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Comparison of clinical and radiographic status around immediately-loaded versus conventional loaded implants placed in patients with type 2 diabetes: 12 and 24-month follow-up results

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Abstract

Background: There are no studies that have compared the clinical and radiographic status around immediately-loaded (IL) and conventional loaded (CL) implants placed in patients with type 2 diabetes mellitus (T2DM).

Objective: The aim was to compare the clinical and radiographic status around IL and CL implants placed in T2DM patients.

Methods: One hundred and eight diabetic patients (55 with IL implants [Group-1] and 53 with CL implants [Group-2]) were included in this cross-sectional study. All implants were placed in healed sites in the maxillary and mandibular premolar and molar regions and supported single restorations. All patients underwent full mouth mechanical debridement biannually. Hemoglobin A1c (HbA1c) levels, clinical (bleeding on probing [BOP] and probing depth [PD]≥4mm) and radiographic (crestal bone loss [CBL]) peri-implant parameters were measured for both groups at 12 and 24-month follow-up. Group comparisons were performed using the Mann-Whitney *U*-Test ($P<0.05$).

Results: The mean age and duration of T2DM in groups 1 and 2 were 50.6±2.2 and 51.8±1.7 years, and 9.2±2.4 and 8.5±0.4 years, respectively. At 12 and 24-month follow-up, the mean HbA1c levels in groups 1 and 2 were 5.4% (4.8-5.5%) and 5.1% (4.7-5.4%) and 5.1% (4.7%-

5.2%) and 4.9% (4.5%-5.2%), respectively. At 12 and 24-month follow-up, there was no statistically significant difference in peri-implant BOP, PD and CBL in both groups.

Conclusion: It was concluded that clinical and radiographic status is comparable around IL and CL implants placed in patients with T2DM. The contribution of careful case selection, oral hygiene maintenance and glycemic control is emphasized.

Key words: Dental implant; Peri-implant parameters; Crestal bone loss; Immediate loading; Conventional loading, Type 2 Diabetes Mellitus

Background

The high predictability of dental implants in the rehabilitation of oral esthetics and function is well-documented. With advancements in clinical implant dentistry, clinicians have progressively commenced to evaluate the possibilities of decreasing treatment time by early placement of the implant-supported restoration. According to Corradini et al (1), immediate loading of implants is a reliable treatment approach for oral rehabilitation. Romanos and Nentwig (2) evaluated the clinical success of immediately-loaded (IL) implants versus delayed-loaded (DL) implants placed in the posterior mandible of healthy individuals. After a mean follow-up of approximately 24 months, the mean scores of plaque index, gingival index and probing depth (PD) were comparable among IL and DL implants. The authors concluded that immediately and delayed loaded implants in healthy individuals had the same prognosis after 24 months (2). A number of randomized controlled trials (RCTs) on healthy subjects have assessed implant failure rates under immediate loading compared with delayed loading (3-8). These studies have reported no statistically significant difference in implant failure rate between IL versus DL implants (2.87% versus 1.8%, respectively) (3-7). However,

contradictory results have also been reported. In a retrospective cohort study, Susarla et al (9) assessed the 12-month survival for DL versus IL implants. The study sample comprised of 677 individuals who had 2,349 DL dental implants and 178 patients who had 477 IL implants. The results showed that IL implants were 2.7 times more likely to fail at 1 year compared with DL implants (9). However, this conclusion was in disregard of the systemic health of the participants.

Chronic hyperglycemia (such as among patients with type 2 diabetes mellitus [T2DM]) is a significant risk factor for peri-implant soft tissue inflammation (10-12). Moreover, crestal bone loss (CBL) around dental implants placed in patients with T2DM has also been shown to be significantly higher compared with non-diabetic individuals (11). However, although there is a higher risk of failure in diabetic patients, experimental studies have shown that the optimization of glycemic control improves the degree of implants osseointegration (13).

Currently, there are no studies that have compared the clinical (peri-implant bleeding on probing [BOP] and probing depth [PD] $\geq$ 4mm) and radiographic (crestal bone loss [CBL]) status around IL and conventional loaded (CL) implants placed in patients with T2DM. In the present study, it was hypothesized that under optimal glycemic control and oral hygiene measures, peri-implant BOP, PD$\geq$ 4mm and CBL are comparable among IL and CL implants placed in patients with T2DM. Therefore, the aim of the present study was to compare the clinical and radiographic status around IL and CL implants placed in patients with T2DM at 12 and 24-month follow-up.

Methods

Study design and participants

A retrospective chart review of patients who were eligible for single implant restoration in the maxillary and mandibular premolar and molar regions was developed for data extraction. The inclusion criteria were as follows: (a) patients with T2DM; (b) patients with IL or CL implants and (c) signing of consent form. Tobacco smokers and chewers, individuals with self-reported diseases other than T2DM (such as type 1 DM and AIDS), patients undergoing cancer therapy, patients having undergone bone augmentation (guided bone regeneration), pregnant and/or lactating females, patients with history of bruxism and/or periodontal disease and patients who reported to have used antibiotics, non-steroidal anti-inflammatory drugs and/or corticosteroids within the past 3 months were excluded.

Surgical protocol and implant-related characteristics

All implants were placed under local anesthesia using surgical guides. Full-thickness mucoperiosteal flaps were raised and bone-level platform-switched implants (Straumann AG, Basel, Switzerland) with diameters and lengths ranging between 3.3 mm and 4.1 mm and 10 mm to 14 mm, respectively were placed. In groups 1 and 2, implants were placed using insertion torques ranging between 30 Ncm and 35 Ncm. Each patient was prescribed amoxicillin (2 g orally one hour before surgery, followed by two additional 500-mg doses that day and then 500 mg 3 times a day for 5 days). Patients with amoxicillin sensitivity were prescribed clindamycin (600 mg 1 hour before surgery, followed by 150 mg four times a day for 5 days). Pain was controlled by analgesics (600 mg ibuprofen one every 8 h for as long as required). Oral hygiene instructions were given and the patients were also recommended to

rinse with an essential-oil based mouthwash (Listerine Zero, Johnson & Johnson Middle East FZ – LLC) twice daily for 2 weeks, 24 hours after surgery. Until 2 years of follow-up, individuals in groups 1 and 2 had been enrolled in a bi-annual dental prophylaxis program in which they received mechanical plaque and calculus removal from all teeth and/or implant surfaces using an ultrasonic scaler (VV DENTA, Guangxi, China).

Immediate loading protocol

The immediate loading was performed two days after implant placement (Group 1) with screw-retained nonoccluding provisional crowns that were replaced with the permanent crowns six weeks later. Temporary abutments (RC Temporary Abutment, Straumann AG, Basel, Switzerland) were attached to the implants using a torque controller (manual torque wrench, Straumann AG, Basel, Switzerland) with a force of 25 Ncm to hold the acrylic crowns. The prefabricated temporary crowns designed with narrow occlusal table were relined with a Bis-acrylic composite (Protemp II; 3M ESPE, Seefeld, Germany). The interproximal contacts were designed as broader contact areas to distribute the forces of mastication and provide support. As a precautionary measure, patients were instructed to avoid hard diet and to wear a nightguard during the first 6 weeks for mandibular implants and 8 weeks for maxillary implants (2). One week after surgery, the patients were recalled to check complications and to reassess occlusion.

Conventional loading protocol and prosthesis-related characteristics

The conventional loading was performed 3.1±0.2 months after implant placement in Group 2. Master models (GC Fujirock EP die stone, GC Europe, Belgium) were obtained from fixture-level impression using transfer impression copings and polyvinyl siloxane (PVS) material (Virtual; Ivoclar Vivadent AG, Schaan Liechtenstein) with the open-tray technique. Jaw relationships were recorded by means of a wax or silicon medium in maximum intercuspation. The stone casts were mounted in a semi-adjustable articulator. For standardization purposes, all implants were restored with screw-retained metal ceramic (MC) crowns with full ceramic coverage to preclude the detrimental effect of extruded excess cement. Customized metal abutments (SynOcta cast gold abutment; Straumann AG, Basel, Switzerland) were cast-on using a precious gold-palladium (Au 49.60%, Pd 29.00 %, Ag 17.5%) alloy (Degubond 4; DeguDent GmbH, Germany). All MC crowns were fabricated by the same dental laboratory following the standard procedures. Then, crowns were torqued in (35 Ncm) according to the manufacturer's recommendation before the abutment screw access channel was filled with polytetrafluoroethylene (PTFE) seal tape (Kanca Makine, Istanbul, Turkey) and light-cured composite resin (Filtek P-60, 3M, St. Paul, MN, USA). The crown occlusion was designed to harmonize with patient's existing physiologic occlusion. Additionally, light centric contacts on the implants were obtained in maximum intercuspation to minimize occlusal forces on the implant and to maximize force distribution to the adjacent natural teeth. Moreover, complete disocclusion was ensured during eccentric movements. Oral hygiene instructions and the follow-up protocol were discussed. All patients in both groups were enrolled in a biannual recall program.

Clinical and radiographic evaluations

Radiographs were taken at the time of implant placement, after loading, and at 12 and 24-month follow-up. All clinical and radiographic assessments were performed by a single trained and calibrated clinician who was blinded to the study groups (*kappa* was 0.91). In both groups, peri-implant BOP and PD ≥ 4mm were measured at 6 sites per implant (mesiobuccal, midbuccal, distobuccal, mesiolingual, midlingual and distolingual) using a plastic periodontal probe (Plast-o-Probe, Dentsply Maillefer). Peri-implant suppuration was also noted. Digital intraoral radiographs (Belmont ACURAY 071A Intra Oral X-Ray System, Hudson, FL, USA) were taken and viewed on a computer screen at 20x magnification using computer software (CorelDraw 11.0, Corel Corporation, Ottawa, Canada). The radiographic paralleling technique was standardized by using a film holder as a guiding device for X-ray beams (Dentsply Rinn, PA, USA). In each group, the mean mesial and distal CBL were recorded in millimeters on digital radiographs using a software program (Scion Image, Scion Corp., Fredrick, Maryland, USA). The software was calibrated before each measurement using the predefined implant length. Mesial and distal CBL was measured on all implants in both groups as the distance from the widest supracrestal part of the implant to the alveolar crest. Together with the clinical and radiographic evaluations, HbA1c levels were measured for all participants at 12 and 24-month follow-up using an HbA1c analyzer kit (Quo-Test, EKF Diagnostics, Magdeburg, Germany). An implant was considered successful if it is satisfactorily functioning with no mobility, sign of radiolucency and/or fracture at the time for loading or at follow-up.

Survival/Success criteria

Survival was defined as presence of the implant and its suprastructure in situ in its original extension at follow-up examination with or without complications. Success was defined as presence of the implant and its suprastructure in situ without any mechanical or technical complications during the entire follow-up period. Success criteria were lack of mobility; absence of peri-implant radiolucency, recurrent peri-implant infection or suppuration, continuous or recurrent pain or tenderness, or structural failure of the implant and/or restoration; and/or > 0.2 mm bone resorption annually after the implant′s first year of service (14).

Statistical analysis

Statistical analysis was performed using software program (SPSS Version 18, Chicago, IL., USA). In groups 1 and 2, BOP, PD≥4mm and CBL were assessed using the Mann Whitney U-test at 12 and 24-month follow-up. P-values less than 0.05 were considered statistically significant.

Results

General characteristics of the study population

A total of 115 male type-2 diabetics (57 with IL and 58 with CL implants) were invited to participate in this investigation. One hundred and eight individuals (Group-1: 55 IL implants and Group-2: 53 CL implants) volunteered to participate. All included implants were with moderately rough surface and platform switching design that were placed in healed sockets at the level of bone crest. There were no dropouts reported during the 24-month

follow-up period. The mean age of patients in groups 1 and 2 was 50.6±2.2 and 51.8±1.7 years, respectively. In groups 1 and 2, the mean duration of T2DM was 9.2±2.4 and 8.5±0.4 years, respectively. At 12 and 24-month follow-up, the mean HbA1c levels among patients in groups 1 and 2 were 5.4% (4.8-5.5%) and 5.1% (4.7-5.4%) and 5.1% (4.7%-5.2%) and 4.9% (4.5%-5.2%), respectively (Table 1). All patients were taking oral hypoglycemic mediations and following dietary control regimens for the management of T2DM. All patients were enrolled in a biannual oral hygiene maintenance program.

Clinical and radiographic parameters

The mean scores of BOP and PD≥4mm in both groups are presented in Table 1. At 12 and 24 months of follow-up, there was no statistically significant difference in peri-implant BOP and PD≥4mm between the two groups.

At the 12-month follow-up, the total CBL in groups 1 and 2 was 0.55 and 0.56 mm, respectively. At the 24-month follow-up, the total CBL in groups 1 and 2 was 0.58 and 0.64 mm, respectively. At 12 and 24-month follow-up, there was no statistically significant difference in the mean mesial, distal and total CBL around implants in both groups (Fig. 1 and 2). The overall implant and crown survival and success rates were 100% in both groups without any serious biologic or mechanical complications (Fig. 3).

Discussion

The aim of the present study was based on the hypothesis that under optimal glycemic control and oral hygiene measures, peri-implant BOP, PD≥ 4mm and CBL are comparable among IL and CL implants placed in patients with T2DM. This hypothesis was confirmed according to the results of the present study. These findings are in line with those reported by Aguilar-Salvatierra et al. (10), which showed that IL implants can safely be placed in diabetic patients provided that blood glycemic levels are under control; however, their study lacks a control group where only immediately-loaded implants were placed merely in the anterior maxilla. Although the present study failed to find differences in clinical and radiographic parameters between IL and CL implants in Type-2 diabetic patients over the 2-year follow-up, emphasis should focus on appropriate case selection (10).

In general, there are many interacting factors that would affect the success of immediately loaded implants such as bone quality and quantity, clinician skill and experience, implant design, implant primary stability, macro- and micromovements and occlusion (15). In the present study, a variety of local and systemic factors may have influenced the presented results. All implants used in the present study were platform-switched (PS). Implant placed according to the PS concept have been reported to undergo significantly less CBL and peri-implant soft tissue inflammation as compared to implants with matching abutment and implant-body diameters (non-PS implants) (16, 17). It may also be proposed that the implant insertion torque used in the present investigation (30 Ncm to 35 Ncm), may also have contributed towards the primary stability of the peri-implant crestal bone levels. Studies (18, 19) have reported that implant insertion torque values of <50 Ncm do not jeopardize the peri-implant crestal bone levels. It is therefore probable that in the

present study, use of PS implants and implant insertion torques of <50 Ncm may have contributed towards the stability of peri-implant crestal bone. However, contradictory results have also been reported (20). In the study by Bidgoli et al. (20), insertion torques values of up to 70 Ncm did not significantly increase CBL around implants. Moreover, occlusal forces were minimized by narrowing the bucco-lingual width of the occlusal table and by maintaining minimum centric contacts and complete disocclusion in eccentric movements.

It is imperative to note that these patients reported in the current investigation had screw-retained implant-supported single restorations, which may perform differently from multiunit or cement-retained prostheses (21). Both favorable (3-5) and unfavorable (6, 9) clinical outcomes have been reported in healthy individuals with immediately-loaded multiunit prostheses or implant-retained overdentures. In addition, dental implants have demonstrated different performance in association with location in the arch due to variations in the quality and quantity of bone, history of trauma to the region, proximity of important structures, need for bone grafting and other supplemental surgical procedures, degree of arterial blood supply, and rate of tissue healing (22). In a recent study by Ozgur et al. (23), it was shown that CBL is higher around implants placed in the posterior maxillary region compared to the mandible. Although, implants included in the present investigation were placed in the posterior maxilla or mandible, no significant differences in tested parameters were demonstrated in both groups. This finding supports a radiographic study by Nandal et al. (24), which showed that CBL was comparable in both maxilla and mandible on both mesial and distal aspects of implants.

Chronic hyperglycemia is a significant risk factor for oral soft tissue inflammation and bone loss around implants (10). Because of the microvascular complications deriving from hyperglycemia, vascularization of the tissue is compromised, healing is delayed and

wounds are more predisposed to infection (13). However, under optimal glycemic control, dental implants can osseointegrate and remain functionally stable for prolonged durations in patients with diabetes mellitus. It is notable that in the present study, patients in groups 1 and 2 had well-controlled T2DM at 12 and 24-month follow-up. All patients included in the present study reported to have been maintaining their glycemic levels via hypoglycemic medications and dietary control. This may have contributed towards a reduced inflammatory stress in the peri-implant tissues, which in turn may have contributed to the stability of crestal bone around IL and CL implants.

In the present study, all participants were undergoing bi-annual mechanical plaque and calculus debridement. Non-surgical periodontal therapy (NSPT) has been reported to play a significant role in minimizing oral soft tissue inflammation and reducing serum glycemic levels among diabetic patients (25). It is therefore likely that oral hygiene maintenance would have contributed towards maintaining a healthy peri-implant soft tissue and minimizing CBL. Moreover, the bi-annual NSPT may also have contributed (in addition to the use of anti-hyperglycemic medications and dietary control) towards the prevention of the development of a chronic hyperglycemic state in the investigated patient population. Both the oral hygiene maintenance and glycemic control may have contributed to 100% success and survival rates of the implants in both groups. This conclusion was previously reported by Degidi et al. (26) who stated that as long as the oral hygiene status is satisfactory, dental implants can exhibit a 100% survival rate.

The criteria to define success in implant dentistry are under constant debate. The loss of 2 mm of bone around the implant neck during the first year after functional loading followed by not more than 0.2 mm per year has long been assumed a successful outcome (14). Due to advancements in surgical techniques, implant design and surface topographic modifications, peri-implant CBL has been progressively decreasing (27). Therefore, recent

studies have questioned the widely accepted success criteria of up to 2 mm CBL at 1 year followed by a maximum of 0.2 mm annually (14,28). It appears that the consideration of CBL rates rather than raw CBL data may improve the ability of clinicians to predict peri-implant disease. Galindo-Moreno et al (14) showed that bone loss rates at 18 months were strongly associated with the initial bone loss rate. If the CBL is higher than the cutoff value of 0.44 mm at 6 months post-loading, CBL progression tends to be significantly higher, with an increased risk of implant failure (14). Although 6-month measurements of CBL were not sought in the present investigation, the present results were in line with this recommendation and other recently published data of micro-roughened implants (14,27,29,30). New success criteria that correspond to the currently accepted values of CBL around micro-roughened surface implants should be developed based on CBL rates during time intervals rather than on the peri-implant CBL value after a given period of time (14).

Potential limitations of the present study are that all included patients were non-smokers with well-controlled T2DM which does not reflect the clinical reality. It is expected that peri-implant soft tissue inflammation is worse and CBL is significantly higher around IL and CL implants placed in smokers with poorly-controlled T2DM. Another limitation would be the well-controlled glycemic level of included diabetic patients, a state that is rarely found in real practice. This condition may be as a result of the high socioeconomic status of included patients as the clinics are located in the high-class commercial district. In addition, the medical service and medications are offered free to the public by the government. Furthermore, all participants in the present study were males, which may have been a source of bias. There is a possibility that hormonal changes in females (particularly in the postmenopausal phase) may influence the oral soft and hard tissue status around IL and CL implants as compared to males. Finally, radiographic assessment of CBL was limited to mesial and distal bone as measurements were based on 2-dimentional radiographs. Therefore,

other areas such as labial/buccal and palatal/lingual surfaces that might have exhibited CBL to an extent could not be assessed. Further studies using cone beam computed tomography (CBCT) may help assess CBL around IL and CL implants in different planes. Different findings could have been demonstrated clinically and radiographically if the follow-up was for a longer duration. However, this timeframe is sufficient to understand the role of immediate loading, in comparison to conventional or delayed loading, on the early clinical performance of dental implants in Type-2 diabetic patients. Further long-term randomized controlled clinical trials are needed to confirm these hypotheses.

Conclusion

Within the limitations of this study, it can be concluded that the clinical and radiographic status was comparable around IL and CL implants placed in patients with T2DM up to 24 months of follow-up. During the follow-up period, both IL and CL implants had similarly acceptable clinical and radiographic outcomes with regard to soft tissue condition, crestal bone levels, and implant and prosthetic success rate in patients with T2DM. Although it seems that differences in implant outcomes do not merely depend on the time of loading, the contribution of careful case selection, oral hygiene maintenance and glycemic control cannot be overlooked.

Conflict of interest and financial disclosure

The authors have stated explicitly that there are no conflicts of interest in connection with this article and that there was no external source of funding for the present study.

Ethical approval

The research protocol was reviewed and approved by the Research Ethics Review committee of the College of Applied Medical Sciences, King Saud University, Riyadh, Saudi Arabia. All participants were requested to sign a consent form. All participants reserved the right to retire from the present study at any stage of the investigation.

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Tables

Table 1. Clinical and radiographic parameters around immediately-loaded (Group-1) and conventional loaded (Group-2) dental implants at 12 and 24 months of follow-up

	Parameters	**Group-1 (n=55)**		**Group-2 (n=53)**	
		Maxilla	Mandible	Maxilla	Mandible
12-month follow-up	HbA1c (%)	5.4% (4.8-5.5%)		5.1% (4.7-5.4%)	
	BOP (%)	12.5±2.5	16.6±3.7	13.4±0.3	16.5±2.2
	PD≥4mm (%)	3±0.1	3.6±0.2	3.3±0.1	4.1±0.2
24-month follow-up	HbA1c (%)	5.1% (4.7%-5.2%)		4.9% (4.5%-5.2%)	
	BOP (%)	10.5±0.5	10.1±0.2	10.2±0.3	9.1±0.2
	PD≥4mm (%)	2±0.1	2.4±0.2	1.8±0.1	2.1±0.2

Legends

Table 1. Clinical and radiographic parameters around immediately-loaded (Group-1) and conventional loaded (Group-2) dental implants at 12 and 24 months of follow-up

Fig. 1. Crestal bone loss (CBL) in groups 1 and 2 at 12- and 24-month follow up. Blue bars represent the mesial CBL; green bars represent the distal CBL and gray bars represent the total CBL.

Fig. 2. Digital radiographs of implant and crown at different follow-up timepoints; Baseline (left), 12 months (Middle), and 24 months (Right).

Fig. 3. Clinical photographs of implant restoration: 12-month buccal view (top), 24-month buccal view (bottom), 24-month occlusal view (Right).