Smoking Impact on Clinical Outcomes of Early Loaded Direct Laser Metal Sintering Implants in Posterior Maxilla

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Abstract: Problem statement: The cumulative negative synergistic effect resulted from the association between smoking impact and poor bone quality presented in posterior maxilla has introduced a serious motivation of authors toward using an innovative Direct Laser Metal Sintering technology applied in implant production to improve implant success rate in such troublesome condition. So, this study was directed to evaluate the impact of smoking on clinical outcomes of early loaded DLMS implants used in posterior maxilla. **Patients and Methods:** Twenty patients including six non-smokers within group (A) and 14 smoking patients were involved in this study representing three separate groups. All the other fourteen patients were subdivided into two equal separate harmoniously distributed groups (B&C); either mild (1- 19 pack-years) or moderate smoking (20-39 pack-years) according to the heaviness of smoking rate. All patients within this study received DLMS dental implant installed in the posterior maxillary region and were subjected to early loading modality within 6-8 weeks. All patients were evaluated clinically at regular time intervals either immediately, at 6 and 12 months postoperatively regarding to implant stability, periodontal probing depth, Modified sulcus bleeding Index (mSBI) and marginal bone loss (MBL). **Results:** Comparing all groups, no statistical significant differences were recorded immediately after placement of final crown (P=0.366-0.104) while, a statistical significant differences were recorded between all groups after 6 and 12 months (P= 0.033-0.001) regarding to implant stability and peri-implant pocket depth. Regarding to (mSBI) a statistical significant differences were recorded between all group at the time of initial loading, 6 and 12 month (P=0.021-0.043-0.023) respectively. Only within group (C), a marked statistical significant differences were recorded during comparing subsequent time intervals of follow up against each other (P=0.0004-0.0002-0.005) respectively. **Conclusion:** Although, the reversible smoking impact was represented as a relative contraindicating condition of implant surgery, the emergence of DLMS implants has introduced an additional positive prognostic effect on implant success especially, in compromised situations such as poor bone quality and variable loading time protocols.

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1. Introduction

Fundamentally, authors believed that smoking is one of the variables that can affect dental implants. Although, smoking is not considered an absolute contraindication for dental implantation, it still represented as a challenge for the implants by its adverse effect on the gingival, periodontal and bone tissues especially, in posterior maxilla. [1-3]

Bain and Moy,[4] reported a marked decrease in the survival rate of implant in smokers when compared with non-smokers. Additionally De Bruyn and Collaert[5] reported a marked failure rate in smokers before the functional load of implants. However, from a retrospective view, the effect of smoking on dental implants is very difficult to be assessed on the basis of implant failure alone.[1]

On the other hand, the surface microstructure of the dental implants, being rough, plays a fundamental role in osteoconduction which allows faster bone formation around implants. Roughened surface promote osseointegration by stimulating the osteoplastic differentiation as well as matrix syntheses and production of PGE_2, $TGFb_1$.[6-8] Moreover, coating with biological molecules and chemical alternations have been introduced as a trial to achieve a micro or nano roughened surface for increasing implant stability and better osseointegration in lower bone quality (type IV).[9-11]

The DLMS (Direct Laser Metal Sintering) technology has been first introduced by Deckard and beaman.[12] In the last few years, DLMS implants have been manufactured by focusing a high energy laser beam allowing a localized region of thin layer metal powder to fuse with the titanium rod repeatly joining very thin sections (from 0.2 to 0.6) together which in turn permits very complex geometrical structure.[11,13]

Such a technology is expected to provide a solution to humans with poor bone quality (type IV). However, there is few histological information about implants produced by DLMS technology placed in poor bony conditions.[14,15] Based on the aforementioned data, this study was directed to evaluate the impact of smoking on clinical outcomes of early loaded DLMS implants used in posterior maxilla.

2. Patients and Methods

Twenty patients were selected from the Outpatient Clinic of Oral and Maxillofacial Surgery Department, Faculty of Dentistry, Mansoura University for replacement of missing posterior maxillary molars and premolars by early loaded dental implants.

All included patients were medically free from systemic diseases that might interfere with surgical intervention and healing process in addition to an acceptable oral hygiene with average smoking rate ≤ 39 pack according to pack-year classification. Patients were free from parafunctional activity affecting occlusion. On the other hand, patients with insufficient distance between sinus floor and the crest of the ridge ≤ 8 mm were excluded from this study.

Patient grouping

Twenty patients including six non-smokers and 14 smoking patients were involved in this study representing three separate groups. Group (A)**;** consisted of six non-smoking patients who received DLMS dental implant (Leader company\ Tixos\Italy) installed in the posterior maxillary region.

All the other fourteen patients with smoking rate ≤ 39 pack-year were subdivided into two equal separate harmoniously distributed groups; either mild or moderate according to the heaviness of smoking rate.

Group (B) (Mild smoking group); consisted of seven patients with smoking rate ranged between 1- 19 pack-years and received DLMS dental implant installed in the posterior maxillary region. Group (C) (Moderate smoking group); consisted of seven patients with smoking rate ranged between 20-39 pack-years and received DLMS dental implant installed in the posterior maxillary region. All implants within this study were subjected to early loading modality within 6-8 weeks.

Study casts were constructed as a pretreatment record for all treated patients in all groups. A surgical drilling guide was constructed over study cast using a sheet of clear acrylic resin vacuum type. Intraoral photographs of the existing condition before implant installation were taken for all patients included in this study (Fig no. 1/A– 2/A).

A panoramic radiograph has been made for each patient preoperatively and a standard parallel periapical radiographs were taken by long cone machine, using a film holding device for all patients to determine bone width in relation to the neighboring tooth and height in relation to the maxillary sinus.

Surgical procedures

Amoxicillin500 mg (Emox, Egyptian Int. Pharmaceutical Industries Co., E.I.P.I.C.O., A.R.E.) was prescribed every 6 hours two days preoperatively as a prophylactic antibiotic. All patients were instructed to rinse his/her mouth using a chlorohexidine mouth wash0.12 %(Hexitol, the Arab Drug Company, Cairo, A.R.E.) before the implant surgery. Following the administration of 2% local anesthesia (Mepivacaine HCL 2% with Levonordefrin 1:20,000. Alexandria Co. for Pharmaceuiticals and Chemical Ind., Alexandria, Egypt.) a crestal incision extending to both neighboring teeth has been made then the flap was reflected using molt no.9 mucoperiosteal elevator (Fig no.1/B – 2/B).

A careful, thorough preparation of the osteotomy site was performed to remove any remnants tissues and bone fragments followed by the drilling steps. The drilling was done using a low speed-reduction, high torque with coolant contra-angle hand-piece with surgical motor unit (i-surge Implant motor, Acteon co, France). Drilling was performed at 600-800rpm at the accurate direction. Sequential drilling with copious irrigation was carried out till the desired dimensions were achieved depending on the selected implant.

The sealed sterile implant package was opened and the implant was guided into its position with light stable finger pressure. The coupling wrench with ratchet was used to complete installation of implant till bone level then the surgical cover screw was then applied into place (Fig no.1/C- 2/C).

The mucoperiosteal flap was repositioned and primary closure was achieved using an interrupted 3/0 black silk sutures. An immediate periapical radiograph was taken to verify the final position of the implant.

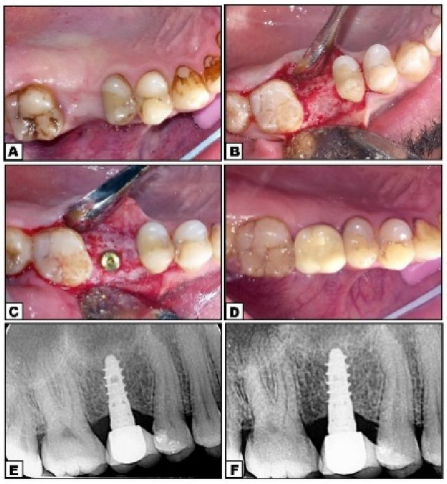
Postoperative medication consisted of continuing Amoxicillin 500mg oral antibiotics every 6 hours for 7 days. Diclofenac Potassium 50mg tablets (Oflam, Mepha Pharma Egypt S.A.E), a non-steriodal anti-inflammatory and analgesic drug was prescribed. Patients were instructed for maintaining optimal oral hygiene with Chlorohexidine HCl (0.12%), and avoid chewing solid textured food. Sutures were removed 1 week after surgery. Second stage surgery was performed at 12 weeks later.[16] The surgical covering screw was exposed and removed. The healing cap was then placed for 10 days. The healing cap is then replaced by the functional abutment. Impression was made with the aid of impression post and laboratory analogue using silicon rubber base material to

fabricate a working cast. Final porcelain fused to metal crown was fabricated and cemented permanently on the abutment. (Fig no.1/D-2/D)

Clinical Evaluation:

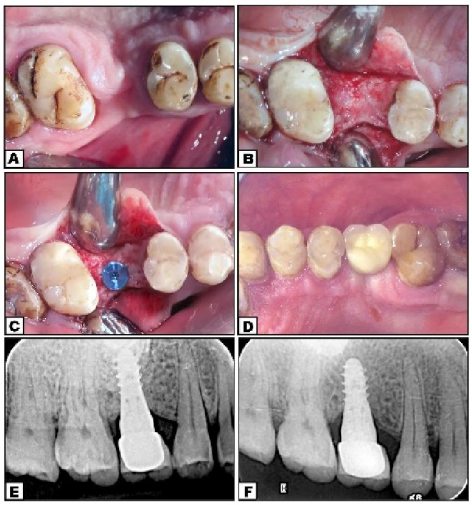
All patients were evaluated clinically at regular time intervals either immediately (at the time of initial loading), at 6 and 12 months postoperatively.

Fig no.1
Group B/Mild Smoking



A-Preoperative intraoral occlusal view, B- Flap reflection. C- Implant placement D- The final restoration in place E- Periapical radiograph after 6 month of loading. F- Periapical radiograph after 12 month of loading.

Fig no.2
Group C/Moderate Smoking



A-Preoperative intraoral occlusal view. B- Flap reflection. C- Implant placement. D- The final restoration in place. E- Periapical radiograph after 6 month of loading. F- Periapical radiograph after 12

1- Implant Stability

Implant stability was assessed at all follow up visits using periotest (Periotest M, Medizintechnik Gulden, Germany). The scores were categorized into 3 grades. [17] Grade 1; which is ranged from -08 to 0 indicates a good osseointegration and the implant can be loaded. Grade 2; which is ranged from +1 to +9 indicates a clinical examination is required and the loading of the implant is generally not (yet) possible. Grade 3; which is ranged from +10 to +50 indicates that the osseointegration is insufficient and the implant must not be loaded.

2- Peri-implant Pocket depth

The distance between the base of the pocket and the gingival margin was measured using a graduated probe. The probe was inserted in a line with the vertical axis of the implant until the blunt edge of the probe contact the base of the pocket. The pocket depth was determined by recording the average mean of measurements collected at 4 sites around each implant (mesiobuccal, buccal, distobuccal and palatal). Measurements were recorded to the nearest 0.5mm.[18]

3- Modified sulcus bleeding Index (mSBI)

The clinical signs and symptoms of the gingival marginal inflammation around dental implants were graded using criteria of modified sulcus bleeding index (mSBI) by Mombelli et al. [19]

The marginal gingiva was examined by collecting the average mean of 2 scoring zones (mesial & distal) around the dental implants according to the following scores. Score 0; indicates no bleeding detected when the periodontal probe passed into the gingival margin around the dental implants. Score 1; indicates isolated bleeding spots visible in the gingival margin around implants. Score 2; indicates blood forms a confluent red line on the margin. Score 3; indicates heavy or profuse bleeding along the margins.

Radiographic evaluation

Using standard periapical radiographs, the changes in the marginal bone level within first year after implant loading have been evaluated. The radiographic evaluation was made by using intraoral periapical radiograph following the paralling (long cone) technique to assess peri-implant bone loss either after 6 months from implant loading (T1) and after (12) months from implant loading (T2) in all groups. The implant–abutment interface was used as a reference point for the bone level measurements. An interproximal bone level was assessed from these reference points to the most coronal bone levels at the

mesial and distal surfaces of each implant and the average mean was recorded. [20] The radiographic magnification error was corrected by measuring the radiographic marginal bone loss then multiplied by the true implant length divided by the implant radiographic one so, determining the actual marginal bone loss that occur.[21]

Statistical Analysis

Data were tabulated, coded then analyzed using the computer program SPSS (Statistical package for social science) version 17.0. Student's t-test was used to compare between the mean of two groups of numerical (parametric) data (inter & intra group comparison). One way Anova was used to compare between the mean of all groups. P value <0.05 was considered statistically significant.

3. Results

This study was conducted on 20 patients for replacement of single missing maxillary posterior teeth. Six patients (3 females & 3 males) included within group (A) (–ve control group) were smoking free with an average mean 28.33±4.7. Seven patients (6 males & 1 female) were included within group (B) (mild smoking group) with an average mean 32.33±2.4 and seven male patients were included within group (C) (moderate smoking group) with an average mean 42.29±4.58.

Eight 1st molars, seven 1st premolars, three 2nd premolars and two 2nd molar were replaced. The most commonly used implant length and diameter in this study were 11.5mm / 3.7mm respectively. All patients received porcelain fused to metal crown restorations after 6-8 weeks (early loading). All patients were evaluated clinically for implant stability, peri-implant pocket depth, marginal bone loss and gingival bleeding.

Clinical evaluation

1- Implant stability

In group (A), the average mean periotest values were ranged between -2.33 ± 1.0 and -2.00 ± 0.632 either at the time of initial loading and after12months of follow up. While, within group (B) the average mean periotest values were ranged between -1.42 ±1.27 and -1.28 ±0.75 either at the time of initial loading and after 12months of follow up. In group (C), the average mean periotest values were ranged between -1.28 ±1.70 and -0.71 ±0.95 for same time intervals of follow up (Table 1).

No statistical significant difference was recorded between all groups immediately at the time of initial loading (T0) (p=0.366). However, a statistical significant differences were recorded between all groups after 6 and 12 months respectively (P=0.0333) (Table 1). A statistical significant differences were recorded between group (A) and group (C) at 6 and 12 month respectively (P=0.015). However, no statistical differences were recorded between group (A) and group (B) at the same time intervals of follow up (P=0.090).

Table 1: Showing the mean periotest values, SD and the level of significance among patients included within all groups during different time intervals of follow up.

Periotest values	Groups						P
	- Ve control		Mild smoking		Moderate smoking		
	Mean	SD	Mean	SD	Mean	SD	
T0	-2.33	1.03	-1.42	1.27	-1.28	1.70	0.366
T1(6month)	-2.00	0.63	-1.28	0.75	-0.71	0.95	0.033
T2(12month)	-2.00	0.63	-1.28	0.75	-0.71	0.95	0.033

2- Peri-implant pocket depth

In group (A), the average mean of peri-implant pocket depth values were ranged between 0.88 ± 0.24mm and 1.25 ± 0.20mm either at the time of initial loading and after 12monthsof follow up. While, within group (B) the average mean of peri-implant pocket depth values were ranged between 1.053 ± 0.14mm and 1.24 ± 0.20mm either at the time of initial loading and after 12months of follow up. In group (C), the average mean of peri-implant pocket depth values were ranged between 1.27 ± 0.45mm and 1.67 ± 0.27mm for same time intervals of follow up (Table 2).

Comparing all groups, no statistical significant difference was recorded immediately after placement of final crown (P=0.104). However, a statistical significant differences were recorded between all groups after 6 and 12 months (P=0.001) regarding to peri-implant pocket depth (Table 2). Furthermore, a marked statistical significant differences were recorded between group (A) and group (C) after 6 and 12 months (P=0.004-0.001) respectively. Also, there was a marked statistical significant differences between group (B) and group (C) regarding the peri-implant pocket depth at 6 and 12 month (P=0.017-0.006) respectively. On the other hand, no statistical significant difference were recorded between group (A) and group (B) for the same time intervals of follow up (P=0.176-0.329) respectively.

Table 2: Showing the mean of peri-implant pocket depth values, SD and level of significance among patients included within all groups during different time intervals of follow up.

Peri-implant pocket depth	Groups						P
	- Ve control		Mild smoking		Moderate Smoking		
	Mean	SD	Mean	SD	Mean	SD	
T0	0.88	0.24	1.05	0.14	1.27	0.45	0.104
T1(6month)	0.93	0.24	1.10	0.13	1.52	0.34	0.001
T2(12month)	1.12	0.20	1.24	0.20	1.67	0.27	0.001

3- Modified sulcus bleeding index

In group (A), the average mean of modified sulcus bleeding index values were ranged between 0.83± 0.40 and 1.16 ± 0.25 either at the time of initial loading and after 12monthsof follow up. While, within group (B) the average mean of modified sulcus bleeding index values were ranged between 1.07 ± 0.45 and 1.35 ±0.55 either at the time of initial loading and after 12months of follow up. In group (C), the average mean of modified sulcus bleeding index values were ranged between 1.57 ±0.45 and 1.85 ±0.37 for same time intervals of follow up (Table 3).

Comparing all groups, a statistical significant differences were recorded between all group at the time of initial loading, 6 and 12 month (P=0.021-0.043-0.023) respectively (Table 3). Furthermore, a statistical significant difference were recorded between group (A) and group (C) at the time of initial loading, 6 and 12 month (P=0.010-0.013-0.002) respectively.

On the other hand, no statistical significant difference were recorded between group (A) and group (B) at the same time intervals of follow up (P=0.338-0.417-0.439) respectively.

Table.3: Showing the mean of modified sulcus bleeding index values, SD and the level of significance among patients included within all groups during different time intervals of follow up.

Modified sulcus bleeding index	Groups						P
	- Ve control		Mild smoking		Moderate smoking		
	Mean	SD	Mean	SD	Mean	SD	
T0	0.83	0.40	1.07	0.45	1.57	0.45	0.021
T1(6month)	1.08	0.37	1.28	0.48	1.71	0.39	0.043
T2(12month)	1.16	0.25	1.35	0.55	1.85	0.37	0.023

B. Radiographic evaluation

Marginal bone loss

In group (A), the average mean of marginal bone loss values were ranged between 0.13 ±0.05mm and 0.71 ± 0.09mm either at the time of initial loading and after 12 months of follow up. While, within group (B) the average mean of marginal bone loss values were ranged between 0.18± 0.06mm and 0.82 ±0.09mm either at the time of initial loading and after 12months of follow up. In group (C), the average mean of marginal bone loss values were ranged between 0.21 ±0.1mm and 1.21 ±0.34mm for same time intervals of follow up (Table 4).

Comparing all groups, a statistical significant difference was recorded after 12 months of loading (P=0.001). However, no statistical significant differences were recorded at the time of initial loading and after 6 months (P=0.220-0.373) respectively (Table 4).

Also, a statistical significant difference was recorded after 12 months between group (A) and group (C) (P=0.008) and between group (B) against group (C)(P=0.026) regarding to MBL. On the other hand, no statistical significant difference was recorded between group (A) and group (B) at the same time interval of follow up (P=0.063) (Table 5).

Only within group (C), a marked statistical significant differences were recorded during comparing subsequent time intervals of follow up against each other (T0VsT1, T0VsT2 & T1VsT2) (P=0.004-0.002-0.005) respectively.

Table 4: Showing the mean of marginal bone loss values, SD and level of significance among patients included within all groups during different time intervals of follow up.

Marginal bone loss	Groups						P
	- Ve control		Mild smoking		Moderate smoking		
	Mean	SD	Mean	SD	Mean	SD	
T0	0.133	0.052	0.186	0.069	0.214	0.107	0.220
T1(6month)	0.633	0.103	0.557	0.127	0.671	0.198	0.373
T2(12month)	0.717	0.098	0.829	0.095	1.214	0.348	0.001

4. Discussion

Bone quality has represented a major challenge for the multiple efforts of variable implant surface treatment modalities. Basically, such treatment modalities have been made to overcome the poor condition of the jaw bone especially, in posterior maxilla as it is the most problematic intraoral implantation site or in poor general health that affect the jaw bone condition as diabetic, osteoporotic or smoking patients. [22,23] Jaffin and Berman, documented a marked failure rate to implants inserted in posterior maxillary region related to type IV bone. [24]

Micro vascular reactivity in response to cigarette smoking was investigated and confirmed that smoking has a significant, direct and reproducible impact.[25] It is proven that cigarette smoking put the individuals in a more vulnerable condition to develop more aggressive forms of periodontal disease.[26,27]

However, smoking is not an absolute contraindication for dental implant. De Bruyn and Collaert reported that a marked failure rate was found in smokers before the functional load of implants. [5] It is will proved that with the conventional methods of implant surface treatment, a marked decrease in the survival rate of dental implants have been found in smokers. [4,5,28]

On the other hand, the direct laser metal sintering (DLMS) technology used in manufacturing and surface treating of dental implants was used in such problematic patients included within our study since, it is not only offers a highly porous, uniform rough surface with isoelastic properties but also showed a great ossteointegration and more bone apposition in a short time interval when compared with the conventional types of implants. [29]

All implants included in this study were subjected to early loading protocol within 6-8 weeks in agreement with Carlo Mangano 2009, who proved that the DLMS implants stimulate and support new bone apposition after unloaded healing period of two months. The histologic and histometric results were superior to those obtained with conventional sandblasted, acid etched implants and machined implants.[30]

In this study, all implants showed ankylotic healing with marked reduction of recorded PTVs using the Periotest M at different loading time intervals of follow up. The periotest values were slightly lower than normal in smoking groups. A statistical significant differences were recorded between all group at T1 and T2 (P=0.033) and between the –ve control group and the moderate smoking group at the same time intervals of follow up (P=0.015)

The regression in the perioteast values may be refereed to smoking impact that can affect osseointegration by lowering blood flow rate in the bone due to platelet aggregation and increased peripheral resistance. [31] Also, the bone quality in posterior maxillary region put the DLMS implants in much more worse condition.[32,33]

Additionally, the regression in PTV may be due to loose of abutment screw, which results in movement of the superstructure. This was seemed so agreeably with the result of Gomez-Roman and his colleagues [34] who found similar finding and concluded that an increased Periotest value over time, therefore, it is important to check the screw loosening. In contrast, Mombelli & Lang [35] reported that the Periotest values depend on the bone quality, the length of the implant, the implant diameter and the measuring abutment. They also reported that further studies are needed to examine whether PTV changes can indicate the initial alterations in the implant bone interface before other clinical parameters are able to do.[35]

Regarding to the modified sulcus bleeding index a marked statistical significant differences between all groups at the time of initial loading, 6 and 12 month of follow up were recorded (P=0.021-0.043-0.023) respectively. Cigarette smoking was investigated and confirmed that it has a significant, direct and reproducible impact. The prolonged inferior periodontal condition caused by smoking leading to increase and prolong the gingival inflammation which in turn increase the gingival bleeding.[2,3] However, the individual variations during the application of the examination tool can also give a false results. [18]

Peri-implant pocket depth is a crucial procedure in diagnosis of the periodontium and therefore evaluation of maintenance phase of periodontal therapy. During assessment of peri-implant pocket depth (PPD) a statistical significant difference were recorded between all groups after 6 and 12 months (P=0.001). Furthermore, statistical significant differences were recorded between –ve control group and moderate smoking group after 6 and 12 months (P=0.004-0.001) and between mild smoking group and moderate smoking group for the same time intervals of follow up (P=0.017-0.006) respectively.

In our study, the increase in the peri-implant pocket depth over time intervals in both smoking groups may be due to the cigarette smoking impact which put the individuals not only in a more vulnerable condition developing more aggressive forms of periodontal disease but also resist the periodontal therapy methods. [26,27,36,37] Hass et al, showed the same result and proved that there is marked increase in the peri-implant pocket depth and peri-implant inflammation associated with smokers versus non-smokers. [1] On the other hand, using the periodontal probe in measuring the peri-implant pocket depth has an individual variation in the amount

of pressure exerted by hand leading to difference during recording accurate readings. [18]

Also in our study, the correlation between the peri-implant pocket depth and the marginal bone loss measured in the periapical x-rays showed a comparable results. At 6 month of follow up, regarding to the peri-implant pocket depth an early statistical significant difference between all groups was recorded (P=0.001) while, the MBL values measured in x-rays showed no statistical difference at the same time interval of follow up (P=0.373). However, both clinical parameters showed a statistical significant difference at 12 month of follow up between groups. (P=0.001) This may be due to the limitations of the 2D periapical x-ray that does not provide an accurate image about the bone statues around dental implants along with the variations in the pressure applied by the periodontal probe itself.

In our study, a statistical significant difference was recorded at 12 month of follow up between all groups regarding the marginal bone loss (P=0.001). Also, the moderate smoking group showed a statistical significant difference when compared with the –ve control and the mild smoking groups at 12 month of follow up (P=0.008-0.026) respectively. However there was no statistical difference between the –ve control group and the mild smoking group at the same interval of follow up.

Such variations of MBL results among groups can be based on, several studies have showed a close results [32,33,38] and refereed the MBL increase in the smoking group to several causes. However, the exact mechanisms by which smoking can do adverse effects on the periodontal tissues is not proven and unclear. [39]

To the best of our knowledge, most of reviewed articles within the literature declared just a fixed cut numbers of cigarette/ day (even variable range between 10-20/day)[40] without clarifying the smoking insult within different subcategories of smokers regarding to smoking rate especially, when smoking is considered as a relative contraindication of implant surgery. We believe that pack-year quantification method used in our study merge the time factor and the amount of cigarette consumption. Since, person-time is an epidemiologic tool that is commonly used when the duration of tobacco consumption varies from person to person. However, the cumulative effect of smoking on the jaw bone which played the major role in decreasing the survivability of dental implants revealed the need to be included within the quantifying method.

Conclusion

Although**,** the reversible smoking impact was represented as a relative contraindicating condition of implant surgery, the emergence of DLMS implants has introduced an additional positive prognostic effect on implant success especially, in compromised situations such as poor bone quality and variable loading time protocols.

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