Diabetes mellitus is one of the most commonly encountered contraindications to dental implant therapy, and glycemic control is viewed as a critical variable in identifying whether patients with diabetes are eligible for implant therapy. A number of studies have reinforced this view of the importance of glycemic control in implant success. Several clinical reports have suggested that dental implant success rates (92-100 percent) in patients with “well-controlled” type 2 diabetes mellitus may not be significantly compromised. In addition, a large multicenter study of dental implant success reported an implant failure rate of only 7.8 percent for 255 implants placed in “selected” patients with type 2 diabetes mellitus. In this study, the number of implant failures for patients with diabetes was not significantly different from that found for patients without diabetes (6.8 percent); however, the selection criteria for the patients relative to type 2 diabetes mellitus were not reported in the...
study. In contrast, two retrospective studies of patients with diabetes who received implant therapy reported considerably higher failure rates. One study retrospectively evaluating implants in 40 patients with diabetes after an average of four years found that 14 percent of implants failed,12 while a second study evaluating consecutively treated patients with implants for up to 20 years reported a more than 30 percent failure rate in patients with diabetes.13 Overall, the available literature leaves in question the effects of diabetes on implant success rates.

Unfortunately, the application of the findings from these studies to clinical practice is limited by the lack of specific information characterizing the subjects’ diabetic status. While most of these studies describe the subjects’ diabetes as being “well-controlled,” the authors do not report how they assessed glycemic control. Only one implant study has reported an objectively measured outcome of glycemic control (glycated hemoglobin [HbA1c] level) for patients with diabetes.14 This prospective study evaluated implant success in 89 monitored subjects with type 2 diabetes mellitus and reported that 91 percent of the implants placed were maintained successfully in 58 subjects followed over five years. In this study, the authors did not find glycemic control to be a significant factor in implant success, but they did not define clearly the subjects’ control levels. For example, 21 subjects had HbA1c levels that were more than 2 percent higher than normal, but the authors did not define normal. Also, only 10 subjects were receiving insulin therapy, while the remaining subjects relied on diet, oral medications or both, suggesting that the subjects’ diabetes was reasonably under control. However, given the likelihood that the subjects with diabetes had reasonable levels of glycemic control, it is important to note that 14 of 89 subjects (15.7 percent) experienced implant failure, with most of these failures (10 of 14) occurring before prosthesis placement.

Factors influencing successful implant therapy for patients with diabetes remain in question, specifically with limited information available on the influence of glycemic control on implant success. In establishing an evidence-based rationale for the optimal use of implant therapy for patients with diabetes, it is essential to first understand the impact of glycemic control on early healing and implant success. Therefore, we conducted a study using well-defined levels of glycemic control to explore the effects of glycemic control on implant success up to the time of restoration in patients with type 2 diabetes mellitus.

SUBJECTS, MATERIALS AND METHODS

We designed a prospective cohort pilot study to examine the impact of glycemic control in patients with type 2 diabetes mellitus on early implant success and clinical complications. We recruited subjects from the San Antonio community and included dental patients seeking treatment at the University of Texas Health Science Center at San Antonio (UTHSCSA) Dental School. We conducted this study in full compliance with the UTHSCSA Institutional Review Board. All of the subjects with diabetes were under the care of a health care provider, and study participation did not limit the medical management they were provided.

Inclusion criteria. We enrolled patients who were missing one or more teeth and whom we recognized as having the potential to benefit from tooth replacement using dental implant therapy. We enrolled both healthy patients without diabetes and patients with type 2 diabetes mellitus. We stratified patients on the basis of their HbA1c levels taken within one month of implant surgery in patients without diabetes (HbA1c level of < 6.0 percent), or in patients with well-controlled type 2 diabetes mellitus (HbA1c level from 6.0-8.0 percent), with moderately controlled type 2 diabetes mellitus (HbA1c level from 8.1-10.0 percent) or with poorly controlled type 2 diabetes mellitus (HbA1c level of > 10.0 percent). We used a single standardized commercial laboratory to evaluate the HbA1c levels.

Phased enrollment. Owing to the lack of significant data on the effects of glycemic control on implant healing, we conducted this prospective cohort study in two enrollment phases. The first enrollment phase included implant therapy initiated for 10 subjects in the nondiabetic group, nine subjects in the well-controlled diabetes group, and three subjects in the moderately controlled diabetes group (all three of these subjects had HbA1c levels of ≤ 8.3 percent). During the second phase of the study, we enrolled 13 additional subjects who had been diagnosed with type 2 diabetes mel-

ABBREVIATION KEY. HbA1c: Glycated hemoglobin.
UTHSCSA: University of Texas Health Science Center San Antonio.
litus, giving us a total of 35 subjects enrolled in the study. The 13 subjects enrolled in the second phase, as stratified using baseline HbA1c levels, included one with well-controlled diabetes, nine with moderately controlled diabetes and three with poorly controlled diabetes.

Inclusion criteria. We enrolled adult patients who had been diagnosed with type 2 diabetes mellitus (self-reported and verified with a physician’s report, HbA1c level results or treatment record) and healthy patients without diabetes (self-reported and verified with HbA1c results). Patients with type 2 diabetes mellitus could be on a modified diet or receiving oral medication, insulin or combination therapies. Implant placement was limited to subjects with diabetes mellitus who had evidence of oral pathology, systemic disorders affecting surgical therapy protocols, current smoking or history of bone grafting at the implant site. We also excluded patients with diabetes from this study if they had a history of microvascular complications. Implant sites had to have had at least four months of healing after tooth extraction before implant placement and adequate bone dimensions for implant placement without the need for bone grafting.

Exclusion criteria. We excluded patients with poorly controlled diabetes. We also excluded patients without diabetes who had evidence of oral pathology, systemic disorders affecting surgical therapy protocols, and current standards of care. We reported the surgical visit as the baseline for the study. We first performed the osteotomy drilling to at least 10 millimeters in depth using a 2.2-mm diameter solid drill, and we then drilled to a final diameter of 3.5 mm to allow for the placement of a 10- or 12-mm length, 4.1-mm diameter, rough-surfaced implant (SLA, Institut Straumann AG).

At the time of implant placement, we made subjective clinical assessments regarding bone type using a four-tier scale based on mineral densities during osteotomy. We maintained the transgingival implant placement with an extended healing cap on the implant. We prescribed postoperative antibiotics for three days to subjects without diabetes, and we prescribed postoperative antibiotics for seven to 10 days for subjects with diabetes. We ensured that the subjects’ occlusal and functional forces were minimized on the implants during the four-month healing period. This four-month healing period before implant restoration was approximately twice the manufacturer’s recommended six- to eight-week healing period. We removed and replaced the healing caps at two- to four-week intervals after implant placement as part of the assessment process during the healing period.

Study outcomes. We assessed the study outcomes in a nonblinded manner. The first study outcome was implant success, which we defined as an implant lacking any signs of clinical mobility, peri-implant radiolucency, clinical findings consistent with the failure of the implant to integrate, pain, or other reasons preventing the restoration of the implant at four months (± two weeks) or requiring the removal of the implant.

The second study outcome we assessed was complications that included, but were not limited to, clinical signs of infection associated with the implant such as suppuration, pain and swelling that did not require implant removal or prevent restoration. Infection included clinical signs of pain, infection, inflammation and swelling in association with the surgical area we judged likely to be related to the surgical procedure and of sufficient nature as to require additional antibiotic or other therapeutic interventions. Clinical complications included rotational movement of the implant or other findings leading to a clinical or investigative alteration of protocol but not consistent with implant failure.

The third study outcome we assessed was adverse events, which we defined as any illness, sign, symptom or clinically significant systemic finding that appeared or worsened during the course of the study.

RESULTS

Subject and site characteristics. Subjects in the nondiabetic group ranged in age from 29 to 61 years, and subjects in the diabetic group ranged in age from 51 to 81 years. Seven of 10 subjects in the nondiabetic group cohort were women, while 10 of the 25 subjects in the diabetic group were women. We placed 16 of the study implants in the maxilla and 34 in the mandible. We placed 39 of the 50 implants in bone types 2 or 3 (Table 1). We found no significant association between bone type and glycemic status (P = .22, χ²). We found a borderline significance between maxillary or mandibular placement and glycemic status (P = .08, χ²), with subjects with diabetes having a greater proportion of implants placed in the mandible.
Glycemic control levels. The subjects’ HbA1c levels ranged from 4.5 to 13.8 percent. Using baseline HbA1c levels, we determined that the study population consisted of 10 subjects without diabetes and 25 subjects with type 2 diabetes mellitus. Among the subjects with diabetes, we classified 10 as having well-controlled diabetes, 12 as having moderately controlled diabetes, and three as having poorly controlled diabetes.

When we evaluated HbA1c levels at the eight-week point, we found that 12 of the 25 subjects with diabetes (48 percent) had HbA1c level changes that would lead to a change in their glycemic control level; nine of these 12 subjects (75 percent) originally were in the moderately controlled diabetes group. Seven of the subjects with moderately controlled diabetes had decreases in HbA1c levels that shifted them into the well-controlled diabetes group, while two subjects had increases in HbA1c levels that shifted them to the poorly controlled diabetes group. Three of the 10 subjects who originally were in the well-controlled diabetes group had elevations in HbA1c levels, which led to them being reclassified into another glycemic control level group. Two subjects had elevated HbA1c levels consistent with the moderately controlled diabetes group, and one subject experienced an HbA1c level elevation of 4.8 percent (from 7.8-12.6 percent) between baseline and the eight weeks and was reclassified into the poorly controlled diabetes group.

When we extended our evaluation of changes in HbA1c levels to 16 weeks, we found a maximum increase in HbA1c levels of 6.0 percent for one subject. The mean change in HbA1c levels from baseline to either the eight- or 16-week assessments for all subjects was 0.004 percent. When we compared the mean changes in HbA1c levels for subjects with a baseline HbA1c level of 8.0 percent or less with those having HbA1c levels of more than 8.0 percent, we found that subjects with poorly controlled diabetes at baseline had a mean increase in HbA1c levels of 0.84 percent, compared with a mean decrease of 0.58 percent in subjects with well-controlled and moderately controlled diabetes during the 16-week period.

Study outcomes. We enrolled 35 study subjects, who received a total of 50 implants. We determined that all 50 implants were clinically integrated at the time of abutment placement and restoration at least four months after implant placement (Table 2). The only clinical complications or adverse events we noted for any of the subjects during the four-month evaluation period were two implants in different subjects that had rotational movement two weeks after placement, and one implant with gingival inflammation associated with a partially submerged healing cap that required replacement with a taller healing cap to displace the soft tissue two weeks after placement. Otherwise, postoperative healing was uneventful for all of the subjects (Figures 1 and 2). For the three subjects who had identified complications, the HbA1c level for the subject who had soft-tissue inflammation was 7.4 percent at baseline, and the HbA1c levels for both subjects who experienced rotational movement of the implants were 8.3 percent at baseline.

Four implants in four subjects had deviations from the placement protocol. These alterations included countersinking the implant to engage the cortical bone crest with the implant collar (one implant); “stripping” the implant-bone interface at placement, decreasing implant stability (one implant); re-preparing the implant site to increase depth (one implant); and requiring placement of a 4.8-mm diameter implant (one implant). However, none of these alterations in

### Table 1

<table>
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<th>HbA1c* LEVEL</th>
<th>LOCATION (NO.)</th>
<th>BONE TYPE (NO.)</th>
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<td></td>
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</tr>
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</tr>
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<td>8.1-10.0%</td>
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<tr>
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</table>

* HbA1c: Glycated hemoglobin.
implant placement protocol had an impact on clinical outcomes or complications.

**DISCUSSION**

The importance of maintaining stringent glycemic control to minimize some of the most common diabetic comorbidities is becoming increasingly appreciated.\textsuperscript{16} Despite these advances, however, a majority of patients with diabetes still are unable to maintain adequate glycemic control.\textsuperscript{17-19} Diabetes mellitus remains a relative contraindication to dental implant therapy that depends on the patient’s level of glycemic control. As a result, many patients who

**TABLE 2**

<table>
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<th>ASSESSMENT</th>
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<td>Diabetic Group</td>
<td>Nondiabetic Group</td>
<td>Diabetic Group</td>
</tr>
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<td>8.1-10.0</td>
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<td><strong>Restored (No.)</strong></td>
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<td><strong>Adverse Events (No.)</strong></td>
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</tbody>
</table>

\* HbA1c: Glycated hemoglobin.

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**Figure 1.** An edentulous 62-year-old woman with diabetes had two mandibular anterior implants placed for overdenture support. A baseline glycated hemoglobin level of 8.5 percent was determined at the time of surgery. Healing representative of the study subjects can be seen at one week after implant placement (A) with sutures intact and at four weeks after implant placement (B).

**Figure 2.** A partially edentulous 55-year-old woman had one mandibular implant placed in the right first molar region. A baseline glycated hemoglobin level of 10.1 percent was determined at the time of surgery. Healing representative of the study subjects can be seen at one week after implant placement (A) and at four weeks after implant placement (B).
have poorly controlled diabetes may be denied the benefits of implant therapy.

Patients with diabetes have increased frequency of periodontitis and tooth loss, which can lead to compromises in chewing function and diet.

The benefits of implant therapy may be even more relevant to patients with diabetes who are at an increased risk of experiencing tooth loss and who are critically dependent on managing their diabetes through diet. In fact, the patients who are most compromised may gain the most from implant therapy. Given the potential for patients with diabetes to benefit from implant-based tooth replacement, we designed this study to enhance the understanding of both the limitations of and the possibilities for implant therapy in patients with diabetes by evaluating the impact of glycemic control on implant success and complications after placement in these patients.

We found no evidence that diminished glycemic control was associated with compromises in implant success or clinical complications for patients with type 2 diabetes mellitus. While preliminary, our findings are relevant to practicing clinicians in assessing the viability of implant therapy in patients with type 2 diabetes mellitus. However, alterations to implant placement and loading protocols may be important in the initial success of implants in these patients regardless of their diabetic status. For example, in our study we used a specific implant system with a delayed restorative protocol that was approximately twice the time the manufacturer recommended, and we prescribed antibiotics to the subjects with diabetes for seven to 10 days after placement. This seven- to 10-day course of antibiotics was longer than that we prescribed to patients without diabetes (three days), owing to the limited information available on the procedural risks for these patients with diabetes. We could not determine the relationship of these protocol alterations to implant success on the basis of our investigation.

Several studies have documented that patients with type 2 diabetes mellitus tend to have greater bone density. This is thought to be due to decreased bone turnover, elevated serum insulin levels and possibly compensatory responses to weight in a predominantly overweight population. Our findings failed to identify any significant differences in alveolar bone density, as determined clinically at the time of implant placement, relative to diabetic status or glycemic control. More research is needed to confirm this observation.

Glycemic control in patients with diabetes is variable. The subjects enrolled in our study were being followed by their practicing physicians, and their physicians made no alterations in their care due to their participation in our study. This gave us a reasonably realistic view of the difficulties of managing diabetes in these subjects. We saw that almost one-half of the subjects changed HbA1c level groups over the four-month study period, with the greatest changes found in the subjects with less well-controlled diabetes. This variability reinforces the importance of understanding the impact of glycemic control on both short- and long-term aspects of implant care. Our findings also suggest that subjects with relatively low HbA1c levels may have dramatic changes in glycemic levels with the potential to affect implant success. Though the results of our preliminary study do not support a detrimental effect of hyperglycemia on implant success, this remains a possible explanation for the inconsistencies found in previous studies of implant success in patients with diabetes.

The short-term success in our study presents a more optimistic view than did previous reports that had an up to 14 percent implant failure rate in patients with diabetes and an up to 31.3 percent failure rate on a per patient basis. A couple of other reports, however, support our results. A prospective evaluation of 58 patients with presumably well-controlled diabetes who received mandibular implants reported that glycemic control was not related significantly to implant success over five years. An investigation of 52 patients with well-controlled diabetes who received two anterior mandibular implants reported no implant failures over two years.

CONCLUSIONS

Our study explored the hypothesis that patients with diabetes are appropriate candidates for implants and that compromises in glycemic control may not exclude implant success. We found no evidence of diminished clinical success or significant early healing complications associated with implant therapy based on the glycemic control levels of patients with type 2 diabetes mellitus.

We feel that our study justifies the continued evaluation of the impact of diabetes on implant success and complications. It also questions the validity of limiting the benefits of implant therapy to only those patients with diabetes who...
have good glycemic control. Our study provides a valuable step toward better understanding of treatment options and prognoses expected for implant therapy in patients with diabetes.