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Clinical and radiographic outcome of pulpotomy using Biodentine, in primary mandibular second molar teeth

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Abstract
Aims: The aim of the study was to assess the clinical and radiographical treatment outcome following pulpotomy using Biodentine, in primary mandibular second molar teeth.
Settings and Design: Tertiary dental health care setting (Government Dental college Thiruvananthapuram), Prospective study
Methods and Material: A total 27 consecutive patients ranging in age from 4-8 years, satisfying the inclusion and exclusion criteria participated in the study. Pulpotomy procedure was carried out using Biodentine and followed up at 3,6,12 month's intervals. The clinical success criteria in terms of absence of pain, pathologic mobility, swelling, sinus and radiographic success criteria in terms of pathologic root resorption, periapical and furcal radiolucency were noted. Evaluation of the treatment outcomes were based on clinical and radiographic examination. The resulting data were tabulated and statistically analyzed.
Statistical analysis used: SPSS version 25.0 was used to analyze the data
Results: At the end of the 1-year follow-up, the clinical and radiographic success rates were 92.5% and 88.9%, respectively.
Conclusions: Biodentine as a pulpotomy agent has a high successful rate and fulfilled all requirements of an ideal pulpotomy medicament. Hence Biodentine could be routinely used in practice for the treatment of carious primary molars. The excellent outcomes of the present study are truly indicative of Biodentine being a promising pulp repair agent for pulpotomy in clinical practice.

Keywords: Biodentine, pulpotomy, clinical and radiographic outcome, primary second molars, vital pulp therapy

Introduction

Maintaining deciduous teeth in function until their natural exfoliation is absolutely necessary. Vital pulp therapy (VPT) is a way of saving carious primary teeth. VPT includes three therapeutic approaches: indirect pulp capping, direct pulp capping and pulpotomy. [1] Pulpotomy is one of the most widely accepted clinical procedures for treating caries affected pulps in symptom free primary teeth. The rationale is based on the healing ability of the radicular pulp tissue following surgical amputation of the affected or infected coronal pulp. [2] Different materials are used to treat remaining vital radicular pulpal tissue. These clinically successful medicaments include Buckley's Solution of formocresol, ferric sulfate, glutaraldehyde and calcium hydroxide. [3] Electrosurgery and lasers have also demonstrated success. However, since mid-1990s, Mineral Trioxide Aggregate (MTA) has been recognized as the reference material for the conservative vital pulp treatments such as pulpotomy in primary teeth. It has shown to stimulate the formation of dentin bridge protecting the pulp markedly more than that observed with calcium hydroxide. [4]

The ideal pulpotomy medicament would be bactericidal and biocompatible, promote the healing of the root pulp, and be compatible with the physiological process of root resorption. Because such a medicament or technique with all of these features remains unavailable and given the lack of clear evidence supporting the superiority of any particular treatment method, research has continued to seek alternative pulpotomy agents that can provide better clinical efficacy without secondary effects. [5]

Formocresol (FC) has been the "gold standard" pulp dressing material used on pulpotomized deciduous molars for the past 70 years. Formocresol contains formaldehyde, a toxic, potentially carcinogenic/mutagenic compound, and concerns have been raised about its safety and its use in dentistry. [6] Different materials have been studied to identify an alternative to FC, and the attention has shifted from preservation to regeneration of residual pulpal tissue. [7]

Recently, the introduction of new pulp therapy agents like MTA, has led to new innovations in dentistry. [8] It showed a high success rate and has gained widespread use as a result of its excellent biocompatibility, good sealing ability, low cytotoxicity, and solubility. However, MTA has delayed setting time (about 4 hours), is difficult to manipulate and expensive. [9]

Biodentine (BD), one of the innovative materials, was designated for the experimental study to overcome the shortages of the previous ones. This material was shown to possess high biocompatibility, good mechanical characteristics, acceptable physical properties and favorable resistance to corrosion. [10] The main advantages of Biodentine over MTA include its ease of handling, high viscosity and shorter setting time (12 minutes), in addition to containing raw material with a known degree of purity making it more suitable in clinical use. [11] This material stimulates the deposition of hydroxyapatite on its surface when exposed to tissue fluids, [12] presents color stability, has nongenotoxic properties, low cytotoxicity and preserves gingival fibroblast viability. [13]

The literature search revealed a few articles on the clinical and radiographical success of Biodentine as a pulpotomy agent, in the treatment of primary teeth. Thus, further clinical research is required to utilize Biodentine as a substitute to formocresol in primary teeth pulpotomy. Moreover, the criteria for indication of VPT needs to be studied further. Hence this study focuses on clinical and radiological success rate of Biodentine for pulpotomy in primary teeth, thereby gradually eliminating the use of formocresol.

Materials and methods

A total of 30 children aged 4-8 years participated in the study in the Department of Pedodontics & Preventive Dentistry at Government Dental College Thiruvananthapuram. Study subjects were selected consecutively by following non probability sampling technique. The present study was a Prospective study after obtaining approval from the Ethical Committee of the Institution (IEC/R/27/2018/DCT/21-12-2018). The sample size was estimated based on the previous literature findings and by consulting a biostatistician.
(Using the formula years.

1. Inclusion criteria

1. Pediatric patients aged 4-8 years.
2. Deep carious lesion present in primary molars.
3. Absence of clinical signs and symptoms of pulpal exposure.
4. Absence of radiographic signs and symptoms of pulpal degeneration.
5. Definitely positive and positive child, evaluated using Frankel's behaviour rating scale.
6. Sufficient tooth structure to support a rubber dam.
7. At least 2/3rd of root remaining.
8. Parents willing to give consent to participate and children from whom assent could be obtained

2. Exclusion criteria

1. Medically compromised children
2. Limited mouth opening
3. Teeth having a history of dental restoration.

Intraoral periapical radiographs of the 30 selected study participants were obtained, prior to the pulpotomy procedure, which was performed as follows:
After administration of local anesthetic and rubber dam application, the caries was removed and coronal access obtained with a no. 330 high speed bur to expose the pulp chamber. A sharp spoon excavator was used for coronal pulp amputation. All remaining pulp tissue was excavated, and the chamber irrigated with normal saline. Hemorrhage was controlled by placing a sterile cotton pellet, using light pressure, over the radicular pulp stump. After achieving hemostasis, amputation stumps were covered with Biodentine paste, over which a composite restoration was placed. Post-operative intraoral periapical radiographs were taken after the procedure. Finally, the teeth were restored with stainless steel crowns.
All the patients were followed up at 3,6,12-month intervals to assess the clinical outcome and the radiological outcome was assessed at 12 months for asymptomatic cases or at anytime for those teeth which became symptomatic during the follow up period. Evaluation of the treatment outcomes were based on clinical and radiographic examination.

Clinical Criteria	Radiographic Criteria
No history of sensitivity, spontaneous pain or discomfort.	Presence of normal periodontal ligament space
No signs of gingival inflammation	Absence of pathologic external root resorption
No abscess or sinus tract.	Absence of internal root resorption
No pathological tooth mobility.	Absence of periapical radiolucency
	Absence of furcation radiolucency

*Guideline on pulp therapy for primary and immature permanent teeth

Teeth that remained asymptomatic and without radiographic signs of periapical pathology, followed up over a period of 12 months were considered successful. Teeth that became symptomatic with or without radiographic signs of periapical pathology or asymptomatic with radiographic signs of periapical pathology followed up over a period of 12 months were considered as failures.

Statistical analysis

SPSS version 25.0 was used to analyze the data. Frequencies and percentages were calculated for the descriptive variables like gender, clinical success, radiological success. Mean ± S.D were calculated for quantitative variables. Effect modifiers like age and gender were controlled through stratification. ChiSquare test was applied to see the effect of these on clinical and radiological success rate. When a P value was found to be < 0.05, it was considered as significant.

Results

Out of the total 30 study participants, three cases were lost to follow up due to the unprecedented covid-19 scenario. Hence our sample size was fixed with the available 27 cases, though only 25 were required as per the formula for sample size calculation. Out of the 27 study samples, 12 (45%) were males and 15(55%) were females. Mean age of the patients was 5.3 years. Two patient cases revealed unfavourable clinical signs and three patient cases showed unfavourable radiographic findings. Abnormal clinical and radiographic findings not seen in any of the 24 remaining cases. Pulp canal obliteration (PCO) was seen in eight of the cases (29.6%). At the end of the 1-year follow-up, the clinical and radiographic success rates were 92.5% and 88.9%, respectively. The data collected were statistically analyzed and the results are presented under the following categories:

Discussion

Biodentine is a tricalcium silicate (Ca3SiO5)-based inorganic nonmetallic restorative cement commercialized and advertised as a 'bioactive dentine substitute' (Zanini *et al*. 2012) [14]. The material is claimed to possess far better physical and biological properties such as material handling, faster setting time, increased compressive strength,

increased density, decreased porosity and induction of reparative dentine synthesis when compared to its competitors. On the biological level, it forms perfectly reactionary dentin, as it stimulates odontoblast activity and reparative dentin by induction of cell differentiation. [15]

The current study was performed under controlled experimental conditions to avoid the influence of confounding variables. These provisions included the use of rubber dam, disinfection of the operating materials, gentle hemostasis of irrigation and complete adaptation of the stainless-steel crown. Controlling these factors affirmed that the statistical results were exclusively in response to the use of Biodentine in teeth. The associations between socio demographic variables, age and gender with clinical and radiological outcome were also tested in this study.

In the current study, the proportion of sample with unfavorable clinical and radiological outcome was found to be highest in the 4 years age group and the clinical and radiographical outcome was relatively good in females compared to males. However, no statistically significant association were found between clinical and radiographical outcome of the children and their chronological age and gender. From the results, it is clear that age and gender had no significant effect on clinical and radiographical outcome.

In this study, children in the age group of 4-8 years were included, which is the stage of stability and maturation which extends from complete root formation to clinically detectable resorption, and where the maturing pulp has a strong dentinogenetic and repair potential. [16] The initiation period of Physiological root resorption was manifested as 8 years for primary second molars in "Kronfeld's Chronology of Dental Development". [17]

Mandibular arch of children have a greater caries prevalence. This may be due to the deep pits and fissures seen in its occlusal anatomy. [18] Aminabadi *et al*. [19] have demonstrated that primary second molars are more accessible than first molars and it can alter the treatment outcome. Hence only primary second molar teeth were included in the study.

Primary teeth have one very distinct feature which sets them apart from the permanent dentition: they undergo physiological resorption leading to shedding. Stage of root resorption can influence the tooth's potential to respond to injury, and this may affect outcome of interventions such as indirect pulp capping or vital pulpotomy. In the present study, 29.6% showed 1/3rd root resorption, whereas 70.4% did not show any evidence root resorption. Though, there was a numerical increase in the number of cases showing 1/3rd root resorption with favorable clinical and radiographical outcome, no statistical significance was noted. ($p > 0.05$). These findings are in accordance with the study done by Nasseh *et al* [20] where a total number of 35 primary molars in stage of physiological root resorption were selected to undergo pulpotomy treatment, and favourable clinical and radiological outcomes were found. These findings are contrary to the study conducted by Basak Durmus, and Ilknur Tanboga [21] where the clinical success rate in pulpotomies were evaluated in terms of the level of physiological root resorption at the 12 month observation time which showed no significant differences. However, according to the results, radiologic success rates of teeth with physiological root resorption were significantly lower than those of teeth without physiological root resorption.

Pulpal status plays a decisive role in the success or failure of VPT. No tools were available to assess how far the inflammation has reached the pulp. Uncontrollable bleeding that is difficult to manage indicates that the pulp is severely inflamed. [22] If the bleeding could not be stopped within 5 to 10 minutes, the inflammation is considered to be uncontrollable and pulpectomy was recommended. [23, 24] In the present study, of the total samples selected, the time taken in minutes for achieving haemostasis was less than 5 in 88.9% and more than 5 in 11.1% of cases. When the time to achieve haemostasis was less than 5 minutes the clinical and radiographical outcome was found to be better compared to cases where time was more than 5 minutes. Thus, it was observed that there was a highly statistically significant association between clinical radiological outcome and time to achieve haemostasis. ($P= 0.001$) Hence it can be assumed that the time to achieve haemostasis can be a clinically reliable indicator for judging the degree of pulpal inflammation. This is in conformity with the study by Matsuo *et al*. [22] However, this observation conflicts the conclusion by Linsuwanont *et al*. [25] and Mutluay *et al*. [26] in that, the time to achieve haemostasis has no effect on treatment outcome. Hence, it can be concluded that this is an area that warrants investigation.

In the present study, pulp canal obliteration (PCO) was the most common radiographic finding in pulpotomized molars treated with Biodentine. This feature is one controversial radiographic outcome with different schools of thought. Follow up radiographs of 29.6% teeth (8 teeth) showed obliteration of pulp canal/calcification after pulpotomy procedure. These findings are in accordance with the study done by Nasseh *et al* [20] who reported a 25.7% of PCO on physiologically resorbed primary molars with reduced healing potential, which was slightly lower than that obtained by our study. This difference in the PCO can be attributed to the high healing potential of the pulp by apposition of reactive dentin in response to physiological stimuli. In the present study, PCO was not considered as a radiographic failure. This is in accordance with the study done by Celik *et al*. [27] where PCO was not regarded as a failure. However, this is contrary to the study performed by Carti O *et al*. [28] where Pulp canal obliteration was considered as a radiological failure.

Considering the clinical outcome in the present study, out of the 27 study samples, 25 subjects showed favorable clinical outcome. Two unfavorable clinical outcomes occurred during the 3rd month of follow-up. Two patients reported with spontaneous pain and gingival inflammation. Both teeth displayed sensitivity to percussion and one showed periapical abcess and abnormal mobility. Besides the two cases with unfavorable clinical outcome, none of the remaining cases showed any abnormal clinical findings, during the entire observation period of the 12 months. Therefore, at the end of the 1-year follow-up, the favorable clinical outcome was observed in 92.6% of cases. The favorable clinical outcome of Biodentine in the present study is in line with results of previous studies by various authors for the same follow-up period [29, 30, 31, 32] and was lesser than results of previous studies by Nasseh *et al* [20], El Meligy *et al*. [33], Musale *et al*. [34] where 100% successful clinical outcomes were observed. The unfavourable clinical outcomes in the current study could be attributable to undiagnosed chronic inflammation existing in the radicular pulp prior to pulpotomy rather than due to exposure of radicular pulp to Biodentin.

Nasrallah *et al*. reported similar results on Biodentine pulpotomies and considered that the chronically inflamed radicular pulps were believed by the clinician to be non-inflamed which led to a preoperative clinical misjudgment of the bleeding nature and time. [16] An inherent problem in treating any exposed pulp is the limitation in judgement of clinicians to accurately diagnose the true condition of the pulp and to predict the pulp's ability to respond to any form of therapy. [35] This is even harder for children where the patient's responses to pulp testing procedures are unreliable. The history of previous pulp involvement is a significant factor as is the degree of caries-associated bacterial penetration. [36] The quality of the coronal restoration plays an important role in the long-term success. Bacterial recontamination through coronal micro-leakage should be avoided for a positive clinical outcome. Therefore, it is considered essential that a well-sealed coronal restoration is mandatory. In the present study, composite restoration was given for all the teeth after initial setting of the Biodentine, followed by stainless steel crowns to ensure the hermeticity of the cavity and to increase the success rate of pulpotomy.

Considering the radiographic outcome evaluation, out of the 27 study samples, 24 subjects showed successful radiological outcome in this study. After the 3rd month, two cases reported with pathological clinical features, which also showed features of unfavorable radiological outcome such as periapical radiolucency and external resorption. So it could not be evaluated radiologically at 6 and 12 months. Another case with unfavorable radiological outcome was found at the 12th month of follow-up; the IOPAR of which suggests internal resorption, but the child did not exhibit any clinical signs indicative of pulpal pathology. Therefore, at the end of the 12 months follow-up, favorable radiological outcome of Biodentine was identified in 88.9% of the patients. This is very similar to the observations by Niranjani *et al*. [37] where favorable radiological outcome of Biodentine was identified in 90% of the patients, while Akhtar *et al*. [30] reported a slightly higher percentage (94.26%). These findings are in accordance with the study done by Wong *et al*. [31] where favorable radiological outcome was identified in 85.6% of cases. A similar finding was reported by Afroz *et al*. [29] (92%) and Musale *et al*. [34] (92.9%) for the same follow-up period. While Laila M. El Habashy [38] (73.3%) and Carti O *et al*. [28] (60%) obtained a lower percentage.

The favourable outcome was lesser than the results of previous studies by Nasrallah *et al*. [16] and El Meligy *et al*. [33] where 100% favorable radiological outcomes were observed. Failure of pulpotomy can be detected radiographically even if the tooth showed favourable clinical outcome.

In the current study, formation of dentin bridges were not taken as a criterion for success since it is difficult to appreciate radiographically and it varies between the observers. It can only be confirmed by histologic examination. [39] To evaluate pulpal status, clinical parameters that are used routinely include pain quality, history and responses to pulp sensitivity tests. Unfortunately, histologic observations do not always correlate to the clinical diagnosis of reversible or irreversible pulpitis. [40] A case diagnosed as irreversible pulpitis based on clinical sign and symptoms may not show a deep inflammation on histologic analysis and vice versa. [41] Therefore evaluation of pain, which is purely a subjective measure, seems inadequate and unreliable for making a final diagnosis.

The optimization of Biodentine was evident in the current study. This pulp dressing material appears to satisfy almost all requirements for pulpotomy medicaments, and this may be due to a combination of its bactericidal and germicidal action, excellent sealing ability, biocompatibility, alkalinity, and ability to regenerate hard tissues. From the results of the present study, it can be concluded that Biodentine pulpotomy is a viable option in the treatment of inflamed pulp. However, further clinical studies are required to refine the clinical criteria for pulpotomy to improve the predictability of the same.

Fig 1: Armamentarium

Fig 2: Pulpotomy procedure using Biodentine

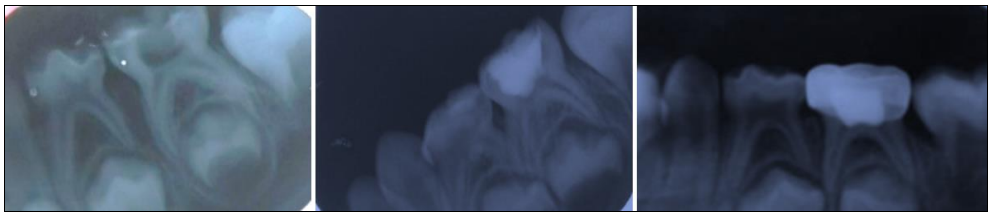
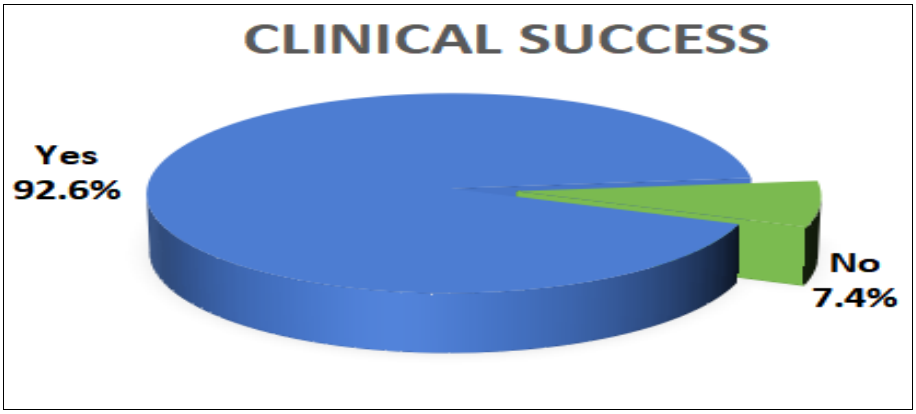
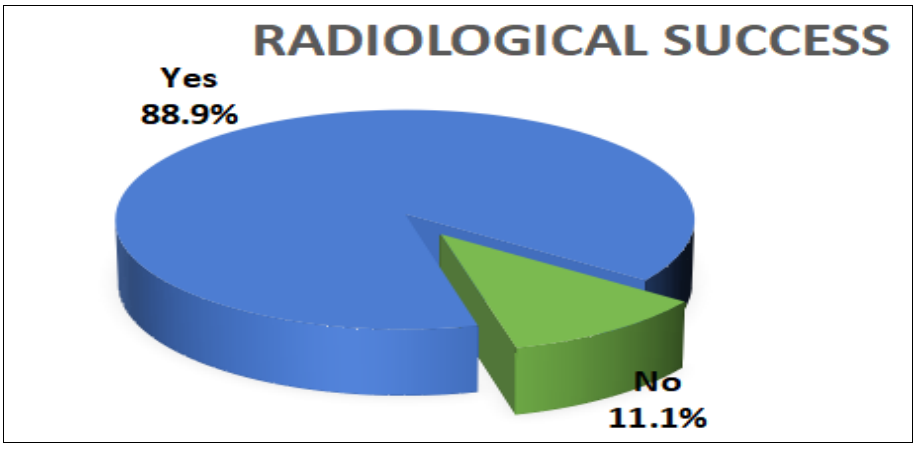


Fig 3: Preoperative and postoperative intraoral radiographs



Graph 1: Percentage distribution of the sample according to Clinical success.
Out of the 27 study samples, 25 subjects (92.6%) showed successful clinical outcome.



Graph 2: Percentage distribution of the sample according to Radiological success.
Out of the 27 study samples, 24 subjects (88.9%) showed successful radiological outcome.

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