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RESEARCH

Effect of 850 nm LED irradiation on the alignment of crowded mandibular anterior teeth: a randomized controlled clinical trial

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Abstract

Introduction This study aims to determine if intraoral 850 nm LED irradiation could reduce the duration of lower anterior crowding alignment.

Methods In a parallel-designed, randomized controlled clinical trial 60 patients with 2 to 6 mm of lower incisor crowding who need non-extraction treatment, were randomly assigned to the intervention and control groups by block randomization (36 females, 24 males, mean age: 19.93 ± 3.05). MBT brackets (0.022 × 0.28-inch) were bonded for both groups and the NiTi wires in sequences were put in place until correction of crowding. The intra-oral LED device with a wavelength of 850 nm and power density of 70 mW/cm^2 was used for 5 min per day in the intervention group. The control group did not receive any light. The primary outcome was the duration of crowding correction. The patient's pain according the modified McGill pain questionnaire was the secondary outcome. The Cox regression model was used to compare groups. Mann–Whitney test was used for pain analysis.

Results The crowding at baseline was the same between the two groups ($P > 0.05$). Duration of treatment in the intervention group was 104.7 days (95% CI: 95.6 -113.8) and significantly shorter than 161.9 days (95% CI: 151.5 -171.2) in the control group. The control group experienced a significantly higher pain score of 6.8 (95% CI: 6.1–7.5) immediately after archwire placement than the intervention group 5.4 (95% CI: 4.6–6.3).

Conclusions Intra-oral LED 850 nm significantly decreased the relieving time of lower incisor crowding by up to 36% and reduced pain experience.

Keywords Orthodontics · Low-Level light therapy · Malocclusion · Crowding, fixed appliances, efficiency, curing lights · Pain

Introduction

Long duration of orthodontic treatment is often associated with patient discomfort, decreased level of cooperation, and increased risk of complications such asalveolar bone resorption, dental caries, and root resorptions [1]. Various biological, physical, biomechanical, and surgical methods have been proposed to decrease the duration of orthodontic treatment [2]. Surgical interventions, vibrations, and photobiomodulations (PBM) have been evaluated in this era [2, 3]. Despite predictability and stable results from surgical procedures, they are not popular because of their cost and invasiveness [2]. Vibration did not show significant efficacy [4]. Therefore, attention has turned to methods based on the laser and red/near-infrared light known as PBM.

Two main light sources are often used for PBM, namely low-level lasers and light-emitting diodes (LEDs). The basic principle of light production is the same in both [5]. The main difference and often discussed superiority of lasers over LED lights is the coherence [6]. When coherent laser light interacts with tissue, small imperfections in the

Protocol: The protocol was not published before trial commencement.

Highlights
1- LED device with 850 nm light could be effective in accelerating tooth movement
2- Adherence to the proper therapeutic window has the utmost importance
3- Different stages of OTM may have different responses to photobiomodulation

Extended author information available on the last page of the article

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light beam appear which are known as “laser speckles.” These speckles with less than one micron in diameter in visible light, are better able to stimulate subcellular organelles (such as mitochondria) than non-coherent LED light, therefore laser irradiation increases the mitochondrial metabolism. It induces angiogenesis in the skin, bone, muscles, nerves and enhances wound healing [7]. However, opponents believed that light coherency is lost when it propagated through the tissues and the speckle’s photobiology effect may be negligible. They also insist that based on the 1st law of photochemistry which denotes "light must be absorbed to induce a chemical reaction" the intensity rather than its phase plays a critical role in low-level light therapy and spatial coherence is not useful [8].

In contrast, several systematic reviews are available regarding the effect of low-level laser therapy (LLLT) on accelerated orthodontic tooth movement (OTM). Gkantidis et al. 2014 showed that low laser therapy is associated with accelerated orthodontic tooth movement in canine retraction over 3 months or longer [9]. However, Long could not find evidence to support this idea in less than one monthbut suggest week evidence for accelerated OTM in two and three months [10]. YI in a systematic review of systematic reviews reported that LLLT was effective in promoting OTM in the short term (1–3 months) with low-quality of evidence [11]. Al Shahrani et al. reported a significant difference between the LLLT compared to the control group on the accelerated OTM [12]. Finally, Hernandez et al. through a meta-analysis found that there is no evidence to support the use of LLLT to accelerate tooth movement [13]. In all of the above reviews, it has been insisted that the results need caution to generalize in clinical practice due to the large heterogeneity across the studies. Further high-quality trials to determine the optimal protocols and standard guidelines have been suggested.

Although there is no systematic review regarding the LED effect, in a few trials with limitations, it was shown that LEDs can decrease treatment time of crowding. Kau studied the LED effect on anterior crowding with an extra-oral LED device. Shaughnessy in a preliminary study, however, showed the efficacy of the LED on anterior crowding with intra-oral device remains to be ascertained in a controlled clinical trial [7, 14, 15].

The present study was designed to assess the effect of an intra-oral 850 nm LED irradiation on the relief of crowded mandibular anterior teeth.

Materials and methods

This study was conducted at the Orthodontics Department of the School of Dentistry of Hamadan University of Medical Sciences from September 2021 to June 2022.

Trial design

A prospective randomized controlled clinical trial was conducted in which the intervention group received intra-oral LED irradiation and the control group received no intervention during orthodontic treatment to relieve mandibular anterior crowding. The results were reported by the Consolidated Standards of Reporting Trials (CONSORT) [16]. In addition, the Cochrane risk of bias tools was considered to increase the quality of the methodology of this trial [17]. For example, since participants were aware of interventions the assessors were kept blind to the outcome.

Participants, eligibility criteria, and settings

The inclusion criteria were: (I) age between 15 to 25 years (II) permanent dentition requiring fixed orthodontic treatment (III) non-extraction orthodontic treatment plan (IV) Little’s irregularity index ≥ 2 mm and ≤ 6 mm (mandibular anterior crowding) (V) acceptable periodontal health (VI) good oral hygiene [18, 19].

The exclusion criteria were: (I) any sign of periodontal disease (II) craniofacial syndromes (III) receiving any medications affecting bone metabolism (such as corticosteroids) and (IV) bracket detachment if not replaced within 2 weeks.

Interventions

After enrollment, Little’s irregularity index (in millimeters) was calculated twice, on the initial casts of all patients by a trained operator unaware of the group allocation (T1). A digital caliper (Mitutoyo, Japan) 150 mm with 0.01 mm accuracy was used for measuring it. Eligible patients were randomly assigned to the intervention and control (no intervention) groups. The intervention group received an intra-oral LED device specifically designed and fabricated by members of the study’s bioengineering team (Fig. 1). After oral hygiene instructions, MBT brackets (0.022×0.028, ortho-technology, Lutz, USA) were bonded to the teeth in both groups. Preformed arch wires were put in place starting from 014 NiTi followed by 016 and 018 NiTi sequentially. All patients visited on a one-month recall basis. After placement of the NiTi 018, they were visited at a two-week interval until complete alignment of mandibular anterior teeth (irregularity index 0 -1 mm). The patients in the intervention group were asked to use the LED device for 5 min per day at bedtime. The power of the emitted light measured by a power meter (PM100D; Thorlabs Optical) showed 50 mW/cm^2 at a minimum distance from the device. The patients were asked to charge the device once every 2 days and record the days of not using the device and the reason. Also, they were requested to fill out the VAS

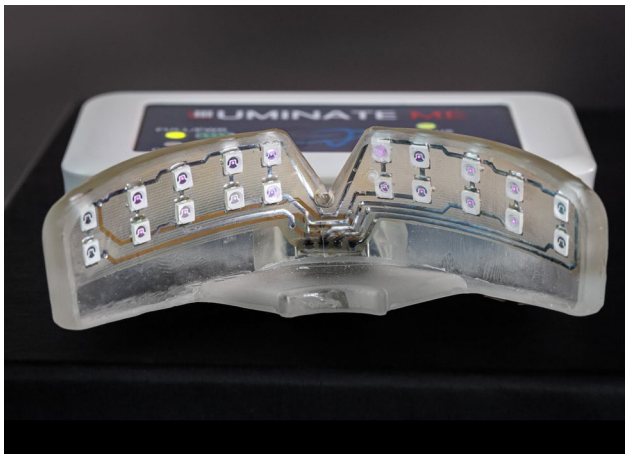

Fig. 1 The intra-oral LED device

questionnaire for pain records immediately after the 1st archwire placement. At the end of the study (T2), an occlusal photograph was obtained from the mandible to record and ensure correction of crowding to less than 1 mm.

Outcomes (primary and secondary)

The primary outcome was the duration of aligning mandibular incisors with and without using the intra-oral LED device. The secondary outcome was pain experienced in each of the two groups.

Sample size calculation

According to a previous study the mean difference in duration of crowding relief between the two groups was found to be 20 days, and the standard deviation 27 days [20]. Assuming the study power of 80%, the minimum sample size was calculated to be 30 in each group.

Interim analyses and stopping guidelines

No interim analyses were performed, and no stopping guidelines were established.

Randomization

Block randomization randomly assigned the patients to the intervention and control groups. Six possible combinations of four participants, two controls (C), and two Interventions (I) were prepared, written on six different cards, and put on separate envelopes. One of the envelopes that might be: "IICC, ICCI, CCII, CICI, ICIC, or CIIC was randomly selected by someone not involved in the study. Considering the gender, the order of participants was accordingly assigned to the intervention or control group until four participants entered the study and then the card returned to the envelopes pool.

Blinding

This study had a single-blind design. The operator who measured the irregularity index and the statistician who analyzed the data were blinded to the group allocation.

Statistical analysis

Data were analyzed by SPSS version 25 (SPSS Inc., IL, USA). The mean and standard deviation of the duration of treatment (in days) and the magnitude of crowding at baseline were calculated and reported for the two groups. The Cox regression model analyzed the effect of gender, age, the magnitude of crowding at baseline, and study groups on the duration of orthodontic treatment for correction of crowding of mandibular anterior teeth. The VAS pain scores were compared between the two groups by the non-parametric Mann–Whitney test due to the non-normal distribution of data. The Chi-square test was applied to compare the two groups regarding gender distribution. The level of significance was set at 0.05.

Results

Participant flow

Patient selection and allocation are demonstrated on the CONSORT flow diagram (Fig. 2). The sample consisted of 60 orthodontic patients in two equal groups of intervention and control. Of 30 patients in the LED group, two patients were lost to follow- up, one due to not being willing to use the LED device and another one due to an accident and trauma to the teeth and lips. There is no difference between intervention and control groups regarding sex and age distribution ($p = 0.75$ and $p = 0.06$ respectively). In addition, the mean baseline crowding was not significantly different between the two groups ($p = 0.15$) (Table 1). The intra-class correlation coefficient for the operator was 96% in the assessment of the primary crowding.

Outcome (primary and secondary)

Primary outcome

Relief of crowding occurred in a significantly shorter time (up to 36%) in the LED group (104.71 ± 24.63 days, 95% CI 95.59–113.84) in comparison with the control group (161.93 ± 27.25 days, 95% CI 151.53–171.20, $p < 0.001$) (Fig. 3).

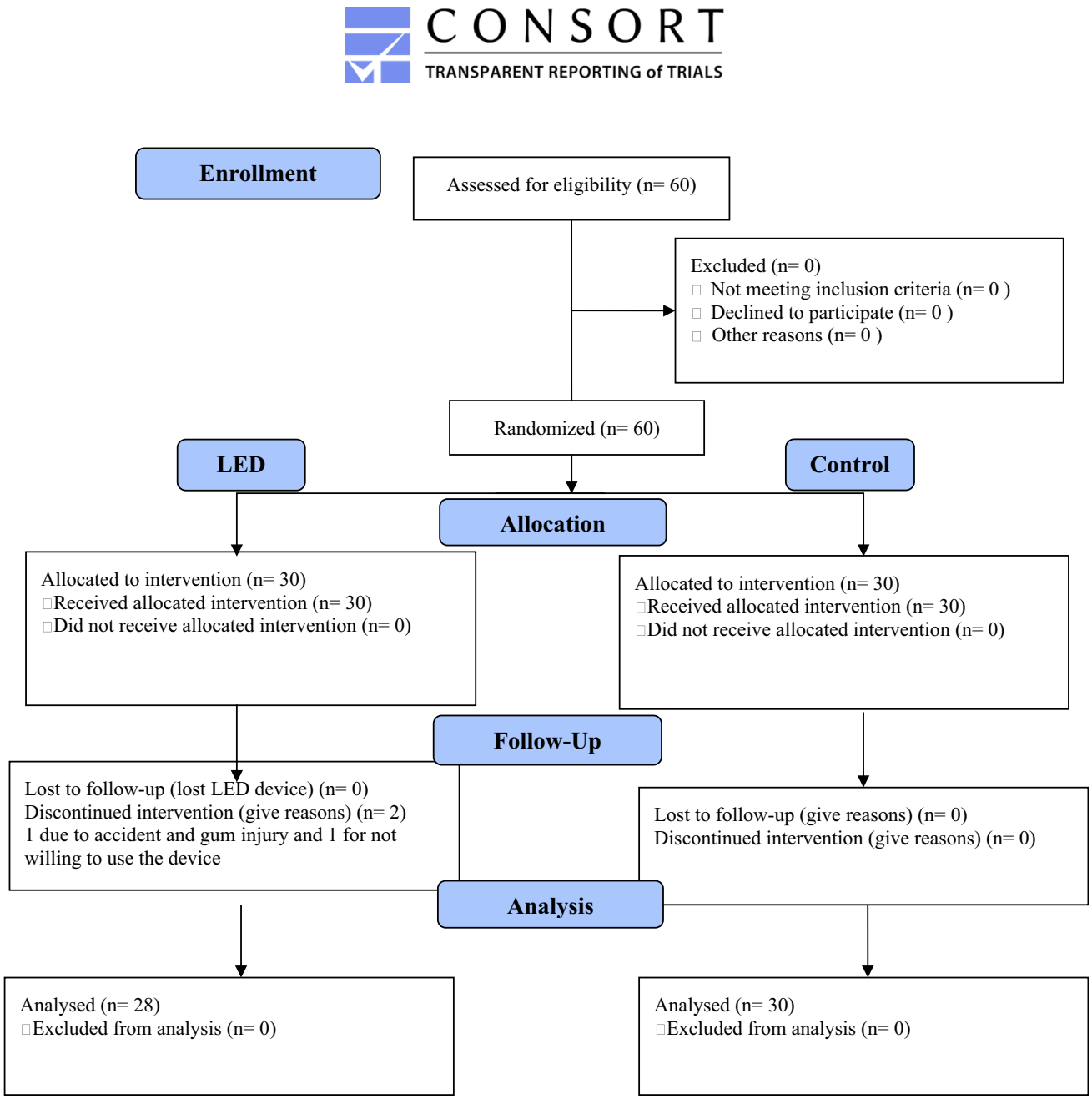

Fig. 2 CONSORT flow diagram of patient selection and allocation to the groups

Table 1 Descriptive information of intervention and control group

	Intervention	Control	*P* value
Crowding (mm)			
Mean(SD)	4.2(0.88)	3.89(0.77)	0.15
Gender			
Female	17 (%61)	17 (%57)	0.75
Male	11 (%39)	13 (%43)	
Age (Years)			
Mean(SD)	19.14 (3.01)	20.67(2.95)	0.06

The speed of crowding relief (millimeter per month) increased by about % 41 in intervention relative to the control group (Table 2).

The regression model showed that gender ($p < 0.75$) and age ($p < 0.79$) had no significant effect on the duration of orthodontic treatment. However, the degree of crowding at baseline had a significant effect on the duration of treatment, such that a higher degree of initial crowding prolonged the course of treatment ($p < 0.001$).

Kaplan–Meier analysis is used to estimate treatment effectiveness over time. The plot shows all of the crowding

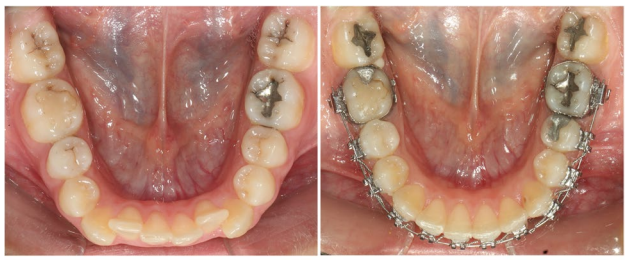

Fig. 3 Before (**a**) and after (**b**) occlusal photo of a patient in the LED group shows crowding reduction after 100 days

Table 2 Duration and speed of crowding relief in intervention and control group

	Intervention	Control	*P* value
Duration of treatment (days)			
Mean(SD)	104.71 (24.63)	161.93 (27.25)	< 0.001
Speed of crowding relief (mm/month)			
Mean(SD)	1.23(0.2)	0.72(0.11)	< 0.001

cases on the top left side and with each well-aligned case shift and step downward to the lower left corner in which all of the cases are completely aligned. A shift to the left and a more perpendicular shape of the LED group curve relative to the control group both show more rapid relief of crowding in the LED group. Complete relief of crowding was seen after 60 days in the LED group while it did not happen earlier than 120 days in the control group (Fig. 4).

The mean percentage of device utilization was 97%. The most common reason for not using the device was reported to be the holidays and trips.

Secondary outcomes

The VAS pain score decreased in both groups over time. The maximum VAS pain score experienced immediately after archwire placement was 5.43 ± 2.18 (95% CI, 4.58–6.27) in the intervention group, and 6.8 ± 1.99 (95% CI, 6.05–7.54) in the control group, which was significantly different according to Mann–Whitney U test ($p = 0.01$). Among all, 10.7% of patients in the intervention group, and 20% in the control group used analgesics for pain control.

Discussion

This study evaluated the impact of 850 nm intraoral LED irradiation on the alignment duration of crowded mandibular anterior teeth. The results showed that the duration of treatment was significantly shorter in the intervention group. In other words, PBM significantly increased biologic activities responsible for tooth movement and decreased the time required for orthodontic correction of the anterior crowding.

The therapeutic window is an important parameter related to the effects of PBM on OTM. The pattern and duration of exposure of tissues are highly important to achieve optimal biological effects because the response to light is in the form of a two-phase dose–response curve (Arndt-Schulz curve). Accordingly, by an increase in energy density, the biological effects increase and reach their peak. From this point on, with an increase in dosage, biological effects decrease, and even inhibition may appear. It seems that out of the range of the therapeutic window, the light is either too weak to have any significant effect or too strong, such that its adverse effects outweigh its benefits [21]. Then there is a challenge in determining appropriate light parameters, particularly its power density and wavelength for OTM [22, 23].

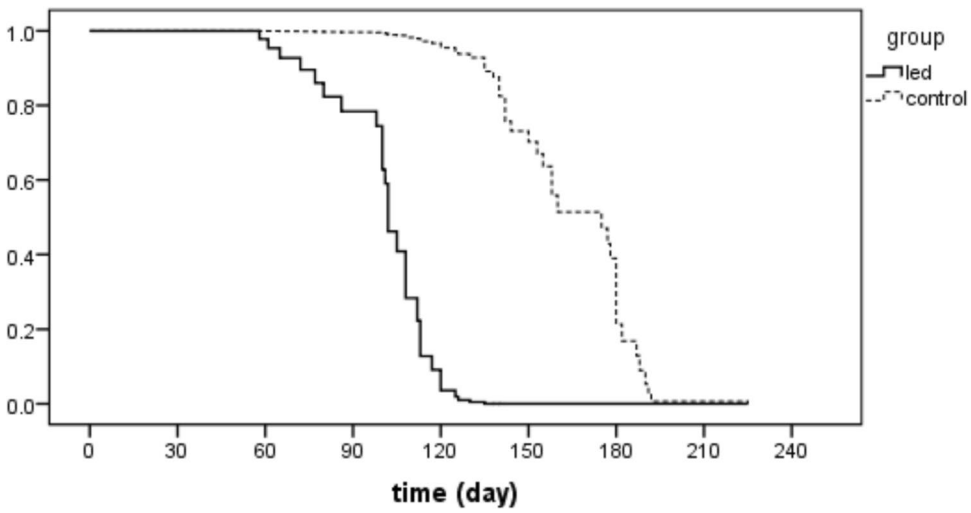

Fig. 4 Kaplan–Meier survival curves for two study groups. The plot shows the proportion of participants who are still in treatment on the y-axis over the time passed from the start of treatment on the x-axis crowding of the 1st case was relieved after about 60 days in LED group and after193 days in the last case in control group

Red and near-red wavelengths of light are the most effective as they penetrate tissues and promote cell proliferation and differentiation without being absorbed by hemoglobin [20]. Giudice et al. showed that a polychromatic device was effective for shortening the duration of decrowding after archwire placement [24]. Kau's application of a near-infrared extraoral LED irradiation at 850 nm and 60 mW/cm^2 resulted in a de-crowding rate nearly twice as fast as the control group, with rates of 0.49 mm/week in the control versus 1.12 mm/week in the experimental group [15]. Nahas et al. used a relatively similar extra-oral device and wavelength and power density of 90mW/cm^2 and found less benefit of LED (about 22% reduced time) for de-crowding of the lower anterior segment [20].

In a preliminary study, Shaughnessy et al. reported significant results with an intraoral LED device using continuous 850 nm wavelength and power density of 42 mW/cm^2 but on a non-randomized sample of 19 patients and a separate control group [7]. Since two different bracket systems have been used in this study i.e., self-ligating in the control group and conventional in the experimental group, they recommended using the same ligation system in future studies.

Ge et al. in a systematic review of LLLT and accelerated tooth movement found that a relatively lower energy density (5–8 J/cm^2) was seemingly more effective than 20–25 J/cm^2 [1]. The output power of the present device was 50 mW (Power density of 70 mW/cm^2) based on power meter measurement (Fig. 5). Patients are advised to use it for five minutes, generating an energy density of 15 J/cm^2. The single-size device provided to all patients may not perfectly conform to the gingival tissue, resulting in light energy attenuation due to the distance from the light source to the gingiva and the thickness of the overlying bone [25].

Our previous study with the intra-oral LED despite an acceptable energy density of 10j/cm^2, failed to demonstrate significant benefit for canine retraction due to the wavelength of 640 nm[26]. Additionally, it should be noticed that relief of lower anterior crowding with rotational and buccolingual movements of adjacent teeth within their alveolar sockets is different from canine retraction which usually requires bodily displacement of the single tooth through the bone. The effect of PBM may diminish as the tooth moves through the bone, as observed in our previous clinical trial and Al-Shafi's split-mouth study [26, 27]. Thus, the wavelength and energy density of light, along with the treatment phase, appear to influence PBM's outcomes on OTM.

Fig. 5 Optical power and energy meter (Thorlabs PM100D Germany)

The modified McGill Pain Questionnaire was used for pain assessment which is highly efficient and covers almost all aspects of pain such as type, duration, location, and intensity of pain, and the need for analgesics, and has high reliability [28]. The results of the present study revealed significantly lower pain scores in the intervention group by about 1.4 unit in VAS measuring scale. Li et al. in a systematic review of 11 randomized clinical trial showed that PBM by laser could reduce pain during orthodontic treatment in the most painful day by about 4.4 unit in VAS measuring scale [29].

Although there is no similar LED study, Sfordrini et al. after application of one dose of laser application, very similar to our LED prescription, found reduced pain after one and 12 h of band placement, but did not found significant effect on initiation, peak, and time of termination of pain [30]. Use of LED device in our study reduced the pain about one scale in VAS measuring scale, which is almost similar to the study by Sfondrini et al. Although effective, laser application may be more effective in pain reduction than LED during orthodontic tooth movement.

Generalizability

From the study design point of view, independent sampling in parallel groups using the randomized allocation gave the result of the present study the maximum possible generalizability. Two samples in the LED group were lost to follow-up, potentially jeopardizing generalizability. However, the intention-to-treat analysis showed no significant statistical effect.

Limitations

The most important limitation of our study was the inability to record the time log of the device. We rely solely on the patient's statements. Built-in time log recorders could be strongly efficient to show patient's compliance. Moreover, since one single-size device was used for all patients and the energy density of light is inversely related to the distance between the light source and target tissue, for better adaptation of the device more flexible designs or custom-made devices are recommended.

Conclusion

Intra-oral irradiation of 850 nm LED, five minutes per day significantly decreased the duration of aligning of crowded mandibular anterior teeth by about 36%. Additionally, it could lead to lower pain and discomfort experience.

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Author contributions N.F: Conceptualization, methodology, investigation, resources, writing-original draft, supervision, drafting the article or revising it critically for important intellectual content, final approval of the manuscript before submission. A.M: Conceptualization, methodology, data analysis, investigation, resources, writing-original draft, supervision, drafting the article or revising it critically for important intellectual content, final approval of the manuscript before submission. H.F: Clinical part of investigation, drafting the article or revising it critically, final approval of the manuscript before submitted. Z.B: Clinical part of Investigation, drafting the article or revising it critically, final approval of the manuscript before submitted. M.F: Statistical analysis, writing-original draft, drafting the article or revising it critically for important intellectual content, final approval of the manuscript before submitted. V.B: Construction of LED light source and calibration, drafting the article or revising it critically, final approval of the manuscript before submitted. Y.A: Project administration and management, data entry and data analysis, investigation, writing-original draft and editing draft and revising critically for submission.

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Declarations

Ethical approval The study was approved by the ethics committee of the university (IR.UMSHA.REC.1400.605) and registered in the Iranian Registry of Clinical Trials (IRCT20120220009086N5).

Informed consent Informed consent was obtained from all individual participants included in the study.

Conflict of interest The authors declare no competing interests.

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