

TREATMENT OUTCOME OF TWO SHORT IMPLANT RETAINED MANDIBULAR OVERDENTURE IN COMBINATION WITH PHOTOBIO-MODULATION

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ABSTRACT:

INTRODUCTION: Restoration of atrophic mandible with short implants has revolutionized dentistry. Computer guided implant surgery has been verified to be an established minimally invasive treatment and Photobiomodulation (PBM) has proven to be an effective modality in accelerating post-surgical healing and implant osseointegration.

AIM OF THE STUDY: To evaluate the clinical and radiographic outcomes of mandibular overdentures retained by two short implants in combination with two different doses of PBM.

MATERIALS AND METHODS: Six completely edentulous patients received two short dental implants (4mm diameter and 7mm length) in canine area. Short implants were inserted via CAD/CAM surgical guide. Patients received 5 PBM sessions immediately after surgery and every 48 hours. Group A (n=6) right side implants received dose of 2.4 J/cm², and group B (n=6) left side implants received dose 4.8 J/cm². Implants were loaded after 3 months. Each implant was evaluated at time of initial prosthetic loading and 6 months later for peri-implant probing depth (PIPD), modified gingival index (MGI), and vertical bone loss. Implant stability was assessed at the time of surgery and 6 months after loading.

RESULTS: The findings of this study indicate that after 6 months, two short implant retained overdentures showed no biological nor mechanical complications. A minor but significant increase ($P < 0.05$) was observed in the PIPD over 6 months in both groups. The MGI values were very low. Radiographic evaluation revealed minimal insignificant marginal bone loss ($P > 0.05$) 0.51±30, 0.38±28 for group A and group B respectively. Implant stability values for group A were almost maintained and there was a slight increase in group B after 6 months. Insignificantly better results were reported with group B.

CONCLUSION: Two short implant retained overdenture can be a viable option for atrophic mandibles and PBM dose of 4.8 J/cm² has a potential positive influence on healing and implants osseointegration.

KEYWORDS: Atrophic mandible, short dental implant; guided implant surgery, photobiomodulation.

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INTRODUCTION

Edentulous patients frequently suffer profound problems with their complete mandibular dentures. The main complaints include, but not limited to; lack of retention and stability of mandibular dentures, coupled with a dramatic reduction in the masticatory efficiency (1). Attributable to the diminished surface area and the unreliable peripheral seal, a mandibular denture must rely on the proper borders' extension while evading overextension that yields denture dislodgement by the muscle attachments while functioning. This alone is an elusive balance to achieve. By combining the problems of poor bone height on the mandibular ridge with large tongues or poor lateral throat form, the mandibular denture becomes the most problematic prosthesis to attain satisfactory retention for the patient during function.

A current well-founded treatment option is to insert endosteal implants in the mandible to retain an overdenture (2,3). The substantial evolution of the implant overdentures has significantly enhanced the clinical performance of complete dentures in aspects of denture support, retention, stability as well as chewing efficiency(4,5). Nonetheless, severe forms of ridge

resorption are regarded to be beyond the scope of implant prosthodontics. Unless adequate bone height is evident, bone augmentation and grafting are considered compulsory prerequisites (6). Seeking alternatives to the time-consuming and risk associated augmentation procedures became a motivating topic for researchers. The reliance on short implants amplified after the initial evidence suggesting that the improved predictability of short dental implants has been supported by the various biomechanical studies (7), advocating that the most crucially involved part in load-bearing is the crestal portion of the implant body. Hence, implant length may not be a cardinal factor for implant failure (7-10). Moreover, this protocol is in line with contemporary inclination towards minimally invasive techniques. Furthermore, digital implantology with computer guided implant surgery propose a wise modality to satisfy the enormously rising demands and can be viewed as one of the most important innovation drivers in the dental arena and its pace keeps rising (11-13). However, there's no consensus on the number of short implants required to retain mandibular overdenture.

Photobiomodulation (PBM) has demonstrated to be a potentially effective modality in accelerating the healing process and enhancing bone formation (14-18). Given the successful application of non-ablative lasers to boost formation of new bone, this promising treatment modality was employed by researchers to accelerate healing of peri-implant bone in attempt to shorten the healing time before definitive prosthesis insertion. The positive outcomes of PBM have provided a modality to accelerate osseointegration. Thus, PBM has become a promising adjuvant therapy in cases of rehabilitation including implant prosthodontics (18,19). Nevertheless, there is no standardized protocol nor dose for the application of PBM to enhance dental implants osseointegration (20). Consequently, this study aims to evaluate and compare the outcomes in terms of; implant stability, peri-implant hard and soft tissues change of two short dental implants retained mandibular overdentures in combination two different doses of PBM.

The null hypothesis of this study was that for a mandibular overdenture retained by two short implants, right side implants irradiated with PBM for 2 minutes and left side implants irradiated for 4 minutes will not reveal difference in the clinical and radiographic parameters assessed.

MATERIALS AND METHODS

The study protocol was approved by research ethics committee of Faculty of Dentistry, Alexandria University, Egypt, to ensure the protection of the participants and it is registered in www.clinicaltrials.gov (ID: NCT03540316).

Patient Selection

Six completely edentulous male patients were selected from the outpatient clinic, Department of Prosthodontics, Faculty of Dentistry, Alexandria University, Alexandria, Egypt. Their mean age is 55 years (range 45 to 65 years), they presented with persistent retention problems with their conventional mandibular complete dentures due to atrophic mandibular ridge. The selected patients were included if they were free from systemic disorders and have healthy mucosa as well as class I ridge relation. Patients were excluded if they were smokers, diabetic or had osteoporosis, or undergone radiotherapy to the head and neck region. All patients signed an informed consent form.

Surgical and Prosthetic Procedures

All patients received new maxillary and mandibular complete dentures. Patients were given instructions to follow strict oral hygiene measures and denture care. A preoperative panoramic radiograph and cone beam computed tomography (CBCT) were done for every patient to locate important anatomical landmarks and evaluate the potential implant placement sites.

Dual scan was performed and the CAD/CAM customized surgical guide was then fabricated by 3D printing (Form2, Formlabs, Somerville, MA, USA) using the scanned radiographic template as reference (21). It was employed to guarantee the implants were placed in a predictable, and accurate parallel manner. Antibiotic (1gm of amoxicillin and clavulanic acid orally/ 12 hours) was prescribed one day pre-operatively and continued for six

Two Short Implant Retained Mandibular Overdenture and PBM days post-operatively. Also, 0.12% chlorhexidine rinse was prescribed two days pre-operatively, it was used twice daily and continued post-operatively (22,23).

Each patient received two short dental implants (4mm diameter and 7mm length; 5.5 mm intra-bony, 1.5 mm soft tissue, Dentium, Korea) bilaterally in the canine region. Implants were placed under local anaesthesia via a flapless implant surgery aided by the customized surgical guide, which was stabilized by fixation pins guided by occlusal index to reproduce the virtually planned position. While the surgical guide in place and according to the manufacturer's instructions, as well as, the calibrated sequential drilling protocol, the osteotomy site was prepared using the appropriate pre-planned drills sequence according to the 3D planning and guided surgery report provided (21). All implants were placed by the same clinician.

After implants were placed, the surgical guide was removed and the implants' primary stability was assessed by Osstell ISQ™ instrument (Integration diagnostics Ltd., Sweden) finally cover screws were fastened on the implants (Fig 1). Patients were instructed to complete the prescribed medications and given detailed instructions with regard to oral hygiene measures. To avoid loading of the surgical area, patients were not allowed to wear the mandibular denture for 2 weeks post-surgically, and later the denture was adjusted to accommodate the cover screws and implants.

The implants remained unloaded for three months. Then, the second prosthetic phase started in which implants were exposed and cover screws removed under local anaesthesia by the same investigator and self-aligning positioner abutments of 2mm trans-mucosal cuff height were screwed in to the implants. Positioner abutments (Superline, Dentium Co. Ltd., Korea) were then attached to the dentures by matching self-aligning positioner attachments (Superline, Dentium Co. Ltd., Korea) by means of a chair-side processing method, direct pickup of the female housings in the fitting surface of the mandibular denture was performed.

Laser Irradiation (PBM) Protocol

PBM by laser irradiation started immediately post-surgical and repeated every two days (48 hours), each patient underwent 5 sessions in total. They received PBM by a semi-conductor diode laser (Sirolaser blue, Sirona, Germany). The wavelength used was; $660 \text{ nm} \pm 5$, an output power of 25 mW (24), the operating mode was continuous wave (CW).

At this stage, split mouth design was adopted and patients were blinded to the PBM doses.; group A was the right-side implant received PBM for 120 seconds and group B; left side implant (same patient) and received PBM for 240 seconds. Multiplying the laser output power in watts by the time of exposure in seconds equals the produced energy, thus energy per session = $0.25\text{W} \times 120\text{s} = 3\text{J}$ for group A and $0.25\text{W} \times 240\text{s} = 6\text{J}$ for group B. Laser spot size (size of irradiated area) was 8mm, resulting in a calculated energy density (Dose) of: 2.4 J/cm^2 for group A and 4.8 J/cm^2 for group B. Implants were irradiated intraorally, orthoradially to the implant's longitudinal axis in non-contact mode by a hand held probe (multi-tip) 1-2 mm away from the implants (Fig. 2).

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Biosafety standards for infection control and waste disposal were strictly implemented throughout all therapy sessions.

Evaluation Phase

The clinical outcome of treatment of resorbed mandibular ridge by using short implants retained overdenture and PBM was evaluated by blinded operator, in terms of; implant stability, peri-implant bone and soft tissue changes.

i. Clinical evaluation:

a. Peri-implant Probing Depth (PIPD):

It is the distance measured between the marginal border of the gingival margin and the most apically probeable part, in millimetres (mm). PIPD was measured at 4 sites around each implant (mesially, distally, labially/buccally, lingually). Then, the mean record for every implant was calculated. It was measured at time of prosthetic loading (baseline) and six months after implant placement (25).

b. Modified Gingival Index (MGI):

To qualify the peri-implant inflammation, modified gingival index (modified Loe and Silness index) was performed. It was measured at 4 sites around each implant (mesially, distally, labially/ buccally, lingually), then, the mean record was calculated for each implant. MGI was evaluated at time of prosthetic loading (baseline) and 6 months after implant insertion (26). The scoring criteria were as follows:

Score 0: normal peri-implant mucosa;

Score 1: mild inflammation, slight change in colour, slight oedema;

Score 2: moderate inflammation, redness, oedema, and glazing;

Score 3: severe inflammation, marked redness, oedema, and ulceration.

c. Implant Stability Test:

To assess the process of osseointegration, implant stability was measured by resonance frequency analysis (RFA). It was carried out at the time of implant insertion and six months later. RFA was done using the Osstell ISQ™ instrument (Integration diagnostics Ltd., Sweden); a non-invasive objective system that doesn't jeopardize the healing process. Measurements were done for buccal/labial, mesial and distal sites. Each measurement was repeated till the same value was recorded twice, which was accepted as the authentic value. Then, the mean Implant stability quotient (ISQ) values for each implant were calculated (27,28).

ii. Radiographic Evaluation:

It was carried out to detect peri-implant vertical marginal bone loss over time. Standardised digital periapical radiographs via paralleling technique with sensor holder was performed. Peri-implant vertical alveolar bone loss was measured (in mm) using Sidexis 4 software (Version 4.1, Dentsply Sirona, GmbH, Germany). In this study, the baseline radiographs were taken at the time of prosthetic loading when transmucosal part pierces the mucosal tissues. Reference line for bone level evaluation was the threaded intra-bony boarder of the implant (smooth/rough interface of the implant which is located 1.5mm apical from the implant shoulder). After six months, measurements were done at the mesial and distal

Two Short Implant Retained Mandibular Overdenture and PBM surface of each implant, then the mean values were calculated(29).

Statistical Analysis

Data were fed to the computer and analysed by SPSS®20.0 software (SPSS Inc., Chicago, IL, USA). Quantitative data was described by mean and standard deviation. For normally distributed data comparison between two independent populations was done using independent t-test while for comparison in the same group paired student t-test was used. Significance test results are quoted as two tailed probabilities. significance of the obtained results was judged at the 5% level. Differences were considered to be statistically significant at $P < 0.05$.

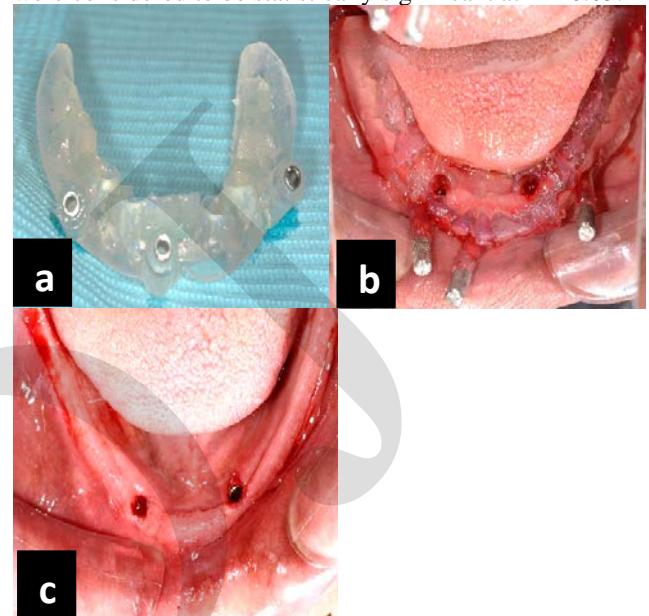


Figure 1: a) 3D printed surgical guide b) implants inserted with surgical guide in place c) surgical guide removed and cover screws tightened.



Figure 2: a) Sirolaser blue device b) Laser multi-tip 1-2 mm from the implants

RESULTS

All the patients enrolled in the present study received the intended treatment and successfully completed the study protocol. All the placed short dental implants were clinically stable and free of symptoms; radiographically no pathological marginal bone loss was

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observed around the implants. The short dental implants' success rate was 100%. All implants were followed-up and considered for the analysis. The implants and related prostheses were stable, and no complications were observed during the follow-up period.

Clinical Parameters

a. Peri-implant Probing Depth:

All patients maintained meticulous good oral hygiene throughout the study period. The mean peri-implant probing depth at the baseline was 1.06+0.27 and 0.94 +0.21 for group A and B respectively. After 6 months follow up these values slightly increased to be 1.98 +0.5 for group A and 1.73 + 0.36 for group B. Thus, a minor but significant change ($P < 0.05$) in probing depths during the evaluation period was observed after 6 months of prosthesis loading (Table 1). Nevertheless, there was no significant difference between both groups after 6 months.

b. Modified Gingival Index

The mean MGI values for both groups at baseline and after 6 months are displayed in (Table 2). At the time of prosthesis loading, no signs of inflammation were reported. After 6 months the mean scores on the modified gingival index were very low at the evaluation period. No significant differences between the groups were observed.

c. Implant Stability Measurement

The mean (ISQ) values for group A and B, at time of surgery (baseline) and after 6 months are shown in (Table 3). The results of t-test showed that the mean difference in ISQ at baseline and after 6 months ($P = 0.13$, $P = 0.15$ respectively) was not significant between both groups. The primary ISQ values were almost maintained in group A during the study period and there was a minor increase in these values for group B. However, no significant differences were demonstrated in the ISQ values between both groups during the examination period.

Radiographic parameters

Digital peri-apical radiographs showed normal peri-implant bone structure with no signs of continuous radiolucency around the implant threads during the observation period. At the start of prosthetic loading after the healing period and bone remodelling, bone levels were stable at the reference line threaded intra-bony boarder of the implant (smooth/rough interface of the implant). The average bone loss after 6 months of loading was 0.51 + 0.30 and 0.37 + 0.28 mm in groups A and B, respectively. No significant differences ($P > 0.05$) in marginal bone loss were observed between both groups. Changes in the marginal bone levels are shown in (Table 4).

Table (1): Comparison between the two studied groups regarding probing depth at base line and after 6 months.

Probing depth	Group A	Group B	t-test I P value
At base line			
Range	0.75-1.50	0.63-1.13	
Mean	1.06	0.94	1.44
S.D.	0.27	0.21	0.19 N.S.
After 6 months			
Range	1.25-2.63	1.25-2.25	
Mean	1.98	1.73	1.48
S.D.	0.50	0.36	0.17 N.S.
t-test 2 P value	4.25	6.98	
	0.001*	0.0005*	

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t-test 1: Comparison between group A and B at the same time.

t-test 2: Comparison between base line and after 6 months in the same group

p is significant if ≤ 0.05 * Significant at level 0.05

N.S. not significant

Table (2): Comparison between the two studied groups regarding gingival index 6 months.

Gingival index 6 months	Group A	Group B	t-test P value
Range	0.25-2.00	0.00-1.25	
Mean	0.96	0.54	1.54
S.D.	0.62	0.51	0.12 N.S.

p is significant if ≤ 0.05

N.S. not significant

Table (3): Comparison between the two studied groups regarding gingival index after 6 months

Implant stability	Group A	Group B	t-test 1 P value
At base line			
Range	63.33-78.33	54.67-73.67	
Mean	69.89	67.17	1.86
S.D.	6.27	7.53	0.13 N.S.
After 6 months			
Range	64.33-74.00	62.67-75.00	
Mean	69.11	72.06	1.82
S.D.	5.46	5.71	0.15 N.S.
t-test 2 P value	0.98	1.69	
	0.315	0.132	N.S.

t-test 1: Comparison between group A and B at the same time.

t-test 2: Comparison between base line and after 6 months in the same group

p is significant if ≤ 0.05

N.S. not significant

Table (4): Comparison between the two studied groups regarding radiographic evaluation after 6 months from the reference point.

	Group A	Group B	t-test P value
Range	0.10-0.80	0.10-0.70	
Mean	0.52	0.43	1.09
S.D.	0.28	0.25	0.20 N.S.

p is significant if ≤ 0.05

N.S. not significant

DISCUSSION

Atrophic mandibular residual ridge is a highly challenging condition and has always sparked controversy among clinicians. In the light of the current trend towards less invasive approaches, short dental implants were introduced as a salvation from the aggressive surgical procedures for severely resorbed ridges. However, there is no sufficient data on their use to retain mandibular overdenture and there is no strong evidence to suggest the minimal number of short dental implants required to retain a mandibular overdenture.

The current clinical study investigated two-short implants retained mandibular overdenture as potential alternative to other high-risk treatment options. Short

dental implants were placed by minimally invasive flapless fully guided surgical approach. Guided digital implant surgery permits implants to be placed in a prosthetic and biologically driven manner into sufficient hard and soft tissue while evading prosthetic complications and compromised aesthetics, as there is an improved control over the implant axis in relation to the position of the prosthetic tooth. Consequently, it brings about a more predictable prosthetic outcome. The pre-surgical 3D implant plan can be transferred to the patient in a more accurate and safe manner, so that implants can be placed in the correct prosthetic positions whilst evading the injury of the vital anatomic structures (30-32).

Besides, operating with a minimally invasive technique -precluding flap elevation, results in facilitated surgical procedure with shorter surgical intervention time. Thus, less post-operative sequelae and patient morbidity, in addition to preserving the soft tissue architecture, as well as maintaining the periosteum intact on buccal and lingual aspect of the alveolar ridge and the supra-periosteal plexus is kept intact and therefore, preserving the osteogenic potential and blood supply to the underlying bone and implant which, in turn, reduces the possibility of bone resorption. Moreover, it may enhance the formation of a biologic seal between the soft tissues and the implant-abutment interface, as it evades the need for flap reflection and suturing (33,34).

Additionally, to accelerate the osteointegration and the healing process the present study employed PBM, as there is a compelling scientific evidence sufficient to prove its significance in proliferation and differentiation of osteoblasts, bone healing and revitalization (15, 35-40), induction mitosis in cultured cells, collagen production, as well as it can boost cellular processes such as synthetization of ATP and synthesis of DNA and RNA (41,42).

In this study PBM was performed using diode laser 660+5 nm, since PBM in a range of 600-1100nm (optical window) results in a deeper tissue penetration and consequently, induces a broader cell-light response (43). The dose-dependent effects of PBM are described by Arndt-Schultz's curve (42). It suggests that, weak stimulus will excite biological activity, moderate stimulus favour it, strong stimulus may halt increased activity, and excessively strong stimulus will retard or stop the biological activity. Meaning that the usage of insufficient dose has no biological effect, but if excessive energy is used a bio-suppressive effect will happen. Fluence within the range of 1–10 J/cm² is best to achieve an optimum biological response (42,43). There's no standardized protocol for its use to promote dental implants' healing. Thus, the study also compared the effect of two different doses of PBM. The manufacturer recommended dose of: 2.4 J/cm² was used for group A and the other tested dose 4.8 J/cm² was utilized for group B. Split mouth study design was adopted because PBM has been shown to evoke a systemic effect in distant areas (44-46). The frequency of sessions every 48 hours was determined based on the literature as PBM has been shown to have a positive effect on the initial stages of implant osseointegration (14, 47,48).

The main findings of this study were that after 6 months of prosthetic loading the two-implant retained mandibular overdentures revealed no biological nor mechanical complications. A minor but significant increase ($P < 0.05$) was observed in the PIPD in both groups after six months but within the accepted values of healthy peri-implant tissues (49).

The modified gingival index values were very low and revealed no inflammation nor edema. The radiographic evaluation displayed a minimal insignificant marginal bone loss ($P > 0.05$) from the reference line; 0.51+30, 0.38+28 for group A and group B respectively. The ISQ also, revealed insignificant changes from the baseline (at time of surgery) till six months after loading and between both groups. Group A values were almost maintained and there was a slight increase in group B values after 6 months of loading. In all the parameters measured, there was no significant differences between group A and group B. Nevertheless, insignificantly improved results were reported with Group B. this may be attributed to the possibility of more effective dose reached the target tissue, considering the amount of energy reflected by the off-contact mode of application.

In this study, we report merits of using a 660 nm diode laser post-surgically, which related to maintaining and/or improving secondary implant stability. In the red to the near-infrared spectrum (600–1500nm), light scattering is more prevalent, and absorption has less impact. Red laser has lower penetration depth in comparison to the infrared one (50). Yet, for the wavelength employed in the present study (660nm) the minimum penetration depth is roughly 3mm (51). Therefore, because of the less penetration depth of the red laser we suggest using energy close to the maximum dose specified by Arndt-Schultz's curve but less than 10 J/cm².

To our knowledge, this is the first study that has investigated the outcome of two short implants retained mandibular overdenture placed with fully guided protocol and irradiated with PBM. Thus, direct comparison of the results of this study with those of other studies is not valid since no similar prospective studies have yet been published. Moreover, published studies which applied PBM clinically, displayed a wide diversity this may be due to the variety in the parameters used; energy density, number of applications, wavelength, and power. furthermore, in many studies the parameters used were not reported at all or inaccurately reported and dose used ranged from 6.2 to 92.1 J/cm² reflecting an absence of uniformity in the ideal dose for LLLT on dental implants. Additionally, it is imperative to consider the biphasic dose response as well as the inherent heterogeneity among patients, when interpreting the findings. Thus, meaningful comparison with other studies is invalid.

Although the present study included a relatively small number of patients, well-defined eligibility criteria of patients were given vigilant attention. A strict PBM protocol was followed to boost the design of the trial, the same implants (brand, surface, length, and diameter) were used for each participant, the same edentulous region was selected and the same study population. It is worth noting, that results of the current study are limited to the specific methodology, and outcomes may vary in different bone

conditions and implants when using other PBM protocols and methodologies as well as in different follow-ups. Therefore, to establish a long-term clinical success with the proposed method, further randomized-controlled clinical trials in long-term and larger sample size are required to support the results of our study.

CONCLUSIONS

Within the limitations of this study, it can be concluded that two short implant retained overdenture can be a viable treatment option for severely resorbed mandibular ridges and PBM dose of 4.8 J/cm² has a potential positive influence on the healing and osseointegration of dental implants.

CONFLICT OF INTERESTS: The authors declare that they have no conflicts of interest.

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