Early progressive versus delayed loading of two implants retained mandibular overdentures

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EARLY PROGRESSIVE VERSUS DELAYED LOADING OF TWO IMPLANTS RETAINED MANDIBULAR OVERDENTURES

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ABSTRACT

Purpose: This work was aimed to evaluate and compare the effect of early progressive and delayed loading of two implants retained mandibular overdentures regarding marginal bone changes and periotest values of implants supporting mandibular overdenture.

Material and Methods: 24 completely edentulous male patients were selected from department of prosthodontics, Faculty of dentistry, Mansoura University. All systemic and radiographic examinations needed for implant planning and placement were performed. All patients received two implants at the mandibular canine regions. Directly after implant placement, the patients were divided equally into two equal groups as follows; Group I: after 3 months submerging period, implants were exposed and overdentures were attached to ball abutments via direct pick-up technique of female socket attachments (delayed loading), Group II: after 4 weeks of implant installation the mandibular overdenture was attached to implant ball abutment via resilient liner and replaced after another 4 weeks by direct pick-up technique of female socket attachments (early progressive Loading). Follow-up records were done at 6, 12 and 18 months intervals after implant loading with overdentures. Study parameters were radiographic evaluation of marginal bone height changes and implant mobility using periotest.

Results: All implants were successful with respect to mobility test with no significant difference between both groups. Generally the mean marginal bone loss and heights changes, both vertically and horizontally, were comparable to the worldwide accepted range. In comparison of both groups, the means of vertical bone loss were higher for group I with no statistical significance. While the means of marginal bone heights were significantly reduced in group I after 6 months and 18 months of study. The means of horizontal bone level were significantly reduced in group I.

Conclusion: Within the limitation of this short prospective clinical study it could be suggested that there is a promising radiographic finding of implant mean marginal bone status of patients treated with two implants retained mandibular overdentures loaded according to early progressive protocol. Results are comparable and even better to delayed loading protocol. A longitudinal study is recommended to compare both treatment regimes.

KEY WORDS: Progressive implant loading, delayed implant loading, implant overdenture.

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INTRODUCTION

Dental implants changed the merits of removable prosthodontic treatment options and expectations. Such treatment modalities need careful diagnoses, good treatment planning, long term evaluation to assure success and survival [1, 2]. Recently, two implant mandibular overdentures are considered the standard treatment option for completely edentulous patients [3] with confirmed validity [4, 5]. Conventionally, implant surgical site should be allowed for a load free period (3 months for mandible and 6 months for maxilla) to allow undisturbed osseointegration [6] to avoid the implant micro-movements caused by functional forces during wound healing phase [7]. The growing concern about enhancement of patient satisfaction and quality of life (QL) makes months of delay before final restoration not acceptable for all patients [8, 9]. To reach this goal, immediate and early loading attracted the attention in the last two decades. The results were promising on the level of success and survival [10, 11]. But most of researches on removable overdentures discussed immediate and early loading based on four or more implants, usually splinted [12-17]. The concept of progressive loading arose in 1980 based on empirical information supporting the idea that low grade bone stimulation of gradual loading will allow bone to mature, grow denser and improve in quality [18, 19]. Progressive loading protocol is a method to control the load applied onto dental implant by controlling the size of occlusal table, location of occlusal contacts, firmness of diet, and absence of cantilevers [20, 21]. Early progressive loading seems reasonable for mandibular two un-splinted implant overdentures but remains inconclusive due to limited evidence for evaluating differences versus delayed loading protocol [22].

Accordingly, this research aimed to compare the effect of delayed versus early progressive loading of two un-splinted implants mandibular complete overdenture regarding the marginal bone height changes and periotest values.

MATERIAL AND METHODS

Patients' selection

Twenty four male complete denture wearers, with age mean 54 ± 4 years, complaining from mandibular denture stability and retention were selected from the outpatient clinic of the Prosthodontic Department, Faculty of dentistry, Mansoura University. Selection was based on specific inclusion and exclusion criteria (Table 1). Included patients were required to have healthy mucosa, sufficient inter-arch space as well as sufficient bone height and bone quality in the inter-foraminal region of the mandible provided by diagnostic digital panoramic radiograph. Patients with systemic diseases affecting bone or risk the implant placement surgery were excluded. Patient's base line criteria were recorded (presented in table 2) including; age, alveolar bone height, period mandible remains edentulous and number of previously worn mandibular dentures.

TABLE (1) Inclusion and exclusion criteria

Inclusion Criteria	Exclusion Criteria
Completely edentulous moderately developed residual ridges with healthy even thickness mucosa free from ulcers or pathosis	Physical disabilities which interfere with the maintenance of implants
	Severe skeletal jaw discrepancies
Dissatisfied their existing mandibular; complaining instability and ill retentive mandibular denture	history of Severe clenching habits
	harmful habits (i.e. smokers "current or previous")
Sufficient bone volume in the intra-foraminal area of mandible to receive implants (at least 18mm height and 6 mm in diameter)	radiotherapy or chemotherapy "current or previous"
	bone affecting diseases (i.e. diabetes "uncontrolled")
Sufficient bone quality (type I & II) [12]	bleeding disorders (i.e. Haemophilia)

TABLE (2) Base line criteria of the study sample at the begin of study

Patients	All patients		Group I		Group II	
	Mean	SD	Mean	SD	Mean	SD
Mean age (years)	57	4	56	3	58	3
Mean bone height (mm)	21.5	2.5	22	2	21	3
Mean period mandible remains edentulous (years)	5.5	2.5	6	1	5	3
Mean of previous dentures	1.5	.5	1.5	.5	1.5	.5

Preliminary prosthetic procedures for all patients

A new conventional complete denture were constructed using shallow cusp acrylic resin teeth (Vitapan®, Vita Zahnfabrik, Bad Säckingen, Germany) according to a balanced occlusion concept. Dentures were delivered to the patient mouth at least two months before surgery (adaptation period).

Radiographic stent was constructed in heat cured clear acrylic resin as a duplicate of the mandibular denture. Two holes were prepared, corresponding to the canine sites, to hold two metal balls (4mm diameter) via auto-polymerized acrylic resin in order to take a preoperative digital panoramic radiograph.

Surgical procedures for all patients

As a pre-surgical preparation the antimicrobial prophylaxis was obtained with the following regimen; (1) mouth rinses with a 0.12% chlorhexidine Hcl solution (Hexitol®, The Arab Drug Company, Cairo, ARE), 3 times a day starting 3 days before surgery and (2) oral antibiotics (2 g per day of clavulanic acid and amoxycillin), started 1 hour before surgery and continued until the third postoperative day.

For every patient, after proper local anesthesia, two implants (Dyna® Dental Engineering, Bergen op Zoom, Netherlands) of 13 mm length and 3.6 mm diameter were inserted in the canine regions of the mandible parallel to each other. The radiographic stent were modified and converted to surgical stent by removing the metal ball inserts and holes were drilled at the implant site to guide initial implant location and direction assignment. After incision, surgical flap was reflected and with the help of surgical stent two initial drilling site points were marked in bone. Osteotomy was done in a successive manner starting with pilot drill under proper cooling till the final drill at 900 rpm.

All implants were inserted at a torque of 30-35 Newton/cm^2 by the same oral surgeon.

After suturing, all patients were instructed to avoid wearing their denture and to follow a soft diet regimen. Also a good post operative care was assured including cold packs, mouth wash and avoiding eating at implant site. One week later patients were recalled for suture removal and the mandibular denture intaglio-surface was relieved as necessary guided by pressure indicating paste (Keystone Industries GmbH Werner-von-Siemens Str. 14a D-78224 Singen, Germany).

Patients were randomly divided into two equal groups as follows; group (I); where patients received conventional "delayed" loaded implant overdenture and group (II); where patients received progressive loaded implant overdenture.

Conventional (delayed) loading group (*Group I*):

Three months after surgery patients were recalled, implants were revealed by tissue punch and healing abutments were attached **(figure 1)**. Intaglio surface of mandibular denture was relieved generously corresponding to the healing abutments. One weeks later, healing abutments were replaced by ball abutments (Dyna Dental Engineering, Bergen op Zoom, The Netherlands). Matrices were connected to overdenture intaglio surface by direct pick up technique using auto-polymerized acrylic resin. A rubber dam sheet was pinched corresponding to implant site and applied intra-orally to prevent escape of resin around ball abutment under the matrix. Occlusion was verified and overdenture was delivered with emphasis on oral hygiene instructions and 3 months regular recall visits.

Early progressive loading group (*Group II*);

Three weeks after surgery patients were recalled, implants were revealed by tissue punch and ball abutments (Dyna Dental Engineering, Bergen op Zoom, The Netherlands) were attached to implants. Patient’s existing mandibular denture fitting surface directly above implants was hollowed out. Patients were instructed to use the denture with soft diet and avoid the use of anterior segment of the mouth **(figure.2)**.

One week later patients were recalled and the intaglio surface of denture was cleaned and dried to receive soft liner (PROMEDICA Dental Material GmbH, Domagkstr. 31 - 24537 Neumünster, Germany). Adhesive were applied (figure.2, A) at the denture surface using brush and left for one minute then the liner was applied by gun to the fitting surface. Denture was fitted intra-orally and left to set for 1 minute while patient in occlusion then for 5 minutes while patient performs mastication like movement. After 10 minutes, excess material was trimmed with scissors and glaze **(figure.3, A,B&C)**

Fig. (1) Intra oral view of revealing implants by tissue punch and healing abutment attached to dental implant

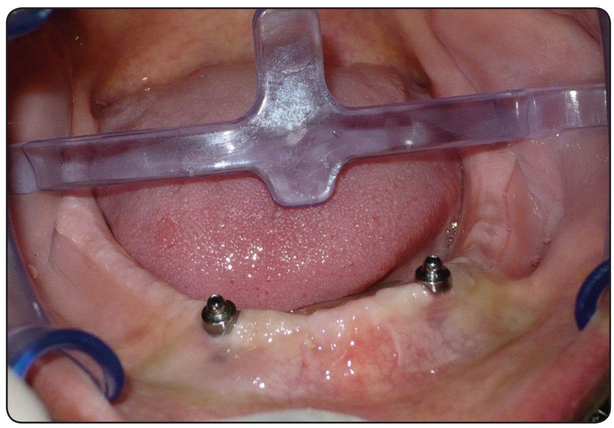

Fig. (2) Intra oral view of ball abutments attached to dental implant

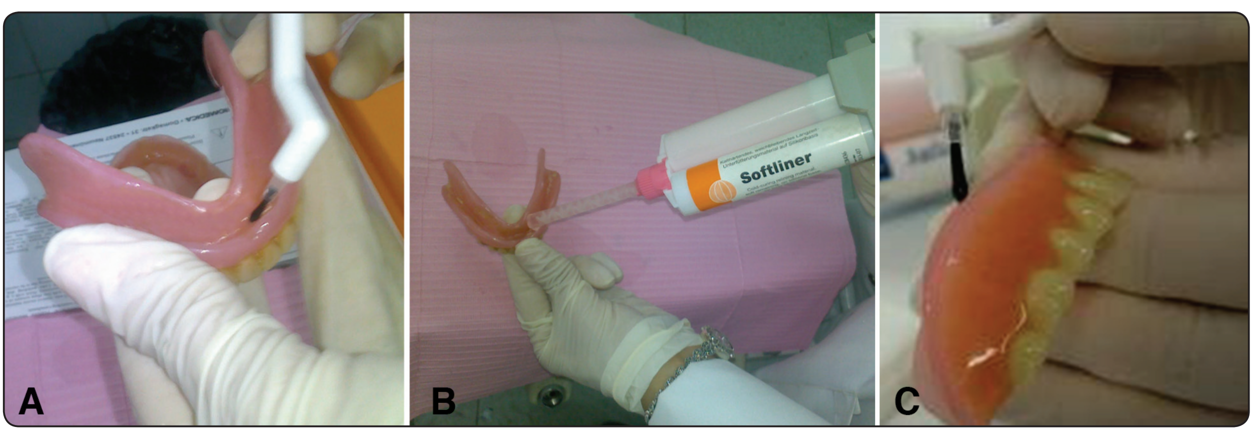

Fig. (3) A- Soft liner Adhesive application. B- Soft liner application C- Soft liner glaze application was applied and left for bench dryness for 10 minutes according to manufacturer instructions. Occlusion was checked and overdenture was delivered.

After four weeks, patients were recalled for replacement of soft liner with ball matrix (Dyna Dental Engineering, Bergen op Zoom, The Netherlands) by direct pick up technique using auto-polymerized acrylic resin **(figure. 4)**. A clean sheet of rubber dam was pinched corresponding to implant site and applied intra-orally to prevent escape of resin around ball abutment under the matrix which render them worthless. Excess material is trimmed, occlusion was refined and denture was delivered with emphasis on oral hygiene instructions and 3 months regular recall visits.

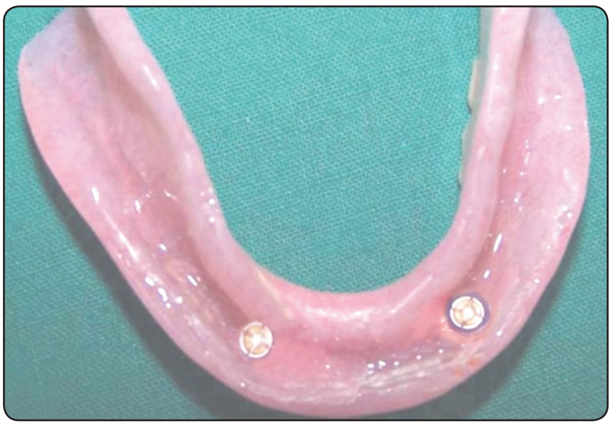

Fig. (4) Ball matrix in place in the fitting surface of mandibular overdenture

Follow up protocol

Radiographical evaluation

Radiographic evaluations were performed at the time of ball abutment attachment and implant loading (T0) referring to, 3 months post operative (group I) and four weeks post operative (group II). Evaluation was performed at 6 months (T1), 12 months (T2) and 18 months (T3) after implant loading and overdenture insertion.

Intraoral periapical radiographs were taken using long cone paralleling technique and a modified film holder designed specifically for implant imaging (Hawe Neos Dental CH-6934, Bioggio, Switzerland). Film–implant distance and cone–implant distance were maintained the same during subsequent film exposures to obtain standardized intraoral radiographs [23].

All radiographs were made with Ultra-speed film (Kodak Co., Rochester, NY, USA) and exposed by using the same X-ray unit (ORIX-70® Ardet Srl, Buccinasco, Italy) with an exposure factor of 70 kVp, 8 mA, 0.144 Kw and a 0.25 s exposure time. All films were processed using an automatic machine (Velopex® Extra-X, Medivance, Harlesden, London, UK).

The periapical films were scanned using a black and white translucent scanner. The digitized radiograph were magnified approximately × 10, lines and reference points (figure.4) were marked using Corel draw program (CorelDraw® 10, Kodak Digital Science). Ratio between implant dimensions in radiographs and actual implant dimensions (magnification error) was used to modify the apparent measurement of peri-implant bone levels in the radiographs to obtain their actual values **(figure.5)**.

Peri-implant marginal alveolar bone changes were determined along vertical and horizontal planes as recommended by Heckmann et al. (2004) [24] and Walter et al. (2000) [25]. For vertical alveolar bone changes; the distance between implant shoulder at

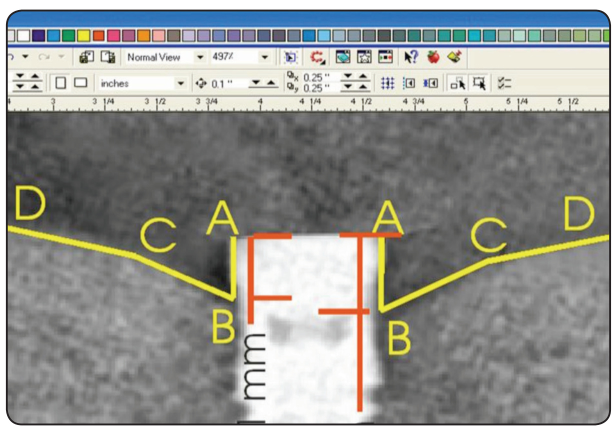

Fig. (5) Print screen of Corel Draw computer program during measuring the radiographic bone loss guided by lines and reference points marked on the screened peri-apical radiograph.

implant platform level (A point) and first bone to implant contact (B point) indicated vertical bone level (VBH) in mm (AB line) (figure.4).Vertical bone loss (VBL) was calculated by subtracting VBH (T1-T0), (T2-T1) and (T3-T2) for 1st, 2nd and 3rd periods of study respectively.

For horizontal alveolar bone changes, the distance between the marginal bone level (C point) [which represents the intersection point of a tangent to the horizontal bone crest (CD line) and another tangent to the crater-shaped defect (CB line)] and the implant perpendicularly indicated horizontal bone level (HBW) in millimeters (figure.4). Horizontal bone loss (HBL) was calculated by subtracting HBW at (T1-T0), (T2-T1) and (T3-T2) for 1st, 2nd and 3rd periods of study respectively.

Implant marginal alveolar bone changes (vertical and horizontal bone levels and bone loss) were measured at mesial and distal surface of each implant.

Periotest evaluation

Implant stability was tested with Periotest (Periotest S™, Siemens AG, Bensheim, Germany) **(Figure 6)**. Measuring tip was applied labially for three times at each implant then the average of both implants was calculated to represent each patient. Periotest measurements were made at the time of abutment connection and at 6, 12, and 18 months after initial prosthetic loading.

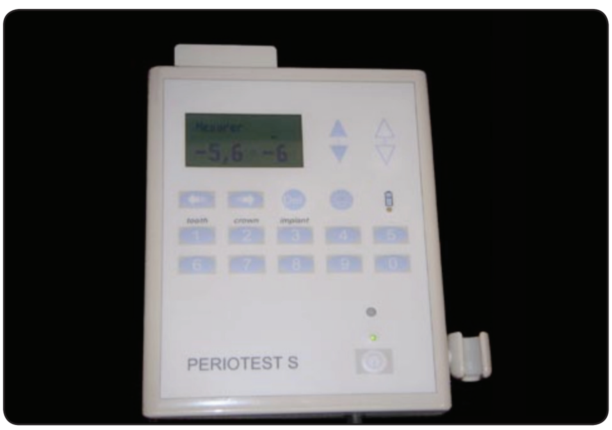

Fig. (6) Periotest S device readings during measuring implant stability

Data collection and statistical processing

Results were collected from three different examiners blindly from the patient group. They measured and calculated the VBL and HBL for each implant as mesial + distal/2. The subject mean VBL and HBL were used for analysis, thus obtaining an effective sample size of 12 per group so patients were presented as the sum of their two implants/ 2. The mean of the three examiners were processed for statistical analysis using computer program (SPSS® 18, Statistical Package for Social Science). Using paired sample t-test at 5% level of significance the following were done; 1- the means of implant marginal bone vertical and horizontal changes were compared between the groups in different periods, 2- the means of implant marginal bone vertical and horizontal levels were compared between the groups in different periods.

One examiner measured the periotest values in group I&II measured at the time of prosthetic loading, 6, 12, and 18 months after prosthetic loading. Each measurement was repeated 5 times and their mean was used. The subject mean periotest values were used for analysis, thus obtaining an effective sample size of 12 per group Mann-Whitney U-test was used to compare Periotest values between groups

RESULTS

This study consisted of 24 male patients with age range 54 ± 4 years. All patients attended follow up visits with no drop outs.

In table 3 the mean VBL in three periods of study after implant loading were as follows; group I: 0.34±0.02, 0.36±0.02 and 0.06±0.02, group II: 0.35±0.03, 0.36±0.02 and 0.07±0.01. The results were insignificant for group I compared to group II at all periods of study (figure 7).

Also in table 3 the mean VBH after implant loading in the three periods of study were respectively as follows; group I: 0.38±0.04, 0.76±0.05 and 0.83±0.05, group II: 0.35±0.03, 0.71±0.03 and 0.79±0.04 . The results were significant for group II compared to group I at 1st and 3rd periods of study (P=0.017 and 0.024 respectively) (figure 8).

In table 4 the mean HBL around implants after loading in the three periods of study for group I was 0.13±0.02, 0.12±0.06 and 0.08±0.02 respectively, while for group II was 0.12±0.04, 0.11±0.03 and 0.07±0.03. The results were insignificant for group I compared to group II at all periods of study (figure 9).

In table 4 the mean HBW around implants in 6, 12 and 18 month after implant loading for group I was 0.25±0.05, 0.37±0.05 and 0.45±0.04 respectively. While for group II was 0.12±0.04, 0.25±0.08 and 0.32±0.09 respectively. The results were significant for group II compared to group I at all periods of study (P=0.00, 0.00 and 0.00 respectively) (figure 10).

In table 5 the medians and ranges of periotest value for group I and group II was presented. No significant differences were found between the 2 groups at 6, 12, and 18 months after implant loading via overdenture (P > .05).

TABLE (3) Comparison of mean peri-implant vertical bone height (VBH) and vertical bone loss (VBL) in millimeters at 6, 12, and 18months after implant loading and overdenture insertion.

Group	6 month after I.L		12 month after I.L		18 month after I.L	
	VBH	VBL	VBH	VBL	VBH	VBL
Group I (X ±SD)	0.38±0.04	0.34±0.02	0.76±0.05	0.36±0.02	0.83±0.05	0.06±0.02
Group II (X ± SD)	0.35±0.03	0.35±0.03	0.71±0.03	0.36±0.02	0.79±0.04	0.07±0.01
P	0.017*	NS	NS	NS	0.024*	NS

Independent samples t-test (level of significance: P < .05).

**** = significant (p ≤ 0.05)   n (number of patients per group) = 12   NS: non-significant***

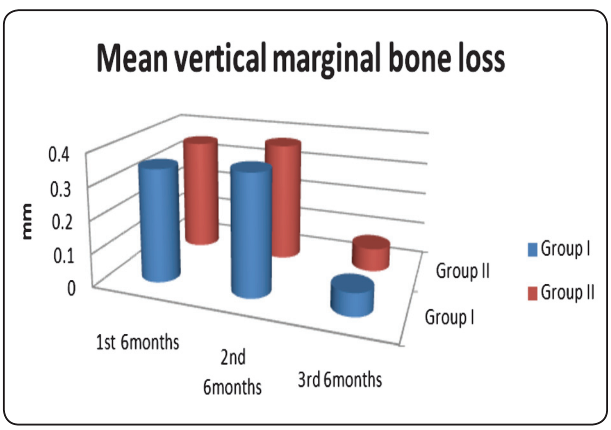

FIG. (7) Mean vertical bone loss in each period of study

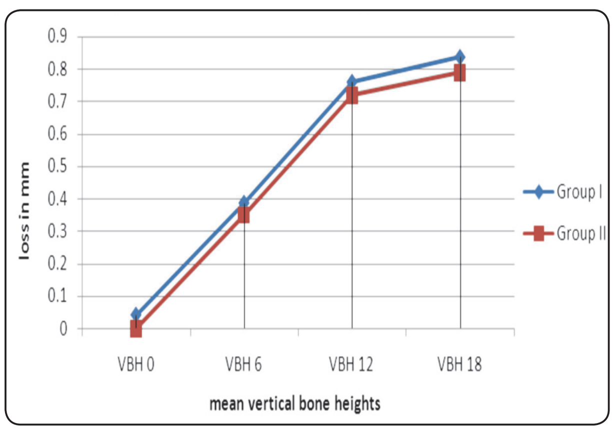

FIG. (8) Mean vertical bone heights during study periods

TABLE (4) Comparison of Mean peri-implant horizontal bone width (HBW) and horizontal bone loss (HBL) in millimeters at 6, 12, and 18months after implant loading and overdenture insertion.

Group	6 month after I.L		12 month after I.L		18 month after I.L	
	HBW	HBL	HBW	HBL	HBW	HBL
Group I (X ± SD)	0.25±0.05	0.13±0.02	0.37±0.05	0.12±0.06	0.45±0.04	0.08±0.02
Group II (X ± SD)	0.12±0.04	0.12±0.04	0.25±0.08	0.11±0.03	0.32±0.09	0.07±0.03
P	.000*	NS	.000*	NS	.000*	NS

Independent samples t-test (level of significance: P < .05). I.L= Implant Loading
** = significant (p ≤ 0.05)* **n** *(number of patients per group) = 12* **NS:** *non-significant*

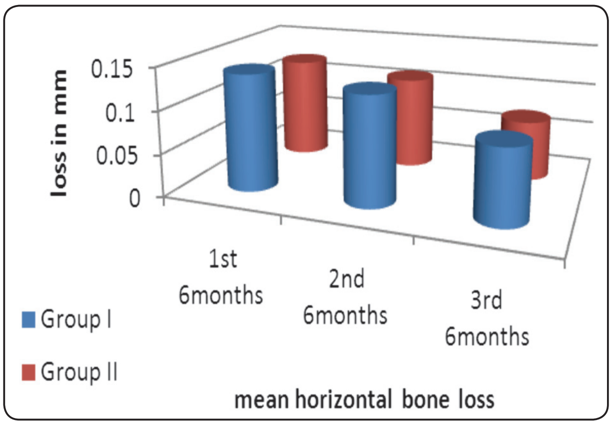

FIG. (9) Mean horizontal bone loss in each period of study

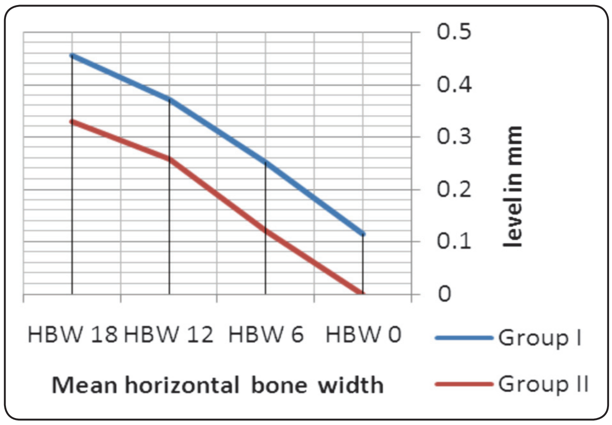

FIG. (10) Mean horizontal bone level during study periods

TABLE (5) Periotest Values in group I and group II

Periotest values (median and range)				
Group	Prosthetic loading	After 6 months	After 12 months	After 18 months
Group I	–2.5 (–4 to 1)	–3 (–5 to –1)	–4.5 (–6 to 1)	–3.5 (–5 to 2)
Group II	–2.5 (–4 to 1)	–2.5 (–6 to –1)	–4 (–6 to –2)	–3 (–4 to 1)
P	NS	NS	NS	NS

Mann-Whitney U test (level of significance: P < .05). n (number of patients per group) = 12 NS: non-significant

DISCUSSION

In this research, cases of two implant mandibular overdenture were studied to compare the effect of two loading protocols, conventional (delayed) and early progressive, in terms of marginal bone changes and implant stability.

Female patients were excluded as they have greater risk of bone resorption due to hormonal factors [26].

Systemic and local patients' selection criteria were planned according to generally acceptable well documented base line [27-30].

Regarding the bone quality, only patients with type I&II bone [12] were selected. This was suggested as sufficient to assure success in cases of shorted submerging time to provide the needed initial stability [31, 32].

Ball and socket attachments were chosen to retain overdenture rather than bars as it is simple, easier, with reduced coast and fewer clinical appointments [33].

Some authors considered rigid splinting of implants through bars as a factor that enhances success especially in low bone quality as maxilla and posterior mandible [34] while others suggested bars to have limited or no value on early loading protocols [35]. Thus to avoid interference with the evaluation parameters monitoring it was avoided.

Practical means of establishing progressive implant loading are limited. Patients are instructed to limit chewing forces (soft diet) and implants are loaded through the use of dentures without attachments i.e. by introducing a soft liner [36].

Ormianer et al [37] studied early loading using that modified loading protocol. The housings were filled with Impregum (TM) (3M Espe AG; Seefeld, Germany) impression material to provide retention as well as reduce forces in the initial phase of loading [37].

The resilient liner was used to provide early moderate loading at the first 4 weeks of loading to provide moderate functional forces on early loaded implants [38]. The female housing was picked up intra-orally, using the resilient liner on the other side as a guide to standardize the process and decrease pick up errors besides being much easier.

Peri-apical radiographs with long cone paralleling technique were used for monitoring the peri-implant marginal bone rather than panoramic radiographs which is of limited value in the anterior mandible due to over-projection of vertebra [39].

There was no implant loss in this study with a success rate of 100%. This percentage was in accordance with other studies addressing the high success rate of delayed implant loading [40-42].

This high survival rate of early loaded implants agrees with Payne and coworkers [40]. They performed a 1 year study for early loaded (average 2 weeks) 4 conical implants, in the anterior mandible with 100%implants survival rate. In another study of the same team a 100% success rate of 6 early loaded (6 weeks) un-splinted implants supporting mandibular overdentures [41]. This was agreed also by Tawse-Smith et al [43] but referred as affected by the implant system used.

On the contrary, Raghoebar et al [44] studied early loaded (6 weeks) 4 implants under overdentures, in the anterior mandible, with 93% implant survival.

The mean implant VBL after 1st, 2nd and 3rd periods of this study was 0.69mm±.06 in the first year and 0.065mm±.015 in the next 6 months. This is in accordance with well documented values for implant marginal bone resorption that ranges from 0.5 mm to 1.4 mm in the 1st year and about 0.2mm to 0.3 in each successive year [2, 11, 45-47]. Bone loss in the first year is attributed to multi-factorial etiology including healing of alveolar bone, bone remodeling, and bone response to loading [18, 48].

Despite the non-significant difference found between groups regarding VBL. After the first 6 months, marginal bone height of group I was significantly reduced due to the early bone loss at the 3 months submerging period which resulted in difference at the base line value. While in the second 6 months of study, the early loaded implants proved stability and comparable results to delayed loaded counter group.

This may be explained through the bone reaction. The submerged implant is susceptible to repair from surgical trauma through the formation of woven bone that is called repair bone which is then converted to lamellar bone with the risk of marginal bone loss [18]. But for early loaded implants, the formed woven bone is called reactive woven bone which allows better adaptation to the biomechanical situation [18].

This was clear at 3rd 6 months period where marginal bone height of early loaded implants was significantly improved compared to the delayed loading control group. Theoretically, early loading is suggested to allow implant bed to minimize woven bone formation to promote lamellar bone maturation to sustain occlusal loads [49, 50].

The significant results of the HBW for all periods of study may assure the idea. It is beneficial to mention that the means of HBL was higher in delayed loading group but with non-significant difference compared to the early loaded one.

These results are in accordance with Appleton et al [51]. They reported less marginal bone height loss compared to delayed loaded implants. Furthermore, their progressively loaded implants showed a progressive increase in the peri-implant bone density. But in contrast to other studies that reported non-significant difference in comparison to delayed loaded control group [43].

This research results may be explained on the bases of Frost [52] mechanostat theory that proposed the bone response to a complex interaction of strain magnitude and time. Based on that theory, bone adapts to loading. Accordingly, the relation between marginal bone loss and loading can be explained on the bases of interfacial bone maturation [53]. In other words, functional loading over a certain physiologic range induces a positive bone response [54].

A number of studies support this hypothesis in the form of greater percentage of bone-to-implant contact and more mature cortical bone than delayed-loaded controls [55-58].

The Periotest values obtained in this study did not present significant differences between the 2 groups and are also consistent with those reported in literatures for delayed loading situations [59, 60]**.** But the range of implant mobility show more stability in early loaded group.

On this respect, Turkyilmaz [58] suggest that a one-week early loading protocol of two implants supporting mandibular overdenture does not compromise implant stability and marginal bone loss.

CONCLUSION

It seems that early loading permits more preservation of alveolar bone around dental implants in mandibular overdenture wearers beside the faster patient rehabilitation.

Within the limitation of this short-term prospective randomized controlled study, early loading of implant supported mandibular overdentures could be considered a viable alternative treatment to the classical delayed protocols. However, it may be premature to recommend these protocols without further longitudinal investigations on larger sample size.

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