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EFFECT OF USING TWO DIFFERENT ATTACHMENT SYSTEMS ON THE MARGINAL BONE HEIGHT AND PATIENT SATISFACTION IN TWO SPLINTED IMPLANTS WITH CANTILEVER BAR RETAINING MANDIBULAR OVERDENTURE (A RANDOMIZED CLINICAL STUDY)

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ABSTRACT

Aim of the study: To evaluate the effect of using two different attachment systems on marginal bone height & patient satisfaction in two implant retained mandibular overdentures (IOD) with cantilever extension.

Materials & Methods: Fourteen completely edentulous patients were selected from the out-patient clinic, Faculty of Dentistry, Beni-Suef University. Patients were rehabilitated with maxillary complete denture & mandibular implant overdenture with two different attachment systems. Group (I): Received two IOD with cantilevered bar-clip attachment. Group (II): Received two IOD with cantilevered bar with ball attachment. Patients were recalled at 3, 6, 9 & 12 months to evaluate marginal bone loss as well as patient's satisfaction.

Results: The mean marginal bone height loss after 3 month for Group- I (Bar & clip attachment) was 0.3889mm ± 0.3915 while for Group II (Bar -ball & socket attachment) was 0.3954mm ± 0.06046. After 6 month, the mean bone loss for Group (I) was 0.6786mm ± 0.06098, while for Group (II) was 0.7056mm ± 0.4157. After 9 month, the mean bone loss for Group (I) was 0.7897mm ± 0.01378 while for Group (II) was 0.7984mm ± 0.02584. After 12 month, the mean bone loss for Group (I) was 0.8556mm ± 0.33802 while for Group (II) was 1.0154mm ± 0.08415. Regarding patient satisfaction: there was a significant difference during the follow-up intervals in both groups.

Conclusions: -Bar/clip attachment may provide better stress distribution & less marginal bone loss than bar/ball attachment. - Patients may be more satisfied with bar/ball attachment than bar/clip attachment.

KEYWORDS: Implant overdenture, Bar/clip, Bar/ball, bone loss, patient satisfaction.

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INTRODUCTION

A valid treatment option for edentulous patients is an implant-retained overdentures (IODs) [1-6] with high implant and prosthesis survival rates.[4, 5, 7]

It has been suggested to use either 2 or 4 implants to retain a mandibular overdenture. [8-10] However, when cost and patient satisfaction is of concern, two implants may be adequate for the mandible. [11-14] This treatment option showed long-term success including increased satisfaction, oral health-related quality of life, and better function. [15]

Several attachments are used to retain overdentures to implants. Selection of the appropriate attachment depends on several factors, from which are the available inter-arch distance, biomechanics, patient's demand, and economic status of the patients. [16] Implants can be with splinted with bars [17] and as mandibular implants are usually placed interforaminally, a cantilever may be added to provide posterior support and to improve the stability of IODs. [18-20]

However adding a cantilever extension to a bar connecting interforaminal implants is debatable as the cantilever length influence forces transferred to the implants and bone which may increase marginal bone loss. Elsyad et al [21] recommended that with two implant mandibular overdentures a 7 mm cantilevered bars is associated with the lowest magnitude of strains.

The amount of load transmitted to the bone during function determines the success of the implant retained overdenture prostheses. [22] The marginal bone loss is affected by excessive occlusal load as well as peri-implantitis caused by plaque accumulation. The attachment system used for the overdenture is one of the most important factors affecting the forces transmitted to the implants.

Some investigators used clips on the cantilever extension; El-Sheikh et al [23] concluded that the retentive configuration without clips on the distal cantilevers results in a significant decrease in compressive forces on the implants than with using clips.

Others used bar-ball attachments; Abozad et al [24] radiographically evaluated the effect of using bar-ball attachment versus bar- locator attachments on implants retaining mandibular overdenture and they concluded that the marginal bone loss around implants with bar-ball attachment was much less than the bar-locator attachment.

A finite element study by Shishesaz et al [25] using three different designs for a mandibular implant retained overdenture using ball attachment, bar-ball attachment and bar-clip attachment where it was concluded that using bar-ball attachment may be advisable to be used due to its lower stress transfer to the peri-implant bone.

Therefore evaluating the stresses around the implant supporting an overdenture caused by different types of attachment systems can provide awareness of the extent of marginal bone loss around the implants as well as the success and survival rate of the prostheses. [26]

The aim of the present study was to evaluate patient's satisfaction as well as marginal bone loss around implants splinted by cantilevered bar with either clip or ball and socket attachment.

The null hypothesis is that no significant difference will be found between cantilevered bar with clip attachment and cantilevered bar with ball attachment system regarding marginal bone loss.

MATERIALS AND METHODS

Sample size calculation

The minimum sample size was calculated based on a previous study which was designed to assess marginal bone loss around implants in mandibular implant-retained overdentures with three different attachment systems. Based on Nejatidanesh et al [27]

results, adopting a power of 80% (b=0.20) to detect a standardized effect size in marginal bone loss was 1.534, and level of significance 5% (α error accepted =0.05), the minimum essential sample size was found to be 7 patients per group. Therefore, the total sample size was 14 patients. Consequently, fourteen healthy completely edentulous patients with age ranging from 55 to 65 years old were selected from the out-patient clinic Faculty of Dentistry, Beni-Suef University.

Inclusion criteria

1. Male with age range between 55-65 years old
2. Angle's class I maxilla-mandibular relation with sufficient inter arch space.
3. Residual alveolar bone with sufficient quantity (height and width) and quality (normal trabecular pattern) anterior to the mental foramen to receive root form titanium implants.
4. Maxillary and mandibular residual alveolar ridges covered with healthy mucosa without any remaining roots or local inflammations.

Exclusion criteria

1. Local and general health contraindications for surgical intervention.
2. Disorders in the TMJ.
3. Habits such as clenching, bruxism and smoking.
4. Diseases that affect the bone metabolism: uncontrolled diabetes.
5. History of radiation therapy in the head and neck region.
6. Non cooperative patients or patient unwilling to perform proper oral hygiene.

Ethical consideration:

Ethical Approval:

The proposal of this research had been presented to ethical committee of Faculty of Dentistry, Beni-Suef University for approval. Ethical Committee issued a certificate of ethical approval bearing the approval number: REC-FDBSU/02032023-03/AM.

All patients were informed about the treatment plan and all possible complications. After their approval, they signed an informed consent.

I- Pre-surgical procedures

a) Denture Construction:

For each patient; complete maxillary and mandibular dentures were constructed according to the conventional protocol; including secondary impression in custom made trays, setting anatomical teeth (Acrostone, Egypt) in balanced occlusion using programmed semi- adjustable articulator (Bio art A7 Plus, Brazil), over contouring of waxed- up denture lingually, long curing cycle, laboratory and clinical remount for occlusal adjustment.

b) Construction of mandibular surgical stent:

The mandibular denture was duplicated into clear auto-polymerized acrylic resin template (Acrostone, England) to construct a radiographic stent. Pre-operative CBCT was made for each patient wearing the radiographic stent.

The radiographic stent was then modified to construct a surgical stent as follows: Two holes were drilled in radiographic stent at the canine areas, one cm height metallic sleeves were fixed into each hole parallel to each other. This surgical guide was then utilized for implant placement.

II- Surgical procedures

Two screw indirect one- piece implants (Direct System) 13mm length, 3.7 mm width and 5 mm platform were installed, one in each canine region with the aid of the surgical guide. The implants were inserted using the standard surgical protocol consisting of prophylactic antibiotics, local antiseptic rinses, block and infiltration anesthesia, low speed of high torque and successive drilling with copious irrigation.

Post-operative medications were prescribed to the patients; including anti-inflammatory, analgesics and systemic antibiotics. Mouth rinse was also used for one week three times a day. After this period, the mandibular denture was functionally fitted into place using a resilient liner (silicone based, PROMEDICA), the occlusion was refined using selective grinding to ensure proper occlusal contact in centric and eccentric positions.

Implant loading:

Implants were immediately loaded one week after implant installation. Impression (Impregum Penta; 3M ESPE) for the implants and mandibular ridge was made in custom trays (Acrostone,Egypt) using abutment transfers. Implant analogues were attached to the abutment transfers and a master cast was poured in dental stone. The bars (OralTronics, Steg-clip-system, Dental Implant Technology Gmbh, Germany) rounded cross sectional bar of diameter 1.85mm with 5mm distal extension bilaterally were constructed for each group of patients, fixed to the implants and the denture was refitted to load the implants thereafter.

Randomization: Patients were divided randomly into two groups according to the type of cantilever attachment system by the aid of a computer with 1:1 distribution. Distribution was performed using identical opaque closed envelops, randomization and distribution was achieved by one of the assistants keeping the allocation table away from the operator, the sealed envelopes were shuffled and the patient was asked to pick one envelop at the time of starting the procedures to be assigned to the following groups.

Group I: Implants were splinted using a bar with bilateral distal cantilever extensions with retaining clips. ***Fig (1)***

The metallic bar was constructed by attaching two plastic copings by fixation screws to the implant analogue heads. A plastic bar was fixed between the two copings with adding a distal extension of 5mm to the copings bilaterally using burn-out self-cured acrylic resin (Duralay, Reliance Dental Manufacturing Co., Chicago, USA).

The bar assembly with the two copings were cast as one piece into nickel chromium alloy (Niadure, DFS Diamon, Germany) according to the conventional casting technique. The cast bar was then finished, tried in the patient mouth for passivity and then polished. ***Fig (1)***

Fig (1) Implants splinted using a bar with bilateral distal cantilever extensions

Group II: Implants were splinted using a bar with bilateral distal cantilever extensions with ball and socket attachments***. Fig (2)***

Bar construction was the same as in group (I) except for adding the burn-out ball abutments on top of the distal extension bar (Normal size OT CAP Ref. 092CAN RHEIN83 40128 Bologna ITALIA)

Direct picking up of attachments:

Group I: All undercuts beneath the bar were blocked using sticky wax, the clip with sleeve was seated in place over the bar and relief of denture's fitting surface was made to accommodate the bar & clip ***Fig (3A)*** with two small holes created in the lingual surface of the denture to allow for the escape of excess acrylic resin while pickup procedure. Self-cure acrylic resin (Acrostone,egypt) was applied into the fitting surface of mandibular denture and

Fig (2) Implants splinted using a bar with bilateral distal cantilever extensions and ball attachments

Fig (4) fitting surface of the denture with the picked up nylon caps and housings of the ball attachment

the denture was fully seated in place while occluded with the opposing denture in centric occluding relation, after complete setting of acrylic resin the denture was removed and checked for any further adjustments. ***Fig (3B)***

Group II: The undercut below the bar and ball abutments were blocked with sticky wax, the ball housings with the nylon cap was seated on the ball attachment and relief of denture's fitting surface was made to accommodate the bar and the ball attachments with the denture fully seated in place with two small holes created in the lingual surface of the denture, direct pick up of the attachment was made as in group I. ***Fig (4)***

Fig (3) (A) Relief of the denture fitting surface to accommodate the bar & clip attachment (B) Fitting surface of the denture with the picked up clips

The patients were informed about the way of denture insertion & removal, cleansing of the denture and strict oral hygiene measures.

Follow- Up & Evaluation:

Digital radiography using a periapical radiograph with long cone paralleling technique (Digora software, Orion Corporation, Soredek medical system, Helsinki, Finland) was used to measure the amount of mesial and distal crestal bone loss around implants during the follow up periods. As all implants were flushing with the crestal bone level during insertion, the top of the implant was considered as the reference line (start point) from which 2 perpendicular lines were dropped on the mesial and distal side of the implants to the most coronal portion of the crestal bone (end point) which was measured in millimeters(mm). ***Fig (5 A, B)*** The mean value of both measurements were considered as the mean bone loss around the implants, for further standardization of the measurements and for guarding against any technical errors, the implant actual length was used for calibration of the image using the Digora software.

Patients were recalled at three, six, nine and twelve month intervals after denture insertion to evaluate bone height loss around implants.

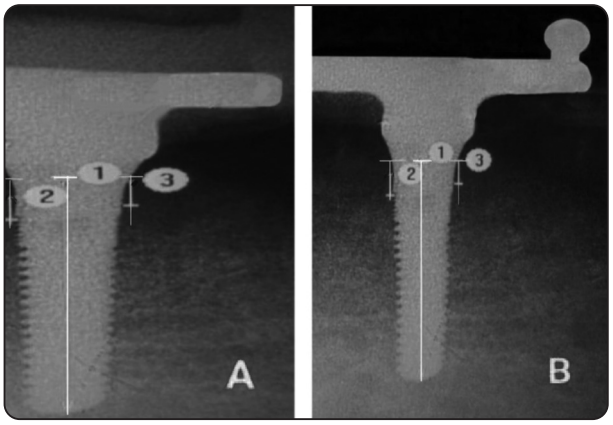

Fig (5) (A) Evaluation of marginal bone loss around implants with distal cantilever extension (B) Evaluation of marginal bone loss around implants with distal cantilever extension with ball attachment.

1: Actual implant length 2: Mesial crestal bone loss measurement 3: Distal crestal bone loss measurement

Patient satisfaction

Recording patient satisfaction in the study groups: it was held by OHIP-EDENT questionnaire, which is used to evaluate edentulous patients receiving new prostheses regarding oral health related life quality. It is a 19 question (questionnaire) about denture problems associated to pain, fit and discomfort as well as chewing ability, questions related to the life quality evaluating if the subjects were being embarrassed, upset and feeling life is less satisfying due to denture problems are also included in the questionnaire. Patients and their responses to the questions were recorded in separate sheets. The scaling of the recorded responses uses a 5 point scale (never = 0 , hardly ever = 1, occasionally = 2, fairly often = 3, and very often = 4). Sum of the scores were calculated to give a score between 0 & 76; absence of problems = 0 and very problematic =76. All participants were evaluated at 6 month (baseline), 9 and 12 month intervals from denture insertion.

Statistical analysis

Data were collected, tabulated & statistically analyzed using SPSS v24 (IBM, USA). Data were expressed as means ± standard deviation (SD) with significance level set at $P \leq 0.05$. Normality test was performed using kolmogorov-smirnov and Shapiro-wilk test, data assumed normal distribution. Repeated measures ANOVA was used to compare marginal bone height loss between the two study groups at different intervals. On the other hand, two-way ANOVA was used to explore the effect of time on marginal bone height loss within each group. When the p-value was significant, Tuckey post hoc test was used for pairwise comparisons between intervals within each group.

RESULTS

Group I: As shown in Table 1, the mean marginal bone height loss after 3 month was 0.3889mm ± 0.3915 while after 6 month was 0.6786mm ± 0.06098 with a statistically significant difference between the 1st and the 2nd interval. After 9 month the mean bone loss was 0.7897mm ± 0.01378 and was 0.8556mm ± 0.33802 after 12 month with no significant difference between the 2nd, 3rd and 4th interval.

Group II: As shown in Table 1, the mean marginal bone height loss after 3 month was 0.3954mm ± 0.06046 while after 6 month was 0.7056mm ± 0.4157 with a significant difference between the 1st and the 2nd interval. After 9 month the mean bone loss was 0.7984mm ± 0.02584 with no significant difference between the 2nd and the 3rd interval, while after 12 month the mean bone loss was 1.0154mm ± 0.08415 with a significant difference between the 3rd and the 4th interval as the p value was < 0.05.

Moreover, there was no significant change in bone height loss between group I and group II at 3, 6 and 9 month intervals (p value = 1.000, 0.192 and 0.192 respectively). However after 12 month, group II showed statistically significantly higher mean values than Group I.

TABLE (1) Descriptive statistics of marginal bone loss measured in mm in Group I & II

Time intervals	Marginal bone loss (mm)		Repeated measures ANOVA (P-value)
	Group I Mean ± SD (Clip attachment)	Group II Mean ± SD (Ball & Socket Attachment)	
0-3 Month	0.3889mm ± 0.3915[d]	0.3954mm ± 0.06046[c]	1.000
0-6 Month	0.6786mm ± 0.06098[a]	0.7056mm ± 0.4157[b]	0.192
0-9 Month	0.7897mm ± 0.01378[a]	0.7984mm ± 0.02584[b]	0.192
0-12 Month	0.8556m ± 0.33802[a]	1.0154mm ± 0.08415[a]	0.05*
Two-way ANOVA (p-value)	*≤ 0.05*	*≤ 0.05*	

**** Significant at P ≤ 0.05, same superscript letters in columns indicate insignificant difference***

Patient Satisfaction Evaluation:

Friedman's test was used to analyze the **OHIP-EDENT** test results to compare the scores of the follow up periods six, nine and twelve month in each group separately as shown in ***Table 2 & 3***. As the p- value < 0.001, there was a significant difference between, six, nine and twelve months follow up in each group. The scores decreased from mean 74.3 (6 month) to 38.8 (9 month) to 0.41 after 12 month in Group I and also it decreased from mean 71.5 (6 month) to 30.7 (9 month) to 0.2 after 12 month in Group II; this indicates a significant increase in patient's satisfaction.

Wilcoxon signed-rank test (Two-tailed test) was used to analyze the OHIP-EDENT test results to compare the scores of each follow up interval between the two groups and as the p- value > 0.001, this means that there was no significant difference between the follow up periods between the two groups, however the records were to some extent in favor for group II than group I.

TABLE (2) OHIP-EDENT scores at the follow up intervals for Group I

Group I	Observations	Minimum	Maximum	Mean	Std. deviation
6 Months(Baseline)	7	70.000	76.000	74.300	2.119
9 Months	7	38.000	41.000	38.800	1.101
12 Months	7	0.000	4.000	0.410	1.265

TABLE (3) OHIP-EDENT scores at the follow up intervals for Group II

Group II	Observations	Minimum	Maximum	Mean	Std. deviation
6 Months (Baseline)	7	69.000	74.000	71.500	2.273
9 Months	7	36.000	56.000	30.700	7.304
12 Months	7	0.000	2.000	0.200	1.269

DISCUSSION

In restoring a mandibular completely edentulous arch, two implants are considered a useful line of treatment; it can be used in severely resorbed ridges to improve the overdenture support and retention.

Implants splinting may allow for better stress distribution and may induce less crestal bone resorption than the un-splinted implants. [28] Bar attachments are used to splint implants, it helps stress distribution, transfer stresses more apically and allows for immediate loading and enhances retention and stability of the prosthesis, it also improves functional mastication and patient satisfaction and comfort.[29] Adding a cantilever may provide posterior support and improve the stability of IODs. [18-20]

In order to improve retention of mandibular implant supported overdenture, clips may be added on the cantilever extension [23] also ball-bar attachment may be used in conjunction with each other. The improved retention by the added attachments may increase patient satisfaction; however it may add stresses to the implants and bone. Several studies evaluated the effect of using bar-ball attachment on marginal bone loss around implants. [24, 25]

The present study was conducted to evaluate patient's satisfaction as well as marginal bone loss around implants splinted by cantilevered bar with either clip or ball and socket attachment.

As there was a significant difference between the study groups at 0-12 interval; hence the null hypothesis was rejected.

In this study, bone height loss around implants in the two studied groups was less than 1.2 mm. This agrees with Turkyilmaz et al [30] whom declared that the mean implant marginal loss was 1.16 ± 0.89 mm after 1-year of implant loading with bar retained overdentures. This finding may be attributed to the splinting action of the bar which had maintained stresses transmitted to the implant / bone interface within the safety limits.

Results showed that the marginal bone height loss in group **(I)** was less than group **(II)** with statistically insignificant differences during the 1st, 2nd & 3rd intervals, however after 12 month; marginal bone loss was statistically significant in group **(II)** than group **(I)**. This increase in bone height loss found in group **(II)** may be attributed to the combined retentive qualities of ball-bar attachment as well as the increased height of the ball attachment than the clip may contribute to more lateral stresses on the implant.

Regarding patient satisfaction, the results of the present study had shown that all patients were satisfied with their implant overdentures in the two studied groups at 6, 9 and 12 month intervals as implant OD may provide better retention, stability, esthetics, phonetics and chewing efficiency with more secure prostheses than conventional complete dentures. However, results of this study had shown that patient's satisfaction in group **(II)** is slightly more than patients of group **(I)** with statistically insignificant difference during the 6, 9 and 12 month intervals; this may be due to the better retention and comfortable feeling accompanying the ball attachments, this agrees with Varshney et al [31] where the attachments used in their study enhanced patient's satisfaction as it provided more retention.

Conclusions: Within the limitations of this study it may be concluded that:

- Both bar/clip & bar/ ball attachments may be recommended for immediately loaded two implant mandibular overdentures.
- Bar/clip attachment may provide better stress distribution & less marginal bone loss than bar/ ball attachment.
- Patients may be more satisfied with bar/ball attachment than bar/clip attachment.

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