Diabetes mellitus (DM) is a metabolic disorder with chronic complications, including cardiovascular disease, stroke, kidney failure, peripheral vascular disease, and diabetic retinopathy.\textsuperscript{1,2} The prevalence of DM is increasing, as 90% of patients have non-insulin-dependent DM or DM type 2 (DMT2).\textsuperscript{3}

One of the main diagnostic tools of DM is a high hemoglobin A1C (HbA1c) value. HbA1c < 5.7% is defined as normal, and patients with values 5.7% < HbA1c < 6.5% are defined as having prediabetes. HbA1c value ≥ 6.5% is defined as DM.\textsuperscript{4}

The American Diabetes Association recommends that most patients maintain HbA1c levels < 7% to avoid glycemic risk. A stricter goal of HbA1c < 6.5% is advocated in cases where it could be achieved without significant risk of hypoglycemia or other adverse effects.\textsuperscript{4}

A common complication associated with DM, especially DMT2, is advanced periodontal disease. The prevalence of periodontal disease is much higher, with earlier onset in these patients compared with the general population.\textsuperscript{5,6} Several studies have concluded that alveolar bone loss and progression of bone loss are much higher in patients with DMT2. The severity of

Marginal Bone Loss of Dental Implants in Patients with Type 2 Diabetes Mellitus with Poorly Controlled HbA1c Values: A Long-Term Retrospective Study

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**Purpose:** The objective of this study was to report implant survival rates, marginal bone loss, and the impact of prosthesis type among patients with type 2 diabetes mellitus (DMT2), with high hemoglobin A1C (HbA1c) values. **Materials and Methods:** This retrospective study utilized patient medical records from an oral surgeon’s office. Patients who had moderately or poorly controlled DMT2 with HbA1c values up to 10% were reviewed. Inclusion criteria were partially or fully edentulous patients diagnosed with DMT2 who were subsequently treated with implant-supported prosthetic restorations. Patients were at least 18 years of age. Exclusion criteria were patients who did not present for annual follow-up visits, patient records with incomplete surgical or restorative data, or nondiagnostic radiographs. All the fixed restorations were cement-retained, and the removable restorations were supported by two to six implants. Marginal bone loss and the consequences of prosthetic type were assessed from the last available radiograph compared with the one taken after the surgical procedure. **Results:** Data of 357 implants were extracted from the records of 38 patients with HbA1c values (6.9% to 10.0%). The mean follow-up was 7.3 years, with a minimum of 5 years. Six implants failed, yielding a 98.4% overall implant survival rate. The patients were divided into two groups according to the HbA1c values before implant placement. The moderately controlled group included 25 patients with DMT2, with HbA1c values of 6.9% to 8.0%, and the poorly controlled group included 13 patients, with HbA1c values of 8.1% to 10.0%. The overall mean bone loss was 2.02 ± 2.43 mm. In both groups, the maxilla demonstrated more bone loss than the mandible (P < .05). Marginal bone loss in moderately controlled and poorly controlled groups was 1.86 (± 2.21) mm and 2.33 (± 2.85) mm, respectively (P < .05). Removable prostheses also revealed greater bone loss rates compared with fixed prostheses in both groups (P < .05). **Conclusion:** Patients with high HbA1c values (8.1% to 10.0%) had more marginal bone loss than those with lower HbA1c values. Removable dentures should be reconsidered as a standard treatment option in these patients. Int J Oral Maxillofac Implants 2021;36:355–360. doi: 10.11607/jomi.8476

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bone loss progression is associated with the degree of glycemic control, determined by HbA1c values. Patients with HbA1c ≥ 9% had greater alveolar bone loss than better-controlled patients with HbA1c < 9%. However, these findings were not statistically significant.7,8

Alveolar bone is a key element in implant stability and implant-supported prosthesis success. The effect of glycemic control among patients with diabetes on alveolar bone around implants has been studied. HbA1c level affects implant stabilization in the alveolar bone after placement. The decrease in implant stability in the first weeks after implant placement due to bone remodeling seems to be higher in patients with HbA1c > 8, compared to patients with HbA1c < 8. The ultimate return of stability to its initial levels took twice as long among HbA1c > 8 compared with HbA1c < 8 and a nondiabetic control group.9

A study comparing implant survival, peri-implantitis, and alveolar bone loss around implants, after 6 years of follow-up, in nondiabetic patients and diabetic patients with strict glycemic control and HbA1c < 6%, demonstrated no statistical differences between the groups in implant survival.10 Another study comparing implant survival in healthy and prediabetic subjects concluded that the prediabetic group experienced more peri-implant inflammatory signs and crestal bone loss near implants.11 A study assessed differences between diabetic patients with well-controlled (HbA1c < 7%) and moderately controlled (7% < HbA1c < 8%) diabetes and a nondiabetic population and found comparable implant survival and bone loss levels. However, an immediate insertion protocol resulted in significantly more bone loss.12 Another study found high implant survival and low complication rates in poorly or moderately controlled DMT2 patients, with HbA1c > 8% at implant placement. This study demonstrated the volatility of HbA1c values among diabetic patients, as the HbA1c values during the follow-up ranged from 6.3% to 13%.13

A meta-analysis investigated the incidence of marginal bone loss and implant failure in diabetic patients compared with nondiabetic patients and concluded that there was no statistically significant difference in implant failure rates.14 However, only 2 of 14 published papers evaluated in this meta-analysis mentioned HbA1c values. The first short-term study examined 50 dental implants in 35 patients within a period of 4 months, including 25 patients with DMT2 with HbA1c values ranging from 6% to 13.8%. The patients were divided into four groups according to HbA1c values (≤ 6%, 6% to 8%, 8.1% to 10%, and > 10%). No significant differences were found in implant survival and the peri-implant healing process.15 The second study (Tawil et al) tested implant complications and survival rates within 1 to 12 years. Among 45 DMT2 patients with 255 implants, only 92 implants were followed for more than 4 years. No difference was found in dental implant survival rates among patients with HbA1c < 7% or HbA1c values of 7% to 9%. On the other hand, this study found that elevated HbA1c values resulted in increased peri-implantitis and marginal bone loss around implants in these patients.16

The influence of prosthesis type on marginal bone loss has been addressed in the literature. A systematic review comparing marginal bone loss around implants supporting fixed and removable prostheses found that marginal bone loss was initially higher in implants supporting removable prostheses but was similar after 4 years of follow-up.17 Three of four studies in the review addressing implant loss reported higher occurrence of implant loss with removable prosthesis.18–20 Corresponding findings in a review by Kern et al showed a significantly lower implant loss with full-arch, fixed implant-supported prostheses than with removable implant-supported prostheses.21

Tsigarida et al investigated peri-implantitis and biologic complications around implant-supported fixed partial prostheses. They reported high incidence of biologic complications, dividing them into minor complications (peri-implant mucositis, defined as bleeding on probing, soft tissue hypertrophy, mucosal recession, suppuration, or fistula) and major complications (peri-implantitis defined as bleeding on probing with radiographic bone loss > 2 mm and implant failure). The study reported the prevalence of at least one complication in 94% of the prostheses and in 84% of the implants. Major complications occurred in 8% of the prostheses and in 5.7% of the implants.22

The consequences of the prosthesis type—fixed or removable—with long-term follow-up, among patients with DMT2, were not reported extensively in the literature. One study reported more denture stomatitis and alterations in salivary vascular endothelial growth factor among DMT2 patients with removable dentures.23

Variability in HbA1c values between studies and the availability of few long-term follow-up studies on prosthetic outcomes impair treatment planning for patients with DMT2. The purpose of this study was to report implant survival rates, marginal bone loss, and the impact of prosthesis type among DMT2 patients with high HbA1c values.

**MATERIALS AND METHODS**

For this retrospective study, the data were collected from the electronic medical records of patients treated with fixed and removable implant-supported prostheses at the private office of one of the authors (A.L.), from 2010 through 2017. The data were gathered by a dental student from Tel Aviv University, School of Dental
The study protocol was approved by the University Ethics Committee.

As standard practice, the medical records of patients of this oral-maxillofacial surgeon office include medical and dental histories, including detailed clinical and radiographic examinations, computed tomography scans, evaluations of oral hygiene, and documentation of annual hygiene prophylaxis and clinical monitoring visits. The standard treatment plan includes fabrication of study models, diagnostic wax-ups, and surgical templates to guide placement of the implants and prostheses. All treatment plans, alternative treatment options, and diagnostic tools and models are documented in the patient medical record. Only patients whose records included the above information were included in this study.

Medical records meeting the inclusion criteria were patients older than 18 years of age who were edentulous or partially edentulous, with missing or unsalvageable teeth, subsequently treated with implant-supported prosthetic restorations. The patients were diagnosed with DMT2 at least 2 years prior to implant placement and had data regarding HbA1c measurements before and at the end of the follow-up period. The medical records included at least 5 years of follow-up with annual follow-up visits, annual hygienist treatments, legible radiographs, and sufficient data regarding implant type, implant length and surgical procedure, date of implant insertion, and type of prosthesis.

Medical records of patients were excluded if they did not have DMT2, lacked HbA1c data or had HbA1c below 6.9% prior to implant placement, or had less than 5 years of follow-up, incomplete surgical or restorative data, nondiagnostic radiographs, or no recorded annual follow-up visits or annual hygienist therapy. Medical records of patients who had been treated for neoplasm (in the 2 years prior to implant placement) with radiation or drugs that are known to harm bone metabolism were also excluded.

DMT2 status was determined by the presence of a document from the patient’s primary physician, summarizing general health status and reporting that the patient had been diagnosed with DMT2 at least 2 years prior to implant placement. The patients’ medical records included documentation of blood tests with HbA1c results above 6.9% 1 week prior to the date of implant placement. The patients were divided into two groups according to pre-implant HbA1c values: a moderately controlled group with HbA1c values of 6.9% to 8.0% and a poorly controlled group with HbA1c values of 8.1% to 10.0%.

Bone loss was measured by comparing the latest available periapical radiograph of the implant with the one performed after the implant placement, assessing changes in the distance from a radiographic landmark (the implant-abutment connection) to the coronal point of marginal bone in contact with the implant. Both mesial and distal surfaces were evaluated. Changes were calculated according to the known distance between the implant-abutment connection and the first thread of the implant (Fig 1). The radiographic assessment was performed using an image processing program (ImageJ, National Institutes of Health). When bone loss of > 1 mm was identified, the radiograph was reevaluated by another student, and the finding was confirmed by one of the researchers.

Implant insertions were performed 4 to 6 months after tooth extraction. Definitive restorations were fabricated 3 to 6 months after implant placement. All the fixed restorations were cement-retained. Removable prostheses were supported by two to six implants.

Implants were described as failures when the implant presented mobility, symptoms of pain, and active periodontal inflammation with exudate.
Statistical Analysis
Study variables were summarized for analytical purposes. A mixed model analysis was used. The dependent variables were the average mesial and distal bone loss measurements. Logarithmic transformations were used to obtain normal deviation. Statistical significance was inferred at the nominal level of type I (alpha) error of .05. All analyses were performed using statistical software (SAS, SAS) on a personal computer (Windows XP operating system, Microsoft).

RESULTS
The review included medical records of 1,438 patients, treated with 5,792 implants. Medical records of 1,400 patients were excluded for failing to meet the inclusion criteria. Medical records of 38 patients (19 men, 19 women, mean age: 65.7 years) with 357 implants (189 maxilla and 168 mandible) met the inclusion criteria. In the moderately controlled group, eight patients underwent bone augmentation and sinus elevation procedures, compared with five in the poorly controlled group. Two types of implants were used: 116 Spiral (SPI) and 117 Dual Fit Implants (DFI; Alpha-Bio Tec). SPI are characterized by a progressive thread design with a tapered body and core. They have a double-lead thread design with a wide step between threads, a lead of 2.1 mm, and a pitch of 1.05 mm. At the coronal part of the implant body, there are shallower and thicker square-shaped threads. At the middle, there are deeper and thinner square-shaped threads, whereas at the apical part, there are deep and narrow V-shape threads, acting as blades. DFI are also characterized by a progressive thread design with the same sequence in the corono-apical direction as the SPI. However, in these double-lead thread implants, compared with the SPI implants, there is a smaller lead of 1.2 mm and a smaller pitch of 0.6 mm, resulting in more threads per implant length with a less pronounced helical angle to the threads. The DFI implant core at the apical portion is wider; thus, the V-shaped threads are shallower compared with the SPI.

The mean follow-up time was 7.25 years (range: 5 to 16 years). The moderately controlled group included 25 patients with 233 implants, and the poorly controlled group included 13 patients with 124 implants (Table 1).

Among 357 implants, 6 failed, 3 in each group. The overall implant survival rate was 98.4%. The survival rate for the moderately controlled group was 98.7%, and for the poorly controlled group, it was 97.6%.

The mean marginal bone loss for both groups was 2.02 (SD ± 2.43) mm. The mean bone loss in the maxilla and in the mandible was 2.38 (± 2.42) mm and 1.62 (± 2.39) mm, respectively. In both groups, the maxilla demonstrated greater bone loss compared with the mandible (P < .05).

The mean marginal bone loss was 1.86 (SD ± 2.21) mm in the moderately controlled group and 2.33 (SD ± 2.85) mm in the poorly controlled group (P < .05). Removable prostheses also demonstrated greater bone loss rates compared with fixed prostheses in both groups (P < .05; Table 2).

Minor changes in HbA1c values occurred during follow-up (Table 3).

No statistical difference was found between the moderately controlled and poorly controlled groups regarding age, sex, and prevalence of sinus elevation or bone augmentation procedures before implant placement.

DISCUSSION
This study examined implant survival rates and bone loss during a minimum of 60 months of follow-up.
among patients with DMT2 and high HbA1c values. The implant survival rate of 98.7% in the moderately controlled group and 97.6% in the poorly controlled group corresponds to previous findings in studies with similar follow-up periods.\textsuperscript{12,16,24} The average marginal bone loss in both groups was 2.02 mm, 1.86 mm in the moderately controlled group and 2.33 mm in the poorly controlled group (\(P < .05\)). These findings are consistent with those of previous reports.\textsuperscript{10,12,25}

The unique feature of this study compared with previous reports is that patients demonstrated poor glycemic control over an extended period of at least 5 years. While elevated HbA1c levels resulted in a statistically significant advance in marginal bone loss, considering the long follow-up, the difference was clinically negligible and acceptable. It was also noted that implant survival did not seem to be affected by HbA1c. Significantly greater bone loss was found in the maxilla (\(P < .05\)), supporting previous reports\textsuperscript{25,26} but in contradiction to others.\textsuperscript{10,11} It is suggested that the difference in bone density between the mandible and the maxilla is the reason for the difference in marginal bone loss.

Previous studies reported that marginal bone loss around implants supporting removable prostheses was initially higher compared with fixed prostheses\textsuperscript{17,18} but did not differ after 4 years.\textsuperscript{17} Others reported contradicting results, but their follow-up period was considerably shorter.\textsuperscript{20} These studies were conducted on nondiabetic patients. The results of the present study showed higher marginal bone loss around implants supporting removable prostheses, even 5 years of follow-up. The fact that the patients had poor glycemic control and elevated HbA1c levels throughout the follow-up period might have contributed to these results.

A few limitations were noted in this study. The sample size of 38 patients and 357 implants was small. HbA1c data were recorded only before implant insertion and at the end of follow-up. Although the results showed small changes in the HbA1c, more frequent measurements would have been better. Bone loss was initially measured by one student. Despite this, most of the cases were reviewed by another student and researcher because the average bone loss after 5 years of follow-up in both groups was > 1 mm (Table 2). The restorations were performed by several prosthodontists who might have had different levels of expertise, which could influence the outcomes. It should be noted that physicians urge their patients to reduce HbA1c values prior to implant therapy. Therefore, it is difficult to locate DMT2 patients with high HbA1c values who undergo implant therapy.

**CONCLUSIONS**

Patients with poorly controlled DMT2 (HbA1c of 8.1% to 10.0%) presented higher marginal bone loss values compared to those with moderate control. Removable dentures caused more bone loss around the implants, which should be considered when choosing this type of restoration for diabetic patients with poor glycemic control.

<table>
<thead>
<tr>
<th>Table 2</th>
<th>Marginal Bone Loss and Consequences of Surgical Procedures, Prosthesis Type, and Implant Location in Moderately Controlled and Poorly Controlled Groups</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group Variable</td>
<td>Moderate control</td>
</tr>
<tr>
<td></td>
<td>Bone loss</td>
</tr>
<tr>
<td>Mean bone loss ± SD (mm)</td>
<td>1.86 (± 2.17)</td>
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<tr>
<td>Mean bone loss in patients with bone augmentation or sinus elevation</td>
<td>1.81 (± 1.32)</td>
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<tr>
<td>Mean bone loss in patients without bone augmentation or sinus elevation</td>
<td>1.87 (± 2.29)</td>
</tr>
<tr>
<td>Mean bone loss and type of prosthesis</td>
<td>1.73 (± 2.28)</td>
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<td></td>
<td>2.64 (± 0.77)</td>
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<tr>
<td>Mean bone loss</td>
<td>1.77 (± 1.47)</td>
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<td></td>
<td>2.02 (± 2.80)</td>
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</tbody>
</table>

*All implants in this group were inserted with sinus elevation or bone augmentation.

<table>
<thead>
<tr>
<th>Table 3</th>
<th>HbA1c Changes Over 5-Year Follow-up in All Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>HbA1c (n = 38)</td>
<td>No.</td>
</tr>
<tr>
<td>HbA1c decrease</td>
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<tr>
<td>HbA1c increase</td>
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</tr>
<tr>
<td>HbA1c stable</td>
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<tr>
<td>HbA1c positive change ≥ 1</td>
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</tr>
<tr>
<td>HbA1c positive change ≥ 0.5</td>
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</tr>
<tr>
<td>HbA1c negative change ≥ 1</td>
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<tr>
<td>HbA1c negative change ≥ 0.5</td>
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</tr>
</tbody>
</table>
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REFERENCES