

Article

Can Photobiomodulation Therapy Using an 810-nm Diode Laser Increase the Secondary Stability of Orthodontic Mini-Screws? A Split-Mouth Double-Blind Randomized Clinical Trial

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Abstract: Background: In orthodontic treatment, mini-screws can provide maximum anchorage conditions. If the miniscrew stability is compromised, this could jeopardize the outcomes of the orthodontic treatment or biomechanics. Photobiomodulation therapy (PBMt) is beneficial for biological tissues since it promotes wound healing with its anti-inflammatory and osteo-stimulatory properties. Objectives: The purpose of this study was to evaluate the effects of 810-nm Diode PBMt on the stability of orthodontic mini-screws for three months. Trial Design: Parallel, allocation ratio 1:1. Methods: Using a split-mouth technique, a total of 40 mini-screws were randomly allocated (1:1) to either a placebo laser application (P group) or a laser PBMt (L group). An 810-nm diode laser irradiation of 1 W output power, operating in continuous wave mode for 50 s, was applied in a sweeping movement at a 22 mm distance from the mini-screws. The allocated mini-screws first received PBMt at baseline, then every other day for five days, and then at each orthodontic visit (every three weeks) for a period of three months. At each visit, the stability of the mini-screws was measured by the Osstell Implant Stability Quotient (Osstell ISQ) at three points: lower, upper, and distal to the mini-screw. Results: The lower, upper, and distal ISQ values of irradiated and non-irradiated mini-screws significantly decreased at each point over time ($p < 0.001$). No significant difference was found in the global ISQ values between the laser and the placebo group ($p > 0.05$). Conclusion: PBM did not significantly increase the stability of orthodontic mini-screws over a period of three months. Trial Registration: Protocol was approved by the Research Ethics Committee of the Faculty of Dental Medicine of Saint Joseph University, Beirut, Lebanon University (#USJ/2019/161).

Keywords: low level laser therapy; photobiomodulation therapy; photobiomodulation; orthodontic mini-screw



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1. Introduction

Biomechanics is an important variable in the orthodontic equation. It includes both a biological element involving the tooth and its periodontium, and a mechanical element defining the force system. In fact, Newton's third law of motion, which defines the orthodontic movement, states that for every action (force) in nature there is an equal and opposite reaction. How does one counteract these reactive forces? It took until 1923 for the term "anchorage" to be defined by Louis Ottofy as "the base against which orthodontic force or reaction of orthodontic force is applied" [1]. Many anchorage systems have been developed since, but it was not until the introduction of skeletal anchorage as a source of fixed

anchorage to orthodontic treatment that many problems, including patient cooperation, were solved [2]. Mini-screws offer many advantages due to their small dimensions, such as: immediate loading, multiple placement sites including interdental areas, relatively simple placement and removal, and low cost. Mini-screws are used to assist and improve the efficacy of orthodontic treatments generally performed with conventional buccal or lingual appliances or aligners [3]. These clinical situations include intrusion of teeth, extrusion of teeth, correction of bite issues, space closure, and correction of asymmetries [4,5]. After loading, however, mini-screws can lose stability [6] or be displaced [7] over time. The literature shows different mini-screw success rates depending on the insertion site with the area of the palate showing the best results [8]. On the contrary, insertion between the roots has shown the lowest values [9]. Nevertheless, Park et al. showed that minimally mobile mini-screws remained clinically successful up to eight months after insertion [10]. In addition, upon loading, Al Maaitah et al. demonstrated that the alveolar bone density around mini-screws increased after three months [11]. For this reason, the considerations pertaining to the volume and density of bone are recognized as some of many critical aspects for achieving adequate stability, and consequently, long-term clinical success [12].

Therefore, measuring implant stability is necessary [13]. The two most commonly used tests to assess implant stability are the Periotest and the Resonance Frequency Analysis (RFA) performed by the Osstell ISQ (Implant Stability Quotient) because they have the least invasiveness and acceptable clinical accuracies [13,14].

Photobiomodulation therapy (PBMt) is a non-invasive remedy that implies the use of a non-ionizing electromagnetic energy that triggers photochemical reactions within cellular structures that are receptive to photons [15]. Mitochondria and light-sensitive ion channels are particularly receptive to this process [16]. The biostimulatory effects of PBM therapy have resulted in beneficial therapeutic outcomes including, but not limited to, the alleviation of pain, decrease of inflammation, immunomodulation, and the promotion of wound healing and tissue regeneration [17]. In the field of dentistry, several studies have investigated an increase in the stability of implants and bone-implant contact (BIC) factor following laser light application [18]. PBMt enhances the process of bone healing and increases primary stability [19]. In addition, it displays a biostimulatory effect on bone tissue by increasing proliferation and differentiation rates of osteoblasts accelerating bone formation and repair [20].

Primary stability is important for achieving successful immediate or early loading of dental implants [21]. Since orthodontic mini-screws are usually lost during the first weeks after loading [22], enhancing the overall stability of the mini-screw is an important step towards achieving successful therapy. A few animal and human studies have investigated the effect of PBMt on the stability of orthodontic mini-screws [11,19]. However, to our knowledge, none of the published studies have evaluated the effects of applying PBMt at each appointment while also measuring the primary stability of the mini-screws for up to three months.

Therefore, to investigate the PBM effectiveness of an 810-nm Diode laser wavelength, a split-mouth, double-blind, randomized controlled trial was conducted according to the CONSORT guidelines. The predictor variable was the ability of 810-nm PBM skills to modulate cell metabolism and homeostasis [23–27]. The primary endpoint was the induced increased stability of the mini-screws.

2. Materials and Methods

2.1. Study Design and Participants

Our double-blinded split-mouth randomized controlled trial (RCT) purposed to evaluate the effect of PBMt on the stability of orthodontic mini-screws during fixed appliance orthodontic treatment followed the CONSORT guidelines (Figure 1). The protocol was approved by the Research Ethics Committee of the Faculty of Dental Medicine of Saint Joseph University, Beirut, Lebanon, (#USJ/2019/161). The steps and purpose were thor-

oroughly explained to all subjects and written consent was signed by each of them before the procedure.

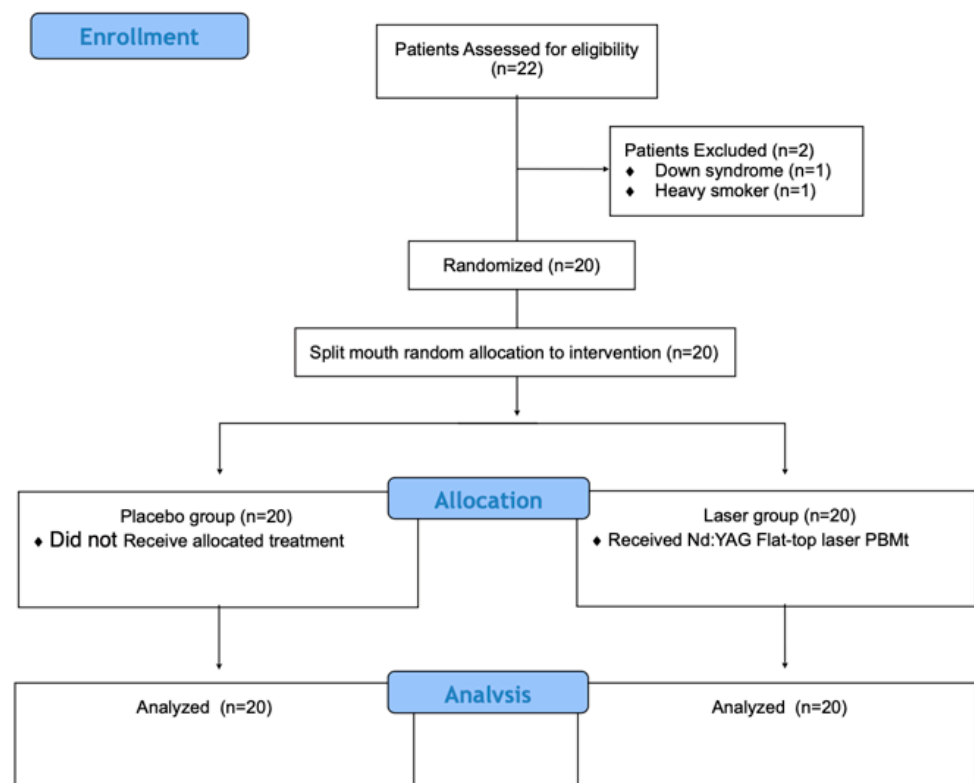


Figure 1. Flowchart illustrating participant enrollment, groups, and interventions.

The study involved the insertion of a total of 40 mini-screws in the maxilla according to the split-mouth technique. Twenty Caucasian patients (8 males and 12 females) with a skeletal and dental Class II relationship and a mean age of 22.9 years \pm 4.78 were recruited. After agreeing on a treatment plan, teeth alignment was achieved using Nitinol archwires (014, 016, and 16 \times 22 NiTi), followed by canine distalization on 17 \times 25 stainless steel archwires.

Mini-screws were inserted after the stainless steel arch wire was placed. Eligible patients were those needing orthodontics using two orthodontic mini-screws in the maxilla, non-smokers or light smokers (less than 10 cigarettes/day) with acceptable oral hygiene, and the presence of an attached gingiva for proper mini-screw insertion. Patients were excluded when failing to fulfil one of these criteria.

2.2. Randomization and Masking

Mini-screws were randomly allocated (1:1) by either a placebo laser application (P group) or by laser PBMT (L group). Randomization was based on a random-sequence program (www.random.org/sequences), accessed on 22 April 2021, where laser application was performed on the right side of the patients who were assigned an odd number, and on the left side of patients who were assigned an even number. On the contralateral side, the placebo application was performed for each patient.

The laser placebo consisted of photobiomodulation therapy irradiation with the device switched on 0 W [18]. A 632-nm visible red-light guide (negligible power) with the laser device switched to silent mode was used during all the irradiation in order to keep the therapies blinded [19]. Therefore, patients and study team members responsible for the administration of the treatment were masked in treatment allocation. The investigator responsible for statistical data analysis was also masked to treatment assignment.

3. Procedure

Regarding mini-screw insertion and stability measurements: 40 mini-screws M.O.S.A.S self-drilling 25M-16208 (Dewimed Medizintechnik GmbH, Tuttlingen, Germany) were inserted with an 8 mm length and a diameter of 1.6 mm using an implant motor with a 40 N torque. All of the mini-screws were positioned at a 90-degree angle in the attached gingiva, 1 mm below the mucogingival junction of the right and the left maxilla between the first and second premolar or the second premolar and first molar (Figure 2).



Figure 2. Mini-screw insertion.

The implant stability measurements were taken using the Resonance Frequency Analysis technique of the Osstell ISQ (W&H Dentalwerk GmbH, Bürmoos, Austria). Osstell's patented technology uses Resonance Frequency Analysis (RFA) measuring the frequency with which a device vibrates. By comparing resonance frequencies, the stability of a dental implant can be determined as the resonance frequency changes with different stabilities. The ISQ has a value between 1 and 100 and gives the surgeon an insight into the stability of the implant after placement. With the ISQ value, the surgeon can monitor the osseointegration. To use the Osstell ISQ on mini-screws, a special device was specifically designed and tested for this study. It had two sides: one side where the SmartPeg could be screwed, and another side where the head of the mini-screw was fixed (Figures 3 and 4).

Three ISQ measures were taken at baseline and at each appointment: lower, upper, and distal to the mini-screw (Figure 5).

To reduce the risk of bias, the mini-screw insertion and the stability measurements were performed by a well-qualified blinded periodontist (S.G).



Figure 3. Device designed to be fixed on the head of the mini-screw from one side and the SmartPeg from the other side.

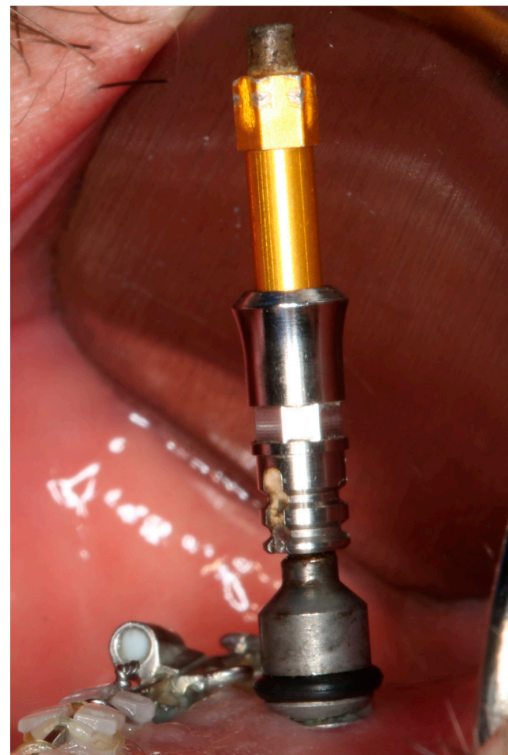


Figure 4. Device fixed on the mini-screw.



Figure 5. Stability measurement by the Osstell ISQ.

3.1. Laser Application

Each patient in this study underwent a laser application on one of the mini-screws and a placebo irradiation on the other in the following manner: first at the day of the implantation (T0) followed by every other day for five days at T0 + 2 days, T0 + 4 days, and at each orthodontic visit (every three weeks) for a period of three months at T0 + 3 weeks, T0 + 6 weeks, T0 + 9 weeks, and T0 + 12 weeks.

For the L group, the laser device employed in the treatment was an 810-nm diode laser (Picasso Lite; AMD lasers, Indianapolis IN, USA). The laser energy was applied in continuous wave mode with an output power of 1 W for 50 s and was used in a sweeping movement over the mini-screws. The diode laser delivery system was an optical fibre with a detachable non-initiated 400 μm quartz tip presenting a Gaussian energy distribution. The aiming beam was a low-power visible red semiconductor diode laser (632-nm, power < 5 mW) and was transmitted coaxially along with the optical fibre. The laser beam was positioned over the mini-screw head at 22 mm height, covering an area of 0.8 cm^2 , with a power density of 1.2 W/cm^2 , a total energy of 50 joules, and an energy density with a movement of 8.3 J/cm^2 . The speed of movement was 1 mm/s.

As for the P group, the irradiation through the placebo laser (0 W, 0 J/cm^2) was performed for 50 s.

The precision of the laser therapy parameter was secured by the Pronto-250 power meter (Gentec Electro-Optics, Inc., Québec, QC, Canada). Adverse events due to a possible undesirable thermal effect were avoided by monitoring the irradiation with a thermal camera FLIR ONE Pro-iOS (FLIR Systems, Inc. designs, Portland, OR, USA) (dynamic range: $-20\text{ }^\circ\text{C}/+400\text{ }^\circ\text{C}$; resolution 0.1 $^\circ\text{C}$). All laser safety measurements were respected in accordance with the American National Standards Institute (ANSI) guideline [18,20].

3.2. Orthodontic Intervention

At each orthodontic appointment, a hygiene level assessment was carried out, followed by tooth movement activation using well-controlled and identical forces on both sides. In fact, a dynamometer was used to measure the force delivered by the power chain, and when an open coil was inserted its length was calculated using the formula: inter-bracket

distance \times 1.5 mm. Force was measured to assure that the same intensity was used on both sides.

3.3. Outcomes

The predictor variable was the 810-nm PBM's ability to interact with the cellular target involved in the energetic metabolic metabolism. The primary endpoint was the induced increased stability of the mini-screws.

4. Data Analysis

The measurements collected were statistically analysed while taking into consideration the mean and standard deviation of the measured data and the statistical power of the sample size.

The statistical software of IBM SPSS Statistics (version 26.0, USA) was used to analyse the data. The Kolmogorov-Smirnov test was used to assess the distribution normality of continuous variables and the reliability by calculating the Cronbach's coefficient ($\alpha < 0.05$). To compare the ISQ (lower, upper, and distal) within times and between the presence or absence of laser treatment, repeated measurement analysis of variance (ANOVA) was used for within-subject comparisons.

This test was followed by univariate analysis and the Bonferroni multiple comparison test.

The level of significance was established at 95%. The value $p < 0.05$ was accepted as the significance level of the tests.

The sample size was calculated by G*Power Statistical Power Analyses Software version 3.1.9.7 [21]. The power analysis showed that to have a power of 80% with an effect size of ($d = 0.8$) and α error of 0.05, a sample size of 40 mini-screws for a within-subject study design was sufficient.

5. Results

5.1. Participants and Randomization

Between January 2020 and February 2021, 22 patients were screened for the study resulting in two patients being deemed ineligible: one patient had Down syndrome and the other was a heavy smoker. Consequently, according to the established inclusion/exclusion criteria, 20 Caucasian patients (8 males and 12 females) with a skeletal and dental Class II relationship and a mean age of 22.9 years \pm 4.78 participated in the study. The study followed a within-subject study design and the split-mouth technique; as such, two mini-screws were inserted in each patient: One was treated without laser (P group) and one was treated with laser (L group). This led to a total of 40 mini-screws (20 mini-screws per condition). A full subject medical history was obtained and a thorough oral examination was done prior to participation in the study. All twenty enrolled patients completed the treatments successfully. No adverse effects were reported.

5.2. Primary Outcome

Comparison of the Lower ISQ over Time with or without Laser

The mean and the standard deviation of the lower ISQ measurement after activation with and without laser are illustrated in Table 1.

5.3. Comparison over Time

After laser treatment, lower ISQ significantly decreased over time ($p < 0.001$), significantly decreasing between T0 and T1 by 7.5 u, then significantly decreasing between T1 and T2 by 2.8 u, then significantly decreasing between T2 and T3 by 5.4 u ($p < 0.05$). The difference, however, was not significant between T3 and T4 ($p = 1.000$).

Table 1. Variation of lower ISQ over time with or without laser treatment.

	N	Lower ISQ		p-Value
		With Laser	Without Laser	
T0: Baseline	20	64.90 ± 3.784 ^a	64.60 ± 3.658 ^a	0.904
T1: 3 weeks	20	57.40 ± 6.603 ^{a,b}	60.30 ± 5.478 ^{a,b}	0.247
T2: 6 weeks	20	54.60 ± 6.586 ^{b,c}	55.20 ± 5.051 ^{b,c}	0.809
T3: 9 weeks	20	49.20 ± 6.286 ^c	49.80 ± 6.989 ^c	0.819
T4: 12 weeks	20	49.10 ± 7.233 ^c	49.90 ± 6.471 ^c	0.748
p-Value		<0.001	<0.001	

a,b,c: letters that indicate the presence of a significant difference according to multiple comparisons.

Without laser, lower ISQ significantly decreased over time ($p < 0.001$), significantly decreasing between T0 and T1 by 4.3 u, then between T1 and T2 by 5.1 u, and then between T2 and T3 by 5.4 ($p < 0.05$). The difference, however, was not significant between T3 and T4 ($p = 1.000$).

5.4. Comparison between Treatments with or without Laser

The change in lower ISQ of laser-treated mini-implants was not significantly different than that of non-laser-treated mini-implants ($p = 0.920$; statistical interaction). The mean values of the lower ISQ were not significantly different between the presence and absence of laser, neither at baseline nor for the entire duration of the follow-up ($p > 0.05$).

The mean and the standard deviation of the upper ISQ measurement after activation with or without laser are illustrated in Table 2.

Table 2. Variation of upper ISQ over time with or without laser treatment.

	N	Upper ISQ		p-Value
		With Laser	Without Laser	
T0: Baseline	20	63.30 ± 2.869 ^a	64.10 ± 2.558 ^a	0.758
T1: 3 weeks	20	60.10 ± 4.383 ^{a,b}	61.20 ± 3.853 ^{a,b}	0.672
T2: 6 weeks	20	58.90 ± 5.820 ^{a,b}	57.50 ± 5.893 ^b	0.591
T3: 9 weeks	20	55.80 ± 5.959 ^b	56.80 ± 6.268 ^b	0.701
T4: 12 weeks	20	56.50 ± 4.905 ^b	57.30 ± 5.519 ^b	0.758
p-Value		0.010	0.008	

a,b,c: letters that indicate the presence of a significant difference according to multiple comparisons.

5.5. Comparison over Time

After laser treatment, the upper ISQ significantly decreased over time ($p = 0.010$), significantly decreasing between T0 and T1 by 3.2 u ($p < 0.05$), stabilizing between T1 and T2 ($p = 0.982$), then significantly decreasing between T2 and T3 by 3.1 u ($p < 0.05$). The difference, however, was not significant between T3 and T4 ($p = 0.998$).

Without laser, the upper ISQ significantly decreased over time ($p = 0.008$), decreasing significantly between T0 and T1 by 2.9 u, then between T1 and T2 by 3.7 u ($p < 0.05$). The difference, however, was not significant between T2, T3, and T4 ($p > 0.05$).

5.6. Comparison between Treatment with or without Laser

The variation of the upper ISQ of the mini-implants treated with laser was not significantly different than that of the mini-implants not treated with laser ($p = 0.955$; statistical interaction). In addition, the mean values of the upper ISQ were not significantly different between the presence and absence of laser at baseline and throughout the follow-up ($p > 0.05$).

5.7. Comparison of the Distal ISQ over Time with or without Laser

The mean and the standard deviation of the distal ISQ measurement after activation with or without laser are illustrated in Table 3.

Table 3. Variation of distal ISQ over time with or without laser treatment.

	N	Distal ISQ		p-Value
		With Laser	Without Laser	
T0: Baseline	20	65.60 ± 4.789 ^a	64.20 ± 3.795 ^a	0.590
T1: 3 weeks	20	56.20 ± 6.512 ^b	59.50 ± 5.817 ^{a,b}	0.208
T2: 6 weeks	20	54.70 ± 6.800 ^b	55.40 ± 4.904 ^{b,c}	0.788
T3: 9 weeks	20	48.60 ± 8.872 ^b	50.60 ± 6.653 ^c	0.443
T4: 12 weeks	20	50.60 ± 6.501 ^b	49.80 ± 5.653 ^c	0.758
p-Value		<0.001	<0.001	

a,b,c: letters that indicate the presence of a significant difference according to multiple comparisons.

5.8. Comparison over Time

After laser treatment, distal ISQ significantly decreased over time ($p < 0.001$), with the ISQ significantly decreasing between T0 and T1 by 9.4 u ($p = 0.027$). The difference, however, was not significant between T1, T2, T3, and T4 ($p > 0.05$).

Without laser, distal ISQ significantly decreased over time ($p < 0.001$), decreasing significantly between T0 and T1 by 4.7 u, then between T1 and T2 by 4.1 u, then between T2 and T3 by 4.8 u ($p < 0.05$). The difference, however, was not significant between T3 and T4 ($p = 0.997$).

5.9. Comparison between Treatments by Laser or Not by Laser

The variation of distal ISQ at the level of the mini-implants treated with laser was not significantly different than that of the mini-implants not treated with laser ($p = 0.689$; statistical interaction). The mean values of the distal ISQ were not significantly different between the treatment with or without laser at baseline and for the entire duration of the follow-up ($p > 0.05$).

5.10. Comparison of the Global ISQ over Time and with or without Laser

The mean and the standard deviation of the global ISQ measurement after activation with or without Laser are illustrated in Table 4.

Table 4. Variation of global ISQ over time with or without laser treatment.

	N	Global ISQ		p-Value
		With Laser	Without Laser	
T0: Baseline	20	64.60 ± 3.193 ^a	64.30 ± 2.782 ^a	0.874
T1: 3 weeks	20	57.90 ± 5.298 ^b	60.33 ± 4.391 ^{a,b}	0.203
T2: 6 weeks	20	56.07 ± 5.397 ^b	56.03 ± 4.206 ^{b,c}	0.986
T3: 9 weeks	20	51.20 ± 5.523 ^c	52.40 ± 5.615 ^c	0.527
T4: 12 weeks	20	52.07 ± 3.848 ^c	52.33 ± 3.833 ^c	0.888
p-Value		<0.001	<0.001	

a,b,c: letters that indicate the presence of a significant difference according to multiple comparisons.

5.11. Comparison over Time

After laser treatment, global ISQ significantly decreased over time ($p < 0.001$), significantly decreasing between T0 and T1 by 6.7 u ($p = 0.023$), stabilizing between T1 and T2 ($p = 0.909$), then significantly decreasing between T2 and T3 by 4.9 u ($p = 0.023$). The difference, however, was not significant between T3 and T4 ($p = 0.994$). Without laser, global ISQ significantly decreased over time ($p < 0.001$), significantly decreasing between

T0 and T1 by 4 u, then between T1 and T2 by 4.3 u, then between T2 and T3 by 3.63 u ($p < 0.05$). The difference, however, was not significant between T3 and T4 ($p = 1.000$).

5.12. Global Comparison between Treatments by Laser or Not by Laser

The change in global ISQ at the level of the mini-implants treated with laser was not significantly different than that of the mini-implants not treated with laser ($p = 0.842$; statistical interaction).

The mean values of the global ISQ were not significantly different between the treatment with or without laser at baseline and for the entire duration of the follow-up ($p > 0.05$).

Note that the lower, upper, and distal ISQ measurements were not significantly different from each other regardless of the follow-up time ($p > 0.05$).

6. Discussion

During the past few years, several animal studies dealing with the same subject have been conducted, and the results found have favoured the use of PBMt to increase mini-screw stability [27,28]. Human studies have also been conducted, but our study was the first to apply PBMt to assess the mini-screw stability for a period up to three months.

It is common knowledge that the stability of mini-screws decreases with time, especially in the first two weeks [29]. However, if the expected results are achieved, this stability decrease does not have a negative influence on the treatment. Instead, it is a physiological phenomenon that arises from several factors, among which immediate or delayed loading of the mini-screws can be cited. It has been suggested that immediate loading be performed because the primary stability of the mini-screw is sufficiently capable of fulfilling its clinical use [3,30]. In our clinical trial, we performed immediate loading, initially using light forces that were later increased progressively.

In fact, Derid Ure et al. demonstrated in their study that the stability of orthodontic mini-screws decreases during the first three weeks but then started to increase between weeks 3 and 5 [9]. Similarly, according to our results shown in Table 1, the stability of the irradiated and non-irradiated mini-screws decreased significantly up to two months post-implantation (T3 and T4) where the changes of ISQ values became non-significant, and the stability curve of mini-screws appears to stabilize. This observation was found interesting because the three-month treatment and follow-up represented the originality of our study. On a clinical basis, this finding could guide us in terms of force magnitude by indicating light forces for the first two months post-implantation to start and then continuing with higher increments in order to rule out one of the risk factors known to jeopardize the clinical stability of the mini-screw.

Furthermore, on the distal side of the L group mini-screws, another non-significant decrease of ISQ values were recorded between the third and twelfth weeks (T1 and T4) (Table 1). Knowing that the distal side of a mini-screw is opposed to the force applied, it is probably the one that undergoes most of the cellular changes and reactions. This is where the PBMt could potentially be the most effective.

Similarly, in the L group between the third and sixth weeks of post-implantation (between T1 and T2), both the ISQ values recorded on the upper side of the mini-screws and the global ISQ values stopped decreasing significantly. As mentioned above, the first week following mini-screw insertion, the PBMt was in fact performed every other day and then carried out after two weeks (T1) during the first follow-up appointment. This likely means that the effect of PBMt was maximal during this period and that this positively influenced the stability of the mini-screws. Hence, PBMt seems to follow this rule: the more, the better. Results favouring the use of PBMt with mini-screws could be obtained if laser applications are more frequent. However, this frequency may seem impractical since orthodontic appointments are normally scheduled every three to four weeks.

Our clinical trial showed no significant difference between the stability of irradiated and non-irradiated mini-screws. While several clinical studies have targeted the same

subject, different protocols were used, and different results have been found. In fact, a study by Maranon-Vasquez et al [31]. evaluated the effect of PBMt on the stability and displacement of mini-screws with immediate and delayed loading. Two types of lasers were used: a red emission laser with a wavelength of 660 nm that was applied only on the same day of implantation, and a second infra-red laser with a wavelength of 808 nm that was applied every two to three days for two weeks. This study included 35 mini-screws and showed a lower loss in stability than in the ones that received PBMt. Concerning mini-screw displacement, no statistically significant difference was found. The results of that study were not in accordance with ours, favouring the use of PBMt to increase mini-screw stability. In fact, they used two types of lasers. According to the same authors, the 660-nm wavelength laser was used immediately after the insertion of the mini-screw to enhance the healing of damaged tissue and to promote the initial inflammatory reaction. In the following days, the 808 nm wavelength laser was subsequently used because it had already been shown that PBMt boosts mini-screw bone healing during the intermediate postoperative period [32]. Another study by Matys et al. [33] used a diode laser at an 808 nm wavelength with an irradiance of 800 mW/cm² for a one-month period of PBMt. It measured the stability of the mini-screws for two months and found an increase after 30 to 60 days. These results proved the theory stating that better outcomes are obtained when a longer follow-up is carried out. The same result was obtained by Osman et al. [34] at a 910 nm laser wavelength with an average power not exceeding 0.7 W for 60s, by Matys et al. [35] in another study using a diode laser at a 635 nm wavelength, 100 mW and 20 J/cm², and by Ekizer et al. [36] using a LED at an irradiance of 20 mW/cm². In the literature, a large variability clearly exists among lasers, wavelengths, and energy densities [37]. In our study, an 810-nm diode laser wavelength at a power density of 1.2 W/cm², a total energy of 50 joules, and an energy density with movement of 8.3 J/cm² delivered with a Gaussian optical fibre beam profile were used. According to the literature, the use of PBMt in patients involves almost exclusively the red and near infrared portion of the electromagnetic spectrum (650 nm–1100 nm). This range of wavelengths, known as the optical window, is where the effective tissue penetration of light is maximized [31]. The effective tissue penetration of light and the specific wavelength of light absorbed by photo-acceptors are two of the major parameters to be considered in light therapy [16].

As discussed earlier, PBMt possesses an anti-inflammatory effect that can increase blood flow, stimulate metabolic activities, and accelerate the healing process [14]. In fact, Yanaguizawa et al. reported in their study high levels of interleukins-8 for non-irradiated mini-screws after 24 h, 48 h, and 72 h of implantation [38]. Matys et al. also concluded that PBMt applied during the early healing phase positively modulates the whole procedure and can improve mini-screw stability after one to two months [33]. This could explain why, in our study, the ISQ values of irradiated mini-screws were stable between T1 and T2.

On the other hand, results similar to ours were obtained by Abohabib et al. [39] and by a meta-analysis conducted by Chen et al. [40] to conclude on this subject. In fact, after analysing all the clinical trials that studied the effect of PBMt on orthodontic mini-screws, they found that the existing data are inconclusive, and that further high-quality human studies are required to obtain scientifically convincing and clinically applicable conclusions. According to this meta-analysis, the study designs of several studies were not highly satisfactory. In fact, it has been demonstrated that the effect of PBMt is related to the treatment protocol, which is why unsuitable protocols may decrease the treatment efficacy. In addition, the wide variety of diode laser wavelengths assessed is characterized by a Gaussian beam profile delivery and the obtained results were inconsistent due to a lack of standardization in the applied laser protocols and techniques. According to the Arndt Schulz curve, when the power density of the laser light is insufficient or is applied for a short period of time, no effect is found on the tissue. Likewise, when using a high energy density or when the time of exposure is long, an inhibitory effect takes place. Thus, the optimal effects are obtained when a balance between the power density and the time of application is found [16]. This may explain the positive outcomes at early stages.

PBMt does induce osteogenesis since it stimulates cell proliferation, vascularization, and osteoblastic activity [41–43]. In fact, in our study the laser therapy promoted the stability of the mini-screws; however, it was not statistically different when compared to the placebo group.

The inconsistency in laser protocol and parameters clearly exists among published studies. Hence, it would be interesting to conduct a comparative study on the effect of different PBMt protocols on the stability of orthodontic mini-screws to finally reach the best combination.

Limits of the presents study include the absence of comparison of different laser applications and a relatively short observation period. Future studies will be necessary after having considered the current study's findings.

7. Conclusions

Based on the orthodontic therapy and scientific approach of this clinical trial, we can conclude that PBMt did not significantly increase the stability of orthodontic mini-screws over a period of three months.

When considering the limitations mentioned above, new strategies could better guide future research on this topic.

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