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COMPARATIVE STUDY OF BONE HEIGHT CHANGES AROUND IMMEDIATELY LOADED POROUS TANTALUM PARALLEL SIDED TRABECULAR & SCREW SHAPED IMPLANTS RETAINING MANDIBULAR IMPLANT- OVERDENTURES USING CBCT (RCT)

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ABSTRACT

Objective: This study was conducted to evaluate the crestal bone height changes of immediately loaded Porous trabecular tantalum dental implants (PTTM) and screw shaped titanium implants in mandibular two implant overdenture with CBCT scan. ***Subjects & Methods:*** Fourteen completely edentulous patients were rehabilitated with maxillary complete dentures & immediately loaded mandibular two implant overdentures. Patients were selected according to certain inclusion & exclusion criteria. Conventional maxillary & mandibular complete dentures were constructed for all patients. Patients were then randomly divided into two equal groups according to the implant type. Group (I-Intervention Group): TM implants & Group (II- control Group): Conventional titanium Screw implants were utilized. Implants were installed in the mandibular interforaminal region. Implants were immediately loaded with ball retained overdentures. Radiographic Evaluation of crestal bone height changes around the implants was made with CBCT scan; at the denture insertion visit, 6, 12 , & 24 months after denture insertion. Data were collected, tabulated & statistically analyzed. ***Results:*** All patients were satisfied with their implant overdentures, No implant loss were recorded during the follow-up Period. The results of this study had revealed that the crestal bone height gradually decreased throughout the study period in the two studied groups. The mean values of crestal bone loss were (0.497mm± 0.161, 0.362mm ±0.045, 0.120mm.±0.13, 0.9 mm±0.67) and (0.65mm± 0.076 , 0.338mm±0. 047, 0.75 ±0.407, 1.20 ±0.108) in group I & Group II respectively at 0-6 month, 6- 12 month, 12- 18 month and from 0-24 month intervals. On comparing the studied Groups: The crestal bone loss was greater in Group (II) than Group (I) along the whole follow-up intervals. In the 1st & 2nd follow -up intervals; (0-6month & 6-12 Months) bone loss was greater in Group (II) than Group- I with statistically insignificant difference (P-values 0.069 ns &0.400 ns respectively). However, in the 3rd interval (6-12months) & (12-18 months) and(0-24months), bone loss was significantly higher in Group-II than Group-I; with (P=0.000*). ***Conclusions: Within the limitation of the current study:*** Trabecular Tantalum Dental Implants (PTTM) may induce less crestal bone loss than conventional screw-shaped titanium implants in immediately loaded mandibular implant overdentures.

KEY WORDS: Porous tantalum, Trabecular metal implants, immediate loading, overdentures, crestal bone loss

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INTRODUCTION

Two implant-retained overdenture has been advocated as the first choice for treatment of completely edentulous mandible with 100% success rate [1&2]Construction of implant overdentures and immediate implants' loading with the denture has gained greater acceptance for the last 15 years. The concept of immediate implant loading provides all the advantages of one-stage surgical technique in addition to decreasing the risk of overloading due to the increased surface area and improved biomechanical stability.[3]

It was reported that the immediately loaded implants are able to osseointegrate, even though they are exposed to the oral environment during early bone remodeling. Moreover, it eliminates the second stage surgery and aids in immediate prosthetic rehabilitation of the patient. [3]

For immediate loading protocol the implant primary stability is essential at the time of implant loading [4,5].

Various modifications had been made for the dental implant surfaces such as grit blasting, acid-etching, coating, or a combination of procedures to improve the bone/ implant attachment. [6,7,8]

the porous TM biomaterial contains a network of pores (~440 μm in size) that interconnect to form large internal dodecahedron shaped healing chambers of regular sizes and shapes. [9-11] TM biomaterial is applied in the midsection of a conventional titanium alloy implant body. [12]This TM dental implant design allows for conventional osseointegration to occur at the tantalum & titanium implant surfaces-bone interface. [12,13] Moreover, intra-membranous like healing occurs which is characterized by rapid bone & bone marrow formation inside the pores (or bone ingrowth) and the internal healing chambers of the TM biomaterial. ([14,15]

The modulus of elasticity of the TM implant is similar to bone; consequently less stresses at the implant/bone interface and less bone resorption may be expected. [11]

Porous coating of TM implants had improved the orthopedic implants integration; this may be applied in the field of dental implants. [16]

It was proved that porous tantalum trabecular metal (PTTM) had provided higher primary stability in the fresh extraction sockets of dogs when compared to the conventionally threaded implants during early healing phase. [15] TM implant has excellent implant stability and osteointegration in knee replacements. [17]

It is assumed that immediate and early loading of PTTM-enhanced titanium dental implants may be recommended due to their special design and surface modification. However, there are no current studies on such topics. Consequently, this clinical trial was conducted to evaluate crestal bone height loss around TM implants & conventional titanium dental implants in immediately loaded two implant mandibular over dentures.

METHODOLOGY

Study Design:

This study was a paralleled randomized controlled clinical trial; CBCT scan was utilized to compare crestal bone height loss around two types of dental implants: (Tantalum or trabecular Implants & conventional titanium dental implants) in immediately loaded mandibular implant overdentures.

Patient Selection criteria:

Fourteen completely edentulous patients were selected with 50-60 years age range from outpatient clinic of Prosthodontics department, Faculty of Dentistry, Ain Shams University.

Patients were selected based on the following criteria: completely edentulous maxillary & mandibular arches. They were medically free

from any systemic disease that might affect bone metabolism or delay post-operative healing.

They had moderately developed residual alveolar ridges covered with firm healthy mucosa, free from any signs of inflammation, ulceration or flabbiness. All patients had Angle's Class-I maxillo-mandibular relationship and sufficient restorative space. Patients with radiographic bone density ranging from 850–1250 Hounsfield units (D2) were enrolled in the study. All selected patients signed a written informed consent containing all details about surgical & prosthetic protocols followed in this study.

Prosthetic Management: Patients had received maxillary & mandibular complete dentures constructed according to the conventional protocol. After complete denture insertion & all necessary adjustments of any arising problem.

The mandibular denture was utilized as a radiographic stent to evaluate the available bone quality & quantity in the area of interest. Consequently, Gutta Percha markers were inserted in the fitting surface of mandibular dentures in canine-premolar areas bilaterally. Patients were instructed to wear the maxillary & mandibular dentures during radiographic evaluation. Cone beam CT Scan was made with i-CAT imaging system.

Patients' Grouping:

Patients were randomly divided into two equal groups according to the implant design. Randomization was made by asking each patient to select one of two opaque envelopes, each representing one of two implant types (TM implants or conventional screw implant). Each group included seven patients.

Group (I): Trabecular Metal™ Dental Implants, Zimmer Biomet, Palm Beach Gardens, FL, USA)

Group (II): Conventional Screw implant. (Zimmer dental, Tapered Swiss Plus, Implant system, USA)

Implants Installation (Surgical Phase):

A surgical guide was fabricated by duplication of the mandibular dentures.

Pre-Operative Medication: Patients were instructed to take antibiotic (Clavulanate-potentiated Amoxicillin) 1gm/ 12 hours the day before surgery and continued for 6 days after. Anti-inflammatory; Ibuprufen 400 mg tablets (Brufen, Kahira Pharm. & Chem. Ind. Co., Under licence from: Abbott Laboratories, Egypt) and Chlorhexidine mouth wash (Hexitol, The Arab Drug Company ADCO, Egypt) were prescribed 3 times daily prior to surgery. The patient peri-oral region was cleaned by antiseptic solution.

- After the patient rinsed with Chlorhexidine 2% mouth wash, bilateral nerve block anesthesia was given to the patient & infiltration field block was given in the area of interest. The surgical guide was then inserted in the patient's mouth & an explorer was used to make a pinpoint puncture to identify the proposed implant sites. (Fig. 1)

Two crestal incisions were made, muco-periosteal flaps were reflected & the sharp bony edges were flattened using bone file.

Implants used: Group (I): Tantalum implants: PTMM trabecular metal material (Zimmer, Parsippany, NJ, USA) diameter 3.7 mm, length 11.5mm.

Group (II): Conventional Titanium Screw implant (Zimmer dental, Tapered Swiss Plus, Implant system, USA) 3.7 mm, length 12 mm.

The envelope containing the randomization code was opened & the operator knew whether the patient would receive trabecular or screw implants. Sequential drilling was made for implant installation with light intermittent; internal irrigation was applied till reaching the required depth.

Implants were installed into their implant beds with slight apical pressure until implants' top flushed

with the crestal bone level. Implants' primary stability was measured with Ostell Device. Implants with ISQ above 60 were subjected to immediate loading. Fig.(1)

Ball attachments (Ball abutments 1.6mm collar height, Zimmer Dental, USA) were installed onto the corresponding implants.

Post - Surgical instructions:

After surgery, patients were instructed to avoid brushing and trauma at the surgical sites. Cold & soft diet was recommended for 7 days post-operative. They were instructed to rinse with Chlorohexidine mouth wash twice daily for 2 weeks and take amoxicillin 500 mg Capsules and Ibuprufen 400 mg tablets every 8 hours for 5 days.

Denture adjustments:

The dentures were fitted onto the ball attachments, adjusted and immediately delivered to the patients. Patients were instructed not to wear their dentures at night to avoid unnecessary stresses on the implants. Patients were recalled after three days, Fig. (2). one week & two weeks after denture insertion to overcome any arising problem. They were recalled every month to ensure oral hygiene maintenance and prosthetic check-ups throughout the study period.

Evaluation of Bone height changes around implants

Patients were recalled every six months to evaluate crestal bone loss around implants. CBCT was utilized to evaluate the crestal bone height loss around implants at the denture insertion visit, six months, twelve eighteen & 24 months after denture use. CBCT scan was made using i-CAT imaging system.

Patients were exposed in the sitting position with their heads immobilized using a headband to stabilize the head against the headrest and chin cup to help in mandibular stabilization. The mid-sagittal plane was made perpendicular to the horizontal plane using vertical and horizontal alignment beams as recommended by the manufacturer.

The bone height was measured between two reference points in vertical plane. The first point was the implant apex while the second was the highest level of the crestal alveolar bone.

Bone height was measured at the mesial & distal aspects of the implants were measured from the panoramic view. The mean values were calculated for each implant in each patient, recorded and tabulated for statistical analysis.

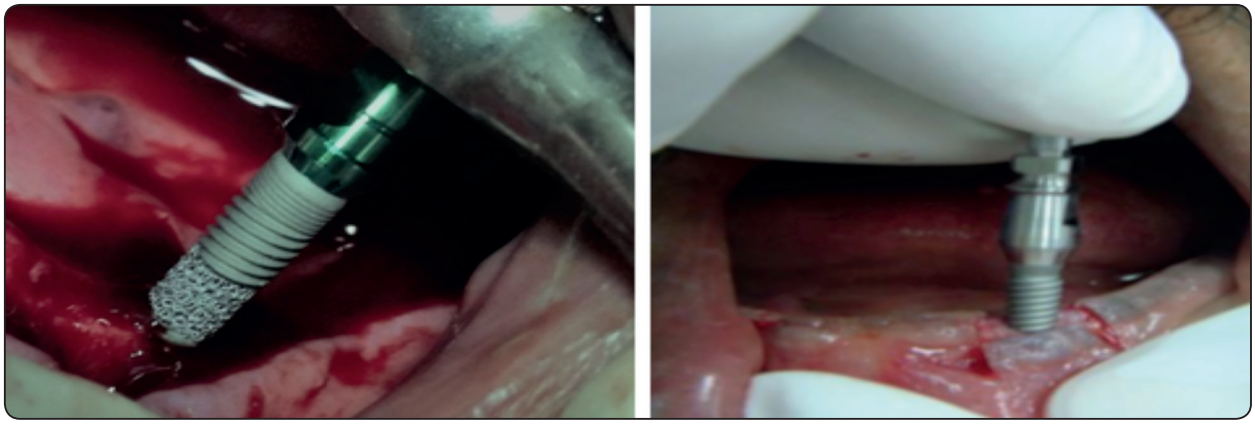

Fig. (1) Installation of TM Implant & Conventional Screw shape implants

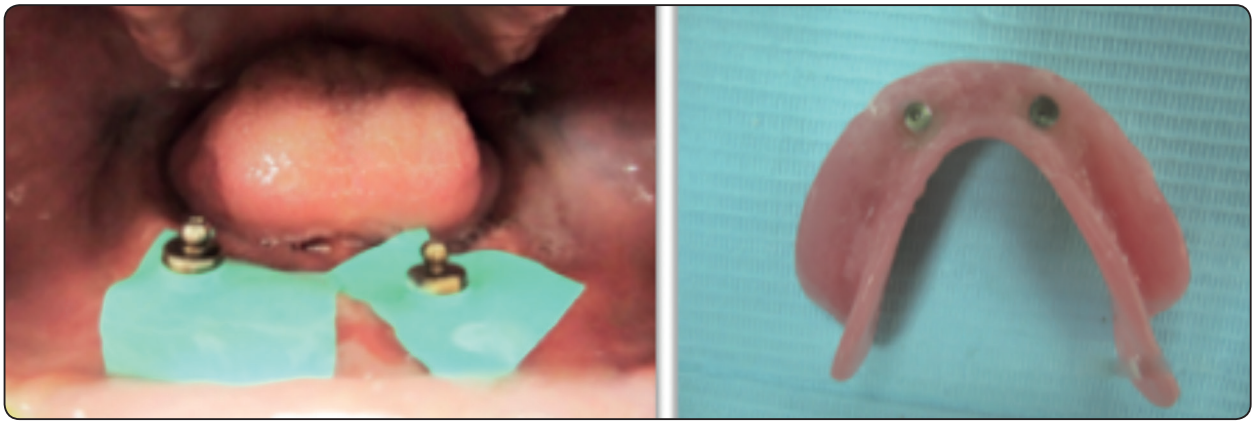

Fig. (2) : Fitting of the dentures onto the ball abutments

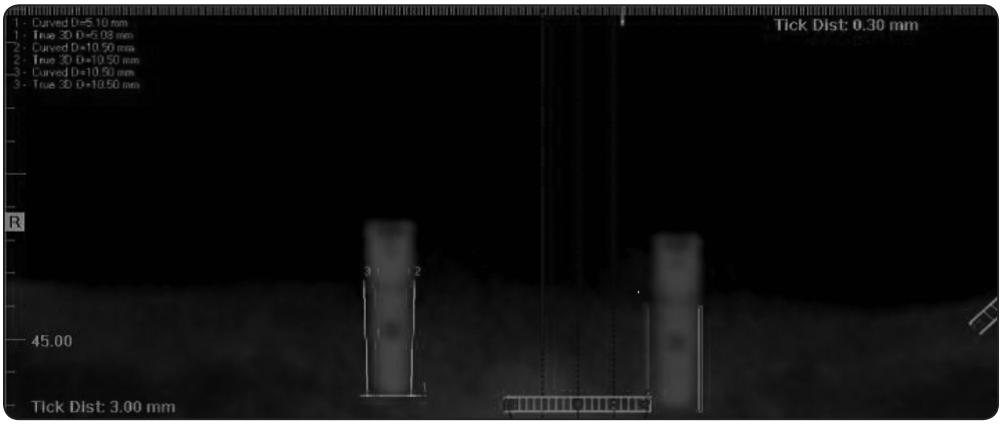

Fig. (3): Radiographic Evaluation of crestal bone loss around implants

Statistical analysis:

Data were presented as mean, standard deviation (SD) values and percentage change. The mean values of bone height were averaged for implants in each patient. One-way ANOVA was used for follow- up periods comparison within each group followed by Tukey's post-hoc test for significant ANOVA pair-wise comparison. Paired t –test was used for inter-group comparison at the same follow-up period.

The significance level was set at $P \leq 0.05$. All statistical analysis was performed using SPSS (Statistical Package for Scientific Studies) v.18.0 (IBM Corp., Armonk, NY, USA).

Results of the study:

All patients had attended all recall visits. During the 18-months follow-up period, no implants were lost with 100% survival rate.

Table (1) is showing the mean values of the crestal bone height loss in mm in group (I & II). Crestal bone height has gradually decreased by time in the two studied groups. The mean values of crestal bone loss were (0.497mm± 0.161, 0.362mm ±0.045, 0.120mm. ±0.13, 0.9 mm±0.67) and (0.65mm± 0.076 , 0.338mm±0. 047, 0.197±0.023, 1.22mm±0.108) in group I & Group II respectively at 0-6 month, 6- 12 month, 12- 18 month and from 0-24 month intervals.

Tukey's post hoc test was made to evaluate level of significance between each follow-up intervals. In the intervals from 0 - 6 months and 6 -12 months, there was no statistically significant difference between groups (p=0.069, p=0.4 respectively). In the intervals from 12 - 18 months and from 0 - 24 months, a higher mean value of bone loss was recorded in group (II), with a significant difference (P=0.000), (Table1)

Table (2) & Fig. (4) show that crestal bone loss was greater in group (II) than Group (I) along the whole follow-up intervals. In the 1st & 2nd follow -up intervals; (0-6month & 6-12 Months) bone loss was greater in Group (II) than Group I with statistically insignificant difference (P-values 0.069 ns &0.400 ns respectively). However, in the 3rd interval (12-18months) & the whole study period (0-24 months), bone loss was significantly higher in Group-II than Group-I; with (P=0.000*).

TABLE (1): Effect of time on the bone height changes in Group (I & II):

Group (I): Porous trabecular tantalum implants				***Group (II): Screw shaped implants***		
Time	***Mean ±SD***	***F- value***	***P-value***	***Mean ± SD***	***F- value***	***P- value***
0-6 month	0.497± 0.161	-2.136	0.069 ns	0.65± 0.076	0.878	0.400 ns
6-12 month	0.362±0.045			0.362±0.047		
12-18 month	0.120±0.13			0.197±0.023		
0-24 month	0.75 ±0.407			1.20 ±0.108		0.000*

Significance level p<0.05, *significant, ns (Non- significant)

TABLE (2): Comparison of the mean values crestal bone loss around implants in studied groups: (independent –t test)

Follow- up intervals	Group (I) (Porous tantalum implant) Mean ± SD	Group (II): (Conventional Screw shaped implant) Mean ± SD	T-Value	P- value
0-6 month	0.497 ± 0.161	0.65 ± 0.076	-2.136	0.069ns
6-12 month	0.362±0.045	0.338 ± 0.047	0.878	0.400ns
12-18 month	0.120±0.013	0.197 ± 0.023	-7.273	
0-24 month	0.75±0. 407	1.20± 0.108	-5.988	0.000*

***Significance level p<0.05, * significant, NS=non-*significant

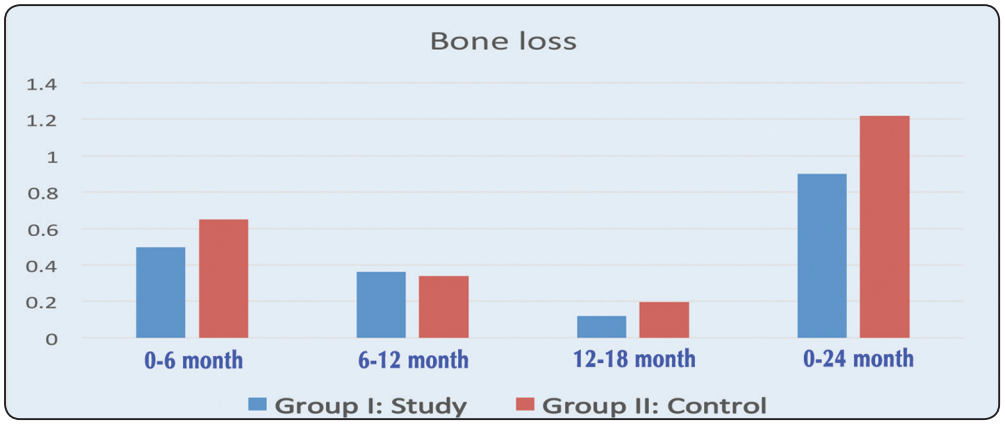

Fig (4): Bar chart comparing the mean values of crestal bone loss in studied groups

DISCUSSION

Patients who participated in this study were satisfied with their implant overdentures regarding denture retention, esthetics and better masticatory efficiency than previous complete dentures. Immediate loading protocol was followed to reduce the treatment period, treatment fees and allow the patient to benefit from the immediate esthetic outcomes. The decision to immediately load the implant is largely dependent on its primary stability. Consequently, implants with 65 ISQ values were enrolled in this study.

The results of the current study support the opinion that the maximum bone loss occurs at the first six-months interval & progressed slowly thereafter in the two studied groups. A total change of 0.497mm+0.161 and 0.65mm± 0.076 was detected in Group-I & Group-II respectively. These findings are comparable to the results of previous studies [18,19] .

This might be due to surgical trauma, bone osteotomy and healing process. Moreover, the marginal bone loss might be considered an immediate bone reaction after prostheses insertion. Crestal bone loss could also be explained by the finding that forces applied on implants are distributed on the crestal bone rather than along the entire implant/bone interface.

Implants of both groups had reported less than 1.5 mm vertical bone loss after the first year follow-up period. This finding is consistent with the criteria of implant success [20,21]

A total change of 0.75mm±0.405 & 1.20mm±0.108 mm was detected for trabecular implants (***Group-I)*** & Titanium Screw shaped implants ***(Group- II)*** respectively throughout 24 months study period. It was obvious that trabecualr metal enhanced implants had shown less crestal bone loss than conventional screw shaped implants ***(Group- I);*** this finding may be due to the alteration of the implant surface topography that offer greater surface area for osseointegration & allowed better load distribution at the implant/bone interface in a three dimensional manner simulating the natural osseous structure.[22,23]

TM implants had shown less crestal bone resorption than conventional screw shaped implants all over the study period; this finding may be due to several factors such as the biocompatibility of the porous structure and the modulus of elasticity which are similar that of cancellous bone, the ability of the PTTM-enhanced titanium implants allowing the ingrowth of blood vessels and vital bone. [24]

Moreover, TM implant design differs from the conventional screw implants by the absence of threads in the midsection of the implant. This mid-section is modified by addition of PTTM material

with circumferential microgrooves and micro-texturing in the cervical region of the implant that extended to within 0.5 mm of the coronal platform. It was reported that implants with microgrooves may significantly preserve crestal bone than implants with machined surfaces. [25]

CONCLUSIONS

Within the limitations of the present study, it may be concluded that Trabecular tantalum Dental Implants (PTTM) induced less crestal bone loss than conventional screw-shaped titanium implants in immediately loaded mandibular implant overdentures.

RECOMMENDATION

More long-term clinical studies are recommended to provide more reliable results & to prove the clinical characteristics of this treatment modality.

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