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Clinical and radiographic evaluation of low-level laser therapy in primary teeth pulpotomy treatment: a randomized clinical trial

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Abstract:

Aim. The aim of this study was to compare the effectiveness of diode laser and low-level laser therapy (LLLT) in primary pulpotomy treatments with deep dentinal caries.

Materials and methods. The study comprised 90 patients (42 females and 48 males) aged 6–9 years with deep dentin caries in the lower second molar. The patients were assigned to the following treatment groups: the diode laser group (n^S= 45) or the LLLT group (n^S= 45). The appointments were scheduled 3, 6, and 12 months after the treatment, and both clinical and radiographic follow-ups were performed.

Results. The diode laser group had a clinical success rate of 95.6% and a radiological success rate of 93.3% at 12 months, while the LLLT group had a clinical success rate of 97.7% and a radiological success rate of 90.9%. There were no statistically significant differences in the success rates of the two groups.

Conclusions. LLLT+CH may be a good treatment alternative for pulpotomy instead of devital diode laser pulpotomy.

Keywords: diode laser, low-level laser therapy, pediatric dentistry, pulpotomy

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Клиническая и рентгенологическая оценка низкоинтенсивной лазерной терапии при лечении пульпотомии молочных зубов: рандомизированное клиническое исследование

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Резюме:

Цель. Целью данного исследования было сравнение эффективности диодного лазера и низкоинтенсивной лазерной терапии (НИЛТ) при первичной пульпотомии при глубоком кариесе.

Материалы и методы. В исследование включены 90 пациентов (42 женщины и 48 мужчин) в возрасте 6–9 лет с глубоким кариесом дентина второго нижнего моляра. Пациенты были распределены на следующие группы лечения: группа диодного лазера (n^S= 45) или группа НИЛТ (n^S= 45). Визиты были назначены через 3, 6 и 12 месяцев после лечения, при этом проводилось как клиническое, так и рентгенологическое наблюдение.

Результаты. В группе диодного лазера уровень клинического успеха составил 95,6%, а уровень рентгенологического успеха^S^= 93,3% через 12 месяцев, в то время как в группе НИЛТ уровень клинического успеха составил 97,7%, а уровень рентгенологического успеха^S^= 90,9%. Не было статистически значимых различий в показателях успеха в двух группах.

Выводы. НИЛТ +СН может быть хорошей альтернативой пульпотомии вместо девитальной лазерной пульпотомии.

Ключевые слова: диодный лазер, низкоинтенсивная лазерная терапия, детская стоматология, пульпотомия.

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INTRODUCTION

Early loss of primary teeth can cause both aesthetic and functional problems with malocclusion.

Thus, to maintain the integrity of the arch, the primary teeth should be healthy until the time of physiological fall [1,2]. Treatment of deep caries in primary teeth using conservative techniques protects the health of teeth and supporting tissues, ensures pulp vitality, reduces the need for pulpectomy, and preserves teeth in a healthy state during the physiological fall affected by deep caries. Pulpotomy treatment with the removal of the coronal pulp tissue is used for primary molar teeth that are vital despite being affected by deep caries [3]. Correct treatment and diagnosis are critical for a successful outcome in pulp treatment. Healing of the dental pulp also depends on the amount of pulp stimulation provided by the material used in the pulpotomy treatment and other factors, such as the sealing of the tooth without leakage [4].

Since the mid-nineties, the potential use of diode lasers in dentistry has been especially important among pediatric patients and in surgical procedures [5]. A diode laser provides ablation of soft tissues by converting the laser energy into heat. Diode lasers with a wavelength of 980 nm are suitable for the pulpotomy technique owing to their high absorption in the dental pulp tissue [6]. The effect of tissue biostimulation of the laser based on cellular mechanisms in tissues has recently gained popularity [7]. Although the primary mechanism of action of low-level laser therapy (LLLT) is not fully understood, in vivo and in vitro studies suggest that it can prevent apoptosis and increase cellular proliferation and motility [8]. Furthermore, it increases ATP [7], cytokine and growth factor production [9], cell membrane Ca+2 permeability [10], cell differentiation and proliferation [11], and cell strength [12] by inducing synthesis reactions and collagen production [13]. Moreover, it helps in relieving pain by supporting angiogenesis [14].

AIM

There are not enough studies in the literature that used LLLT in the pulpotomy treatment. In addition, there is no study examining the success of low-energy vital pulpotomy with diode laser and high-energy devital pulpotomy [15,16,17,18]. We aimed to compare the 12-month clinical and radiographic results of pulpotomy, wherein diode laser and LLLT were used to treat deep dentin caries in lower primary second molars with pulp perforation.

MATERIALS AND METHODS

Ethical approval

This study was registered with www.clinicaltrials.in.th (identification number: NCT05680285) after receiving approval from the Human Research Ethics Committee of University (certificate number: 204-204-04) and the Ethics Committee of the Medicines and Medical Devices Agency. Informed consent was obtained from the children's parents.

Sample calculation

The inclusion criteria for this study comprised at least 43 teeth in each group using G* Power software version 3.1.9.2, as a result of the data obtained from a similar study [19]. The sample size estimation was performed based on a type I error (α) of 0.05, and the power of the study was set at 80%, with a proposed effect size of 0.25 for a two-tailed hypothesis. In total, 90 teeth were included in this study, with the possibility of patients not being followed up.

3.3. Participants

We examined 112 children aged 6–9 years in the University Department of Pediatric Dentistry. This study was conducted between January 2021 and May 2022.

Inclusion criteria

Clinical Criteria

The clinical criteria were as follows: no systemic disease; not allergic to the materials used; children with scores of 3 and 4 according to the Frankl Behavioral Scale; permanent first molar eruption; occlusion with opposing teeth; no bad oral habits; no structural anomalies in the teeth; no spontaneous or nocturnal pain; no sensitivity to palpation or percussion; abscess and sinus tract-free; no pathological mobility; pulpal bleeding which can be controlled in 5 minutes.

Radiographic Criteria

The radiographic criteria were as follows: deep dentin caries lesions near the pulp; no resorption in the bifurcation and periapical areas; healthy periodontal space; no periapical region pathology; absence of internal and external root resorption; no calcified masses in the pulp; teeth that did not exceed one-third of physiological root resorption.

Procedure

All pulpotomy procedures were performed by a single pediatric dentist. For selected teeth, a lidocaine-containing spray was applied as topical anesthesia, followed by mandibular regional anesthesia with epinephrine-containing articaine. Subsequently, the tooth was isolated using a rubber dam. After the caries were cleaned, the pulp cap was removed with a sterile (no. 330) diamond bur attached to a fast-rotating instrument (an aerator). The exposed pulp tissue was first removed with a slow-speed round carbide bur (number six or eight) and then with a sharp excavator. The cavity was washed with a sterile serum to remove the tissue debris. To control the bleeding of the remaining root pulp, a sterile cotton pellet moistened with sterile serum was applied to the pulp tissue under light pressure and allowed to stand for 5 minutes. Teeth that did not stop bleeding within the specified time period were excluded from the study. The participants were divided into two equal groups using the coin-randomization method. While conventional diode laser application was applied in the first group, LLLT was applied in the second group. A diode laser (Solase-976 Dental Diode Laser; Lazon Medical Laser Co., Inc., China) irradiation and treatment parameters were applied according to the manufacturer's instructions (Table 1). In the first group, zinc oxide and glass ionomer cement were placed in the cavity after the pulpotomy procedure. In the second group, after the pulpotomy procedure, calcium hydroxide powder was mixed with distilled water, turned into a paste, and applied to the pulp; the cavity was closed with zinc oxide and glass ionomers. In both groups, the teeth were restored using PCC in the same session.

Follow-up

At 3, 6, and 12 months after the treatment, the patients were called again, and their clinical and radiographic controls were performed by two pedodontists. Follow-up information

Table 1. **Treatment parameters of the laser used in groups**

Таблица 1. **Параметры лечения лазером, использованным в группах**

Treatment parameters	Diode Laser	LLLT
Center wavelength (nm)	980	980
Frequency (Hz)	110	165
Average radiant power (W)	1	0,2
Beam spot size at target (cm^2)	400	400
Pulse on duration (seconds)	1 ms to 8 ms	2 ms to 4 ms
Mode	Pulsed wave	Pulsed wave
Application technique	Contact mode	Noncontact mode
Exposure duration (seconds)	3	10
Energy (j)	3	2
Power density (mW/cm^2)	30/567	5/567

was recorded on the form. Intraobserver and interobserver reliabilities were evaluated using the kappa test. The kappa values were determined to be 0.85 and 0.76, respectively.

During follow-up visits, teeth with no signs of spontaneous pain, tenderness on palpation and percussion, pathological mobility, sinus tract or gingival abscess formation, or lymphadenopathy in the relevant region were considered clinically successful; teeth with no signs of pathological internal and external root resorption, periodontal space enlargement, or radiolucency in the periapical and furcation region were considered radiographically successful.

Statistical method

The data were analyzed using IBM SPSS V23 (IBM, Armonk, New York, USA). Conformity to normal distribution was evaluated using the Shapiro–Wilk test. The Mann–Whitney U test was used to compare data that were not normally distributed among the paired groups. Chi-square and Fisher's exact tests were used to compare categorical variables between the groups. Analysis results are presented

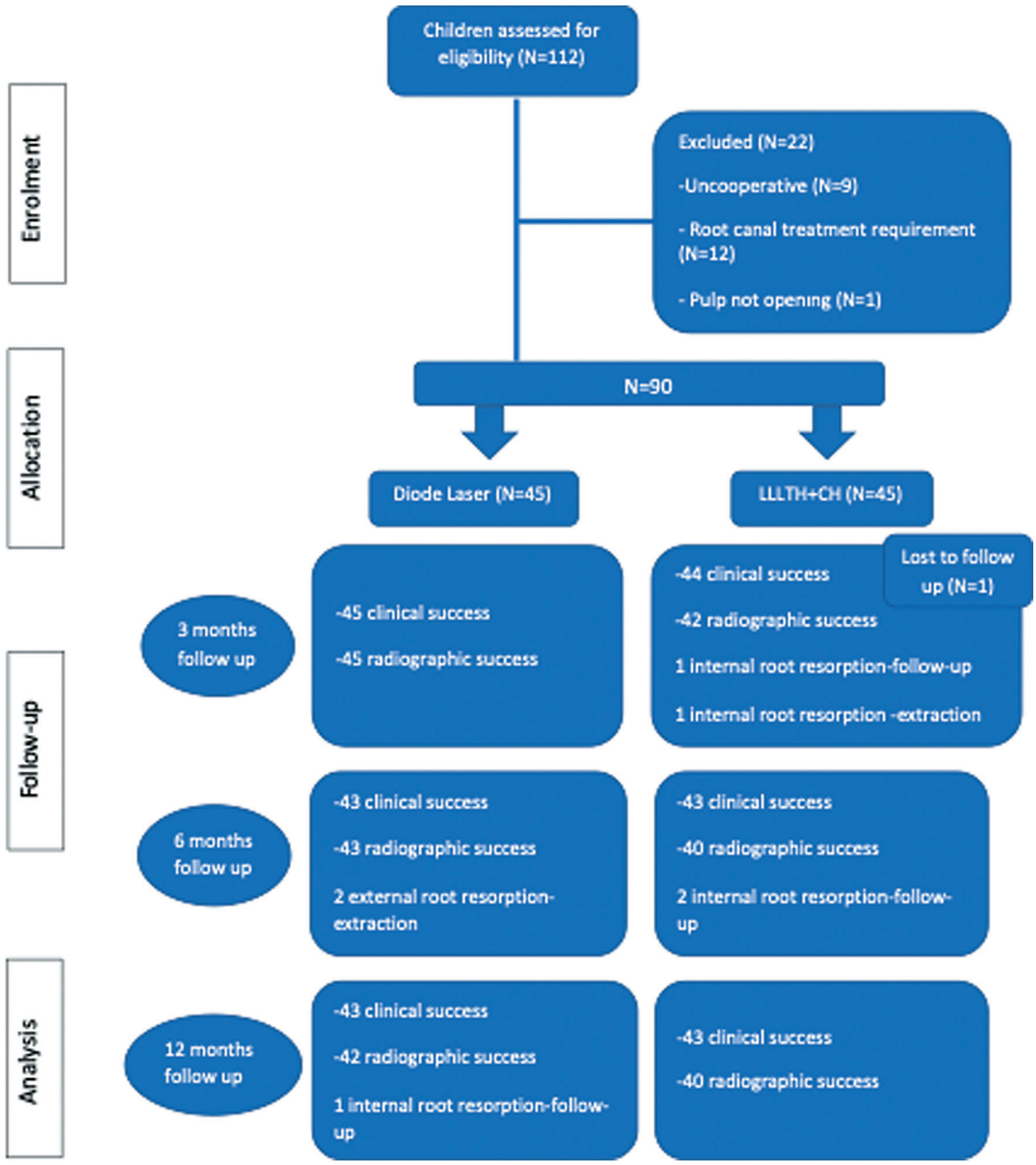

Fig. 1. **A CONSORT diagram showing the flow of the study**

Рис. 1. **Диаграмма CONSORT, показывающая ход исследования**

as mean±standard deviation and median (min.–max.) for quantitative data and frequency (percentage) for categorical data. The significance level was set at $p < 0.05$.

RESULTS

In our study, 112 children were evaluated, and nine patients were excluded due to cooperation with treatment, one patient whose pulp did not open, and 12 patients due to the requirement of root canal treatment (Fig. 1). One patient in the pulpotomy group with LLLT+CH was excluded from the study due to his/her absence at follow-up appointments (N = 44).

Our study included 89 patients, 47 males and 42 females, with a mean age of 7.5±0.8 years. There was no statistically significant difference between the sex distributions of the groups (p = 0.072). Our study included 48 lower right second molars and 41 lower left second molars. There was no statistically significant difference in the tooth number distributions according to the laser used (p = 0.909) (Table 2).

There was no difference in the distribution of clinical success at 6 and 12 months between the groups (p = 1.000). In the third month, a 100% success rate was obtained in both groups. The intra-group comparison of clinical success by month was not statistically significant (diode laser, p = 0.112; LLLT+CH, p = 0.392). There was no difference in the radiographic control success distributions at 3, 6, and 12 months (p = 0.242, 0.434, and 0.714, respectively). There

Table 2. **Characteristics of the cases according to the groups**

Таблица 2. **Характеристика случаев по группам**

		Diode Laser	LLLT+CH	Total	p
Sex N (%)	Male	28 (62,2)	19 (43,2)	47 (52,8)	0,072*
	Female	17 (37,8)	25 (56,8)	42 (47,2)	
Number of teeth	85	24 (53,3)	24 (54,5)	48 (53,9)	0,909*
N (%)	75	21 (46,7)	20 (45,5)	41 (46,1)	
Age (years) Mean SD		7,5 ± 0,8 7,0	7,5 ± 0,9 8,0	7,5 ± 0,8 8,0	0,889**
Median (min-max)		(6,0 – 9,0)	(6,0 – 9,0)	(6,0 – 9,0)	

* *Chi-Square test*
** *Mann-Whitney U test*
Value significant at p < 0,05

Table 3. **Clinical and radiographic success values according to groups**

Таблица 3. **Клинические и рентгенологические показатели успеха по группам**

		Clinical success and failure				Radiographic success and failure			
		Diode Laser N (%)	LLLT+CH N (%)	Total N(%)	p*	Diode Laser N (%)	LLLT+CH N (%)	Total N(%)	p*
3 months	Success	45 (100)	44 (100)	89 (100)	-	45 (100)	42 (95,5)	87 (97,8)	0,242
	Failure	0	0	0		0 (0)	2 (4,5)	2 (2,2)	
6 months	Success	43 (95,6)	43 (97,7)	86 (96,6)	1,000	43 (95,6)	40 (90,9)	83 (93,3)	0,434
	Failure	2 (4,4)	1 (2,3)	3 (3,4)		2 (4,4)	4 (9,1)	6 (6,7)	
12 months	Success	43 (95,6)	43 (97,7)	86 (96,6)	1,000	42 (93,3)	40 (90,9)	82 (92,1)	0,714
	Failure	2 (4,4)	1 (2,3)	3 (3,4)		3 (6,7)	4 (9,1)	7 (7,9)	
	p**	0,112	0,392			0,061	0,051		

* *Fisher's Exact test*
** *Cochran's Q test*
Value significant at p<0,05

Table 4. **Reasons for failure of the groups at the end of 12 months**

Таблица 4. **Причины неуспеваемости групп по истечении 12 мес.**

		Diode Laser	LLLT+CH
Clinical reasons for failure	Presence of abscess and sinüs tract	1	0
	Abnormal mobility	1	0
	Spontaneous pain	2	0
	Percussion and palpation sensitivity	2	0
Radiographic reasons for failure	Internal root resorption	1	4
	Interradicular resorption	2	0
	External root resorption	2	0
	Widening of periodontal ligament space	0	0

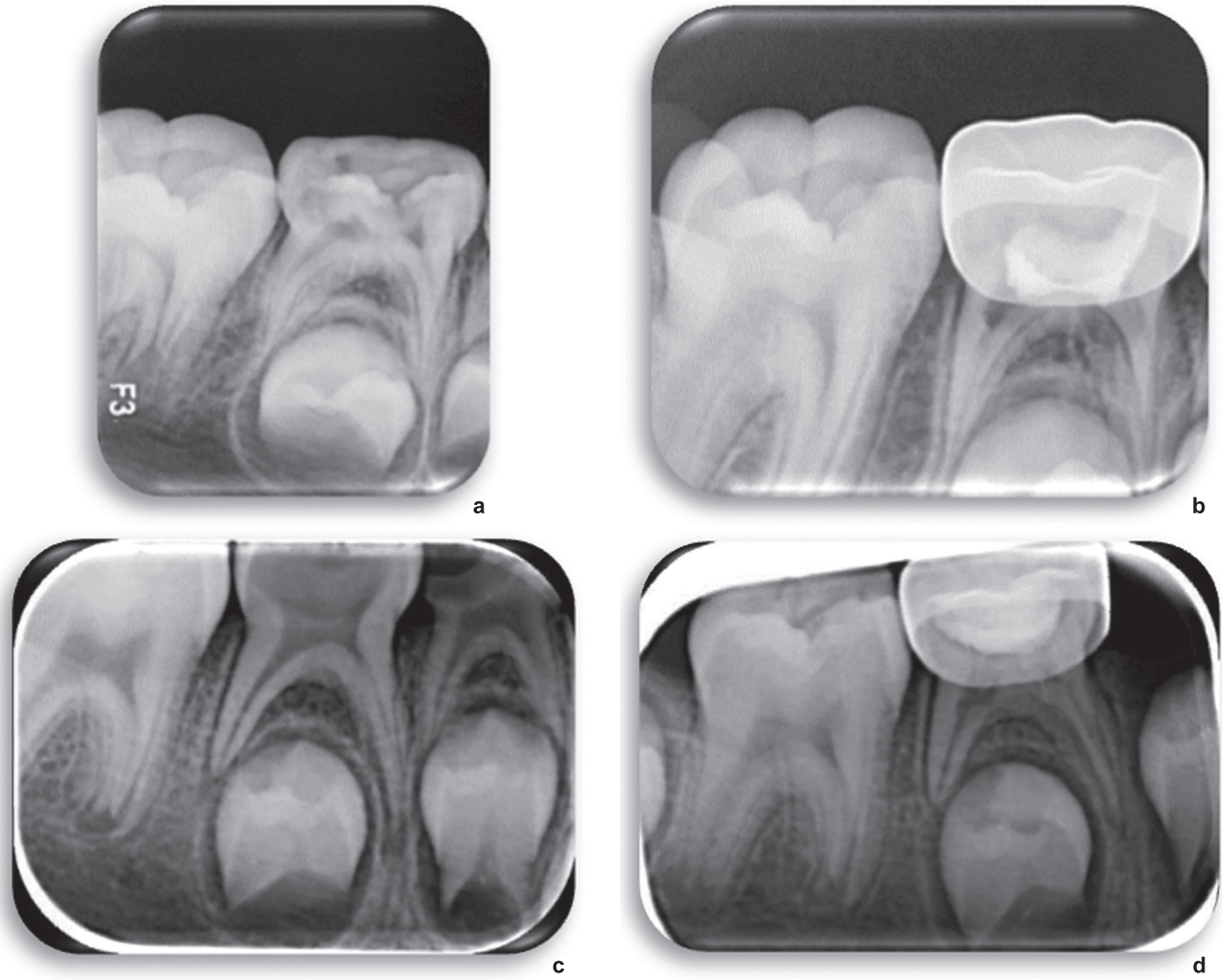

Fig. 2. **a and c – Preoperative periapical radiographs showing carious teeth. b – Internal resorption seen in the 12th month of control of the diode laser-treated tooth. d – Internal resorption seen in the 12th month of control of the LLLT+KH-treated tooth.**

Рис. 2. **a и c – Предоперационные периапикальные рентгенограммы, показывающие кариозные зубы. b – Внутренняя резорбция, наблюдаемая на 12-м месяце контроля зуба, обработанного диодным лазером. d – Внутренняя резорбция, наблюдаемая на 12-м месяце контроля зуба, обработанного LLLT+KH.**

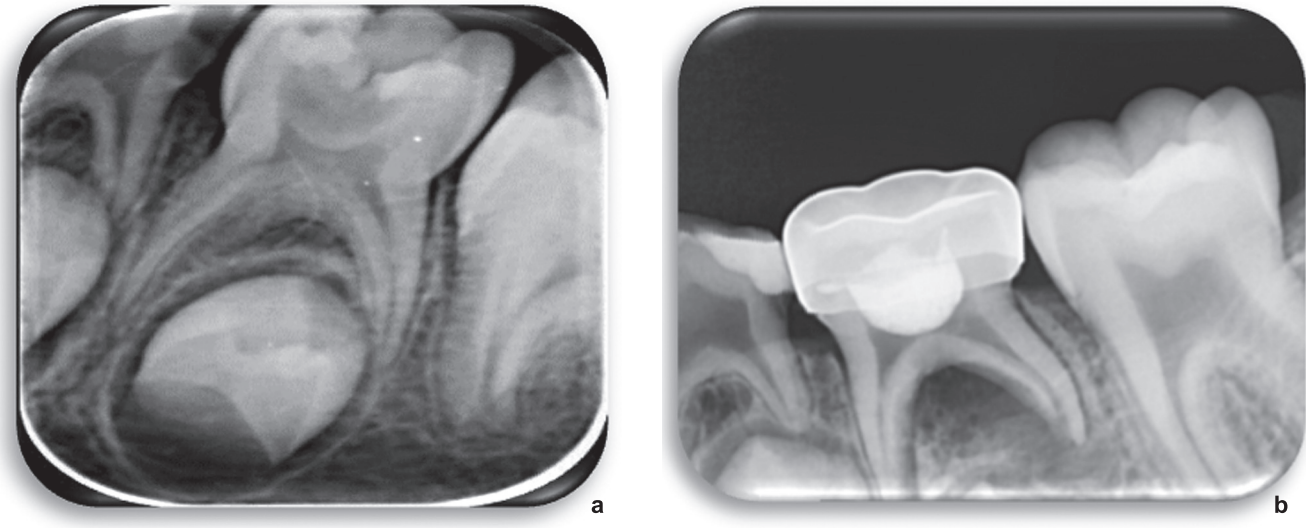

Fig. 3. **a – Preoperative periapical radiographs showing carious teeth. b – External resorption was seen in the 12th month control of the diode laser-treated tooth**

Рис. 3. **a – Предоперационные периапикальные рентгенограммы, показывающие кариозные зубы. b – Внешняя резорбция наблюдалась на 12-м месяце контроля зуба, обработанного диодным лазером.**

was no difference between the success rate distributions according to time in the diode laser and LLLT+CH groups (p = 0.061 and p = 0.051, respectively) (Table 3).

As seen in Table 4, external root resorption was observed in two teeth, and internal root resorption was observed in one tooth with bone loss in the interradicular area at the end of 12 months in the diode laser group; four internal root resorptions were observed in the LLLT+CH group at the end of 12 months (Figs. 2 and 3).

DISCUSSION

In pediatric dentistry, diode laser application is sometimes performed in various soft tissue treatment procedures as an alternative or as a complement treatment [20]. Pulpotomy treatment with diode laser application is generally known as a non-pharmacotherapeutic devitalization technique [21]. Low-level laser therapy (LLLT) is a relatively new, minimally invasive technique in pulpotomy that can exert its cellular effect without generating heat or destructive changes [22]. In our study, the effect of using the diode laser device at low and high energy levels on the success of pulpotomy was evaluated, and no statistically significant difference was observed.

The expected effects of a diode laser applied to tissue are coagulation, vaporization, and ablation [7]. The desired coagulation effect occurs when the tissue reaches a temperature of 60 °C. However, the uncontrolled use of laser energy causes a temperature increase of up to 200 °C in the target tissue, causing tissue carbonization and collateral thermal trauma in the surrounding soft tissues [23]. Thus, in our study, 1 watt, which is the lowest level recommended by the relevant device and has a high output power, was used. There is no standardization of the diode laser application time to the pulp tissue. In previous studies with different application times, dentin bridge formation, necrosis, periapical abscess, carbonization, hemorrhage, edema, and inflammatory infiltration were observed [6,24]. In a study investigating the effect of application time on dog pulp cells (1-, 3-, and 5-second application times), odontoblasts remained intact in addition to providing hemostase in pulp tissues that were laser applied for 1 and 3 seconds. In contrast, there is cellular regression in pulp tissues where the laser is applied for 5 seconds [5]. Based on these results and in line with the recommendations of the laser device's user manual, in our study, a high-dose diode laser was applied to the pulp for 3 seconds. During the application of the diode laser to the tissue, a continuous or pulsed mode was used according to the excited emission theory. While the continuous mode is recommended in surgical procedures, the pulsed mode is recommended for pulpotomies because it is more controlled [5]. Our device was used in pulsed mode during the diode laser application.

In pulpotomy with lasers, any change in the parameters of the laser, such as power, exposure time, and frequency, caused different results in pulp tissue. Thus, the results of pulpotomy studies performed using lasers were inconsistent [25]. Pei et al. [26] compared diode laser and formocresol pulpotomies by applying laser energy with a wavelength of 980 nm, a power output of 2 watts, and a frequency of 100 Hz in continuous mode with a 300 μm fiber optic in contact with the pulp tissue at each canal. Similar to our study, the clinical success rates in the laser group were 100% at 3 months, 96.8% at 6 months, and 92.9% at 12 months, while the radiographic success rates in the laser group were 100%, 90.3%, and 78.6%, respectively. There were no statistically significant differences between the two groups in clinical and radiographic terms. Additionally, in another study conducted by Durmus and Tanboga [25], using a laser with a wavelength of 810 nm and an output power of 1.5 W in continuous mode for 10 s without non-contact of the pulp, the diode laser was compared with ferric sulfate and formocresol (FC) amputations for 12 months, and the clinical success rates were 100%, 95%, and 97%, respectively, while the radiographic success rates were 75%, 79%, and 87%, respectively. The reason for the lower radiographic success in these studies is the thermal trauma of the diode laser in the surrounding tissues.

LLLT has a distinctive neuropharmacological effect on neurochemical cell synthesis, release, and metabolism owing to serotonin, acetylcholine, histamine, and prostaglandins found in the cell. Thus, cellular and functional activity, proliferation, anti-inflammatory, analgesic, antioxidant effects, vasodilation, and microcirculation activity of pulp tissue are observed in the cell [18]. Utsunomiya et al. [27] found that LLLT accelerated wound healing while also increasing lectin and collagen expression in the pulp. Low-dose laser therapy increases the formation of calcified nodules, alkaline phosphatase activity, and osteocalcin production in pulp fibroblasts. Another study argued that LLLT induces reactive dentinogenesis in human teeth. It also has positive effects on inflammation, cell proliferation, and tissue maturation, which are stages of tissue repair [28].

There is insufficient research on low-dose diode laser pulpotomy [15,16,17,18]. Fernandes et al. [15] evaluated FC, KH, LLLT, and LLLT+KH pulpotomies with low-energy diode laser parameters in continuous mode in contact for 10 s with a 320 μm fiber optic tip with a wavelength of 660 nm and a power output of 10 mW. At the end of 12 months, the radiographic success rates were 100%, 50%, 79%, and 80% in the FC, CH, LLLT+CH, and LLLT groups, respectively. All teeth were treated successfully after 12 months. Similar to our study results, the most common failure was internal resorption. This was attributed to the increased osteoclastic activity of KH in the pulp and the toxic effect of ZOE, the base material used for the pulp. Golpayegani et al. [16] compared LLLT and FC materials with a 500 μm fiber optic tip and 632 nm wavelength for 31 seconds in CW mode without contact; patients undergoing low-dose laser therapy were included. All treatments were clinically successful at the end of 12 months; however, radiographic success rates were 67% and 80%, respectively. The low success rates in this study were due to deficiencies in diagnosis and treatment procedures. Alamoudi et al. [17] revealed the clinical success of the LLLT group at the end of 12 months to be 96.1% and reported 100% radiographic success. Spontaneous pain in clinical failure is associated with iatrogenic factors. In a study comparing MTA and LLLT (810 nm wavelength, continuous mode, 10 s) pulpotomy techniques, at the end of 12 months, the LLLT group showed 80% clinical and radiographic success, while the MTA group had a success rate of 94.7%. However, no statistically significant differences were observed in these results. According to the study, the pulp was affected by parameters such as wavelength, output power, dose, and frequency of LLLT, and there was the consequent occurrence of failed teeth [18]. Guler et al. [29] examined the histopathological changes caused by applying different intensities of diode laser to the dental pulp of rats. They divided rat pulp cells into four groups. No laser therapy was administered to the G1 group. The G2 group applied 15 mJ/cm2, 0.3 W for 30 seconds; the G3 group applied 30 mJ/cm2, 2 W for 30 seconds; and the G4 group applied 60 mJ/cm2, 4 W for 30 seconds using a laser with a 300 μm diameter fiber optic tip perpendicular to the tissue and 1 mm away from

the tissue surface. The pulps in the control group showed a normal histological structure. Dental pulp, fibroblasts, odontoblasts, and large vascular structures were also observed. In the G2 group, mild histopathological changes such as odontoblast cell irregularities and irregularities in cell extensions were observed. They also reported the presence of a large number of capillaries in the odontoblast layer. The odontoblast cell irregularities and irregularities in cell extensions were more prominent in the G3 group than in the G2 group. They also observed vacuoles in some odontoblastic structures near dentin and reported that the appearance of the pulpal core was similar to that in the G2 group. In the G4 group, however, significant histological changes were recorded in the odontoblast layer, such as a decrease in odontoblast cell density and a decrease in both the cytoplasm and structure of odontoblast cells in many vacuoles. Additionally, an increase in pulp cell density was evident in the pulp center considering that in the control group. Although the lowest odontoblast layer thickness was measured in G4, the difference in thickness between the groups was not statistically significant. LLLT applications can be used safely because they do not cause irreversible damage or loss of vitality [29].

In AAPD evidence-based recommendations, the use of calcium hydroxide as an amputation material is not recommended [30]. We aimed to reduce the negative consequences of CH by reducing the osteoclast activation-increasing effect that may occur in primary teeth by utilizing the regenerative effect of low-dose laser. Marques et al. [31] used a low-dose laser (660 nm wavelength, continuous mode, contacted, 10 mW power output, for 10 seconds) for pulpotomy separately with ZOE and KH, compared it with FC and KH materials, and examined them histologically. Histological analysis of all teeth revealed that the remaining radicular pulp tissues had different degrees of inflammation and vitality. Histological analysis of the LLLT+ZOE group showed mild to moderate inflammatory infiltration, whereas the hard tissue barrier, odontoblastic layer, and internal resorption were not observed in these cases. In the LLLT+CH group, while regular vascularization and a hard tissue barrier on the odontoblastic layer were observed in most cases, there was no internal resorption and minimal pulp inflammation. The findings of this study show that LLLT preserves pulp vitality and does not cause adverse effects during the amputation of primary teeth. Therefore, CH was applied after LLLT in the present study. However, in primary tooth amputations, osteoclastic activity and the apical blood supply of CH can trigger an inflammatory reaction in the primary teeth [32]. In our study, internal resorption was the most common cause of failure in the LLLT+CH group.

The reason for only including lower second molars was the superposition of the maxillary sinus; moreover, it is difficult to obtain a good radiographic image of permanent teeth during maxillary primary molar pulpotomy treatment [33].

The limitations of our study include the short follow-up period and the lack of histological examination of the teeth. The study was conducted during the COVID-19 pandemic, and pediatric patient treatment follow-up is difficult; thus, the treatments were followed for 12 months. Furthermore, histological examination of pulp inflammation in treated teeth was deemed unethical because it required tooth extraction.

CONCLUSIONS

When the 12-month clinical and radiological results of diode laser and LLLT+CH amputations were evaluated, no statistically significant differences were found. However, when the studies on dental lasers were evaluated, the results showed different success rates. This was thought to be related to the lack of standardization in many factors, such as laser power, wavelength, frequency, contact state, pulse shape, application time, and fiber optic tip diameter. Therefore, there is a need to determine safer and optimal laser parameters for both dentists and patients and to conduct longer follow-up studies with larger sample groups.

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