

Dental Endosseous Implant Assessments in a Type 2 Diabetic Population: A Prospective Study

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Diabetes mellitus, a prevalent disorder worldwide, is associated with systemic adverse sequelae, such as wound healing alterations, which may affect osseointegration of dental implants. This prospective multicenter study assessed the success of 2-stage endosseous root-form implants (3 different implant systems) placed in the mandibular symphysis of 89 male type 2 diabetic subjects. The implants were uncovered approximately 4 months after placement, restored with an implant-supported, Hader bar clip-retained overdenture, and maintained at scheduled follow-up data collection examinations for 60 months after loading. Sixteen (9.0%) of the 178 implants failed. Life table methods calculated implant survival at approximately 88%, from prosthesis placement through the 60-month follow-up, and at approximately 90% from implant placement through the observation period. No implants failed between surgical placement and uncovering, 5 failed at uncovering, 7 failed after uncovering before prosthesis placement, and 4 failed after prosthesis placement. Fasting plasma glucose (FPG) and glycosylated hemoglobin (HbA1c) values were determined before implant placement (baseline) and approximately 4 months later at surgical uncovering (follow-up). The 5-year implant outcomes (successes versus failures) were analyzed against the following predictor variables: (1) baseline and follow-up FPG values, (2) baseline and follow-up HbA1c values, (3) subject age, (4) duration of diabetes (years), (5) baseline diabetic therapy, (6) smoking history, and (7) implant length. Regression analysis found only duration of diabetes ($P < .025$) and implant length ($P < .001$) to be statistically significant predictors of implant failure. There was no statistically significant difference in failure rates between the 3 different implant systems used. This study supports the use of dental implants in type 2 diabetic patients. (INT J ORAL MAXILLOFAC IMPLANTS 2000;15:811-818)

Key words: dental implants, diabetes, multicenter study, prospective studies

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Diabetes mellitus (DM) is a significant disorder seen all around the world.¹ In the United States, it is estimated that 16 million people have this disease.² Non-insulin-dependent DM (type 2 diabetes) accounts for about 90% of all DM cases and is associated with a number of adverse systemic sequelae.³

Clinicians might be hesitant to prescribe dental implant therapy for the diabetic patient for a variety of reasons, including delayed wound healing,⁴⁻⁶ prevalence of microvascular disease,^{7,8} impaired response to infection,⁹⁻¹² and susceptibility to periodontal disease.¹³⁻¹⁷ Osseointegration has been studied extensively in the general population and, to a lesser degree, in various subgroups, eg, the elderly¹⁸⁻²⁰ and the medically compromised.²¹⁻²³ Few implant studies specifically address the diabetic patient population.



Fig 1a Two mandibular implants with abutments.

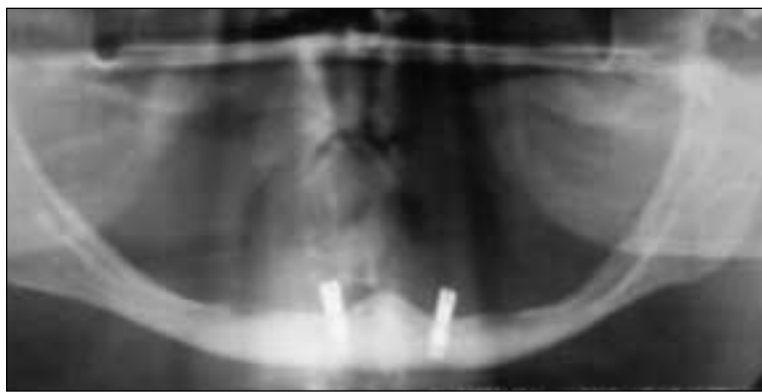


Fig 1b Panoramic radiograph of mandibular implants.

In a recent study, Kapur and coworkers²⁴ reported no implant failures over a 24-month interval in 52 type 1 and 2 diabetic patients restored with 2 mandibular implants and an overdenture. In another study,²⁵ the overall 5-year success rate for implant survival exceeded 90% in 59 patients, of whom 23 were diagnosed with DM. Unfortunately, the medical condition specific for those patients in whom the failures occurred was not given. Smith and colleagues²¹ reported no implant failures in 4 patients with type 1 DM and 1 patient with type 2 DM. Shernoff and associates²⁶ reported a 1-year implant success rate of 92.7% for 178 implants placed in 89 type 2 diabetes patients. The 5-year results of this prospective investigation are presented in this article.

MATERIALS AND METHODS

This project was conducted by study teams from 13 Department of Veterans Affairs Medical Centers. Each team was made up of an endocrinologist, an oral surgeon or periodontist, and a prosthodontist or general dentist. Eighty-nine male edentulous type 2 diabetic patients received medical and dental examinations and were subsequently monitored by the principal investigator at each center throughout the study. Female subjects were not excluded; their absence was a coincidence resulting from the predominance of males in the veteran population. At the time of implant placement surgery, the mean age for subjects was 62.7 ± 7.6 years (range 40 to 78).

Diabetes was controlled by the managing physician prior to implant placement with a regimen of diet alone or diet plus oral hypoglycemic agents and/or insulin as required. Approximately 14 days before stage I implant placement surgery, the patients' diabetes control was assessed, and both

fasting plasma glucose (FPG) and glycosylated hemoglobin (HbA1c) levels were determined. Efforts were made to meet or come as close as possible to the plasma glucose levels recommended by the American Diabetes Association (fasting plasma glucose of ≤ 140 mg/dL and 2-hour postprandial glucose of ≤ 200 mg/dL).

The VA medical centers were each assigned to 1 of 3 different dental implant systems. Four centers placed titanium alloy basket implants (72 implants/36 patients, Paragon Implant Company, Encino, CA); 4 placed a pure titanium screw (42 implants/21 patients, Nobel Biocare, Yorba Linda, CA); and 5 placed a titanium plasma-sprayed [TPS] cylinder (64 implants/32 patients, Interpore Corporation, Irvine, CA). At stage I surgery, each of the 89 subjects received 2 endosseous root-form implants placed in the mandibular symphysis following each manufacturer's established surgical guidelines (Figs 1a and 1b). The patients' medical status was evaluated postoperatively at the end of the first week, second week, and fourth week after surgery and then monthly until the prostheses were placed (mean interval of 10.4 months, range 5.9 to 25.9). During the healing period, self-monitoring of blood glucose was done with corrective measures for diabetic control taken by the managing physician when required. Stage II implant uncovering surgery was completed 4 months after placement (mean 4.8 months, range 2.6 to 22.0). Prior to stage II surgical uncovering, diabetic control was assessed with FPG and HbA1c evaluations.

A conventional maxillary complete denture and a mandibular implant-supported, Hader bar clip-retained overdenture were fabricated for each patient (Figs 2a and 2b). Plastic denture teeth (Dentsply Corporation, York, PA) were arranged in either a balanced monoplane or lingualized occlusal scheme.



Fig 2a Mandibular implants with Hader bar.



Fig 2b Mandibular bar-retained complete denture in place.

Patients were scheduled for follow-up examinations at prosthesis placement and at 3, 6, 12, 18, 24, 30, 36, 42, 48, 54, and 60 months after prosthesis placement. Panoramic or periapical radiographs were taken preoperatively, at stage II uncovering, at prosthesis placement, and at 6, 12, 24, 36, 48, and 60 months after prosthesis placement. The following study parameters were assessed and recorded at follow-up examinations.

1. Implant mobility when force was applied to 2 opposing hand instruments (1 = yes, 2 = no)
2. Peri-implant inflammation (1 = none, 2 = slight, 3 = moderate, 4 = severe)
3. Tissue levels, measured from the top of the abutment to the tissue margin on the buccal and lingual of each implant
4. Pocket depth (buccal, lingual, mesial, and distal)
5. Presence of plaque (1 = yes, 2 = no)
6. Presence of calculus (1 = yes, 2 = no)

Subject satisfaction was assessed by the use of a patient-completed questionnaire at 6 and 60 months. Implant failure was determined upon the clinical detection of implant mobility when force was applied with 2 opposing instruments. Peri-implant crestal bone loss was not used to determine success/failure.

Cumulative success rates for the implants were determined by life table survival analyses²⁷ from prosthesis placement to end of follow-up and from implant placement to the end of the observation period. Regression analysis of the paired data (2 implants per patient) by means of generalized estimating equations (GEE) was used to assess success and failure against several variables.²⁸ The potential predictor variables used in this analysis were:

1. Fasting plasma glucose values at baseline and implant uncovering
2. Glycosylated hemoglobin levels at baseline and implant uncovering
3. Patient age
4. Duration of diabetes in years
5. Baseline diabetic therapy (insulin, hypoglycemic medications, or diet alone)
6. Smoking history
7. Implant length

Data that were calculated to be skewed were corrected by logarithmic transformation to achieve normality. An analysis of proportions by means of a weighted Chi-square test was used to compare the success rates among the 3 different implant systems.²⁹

RESULTS

Sixteen (9.0%) of the 178 implants in 14 of the subjects failed after becoming mobile and were removed. None failed between the stage I placement and stage II uncovering surgical procedures. Five failed at stage II uncovering, 7 failed after stage II uncovering before prosthesis placement, and 4 failed after prosthesis placement. Two subjects lost both implants before the prosthesis was placed and were terminated from the study. Of the 12 subjects who lost 1 implant, 5 were followed with 1 implant restored with a conventional overdenture (2 of the restorations had a ball retainer on the single implant for improved retention) and 7 received another implant and were restored with a bar-retained overdenture. These 7 replacement implants were not included in this study.

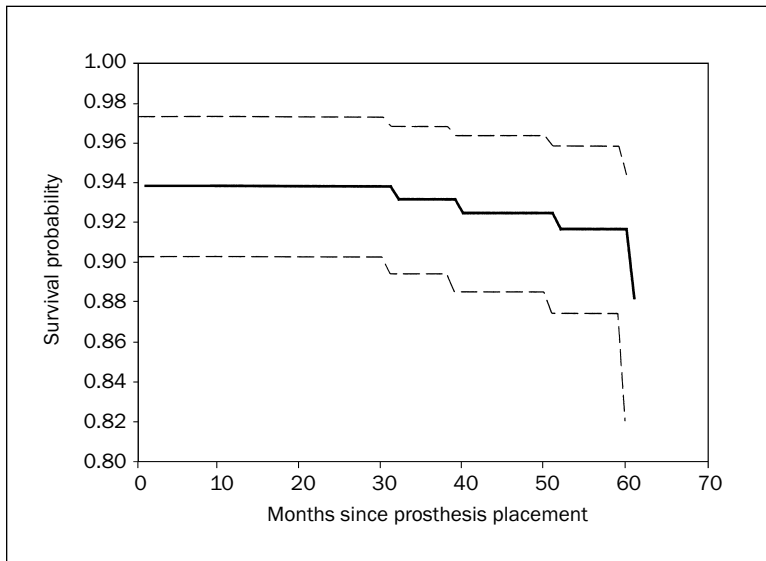


Fig 3 Life table analysis from placement of prostheses through the 60-month follow-up period. The broken lines show the probability within a 95% confidence interval, and the solid line represents the cumulative survival rate. At 60 months, the overall survival rate was approximately 88%, at a 95% confidence interval of 94% to 82%. (Twelve implants were lost before the prostheses were placed.)

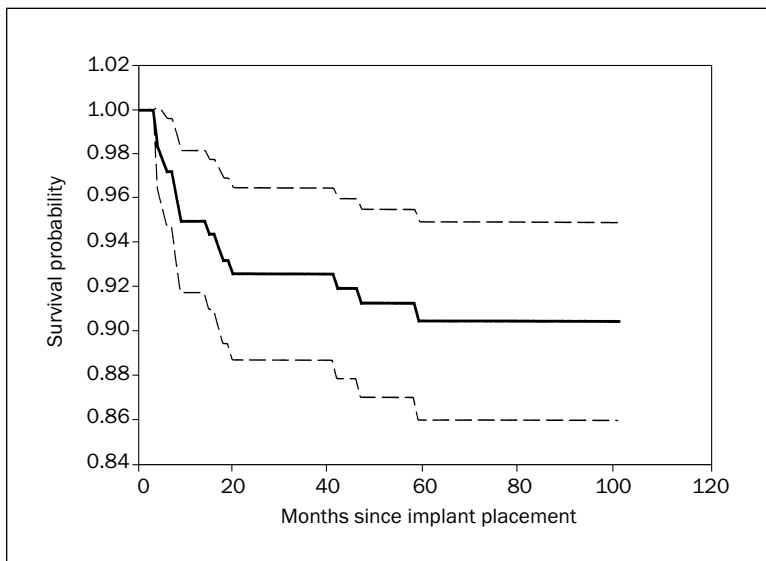


Fig 4 Life table analysis from placement of implants through the observation period (includes placement of implant to surgical uncovering, uncovering to prosthesis delivery, and the 60-month follow-up). The broken lines show the probability within a 95% confidence interval, and the solid line represents the cumulative survival rate. At 101 months, the overall survival rate is over 90%, at a 95% confidence interval of 95% to 86%.

The 60 months of follow-up began at the prosthesis delivery appointment. The mean follow-up interval was 46.9 months (range 0 to 60, SD 20.1) (implants lost before prosthesis placement had 0 months follow-up). Fifty-eight of the 89 subjects completed the 60-month follow-up schedule, while 31 subjects were terminated prematurely. The 31 terminations were attributed to: death of 23 subjects sometime between 2 and 54 months, relocation or inability to locate 5 subjects between 43 and 59 months, loss of both implants in 2 subjects before prosthesis placement, and non-compliance of 1 subject at 2 months.

To determine the long-term survival of implants and best account for the 31 terminations, the cumulative survival rate was calculated using life table analysis. The overall survival rate from prosthesis placement through the 60-month follow-up was approximately 88% at a 95% confidence interval of 94% to 82% (Fig 3). The overall survival rate from implant placement through an observation period, which included from implant placement to implant uncovering, uncovering to prosthesis placement, and the 60-month follow-up, was slightly over 90% at a 95% confidence interval of 95% to 86% (Fig 4).

Table 1 Implant Length and Failed Implants

Implant length (mm)	n	No. of failed implants	Percent of failed implants
8	9	2	22.2
10	3	0	0
10.5	6	2	33.3
11	2	1	50.0
13	73	8	11.0
15	39	3	7.7
16	34	0	0
18	9	0	0
20	3	0	0

At baseline, approximately 14 days before stage I implant placement surgery, the mean age of the subjects was 62.7 years (range 40 to 78, SD 7.6). The number of years with DM (duration of DM) ranged from 1 to 35 years (mean 8.7, SD 7.5). Ten subjects were on insulin therapy, 68 took oral hypoglycemic medications, and 11 controlled their DM through diet only. At baseline, the mean FPG was 154 mg/dL (range 78 to 272, SD 42.1). The HbA1c levels were within the normal ranges for 32 subjects, elevated (up to 2% above the normal range) in 34 subjects, and high (more than 2% above the normal range) in 21 subjects (data missing for 2 subjects). Thirty-four subjects (38%) were current smokers, 42 (47%) were previous smokers, and 13 (15%) had never smoked. At follow-up (prior to stage II uncovering surgery), the mean FPG was 164 mg/dL (range 69 to 352, SD 53.1). The HbA1c levels were within normal ranges for 32 subjects, elevated in 33 subjects, and high in 22 subjects (data missing for 2 subjects). The data for age, duration of diabetes, and baseline and follow-up FPG were skewed and corrected by logarithmic transformation.

Implant failure related to implant length can be seen in Table 1. Regression analysis by GEE of success and failure against the predictor variables found only duration of diabetes ($P < .025$) and implant length ($P < .001$) to be statistically significant predictors of implant failure.

Failure rates for the 3 implant systems were: alloy baskets, 8 of 72 (11.1%); pure titanium screws, 4 of 42 (9.5%); and TPS cylinders, 4 of 64 (6.3%). A comparison of the proportions was used to evaluate the differences in failure rates of the 3 different implant systems. The computed weighted Chi-square value was 0.993, which indicated no statistically significant difference between the 3 implant systems ($P > .05$).

Table 2 Results of Patient Survey Questionnaires at 6 and 60 Months

Survey questions/results*	6 months (n = 82)†	60 months (n = 58)†
1. Chewing problems		
No	64 (79%)	46 (85%)
Yes, better	15 (19%)	7 (13%)
Yes, same	0 (0%)	1 (2%)
Yes, worse	2 (2%)	0 (0%)
2. Speaking problems		
No	76 (94%)	51 (94%)
Yes, better	3 (4%)	3 (6%)
Yes, same	1 (1%)	0 (0%)
Yes, worse	1 (1%)	0 (0%)
3. Satisfaction with appearance		
Yes	77 (95%)	53 (94%)
No, better	1 (1%)	1 (6%)
No, same	3 (4%)	0 (0%)
No, worse	0 (0%)	0 (0%)
4. Dentures and diabetic diet		
Help diet	65 (80%)	47 (87%)
Do not help	1 (1%)	0 (0%)
No difference	15 (19%)	7 (13%)
5. Mandibular denture		
Satisfactory	74 (91%)	52 (96%)
Unsatisfactory, better	5 (6%)	1 (2%)
Unsatisfactory, same	1 (1%)	1 (2%)
Unsatisfactory, worse	1 (1%)	0 (0%)
6. How well does lower denture stay in place		
Better	81 (100%)	54 (100%)
Same	0 (0%)	0 (0%)
Worse	0 (0%)	0 (0%)
7. Overall satisfaction		
Satisfied	78 (96%)	53 (98%)
Unsatisfied	2 (2%)	1 (2%)
No opinion	1 (1%)	0 (0%)
8. Recommended implants to other patients		
Would	78 (96%)	52 (96%)
Would not	3 (4%)	2 (4%)

*Refers to comparison with patients' initial conventional dentures.

†One survey was not returned at 6 months; at 60 months, 4 surveys were not returned.

The results of the 6- and 60-month patient survey questionnaires are summarized in Table 2. The overall majority of subjects were able to successfully wear their mandibular prostheses and reported improvements in mastication, speaking, and appearance, along with overall satisfaction with the procedure.

DISCUSSION

The implant survival rates of slightly over 90% from placement of implants (see Fig 4) and approximately

88% from prosthesis placement (Fig 3) are considered to be an acceptable outcome.^{30,31} These results are comparable to those reported for non-diabetic populations in other studies.^{25,32-34}

Statistical analysis of the data revealed that FPG and HbA1c values at baseline and follow-up (at uncovering), subject age, baseline diabetic therapy, and smoking history did not statistically predict implant success/failure in this study. The FPG and HbA1c values at baseline and follow-up (at uncovering) were used to assess diabetic control. Levels of FPG in these study patients at the time of study initiation were often well above that recommended by the American Diabetes Association (≤ 140 mg/dL) (the present ADA goal is 80 to 120 mg/dL). The HbA1c levels reflect the state of glycemia over the preceding 8 to 12 weeks (half-life span of red blood cells) and are useful in monitoring diabetic control.³⁵ Glycosylated hemoglobin is abnormally high in diabetics with chronic hyperglycemia. The subjects in this study exhibited varying levels of diabetic control, in that the baseline FPG range was 78 to 272 mg/dL and the follow-up FPG range was 69 to 352 mg/dL. In addition, HbA1c levels, recorded at baseline and follow-up, were found to be within the normal range for 32 and 32 subjects, elevated up to 2% above normal for 34 and 33 subjects, and high (more than 2% above normal) for 21 and 22 subjects, respectively. Statistical analysis indicated that the degree of diabetic control at baseline and at the follow-up did not make a significant difference in implant outcome.

Tobacco use has been found to have an association with an increased risk for implant failures.^{36,37} No relationship was found between smoking and implant failure in this study.

Implant length was found to have a statistically significant relationship to implant success/failure ($P < .001$), in that longer implants experienced fewer failures. This finding has been reported in other studies.^{38,39}

The duration of DM for subjects also had an effect on implant success/failure. Implant failure had a statistically significant association with an increase in years of diabetic history ($P < .025$). Duration of DM is associated with increased classic microvascular complications, retinopathy and nephropathy, and, in individuals with type 2 DM, higher cardiovascular mortality.⁴⁰ Thus, an increase in microvascular disease may be postulated to have contributed to implant failure, and an increased risk for cardiovascular disease may have contributed to the high mortality rate seen in this study.

Twenty-three (25.8%) of the 89 subjects died during this 5-year study. This death rate is comparable to that seen in other long-term studies in high-

risk groups of type 2 diabetic patients of similar age and duration of diabetes. For instance, an investigation of aspirin's effects in diabetes experienced 327 (25.4%) deaths in 1,284 patients followed over a 5-year period.⁴¹ In a study by Pyorala et al, there were 24 (24.7%) deaths in 97 diabetic subjects randomized to placebo therapy over the 5.4 years of the study.⁴² In this study of elderly edentulous type 2 diabetic subjects, it is likely that the smoking history (85% past or present smokers) may have contributed to their high mortality rate. The adverse influence of smoking on mortality in type 2 diabetes has been well documented in previous studies.⁴³

CONCLUSION

This study supports the concept of endosseous dental implant placement in the mandibular symphysis of type 2 diabetic patients as a predictable procedure. The results suggest that the duration of diabetes may be associated with implant failure and is in agreement with other studies, which have demonstrated that longer implants experience fewer failures.

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