Effect of Low-Level Laser Irradiation on Stability and Marginal Bone of Narrow Implants Retaining Overdentures in Moderately Controlled Diabetic Patients

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The researchers investigated the influence of low-level laser irradiation (LLLI) on implant stability and marginal bone of small-diameter implants retaining mandibular overdentures in patients with moderately controlled diabetes. Twenty patients (mean age = 59.32 ± 4.1 years) with moderately controlled diabetes mellitus (glycated hemoglobin A1c [HbA1c] = 8.1%–10.0 %) were rehabilitated by maxillary and mandibular conventional dentures. Two small-diameter implants (3 × 12 mm) were inserted in the canine areas of the mandible and immediately loaded by mandibular dentures. In a split-mouth design, LLLI was applied to 1 of the 2 implants in a random order (study group [SG]); the other implant was left as a control (control group [CG]). For each patient, gallium aluminum-arsenide diode low-level laser (940-nm wavelength, 0.50 ± 2 mW output power, 0.004 cm^2 spot size; Epic, Biolase, Inc, San Clemente, Calif) was applied around each implant with total delivered energy of 90 J (equally divided by 6 irradiation points) in 3 sessions. The application was done immediately after implant insertion, 3 days and 1 week after surgery. Implant stability (measured by Periotest) and marginal bone loss (MBL; measured by cone beam computerized tomography) were evaluated at implant loading (T1), 6 months (T6), and 12 months (T12). One implant failed in the CG and no failures occurred in the SG, resulting in 95% and 100% survival rates, respectively. The SG recorded higher Periotest values than the CG at all observation times. However, the difference was significant ($P = .039$) at T6 only. The SG recorded lower MBL values than the CG. No difference in MBL was detected between groups or peri-implant sites (mesial, distal, buccal, and lingual) at T6 and T12. Within the limits of this study, LLLI had no effect on marginal bone around immediately loaded small-diameter implants retaining overdentures in patients with moderately controlled diabetes. However, it was beneficial in improving implant stability 6 months after overdenture insertion.

Key Words: low-level laser, small-diameter implants, patients with diabetes

INTRODUCTION

Oral rehabilitation with 2-implant retained overdentures has become the standard option for edentulous patients as they improve quality of life with reduced costs.[1] In case of reduced buccolingual width of alveolar ridge in the canine regions, guided bone regeneration, autogenous onlay graft, and horizontal distraction osteogenesis may be used to increase ridge width.[2,3] Alternative treatment options include ridge expansion[4] and the use of small-diameter or mini dental implants,[5,6] which reduce the morbidity and costs of bone grafting procedures, especially for geriatric patient who are debilitated. Survival rates of narrow-diameter implants retaining mandibular overdentures are similar to those of conventional-diameter implants.[7] Small-diameter implants are usually placed with a flapless surgical approach, which provides several advantages, such as minimal postoperative bleeding and discomfort,[8] short healing time.[9] and preservation of peri-implant bone.[10,11] Moreover, the primary stability of small-diameter implants is mostly suitable for immediate loading with immediate restoration of mastication and esthetics.[12]

Diabetes mellitus, a common carbohydrate metabolic disease accompanied by hyperglycemia, has been considered a relative contraindication for implant treatment because of complications that may affect healing, such as microvascular disease, susceptibility to infection, and delayed wound healing.[13] Moreover, implants in patients with diabetes were subjected to occlusal overload because of decreased bone-to-implant contact, which may affect implant osseointegration.[14] However, several studies showed that the implant success in

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persons with well-controlled diabetes is equal to that for persons without diabetes.[15]

Low-level laser irradiation (LLLI) has been shown to stimulate osseointegration through increase of blood flow, proliferation of osteoblasts, and formation of collagen and bone if used in the early stages of bone repair and during cell proliferation.[16–18] Use of LLLI has also enhanced nondirect accelerated bone healing in animal studies by the biostimulatory effect.[19] Khadra and collegues[20] reported more bone-to-implant contact, high calcium/phosphorus levels, and improved wound healing around titanium implants in laser-irradiated animals compared with controls. Pinheiro et al[21] observed that LLLI improves bone repair at the tissue-implant surface in the initial stages of wound healing in the tibias of dogs. Moreover, laser application on implants promotes patient comfort, reduces postoperative pain and edema, and treats peri-implantitis.[22]

Despite the fact that LLLI was shown to have several advantages regarding osseointegration in animal studies, limited human clinical studies in the literature have analyzed the influence of this treatment on implant osseointegration.[23] The purpose of this study was to evaluate the influence of LLLI on the clinical and radiographic outcomes of small-diameter implants retaining mandibular overdenture in patients with moderately controlled diabetes. The null hypothesis was that LLLI will have no significant effect on the clinical and radiographic outcomes of these implants.

Materials and Methods

Twenty edentulous patients (age range = 55 to 65 years, mean = 59.32, SD = 4.1) with problems adapting to mandibular dentures were selected from the outpatient clinic of the Prosthodontic Department. The sample size was selected to yield a power of 80% ($\alpha = 0.05$) based on the results of a previous study[24] in which the authors found a 10% significant difference between implant stability measurements (SD = 7). The inclusion criteria were (1) reduced buccolingual width of mandibular ridge in the interforaminal region (verified by preoperative cone beam computerized tomography [CBCT]; range = 5 to 7 mm), (2) moderately controlled type 2 diabetes mellitus with glycosylated HbA1c ranging from 8.1% to 10.0%[25] on regular 3-month checks, and (3) at least 6 months since last extraction. Exclusion criteria were (1) smoking habits, (2) history of microvascular or macrovascular diseases, (3) cardiovascular disorders or liver diseases, and (4) history of anticoagulant therapy. Detailed information about the treatment was given to the patients. All patients agreed to share and follow the instructions given to them in the form of signed consent. The faculty's ethics committee approved the research protocol (FDASU-REC. No. 47). Protection of humans in this randomized controlled study was according to the ethical principles for medical research involving human subjects stated in the Declaration of Helsinki. Consolidated Standards of Reporting Trials (http://www.consort-statement.org/).

Surgical and prosthetic procedures

Maxillary and mandibular complete dentures were constructed using the conventional steps and delivered to the patients 3 months before implant insertion to enhance muscle adaptation. The lingualized balanced concept of occlusion was used. The mandibular denture was duplicated for all patients with clear acrylic resin and used as a surgical stent. The flapless surgical technique was used to install 2 implants (3 × 12 mm, Mini plus implants, Cowellmedi Co, Ltd, Busan, South Korea) in the canine regions of the mandible. A pilot drill was used to penetrate the crestal bone for 3–4 mm vertically. A series of twist drills (1.3, 1.8, 2.3, and 2.6 mm in diameter) was used in consecutive order to widen the pilot holes to a depth of 12 mm. Implants were inserted with a minimum torque of 40 Ncm (Figure 1). The same oral and maxillofacial surgeon performed the surgical procedures.

The implants were loaded by mandibular dentures immediately after implant insertion. The mandibular dentures were sufficiently relieved over the implant positions. Rubber dam discs were placed through the implants' ball heads to prevent the acrylic resin from locking onto the implants. The metal housings were seated over the implant balls in the patient's mouth and picked up to the mandibular dentures using autopolymerizing acrylic resin while the patients close into centric occluding relation (Figure 2). Patients were instructed to perform good oral hygiene and eat a soft diet. Three-month regular visits were scheduled for follow-up.

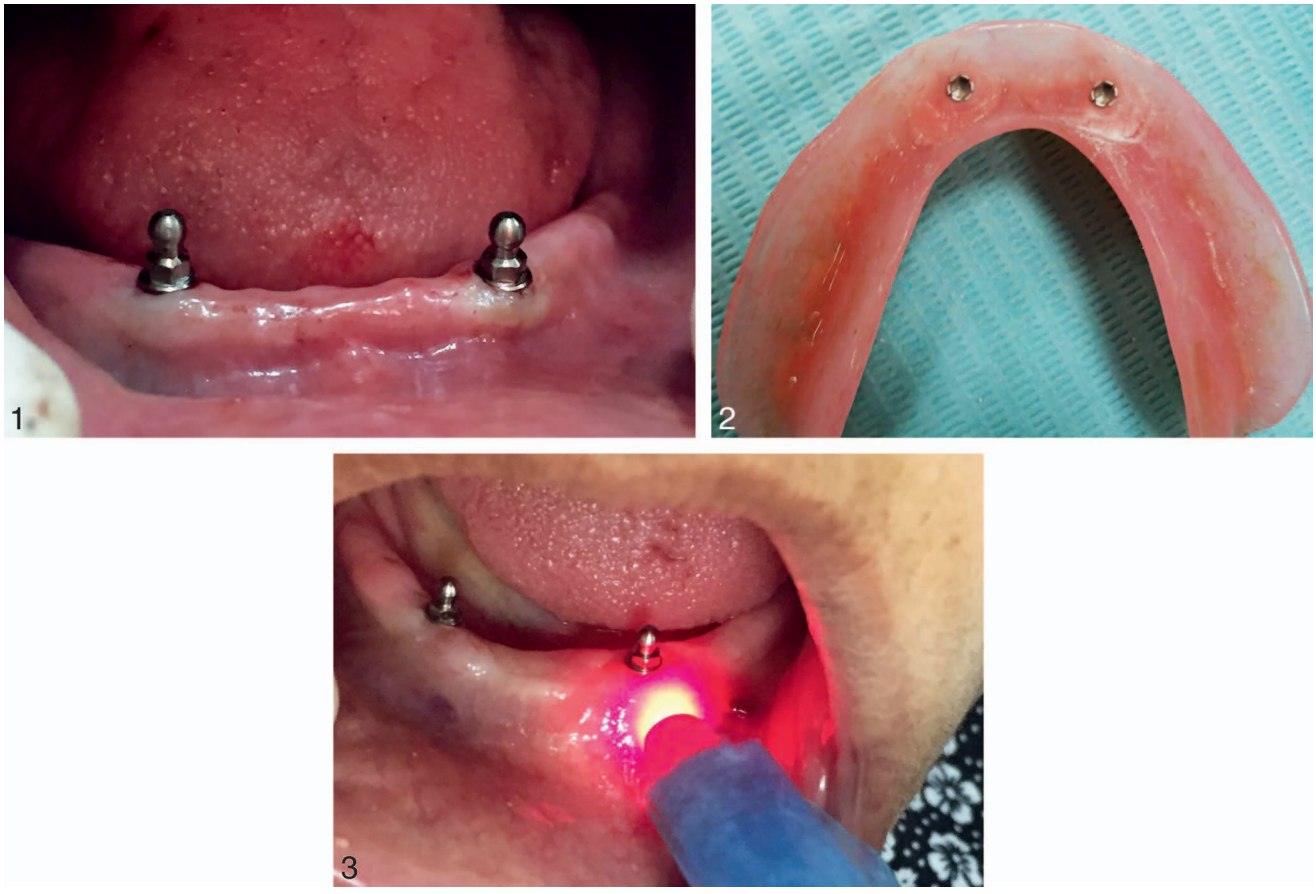
In an attempt to increase the internal validity of this study, a split-mouth design was used. One calibrated operator (E.M.A.) randomly determined the implant (side) to be irradiated (study group [SG]), and the other implant (side) served as the control (control group [CG]). The side to be irradiated was selected using randomly generated numbers created in an Excel spreadsheet.

Low-level laser irradiation (LLLI)

For patients in the SG, LLLI was applied mesially, distally, buccally, and lingually around each implant. Irradiation was performed with a gallium aluminum-arsenide diode low-level laser with continuous emission of 940-nm wavelength (Epic, Biolase, Inc, San Clemente, Calif). The laser output power was 0.50 ± 2 mW, and spot size was 0.004 cm^2. Irradiation time was 60 seconds per point through a noncontact mode. The total energy was 90 J, equally divided by 6 irradiation points (2 buccally, 2 lingually, 1 mesially, and 1 distally). The buccal and lingual point locations were opposite to crest (superior points) and in the middle (inferior points) of implants. The handpiece of the device was positioned perpendicular to the long axis of each implant 2–3 mm away from the mucosa. The irradiation was delivered through a fiber tip (diameter = 300 μm; Figure 3). The total irradiation time for each implant was 360 seconds. The LLLI was applied by the same clinician (G.R.M.) after training, instruction, and calibration. Both patient and clinician followed laser safety measures by wearing protective eye goggles. The LLLI was applied in 3 sessions for each patient (immediately after implant insertion, 3 days and 1 week after insertion.

Clinical and radiographic outcomes

Implant stability and marginal bone were evaluated at time of implant loading (T1), 6 months (T6), and 12 months (T12). Three



Figures 1–3. Figure 1. Three-mm diameter implants (with ball attachments) installed in a patient's mouth. **Figure 2.** The metal housings (sockets) picked up to the fitting surface of mandibular denture. **Figure 3.** Fiber tip used for irradiation.

calibrated examiners (A, B, and C) with sufficient experience in using the Periotest device (Medizintechnik Gulden. Modautal, Germany) and CBCT software tools performed the measurements. Examiner data were collected interpersonally and intrapersonally (3 times on the same day). The examiners were blinded to the site of irradiation.

Implant stability

A Periotest instrument was used to measure the stability of the implants, which was recorded as Periotest values (PTVs). Patients were instructed to sit in as upright position as possible. The handpiece was placed perpendicular to the longitudinal axis of the implant, and the distance from the tapping head to the implant ball head was 2 mm. The mean value was calculated from 3 consecutive measurements.[26]

Radiographic evaluation

The mesial, distal, buccal, and lingual marginal bone heights around the implants were measured using CBCT (i-CAT device, Imaging Sciences International, Hatfield, Pa) to calculate the marginal bone loss (MBL) during the follow-up period.[27] For standardization, scan parameters were set at 120 kVp, 5 mA, 0.25 mm voxel size, 8.9-second acquisition time, and 8×16 cm field of view. The reconstructed 3-dimensional images were saved as Digital Imaging and Communications in Medicine (DICOM) files and processed with software (OnDemand3DApp Software, CyberMed Inc, Version 1.0.10.5385, Seoul, South Korea). The X and Y planes perpendicular to each implant were reconstructed to give 2 cross-sectional images: (1) a mesiodistal (MD) image formed by bisecting the bone and the implants mesiodistally and (2) a buccolingual (BL) image formed by bisecting the implant buccolingually (Figure 4). The cross-sections resulted in 4 measurement sites: distal, buccal, mesial, and lingual.

For the mesiodistal and buccolingual cross-sectional images, vertical bone heights were measured at 4 sites: distal, buccal, mesial, and lingual. Vertical bone height was calculated from the implant-abutment junction to the first bone-implant contact in millimeters. Vertical bone levels at T6 and T12 were subtracted from levels at T1 to give MBL.

Statistical analysis

The statistical methodology was reviewed by an independent statistician. The data of PTVs and MBLs were normally distributed as detected by Kolmogorov-Smirnov and Shapiro-Wilk tests. The reliability of intra- and interpersonal data was tested by Cronbach α test. Two-way repeated measures analysis of variance was used to compare PTVs and MBLs (dependent variables) between groups and peri-implant sites (between-subject variables) and between observation times

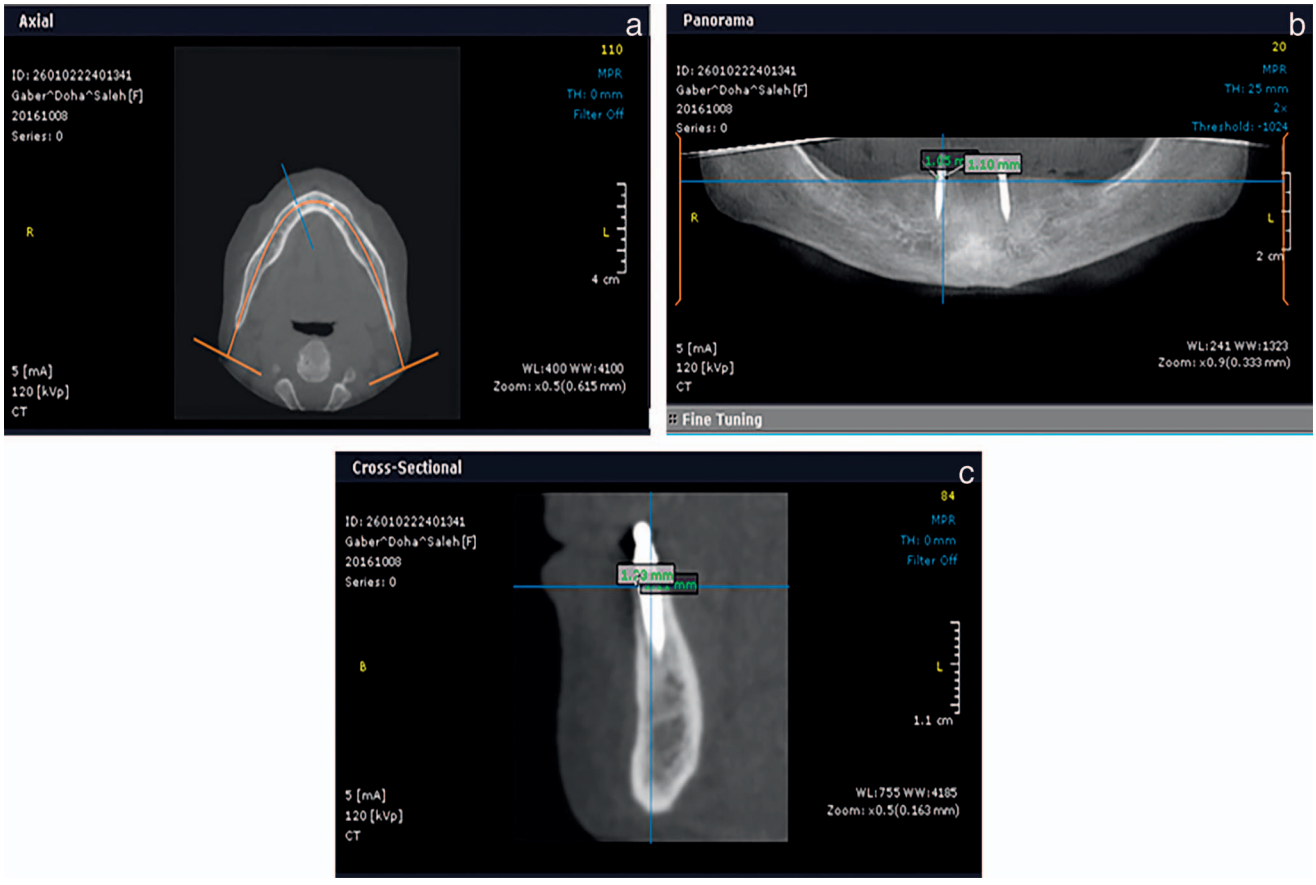


Figure 4. Measurement of peri-implant bone height. (a) Curved tool bisecting the ridge and the implant mesiodistally (axial view). (b) Panoramic image (mesiodistal view). (c) Cross-sectional image (buccolingual view).

(within-subject variable) followed by Bonferroni test for pairwise comparisons. *P* values $<.05$ were considered significant.

Results

One implant failed in the CG after 4 months, and no implant failures occurred in the SG. The failures yielded 95% and 100% survival rates in the CG and SG. respectively. The survival rate did not differ between groups (log rank test, $P = .317$). Intraclass correlation coefficients for PTVs and MBLs are presented in the Table.

Implant stability

The PTVs of the CG were –1.12 ± 0.49 at T1, –1.34 ± 0.42 at T6. and –1.48 ± 0.51 at T12. The PTVs of the SG were –2.00 ± 0.86 at T1, –2.54 ± 1.58 at T6, and –2.36 ± 0.78 at T12. For both groups, no significant difference in PTVs between observations was noted. The SG recorded higher PTVs at all observation times than the CG. However, the difference was significant at T6 only ($P = .039$).

Marginal bone loss (MBL)

For the CG, MBL was 0.49 ± .21 (T6) and 0.67 ± .23 (T12) at the mesial site, 0.48 ± 0.36 (T6) and 0.79 ± 0.51 (T12) at the distal site, 0.55 ± 0.38 (T6) and 0.74 ± 0.41 (T12) at the buccal site, and 0.45 ± 0.29 (T6) and 0.66 ± 0.35 (T12) at the lingual site. For the SG, MBL was 0.41 ± 0.18 (T6) and 0.64 ± 0.25 (T12) at the mesial site, 0.21 ± 0.07 (T6) and 0.37 ± 0.10 (T12) at the distal site, 0.27 ± 0.13 (T6) and 0.45 ± 0.14 (T12) at the buccal site, 0.35 ± 0.17 (T6) and 0.50 ± 0.20 (T12) at the lingual site.

For all peri-implant sites (mesial, distal, buccal, and lingual), MBL at T12 was significantly higher than MBL at T6 ($P < .05$). No significant difference was detected between groups at T6 and T12. Comparison of MBL between peri-implant sites (mesial, distal, buccal, and lingual) is presented in Figure 5. No significant difference in MBL was detected between peri-implant sites for both groups at T6 and T12.

Discussion

The dose of LLLI may affect the osseointegration of the implant. However, no standard protocol is reported in the literature for the use of laser irradiation to improve osseointegration of implants.[18] The total delivered dose (90 J) was similar to that used by García-Morales et al.[28] CBCT was used to evaluate marginal bone level as it provides additional information around buccal and lingual MBL that cannot be obtained by the peri-apical radiographs.[29] The use of CBCT for measuring the MBL around implants retaining mandibular overdentures have been reported previously.[27] The

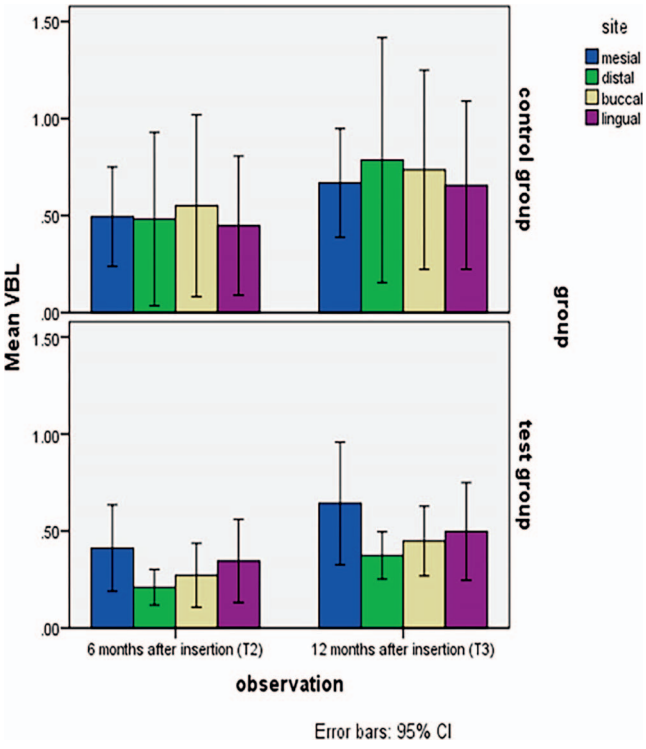


Figure 5. Comparison of marginal bone loss between different sites for both groups at 6 months and 23 months after insertion.

Periotest device was used to measure implant stability as it is sensitive in detecting early implant failure and has a greater ability to assess implant stability during the integration phase.[30] Although some studies have suggested that the Osstell device is more precise than the Periotest device in evaluating primary implant stability, The use of 1-piece implants in this study precluded the use of the smart peg of the Osstell device.

Despite the patients' moderate glycemic control, the implant survival rate was high in both groups. Similarly, several studies have reported that successful osseointegration of immediately loaded implants can be obtained in patients with diabetes if their plasma glucose levels are controlled.[31–33] No difference in implant survival rate between groups was also noted. The high survival rate could be attributed to the increased bone density in the anterior mandibular area.

In this study, PTVs were negative, indicating good bone anchorage (osseointegration) of the implants in patients with moderately controlled diabetes. Similarly, several authors[34–36] have reported high levels of implant stability and survival in patients with type 2 diabetes who had HbA1c levels as high as 12%. No significant difference in implant stability between groups was noted after 12 months. This result was in line with finding of García-Morales et al[24] and Mandic et al[37] who reported a nonsignificant effect of LLLI on implant stability. This could be attributed to the increased bone density and rigid bone-implant interface in the interforaminal area, as stated previously, which results in high initial stability. Such stability may mask the effect of LLLI throughout the follow-up period. Another cause of increasing implant stability may be attributed to the bone-condensing technique used, which is reported to enhance primary stability by increasing the bone density around implants.[38]

Table

Intraclass correlation coefficient for Periotest values (PTVs) and marginal bone loss (MBL) parameters

			MBL			
Examiner	Group	PTVs	Mesial	Distal	Buccal	Lingual
A vs B	Control	0.8654*	0.8831*	0.9057*	0.8964*	0.9854*
	Study	0.8618*	0.8784*	0.8758*	0.9606*	0.9584*
B vs C	Control	0.8944*	0.8798*	0.8953*	0.8213*	0.9318*
	Study	0.8311*	0.8834*	0.8521*	0.9218*	0.9658*
A vs C	Control	0.8758*	0.8539*	0.8843*	0.9478*	0.9863*
	Study	0.9424*	0.9166*	0.9674*	0.8521*	0.9410*
A vs A	Control	0.9636*	0.8825*	0.9586*	0.9388*	0.9578*
	Study	0.9362*	0.8651*	0.9431*	0.9412*	0.9658*

*$P \leq .001$. All coefficients were more than 0.80, which suggested strong correlation between examiners' measurements.

The only difference in implant stability between groups was detected 6 months after implant loading, where the SG recorded significantly higher stability than the CG. This observation was in agreement with that of García-Morales and colleagues,[24] who noticed superior implant stability in the SG compared with the CG, although the difference was not significant. The cause of this initial better stability may be increased cellular proliferation and bone matrix formation promoted by the biomodulatory effect of the laser during the early phase of proliferation and differentiation of cells. The increased deposition of bone matrix enhances incorporation of calcium hydroxyapatite and increases bone density.[39] However, this effect was temporary as the difference between groups disappeared at the end of the study.

Both groups showed favorable means of MBL at the end of follow-up period. The total mean MBL was 0.60 $\pm$ 0.34 mm and 0.4 $\pm$ 0.197 mm for the CG and SG, respectively, suggesting successful osseointegration. These values were within the normal range of bone resorption (1.2 mm in the first year) reported in the literature.[40,41] The reduced bone loss in this study may be attributed to the fact that the implants were inserted in the anterior mandibular area with dominance of dense bone, which is less liable to bone resorption.[42] There was no significant difference in MBL between groups and implant sites after 6 and 12 months. This could be attributed to several reasons. First, the self-tapping nature of the implants used is reported to maximize the bone-implant contact and increase the bone attachment to the implant after healing.[37] Second, the absence of microgap at the bone crest in single-piece implants allows undisturbed healing of the soft tissue, avoids disruption of the tissue seal, and reduces peri-implant inflammation and bone loss.[43] Third, the 1-stage surgery with immediate loading protocol used in this study reduces the possibility of bone loss that may occurs after implant uncovering and abutment connection.[44] The significant increase of MBL at T12 compared with T6 may be attributed to the prosthesis loading and bone reorganization combined with function stresses.

Although there was no significant difference in MBL between groups, the SG showed lower MBL than the CG. This may be due to the effect of LLLI, which inhibits bacterial count around the implants,[45] enhances bone formation at the bone-implant interface.[46] and forms more bone-to-implant contact

with high percentages of calcium and phosphorus at attachment of titanium implants.[20] The lack of significant difference in MBL between groups may be attributed to the small sample size of the patients in this study. Therefore, a future study using similar methodology, but with a greater sample size, may be needed to confirm the results of this study.

With the exception of improved implant stability after 6 months of implant loading, the null hypothesis could not be rejected. However, the study contains several threats to external validity, such as small sample size, restricted age of the patients, reduced buccolingual width of mandibular ridge, and inclusion of only patients with moderately controlled diabetes. Furthermore, the immediate loading protocol used in this study may also have affected the reported outcomes (PTVs and MBL). Therefore, the results cannot be generalized to other situations and people. These limitations may have affected the quality of the evidence derived from this study and increased the risk of bias in the direction of overestimating LLLI benefit. Despite these limitations, the study had several strengths. The split-mouth design helped to control all confounding variables, such as patient age, gender, degree of glycemic control, anatomy of the residual ridges, degree of muscle activity, and amount of bite force, which may affect the reported clinical and radiographic outcomes. This design helped to improve the internal validity of the study. Also, measurement of MBL was performed in buccal and lingual peri-implant sites. which were usually overlocked as the majority of the studies evaluate mesial and distal MBL only.

Overall, the null hypothesis was partially rejected since LLLI improved implant stability after 6 months and did not affect marginal bone around immediately loaded small-diameter implants. Future randomized well-controlled clinical studies with larger sample size are recommended to confirm the negative results of this study. Moreover, the investigation of the clinical effect of LLLI on peri-implant soft-tissue health is still needed in patients with normal mandibular ridge width, reduced bone quality of maxillary ridges. and conventional implant loading protocol. Also, the effect of LLLI on peri-implant hard and soft tissue heath in patients with poorly controlled diabetes still needs to be determined clinically. Finally, evaluation of labial and lingual cortical bone thickness before and after insertion of the implants in narrow mandibular ridges should also be investigated in future researches.

Conclusion

Within the limitations of this study, regarding the reduced external validity (small sample size, restricted age of the patients, and reduced buccolingual width of mandibular ridge), LLLI has no effect on marginal bone loss of immediately loaded small-diameter implants retaining overdentures in patients with moderately controlled diabetes. However, it may be beneficial in improving implant stability 6 months after overdenture insertion.

Abbreviations

CG: control group
CBCT: cone beam computerized tomography
HbA1c: glycated hemoglobin A1c
LLLI: low-level laser irradiation
MBL: marginal bone loss
PTVs: Periotest values
SG: study group
T0: time of insertion
T6: 6 months after insertion
T12: 12 months after insertion

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Note

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