

Hussein Adel Fathallah¹; Amr Aly El-Swify¹; Ahmed Abbas Zaky²; Ahmed El Rawdy³

¹Oral and Maxillofacial Surgery Department, Faculty of Dentistry, Suez Canal University, Egypt. ² Medical Applications of Laser Department, National Institute of Laser Enhanced Sciences, Cairo University, Egypt.

³ Oral Radiology Department, Faculty of Dentistry, Suez Canal University, Egypt.

Corresponding author: Hussein A. Abd_Elgalil, Email: hussein.adel8911@gmail.com

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ABSTRACT

Background: The use of dental implants to compensate the loss of teeth has increased through the last 30 years. The aim of the present study was to evaluate Low Level Laser Therapy (LLLT) on Implants Osseointegration in Posterior Maxillary Edentulous Region in Postmenopausal Patients. Patients and methods: The study was inducted on sixteen implants on eight postmenopausal patients with age range 54-57 years. Patients were divided equally into control group consisted of 4 individuals who had 8 implants inserted, and study group consisted of 4 individuals who had 8 implants inserted followed by low-level laser therapy. All patients were evaluated by CBCT preoperatively and by digital radiograph 2 weeks after implant placement, 3 months and 6 months postoperatively. All implants were clinically evaluated for implant stability OSTELL device immediately after implant placement and 6 months postoperatively. Results: No clinical postoperative infection was observed in all cases. LLLT plays a good role as a pain killer and lowering the swelling possibility. There was a significant difference between the immediate and 6months in control (P<0.001) and laser (P=0.002) groups. There was a highly significant difference between clinical and X-ray results in the control and laser groups at immediate and after 6 months. The mean values were high in the laser group compared with control group. Conclusion: The use of low level laser therapy with implants on maxillary posterior region on postmenopausal patients provides better implant stability and enhances osseointegration.

Keywords: Postmenopausal Patients ; Osseointegration; Low Level Laser Therapy

Introduction

Dental implants have become a very popular solution due to their high success rate and predictability of the procedure, as well as their relatively few complications (1).

Osseointegration is a direct structural and functional connection between ordered living bone and the surface of a load-bearing implant". In recent years, there has been a vast amount of scientific research and development in implant geometry, design, materials and techniques with the objective of enhancing the success of implant treatment (2). Recently Low-level laser treatment has become a well-accepted adjuvant medical tool to enhance wound healing processes and to treat functional disorders (3).

The effect of low-level laser therapy (LLLT) on implant wound healing in an animal study with rabbits by using a GaAlAs diode laser device, and they reported that the results of tensile testing, histomorphometry and X-ray microanalysis showed that LLLT had a positive effect on the functional fixation of titanium implants in bones (4,5).

Acute estrogen deficiency like in postmenopausal females, would make that mechanism switch remodeling of bone next to marrow to its disuse mode. The resulting losses of bone next to marrow would expand marrow cavities, thin cortices, and reduce trabecular bone "mass," but would not reduce outside bone make this bone type 3 or 4 osteointegration around implants in this bone type is the big challenge (6).

The big challenge for the surgeon is to establish the successful inserted implant in postmenopausal female patients with edentulous maxillary molar region (7).

So, the aim of the present study was to evaluate LLLT on Implants Osseointegration in Posterior Maxillary Edentulous Region in Postmenopausal Patients.

PATIENTS AND METHODS

The present study was conducted on eight medically free postmenopausal female patients where sixteen implants were inserted. Implants were placed in the maxillary posterior edentulous region. Patients randomly distributed into two groups:

Group I: eight implants was inserted in four patients (a control group).

Group **II**: eight implants was inserted in four patients and followed by low level laser therapy sessions (a study group).

Both groups had received oxy implants K1 line conical connection made in Italy. All patients were evaluated by CBCT preoperatively and by digital radiograph two weeks after implant placement, three months and six months postoperatively.All implants were clinically evaluated for implant stability by OSTELL device immediate after implant placement and six months postoperatively. For each patient a pre-surgical, clinical and radiographic examination had performed to evaluate bone depth and height.

Inclusion criteria:

Postmenopausal female patients aged over 55 years old. Patients with Posterior Maxillary Edentulous Region. Clinically healthy patients with adequate oral hygiene. No radiographic evidence of bone loss.

Exclusion criteria

Patients have vertical or horizontal bone loss. Patient with no adequate inter arch space Smoking patients. Bruxism, malocclusion, mouth breathing patients were also excluded.

Ethical Consideration:

All selected patients were informed about the details of the study and signed an informed consent. Approval of the Research Ethical Committee was obtained before starting

the study from Suez Canal University (320/2021). Patients were divided into two equal groups randomly using a research randomizer software (<u>https://www.randomizer.org/</u>).

I. Preoperative assessment:

Medical history was taken from patients preoperatively to exclude medically compromised patients or patients with bad habits affecting Osseointegration. Oral hygiene of the patients was assessed and referred to Perioental Department to undergo scaling and polishing for all the patients preoperatively. Clinical examination including interocclusal arch space was determined preoperatively. Bone width was determined clinically. Radiographic assessment pre-operatively by CBCT to detect patient having extracted premolar or molar in the upper arch (**Figure 1**).

Preoperative cone beam computed tomographic radiographs using the Scanora 3D imaging system using a CMOS flat panel detector with isotropic voxel size 133 μ m, the x-ray tube which is used to scan the patients possess a current intensity 10 mA, 90 KVp and a focal spot size 0.5mm. The scanning time is 14 seconds of pulsed exposure resulting in an effective exposure time of 3.2 seconds to scan FOV (field of view) of 14 cm height ×16.5 cm width. The primary reconstruction time for DICOM data set is 2 minutes.

Each patient was evaluated for bone quantity, quality, mesio-distal distance and buccolingual dimension of the potential site for implant insertion and the evaluation of major carious lesions in the remainder of the dentition and the detection of the remaining roots or any suspected pathological lesions. Cone beam computed tomographic evaluation will be performed to allow for a more comprehensive overall view and better interpretation of the anatomic structures (**Fig. 1**).

Scanora 3D is a cone beam CT machine designed for making 3D images of maxillofacial structures. It is one of many imaging modalities manufactured by Soredex (Soredex Co., Tuusula, Finland).



Figure (1): Preoperative assessment showing (a) clinical photograph showing enough interocclusal space; (b) photograph showing CBCT to detect bone width and length at the interested area.

Methodology

A slightly lingual crestal incision with buccal full-thickness flap to expose the alveolar ridge. The width of the alveolar crest was measured using calipers. The proposed implant site was marked with an initial bur (1.8 mm in diameter) at 800 rpm & torque 30Ncm. An initial rotatory taper drill was used first, successively larger rotatory tapered drills in diameter was used to expand the implant area to the desired diameter. Speed between 300-500rpm with irrigation (8).

Then, the implant was seated manually by screwdriver to reach 2/3 of the implant length and completed by using wrench to be submerged 2mm below alveolar crest. A covering screw

was used to plug the implant. Finally, the reflected flap was repositioned and sutured using 3/0 black Silk (9).

Post-operatively anti-inflammatory drugs (Cataflam tablet 50mg two times/day) was prescribed for five days. At the second day after surgery, all patients was instructed to rinse 4 times per day with a mouth wash (chlorexidine glucomat 0.12 %). Sutures was removed 7 to 10 days post-operatively.

Regular checkups were made daily in the first week then weekly bases during the first three months then at six months post-operatively to evaluate the healing process of the surgical site and the osseointegration of the implants.

Surgical procedure

All the surgical procedures were performed by the same surgeon using standardized technique under aseptic condition. All patients were operated under local anesthesia using Articaine hydrochloride 4% (Artinibsa) with 1:100.000 epinephrine .All the patients were anesthetized by infiltration technique for the buccal mucoperiostium and infiltration technique for the palatal mucoperiostium. All patients received oxy implants K1 line from Italy.

(A) Surgical procedure for study group (1):

Implant preparation osteotomy was done (figure 4) and oxy implant with suitable size and length was placed. Implant stability was measured initially at the time of implant placement with the Osstell device by using smart beg attached to the implant. Suturing was performed (**Fig. 2**). Prescription of antibiotics (Amoxicillin trihydrate 875mg + Clavulanate potassium 125mg), anti-inflammatory drugs (Cataflam tablet 50mg two times/day) was prescribed for five days.



Figure (2): Surgical procedure for study group showing (a,b):osteotomy site for implant preparation; (c,d): implant placement ;(e) smart beg attached to the implant for implant stability reading with Osstell device on surgery day;and (f): suturing.

(B) Surgical procedure for implant placement and soft tissue laser application in study group (2)

Implant preparation osteotomy was done and oxy implant with suitable size and length was placed. Low Level Laser was applied buccally and lingually on implant site in circular motion (zolar soft tissue DIODE laser) immediately post-operative, then at the 4^{th} day of surgery, the third one was on the 7^{th} day (**Fig. 3**).



Figure (3): laser application: (a) on the day of surgery; (b) on the 4th day of surgery; (c) on 7th day after surgery

Post-operative follow up

I. Postoperative Clinical Assessment by Osstell device:

It possible to monitor osseointegration in a precise and objective manner. Osstell helps you to objectively and non-invasively determine implant stability. The prob attached to the instrument via a cable and measurements are displayed on the black lit display. Implant stability was measured initially at the time of implant placement with the Osstell device by using a smart beg attached to the implant. The implant stability was assessed after 6 months, where abutment placement decision was based on the OSSTELL readings. When the reading was 70 or more abutment was placed, then the final prosthesis was fabricated.

II. Post-operative Digital Radiographic Assessment:

The image analysis was performed using IDRISI Kilimanjaro software that facilitated image restoration, enhancement, and densitometric measurements. Image restoration allowed for retrieve of images, followed by image enhancement which allowed contrast adjustment of all images and facilitated determination of the implant edge.

Statistical analysis:

Data analyzed using Microsoft Excel software then imported into Statistical Package for the Social Sciences (SPSS version 20.0) software for analysis. According to the type of data qualitative represent as number and percentage , quantitative continues group represent by mean \pm SD. Differences between quantitative independent multiple by ANOVA or Kruskal Wallis. P value was set at <0.05 for significant results &<0.001 for high significant result.

Results

We detect the difference between control group and laser group clinically after surgery on pain and swelling. Low level laser therapy plays a good role as a pain killer and lowering the swelling possibility (**Table 1**).

The descriptive statistics including the minimum, maximum, mean, standard division and median for implant stability using osstell device was illustrated in **Table (2)**. In Control group; the clinical test ranged from 57 to 74.0 with mean 66.81 ± 6.23 and median 68.500. After 6 months; the clinical test ranged from 65.00 to 78.50 with mean 69.33 ± 5.71 and median 69.75. While, laser group showed the clinical test ranged from 59.0 to 76.75 with mean 69.33 ± 5.71 and median 69.75. After 6 months: the clinical test ranged from 71.50 to 94.10 with mean 83.58 ± 7.70 and median 83.50 (**Table 2**).

Bone osseointegration around implant using idrissi program on digital periapical x-ray was showed in **Table (3)**. In Control group; X-ray test ranged from 117.50 to 170.50 with mean 144.13 ± 17.74 and median 141.00 after 2 weeks. X-ray test ranged from 100.35 to 158.00

with mean 130.98 ± 17.27 and median 130.53 after 3 months. X-ray test ranged from 124.75 to 181.15 with mean 161.01 ± 220.11 and median 168.75 after 6 months. While, in laser group: X-ray test ranged from 116.90 to 190.10 with mean 160.70 ± 22.07 and median 161.59 after 2 weeks. X-ray test ranged from 107.10 to 176.90 with mean 140.25 ± 23.95 and median 144.55 after 3 months. X-ray test ranged from 180.60 to 225.25 with mean 198.31 ± 14.70 and median 194.65 after 6 months (**Table 3**).

The comparison between the control group and laser group at immediate and after 6 months for implant stability for clinical test was illustrated in **Table** (4). At immediate, statistical analysis showed no significant difference between the control and laser group using independent sample T-test (P.0.058). At 6 months there are highly significant difference between the two groups (P=0.001).

There was a significant difference between the immediate and 6months in control (P<0.001) and laser (P=0.002) groups using T-test. Generally, the mean values were clearly high for laser group than control group and also, the values were high after 6 months compared with the mean values in immediate (**Fig. 4**).

Table 1:	Comparison	between	control	and laser	at for	swelling a	nd pain
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	Control g	Control group (N=8)		oup (N=100)			
	N	N %		%			
Swelling	4	50%	0	0%			
Pain							
No received tablet	2	25%	7	87.5%			
tablet 1	0	0%	1	12.5%			
tablet 2	4	50%	0				
Tablet 3	2	25%	0				

Table 2: descriptive data for clinical test amo	ong the studied patients.
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	Contro	ol	Laser	•
	Immediate	6 M	Immediate	6 M
Mean	66.81	72.56	69.33	83.58
SD	6.23	4.80	5.71	7.70
Min	57.00	65.00	59.00	71.50
Max	74.00	78.50	76.75	94.10
Median	68.50	73.00	69.75	83.50

Table 3: Descriptive data fo	or X ray test among	the studied patients.
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	Control			Laser			
	2 weeks	3 M	6 M	2 weeks	3 M	6 M	
Mean	144.13	130.98	161.01	160.70	140.25	198.31	
SD	17.74	17.27	20.11	22.07	23.95	14.70	
Min	117.50	100.35	124.75	116.90	107.10	180.60	
Max	170.50	158.00	181.15	190.10	178.25	225.25	
Median	141.00	130.53	168.75	161.59	144.55	194.65	

	Control		Laser	Laser		P value
	Mean	SD	Mean	SD	T -Test	
Immediate	66.81	6.23	69.33	5.71	2.067	0.058
6 Months	72.56	4.80	83.58	7.70	4.204	0.001**
paired-T – Test	8.783		4.99			
P value	<0.001**		0.002**			

Table 4: Comparison between control and laser at the same time and the time intervalfor each group in clinical test

**, means significant difference



Figure (4): Time interval for each group in clinical test.

The comparison between the control and laser group at 2 weeks, 3 months and 6 months for bone osteointegration was shown in **Table (5)**. At 2 weeks and 3 months, statistical analysis showed no significant difference between the control and laser group using independent sample T-test (P=0.120; P=0.140). At 6 months there are highly significant difference between the two groups (control and Laser) (P<0.001) (**Table 5**).

There was a significant difference between 2 weeks, 3 months and 6 months in control (P=0.013) and laser (P=0.0003) groups using one way ANOVA test at significant levels P<0.05. Generally, the mean values were clearly high for laser group than control group and also, the values were high after 6 months than immediate and 32months (**Fig. 5**).

The comparison between the clinical and X-ray for control and laser groups at immediate, and after 6 months for bone osseointegration and implant stability. There was a highly significant difference between clinical and X-ray results in the control and laser groups at immediate and after 6 months using independent sample T-test(P<0.001) **Table (6)**.

Finally, the mean values were clearly high for X-ray group than Clinical group and also, the mean values were high in the laser group compared with control group (**Fig. 6**).

 Table 5: Comparison between control and laser at the same time and the time interval for each group in X-ray test

	Contr	ol	Lase	r	T- Test	P value
	Mean	SD	Mean	SD		
2 weeks	144.13b	17.74	160.7b	22.07	1.655	0.120
3 Months	130.98 с	17.27	140.25 с	23.95	1.562	0.140
6 Months	161.01 a	20.11	198.31a	14.7	4.235	0.001**
ANOVA Test	5.345		12.47			
P value	0.013**		0.0003**			

**, means significant difference



Figure (5): time interval for each group in X-ray test

Table 6: Comparison between clinical and X-ray in each time under control and laser test

		Clinical	X-ray	Indep-T-test	P value
Immediate	Control	66.81±6.23	144.13±17.74	11.62	<0.001**
	Laser	69.33±5.71	160.70 ± 22.07	11.33	<0.001**
6 months	Control	72.56±4.80	161.01 ± 20.11	12.09	<0.001**
	Laser	83.58±7.70	198.31±14.70	19.55	<0.001**



Figure (6): Comparison between clinical and X-ray at immediate and 6 months.

DISCUSSION:

Restoring masticatory function and replacing missing teeth with minimal pain and discomfort are the most important issues for the patient and clinician. Nowadays dental implants became the most popular line of treatment to replace missing teeth: offering a comfortable long-lasting prosthesis (1). Although there are a large number of in vitro and animal studies on this subject, human studies are quite limited. The literature has shown that clinical studies on this subject have been conducted over the last 10 years (5). As far as we know, there are very few clinical studies about LLLT on the osseointegration of implants in the literature.

At their clinical study on 24 cases Soleimani et al. concluded that the use of LLLT enhances the proliferation of mesenchymal stem cells and their differentiation into osteoblasts. The activity in bone cells after application of LLLT close to the site of the bone injury and concluded that LLLT increases the activity in bone cells and remodelling process (resorption and formation) around the repair site without changing the bone architecture (10).

Clinical study on 40 cases puplished by **Khadra et al. (11)** evidenced in a cellular model that LLLT enhanced the adhesiveness and multiplication of human mandibular bone cells cultured on titanium implant material. Exposure to laser with energy density of 3 J/cm2 significantly enhanced osteocalcin and TGF-b1 production, which suggested the stimulation of osteoblast-like cells differentiation in a dose-dependent fashion. The authors concluded that LLLT is able to modulate the activity of cells and tissues surrounding an implant. They also

concluded that LLLT improves the functional attachment of titanium implants to bone and promotes bone healing and mineralization.

Also, **Mayer et al.(12)** in an experimental study, monitored significant differences in percent of newly formed bone volume and implant stability quotients following application of 830 nm wavelength diode laser therapy with 50 mW output power.

Our current study which was conducted on sixteen implants in eight postmenopausal patients and found that using of LLLT enhance the osseointegration which was agreement with the other mentioned investifations.

Similar to our study, **Radwan** (13) proved in an in vivo study that LLLT significantly enhanced bone density around delayed immediate titanium implants. Laser was delivered to subjects of laser group immediately after implant insertion surgery. They used laser parameters of 904 nm as a wave length, 30 mW as an output power, and a frequency of 9999 Hz. in a continuous mode for 3 minutes. Using densiometric analysis, they concluded that laser irradiation significantly improved bone density around implants.

As a matter of fact, **Mandic et al.(14)** had applied LLLT to 20 implants placed in the maxillary bone. The irradiated implants achieved higher stability than the implants in the control group during the follow-up, and the difference was statistically significant at the 5^{th} postoperative week.

A similar conclusion was reached by **Renno et al. (15)** reported that laser application at a wavelength of 830 nm provided a significant increase in the proliferation of osteoblasts. Likewise, **Pretel et al. (16)** and **Fávaro-Pípi et al.(17)** reported that LLLT administration had positive effects on bone healing.

The study conducted by **Morales et al. (18)**, LLLT was applied to implants in the mandible and the implant stability quotient was measured using resonance frequency analysis. It was found that implant stability quotient values gradually increased from week 6 to week 12 in the irradiated group.

In addition, **Matys et al. (19)** who reported that implants irradiated with a diode laser at 635 nm wavelengths were showed significantly greater bone density and secondary stability in comparison to control implants.

The result of the current study was in agreement with such work concerning the implant stability measured by ostell. On the other side, our results disagreed with, **Morales et al.** (18) who reported that the using of 830 nm wavelength diode laser did not significantly increase implant stability.

These result was not in agreement with our study, it may be due to using only 830 nm for one session only but we used higher wavelength of LLLT and for three sessions. While in the study by **Torkzaban et al. (20)** seven sessions of LLLT were irradiated on the buccal and palatal sides of implants. While an increase was observed in the implants in the laser group over time, there was no statistically significant difference between the laser and control groups.

This contra verses may be due to they used a very low wave length just 630 nm but in these study we used higher wave length 980 nm.

As a matter of fact other investigation were in disagreement to the current study, Gokmenoglu et al. (21) used the light-emitting diode (LED) device at a wavelength of 626nm and they found that the stability values of the implants in the LED group did not change, while the stability values of the implants in the control group decreased over time.

As in our study the stability values of the implants in the laser group increasd and this may be due to we used three sessions of laser biostimulation not just two like this study and we

used higher wave length too (980 nm).

Conclusion:

From the outcome of results, it can be concluded that the use of Low Level Laser Therapy with implants on maxillary posterior region on postmenopausal patients provides better implant stability and enhances osseointegration.

Further investigations for the role of Low Level Laser Therapy regarding enhancement of implant osseointegration and stability using different Laser wavelength

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