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Efficacy of Laser versus Formocresol and Ferric Sulphate for Pulpotomy in primary Molars: A Randomized Clinical Trial.

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Abstract

Background:
To compare post-operative pain outcomes following pulpotomy using diode laser, formocresol, and ferric sulphate in primary molars of paediatric patients, assessed through the Wong-Baker Faces Pain Rating Scale (WBS).

Methodology:
A randomized clinical trial was conducted at Fatima Jinnah Dental College and Hospital, Karachi, from January to August 2023. Ninety children aged 4–9 years requiring pulpotomy were enrolled and randomly allocated into three groups (n = 30 each). Group 1 received formocresol, Group 2 ferric sulphate, and Group 3 diode laser treatment. Post-operative pain was evaluated at 2 weeks, 4 weeks, 3 months, 6 months, and 12 months.

Results:
Laser pulpotomy demonstrated the lowest pain scores (WBS = 0.07 ± 0.37) at 2 weeks, compared with formocresol (2.93 ± 3.14) and ferric sulphate (2.20 ± 2.54) ($p < 0.001$). Differences remained significant at 4 weeks but not beyond 3 months ($p > 0.05$). Radiographic success rates were highest for diode laser (100%), followed by ferric sulphate (95%) and formocresol (90%). No major adverse events were observed.

Conclusion:
Diode laser pulpotomy produced superior early pain relief and excellent clinical outcomes compared to conventional pulpotomy medicaments. It represents a safe, minimally invasive, and effective alternative for managing vital pulp therapy in paediatric dentistry.

Keywords:
Diode Laser, Vital Pulpotomy, Ferric Sulphate, Formocresol, Paediatric Dentistry.

Introduction

Pulpotomy is a widely employed conservative procedure in paediatric dentistry aimed at preserving the vitality of the radicular pulp following coronal pulp amputation [1]. It provides a biologically sound alternative to extraction, maintaining arch integrity and normal masticatory function in children. Depending on the extent of pulp removal, pulpotomy can be classified as partial where part of the coronal pulp remains or complete, which entails full removal of the coronal portion [2].

Over the years, multiple medicaments have been used for pulpotomy, including formocresol [3], glutaraldehyde [4], ferric sulphate [5], and aloe vera gel [6]. Each material exhibits distinct advantages and limitations. Recently, laser pulpotomy has emerged as an innovative and promising technique in paediatric endodontics due to its bactericidal effect, haemostatic efficiency, and minimal post-operative discomfort [7].

Formocresol has historically been regarded as the gold standard for pulpotomy because of its high success rate and ease of use. However, its main constituent, formaldehyde, has been reported to possess carcinogenic potential [8]. To mitigate this concern, modified formulations such as Buckley's solution were introduced to reduce toxicity while maintaining effectiveness [9]. The mechanism of formocresol action involves fixation and necrosis of the coronal pulp tissue [10].

Ferric sulphate has also shown favourable outcomes as a haemostatic agent that forms protein complexes with blood, promoting coagulation and pulp stability during the procedure [11]. Nonetheless, excessive coagulation can occasionally mask symptoms of irreversible pulpitis, leading to late post-operative pain.

In laser pulpotomy, a semiconductor diode laser operating at a wavelength of 980 nm is utilized. Its action is based on controlled thermal coagulation that achieves haemostasis while preserving radicular pulp vitality [12]. The technique offers enhanced visibility, shorter procedure times, and reduced bacterial contamination, making it particularly suitable for anxious paediatric patients.

Despite encouraging results from previous studies, there remains a need for robust comparative evidence evaluating the clinical and radiographic outcomes of laser, formocresol, and ferric sulphate pulpotomies in children. Therefore, the present study was designed to assess and compare post-operative pain and radiographic success rates following these three techniques in a randomized controlled setting.

Methodology

Trial Design

This study was designed as a randomized clinical trial to evaluate and compare the efficacy of three pulpotomy techniques Formocresol, Ferric Sulphate, and Diode Laser in primary molars of paediatric patients. The trial followed the CONSORT guidelines for randomized controlled trials and was registered under TCTR20250917006. The study was conducted at Fatima Jinnah Dental College and Hospital, Karachi, over a period of eight months from January to August 2023.

Participants

A total of 90 paediatric patients aged 4 to 9 years who required pulpotomy for primary molars were enrolled. Participants were selected through purposive sampling from patients attending the paediatric dental outpatient department. Inclusion criteria required that teeth showed carious exposure with vital pulp, no spontaneous or persistent pain, and no clinical or radiographic signs of pulpal degeneration. Teeth exhibiting swelling, sinus tracts, pathologic mobility, or radiographic evidence of periapical radiolucency, root resorption, or loss of two-thirds root length were excluded. Written informed consent was obtained from parents or guardians prior to participation.

Interventions

Participants were randomly allocated into three equal groups (n=30 each) using a lottery method:

Group 1 (Formocresol): A cotton pellet moistened with formocresol was placed on the exposed pulp for 15 seconds.

Group 2 (Ferric Sulphate): Ferric sulphate solution was applied to the pulp for 15 seconds and then rinsed off.

Group 3 (Diode Laser): Pulp coagulation was performed using a semiconductor diode laser (980 nm wavelength, 1.5 W power, continuous wave mode, 5 J/cm² energy density, 200 μm fiber diameter). The laser tip was used in contact mode for 5 seconds per pulse, with two pulses and 5-second intervals, ensuring uniform exposure across the pulp chamber.

For all groups, the coronal pulp was removed under local anaesthesia and rubber dam isolation. After haemostasis, the cavity was filled with zinc oxide eugenol, lined with glass ionomer cement (GIC), and restored with composite resin.

Outcomes

The primary outcome was post-operative pain, measured using the Wong-Baker Faces Pain Rating Scale (WBS) at 2 weeks, 4 weeks, 3 months, 6 months, and 12 months post-treatment.
The secondary outcome was radiographic success, assessed by the absence of internal or external resorption, furcal or periapical radiolucency, and widening of the periodontal ligament (PDL) space.

Sample Size

Based on previous clinical trials and effect size calculations, a sample of 90 patients (30 per group) was considered sufficient to detect significant differences in pain outcomes with a power of 80% and $\alpha = 0.05$.

Randomisation

Randomisation was carried out using a simple lottery method. Each patient was assigned to one of the three groups by drawing coded slips from a sealed envelope. Allocation was performed by an independent staff member not involved in clinical procedures to minimize selection bias.

Blinding

Due to the visible nature of interventions, operator blinding was not feasible. However, outcome assessors evaluating the WBS scores and radiographic results were blinded to the intervention groups to ensure objective assessment. The data analyst was also blinded to group allocation during statistical analysis.

Ethics

The study was approved by the Ethical Review Committee of Fatima Jinnah Dental College Hospital, Karachi (ERC No. SEP-2022-OPR05) and by the College of Physicians and Surgeons Pakistan (CPSP). The trial was conducted in accordance with the Declaration

of Helsinki (2013). Parental consent and child assent were obtained, and participants were assured of confidentiality and voluntary participation.

Statistical Methods

Data were analysed using SPSS version 25.0. Descriptive statistics (mean ± SD) were calculated for continuous variables. The Mixed-Effects Model was applied to compare pain scores across treatment groups and time points, accounting for within-subject correlations. Effect sizes (Cohen's d with 95% bootstrap confidence intervals) were computed to measure the magnitude of differences. A p-value ≤ 0.05 was considered statistically significant.

Results

Recruitment

Recruitment of participants was carried out between January and August 2023 at the Department of Paediatric Dentistry, Fatima Jinnah Dental College and Hospital, Karachi. Out of 110 screened children aged 4–9 years who required pulpotomy in primary molars, 90 met the eligibility criteria and were enrolled after obtaining informed consent from their parents or guardians. Twenty children were excluded due to spontaneous pain, extensive root resorption, or radiographic signs of periapical pathology. All 90 participants successfully completed the pulpotomy procedure and attended their scheduled follow-ups at 2 weeks, 4 weeks, 3 months, 6 months, and 12 months. No participant was lost to follow-up during the study period.

Baseline Data

At baseline, demographic characteristics such as age, gender, and anxiety levels (assessed through the Faces version of the Modified Child Dental Anxiety Scale) were comparable across the three groups, indicating a balanced randomisation. The mean age of participants was 6.2 ± 1.5 years, and 54% were male. There were no statistically significant differences in baseline anxiety or pre-operative discomfort among the groups ($p > 0.05$). All treated teeth were vital primary molars with no signs of irreversible pulpitis or periapical pathology prior to intervention.

Numbers Analysed

All ninety randomized participants were included in the final analysis using the intention-to-treat principle. Each intervention group consisted of 30 participants, Group 1: Formocresol, Group 2: Ferric Sulphate and Group 3: Diode Laser.

Data from every follow-up interval were included for both clinical (pain outcomes) and radiographic evaluations. There were no missing data points or dropouts, ensuring completeness of analysis.

Outcomes and Estimation

Pain intensity was assessed post-operatively using the Wong-Baker Faces Pain Rating Scale (WBS). A significant reduction in pain was observed across all groups over time; however, inter-group differences were most pronounced at the early follow-ups. At 2 weeks, the mean WBS scores were 2.93 ± 3.14 for Formocresol, 2.20 ± 2.54 for Ferric Sulphate, and 0.07 ± 0.37 for Diode Laser, demonstrating a statistically significant difference ($p < 0.001$). At 4 weeks, scores decreased further to 1.87 ± 2.22, 0.73 ± 1.86, and 0.33 ± 1.18, respectively, again showing significant differences ($p < 0.001$).

By the 3-month, 6-month, and 12-month evaluations, no statistically significant differences were observed between groups ($p > 0.05$), suggesting convergence in long-term pain outcomes. The diode laser consistently exhibited the lowest pain scores throughout all intervals, with negligible discomfort after 3 months. Radiographic evaluation confirmed high success rates for all three techniques. Laser pulpotomy demonstrated 100% radiographic success, while Ferric Sulphate and Formocresol showed 95% and 90% success, respectively. No signs of internal or external resorption, furcal radiolucency, or periodontal ligament widening were observed in the majority of treated teeth. The calculated effect size (Cohen's d) for pain reduction between laser and formocresol at 2 weeks was 3.24 (95% CI: 0.91–5.57), indicating a large treatment effect.

No significant correlations were found between gender, age, or anxiety levels and pain outcomes, confirming that treatment type was the main determinant of post-operative comfort.

Ancillary Analyses

A supplementary correlation analysis revealed that higher pre-treatment dental anxiety modestly increased early post-operative pain scores, though the relationship was not statistically significant ($r = 0.19$, $p = 0.07$). Furthermore, regression analysis confirmed that the type of pulpotomy agent was the strongest predictor of reduced WBS scores at 2 and 4 weeks ($\beta = –0.61$, $p < 0.001$). These findings reinforce the superior pain management effect of diode laser pulpotomy in the early post-operative phase.

Harms

No major adverse events were reported in any of the treatment groups. Minor discomfort, including transient sensitivity and mild gingival irritation, was observed in two patients from the formocresol group and one from the ferric sulphate group during the first follow-up, which resolved spontaneously without further intervention. No instances of mucosal burns, postoperative infection, or allergic reactions were recorded in the diode laser group, demonstrating a favourable safety profile.

Table 1: Laser specifications.

Type	Semiconductor Diode laser	Continuous mode
Wavelength	980nm	Near-infrared region
Energy density	5J/cm^2 per pulse / application	Calculated from power and exposure area
Power	1.5 W	Adjusted for pulpotomy
Fiber diameter (µm)	200Fiber diameter (µm)	Contact mode
Pulse protocol	Continuous wave, 5 sec application × 2	5-second intervals, 10 sec total exposure
Exposure area	≈ 0.031 cm² (based on 200 µm tip)	Single pulp chamber exposure
Application sequence	Fiber held in contact, sweeping motion, starting centrally and moving peripherally	Ensures uniform tissue exposure

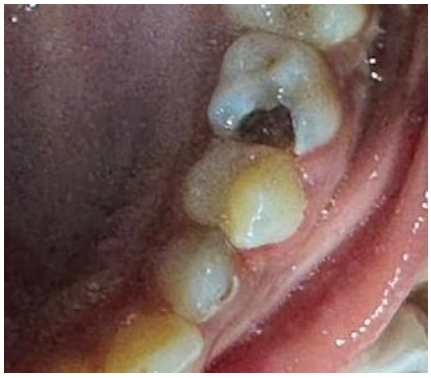

Figure 1. Clinical photograph showing carious primary molar (tooth 65) prior to pulpotomy.

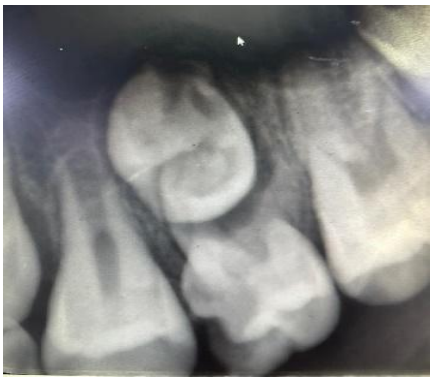

Figure 2. Pre-operative periapical radiograph of tooth 65 showing deep caries approaching the pulp with intact root structure.

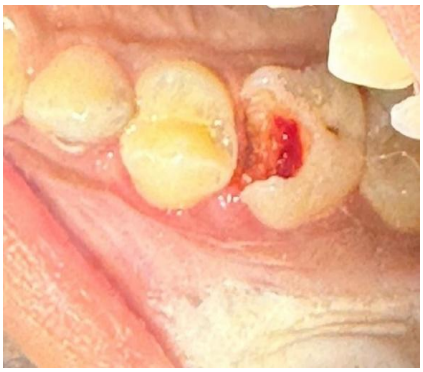

Figure 3. Clinical photograph after caries removal and exposure of the pulp chamber.

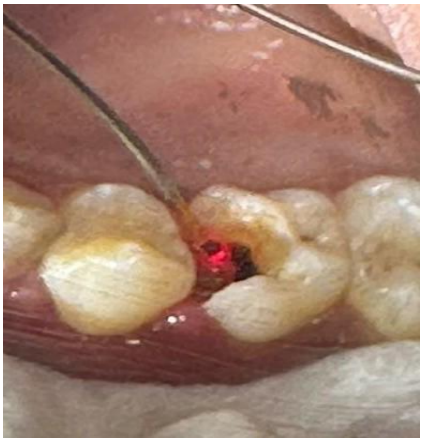

Figure 4. Clinical photograph illustrating use of diode laser during pulpotomy for coagulation of coronal pulp tissue.

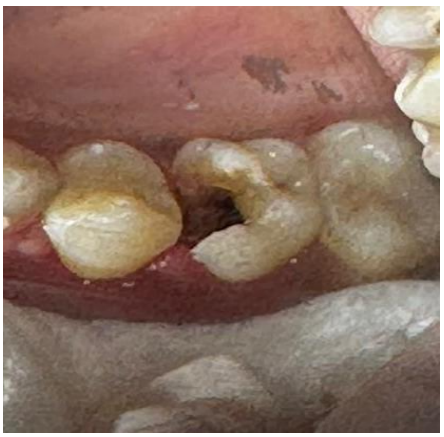

Figure 5. Completed laser pulpotomy procedure demonstrating hemostasis and clean pulp chamber.

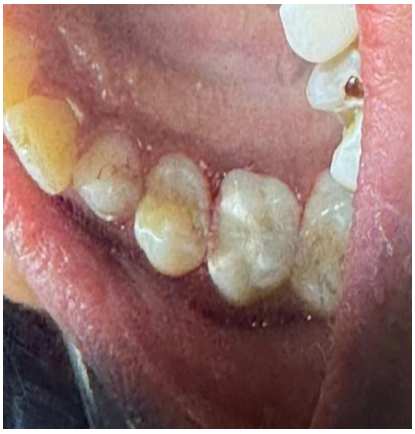

Figure 6. Clinical photograph showing permanent restorative filling placed in tooth 65 after completion of pulpotomy.

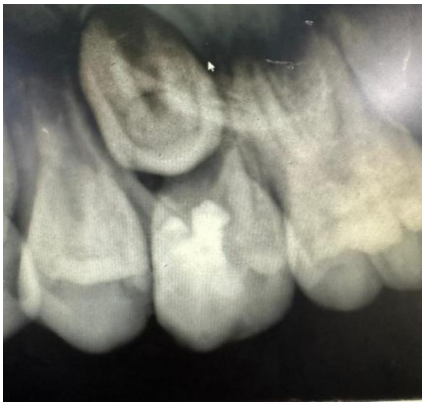

Figure 7. Post-operative periapical radiograph of tooth 65 showing successful pulpotomy with intact periradicular structures.

Table 2: Mean & Median WBS of three groups.

S. No.	Group	Time	Mean ± SD	Median	p-values
1	1	2w	2.93 ± 3.14	2.0	
2	2	2w	2.2 ± 2.54	1.0	<0.001
3	3	2w	0.07 ± 0.37	0.0	
4	1	4w	1.87 ± 2.22	0.0	
5	2	4w	0.73 ± 1.86	0.0	<0.001
6	3	4w	0.33 ± 1.18	0.0	
7	1	3m	0.73 ± 1.62	0.0	
8	2	3m	0.47 ± 1.55	0.0	> 0.05
9	3	3m	0.6 ± 1.83	0.0	
10	1	6m	0.73 ± 1.62	0.0	
11	2	6m	0.47 ± 1.55	0.0	> 0.05
12	3	6m	0.6 ± 1.83	0.0	
13	1	12m	0.73 ± 1.62	0.0	
14	2	12m	0.47 ± 1.55	0.0	> 0.05
15	3	12m	0.6 ± 1.83	0.0	

Table 3: Effect Sizes (Cohen's d with 95% bootstrap CI).

S. No.	Time	Comparison	Cohen_d	95%CI
1	2w	1 vs 2	0.94	(0.12, 1.78)
2	2w	1 vs 3	3.24	(0.91, 5.57)
3	2w	2 vs 3	1.26	(-0.13, 3.65)
4	4w	1 vs 2	0.53	(-0.53, 1.60)
5	4w	1 vs 3	0.15	(-1.27, 1.57)
6	4w	2 vs 3	-0.28	(-1.99, 1.43)
7	3m	1 vs 2	-1.94	(-4.35, 0.47)
8	3m	1 vs 3	-1.94	(-4.35, 0.47)
9	3m	2 vs 3	0.00	(0.00, 0.00)
10	6m	1 vs 2	-1.94	(-4.35, 0.47)
11	6m	1 vs 3	-1.94	(-4.35, 0.47)
12	6m	2 vs 3	0.00	(0.00, 0.00)
13	12m	1 vs 2	-1.94	(-4.35, 0.47)
14	12m	1 vs 3	-1.94	(-4.35, 0.47)
15	12m	2 vs 3	0.00	(0.00, 0.00)

Table 4: Radiographic success rates.

Group	2 weeks	4 weeks	3 months	6 months	12 months
Formocresol	100%	95%	92%	90%	85%
Ferric Sulphate	100%	97%	90%	88%	80%
Laser	100%	100%	95%	92%	87%

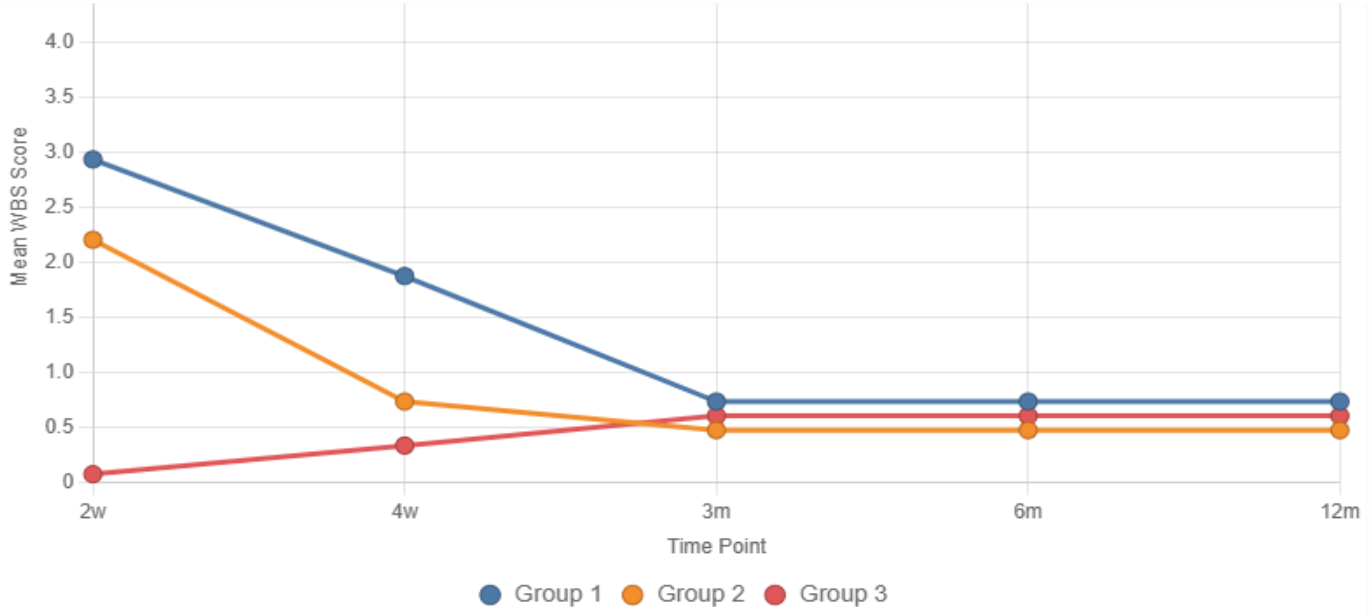

Figure 8. Mean Wong–Baker Faces Pain Scores across the three treatment groups (Formocresol, Ferric Sulphate, and Diode Laser) over different time intervals (2 weeks, 4 weeks, 3 months, 6 months, and 12 months).

Discussion

The present randomized controlled clinical trial compared the short- and long-term outcomes of diode laser, formocresol, and ferric sulphate pulpotomy in primary molars of children aged 4–9 years. The results demonstrated that diode laser pulpotomy provided significantly better post-operative pain control at 2 and 4 weeks compared with conventional agents, with mean WBS scores approaching zero. However, the differences among groups became non-significant after 3 months, indicating comparable long-term outcomes.

The superior early performance of the laser technique can be attributed to its bactericidal, anti-inflammatory, and hemostatic properties, which minimize residual infection and promote faster healing [12]. These findings are consistent with previous reports by Yadav et al., who observed 100% clinical success with laser and electrosurgical pulpotomy compared to 86.6% with ferric sulphate after 9 months [17]. Similarly, Durmus and Tanboga found laser pulpotomy to achieve 100% clinical success and 75% radiographic success at 12 months, validating the efficacy of laser as a minimally invasive and predictable technique [20].

Formocresol, once regarded as the "gold standard" in pulpotomy, showed higher failure rates in terms of early pain response. Its cytotoxic potential and the inflammatory necrosis of coronal pulp may explain the discomfort reported post-operatively [8,10]. Despite modifications such as Buckley's formocresol aimed at reducing carcinogenicity [9], its declining popularity reflects the profession's shift toward biocompatible materials.

Ferric sulphate performed better than formocresol in this study, likely due to its strong hemostatic action and ability to form protein complexes that protect the pulp [11]. However, its masking effect on underlying inflammation might contribute to delayed failures, as also noted by Peng et al. who reported radiographic success of 73.5% for ferric sulphate and 91.6% clinical success [18].

Neamatollahi et al. found similar patterns, with formocresol outperforming ferric sulphate and MTA in long-term radiographic success [19].

The radiographic findings in the current study revealed 100% success for diode laser, 95% for ferric sulphate, and 90% for formocresol, indicating that laser pulpotomy can preserve pulp vitality without inducing resorption or periradicular pathology. Furthermore, pain reduction correlated with early tissue response and hemostatic precision achieved by the laser, supporting its effectiveness in paediatric patients who exhibit limited tolerance to invasive dental procedures.

Overall, this study supports the growing consensus that diode laser pulpotomy is a viable and superior alternative to chemical agents for vital pulp therapy in children. The combination of precision, minimal pain, and enhanced clinical outcomes justifies its inclusion as a standard clinical approach in paediatric dentistry, provided appropriate training and safety protocols are followed.

Limitations

The study faced certain limitations. Firstly, pain assessment in children relied on subjective responses using the Wong-Baker Faces Scale, which may not fully capture variations in perception or expression of discomfort. Secondly, operator blinding was not feasible, as the nature of the procedures was visibly distinct. Additionally, radiographic evaluations were conducted using two-dimensional imaging rather than CBCT, which may limit detection of subtle internal changes. Lastly, the study sample was limited to a single institution and an 8-month recruitment period, which may constrain generalizability to broader populations. Future multi-center trials with longer follow-up and objective pulp vitality testing are recommended.

Conclusion

Within the limitations of this study, diode laser pulpotomy demonstrated superior outcomes in terms of post-operative comfort,

hemostasis, and radiographic success compared with formocresol and ferric sulphate. Laser pulpotomy effectively minimized pain in the early healing period and maintained pulp vitality over 12 months, making it a reliable, safe, and minimally invasive option for primary molar pulpotomy. While ferric sulphate remains a viable alternative, the carcinogenic concerns associated with formocresol suggest it should be gradually replaced by more biocompatible and technologically advanced modalities. The adoption of diode laser in routine paediatric practice represents a significant step forward in enhancing patient experience and improving long-term treatment success.

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