ORIGINAL RESEARCH

Biodentine™ Pulpotomy in Stage I Primary Molars: A 12-month Follow-up

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Abstract

Aim: This study aims to evaluate, over 12 months of clinical and radiographic follow-ups, the performance and outcomes of Biodentine™ pulpotomy in stage I primary molars.

Materials and methods: A total number of 20 stage I primary molars requiring pulpotomy were selected from eight healthy patients aged between 34 and 45 months. Patients presenting a negative attitude toward dental treatment on the dental chair were scheduled for dental treatments under general anesthesia.

Pulpotomy with Biodentine™ as a pulp-dressing material was performed on all selected molars. The patients were called back at 1 and 3 months for clinical follow-ups, then at 6 and 12 months for clinical and radiographic follow-ups. Data were tabulated according to follow-up intervals and occurrence of any changes in root maturation, pulp canal obliteration (PCO), periodontal ligament space (PLS), and bone or root lesion.

Results: No statistically significant differences were recorded at 1, 3, 6, and 12 months. There was a statistically significant increase in number of roots with closed apices from six roots at 6 months to 50 roots at 12 months ($p < 0.0005$) and the PCO was present in all 50 roots at 12 months, after it was present in 36 roots only at 6 months ($p = 0.0001$).

Conclusion: This is the first randomized clinical trial that evaluates the performance of Biodentine™ as a pulp-dressing agent in stage I primary molar pulpotomy over 12 months of follow-up. Contrary to previous studies, the present work highlights the continued root formation and apical closure (AC) in pulpotomized immature primary molars.

Keywords: Apical closure, Biodentine™, Primary teeth, Pulpotomy, Root edification.

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Introduction

A major objective in pediatric dentistry is to preserve primary dentition in a healthy state before the eruption of the permanent successors.[1,2]

It is fundamental to maintain the integrity of primary teeth for physiological functions (i.e., speech and mastication) as well as to maintain arch length, esthetics, and prevention of abnormal habits.[3,4] Early childhood caries and dental trauma with their complications are still main serious clinical problems causing a serious challenge to preserve the pulp vitality.[5]

Pulpotomies are the most routine vital pulp therapy procedure to treat an asymptomatic tooth with deep carious lesions adjacent to the pulp.[3,4,6]

The procedure involves amputation of the coronal pulp and subsequent treatment of the remaining vital radicular tissue surface with a long-term clinically evaluated medicament to preserve the vitality and function of the tooth.[6]

The primary tooth is characterized by three evolutionary stages that altered its reaction to various attacks: stage I is the period of the immaturity of the root and the maturing pulp has a strong dentinogenetic and repair potential, stage II corresponds to the complete maturity period of the tooth, and stage III consists of the physiological root resorption of the primary tooth.[7,8]

Pulpotomy is an indicated pulp treatment in the three physiological stages of primary teeth.

In 2019, Chen et al. stated that immature permanent teeth are prone to caries and trauma which can cause pulp degeneration which stops root formation, leaving teeth with incomplete root formation. It is vital to preserve the pulp vitality otherwise the incompletion of root might result in the fragility of teeth.[9]

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In the same vein, the preservation of the vitality of an immature primary tooth is crucial for the completion of its root formation and consequently its longevity and strength.

Historically, a wide variety of medicaments have been suggested to be used as pulpotomy medicaments.[5,10] The ideal pulp capping cement should have good physical and biological properties such as being biocompatible, bactericidal, harmless to the pulpal tissue and surrounding structures, promoting healing of the radicular pulp, not interfering with normal physiological root resorption, and preserving the radicular pulp without any clinical or radiographic symptoms.[10–12]

Biodentine™ is a brand-new dentine substitute based on the Active Biosilicate Technology designed to treat damaged dentine both for crown and root indications; additionally, it can be used for pulpotomy because it is very successful in the formation of a dentine bridge.[13,14]

Biodentine™ is an inorganic nonmetallic restorative cement. The material is claimed to possess far better physical and biological properties such as material handling, a faster setting time within 12 minutes (conferred by the calcium chloride)[15] and high strength (conferred by the low water-to-cement ratio made possible by the water-soluble super-plasticizing agent), increased density, decreased porosity, and induction of reparative dentine synthesis when compared to its competitors.[14]

An *in vitro* investigation done by Shayegan et al. has evaluated the use of Biodentine™ in pulpotomies of primary pig teeth. Pulp canal obliteration was observed after 90 days in all samples.[16] Another *in vitro* study in human molars demonstrated by tomographic evaluation that Biodentine™ showed the highest thickness of dentin bridges in comparison with mineral trioxide aggregate (MTA) and other materials.[15,16] All that ample evidence for positive effects of Biodentine™ on vital pulp cell, for stimulating tertiary dentin formation, and early formation of reparative dentin, makes Biodentine™ a possible choice of use as a pulp-dressing agent for pulpotomies in primary molars.[5,15]

Grewal et al. compared Biodentine™ and calcium hydroxide (CH) and found that primary teeth treated with Biodentine™ showed a favorable regenerative potential along with clinical success compared to the children treated with CH.[13,17]

Recent studies were conducted on stages II and III primary molars that underwent pulpotomy with Biodentine™.[18,19]

The aim of this study was to assess, over 12 months, the clinical and radiographic outcomes when using Biodentine™ pulpotomy material to maintain the vitality of decayed immature primary molars (stage I).

The variables to analyze were root edification, AC, PLS, and PCO.

Materials and Methods

Ethical clearance of this research was delivered from the Lebanese University Institutional Review Board (#CUER 58-2021).

The study was conducted at the Department of Pediatric and Preventive Dentistry, School of Dentistry, Lebanese University.

The procedure with its associated risks and benefits was explained to the child's parent or guardian before they signed a written informed consent. All participants were screened by taking a detailed history and performing a clinical and radiographic examination.

A total number of 20 carious stage I primary molars (10 upper molars and 10 lower ones) were selected from eight healthy patients aged between 34 and 45 months, presenting a negative attitude toward dental treatment on the dental chair. The young patients were scheduled for dental treatments under general anesthesia.

Teeth Selection

The 20 selected molars (with a total number of 50 roots) presented symptom-free deep carious lesions and incomplete roots formation with open apices on radiographs. The final selection for inclusion in the study was done intraoperatively, only when hemostasis was adequately achieved within 5 minutes after coronal pulp amputation.

Every tooth showing one or more of the following clinical or radiographic signs was considered excluded:

- Spontaneous pain.
- Internal or external root resorption.
- Pathological mobility.
- Periodontal ligament space widening (PLSw).
- Inter-radicular bone destruction and/or apical bone destruction.
- Presence of swelling or fistulous tract.
- Proper hermetic restoration not possible.

Study Design

Under general anesthesia, one operator conducted all pulpotomies. Isolation of the tooth was performed (using either rubber dam or cotton rolls or suction). Complete caries was removed using a sterile diamond bur in a high-speed handpiece. Access to the pulp chamber was performed using a sterile low-speed round steel bur. The pulp was amputated with a sterile carbide round bur in a low-speed handpiece with continuous water irrigation. After pulp amputation and pulpal debris removal by flushing with saline solution, hemostasis was achieved by compression with a cotton pellet soaked in sterile saline for 5 minutes. The Biodentine™ material was prepared as per the manufacturers' instructions to obtain a putty-like consistency. The mixture was delivered to the pulp stumps and condensed lightly with a moistened sterile cotton pellet to ensure a thickness of 2–3 mm. Zinc oxide-eugenol cement (IRM®) was placed over the Biodentine™ to completely fill the cavity. After crown preparation, all molars were restored with stainless steel crowns (SSCs) (3M ESPE, St. Paul, MN, USA) cemented with glass ionomer cement (Ketac-Cem, 3M ESPE, St. Paul, MN, USA).

A postoperative periapical digital radiograph was taken immediately after the treatment to define the baseline.

Parents were provided with all the general oral hygiene instructions and specific instructions in relation to the treated tooth. Parents were asked to report immediately in case of any postoperative pain, swelling, pus discharge, or discomfort in the treated tooth.

All patients were called back at 1 week, 1 and 3 months for clinical follow-ups, then at 6 and 12 months for clinical and radiographic follow-ups.

The clinical and radiographic success was evaluated by two experienced specialist blinded examiners independently. Radiographic evaluations were performed by digital periapical radiographs taken at (t-1): preoperatively during the first consultation in the dental clinic or directly before the intervention in the operating room, (t 0): directly after performing pulpotomy, (t 1): at 6-month follow-up, and (t 2) at 12-month follow-up (Fig. 1).

These digital radiographs were obtained using a RINN Endo Ray sensor positioner and the Kodak portable intraoral machine (model 2100) set at 70 kV, with 0.3 seconds exposure time for the maxillary molars, and 0.2 seconds for mandibular molars.

The clinical success was defined by the absence of spontaneous pain, sinus tract, swelling, or abnormal mobility. The radiographic success criteria must include continued root edification and AC of the 50 dental roots, normal development of the successor tooth, presence of a normal PLS, and presence of PCO in the 50 roots.

However, any radiographic evidence of PCO was not considered a failure as it shows that the pulp is still vital and active.

At the end of the treatment session, the data were recorded on a form for each patient. Clinical parameters were evaluated at 1, 3, 6, and 12-month intervals and the radiographic ones at 6 and 12 months.

Figure 1 shows radiographs of one successfully treated tooth.

In case of loss of the SSC during the follow-up period, the tooth was excluded from the study.

Twenty primary molars with their 50 roots were studied to compare:

- The clinical parameters (sinus tract, tooth mobility, spontaneous pain, or infection) after 1 week, and after 1, 3, 6, and 12 months.
- The radiographic parameters (root completion/AC, PLSw, bone lesion, PCO, pathologic root resorption, and normal development of succedaneous teeth) at the 6- and 12-month follow-up.
- The outcomes of the pulpotomy at all time frames.

Clinical and radiographic data were tabulated respectively in Tables 1–3.

Statistical Analysis

Data analysis was performed using SPSS version 24.0 (IBM Corp., Armonk, NY). Clinical as well as radiological outcomes were reported as frequencies and percentages. Fisher's exact test was used to evaluate bivariate associations between outcomes at each session (1, 3, 6, or 12 months). McNemar's test was used to evaluate within-group changes between follow-ups in terms of AC and PCO. The level of significance was set at $p < 0.05$. All tests were two-sided.

Results

Clinical Findings

All of the 20 teeth were available for follow-up and did not show any sign/symptom of failure.

Among the 20 teeth treated with Biodentine™, no tooth revealed abnormal clinical findings at the end of the 1st, 3rd, 6th, and 12th month. Moreover, the clinical examination revealed no changes from the previous visit. The patient was reported at all time frames as asymptomatic (Table 1).

Radiographic Findings

Periodontal ligament space widening, bone lesion, pathologic root resorption, and development of successors were evaluated for 20 molars (Table 2).

Pulp canal obliteration and AC were studied for 50 roots (30 uppers and 20 lowers) (Table 3).

After 6 Months

Periodontal ligament space widening and bone lesion were not seen in any of the 20 cases. No pathological root resorption and no

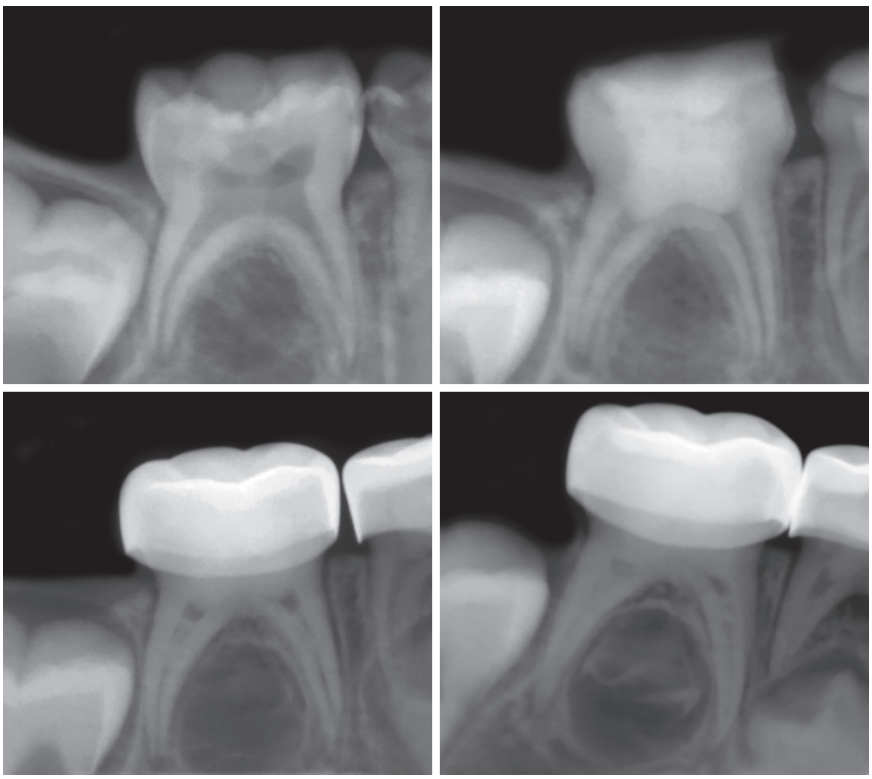

Fig. 1: Preoperative and postoperative periapical radiographs of mandibular second primary molar treated with Biodentine™ pulpotomy. (t-1) Preoperative radiograph; (t 0) postoperative radiograph taken immediately after Biodentine™ pulpotomy; (t 1) 6-month follow-up periapical radiograph showing PCO, Root Edification; (t 2) 12-month follow-up periapical radiograph with PCO, root development with AC

Table 1: Clinical follow-up over 12 months

	Clinical follow-up															
	Status of sinus tract				*Status of tooth mobility*				*Status of spontaneous pain*				*Swelling*			
Number of molars	*1 month*	*3 months*	*6 months*	*12 months*	*1 month*	*3 months*	*6 months*	*12 months*	*1 month*	*3 months*	*6 months*	*12 months*	*1 month*	*3 months*	*6 months*	*12 months*
20	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A

A, absence

pulp necrosis was noticed in any of the cases and all the successors were progressing normally. None of the teeth exhibited a periapical widened or diffusely outlined periodontal space (Table 2). The radicular pulp lumen thinning was observed in 36 roots. The lumen of the root canals was incompletely closed by a newly formed homogeneous mineralized tissue (Figs 2 and 3). Apical closure was detected in six roots (Table 3).

After 12 Months

No bone lesion was seen in any of the cases. No PLSw or pathological root resorption was detected (Table 2).

Concerning the PCO, it was observed in all 50 roots (Fig. 1).

Root maturation was observed as a significant progression when compared with the preoperative radiographs. The periapical radiographic assessment showed continued root development and AC in all roots (Table 3).

Clinical Success

After 1, 3, 6, and 12 months, Biodentine™ showed 100% clinical success rates.

No statistically significant differences were recorded between any of the groups at 1, 3, 6, and 12 months.

There is no difference between status of sinus tract, tooth mobility, spontaneous pain and swelling, separately, in the 1st, 3rd, 6th, and 12th month of follow-ups.

Radiographic Success

The Biodentine™ pulpotomies had a radiographic success rate of 100% at 6- and 12-month follow-up periods. No pathological signs were observed radiographically in all treated molars

Apical closure was observed in 6/50 cases (12%) at 6-month follow-up and in 50/50 cases (100%) at 12-month follow-up.

Pulp canal obliteration was observed in 36/50 cases (72%) at 6-month follow-up and in 50/50 cases (100%) at 12-month follow-up (Table 3) after it was present in 36 roots only at 6-month ($p = 0.0001$, McNemar's test).

There was a statistically significant increase in number of roots with closed apices from six roots at 6 months to 50 roots at 12 months ($p < 0.0005$, McNemar's test). Moreover, PCO was present in all 50 roots at 12 months, after it was present in 36 roots only at 6 months ($p = 0.0001$, McNemar's test).

No association was found between AC and PCO at 6-month ($p = 1.0$, Fisher's exact test).

Discussion

The primary tooth goes through three physiological evolutionary stages that influence its reaction to different aggressions. Stage I is the period of immaturity of the root. At this stage, the maturing pulp has a strong dentinogenetic, healing, and repair potential.[7,8]

Table 2: Radiographic follow-up over 12 months

	Radiographic follow-up							
	PLSw		*Status of bone lesion*		*Pathologic root resorption*		*Normal development of successor*	
Number of molars	*6 months*	*12 months*	*6 months*	*12 months*	*6 months*	*12 months*	*6 months*	*12 months*
20	A	A	A	A	A	A	P	P

A, absence; P, presence

Table 3: Radiographic follow-up of 50 roots over 12 months

	Number of roots involved		
	6 months	*12 months*	*p-value*
AC	6 (12%)	50 (100%)	<0.0005*
PCO	36 (72%)	50 (100%)	0.0001*
Total	50 (100%)	50 (100%)	

* means statistically significant

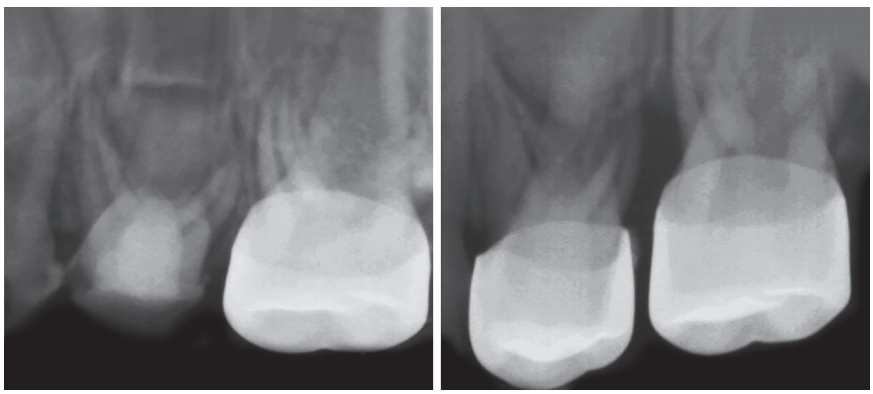

Fig. 2: Preoperative and postoperative periapical radiographs of a first upper primary molar treated with Biodentine™ pulpotomy. (t 0) postoperative radiograph taken immediately after Biodentine pulpotomy; (t 1) 6-month follow-up periapical radiograph showing PCO in the mesial and palatal roots while the distal root shows a normal pulp lumen

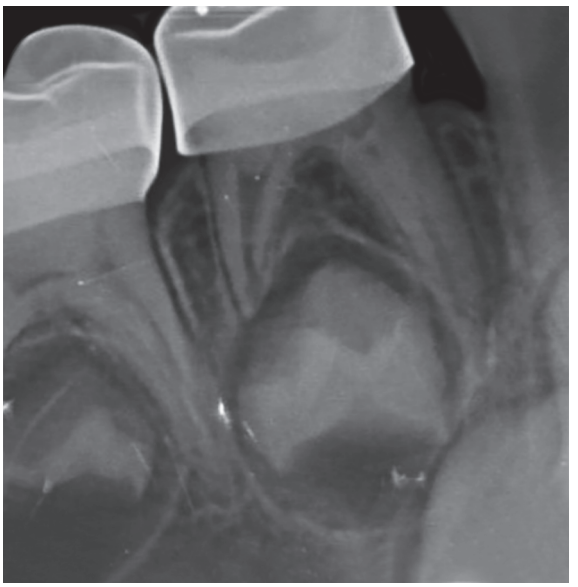

Fig. 3: The mesial root of the first primary molar shows PCO at 6-month follow-up, while the pulp lumen is normal in the distal root

The present clinical trial was conducted to examine and compare the effectiveness of Biodentine™ pulpotomy in human primary molars in stage I of root formation.

The main findings of the present study showed that clinical and radiographic success rates were 100% (as shown in Tables 1 and 2, respectively). A new finding was the radiographic evidence for continued root development as well as AC with no sign of pathology.

There is very little reference about pulpotomy on molars in stage I despite the importance of conserving all primary teeth early in childhood for their role in the eruption of healthy permanent teeth.[20]

Unfortunately, the younger the child is the more acute carious process progresses, which leads usually to dental pulp treatment at early age.[21]

Pulpotomy is performed in a primary tooth with extensive caries but without evidence of radicular pathology and it combines a pulp treatment and a medicament which has to form a protective layer over the exposed vital pulp.[22,23]

Biodentine™ was shown to be biocompatible, it does not damage pulpal cells *in vitro* or *in vivo*, and is capable of stimulating tertiary dentin formation.[24,25]

Biodentine™ is stimulating dentine regeneration by inducing odontoblast differentiation from pulp progenitor cells.[24,26] It has a significant potential for pulp healing, an excellent sealing property, and no cytotoxic effects on pulp cells or periodontal ligament.[5,18] All these biointeractive properties of this material would transform the process of inflammation to a process of healing.[27]

The use of the SSC in the present study was aimed to ensure the hermeticity of the cavity and to increase the success rate of pulpotomy.[14] While some studies reported that SSC increases the success rate of pulpotomy, others did not find any significant differences compared to teeth treated with conservative restorations.[12,13,28]

In fact, Guelmann et al. showed that there were no significant differences in terms of the success in teeth treated with SSCs and teeth treated with conservative restorations.[28] However, Kuo et al. demonstrated that teeth restored with SSCs after pulpotomy had a significantly higher success rate (80.0%) than those restored with composite resin (45%).[29]

During the 12-month observation period, none of the teeth showed any abnormal clinical findings regardless of the intervention at all time-point (20 teeth).

Considering the radiographic evaluation, the present results did not show any PLSw, bone lesion, or pathological root resorption.

In addition, the application of Biodentine™ did not show changes in the pericoronal sac associated with the underlying developing permanent teeth in any of the patients regardless of the intervention structural.

The succedaneous teeth were periodontally and morphologically normal.

The 100% radiographic success of Biodentine™ is in line with the success rate at 12 months observed, in 2019, by El Meligy et al.,[30] while Çelik et al. reported a slightly lower percentage (89.4%) at the end of the 24-month follow-up.[27]

In the review by Caruso et al., the radiographic success rate of Biodentine™ pulpotomies after 9 and 18 months was 94% and 90.5%, respectively.[13] Exfoliation, root resorption, and PLSw showed similar percentages.[13]

A study by Niranjani et al. reported success rates of 90% for Biodentine™ at the end of a 6-month follow-up period;[31] Cuadros-Fernández et al. reported radiographic success rates of 95% for Biodentine™ at the end of 12 months.[15]

The radiographic success rate of Biodentine™ found in the present study is within the range of those reported previously. Moreover, this result was also similar to the studies conducted by Guagnano et al. (2021)[32] and Ramanandvignesh et al. (2020).[33]

This clinical trial evaluating the performance of Biodentine™ as a pulp-dressing material in stage I molars showed the most interesting radiographic findings: AC (continuity of root edification) and PCO.

The radiographic examination was done by root as these physiological changes neither occurred simultaneously for all 50 roots nor inside the same molar; at 6-month follow-up, six roots showed an AC and 36 roots demonstrated PCO.

At 6-month, AC was evident in 6 roots (12%). This has increased significantly to reach all 50 roots at 12-month ($p < 0.0005$) (Table 3). It could be related to the stage of root maturation and/or the diameter of the apical orifice.

Several studies highlighted the importance of root edification and AC to preserve the tooth vitality. Pulp degeneration in immature tooth causes its fragility and compromises its lifespan in mouth.[9] Maintaining the pulp promotes continued root development leading to strengthening of the root structure and AC.[34,35]

The 100% AC obtained after 12 months of follow-up could explain the capacity of Biodentine™ for further root development and apexogenesis after performing pulpotomy on stage I primary molars.

Concerning the PCO, some classify it as a radiographic failure as it shows a deviation from a normal pulp,[36] others argue that PCO is considered as a success.[12,18,19] In this study, none of the teeth with PCO had other concomitant radiographic or clinical signs of failure, and therefore their presence was categorized as a radiographic success. At 12-month follow-up, the results showed 100% of PCO in the 20 stage I molars and in their 50 roots, while in stage II and stage III, the percentages were 54.1% and 25.7%, respectively.[18,19]

The majority of roots (72%, 36 roots) at 6-month follow-up already showed evidence of PCO. Furthermore, all the remaining roots (28%, 14 roots) showed PCO at 12-month follow-up.

It suggests that the effect of Biodentine™ pulpotomy on stage I primary molar stimulating pulp healing starts for most of the roots early after the treatment then goes on for the rest of the dental roots.

Every attempt is made to preserve the vitality of immature teeth until maturation is occurred.[37]

Our new findings in primary teeth are in agreement with these studies on permanent teeth and moreover speculated that primary teeth in stage I of root formation could indicate a potential for sensation, healing, and repair higher than teeth in stage II (stage of stability) and in stage III (stage of resorption).

However, there is no study that suggests apexogenesis on primary teeth. Moreover, Borum and Andreasen pointed out that no well-established treatment guidelines exist concerning healing processes and complications in primary teeth.[37,38]

Radiographs should be of optimal quality representing the images of the teeth without undue distortion because interpretation of primary molars is always complicated by succedaneous teeth.[38]

Conclusion

This is the first randomized clinical trial that evaluates the performance of Biodentine™ as a pulp-dressing agent in stage I primary molar pulpotomy with a follow-up of 12 months.

With proper case selection and indication, Biodentine™ pulpotomy may be a feasible and valuable treatment modality for immature primary teeth. The evaluation of the parameters was done not only by tooth but by dental root as the appearance of the AC and the PCO did not occur simultaneously in all roots.

The preliminary results obtained are promising as the findings suggest the potential of Biodentine™ in stimulating pulp healing and inducing apexogenesis in stage I primary molars.

Future studies will involve the expansion of the trial with a bigger sample size and over a longer period, which will allow to assess the influence of this material and other potentially important endodontic cement on clinical success and radiographic outcomes.

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