

RANDOMIZED CONTROL TRIAL

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Clinical and Radiographic Success of Low-Level Laser Therapy Compared with Formocresol Pulpotomy Treatment in Primary Molars

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Abstract: *Purpose:* The purpose of this study was to assess and compare the clinical and radiographic success rates of low-level laser therapy (LLLT) and formocresol (FC) for pulpotomy in primary teeth. **Methods:** Utilizing a split-mouth technique, 106 primary molars of 36 five- to eight-year-olds were included. The teeth were selected according to specific clinical and radiographic inclusion criteria and randomly assigned to the LLLT group and FC group. A pulpotomy was performed on each molar; 53 teeth were treated with LLLT, and 53 teeth were treated using FC. Children were followed at six and 12 months for clinical and radiographic evaluation. **Results:** At six months, the clinical success rate was 98 percent for each group. Radiographic success was 100 percent for the LLLT group and 98 percent for the FC group. At 12 months, both groups showed a clinical success of 96.1 percent. Radiographic success at 12 months was 100 percent and 98 percent for LLLT and FC, respectively. **Conclusions:** Both low-level laser therapy and formocresol pulpotomy techniques showed favorable clinical and radiographic outcomes in human primary molar teeth over 12 months. Further longitudinal studies with longer follow-up periods and larger sample sizes are encouraged. (*Pediatr Dent* 2020;42(5):359-66) Received October 13, 2019 | Last Revision June 7, 2020 | Accepted June 8, 2020

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Dental caries is an infectious disease that is considered a major public health issue.¹ It is the most common chronic disease among children worldwide.² Untreated dental caries in primary teeth may lead to premature tooth loss, which markedly decreases the quality of life by affecting esthetics, phonetics, and occlusal functions in children.³

A pulpotomy is a vital pulp therapy performed in cases of carious or mechanical exposure of the coronal pulp of primary teeth, while the radicular pulp is still healthy.⁴ Devitalization is an attempt to preserve the vital noninfected radicular pulp. In 1904, Buckley⁵ published his method of using formocresol (FC) on necrotic pulps. His formula consisted of 19 percent formaldehyde, 35 percent tricresol, 15 percent glycerin, and 31 percent water base.⁶ In 1962, the number of visits was reduced from five to two, for financial and behavioral management considerations.⁷ Then, Spedding et al.⁸ and Redig⁹ used a one-visit technique during which FC was used for five minutes only. In the early 1970s, it was reported that the use of one-to-five diluted FC and full-strength FC produced similar results.¹⁰

Formocresol has been considered the gold standard pulp dressing material for the past 60 years.¹¹ This material is widely accepted by dentists, owing to its ease of application, fixative ability, and bactericidal action.¹² However, its adverse effects are well-known, including potential carcinogenicity, mutagenicity, and cytotoxicity.¹³

Low-level laser therapy (LLLT) is a technique that has many advantageous characteristics. It exerts an antiinflammatory action through its ability to boost collagen synthesis, reduces inflammatory exudation, and enhances revascularization and epithelialization.¹⁴ The application of this type of laser also relieves pain and changes its threshold by increasing the release of endorphins and decreasing bradykinin.¹⁵ Moreover, LLLT enhances the immune system.¹⁶ Few studies have investigated the effects of LLLT on primary teeth pulps and have mostly focused on clinical and radiographic success rates of this pulpotomy technique.¹⁷⁻²¹ To date, only one study¹⁸ has evaluated the histological effects of LLLT on primary molar pulps. However, these previous studies involved a small number of teeth and did not use sample size calculations. Also, the available literature on the success rate of low-level laser pulpotomy has reported conflicting results. Therefore, more clinical trials are needed to establish whether this technique is an alternative to FC and to elucidate its mechanism of action.

The purpose of this study was to compare the clinical and radiographic success rates of low-level laser therapy and formocresol in human primary molar pulpotomies. This study hypothesized that there would be no difference between both groups in the pulpotomy of primary teeth.

Methods

Study design. This split-mouth, randomized, controlled clinical trial was conducted in the Pediatric Dentistry Clinics, Faculty of Dentistry, King Abdulaziz University, Jeddah, Saudi Arabia, between August 1, 2016, and August 31, 2017.

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Ethical approval. The study was approved by the relevant Research Ethics Committee (approval no. 099-07-16).

Sample size and power calculation. The required sample size for this randomized controlled trial was measured using Open Source Epidemiologic Statistics for Public Health online software (www.openepi.com). It was calculated using estimates provided in previous reports and indicating approximately a 20 percent difference in success rate between the two groups favoring LLLT over FC (78.8 percent versus 57.8 percent; and 71.42 percent versus 90.47 percent).^{22,23} The sample size calculated based on averages of these estimates indicated that a sample size of 51 teeth in the test group and 51 teeth in the control group was necessary for 80 percent power, which is considered an adequate power level.

Subjects' inclusion criteria. One experienced pediatric dentist recruited the sample of this study by examining pediatric patients attending the pediatric dental clinics at King Abdulaziz University, Jeddah over one year. It included five- to eight-year-olds with at least two bilateral deep carious primary molars indicated for pulpotomy. The included children were physically and mentally healthy without any known medical history of systemic conditions contraindicating pulp therapy. The selected children had "positive" or "definitely positive" behavioral ratings according to the Frankl behavior classification scale.²⁴ Each parent signed informed consent for the child's participation in the study. No children were excluded based on gender, race, social status, or economic status.

Tooth inclusion criteria. Teeth were included if they had: restorable crowns with vital carious pulp exposure; no clinical signs and symptoms of pulp degeneration, such as swelling, fistula, abnormal mobility, spontaneous pain or sensitivity to percussion; no radiographic evidence of internal or external resorption and periapical or interradicular radiolucency; and if no more than one-third of the root had been resorbed naturally. Teeth were excluded if any of the aforementioned inclusion criteria were not met. Preoperative periapical radiographs of the molars considered for treatment were obtained using the XCP-extension cone-paralleling technique.

Of the 50 screened children, 36 met the aforementioned inclusion criteria. Exclusion was based on the refusal of the parent/guardian to participate in the study (one child), non-restorability of the tooth (five children), sensitivity to percussion (two children), and evidence of radiographic pathology (six children). Among the 36 included children, 106 teeth were eligible for the pulpotomy procedure (Figure 1). Utilizing a split-mouth approach, the included teeth were randomly and evenly assigned to either the LLLT group or FC group (53 teeth per group). It was specified to start with the right side, despite the technique being chosen by randomization. Therefore, randomization was carried out for the technique only. Before recruitment started, 53 sealed envelopes containing the randomization results were prepared, sealed, and blindly mixed in a box. Each envelope represented a pair of matched contralateral teeth. Next, these envelopes were numbered from one to 53. The number of each envelope also determined the pair order in the sequence of treatment (envelope number one indicated the first treated pair and so on). Each envelope was unsealed after the parent signed the informed consent and immediately before the pulpotomy procedure was performed.

Pulpotomy procedure. The same pediatric dentist who recruited the children performed all pulpotomies. After applying topical anesthesia, teeth were anesthetized using 27-gauge short needles and syringes loaded with carpules containing

1.8 ml of lidocaine HCl 2 percent with an epinephrine concentration of one in 100,000 (Octocaine 100, Novocel Healthcare Inc., Cambridge, Ontario, Canada). Each tooth was isolated using a rubber dam and an appropriate clamp. The pulpotomy procedure included caries removal and deroofing of the pulp chamber by using a no. 330 high-speed bur with water spray. Coronal pulp amputation was performed using a sharp spoon excavator or slow-speed round carbide bur (number six or eight). Then, the pulp chamber was irrigated with distilled water and bleeding was controlled by placing a cotton roll moistened with normal saline in the pulp chamber for five minutes. However, if hemostasis was not achieved within five minutes after a wet cotton pellet was directly applied to the pulp stumps or the radicular pulp tissue was not vital due to the presence of suppuration or purulent necrosis (pus discharge), teeth were planned to be excluded. In this study, hemostasis was successfully achieved in all of the cases and none were excluded because of excessive bleeding from the radicular pulp.

For the LLLT group, safety goggles were used by the operator, patient, and parent during LLLT. Laser radiation with a wavelength of 810 nm (Photon Dental Diode Laser, Zolar Technology and Manufacturing Co. Inc., Mississauga, Ontario) was delivered through a 200-μm-diameter optical fiber, without contact with the pulp tissue (two mm away from the pulp). The laser parameters were set on low-level settings using the

Table 1. LASER IRRADIATION AND TREATMENT PARAMETERS ACCORDING TO THE MANUFACTURER'S INSTRUCTIONS*

Irradiation parameter [unit]	Value, measurement method, or information source
Center wavelength (nm)	810
Operating mode	Continuous or pulsed wave
Frequency (Hz)	0.1-50 KHz
Pulse on duration (seconds)	0.01 ms to 9.9 s
Pulse off duration (seconds) or duty cycle (%)	Variable
Energy per pulse (J)	4
Average radiant power (mW)	2
Beam profile	Gaussian
Treatment parameter (unit)	Value
Beam spot size at target (cm ²)	105 μm
Exposure duration (seconds)	40
Radiant exposure (J/cm ²)	6.7
Radiant energy (J)	4
Number of points irradiated	1
Application technique	Noncontact mode
Number and frequency of treatment sessions	1 session
Total radiant energy (J)	4

* Abbreviations used in this table: Laser device model: Photon Dental Diode Laser, Zolar Technology and Manufacturing Co. Inc., Mississauga, Ontario, Canada; nm=nanometer; Hz=hertz; KHz=kilohertz; s=seconds; ms=milli-seconds; J=joule; mW=milliwatt; cm²=square centimetre; μm=micrometer; J/cm²=joules per square centimeter.

bio-stimulation program, at three W power output, five W/cm² power density, four Joules energy, 6.7 J/cm² energy density, one to 50 kHz frequency, 105-μm focus beam diameter, and an irradiation time of 40 seconds (per tooth) in continuous mode. The tip was rotated over all pulp stumps during the application. The laser irradiation and treatment parameters were used according to the manufacturer's instructions (Table 1).

For the FC group, a cotton pellet moistened with 1:5 dilution of FC (Viarden Dental, Marcelino Dávalo, Algarín, Mexico) was placed in contact with the surface of the pulp stumps for five minutes.

In both groups, the pulp chamber was filled with reinforced zinc oxide-eugenol (IRM, Dentsply, Mount Waverley, Australia) to ensure proper sealing. Then, each tooth was finally restored with a stainless steel crown (SSC) (3M/ESPE, St. Paul, Minn., USA). After the pulpotomy procedure, each molar was prepared and the crown was fitted in the same visit and cemented onto the tooth using glass ionomer cement (Rely-X, 3M/ESPE). Finally, a postoperative periapical radiograph was taken for each tooth to confirm proper dressing of the remaining pulp tissues.

Parents and children were provided with the needed general oral hygiene instructions and specific instructions about the treated teeth. Moreover, all possible outcomes were explained to them in detail, and they were asked to report any pain, discomfort, swelling, or pus discharge immediately. No radiographic evaluation was planned before six months unless the parents reported complaints. If the patient complained of pain related to the crown and clinical and radiographic examinations revealed improper positioning or long margins, the crown was decided to be replaced under rubber dam isolation and considered a successful case. However, if the patient complained of pain related to the crown with normal findings radiographically, it was decided to reinforce oral hygiene instructions and monitor

the patient until the next scheduled appointment; at that point, the case was considered a successful one.

Follow-up. All included patients were recalled after six and 12 months for clinical and radiographic assessment. The same operator who performed all pulpotomy procedures evaluated the teeth clinically and radiographically. To assess intraexaminer reliability, the examiner reevaluated the radiographs of 10 cases at one week after the initial evaluation; there was no difference between evaluations. During the clinical and radiographic evaluation, the examiner was blinded to the group allocation.

Outcome assessment criteria. Clinical success was considered as the absence of any adverse clinical signs or symptoms, such as sensitivity, mobility, pain, or swelling. Radiographic success was confirmed in teeth presenting the absence of periapical radiolucency, furcation involvement, widening of periodontal ligament space, and pathologic internal/external root resorption. Internal root resorption may be self-limiting and stable. The clinician should monitor the internal resorption, removing the affected tooth if perforation causes loss of supportive bone and/or clinical signs of infection and inflammation. There should be no harm to the succedaneous tooth.⁴

Statistical analysis. Data were analyzed using SPSS 16.0 software (SPSS Inc., Chicago, Ill., USA). Descriptive statistics are presented with frequency and percentages. The success for each tooth was compared between the six and the 12 months using McNemar's test. The level of significance was set at $P<0.05$. For significant P -values, relative risk and 95 percent confidence intervals were calculated.

Results

A CONSORT diagram²⁵ showing the flow of patients and teeth treated with pulpotomy up to the 12-month follow-up was presented in Figure 1. One hundred six molars in 36 patients (52.8 percent boys and 45.3 percent girls; mean age equals 6.18 ± 0.99 [standard deviation] years old) were equally and randomly assigned to either the LLLT or the FC groups, using a split-mouth approach. Regarding the number of pairs, 23 children (63.9 percent) had a single pair of teeth, 10 children (27.8 percent) had two pairs of teeth, two children (5.6 percent) had three pairs of teeth, and one child (2.7 percent) had four pairs of teeth (Table 2). In general, mandibular molars (54 out of 106; 50.9 percent) were slightly more frequently recruited than maxillary molars (52 out of 106; 49.1 percent). The most frequently treated in this study were mandibular second molar teeth (33 out of 106; 31.1 percent), followed by the maxillary second molar (30 out of 106; 28.3 percent), maxillary first molar (22 out of 106; 20.8 percent), and mandibular first molar (21 out of 106; 19.8 percent). Two patients only failed to attend the six-month follow-up after moving to distant cities. These teeth were excluded from the analysis. At 12 months, all of the treated children returned for follow-up. Hence, 102 primary molars were clinically and radiographically evaluated at the end of the six and 12 months.

Table 3 shows the clinical and radiographic outcomes at six- and 12-month follow-up examinations. At the six-month follow-up visit, 51 teeth in each of the LLLT and FC groups were available for clinical and radiographic examination. Both groups showed a 98 percent clinical success rate. One primary molar from the LLLT group had nonspontaneous pain as well as grade one mobility while one tooth in the FC group experienced nonspontaneous pain only. The radiographic success rates for the LLLT and FC groups were 100 percent and 98 percent, respectively. Furcation involvement was diagnosed in one

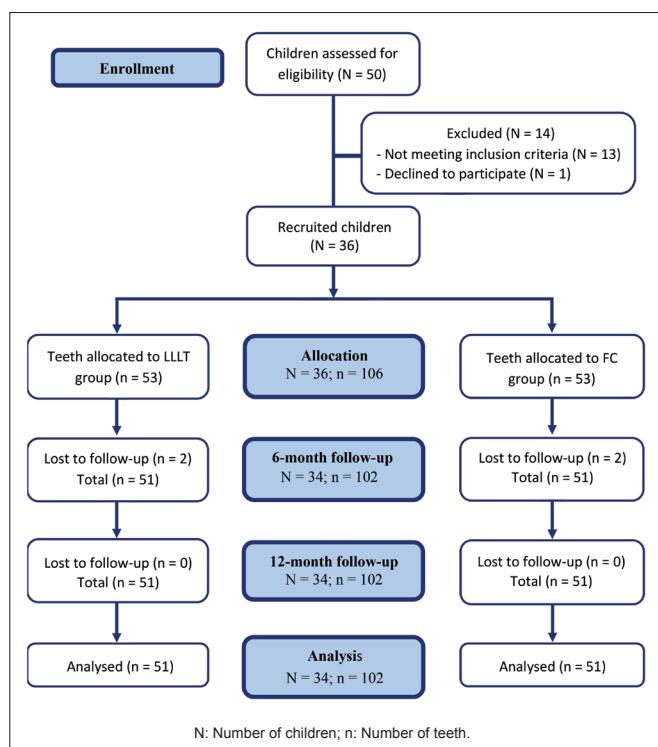


Figure 1. CONSORT diagram showing the flow of patients and teeth treated by pulpotomy up to 12 months follow-up.

primary molar from the FC group. No statistically significant differences were found between the two groups. The molar in the LLLT group showed normal findings radiographically. It was decided to monitor the child for any other signs. The tooth in the FC group showed signs of furcation involvement. Later, the parent reported the presence of an abscess related to that tooth, and it was extracted.

At the 12-month follow-up visit, 51 teeth in each of the LLLT and FC groups were available for clinical and radiographic examination. No statistically significant differences in clinical and radiographic success were found between the two groups at the 12-month follow-ups. There was a drop in the clinical success rates of LLLT and FC groups reaching 96.1 percent. Two teeth in each group showed clinical signs of treatment failure. In

the LLLT group, the same molar that had pain and grade one mobility at the six-month follow-up visit presented with pain and grade three mobility and the tooth was extracted. Figure 2 shows the molar with grade 3 mobility and its associated radiographic findings. Another molar had grade one mobility and it was decided to be monitored. In the FC group, two primary molars presented with grade two mobility, and it was determined that they warranted further follow-up. No radiographic abnormalities were indicated at that stage; therefore, the radiographic success rates for the LLLT and FC groups remained 100 percent and 98 percent, respectively. Figures 3 and 4 show radiographs of two successfully treated teeth for each of the two groups.

Discussion

The American Academy of Pediatric Dentistry (AAPD) recommends ongoing research on new modalities and techniques in addition to biologically compatible pulpotomy materials,⁴ since the majority of research has not involved randomized clinical trials.²⁶ LLLT has demonstrated many successes in multiple applications and is considered to be a relatively recent technique in pulpotomy as well as a minimally invasive and less time-consuming method.²⁷ Although its mechanism is not well known, this technology has been suggested to facilitate a devitalization reaction through biomodulation on dental pulp cell development, reactionary dentine biostimulation, and a less-intense inflammatory process.²⁸ When added to the dentin pulp interface after tooth preparation, LLLT appears to promote the regeneration of the dental structure,²⁸ reduce hypersensitivity to dentin,²⁹ and eliminate pain caused by dental procedures.³⁰ The reasoning behind this assumption is that LLLT causes a calcification boost on the wound surface and promotes calcified tissue formation.³¹ Until now, there is a paucity of studies that investigated the effects of LLLT on primary teeth pulps, and these have yielded conflicting results. These findings along with AAPD recommendations encouraged the authors to conduct the present study to investigate the effectiveness of LLLT as a pulpotomy technique.

Table 2. CHARACTERISTICS OF THE INCLUDED CHILDREN

Item	Category	Total number of children	
		N	%
Number of pairs of teeth*	Single pair of teeth	23	63.9
	Two pairs of teeth	10	27.8
	Three pairs of teeth	2	5.6
	Four pairs of teeth	1	2.7
Sex	Male	19	52.8
	Female	17	47.2
Age (years)	5	11	30.6
	6	12	33.3
	7	8	22.2
	8	5	13.9

* Twenty-three children had a single pair of teeth=23x2=46 teeth; 10 children had two pairs of teeth=10x (2x2)=40 teeth; two children had three pairs of teeth=2x (3x2)=12 teeth; and one child had four pairs of teeth=1x (4x2)=eight teeth.

Table 3. CLINICAL AND RADIOGRAPHIC SUCCESS AND FAILURE RATES FOR THE LOW-LEVEL LASER THERAPY (LLLTT) GROUP AND FORMOCRESOL (FC) GROUP AT SIX- AND 12-MONTH FOLLOW-UPS

Follow-up	Clinical success and failure rates								Radiographic success and failure rates									
	LLLTT*				FC*				P-value† RR* (95% CI*)	LLLTT				FC				P-value† RR (95% CI)
	N*	Success	Failure	N	Success	Failure	N	Success		N	Success	Failure	N	Success	Failure			
		N	%	N	%	N	%	N		N	%	N	N	%				
6 mos	51	50	98	1	2	51	50	98	1	2	1	1.000 (0.020-49.4)	51	51	100	0	0	0.498 0.33 (0.014-7.996)
12 mos	51	49	96.1	2	4	51	49	96.1	2	4	1	1.000 (0.020-49.4)	51	51	100	0	0	0.498 0.33 (0.014-7.996)

* LLLT=Low-level laser therapy; FC=Formocresol; RR=relative risk; CI=confidence interval; mos=months; n=total number of treated teeth in each group/number of successful and failed teeth in each group.

† Significance level is set at $P<0.05$ using McNemar's test.

Formocresol as a pulp-capping material promotes a similar devitalization cycle with an unfavorable histological response in the remaining radicular pulp, showing areas of necrosis and connective tissue with chronic inflammation ranging from low to high.³² It was selected as the control pulpotomy treatment in this study due to its ease in use and long-term clinical success, even though its adverse effects remain a concern.⁴ Though a lot of debate exists regarding its adverse effects and concerns remain regarding its safety,³³ UK National Clinical Guidelines in Pediatric Dentistry have proposed FC at a one-in-five dilution rate as one of the choices of materials to be used for primary tooth pulpotomy.³⁴



Figure 2. A primary mandibular second molar treated by pulpotomy using low-level laser therapy presented with grade three mobility after 12 months.

Previous trials had assessed the effectiveness of LLLT as a pulpotomy technique.¹⁷⁻²¹ However, the laser parameters were set differently in each of these studies. Golpayegani et al.¹⁹ used a wavelength of 632 nm, whereas, Marques et al.¹⁸ and Fernandes et al.¹⁷ each used 660 nm. The variation in any of the laser application parameters, including power, frequency, exposure time, and wavelength could have different effects on pulp tissue.¹⁸ The wavelength used in the present study (810 nm) was similar to that used by Uloopi et al.²⁰ and Durmus and Tanboga.²¹ Studies have shown that the use of the 810 nm wavelength increased DNA synthesis,³⁵ stimulated proliferation of human gingival fibroblasts,³⁶ and enhanced completion of immature root formation in rat teeth following pulpotomy.²⁰

The success rate of pulpotomies has been measured traditionally as the percentage of teeth showing no clinical or radiographic evidence of disease at different assessment intervals.²⁰ Similarly, in this study, the success rate of the pulpotomy treatments was defined as the absence of any clinical or radiographic pathology at the follow-up appointments. The results of this clinical trial revealed no statistically significant differences in the clinical and radiographic success rates of LLLT and FC pulpotomy.

At the 12-month recall visit, high clinical success rates were observed for LLLT and FC, with no statistically significant differences noted between the two groups. This might be due to the satisfactory study sample size in addition to the relatively low dropout rate. These findings agree with those by Durmus and Tanboga,²¹ who reported 100 percent and 97 percent clinical success rates for LLLT and FC groups, respectively, and with Fernandes et al.¹⁷ who reported success with all study groups after a clinical evaluation during the follow-up period. By contrast, Uloopi et al.²⁰ reported a lower success rate for LLLT (80 percent). The reason behind the difference in the success rates for LLLT measured by that study and the present study

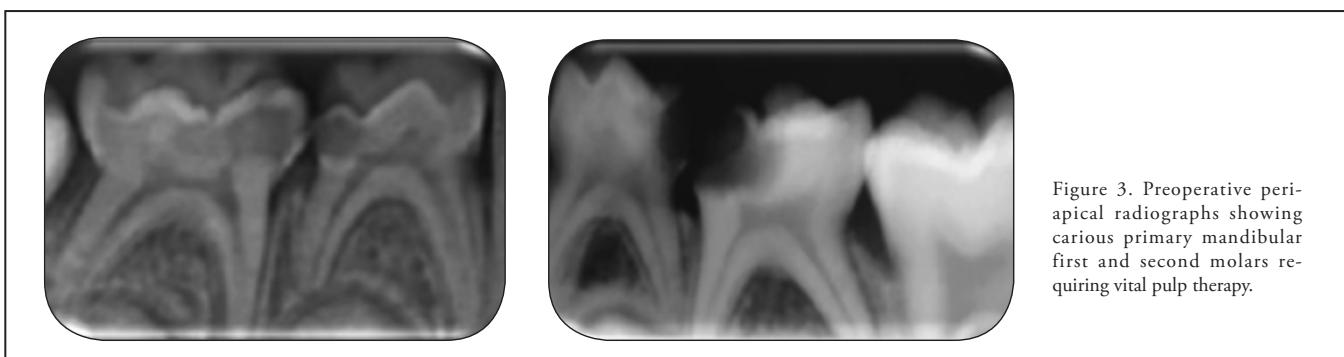


Figure 3. Preoperative periapical radiographs showing carious primary mandibular first and second molars requiring vital pulp therapy.

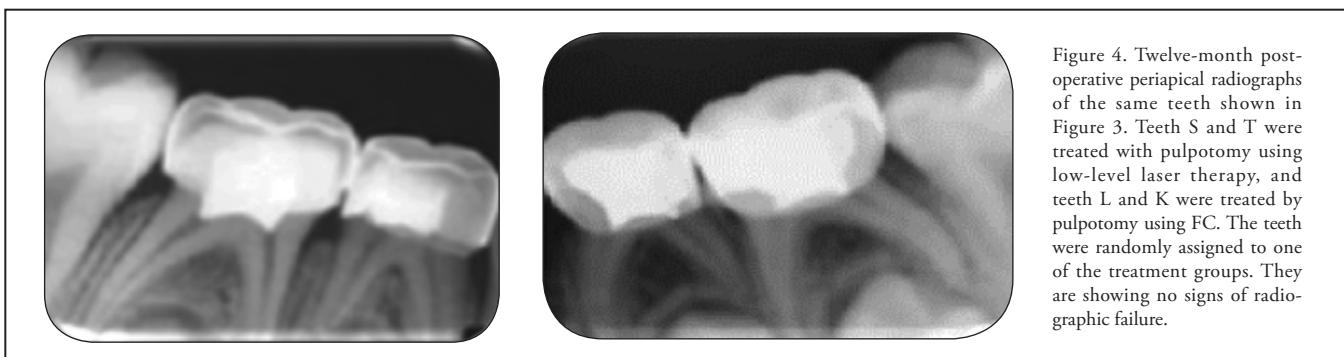


Figure 4. Twelve-month post-operative periapical radiographs of the same teeth shown in Figure 3. Teeth S and T were treated with pulpotomy using low-level laser therapy, and teeth L and K were treated by pulpotomy using FC. The teeth were randomly assigned to one of the treatment groups. They are showing no signs of radiographic failure.

can be attributed to differences in the outcome analysis between both studies. Uloopi et al.²⁰ combined the clinical and radiographic outcomes to determine the overall success of each technique in every follow-up recall-visit. Any radiographic failure, with or without signs of clinical failure, was documented as a failure. By contrast, the present study evaluated clinical success rates independently from radiographic success for each material.

The most reported clinical failure criterion in the current study was postoperative pain, observed in five cases. Similarly, Gupta et al.³⁷ and Niranjani et al.³⁸ reported some cases demonstrating pain during the study recall visits. These findings, however, were different from Kuo et al.³⁹ in that none of the teeth in the laser group reported any clinical signs or symptoms of failure; however, their study design was retrospective. The failure in the pulpotomy could be attributed to several factors, such as improperly adapted crowns, voids in the cement material, and areas of residual caries or remaining coronal pulp tissue in addition to the fact that the laser pulpotomy is a more operator-sensitive technique according to Niranjani et al.³⁸

In the current study, postoperative pain was accompanied by normal radiographic findings during the first follow-up visit. When the causes of pain were addressed, the patients were monitored and no pain or other signs of failure were reported. After six months, one tooth was extracted due to pain and furcation involvement, dropping FC's clinical success rate to 98 percent. At 12 months, another tooth in the LLLT group was extracted due to pain and grade three mobility, leading to a clinical success rate of 96.1 percent. Abnormal mobility of teeth was reported in three cases for nine-year-old patients. In the LLLT group, the same molar that had pain showed grade one mobility at six months and grade three mobility at 12 months, and the tooth was extracted. In the FC group, two primary molars presented with grade two mobility and further follow-up was made. These findings agree with Ansari et al.,⁴⁰ who reported two cases with degrees of mobility: one at the six-month follow-up and another at the 12-month follow-up. Both cases were judged as failures.

The current study findings coincide with other studies finding that FC pulpotomy was associated with early exfoliation of primary teeth and early eruption of permanent successors.^{21,22} Additional studies are needed to confirm if LLLT is associated with premature shedding of primary teeth. Despite these reported clinical findings in both LLLT and FC groups, radiographic pathology was not established. This agrees with Farsi et al.,⁴¹ who reported clinical failures without evidence of radiographic pathology. This discrepancy may have been the result of an early, histologically observable pulp pathology, but it had not yet materialized into a pathological radiographic finding.

In the present study, the LLLT group showed 100 percent radiographic success rates after 12 months of treatment reporting no statistically significant differences compared to the FC group. These findings are similar to Saltzman et al.,⁴² who found that diode laser pulpotomy can be an alternative to FC pulpotomy when no statistically significant difference was found between both groups regarding radiographic success criteria. These findings were different from Golpayegani et al.¹⁹ and Fernandes et al.¹⁷ The difference between their findings and those of the present study can be attributed to differences in laser parameters used as treatment outcomes; LLLT is affected by various factors, including wavelength, power output, dose, and pulse frequency, according to Laksoo et al.⁴³ In the present study, LLLT was used at an 810 nm wavelength, four J energy,

and 40-second application time under continuous mode. Golpayegani et al.¹⁹ reported a radiographic success rate of 67 percent with LLLT, which was performed using a 632 nm wavelength under a continuous mode with an energy of 4.0 J/cm² for approximately 30 seconds, with the tip of the fiber two mm away from root stumps.²⁰ Also, this study's results do not coincide with the 80 percent radiographic success rates of LLLT recorded by Fernandes et al.¹⁷ at both intervals. This might be due to the differences in the sealing approach following the pulpotomy procedure. In this study, all teeth treated by pulpotomy were restored with SSCs to ensure proper seal against any microleakage for the entire restoration interface. Fernandes et al.¹⁷ restored all teeth treated by pulpotomy with a resin-modified glass ionomer sealant.

This study had a low dropout rate, and most of the patients were obliged to attend their follow-up visits. The main limitation of this study is that the same operator who performed all pulpotomies evaluated the teeth clinically and radiographically. Also, this study did not use a pain scale to differentiate between the pain that was related to failed pulpotomy and pain due to food impaction and poor oral hygiene, which might be a reason for the presence of clinical failures with normal radiographic findings. Another limitation is that the estimates upon which sample size was based differed from the success rates the authors eventually obtained after analysis. The estimates the authors used for sample size calculation assumed larger differences between groups due to a more modest performance observed for FC than that observed in the present study. This study's findings support the null hypothesis, although the present study has a risk of being underpowered. The authors conducted a posthoc power analysis to assess whether there was adequate power to support a claim that LLLT is not inferior to FC (using a non-inferiority margin of 10 percent); the results showed a power greater than 98 percent (<http://powerandsamplesize.com/Calculators/Compare-2-Proportions/2-Sample-Non-Inferiority-or-Superiority> and https://www2.ccrb.cuhk.edu.hk/stat/proportion/tspp_sup.htm#2). Thus, this study's findings do not support that LLLT is better than FC, although the claim that its success rate is not inferior to FC within 10 percent margin can be supported. Further studies are needed based on estimates obtained in the current research with a longer duration so that conditions similar to actual clinical scenarios can inform decision-making and selection of pulpotomy agents.

Conclusions

Based on this study's results, the following conclusions can be made:

1. Both low-level laser therapy and formocresol pulpotomy techniques showed favorable clinical and radiographic outcomes in human primary molar teeth over 12 months.
2. Further longitudinal studies with longer follow-up periods and larger sample sizes are encouraged.

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