Long-term clinical and radiographic evaluation of a novel implant design: A retrospective study

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Abstract _

Background: The overall outcomes of an implant system with a novel implant design featuring a machined collar to reduce biofilm accumulation, crestal microthreads for crestal bone maintenance, a tapered form with reverse sharp buttress threads to establish primary stability, and a surface treated with resorbable blast media to promote osseointegration has previously been evaluated in a 2-year retrospective study. This study aimed to assess long-term clinical performance of this implant system with respect to success rate, survival evaluation, and mean bone loss (MBL).

Materials and Methods: A total of 327 implants were placed in 117 consenting patients from 2015-2021 and were retrospectively evaluated; the removed implants and

the surviving implants with radiographic follow-up gave a total of 238 implants which were ultimately included in this study. Success rates, as well as MBL, were assessed.

Results: Our study revealed that, over the 6-year period, a success rate of 96.2% was obtained. An overall MBL of 0.6 ± 0.753 mm was observed; MBL was significantly lower in implants restored with a single crown than those restored with either a short-span or full-arch bridge (0.46 ± 0.63 mm vs. 0.94 ± 0.87 mm, 0.92 ± 0.94 mm; p<0.01).

Conclusion: Treatment with the Glidewell HT™ Implant System (formerly the Hahn™ Tapered Implant System) provides reliable outcomes with high success and survival rates as well as maintenance of crestal bone height.

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Introduction _

The Hahn™ Tapered Implant System was introduced to the market in 2015 and has gained wide acceptance in the ensuing years. Now branded as the Glidewell HT™ Implant System, the design features a 1 mm machined collar to reduce biofilm accumulation and 1 mm crestal micro-threads to aid in maintaining the integrity of the marginal bone during functional loading.1 The implant surface is treated with Resorbable Blast Media (RBM), which provides a moderately rough surface using a biocompatible calcium phosphate material. This moderately roughened surface has been shown to promote osseointegration by increasing the bone to implant contact ratio.^{2,3} The shape and design of the implant including its tapered form with reverse sharp buttress threads, dual self-tapping grooves, crestal micro-threads, and platform-shifted abutment connection help establish primary stability and maintain crestal bone levels.4-6

Determining the long-term stability of the marginal bone levels is an important component of determining success rates. The first to include this set of criteria for implant success was Schnitman et al., who determined that for an implant to be a success, the bone loss should not be greater than one-third of the vertical height of the existing bone.7 Adell et al. released a 15-year study on osseointegrated implants and obtained a 1.5 mm mean bone loss for the first year and after that 0.1 mm bone loss per consecutive year.8 Cranin et al. stated that there should be a lack of crestal V-shape loss or saucerization and no widening of the peri-implant space on the radiographs.9 Not long after that, Albrektsson et al. stated that a 1 mm mean bone loss after the first year of placement on asymptomatic implants was considered acceptable; after that, less than 0.2 mm/ year of mean bone loss is expected. 10 Papaspyridakos et al.11 concluded that success should ideally be based upon the implant-prosthetic complex as a whole.

It is crucial to differentiate between the concepts of survival and success. Implant survival refers to implants that are in situ at the time of examination, whether or not they have been prosthetically loaded. In contrast, implant success denotes that the implants are not only in situ but are also functionally loaded.¹² Pjetursson has released two systematic reviews of survival and complication rates covering approximately forty-five years. The most recent review found no difference between survival rates in retrospective and prospective studies, and that after 5-years, there was a 95.6% survival rate of the implant-supported fixed prosthesis.¹³ The present study determined success rates, because all the implants followed had been fully restored.

This study is a continuation of a two-year retrospective evaluation⁶ published in 2018, with continuing follow-up on the cases from that study, as well as follow-up of subsequent cases. The objective of this report is to evaluate the long-term clinical performance and radiographic outcome of this novel implant design with respect to type of prosthesis placed, crestal bone loss, and medical conditions observed for patients treated at one clinic.

Materials and Methods

327 Glidewell HT Implants with various diameters and lengths were placed in 117 patients between April 2015 and April 2021 at one clinic by six dentists. Follow-up intraoral radiographs were taken to evaluate the interproximal bone surrounding the implants. The radiographs were taken using a Nomad Pro™ handheld X-ray system (Aribex, Inc.; Charlotte, N.C.) set at 60 kVp and 2.5 mA, using the parallel technique. All patients treated during this time span were evaluated, but only implants with at least one annual intraoral radiographic follow-up and which had received the final restoration were included in the crestal bone loss evaluation. All removed implants were included to evaluate the overall success and survival rate, regardless of whether they had radiographic follow-up. From the 327 implants, 89 were excluded for having either a follow-up period of less than one year or intraoral radiographs of insufficient quality for evaluation. Thus, 238 implants placed in 101 patients were included in this study (Figure 1).

For crestal bone loss evaluation, the intraoral radiographs evaluated were the immediate post-surgical image and the most recent follow-up. To be included in our analysis, the threads of the implants were required to be visible on both

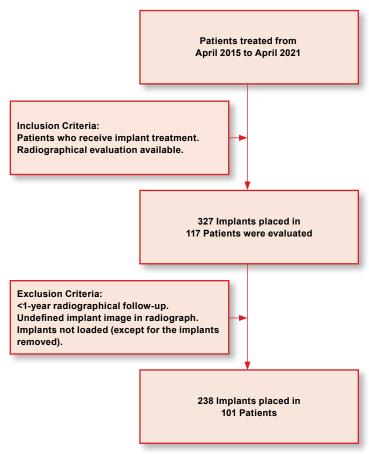


Figure 1: Flowchart illustrating the evaluation process and study design.

the distal and mesial of the implant. Bone loss was evaluated using the DEXIS™ dental imaging software. The implant diameter was used to calibrate the image dimension with a magnification factor of 1.0 to not apply any magnification correction to the calibrated image (Figure 2-A). The linear distance from the implant shoulder to the first contact of bone to implant was measured on both the mesial and distal side, as observed in Figure 2-B. Measurement of the radiograph was repeated at a one-week interval to increase the reliability of the measurements and the mean measurements were used for the analysis. The Mean Bone Loss (MBL) was established as the difference between the measurements of the initial post-operative intraoral radiograph and the most recent follow-up radiograph. MBL was also evaluated in relation to placement site and type of final restoration.

Implant survival was determined by the presence of an implant in situ at the follow-up. Meanwhile, implant success was determined by: (1) functional implant supporting a definitive restoration; (2) asymptomatic implant in situ; and (3) absence of continuous radiolucency surrounding the implant.

The statistical analysis used for this study was performed through IBM SPSS Statistics for Windows (version 21.0.0.0; IBM Corp., Armonk, NY, USA). To determine the relationship between the tested parameters, a Log Rank (Mantel-Cox) and Pearson's r analysis were carried out; a P-value was considered significant if p < 0.05 and p < 0.01 respectively. A Kaplan-Meier survival analysis was used to determine the cumulative survival of implants placed over the course of 6 years, as well as survival rates with respect to the implant site and length.

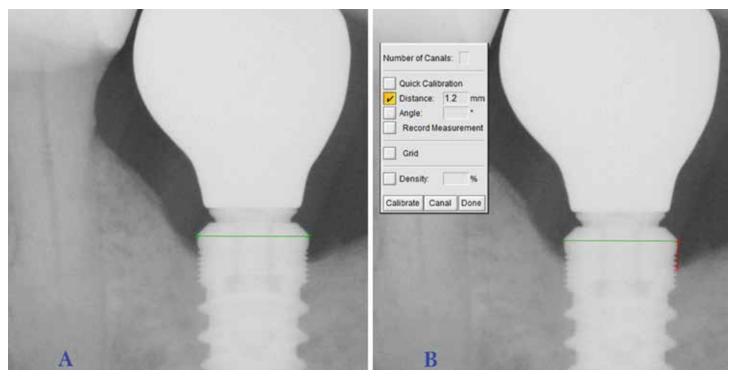


Figure 2: A - Radiograph depicting the calibration of the implant by measuring the diameter at the implant shoulder (green line). B - Bone loss measurement (red line) from the implant shoulder to the first contact of bone to implant.

Results

A total of 101 patients with a mean age of 44.9±12.8 were evaluated; 48 males and 53 females were assessed in this study (Table 1). From the 101 included patients, 47 patients were affected by medical conditions, with high blood pressure being the most frequently observed (Table 2).

Table 1. Patient Demographics.

Description	Age	Std. Deviation	Subjects
Overall Mean Age	44.9	12.80	101
Mean Age (Males)	44.4	12.78	48
Mean Age (Females)	45.8	11.85	53

Table 2. Descriptive data of the medical conditions affecting the included patients.

Medical Conditions	Subjects affected	No. of Implants
Smoking	5	12
Diabetes	6	15
High Blood Pressure	23	60
Gastroesophageal reflux disease	3	11
Thyroid Disorder	7	17
Chemoradiotherapy	2	4
Epstein Barr Virus	1	4
Total	47	123

The overall cumulative survival rate for the six-year follow-up period for the 238 evaluated implants was 96.2% (Figure 3). The Kaplan Meier analysis was used to calculate the overall cumulative survival rate as well as the survival rate regarding the implant site and length (Table 3). However, the Log Rank test of equality of survival distribution showed no statistically significant differences in the survival rates for the different implant sites and implant lengths (Table 4).

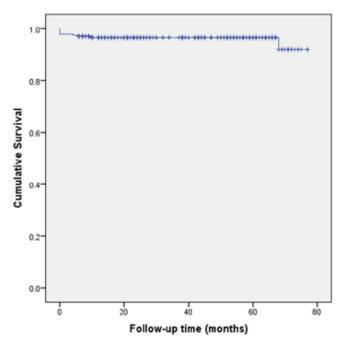


Figure 3: Cumalative survival rate of the implants according to the Kaplan-Meier survival analysis plot.

Table 3. Kaplan-Meier survival analysis results.

	Mariable	Implanta	Failed	Survival Analysis	
	Variable	Implants	Implants	N	Percent
Implant Site	Posterior Maxilla	86	6	80	93.0%
	Anterior Maxilla	42	1	41	97.6%
	Posterior Mandible	93	1	92	98.9%
	Anterior Mandible	17	1	16	94.1%
Implant Length	8mm	39	3	36	92.3%
	10mm	53	3	50	94.3%
	11.5mm	85	2	83	97.6%
	13mm	51	1	50	98.0%
	16mm	10	0	10	100.0%
Overall		238	9	229	96.2%

Table 4. Log Rank (Mantel-Cox) test of equality of survival distributions.

Variables evaluated	Chi-Square	df	Sig.
Implant site	4.184	3	.242
Implant length	3.666	4	.453

*Significance level p < 0.05.

There were nine failed implants observed in eight patients, distributed almost equally between genders and with ages ranging from 28 to 62 years old. 67% of the failed implants were located in the posterior maxilla, with 78% of the failed implants placed free-hand and 22% placed using a digitally guided template. Fewer than 60% of the failed implants received a bone graft, and almost half were removed before the first month after placement (Table 5).

Table 5. Specifical	tions of the nine falled	implants inclu	ded in th	his study			
Implant diameter & length	Location	Medical Conditions	Age	Sex	Surgical placement	Bone graft	Time of failure (months)
Ø3.5 x 8mm	Posterior Mexilla	None	62	м	Free-hand	Yes	4
Ø3.5 x 10mm	Anterior Maxilla	None	62	м	Free-hand	Yes	10
Ø3.5 x 11.5mm	Posterior Mexilla	Diabetes	39	F	Guided	No	68
Ø4.3 x 10mm	Posterior Maxilla	EBV	53	F	Free-hand	Yes	6
Q4.3 x 11.5mm	Posterior Mandible	None	38	F	Free-hand	No	0
Ø4.3 x 13mm	Anterior Mandible	HBP	60	м	Guided	No	0
Ø5.0 x 8mm	Posterior Maxilla	None	28	м	Free-hand	Yes	0
Ø5.0 x 10mm	Posterior Medilla	HBP/CRT	38	F	Free-hand	No	0
Ø7.0 x 8mm	Posterior Maxilla	None	39	м	Free-hand	Yes	0

HBP, High blood pressure; EBV, Epstein Barr Virus; CRT, Chemoradiotherapy; M, Male; F, Fernale.

Crestal bone levels were evaluated for 229 implants, with failed implants excluded from MBL measurements. Overall MBL of 0.6±0.753 mm was obtained, and a normal distribution in relation to the frequency can be seen in Figure 4.

MBL was assessed relative to the implant site and type of final restoration (Figure 5). Several instances of increased bone height at the implant crest are indicated by a negative value for MBL, as seen in Table 6 and depicted on both mesial and distal of the implant in Figure 6. No significant correlation was found between MBL and the implant site. While implants in the anterior mandible showed the highest MBL (1.095 mm) among the four assessed sites, the finding was not statistically significant (Table 7). MBL was similar in the posterior maxilla and mandible, with a measurement of 0.554 mm and 0.529 mm, respectively. There was a significant positive correlation between MBL and the type of final restoration. Almost 70% of the implants were restored

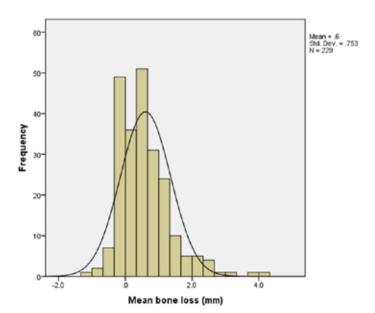
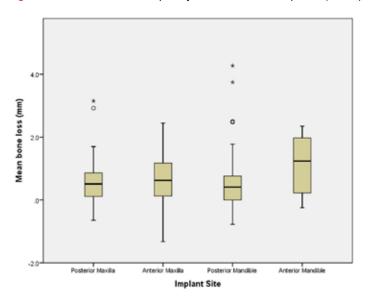


Figure 4: Mean bone loss frequency of the evaluated implants (n=229)



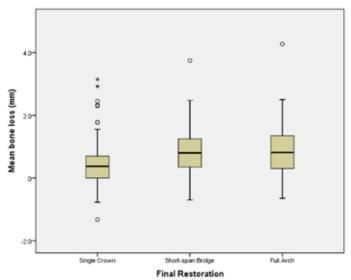


Figure 5: Mean bone loss box plots in relation to Implant site and Final restoration.

with a single crown, and this group showed the lowest MBL among the three types of final restorations used. Implants restored with short-span bridges and full-arch fixed restorations showed similar MBL of 0.935 mm and 0.924 mm, respectively. However, the highest MBL of 4 mm was seen on only two implants, one of them restored with a short-span bridge and the other with a full-arch bridge.

Table 6. Results obtained from the Mean bone loss evaluation.

Variable	Implants	MBL	Value (mm)
Posterior Maxilla	80	Mean	.554
		Std. Deviation	.6409
		Minimum	7
		Maximum	3.2
Anterior Maxilla	41	Mean	.679
		Std. Deviation	.7866
		Minimum	-1.3
		Maximum	2.5
Posterior Mandible	92	Mean	.529
		Std. Deviation	.7739
		Minimum	8
		Maximum	4.3
Anterior Mandible	16	Mean	1.095
		Std. Deviation	.9185
		Minimum	3
		Maximum	2.4
Single Crown	158	Mean	.458
		Std. Deviation	.6307
		Minimum	-1.3
		Maximum	3.2
Short-span Bridge	37	Mean	.935
		Std. Deviation	.8606
		Minimum	7
		Maximum	3.8
Full Arch	34	Mean	.924
		Std. Deviation	.9393
		Minimum	7
		Maximum	4.3
Overall MBL	229	Mean	.604
		Std. Deviation	.7527
		Minimum	-1.3
		Maximum	4.3

MBL, Mean bone loss; mm, Millimeters.

Table 7. Pearson correlation between MBL, implant site, and final restoration.

Variable	N	Pearson Correlation	Significance (two-tailed)
Implant Site	229	.075	.260
Final Restoration	229	.268"	.000

^{**.} Significance level p = 0.01 (two-tailed); MBL, Mean bone loss



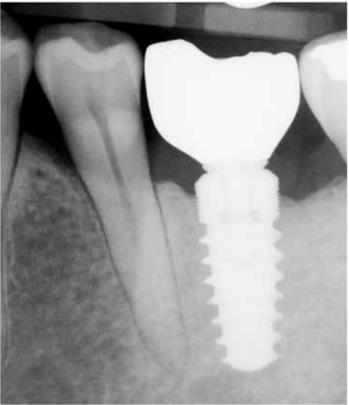


Figure 6: Post-op and follow-up radiograph exemplifying the increase of crestal bone height.

Discussion

After six years of clinical follow-up, the cumulative implant survival rate found in this study of the Glidewell HT Implant System was 96.2%. This result compares quite favorably with other studies with similar follow-up times which have reported survival rates that range from 93% to 95.6%. ^{10,13} Furthermore, implant success, determined by an asymptomatic implant in situ with its respective final restoration and absence of continuous radiolucency surrounding the implant, was also found to be 96.2%. We anticipate that clinicians will find this type of data to be useful in order to confidently inform patients of the expected success rate of the implant to be used.

The most significant limitation of this study is the usage of intraoral X-rays to assess the interproximal crestal bone levels. As a two-dimensional diagnostic tool, it does not accurately measure the buccolingual bone level, which is a crucial determinant of implant longevity. However, this is currently the diagnostic tool of choice because of low radiation exposure and cost.¹⁴ The correlation found between MBL and the type of final restoration is shown by the smaller mean bone loss found on implants loaded with a single crown than those receiving short-span or full arch bridges. This result is similar to that reported by Alhammadi et al., where the mean marginal bone loss of implants with short-span bridges was greater than that on single implant-supported crowns.¹⁵

Retrospective studies carry several inherent downsides; this study had incomplete medical histories and missing follow-up radiographs reducing the usable sample size. We were unable to control for several variables including age, health (e.g., smoking, periodontal disease), bone quality, bone augmentation procedures, and treatment procedure for each patient. A prospective controlled study with adequate medical and dental history collection should be considered to expand on the current analysis.

Conclusion

This six-year study demonstrated that Glidewell HT Implants have a high success rate of 96.2% and maintained crestal bone levels with an overall MBL of 0.6 mm. Within the limitations of this retrospective study, the results obtained suggest that Glidewell HT Implants are a successful and reliable implant system for the replacement of missing teeth.

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