Long-Term Bone Stability around 312 Rough-Surfaced Immediately Placed Implants with 2–12-Year Follow-Up

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ABSTRACT

Purpose: The purpose of this study was to retrospectively evaluate bone stability around implants with anodic oxidized surfaces and correlate this with variables compared in a previous study.

Materials and Methods: A total of 312 implants with anodic oxidized surfaces were separated from a pool of 1,187 implants placed immediately following tooth extraction. Radiographs made at the time of implant placement were compared to radiographs taken at 2–12 years' follow-up. An independent radiologist used the known distance (mm) between peaks of adjacent threads to calculate actual bone loss measurements. Measurements were evaluated by thread of bone fill on both the mesial and distal of each implant. If <50% of the thread had bone fill, the entire thread was assumed devoid of bone. All 312 implants were measured and a Mann–Whitney rank-sum test performed to test the significance of differences in mean bone loss relative to the factors studied.

Results: The overall mean bone loss of the 312 implants was 0.4 mm (± 0. 80 mm) over a 2–12-year follow-up period with a mean duration of 7.4 years. Bone measurements in 95.5% of the implants were performed 6 years or more post-placement. Bone loss of <1.5 mm was found in 92% of implants. No statistically significant differences were seen in mean bone loss by gender, smokers versus non-smokers, tooth position (except for molars), or immediately loaded or immediate tooth replacement versus two-stage implants. Parameters that demonstrated statistically significant differences were splinted versus non-splinted implants, molars in maxilla versus mandible, regular (3.75–4.0 mm diameter) versus wide (5.0–6.0 mm diameter) platforms, and anodic oxidized surfaces versus other implant surfaces studied.

Conclusions: The mesial–distal bone loss of anodic oxidized surface (TiUnite) implants over a 2–12-year period (mean 7.4 years) was significantly less compared with machined implants placed with the same immediate implant placement protocol (0.4 mm vs 0.6 mm). Although several variables showed statistically significant differences in bone loss, the clinical significance could be questioned, as the maximum mean bone loss was 0.3 mm or less when comparing the various factors. The procedures used to place the implant and the strict maintenance protocol appear to be important aspects of the overall long-term success reported in this study in terms of measuring marginal bone loss around immediately placed implants.

KEY WORDS: anodic oxidized surface, immediate implant placement, marginal bone loss, smokers, splinted implants, wide-platform implants

INTRODUCTION

Immediate implant placement (IIP) into an extraction socket has been reported to be a predictable option for patients receiving implant-supported restorations.[1–4] Advantages of this procedure as compared with delayed implant placement have been described and include decreases in number of surgical visits, time in treatment, and cost to patients.[5–7] Two long-term retrospective studies have evaluated immediate implant placement into fresh extraction sites.[8,9] The first evaluated the survival rate over a period of 1–16 years for 1,925 consecutively placed implants. The second study evaluated the

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mesial–distal bone stability of these implants over a period of 1–22 years.

In the first study, the overall survival rate was 96%. When comparing the survival rate of machine-surfaced implants (1,398) to roughened-surface implants (527), there was a statistically significant difference in favor of roughened-surface implants (4.6% to 2.3%, $p = .02$).[8]

In the later study, the mean bone loss for all implants followed for 1–22 years (mean follow-up time 10.18 years) was 0.5 ± 0.8 mm.[9] One of the factors that showed a correlation to bone stability was surface morphology, with machined implants ($n = 873$) demonstrating an increased mean bone loss (0.6 ± 0.8 mm) compared with roughened-surface implants ($n = 314$; 0.4 ± 0.8 mm) ($p = .005$). Of the 314 rough-surface implants, 312 had an anodic oxidized surface (AOS) and were TiUnite implants manufactured by Nobel Biocare (Göteborg, Sweden). As there were a large number of implants with the same surface, these implants were segregated and evaluated as a separate group. The purpose of the current study was to evaluate bone stability around implants with an AOS and correlate this with the same variables that were included in the previous study.

MATERIALS AND METHODS

Three hundred and twelve implants with the AOS were separated from the total of 1,187 evaluated in the original study.[9] None of the 312 AOS implants in the previous study were lost for evaluation in the present study. The protocol for inclusion and method of evaluation were similar to that study. To briefly review, all patients were surgically treated in the same periodontal practice, and data associated with their care were collected and included in this study. All implants were consecutively placed. As all implants were placed into an immediate extraction socket, a bone graft was used both to fill the space around the implants and to widen the ridges where necessary. The sockets were overfilled over the top of the implant, as resorption and shrinkage are expected with all bone graft materials. All treatments were carried out within the Helsinki Accords (2000).[10] The evaluations were performed in a private practice setting. All data were open to external evaluation.

The data collection method utilized the software programs Implant Tracker, LLC, West Hartford CT. Patients included in the study consisted of 179 females (57.4%) and 133 males (42.6%), and 95.5% of the implants were followed for 5–12 years after implant placement. The parameters considered included implant diameter (regular-platform [3.75–4.0 mm] vs wide-platform [5.0–6.0 mm]), implant surface, patient age at the time of implant insertion (<50 or >50 years old), gender, and anatomic location of the implant. These parameters were assessed in the present study relative to changes in bone height to determine any correlation between bone change and the aforementioned variables. In addition, differences in several other variables were evaluated, including smokers (more than half a pack per day) versus nonsmokers, implants that were free-standing versus splinted, bone loss between years 2 and 12, and implants immediately loaded with provisional restorations versus two-stage implants. Comparisons were made with the results of the previous study by segregating the AOS implants from all other implants studied (machined and other surfaces) and evaluating the AOS implants as a separate group.

Radiographs were taken at the time of implant placement, and follow-up radiographs were taken upon patient return to the surgical practice or restorative practice, as well as in succeeding years during maintenance visits. Final recorded measurements were made relative to the top of the first thread of the implant as the reference point. Changes in bone height relative to the reference position were calculated. All radiographs were evaluated by an independent oral and maxillofacial radiologist who was not part of the study. Bone change was measured as an absolute figure. In the present study, these measurements are reported in millimeters based on the known distance between the peaks of the threads per the manufacturer's specifications. Hence, a ratio was developed, with the known peak-to-peak distance relative to the measured peak-to-peak distance as viewed on the radiograph allowing the actual bone level in millimeters to be calculated. As in the previous study, using the known distance of 0.8 mm between the peaks of adjacent threads with wide-diameter implants (5.0 or 6.0 mm) and 0.6 mm for regular-diameter implants (3.75 or 4 mm), a determination was made of the magnitude of bone level that was present after the implants were placed in function by calculating the amount of bone filling the thread. In order to properly access the bone between the threads, the radiologist magnified each radiograph. Measurements were then evaluated by half-thread of

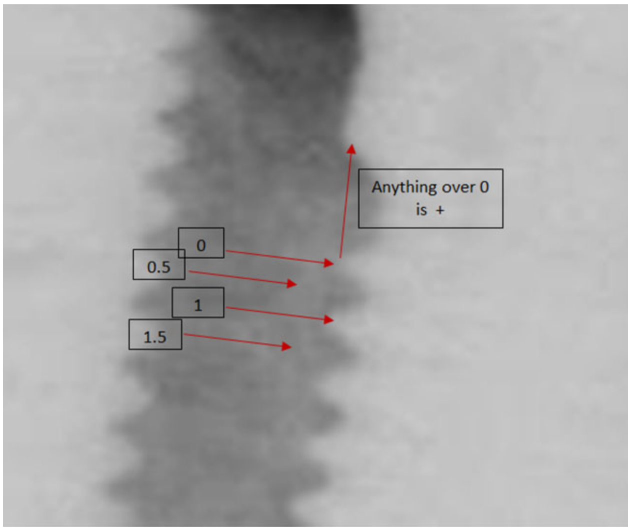

Figure 1 Radiologist calibrations by 0.5 mm thread filled with bone. All bone loss measurements were calibrated by the same radiologist.

bone fill (Figure 1). If <50% of the thread had bone fill, the thread was assumed devoid of bone. These known distances provided measurements that allowed an accurate assessment on each separate radiograph, regardless of differences in angulation or magnification of the radiographs (Figures 2–4).[9] Bone above the top of the first thread was considered as being level with the top of the first thread. As no accurate calculation for bone gain above the first thread could be made, bone gain in all cases was recorded as zero bone loss.

A Mann–Whitney rank-sum test was performed to test the statistical significance of differences in average mean bone loss relative to the factors studied. Statistical analysis was performed using standard statistical software (SAS Institute, Cary. NC, USA), and a p value of less than .05 was established as the threshold for

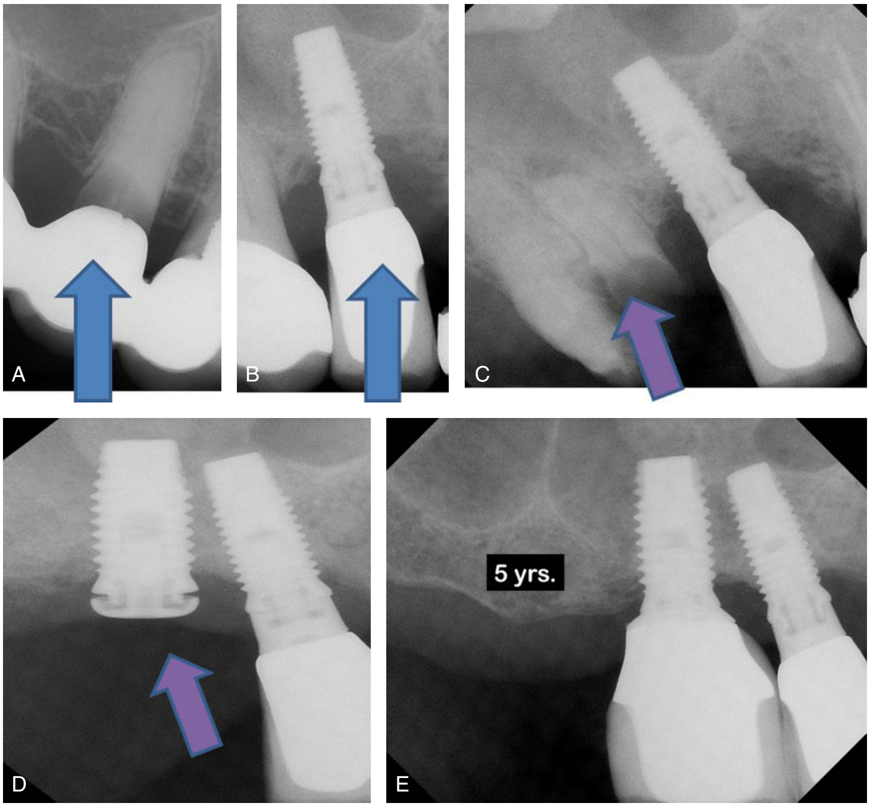

Figure 2 *A*, Maxillary right second bicuspid was decayed and extracted. There is minimal distance to the sinus and a wide root. *B*, Radiograph taken at the time of placement of final restoration. There is 0.6 mm loss on the mesial and 0.0 mm loss on the distal. *C*, Radiograph taken of the bicuspid 4 years later. The distal molar was now hopeless and had to be removed and replaced with an immediate implant. *D*, A wide-body implant was placed with an internal sinus lift and bone augmentation. This radiograph was taken after 6 months' healing of the implant. *E*, The patient was recalled for radiographic evaluation 5 years after the placement of the molar and 9 years after the placement of the bicuspid. The molar exhibited 0.0 mm bone loss on both the mesial and distal aspects. The bicuspid had 0.6 mm loss on the mesial aspect and 0.6 mm on the distal. All bone loss measurements were calibrated by the same radiologist.

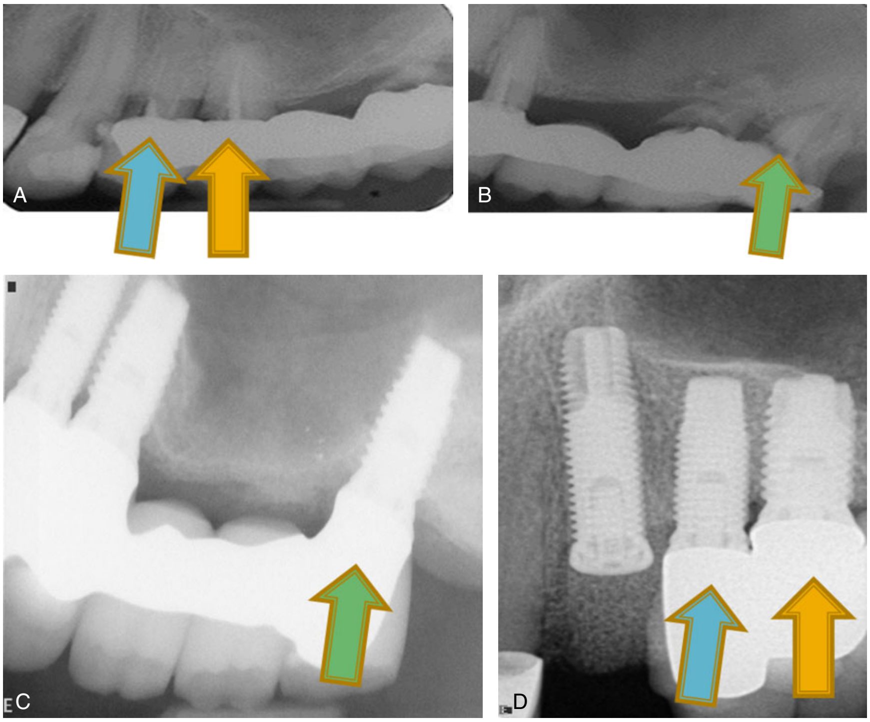

Figure 3 *A* and *B*, The failing fixed restoration on the maxillary left bicuspids and molars and abutments were removed. Note the close proximity of the maxillary sinus around abutment teeth. *C*, Three implants were placed in both bicuspid areas and the distal molar position. All were placed with an internal sinus lift and bone augmentation. The radiograph was taken 3 years post-insertion. The molar exhibited 0.0 mm bone loss on the mesial and distal aspects. *D*, The patient returned 9 years after implant placement to replace the failing maxillary cuspid. This radiograph demonstrates the bone heights around the original implants. There was 0.0 mm bone loss on both the mesial and distal aspects of the second bicuspid. The first bicuspid had 0.0 mm bone loss on the mesial aspect and 1.5 mm bone loss on the distal. All bone loss measurements were calibrated by the same radiologist.

statistical significance. All statistical analysis was performed by an independent statistician.

RESULTS

The overall mean bone loss of the 312 implants was 0.4 mm (± 0.8 mm) over a 2–12-year follow-up period with a mean duration of 7.4 years (Table 1). Base measurements in 95.5% (298) of the implants were performed 6 years or more post-placement, while 4.5% (14) were calculated 1–5 years post-placement. Bone loss of <1.5 mm was found in 92% of implants (Table 2) .

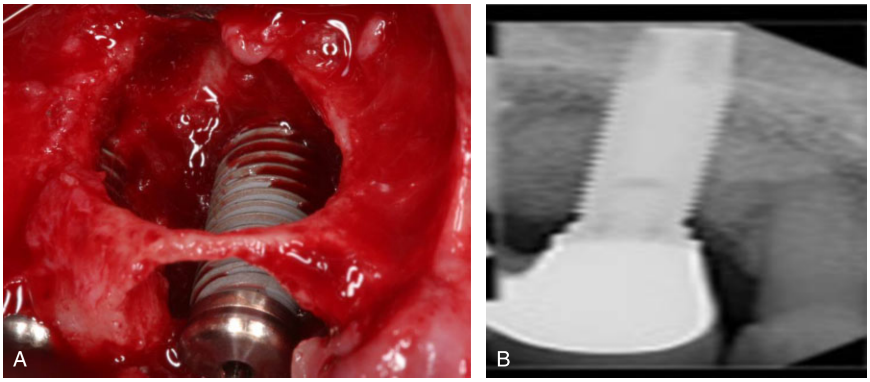

Figure 4 *A*, Significant bone loss existed secondary to removal of an infected tooth. The implant was immediately placed and was stabilized following extraction. Bone augmentation was performed around the implant. *B*, The patient was recalled 6 years after placement of the implant. Bone stability is apparent in this magnified radiograph. The cuspid demonstrated 0.0 mm bone loss on the mesial aspect and 0.6 mm bone loss on the distal. All bone loss measurements were calibrated by the same radiologist.

TABLE 1 Mean Bone Loss from the Time of Implant Placement of the 312 Implants

Mean bone loss (mm)	0.4
Standard deviation	0.8
n	312

Several of the parameters evaluated did not demonstrate statistically significant differences in bone loss, including the following:

- Anterior versus posterior implants ($p = .23$)
- Mean bone loss by tooth position between the maxilla and mandible (for incisors, cuspids, and bicuspids) ($p \geq .05$)
- Mean bone loss in smokers versus nonsmokers ($p = .40$)
- Mean bone loss between years 1–4, years 5–8, and years 9–12 ($p = .35$)
- Bone loss by gender ($p = .82$)
- Immediate loading or immediate tooth replacement versus two-stage implants ($p = .35$)

Those parameters that did demonstrate statistically significant differences were the following:

- Single versus splinted implants (Table 3) ($p = .23$)
- In molars between maxilla and mandible (Table 4) ($p = .0006$)
- Bone loss between years 10 and 11 and compared with other years (Table 5) ($p = .02$)
- Regular-platform (3.75–4.0 mm diameter) versus wide-platform (5.0–6.0 mm diameter) implants (Table 6) ($p = .007$)

TABLE 2 Bone Loss around Implants

Bone Loss (mm)	Number of Implants	%
0	151	48.4
0.5	84	26.9
1	40	12.8
1.5	12	3.8
2	9	3.0
2.5	5	1.6
3	5	1.6
3.5	1	0.3
4	2	0.6
5	3	1.0
Total	312	100

Most implants (92%) demonstrate 1.5 mm or less bone loss.

TABLE 3 Comparison of Bone Loss around Single versus Splinted Implants

Type	Number	Mean (mm)	SD (mm)	*p**
Single	72	0.30	0.65	0.023
Splinted	240	0.5	0.8	

*Mann–Whitney rank-sum test.

- Comparison of anodic oxidized surfaces versus all other implants (machined and Osseotite surfaces) included in the previous study (Table 7) ($p = .001$)

In evaluation of bone loss by years using the Kruskal–Wallis test, there was no statistically significant difference in bone loss between the years in function, with the exception of years 10 and 11, which demonstrated increased bone loss when compared with all other years (1.5 and 1.9 vs <0.6 mm). A comparison of regular-platform implants (3.75 and 4.0 mm diameters; $n = 236$) was made with wide-platform implants (5.0 mm diameter; $n = 76$), demonstrating more bone loss around the wider implants ($p = .007$). Implants that were splinted ($n = 240$) demonstrated increased bone loss when compared with single implants ($n = 72$) ($p = .0023$) by the Mann–Whitney rank-sum test. Comparison of bone loss by tooth position (anterior vs posterior) when evaluating the maxilla versus the mandible showed no statistically significant differences in comparison of incisors, canines, and bicuspids. There was, however, a statistically significant difference between maxillary and mandibular implants when comparing molars ($p = .0006$).

The bone loss associated with implants with an anodic oxidized surface compared with other implants (Nobel and Biomet 3i machined and Biomet 3i Osseotite implants) was calculated. To evaluate this, the authors went back to the original study of bone loss around implants and removed all of the AOS implants from the

TABLE 4 Comparison of Bone Loss between the Maxilla and Mandible in Molars

Tooth Positions	Jaws	Number	Mean (mm)	SD (mm)	*p**
Molars	Mandible	52	0.3	0.7	.0006
	Maxilla	52	0.6	0.9	

*Mann–Whitney rank-sum test.

TABLE 5 Comparison of Bone Loss by Years after Implant Placement

Years after Implant Placement	Number	Mean (mm)	SD (mm)	*p**
2	1	0.6	NA	.02
3	1	0	NA	
4	2	0.3	0.4	
5	10	0.5	0.7	
6	59	0.2	0.5	
7	96	0.5	0.9	
8	83	0.4	0.7	
9	50	0.3	0.6	
10	3	1.5	1.5	
11	6	1.9	1.5	
12	1	0	NA	

*Kruskal–Wallis test.
NA, not applicable.

original database. The bone loss around all implants in that study for all parameters was compared with the AOS implants in the current study. The Mann–Whitney rank-sum test showed there was less bone loss around the AOS implants when compared with non-AOS implants ($p = .0011$).

DISCUSSION

The result obtained in the present study of a mean marginal bone loss of 0.4 mm with immediately placed AOS implants compares favorably with that reported in a systematic review and meta-analysis (0.58 mm) for single implant-supported prostheses.[11] Although the review was of studies that included a total of 1,591 Nobel Biocare implants with follow-ups ranging from 1 to 20 years, all implants included had an external connection with machined surfaces.

A multicenter study using only implants with an AOS reported a mean marginal bone loss of 1.4 mm

TABLE 6 Differences in Mean Bone Loss when Comparing Regular-Platform (3.75–4.0 mm Diameter) and Wide-Platform Implants (5.0–6.0 mm Diameter)

Table	Number	Mean (mm)	SD (mm)	*p**
Regular	236	0.4	0.7	.007
Wider	76	0.6	0.9	

*Mann–Whitney rank-sum test.

TABLE 7 Comparison of Anodic Oxidized Surfaces versus Other Implant Surfaces

Type of Implant*	Number	Mean	SD	$p^{\dagger}$
Non-Ti (others)	882	0.6	0.8	.001
Ti-only (TiUnite)	312	0.4	0.8	

*Machined, Osseotite.
†Mann–Whitney rank-sum test ($\alpha = 0.05$).

after 1 year as measured from the time of abutment connection to the first annual examination.[12] However, the difference in the protocol between that study and the current one was that a two-stage surgical procedure was the treatment of choice, and an immediate implant protocol was only used with nine implants.

A more recent study of 46 patients with 121 AOS implants reported a mean marginal bone loss of $0.77 + 1.35$ mm based on 106 readable pairs of x-rays from baseline and the 10th annual examination. Although this was a significant finding, 20% of the implants were immediately loaded and 80% placed in a two-stage procedure, thus differing from the IPP used in the present study.[13]

Another study with 3–7-year follow-up reported a mean marginal bone loss between implant insertion and loading of 1.2 mm with 80 implants.[14] However, although all implants had TiUnite surfaces, all were placed in the maxilla using a two-stage procedure.

A recent multicenter study on survival rates and bone level changes around AOS implants included 817 implants. The cumulative survival rate reported was 93%, with no significant change in average crestal bone loss for the 102 surviving implants. However, various protocols for implant placement, including two-stage buried, flapless, immediate placement, immediate placement flapless, and one-stage were used.[15]

Only mesial and distal bone measurements were taken, although reports in the literature have shown that bone loss can be expected in the labial aspect after extractions.[16,17] The only accurate way to measure the labial and lingual changes in bone height was to expose the large number of patients to dental scans, which was not feasible for this study.

Differences in protocols, areas of implant placement, and time of follow-up make comparisons difficult, even though all studies cited used implants with an AOS (TiUnite). The current study, in which all implants with an anodic oxidized surface were placed by the same clinician using the IIP protocol, is therefore unique. At the time this study was initiated, it was not within the protocol to probe around implants.[18] Moreover, the follow-up maintenance examinations and radiographs were at times done by the restorative dentist. Thus, standardization of probing and measurements of bleeding would have been variable. Because of this lack of standardization, probing depths and bleeding scores were not assessed. The IIP protocol used in the present study has been described previously.[9] To briefly summarize, following extraction of the tooth, the socket was thoroughly debrided, the osteotomy created, the implant placed with bone tightly packed around the implant and added to ridge width if necessary, and a restorable membrane placed. Of note is that many implants in the study were placed into significantly infected sites or sites that demonstrated a large amount of bone loss (Figures 2–4). Consequently, it is important for the clinician to look at the variables that affected bone loss on the mesial and distal surfaces around these implants. The parameters that showed statistically significant differences were single versus splinted implants, bone loss between years 10 and 11 compared with other years, and the use of regular versus wide-platform implants. Another statistically significant variable was that less bone loss was seen around AOS implants (0.43 mm) compared with all other implants placed with the same protocol (0.57 mm) ($p = .0011$). A comparison of these results with those in a previous study showed that these variables also showed statistically significant differences.[9] However, two variables, gender and the age of the patient at implant placement, did not show statistically significant differences in the previous study or in the current study using only AOS implants.

As noted in a previous paper, even the factors that showed statistically significant differences in bone loss in the present study when using implants with an AOS (single vs splinted, comparison of molars in the maxilla and mandible, bone loss between years 10 and 11, and the regular vs wide-platform) failed to demonstrate differences in bone loss patterns that would be considered clinically significant.[8] All of the above differences, although statistically significant, were 0.32 mm or less (Table 8). Therefore, from a clinical standpoint, the procedures used to place AOS implants with an IIP protocol should be considered highly predictable, regardless of the variables considered in this and the previous study.[9]

As all implants were placed at or just below the crest of bone, the top of the first tread was used as the reference point for the baseline of mesial and distal measurements of bone. Bone levels were then calculated at the times of recall (2–12 years post placement). The fact that one radiologist evaluated all the radiographs eliminated any interevaluator discrepancies that might have occurred. As various amounts of marginal bone loss have been reported following implant placement and loading due to physiologic remodeling, reformation of the biologic width, and repeated removal of abutments, the amount of bone loss reported in the current study might have been greater than the actual loss that would have occurred due to the above factors.[19–23] In addition, in a study such as this, bone loss for immediate implant restoration might be influenced by location of the implant or the width of the occlusal table after implant insertion. If the platform was below the bone margin, subsequent bone loss might have been influenced by where the implant was placed. Other evaluators have used similar techniques in evaluating mesial and distal bone loss within the threads of the implants,[15] where mesial and distal bone measurements were made from the bottom of the prosthetic table to the first mesial and distal contact (using the NIH ImageJ program). The authors feel that in a large cross-sectional study, the technique of utilizing the first thread as the reference

TABLE 8 Millimeter Differences for Bone Loss in Parameters that Demonstrated Positive Statistical Significance

Parameters	p Value	Mean Difference (mm)
Single versus splinted implants	.023	0.2
In molars between the maxilla and mandible	.0006	0.3
Bone loss between years 10 and 11	.02	0.3
Regular-platform versus wide platform implants*	.007	0.2
Anodic oxidized surfaces versus other surfaces†	.0011	0.1

*Regular-platform, 3.75–4.0 mm diameter; wide platform, 5.0–6.0 mm diameter.
†Machined and Osseotite surfaces.

point is the most accurate available. The peak-to-peak distances are known from the manufacturer's specifications for the implants. Any measurements taken above that point would be proportional and depend upon the angulations of the radiographs and other factors. Any radiograph in which the radiologist could not read the bone within the threads when it was magnified would be eliminated from the study. Thus, the measurement data from the radiographs accurately portray bone loss on the implants.

Of note is that the standard deviations are at times larger than the mean. For example, in Table 5, the comparison of wide-platform and regular-platform implants the mean for regular is 0.4 mm with a standard deviation of 0.7 mm. When the dataset has large variability – in other words, when there are large number of data values distant from a mean value – the SD can be larger than the mean. Thus, when the SD is greater than the mean, it can interpreted that the datasets of both regular and wide-diameter implants have a dispersed distribution of data values. Thus, the Mann–Whitney rank-sum test is the preferred test to use. While regression analysis (a parametric test) must be used when the distribution is normal (bell-shaped), the Mann–Whitney (nonparametric) is a better analytical tool when there are large numbers and thus a greater dispersion.

Others have reported slightly more bone loss over time for 5.0 mm wide implants. Becker and colleagues reported that 5.0 mm–wide implants lost 0.2 mm more than 4.0 mm wide implants ($p = .7$).[24]

An important finding in the current study was that 287/312 (92%) implants lost less than 1.5 mm of bone over the 2–12 year follow-up. Only 3 implants (1%) lost 5 mm bone. Moreover, 7.1% ($n = 22$) of the implants lost between 2.0 mm and 4.0 mm of bone (Figure 2). According to the Albrektsson and the Smith and Zarb criteria for implant success, which include a bone loss of no greater than 0.2 mm annually following the implant's first year of function, the present study showed that 92% of implants would be considered a success.[25,26] This compares favorably with the 96% survival rate reported in a previous study using implant survival as the outcome criterion. This also underscores the importance of adhering to the diagnostic, planning, and placement protocol as described in a previous paper when utilizing IIP.[9] These include the ability to achieve apical or lateral stabilization in host bone, ability to totally remove residual infection and overfill residual defects with bone graft material. An important factor to note is that the patients included in the current study followed a strict maintenance protocol in a periodontal practice or alternating with the restorative dentist.

CONCLUSIONS

The current study evaluated bone stability around 312 AOS implants (TiUnite) and found an average mean bone loss of 0.4 mm. This represented a statistically significantly lower bone loss compared to all other implants placed with the same protocol (0.6 mm; $p = .0011$), as reported in a previous study by the same authors using the identical IIP protocol. Implants were evaluated from 2 to 12 years post-placement, with a mean of 7.4 years. Statistically significant differences in bone loss around these AOS implants occurred in single versus splinted implants, in maxillary versus mandibular molars, between years 10 and 11 compared with other years, and with regular versus wide-platform implants. However, these differences did not exceed 0.3 mm and may therefore be considered clinically insignificant. The key factors in the success of the AOS implants using an immediate placement technique appear to be close adherence to the protocol used in this study together with an effective maintenance regimen.

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