Assessment of a single versus double application of low-level laser therapy in pain reduction following orthodontic elastomeric separation: A randomized controlled trial

Ocena pojedynczego lub podwójnego użycia lasera małej mocy w redukowaniu bólu związanego z separacją elastomerową – randomizowane badanie kontrolowane

Mai Mohammed Erfan Almallah^{1,B–F}, Mohammad Younis Hajeer^{2,A,C–F}, Wael Housam Almahdi^{1,A,D–F}, Ahmad Sharaf Burhan^{2,C–F}, Youssef Latifeh^{3,4,A,D–F}, Suha Khaled Madkhaneh^{1,B,D,F}

¹ Department of Periodontics, Faculty of Dentistry, University of Damascus, Syria

² Department of Orthodontics, Faculty of Dentistry, University of Damascus, Syria

³ Department of Psychiatry, Faculty of Medicine, University of Damascus, Syria

⁴ Department of Internal Medicine, Faculty of Medicine, Syrian Private University, Damascus, Syria

A – research concept and design; B – collection and/or assembly of data; C – data analysis and interpretation;

D – writing the article; E – critical revision of the article; F – final approval of the article

Dental and Medical Problems, ISSN 1644-387X (print), ISSN 2300-9020 (online)

Dent Med Probl. 2020;57(1):45–52

Address for correspondence

Mohammad Younis Hajeer

E-mail: myhajeer@gmail.com

Funding sources

This work was supported by the University of Damascus Postgraduate Research Budget (Ref No. 83324208070DEN).

Conflict of interest

None declared

Received on August 14, 2019

Reviewed on September 11, 2019

Accepted on October 24, 2019

Published online on March 31, 2020

Cite as

Almallah MME, Hajeer MY, Almahdi WH, Burhan AS, Latifeh Y, Madkhaneh SK. Assessment of a single versus double application of low-level laser therapy in pain reduction following orthodontic elastomeric separation: A randomized controlled trial. *Dent Med Probl.* 2020;57(1):45–52. doi:10.17219/dmp/113332

DOI

10.17219/dmp/113332

Copyright

© 2020 by Wrocław Medical University

This is an article distributed under the terms of the Creative Commons Attribution 3.0 Unported License (CC BY 3.0) (<https://creativecommons.org/licenses/by/3.0/>)

Abstract

Background. Periodontal ligament (PDL) pain, associated with the insertion of elastomeric separators, is one of the most annoying experiences at the beginning of orthodontic treatment. Low-level laser therapy (LLLT) has recently been suggested as a method of controlling this pain.

Objectives. The aim of this study was to evaluate the effectiveness of LLLT on reducing the pain associated with elastomeric separation and to compare a single dose of LLLT (1 h before the insertion of elastomeric separators) vs 2 doses of LLLT (1 h before and immediately after the insertion).

Material and methods. This randomized controlled trial was conducted at the Department of Orthodontics, Faculty of Dentistry of University of Damascus and at the Department of Orthodontics of Adib-Allah Center in Damascus, Syria. The sample population was comprised of 36 patients, aged between 12 and 25 years (mean age: 17 ± 3.7 years), and the patients were randomly divided into 2 groups. A split-mouth design was employed. One group received 1 dose of laser therapy 1 h before the insertion of elastomeric separators, whereas the other one received 2 doses of laser therapy – 1 h before and immediately after the insertion of elastomeric separators. A GaAlAs laser with a wavelength of 830 nm and a power of 100 mW was used. The pain levels were recorded using the Visual Analog Scale (VAS) after 1, 6, 24, 48, and 96 h. Student's *t*-test and the repeated measures analysis of variance (ANOVA) were employed to detect significant differences.

Results. Low-level laser therapy significantly reduced post-separation pain when the experimental side was compared to the placebo side in the single-irradiation group ($p < 0.05$). Low-level laser therapy significantly reduced separation pain with no statistical difference between single and double irradiation protocols ($p > 0.05$).

Conclusions. Low-level laser therapy had a positive effect on reducing the pain associated with elastomeric separation, whether it was applied as a single dose before elastomeric separation or as a double dose before and after this procedure.

Key words: pain control, low-level laser therapy, elastomeric separators, periodontal ligament pain

Słowa kluczowe: kontrola bólu, terapia laserem małej mocy, separatory elastomeryczne, ból więzadeł przyzębnych

Introduction

The periodontal ligament (PDL) is a slightly elastic, fibrous structure connecting the tooth to the alveolar bone.¹ It plays a key role in the physiological and orthodontic movements of the tooth.² When the tooth moves, tensile strain occurs in PDL, which is then transferred to and received by the receptors in the alveolar bone.¹ Orthodontic forces stimulate the production of pro-inflammatory mediators, such as histamine, dopamine, serotonin, glycine, prostaglandins, and cytokines.³ This may cause severe pain due to the inflammatory process occurring in PDL, which may hamper routine oral hygiene.⁴ Many surveys have considered pain to be the main cause of the interrupted orthodontic treatment.⁵ Other studies have revealed that 70–90% of patients complain about pain during orthodontic treatment,⁶ and that 30% of patients discontinue the treatment.⁷ Dental separation is used during fixed orthodontic treatment,⁸ aiding in the case of impacted teeth – in particular the second molars⁹ – prostheses and interproximal dental restorations.¹⁰

Elastomeric separators are widely used due to their durability and ease of use with children and adolescents.^{11,12} The application of elastomeric separators is usually accompanied by pain.^{7,13} This pain typically starts within 24 h of insertion,^{7,13,14} increases over the next 24–48 h^{7,15} and subsides within 5–7 days.^{8,14,15} The patient may need an analgesic to relieve it.¹⁶ Non-steroidal anti-inflammatory drugs (NSAIDs) are widely used in dentistry to control the pain which accompanies various dental procedures.¹⁷ A prophylactic dose seems to be more effective in controlling pain than the standard method of administering analgesics after treatment.^{18,19} It seems that taking a prophylactic NSAID allows enough time for it to be metabolized and begin its analgesic effect before pain sets in.¹³ Non-steroidal anti-inflammatory drugs should be avoided in patients suffering from allergic reactions (especially to aspirin), gastric ulcers, respiratory ailments (asthma), kidney or liver injuries, bleeding from an unknown source, hypertension, bone marrow disorders, or epilepsy.²⁰

Analgesics should be avoided during orthodontic treatment, as they interfere with it and may prolong the duration of the treatment.²¹ These precautions have encouraged researchers to seek other analgesic methods that would be safer and possibly produce no side effects.¹⁶ Some researchers have suggested non-medicinal methods of controlling pain during orthodontic treatment.²² These methods include biting on a plastic rod, an acrylic stent or cotton rolls^{22,23}; swishing warm water around the mouth also has some analgesic effect if done at the onset of pain.²³ These aforementioned methods increase the supply of blood to the periodontium, and therefore may accelerate pain relief.²²

Low-level laser therapy (LLLT) has been suggested to reduce pain, and is globally considered to be a safe and effective method for pain management.¹⁷ Low-level laser therapy stimulates cells to produce enkephalins and endorphins,²⁴

and blocks nervous impulses in the slow-conduction velocity peripheral nerves.²⁵ It can obstruct the Na⁺/K⁺ pump in the cell membrane, thus blocking pain impulses and causing an analgesic effect.²⁶ Low-level laser therapy might induce the production of bradykinin, reducing the efficacy of C-nerve fibers and changing the pain threshold.²⁷ It reduces edema and decreases pain by reducing the production of prostoglandin E2 (PGE2) and cyclooxygenase-2 (COX-2).⁷ It may also reduce the production of tumor necrosis factor alpha (TNF- α) during acute inflammation.²⁸ The therapy is used in dentistry to control the pain that accompanies extraction and endodontic treatment^{29,30} as well as the pain induced by elastomeric orthodontic separation.^{31–33}

Several recent studies have found LLLT to be effective in pain reduction when used in conjunction with the insertion of elastomeric separators.^{31–33} Eslamian et al. evaluated the effect of double LLLT irradiation on pain reduction and found it to be of great benefit,⁷ but no previous studies have tried to compare different protocols of LLLT application to arrive at the best choice for pain control. Therefore, the objectives of this randomized controlled trial were to evaluate the efficacy of LLLT in controlling the pain caused by elastomeric separators and to compare a single irradiation dose 1 h before the insertion of elastomeric separators vs double irradiation, conducted 1 h before and 1 h after the insertion, in terms of pain reduction.

Material and methods

This was a randomized, compound controlled clinical trial, i.e., a two-arm, parallel-group trial and a split-mouth design in each group. The subjects were selected from the patients of the Department of Orthodontics, Faculty of Dentistry of University of Damascus and the Department of Orthodontics of Adib-Allaham Center (Ministry of Health) in Damascus, Syria, between November 2014 and June 2015. This study was approved by the Faculty of Dentistry's Local Research Ethics Committee (reference No. UDDS-380-30032014/SRC-2209) and was registered at <https://clinicaltrials.gov> (identifier: NCT02209818) before the commencement of data collection. The trial was funded by the University of Damascus Postgraduate Research Budget (Ref. No: 83324208070DEN). The candidates for inclusion were given information sheets and their consent was obtained.

Sample size calculation

The calculation of the sample size was performed using Minitab®, v. 17 (Minitab LLC, State College, USA) with an alpha level of 0.05 and a power of 90%, assuming that the smallest difference requiring detection in the pain level was 10 mm on the Visual Analog Scale (VAS) with a variation (standard deviation – SD) of 8.1, based on a previous study.

A sample of 30 patients (15 in each group) was required. The study included 36 patients to compensate for any potential withdrawals.

Eligibility criteria

The inclusion criteria were patients undergoing orthodontic treatment with the need of molar separation before banding and in the age range of 12–25 years. The exclusion criteria comprised chronic disease, chronic or neural pain, periodontitis, treated or untreated apical lesions on the first molar, loose mesial and distal contact points on the first molar, and the presence of gingival pigmentation in the area to be irradiated.

Study groups

The study groups were selected randomly using a list of random numbers generated by a computer program (Minitab, v. 17), which allocated patients to one of 2 equal groups (Fig. 1). The 1st group received a single irradiation dose and the 2nd group received double irradiation. Either the upper or lower jaw was irradiated for each patient, never both. The treatment and placebo sides in each patient were also selected randomly using the list of different allocations generated in Minitab, v. 17.

Fig. 1. CONSORT (Consolidated Standards of Reporting Trials) flow diagram of patient recruitment and follow-up

Laser irradiation technique

After isolating the field using cotton rolls, a laser was applied on the experimental side 1 h before the insertion of elastomeric separators in the single-irradiation group, and 1 h before and immediately after the insertion of elastomeric separators in the double-irradiation group. Eight points were irradiated: mesial and distal of the first molar, distal of the second premolar, and mesial of the second molar, on both the buccal and lingual sides (Fig. 2). A GaAlAs laser with a wavelength of 830 nm, an energy density of 4 J/cm² and a power output of 100 mW was used for an automated duration of 28 s per point and a laser spot diameter of 7 mm (DioBeam®; CMS Dental, Copenhagen, Denmark) (Fig. 3).

On the placebo side, the same laser device was used after the safety cover was removed so that the device produced the same sounds, but no irradiation occurred. The tip was applied to the same points and for the same duration. The dentist and the patient wore laser protective goggles to prevent any harm to the eyes. To prevent any deviations due to gender, age or personal pain threshold,³⁴ the patients were not aware of which side represented the placebo (double-blinded study design).

Fig. 2. A – laser irradiation on the buccal side; B – laser irradiation on the lingual side

Fig. 3. Laser device used in the current trial

Pain assessment

The patients were given questionnaires to evaluate their perception of pain at the following assessment time points: 1, 6, 24, 48, and 96 h after separation. Every patient was instructed to rate the level of their pain on VAS.

A 100-mm line was used, with the left side representing no pain (i.e., score 0) and the right side representing the worst pain (i.e., score 100). The patients were asked to put a vertical mark on the line at the point which best represented the level of pain they felt. The pain assessment was done by measuring the distance from the left side to the vertical mark in millimeters. The patients were instructed not to take any analgesics during the pain assessment period. In case of severe pain, they were allowed to take 1 or 2 500-mg tablets of paracetamol (acetaminophen), but they were asked to fill in the questionnaire before taking any analgesics.

Statistical analysis

The Microsoft® Excel files (Office Excel 2013; Microsoft Corporation, Redmond, USA) were used for data entry. The statistical analysis was done using Minitab, v. 17 and IBM SPSS Statistics for Windows, v. 21 (IBM Corp., Armonk, USA). Two-sample *t*-tests were employed to evaluate the efficacy of LLLT in reducing pain by comparing the single- and double-irradiation groups. The repeated measures analysis of variance (ANOVA) was employed to evaluate changes in pain perception over time in each group, and the least significant difference (LSD) method was used for the post-hoc tests.

Results

This study was conducted on 36 patients (12 males and 24 females) at an average age of 17.44 years (range:

12–25 years) (Table 1). Pain perception on 1 or both sides started after 1 h in 63.89% of the sample, after 6 h in 13.89% of the sample and after 24 h in 11.11% of the sample. Surprisingly, 4 patients (11.11%) never felt pain at any assessment time point. The maximum pain perception was recorded at 24 h after separation.

In the single-irradiation group, pain increased over time, then decreased, with no significant differences in the pain levels between the assessment time points, whether the comparisons were made on the experimental side or the placebo side (Table 2). In the double-irradiation group, pain increased, then decreased, with statistically significant changes in the pain levels for both the experimental and the placebo sides (Table 2). The post-hoc tests in this group revealed that there were significant differences between the pain levels 1 h after separation as compared to 24 and 48 h, and between the pain levels 24 and 48 h after separation as compared to 96 h (Table 3). On the placebo side, significant differences were found between the pain levels 1 h after separation as compared to 6, 24 and 48 h, and at 24 and 48 h after separation as compared to 96 h (Table 4).

Significant differences in the pain levels were found between the placebo and experimental sides at 6, 24 and 48 h after separation in the single-irradiation group (Table 5). Significant differences in the pain levels were also found between the 2 sides at all assessment time points (at 1, 6, 24, 48, and 96 h) in the double-irradiation group (Table 5). Regarding the experimental sides, when single irradiation was compared to double irradiation, no significant differences between them were observed at any assessment time point (Table 6).

Table 1. Baseline characteristics of the study population

Variable	Single-irradiation group		Double-irradiation group		Total
	male	female	male	female	
Gender n (%)	6 (16.67)	12 (33.33)	6 (16.67)	12 (33.33)	36 (100)
Maximal age [years]	25	21	23	22	25
Minimal age [years]	14	12	20	12	12
Age mean $\pm$ SD	18.67 $\pm$ 4.13	16.42 $\pm$ 3.50	20.83 $\pm$ 1.17	16.17 $\pm$ 3.69	17.44 $\pm$ 3.73
Separation in the maxilla n (%)	5 (13.89)	10 (27.78)	6 (16.67)	9 (25.00)	30 (83.33)
Separation in the mandible n (%)	1 (2.78)	2 (5.56)	0 (0)	3 (8.33)	6 (16.67)

SD – standard deviation.

Table 2. Descriptive statistics of the pain levels in the study groups at the different assessment time points, with the *p*-values of the repeated measures analysis of variance (ANOVA) test

Group	Side	T1	T2	T3	T4	T5	F-value	p-value
Single-irradiation	experimental	8.50 $\pm$ 14.29	13.44 $\pm$ 19.39	22.61 $\pm$ 28.16	19.28 $\pm$ 24.59	17.06 $\pm$ 25.40	1.772	0.171
	placebo	14.94 $\pm$ 23.99	27.17 $\pm$ 26.99	33.28 $\pm$ 31.70	31.22 $\pm$ 29.60	23.39 $\pm$ 29.77	2.618	0.071
Double-irradiation	experimental	9.56 $\pm$ 15.77	19.94 $\pm$ 27.21	30.28 $\pm$ 28.22	22.61 $\pm$ 25.74	15.17 $\pm$ 23.83	3.499	0.027*
	placebo	20.17 $\pm$ 18.10	36.95 $\pm$ 28.69	42.06 $\pm$ 26.57	37.61 $\pm$ 28.66	21.50 $\pm$ 23.44	4.602	0.006**

T1 – 1 h after separation; T2 – 6 h after separation; T3 – 24 h after separation; T4 – 48 h after separation; T5 – 96 h after separation;

* significant difference at $p < 0.05$; ** significant difference at $p < 0.01$. Data for T1–T5 presented as mean $\pm$ SD.

Table 3. Descriptive statistics of the changes observed between the different assessment time points (pairwise comparisons) in the double-irradiation group on the experimental side

Time point	Comparison	Mean $\pm$ SD	T-value	p-value	95% CI	
					lower limit	upper limit
T1	T1 vs T2	-10.39 $\pm$ 23.04	-1.91	0.073	-21.85	1.07
	T1 vs T3	-20.72 $\pm$ 29.35	-3.00	0.008**	-35.32	-6.13
	T1 vs T4	-13.06 $\pm$ 19.78	-2.80	0.012*	-22.89	-3.22
	T1 vs T5	-5.61 $\pm$ 19.26	-1.24	0.233	-15.19	3.97
T2	T2 vs T3	-10.33 $\pm$ 29.73	-1.47	0.159	-25.12	4.45
	T2 vs T4	-2.67 $\pm$ 29.24	-0.39	0.704	-17.21	11.88
	T2 vs T5	4.78 $\pm$ 31.82	0.64	0.533	-11.05	20.60
T3	T3 vs T4	7.67 $\pm$ 25.39	1.28	0.217	-4.96	20.29
	T3 vs T5	15.11 $\pm$ 22.40	2.86	0.011*	3.97	26.25
T4	T4 vs T5	7.44 $\pm$ 14.71	2.15	0.046*	0.13	14.76

CI – confidence interval; * significant difference at $p < 0.05$; ** significant difference at $p < 0.01$. The post-hoc tests were performed using the least significant difference (LSD) method and the p -values of the significance tests are given.

Table 4. Descriptive statistics of the changes observed between the different assessment time points (pairwise comparisons) in the double-irradiation group on the placebo side

Time point	Comparison	Mean $\pm$ SD	T-value	p-value	95% CI	
					lower limit	upper limit
T1	T1 vs T2	-16.78 $\pm$ 26.45	-2.69	0.015*	-29.93	-3.63
	T1 vs T3	-21.89 $\pm$ 29.14	-3.19	0.005**	-36.38	-7.40
	T1 vs T4	-17.44 $\pm$ 23.08	-3.21	0.005**	-28.92	-5.97
	T1 vs T5	-1.33 $\pm$ 26.54	-0.21	0.834	-14.53	11.86
T2	T2 vs T3	-5.11 $\pm$ 27.58	-0.79	0.443	-18.83	8.60
	T2 vs T4	-0.67 $\pm$ 29.08	-0.10	0.924	-15.13	13.79
	T2 vs T5	15.44 $\pm$ 38.03	1.72	0.103	-3.47	34.36
T3	T3 vs T4	4.44 $\pm$ 28.15	0.67	0.512	-9.55	18.44
	T3 vs T5	20.56 $\pm$ 26.84	3.25	0.005**	7.21	33.90
T4	T4 vs T5	16.11 $\pm$ 24.56	2.78	0.013*	3.90	28.33

* significant difference at $p < 0.05$; ** significant difference at $p < 0.01$. The post-hoc tests were performed using the LSD method and the p -values of the significance tests are given.

Table 5. Descriptive statistics of the differences between the experimental and placebo sides in each group at each assessment time point, with the p -values of the paired t -test

Group	Time point	Difference between the experimental and placebo sides mean $\pm$ SD	T-value	p-value	95% CI	
					lower limit	upper limit
Single-irradiation	T1	6.44 $\pm$ 15.88	0.103	1.72	14.34	-1.45
	T2	13.72 $\pm$ 18.21	0.005**	3.20	22.78	4.67
	T3	10.67 $\pm$ 20.80	0.044*	2.18	21.01	0.32
	T4	11.94 $\pm$ 21.19	0.029*	2.39	22.48	1.41
	T5	6.33 $\pm$ 15.31	0.097	1.75	13.95	-1.28
Double-irradiation	T1	10.61 $\pm$ 16.10	0.012*	2.80	18.62	2.61
	T2	17.00 $\pm$ 21.84	0.004**	3.30	27.86	6.14
	T3	11.78 $\pm$ 17.69	0.012*	2.82	20.58	2.98
	T4	15.00 $\pm$ 17.14	0.002**	3.71	23.52	6.48
	T5	6.33 $\pm$ 10.36	0.019*	2.59	11.48	1.18

* significant difference at $p < 0.05$; ** significant difference at $p < 0.01$.

Table 6. Descriptive statistics of the differences between the single-irradiation and double-irradiation groups on the experimental side at each assessment time point, with the *p*-values of the paired *t*-test

Time point	Single-irradiation group mean $\pm$ SD	Double-irradiation group mean $\pm$ SD	Mean difference	T-value	<i>p</i> -value	95% CI	
						lower limit	upper limit
T1	8.50 $\pm$ 14.29	9.56 $\pm$ 15.77	9.15	-11.26	0.835	-0.21	-1.06
T2	13.44 $\pm$ 19.39	19.94 $\pm$ 27.21	9.58	-22.58	0.416	-0.83	-6.50
T3	22.61 $\pm$ 28.16	30.28 $\pm$ 28.22	11.45	-26.78	0.420	-0.82	-7.67
T4	19.28 $\pm$ 19.28	22.61 $\pm$ 25.74	13.74	-20.40	0.694	-0.40	-3.33
T5	17.06 $\pm$ 17.06	15.17 $\pm$ 23.83	18.59	-14.81	0.819	0.23	1.89

Discussion

Many studies have used LLLT to reduce the pain caused by elastomeric separation and most of these studies applied single irradiation immediately after inserting elastomeric separators. The results have differed greatly between these studies, ranging from a significant reduction in pain with the use of LLLT to no difference at all.^{16,32–36} Reviewing the literature reveals that no previous study has evaluated the use of LLLT before the insertion of elastomeric separators; therefore, no papers are available to compare the current results with.

The pain caused by elastomeric separation is inflammatory in nature. That is why it is important to use a laser that has an anti-inflammatory effect, one which does not cause any thermal changes in the irradiated area. This feature can be found in lasers with a wavelength of 600–1,000 nm.³⁷ In this study, a GaAlAs laser with an 830-nm wavelength was used. It has been shown to have excellent tissue penetration and to be highly effective in reducing pain in comparison with other lasers.^{35,36} Kim et al. used an AlGaInP laser with a wavelength of 635 nm.³⁴ They used multiple irradiations and found significant differences in pain reduction only on the 1st day, not on the following days.³⁴ Different outcomes might be due to the use of different types of lasers with different wavelengths. As mentioned previously, a GaAlAs laser with a wavelength of 830 nm is more effective in reducing pain according to previous studies.^{35,36}

In the present study, a GaAlAs laser was applied to 8 points: mesial and distal of the first molar, mesial of the second premolar and distal of the second molar, both buccally and lingually. This was similar to what Eslamian et al. used in their study.⁷ It has also been documented that low doses of laser irradiation would achieve the desired effect, whereas higher doses (exceeding 5 J/cm² per point and 20 J/cm² per tooth) could eliminate the analgesic and anti-inflammatory effect.^{7,37,38} In the present study, a dose of 4 J/cm² was used at each irradiated point, totaling 16 J/cm² per tooth;

thus, the recommended 20 J/cm² limit was not exceeded. Furquim et al. used a high dose of 80 J/cm² and found no significant differences between the treatment and placebo sides.³³ This might be due to exceeding the suggested dosage of 0.3–19 J/cm².³⁸

The current study applied a laser to only 1 jaw in an attempt to prevent the radiation of pain from one jaw to the other.³⁹ No jaw was preferred over the other, as pain perception in both jaws is similar.^{31,37} This was similar to what Eslamian et al. and Marini et al. did in their studies.^{7,31}

Eslamian et al. used a double-irradiation method, immediately and 24 h after separation, and found positive results on the side of double irradiation.⁷ Few studies have tried to employ multiple-irradiation methods.^{19,34} A quick comparison between the studies of Abtahi et al. and Kim et al. reveals no difference in the final outcomes in terms of pain control despite the fact that the 2 studies used different kinds of laser devices, application protocols, laser parameters, and sample sizes.^{19,34} Abtahi et al. used a GaAr laser with a wavelength of 904 nm, 6 J of energy and a 7-mm tip diameter,¹⁹ whereas Kim et al. used an AlGaInP laser with a wavelength of 635 nm, 10 J of energy and a 5.6-mm tip diameter.³⁴ The sample size in the former study was 29 patients divided into 2 groups (the laser group and the control group), with the laser group receiving laser irradiation once per day for 5 days¹⁹; the sample size of the latter study included 88 patients divided into 3 groups (the laser group, the placebo group and the control group), with laser irradiation being applied every 12 h for 7 days in the laser group.³⁴ Both studies found that laser application was useful in reducing the peak of pain perception, which generally occurs 24 h after separation, but at the same time they found no statistically significant differences between the laser and control groups at other observation time points.^{19,34}

Lim et al. assessed pain in 39 patients after applying different laser doses on each quadrant of both the upper and lower jaws, and found no significant differences between the 4 quadrants regarding pain perception.⁴⁰ This might be attributed to the presence of multiple pain-stimulating points (i.e., 4 quadrants), thereby

affecting the patient's ability to point out or distinguish the source of pain, or it might be due to pain radiating from one jaw to the other.

The time of pain perception differed between the patients studied, starting after 1 h in 63.89% of the sample, after 6 h in 13.89% of the sample and after 24 h in 11.11% of the study population. Thus, the majority of patients perceived pain within 1–24 h after dental separation. These results were similar to what Shetty et al. and Artés-Rebas et al. found in their research.^{13,35} They found that pain started within 2–24 h of the insertion of elastomeric separators.^{13,35} Eslamian et al. found that pain appeared immediately and up to 24 h after separation, and Ngan et al. reported that pain perception began 4–24 h after separation.^{7,14}

In the current study, the maximum pain perception was recorded 24 h after the insertion of elastomeric separators, which is in agreement with the findings of Eslamian et al. and Fujiyama et al.,^{7,16} whereas Abtahi et al. recorded the maximum pain perception 48 h after separation.¹⁹ This delay might be attributed to the different number of laser applications. Abtahi et al. applied the laser daily for 5 days,¹⁹ whereas Eslamian et al. performed double irradiation⁷ and Fujiyama et al. administered a single irradiating dose.¹⁶

In the current study, no significant differences were found between the experimental sides in the single- and double-irradiation groups, indicating that double irradiation had a similar action to a single application of a laser. However, within each group in this trial, double irradiation appeared to have a superior effect on pain reduction, since all of the comparisons made between the experimental and placebo sides revealed statistically significant differences, whereas in the single-irradiation group significant differences were observed only at 3 assessment time points.

Previously published work has shown that elastomeric separation pain usually decreases within 48–72 h³⁶ and subsides after 5–7 days.^{8,14} Therefore, any assessment after 96 h (i.e., 4 days) would be of great benefit in evaluating the pain levels at later stages, before pain disappears. However, it should be noted that one of the shortcomings of the current study is that the last assessment time was 4 days after separation, and the assessment of the pain levels should have been taken 5, 6 or 7 days after the insertion of separators.

The present study found LLLT to be of significant benefit in pain reduction. This effect was similar to the ones reported in different studies when pharmaceutical analgesics were used at the same time points as those used in the current study for laser irradiation.^{18,41,42} Low et al. and Minor et al. used an analgesic 1 h before separation.^{18,41} Bernhardt et al. administered an analgesic 1 h before separation and 5 h after separation.⁴² The results of these studies were similar to those of the current study, indicating the possibility of replacing medication with LLLT when the use of separators is planned.

Limitations

Pain control in the early phase of orthodontic treatment was not studied in this trial, though light should be shed on this very important stage of orthodontic treatment. Comparisons should be made between analgesics and LLLT to find out which is more effective in controlling pain in the daily practice of orthodontists. Future work should also focus on the best laser parameters to yield the most effective pain control during orthodontic treatment.

Conclusions

The application of LLLT significantly reduced the pain induced by elastomeric separation. Low-level laser therapy was beneficial in pain reduction, whether applied in a single dose or a double dose, with no significant differences between the 2 methods.

ORCID iDs

Mai Mohammed Erfan Almallah <https://orcid.org/0000-0002-4885-4561>
 Mohammad Younis Hajeer <https://orcid.org/0000-0003-0640-1297>
 Wael Housam Almahdi <https://orcid.org/0000-0002-8887-5463>
 Ahmad Sharaf Burhan <https://orcid.org/0000-0002-0727-2653>
 Youssef Latifeh <https://orcid.org/0000-0003-2832-1212>
 Suha Khaled Madkhaneh <https://orcid.org/0000-0001-5794-4107>

References

1. Johnson RB. Synthesis of alveolar bone Sharpey's fibers during experimental tooth movement in the rat. *Anat Rec A Discov Mol Cell Evol Biol.* 2005;284(1):485–490.
2. Bosshardt DD, Bergomi M, Vaglio G, Wiskott A. Regional structural characteristics of bovine periodontal ligament samples and their suitability for biomechanical tests. *J Anat.* 2008;212(3):319–329.
3. Alhashimi N, Frithiof L, Brudvik P, Bakhtiet M. Orthodontic tooth movement and de novo synthesis of proinflammatory cytokines. *Am J Orthod Dentofacial Orthop.* 2001;119(3):307–312.
4. Singh G. Separators in dentistry. *J Oral Hyg Health.* 2013;1:e103.
5. Klumper GT, Hiser DG, Rayens MK, Jay MJ. Efficacy of a wax containing benzocaine in the relief of oral mucosal pain caused by orthodontic appliances. *Am J Orthod Dentofacial Orthop.* 2002;122(4):359–365.
6. Scheurer PA, Firestone AR, Bürgin WB. Perception of pain as a result of orthodontic treatment with fixed appliances. *Eur J Orthod.* 1996;18(4):349–357.
7. Eslamian L, Borzabadi-Farahani A, Hassanzadeh-Azhiri A, Badiie MR, Fekrazad R. The effect of 810-nm low-level laser therapy on pain caused by orthodontic elastomeric separators. *Lasers Med Sci.* 2014;29(2):559–564.
8. Asiry MA, Albarakati SF, Al-Marwan MS, Al-Shammari RR. Perception of pain and discomfort from elastomeric separators in Saudi adolescents. *Saudi Med J.* 2014;35(5):504–507.
9. Davidovitch M, Papanicolaou S, Vardimon AD, Brosh T. Duration of elastomeric separation and effect on interproximal contact point characteristics. *Am J Orthod Dentofacial Orthop.* 2008;133(3):414–422.
10. Abraham J, Pierce C, Rinchuse D, Zullo T. Assessment of buccal separators in the relief of bruxist activity associated with myofascial pain-dysfunction. *Angle Orthod.* 1992;62(3):177–184.
11. Malagan MA, P P B, Muddaiah S, et al. Comparison between efficacy of four different types of orthodontic separators. *J Clin Diagn Res.* 2014;8(8):ZC41–ZC44.
12. Cureton SL, Bice RW. Comparison of three types of separators in adult patients. *J Clin Orthod.* 1997;31(3):172–177.
13. Shetty N, Patil AK, Ganeshkar SV, Hegde S. Comparison of the effects of ibuprofen and acetaminophen on PGE2 levels in the GCF during orthodontic tooth movement: A human study. *Prog Orthod.* 2013;14:6.

14. Ngan P, Kess B, Wilson S. Perception of discomfort by patients undergoing orthodontic treatment. *Am J Orthod Dentofacial Orthop.* 1989;96(1):47–53.
15. Bondemark L, Fredriksson K, Ilros S. Separation effect and perception of pain and discomfort from two types of orthodontic separators. *World J Orthod.* 2004;5(2):172–176.
16. Fujiyama K, Deguchi T, Murakami T, Fujii A, Kushima K, Takano-Yamamoto T. Clinical effect of CO(2) laser in reducing pain in orthodontics. *Angle Orthod.* 2008;78(2):299–303.
17. Xiaoting L, Yin T, Yangxi C. Interventions for pain during fixed orthodontic appliance therapy. A systematic review. *Angle Orthod.* 2010;80(5):925–932.
18. Law SL, Southard KA, Law AS, Logan HL, Jakobsen JR. An evaluation of preoperative ibuprofen for treatment of pain associated with orthodontic separator placement. *Am J Orthod Dentofacial Orthop.* 2000;118(6):629–635.
19. Abtahi SM, Mousavi SA, Shafae H, Tanbakuchi B. Effect of low-level laser therapy on dental pain induced by separator force in orthodontic treatment. *Dent Res J (Isfahan).* 2013;10(5):647–651.
20. Bertolini A, Ferrari A, Ottani A, Guerzoni S, Tacchi R, Leone S. Paracetamol: New vistas of an old drug. *CNS Drug Rev.* 2006;12(3–4):250–275.
21. Barbosa KGN, Sampaio TPD, Rebouças PRM, Catão MHCdV, Gomes DQdC, Pereira JV. Analgesia during orthodontic treatment with low intensity laser: Systematic review. *Revista Dor São Paulo.* 2013;14(2):137–141.
22. Bruno MB, Bruno MAD, Krymchantowski AV, da Motta AFJ, Mucha JN. A double-blind, randomized clinical trial assessing the effects of a single dose of preemptive anti-inflammatory treatment in orthodontic pain. *Prog Orthod.* 2011;12(1):2–7.
23. Mangnall LA, Dietrich T, Scholey JM. A randomized controlled trial to assess the pain associated with the debond of orthodontic fixed appliances. *J Orthod.* 2013;40(3):188–196.
24. Montesinos M. Experimental effects of low power laser in encephalin and endorphin synthesis. *J Eur Med Laser Assoc.* 1988;1(3):2–7.
25. Baxter GD, Walsh DM, Allen JM, Lowe AS, Bell AJ. Effects of low intensity infrared laser irradiation upon conduction in the human median nerve in vivo. *Exp Physiol.* 1994;79(2):227–234.
26. Musch MW, Walsh-Reitz MM, Chang EB. Roles of ZO-1, occludin, and actin in oxidant-induced barrier disruption. *Am J Physiol Gastrointest Liver Physiol.* 2006;290(2):G222–G231.
27. Honmura A, Yanase M, Obata J, Haruki E. Therapeutic effect of Ga-Al-As diode laser irradiation on experimentally induced inflammation in rats. *Lasers Surg Med.* 1992;12(4):441–449.
28. Aimbire F, Albertini R, Pacheco MTT, et al. Low-level laser therapy induces dose-dependent reduction of TNFalpha levels in acute inflammation. *Photomed Laser Surg.* 2006;24(1):33–37.
29. Asnaashari M, Mohebi S, Paymanpour P. Pain reduction using low level laser irradiation in single-visit endodontic treatment. *J Lasers Med Sci.* 2011;2(4):139–143.
30. Ferrante M, Petrini M, Trentini P, Perfetti G, Spoto G. Effect of low-level laser therapy after extraction of impacted lower third molars. *Lasers Med Sci.* 2013;28(3):845–849.
31. Marini I, Bartolucci ML, Bortolotti F, Innocenti G, Gatto MR, Alessandri Bonetti G. The effect of diode superpulsed low-level laser therapy on experimental orthodontic pain caused by elastomeric separators: A randomized controlled clinical trial. *Lasers Med Sci.* 2015;30(1):35–41.
32. Farias RD, Closs LQ, Miguens SA Jr. Evaluation of the use of low-level laser therapy in pain control in orthodontic patients: A randomized split-mouth clinical trial. *Angle Orthod.* 2016;86(2):193–198.
33. Furquim RD, Pascotto RC, Rino Neto J, Cardoso JR, Ramos AL. Low-level laser therapy effects on pain perception related to the use of orthodontic elastomeric separators. *Dental Press J Orthod.* 2015;20(3):37–42.
34. Kim WT, Bayome M, Park JB, Park JH, Baek SH, Kook YA. Effect of frequent laser irradiation on orthodontic pain. A single-blind randomized clinical trial. *Angle Orthod.* 2013;83(4):611–616.
35. Artés-Ribas M, Arnabat-Dominguez J, Puigdollers A. Analgesic effect of a low-level laser therapy (830 nm) in early orthodontic treatment. *Lasers Med Sci.* 2013;28(1):335–341.
36. Nóbrega C, da Silva EMK, de Macedo CR. Low-level laser therapy for treatment of pain associated with orthodontic elastomeric separator placement: A placebo-controlled randomized double-blind clinical trial. *Photomed Laser Surg.* 2013;31(1):10–16.
37. Esper MA, Nicolau RA, Arisawa EA. The effect of two phototherapy protocols on pain control in orthodontic procedure – a preliminary clinical study. *Lasers Med Sci.* 2011;26(5):657–663.
38. Bjordal JM, Johnson MI, Iversen V, Aimbire F, Lopes-Martins RAB. Low-level laser therapy in acute pain: A systematic review of possible mechanisms of action and clinical effects in randomized placebo-controlled trials. *Photomed Laser Surg.* 2006;24(2):158–168.
39. Chetruş V, Roman I, Ciobanu S. Early diagnosis of acute diffuse pulpitis, treatment success. *Rom J Oral Rehab.* 2014;6(1):49–52.
40. Lim HM, Lew KK, Tay DK. A clinical investigation of the efficacy of low level laser therapy in reducing orthodontic postadjustment pain. *Am J Orthod Dentofacial Orthop.* 1995;108(6):614–622.
41. Minor V, Marris CK, McGorray SP, et al. Effects of preoperative ibuprofen on pain after separator placement. *Am J Orthod Dentofacial Orthop.* 2009;136(4):510–517.
42. Bernhardt MK, Southard KA, Batterson KD, Logan HL, Baker KA, Jakobsen JR. The effect of preemptive and/or postoperative ibuprofen therapy for orthodontic pain. *Am J Orthod Dentofacial Orthop.* 2001;120(1):20–27.