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original article

The effect of intra-oral LED device and low-level laser therapy on orthodontic tooth movement in young adults: A randomized controlled trial

Nasrin Farhadian [1,4], Amirfarhang Miresmaeili [1,4], Hana Salehisaheb [1], Mozhde Borjali [1], Maryam Farhadian [2], Loghman Rezaei-Soufi [3], Sara Alijani [1], Sepideh Soheilifar [1], Homa Farhadifard [1]

Available online:

1. Hamadan University of Medical Sciences, School of Dentistry, Department of Orthodontics, Hamadan, Iran
2. Hamadan University of Medical Sciences, School of Public Health and Research Centre for Health Sciences, Department of Biostatistics, Hamadan, Iran
3. Hamadan University of Medical Sciences, Dental Research Centre, Department of Restorative Dentistry, Hamadan, Iran

Correspondence:
Hana Salehisaheb, Orthodontics Department, Dental school, Shahid Fahmideh Street, 65417838741 Hamadan City, Hamadan Province, Iran.
hanasalehisaheb@gmail.com

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Tooth movement
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Phototherapy

Summary

Introduction > This randomized controlled clinical trial aimed to assess the effect of LED[5,] and LLLT[6] in a three-arm parallel setting.
Methods > Sixty patients who needed the maxillary first premolar extraction were allocated to three groups using the stratified block randomization method. In the LED group, a custom-made device with a wavelength of 640 nm and a power density of 40 mW/cm^2 was used 5 min/day. In the laser group, Ga Al As[7] laser with a wavelength of 810 nm and a power of 100 mW was used on days 0, 3, 30, and 60 each time for 18 seconds. Patients in the control group received placebo treatment as the laser group protocol, using a coated light cure device. Models were made at baseline and monthly until the end of the retraction. The rate of canine retraction was the primary outcome, while canine rotation and pain were secondary outcomes. The final data were anonymous for the outcome assessor and statistical consultant. Data were analyzed per protocol using a linear mixed model.
Results > The rate of canine retraction significantly increased by 60.8% in the laser group, while it increased not significantly by 26% in the LED group compared with the control group. There was no significant difference among the groups in terms of tooth rotation and pain.

[4] Professor Nasrin Farhadian is the first author.
[5] Light Emitting Diode.
[6] Low Level Laser Therapy.
[7] Gallium Aluminium Arsenide.

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Conclusions > LLLT can accelerate orthodontic tooth movement (OTM). LED with the present setting couldn't increase the rate of OTM. LLLT and LED did not affect canine rotation or pain.
Trial registration > IRCT20120220009086N4. On 1 June 2019 was retrospectively registered.

Introduction

Orthodontic treatment duration, which is one of the major concerns of patients and practitioners, lasts 20 to 30 months [1]. In addition to reducing patient's cooperation, it accumulates time-dependent side effects such as external root resorption, caries, and periodontal disease [2]. Therefore, there is constant research to find methods to increase the rate of orthodontic tooth movement (OTM).

Surgical and non-surgical techniques were introduced to increase OTM. Non-surgical methods for OTM acceleration were assessed in a systematic review (Low-level laser therapy (LLLT), resonance vibration, pulsed electromagnetic waves, pharmacological methods, etc.), and only two studies had met the inclusion criteria of having parallel design using a vibratory device with a very low level of evidence of effectiveness. They recommended further well-designed, rigorous randomized clinical trials (RCTs) to determine whether non-surgical interventions could effectively reduce orthodontic treatment duration [3].

Gkantidis et al. showed that based on low- to moderate-quality of evidence, corticotomy and low-intensity laser therapy can increase the canine retraction rates during the first month and in a period longer than 3 months, respectively [4].

LLLT was shown to improve angiogenesis by up-regulating chemical mediators such as vascular endothelial growth factor (VEGF) [5], facilitate the proliferation and differentiation of osteoclast and osteoblast cells [6], and accelerate OTM [1,7–12]. However, regarding some clinical studies, LLLT had no positive effect on the rate of OTM [13–15]. Besides, Chung et al. reviewed animal and human studies and found conflicting results regarding photobiomodulation effect on the rate of OTM [16]. Imani et al. observed that the rate of OTM in the LLLT group was progressively increased from day 21 until 4.5 months after the start of canine retraction, relative to the control group [17].

Al-Shahrani et al. reported that the low-level Ga Al As diode laser with a wavelength of 740–900 nm, energy density of 2.25–8 J/sq.cm, and 20–100 mW power output has positive effects on the rate of OTM [18]. Both of these reviews have emphasized the need for further studies to standardize the protocol and characteristics of laser used to accelerate the OTM.

Appropriate power density and exposure time are the most important factors to achieve the biological effect. One important issue that led to conflicting results is the lack of attention to the therapeutic window (Arndt Schulz's law) [19]. The effect of adjunctive interventions on OTM acceleration in previous systematic review studies was investigated. It was concluded that a low-energy laser of 5–8 j/cm^2 could accelerate the OTM in short term, although the evidence was of low quality [2].

On the other hand, some studies assessed light-emitting diode (LED) [20] devices' effect on de-crowding rate. An average 120% increase in the rate of de-crowding during the alignment phase was reported with an extra-oral device [21], and others found less positive effect, but meaningful with an intra-oral LED appliance named Orthopulse [22,23].

Specific objectives or hypothesis

There is an important debate in the choice of light sources between laser and LED. Lack of a high level of evidence in a parallel study design encouraged us to present a randomized controlled clinical trial to compare the effect of an intraoral LED device (Biolight®) and LLLT with a control group on OTM acceleration. The primary objective was to assess the rate of maxillary canine retraction, and the secondary objectives were to compare canine rotation and pain among the three experimental groups.

Materials and methods

Trial design

This study was designed as a randomized controlled clinical trial in a three-arm parallel setting to compare the conventional orthodontic treatment (control group) and photobiomodulation-assisted orthodontic treatment (LED and LLLT groups). The allocation ratio of experimental groups was 1:1:1.

Participants, eligibility criteria, and settings

The ethics committee approved this randomized controlled trial. After the purposes, risks, and benefits of the study were explained, informed consent was obtained.

Sixty patients who met the inclusion criteria from the orthodontics department of Hamadan university of medical sciences and its affiliated clinic were enrolled from June 2019 to February

Glossary

OTM orthodontic tooth movement
RCT randomized clinical trial
LLLT low level laser therapy
VEGF vascular endothelial growth factor
LED light emitting diode

2020. The inclusion criteria were as follows: 1) Patients scheduled for fixed orthodontic treatment of the upper arch with bilateral or unilateral extraction of the maxillary first premolar, followed by canine retraction; 2) Patients should have their teeth extracted at least three months before the beginning of canine retraction; and 3) The range of patient's age was from 15 to 30 years. The exclusion criteria were as follows: 1) Inappropriate periodontal health; 2) History of previous orthodontic treatment; 3) Systemic diseases which could affect the bone structure or density; 4) Long-term intake of non-steroidal anti-inflammatory drugs and hormonal supplements; 5) Pregnancy and Breastfeeding; and 6) Severe canine root dilacerations.

Randomization

Sixty patients were enrolled (M.B.) and assigned a therapeutic intervention (H.S.) using stratified block randomization method (according to gender and slot size). The size of the blocks was kept hidden. Someone outside the research team performed the randomization process. Sequentially numbered containers generated the random allocation sequence. Therapeutic interventions were placed in opaque envelopes.

Interventions

MBT system brackets with 0.022 × 0.028-inch slots (Ortho Technology, Lutz, USA) or Roth system with 0.018 × 0.030-inch slots (Dentaurum, Ispringen, Germany) were used for the patients based on clinician's preferences. After the completion of levelling and alignment, a 0.019 × 0.025-inch stainless steel wire (Dentaurum, Ispringen, Germany) for the patients with the MBT bracket system and 0.016 × 0.022-inch stainless steel wire (Dentaurum, Ispringen, Germany) for the patients with Roth system was used for canine retraction phase. A 6-mm nickel-titanium closed-coil spring (Ortho Technology, Lutz, USA) was used for canine retraction. The springs were activated using a ligature wire to exert a force of 150 grams. The force was adjusted at each visit. The anchorage was reinforced by trans-palatal arch or bonding maxillary second molars, if necessary. Alginate impressions (Kulzer, Hanau, Germany) were made for each patient at baseline and monthly thereafter until the end of canine retraction. The obtained models were scanned with an Emerald scanner (Planmeca, Helsinki, Finland), and three-dimensional (3D) models were prepared for each patient.

LED Group

An intraoral LED device named Biolight®, similar to Orthopulse®, with a wavelength of 640 nm, energy density of 10 j/cm^2, and 40 mW/cm^2 power density was used (*figure 1*). The inner part of the device has 2 pairs of diodes bilaterally located, irradiating the buccal surface of the canine and extraction site. At the beginning of canine retraction, the patients were educated to use the device for maxillary dental arch 5 min/day.

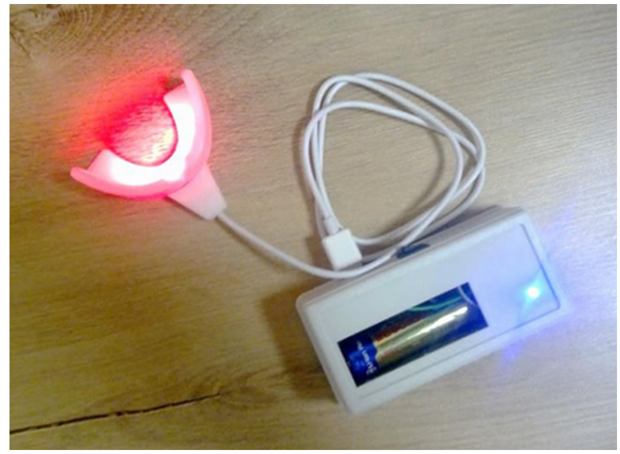

FIGURE 1
The intra-oral LED device (Biolight®)

LLLT Group

LLLT is performed using a Cheese II dental diode laser device (Wuhan Gigaa Optronics Technology Corporation, Wuhan, China). Ga Al As diode laser was used with a wavelength of 810 nm and a power of 100 mW. The diameter of the laser tip was 3.1 mm, and the energy density was 4 j/cm^2. LLLT was performed on days 0 (at the beginning of canine retraction), 3, 30 and, 60. The laser was irradiated to 3 points on the buccal and 3 points on the canine's palatal surface (cervical, mid-root and apical), 3 seconds each point.

Outcomes (primary and secondary)

The measurements of canine retraction and canine rotation were performed by Dolphin Imaging software version 11.9 (Patterson Dental Supply, Chatsworth, USA). At first, 3D models were oriented alike. Midpalatal raphe (MPR) was drawn as a reference line, and then the rugae line (RL) was drawn perpendicular to MPR from the medial end of the third palatal rugae [24]. The canine retraction was measured by the distance from the tip of the canine to RL in millimeters at different time intervals. The angle between the line connecting the mesial and distal edges of canine and the MPR in occlusal view was considered as canine rotation (*figure 2*).

The patient-centred outcomes were recorded with a modified McGill pain questionnaire, along with a visual analogue scale [25]. In the first session, all patients received the questionnaire and were asked to fill it out and bring it back on the next appointment. The questionnaire included questions about the onset of pain, description, locality, duration, intensity, triggers, and analgesic consumption following orthodontic appliance placement.

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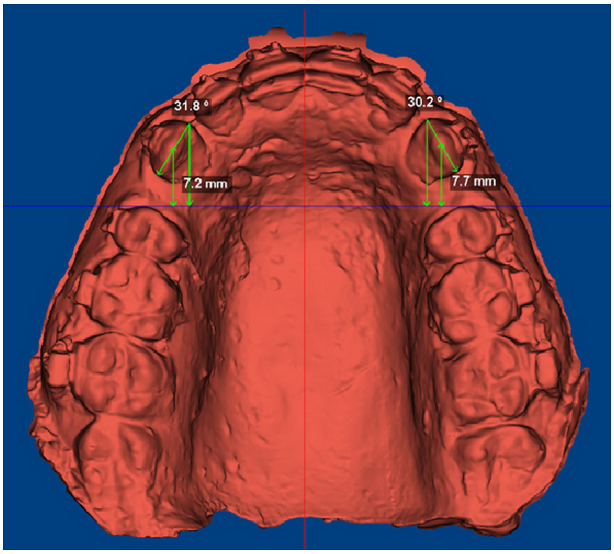

FIGURE 2

Method of measuring the amount of canine retraction and rotation

Blinding

The final data were anonymous for the outcome assessor and statistical consultant. Patients in the control group received placebo treatment as the laser group protocol, using a coated light cure device.

Statistical analysis

Due to the limited studies in the field of LEDs, the sample size calculation was performed based on a study in the field of laser [1]. Below equation was used to sample size calculation:

$$N = \frac{\left(Z_{1-\frac{\alpha}{2}} + Z_{1-\beta}\right)^2 * \sigma^2 * 2 * [1 + (T-1)\rho]}{\gamma^2 T}$$

Where N is the sample size in each group ($N = 18$), σ is the standard deviation of the outcome variable (mean rate of OTM) ($\sigma = SE * \sqrt{n} = 0.004 * \sqrt{18} = 0.018$), T is the number of follow-up measurements ($T = 3$), ρ is the average correlation coefficient of the repeated measurements ($\rho = 0.8$), and γ is the difference in mean value of the outcome variable between the two groups (laser-control). Also, significant level set on a 5% level and a power of 80%.

The smallest difference in the mean rate of OTM between the two groups that will be significant in this study is about 0.014 mm/day or 0.42 mm/month. Therefore, this power analysis shows that the number of participants ($N = 18$) to run our study is an appropriate sample size with the power about 80%.

The study data were collected and analysed using Statistical Package for the Social Sciences (SPSS) software version 24 (SPSS Inc., Chicago, USA). Because the study coincided with the Covid-19 pandemic, some patients did not attend their last visit as scheduled, and as a result, the time intervals of the patients were not the same. Due to the time intervals' inequality, the mean comparisons of the rate of canine retraction and canine rotation among the three groups were performed using the linear mixed model. Modified McGill questionnaires were analysed using the Chi-Square test except for VAS question, which was analysed with Kruskal-Wallis nonparametric tests. To evaluate the reproducibility of results, the measurements were carried out by two observers. Due to the high inter-examiner correlation (intra-class correlation coefficient = 0.97), one set of the measurements of two observers was used for subsequent analysis. The present manuscript was written in compliance with CONSORT Checklist.

Results

Patient characteristics

Sixty patients which included 14 males (23%) and 46 females (77%) with a mean age of 21.7 ± 5 years were randomly allocated to the test groups (laser, $n = 20$/LED, $n = 20$) and control group ($n = 20$). Patient recruitment began in June 2019 and ended in February 2020.

The groups were statistically homogeneous in terms of age ($p = 0.84$), gender ($p = 0.40$), and the number of patients in

TABLE I

Descriptive data of the patients.

Variables	Laser group ($n = 17$)	LED group ($n = 19$)	Control group ($n = 20$)
Age (mean ± SD)	20.9 ± 5.5	21.7 ± 4.2	22.7 ± 5.3
Gender			
Male	2	5	6
Female	15	14	14
Retraction			
Unilateral	8	8	7
Bilateral	9	11	13
Bracket system			
MBT	11	16	19
Standard	6	3	1
Number of cases			
T1	17	19	20
T2	17	19	20
T3	17	17	18
T4	8	8	2

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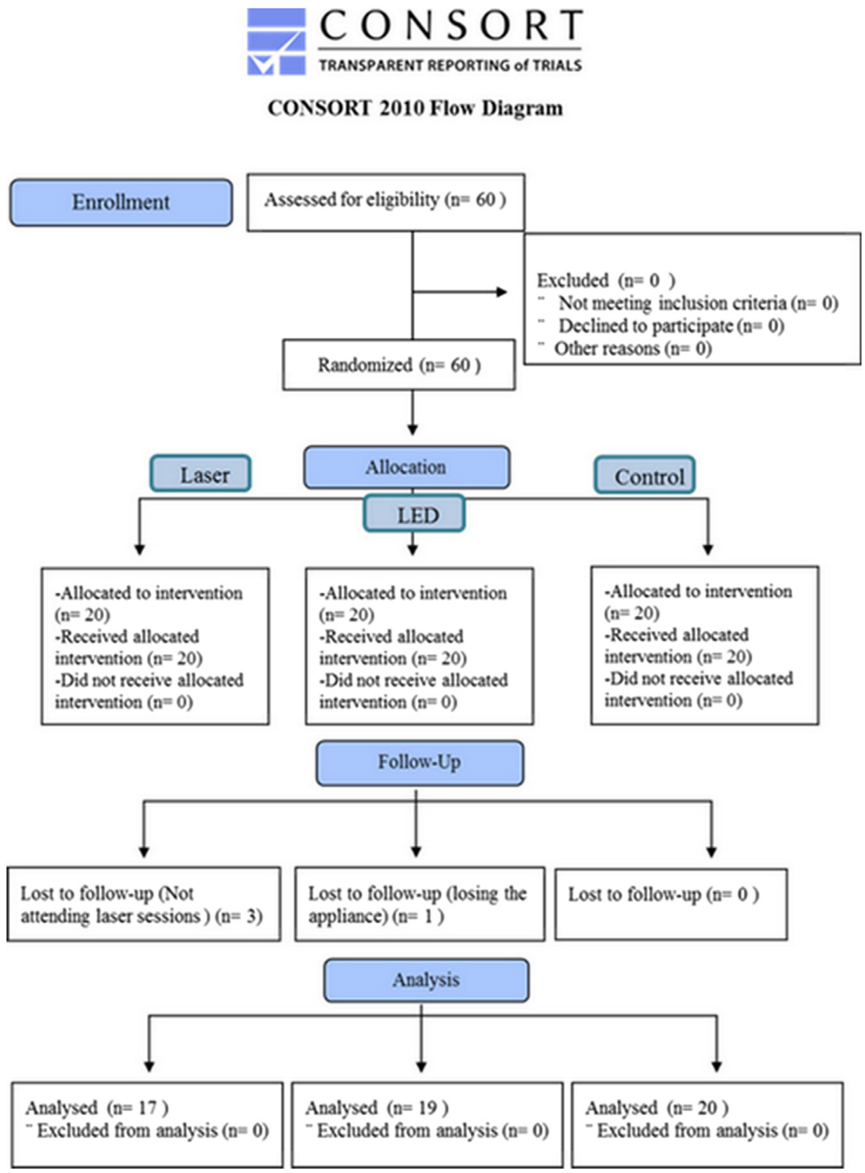

FIGURE 3
Consort flow diagram

different experimental groups at each time interval (p = 0.61). The baseline demographics and clinical characteristics for each experimental group were presented in *table I*. In 33 patients, the retraction was bilaterally performed, in which both sides were included in the statistical analysis. The MBT system brackets with 0.022 × 0.028-inch slots were used for 49 patients, and the Roth system brackets with 0.018 × 0.030-inch slots were used for 11 patients, which their distribution among groups was homogenous (p = 0.13). The patient follow-up period was until the end of canine retraction. 4 patients were lost to follow-up due to losing the LED device (n = 1) and not attending laser sessions (n = 3). Finally, the results of 56 patients were analysed (*figure 3*). No harm or negative effects due to LLLT or LED were observed during the study.

Outcomes

Estimation of the results of linear mixed model fitting of the rate of canine retraction is presented in *table II*. The rate of canine

TABLE II
Estimation of the results of linear mixed model fitting of the rate of canine retraction.

Parameter	Estimate	Std. Error	*P* value	95% Confidence Interval	
				Lower Bound	Upper Bound
Intercept	.034	.009	.001	.015	.054
LED group	.005	.003	.150	−.001	.012
Laser group	.014	.004	.000	.006	.022
Control group	Reference category	Reference category	–	–	–
Gender = Male	.001	.004	.752	−.006	.009
Gender = Female	Reference category	Reference category	–	–	–
Side = Right	−0.003	0.003	0.313	−0.008	0.003
Side = Left	Reference category	Reference category			
Bracket.sys = MBT	.000	.004	.829	−.007	.009
Bracket.sys = Standard	Reference category	Reference category	–	–	–
Age	-.000	.000	.052	−001	.000

TABLE III
Mean rate of orthodontic tooth movement in experimental groups (mm/day).

Group	Mean (mm/day)	Std. Error	95% Confidence Interval	
			Lower Bound	Upper Bound
LED	.029	.004	.022	.037
Laser	.037	.004	.030	.045
Control	.023	.004	.016	.031

retraction was significantly higher in the laser group than the control group ($p = 0.004$); the former indicated a 60.8% increase in the rate of OTM as compared with the latter. This variable is also higher in the LED group than the control group by 26%, but it was not statistically significant ($p = 0.17$). Mean rate of orthodontic tooth movement in experimental groups is shown in *table III*.

According to *figure 4*, in T1–T2 and T2–T3 the rate of canine retraction in the LED and laser groups was higher than the control group. However, in T3–T4, the rate is higher in the control group, but it should be considered that only the information of two patients in the control group was examined. The canine rotation during retraction was not significantly different between the laser ($p = 0.94$) and LED groups ($p = 0.45$) compared with the control group.

Gender and bracket system did not affect the rate of canine retraction and canine rotation (*table IV*). After fitting the linear mixed model, age significantly affected the OTM rate as a covariate ($p = 0.04$). It was estimated that for every 5 years of aging, the rate of OTM decreases by 0.1 mm/month.

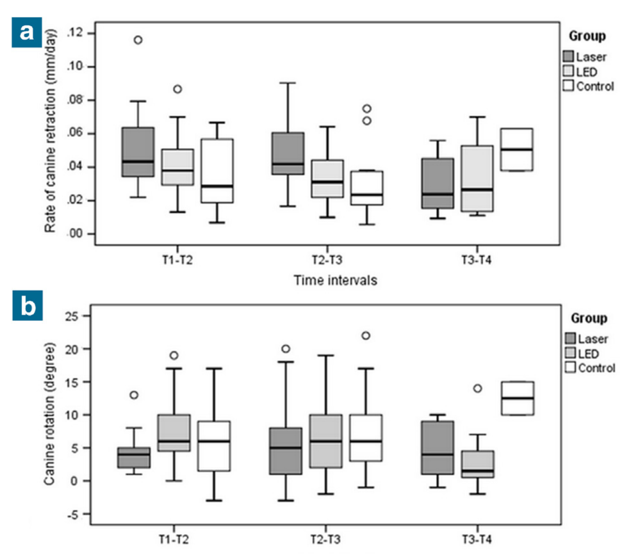

FIGURE 4
Box Plots show the mean rate of canine retraction (a), and canine rotation (b) between the experimental Groups. The dots represent the outlier values

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Table IV
The results of linear mixed model fitting of the angle changes during canine retraction.

Parameter	Estimate	Std. Error	*P* value	95% Confidence Interval	
				Lower Bound	Upper Bound
Intercept	.228	.073	.003	.083	.374
LED group	.023	.028	.399	−.032	.079
Laser group	.002	.031	.935	−.060	.065
Control group	Reference category	Reference category	–	–	–
Gender = Male	.001	.029	.966	−.058	.060
Gender = Female	Reference category	Reference category	–	–	–
Side = Right	−.009	.017	.596	−.044	.025
Side = Left	Reference category	Reference category			
Bracket.sys = MBT	−.009	.032	.770	−.074	.055
Bracket.sys = Standard	Reference category	Reference category	–	–	–
Age	−.003	.002	.129	−.008	.001

Age (p = 0.55) and gender (p = 0.39) did not affect pain onset, its description, locality, duration, intensity, and triggers. Based on the VAS ranging from 0 to 10, the pain level after canine retraction reached an average of 3.1 ± 2.4 in the laser group, 4.3 ± 2.4 in the LED group and 3.5 ± 2.1 in the control group. No difference was observed among the three groups in pain intensity (p = 0.45) and other parameters.

Discussion

The objective of the present RCT was to assess the effect of an intraoral LED device and LLLT on the rate of canine retraction compared to the control group. Unlike the previous studies, the present research was designed in a parallel setting to reduce the risk of bias. Besides, the canine movement was measured relative to RL [24], which is more reliable than dental references like molars. Measuring the rate of canine retraction [1,7,14], at which the tooth moves through the alveolar bone, appears to be a more relevant study design than the rate of de-crowding [22,23,26] in the anterior region.

The present study results showed that the rate of canine retraction in the control group (0.69 mm/month) was similar to that reported in conventional techniques, which is from 0.5 to 1 mm/month [27]. The rate of canine retraction was significantly increased by 60.8% in the laser group similar to previous studies which have shown that LLLT could accelerate OTM from 17 to 102% [1,7–12]. A systematic review conducted in 2020 indicated that the majority of RCTs related to accelerating OTM used wavelengths from 780 to 830 nm [28], which is comparable to our study with 810 nm.

A correct irradiance and exposure time are of the utmost importance to obtain positive biological effects as it has a biphasic dose-response (Arndt-Schulz curve). Due to Arndt-Schulz law, low dosages stimulate and high dosages inhibit the biological responses. It seems to be upper and lower thresholds in which LLLT is effective. Outside these thresholds, the light is either too weak to have any effect or so strong which its harmful effects outweigh its benefits [19].

In a study which conducted by Yassaei et al., Ga Al As laser with a wavelength of 980 nm was applied on days 0, 7, 14, 21, and 28 of each month. They did not find a significant difference in the rate of canine retraction between the laser and control sides [29]. Limpanichkul et al. used LLLT with a wavelength of 860 nm, a power of 100 mW, and an energy density of 25 j/cm^2. They did not find any difference in the rate of canine retraction between the laser and control sides [14]. Dominguez et al. used a 670 nm laser in their study. They found that only on day 30 from the start of premolar retraction, the higher rate was shown on the laser side than on the control side, but there was no difference between two sides at other time intervals [30]. These negative results may be due to overexposure, the upper limit of the selected wavelength, or related to parameter controls in each study.

The rate of canine retraction in the LED group increased by 26% compared to the control group, which was not significant. In our LED device (Biolight®), emitting light had a wavelength of 640 nm, energy and power density were 10 j/cm^2, and 40 mW/cm^2 respectively, and the emitting protocol was 5 min/day. Two studies investigated the effect of a similar intraoral LED device named Orthopulse with a wavelength of

850 nm. One of the studies used the device with an energy density of 9.5 j/cm^2 for 3.8 min/day [22] and the other used it with an energy density of 0.065 j/cm^2 for 5 min/day [23]. They concluded that LED with mentioned settings nearly reduced alignment phase duration by 50%. We used 640 nm LED instead of 850 nm, however power density was set around 40 mW/cm^2 as Shaughnessy et al. study. It can be concluded that wavelength may be a more important parameter than power density. Lo Giudice et al. used a multi-panel extra-oral LED device with a combined wavelengths range from 480–835 nm called ATP38 to compare the de-crowding rate in the two groups of LED and control. In this device, every 14 days, light irradiation was performed for 3 cycles of 6 minutes and the teeth received a total energy density of 144 J/cm^2, and as a result, the duration of treatment in the LED group was significantly reduced compared to the control group [31]. Positive results from above mentioned studies may indicate a different response to LED irradiation in two different study models, i.e., de-crowding versus canine retraction. During de-crowding, tooth movement occurs in the form of rotational and buccolingual movements, which requires minimum alveolar socket remodeling, but in canine retraction, the tooth moves through the alveolar bone, and light needs to penetrate to deeper parts of the alveolar bone, so the anterior teeth more easily affected by LED light during de-crowding relative to canine while retracted through the alveolar bone. Furthermore, the whole mandibular and/or maxillary dental arch was irradiated with LED light in all of the above studies, while in the present study, only the canine and premolar sites were irradiated. Biolight® LED devices were made in one standard size. Due to the difference in the size of the patient's dental arch, light sources may not be placed in their proper position and distance. It may be a reason why the optimal result was not achieved and can be solved by producing different sets of sizes.

In both the LED and control groups, the rate of canine retraction decreased in T2–T3 period relative to T1–T2 period with a similar gentle slope. Because of the extensive reduction of sample size at T3–T4, a reliable conclusion could not be possible. On the other hand, the canine retraction rate remained almost constant in the laser group from T1–T2 to T2–T3, so increasing laser application intervals may be plausible (*figure 4*) while the wavelength may need to be changed in LED group.

LED light on Biolight® devices were put on buccal side. If both buccal and palatal sides were irradiated, positive effects of LED on the rate of OTM may be increased. Due to dependence on the patient's cooperation in using LED device and the possibility of over or under treatment, it is recommended that a time recorder log or a temperature sensor be embedded in the devices to record the patient's compliance. Due to COVID-19 incidence during the study, some patients in all three groups were late for their treatment sessions, and the desired time intervals were not achieved.

LLLT and LED did not affect canine buccopalatal rotation during retraction. It might be due to the high quality of technical standards and good control of tooth movement. It is in line with the result of only one recent study which assessed the LLLT effect on canine rotation [15]. Photobiomodulation effect on pain quality was examined, and LLLT and LED had no effect on perceived pain during treatment which was similar to the result of previous studies [8,13,32].

If orthodontic treatment duration was reduced from 30% to 50%, most of the orthodontists would be willing to use non-invasive methods to increase the rate of OTM [33]. Further research with appropriate wavelength of 850 nm LED devices seems to be conclusive.

Conclusions

In the present study conditions, LLLT appeared to be effective in accelerating OTM by 60%, but the LED could not increase the rate of OTM significantly. During retraction, no difference in canine rotation was observed in either group. It was estimated that for every 5 years of aging, the rate of OTM decreases by 0.1 mm/month. The patient-centred outcomes revealed that LLLT and LED did not affect perceived pain during treatment. Due to these results, photobiomodulation can be considered a promising therapeutic tool for orthodontic treatment.

Disclosure of interest: The authors declare that they have no competing interest.

Consent to participate: after the purposes, risks, and benefits were explained, informed consent was obtained from all individual participants included in the study.
the study was approved by the Ethics Committee of Hamadan University of Medical Sciences (IR.UMSHA.REC.1398.079) and registered in the Registry of Clinical Trials available at http://www.irct.ir (identifier: IRCT20120220009086N4).

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Sharing Protocol: the study data set can be shared after hiding patients' identities. The access period starts 3 months after the results are published and lasts up to 20 years. The preferred way to communicate is via email.

Contribution: Nasrin Farhadian: Conceptualization, Methodology, Investigation, Resources, Writing-original draft, Supervision, drafting the article or revising it critically for important intellectual content, final approval of the version to be submitted.
Amirfarhang Miresmaeili: Conceptualization, Methodology, Formal analysis, Investigation, Resources, writing-original draft, Supervision, drafting the article or revising it critically for important intellectual content, final approval of the version to be submitted.
Mozhde Borjali: Validation, Formal analysis, Investigation, Resources, Data curation, Writing-original draft, Project administration, drafting the article or revising it critically for important intellectual content, final approval of the version to be submitted.
Hana Salehisaheb: Validation, Formal analysis, Investigation, Resources, Data curation, Writing-original draft, Writing-review and editing, Project administration, drafting the article or revising it critically for important intellectual content, final approval of the version to be submitted.
Maryam Farhadian: Formal analysis, Writing-original draft, drafting the article or revising it critically for important intellectual content, final approval of the version to be submitted.

Loghman Rezayi Soofi: Methodology, Investigation, drafting the article or revising it critically for important intellectual content, final approval of the version to be submitted.
Sara Alijani: Investigation, Resources, drafting the article or revising it critically for important intellectual content, final approval of the version to be submitted.
Sepideh Soheilifar: Investigation, Resources, drafting the article or revising it critically for important intellectual content, final approval of the version to be submitted.
Homa Farhadifard: Investigation, Resources, drafting the article or revising it critically for important intellectual content, final approval of the version to be submitted.

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