

A CBCT EVALUATION OF MARGINAL BONE LOSS IN TWO VS. FOUR IMPLANTS-BAR SUPPORTED MANDIBULAR OVERDENTURE: **RANDOMIZED CLINICAL TRIALS**

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ABSTRACT

Purpose: The aim was to compare the effect of using different number of implants (two and four implants) on marginal bone loss around implant in implant -bar supported mandibular overdenture.

Material and methods: Twelve edentulous patients were randomly divided into two groups. Group I received two implants-bar supported overdenture while group II received 4 Implantsbar supported overdenture. Fixtures were surgically inserted with its top level 0.5mm below the crestal bone level. Each patient was recalled two months after implant insertion for superstructure placement. Crestal bone loss around the implants were measured on CBCT images taken at time of final prosthesis pick-up, 3 months, 6 months and 12 months after overdenture pickup. Repeatedmeasure ANOVA with Tukey post hoc test was used to compare between the two groups at the different time points.

Results: There was a significant main effect of time on bone resorption (p<0.001). however, there was no significant main effect of group on bone resorption (p=0.132). There was no significant interaction between time and group. Multiple comparisons showed a significant difference between the baseline and 12 month time point in each group (p=0.006 and p=0.041, respectively). Also, there was a significant difference in bone resorption between the two groups at 12 month time point (p=0.044).

Conclusion: Four implants-bar supported overdenture provided better preservation of marginal bone than two implants-bar supported overdenture. Therefore, its recommended for clinicians to consider the design of four implants-bar supported overdenture specially when the bone of jaw is compromised.

Keywords: Implant-assisted Overdenture, two implants-bar supported overdenture, four implants-bar supported overdenture, CBCT, marginal bone loss.

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INTRODUCTION

The patients problems of inadequate retention and stability with mandibular complete dentures can be adjusted effectively with Implant-supported mandibular overdentures ⁽¹⁾; furthermore, Implantsupported mandibular overdentures significantly provide good occlusal force, chewing ability and stable centric occlusion. ⁽²⁾

A systematic review revealed that the bar attachment has a good survival rate for 5 years, i.e., 94.2%. While this attachment had a lot of problems such as bone resorption and gingival inflammation, and mucosal changes. The maintenance rate of this attachment was significantly low (0.8/individual). The survival rate of implant was 97.9% and 96.7% in the bar group and locator group respectively. So, the bar group was better than the ball group. ⁽³⁾

Satisfaction between patients with bar and ball attachments retained two implant mandibular overdentures were nearly the same at early evaluation and after 10 years of function. Moreover; it was stated that the peri-implant health mucosa and crestal bone loss were nearly the same between ball and bar attachment, however, rate of repair and technical complications was greater in bar than ball attachments.^(4&5)

In addition, statistically significant difference exists between the different attachment systems, as the bar attachment had a higher retaining force value compared with ball and locator attachments. While bar attachment has a few drawbacks such as initially high cost, hard to fix, and it seems difficult to maintain oral hygiene, particularly for weak elderly people a wide variety of bar attachments forms are available and could be either prefabricated or custom made.^(6&7)

Completely edentulous patients with screw retained prosthesis had a good history of successful application. Retrievability is considered the main advantage of screw retained restorations moreover; easy periodic replacement of prosthodontic components, fractured abutments, fractured fastening screws and prosthesis modification after loss of an implant⁽⁸⁾.

Marginal bone loss (MBL) is an important factor in the assessment of the implant success rate. high bone loss around the implants is the major cause in implant-assisted restoration failure. Significantly, the preservation of peri-implant bone remains a critical consideration for promising prosthetics and long-term aesthetic results of implant dentistry, the amount of bone resorption is roughly 0.9-1.6 mm after implant function by one year. In addition, the average annual bone resorption of 0.05 to 0.13 mm in the following years is considered normal however; If more than half of the bone around the implant is lost, that implant is considered to have failed however; Bone loss can occur either from mechanical or biological (peri implantitis) components, or from a mixture of both (9&10).

The most important factor are the characteristics of occlusal force, implant related factors, connection between implant and abutment, bone quality and density, and prosthetic material and design. The saucerisation patterns of MBL are noted in some types of implants after first year of function because of the stress concentrated around the marginal region as bone and fixtures have different modules of elasticity⁽¹¹⁾

MATERIAL AND METHODS

Twelve completely edentulous patients were chosen from the Outpatient clinic, Prosthodontic Department, Faculty of Dentistry, Fayoum University with the following inclusion criteria: 1) Age of all patients ranged between 45 and 60 years old, 2) Atrophy of posterior mandibular ridge, 3) Healthy gingiva, 4) Sufficient amount of bone in the interforaminal area (at least 13 mm available bone height). Exclusion criteria include: 1) Radio therapy for head and neck, hepatic disease

(3851)

and bleeding disorders, 2) Patients with diabetes mellitus and osteoporosis that may affect implant osseointegration.

All patients signed informed consents and the study plan was approved by local ethical committee. The patients were randomly assigned into two groups (ratio: 1:1). By generating a random number in excel spread sheet was given to each participant and the numbers were kept in sealed envelopes. A blind dental assistant randomly assigned the patients number into two groups using simple random method. Group I; included six participants Who received two implants-bar supported overdenture while, Group II; included six participants who received 4 Implants-bar supported overdenture.

Extra and intraoral examinations were carried out in conjunction with the necessary laboratory tests, such as a blood picture and blood glucose level. A preoperative panoramic radiograph (1:1) was used to rule out patients with remaining roots or atypical pathological conditions, and a diagnostic Cone Beam Computed Tomography (CBCT) image was taken with i-CAT to assess bone volume (width) at the intended implant site (canine region).*

All of the processes of the acrylic complete denture construction were completed, starting with the primary impression, final impressions, jaw relation, try-in for artificial teeth, and final delivery of the acrylic complete denture. The denture was copied into a clear acrylic resin model, which was then scanned using a CBCT scanner and the DICOM data was processed to create an STL file.

For each patient, standard CBCT scanning methods were used, with a standardized setting of 90 kV, 6.3mA, a 12 s exposure time, and a voxel size of 0.2 mm. The radiologist who did the scan was the same. The generated CBCT was loaded into the implant planning software for virtual planning of the implant surgical guide^{**}. The virtual implant was implanted in the most appropriate spot according to the surgical and prosthetic design using digital image segmentation.

The planned virtual template was converted to STL files and printed on a three-dimensional printer^{***}. The guided surgical metal sleeves were manually pushed into the corresponding knot. (Fig 1)



Fig. (1): Surgical guide fixed intraorally

All patients should be given a broad range antibiotic ****24 hours prior to surgery and non-steroidal anti-inflammatory analgesics***** every 12 hours following surgery for the next 5 days.

The surgical technique of implant size 3.4 x10mm^{******} insertion was done until completion of the osteotomy sites, then the platform was made using a counter sink drill at a speed of 1000 RPM and a torque of 30-45 N/cm, and the countersink drill's actual diameter is 0.1mm greater than the fixture platform's. In order for the top level of the fixture to be 0.5mm below the marginal crestal bone level, the countersink drilling depth was increased.

^{*} Planmeca promax 3D classic, Planmeca, Finland.

^{**} Blue Sky Plan® V3, Blue Sky Bio, n® LLC, USA .

^{***} Form 1+, Form labs, USA.

^{****} Augmentin 1g- Beecham MUP.

^{*****} Ibuprofen, Knoll, Ludwigshafen, Germany.

^{*****} Simplex, Implura dental implant, Glockenring3, Germany.

The implant was threaded until the implant top flushes with the alveolar bone surface.

After confirming Osseo integration, two months after implant insertion. Fixture position was detected with the help of the surgical stent; a diagnostic probe was inserted through the hole of the surgical stent to make a bleeding point on the mucosa covering the proposed implant site. The implant covering screw was exposed in the oral cavity using a surgical punch, then the covering screw was unthreaded, the healing abutment was threaded into the implant and tightened well with a hex screw driver. After a healing period of 2 weeks the healing abutments were removed, and the field was thoroughly cleaned with sterile saline solution.



Fig (2): Healing abutment in place

Healing abutments were removed and impression copings with long retention screw were screwed to the implant fixture. Impression coping were splinted together rigidly using orthodontic ligature wire and light cure composite with a free space between the mucosa and splinting connection to allow injection of impression material. (Fig 2)

Open tray impression was taken in special tray using vinyl polysiloxane regular body impression material

A verification jig was made to ensure accuracy of the impression and check it in the patient mouth and by periapical radiograph. (Fig 3)

And then, UCLA abutments were attached onto the implant analogues on the poured cast and connected with a bar it's round surface in the top which are incorporated in to the wax pattern, after investing, the plastic bar and abutments were burned -out of the wax pattern and molten alloy was cast into the investment mold creating a framework pattern which provide cast interface that match directly with the implants.

The cast framework (Hadar bar) was tried on the cast and inside the patient's mouth to ensure passive fit clinically by one screw test (sheffield test) and radiographically by periapical radiograph, and then the space between the bar and the gingiva was evaluated to ensure the presence of sufficient relief space. (Fig4)



Fig. (3): Verification jig



Fig. (4): Checking of the bar intraorally.

Before Pick-up of the denture Blocking out the undercuts beneath the bar using elastomeric impression material was done and then the plastic clip attachments were secured over the bar. (Fig 5)

Directly in the patient's mouth pickup of the clip was done. a sufficient relief was made in the prosthesis fitting surface opposite to the clip and a small hole was made at the lingual flange to allow for escaping of excess material then the fitting surface at this area was conditioned with acrylic monomer. Mixing and Application of Auto polymerizing resin was done in the holes. With the prosthesis inside patient's mouth the patient closed in proper occlusion. After setting of the resin material, excess material was trimmed. (Fig 6)

Patients in all groups received CBCT immediately after the implant loading, 3 months, 6 months and 12 months after insertion of the overdenture. Each implant was evaluated from the crestal bone level. The first bone contact distally and mesially to implant shoulder was measured from the CBCT using Invivo 5 software (version 5.3Anatomage, San Jose, USA) were used for the assessment of crestal bone level (Fig 7). The radiographs were compared with base line radiographs. The marginal bone level was assessed at distal and mesial side of fixture on the radiographs. The height of the alveolar bone on mesial and distal sides of the implant was measured as follow: Average bone height = (Mesial bone height + Distal bone height)/2.

Statistical analysis:

Statistical analysis was done by IBM® SPSS® Statistics Version 20 for Windows. The mean and standard deviation of amount of Bone resorption over time were calculated. The data were explored for normality using Shapiro-Wilk tests, and showed parametric (normal) distribution. Paired sample t-test was used for comparing right and left sides in each group and showed no significant difference.

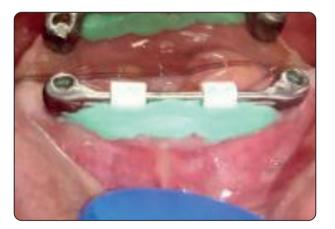


Fig. (5): Block out the undercuts beneath the bar



Fig. (6): pickup of the clip

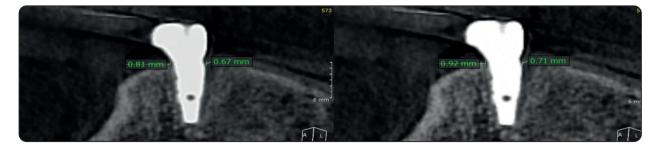


Fig. (7): Marginal bone resorption

Therefore, data from both sides were combined. Repeated-measure ANOVA with Tukey post hoc test was used to compare the bone loss between the two groups at the different time points. The significance level was set at $P \le 0.05$.

RESULTS

Repeated-measure ANOVA showed a significant main effect of time on bone resorption (p<0.001). the significant difference in the two and four implants groups was p=0.036 and p=0.042, respectively. Multiple comparisons showed a significant difference between the baseline and

12 month time point in each group (p=0.006 and p=0.041, respectively). No statistically significant difference was found among any other time points for both groups (Table 1and 2, Fig 8).

There was no statistically significant main effect of group (p= 0.132). however multiple comparison showed a significant difference in bone resorption between the two groups at 12 month time point (p=0.044). while the other time points showed no significant differences between groups. There was no significant interaction between time and group (Table 1 and 2, Fig 8).

TABLE (1): The mean, standard deviation (SD) values of bone height formation of different groups.

- Variables -	Bone resorption					
	Group 1 (Two implants)		Group 2 (Four implants)		p-value	
	Mean	SD	Mean	SD	-	
Baseline	1.38	0.16	1.31	0.19	0.492	
After 3m	1.59	0.71	1.56	0.34	0.912	
After 6m	1.74	0.22	1.70	0.15	0.689	
After 12m	2.21	0.38	1.73	0.34	0.044*	
p-value	0.036*		0.042*			

*; significant (p<0.05).

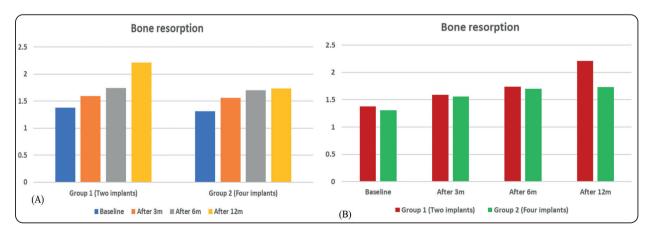


Fig (8): Bar chart representing bone resorption for different groups and different time periods

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Corrected Model	3.201	7	0.457	3.592	0.004
Intercept	130.746	1	130.746	1026.929	0.000
Groups	0.301	1	0.301	2.363	0.132
Time	2.488	3	0.829	6.515	0.001
Groups * Time	0.412	3	0.137	1.078	0.369
Error	5.093	40	0.127		
Total	139.040	48			
Corrected Total	8.294	47			

TABLE (2): Results of Two-way ANOVA for the effect of different variables.

df: degrees of freedom = (n-1), * Significant at $P \le 0.05$

DISCUSSION

This research was performed to study the effect of different numbers of dental implants-bar supported overdenture on marginal bone loss. two and four implants were evaluated for average marginal bone loss at different time intervals at loading ,3 ,6 and 12 months.

For completely edentulous patients, who is contraindicated for fixed prosthesis with implant because of anatomical limitations and poor posterior bone quality, we can select them for the current study.⁽¹²⁾

The attachment type selection depends on a lot of factors such as alveolar bone height and width, the space between upper and lower jaw, retention degree required, patient's financial state, patient's expectation and clinician preference. The minimum inter-arch space available for bar and telescopic attachment is 13-14 mm, ball attachment is 10–12 mm, locator and magnet attachment is 8.5mm.⁽¹³⁾

Flapless surgery was used as it showed fewer traumas during surgery to the soft and hard tissues, healing rapidly, less postoperative complications and reduced risk of infection. Surgical guides were used to ensure parallel implant placement as parallelism between the implants was mandatory to prevent any prosthetic challenges of bar construction and to achieve passive fit of the bar. ⁽¹⁴⁾

Bar attachment can manage non-parallelism implant using abutments with angulation. while, the implant-supported overdenture is associated with peri-implant hard and soft tissue problems, loosening of overdenture attachment, a lot of followup visits and prosthetic failure may occur.^(15&16)

The amount of bone loss in four dental implantsbar supported mandibular overdenture over one year in our study was 0.42 mm which is in line with previous studies such as Heschl et al which showed about 0.63 mm ^{(17).}

In our result the amount of bone loss over the year was 0.42 mm in the four implants-bar supported ovedenture. However it was 0.83 mm in the two implants-bar supported ovedenture. This is may be due to four implants attached to bar attachment effectively preventing micro-movements, non-axial rotation and excessive loading,

Awaad et al implemented that no statistically significant differences were monitored regarding marginal bone loss between four and two implants at 3 and 6 months. Meanwhile, evaluated marginal bone loss after 8 years follow up demonstrated a significantly higher marginal bone loss in the patients who received two implants than four implants, which was in the same line with our study.⁽¹⁸⁾

Up to our knowledge the clinical trials comparing dental implants number with different attachments for over denture were limited. The majority of these study provide only one year follow up for crestal bone loss. So, a lot of randomized controlled trials with more than one year follow up and large sample sizes are needed to be able to answer the questions of what is the ideal number for implant placement for overdenture and which attachment can be used to minimize the crestal bone loss.

CONCLUSION

Four implants-bar supported overdenture provides better preservation of marginal bone than two implants-bar supported overdenture, where the four implants –bar overdenture provide wide stress distribution on the implants resulting in reducing the amount of marginal bone loss around the implant when used in implant supported mandibular over denture

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