Immediate implant-prosthetic dental rehabilitation of patients with diabetes using four immediately loaded dental implants: a pilot study

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Abstract

Objectives: Type 2 diabetes mellitus (T2DM) involves endocrine changes that cause a persistent increase in blood glucose. Many disorders are associated with T2DM, including disorders that affect the oral cavity. Oral cavity disorders interfere with a patient's capacity to follow a correct diet, which results in worsening systemic disease. Oral rehabilitation is necessary for patients with T2DM. Therefore, this prospective study was performed to evaluate the immediate dental rehabilitation capacity of patients with T2DM using four immediately loaded dental implants.

Methods: In this prospective study, four implants each were placed in four patients with T2DM and loaded within 24 hours. Demographic characteristics were assessed at baseline; systemic and oral health parameters were assessed at baseline and at 6 months after implant placement.

Results: The mean glycated hemoglobin (HbA1c) level was 7.05% (range, 6.8%–7.3%). The mean Implant Stability Quotient of the dental implants was 74.5 (range, 67–85). Postoperative evolution was favorable: only one implant exhibited inflammation of the prosthetic stump.

Conclusions: Immediate prosthetic rehabilitation using four maxillary dental implants was an effective treatment modality for patients with T2DM in this study. Larger studies are needed to confirm these findings.
Keywords
Immediate implant, diabetes, all-on-four, glycated hemoglobin, maxilla, tooth loss, Implant Stability Quotient, osseointegration

Introduction
Type 2 diabetes mellitus (T2DM) involves complex endocrine changes characterized by a persistent increase in blood glucose due to insufficient insulin activity.\(^1\)\(^2\) T2DM is associated with a wide range of systemic complications such as retinopathy, nephropathy, neuropathy, and cardiovascular pathology.\(^3\)\(^-\)\(^5\) Notably, T2DM complications can occur in the oral cavity.\(^3\) The association between T2DM and periodontal disease has been extensively described; notably, some authors have reported a strong association between these disorders even in the prediabetes stage.\(^6\) A number of studies have shown positive associations between T2DM and various dental diseases, such as dental caries and periodontal disease,\(^3\)\(^-\)\(^7\) which may result in tooth loss.

Currently, tooth loss is optimally treated by dental implants; this oral rehabilitation method is safe and predictable, with a success rate of 89.7% after 10 years.\(^8\)\(^,\)\(^9\) The treatment of patients with T2DM using dental implants was previously controversial because of tissue changes related to hyperglycemia.\(^9\) Dental implants are currently considered a safe and predictable treatment for patients with diabetes, with a success rate similar to that of non-diabetic patients;\(^9\) however, some authors have reported differences involving short implants.\(^10\)

Frequently, there is minimal bone reserve available for dental implant placement. The all-on-four approach was created to address this limitation; it allows immediate functionalization and avoids the use of regenerative procedures that may complicate treatment.\(^11\) Based on this concept, two implants are placed axially in the anterior region, while two are placed laterally at an angle to support up to 12 teeth.\(^11\)\(^,\)\(^12\) Studies analyzing the distribution of forces have shown that the placement of implants at angles of 30° to 40° allows better distribution of occlusal forces, compared with vertical implants; notably, teeth in the supporting area are subjected to higher masticatory forces.\(^13\) This approach is stable for long-term treatment and exhibits wide clinical applicability.\(^11\)\(^-\)\(^14\)

To the best of our knowledge, there have been few studies regarding the use of the all-on-four approach for treatment of patients with metabolic disorders, despite the wide use of dental implants in patients with T2DM;\(^8\)\(^,\)\(^9\) however, these patients have higher risks of oral complications.\(^15\) The aim of this study was to prospectively evaluate the immediate dental rehabilitation capacity of patients with T2DM using four immediately loaded dental implants, in accordance with the all-on-four approach.

Materials and methods
Patient selection and study design
For this study, patients with T2DM were initially evaluated if they voluntarily presented for evaluation of oral health status. Patients who desired oral rehabilitation using the Fast and Fixed system provided
by Bredent Medical were then recruited. Criteria for inclusion in the study were as follows: adult age, comorbid T2DM, no other diseases potentially affecting bone metabolism, total maxillary tooth loss (including loss due to dental foci treatment), written informed consent for inclusion in the study, sufficient bone reserve for dental implant placement, and sufficient primary stability of dental implants for immediate loading. The study protocol was approved by the Ethics Committee of the University of Oradea Faculty of Medicine and Pharmacy (approval no: 4/20.04.2018).

The variables monitored in this study were: demographic characteristics (i.e., age and sex); T2DM characteristics (i.e., glycated hemoglobin [HbA1c] level, T2DM duration, treatment used, and diabetes compensation or control); other systemic disorders; dental implant variables (i.e., size, peri-implant bone resorption at 6 months, complications, additional treatments, primary stability, stability at 6 months, and location relative to post-extraction alveoli); and provisional prosthetic system variables (i.e., stability and complications). Peri-implant bone resorption was assessed on panoramic radiographs, using measurements mesial and distal to the implants. T2DM was considered to be compensated (i.e., controlled) at HbA1c levels ≤7%. The monitored variables were centralized using Microsoft Excel and were analyzed descriptively statistically.

Preoperative imaging evaluation and preparation for the laboratory

All patients included in the study underwent preoperative imaging assessment using cone-beam computed tomography. Thus, the bone reserve (Figure 1), residual teeth status, and dental implant positions were evaluated. Subsequently, for each patient, the four implants were placed in the maxilla: two posterior implants (12 mm long and 3.5 or 4 mm in diameter) were placed at an angle of 35°, while two anterior implants (10 mm long and 3.5 or 4 mm in diameter) were placed vertically (Figure 2). The diameter of each dental implant was chosen depending on the available bone volume. A preoperative impression of the maxillary arch and the antagonist teeth was made to establish the vertical occlusal dimension (i.e., position of teeth in the arch). The color for provisional reconstruction was also established.

Figure 1. Evaluation of bone reserve for dental implant placement.

Figure 2. Placement of dental implants on the three-dimensional reconstruction.
preoperatively. Postoperatively, non-steroidal anti-inflammatory treatment was initiated for up to 5 days.

**Operative protocol**

Under locoregional anesthesia achieved by infiltration with 4% articaine and 1:100,000 epinephrine, an incision of the maxillary alveolar margin was made from a distal point to the alveoli of the maxillary second premolars. For patients who required dental treatments, tooth extractions were performed and pathological periodontal tissue was curetted. Subsequently, two mucoperiosteal flaps, one palatal and one vestibular, were detached over a maximum length of 5 mm from the crestal incision. Four dental implants were placed in each patient, based on the imaging evaluation plan. The implants were placed bilaterally at the locations of maxillary second premolars and lateral incisors. Prosthetic stumps were applied bilaterally to the implants at angles of 35° posteriorly and 0° anteriorly. All dental implants were placed with a peak insertion torque of 50 N/m. Subsequently, the primary stability of each dental implant was analyzed by Resonance Frequency Analysis with the Implant Stability Quotient (ISQ), which uses a scale ranging from 1 to 99. Stability measurements were performed using the Bredent PenguinRFA; implants with an ISQ $\geq 65$ were considered satisfactory for immediate prosthesis placement. The mucoperiosteal flaps were reapplied and suturing was performed with non-resorbable sutures at separate points. Subsequently, closed tray impressions were made and sent to the dental laboratory, where a fixed provisional prosthesis was constructed. For up to 24 hours, healing caps were placed over the prosthetic stumps. Provisional rehabilitation with dental implant support was achieved by using provisional screw-retained acrylic restorations. Following insertion of the provisional prosthesis at 24 hours after dental implant placement, a control X-ray image was taken (Figure 3).

**Postoperative monitoring**

Patients were asked to return at 6 months after dental implant placement for the final prosthetic restoration. During this 6-month follow-up interval, patients also returned for suture removal at 7 days postoperatively, as well as when needed. Prior to definitive prosthetic treatment, a control X-ray image was taken (Figure 4).

**Results**

**Patient characteristics**

For this study, 128 patients with T2DM were initially evaluated; nine patients were
then recruited. Five patients did not meet local or dental implant stability criteria for inclusion in the study. The remaining four patients were enrolled in the study; two were men and two were women (age range, 52–60 years). All included patients exhibited moderate control of T2DM, with respect to the duration of disease. In total, 16 maxillary dental implants were placed (four per patient); nine were placed in post-extraction alveoli or immediately adjacent to these, while seven were placed in areas where teeth had been missing for >12 months.

**T2DM characteristics**

Analysis of T2DM characteristics revealed a mean HbA1c level of 7.05% (range, 6.8% to 7.3%). The mean interval from the diagnosis of systemic disease to the implementation of the treatment plan was 30.5 months (range, 19–45 months). Three patients received oral diabetes medication (metformin 1 g every 12 hours) and one patient also received insulin treatment (25 IU daily). Two patients had HbA1c levels <7%, which indicated that the systemic disease was controlled. In our study, we set as reference an HbA1c level similar to the 7% threshold established by Resnick et al.,16 with adjustment for the duration of T2DM, being utopic to have the same treatment target for a patient that has T2DM for 1 year and for one that has is for 10 years.

**Implant characteristics**

The mean primary ISQ of the implants was 74.5 (range, 67–85). The mean extent of bone resorption around dental implants placed in areas where teeth had been missing for >12 months was 0.67 mm (range, 0–1.5 mm); the mean extent of bone resorption around dental implants placed in post-extraction alveoli or immediately adjacent to them was 1.36 mm (range, 0–2.6 mm) (Figure 5). The mean ISQ of dental implants at 6 months after placement was 82.31 (range, 78–92) (Figure 6).

**Complications during follow-up**

The following complications occurred during the 6-month follow-up period. Three patients exhibited partial provisional tooth fracture, two patients exhibited provisional restoration fracture, and one patient exhibited prosthetic stump inflammation. Defects of the provisional prosthetic system were rehabilitated by replacement of the fractured teeth, while fractured prosthetic restorations were reconstructed and metal palatal supports were introduced. Inflammation that developed around the prosthetic stump during the monitoring period was drained; this was followed by gingivectomy at 1 week after drainage.

![Figure 4. Control X-ray taken at 6 months after dental implant placement.](image-url)
The HbA1c level in the patient with prosthetic stump inflammation was <7% at baseline and remained at this level throughout the monitoring period.

**Discussion**

This study showed that immediate implant-prosthetic rehabilitation supported on four implants is feasible in patients with T2DM. Exclusion of the five patients who were initially recruited was not based on their systemic pathology; instead, it was due to absence of the bone reserve necessary for this type of restoration or due to cystic lesions in the bone that prevented adequate primary stability of the dental implants. The mean primary ISQ of the implants placed in this study was 74.5, similar to that reported previously for non-diabetic patients. Primary stability is unlikely to be influenced by the presence of T2DM;
presumably, stability is more strongly influenced by implant position in the arch, as well as the type of bone present at this level. However, inadequate peri-implant bone healing has been observed in patients with decompensated (uncontrolled) T2DM who exhibited poor hygiene. The degree of control of T2DM in our patients did not influence the primary stability of the dental implants or their postoperative evolution. Nevertheless, HbA1c levels in our patients were relatively low, including in patients who exhibited decompensated T2DM; this may have influenced our findings.

Postoperative evolution was marked by few peri-implant or prosthetic stump complications. One implant was associated with inflammation in a prosthetic stump of a patient with relatively well-controlled T2DM (HbA1c level <7%). In contrast, a higher peri-implant inflammation rate has been observed with increasing HbA1c levels; notably, poor hygiene was also reported in patients with high HbA1c levels. Hence, it remains unclear whether poor hygiene or HbA1c level leads to the increased rate of peri-implant inflammation. The relatively small number of implants assessed in this study does not provide a comprehensive assessment; however, inflammation was probably caused by poor hygiene in the affected patient in our study. Notably, following removal of the inflamed gingiva and small adjustments of the prosthetic system to facilitate better hygiene, the inflammation was resolved and healing was optimal. The stability of dental implants was better at 6 months after placement than at baseline; the implants in this study demonstrated good osseointegration in patients with T2DM. These findings are consistent with those of prior studies in which patients with T2DM were compared with patients without associated pathology. Published data suggest that peri-implant hygiene and glycemic control are necessary for favorable postoperative evolution.

The immediate placement of dental implants into infected sockets remains controversial. Some studies have shown no statistically significant difference in the risk of failure between dental implants placed immediately into infected sockets and dental implants placed into non-infected sites; conversely, other studies have shown a three-fold increase in the risk of failure following immediate dental implant placement into an infected socket, compared with placement in an uninfected socket. In our study, all immediately inserted dental implants exhibited osseointegration. This high success rate is potentially because dental implants were inserted in areas with minimal inflammation (related to marginal periodontium) and not in sockets with periapical infections. The extracted teeth had either extended coronal and radicular destruction or had no prosthetic utility.

A major advantage of immediate fixed prosthetic restoration is the superior masticatory efficiency for patients with fixed prosthetic restorations, compared with patients who have extensive tooth loss or removable prosthetic restorations. For patients with T2DM who were included in this study, the alternative to immediate prosthetic restoration was removable prosthetic restoration. This approach would have had a great impact on the quality of life of these patients, as well as on the hygienic-dietary regimen required for management of T2DM. Masticatory efficiency and adequate dental status are reportedly necessary for patients with T2DM to follow a diet that enables them to control their systemic disease. Good masticatory efficiency in patients who underwent oral rehabilitation with four immediately loaded dental implants was demonstrated by the relatively frequent fracture of the provisional prosthetic
restorations. Notably, the antagonist arch in each patient was represented by natural teeth or by removable prosthetic restorations supported on natural teeth. The relatively frequent fracture of the provisional prosthetic system is an important shortcoming of this type of oral rehabilitation. Similar results have been reported previously, which indicates that the mechanical complications of the provisional prosthetic system can affect more than half of patients in whom this system is used.12,27 Urgent repair of provisional prosthetic restorations is necessary to avoid potential lesions of implants or adjacent tissues; such repair requires the patient to have easy and rapid access to the services of the treating doctor, which may not be feasible for some patients.

Conclusion
Immediate prosthetic rehabilitation using four maxillary dental implants may be an effective treatment modality for patients with T2DM. However, larger studies are needed to confirm our findings.

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Declaration of conflicting interest
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