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Abstract	power or high power diod trial, 63 mandibular secon achieving hemostasis, MT (LLLT-MTA) and 3 (DL- diode laser radiation prior (spontaneous pain, tender	e clinical and radiographic effectiveness of MTA partial pulpotomy with low le laser irradiation in primary molars. In this randomized single-blind clinical ad molars were assigned into three groups ($n = 21$). After pulp amputation and CA was placed over pulp stumps in group 1 (MTA). The patients in groups 2 MTA) underwent low level (660 nm, 200 mW) and high power (810 nm, 1 W) to MTA placement, respectively. The occurrence of clinical failure ness upon percussion, swelling, fistula, mobility) and radiographic failure lening, external or internal root resorption, periapical or furcal radiolucency) nths after therapy.
Keywords (separated by '-')		Photobiomodulation - Low level laser therapy - Low power laser therapy - y dentition - Primary molar - Mineral trioxide aggregate
Footnote Information		

ORIGINAL ARTICLE

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² Clinical and radiographic effectiveness of mineral trioxide aggregate

- 3 (MTA) partial pulpotomy with low power or high power diode laser
- ⁴ irradiation in deciduous molars: a randomized clinical trial

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8 Abstract

⁹ This study investigated the clinical and radiographic effectiveness of MTA partial pulpotomy with low power or high power

- ¹⁰ diode laser irradiation in primary molars. In this randomized single-blind clinical trial, 63 mandibular second molars were ¹¹ assigned into three groups (n = 21). After pulp amputation and achieving hemostacis. MTA was placed over pulp stumps
- ¹¹ assigned into three groups (n=21). After pulp amputation and achieving hemostasis, MTA was placed over pulp stumps ¹² in group 1 (MTA). The patients in groups 2 (LLT MTA) and 3 (DL MTA) underwent low level (660 nm, 200 mW) and
- ¹² in group 1 (MTA). The patients in groups 2 (LLLT-MTA) and 3 (DL-MTA) underwent low level (660 nm, 200 mW) and ¹³ high power (810 nm, 1 W) diode laser radiation prior to MTA placement, respectively. The occurrence of clinical failure
- ¹³ high power (810 nm, 1 W) diode laser radiation prior to MTA placement, respectively. The occurrence of clinical failure
 ¹⁴ (spontaneous pain, tenderness upon percussion, swelling, fistula, mobility) and radiographic failure (periodontal ligament
- ¹⁵ widening, external or internal root resorption, periapical or furcal radiolucency) was recorded up to 18 months after therapy.
- ¹⁶ MTA and LLLT-MTA groups showed clinical success rate of 100% throughout the experiment. The clinical success rate
- ¹⁷ of DL-MTA group was 95.2%, 95.2%, and 87.5% after 6, 9, and 18 months. The radiographic success rates were 90.5%,
- ¹⁸ 90.5%, and 87.5% in the MTA group; 100%, 95.2%, and 88.2% in the LLLT-MTA group, and 85.7%, 76.2%, and 68.7% in the
- ¹⁹ DL-MTA group, at 6-, 9-, and 18-month follow-ups, respectively. No significant differences were found in the frequency of
- ²⁰ clinical or radiographic failure among the groups at any interval (p > 0.05). MTA partial pulpotomy was a suitable technique
- ²¹ for vital pulp therapy in deciduous teeth. The addition of low power or high power diode laser radiation to the procedure did
- ²² not cause a significant difference in success rate values.
- Keywords Pulpotomy · Diode laser · Photobiomodulation · Low level laser therapy · Low power laser therapy · Deciduous
 molar · Primary dentition · Primary molar · Mineral trioxide aggregate

AQ1 Introduction

Preserving the teeth during childhood is of great importance,
as the deciduous teeth play a major role in esthetics, mastication, and phonetics, and they also maintain arch length

²⁹ and integrity until the eruption of permanent successors into

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the oral cavity. It is assumed that 75% of primary teeth with deep caries would experience pulpal exposure during cavity preparation and require pulpal treatment [1]. In cases of reversible pulpal injuries, vital pulp therapy (VPT) is the more conservative and preferred option and may be performed through various therapeutic approaches. Indirect pulp treatment (IPT) is used in cases of deep dentinal cavities, whereas direct pulp capping (DPC) or pulpotomy is employed when the pulp exposure occurs [2]. Choosing the appropriate treatment modality is a challenging issue in primary molars with deep carious lesions [3]. Although DPC is not routinely performed in the clinical practice, a recent guideline of American Academy of Pediatric Dentistry (AAPD) states that IPT, DPC, and pulpotomy are all viable options of VPT in the primary dentition [3, 4]. It should be noted that the occurrence of saliva contamination during VPT may oblige the clinician to shift to a more aggressive pulp treatment such as pulpectomy of primary teeth.

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48 Pulpotomy is generally considered as the most popular and successful technique of VPT in deciduous molars [5]. 49 Partial pulpotomy is a less invasive form of pulpotomy, 50 with more biologic principles and conservative hypothesis 51 to achieve better clinical outcomes [6]. Partial pulpotomy 52 was first proposed by Cvek [7] in 1978 to treat traumatically 53 exposed pulps of permanent incisors. This technique was 54 later employed for conservative treatment of carious pulp 55 exposures in which hemostasis could be obtained within a 56 few minutes [8]. Partial pulpotomy involves removing 2 mm 57 of inflamed coronal pulp adjacent to the exposure site and 58 then covering the amputated pulp with a suitable covering 59 agent to preserve the remaining coronal and radicular tissues 60 [3, 6]. This treatment modality is associated with several 61 advantages including preservation of healthy coronal pulp, 62 creating a clean wound by removal of infected dentinal chips 63 and injured odontoblasts, minimal loss of tooth structure, 64 easier control of bleeding, and shorter surgical time [3, 65 66 6, 9]. The characteristics of the pulp covering agent has a great effect on the success of partial pulpotomy by provid-67 ing improved strength and anti-microbial seal [6]. Various 68 regenerative biomaterials including calcium hydroxide (CH), 69 mineral trioxide aggregate (MTA), and calcium-enriched 70 mixture (CEM) cement have been employed as capping 71 agents for VPTs of primary teeth [9, 10]. 72

Lasers are currently employed as adjuncts in various 73 branches of dentistry including endodontic and pediatric 74 procedures. High power lasers (> 500 mW) have cutting, 75 hemostatic, antimicrobial, and even analgesic properties and 76 can be used to induce a superficial zone of coagulation in 77 78 an atraumatic and aseptic way [11-13], whereas low power (also called low level) lasers (< 500 mW) are generally 79 applied for photobiomodulation (PBM) therapy. Photobio-80 modulation is a term used to describe photochemical reac-81 tions in biological systems induced by irradiation with light 82 of low power intensity. A variety of light sources, especially 83 low level lasers and light emitting diodes (LEDs), could be 84 applied in this procedure. Low level laser therapy (LLLT) 85 has been used in pulp therapy to stimulate dental pulp cells, 86 reduce pulpal inflammation, provide analgesic effect, and 87 enhance the wound healing process [14]. Previous studies 88 evaluated the efficacy of high power and low power lasers 89 90 in cervical pulpotomy of deciduous molars [11, 12, 14, 15]. In these cases, following pulp amputation and achieving 91 hemostasis, the laser was irradiated to the openings of root 92 93 canals to either induce blood coagulation or enhance the healing process. 94

There are few studies on the success rate of partial pulpotomy as a conservative approach of vital pulp therapy in primary molars with the use of MTA for pulp coverage. Furthermore, the literature contains heterogeneous reports concerning the effectiveness of different lasers in conventional pulpotomy of primary molars [16, 17], and the effect of low

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power and high power diode lasers on the outcomes of par-101 tial pulpotomy has not been assessed in previous investiga-102 tions. The present randomized clinical trial was conducted 103 to determine the clinical and radiographic effectiveness of 104 partial pulpotomy with MTA sealing in primary molars over 105 a period of up to 18 months and to investigate whether low 106 level laser therapy (LLLT) or high power diode laser (DL) 107 radiation could enhance the success rate of this procedure in 108 vital pulps of lower primary second molars. 109

Materials and metho	ds
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Study design and ethics

This was a randomized, single-blind, controlled clini-112 cal trial. The study protocol was approved by the ethics 113 committee of Mashhad University of Medical Sciences, 114 and it was also registered in the Iranian Registry of Clini-115 cal Trials (IRCT) website under the identification number 116 IRCT2015100524373N1. The possible risks and benefits of 117 the procedure were explained thoroughly for the parents/ 118 guardians of the children, and informed consent forms were 119 signed by them before the study commencement. A sample 120 of consent form has been presented in Table 1. 121

Sample size and power calculation

The sample size was calculated considering the reported 123 success rate of MTA pulpotomy with or without laser irra-124 diation (100% for MTA pulpotomy [18] and 70.8% for laser-125 assisted MTA pulpotomy [11], considering the significance 126 level of 5% and power of 80%. The sample size was calcu-127 lated as n = 18 per group and then increased to 21 in order 128 to compensate for the possible drop-outs of the patients 129 throughout the follow-up periods. 130

Participants

The participants were selected from those attending the 132 Department of Pediatric Dentistry at Mashhad University 133 of Medical Sciences, Mashhad, Iran. The inclusion criteria 134 involved healthy children aged 4 to 7 years who had at least 135 one second primary molar in the lower jaw with deep car-136 ies, normal clinical findings (no history of spontaneous or 137 nocturnal pain, no tenderness to percussion or palpation, 138 no abscess, no fistula, and no mobility), and normal radio-139 graphic appearance (no widening of the periodontal liga-140 ment space, no pathologic external or internal root resorp-141 tion, no periapical or furcal radiolucencies). The exclusion 142 criteria involved subjects who used analgesic or sedative 143 drugs as well as patients with systemic diseases, mental dis-144 ability, allergy to the materials and medications used in the 145

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AQ1 Table 1 The consent form used in this study

Patient Consent Form

To record a patient's consent to publication of information and images relating to them or a relative, in a journal

Name of patient:

Name of parent/guardian and relationship to patient:

Title of publication: Clinical and radiographic effectiveness of Mineral Trioxide Aggregate (MTA) partial pulpotomy with low power or high power diode laser irradiation in deciduous molars: a randomized clinical trial

Principal author: Professor Masoumeh Ebrahimi

Principal author's address: Department of Pediatric Dentistry, School of Dentistry, Mashhad University of Medical Sciences, Mashhad, Iran

I, [Name of parent/guardian], give my permission to use clinical information/radiographic material relating to [Name of patient and relationship] in the publication identified above to be published by all media and languages throughout the world

This consent is given based on the verbal and written information provided. I am free to ask questions at any time. I have the option to decline to take part or to withdraw from the study at any time without incurring any penalty or loss of benefits otherwise available, including medical care at this institution. I understand that the information/radiographic material will be used only in educational publications intended for health professionals. The name of patient will not be published and she/he cannot be identified from the clinical information, other than in relation to identifiable material (such as radiographic material) for which I give consent

Signature of parent/guardian Address

Date
Signature of professional obtaining permission
Address
Date

procedure, and suppressed immune system. Furthermore,
teeth with no pulpal exposure after caries removal and those
with large exposure sites or uncontrolled bleeding after
exposure were excluded from the sample during treatment.

From the 174 teeth assessed for eligibility, 75 teeth in 150 64 children met the inclusion criteria and recruited for the 151 study. Twelve teeth were excluded during treatment and 152 received an alternative therapy such as cervical pulpotomy, 153 pulpectomy, or restoration. Therefore, the final sample con-154 sisted of 63 teeth in 53 children. The participants were 24 155 boys and 29 girls with the mean age of 5.5 ± 0.91 years at 156 the time of therapy. 157

158 **Randomization and blinding**

Sixty-three primary mandibular second molars were ran-159 domly assigned into three groups (n=21), according to the 160 partial pulpotomy procedure performed: group 1 (control), 161 MTA; group 2, low level laser therapy (LLLT) + MTA; and 162 group 3, diode laser (DL) + MTA. The block randomization 163 was used for patient assignment in this study in order to 164 achieve equal samples across the groups over time. Since 165 there were six different ways to order the three groups, six 166 blocks of size three were created and named from 1 to 6 167 (considering A, B, and C as the treatment groups, 1 = ABC, 168 2 = ACB, 3 = BAC, 4 = BCA, 5 = CAB, 6 = CBA). Using a 169 170 random numbers table, a number in the range of 1 to 6 was chosen, and the sequence of treatment was set accordingly. 171 In patients with right and left second primary molars, the 172 left side was treated first, and the right side was scheduled 173

as the next treatment. The patient assignment was performed 174 by an independent person not involved in the study process. 175

All treatments were provided by a postgraduate student 176 of pediatric dentistry, who was thoroughly trained about 177 the details of the technique and procedures involved. The 178 patients and their parents were blinded to the group assign-179 ment, but the operator was not, as the devices and proce-180 dures were different in the study groups. The statistician who 181 performed the data analysis was also blinded to the group 182 assignment. The study was carried out at the Department of 183 Pediatric Dentistry at Mashhad University of Medical Sci-184 ences, Mashhad, Iran, between January 2015 to September 185 2015, and the follow-ups were set between July 2015 and 186 March 2017. 187

Clinical interventions

The treatment was accomplished at a single visit. The cari-189 ous molar was anesthetized through an inferior alveolar 190 nerve block using 2% lidocaine with epinephrine 1:80,000. 191 Following complete isolation by a rubber dam, the tooth 192 surface was cleaned and disinfected with rubber cup and 193 5.25% sodium hypochlorite solution. Then, carious enamel 194 was removed by means of a fissure diamond bur (#835/009; 195 Tees Kavan Co., Tehran, Iran) at high speed under water 196 spray, and dentin decay was completely excavated by a low-197 speed round carbide bur (#C1/023; Tees Kavan Co.). 198

When a pinpoint pulp exposure occurred at the final 199 stage of caries removal, the very superficial inflamed layer 200 of the pulp was gently removed to a depth of 2 mm using a 201

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sterile round diamond bur (#801/014; Tees Kavan Co.) and a 202 water-cooled high-speed handpiece with light hand pressure. 203 If pulp exposure diameter was large, multiple exposures 204 occurred, or there was no pulpal exposure, the tooth was 205 excluded from the study. Following pulp amputation, the 206 wound surface was thoroughly irrigated with sterile normal 207 saline solution until bleeding ceased. A dry sterile cotton 208 pellet was then applied over the pulp stumps with light pres-209 sure to achieve normal hemostasis. In cases that hemostasis 210 was not obtained within 4 min, it was considered that the 211 pulp tissue was still infected and the tooth was excluded 212 from the sample. 213

After achieving hemostasis, the treatment was continued 214 in the study groups as follows: 215

Group 1 (MTA): This was considered as the control group 216 of the study. Following hemostasis, the gray MTA (Angelus, 217 Londrina, PR, Brazil) was prepared according to the manu-218 facturer's instructions and placed over the amputated pulp 219 stumps with a sterile amalgam carrier. Light pressure was 220 applied with a moistened cotton pellet to adapt the paste with 221 the exposure site. Because of its long setting time, the MTA 222 material was covered by light-cured glass-ionomer cement 223 (GC Fuji II, GC Corporation, Tokyo, Japan) to provide a 224 firm foundation and stabilize the unset material. A stainless 225 steel crown (3 M ESPE, St. Paul, MN, USA) was then fit-226 ted and cemented by glass-ionomer cement (GC Fuji I, GC 227 Corporation, Tokyo, Japan) to serve as a final restoration. 228

Group 2 (LLLT-MTA): After hemorrhage control in 229 this group, the pulp stumps underwent low level laser ther-230 apy (LLLT) by an indium-gallium-aluminum-phosphide 231 (InGaAIP; Thor DD2 Control Unit, Thor, London, UK) 232 diode laser. The device emitted a red light at the wavelength 233 of 660 nm and was operated at the power of 200 mW and 234 continuous wave mode. The laser probe was held stationary 235 (immobile) in contact with the intact part of the occlusal 236 surface of the tooth and at a distance of about 4 mm from 237 the exposure site over a period of 10 s. Each tooth received 238 energy of 2 J, and the energy density was calculated as 7.1 J/ 239 cm2, considering the spot size of 0.28 cm^2 at the 4-mm dis-240 tance from the probe aperture (beam divergence 60°, cir-241 cular spot shape). The MTA material was then placed over 242 the exposure site by a sterile amalgam carrier and pressed 243 gently with a moistened cotton pellet. The procedure was 244 continued, as explained in the control group. 245

Group 3 (DL-MTA): After hemostasis in this group, the 246 pulp tissue was ablated using a high power gallium alu-247 minum arsenide (GaAlAs; ARC Laser GmbH, Nürnberg, 248 Germany) diode laser (DL). The laser irradiated a wave-249 length of 810 nm and was set at the power of 1 W with a 250 continuous wave mode. The beam was delivered through a 251 300-µm-diameter optical fiber in contact with the pulp tis-252 sue. The tip was cut before using for each patient and initi-253 ated before application. The energy density at the point of 254

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contact was calculated as 1428 J/cm². The laser handpiece 255 was slowly moved (1-2 mm/s) over the exposure site for 10 s 256 to prevent overheating of the underlying tissues. After that, 257 the MTA material was placed over the wound surface and 258 pressed gently with a moistened cotton pellet. The procedure 259

The treatments in groups 2 and 3 were made in a specially designed laser room with luminous laser signs. The devices were tested before application, using the power meter of the device in group 2 and using a fire test in group 3. Both patient and clinician wore safety glasses (optical density = 5) during treatment.

was continued, as mentioned in the control group.

Follow-up examinations

The patients were followed-up at 6, 9, and 18 months after 268 treatment, and the clinical and radiographic parameters were 269 assessed to delineate the frequency of failures. The periapi-270 cal radiographs were taken by the parallel technique. The 271 assessments were made by two calibrated and experienced 272 clinicians, and in cases of disagreement, the investigators 273 were discussed until consensus was achieved. 274

The teeth were rated as clinical failures if they had any of the following criteria: 1, spontaneous pain; 2, tenderness upon percussion or palpation; 3, swelling or abscess; 4, fistula; or 5, mobility.

The radiographic signs indicating treatment failure were 279 as follows: 1, periodontal ligament widening; 2, pathologic 280 external root resorption; 3, internal root resorption; 4, peri-281 apical radiolucency; and 5, furcal radiolucency. The pulp 282 calcification or pulp canal obliteration was not considered 283 as a radiographic sign of failure. 284

At each checkup, the frequency of clinical or radiographic 285 success was measured by subtracting the number of clinical 286 or radiographic failures from the total number of evaluated 287 cases. The failed cases were considered in calculation of 288 success rate at all assessment intervals. The success rate (%)289 was then calculated by dividing the number of cases show-290 ing clinical or radiographic success by the total number of 291 evaluated cases and multiplying the result by 100. The teeth 292 that presented radiographic failure were monitored at regular 293 intervals and those with clinical failure received an appropri-294 ate treatment such as pulpectomy or extraction. 295

Statistical analysis

The data were analyzed using SPSS 18.0 software (SPSS 297 Inc, Chicago, IL, USA). The differences in age and gender 298 among the groups were analyzed by one-way analysis of 299 variance (ANOVA) and chi-square test. The Fischer's exact 300 test was applied to find any significant difference in the 301 frequency of failures among the study groups at different 302 follow-up periods. The significance level was set at p < 0.05. 303

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304 **Results**

A total of 63 mandibular second molars from 53 children 305 were treated. All cases returned at 6 and 9 months after 306 therapy, but there was a 22% dropout in the total number 307 of cases assessed at the 18-month visit. Five patients in 308 the MTA group, 4 patients in the LLLT-MTA group, and 309 5 patients in the DL-MTA group did not refer at the last 310 recall due to different reasons (disagreement of the guard-311 ians to come for further follow-ups or moving to another 312 city). Figure 1 indicates a flowchart of the study protocol 313 up to the 18-month follow-up. Table 2 presents the age 314

and gender distribution of the participants in the study315groups at the baseline examination. The study groups were316well matched in age and gender at the start of treatment317(p > 0.05; Table 2).318

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The results of clinical examination at the three follow-up periods

Table 3 presents the frequencies of clinical failure and suc-
cess in the study groups at the three follow-up visits. At the
6-month checkup, all teeth were scored as clinically sound,
except for one molar in the DL-MTA group that showed
sensitivity to percussion, mobility, swelling, and fistula. This321
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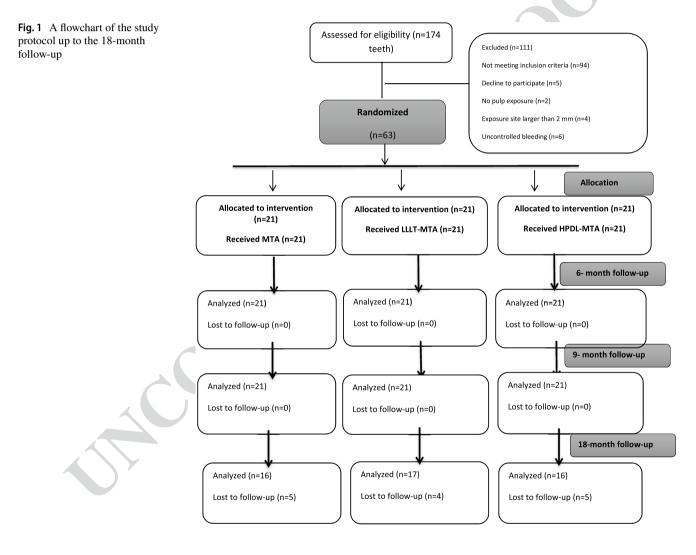


Table 2 Comparison ofbaseline characteristics of theparticipants in the study groups

Study groups		MTA	LLLT-MTA	DL-MTA	Significance
Age Gender	Female Male	5.39±0.90 13 (61.9%) 8 (38.1%)	5.50±0.93 7 (33.3%) 14 (66.7%)	5.72±0.92 14 (66.7%) 7 (33.3%)	p = 0.505 p = 0.064

*The age has been shown by mean \pm standard deviation (SD) and the gender distribution by frequency (%)

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Follow-up	6-month		9-month		18-month	
Study groups	Clinical failure**	Clinical Success (%)	Clinical failure (%)	Clinical Success (%)	Clinical failure	Clinical success (%)
MTA	0	21 (100)	0	21 (100)	0	16 (100)
LLLT-MTA	0	21 (100)	0	21 (100)	0	17 (100)
HPDL-MTA	1	20 (95.2)	1	20 (95.2)	2	14 (87.5)
p value*	<i>p</i> >0.99		P>0.99		P=0.204	

 Table 3
 The frequency of clinical failure and the frequency (percentage) of clinical success in the study groups at different follow-up periods, as compared to the baseline examination

 $p^* < 0.05$ indicates a statistically significant difference among the study groups

**The criteria indicating clinical failure were spontaneous pain, tenderness upon percussion or palpation, swelling or abscess, fistula, and mobility

case was deemed a clinical failure. Therefore, the clinical
success rate was 100% in the MTA and LLLT-MTA groups
and 95.2% in the DL-MTA group.

At the 9-month checkup, no additional failure was observed in any of the study groups. The clinical success rate in the MTA, LLLT-MTA, and DL-MTA groups were 100%, 100%, and 95.2% at the 9-month follow-up.

After 18 months of therapy, one new case of clinical failure was found in the DL-MTA group due to spontaneous pain. Therefore, the clinical success rate at the 18-month follow-up was 100% in the MTA group, 100% in the LLLT-MTA group, and 87.5% in the DL-MTA group.

The Fisher's exact test revealed no significant difference in the frequency of clinical failure among the study groups at any of the assessment intervals (p > 0.05; Table 3).

The results of the radiographic examinationat the three follow-up periods

Table 4 presents the frequencies of radiographic failure and
success in the study groups at the three follow-up visits. At
the 6-month checkup, radiographic evaluation demonstrated
failure in two teeth in the MTA group. One tooth showed

periodontal ligament widening, external root resorption, and 347 furcal and periapical radiolucencies, whereas the next one 348 had only furcal radiolucency. Furthermore, three teeth in 349 the DL-MTA group showed radiographic failure. One tooth 350 that was also rated as clinical failure showed periodontal 351 ligament widening, furcal and periapical radiolucencies, 352 and the next two had only furcal radiolucency (Table 4). No 353 case of radiographic failure was observed in the LLLT-MTA 354 group. The radiographic success rates in the MTA, LLLT-355 MTA, and DL-MTA groups were 90.5%, 100%, and 85.7%, 356 respectively, at the 6-month checkup. 357

The 9-month radiographic examination demonstrated 358 radiographic failure in one tooth in the LLLT-MTA group 359 due to furcal radiolucency. Furthermore, two new cases of 360 failure occurred in the DL-MTA group. These teeth exhib-361 ited periodontal ligament widening and furcal and periapi-362 cal radiolucencies. At the 9-month follow-up, 90.5% of the 363 MTA group, 95.2% of the LLLT-MTA group, and 76.2% 364 of the DL-MTA group were found as radiographic success. 365

At the 18-month checkup, one new case of radiographic 366 failure was observed in the LLLT-MTA group. This patient 367 had PDL widening and furcal and periapical radiolucencies. 368 The overall success rate at the 18-month checkup was 87.5% 369

Follow-up	6-month		9-month		18-month	
Study groups	Radiographic failure**	Radiographic success (%)	Radiographic failure	Radiographic success (%)	Radiographic failure	Radio- graphic success (%)
MTA	2	19 (90.5)	2	19 (90.5)	2	14 (87.5)
LLLT-MTA	0	21 (100)	1	20 (95.2)	2	15 (88.2)
DL-MTA	3	18 (85.7)	5	16 (76.2)	5	11 (68.7)
p value*	p = 0.354		p = 0.249		p = 0.418	

 Table 4
 The frequency of radiographic failure and the frequency (percentage) of clinical success in the study groups at different follow-up periods as compared to the baseline examination

 $p^* < 0.05$ indicates a statistically significant difference among the study groups

**The criteria indicating radiographic failure were periodontal ligament widening, pathologic external root resorption, internal root resorption, periapical radiolucency, and furcal radiolucency

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for the MTA group, 88.2% for the LLLT-MTA group, and 68.7% for the DL-MTA group.

There were no statistically significant differences in the frequency of radiographic failure among the groups at any of

the follow-up intervals (p > 0.05; Table 4). Some representative radiographs of successful and failed cases in the study

groups are shown in Figs. 2, 3 AND 4.

377 Discussion

The present randomized controlled trial investigated the 378 clinical and radiographic success of MTA partial pulpot-379 omy either alone or combined with low power or high power 380 diode laser radiation for treatment of deep carious lesions 381 in primary molars. The primary mandibular second molars 382 were employed to enhance the accuracy of radiographic 383 examination, as overlapping of the roots of upper primary 384 molars with underlying successors can make the detection 385 of pathologic findings difficult. The long-term success of 386 pulp treatment is greatly influenced by the suitability of 387 final restoration to defeat against microleakage along the 388

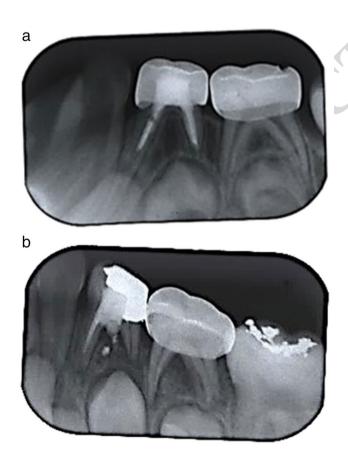


Fig. 2 The 18-month periapical radiographs in two patients after partial pulpotomy with MTA. A A successful result in tooth 75; **B** a failed outcome in tooth 75, displayed by widened PDL space and periapical and furcal radiolucencies

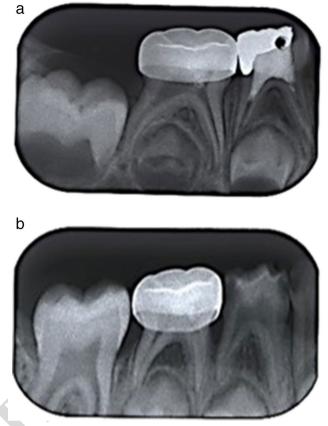


Fig.3 The 18-month periapical radiographs in two patients after partial pulpotomy in the LLLT-MTA group. **A** A successful result in tooth 85; **B** a failed outcome in tooth 85, represented by furcal radio-lucency

interfaces of restoration. Therefore, all teeth were restored 389 with SS crowns in the present study. A rigorous method was 390 employed for calculating the success rate, so that cases with 391 any sign of clinical or radiographic failure were considered 392 unsuccessful throughout the experiment, even if they did 393 not refer at the last recall. Only two cases of clinical failure 394 were observed in this experiment. One case reported sensi-395 tivity to percussion, mobility, swelling, fistula, and the other 396 experienced spontaneous pain. The most frequent sign of 397 radiographic failure was furcation involvement, which was 398 observed in 9 teeth, followed by periapical radiolucency and 399 PDL widening (observed in 5 teeth). It is believed that the 400 radiographic signs of failure are not an indication for inter-401 vention as long as the tooth is free of clinical symptoms 402 and the underlying permanent tooth has not been involved 403 [19]. Therefore, different strategies should be selected upon 404 facing clinical versus radiographic failures. In the current 405 study, the cases with clinical failure underwent retreatment, 406 whereas those with the sole radiographic failure were only 407 observed annually to see whether any further treatment 408 would be required. 409

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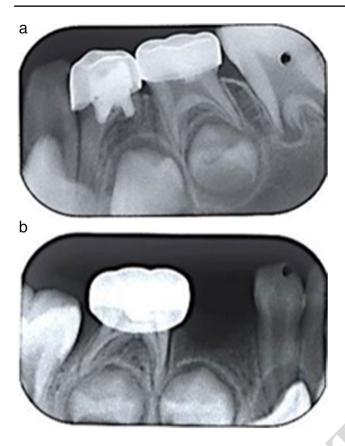


Fig. 4 The 18-month periapical radiographs in two patients after partial pulpotomy in the DL-MTA group. A a successful result in tooth 75; **B** a failed outcome in tooth 85, exhibited by widened PDL space and periapical and furcal radiolucencies

The mineral trioxide aggregate (MTA) was used as the 410 pulp capping material in this study. MTA is a regenerative 411 medicament with the capacity for promoting dentin forma-412 tion, satisfactory antimicrobial properties, and superior 413 biocompatibility [3, 11, 20, 21]. The clinical success rate 414 of MTA partial pulpotomy (without laser irradiation) was 415 100% throughout the study. The radiographic signs of fail-416 ure were observed in two cases after 6 months of therapy, 417 and no new case of radiographic failure was observed at 418 419 the 9- and 18-month intervals. Therefore, the radiographic success rate of partial pulpotomy with MTA was 90.5% at 420 the 6- and 9-month follow-ups and 87.5% at the 18-month 421 checkup. These findings imply that partial pulpotomy with 422 MTA sealing can serve as a successful approach in decidu-423 ous molars, as demonstrated by several investigations [3, 9], 424 22]. Schröder et al. [22] demonstrated the success rate of 425 83% for partial pulpotomy over a 1-year period, which was 426 not significantly different from the outcomes of cervical pul-427 428 potomy. The success rate values observed in this study were a little higher than those reported by previous authors [3, 9, 429 22]. This could be ascribed to the use of MTA instead of CH 430 [22] as the pulp capping agent; to the use of a stainless steel 431

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crown for final restoration as opposed to the amalgam filling 432 [22]; and to the immediate restoration instead of implementing it at the next visit [3]. 434

The combination of MTA partial pulpotomy with LLLT 435 caused the clinical success rate of 100% throughout the 436 study. The radiographic failure was observed in one patient 437 after 9 months and in another patient after 18 months of 438 therapy. Therefore, the radiographic success rate of partial 439 pulpotomy in the LLLT-MTA group was 100%, 95.2%, and 440 88.2% at the 6-, 9-, and 18-month follow-ups, respectively. 441 The benefits of LLLT in increasing ATP synthesis, alleviat-442 ing pain, modulating pulpal inflammation, enhancing angio-443 genesis, and accelerating the wound healing process have 444 been demonstrated in several studies [15, 23-27]. Others 445 suggested that the irradiation of low power lasers is capable 446 to enhance the production activity of fibroblasts and promote 447 the hard tissue barrier formation [14, 15, 28]. In the present 448 study, the success rate in the LLLT-MTA group was similar 449 to the control group. This implies that LLLT is associated 450 with no adverse effect on dental pulp vitality, although any 451 possible benefits of laser therapy on the partial pulpotomy 452 procedure should be assessed in larger sample sizes and 453 longer follow-up periods. The laser device used in this study 454 emitted a 660 nm wavelength, and delivered the energy of 455 2 J with energy density of 7.1 J/ cm^2 to the exposure site. It 456 has been demonstrated that among the different wavelengths 457 of low level lasers (600-1300 nm), a spectrum between 600 458 and 700 nm has high stimulatory effects on cellular prolifer-459 ation of various cultured cell lines [29]. The energy density 460 used in the present study was within the therapeutic window 461 to produce biological effects, as proposed by Arndt-Schulz 462 law (between 0.01 and 10 J/cm²) [30] and recently modified 463 by Cronshaw et al. (between 2 and 10 J/cm²) [31]. 464

Different kinds of high power lasers such as CO2, 465 Nd:YAG, Er:YAG, and diode have been used in primary 466 molar pulp therapy. The diode laser is more popular in 467 dental offices due to its versatility, durability, a light 468 weight, and suitable cost [32]. The wavelength of high 469 power diode laser (808 to 980 nm) is highly absorbed by 470 pigmented tissues such as hemoglobin and melanin, mak-471 ing it a suitable option in the vital pulp treatment. The 472 diode laser is generally employed for the completion of 473 pulp treatment in order to induce a superficial zone of 474 coagulation necrosis [12, 33]. This layer can act as a bio-475 logic dressing, which is compatible with the underlying 476 pulp tissues, and actually isolates the pulp from the resto-477 ration [12]. In the present investigation, the success rate in 478 the DL-MTA group was lower than the other study groups, 479 although this difference was not statistically significant. 480 The clinical success rate of partial pulpotomy with diode 481 laser was 95.2% after 6 and 9 months (one case of failure) 482 and 87.5% after 18 months of therapy (two failures). The 483 radiographic failures were observed in 3 patients at the 484

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6 month interval and 5 patients at the 9- and 18-month 485 checkups. The higher rate of failure in the DL-MTA group 486 was probably related to the blood coagulation effect of 487 diode laser, which could mask a hyperemic pulp condi-488 tion and lead to chronic inflammation over time [11]. 489 Another factor that may cause a higher rate of failure is 490 the induction of thermal damage to the surrounding tis-491 sues of the impact site. In the present study, the diode 492 laser was radiated after 4 min of applying a wet sterile 493 cotton pellet on the pulp stumps to ensure the detection of 494 uncontrolled pulpal hemorrhage. Furthermore, the poten-495 tial thermal damage was reduced by lowering the output 496 power (1 W) and using scanning movement over a short 497 period of time (10 s). Despite the procedures performed 498 in this study to reduce the hemostatic and thermal effects 499 of diode laser, it appears that the diode laser contributed 500 to the higher frequency of failure in the DL-MTA group. 501 The higher rate of failure in the DL-MTA group may have 502 clinical implications in a larger sample size, and thus this 503 technique should be used cautiously in pulp treatment of 504 deciduous teeth. 505

The present study revealed no significant differences in 506 the failure rates of partial pulpotomy when either low power 507 or high power diode laser was applied as a supplement to 508 the conventional procedure. Since there is no study con-509 cerning laser-assisted partial pulpotomy in deciduous teeth, 510 the present outcomes are compared with those that imple-511 mented cervical pulpotomy with low or high power lasers. 512 The results of this study are consistent with the findings 513 of several investigations that reported no significant differ-514 ence between the LLLT pulpotomy and conventional pul-515 potomy techniques, as demonstrated by similar success rate 516 values [14, 15, 34]. The higher frequency of clinical and/or 517 radiographic failure in the high power laser group than the 518 control group has also been demonstrated in previous stud-519 ies although the difference between groups was statistically 520 insignificant [11, 35, 36]. Durmus and Tanboga [35] per-521 formed pulpotomy in 120 primary molars using formocresol 522 (FC), ferric sulfate (FS), and diode laser (DL). They found 523 a high rate of radiographic failure in the DL group, as com-524 pared to FC and FS pulpotomies [35]. The outcomes of the 525 present study, however, are in contrast with those of several 526 investigations [12, 14, 15, 37–39] that exhibited substantial 527 benefits for additional laser radiation to the conventional 528 technique of pulp therapy. Fernandes et al. [14] reported 529 higher radiographic success rate in the pulpotomy group 530 treated with low level laser followed by calcium hydrox-531 ide (LLLT + CH) as compared to the group treated by CH 532 alone. Gupta et al. [12] treated 30 primary teeth with ferric 533 sulfate (FS), electrosurgery (ES), and diode laser pulpotomy. 534 After 12 months of therapy, the laser group (980 nm, 3 W) 535 displayed clinical and radiographic success rates of 100%, 536 which was significantly superior to both FS and ES groups 537

(80%). The differences observed between the results of this
 study and those of previous investigations may be related to
 different laser parameters or the different techniques of VPT.

The limitations of this study were the relatively small 541 sample size, single blindness, and the dropout rate of about 542 22% at the 18-month follow-up, which may compromise the 543 validity of the results. We considered MTA partial pulpot-544 omy as the control group in this study and did not compare 545 the results with a more conventional technique such as cervi-546 cal pulpotomy. Thus, further randomized clinical trials using 547 larger patient samples and longer follow-up periods are war-548 ranted to determine the success rate of partial pulpotomy 549 applied with low power or high power lasers as a suitable 550 approach in vital pulp therapy of deciduous molars. Further 551 studies should also be conducted to find the optimum laser 552 parameters to decrease the chance of failure following the 553 partial pulpotomy procedure. 554

Conclusion

Within the limitations of this study, it can be concluded the 556 following: 557

- The clinical success rate of MTA partial pulpotomy either alone or combined with a low power diode laser radiation was 100% during 18 months of follow-up. When a high power diode laser was added to the standard partial pulpotomy procedure, the clinical success rate reduced to 87.5% after 18 months of treatment.
- At the 18-month checkup, radiographic failure was observed in 2 teeth treated by MTA partial pulpotomy, 2 teeth treated by MTA partial pulpotomy supplemented with low level laser therapy, and 5 teeth treated by MTA partial pulpotomy combined with high power diode laser radiation.
- 3. There was no significant difference in the success rate 570 of MTA partial pulpotomy when either low power or 571 high power diode laser was added to the procedure. 572 Therefore, partial pulpotomy was a suitable technique 573 for vital pulp therapy of primary molars. The addition 574 of low power or high power diode laser radiation to the 575 conventional procedure did not cause a significant dif-576 ference in success rate values. 577
- Despite the comparable success rate values, the frequency of clinical and radiographic failures was a bit higher in the high power diode laser group than the other groups, implying that this technique should be used cautiously in pulp treatment of deciduous molars.

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590 Declarations

Ethics approval The study protocol was approved by the ethics committee of Mashhad University of Medical Sciences, and it was also registered in the Iranian Registry of clinical Trials (IRCT) website under the identification number IRCT2015100524373N1.

Consent to participate The procedure was explained in detail for all
 the patients, and signed consents were taken before the study commencement.

598 Conflict of interest The authors declare no competing interests.

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