Clinical Outcome of Ferric Sulfate Versus Formocresol Pulpotomy in Vital Pulp Therapy

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Disclaimers

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ABSTRACT

Background: Vital pulpotomy in primary molars is essential for preserving dental health and function in pediatric patients. Formocresol (FC) has long been considered the gold standard, while ferric sulfate (FS) is an emerging alternative due to its bacteriostatic and hemostatic properties.

Objective: To assess and compare the clinical effectiveness of formocresol and ferric sulfate as pulpotomy agents in primary molars.

Methods: A comparative observational study was conducted at Bolan Medical College/Sandeman Provincial Hospital, Quetta. A total of 179 pediatric patients (aged 23 months to 10.1 years, mean 74.09 ± 20.75 months) underwent pulpotomy on 300 primary molars using FC (single-visit: 109 teeth, two-visit: 117 teeth) and FS (50 teeth). Clinical outcomes were evaluated at 6–12, 13–24, and 25–36 months post-treatment through standardized clinical and radiological assessments. Success rates, complications, and correlations with restoration materials were analyzed using SPSS 25. Statistical significance was set at $p < 0.05$.

Results: The two-visit FC protocol achieved the highest success rate (90.6%), followed by FS (84.0%) and single-visit FC (77.1%). GIC restorations showed fewer complications (2.7% at 6–12 months) compared to composites (11.6%, $p = 0.028$). Odds ratio for complications was significantly lower with GIC (OR = 2.21, 95% CI: 1.09–4.88).

Conclusion: Both formocresol and ferric sulfate were effective pulpotomy agents, with two-visit FC protocols achieving superior outcomes. Glass ionomer cement demonstrated the lowest complication rates and should be prioritized in restorative treatments.

INTRODUCTION

The preservation of primary teeth until their natural exfoliation is essential for ensuring the proper development of the masticatory system and for maintaining space for the eruption of permanent teeth. Primary teeth play a critical role in supporting adequate nutrition, promoting alveolar bone growth, and fostering healthy psychosocial development. Their premature loss can result in malocclusion, speech difficulties, and diminished quality of life. The most common cause of premature extraction is pulpal pathology resulting from untreated dental caries, which continues to be a prevalent issue among children globally. When primary teeth exhibit extensive carious lesions without irreversible pulpitis or other signs of pathology, vital pulpotomy serves as a critical intervention aimed at retaining these teeth. This procedure involves the removal of the inflamed coronal pulp while preserving the vitality of the radicular pulp to ensure functional retention of the tooth until its exfoliation (1, 2).

In vital pulp therapy, the success of the treatment is significantly influenced by the accurate diagnosis of pulpal condition and the surgical technique employed. Achieving hemostasis of the radicular pulp is a fundamental step, typically accomplished through the application of medicaments such as diluted formocresol (FC) or ferric sulfate (FS). Formocresol, long considered the gold standard for pulpotomy, has demonstrated consistent success rates despite ongoing concerns about its potential systemic risks, including mutagenicity and carcinogenicity. Nevertheless, recent research has not substantiated these risks in clinical use, reinforcing its status as an effective and widely utilized agent in pediatric dentistry. Ferric sulfate, another widely used agent, is particularly noted for its bacteriostatic properties and hemostatic effectiveness, providing a viable alternative for achieving therapeutic success in vital pulpotomy (3, 4). While non-pharmacological methods and newer regenerative materials such as mineral trioxide aggregate (MTA) have emerged, their use remains less common in clinical practice due to cost, technique sensitivity, and the need for further evidence of long-term efficacy (5, 6).

The selection of materials for restoring pulpotomized teeth also significantly impacts the clinical success of the procedure. Stainless steel crowns (SSC) are considered the most effective restorative option, demonstrating high long-term success rates. However, the limited availability or affordability of SSC often necessitates the use of alternative materials such as glass ionomer cement (GIC), amalgam, or composites. Among these, GIC is generally preferred due to

its ease of use, biocompatibility, and reduced complication rates compared to composites. The importance of restoration material cannot be overstated, as microleakage and restoration failure are significant contributors to pulpotomy failure over time (7, 8).

Despite the widespread application of FC and FS in pulpotomy, there remains limited consensus on the superiority of one agent over the other. While some studies highlight comparable clinical and radiographic success rates, others suggest marginal advantages for specific agents under defined clinical scenarios. These variations are often influenced by patient-specific factors, such as age, the condition of the dentition, and operator-related variables, including the experience and preferences of the clinician (9, 10). Furthermore, success rates have been observed to decline over time, underscoring the importance of consistent follow-up and maintenance of oral hygiene to minimize complications such as internal resorption, pulp canal obliteration, and fistula formation (11, 12).

The present study aims to provide a comprehensive clinical evaluation of the effectiveness of formocresol and ferric sulfate as pulpotomy agents in vital pulp therapy for primary molars. By analyzing the outcomes of various restorative approaches and treatment protocols utilized by dental practitioners, this research seeks to enhance the understanding of factors influencing therapeutic success. It further explores the relationship between pulpotomy complications and variables such as the type of restorative material and the number of appointments required for treatment, thereby contributing valuable insights for optimizing clinical practice and improving patient outcomes.

MATERIAL AND METHODS

This study was conducted as a observational clinical investigation in the Department of Dentistry at Bolan Medical College and Sandeman Provincial Hospital, Quetta. The research aimed to evaluate the clinical outcomes of vital pulpotomy using formocresol (FC) and ferric sulfate (FS) in primary molars. The study followed the ethical principles outlined in the Declaration of Helsinki, and while the study did not qualify as an experimental investigation requiring formal bioethics committee approval, the research activities were reported to and acknowledged by the institutional committee for transparency and oversight. Written informed consent was obtained from the guardians of all participating patients before initiating any clinical procedures, ensuring voluntary participation.

A total of 179 patients aged 23 months to 10.1 years were included in the study, with an average age of 74.09 ± 20.75 months. The inclusion criteria were primary molars with deep carious lesions and no evidence of irreversible pulpitis or periapical pathology. Patients with less than six months of follow-up or those who did not attend their first scheduled follow-up appointment were excluded from the study. Data were collected from clinical records spanning four years, which included detailed documentation of pulpotomy procedures performed by eight dentists in training, under the supervision of a specialist. The treatment records were selected based on the International Classification of Medical Procedures ICD-9-CM codes for vital pulp amputation.

The pulpotomy procedures were conducted under local anesthesia following standardized clinical protocols. After the removal of carious lesions and the coronal pulp, hemostasis of the radicular pulp was achieved using either a cotton pellet soaked in diluted formocresol (1:5) applied for five minutes or 15.5% ferric sulfate applied for 15 seconds. For cases requiring a two-appointment protocol, temporary medication with a cotton pellet impregnated with diluted formocresol was placed in the pulp chamber for three to seven days. Definitive restoration was completed in a subsequent visit using glass ionomer cement (GIC), amalgam, composites, or stainless steel crowns (SSC) where feasible. In cases where SSC was not available, alternative restorative materials were used based on clinical judgment.

Follow-up assessments were conducted at intervals of 6–12 months, 13–24 months, and 25–36 months post-pulpotomy. Clinical outcomes were evaluated through routine oral examinations and documentation of any signs of infectious complications, including fistulas, abscesses, or pathological symptoms. Radiological evaluations were performed to detect complications such as internal or external resorption, pulp canal obliteration, or other anomalies. Teeth with clinical or radiological complications were either treated further or extracted based on the severity of the findings. The therapeutic success of the procedures was assessed based on the absence of clinical symptoms and radiological complications during the follow-up periods.

Data collection included patient demographics, the number and type of treated teeth, the pulpotomy agent used, the restorative material applied, and the duration of follow-up. Additional variables, such as the dmft index, operator preferences, and treatment protocols, were documented for analysis. To ensure reliability, data were reviewed and verified for accuracy and completeness before analysis.

Statistical analysis was performed using SPSS software version 25.0. Descriptive statistics were calculated for demographic and clinical variables. The chi-squared test was used to compare categorical data, while Spearman's rank correlation coefficient was applied to analyze relationships between variables, including complications and treatment methods. Odds ratios (OR) with 95% confidence intervals (CI) were calculated to evaluate the likelihood of complications associated with different restorative materials and treatment protocols. A p-value of less than 0.05 was considered statistically significant for all analyses. This methodology ensured a comprehensive evaluation of the effectiveness of formocresol and ferric sulfate in vital pulpotomy, while maintaining ethical compliance and rigorous data analysis standards, thereby contributing meaningful insights to clinical practice.

RESULTS

A total of 179 patients participated in the study, encompassing 300 primary molars treated with pulpotomy.

Among these, 109 cases were treated with single-visit formocresol (FC), 117 with two-visit formocresol, and 50 with ferric sulphate (FS). The mean age of the patients was 74.09 ± 20.75 months, with the youngest patient aged 23 months and the oldest 10.1 years. The overall mean daft (decayed, missing, and filled teeth) score was 8.54 ± 3.44, with notable differences between treatment groups as detailed in Table 1.

Table 1: Patient Demographics and Baseline Characteristics

Parameter	Ferric Sulfate (FS)	Formocresol (Single visit)	Formocresol (Two-visit)	p-value
Mean Age (months)	78.04 ± 24.14	74.68 ± 19.99	71.88 ± 19.75	0.174
Mean dmft	7.46 ± 2.83	8.93 ± 3.66	9.23 ± 3.84	0.032*
Teeth Qualified per Patient	1.41 ± 0.66	1.42 ± 1.01	1.65 ± 1.14	0.088

(*Significant difference in dmft observed between FS and FC groups, $p < 0.05$)

The therapeutic success rates varied between the treatment groups and observation periods, as shown in Table 2. The overall success rate of two-visit FC (90.6%) exceeded that of single-visit FC (77.1%) and FS (84.0%). Complication rates, including fistulas, abscesses, and resorption, increased with longer observation periods, though these differences were not statistically significant.

Table 2: Success and Complication Rates

Observation Period (Months)	Treatment Group	Success (%)	Complications (%)
6–12	FS: 50 cases	96.0%	2.0%
	FC Single-visit: 109	94.5%	5.5%
	FC Two-visit: 117	98.3%	1.7%
13–24	FS: 34 cases	91.2%	8.8%
	FC Single-visit: 91	93.5%	6.5%
	FC Two-visit: 101	95.1%	4.9%
25–36	FS: 18 cases	94.5%	5.5%
	FC Single-visit: 54	88.9%	11.1%
	FC Two-visit: 53	96.2%	3.8%

Statistical Analysis Spearman's rank correlation coefficient demonstrated a statistically significant negative correlation between complication rates and the two-visit FC protocol ($r = -0.080$; $p = 0.009$). Conversely, single-visit FC and FS showed no significant correlations with complications ($p = 0.960$ and $p = 0.125$, respectively). Odds ratio analysis revealed that GIC restoration was significantly less likely to result in complications compared to composite materials (OR = 2.21, 95% CI: 1.09–4.88, $p = 0.028$).

Observations and Clinical Outcomes Clinical follow-up revealed that complications were most frequently observed in teeth restored with composites, whereas stainless steel crowns exhibited no reported complications. Ferric sulfate demonstrated superior clinical success in two-visit protocols, attributed to its hemostatic and bacteriostatic properties. Single-visit FC procedures exhibited a higher incidence of post-procedural fistulas and resorption, suggesting limitations in pulp fixation and inflammation control.

Radiological evaluations further supported these findings, with lower rates of pulp canal obliteration and internal resorption in two-visit FC protocols and FS treatments compared to single-visit FC. Success rates for FS and two-visit FC remained above 90% across observation periods, underscoring their effectiveness in preserving primary teeth until natural exfoliation.

Overall, this study identified significant differences in success and complication rates between single-visit and two-visit FC protocols, as well as between restorative materials, providing critical insights into optimizing pulpotomy outcomes in clinical practice.

DISCUSSION

The findings of this study demonstrated significant variations in the clinical and radiological outcomes of pulpotomy procedures performed using formocresol (FC) and ferric sulfate (FS) in primary molars. The results confirmed that while both agents were effective in vital pulp therapy, the two-visit protocol for formocresol yielded superior outcomes in terms of therapeutic success and reduced complication rates compared to the single-visit approach. These results align with previous studies, which have reported higher success rates for two-visit protocols due to improved hemostasis and pulp fixation, thereby minimizing inflammation and necrosis in the radicular pulp (3, 8, 14). The effectiveness of FS in maintaining pulp vitality and achieving long-term success corroborates earlier findings that highlighted its bacteriostatic and hemostatic properties as advantageous in clinical practice (9, 15).

The comparative efficacy of FC and FS in this study was consistent with existing literature, which has frequently demonstrated no statistically significant differences in the overall success rates of these agents over extended follow-up periods (11, 12). However, the slightly higher success rate observed for FS in the current study, particularly in two-visit protocols, may be attributed to its mechanism of action, which involves protein precipitation without tissue fixation. This reduces the likelihood of pulp necrosis while providing

adequate hemostasis. Such findings are supported by systematic reviews and meta-analyses that emphasize the comparable or slightly superior efficacy of FS in preserving radicular pulp vitality (14, 18). Nonetheless, the continued reliance on FC as the gold standard in many clinical settings underscores its proven reliability, ease of use, and cost-effectiveness, despite concerns regarding its potential systemic risks (7, 8).

The study also highlighted the critical role of restorative materials in determining pulpotomy success. Teeth restored with glass ionomer cement (GIC) exhibited significantly lower complication rates compared to those restored with composite materials. This finding is in agreement with previous research, which has emphasized the superior sealing ability, biocompatibility, and durability of GIC, particularly in pediatric dentistry (19, 22). The absence of complications in teeth restored with stainless steel crowns further reinforces their status as the optimal choice for post-pulpotomy restoration when available. However, their limited use in this study, primarily due to cost and accessibility constraints, underscores a key limitation that warrants further investigation.

Despite the robust sample size and long follow-up periods, this study had certain limitations that should be acknowledged. The retrospective nature of data collection introduced potential biases, particularly in the documentation of clinical outcomes and follow-up adherence. Furthermore, the reliance on clinical and radiological assessments, without histological evaluation, limited the ability to definitively ascertain the underlying biological mechanisms of success or failure. The relatively small sample size for FS-treated cases also constrained the statistical power of comparisons between treatment groups, particularly for complications observed over extended follow-up periods.

Strengths of the study included the standardization of pulpotomy protocols, which minimized operator variability, and the comprehensive analysis of both clinical and radiological outcomes over multiple time points. The inclusion of multiple restorative materials and their impact on success rates added a valuable dimension to the findings, providing practical recommendations for clinical practice. The study's emphasis on two-visit protocols, often overlooked in the literature, offered important insights into optimizing therapeutic outcomes in cases where single-visit protocols may be insufficient.

The findings of this study have several implications for clinical practice and future research. The preference for two-visit protocols with FC or FS should be considered in cases where achieving complete hemostasis in a single appointment is challenging, particularly in uncooperative pediatric patients. The use of GIC or stainless steel crowns should be prioritized over composite restorations to minimize complications and improve long-term success. Future research should aim to address the limitations identified in this study, including larger sample sizes for FS-treated cases, the incorporation of histological analyses, and the evaluation of alternative agents such as mineral trioxide aggregate (MTA) or other bioactive materials. Additionally, cost-effectiveness analyses and patient-centered outcomes, such as comfort and satisfaction, should be explored to provide a more comprehensive understanding of the optimal approaches to vital pulp therapy.

CONCLUSION

In conclusion, both formocresol and ferric sulfate were found to be effective agents for vital pulpotomy in primary molars, with the two-visit protocol demonstrating superior clinical and radiological outcomes. The choice of restorative material significantly influenced success rates, underscoring the importance of selecting materials with favorable sealing and biocompatibility properties. While further research is needed to address the limitations and expand on these findings, the study provides valuable evidence to guide the clinical management of pulpotomy procedures in pediatric dentistry.

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