cavity walls is the main factor influencing pulp reaction under restorative materials and, consequently, the clinical success [40].

Two of the three radiographic failures reported in our clinical trial involved internal root resorption; this finding was also reported in our previous clinical trial of pulp agents [41]. All molars in the previous study that showed internal root resorption were left for observation if asymptomatic and did not show any signs of clinical failure. In this study, these molars are under observation and remain asymptomatic. Regarding clinical results, all clinical failures in the present study involved gingival swelling, which has long been considered a clinical failure after a primary molar pulpotomy [20, 26, 29, 42, 43]. However, the molars suffering from gingival swelling observed in this study were resolved by basic oral hygiene instructions, as was done in our previous clinical trial on pulpotomies [34]. Although no clear evidence has demonstrated a link between Stainless Steel Crowns and gingivitis, the

patient's level of oral hygiene with Stainless Steel Crowns has a significant effect on the gingival index [44] so that swelling observed in both our present and previous studies could be due to a combination of both Stainless Steel Crowns and the patient's gingival index.

Compared with MTA, Biodentine offers many advantages (shorter setting time, enhanced compressive strength, micro-hardness, and lower cost) and represents a promising material for use in pulpotomies. However, long-term results must be evaluated. Although this study shows preliminary short-term follow-up results in primary molar pulpotomies, our findings highlight the different strengths in methodology: all molars were treated under rubber dam isolation and restored with stainless steel crowns, which have excellent marginal adaptation that makes them the restoration of choice for this treatment. In addition, all molars were clinically and radiographically re-evaluated in two follow-ups (at 6 months and 12 months), with a high recall rate in the second evaluation (93 %).

To date, there is just one clinical study evaluating the effectiveness of the use of Biodentine during pulpotomies of primary molars after 6 months of follow-up [45]. However, there are many disparities in methodology with the present study: the authors do not explain how many operators performed the pulpotomies and how the clinical and radiographic evaluations were performed. No total success rate of the materials was calculated, and the authors think their failures might be due to iatrogenic errors like "poorly adapted stainless steel crowns, a thin base, voids in the cement and areas of residual caries or coronal pulp tissue." These could be solved with a postoperative radiograph after pulpotomy and placement of the stainless steel crowns.

Overall, our results are in line with this paper comparing MTA to Biodentine in primary teeth pulpotomies which also showed that both materials were equally efficient in this clinical indication [45].

This is the first randomized clinical trial to evaluate the performance of Biodentine as a pulp-dressing agent during primary molar pulpotomy with a follow-up of 12 months. The preliminary results obtained using Biodentine as a pulpotomy agent after 12 months of follow-up are promising; however, further studies with a larger sample size and a longer follow-up period are necessary.

Compliance with ethical standards

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Conflict of interest There were no conflicts of interests.

Informed consent Informed consent was obtained from all individual participants included in the study.

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