

Immediate versus Delayed Loading of Mandibular Bar Retained Implant Overdenture

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Abstract. Immediate implant loading protocol is popular to patients' over the delayed loading protocol. Due to its high risks association, documented results were essential. Study objective; assess the bone height and density change using direct digital radiography in immediately loaded implants connected by a bar, and compare the results with those of the delayed loaded implants. 10 completely edentulous patients participated in a randomized controlled trial. All patients were treated by; conventional maxillary complete denture; mandibular overdenture supported by a prefabricated bar connecting two implants placed in the canine region. Patients were randomly divided into; test group (Group A) with immediate loaded implants and control group (Group B) with implants submerged and loaded three months after insertion. Intraoral direct digital radiography used to measurement marginal bone height level and radiodensitometric analysis of bone at intervals time of loading at 3, 6, 9 and 12 months. The result statistically revealed: an insignificant difference ($p \leq 0.05$)

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Accepted for publication: 25 June 2013. Received: 18 March 2013.

in the mean marginal bone loss between both groups; a significant increase ($p \leq 0.05$) in the bone density measurements adjacent to the immediately loaded implants from time of loading. In conclusion, immediate loading of two mandibular implants splinted passive bar is a predictable alternative treatment comparable to delayed loading.

Keywords: Immediate loading, Delayed loading, Prefabricated bar overdenture, Implant direct digital radiography.

Introduction and Review of Literature

Two stage surgical protocol with implants loaded three to six months after implant placement was considered necessary to obtain a direct bone to implant interface^[1]. It was stated that ‘Conventional’ delayed implant loading after a three-month healing period has not been proven to be the only acceptable protocol for mandibular implant supported overdenture^[2].

The waiting period that was thought to be necessary for successful osseointegration seems to be unsatisfactory for some edentulous patients. Therefore, shortening of the treatment time *via* immediate loading has been proposed. Immediate implant loading should be functionally loaded by the prosthesis within 72 hrs following implant placement, or at the same visit following implant installation^[3]. It was stated that many implants should be used with immediate loading technique in completely edentulous patients but this increases the cost of treatment and makes the patient acceptance less likely. Moreover, anatomic restrictions may limit the number of implants that can be used or require more complicated and costly procedures. Mandibular overdenture on two implants and a bar was claimed to have fewer complications^[4]. However, a recent literature review reported no conclusive evidence on the number of implants required for immediate overdenture could be found in the literature^[5].

Criteria for evaluating implant success were proposed by Albreksson *et al.*^[6]. The successful outcome of implant procedures depends on many interrelated factors. These factors include: Biocompatibility of implant material, macroscopic and microscopic nature of implant surface, health and quality of implant site, surgical technique, undisturbed healing as well as prosthetic design and loading^[6]. Status of the bone/implant site and implant loading conditions have been proposed as preoperative diagnostic implications, whereas implant design, surgical technique, and

implant finish may compensate for less-than-ideal site and loading conditions^[7]. A systematic review of randomized controlled trials showed that successful immediate or early loading can be achieved in selected patients, and one of the prerequisites for this success is a high degree of implant stability^[8].

There is a controversy in the literature concerning survival of immediately loaded implants. Although, it was concluded that immediately loaded implants were 2.7 times more likely to fail at one year compared with delayed loaded implants^[9]. A systematic review evaluating the scientific and clinical evidence of implant loading protocols was presented. It was found that the conventional implant loading for mandibular overdenture represented the highest level of scientific and clinical validation. While, insufficient clinical or scientific validation was found for immediately loaded maxillary overdenture, as well as immediate loading of immediately placed implants in either jaw^[10]. A more recent literature search analysis based on human and animal studies revealed similarity of overall long term implant survival rate of immediate, and conventional loaded implants^[11]

Implant retained mandibular overdenture on two implants has been called by some researchers the standard of care for edentulous patients^[12]. However, immediate loading of only two implants may lead to early implant loss by overloading. To increase the chances for success advancements in implant systems, surface characteristics and designs as well as using different attachment designs are under investigations.

Implant retained overdentures can be retained by attachments or even resilient liners may be used when low retention is required or to retain an immediately loaded implant supported prosthesis^[13]. The attachment of implant retained removable restorations can be accomplished through individual attachments on free standing implants or bar assembly, and these attachments may be either rigid or resilient^[14]. The tissue supported overdenture requires an attachment that allows the prosthesis to rotate and settle onto the resilient tissues of the residual alveolar ridge. On the contrary, implant supported overdenture does not need such stress breaking but only needs an attachment to fix the denture to the implants^[15]. It was advocated that the bar design that is appropriate to be used with two implants is the resilient (round or oval) one, which should parallel the hinge axis. The aim was to enhance free

rotation during posterior loading minimizing the load transmitted to the implants^[16].

Several studies reported no major differences in implant survival or peri-implant tissue health and marginal bone loss with solitary or bar attachments^[17-19]. Nevertheless, other parameters such as occlusion and superstructure fit may have more influence on implant loading rather than their connection^[20]. In comparative studies on splinted versus un-splinted attachments of two implants retaining mandibular overdenture, the bar showed the highest retention, which is maintained for prolonged periods and lowest prosthetic complications. However, more mucositis and gingival hyperplasia were revealed under the bar^[21-23].

Moreover, in order to avoid excessive wear of un-splinted attachment in case of severe implant misalignment (more than 10 degrees), a bar attachment is indicated to provide a favorable path of insertion for the prosthesis^[24].

Digora system is a direct digital scanning, management and achieving system for intra-oral radiographic images. Advantages of direct digital radiography are: Reduction in radiation dose to the patient; image optimization and computer-aided feature extraction; workflow improvement; avoidance of shipping darkroom, or chemical processing errors; environmental waste reduction; improved electronic communications; image archiving; and projecting a technologically advanced practice image. Direct digital radiography (DDR) may provide a faster and more confident diagnostic option that is as accurate as periapical radiographs in detecting peri-implant radiolucencies^[25,26].

The aim of the study is to evaluate the effect of immediate versus delayed loading of two bar splinted implants under mandibular overdenture on bone osseointegration. The marginal bone height level and bone density around the implants were assessed by using DDR system. The hypothesis of the study was that there was no difference in implant bone height and density outcomes as related to the timing of loading.

Materials and Methods

The study protocol was approved by the Ethical Committee at Cairo University. Ten completely edentulous male were selected from the

outpatient dental clinic from the Department of Removable Prosthodontics, Faculty of Oral and Dental Medicine, Cairo University, Egypt to participate in this study. Their age ranged between 48 to 65 years old. All patients were selected according to the following criteria:

- Free of systemic diseases as detected from a written questionnaire
- Nonsmokers
- Normal TMJ movements
- Square or U shaped mandibular arch was preferred while, V shaped arches were excluded
- Adequate inter-arch space to accommodate the bar attachment
- Mandibular inter-canine region of sufficient bone thickness and height that is suitable for the proposed implants
- Normal maxillomandibular relationship

Preoperative Diagnostic Procedures

The diagnostic procedures included a medical history questionnaire as well as history of any previous prosthesis and any problems associated with it. Clinical examination and radiographic evaluation were also carried out. For all patients maxillary and mandibular alginate impressions were made in suitable stock trays and poured to obtain study casts. Acrylic occlusion blocks were fabricated. A tentative jaw relation was recorded to mount the casts on articulator for evaluation of the maxillomandibular relationship and interarch space. Under the effect of local anesthetic, ridge mapping of the mandibular cast was performed to assess the bone width at the proposed implant sites.

Once the patients met the selection criteria, they were informed about the nature of the research. The patients whom approved to participate in the study were asked to sign an informed consent form.

All patients were treated by conventional maxillary complete dentures and mandibular overdentures. The mandibular overdenture was retained by a prefabricated bar connecting two Dyna Helix Octa implants (Dyna Dental Engineering b.v., Bergen op Zoom, The Netherlands) placed in the canine region. The implants were 11.5 mm in length and 3.6 mm in diameter with acid etched roughened titanium surface and self-tapping threads.

The dentures were fabricated in a conventional manner using acrylic resin teeth of appropriate shape and size, following the lingualized occlusion concept, and then, tested in the patient's mouth. At the proposed area for the bar the ridge was built up with stone to dimensions comparable to or slightly larger than the height and width of the bar assembly. The anterior teeth as well as the labial flange were removed from the mandibular trial denture base. The removed flange with the teeth was adjusted at areas of interferences with the built ridge until fully seated. The teeth set up were refined and the dentures were waxed up, flaked and processed in heat cure acrylic resin. A relief space was created within the fitting surface of the lower denture to accommodate the bar attachment (*Dyna instant adjusting bar*). After deflasking, the dentures were laboratory remounted and the occlusion was refined. Dentures were finished and polished, then stored in water till delivery.

The mandibular denture was duplicated into clear acrylic resin using alginate, Cavex CA37, Fast Set, (Cavex Holland BV, Haarlem, The Netherlands) impression material. This duplicate was used as radiographic and surgical stent. Two stainless steel balls 4 mm in diameter were fixed in the canine region with sticky wax. A panoramic radiograph was made in order to assess the exact bone height at the selected implant sites with the radiographic stent.

The radiographic stent was modified to act as a surgical stent. The lingual flange between the two canines was removed. The canines and lateral incisor teeth were cut down to the cervical margin. The surgical stent was stored in 0.2% chlorhexidine solution till the time of surgery.

Surgical Procedures

The surgical procedures were performed by the same operator. One hour before surgery, all patients were premeditated by a prophylactic dose of 625 mg of a combination of Amoxicillin and clavulanic acid and 400 mg of non-steroidal anti-inflammatory analgesic. Infection control measures were strictly followed. Patient was anaesthetized by bilateral mandibular nerve block injections assisted by infiltration field block anesthesia.

The surgical guide was used to mark the proposed implant sites at equal distance from the midline. The implant sites were limited to a distance between 16 mm and 26 mm corresponding to the prefabricated

bar length according to the arch curvature. A full thickness mucoperiosteal flap was reflected exposing the bone.

The implant sites were prepared at both canine regions equidistant from the midline parallel to it and to each other. The implants were inserted into the prepared sites and slowly threaded into its final position.

The patients were randomly divided using subject identification number into two groups:

- Group A, the bar was inserted and the implants were immediately loaded after implant installation.
- Group B, the implants were submerged then the bar was inserted and the implants were loaded three months after their installation.

Group A, during implant insertion a minimum of 35 Ncm tightening torque was a prerequisite to be included in the immediate loading group. After the implants were fully seated the extension abutments were selected and screwed to the implants. The mucoperiosteal flap was sutured and the bar was assembled (Fig. 1).



Fig. 1. Abutments and bar are screwed and the mucoperiosteal flap is sutured for the immediate loading (first group).

The lower denture was verified for proper seating by appropriate occlusion with the upper denture. A silicon putty impression (Zetaplus: very high viscosity c-silicon putty, Zhermack SpA at *Via Bovazecchino*, Badia Polesine, Italy) material was used to block the space beneath the bar and to cover the extension abutments. The riders were picked up intra-orally using a soft mix of auto polymer acrylic resin (Acrostone Manufacturing and Import Co., Cairo, Egypt) (Fig. 2). The material was allowed to polymerize while the patient was occluding in centric relation. After complete polymerization of the acrylic resin, the denture was removed and examined. Finally, the occlusion was checked and re-adjusted. Postoperative and denture instructions were emphasized.

Group B, the implants were submerged and the dentures were relined with tissue conditioning material. Three months later, the implants were exposed and the healing abutments were screwed to the implants (Fig. 3). The healing abutments were left for two weeks then, replaced with the appropriate extension abutments. The bar was assembled followed by direct intraoral pick up of the rider into the fitting surface of the lower denture.



Fig. 2. Riders are picked up into the fitting surface of the denture.



Fig. 3. Abutments and bar are screwed three months after implants installation in the delayed loading(second group).

Radiographic evaluation of the marginal bone height and bone density were measured at mesial and distal aspects of the implants in both groups, using intraoral DDR by Digora Software System (SOREDEX, Tuusula, Finland) (Fig. 4A, B). The radiographic measurements were performed at time of loading then at three, six, nine and twelve months after loading.

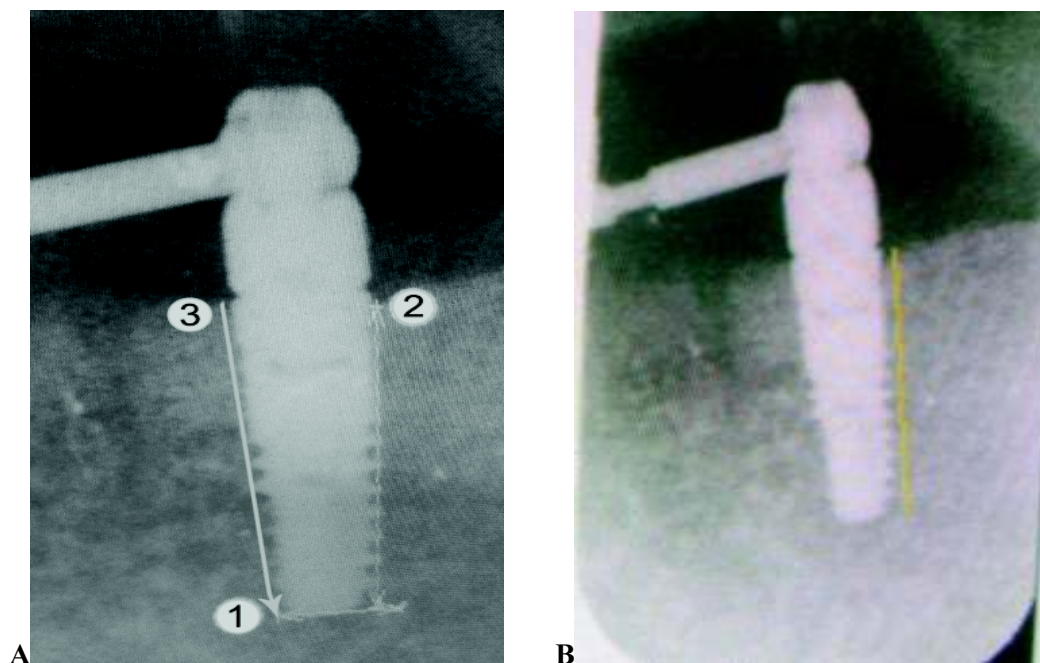


Fig. 4. (A) Linear measurements of the marginal bone height, and (B) Radiodensitometric line measurement around the fixture using Digora software system.

The procedures for marginal bone height measurements were as follows: A line tangential to the apex and perpendicular to the long axis of the implant was first drawn using the Digora software. Another line was drawn on the mesial and distal aspect of the implant. This line was extended from the alveolar crest to the first line, and was drawn tangential to the flutes of the implant. The measurements were carried out by the same examiner at three different times and the mean of the three trials was recorded. The mean values of the mesial and distal bone height measurements for each implant during the follow up intervals were calculated.

The procedures for bone density measurements were carried out as follows: Three lines were drawn parallel to the mesial and distal implant surfaces. The first line extended from the first flute of the implant to the implant apex passing tangential to the implant flutes and perpendicular to a tangent drawn to the implant apex. The second line was one millimeter apart, equal and parallel to the first line. The same procedure was repeated for the third line. Bone density along each of the three lines was recorded, and then, the mean value of the three readings was calculated for each surface. The mean values of the mesial and distal bone density measurements for each implant during the follow up intervals were calculated.

Results

Data were statistically analyzed using Kolmogorov – Smirnov test. The results revealed that there was no significant difference from normality ($p > 0.05$). Homogeneity of variances among the groups was tested using Levene test, and the variances were found to be homogenous ($p > 0.05$).

Paired t test was used to compare between right and left sides. These comparisons yielded non-significant difference between right and left sides. These results are shown in Table 1, 2, 3, and 4. Therefore, the mean values of both sides were obtained and used in the comparisons. Paired t test was also used to compare the measurements between mesial and distal sides and to study the changes by time in each group. "Student's" t test was used to compare between the two groups. The significance level was set at $p \leq 0.05$.

Table 1. The means, standard deviation (SD) values and results of paired *t* test for comparison between mean changes in bone height at the right and left sides in the immediate loading group.

Group	Site	Time	Right		Left		<i>p</i> -Value
			Mean	SD	Mean	SD	
Immediate loading	Mesial	At loading	11.5	0	11.5	0	-
		3 months	11	0.2	11.1	0.264	0.211
		6 months	10.5	0.208	10.8	0.493	0.161
		9 months	10,6	0.378	10.8	0.346	0.339
		12 months	10.8	0.3	10.7	0.404	0.403
	Distal	At loading	11.5	0	11.5	0	-
		3 months	11.03	0.351	10.4	0.665	0.073
		6 months	10.6	0.251	10.2	0.781	0.311
		9 months	11.06	0.208	10.4	0.776	0.339
		12 months	10.7	0.264	10.2	0.665	0.124

*: Significant at $p \leq 0.05$.

Table 2. The means, standard deviation (SD) values and results of paired *t* test for comparison between mean changes in bone height at the right and left sides of the delayed loading group.

Group	Site	Time	Right		Left		<i>p</i> -Value
			Mean	SD	Mean	SD	
Delayed loading	Mesial	At loading	10.6	0.734	10.4	0.986	0.262
		3 months	10.1	0.884	10.04	2.819	0.333
		6 months	9.96	0.841	9.82	0.941	0.343
		9 months	9.86	1.001	9.84	0.792	0.483
		12 months	9.8	0.796	9.8	1.202	0.5
	Distal	At loading	10.2	0.496	10.1	0.665	0.122
		3 months	10.04	0.492	9.8	0.572	0.178
		6 months	10	0.254	9.9	0.79	0.383
		9 months	9.7	0.645	9.6	1.105	0.397
		12 months	9.5	0.563	9.3	1.14	0.25

*: Significant at $p \leq 0.05$.

Table 3. The means, standard deviation (SD) values and results of paired *t* test for comparison between changes in mean bone density at the right and left sides in the immediate loading group.

Group	Site	Time	Right		Left		<i>p</i> -Value
			Mean	SD	Mean	SD	
Immediate loading	Mesial	At loading	138.6	53.7	114.5	16.97	0.293
		3 months	160.3	42.6	172.6	21.1	0.218
		6 months	189.3	20.5	184.1	20.1	0.338
		9 months	204	20.4	203.8	7.78	0.492
		12 months	194.1	19.7	214	8.7	0.116
	Distal	At loading	150.6	49.5	114.2	19.05	0.206
		3 months	164.9	44.4	177.6	19.6	0.244
		6 months	182.6	18.09	196.5	30.7	0.1007
		9 months	204.5	14.5	208.5	11.7	0.169
		12 months	201	16.3	211.8	21.01	0.268

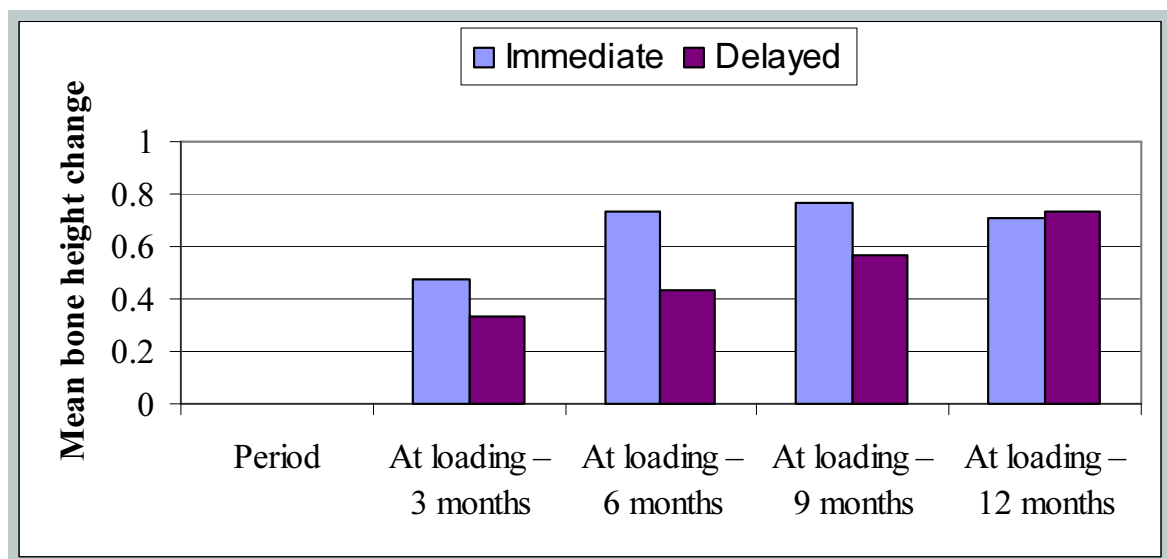
*: Significant at $p \leq 0.05$.

Table 4. The means, standard deviation (SD) values and results of paired *t* test for comparison between mean changes in bone density at the right and left sides in the delayed loading group.

Group	Site	Time	Right		Left		P-value
			Mean	SD	Mean	SD	
Delayed loading	Mesial	At loading	173.2	38.1	105.6	95.5	0.173
		3 months	168.2	26.3	97.3	100.3	0.226
		6 months	188.6	24.7	106.6	15.8	0.373
		9 months	199.5	20	109.7	126.9	0.336
		12 months	200.4	22.9	111.6	125.4	0.383
Delayed loading	Distal	At loading	177.6	36.08	157.6	33.8	0.103
		3 months	171.5	29.01	174	13.3	0.395
		6 months	191.6	21.2	180.5	33.8	0.191
		9 months	203	26	195	10.4	0.284
		12 months	205.5	28.7	195.2	17.9	0.264

*: Significant at $p \leq 0.05$

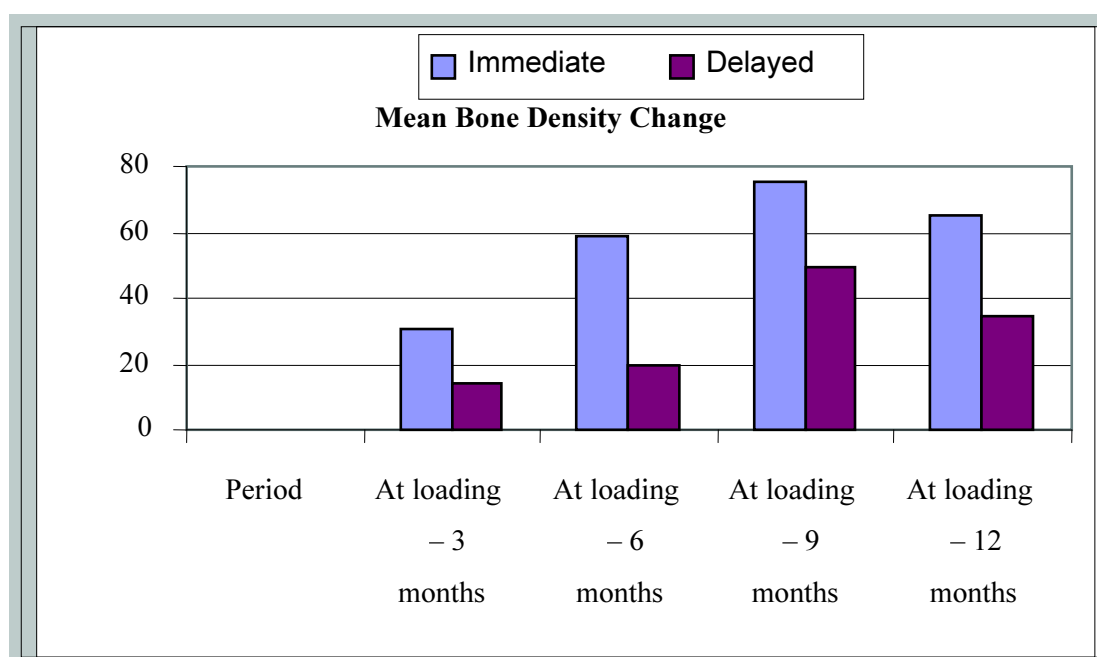
The mean values of the marginal bone loss for the immediate. The delayed loading groups throughout the follow-up periods are illustrated in Bar Chart 1, which reveals statistically insignificant difference in the mean values of measurements for marginal bone loss between the immediately loaded, and the delayed loaded implants throughout all the studied periods.



Bar Chart 1. Comparison of the mean marginal bone height change between the immediate and the delayed loading groups.

The mean values of the bone density changes for the immediate and the delayed loading groups throughout all the studied periods are

illustrated in Bar Chart 2. This reveals statistically significant difference in the mean values of bone density change between the immediately loaded, and the delayed loaded implants, at the intervals between time of loading to 3, 6, and to 12 months after loading. However, there was a statistically insignificant difference between the two groups at the interval between times of loading to 9 months after loading. Collectively, there was a higher statistically significant increase in bone density surrounding the immediately loaded implants than the delayed loaded implants throughout the study period.



Bar Chart 2. Comparison of the mean bone density change between the immediate and the delayed loading groups.

Discussion

This study was carried out on twenty acid etched roughened titanium endosseous implants inserted into the mandibles of ten completely edentulous patients. During the follow-up period no implant was lost in the delayed loading group. One patient of the immediate loading group lost his two implants within six weeks; this was attributed to his dense type I bone quality. Dense bone is hard to drill and needs increased drilling speed as well as pressure that usually results in heat generation. It has been reported that thermal injury to bone might result in

osteonecrosis and fibrous encapsulation around the implant. Moreover, dense bone is less vascular and has less healing power^[27].

Females were excluded from the study to eliminate effect of postmenopausal osteoporosis as the risk for failure of implant to osseointegrate increases when it is placed in compromised bone^[28].

Two implants were connected by a prefabricated bar was the design used in this study. It was reported that mandibular overdenture supported by two implants is a more satisfactory treatment than a conventional denture particularly when opposed by a conventional maxillary denture^[29].

The direct technique of bar rider pick up was performed in this study has many advantages as simple, economic, quick, and allows the patient to retain the prosthesis which allow immediate functional loading by the prosthesis^[30]. It was evident by many authors^[30,31], that the rider pick up was carried out after impressions and denture fabrication to enhance the passive fit, which is an important requirement for successful osseointegration. Similarly, allows movement in only anteroposterior direction as it is not supplied by a spacer. The pickup procedures were carried out under biting forces to allow rider contact with the bar together with tissue contact, which would not be possible with the indirect technique

The mean marginal bone loss over the follow-up period in the present study was 0.7 mm in both groups. This is considered to be within the normal limits of the commonly used success criteria, hence, comparable with the findings of similar bone level change after one year of function in a systematic review evaluating implant loading protocols^[32]. Several theories have been proposed to explain crestal bone loss in the first year which was be related to surgical trauma from flap reflection and bone drilling^[33].

From the results, it was revealed a statistical insignificant difference in marginal bone loss next to the immediately and the delayed loaded implants. Therefore, the splinted, with passively fitted bars, limits the amount of stress transferred to the bone-implant interface and ensures long-term osseointegration. The bar design used in this study was of particular importance to the immediately loaded implants. This design does not require any additional procedures to ensure passive fit;

therefore, it allows the prosthesis to be delivered immediately after surgery. The advantages of this bar design were reported by another study which applied similar bar design^[34]. This prosthetic design was also, consistent with a review on immediate loading prosthetic requirements. This review reported that; to obtain successful outcome with immediate loading the implants should be splinted by bar and acrylic prosthesis until full osseointegration^[35].

The results of bone density change after 12 month of function revealed a higher statistically significant difference between the immediately loaded and the delayed loaded implants. These findings are comparable with other study in the literature^[36], which was reported that the immediately loaded splinted implants can become osseointegrated, and may have the potential to increase ossification of the alveolar bone around endosseous fixture. The increase in bone density may be explained by bone response to stresses within physiologic tolerance as new bone formation, and active remodeling may be observed when the bone is mechanically stimulated during the first 6 months to one year of loading^[34].

The lesser density in bone supporting the delayed loaded implants was explained based on the phenomenon of disuse atrophy in bone without loading. It was stated that, the bone is less dense and weaker at implant exposure than it is after one year of prosthetic loading^[36].

Conclusion

Within limitations of this study, it was concluded that immediate loading of two mandibular implants splinted with bar design could be a predictable treatment alternative comparable to delayed loading. Moreover, this method significantly shortens the treatment period, thus, improving patient satisfaction. It was recommended that immediately loaded implant overdenture retained by bar attachment should be removed with caution during early osseointegration, as it possesses high retentive force. Careful case selection in terms of bone quality is an important factor for success of immediately loaded implants. Further long term studies using larger sample size are needed to confirm the results of this study.

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تقييم التحميل الفوري بالتأخر للغرسات المترابطة بالفك السفلى باستخدام الأطقم المحمولة

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المستخلص. إن التحميل الفوري للغرسات مفضل لدى المرضى عن التحميل المتأخر. ولأن التحميل الفوري الأكثر تعرضاً للمخاطر فلا بد من توثيقه. الغرض من هذه الدراسة هو تقييم ارتفاع وكثافة العظام باستخدام نظام الأشعة الرقمي المباشر للغرسات المترابطة بمجموعة التحميل الفوري ومقارنة النتائج بتلك التي تم الحصول عليها بمجموعة التحميل المتأخر. تضمنت الدراسة عشرة من المرضى ممن لديهم فقد كلي للأسنان. تمت معالجة جميع المرضى بأطقم علوية تقليدية وأطقم سفلية محمولة مثبتة باستخدام الأعمدة سابقة الصنع التي تربط اثنين من الغرسات بالمنطقة النابية. تم تقسيم المرضى عشوائياً إلى: المجموعة الأولى للتحميل الفوري والمجموعة الثانية تم تحميل الغرسات بعد ثلاثة أشهر من الغرس. باستخدام نظام الأشعة الرقمي المباشر، تم قياس ارتفاع وكثافة العظام المحيطة بالغرسات المعدنية فور التحميل ثم بعد ثلاثة، ستة، تسعة واثني عشر شهراً. وقد أسفرت النتائج عن حدوث تغير غير ملحوظ إحصائياً في متوسط الفقد في ارتفاع

العظام المحيطة بالغرسات المعدنية. حدوث ارتفاع ملحوظ إحصائيًا في قيم كثافة العظام المحيطة بالغرسات لمجموعة التحميل الفوري منذ بدء التحميل ثم بعد ثلاثة، ستة، تسعة، واثنى عشر شهرًا. وقد تم استنتاج أن التحميل الفوري للغرسات الداعمة للأطقم السفلية المحمولة والمترابطة بأعمدة يمكن اعتبارها طريقة علاج بديلة للتحميل المتأخر.