

Rehabilitation of Atrophic Mandible with Ultrashort Implants Combined with Photobiomodulation Therapy: A Split-Mouth Design Study

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Abstract

Background: Atrophic edentulous mandible is a challenging clinical condition. Studies assessing the use of ultrashort implants to support overdentures are scarce; the optimum photobiomodulation (PBM) dose for enhancing osseointegration is yet unknown.

Objective: This study aimed to evaluate and compare mandibular overdentures assisted by two versus four ultrashort implants with adjunctive PBM therapy using two doses.

Materials and Methods: A total of 36 implants were placed in 12 edentulous male participants and they were randomly allocated to Group I (mandibular overdentures assisted by two ultrashort implants) or Group II (by four ultrashort implants). Fully guided implant placement was performed, and then a split-mouth design was implemented. The participants received PBM by diode laser (660 nm). Dose A (3.75 J/cm²) and Dose B (7.5 J/cm²) were applied to the right and left implant (s), respectively. Implant stability, peri-implant probing depth (PIPD), and modified gingival index (MGI) were evaluated at baseline, and at 6 and 12 months after loading.

Results: After 12 months, the implant stability values were significantly higher in Group II compared with Group I ($P < 0.001$). A significant difference was observed in between the PIPDs of both groups (Group I: 2.35 ± 0.54 mm; Group II: 1.69 ± 0.35 mm; $P = 0.001$). The mean MGI values were low for both groups (Group I: 0.75 ± 0.58 ; Group II: 0.51 ± 0.41).

Conclusions: Mandibular overdentures supported by four ultrashort implants had a more favorable clinical outcome, while PBM doses A and B were comparable in all evaluated parameters.

Trial Registration: ClinicalTrials.gov Identifier: NCT03540316.

Keywords: Atrophic mandible, implant stability, osseointegration, overdentures, photobiomodulation, short implants

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INTRODUCTION

Atrophic edentulous mandible presents numerous challenges. Extensive mandibular alveolar bone resorption

results in prominent internal oblique ridges and genial tubercles as well as high muscle attachments that elevate the denture during function. Subsequently, the retention and

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stability of the mandibular prostheses are compromised, leading to exaggerated movements, increased sore spots, and thus, impaired function.^[1] These result in deleterious effects on both physical and mental health, and therefore, dramatically impact the patient's quality of life and wellbeing.^[2,3]

Implant-supported overdentures have profoundly improved the clinical performance of removable dentures in terms of denture retention, support, stability, and chewing efficiency.^[4] Moreover, sore spots, pain, and bone loss are significantly reduced, leading to predictable outcomes and high success rates.^[4-6] However, in severely resorbed mandibular alveolar ridge, anatomical limitations such as the proximity of inferior alveolar canal complicates and prevents the placement of a standard-length implant (i.e., >8 mm in length).^[7]

Consistent with the current inclination toward minimally invasive approaches, short and ultrashort dental implants were introduced as a treatment modality in cases of vertical bone deficiency. The European Consensus Conference defined short implants as those with intra-bony length ≤ 8 mm and diameter ≥ 3.75 mm, and referred to ultrashort implants as those with <6 mm intra-bony length.^[8] The reliance on short implants has increased after substantiated evidence supported by biomechanical studies have revealed that short implants have high predictability because the crestal is the most involved part of the implant in the load-bearing,^[9-12] and thus, the length of implant may not be a primary factor in the failure of implants.^[13] The improved survival rate of short dental implants has been attributed to the enhanced surface structure that results in higher bone-implant contact. Subsequently, it has been suggested that with an optimized implant design and surgical protocol, short implants could offer long-term clinical success.^[14] In addition, a predictable treatment option can be offered by placing implants by means of computer-guided implant surgery. This process starts with the anticipated prosthetic outcome, in other terms, it is "prosthodontically-driven implant placement," in which the implant is inserted considering the appropriate angulation and position relative to the adjacent vital structures and underlying bone.^[15,16]

The therapeutic effect of low-dose biophotonics has been acknowledged in the recent decades. In this scenario, photobiomodulation (PBM) has been studied as a potential noninvasive and painless therapeutic modality to boost bone healing and implant osseointegration.^[17,18] PBM was shown to improve implant stability, as it can accelerate healing by promoting angiogenesis as well as enhancing

osteoblast proliferation.^[19,20] More evident bone maturation and increased bone-to-implant contact was found in sites treated with PBM compared to control sites.^[20-22] The plausible explanation for this is that PBM increases ATP synthesis and angiogenesis, processes that are involved in tissue healing, and in turn accelerates healing around the surgical site.^[18]

Considering the clinical performance, patient satisfaction, and cost, it is widely accepted that the two-standard length implant-assisted mandibular overdenture is the recommended treatment for most edentulous patients.^[23-26] However, there is no conclusive evidence on the use and the number of ultrashort implants required to support a mandibular overdenture. Moreover, despite evidence supporting the positive influence of PBM on bone healing, there is no standardized protocol for the application of PBM to promote dental implant osseointegration. Therefore, the purpose of this study was to assess and compare the implant stability and peri-implant soft tissue changes in mandibular overdentures assisted by two or four ultrashort implants. Furthermore, the influence of two PBM doses on implant stability was analyzed. The null hypothesis was that there would be no difference in implant stability and changes in peri-implant soft tissue between mandibular overdentures supported by two or four ultrashort implants and irradiated with two different PBM doses.

MATERIALS AND METHODS

The study protocol was approved by the Ethics Committee of Alexandria University, Alexandria, Egypt. The study was registered at ClinicalTrials.gov (Identifier: NCT03540316). The present study also complied with the CONSORT guidelines [Figure 1]. All participants provided written informed consent and agreed to participate in a postoperative control program for ongoing care and data collection.

Study design and participants

In this *in vivo* study, a total of 36 ultrashort implants (diameter 4 mm/surgical length 5.5mm; SuperLine, Dentium Co., Seoul, South Korea) were placed in 12 healthy completely edentulous male participants with a mean age of 55 years (range, 45–65 years) and who were suffering from denture soreness and poor retention of their conventional mandibular dentures. Participants were enrolled based on the following eligibility criteria: good general health (American Society of Anesthesia classification I); class I maxillomandibular relationship; bone height of 8 mm and minimum bone width

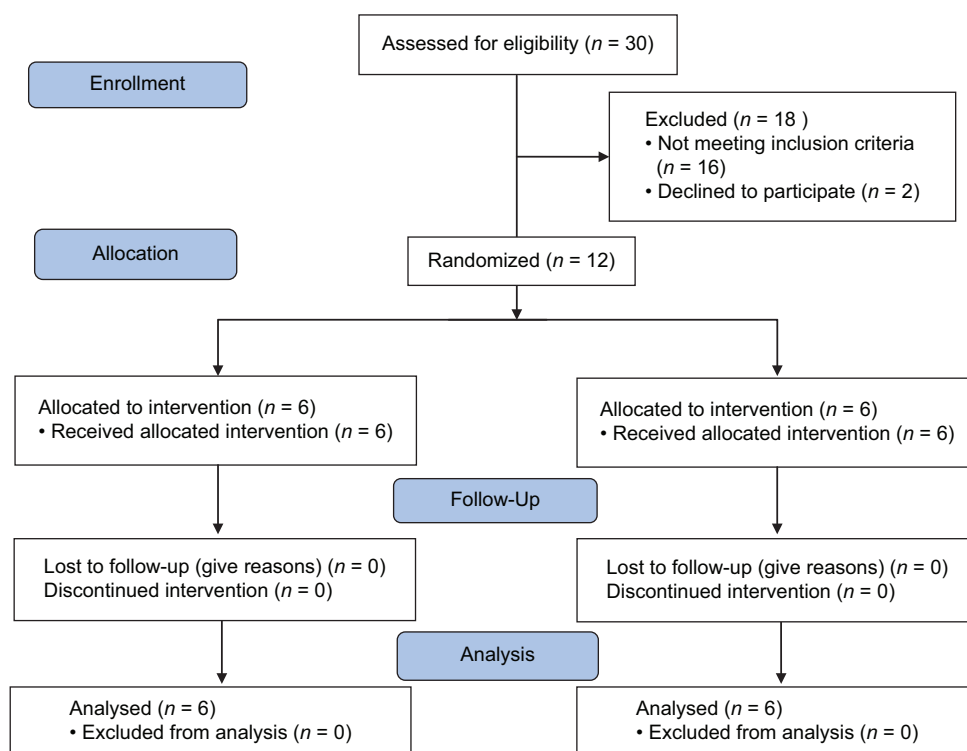


Figure 1: Patient recruitment flow diagram

of 7 mm [as measured on pre-operative cone beam computerized tomography (CBCT)]; healthy mucosa of at least 2 mm zone of keratinized mucosa. Exclusion criteria were presence of any systemic medical conditions that contraindicates implant placement, medication that may influence bone metabolism, radiotherapy in the head and neck region, osteoporosis, diabetes, history of drug/alcohol abuse, and smoking. Participants were assigned randomly to two identical groups (allocation ratio, 1:1): Group I received two ultrashort implants, while Group II received four ultrashort implants. Randomization was performed using a research randomizer (<https://www.randomizer.org>).

Procedure

All the participants received a new set of conventional complete dentures. Before implant placement, a customized stereolithographic surgical guide was constructed for each participant. The mandibular complete dentures were modified into radiographic templates by incorporating gutta percha point fiducial markers on three different planes. Dual scanning technique was used, such that two CBCT scans (Scanora 3Dx; Soredex, Helsinki, Finland) were taken: The first CBCT scan was of the patient wearing the radiographic template, and biting on inter-occlusal rigid silicone index in the correct occlusal position with the occlusal plane parallel to the axial slices. Using the same CBCT scanner settings and the same orientation

as in the patient's mouth, the second scan was done for radiographic template only. Then, the two scans were superimposed by the planning software (Blue Sky Plan; Blue Sky Bio, Grayslake, IL, USA) and used for virtual prosthetic-driven implant treatment planning and surgical guide planning [Figure 2]. A safety margin of 2 mm from the inferior alveolar canal was considered in the plan. Once the design process was completed, the data set were exported as an STL file and converted directly into the physical surgical guide by 3D printing (Form2, FormLabs Inc.).

At the time of surgery, the surgical guide was positioned in place guided by the maxillary denture and the interocclusal index, then fixed in place by three anchoring pins. Ultrashort implants were placed under local anesthesia by means of a flapless fully guided implant surgery using customized surgical guide such that the smooth/rough interface was at the bone level [Figure 3]. Group I participants received implants bilaterally in the canine area, and for group II, implants were inserted in the canine and second premolar areas. The surgical guide was removed after implant insertion, the primary stability of the implant was assessed by Osstell ISQ™ instrument (Integration Diagnostics Ltd., Gothenburg, Sweden), and then cover screws were fastened on the implants. Chlorhexidine 0.12% mouth rinse was prescribed 2 days preoperatively; it was used twice daily and continued postoperatively. Patients

were not allowed to wear the mandibular denture for 2 weeks after surgery, and later, the mandibular dentures were adjusted to accommodate the cover screws and the implants. The intaglio surface of the mandibular denture was relieved over the cover screw and filled with room temperature vulcanizing addition-type silicone soft-lining material (Acrostone; Dental and Medical Supplies, Cairo, Egypt). Participants were meticulously instructed on denture and oral hygiene measures.

Three months after implant insertion, the implants were exposed under local anesthesia by the same surgeon. Positioner abutments (Superline, Dentium Co.) of 2-mm transmucosal cuff height were screwed into the designated implants with an insertion torque of 10 Ncm. The mandibular complete denture was transformed into implant overdenture opposed by the pre-existing maxillary complete denture. The abutments were attached to the mandibular dentures by matching self-aligning stud attachments (Positioner, Dentium Co.) by means of a chair-side direct pickup of the female housings in the fitting surface of the denture using auto-polymerizing resin (Acrostone; Dental and Medical Supplies). The participants were instructed to leave the denture out at night, and oral and denture hygiene instructions were emphasized.

Immediately after the surgery completed, all the participants received PBM therapy by semiconductor diode laser (Sirolaser blue, Sirona Dental Systems GmbH, Bensheim, Germany). PBM irradiation parameters were as follows: wavelength, 660 ± 5 nm, continuous wave; power, 0.025 W; spot size, 0.8 cm^2 ; irradiance, 0.0312 W/cm^2 ; exposure duration, 120 and 240 seconds for subgroups A and B, respectively.

At this phase, split-mouth design was applied and each group was further subdivided into 2 subgroups: subgroup A was the right-side implant(s), received PBM dose A of 3.75 J/cm^2 (the standard settings of the device for healing, i.e., manufacturer recommendation); and subgroup B was the left side implant(s) (same patient), received PBM dose B of 7.5 J/cm^2 . The patients, the statistician, and the team collecting the data were blinded to the two different PBM doses. Participants were irradiated intraorally, in non-contact mode (2 mm) by a hand-held probe [Figure 4]. Laser sessions were repeated every 48 hours for a total of five sessions.

At the follow-up appointments, all measurements were recorded by a calibrated clinician blinded to the PBM doses. Peri-implant probing depth (PIPD) was measured by using

a pressure-sensitive calibrated periodontal probe (PDT sensor probes; DenMat, CA, USA). PIPD was measured at the mesial, distal, labial/buccal and lingual sites of each implant. Then, the mean record for each implant was calculated. It was measured at the time of prosthetic loading (baseline), and then at 6 and 12 months later.

To quantify the peri-implant inflammation, the modified Löe and Silness index was used. The modified gingival index (MGI) was measured and recorded as mentioned for PIPD. A score of 0 was considered as normal peri-implant mucosa; 1 as mild inflammation, slight change in color, and slight edema; 2 as moderate inflammation, redness, edema, and glazing; 3 as severe inflammation, marked redness, edema, and ulceration.

Resonance frequency analysis (RFA) was used to assess the process of osseointegration through the measurement of implant stability. RFA was done at baseline (i.e., when the implant was inserted), and then 6 and 12 months after prosthetic loading using the Osstell ISQ™ instrument, which does not compromise the healing process. Measurements were done for the mesial, distal, and labial/buccal sites and repeated until the same value was recorded twice. Then, the mean implant stability quotient (ISQ) values for each implant were calculated.

Statistical analysis

Statistical analysis was conducted with SPSS (version 23, Chicago, IL, USA). For descriptive analyses, means and standard deviations (SD) were calculated. Parametric tests were used. T-test was used for comparing groups I and II at each time point and paired-t test was used for comparing the two subgroups (A and B) of each group at each time point. One-way ANOVA was used to compare all the subgroups at each time point. Repeated measures ANOVA was used for comparing variables in each group/subgroup at different time points, followed by Bonferroni post hoc test ($\alpha = 0.05$). A linear regression analysis was also conducted to determine the regression coefficient of two potential factors at 6- and 12-month time points. The level of significance was at $P < 0.05$ and the confidence level was at 95%.

RESULTS

All participants completed the PBM sessions and the follow-up appointments. One year after loading, no implants were lost (i.e., a 100% implant survival rate). The mean values of implant stability are shown in Tables 1 and 2. At the 6-month recall appointment, group I showed 4.8 times significantly lower implant

stability than group II ($P = 0.009$). The implant stability of dose A (3.75 J/cm^2) was insignificantly less ($P = 0.35$) by 1.5 times than dose B (7.5 J/cm^2). After 12 months, the implant stability of group I was significantly less than that of group II by 4.9 times ($P < 0.001$). Nevertheless, there was an insignificant decrease ($P = 0.62$) in the implant

stability values with dose A compared with dose B at both observation time points [Tables 3 and 4].

The mean scores for the investigated clinical parameters are depicted in Tables 1 and 2. The PIPD after 6 months for group I was 0.5 times significantly higher than that of group II ($P < 0.001$). Likewise, it was 0.8 times significantly greater for group I after 12 months ($P < 0.001$). Nonetheless, there was no significant difference in PIPD between the two different PBM doses at the investigated time intervals. The MGI scores at the 6-month follow up were insignificantly higher for group I and dose A compared with group II and dose B, respectively. After 12 months, the MGI scores were 0.6 times significantly higher for group I ($P < 0.001$), but there was no significant difference ($P = 0.08$) between dose A and B [Tables 3 and 4].

DISCUSSION

This study found that overall, the peri-implant conditions were mainly healthy: after 12 months of functioning, the recorded mean values of PIPD were $<3 \text{ mm}$ and the MGI mean scores were <2 . Nonetheless, at 12 months, the ISQ and peri-implant soft tissue changes in mandibular overdentures assisted by four ultrashort implants were significantly better than those with two ultrashort implants; thus, the null hypothesis was rejected. The difference may be because overdentures supported by two implants are predominately mucosa supported and present a rotational hinge axis, causing lever arms and bending moments, while those supported by four implants are placed in an optimal anterior–posterior spread and provide a non-rotational support area.^[27]

It is worth mentioning that the mean values of the evaluated parameters in the two ultrashort implants group were well

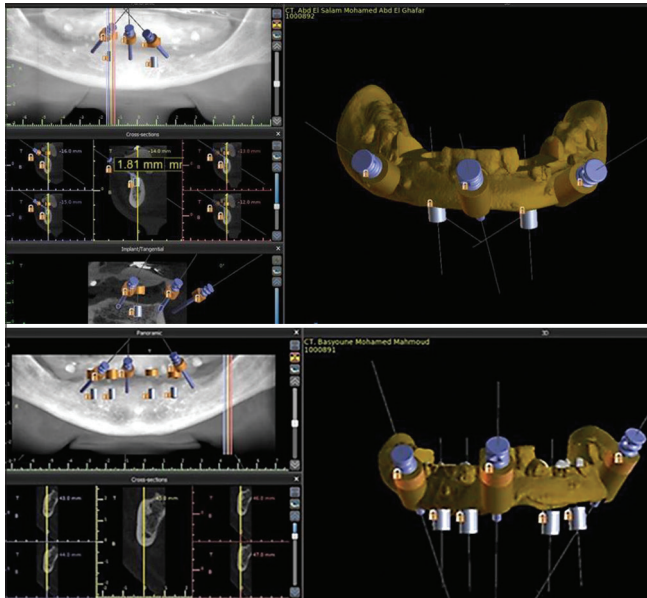


Figure 2: Super-imposition and guide planning for two and four implants

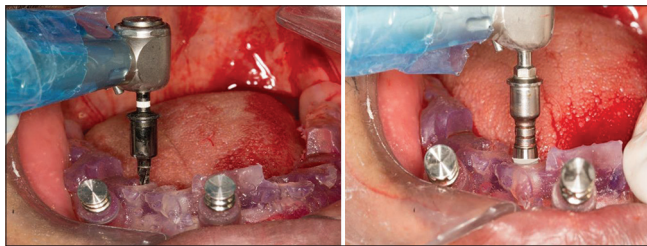


Figure 3: Osteotomy preparation and final implant seating through the surgical guide

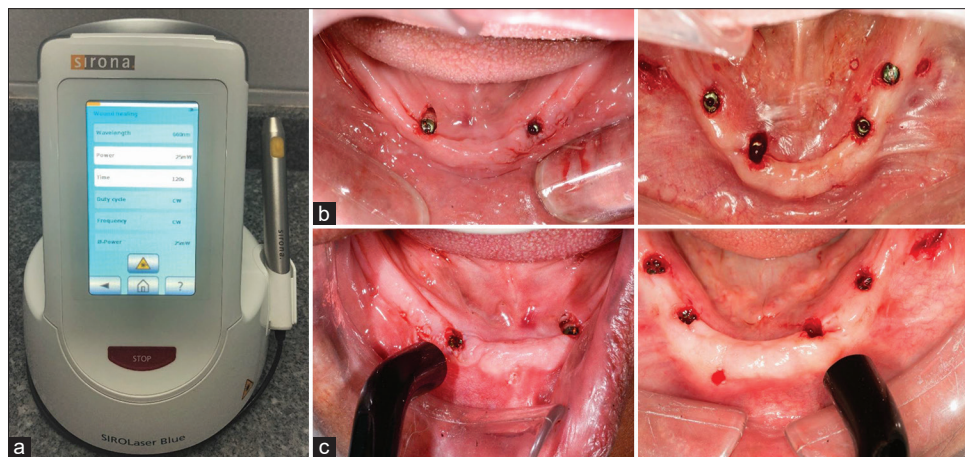


Figure 4: (a) PBM device settings (b) Group I, implants were inserted bilaterally in the canine area, and Group II in the canine and second premolar area (c) PBM therapy irradiated intraorally

Table 1: Comparison of implant stability, peri-implant probing depth and modified gingival index between Group I and Group II

Parameters	Mean±SD		t-test (P)
	Group I	Group II	
Implant stability			
Baseline	67.53±7.05	69.85±5.60	1.07 (0.29)
6 months	70.58±4.76	77.72±2.76	4.81 (<0.001*)
12 months	69.92±3.62	77.08±2.87	6.48 (<0.001)
Mean difference (6 months from baseline)	3.06±5.80	7.88±4.38	2.79 (0.009*)
Mean difference (12 months from baseline)	2.39±6.84	7.24±4.48	2.56 (0.04*)
Repeated measures ANOVA (P)	1.84 (0.18)	69.59 (<0.001*)	
PIPD			
Baseline	1.00±0.24	1.10±0.34	0.93 (0.36)
6 months	1.85±0.43	1.46±0.36	2.85 (0.007*)
12 months	2.35±0.54	1.69±0.35	3.88 (0.001*)
Mean difference (6 months from baseline)	0.85±0.31	0.36±0.22	5.46 (<0.001*)
Mean difference (12 months from baseline)	1.35±0.42	0.59±0.22	7.21 (<0.001*)
Repeated measures ANOVA (P)	99.31 (<0.001*)	107.62 (<0.001*)	
MGI			
Baseline	0.00±0.00	0.00±0.00	N/A
6 months	0.75±0.58	0.51±0.41	1.43 (0.16)
12 months	1.19±0.51	0.55±0.38	4.19 (<0.001*)
Mean difference (6 months from baseline)	0.75±0.58	0.51±0.41	1.43 (0.16)
Mean difference (12 months from baseline)	1.19±0.51	0.55±0.38	4.19 (<0.001*)
Repeated measures ANOVA (P)	32.53 (<0.001*)	35.71 (<0.001*)	

*Statistically significant at $P < 0.05$. PIPD – Peri-implant probing depth; MGI – Modified gingival index; NA – Not available; SD – Standard deviation

Table 2: Comparison of implant stability between photobiomodulation Dose A and Dose B

Parameters	Mean±SD		t-test (P)
	Dose A	Dose B	
Implant stability			
Baseline	68.67±6.48	69.48±5.91	0.39 (0.70)
6 months	74.17±4.50	76.52±5.07	1.47 (0.15)
12 months	73.83±4.30	75.56±4.87	1.13 (0.27)
Mean difference (6 months from baseline)	5.50±6.80	7.04±3.34	0.86 (0.40)
Mean difference (12 months from baseline)	5.17±7.06	6.07±4.25	0.47 (0.64)
Repeated measures ANOVA (P)	10.20 (<0.001*)	41.02 (<0.001*)	
PIPD			
Baseline	1.08±0.28	1.06±0.34	0.18 (0.86)
6 months	1.60±0.47	1.58±0.39	0.15 (0.89)
12 months	1.99±0.62	1.83±0.40	0.96 (0.35)
Mean difference (6 months from baseline)	0.53±0.37	0.52±0.32	0.02 (0.98)
Mean difference (12 months from baseline)	0.92±0.56	0.77±0.36	0.94 (0.35)
Repeated measures ANOVA (P)	44.99 (<0.001*)	60.77 (<0.001*)	
MGI			
Baseline	0.00±0.00	0.00±0.00	N/A
6 months	0.68±0.51	0.50±0.45	1.13 (0.27)
12 months	0.89±0.58	0.64±0.44	1.46 (0.15)
Mean difference (6 months from baseline)	0.68±0.51	0.50±0.45	1.13 (0.27)
Mean difference (12 months from baseline)	0.89±0.58	0.64±0.44	1.46 (0.15)
Repeated measures ANOVA (P)	32.30 (<0.001*)	22.28 (<0.001*)	

*Statistically significant at $P < 0.05$. PIPD – Peri-implant probing depth; MGI – Modified gingival index; NA – Not available; SD – Standard deviation

within the acceptable range for successful implants.^[28] Furthermore, the mean ISQ values recorded in the present study for all the studied groups after 12 months of implant loading indicate medium to high implant stability and are within the range (70-75 ISQ) reported in the literature for successfully integrating implants.^[29] These favorable ISQ values might be attributed to the application of PBM therapy. Numerous preclinical studies,^[30-32] as well as clinical trials^[33-35] have been conducted and validated that PBM

has beneficial influence on bone healing and accelerates the regeneration process, and thus, was described as an extrinsic stimulus of osseointegration.

There was no statistically significant difference between the investigated PBM doses regarding implant stability. The possible explanation for this is that both the PBM doses used are within the fluence range recommended by the World Association for Laser Therapy to elicit

Table 3: Linear regression for the effect of different implant systems and photobiomodulation on mean difference of peri-implant probing depth, modified gingival index and implant stability (6 months–baseline)

Parameters	PIPD		MGI		Implant stability	
	B (95% CI)	P	B (95% CI)	P	B (95% CI)	P
Group I (two implants) versus Group II (four implants)	0.49 (0.31–0.68)	<0.001*	0.24 (–0.10–0.58)	0.16	–4.82 (–8.34––1.30)	0.009*
Dose A versus Dose B	0.002 (–0.17–0.18)	0.98	0.18 (–0.14–0.50)	0.26	–1.54 (–4.85–1.78)	0.35
Model F	14.48		1.68		4.33	
Adjusted R ²	0.47		0.09		0.21	
P	<0.001*		0.20		0.02*	

*Statistically significant at $P < 0.05$. B – Regression coefficient; CI – Confidence interval; PIPD – Peri-implant probing depth; MGI – Modified gingival index

Table 4: Linear regression for the effect of different implant systems and photobiomodulation on mean difference of peri-implant probing depth, modified gingival index and implant stability (12 months–baseline)

Parameters	PIPD		MGI		Implant stability	
	B (95% CI)	P	B (95% CI)	P	B (95% CI)	P
Group I (two implants) versus Group II (four implants)	0.77 (0.56–0.98)	<0.001*	0.64 (0.34–0.93)	<0.001*	–4.85 (–8.74––0.95)	<0.001*
Dose A versus Dose B	0.15 0.15 (–0.05–0.35)	0.14	0.25 (–0.03–0.53)	0.08	–0.91 (–4.58–2.77)	0.62
Model F	28.03		10.98		3.33	
Adjusted R ²	0.63		0.40		0.17	
P	<0.001*		<0.001*		0.048*	

*Statistically significant at $P < 0.05$. B – Regression coefficient; CI – Confidence interval; PIPD – Peri-implant probing depth; MGI – Modified gingival index

beneficial physiologic response, which explains the difference between the outcomes not being significantly different. Nonetheless, implant stability with dose B was non-significantly more favorable. This could be because of a more clinically effective dose reaching the target tissue by increasing the energy density at the tissue surface, thus compensating the energy reflected by the off-contact mode of application.

The effectiveness of PBM therapy is highest when used during osteoblast proliferation.^[36,37] It is worth noting, the current study design was implemented because PBM was shown in another research to induce a systemic effect in distant areas.^[38] Yet, the side that received a higher dose may still show different outcomes because the local effect of PBM (higher dose) is more dominant than the potential miniscule systemic effect. In the current study, the use of a split-mouth design minimized the risk for inter-individual contributing factors such as the healing ability of a subject. However, the risk for intra-individual variations, such as bone quality and quantity at the implant sites, remained.

The findings of this study cannot be compared with those of other studies in the literature, as this is the first such study. In addition, the variety of wavelengths, laser, and LED device types used for PBM therapy with disparate energy output modes and setting parameters, produced diverse treatment protocols with different and sometimes contradictory outcomes, hampering meaningful comparison of the results and potentially

raising skepticism on the advantageous outcome of this approach.^[17] Nonetheless, the results of this study are in line with the conclusion of Guljé *et al.*,^[26] who reported that four short implants (of 6-mm length) connected with a bar and inserted in the inter-foraminal area of the atrophic edentulous mandible (basal bone) had an acceptable 1-year implant survival rate of 96% and can provide a base to support a mandibular overdenture. Our results are also consistent with those of a long-term study on geriatric patients treated with two implants (8-mm length) retained overdentures.^[39]

The fully guided ultrashort implant placement protocol in severely resorbed mandibular ridge combined with PBM therapy favored the healing process and resulted in minimally invasive procedure. Therefore, this is a viable alternative to the higher risk, time-consuming, and costly vertical augmentation techniques. Further research is required to identify other clinical situations that may benefit from the application of this protocol, for instance, in geriatric or diabetic patients. Furthermore, additional randomized controlled clinical trials with a larger sample size and longer follow-up periods are needed to support the results of the present study.

CONCLUSIONS

After 1 year of function, overdentures supported by four ultrashort implants demonstrated a more favorable clinical outcome compared to those retained by two ultrashort implants. The studied PBM doses revealed comparable outcome on implant stability. Therefore, a minimally

invasive treatment modality for atrophic mandible can be offered by fully guided ultrashort implant placement to support an overdenture; and PBM can be used as adjunctive therapy to enhance healing and osseointegration.

Ethical considerations

The study received approval from the Ethics Committee of Alexandria University, Alexandria, Egypt (Ref. no.: IORG000883; dated: March 19, 2019). All participants provided written informed consent. The study was conducted in adherence with the guidelines of Declaration of Helsinki, 2013.

Data availability statement

The datasets generated during and/or analyzed during the current study are not publicly available but are available from the corresponding author on reasonable request.

Peer review

This article was peer-reviewed by three independent and anonymous reviewers.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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