VOL. 64, 1763:1772, APRIL, 2018

I.S.S.N 0070-9484



Fixed Prosthodontics, Dental materials, Conservative Dentistry and Endodontics

www.eda-egypt.org • Codex : 219/1804

EVALUATION OF SINGLE IMPLANT ASSISTED MANDIBULAR OVERDENTURE IN DIABETIC PATIENTS

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ABSTRACT

EGYPTIAN

DENTAL JOURNAL

Purpose: To evaluate single implant assisted mandibular overdenture in controlled type II diabetic patients after two years of function.

Materials and Methods: Thirty, completely edentulous patients with a mean age of fifty years old were included in this study. For each patient single implant (**3.5*13mm Anyone Two- piece dental implant, Mega Gen Implant System, Korea**) was placed at the anterior midline region with equator attachment to retain mandibular overdenture. Each patient was evaluated clinically concerning plaque index, probing depth and implant stability by using resonance frequency analysis and radiographically concerning marginal bone loss at baseline (overdenture insertion) and after 6, 12, 24 months after insertion. Data were collected and statistically analyzed using repeated measures ANOVA test.

Results: The cumulative implant success rate at two years was 100%. There were no statistical significant differences along the time intervals ($P \ge 0.05$) regarding probing depth, implant stability and marginal bone loss.

Conclusions: Within the limitations of this study, single midline dental implant can be used successfully to assist mandibular overdenture in controlled type II diabetic edentulous patients.

KEYWORDS: Single implant, Implant overdenture, Type II diabetes.

INTRODUCTION

Tooth loss is one of the major handicaps in elderly patients, compromising their chewing efficiency and thus the nutritional status¹. Rehabilitation using complete dentures on edentulous patients who suffer from a compromised alveolar bone often results in denture soreness, poor retention and instability, unclear pronunciation, and low chewing efficiency^{2,3}.

Compared to the conventional complete denture, two or more implant-assisted mandibular overdentures can promote function and enhance success rates⁴⁻⁶. Although there are no reliable evidences on the ideal number of implants

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for retention of a mandibular overdenture⁷, the York consensus statement recommends at least two implants to support a mandibular overdenture(opposing complete maxillary dentures) for edentulous patients. However, economic constraints especially among the emerging elderly population in developing countries – make this treatment strategy financially challenging^{8,9}.

In order to reduce the cost and treatment time, the concept of single implant-retained overdenture provides another option for elderly populations. The concept of a single median implant in an edentulous mandible was introduced by Cordioli in 1993 and the first 5-year results were published in 1997 with implant success rates of 100% ^{10,11}.

An in vitro model study demonstrated that the single implant-supported overdenture increased retention and stability as compared with the conventional complete overdenture; furthermore, the biomechanical effects and patient satisfaction were comparable to those observed in a mandibular two-implant retained overdenture¹².

Most studies reported a 100% post-loading survival and there is no difference in the single implant survival compared to the 2-implant overdenture, when delayed loading was used¹³⁻¹⁵. A low number of early failures were observed for immediately or early loaded implants^{14,16}.

Diabetes mellitus has long been considered a relative contraindication for implant procedures¹⁷. Well-controlled diabetic patients can be considered appropriate for implant therapy, while those lacking good glycemic control may be denied the benefits of implant therapy¹⁸. However; the potential benefits of implant therapy may be important for diabetic patients provided that their plasma glucose level is under metabolic control¹⁹.

Patients in good general health conditions are best candidates for implant therapy, however since single implant-assisted overdenture is a simplified and less invasive approach, it is a more feasible option for older and/or debilitated patients who have health restrictions or systemic conditions that increase the risk of extensive implant surgical procedures. If any systemic condition or disease is present, like diabetes or hypertension, it must be controlled and properly managed as part of the treatment planning and during the surgical interventions^{20,21}.

Although single implant-assisted overdentures are a promising alternative for compromised edentulous controlled diabetic patients, the limited research dedicated to this treatment concept has restricted its acceptance and implementation. The aim of this study was to evaluate single implant assisted mandibular overdenture in controlled type II diabetic patients after two years of function.

MATERIALS AND METHODS

This study was carried out on thirty completely edentulous, Type II diabetic patients with a mean age of 50 years old. Patient's general health was evaluated by taking full medical history. Laboratory investigations included the Glycosylated Hemoglobin Test (HbA1c Test) to ensure that all selected patients were controlled with levels ranging from 6.5% up to $7.0\%^{22}$ and free from any other systemic diseases that might have an effect on implants osseointegration.

Patients whose HbA1c level was above 7%, alcoholic, drug abuse, poor oral hygiene were excluded from this study.

Cone Beam CT was taken for all patients to show the height and width of bone as well as the bone density in the mandibular anterior midline area, and to check for any clinically undetectable pathology or bone abnormality. An informed consent approved by the ethics committee was signed by each patient after discussing the treatment plan with them and prior to initiation of treatment. An acrylic complete denture was fabricated for each patient with the conventional technique using semi-anatomic acrylic teeth set on semi-adjustable articulator. Mandibular acrylic dentures were duplicated using clear autopolymerized acrylic resin to produce surgical templates to aid in implant insertion in the anterior midline area. For each patient single implant (3.5*13mm Anyone Twopiece dental implant, Mega Gen Implant System, Korea) was placed at the anterior midline region using flapless technique.

Patients were allowed to use the new complete dentures for about 3months to ensure proper adaptation. After about 3months; assessing the implant osseointegration by means of periapical film and intro-oral examination, patients were recalled, attaching abutments with implant fixtures after minimal surgical exposure of implant fixtures and each mandibular denture was relieved at the implant location, the plastic cap was placed on the implant abutment making sure that the denture was securely seated, the head of implant was then covered with a small shim to prevent excess acrylic resin from engaging any undercuts. The relieved area of the fitting surface of the mandibular denture was filled with autopolymerized acrylic resin, dentures were seated and patients were instructed to bite gently during setting of the acrylic resin. After the resin set, the dentures were removed, the plastic cap inside the mandibular denture was examined, and any excess resin was trimmed and inserted in the patient's mouth. Patients were then instructed on how to clean the denture and were asked to return on the following day to examine the denture bearing area and check for signs of tissue irritation (Fig, 1& 2).

Patients were evaluated clinically and radiographically at baseline (overdenture insertion) and at 6, 12 and 24 months after overdenture insertion as follows:



Fig. (1): Anterior midline single implant inserted in the mandibular edentulous arch.



Fig. (2): A radiograph of the anterior midline single implant inserted in the mandibular edentulous arch.

Plaque index:

Plaque adherent to implant 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 Lang²³:

- 0 = No plaque is visible
- 1 = A film of plaque adhering to the free gingival margin and adjacent area of the implant, seen

only after application of disclosing solution or by running the explorer across the implant surfaces.

- 2 = Moderate accumulation of soft deposits within the gingival pocket and on the gingival margin and/or adjacent to implant surface that can be seen by the naked eye.
- 3 = Abundance of soft matter within the gingival pocket and/or the gingival margin and adjacent implant surface.

The PI score was obtained by taking the average of the four plaque scores for the single implant.

1. Probing depth²⁴:

The probing depth was measured using a plastic periodontal probe (CPITN, R.O.R. international, Copenhagen, Denmark) around the implant surfaces in four areas (mid-buccal, mid-lingual, mid-mesial and mid-distal). The score was obtained by taking the average of the four scores for the single implant. Measurements of probing depth ≤ 1 mm was recorded as 1mm, measurements exceeding 1mm, but less than 2 mm was recorded as 2 mm, and so on.

- 2. Stability test by using OSSTELL ISQ (Implant stability quitent) (Osstell Mentor Göteborg, Sweden) ²⁵:
- Smart peg was inserted inside the fixture and firmly screwed into it.
- The probe of Osstell was directed toward the smart peg without touching it (3mm away from it) in two directions bucco- lingual and mesio-distal.
- The average of two readings was calculated .
- Values less than 50 ISQ have a higher risk of failure. An increase in ISQ value during longterm examination implies that the implant became more stable ²⁶. Reports indicate that ISQ values are proportional to the extent of bone formation ²⁷.

• Reading above 50 ISQ indicate stable implants.

3. Periapical radiographs²⁸:

Periapical X-ray films were used to measure the marginal bone loss around the implants. The long cone paralleling technique using the Rinn XCP instrument (Rinn Co. Dentsply division, York, PA, USA) was used. It included the use of standardized periapical radiographs to detect changes in alveolar bone surrounding implant during the follow-up period. The standardized periapical radiographs were taken by the Xerograph Coping Process holder with a personalized bite registration record, made from putty rubber base impression material 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 putty rubber base impression material (Express XT VPS, 3M ESPE AG, Germany) was folded around the bite-block, then a bite registration was obtained for X-ray film in closed mouth position, the putty bite-block with the occlusal registration was kept aside for the followup recall visits. Repeatable standardized periapical radiographs were made for implant to measure the mesial and distal bone heights. The measurements were made from the implant platform 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 images were displayed on a 17 inches View sonic (3) colored monitor ($1024 \times 768 \text{ DPI}$). The digital image was then saved in an uncompressed format on the patient file. The stored images of each patient were then interpreted at the end of the follow-up period.

The marginal bone loss 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:

All clinical and radiographic data were tabulated for each patient. Summary statistics (mean, standard deviation) were calculated and also tabulated; data were statistically analyzed using repeated-measures ANOVA test at 0.05 significance level.

RESULTS

Thirty patients were enrolled in this investigation. During the observation period, no implants were lost nor did fractures occur.

Plaque Index:

Figure (3) depicts the mean plaque index values at different periods of follow up and Table (1) lists the results of the repeated-measures ANOVA analysis for plaque index over time. On the initial examination after prosthesis insertion, mean±standard deviation of plaque index scores of all patients was (1.44±0.25). During the follow-up period there was a statistical significant decrease of the plaque index (P < 0.001) where the mean for plaque index score decreased from those recorded at the previous observation periods to a value of (0.66 ± 0.18) after 24 months of follow-up.

Probing depth:

Figure (4) shows the mean probing depth values at different periods of follow-up and Table (2) lists the results of the repeated-measures ANOVA analysis for probing depth over time.

TABLE (1): Results of the repeated-measures ANOVA for plaque index at different follow up periods.

	PI			RANOVA					
	Mean	SD	F	P-value	Time	Mean	D volue	95% Confidence Interval for Difference ^a	
то	1.44	0.25			Time	Difference	P-value	Lower Bound	Upper Bound
T6	1.10	0.27	94.731	<0.001*	T0-T6	0.34	<0.001*	0.189	0.453
T12	0.86	0.27			T0-T12	0.58	<0.001*	0.357	0.533
T24	0.66	0.18			T0-T24	0.78	<0.001*	0.436	0.644

*Significance: P < 0.05

T0: At insertion. T6: after 6 months. T12: after 12 months. T24: After 24 months.



Fig. (3): Mean values of the plaque index at different periods of follow up.

After prosthesis insertion, mean±standard deviation for probing depth measurements of all patients was (1.00 ± 0.00) . During the follow up period, there were no statistically significant differences of the probing depth (P = 0.178). The mean of probing depth measurements trended higher over time compared to those recorded at the previous observation periods and was 1.26 ± 0.19 (mean±SD) at the end of the 24-month follow-up.

TABLE (2): Results of the repeated-measures ANOVA for probing depth at different follow up periods.

	Р	Ď			
	Mean	SD	F	P-value	
T0	1.00	0.00		0.178	
T6	1.08	0.11	1 657		
T12	1.17	0.16	1.037		
T24	1.26	0.19			

*Significance: P < 0.05

T0: At insertion. T6: after 6 months. T12: after 12 months. T24: After 24 months.

Stability Test (Osstell ISQ):

Figure (5) shows the mean of the stability test



Fig. (4): Mean values of the probing depth at different periods of follow up.

scores (Osstell ISQ) at different periods of followup and Table (3) lists the results of the repeatedmeasures ANOVA analysis for the stability test scores (Osstell ISQ) over time. After prosthesis insertion, mean±standard deviation for the stability test scores (Osstell ISQ) of all patients was (70.73 \pm 2.78). During the follow up period, there were no statistically significant differences of the stability test scores (Osstell ISQ) (*P* = 0.166). The mean of the stability test scores (Osstell ISQ) increased by time compared to those recorded at the previous observation periods and was 73.63 \pm 2.74 (mean \pm SD) at the end of the 24-month follow-up.

TABLE (3): Results of the repeated-measures ANOVA for implant stability at different follow up periods.

	IS	Q	RANOVA		
	Mean	SD	F	P-value	
T0	70.73	2.78		0.177	
T6	71.83	3.0	1 724		
T12	72.0	2.75	1./34	0.166	
T24	73.63	2.74			



T0: At insertion. T6: after 6 months. T12: after 12 months. T24: After 24 months.



Fig. (5): Mean values of the stability test scores (Osstell ISQ) at different periods of follow up.



Figure (6) shows the mean of the marginal bone loss measurement values at different periods of follow-up and Table (4) lists the results of the repeated-measures ANOVA analysis for marginal bone loss over time. After prosthesis insertion, mean and standard deviation of marginal bone loss measurement of all patients was (0.77± 0.24). During the follow up period there were no statistically significant differences of the marginal bone loss (P = 0.308). The mean marginal bone loss reading trended higher over time compared to those recorded at the previous observation periods and was 1.25 ± 0.42 (mean ± SD) after 24 months of follow-up.

TABLE (4): Results of the repeated-measures ANOVA for marginal bone loss at different follow up periods.

	Marginal	Bone Loss	RANOVA		
	Mean	SD	F	P-value	
T0	0.77	0.24			
Т6	0.93	0.30	1 674	0.200	
T12	1.08	0.39	1.074	0.308	
T24	1.25	0.42			

*Significance: P < 0.05

T0: At insertion. T6: after 6 months. T12: after 12 months. T24: After 24 months.



Fig. (6): Mean values of the marginal bone loss at different periods of follow up.

DISCUSSION

It has been widely accepted that two implants assisted mandibular overdentures should be recommended for edentulous patients, although single implant assisted overdentures also show practical and clinical potential.

Implants were placed in the anterior area of mandible. This region is the preferred site for single implant assisted overdenture for the following reasons: thicker cortical bone, lowered surgery risk by avoiding the inferior alveolar nerve and blood vessels, and, finally, a larger tissue-supporting area to prevent overloading on implant. Although there was some concern regarding the potential risk of mandibular fracture because of the anatomical structure²⁹, there was little difference found between the risk anticipated in overdentures assisted by one implant and those assisted by two implants³⁰.

A 3D finite element analysis done by Liu et al. in 2013 showed that single implant assisted mandibular overdenture does not show any damaging strain concentration in the bone around an implant because when vertical load is applied on the implant overdenture, it rotated side to side but under same loading conditions. Two-implant assisted mandibular overdenture showed more apparent rotations around the fulcrum line passing through the two implants and the maximum equivalent stress in the abutments was higher in the other models³¹.

In this study, a significant decrease in plaque index was observed over two years of follow-up and may be attributed to routine hygienic recall visits and to the patients' efforts in maintaining a high level of oral hygiene. This matches the results from previous studies which reported successfully osseointegrated implants in patients who followed regular oral hygiene instructions^{32,33}. This may explain the results form Ferreira et al³⁴ where implants in diabetic patients with good glycemic control were found not to be associated with an increased risk of peri-implantitis when compared with non diabetic subjects.

It was also observed a slight trend of increasing probing depth around the implants during the followup periods, although it did not reach statistical significance. These findings could be attributed to bone resorption during the first year after implant placement; the increases were within acceptable values and are in agreement with previously reported results of a probing depth increase after one year follow-up period and explanation that this phenomenon of up to 1 mm marginal bone loss is related to maturation of bone after implant placement and adaptation of bone to withstand functional forces³⁵. The results this study are also in agreement with the work from Turkyilmaz³⁶ who reported no pathological probing depth changes in patients with well-controlled Type II diabetic patients through one year follow-up period, and no evidence of diminished clinical success or significant complication related to implant treatment was found for this patient population.

Slight increasing of marginal bone loss around the implants was observed during the follow-up periods. Although statistically insignificant, these changes match the results of multiple clinical trials concluding that single median implant can retain a mandibular over denture well for up to 5 years without the implant failing, when delayed loading was used¹³⁻¹⁵. These results provide further support to Chrcanovic et al³⁷ conclusion that the difference between the insertion of dental implants in non-diabetic and diabetic patients did not statistically affect the implant failure rates, provided that they present with moderate HbA1c values indicative of good glycemic control. The amount of bone level changes in this study was within the criteria for implant success suggested by Albrektsson and coworkers³⁸.

In this study, the use of flapless implant surgery might be a reason of the success rate of the implants. The flapless implant surgery "minimally invasive" preserves maximum amount of blood supply to the bone resulting in decreasing the amount of the marginal bone loss around the implants³⁹.

Implant stability is a critical factor that determines the long-term success of dental implants⁴⁰. In this study, all the Osstell ISQ values are more than 70 and this indicates successful Osseointegration⁴¹. An ISQ range of 70–74 could, therefore, represent a state of stability for implants in the midline of the mandible assisted mandibular single-implant overdentures. This matches the results from previous studies which reported improved stability for implants in the midline of the mandible⁴²⁻⁴⁵.

Due to the limitations of this study, the authors suggest that the small sample size may have affected the power to show a statistical significant change in probing depth, marginal bone loss and implant stability. Also longer evaluation period may be needed to asses success of single anterior median implant assisted over denture in type II diabetic patients.

CONCLUSION

Within the limitations of this study concerning evaluation period and sample size, single anterior median implant can assist a mandibular over denture well for up to two years without the implant failing, when delayed loading was used in controlled type II diabetic edentulous patients.

Conflict of interest:

The Authors declare that they have no conflict of interest, have full control of all primary data.

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