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### Informed Consent Statement

Informed consent was obtained from the subjects involved in the study.

### Conflict of Interest

The authors declare no conflict of interest.

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## Original Article

# Effect of Glycemic Control on the Incidence of Dental Implant Complications in Diabetic Patients

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## Abstract

**Purpose:** This retrospective cohort study aimed to explore the impact of glycemic control on the survival of dental implants and the rates of post-loading complications in patients with well to fairly well-controlled diabetes. Although diabetes is acknowledged as a relative risk factor for dental implants, few studies have investigated the incidence of complications or implant survival in individuals with treated diabetes.

**Materials and Methods:** A total of 128 patients with 347 implants were enrolled. Patients and implants were grouped into two categories based on glycated hemoglobin (HbA1c) values in the pre- or postoperative period within two months: < 7% (well-controlled group) and 7% to < 9% (fairly well-controlled group). Comparative analyses included cumulative survival rates (CSR) and the occurrence of biological and technical complications between the two HbA1c levels.

**Results:** After six years, implant survival was 98.0% in the well-controlled group and 98.8% in the fairly well-controlled group, with no statistically significant difference observed between the two groups ( $p = .853$ ). The higher HbA1c level group exhibited a greater incidence of soft tissue complications than the lower HbA1c level group ( $p < .005$ ).

**Conclusion:** Implant therapy demonstrates predictability and satisfactory survival rates in patients with controlled diabetes. However, individuals with higher glycemic levels are more susceptible to soft tissue complications and bone loss following implant therapy.

**Keywords:** Dental implants, Diabetes mellitus, Diabetes-related complications, Glycated hemoglobin, Survival rate

## 1. Introduction

Compromises in masticatory function that lead to alterations in dietary behaviors in patients with diabetes may be an essential consideration in the overall disease management

for these patients, directly impacting glycemic control.<sup>1</sup> Therefore, oral health and, specifically, functional tooth replacement must be considered in the overall dietary and nutritional management of patients with diabetes.<sup>2</sup>

Diabetes mellitus is defined as a “group of metabolic diseases characterized by hyperglycemia resulting from defects in insulin secretion, insulin action, or both”.<sup>3</sup> Diabetes is considered a relative risk factor for dental implants as it is associated with delayed wound healing,<sup>4</sup> prevalence of microvascular disease,<sup>5</sup> and impaired response to infection.<sup>6</sup> Currently, diabetes is considered a relative contraindication to dental implant therapy, depending on glycemic control.<sup>7</sup> Consistent with these associations, hyperglycemia is shown to have adverse effects on bone formation and implant integration in animal models.<sup>8-10</sup> However, systematic reviews have shown that successful dental implant osseointegration can be achieved in diabetic subjects with good metabolic control, similar to subjects without diabetes.<sup>11-13</sup>

Clinical studies have reported highly variable implant failure rates, ranging from 0–14.4%. Most studies reported reasonable implant success rates in patients with diabetes and in non-diabetic patients.<sup>14-19</sup>

Glycated hemoglobin (HbA1c) reflects the mean blood glucose (BG) level over the previous 2–3 months and has been proposed as a diagnostic criterion for diabetes. Therefore, HbA1c monitoring has become an accepted means of assessing glycemia and is a standard part of diabetes management. Because absolute control is difficult to achieve, an acceptable level of control can be defined as an HbA1c level < 7%.<sup>20</sup>

Persons with HbA1c  $\geq 8.1\%$  show a greater maximum decrease in stability from baseline and require a longer time for healing, as indicated by the return of stability levels to baseline.<sup>18</sup> However, other studies have reported no failures in patients treated with implant-supported overdentures despite relatively elevated HbA1c values (> 9%) in the operative period, with no statistically significant differences in the success rate between the insulin-treated and non-insulin-treated patients.<sup>14</sup> Moreover, no significant difference has been observed in the implant survival rate between individuals with well-controlled (HbA1c < 7%) diabetes and controls without diabetes.<sup>16</sup>

Taken together, the varied success rates and lack of a definition of glycemic control reinforce the need for a better understanding of the influence of glycemic control on implant success in patients with diabetes.

Although implantation techniques are generally reliable, fabricating a restoration without complications is not always feasible. In the literature, complications related to implants are typically classified into two categories: technical and biological.<sup>21-24</sup> The general category of technical complications refers to any mechanical damage to the implant, implant components, and supra-structures, whereas biological complications are disturbances in implant function that affect the supporting peri-implant tissues.<sup>24</sup>

Although previous studies have evaluated peri-implant tissue in diabetic patients, few have assessed

the effects of glycemic levels on biological and technical implant complications.<sup>16,25</sup> Therefore, the present study was conducted to retrospectively investigate the effects of glycemic control on implant survival and the incidence of post-loading complications in patients with well-to fairly well-controlled diabetes.

## II. Materials and Methods

### 1. Study Design

This study was a retrospective analysis of the cumulative survival rates (CSR) and incidence of dental implant complications in patients with diabetes ( $n = 128$ ) and was approved by the Ethics Committee of Asan Medical Center (Seoul, Korea; 2014-0998).

### 2. Patient Selection and Subgroups

All patients were treated at the Department of Periodontics, Asan Medical Center, Seoul, Korea, between January 2007 and December 2010. A thorough and complete review of the medical records of the enrolled patients was performed, and all data were entered into spreadsheets (Microsoft Excel 2007, Microsoft Inc., Redmond, WA, USA).

The included patients were grouped into two categories according to the degree of glycemic control based on HbA1c values in the pre- or postoperative period within two months:  $< 7\%$  (well-controlled group) and  $7\%$  to  $< 9\%$  (fairly well-controlled group).

### 3. Collected data and Examination Criteria

The collected data included the glycemic level (HbA1c) within two months before or after implant installation, date of fixture installation, date of prosthesis delivery, date of the last visit, date of fixture removal due to failure (if any), thread exposure in follow-up radiographic images taken after at least three months of loading, soft tissue complications, chipping of the veneering material, implant fracture, crown fracture, loosening or fracture of the abutment or screw, loss of retention, and loss of access hole-filling material.

Thread exposure in radiographic images is characterized by marginal bone loss that encompasses the exposure of more than two threads in an external connection system or extends beyond the microthread region in a bone-level internal connection system.<sup>21,26</sup> Soft tissue complications were determined based on records indicating signs, such as inflammation, bleeding on probing, suppuration, hyperplasia, or dehiscence in the peri-implant mucosa. Probing pocket depth  $> 4$  mm, thread exposure during follow-up

radiographic imaging, and soft tissue complications were considered biological complications, whereas chipping of the veneering material, implant fracture, crown fracture, loosening or fracture of the abutment or screw, loss of retention, and loss of access hole-filling material were considered technical complications.

The observation period for an implant was defined as the duration between the day of prosthesis delivery and the last visit, as documented in the patient's medical records. Survival was characterized by the implant remaining in place with or without modifications. Failure was defined as a condition that necessitated implant removal.<sup>27</sup>

#### 4. Statistical Analysis

The CSR was computed using time-table survival probabilities, and the log-rank chi-square test was employed to assess and compare the survival rates between the two HbA1c level groups. The incidence of biological and technical complications among the groups was compared using Pearson's chi-square test. Statistical analysis was performed using IBM SPSS Statistics (version 22.0; IBM Co., Armonk, NY, USA), with P-values less than 0.05 indicating statistical significance.

### III. Results

#### 1. Patient Population

The study included 128 patients, with 53 females ranging from 21 to 86 years of age (mean,  $57.2 \pm 10.6$  years) at the time of fixture installation. In total, 347 implants were used in this study. Patients and implants were categorized into two groups based on HbA1c values within two months before or after implant placement. Among the 128 treated patients, 93 were in the well-controlled group (HbA1c < 7%) and received 246 implants. The fairly well-controlled group (HbA1c 7–9%) comprised 35 patients who received 101 implants. The mean observation periods after implant surgery for each group were  $27.7 \pm 16.0$  months and  $28.2 \pm 19.3$  months, respectively (Table 1).

**Table 1.** Patients, implant distribution, and observation period according to the glycemic level.

HbA1c	< 7%	7–9%
Patients ( <i>n</i> )	93	35
Implants ( <i>n</i> )	246	101
After final prosthesis (M)	$20.9 \pm 15.7$	$20.6 \pm 19.8$
After fixture installation (M)	$27.7 \pm 16.0$	$28.2 \pm 19.3$

n, numbers; M, months.

## 2. Cumulative survival rate

After six years, the CSR showed an overall rate of 98.2%. Specifically, the CSR was 98% in the well-controlled group and 98.8% in the fairly well-controlled group. No statistically significant differences between the two groups were observed ( $p = .853$ ). All implant failures in both groups occurred within the first year after surgery (Table 2).

**Table 2.** Life-table analysis of the cumulative survival rates of the two subgroups

Period (M)	Overall					HbA1c < 7%					HbA1c 7–9%				
	I	W	F	SR	CSR	I	W	F	SR	CSR	I	W	F	SR	CSR
0	347	120	2	0.993	0.993	246	84	1	0.995	0.995	101	36	1	0.988	0.988
12	225	83	2	0.989	0.982	161	50	2	0.985	0.980	64	33	0	1.000	0.988
24	140	79	0	1.000	0.982	109	71	0	1.000	0.980	31	8	0	1.000	0.988
36	61	25	0	1.000	0.982	38	16	0	1.000	0.980	23	9	0	1.000	0.988
48	36	31	0	1.000	0.982	22	22	0	1.000	0.980	14	9	0	1.000	0.988
60	5	5	0	1.000	0.982						5	5	0	1.000	0.988

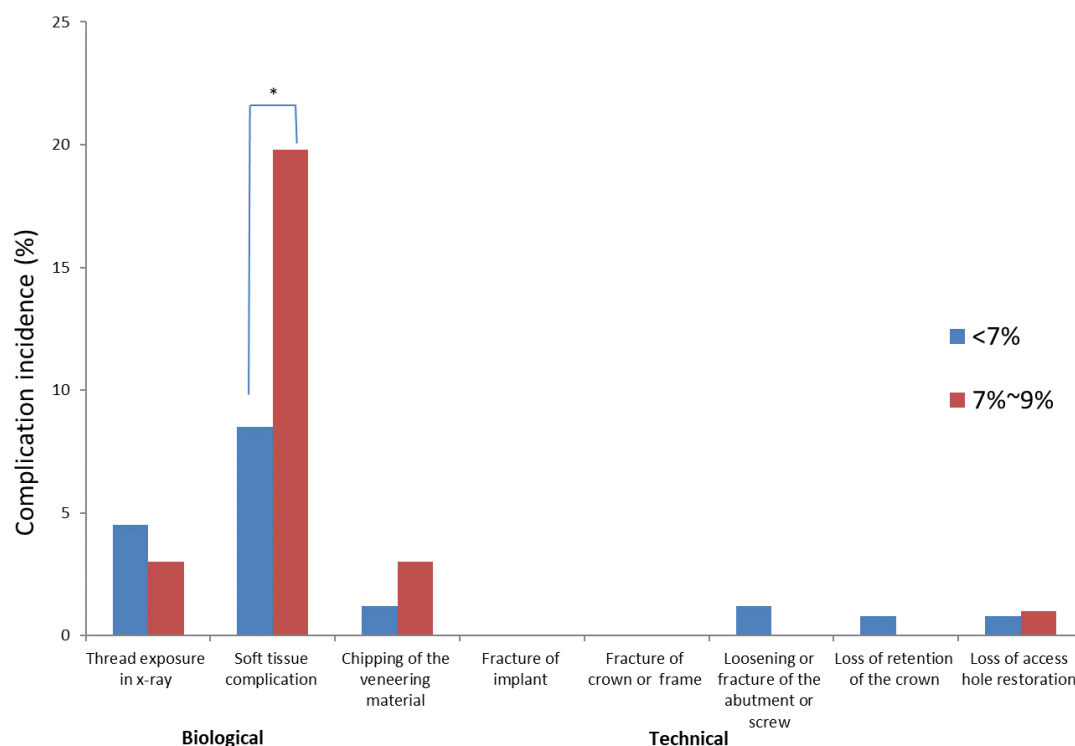
There was no statistically significant difference in the CSR between the subgroups according to the log-rank test ( $p = .853$ ). M, months; I, Initial; W, Withdrawn; F, Failed; SR, survival rate; CSR, cumulative survival rate.

## 3. Complication incidence

Table 3 presents the incidence of complications, revealing that biological complications (3–19.8%) were more prevalent than technical complications (0.8–3%) in both groups. Among all investigated complications, soft tissue had the highest incidence (8.5% in the well-controlled group and 19.8% in the fairly well-controlled group), followed by thread exposure on radiographs (4.5% and 3%, respectively),

**Table 3.** Complication incidence in the two glycemic level groups. Soft tissue complications, belonging to biological complications, occurred more often in the fairly well-controlled group.  $*p < .01$

HbA1c	<7%	7–9%	<i>p</i>
<b>Biological complications</b>			
Thread exposure in X-ray	11/246	3/101	.519
Soft tissue complication	21/246	20/101	.003
<b>Technical complications</b>			
Chipping of the veneering material	3/246	3/101	.256
Fracture of implant	0/246	0/101	
Fracture of crown or frame	0/246	0/101	
Loosening or fracture of the abutment or screw	3/246	0/101	.265
Loss of retention of the crown	2/246	0/101	.363
Loss of access hole restoration	2/246	1/101	.871



**Fig. 1.** Complication incidence in the two glycemic level groups. Soft tissue complications, belonging to biological complications, occurred more often in the fairly well-controlled group. \* $p < .01$ .

and chipping of the veneering material (1.2% and 3%, respectively). The incidence of other complications was <3% and no fractures of the implant or crown were observed. Notably, the high HbA1c level group tended towards more soft tissue complications than the low HbA1c level group ( $p < .005$ ). However, other complications did not show significant variations based on the patients' HbA1c levels, as depicted in Fig. 1.

## IV. Discussion

The present study showed satisfactory outcomes in terms of survival rates of patients with diabetes. The overall CSR after six years in patients with diabetes was 98.2%. This outcome was similar to that of a previous retrospective study performed at the same center.<sup>28</sup> This result is consistent with a previous systematic review showing that diabetes did not significantly affect implant failure.<sup>19</sup>

Most studies on the effects of diabetes on implant failure do not report a methodology for assessing glycemic levels.<sup>19</sup> Few studies have accurately reflected actual glycemic control (through HbA1C). Dowel et al. defined poorly controlled diabetes as an HbA1c > 10%, whereas Tawill et al. defined it as an HbA1c > 9%.

Recent recommendations for strict glycemic control in individuals with diabetes have targeted maximal HbA1c levels ranging from 6.5 to 7%.<sup>29</sup> Most studies have shown that implant therapy in patients with diabetes is predictable, provided that these patients fall within a controlled range of glycemic levels. The majority of treated diabetic patients can be well-controlled with insulin or oral hypoglycemic agents.<sup>12,16,19</sup> Therefore, we included controlled diabetic patients with HbA1c  $\leq$  9% in the perioperative period.

In our investigation of the impact of glycemic control on implant failure, we found CSR of 98% and 98.8% in the well-controlled and fairly well-controlled groups, respectively. These outcomes are consistent with those of previous studies.<sup>16,30,31</sup> Interestingly, our observations suggest that glycemic levels do not significantly influence implant success in patients with diabetes. Previous studies have also failed to find a statistically significant difference in implant survival based on HbA1c levels and concluded that HbA1c is the most important factor affecting implant complication rates.<sup>16,18,32</sup>

Previous studies investigating the effects of diabetes on implant complications have focused on osseointegration, implant failure, and peri-implant bone loss.<sup>12,19,25,33,34</sup> However, few studies have compared the biological and technical complications in diabetic patients with different glycemic levels.

Functional complications of the dental implants were categorized based on the criteria established by Misch and Wang,<sup>24</sup> ensuring the applicability of our data for future systematic reviews or meta-analyses. In this study, we concurrently explored both the biological and technical complications within the identified categories. Notably, soft tissue complications exhibited the highest frequency among patients with diabetes, particularly in the subgroup with elevated glycemic levels.

The heightened occurrence of soft tissue complications in the patient group with elevated glycemic levels may be attributed to the accumulation of advanced glycation end products. These end products irreversibly accumulate on the vessel walls, resulting in vascular complications and altering the phenotype of immune cells. Consequently, this increases susceptibility to infection, vascular changes, and impaired healing.<sup>35</sup> Several animal studies have demonstrated a more persistent inflammatory response that may increase osteoclastic activity in a hyperglycemic state.<sup>36,37</sup> A previous prospective study showed that HbA1c values were related to postoperative complications, peri-implantitis, and peri-implant bone loss.<sup>16</sup> The meticulous control of glucose levels through intensive insulin therapy in the perioperative period has significantly reduced postoperative complications. A recent prospective study demonstrated that bleeding upon probing showed a statistically significant increase with higher HbA1c levels and that marginal bone loss increased with an increase in HbA1c levels.<sup>25</sup>

Considering the findings of these studies, we propose that soft tissue complications, including indicators of inflammation, bleeding on probing, and suppuration in the peri-implant mucosa, may be correlated with glycemic levels in patients with diabetes.

In both groups, all instances of failure were early failures within the first year and were linked to incomplete osseointegration. No implants were removed because of implant fixture fractures. Consistent with animal studies on the effects of hyperglycemia on implant osseointegration,<sup>38,39</sup> human studies identified significantly compromised implant integration in patients with diabetes.<sup>30</sup>

The second most common complication was implant thread exposure on radiographs, categorized as a biological complication. Recent systematic reviews have reported that the cumulative complication rate of > 2 mm of bone loss in implants was 5.2%,<sup>40,41</sup> and two other systemic reviews have shown marginal bone loss rates of 2.6% and 5.7%.<sup>41,42</sup> In our previous studies conducted at the same center, thread exposure in radiographs showed an incidence of 2.3%.<sup>28</sup> In this study, the thread exposure rate among all diabetic patients was 3.8%, with an incidence of 4.5% in the well-controlled group and 3% in the fairly well-controlled group. Although the incidence was slightly higher in the lower glycemic level group, the difference was not statistically significant. A previous prospective study showed that marginal bone loss increased with an increase in HbA1c levels.<sup>25</sup> Other studies found an increase in alveolar bone loss in patients with diabetes.<sup>12,43</sup>

Regrettably, there is a lack of prior studies comparing technical complication rates among patients with diabetes with varying glycemic levels. Chipping of the veneering material had incidences of 1.2% and 3% in the well-controlled and fairly well-controlled groups, respectively. The incidence of other technical complications was < 1.5%. No fractures involving the implant or crown were observed. Taken together, these results did not indicate a significant association between glycemic levels and the technical complications of implants.

## V. Conclusion

Despite the limitations inherent to this retrospective study, implant therapy in patients with controlled diabetes has demonstrated predictability and satisfactory survival rates. However, individuals with diabetes with higher glycemic levels exhibit heightened susceptibility to soft-tissue complications and bone loss following implant placement. Consequently, the management and treatment of periodontal infections should be considered crucial components in the comprehensive care of patients with diabetes, as they play a significant role in ensuring the success of implant therapy.

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