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Radiographic Evaluation of Biodentine as a Pulpotomy Material in Primary Molars

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ABSTRACT

Introduction: Dental caries is very common in children, and many times leads to inflammation of the pulp. Pulpotomy can be extensively carried out to preserve the function and longevity of these teeth. Formocresol is the traditional pulpotomy material and has been mentioned; however, concerns about its toxicity have prompted the quest for safer substitutes. Biodentine, as a bioactive calcium silicate-based substance, is currently a prospective alternative due of its beneficial biological features. This study compared the clinical and radiographic outcomes of biodentine and formocresol as pulpotomy agents in primary molars during a 12-month period in Bangladeshi children.

Materials and Methods: The prospective comparative study was carried out at Bangabandhu Sheikh Mujib Medical University, Dhaka, from July 2022 to August 2023. Forty-four children aged 4 to 8 years utilizing life-necessary cariously exposed primary molars were incorporated right into the research and placed at random for pulpotomy that consisted of formocresol (Group A) or biodentine (Group B). Clinical and radiographic follow-ups were performed at intervals of 3, 6, and 12 months, and obtained parameters included pain, swelling, formation of a dentinal bridge, and root resorption. The chi-square test was used for statistical analysis.

Results: At the 12-month follow-up, pulpotomy using biodentine had significantly greater clinical and radiographic success rates (95.45%) than formocresol (72.73%; $p < .05$). Biodentine was more effective in progressive and significant dentinal bridge formation and less post-operative pain and swelling. Pathological root resorption was less in the biodentine group but was not statistically significant.

Conclusions: Biodentine can be considered as a better pulpotomy medicament than formocresol in primary molars, with better clinical and radiographic results, allowing it to be currently being adopted as a first-line medicament in pediatric dentistry.

Keywords: Biodentine, formocresol, pulpotomy, primary molars, radiographic evaluation.

INTRODUCTION

Dental caries remains one of the most common diseases among children all over the world and can often involve the pulp in primary teeth of children if left unattended for too long. Among the various vital pulp therapies, pulpotomy is considered the

most frequently performed and effective viable procedure as the treatment of choice for the treatment of extensively carious yet vital deciduous maxillary and mandibular primary molars. Pulpotomy is performed intentionally to keep the radicular pulp in a physiological condition, if possible, while keeping the function and the arch integrity of the affected tooth up to the natural shedding.[1] A perfect pulpotomy agent should have biocompatibility, antimicrobial component, induction of healing and formation of dentin-bridge, non-cytotoxicity and economical features.[2]

Formocresol has been considered the "gold standard" in pulpotomy for decades because of its ease of use as well as high short-term success rates.[3] However, it has been in its continued use which has caused considerable controversy in literature. Studies have reported possible formocresol systemic distribution awareness and have revealed its properties and mutagenic, toxic and carcinogenic aspect.[4] This has led to an emerging consensus within the discipline of pediatric dentistry to look for safer and biologically acceptable alternatives especially for use in children in whom long-term systemic effects are of more concern.

In recent years, biodentine, a calcium silicate-based bioactive material, has emerged to be a promising substitution of formocresol for pulpotomy procedures. Biodentine has many attractive features in non-coincidence, such as biocompatibility, bioactivity, strong compressive strength, minimal pressure reaction times and the ability to induce odontoblastic differentiation as well as biomineralization.[2] Several clinical studies provided proof of the efficacy of this technique since it showed comparable or better success ratios than traditional formocresol-based pulpotomies.[5,6] For example, Ahuja et al.[5] found positive clinical and radiographic findings of biodentine compared with mineral trioxide aggregate and formocresol. Similarly, El Meligy et al.[6] found a higher success rate for biodentine pulpotomy than formocresol after 12 months follow-up in a randomized controlled trial. More recently, Gisour et al.[7] confirmed the superior clinical performance between biodentine and Endo Repair with respect to Formocresol from a randomized clinical trial.

These findings are further corroborated with results from systematic reviews and meta-analyses. Firoozi et al.[8] have found that biodentine also resulted in better clinical and radiographic outcomes than formocresol and preferably is a safer, and a predictable material for pediatric pulp therapy. In addition, Jasani et al.[9] also observed that biodentine was not only effective but also at the same time, better in terms of long-term biological response. It confirms the shift away from formocresol.

Radiographic evaluation is important in deciding the success of treatment of pulpotomy procedures. Traditionally, the periapical and bitewing radiographs have been the mainstay of complete radiological evaluation, and with these pictures, the clinician could detect periapical or furcal pathosis. Furthermore, with a notable lack of region-specific data from Bangladesh, where the prevalence of dental caries is still high and clinical caretaking practices often continue to rely on conventional medicaments such as formocresol. With increased emphasis on evidence-based dentistry, should be a major need is arising to develop evidence-based localized study data on the performance of newer biomaterials for pediatric groups.

Although there are many worldwide studies about the effectiveness of biodentine, there is a dearth of information from Bangladeshi populations, specifically in relation to radiographic results in primary molar pulpotomy treatment. The current study conducted at Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka, Bangladesh, with an attempt to fill this gap in knowledge by comparing the radiographic effectiveness of biodentine and formocresol in primary molar pulpotomy for a 12-month follow-up period. Ultimately, this study was meant to prove the use of biodentine also as a safe, biocompatible, and effective pulpotomy material and to show the worth of updated radiographic assessment for better diagnostic certainty and treatment results.

MATERIALS AND METHODS

The prospective comparative study was done in the department of Pediatric Dentistry, Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka, Bangladesh, between July 2022 and August 2023. The study protocol was approved by the Institutional Review Board (IRB) of BSMMU (Memo no. BSMMU/2022/10589).

The sample size was calculated based on a one-sided Z-test with unpooled variance, considering a significance level (α) of 1% and a statistical power of 70%. The expected success rates in the two groups were assumed to be 73% (π_0 =0.73) and 96% ($\boldsymbol{\pi}_1$ =0.96), with a pooled proportion ($\bar{P}$) of 0.85. Using the formula described by Ryan et al. (2013) and Chotitanmapong et al. (2019), where u =1.28 corresponding to a one-tailed α error of 1% and v =0.52 corresponding to 70% power, the minimum required sample size was calculated to be 20.25 participants per group. This value was rounded up to 20 participants in each group. To account for potential participant dropouts, incomplete data collection, and possible instrumental or radiological errors, the sample size was increased to 22 participants per group. Therefore, the final study sample consisted of 44 primary molars, divided equally into two groups: Group A included 22 cases undergoing pulpotomy with formocresol, and Group B included 22 cases undergoing pulpotomy with biodentine.

The participants were consistently sampled into two groups: Group A (formocresol) and Group B (biodentine). Inclusion criteria were children of 4-8 years of age; primary molar teeth

exposed vital pulp secondary to caries; restorable crown structure (affording at least two-thirds of root length) and adequate bone support. Exclusion criteria included history of irreversible pulpitis; clinical findings of pulpal degeneration (augmentation, centrum percussion pain, sinus tract); radiographic findings of pulpal degeneration (internal and external root resorption, periapical lesions, and furcal infection); and medically compromised patients.

Independent variables were age, sex, and number of affected teeth. Primary outcome variables included radiological parameters (dentinal bridge formation and pathological root resorption). Success criteria for pulpotomy were defined as clinical success such as absence of pain, tenderness to percussion/palpation, gingival swelling, sinus tract formation or pathological mobility; and the radiographic success was defined as absence of new pathological lesions, pathological external/internal root resorptions, furcation involvement or periapical radiolucency.

All procedures followed strict aseptic protocol and proper sterilization and isolation using a rubber dam where feasible. After application of local anesthesia, complete caries removal was done with sterile round burs with continuous water irrigation.

For Group A (formocresol), following the coronal pulp amputation and hemostasis, a cotton pellet dipped in formocresol was left over pulp stumps for 4 minutes. Brownish discoloration indicated sufficient fixation. Zinc oxide eugenol was then applied followed by glass ionomer cement restoration. For Group-B (biodentine) after obtaining hemostasis, biodentine was prepared according to the recommendations of the manufacturer (5 droplets of liquid for 30 seconds using a triturator), then condensed on the pulp stumps using an amalgam carrier. After 9-12 minutes to complete this setting period, the restoration with glass ionomer cement was finished.

The first technique employed to develop a radiographic plane that showed the formation of dentinal bridges was the exclusion of the use of stainless-steel crowns, the insertion of which was delayed until completion of the final follow-up. For a comprehensive clinical and radiological evaluation, the patients were recalled after 3, 6, and 12 months. The radiographic examinations were performed in an intra-oral periapical view. SPSS v.26 was used to analyze data using Fisher's Exact Test at p <0.05 level of significance.

RESULTS

The study enrolled 44 children with a mean age of 6.09±1.11 years. Group A (formocresol) had a mean age of 6.40±1.14 years, while Group B (biodentine) averaged 5.77±1.02 years, showing in Table 1. Gender distribution favored males in both groups (73% in Group A, 68% in Group B) (Table 2). Tooth distribution revealed predominant involvement of mandibular molars in both groups (63.63% in Group A, 86.36% in Group B).

Table 1: Age distribution of participants. (n =44)

Age (years)	Group A (formocresol) n (%)	Group B (biodentine) n (%)
4	0 (0.00%)	1 (4.55%)
5	7 (31.82%)	10 (45.45%)
6	3 (13.64%)	5 (22.73%)
7	8 (36.36%)	5 (22.73%)
8	4 (18.18%)	1 (4.55%)
Mean ± SD	6.40 ± 1.14 years	5.77 ± 1.02 years
Range	5–8 years	4–8 years

Table 2: Gender distribution of participants. (n =44)

Gender	Group A (formocresol) n (%)	Group B (biodentine) n (%)
Male	16 (72.73%)	15 (68.18%)
Female	6 (27.27%)	7 (31.82%)

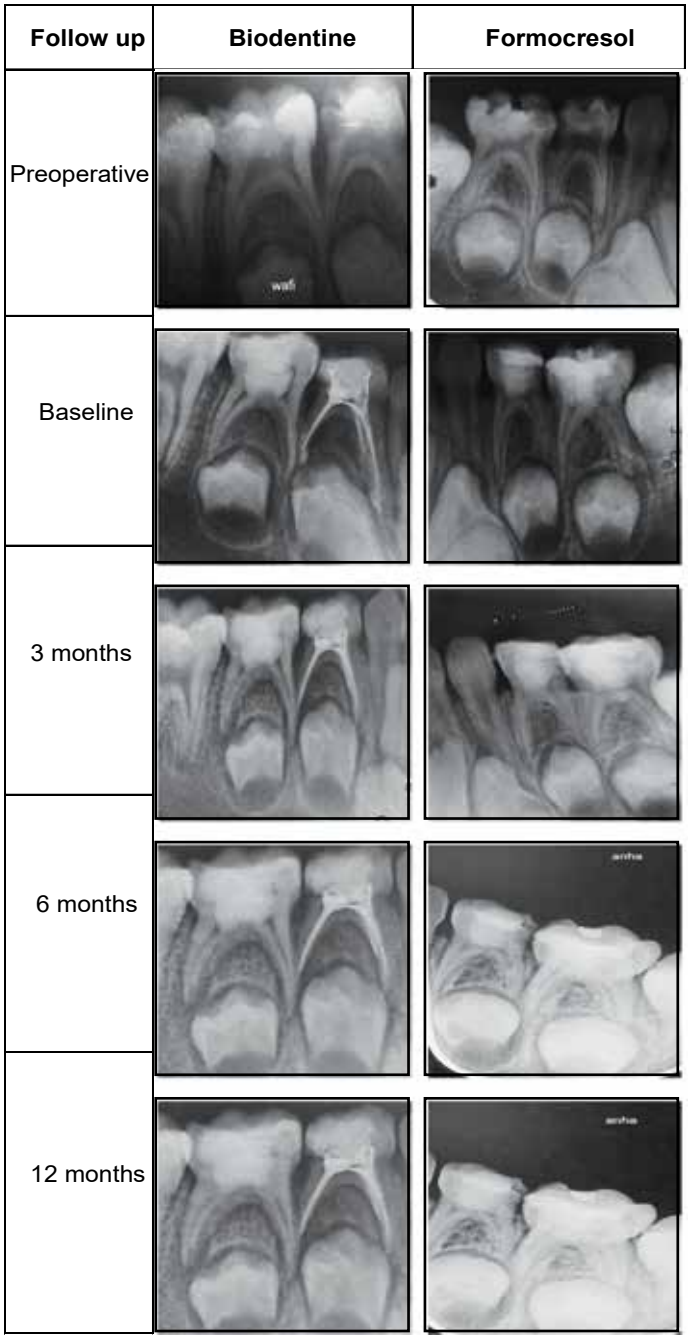
The most striking difference between groups was observed in dentinal bridge formation. Group A (formocresol) showed no evidence of dentinal bridge formation throughout the entire 12-month study period. Conversely, the group B (biodentine) demonstrated progressive bridge formation: 2 cases (9.09%) at 3 months, 7 cases (31.81%) at 6 months, and 12 cases (54.54%) at 12 months. Table 3 shows the dentinal bridge formation over 12 months of follow-up. Group B showed a significant and progressive increase in dentinal bridge formation over time, whereas the group A showed no dentinal bridge formation throughout the study period. Figure 1 shows the preoperative and postoperative radiographs of a tooth treated (pulpotomy) by biodentine and formocresol. Fisher's Exact Test demonstrated no significant difference in dentinal bridge formation between the two groups at baseline (p =1.000) and 3 months (p =0.488). However, a significantly higher proportion of dentinal bridge formation was observed in the group B compared with the group A at 6 months (31.8% vs. 0%; p =0.008) and 12 months (54.5% vs. 0%; p <0.001).

Table-3: Dentinal bridge formation over 12 months of follow up. (n =22)

Period	Dentinal bridge formation	Formocresol group n(%)	Biodentine group n (%)	*p*-value
Baseline	Present	0 (0%)	0 (0%)	1.00
	Absent	22 (100%)	22 (100%)	
After 3 months	Present	0 (0%)	2 (9.09%)	0.488
	Absent	22 (100%)	20 (90.90%)	
After 6 months	Present	0 (0%)	7 (31.81%)	0.008*
	Absent	22 (100%)	15 (68.18%)	
After 12 months	Present	0 (0%)	12 (54.54%)	<0.001*
	Absent	22 (100%)	10 (45.45%)	

* Fisher's Exact Test; statistically significant at p <0.05.

Fig. 1: Preoperative and postoperative radiographs of teeth treated by pulpotomy using biodentine and formocresol.



At 12 months, pathological root resorption occurred in 3 cases (13.63%) in group A compared to 1 case (4.54%) in the group B (p =0.29; not statistically significant). Table 4 shows the pathological root resorption status over the study period. This table shows that pathological root resorption was observed at 12 months more frequently in group A than in the group B, but the difference was not statistically significant.

Table-4. Pathological root resorption status over study period. (n=22)

Period	Pathological root resorption status	Formocresol group n (%)	Biodentine group n (%)	*p*-value
Baseline	Present	0 (0%)	0 (0%)	1.00
	Absent	22 (100%)	22 (100%)	
After 3 months	Present	0 (0%)	0 (0%)	1.00
	Absent	22 (100%)	22 (100%)	
After 6 months	Present	0 (0%)	0 (0%)	1.00
	Absent	22 (100%)	22 (100%)	
After 12 months	Present	3 (13.63%)	1 (4.54%)	0.2943 #
	Absent	19 (86.36%)	21 (95.45%)	

Not statistically significant (p >0.05)

Final clinical outcome at 12 months, defined by absence of pain and swelling, was achieved in 16 cases (72.72%) in group A versus 21 cases (95.45%) in the group B (p<0.05). When considering all outcome parameters, overall treatment success was recorded as 16 cases (72.73%) for formocresol and 21 cases (95.45%) for biodentine (p <0.05). Table 5 demonstrates overall success rates.

Table-5. Overall success rates. (n=22)

Outcome Parameter	Formocresol n (%)	Biodentine n (%)	*p*-value
Absence of Pain (positive outcome)	16 (72.72%)	21 (95.45%)	0.0393*
Absence of Swelling (positive outcome)	16 (72.72%)	21 (95.45%)	0.0393*
Overall Treatment Success (All Parameters)	16 (72.73%)	21 (95.45%)	0.0393*

*Statistically significant (p <0.05).

DISCUSSION

This prospective study has delivered strong and compelling evidence for the superior clinical and radiographic performance of biodentine compared with formocresol in the primary molar pulpotomy procedures. The findings are consistent with the new consensus around the world regarding the use of calcium silicate-based materials against formocresol-based methods.[6]

The 95.45% clinical success rate with biodentine was significantly higher than the 72.72% success obtained with formocresol, and this limited data is in accordance with what has been derived from several internationally run studies. El Meligy et al.[6] reports similar clinical success rates of 100% for

both materials with time periods of 12 months, although with superior radiographic success for biodentine. The lower success obtained with our formocresol group may be manifested by the limitations of devitalizing agents themselves for long-term maintenance of the pulp health.[7]

Recent systematic reviews have shown biodentine's superior biocompatibility, and greater post-operative complications are shown. A comprehensive meta-analysis based on the results of Firoozi et al. concluded that although no important differences existed in terms of the clinical outcome, radiographic success rates significantly favored biodentine over formocresol.[8]

The most surprising observation was the distinct dentinal bridge-forming ability of biodentine that was seen in 54.54% of the cases at 12 months, whereas there was no sense of bridge formation in the formocresol group. This drastic difference stands for the essential difference in the mode of action: formocresol is a devitalizing agent that leads to tissue fixation and mummification, while the odonto-inductive compound biodentine, on the other hand, stimulates active regeneration of the tissues through the formation of calcium hydroxide and a high pH environment.[10]

The capability of biodentine to induce odontoblast-like cell differentiation and biomineralization was consistently reported in research and promoted the bioformation of reparative dentin bridges. This regenerative ability constitutes a paradigm shift from conventional pulpotomy-based treatment concepts of tissue preservation, rather than tissue repair and regeneration.[11]

The present study findings are supported by recent clinical trials in different geographic areas. Gisour et al. reported the success rate of biodentine to be 94.7%, and for formocresol at 12 months, the rate was 70%. Similarly, Ahuja et al.[12] was able to show clinical success of 100% and radiographic success of 95% using Biodentine compared with 70% clinical success and 25% radiographic success using formocresol in 9 months.

The homogeneity of better biodentine outcomes between different populations, including this South Asian population, implies the applicability of the results regardless of geographical /demographic differences. While not statistically significant, the tendency towards a decrease of pathological root resorptions in biodentine (4.54% versus 13.63% in the Formocresol group) indicated better mineralization of the root structure and of the cementary tissue. This finding is of particular relevance to primary teeth, as retention of structural integrity until natural exfoliation is important for normal eruption of the permanent dentition and for normal arch development.

The efficacy of biodentine results suggests that it is a primary choice as a pulpotomy medicament in primary teeth. The biocompatibility, ease of handling, fast setting time, and regenerative modalities make it an ideal substitute for formocresol in pediatric dentistry.[10]

However, cost-effective provisions and the availability of equipment in the developing world, such as South Asia, also still play a crucial part in extensive adoption. Whilst biomaterials: biodentine may appear, at times, to have a slightly higher material cost, this may be avoided due to the better outcomes over time and because of a lower need for retreatment. The shortcomings of this study are a short follow-up period (12 months) and small sample size. Furthermore, an unavailability of biodentine in the local markets and rubber dam isolation problems in some pediatric patients may have had an impact on the standardization. Subsequent research should be focused on long-term follow-up investigations, histopathology study of the response of the pulp tissue, and large multicenter trial studies to establish the definite clinical guidelines for use of biodentine for the pediatric pulpotomy procedures.

CONCLUSIONS

This prospective study provides supportive evidence in favor of biodentine over formocresol in primary molar pulpotomy. Biodentine showed significant clinical benefits over formocresol with clinical success and the ability to create a dentinal bridge, and this is another benefit in clinical success as well as long-term tissue regeneration. Its higher success rate, ability to promote dentinal bridge formation, and reduction in postoperative pain and swelling highlight its regenerative and biocompatible properties. Unlike formocresol, biodentine supports tissue repair without concerns regarding cytotoxicity or carcinogenicity. These findings support its use as a preferred pulpotomy medicament for primary teeth, particularly in Bangladesh. However, further large-scale, multicenter studies with longer follow-up periods are needed to confirm their long-term effectiveness and establish standardized clinical protocols for pediatric dental practice.

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