The Saudi Dental Journal 36 (2024) 334–339

Contents lists available at ScienceDirect

The Saudi Dental Journal

journal homepage: www.ksu.edu.sa
www.sciencedirect.com

Original Article

Effect of low-level laser therapy on pain reduction in orthodontic patients during molar distalization: A randomized controlled trial

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ARTICLE INFO

Keywords:
Low-level laser therapy
Pain
Orthodontic treatment
Molar distalization

ABSTRACT

Aim: To investigate the effects of low-level laser therapy (LLLT) on pain reduction in orthodontic patients during molar distalization.
Materials and methods: Twenty patients requiring bilateral maxillary first molar distalization were randomly assigned to two groups: the intervention group (mean age 15.61 ± 1.03 years) received multiple LLLT after every activation of the distalizing appliance (immediately and on the 3rd, 7th, and 14th days) and the control group (mean age 15.64 ± 1.08 years) who did not receive LLLT. Patients reported pain levels every day for 7 days following activation of the appliance using an 11-point numeric rating scale (NRS), then the pain experience of both the intervention and control groups was compared using Mann-Whitney *U* test.
Results: The mean pain scores on the 1st day were higher in the intervention group (9.27 ± 1.01) compared to that of the control group (8.80 ± 1.03). However, the mean pain scores of the intervention group (6.55 ± 1.29, 4.00 ± 1.26, 2.55 ± 1.29, 0.91 ± 1.04, 0.00 ± 0.00 and 0.00 ± 0.00, respectively) were lower than the control group (7.40 ± 1.90, 5.60 ± 2.07, 4.20 ± 1.99, 2.80 ± 1.93, 1.60 ± 1.58 and 0.40 ± 0.84, respectively) from the 2nd to the 7th day. All the differences were not statistically significant except on the 6th day (P-value = 0.003). The peak pain level was experienced by both groups on the 1st day, followed by a statistically significant gradual decrease in pain levels. Patients in the intervention group reported a shorter overall duration of pain.
Conclusion: Although LLLT, with the used parameters, reduced the overall duration of pain experience following maxillary first molar distalization, it was not effective during peak pain levels.

1. Introduction

Pain is an unpleasant sensation triggered by an array of stressful stimuli and is among the most reported negative side effects of orthodontic treatment (Kluemper et al., 2002). In a survey investigating patients' perceptions of orthodontic treatment, pain was among the top worries before treatment and the most unfavorable drawback during orthodontic treatment (O'Connor, 2000).

It has been shown that low-level laser therapy (LLLT) has pain relief capabilities due to its biostimulatory effects (Soriano and Ríos, 1998). It was reported that LLLT application increased vascular activity and cellular metabolism, thereby increasing tooth movement (Caccianiga et al., 2016,2017). In addition, LLLT seems to have an analgesic effect by preventing arachidonic acid release to reduce prostaglandin E2 levels (Mizutani et al., 2004; Bicakci et al., 2012) and up-regulating beta-endorphin release (Arias and Marquez-Orozco, 2006). Clinical trials have reported that LLLT possesses an analgesic effect on pressure-induced pain caused by orthodontic separators and bands (Bicakci et al., 2012; Almallah et al., 2016,2020) but evidence quality was low (Zhi et al., 2021). Therefore, this randomized controlled trail (RCT) evaluated the effects of LLLT on pain reduction in orthodontic patients during molar distalization. Our null hypothesis is that the application of LLLT does not have an impact on pain levels during molar distalization.

2. Subjects and methods

2.1. Sample size calculation

We based the sample size calculation on the assumption that the minimal clinically important change in mean pain scores on an 11-point

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https://doi.org/10.1016/j.sdentj.2023.11.016
Received 25 August 2023; Received in revised form 12 November 2023; Accepted 14 November 2023
Available online 22 November 2023

numeric rating scale (NRS) is 1.65 ± 1.58 (Bahreini et al., 2020) with the following parameters: 80% power, the sample size for the unpaired *t*-test, and significance level (alpha) = 0.05 (two-tailed). A sample of 18 patients was estimated to be sufficient to detect a clinically relevant difference; so, 20 patients were recruited to be prepared for dropouts during the data collection period.

2.2. Eligibility criteria

2.2.1. Inclusion criteria

Patients were included in our sample according to the following criteria: aged 14–17 years with all permanent teeth (except for third molars); bilateral dental Class II malocclusion with skeletal Class I or mild Class II relationship (the accepted range of ANB angle was 2–7°); normal or reduced vertical face height (the accepted range of maxillary-mandibular plane angle was 20–32°); no posterior crowding or spaces; absence of systemic diseases or conditions that could interfere with orthodontic tooth movement; no previous orthodontic treatment; and good oral hygiene.

2.2.2. Exclusion criteria

Patients were excluded from participation in this trial if they had skeletal Class II discrepancies that required orthognathic surgery (ANB angle > 7°), congenital dentoskeletal disorders, or missing or mutilated teeth in the maxillary arch.

2.3. Patient recruitment and randomization

The patients were recruited from those attending the Orthodontic Clinic, Faculty of Dental Medicine (Boys), Al-Azhar University, Cairo, Egypt. All patients or their parents provided written informed consent before starting treatment. The patients were randomly and equally allocated to either a control group in which they did not receive LLLT during treatment (n = 10) or an intervention group which received LLLT during treatment (n = 10).

2.4. Ethical considerations

The ethical approval for this study was granted by the Ethics Committee, Faculty of Dental Medicine (Boys), Al-Azhar University, Cairo, Egypt (no: 647/1760) and registered at ClinicalTrials.gov (ID number: NCT05465473).

2.5. Periodontal prophylaxis

All the included patients underwent intensive prophylaxis procedures including scaling and gingival treatment to standardize the pre-treatment periodontal status for all the participants. In addition, all the patients were given a home care instruction form and enrolled in a home care program for 1 month before starting treatment to assess their motivation and attitude toward home care procedures.

2.6. Interventions

2.6.1. The skeletally anchored distal jet (SADJ) appliance

The appliance was fabricated as a unit with four solder joints at the first premolar and first molar bands. Micro-implant insertion slots 2 mm in diameter were fabricated from 2 mm stainless steel wire and positioned 1 mm distal to the third rugae area, 3 mm lateral to the mid-palatal raphe, and 3 mm away from the palatal mucosa. Finally, the appliance was washed, polished, and finished in preparation for use.

Five days before appliance insertion, elastomeric separators were placed in the mesial and distal contact areas around the maxillary first premolars and first molars and removed on the day of appliance insertion. In preparation for cementation, the teeth were polished, rinsed, and dried, and the appliance was tried-in to ensure that it fitted properly. A thin coat of glass ionomer cement (Medicem, Germany) covering the inner surfaces of all bands was applied for appliance cementation in a dry field. Excess cement was removed after the initial setting, using a sharp dental scaler. Palatal infiltration of a local anesthetic (Artinibsa 40 mg/0.01 mg/mL, Spain) was administered near the micro-implant placement sites. Betadine antiseptic solution was applied topically at the micro-implant placement sites using a small cotton pellet, and the patient was allowed to spit any excess solution without rinsing. Two micro-implants with 1.8 mm diameter and 11 mm long (OAS-T1511, Biomaterials Korea Inc.) were installed into the appliance insertion slots perpendicular to the palate and directed away from the roots of the neighboring teeth (Fig. 1). Nickel-Titanium (NiTi) springs were fully activated to obtain 240 g of force on both sides to initiate the appliance. Subjects presented every 4 weeks for reactivation of the springs to attain the same initial activation force.

2.6.2. Low-level laser therapy (LLLT)

The laser used was a semiconductor gallium-aluminum-arsenide diode laser (SMART m PRO, LASOTRONIX, Poland) with a 635 nm wavelength, 30 J/cm^2 energy density, 100 mW power output, and 8 mm diameter laser probe tip size, and it could be operated in a continuous mode. The patients in the intervention group received LLLT after every activation of the distalizing appliance for the entire treatment duration; immediately after the activation of the appliance; and on the third, seventh, and fourteenth days.

The mucosa covering the roots of each maxillary first permanent molar was exposed to 10 laser irradiations (5 exposures from the buccal side and 5 from the palatal side) of 9 s (total of 90 s per molar). At the end of each irradiation session, each molar received a total energy of 9 j (18 j for the two maxillary first molar segments). The mucosa around the tooth was dried before laser beam application, and then the tip of the laser handpiece was oriented perpendicular to and contacting the mucosa. To cover the entire periodontal tissues around the tooth, each side was divided into three sections (cervical, apical, and middle thirds), and the laser exposure was distributed as per the protocol established by Genc et al. (2013): two irradiations (mesial and distal) on the cervical third, two irradiations (mesial and distal) on the apical third, and one irradiation (center) on the middle third (Fig. 2).

After each laser session, the handpiece body and the optic tips were cold sterilized. This protocol was repeated every 4 weeks after activation of the appliance until the treatment objective was established (achieving Class I molar relationship). During the laser application sessions, appropriate protective eyeglasses were worn by the patient and the clinician. For standardization, all clinical procedures and laser administration were performed by one clinician.

2.7. Outcomes

The patients reported pain levels daily after activation of the distalizing appliance for seven consecutive days using an 11-point NRS from 0 to 10, where 0 was “no pain” and 10 was “severe pain.”.

2.8. Statistical analysis

Statistical Package for Social Sciences (SPSS) software version 20 (IBM Corp., Armonk, NY, USA) was used for statistical analyses. Numerical data are presented as mean, standard deviation, median, and range. Normal distribution of the data was assessed using the Shapiro–Wilk and Kolmogorov–Smirnov tests. Intergroup comparisons of nonparametric numeric values were performed using the Mann–Whitney *U* test, and the significance level was adjusted using Bonferroni’s correction for multiple testing. Comparisons within the same group (effect of time) were performed by Friedman test and Wilcoxon signed-rank test. All P-values were two-sided and a P-value ≤ 0.05 was considered significant.

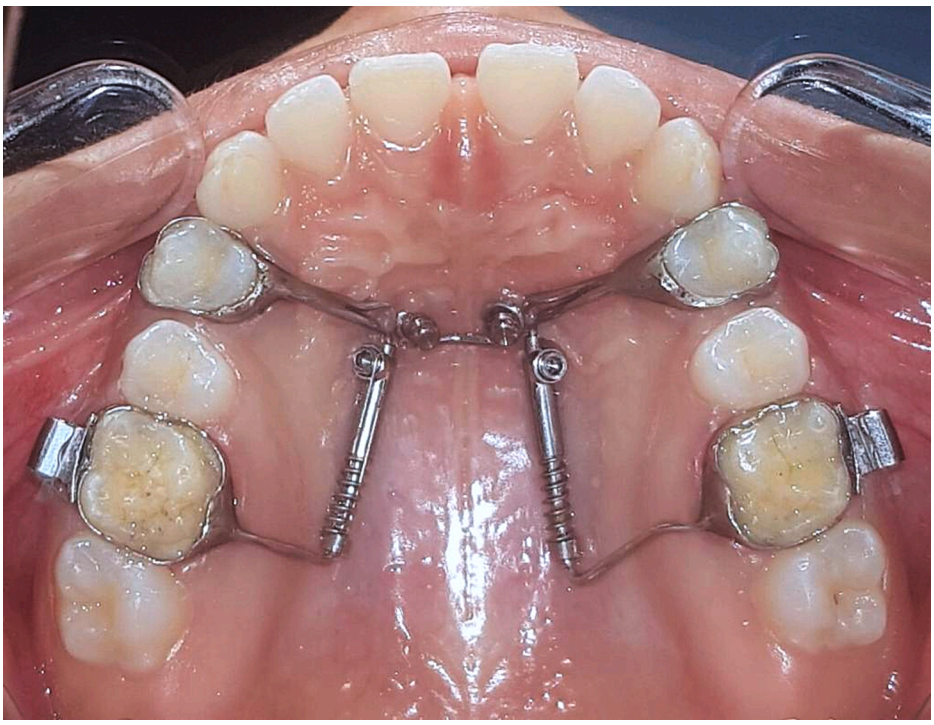

Fig. 1. Occlusal view of the upper arch showing the skeletally anchored distal jet molar distalizing appliance.

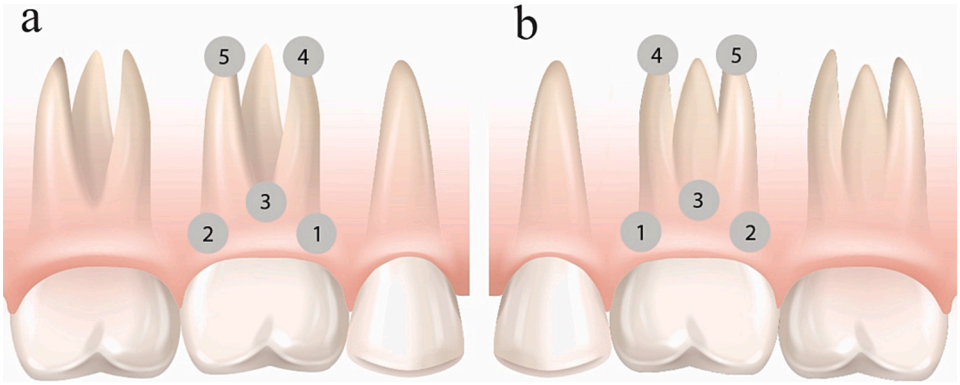

Fig. 2. Illustrations showing the LLLT points of application from the (a) buccal and (b) palatal aspects. 1: Mesial point on the cervical 3rd, 2: distal point on the cervical 3rd; 3: center of the middle third; 4: mesial point on the apical third 3rd; 5: distal point on the apical 3rd.

3. Results

3.1. Participant demographics

The participants' ages ranged from 14 to 17 years with a mean age of 15.64 ± 1.08 in the control group and 15.61 ± 1.03 in the intervention group. The control group consisted of 8 females and 2 males, while the intervention group consisted of 6 females and 4 males, with no significant difference in gender distribution between the groups (p = 0.329); (Table 1).

Table 1
Patient's demographic data.

		Control group	Intervention group	P-value
Age (years)	Min–Max	14–17		0.95 NS
	Mean ± SD	15.64 ± 1.08	15.61 ± 1.03	
Gender n (%)	Males	2 (20%)	4 (40%)	0.329 NS
	Females	8 (80%)	6 (60%)	

Significance level P ≤ 0.05, NS = *non-Significant*.

3.2. Comparison of the mean pain scores

The pain scores are summarized in Table 2 and Fig. 3, showing no significant difference between the groups except on the sixth day (P = 0.003). Overall, the mean pain scores of the intervention group were lower than those of the control group except on the first day, when it was slightly higher. In both groups, the peak of the pain level was noted on the first day, with a statistically significant gradual decrease in pain levels. The patients in the intervention group reported no pain sensation on the sixth and seventh days, whereas the patients in the control group reported experiencing pain until the seventh day (the mean pain score is 0.40 ± 0.84).

4. Discussion

This (RCT) investigated the effect of LLLT on pain reduction in

Table 2
Patients' pain scores.

	Control group		Intervention group		P-value between groups
	Mean ± Std. Dev	Median {min; max}	Mean ± Std. Dev	Median {min; max}	
1st day	8.80 ± 1.03	8[a] {8; 10}	9.27 ± 1.01	10[k] {8; 10}	0.290
2nd day	7.40 ± 1.90	8[b] {4; 10}	6.55 ± 1.29	6[l] {4; 8}	0.241
3rd day	5.60 ± 2.07	6[c] {2; 8}	4.00 ± 1.26	4[m] {2; 6}	0.055
4th day	4.20 ± 1.99	4[d] {2; 8}	2.55 ± 1.29	2[n] {0; 4}	0.049
5th day	2.80 ± 1.93	2[e] {0; 6}	0.91 ± 1.04	0[o] {0; 2}	0.013
6th day	1.60 ± 1.58	2[f] {0; 4}	0.00 ± 0.00	0[p] {0; 0}	0.003*
7th day	0.40 ± 0.84	0[g] {0; 2}	0.00 ± 0.00	0[p] {0; 0}	0.128
P-value within group	<0.0001*		<0.0001*		

*Significant.
Mann Whitney *U* test for comparisons between groups, the significance level was adjusted using Bonferroni's correction for multiple testing ($P \leq 0.007$ is considered significant).
Wilcoxon signed Rank test: within the same column, values with different superscript letters are significantly different ($P \leq 0.05$ is considered significant).

orthodontic patients during molar distalization–the process of moving the terminal molars distally. This procedure is often used to treat Class II malocclusion, which is when the upper teeth are too far forward compared to the lower teeth or when we need to create space for other teeth that are crowded or impacted. Molar distalization, akin to other orthodontic tooth movements, can cause pain for some patients, which can affect their quality of life and compliance with treatment. The pain can vary in intensity, duration, and location depending on the individual and the type of appliance used. Factors that influence the pain include the eruption stage of the second molar, the amount of tooth movement, the direction of force, and the patient's pain threshold and coping strategies. Pain can be managed using analgesics such as nonsteroidal anti-inflammatory drugs (NSAIDs), but they interrupt osteoclast activity resulting in a slower tooth movement (Xiaotinga et al., 2010).

Alternatively, LLLT was proposed for pain control during orthodontic treatment. It is an application of low-intensity light and is a noninvasive and nonpharmacological method that stimulates cellular metabolism and modulates inflammatory and analgesic mediators (Suzuki et al., 2016; Celebi et al., 2021). Specifically, exposure of tissues to the laser beam triggers cellular proliferation and differentiation, thereby increasing the blood supply and faster clearance of inflammatory mediators that may induce pain (Verschueren et al., 1975). In a recent RCT, the authors compared the efficacy of paracetamol/caffeine administration to LLLT in reducing pressure-induced pain from placing elastomeric separators around the first molars, reporting that both protocols resulted in similar pain control potential (Owayda et al., 2022). However, the evidence regarding the effectiveness of LLLT in orthodontic pain relief is still controversial as previous studies reported varying results (Lim et al., 1995; Bicakci et al., 2012; Doshi-Mehta and Bhad-Patil, 2012; Zhi et al., 2021).

In this study, we exposed each maxillary first molar in the intervention group to multiple doses of irradiation following every activation of the distalizing appliance (immediately after activation of the appliance and on the third, seventh, and fourteenth days after activation); (Youssef et al., 2008; Doshi-Mehta and Bhad-Patil, 2012). It has been reported that cells are more sensitive to laser irradiation during the early phases of differentiation, and the multiple application of LLLT during this time may increase the cellular response (Ng et al., 2004). The participants were asked to report pain intensity daily for seven consecutive days immediately following every activation, showing that they started to experience pain within the first 24–48 h of orthodontic force application, which returned to normal after 7 days (Youssef et al., 2008).

All the participants in this study reported peak pain intensity on the

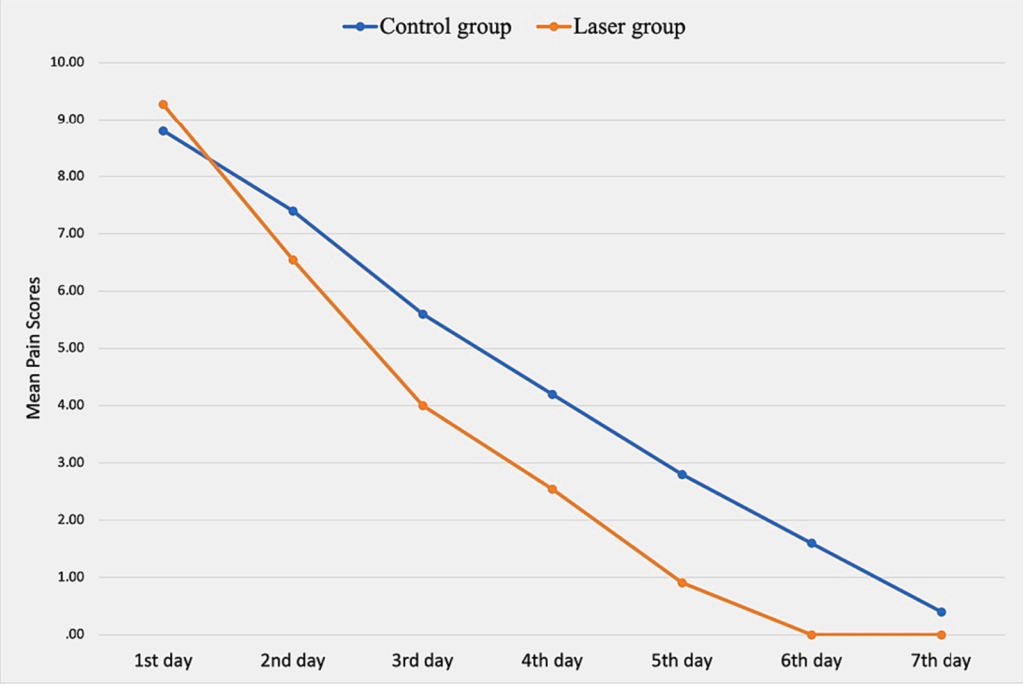

Fig. 3. Mean pain scores in the control and intervention groups over the treatment duration.

first day following activation of the distalizing appliance with a gradual and significant decrease in pain intensity thereafter. The pain intensity was higher in the intervention group than in the control group on the first day but lower from the second to the seventh day and was only significantly different on the sixth day. Our findings suggest that LLLT resulted in an overall shorter pain duration but had no significant effect on pain levels during the peak pain intensity (the first day following the activation of the appliance). Given the inconsistencies in these study results, the null hypothesis was accepted.

Previous investigations that studied the analgesic effect of LLLT on orthodontic pain reported a wide range of outcomes. Similar to our results, Domínguez et al. in their RCT performed multiple applications of diode laser with a 670 nm wavelength on maxillary first premolars during their retraction and reported little lower pain perception in laser-irradiated teeth (Domínguez et al., 2015). Another study in which the authors performed a single-dose laser application (830 nm wavelength) to the upper six anterior teeth immediately after placing the fixed appliances reported lower pain perception in the laser subjects compared to controls. However, the differences were only significant 72 h after the braces were placed (Alsayed Hasan et al., 2020). In contrast, El-Bialy et al. applied an infrared laser (810 nm wavelength) once a week to the maxillary molars during their distalization and the patients reported significantly lower pain scores in the LLLT group in the first three days (El-Bialy et al., 2021). Similarly, Brito et al. (2022) performed single-dose irradiation using an infrared laser (808 nm wavelength) of all teeth for patients undergoing non-extraction fixed orthodontic treatment and compared pain perception with control subjects, reporting significantly lower pain scores in the laser group with overall shorter pain duration compared to the control group.

The differences in the outcomes may be explained by the large number of adjustable parameters when using LLLT, various wavelengths ranging from 635 nm to 980 nm, different power outputs, and energy densities (Qamruddin et al., 2017; Guram et al., 2018; Matys et al., 2020). Deana et al. (2017) conducted a *meta*-analysis and found that an infrared laser with a wavelength ranging from 800 to 830 nm was the most effective for orthodontic pain relief (Deana et al., 2017). However, the available studies are mostly of low quality and reported conflicting results; thus, there is a need for further research to establish standard protocols that can be used clinically for effective orthodontic pain reduction (Zhi et al., 2021).

5. Conclusion

Although LLLT reduced the overall duration of pain experience following maxillary first molar distalization, it was not effective during peak pain periods. Therefore, more research is required to determine the optimal conditions and mechanisms of action of LLLT for effective orthodontic pain relief.

Funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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