

MINIMALLY INVASIVE IMPLANT MANDIBULAR OVERDENTURE FOR TYPE-1 DIABETIC PATIENTS

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ABSTRACT

INTRODUCTION: Diabetes Mellitus (DM) is a systemic disease that affects large part of the population and is considered a relative contraindication to implant therapy. However, there are studies showing that the survival rate of implants in type-2 diabetic patients is approximately 90%, approaching that of non-diabetic patients. It is also shown that these results are strictly correlated with the importance of glycemic control to provide predictability of success rates and improve osseointegration of the implants inserted. There is no evidence whether controlled type-1 diabetes is or is not a risk factor for implant failure.

OBJECTIVES: The objective of this study was to clinically and radiographically evaluate the success of implant overdenture in controlled type-1 diabetic patients.

MATERIALS AND METHODS: Ten completely edentulous well controlled type-1 and ten non-diabetic patients were selected and divided into group I and II respectively. All patients received three implant assisted mandibular overdentures through minimally invasive flapless technique. Clinical evaluation of implant stability was performed using Osstell ISQ immediately after implant placement (base line), four months and one year after prosthesis insertion. Level of alveolar bone loss around each abutment was also evaluated using Cone Beam Computed Tomography (CBCT) at the time of final prosthesis insertion (base line), four months and one year after insertion.

RESULTS: Of the ten patients in the study group, two patients were lost yielding a success rate of 80 % in group I. Clinical results of implant stability test showed significant decrease in stability in the study group as compared to the control group, also radiographical results revealed significant increase in amount of average crestal bone loss in the diabetic patients.

CONCLUSIONS: Within the limitations of this study, and based on the clinical level, the implant overdenture may be recognized as being predictable treatment option for controlled type-1 diabetic patients.

KEYWORDS: Diabetes, Type 1, Implant overdenture, Minimally Invasive.

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INTRODUCTION

Zarb (1) described edentulous patients who lost their ability to function as 'denture cripples'. The restoration of missing teeth with endosseous implants for the rehabilitation of edentulous patients has turned to be a standard of care in the previous two decades (2). To achieve and maintain osseointegration, indications and contraindications must be carefully considered, and proper patient selection is thus a key issue in treatment planning (3). There is a lack of data regarding the influence of systemic diseases, especially DM, on dental implant integration and long-term success rate in humans (4, 5).

Diabetes mellitus affects the blood circulation and is associated with many complications. But the most obviously apparent complication is periodontal disease which, might lead to tooth loss and complete or partial edentulism in case of uncontrolled DM. Diabetic patients also were believed to be more prone to infection (6-8). In addition, healing after surgery appears to be more slowly which might expose the tissues to complications such as tissue necrosis (9). Unfortunately, diabetes has always been considered as a relative contraindication to dental implants (10-12).

However, as regimens for managing diabetes have elaborated, evidence has accumulated that diabetic patients who effectively control their disease are subjected to a lower risk of several health complications than their uncontrolled cohorts (13). A systematic review conducted on survival rate of dental implant in diabetic patients concluded that survival rate of dental implants in well controlled patients is similar to non-diabetics, so this disease, if properly controlled, is not a contraindication (14).

However, evidence is unclear on whether there is a difference in implant success between well controlled type-1 and type-2 diabetics (15). Moraschini et al (16) conducted a systematic review to analyze the differences in failure rate and marginal bone loss between type-1 and type-2 diabetes subjects. However, only one article investigating type-1 diabetes subjects and implants was identified (17).

After reviewing the subgroups of the two types of diabetes, there was no statistically significant difference in implant failure. The low number of published studies in relation to type-1 diabetes when compared to type-2 diabetes could be the result of the greater prevalence of the latter (>90% of cases) (18). The implant failure rate in diabetic versus non-

diabetic subjects showed no statistically significant difference for type-1 or type-2 diabetic subjects (16).

The American Society for Anesthesiology suggested that patients on oral agents for diabetes are suitable candidates for dental implants, whereas patients on insulin are not (19). However, another study suggested that diabetic patients who are well controlled with insulin are suitable for implant surgery under antibiotic cover (20). Furthermore, Valero et al (21) claimed that in both type-1 and type-2 diabetes, the therapeutic goal focuses on maintaining blood-glucose at normal or near-normal levels.

There are no studies that exclusively reported the survival/success of implant in type-1 diabetes. Thus, it is important to stress that as type-1 and type-2 diabetes could have different responses to implant therapy, depending on their level of control, evaluating these two conditions together adds an uncontrolled variable (22). Hence, it is important to study the two types of DM separately (23).

Factors influencing successful implant therapy for patients with diabetes remain in question, several factors have been studied related to the success or failure of dental implants, including, the implant design (length, shape or surface texture), medical risk factors related to the patient (systemic diseases or habits like smoking) and factors related to surgery (experience of the surgeon or surgical planning) (24, 25). However little or no researches have focused on the type of implant restoration and its effect on implant survival in diabetic patients especially type-1 DM. Thus, further researches are needed to evaluate the effect of controlled type-1 diabetes on implant overdenture success. So the aim of this study was to compare and evaluate clinically and radiographically the success of implant assisted mandibular complete overdenture in type-1 controlled diabetic compared to non-diabetic patients.

MATERIALS AND METHODS

Informed consent

All patients in this study received thorough explanations about the planned treatment and its potential risks and complications, and signed a written informed consent form prior to being enrolled in the study. It was also mentioned that the patient had the right of withdrawal from the study anytime without any consequences. Ethical approval for this study was obtained from the research ethics committee, Faculty of Dentistry, Alexandria University before beginning the study.

Patient Selection Criteria:

A total of twenty completely edentulous male patients with comparable age were selected in this study. Patients were equally divided into two groups, diabetic study group and the control group. Patients in the diabetic group were diagnosed by type-1 DM and had been taking insulin for at least 10 years. All patients had adequate zone of keratinized mucosa, sufficient inter-ridge space greater than 12 mm and anterior mandibular alveolar ridge height and width not less than 15 mm and 8 mm, respectively as detected by CBCT. All patients were free of any metabolic, systemic or endocrine diseases other than DM. Patients who showed para-functional habits and heavy smokers were excluded from this study, as well as patients who were unwilling to accept implant overdenture as a treatment modality.

Prior to any treatment approach, a sheet record was registered for each patient including, personal data, duration of the disease, type of treatment and prescribed dose.

Laboratory investigations for diabetic group showed a good level of glycemic control (fasting blood sugar: 70-130 mg/dl; postprandial blood sugar: < 180 mg/dl; HbA1c: ≤ 7 %).

All patients were prescribed Amoxicillin clavulanate 1gm (Augmentin, MUP, ARE) one hour before the procedure and were instructed to continue this medication twice daily for 8 days. In addition, the use of 0.12% chlorhexidine mouthwash (Hexitol, ADCO, ARE) was instructed one day before the surgery and was continued for 2 weeks. Ibuprofen 400 mg (Brufen, Kahira Pharm. & Chem. Ind. Co., Egypt) was also prescribed to all patients 1 day before the surgery and to be continued for 8 days. Diabetic Patients were instructed to take half their daily dose of insulin the morning of the treatment; then, after the intervention, the whole insulin dose should be taken.

Complete maxillary and mandibular dentures were fabricated for every patient according to the standardized conventional technique to be used as radiographic template. Radiopaque glass beads were incorporated into the mandibular denture to select optimal implant sites. Radiographic scanning using CBCT (J. Morita, Veraview R100, Japan) was done for each patient to aid in fabrication of CAD/CAM based surgical template following a dual scan procedure.

Surgical procedure for the three interforaminal implants (Dentium NR Line, Dentium Co.Ltd, Korea) was performed under local anesthesia with a flapless approach after fixation of the surgical template onto the bone by the aid of pre-planned fixation screws following the recommendations of the manufacturer (figure 1).



Figure 1: showing fixation of the surgical template by the aid of pre-planned fixation screws.

The mini ball abutments (Ball abutment, Dentium Co.Ltd, Korea) were screwed on the implant and tightened to 30 N-cm with a torque wrench (according to manufacture instructions), to avoid second stage surgery. The height of the mini ball abutment was chosen according to the thickness of the trans-mucosal portion (figure 2).



Figure 2: showing mini ball abutments screwed on the implant to avoid second stage surgery.

All patients were instructed to complete the prescribed medication including; antibiotics as a prophylaxis for any anticipated infection, analgesic and anti-inflammatory to control post-operative pain and anti-oedematous to prevent any postoperative swelling.

The patient was left for two weeks without the denture as a healing period before loading. The old mandibular denture of the patient was then relieved and refitted using silicon soft liner material (Promedica Dental Material GmbH, German). A new denture was then constructed for each patient after four months period from the date of surgery. The mandibular denture base fit was checked to the attachments using an indelible pencil to confirm seating of the denture while in maximum intercuspation, and then occlusal adjustments were performed using articulating paper.

The housings were then placed on the attachments and the areas over the housings were relieved with an acrylic bur until the denture was fully seated passively in the patient's mouth without contacting the housings while again in maximum intercuspation.

Block out spacers were placed on the abutments to block out any undercuts around the abutments that may interfere with the pick-up process. Small holes were then prepared at the lingual side to allow escaping of excess acrylic resin and to avoid creation of undue pressure, which may affect the denture settling during the direct pick-up process.

On the denture, the housing sites were filled with a mix of auto-polymerized acrylic resin "pick-up material" using plastic filling instrument and it was inserted inside the patient's mouth using an inter-occlusal bite registration silicone index that was previously fabricated to ensure maximum intercuspation (figure 3).



Figure 3: showing direct pickup process of the housings.

The denture was then removed and verified that the positions of the attachments were correct. The block-out spacers were removed and the excess resin was carefully

trimmed away. The denture was then seated inside the mouth and the final occlusal adjustments were performed. The patient was finally instructed about the care of the denture and the oral hygiene procedures (figure 4).

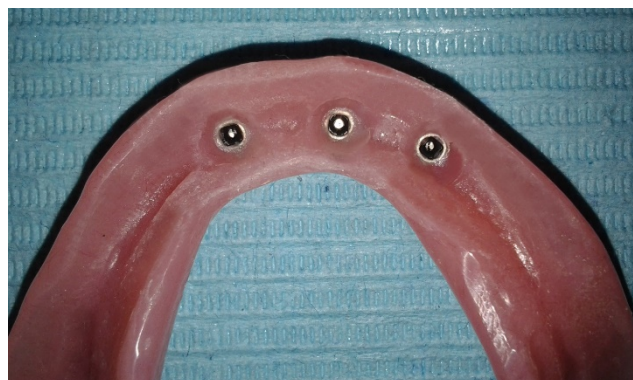


Figure 4: showing housings embedded in the tissue surface of the denture.

Screening tests and radiographic evaluations for the patients were scheduled at the time of final prosthesis insertion (base line), four months and one year after insertion.

The radiographic evaluations were conducted for assessment of the crestal bone changes around each implant from the four aspects; mesial, distal, buccal and lingual using the linear measurement system available on the OnDemand3D software (Cybermed International, Seoul, Korea) supplied by CBCT.

Implant stability was assessed using resonance frequency analysis measured with the Osstell device instrument (Integration Diagnostics Ltd., Goteborgsvagen, Sweden) at the time of fixtures installation (base line), four months later and one year after prosthesis insertion.

Statistical analysis

Data were fed to the computer and analyzed using IBM SPSS software package version 20.0. Quantitative data were described using Range (minimum and maximum), mean and standard deviation. Data analysis was performed with ANOVA with repeated measures, Post Hoc test (LSD) and Student t-test. Significance of the obtained results was judged at the 5% level. A p-value of less than 0.05 was considered statistically significant.

RESULTS

During follow up, two diabetic patients from the study group were lost yielding a success rate of 80% for group I. Failure in one of these 2 patients was related directly to poor glycemic control. While the other patient lost to follow up and thus implants in this patient were considered as failed implants.

Radiographic Evaluation:

Radiographic evaluation of implants showed statistically significant increase in average bone loss in group I from baseline to four months, from four months to one year and from baseline to one year ($p=0.006^*$, $p=0.001^*$, $p=0.003^*$ respectively) as compared to the control group through the three different periods of follow up (Table 1).

Table (1): Comparison between the two studied groups regarding Average bone loss at different periods of follow up

Average Bone loss	Base line - 4 months	Base line - 1 year	4months-1year	F, p	P1	P2	P3
Group I "n=8"							
Range	0.36-1.07	1.37-1.94	0.8-1.1	5.26 0.018*	0.023*	0.207	0.048*
Mean	0.94	1.94	1.00				
S.D.	0.14	0.24	0.106				
Group II "n=10"							
Range	0.01-0.63	0.29-1.01	0.13-0.42	3.98 0.048*	0.042*	0.386	0.045*
Mean	0.43	0.72	0.31				
S.D.	0.046	0.06	0.03				
P4	0.006*	0.003*	0.001*				

F: F test (ANOVA) with repeated measures
 Sig. bet. periods was done using Post Hoc Test (LSD) for ANOVA with repeated measures
 P1: P value for comparing between baseline-4m and baseline-1yr
 P2: P value for comparing between baseline-4m and 4m-1yr
 P3: P value for comparing between baseline-1yr and 4m-1 yr
 P4 comparison between group I and II at the same time (T-test)
 *: Statistically significant at p ≤ 0.05

Clinical Evaluation:

Implant stability was evaluated by Osstell ISQ and results showed that there was insignificant decrease in stability from baseline to one year for group I (p=0.29), while stability increased significantly from baseline and through all follow up times for group II (p= 0.003*). There was a statistically significant difference in favor of diabetic patients regarding implant stability between the two groups after 4 months (p=0.045*) and after 1 year from prosthesis insertion (p=0.001*). However, implant stability levels at baseline were insignificantly different when both groups were compared (p=0.203) (Table 2).

Table (2): Comparison between the two studied groups regarding implant stability at different periods of follow up

	Baseline	4 months	1 year	F, p	P1	P2	P3
Group I "n=8"							
Range	60.0-85.0	59.0-82.0	57.0-70.0	2.01 0.29	0.42	0.322	0.284
Mean	73.6	71.0	68.1				
S.D.	7.2	6.1	6.02				
Group II "n=10"							
Range	62.0-80.0	65.0-82.0	70.0-85.0	8.11 0.003*	0.036*	0.022*	0.016*
Mean	70.4	75.1	79.0				
S.D.	4.2	3.9	4.1				
P4	0.203	0.045*	0.001*				

F: F test (ANOVA)
 P: P value for ANOVA test
 Sig. bet. periods was done using Post Hoc Test (LSD) for ANOVA
 P1: P value for comparing between base line and 4months
 P2: P value for comparing between base line and 1 year
 P3: P value for comparing between 4 months and 1 year
 P4: P value for comparing between group I and II at the same time (was done by t-test)
 *: Statistically significant at p ≤ 0.05

DISCUSSION

Type-1 DM is an auto-immune disease characterized by destruction of the beta cells in the pancreas that produce insulin, all type-1 diabetic patients require insulin therapy to maintain normglycemia and prevent or delay complications. The incidence of type 1-diabetes is on the rise at a rate of 3–5% per year that is doubling every 20 years (26).

The greatest long-term danger of diabetes, irrespective of the etiology, lies in the potential for complications. The complications of the disease are insidious, and difficult to reverse; hence, there is great urgency to identify specific means to prevent or reduce these complications (26).

In a review conducted by Marchand et al (27), conditions for implant success in diabetic patients were attributed to the stabilization of glycaemic control (HbA1c around 7%), as well as preventive measures against infection yielding implant survival rates between 85% and 95%.

This was best assessed by measuring the glycosylated hemoglobin (HbAc1); levels less than 7% for HbAc1 measured 6-8 weeks previous to the surgery was considered a good level of glycemic control (21).

Since hyperglycemia may result from stress, diabetic patients were instructed to take half of their daily dose of insulin before the surgery as a stress dose to prevent hyperglycemia. Furthermore, it has been observed that insulin not only reduces the deleterious effects of hyperglycemia by controlling it but also stimulates osteoblastic activity (28).

Owing to the fact that type-1 DM is considered a risk factor with regard to suffering infection, when performing invasive dental procedures such as implant surgery, the usual guidelines for the antibiotic prophylaxis should be followed (29).

The antibiotic of choice was Amoxicillin clavulanate (1gm), as the pathogens most frequently causing post-operative complications following the placement of implants are Streptococci, Gram-positive anaerobes and Gram-negative anaerobes (29).

In addition to antibiotic usage, chlorhexidine mouthwash is a well proven antibacterial rinse that has proved to lessen the infectious complications and failure rates of implant in diabetic patients when administrated pre-operatively (30).

The use of fewer and less invasive surgical procedures such as flapless surgical technique for implant placement are beneficial due to a shorter healing period, decreased patient discomfort that is represented by minimal swelling and pain, maintaining the soft tissue architecture, and leaving the periosteum intact on buccal and lingual aspect of the ridge which, in turn, maintains a better blood supply and thus reduces the likelihood of bone resorption (31).

These fine characters of flapless surgery make it especially advocated in diabetic patients, in which it is necessary to induce the minimum possible damage to the patient and reduce the operation time (32).

In this study, the flapless surgery was performed with the aid of CAD/CAM based surgical guides fabricated by dual CT-scanning technique, permitting better visualization of soft tissue thickness and uses a calibration procedure which has the benefit of more precise implant installation with more accurate implant axis (33).

However, some limitations still exist in the application of this new technology such as the large amount of attached gingiva needed, and the considerable experience that are required to evaluate if part of the implant surface is out of the bone and if the planned implant position matches perfectly the clinical situation (33).

The implant system used in this study was Dentium NR Line fixtures with body diameter 3.1 mm. The narrow implant diameter was used to ensure sufficient bone thickness and blood supply around the implant for more predictable survival. The mini-ball abutment was chosen to

decrease torque on implants. It was screwed on the implant on the surgery day to avoid second stage surgery and thus reduce possible post-operative complications in diabetic patients.

The use of three implants is thought to create an angular relationship. The most anteriorly placed implant prevents antero-posterior rotation of the denture in sagittal plane by providing indirect retention for an overdenture supported by three implants (34).

Implant success largely depends on the implant location in the jaws and should be even more so in diabetic patients. The best location for implants, gaining the greatest success rate, is the symphysis area of the mandible (17).

Radiographic analysis showed that there was a statistical significant increase ($p=0.018^*$) in average bone loss in the diabetic group when compared to the control group. This finding may be explained by researches that found that type-1 diabetes produces a reduction in bone mineral density through mechanisms that have been attributed to both a lower formation of bone and also to a greater bone resorption (18).

Moreover, the results were in agreement with Albrektsson et al (35) who reported an average marginal bone loss of function of more than 0-2 mm in year one, and thus concluded that type-1 diabetics failed to meet standard international criteria for implant success. In addition, Mathiassen et al (36) reported long-term bone loss more severe in type-1 than in type-2 diabetic patients.

Results of measuring implant stability in this study showed that implant stability quotient values in group I were insignificantly decreased ($p=0.29$) from baseline and up to 1 year follow up period, however, still within the range reported for successfully integrated implants (57–82) according to Kokovic et al (37). Unlike group II in which stability quotient values showed a significant increase from baseline and through all follow up periods (Table 3).

Table (3): Comparison between the two studied groups regarding percent of change in implant stability at different periods of follow up

	Base line - 4 months	Base line - 1 year	4months- 1year	F, p	P1	P2	P3
Group I "n=8"							
Range	-1.7 -- -5.9	-5.0- -17.6	-3.4 -- -12.5	2.11	0.102	0.432	0.12
Mean	-3.5	-7.5	-4.1	0.089			
S.D.	-1.53	-1.64	-1.3				
Group II "n=10"							
Range	4.8-9.5	6.3-15.5	3.7-7.7	4.65	0.036*	0.048*	0.001*
Mean	6.7	12.2	5.2	0.016*			
S.D.	17	2.4	1.5				
P4	0.011*	0.001*	0.001*				

F: F test (ANOVA) with repeated measures

Sig. bet. periods was done using Post Hoc Test (LSD) for ANOVA with repeated measures

P1: P value for comparing between baseline-4m and baseline-1yr

P2: P value for comparing between baseline-4m and 4m-1yr

P3: P value for comparing between baseline-1yr and 4m-1 yr

P4 comparison between group I and II at the same time (T-test)

Several investigations (38, 39) have shown that the ISQ value of a stable osseointegrated implant increases with time, suggesting an increase in the bone-implant contact area. On the other hand, crestal bone loss around implants

has been correlated with loss of implant stability (40), which explains the decrease in stability values of group I.

CONCLUSION

Within the limitations of this study regarding the sample size and short study periods; and based on clinical levels it is possible to conclude that the implant assisted overdenture may be recognized as being predictable and successful treatment option for controlled type-1 diabetic patients considering strict glycemic control measures, following a minimally invasive surgical protocol such as the flapless surgical technique and avoiding immediate implant loading.

CONFLICT OF INTEREST

The authors declare that they have no conflicts of interest.

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