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# IMMEDIATE VERSUS DELAYED LOADING FOR DENTAL IMPLANTS SUPPORTING MANDIBULAR OVER-DENTURES IN TYPE II DIABETIC PATIENTS

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***ABSTRACT***

The aim of this study is to evaluate the effect of immediate loading on dental implants supporting mandibular complete overdenture in controlled type II diabetic patients both clinically and radiographically. Fourteen completely edentulous males; controlled type II diabetic patients were selected for the study. Their HbA1c (Glycosylated Hemoglobin) level was around 7. All were examined with pre-operative CBCT (cone-beam computed tomography) to evaluate the future implant site, and for proper selection of implant size. First implant was installed in one side of the inter-foraminal region of the mandible, then after 4 months the second implant was installed in the other side. Two weeks later both implants were loaded by incorporation of O-ring attachments into the existing mandibular complete denture as a direct clinical procedure in the mouth. Both radiographic evaluation of crestal bone loss using CBCT, and clinical evaluation of implant stability using resonance frequency analysis (Osstell device) were made at time of loading, 3, 6, 12 and 24 months after loading. The results showed that after 24 months of loading no significant difference observed between the immediate and delayed loading protocols either clinically (Implant stability), or radiographically (Crestal bone loss). The only significant difference observed in the implant stability between both groups was at time of loading. In this study all clinical and radiographic results suggested that dental implants could be used as a successful and predictable treatment to retain mandibular complete overdentures in controlled type II diabetic patients with a very high success rate either immediately or delayed loaded.

**KEY WORDS:** Immediate loading, Delayed Loading, Overdenture, Diabetes Mellitus, HbA1c, CBCT, Resonance Frequency Analysis

## INTRODUCTION

Edentulism is the state of having lost all of one's natural teeth, and this associated with a lot of problems [1,2]. The traditional way to rehabilitate edentulism is complete dentures with their known problems during speaking and eating [3]. With the introduction of dental implants that stabilize

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dentures, many conventional complete denture limitations are eliminated. Mandibular implant supported overdentures have been found to improve patient satisfaction, quality of life, and masticatory function [4].

Diabetes mellitus (DM) is a metabolic disorder resulting in hyperglycemia, and it is considered the most prevalent endocrine disease, comprising the third highest cause of disability and morbidity [5, 6]. There are two main types of diabetes mellitus, Type I DM (previously defined as insulin- dependent DM) is caused by the autoimmune destruction of β – cell, which leads to partial or complete insulin deficiency. Type II DM (previously defined as non-insulin-dependent DM) develops in response to genetic and environmental factors and is characterized by variable degrees of insulin resistance in peripheral tissue, impaired insulin secretion, and increased glucose production[7]. Non- insulin dependent DM (Type II diabetes) accounts for about 90% of all DM cases [8].

Clinician might be hesitant to prescribe dental implant therapy for the diabetic patient for a variety of reasons, including delayed wound healing, prevalence of microvascular disease and impaired response to infection[8]. Normal preoperative glucose levels have been shown to improve healing and should be considered essential in the preoperative, perioperative, and postoperative settings [9]. Diabetes control is critical for reducing the long term micro and macrovascular complications of the disease, and so high implant success rate in the well-controlled type II diabetic patients[10, 11]. There is lot of studies confirming that; dental implants can be successfully used in controlled diabetic patients, with success rates similar to those of non-diabetic subjects [5-8, 10, 12, 13]

Three dimensional (3D) assessment of the implant site is an essential part of the pre-surgical evaluation for any implant patient. This evaluation is increasingly being provided by cone beam CT (CBCT) imaging, which is considered a precise imaging modality and is a valuable tool for use in dental applications [18]. The advent of CBCT, helped in overcome most of the drawbacks of Conventional CT, periapical, and panoramic x-ray techniques [14].

Implant stability could be considered as a clinical condition without mobility, and defined as the capacity to withstand loading from axial, lateral, and rotational directions[15]. Therefore, maintain implant stability is an essential condition for the successful clinical outcome of implants[15, 16]. In late 1990s; Meredith[17], developed an easy, noninvasive, reproducible method known as resonance frequency analysis (RFA). With this method implant stability can be measured by reading an implant stability quotient (ISQ) derived from the resonance frequency given by Osstell equipment [18,19].

There are several types of loading of dental implants depending on time of loading. Delayed (Conventional) loading is a situation where the prosthesis is attached to the implant after an unloaded healing period of at least three months in the mandible and six months in the maxilla respectively. Immediate loading is defined as a situation where the superstructure is attached to the implants in occlusion with the opposing dentition within 48-72 hours [20, 21]. The term nonfunctional immediate loading and immediate restorations are used when prosthesis is fixed to an implant within 72 hours without achieving full occlusal contact with the opposing dentition [20, 22]. Mish [23] suggested a terminology for immediate occlusal loading protocol as; an implant supported temporary or definitive restoration in occlusal contact within two weeks of the implant insertion. Non -functional immediate restoration describes implant prosthesis with no direct occlusal load within two weeks of implant insertion. Non -functional early restoration describe a restoration delivered between two weeks

and three months after implant insertion[20]. Upon reviewing the literature there were few researches comparing the effect of both immediate and delayed loading protocols of implants retained overdentures in controlled Type II diabetic patients.

### Aim of the study

The aim of the current study is to evaluate the effect of immediate loading on dental implants supporting mandibular complete overdenture in controlled type II diabetic patients both clinically and radiographically.

## MATERIALS& METHODS

### Selection of the patients

Fourteen male completely edentulous controlled type II diabetic patients "non-insulin dependent" have been selected for the study, there were certain selection criteria including: age range 45- 60 years, cooperative person accepting implant overdenture treatment modality and willing to comply with follow-up protocol, free from any other metabolic, systemic and endocrine diseases, had adequate zone of attached mucosa , Class I Maxillo-mandibular relationship, and had sufficient inter-arch space to accommodate the overdenture. HbA1c test was made for all patients and its level in the all selected patients was around 7. All the patients signed an informed consent including the procedure that will be made and all possible hazards.

### Pre-operative CBCT

Pre-operative CBCT scanning (**Scanora 3D, Soredex. Finland**) was made for every patient to exclude the presence of any pathological condition and to check the quality and quantity of the available alveolar bone at the planned implant site in 3 dimensions. **(Fig 1)**

### Prosthetic phase I

It included construction of conventional complete denture using the conventional standardized technique, and radiographic stent construction. The radiographic stent was constructed from a clear heat cured acrylic replica of the prefabricated mandibular complete denture, two channels perpendicular to the occlusal plane and parallel to each other were drilled at the canine area bilaterally. These channels were prepared just short to the fitting surface; filled with amalgam acrylic powder mix of 1:3 by weight and sealed with wax [24]. These channels represented the future implant sites, and appeared in the CBCT as radiopaque channels without distortion or streak defect. **(Fig 2)**

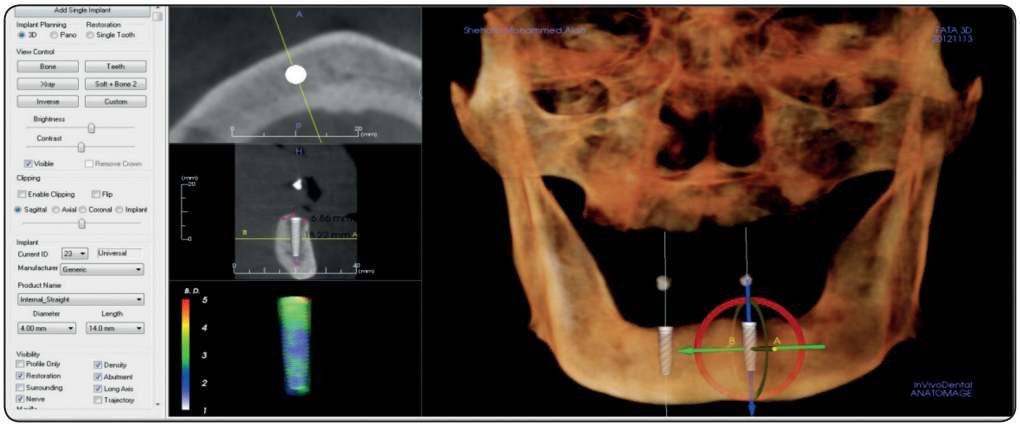


Fig. (1) Pre-operative CBCT to determine the suitable size of the implant showing bone height, width, and density at the planned implant site.

Fig. (2) Radiographic stent with two channels filled with amalgam acrylic mix 1:3 by weight

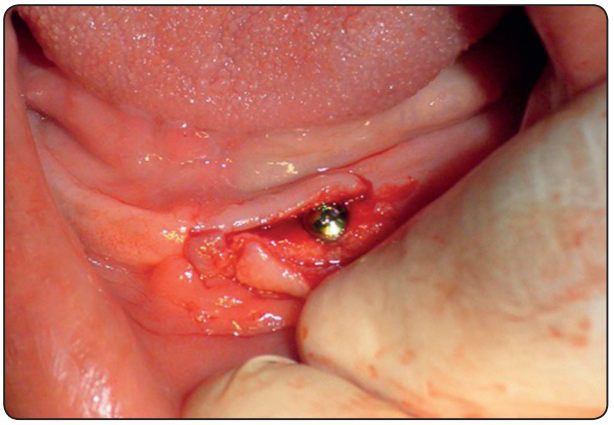

Fig. (3) Installation of the first implant in one side for delayed loading group.

**Preparation of the surgical stent**

The radiographic stent modified to be used as a surgical stent by removing the mix of amalgam powder and acrylic resin removed and the channels extended to penetrate the fitting surface.

**Pre-surgical preparation of the patient**

Pre-surgical medications were given to each patient before the surgery and included Amoxicillin 2gm one hour before surgery, then 500mg three times a day for 5 days, and the use of 0.12% chlorhexidine mouth wash before and after the surgery. [13]

**First stage surgery: (Figure 3)**

The standard surgical protocol was used; mucoperiosteal flap was reflected for the installation of the first implant in one side of the interforaminal region. The implant (**Superline, Dentium Co, Korea.)** osteotomy site was prepared according to the standard technique of successive drilling, low speed, high torque and double coolant. The surgical site was closed by interrupted sutures then; the denture was delivered to the patient after refitting with tissue conditioning material, which was replaced every week till the end of the healing period.

**Second stage surgery**

After four months, the installed implant fixture was exposed using punch technique, with the help of surgical stent, and the second implant was installed in the other side of the interforaminal region by reflection of the mucoperiosteal flap also. The two implants used in the both sides were of the same diameter and length. Then, the healing caps were connected for the both implants, left for healing period of two weeks. Then, the denture was delivered to the patients after refitting with tissue conditioning material, and relief opposite the healing caps.

**Prosthetic phase II: (Fig.4, 5)**

After 2 weeks, the O-ring attachment was incorporated into the existing mandibular complete denture as a direct clinical procedure in the mouth according to conventional method, using hard linear acrylic (**Hardliner CD, Promedica, Germany** ) applied by a mixing gun. A clinical remount procedure and occlusal equilibration was then completed and the denture was delivered to the patient after giving him the instructions including denture hygiene and post-operative care.

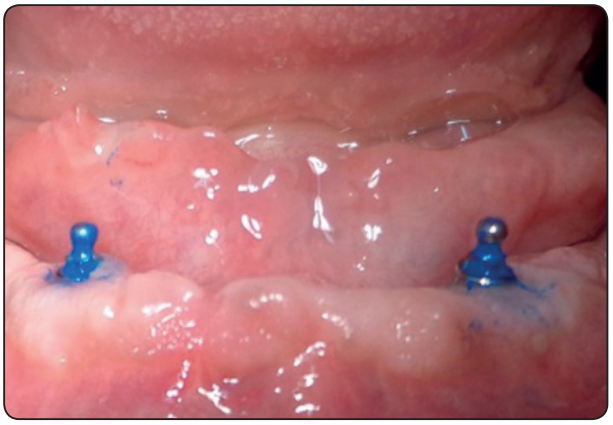

Fig. (4) Two ball abutments were attached to the implants and marked with indelible pencil to help transfer their position to the tissue bearing surface of the lower denture for direct clinical pick up procedure.

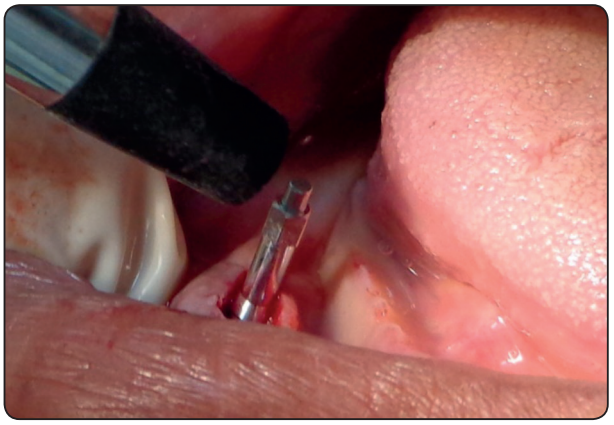

Fig. (6) Measuring of primary stability for immediate loading implants. The Osstell device was used to measure ISQ values in four directions (Labial, Lingual, Mesial, and Distal).

Fig. (5) Proper orientation of the metal housing in the fitting surface of lower denture after clinical pick up

### Clinical Evaluation

Implant stability was examined using Osstell Mentor.* **(Osstell, Integration Diagnostics, Goteborg, Sweden)**, immediately at time of loading, three, six, twelve and twenty four months after implant loading. A compatible Smart Peg was mounted on each implant and tightened by hand using rubber smart peg holder. Resonance frequency (RF) values are represented by a quantitative unit called the implant stability quotient (ISQ) on a scale from1 to 100. The RF value was measured **(Fig.6)** four times in four directions (every 90°) for each implant surface (Labial, Lingual, Mesial, and Distal), and the results were tabulated [25].

### Radiographic Evaluation [26] (Fig.7)

Radiographic assessment of the vertical bone loss was carried out through mandibular cone beam CT using On Demand 3D Project Viewer Program. The marginal bone height around the implants was measured immediately after implant loading, three, six, twelve and twenty four months later. A tangential line was drawn at the apex of the implant perpendicular to the long axis of the implant. The bone height was measured by measuring the distance from the apex of the implant to the crest of the alveolar ridge. The labial and lingual bone heights were measured on the sagittal view screen, while the mesial and distal bone heights were measured on the coronal view screen, the results were tabulated.

### Statistical testing

The collected data both clinically or radiographically were tabulated and analyzed using the **S**tatistical **P**ackage for **S**ocial **S**ciences (SPSS) ver. 20. Descriptive analysis of raw data has been performed using mean and standard deviation. Comparisons between the relevant variables in the two groups was calculated using paired sample t-test, at significance level $p<0.05$.

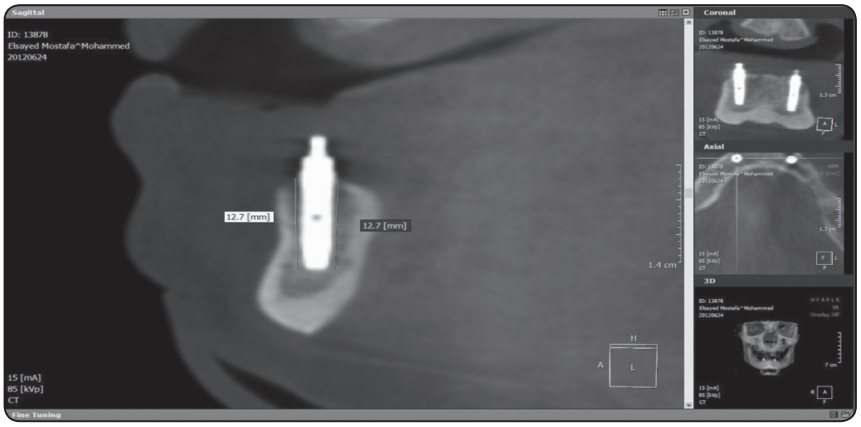


Fig. (7) Measurement of Labial & Lingual bone height changes using CBCT in sagittal view.

## RESULTS

Overall 28 implants were placed in the mandibular interforaminal regions of type II diabetic patients, all the implants survived the healing period and remained functioning during the entire observation period in both groups (immediately or delayed loaded), so the success rate was 100% .

The means and standard deviations of ISQ values (Implant stability) of both immediately and delayed loaded implants groups are shown in **(Table I)**. In immediately loaded implants group, there is decrease in the mean of ISQ values between time of loading in comparison to 3 months after loading, and then there is constant increase in the mean of ISQ values until the end of follow up periods. In delayed loaded implants group, the mean of ISQ values at time of loading was the same as 3 months after loading then there was constant increase in the mean of ISQ values until the end of follow up periods. Comparison between the two groups shows that there was non-significant statistical difference in the means of ISQ values in all follow up stages between the two groups, except at the time of loading only (69.6±6.1 ISQ values for immediately loaded implants group, and 66.7±6.9 for delayed loaded group)**.**

TABLE (I) Mean ISQ Values and Statistical Analysis at Different Intervals for both groups

| **Follow up Interval** | **Immediate** | **Delayed** | **Statistical Analysis** | |
|---|---|---|---|---|
| | Mean ± SD | Mean ± SD | t | P |
| Loading | 69.6±6.1 | 66.7±6.9 | t1=3.696 | p1=0.005* |
| 3rd Month | 67.5±4.5 | 66.7±4.9 | t2=0.475 | p2=0.646 |
| 6th Month | 70.2±4.7 | 69.9±6.0 | t3=0.323 | p3=0.754 |
| 12th Month | 72.1±6.3 | 70.9±6.8 | t4=0.887 | p4=0.398 |
| 24th Month | 74.2±5.2 | 72.5±5.8 | t5=0.788 | p5=0.498 |

***t: paired sample t-test*** ****: statistically significant at p <0.05***

TABLE (II) Mean Crestal bone loss Values and Statistical Analysis at Different Intervals for both groups

| Follow up Interval | Immediate | Delayed | Statistical Analysis | |
|---|---|---|---|---|
| | Mean ± SD | Mean ± SD | t | p |
| Loading-3months | 0.6±0.21 | 0.59±0.18 | t1=0.079 | p1=0.939 |
| Loading-6months | 0.98±0.22 | 1.15±0.24 | t2=1.655 | p2=0.132 |
| Loading-12months | 1.35±0.30 | 1.49±0.23 | t3=1.254 | p3=0.241 |
| Loading-24months | 1.54±0.24 | 1.61±0.25 | t4=1.754 | p3=0.441 |

***t: paired sample t-test*** ****: statistically significant at p <0.05***

The means and standard deviations of bone height changes (Crestal bone loss) for immediately and delayed loaded implants groups are shown in **(Table II).** There was a constant increase in the mean of crestal bone loss throughout the 24 months study period after loading in both groups. Comparison between the immediately and delayed loaded implants groups revealed non- significant statistical difference in the means of crestal bone loss between the two groups in all follow up stages **.**

## DISCUSSION

In this study, great care was directed toward the proper selection of the patient. Therefore, all the patients selected for this study were selected from type II diabetic patients who had fewer complications. Such diabetic complications are more prevalent and acute in type I diabetes [27]. All the selected patients were controlled type II diabetics as confirmed by blood testing. Diabetics who effectively control their disease incur a low risk of various health complications than uncontrolled diabetics [28].

To ensure that the patients are under proper control; glycosylated hemoglobin level (HbA1c) was done for every candidate. The recent consensus of the American Diabetes Association (ADA) and the European Association for the study of diabetes [29,30] advocate glycated hemoglobin as the main parameter to assess the metabolic control. This test indicates the degree of hyperglycemia during the three months immediately before testing [31]. All the selected patients had their HbA1c level around7%, which complied with the ADA recommended HbA1c level for controlled diabetics [5,12,29]. HbA1c around 7% has been shown to reduce microvascular and neuropathic complications of diabetes[32].

Preoperative CBCT was done for every patient. Proper assessment of bone volume and quality may allow better predicting a successful outcome of implant placement. Also the anatomical structures that could represent a risk during surgery like the mandibular canal, or any bony abnormalities or pathology that may interfere with implant placement can be easily detected [33]. Dawood et al [19] proposed that, three dimensional (3D) assessment of the implant site must be a part of the pre-surgical work-up for any implant patient and is increasingly being provided by cone beam CT(CBCT) imaging. Before the use of CT, the information about jaw bone was obtained from panoramic, intra-oral and cephalometric radiographs [34]. Although, these views are useful they cannot be used to determine the buccolingual width of the jaw bone accurately, and the clinician had to rely mainly on clinical examination to determine whether the alveolar process is thick enough to place an implant [35].

Amalgam acrylic powder mix of 1:3 by weight used as a marker in our study, and appear in the CBCT as radiopaque channels without distortion or streak defect. This combination was found in a previous study [24] to produce excellent visibility with minimum cost, availability and easy manipulation as it fills the channels very easily.

Good preoperative preparation of the diabetic patients before implant surgery was necessary to overcome any possible complications [36]. In addition to be sure of the controlled blood glucose level, pre-surgical medication was given to each patient before the surgery, includes Amoxicillin 2gm one hour before surgery, then 500mg three times a day for 5 days after surgery [13]. Morris and associates [37, 38] reported improved implant survival for patients who were treated with antibiotics either diabetic or non-diabetic compared to those not receiving antibiotic coverage. Also 0.12% chlorhexidine gluconate mouth wash was used before and after surgery for two weeks. Improved outcome of the patients treated with chlorhexidine gluconate was reported previously to reduce the failure rate in type 2 diabetes patients from 13.5% to 4.4%. [38]

A split mouth design was used for this study because it eliminates issues of age and blood glucose level matching between patients. In addition bone density in both sides of the jaw is comparable [39, 40].

The type of attachment used in this study was O-ring attachment They possess a number of advantages including low cost, ease of changing attachments, minimal chair time, patient satisfaction and it allows prosthesis movement in all directions so releases stresses [41]. Some studies showed that O-ring attachments transferee less stresses to the implants than other types of attachment when occlusal and lateral load were applied, which is very important for the stability and longevity of the implant [42]. Another study found that O-ring ball attachment offers increase stability and comfort, while keeping a high implant success rate in case of immediate loading of two implants by means of mandibular complete denture [43].

The conventional loading has many advantages in that no implant micro movement exists during the healing and so avoids fibrous tissue formation. In addition, coverage of an implant prevent infection and epithelial down growth. However, certain problems remain when this conventional technique is used. These include: inability to use any prosthesis for a period of time, loose denture, pain, and the necessity of additional surgery to expose implant fixtures. Therefore, focus on loading implants soon after their placement has been attempted and has gained some acceptance among clinicians [44].

For a long time, it was presumed that premature loading would inhibit direct bone apposition onto the implant surface (osseointegration), but several experimental and clinical studies have shown that immediate loading does not necessarily lead to fibrous tissue healing, but a bone-to-implant contact similar to that of conventionally loaded implants maybe achieved [43-48].

Immediate loading has a lot of advantages include shortened treatment time, gives immediate functional benefits, offer good esthetics, reduce the number and length of office visits, eliminates the inconvenience of a second surgery for the placement of abutments, necessitates fewer provisional restorations so potentially lower costs, improve the patients quality of life, and the psychology of the patient[20, 46].

Some studies showed that there is no significant difference between the survival rate of implants placed according to the conventional loading technique, and those placed according to the immediate loading technique [20, 47, 48]. Other studies concluded that controlled diabetic patients can undergo immediate loading protocol [22, 49, 50].

Overall 28 implants were placed in the mandibular interforaminal regions of type II diabetic patients,

no implants were failed during the observation period, with success rate 100% either immediately or delayed loaded, this result attributed to good selection of the diabetic patients suitable for implant treatment, non-traumatic technique used, good pre-surgical preparation of the patient and postsurgical prophylaxis, glycemic control and periodic follow up of blood glucose level, in addition to following the oral hygiene instructions.

There are different diagnostic methods used in the assessment of implant stability and the most commonly used methods now are Periotest, and resonance frequency analysis (Osstell device) [51]. Periotest has limitations in that it has narrow range of values, from approximately -5 to +5 for measuring implant mobility and the sensitivity of this method is not sufficient [14, 52, 53] .

The Osstell Mentor is the most recently developed method of resonance frequency analysis. In studies on the prognostic value of Periotest and Osstell, the cutoff value for Periotest was -2, with 84% sensitivity and 39% specificity. For Osstell, the cutoff ISQ value was 47, with sensitivity of 100% and specificity of 97%. Presently, resonance frequency analysis has been used more extensively for the evaluation of implant stability in clinical studies[14].

Accordingly, in this study Osstell device was used in the evaluation of implant stability, and the results showed non- significant difference between the immediately and delayed loaded implants regarding implant stability in any stage of the follow up procedure. The only exception was at the stage of loading and this may be attributed to the type of stability. For the immediately loaded implant the implant stability was mechanical in the form of direct anchorage of the implant threads to the bone. These implants had higher mean of ISQ values at time of loading (69.6±6.1), while for delayed implant group was 66.7±6.9 which may represent the ongoing bone deposition around the implants and maturation. These findings matched the results of Zhou et al [54] who compared the stability of immediately loaded with delayed loaded implants at time of loading and observed that ISQs for immediately loaded implants were significantly higher.

With observation of the next stages of follow up after 3, 6, 12 months of loading no significant difference was observed between both groups. There is also another observation that the mean of ISQ values decreased after 3 months of loading in the immediately loaded implants group but it was still with the acceptable values 67.5±4.5, in comparison to its level at loading stage 69.6±6.1. The recorded values remained essentially the same for delayed loaded implants 66.7±4.9. This could be attributed to the transformation from primary stability (Mechanical) to secondary stability(Biological) at this stage which it is accompanied by bone modeling and remodeling around the implant surface, with the formation of lamellar bone from woven bone, which may actually cause a decrease in primary bone contact so decrease implant stability [17, 51, 55]. By observation of the mean of ISQ values in the remaining follow up stages, it was found that it started to increase until the end of the follow up, which may be attributed to increasing the reinforcement of the preformed woven bone scaffold by mature lamellar bone, which provide increase of the secondary implant stability [56-58]. Several studies had shown non- significant difference in the implant stability between the immediate and delayed loading protocols[60 ,59 ,45) ]. It must be remembered however that the primary prerequisite for good results with immediate loading is excellent initial implant stability which was adhered to in the present study.

In this study CBCT was used for the evaluation of bone height changes, because it provide 3-diminsionsal images, not 2 dimensions only as in periapical, and panoramic x rays, which allows evaluation of bone height changes from all surfaces [24, 61]. Conventional CT scans in this study were not used because of its like high radiation dose

in comparison to CBCT [62], which would have been unjustified hazard to the patient for the consecutive follow up visits.

Results of the radiographic evaluation demonstrated constant increase in the means of crestal bone loss in both groups, there was non-significant difference observed between the groups in the means of crestal bone loss all over the follow up periods. These findings matched results of several studies [3,26,47,60,63]. The mean crestal bone loss 12 months after loading for immediately loaded implants was 1.35±0.3, and for delayed loaded implant group was 1.49±0.23, and both of them are accepted for the first year after loading, and this matched the results of several studies [64-66] who have considered less than 1.5 mm of marginal bone loss during the first year of loading as success criteria. other studies suggested that the marginal bone loss after 1 year of follow up should be less than 1mm [60]. Another study; Roe et al[67] found that marginal bone loss around oral implants during the first year of function of implant overdenture cases range from 0.19mm to 2.38mm at time interval of 12 months. Such differences may be the result of different radiographic evaluation technique with possibility of overlapping and error. Moreover it may be due to differences of recording time (day zero before loading immediately or at day of surgery). The possibility of effect of diabetes on bone loss still exists [7]. On the other hand the very slight change between 12 month and 24 months of follow up regarding bone loss confirms that both treatment modalities (immediate or delayed loading) are successful and has no detrimental effect on the implants. This was also confirmed by the results of ISQ values which showed steady increase denoting functional bone formation and maturation.

## CONCLUSION

*Under the limitations of the current study it could be concluded that:* **In controlled type II diabetic patients**

- Dental implants can be used as a successful and predictable treatment to retain mandibular complete overdentures with excellent success rate either immediately or delayed loaded.
- Non-significant difference exists between immediate or delayed loading of dental implants in diabetic patient regarding implant stability with acceptable ISQ values all over the follow up periods in both groups indicating successful osseointegration. The only exception was at the time of loading.
- Crestal bone around the dental implants loaded immediately or in conventional manner are comparable both together and to the data found in literature

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