

ORIGINAL RESEARCH

Biodentine as a pulpotomy medicament for primary molars: a retrospective chart review

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Abstract

This retrospective chart review study investigates the long-term clinical outcome of Biodentine® (Tricalcium silicate) as a medicament for pulpotomy in primary molars. Data in this retrospective study was collected from the dental records of all patients that had at least one primary molar receive pulpotomy treatment (CDT code: D3221) between 01 July 2012 and 01 July 2015. This data includes child's age, medical history, dental history, dental radiographs, pulpotomy procedure details and follow-up clinical notes. Kaplan-Meier Estimate was used to measure the fraction of successful pulpotomy procedures for up to 24 months. A total of 1758 pulpotomy procedures were performed on 1032 patients in our institute in the three-year period and 21.4% of them (N = 376) had follow-up dental records that qualified for the study. Eleven teeth out of 376 teeth were excluded from the statistical analysis due to loss of/broken stainless steel crowns (3.1%). Seventeen pulpotomy failures were identified out of the remaining 365 procedures. The survival probability of using Biodentine® as a pulpotomy medicament is 96.3% for 18-month follow-up and 95.4% for 24-month follow-up. Biodentine®, a tricalcium silicate formulation, used as a pulpotomy medicament demonstrates a high clinical success rate (95.4%) over a 24-month period in primary molars.

Keywords

Biodentine®; Pulpotomy; Primary molars; Pulp therapy; Mineral trioxide aggregate

1. Introduction

Primary molar pulpotomy is one of the standard vital pulp therapies when coronal pulpal tissues are exposed during caries removal or due to trauma [1]. This method involves the amputation of the coronal pulp chamber and the placement of a suitable medicament to preserve the vitality of the remaining radicular pulp. Buckley's formocresol (Sultan Healthcare, Hackensack, N.J., USA) has long been considered the gold standard for pulpotomy medicament in primary molars [2]. However, the adverse effects of formocresol such as carcinogenicity, cytotoxicity and mutagenicity [3] caused many clinicians to seek comparable alternatives. Materials such as ferric sulfate [4], mineral trioxide aggregate (MTA) [5], calcium hydroxide [6] and even laser therapy [7] have been proven to have a good overall long-term success (24 months) [1].

MTA, a tricalcium silicate material, has recently been widely accepted as a comparable alternative to formocresol if cost is not an issue [1]. MTA is biocompatible [8], has antimicrobial effects [9] and promotes secondary dentinal bridge formation [10]. Systematic reviews demonstrate that MTA has superior clinical and radiographic outcomes when used as a medicament for primary molar pulpotomy [11, 12]. Biodentine® (Septodont, Saint-Maur-des-fossés Cedex, France) is also a

tricalcium silicate which was introduced to the market in 2009. Biodentine® is a powder/liquid two-component material [13]. The primary ingredient in powder is tricalcium silicate and the liquid contains calcium chloride as a setting accelerator and polycarboxylate as a water reducing agent. Biodentine® also shows excellent biocompatibility, antibacterial properties and can stimulate pulpal healing [14]. In addition, compared to MTA, Biodentine® has a significantly shorter setting time, higher adhesion to the dentin surface, higher compressive strength, lower porosity, increased resistance to erosion and decreased microleakage [15]. However, for primary teeth expected to be retained for 24 months, the American Academy of Pediatric Dentistry (AAPD) recommends using only MTA or formocresol as pulpal medicaments [16]. Although Biodentine® was shown with superior properties as a pulpal medicament compared to MTA, there are limited studies on analyzing the long-term clinical outcomes of Biodentine® as a pulpotomy treatment agent for primary molars in a large patient population [17–20]. Some clinical trials focused on short term posttreatment outcomes (6, 12 and 18 months) while some studies enrolled small numbers of study subjects [21–23]. The Department of Pediatric Dentistry in University Hospitals Rainbow Babies and Children's Hospital (RBC) has adopted Biodentine® as the primary medicament for pulpotomy since 2012. Therefore, a large sample size with long term post-

treatment follow-up data were available in the institute for retrospective chart review. The purpose of this retrospective study is to investigate the clinical outcomes of Biodentine® pulpotomies with both radiographic and clinical examinations with up to 24 months posttreatment.

2. Materials and methods

There are two inclusion criteria for the retrospective chart review study: (1) patient with at least one primary molar treated with a Biodentine® pulpotomy and restored with a stainless steel crown. (2) the patient must have follow-up examination (recall appointment or emergency basis), during which postoperative radiographs of teeth with pulpotomy and examination were recorded. There were 1032 patients that received a total of 1758 primary molar pulpotomies from 01 July 2012 to 01 July 2015 at the Rainbow Babies and Children Hospital (RBC) dental clinic. Charts were reviewed for patients past medical and dental history, preoperative clinical examination findings and radiographs, follow-up examination findings and radiographs, and any necessary interventions rendered.

Based on the recommendation from AAPD [1], pulpotomies were performed only when the following criteria were fulfilled: (1) primary molars presents with normal pulpal responses or reversible pulpitis; (2) no radiographic pathologic signs were present; (3) the pulp was exposed during caries removal or mechanical pulp exposure; (4) pulp was vital as bleeding was observed from the pulp; (5) hemostasis after amputation of the coronal pulp tissue was achieved within normal limits, indicating unaffected radicular pulp tissue. Primary molars that were excluded from the study were those that demonstrated loss of/defective stainless steel crown since it made the clinical outcome inconclusive. The clinical outcomes beyond 24 months were obtained but not included in the statistical results. Failure of pulpotomy treatment was defined as any primary molar demonstrating: (1) furcation radiolucency; (2) periapical bone destruction/radiolucency; (3) external root resorption; (4) swelling, abscess or sinus tract indicating a necrotic pulp; (5) adverse clinical signs or symptoms such as sensitivity and/or pain [1]. Natural exfoliation of the primary molars, internal root resorption, calcific metamorphosis of the pulp, and pulp canal obliteration was not regarded as a failure.

Primary molars that were indicated for pulpotomy had a diagnostic pre-operative radiograph taken. If patients were seen under general anesthesia, no local anesthetic agent was administered. If the patients were treated in the dental clinic, 2% lidocaine with 1:100,000 epinephrine was administered before the operative treatment began (Henry Schiene, Novi, MI, USA). Rubber dam was used as the isolation technique. Fig. 1A shows a pre-operative photo of a mandibular first primary molar with large deep caries. A pear-shaped carbide bur was used to create an access opening to the pulpal chamber and remove decay. A large sized round bur and/or spoon excavator was used to amputate the coronal tissue (Fig. 1B). According to the AAPD, chlorhexidine is recommended as a bactericidal irrigant to help control pulpal bleeding before the pulpotomy site is covered by a medicament [24]. In our dental clinic, we placed a cotton pellet soaked in 0.12% Chlorhexidine gluconate (3M ESPE Dental Product, St. Paul, M.N,

USA) on the radicular pulp stumps for 2–5 minutes after caries and coronal pulp were completely removed. The cotton pellet was subsequently removed and a dry sterile cotton pellet was placed to confirm adequate hemostasis (Fig. 1B). Biodentine® powder was mixed with its liquid according to manufacturer instructions and was firmly compacted into the pulpal chamber by using an amalgam carrier (Fig. 1C). Then 3M™ Ketac™ CemMaxicap™ cement (3M ESPE Dental Product, St. Paul, MN, USA) was utilized to cement a stainless steel crown (3M ESPE Dental Product, St. Paul, MN, USA) that served as a full coverage restoration (Fig. 1D).

Due to the nature of the retrospective study, some subjects exited the study early due to various reasons (uncooperative with treatments, moving, loss of contact or returning to referring dental home., *etc.*). A Kaplan-Meier Estimate is the simplest way of computing the success of treatment (survival) overtime in spite of all these difficulties associated with subjects or situations [25]. In the Kaplan-Meier Estimate analysis, no returning follow-up was labeled as censored observations. Analysis was performed by using IBM SPSS Statistics (SPSS) 28.0 software (IBM, SPSS Inc. Armonk, NY, USA).

3. Results

There are 1032 patients who received 1758 pulpotomy treatment from 01 July 2012 to 01 July 2015. Out of 1758 of them, 376 primary molar pulpotomies have met study criteria. The mean age when pulpotomy treatment was completed is 5.1 ± 1.9 years.

In our retrospective chart review, we identified 11 broken/loss of crowns in the primary molars (2.9%) treated with pulpotomy and they were excluded from the study. As a result, a total of 365 primary molars remained for study analysis. The distribution of the qualified teeth by tooth type is listed in Table 1.

TABLE 1. Distribution of primary molars by type and arch.

	1st molar (N)	2nd molar (N)	Total (N)
Maxillary (N)	79	79	158
Mandibular (N)	110	97	207
Total (N)	189	176	365

Overall, the majority of primary molars receiving pulpotomy procedure rendered successful follow-ups (95.3% N = 348 out of 365). The distribution of pulpotomy failures by type and arch is shown in Table 2. There is no significant difference in terms of the distribution of the pulpotomy failure among each molar type.

TABLE 2. Distribution of pulpotomy failures by type and arch.

	1st molar (N)	2nd molar (N)	Total (N)
Maxillary (N)	3	4	7
Mandibular (N)	5	5	10
Total (N)	8	9	17

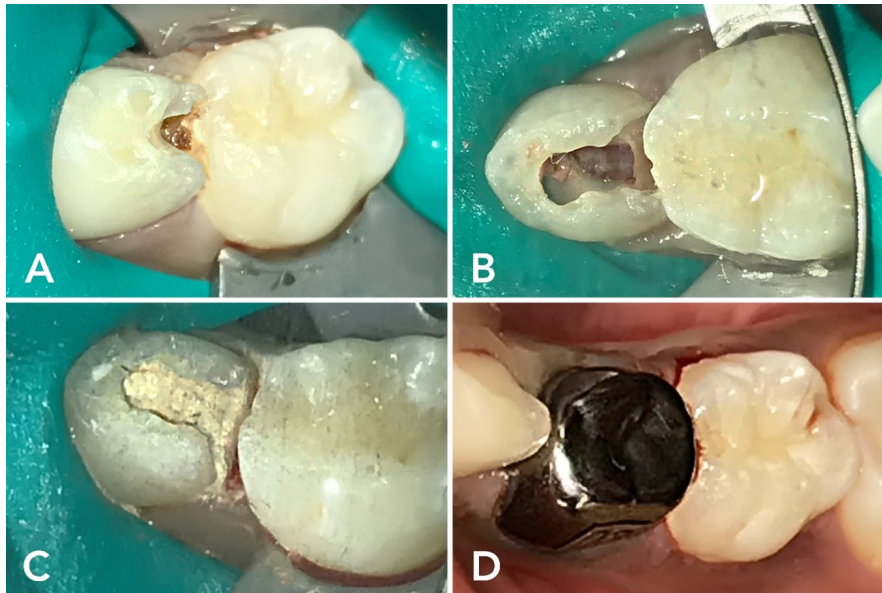


FIGURE 1. The operative procedure of pulpotomy using Biodentine® as a medicament. (A) Mandibular right first primary molar was treatment planned for pulpotomy and stainless crown due to extensive decay involving the pulp and breakdown of distal marginal ridge. (B) The coronal portion of the pulp was amputated with a handpiece and the pulp chamber was disinfected with 0.12% Chlorhexidine gluconate. Hemostasis was achieved by apply cotton pellets with gentle pressure after several minutes. (C) Biodentine® was mixed according to the manufacturer recommendation and packed in the entire pulp chamber with controlled force. (D) A stainless steel crown was cemented to the tooth with 3M™ Ketac™ CemMaxicap™.

Seventeen primary molars met the criteria of a failed pulpotomy treatment based on clinical and radiographic findings. All failures presented both clinical symptom and radiographic pathology. In clinical examination, majority of the failures (N = 16 out of 17) presented with soft tissue pathology (abscess, fistula and gingival swelling around the affected teeth) and one with tooth pain. In radiographic examination, furcation radiolucency (N = 10) was the most common pathological finding. The remaining findings include external root resorption (N = 4) and periapical radiolucency (N = 3) (Table 3).

Based on Kaplan-Meier survival analysis, the cumulative probability of clinical and radiographic survival for Biodentine® is 98.5% for 12-month follow-up, 96.3% for 18-month follow-up and 95.4% for 24-month follow-up (Fig. 2). There are 4 pulptomy failures before 12 months (23.5%), 11 failures before 18 months (64.7%). All the failures came from 16 patients and one patient has two failures.

4. Discussion

The importance of an effective vital pulp therapy medicament in primary molars when pulpal tissue is exposed is determined by a multitude of factors. The first is the longevity of the primary molar as determined by the eruption table. The AAPD eruption table illustrates that maxillary first primary molars exfoliate between 9–11 years; maxillary second primary molars between 9–12 years; mandibular first primary molars between 10–12 years, and mandibular second primary molars between 11–13 years [26]. The mean age of the population in our study is 5.1 years old (standard deviation (SD) = 1.9). The population in this study required a vital pulp therapy medicament that would last greater than 24 months. With the high success

rate at 24-months, Biodentine®-treated primary molars serve as a natural space maintainer that preserves the arch length until patients reach late mixed dentition or adolescent dentition stage.

The second is the ability to maintain proper function including chewing, speech and maintaining space for permanent teeth. An important goal of pulp therapy in primary teeth is to maintain the primary tooth as long as possible. The average age of the population in our study is during a critical time of growth and development. Maintaining their teeth as long as possible was crucial to their speech, maintaining proper nutrition and jaw growth.

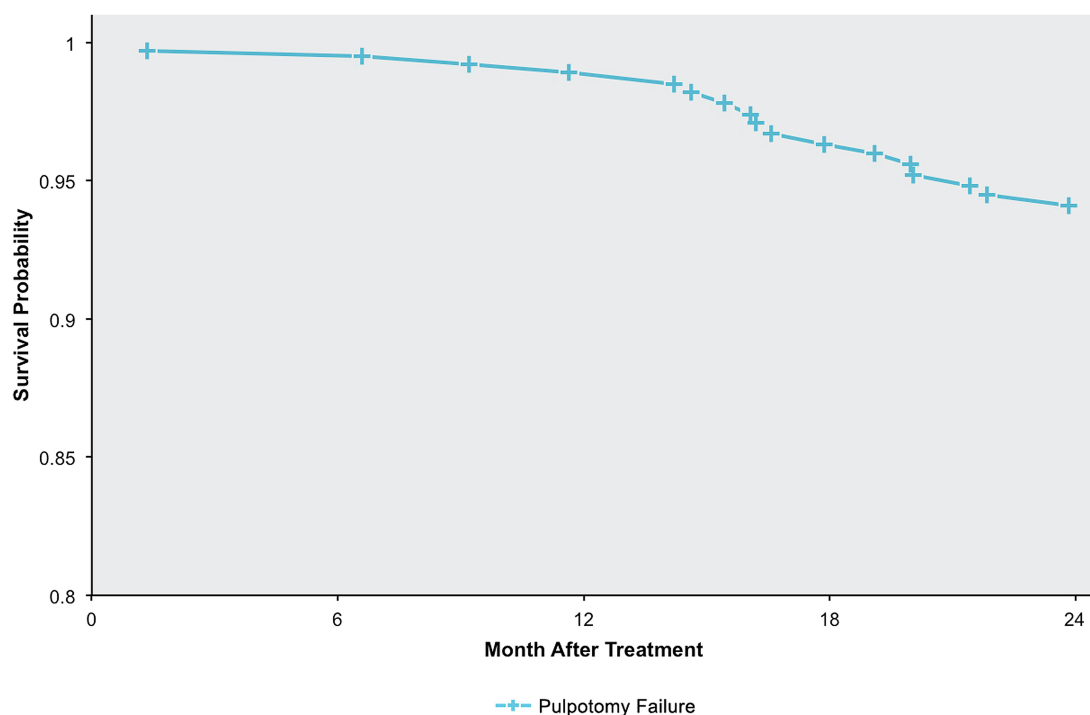
The third is that the other options are non-vital therapies. This includes pulpectomy and extraction of the primary tooth both of which can create undue consequences. A pulpectomy of a primary tooth is the complete removal of pulpal tissue. This is a time consuming difficult technique that has an unclear success rate that decreases rapidly at 12 months [27, 28]. The other alternative is extraction of the tooth which can cause space loss and can create an additional financial burden on a family later in life unless an appliance (*i.e.*, space maintainer) is created and tolerated by the child.

An effective vital pulp therapy medicament should include biocompatibility to the pulpal tissues, high success rate over long period time, easy clinical adaptation and low toxicity. Based on current AAPD guideline, only formocresol and MTA are recommended as the medicament of choice for teeth expected to be retained for 24 months or more [1]. The mechanisms of action for formocresol are bactericidal and fixes the pulp material. However, for the past three decades, concerns have risen about the safety of using formocresol due to its carcinogenicity, cytotoxicity and mutagenicity [3]. This has

TABLE 3. Clinical and radiographic failures after pulpotomy procedures.

Tooth type	Failure observed	Clinical failure presentation	Radiographic failure presentation
Maxillary right first molar	21 mon, 25 d	Fistula	External root resorption
Maxillary right second molar	14 mon, 19 d	Abscess	External root resorption
Maxillary right second molar	19 mon, 29 d	Abscess	Furcation radiolucency
Maxillary right second molar	14 mon, 6 d	Gingival swelling	Furcation radiolucency
Maxillary left first molar	19 mon, 3 d	Abscess	External root resorption
Maxillary left first molar	16 mon, 17 d	Pain	Periapical radiolucency
Maxillary left second molar	5 mon, 18 d	Abscess	Periapical radiolucency
Mandibular left first molar	9 mon, 6 d	Abscess	Furcation radiolucency
Mandibular left first molar	15 mon, 13 d	Gingival swelling	Furcation radiolucency
Mandibular left first molar	11 mon, 19 d	Abscess	Furcation radiolucency
Mandibular left second molar	16 mon, 6 d	Abscess	Furcation radiolucency
Mandibular right first molar	21 mon, 13 d	Abscess	Furcation radiolucency
Mandibular right first molar	17 mon, 26 d	Fistula, pain	Furcation radiolucency
Mandibular right second molar	23 mon, 28 d	Abscess	External root resorption
Mandibular right second molar	20 mon, 1 d	Abscess	Furcation radiolucency
Mandibular right second molar	16 mon, 2 d	Abscess	Furcation radiolucency
Mandibular right second molar	1 mon, 11 d	Abscess	Periapical radiolucency

SURVIVAL FUNCTION

**FIGURE 2. Kaplan-Meier survival analysis of Biodentine® pulpotomy.**

prompted finding alternatives to formocresol. The efficacy of various pulpotomy medicaments have been tested in the past several decades [16]. Biodentine® formulated as MTA-based cement with faster setting time, and easier manipulation makes it a favorable dentin replacement and repair material [10, 18]. Biodentine® has showed success in pulpotomy for permanent teeth [29, 30]. Also, an *in vitro* study showed that placing various immediate definitive restorative materials have no effect on Biodentine® final setting [31]. This ability allows for time-effective pulpotomy protocols when utilizing Biodentine®. Our pulpotomy protocol also shows that placing full coverage stainless steel crowns immediately after Biodentine® has not affected cement setting. This allows us to complete the pulpal and restorative treatment in primary molars in one visit. However, there have been few studies that show the long-term (24 months) success rate of Biodentine® in primary molar pulpotomy with a large sample size due to the novelty and the cost of the product. Our dental clinic has adopted the use of Biodentine® as a vital pulpal agent since July 2012 providing a large sample size for long term follow-up. Our results showed 95.4% 24-month success rate using Biodentine®. This is comparable to the 24-month success rate of formocresol (85.0%) and MTA (89.6%), which had the greatest success rate of all the evaluated pulpotomy medicaments [32].

Our data shows an even distribution of the primary molars by type and arch. In addition, there is no distinct difference among the distribution of pulpotomy failures by type and arch (Tables 1 and 2). Based on examining the radiographs of the failed pulpotomy teeth, furcation radiolucency is the most common type of radiographic failure (N = 10 out of 17), followed by external root resorption (N = 4 out of 17) and periapical radiolucency (N = 3 out of 17). Almost all failed teeth presented with soft tissue pathology such as fistula and/or abscess (N = 16 out of 17). The most probable cause to these failures could be inaccurate pulpal diagnosis. According AAPD, pulpotomy is indicated in a primary tooth when caries removal results in a pulpal exposure with a normal pulp or reversible pulpitis [1]. This study consists of various dental providers including pediatric dental residents. This can create an inconsistency of pulpal health diagnosis and clinical skill level with pulpotomy procedures. For example, completing a pulpotomy procedure on a primary tooth with irreversible pulpitis could create a failure. There can be a difficulty diagnosing the pulpal health of primary molars especially with younger patients that cannot tolerate standard pulpal tests like cold, heat and electric stimuli. Therefore, clinical diagnosis is largely dependent on the report of symptoms from parent or legal guardian, which can also be inaccurate and lead to a wrong diagnosis.

While the result is promising, the study comes with several limitations. As a retrospective chart review study, multiple factors can influence the results: (1) as mentioned above, no pre-operative measurements available to determine if a pulpotomy is the proper treatment option for each deep carious tooth; (2) clinical procedures and records at the time of the procedure were not collected for the purpose of study; (3) multiple providers at different skill levels: majority of the pulpotomies were completed by pediatric dental residents; (4) also a lack of consistent clinical and radiographic follow-ups.

Our clinic as a hospital-based dental practice located in a metropolitan area serves children primarily from low-social economic families. These children tend to have high caries risks, poor diet and oral hygiene, and less frequent dental home visits. Hence, the study samples may not represent patient samples from other geographic and social economic families. The follow-up visit in this study is only 21.8% because our dental clinic receives a significant amount of referrals from local dentists in which patients ultimately returned to their primary dental home for recall after treatment was completed. Therefore, this resulted in a decreased number of follow-up visits. In addition, a large portion of the patients were not compliant with regular recall appointments and more often present for emergency dental needs. With the majority of procedures (N = 1382) in this study having no follow-up data (78.6%), the actual clinical outcomes in this three-year period may potentially be significantly different.

5. Conclusions

Biodentine®, a tricalcium silicate formulation, used as a pulpotomy medicament demonstrates a high clinical success rate (95.4%) over a 24-month period in primary molars. While acknowledging the limitations of a retrospective chart review study, Biodentine® use for the treatment of vital pulpotomies in primary molars can be accomplished in one visit. This result is also dependent on if an optimal seal can be achieved with a full coverage restoration.

ABBREVIATIONS

MTA, mineral trioxide aggregate; AAPD, American Academy of Pediatric Dentistry; RBC, Rainbow Babies and Children Hospital; SD, standard deviation.

AVAILABILITY OF DATA AND MATERIALS

Providing study data will violate HIPAA compliance. Therefore, the authors do not wish to share their data.

AUTHOR CONTRIBUTIONS

YA, MF and GAF—designed the research study and provide advice on data collection. YA, RB, EP and GAF—performed the research and analyzed the data. YA—wrote the manuscript. YA, MF, GAF, RB and EP —contributed to editorial changes in the manuscript. All authors read and approved the final manuscript.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

This retrospective study was approved by the Case Western Reserve University Hospitals Institutional Review Board (IRB). The IRB study number is CR00002170. Informed Consent was signed by the legal guardians of all of the patients in this study. This is a retrospective chart review. All patients signed a blanket consent which includes the permission to publish

non-identifiable patient treatment data.

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CONFLICT OF INTEREST

The authors declare no conflict of interest. Gerald A. Ferretti is serving as one of the Editorial Board members of this journal. We declare that Gerald A. Ferretti had no involvement in the peer review of this article and has no access to information regarding its peer review. Full responsibility for the editorial process for this article was delegated to GS.

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