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Research Article

Retrospective Evaluation of Biodentine Pulpotomy Outcomes in Primary Molars: A Clinical and Radiographic Perspective

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ABSTRACT

Background: Preservation of the vitality of primary molar teeth affected by deep caries remains a central goal in pediatric restorative dentistry. Conventional pulpotomy medicaments such as formocresol have raised concerns regarding cytotoxicity and systemic distribution. Biodentine™, a bioactive tricalcium silicate-based material, has recently gained attention as a biocompatible alternative with favorable handling and sealing characteristics.

Objective: To retrospectively assess the clinical and radiographic success of Biodentine™ used in pulpotomy procedures in children treated at a tertiary dental center.

Methods: Dental records of 120 pediatric patients (aged 4–11 years) who underwent pulpotomy using Biodentine™ between January 2022 and December 2023 were reviewed. Clinical outcomes were evaluated in terms of absence of pain, swelling, sinus formation, or pathologic mobility. Radiographic success was defined by the absence of periapical or furcal radiolucency and internal or external resorption. Follow-up data at three months were analyzed using descriptive and inferential statistics.

Results: Among 120 treated teeth, 114 (95.0%) exhibited clinical success and 111 (92.5%) demonstrated radiographic success at the three-month review. No statistically significant association was found between age or gender and treatment outcome ($p > 0.05$).

Conclusion: Biodentine™ appears to be a reliable pulpotomy material in primary molars, offering high short-term clinical and radiographic success. Its favorable biological profile and ease of manipulation make it a viable substitute for formocresol in pediatric endodontics.

Keywords: Biodentine, Pulpotomy, Primary Molars, Pediatric Dentistry, Clinical Success, Radiographic Evaluation.

INTRODUCTION

Maintaining the health and vitality of the primary dentition until its physiological exfoliation is fundamental to ensuring normal function, arch integrity, speech development, and esthetics in children. Deep carious lesions that extend into the pulp represent one of the most common challenges in pediatric dentistry. When the coronal pulp becomes irreversibly inflamed but the radicular pulp remains vital and symptom-free, pulpotomy is the treatment of choice. The success of this procedure depends primarily on the selection of an appropriate medicament that can preserve pulp vitality, prevent bacterial ingress, and promote reparative dentin formation.

For several decades, formocresol has been considered the "gold standard" for pulpotomy in primary molars due to its bactericidal and fixative properties. However, mounting evidence has revealed its cytotoxic, mutagenic, and potential carcinogenic effects, raising concerns about its safety, especially in pediatric populations (Silva et al., 2020; Waterhouse et al., 2021). Consequently, alternative materials such as ferric sulfate, glutaraldehyde, calcium hydroxide, and electrosurgical or laser pulpotomy techniques have been proposed. Despite these innovations, none have consistently demonstrated the ideal combination of biocompatibility, dentin bridge formation, and long-term clinical success required for an optimal pulpotomy agent.

The introduction of bioactive calcium silicate–based materials such as Mineral Trioxide Aggregate (MTA) and Biodentine™ marked a paradigm shift in vital pulp therapy. MTA, though well-documented for its sealing ability and excellent biological outcomes, has practical drawbacks — notably long setting time, difficult handling, and potential for tooth discoloration (Nowicka et al., 2021; Aksoy et al., 2022). These shortcomings prompted the development of next-generation materials such as Biodentine™, which is formulated from tricalcium silicate, calcium carbonate, and zirconium oxide. Its reduced setting time (around 12 minutes), dentin-like mechanical strength, and superior handling characteristics make it particularly suitable for use in pediatric dentistry (Sanz et al., 2022; Deepa et al., 2023). Biologically, Biodentine™ has shown a unique ability to stimulate odontoblastic differentiation and mineralization by releasing calcium and silicon ions that activate signaling pathways involved in dentinogenesis. Studies using gene expression profiling have demonstrated that Biodentine™ upregulates alkaline phosphatase, osteocalcin, and dentin sialophosphoprotein (DSPP), which are essential for reparative dentin bridge formation (Malkondu et al., 2020; Abdelmegid et al., 2024). Additionally, it exhibits excellent sealing ability and marginal adaptation, reducing microleakage and bacterial penetration at the pulp interface — two critical factors influencing long-term pulpotomy success (Sanz et al., 2022).

Recent clinical trials and meta-analyses have reinforced these laboratory findings. Biodentine™ has achieved clinical success rates exceeding 90% at 6–12 months post-treatment, comparable or superior to MTA, and significantly higher than formocresol or ferric sulfate-based protocols (Nowicka et al., 2021; Deepa et al., 2023). These outcomes, combined with favorable biological performance and cost-effectiveness, have led to its recommendation as a first-line pulpotomy material in updated pediatric endodontic guidelines (Abdelmegid et al., 2024).

Despite these promising results, regional data remain limited, particularly from developing countries where patient compliance, treatment environment, and operator variability can differ from controlled research settings. Evaluating Biodentine's real-world performance within South Asian pediatric populations is critical for validating its effectiveness in diverse clinical contexts.

Therefore, the present retrospective clinical investigation aimed to assess the short-term clinical and radiographic success of Biodentine™ used for pulpotomy in primary molars of children treated at a tertiary care dental institution. By analyzing outcomes across a representative patient popu3lation, this study seeks to contribute valuable region-specific evidence supporting the broader use of Biodentine™ as a safe, efficient, and biocompatible alternative to traditional pulpotomy agents.

MATERIALS AND METHODS

Study Design and Setting

This study was designed as a retrospective clinical evaluation conducted at the Department of Operative and Pediatric Dentistry, a tertiary dental teaching hospital in Pakistan. Dental records of pediatric patients who underwent pulpotomy procedures between January 2022 and December 2023 were reviewed. The study protocol was approved by the Institutional Ethical Review Committee, and the investigation adhered to the principles outlined in the Declaration of Helsinki (2013 revision) regarding the use of human data for research purposes.

Sample Selection

Records of children aged 4–11 years who had undergone pulpotomy treatment using Biodentine™ (Septodont, France) were included. Cases were selected through a non-probability consecutive sampling method. A total of 120 patient records met the inclusion criteria.

Inclusion Criteria

- Deep carious primary molars with vital pulp exposure.
- Absence of spontaneous pain or history of swelling, sinus tract, or mobility before treatment.
- No radiographic evidence of periapical or furcal pathology.
- Teeth with restorable crown structure.

Exclusion Criteria

- Non-vital or previously treated primary teeth.
- Teeth showing signs of internal or external resorption at baseline.
- Children with systemic diseases affecting bone or tooth development.

Clinical Procedure

All pulpotomy procedures had been performed by experienced postgraduate trainees or faculty members under standard aseptic conditions. Local anesthesia was achieved using 2%

lidocaine with 1:100,000 epinephrine (Huons Co. Ltd, Korea). Isolation was maintained using cotton rolls and high-volume suction; a rubber dam was employed when patient cooperation permitted.

After removal of caries, the coronal pulp was amputated with a sterile high-speed diamond bur under water spray, and the pulp chamber was irrigated with sterile saline. Hemostasis was achieved by placing a sterile cotton pellet over the radicular pulp for 3–5 minutes. In cases where bleeding was easily controlled and bright red, indicating a healthy pulp, Biodentine™ was prepared per manufacturer's instructions and placed gently over the pulp stumps.

A base of intermediate restorative material (IRM) was placed, followed by permanent restoration using glass ionomer cement (Fuji IX, GC, Japan) or amalgam, depending on the case.

Follow-up and Outcome Assessment

Follow-up records were reviewed at three months post-treatment. Two calibrated examiners, blinded to patient demographic data, assessed outcomes using standardized criteria:

- Clinical success: absence of spontaneous pain, swelling, sinus formation, tenderness to percussion, or pathological mobility.
- Radiographic success: absence of periapical or furcal radiolucency, internal or external resorption, and maintained lamina dura.

Any tooth exhibiting one or more signs of failure was categorized as unsuccessful. Inter-examiner reliability was assessed using Cohen's kappa statistic ($\kappa = 0.91$), indicating excellent agreement.

Data Analysis

Data were compiled and analyzed using SPSS version 25.0 (IBM Corp., Armonk, NY, USA). Descriptive statistics were calculated for age, gender, and outcome variables. Success rates were expressed as percentages. Associations between clinical success and potential modifiers (age, gender, tooth type) were evaluated using the Chi-square test, with $p < 0.05$ considered statistically significant.

RESULTS

A total of 120 pediatric patients (70 males, 50 females) aged 4–11 years were included in this retrospective evaluation. The mean age of the study population was 7.42 ± 1.52 years. The distribution of clinical and radiographic outcomes according to gender and age group is summarized below.

Table 1. Age and Gender Distribution of Study Participants

Variable	Category	n	Mean age ± SD (years)	Minimum	Maximum
Gender	Male	70	7.35 ± 1.48	4	11
	Female	50	7.52 ± 1.57	4	11
Total	—	**120**	**7.42 ± 1.52**	**4**	**11**

Clinical Success

At the three-month follow-up, 114 teeth (95.0%) demonstrated clinical success, defined as the absence of pain, swelling, sinus tract formation, or pathological mobility. Only 6 teeth (5.0%) exhibited minor postoperative symptoms, including intermittent discomfort or sensitivity to percussion, and were considered clinical failures.

Radiographic Success

Radiographic evaluation revealed that 111 teeth (92.5%) maintained a normal periapical and furcal appearance, with intact lamina dura and absence of internal or external resorption. Nine teeth (7.5%) displayed radiographic changes suggestive of failure—primarily furcal radiolucency or early signs of internal resorption.

Gender-Related Differences

Clinical success was achieved in 67 of 70 male patients (95.7%) and 47 of 50 female patients (94.0%). Radiographic success was comparable between males (65 of 70; 92.8%) and females (46 of 50; 92.0%). No statistically significant difference was observed between gender and clinical or radiographic success ($p > 0.05$).

Table 2. Association between Gender and Clinical/Radiographic Success

Outcome Type	Gender	Successful (n)	Failed (n)	Total	Success (%)	*p*-value (Chi-square)
Clinical success	Male	67	3	70	95.7	0.62
	Female	47	3	50	94.0	
	Total	114	6	120	95.0	

Radiographic success	Male	65	5	70	92.8	0.73
	Female	46	4	50	92.0	
	Total	**111**	**9**	**120**	**92.5**	

Age-Related Trends

Patients were categorized into two age groups: 4–7 years and 8–11 years. The younger group demonstrated a clinical success rate of 96.2%, while the older group showed 94.1%, a difference that was not statistically significant ($p = 0.48$). Radiographic success followed a similar pattern.

Overall Summary

The combined clinical and radiographic success rate of Biodentine™ pulpotomy in this cohort was 93.8%, indicating excellent short-term outcomes. No cases of postoperative swelling, abscess formation, or premature tooth loss were recorded during the study period.

Table 3. Association between Age Group and Treatment Outcomes

Age Group (years)	N	Clinical Success (n)	Clinical Success (%)	Radiographic Success (n)	Radiographic Success (%)	p-value (Chi-square)
4 – 7 years	63	61	96.8 %	59	93.6 %	0.48
8 – 11 years	57	53	93.0 %	52	91.2 %	0.57
Total	**120**	**114**	**95.0 %**	**111**	**92.5 %**	**—**

DISCUSSION

This retrospective evaluation found high short-term clinical (95.0%) and radiographic (92.5%) success rates following pulpotomy with Biodentine™ in primary molars at three months. These findings align with recent randomized trials and systematic reviews that report similarly favorable outcomes for Biodentine™, suggesting that it is a reliable option for vital pulp therapy in primary teeth.

Several randomized clinical trials and comparative studies have reported no statistically significant difference in clinical and radiographic outcomes between Biodentine™ and mineral trioxide aggregate (MTA), with both materials demonstrating high success in pulpotomy procedures. A randomized double-blind trial reported comparable survival and healing rates for Biodentine™ and MTA over long-term follow up, supporting the interchangeability of these calcium-silicate materials in many clinical scenarios (Eshghi et al., 2022).

Systematic reviews and recent meta-analyses further corroborate these findings. A 2024–2025 body of evidence summarized in systematic reviews indicates that Biodentine™ achieves clinical success rates often exceeding 90% at short-term follow up (6–12 months), with radiographic success generally in the low-to-mid 90s percentile range — results consistent with our retrospective cohort. These analyses emphasize that, although heterogeneity exists between trials (differences in follow-up duration, restoration type, and operator experience), overall outcomes position Biodentine™ as at least comparable to MTA for pulpotomy in primary and immature permanent teeth (Laser et al., 2024).

The favorable clinical performance of Biodentine™ can be attributed to a combination of its biological activity and clinical handling properties. Laboratory and animal studies have demonstrated that Biodentine™ releases calcium and silicon ions that stimulate odontoblastic differentiation and mineralized tissue deposition, thereby promoting reparative dentin bridge formation and pulp healing. Its physico-mechanical characteristics — dentin-like compressive strength, good marginal adaptation, and shorter initial setting time compared with conventional MTA formulations — facilitate placement in a single visit and reduce the risk of restorative failure due to material washout during the appointment. These mechanistic and practical advantages likely contribute to the high short-term success documented in both controlled trials and real-world practice (Nagendrababu et al., 2018).

Clinical context and restorative protocol are important modifiers of outcome. Recent guidance and position statements recommend the use of calcium-silicate cements for vital pulp therapy in pediatric patients, emphasizing that adequate isolation and a durable coronal seal are critical for long-term success. The

importance of a proper definitive restoration (for example, stainless-steel crowns for heavily broken primary molars) to prevent microleakage has been repeatedly highlighted; studies show that inadequate restorations correlate with higher failure rates regardless of the pulpotomy medicament used. In our cohort the majority of teeth received a restorative protocol that emphasized immediate sealing (intermediate base and glass ionomer or equivalent), which may have contributed to favorable short-term outcomes (Biedma-Perea et al., 2025).

Despite the encouraging short-term results, several limitations must be acknowledged. First, the retrospective design limits control over baseline variables (operator variability, exact restorative material used in every case, and precise timing of follow-up radiographs). Second, the follow-up duration of three months is short relative to the lifespan of primary molars; radiographic changes such as internal resorption or late furcal pathology can manifest after this period. Most randomized trials and meta-analyses report outcomes at 6–24 months, and longer follow-up is desirable to confirm the durability of the observed success rates. Third, although inter-examiner reliability was high in radiographic scoring in this study, retrospective radiographic assessment may be subject to differences in exposure angulation and image quality that prospective standardized protocols better control.

Clinically, the findings support the growing trend toward adopting Biodentine™ as a pulpotomy material in pediatric practice, particularly where single-visit management and favorable handling are priorities. For teaching hospitals and public clinics that treat children with limited chair time and variable cooperation, the shorter setting time and ease of manipulation represent practical advantages without apparent compromise of biologic outcomes. Nevertheless, clinicians should ensure strict case selection (absence of preoperative signs of irreversible pulpal necrosis), meticulous hemostasis, and a durable coronal restoration to maximize the likelihood of success.

Future prospective, randomized studies with standardized restorative protocols and longer follow-up intervals in diverse clinical settings are needed to strengthen the evidence base and to evaluate cost-effectiveness in resource-constrained environments. In addition, subgroup analyses exploring age, molar type, and operator experience would help clarify whether certain clinical scenarios confer higher risk of failure.

In summary, this retrospective evaluation adds to the accumulating evidence that Biodentine™ produces excellent short-term clinical and radiographic outcomes when used for pulpotomy in primary molars. When combined with appropriate case selection and a reliable coronal seal, Biodentine™ can be considered a safe and effective alternative to traditional pulpotomy agents such as formocresol and a practical substitute for MTA in many pediatric clinical contexts (Laser et al., 2024).

CONCLUSION

Within the limitations of this retrospective study, Biodentine™ demonstrated excellent short-term clinical and radiographic success when used as a pulpotomy medicament in primary molars. Its favorable biological characteristics, high biocompatibility, and superior handling properties make it a reliable alternative to formocresol and a practical substitute for mineral trioxide aggregate (MTA) in pediatric endodontics.

The results support the growing clinical shift toward calcium silicate–based biomaterials for vital pulp therapy. High success rates observed in this cohort suggest that Biodentine™ can be safely and effectively integrated into routine pediatric dental practice, provided that case selection, aseptic technique, and a durable coronal seal are maintained.

However, the relatively short follow-up period and retrospective nature of this study warrant further long-term, multicenter clinical trials to validate these findings and determine the material's sustained performance over time.

Clinical Significance

Biodentine™ offers a biocompatible, user-friendly, and efficient alternative to traditional pulpotomy agents in pediatric dentistry. Its rapid setting time and dentin-like properties make it particularly suitable for children with limited treatment tolerance, enabling predictable pulp preservation and long-term tooth retention.

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Conflicts of Interest

"The authors declare that there is no conflict of interest regarding the publication of this paper."

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