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Immediately-Loaded Implant Retained Mandibular Overdenture In Controlled Diabetic Patients: Results Of Five Years, Prospective Clinical Study

Research Article

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Abstract

Objectives: This cohort study was done to evaluate dental implants assisted overdenture in controlled type II diabetic patients after five years of immediate loading.
Material and Methods: Thirty, completely edentulous patients (18 men and 12 women) with a mean age of sixty-two years old were included in this study. For each patient, two immediately loaded implants were inserted at the interforaminal region with ball and socket attachment to support mandibular overdenture. Patients were evaluated clinically and radiographically at baseline (complete denture insertion) and after 6 months, one year, three years and five yearsafter loading. Data were collected and statistically analyzed using repeated measures ANOVA test.
Results: The cumulative implant success rate at five years was 100%. There was no statistical significant difference along the time intervals ($P \geq 0.05$). Marginal bone loss was (0.796 ± 0.187) after five years of function. No complications or implant failure were reported.
Conclusions: Within the limitations of this study, dental implants can be immediately loaded successfully to retain overdentures in type II diabetic edentulous patients.

Keywords: Diabetes; Immediate Loading; Implants; Implant Supported Overdenture; Implant Retained Overdenture.

Introduction

DeDiabetes' oral complications are well known and reported in the literature especially rapid increased bone loss rate than healthy edentulous patients. [1-5]

Implant retained overdentures have better psychological effect to the edentulous patients as it increases patients' satisfaction and quality of life more than ordinary complete dentures or leave the patients in an edentulous condition. [6]

Diabetes mellitus has long been considered a relative contraindication for implant procedures.[7] Well-controlled diabetic patients can be considered appropriate for implant therapy, while those lacking good glycemic control may be denied the benefits of implant therapy.[8] However; the potential benefits of implant therapy may be important for diabetic patients provided that their plasma glucose level is under metabolic control.[9]

Whilehigh failure rate of implants was reported in diabetic patients with adequate metabolic control [10] and animal studies showed negative effects of hyperglycemia, not only on bone formation, but also on bone strength and fracture healing. [11, 12] Other studies showed evidence of peri-implants bone formation in animals induced with diabetes.[13, 14]

While immediately loaded implantswere found to have a high success rate incontrolleddiabetic patients when using conventional loading protocols;[15, 16] diabetic patients were excluded from studies that used immediate loading protocol.[17] More over; long term predictable clinical and radiographical results were reported. [18]

The subject is conflicting and the availableliterature till nowadays

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lacks evidence-based studiesinsertingimmediately-loaded implants in diabetic patients.[9, 19, 20] It wasclaimed that Type II diabetes have been even claimed not to be an absolute risk factor for immediate loading protocols.[21] A systematic review [22] was performed to analyze the influence of diabeteson survival of implants. The authors advocated that the results of the analysis should be interpreted with caution because of the presence of uncontrolled confounding factors in studies they included and that the apparent lack ofdifference between the insertion of dental implants in non-diabetic and diabetic patients may have affected the implant failure rates.

This prospective study aimed to evaluate immediately-loaded implants retaining mandibular overdenture in controlled diabetic patients after five years of service to test the null hypothesis that dental implants can be immediately loaded in controlled diabetic patients type II.

Material and Methods

The current study was carried out on thirtyType II diabetic, completely edentulouspatients(Twelve females and eighteenmales), with age range (55-69) years old and mean age of 62 years old free from any other systemic diseases that may influence implants osseointegration and have suffered from the disease for at least twenty years ago. Laboratory investigations included the Glycosylated Hemoglobin Test (HbA1c Test) to ensure that all selected patients were controlled with levelsranging from 6.5% up to 7.5%.[23] Patients whose HbA1c levels were 8% or above, drug abuse, alcoholic, poor oral hygiene were excluded from this study. Preoperative panoramic radiographswere taken for all patients to explore the relative anatomical mandibular landmarks and the dimensions of bone in the interforaminal areaand to check for any clinically undetectable pathology or bone abnormality. An informed consentapproved by the ethics committee was signed by each patient after discussing the treatment plan with them and prior to initiation of treatment.

An acrylic maxillary and mandibular complete denture was fabricated for each patient with semi-anatomic acrylic teeth set on semi-adjustable articulator. After try-in visit and before processing, duplication of the mandibular try-in record base was done to produce a non-limited surgical guide from clear autopolymerized acrylic resin to aid in implants insertion.

All patients were prescribed an antibiotic containing amoxicillin and clavulanic acid twice daily and mouthwash containing 2% chlorohexidine to be used two days before and at least 4 days after the surgical operation.

Surgical procedures

Two immediately-loaded one piece implants 3.8 mm diameter and 13 mm in length (OsteoCare Dental Implant System Ltd. Epsom, United Kingdom) were inserted at the anterior region of the mandible using flapless technique. After implant insertion; primary stability of implants was tested using the insertion torque that exceeded reading of 35 N/cm during implant insertion and with the Osstel® device (Osstel W&H, Göteborg, Sweden), if the readings were (65) or above; the ball and socket attachments were screwed to the implants to retain the mandibular overdenture (Figure 1). Patients were recalled after one day and each mandibular denture was relieved at implant locations, it was made sure that dentures were seated securely over the ridges without any rocking. The plastic caps of the ball attachments (Osteo Care Dental Implant System Ltd. Epsom, United Kingdom) were placed on the implants. Each ball abutment undercut was covered with a small shim to prevent excess acrylic resin from engaging any undercuts. The relieved areas of the fitting surface of the denture were filled with auto polymerized acrylic resin (Acrostone cold cure, Acrostone, Egypt), denture was seated in patient's mouth instructing the patient to bite gently during setting of the acrylic resin. After setting, denture was removed, excess resin trimmed, plastic cap inside the denture was examined and inserted again in patient mouth. Patients were asked to return on the following day to examine the denture bearing area and check for signs of tissue irritation. All patients were then scheduled for recall appointments to monitor and improve their oral hygiene regimen every one month and also clinical and radiographic follow-up visits.

Each patient was asked to perform the Glycosylated Hemoglobin Test (A1C Test) every three months all over the study period to ensure glycemic control with Glycosylated Hemoglobin levels ranging from 6.5 to 7.5%.

All patients were evaluated clinically and radiographically at baseline (complete denture insertion 24 hours after inserting the implants), 6 months, one, three and five years after complete denture insertion as follows:

1. Plaque index:

Plaque adherent to the implants' surfaces was quantified at four sites, buccal, lingual, mesial and distal, using a mouth mirror and a plastic dental explorer after air drying of the implant and gingiva. Each of the four areas was scored on a 4-point scale of 0-3 as described by Mombelli and Lang [24]:

0 = No plaque is visible
1 = a film of plaque adhering to the free gingival margin and adjacent area of the implant/tooth, seen only after application of disclosing solution or by running the explorer across the implant / tooth surfaces.
2 = Moderate accumulation of soft deposits within the gingival pocket and on the gingival margin and/or adjacent to implant/tooth surface that can be seen by the naked eye.

Figure 1. Clinical picture showing the two implants inserted in the mandibular edentulous arch.

3 = Abundance of soft matter within the gingival pocket and/or the gingival margin and adjacent implant/tooth surface.
The PI score was obtained by taking the average of the four plaque scores for the single implant or tooth.

2. Periapical radiographs:

Periapical radiographic films were used to measure the marginal bone loss around the implants using long cone paralleling technique and Rinn XCP instrument (Rinn Co. Dentsply division, York, PA, USA) were used. It included the use of standardized periapical radiographs to detect changes in alveolar bone surrounding the implants during the follow-up period. The standardized periapical radiographs were taken by the Xerograph Coping Process holder with a personalized bite registration record (Imprint Bite,3M ESPE AG, Germany) for extension cone (35 cm) paralleling technique. Every X-ray film was inserted into a slot in the bite-block. To ensure accurate repositioning of the film every time the radiograph was taken, the bite registration materialwas folded around the bite-block. Bite registration was obtained for each film in closed mouth position, the bite-block with the occlusal registration was kept aside for the follow-up recall visits. Repeatable standardized periapical radiographs were made for each implant to measure the mesial and distal bone heights. The measurements were made from the base of the implant to the most coronal point of bone adjacent to the implant surface.

All radiographs were exposed using ultra speed periapical film (Kodak, Paris, France) with X-ray grid and X- ray unit set at 70 KV and 10 mA. With similar exposure times, the radiographs were developed under standardized condition using automatic process. The scanning settings were adjusted and noted down in order to be used each time with all the radiographs before each scan, 2600 DPI (dot per inch) high quality resolution, 100% (1:1) scaling, fixed brightness and contrast setting, and no filter or other modifications were selected.The digital images were then saved in an uncompressed format on the patients' files. The stored images of each patient were then interpreted at the end of the follow-up period.

The marginal bone-level measurements were made from the reference point to the lowest observed point of contact of the marginal bone with the fixture. The reference point for the fixture was the fixture–abutment interface. The distance was measured to the nearest 0.01 mm. These measurements were done using an analysis software program (Adobe Photoshop, Adobe Systems Incorporated, San Jose, CA, USA). The actual implant length served as a standard to calculate the bone height, calculations were made according to the following formula:

CBL = IL*BR/MIL

Where CBL is the calculated bone resorption, IL: Actual implant length, BR: measured bone resorption (mean mesial and distal) and MIL: measured implant length.

Data analysis

Clinical and radiographic readings were tabulated for each individual and group. Differences in bone loss measurements were calculated. Summary statistics (mean, standard deviation) were calculated and also tabulated, data were statistically analyzed using repeated-measures ANOVA testat 0.05 significance level.Statistical analysis was performed by using SPSS program version 20 (SPSS 20; Inc. Chicago, USA).

Results

All thirty patients included in this study received two dental implants and immediately loaded with removable complete dentures after confirmation that implants gained primary stability. (i.e: Ostell readings were ≥ 65.

Plaque Index

Mean plaque index values at different periods of followup showed in Table (1) lists the results of the repeated-measures ANOVA analysis for plaque index over time.On initial examination after prosthesis insertion, mean ± standard deviation (SD) of plaque index scores of all patients was (1.192±0.27). During the follow-up period there was a statistical significant decrease of the plaque index (P< 0.001) where themean forplaque index score decreased from those recorded at the previous observation periods to a value of (0.587 ± 0.19) after 60 months of follow-up.

Table 1. Results of the repeated-measures ANOVA for plaque index.

	PI		RANOVA						
	Mean	SD	F	P-value	Time	Mean Difference	P-value	95% Confidence Interval for Differencea	
								Lower Bound	Upper Bound
T0	1.1925	0.2745							
T6	0.9525	0.2940			T0-T1	0.240	<0.001*	0.174	0.306
T12	0.8075	0.2238			T0-T2	0.358	<0.001*	0.326	0.444
T24	0.7275	0.1853	73.452	<0.001*	T0-T3	0.465	<0.001*	0.404	0.526
T36	0.6525	0.1909			T0-T4	0.540	<0.001*	0.465	0.615
T48	0.6221	0.1911			T0-T5	0.571	<0.001*	0.496	0.688
T60	0.5874	0.1936			T0-T6	0.605	<0.001*	0.535	0.712

PI: plaque index. SD: standard deviation. F: f-value. T0:At insertion. T6: after 6 months. T12: after 12 months. T24: After 24 months. T 36: After 36 months. T 48: After 48 months. T 60: After 60 months. (P > 0.05): Statistically significant.

Table 2. Results of the repeated-measures ANOVA for marginal bone level loss.

	MBL		RANOVA	
	Mean	SD	F	P-value
T0	0.663	0.173	1.775	0.364
T6	0.672	0.183		
T12	0.713	0.177		
T24	0.717	0.23		
T36	0.778	0.186		
T48	0.787	0.153		
T60	0.796	0.187		

MBL: Marginal bone level loss, (P > 0.05): Statistically Significant

Marginal bone loss

The marginal bone level measurement values at different periods of follow-up showed in Table (2) lists the results of the repeated-measures ANOVA analysis for difference in marginal bone levelloss over time. After prosthesis insertion, mean and standard deviation of marginal bone level measurement of all patients was (0.663± 0.173). During the follow up period there were no statistically significant differences of the marginal bone loss (P= 0.364). The mean marginal bone level reading trended higher over time compared to those recorded at the previous observation periods and was (0.796 ± 0.187) after 60 months of follow-up.

Discussion

Although an evidence-based systematic review has introduced information regarding patients with diabetes mellitus who showed an increasing trend of implant failure during the period of osseo integration and the first year of loading, [25] the current study provides supporting evidence to Ganeles et al; 18 that Type II diabetes may not be an absolute risk factor for immediate loading protocols and that dental implants are safe and predictable procedures for dental rehabilitation in diabetics surviving five years of service following immediate loading. [26]

In this study, a marked decrease in plaque accumulation and plaque indexwas observedover the first three years offollow-up and continues in a steady level till the fifth year, this may be due to routine oral hygienic recall visits and to patients' efforts performing an excellent regimen of oral hygiene. This coincides with resultsfrom previousstudies whichreported successfully osseointegrated implants in patients who followed regular oral hygiene instructions.[27] and that high performed oral hygiene regimen maintenance reduces peri-implantitis around immediately loaded dental implants placed in diabetic patients even when compared with non diabetic patients. [28, 29]

A slight increase ofmarginal bone lossaround the implants was observed during the follow-up periods. Although statistically insignificant, these changes match the results of previously published studies [22, 30] concluding that edentulous Type II diabetic patients can be treated with implant supported restorations with immediate loading safely and successfully providedthatdiabetic patients maintaingood glycemic control.

Although a recent published systematic review [31] has addressed a question:"Is diabetes mellitus a risk factor for implant survival?" and concluded that risk assessment for an implant patient should be based on former and current diseases. The current study results provide further support to Chrcanovic et al [22] conclusion that the difference between the insertion of dental implants in non-diabetic and diabetic patients did not statistically affect the implant failure rates.But in opposite to earlier published systematic review declared that there was statistically significant difference in bone loss favoring non-diabetic patients. [32] The amount of bone level changes in this study was within the criteria for implant success suggested by Albrektsson and coworkers.[33]

In this study, the use of flapless one-stage surgerywithout a second surgical phasemight be a reason of the success rate of the implants.The"minimally invasive" procedures preserve untouched periosteum and maximum amount of blood supply to the bone. On the other hand, reflection of flap in the second stage will interfere with the tissues vascularization and compromises part of blood supply coming from soft tissue to bone.[34]

The inherent limitations of this study include that all patients were type II controlled diabetic patients, mean age and small sample size. The last limitation may have affected the power to show a statistical significant change in crestal bone level around implants. Nevertheless, it is needed to evaluate the crestal bone loss around the immediately loaded implants supporting overdentures for longer time periods and different levels of glycemic control.

Conclusions

Within the limitations of this study, dental implants can be immediately loaded successfully to retain mandibular overdentures in controlled type II diabetic edentulous patients.

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