

Ten Years Later. Results from a Prospective Single-Centre Clinical Study on 121 Oxidized (TiUnite™) Brånemark Implants in 46 Patients

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ABSTRACT

Background: Concerns have been raised that use of surface-modified implants may result in peri-implant infection and marked marginal bone loss over time.

Purpose: The aim of this prospective study was to evaluate the survival rate, marginal bone, and soft tissue conditions at surface-modified titanium dental implants after 10 years of function.

Material and Methods: Forty-six totally and partially edentulous patients were provided with 121 Brånemark oxidized implants (TiUnite™, Nobel Biocare AB, Gothenburg, Sweden). Twenty-four (20%) implants were immediate loaded and 97 (80%) were placed using a two-stage procedure. A total of 22 single, 23 partial, and 7 total restorations were delivered. Clinical and radiographic checkups were carried out after 3, 6, 12 months, and thereafter annually up to 10 years. At these occasions, oral hygiene was evaluated and peri-implant mucosa examined by probing. If needed, patients were enrolled in an individual program for hygiene controls and professional cleaning. Marginal bone loss was evaluated in intraoral radiographs taken at baseline and after 1, 5, and 10 years of function.

Results: One (0.8%) implant failed after 8 years giving a Survival Rate (SR) of 99.2% after 10 years. A total of 11 sites (9.2%) showed bleeding on probing (BP) at the 10th annual checkup. The mean marginal bone loss was 0.7 ± 1.35 mm based on 106 readable pairs of radiographs from baseline and from the 10th annual examination. Twelve (11.3%) implants showed more than 2 mm bone loss, and five (4.7%) showed more than 3 mm of bone loss after 10 years. For the latter, all patients were smokers and had poor or acceptable oral hygiene. All five implants with >3 mm bone loss showed BP and two (1.9%) showed suppuration from the pocket. For the remaining seven implants with more than 2 mm bone loss, no correlation to smoking, oral hygiene, bleeding, or pus could be seen. Time/marginal bone level plots of the 12 implants with more than 2 mm bone loss after 10 years, showed minor changes from the first annual checkup except for the two infected implants.

Conclusions: It is concluded that good long-term clinical outcomes can be obtained with oxidized titanium dental implants. Only 1.9% of examined implants showed significant marginal bone loss together with bleeding and suppuration after 10 years of function.

KEY WORDS: long-term clinical study, marginal bone resorption, oxidized implant surface, soft tissue

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INTRODUCTION

The use of dental implants for prosthetic replacement of missing teeth is a well-documented and predictable treatment modality, although mechanical and biological complications occur.¹ Achievement and maintenance of implant stability in bone are preconditions for a successful outcome.² Of equal importance for the long-term result is the establishment and maintenance of a soft tissue barrier around the implant abutment to protect the interface.³ Implant failure occurs either at an early

stage, due to failed integration during healing, or later, seen as loss of integration and stability after healing and during functional loading. Smoking, soft bone density, short implants, irradiation, infection, and relative overload are some of the described risk factors that may lead to loss of implant stability.^{1,4} Various degree of marginal bone loss is normally seen around dental implants, which probably reflects remodeling/adaptation following surgery and during loading. In general, up to 1.5 mm of bone is lost during the first year in function followed by a period of minimal annual bone loss.⁵ However, during clinical function some implants may show extensive and sometimes continuous bone loss. The primary cause for this is not well understood but may be ongoing atrophy after tooth loss or a noninfectious reaction to surgery, load, local bone morphology, or due to other factors.⁶ It is also possible that infection may be a primary cause for bone loss as well as implant sites may be infected after bone loss has occurred for other reasons. Continuous bone loss with clinical signs of infection such as bleeding and suppuration is referred to as peri-implantitis, irrespective of the sequence of events.⁷ Depending on definition, the prevalence of continuous bone loss has from long-term studies been reported to be from 7.7 to 39.7%^{8,9}; although, some authors have regarded this as unrealistically high.⁶ These figures are mainly based on implants with a machined and relative smooth surface. Today, most implants have some type of surface treatment to promote a stronger bone tissue response, such as blasting, etching, anodic oxidation and combinations of techniques.¹⁰ Concerns have been raised that bone loss and subsequent exposure of a rough implant surface may facilitate establishment of a peri-implant infection.¹¹ However, few clinical studies with 10 years or longer follow-up on modern surface modified implants evaluating marginal conditions can be found in the literature.^{12–15}

The aim of the present prospective study was to evaluate clinical function and marginal soft- and bone-tissue conditions around oxidized titanium implants during 10 years of function.

MATERIALS AND METHODS

Patients

Forty-six consecutive patients (28 female and 18 male) planned for treatment with implant-supported crowns/bridges in one clinic participated in the study (Table 1).

TABLE 1 Number of Patients and Prosthetic Constructions

	Patients	Prosthetic Constructions
Female	28	31
Male	18	21
Total	46	52

Presurgical radiographic examinations were made using orthopantomogram (OPG) and intraoral radiographs and computed tomography scans when needed. Inclusion criteria were (1) loss of one or several teeth; (2) presence of residual bone volume sufficient to house at least 8.5 mm long implants; and (3) signed consent form. Exclusion criteria were age less than 18 years and general contraindications for oral surgery. Patients were thoroughly informed about the treatment and were after approval enrolled in a computer-based quality assurance system. All treatment steps were part of the routine procedures at the clinic and no extra measures were taken for the cause of the study. The study was conducted in full accordance with ethical principles, including the World Medical Association Declaration of Helsinki.

Surgery

The patients were given 3 g of amoxicillin (Amimox®, Tika Läkemedel AB, Lund, Sweden) Infiltration anesthesia (Xylocaine®-Adrenaline, AstraZeneca, Södertälje, Sweden) was used. A mid-crestal incision was performed in each case. After reflection of the flap, evaluation was made to decide optimal implant position from both aesthetical as well as biomechanical point of view. Bone quality and quantity were determined according to Lekholm and Zarb's criteria.¹⁶ A total of 121 implants (Mark III, $n = 113$ or Mark IV, $n = 8$, TiUnite™, Nobel Biocare AB, Göteborg, Sweden) were installed (Table 2). Thirty-three (33) implants were placed in fresh extractions sockets or 3 to 6 weeks after extraction. Cover screws were applied to two-stage implants ($n = 97$), which were allowed to heal for 3 to 6 months. At second stage surgery, either healing abutments or final prosthetic abutment (Multi-Unit Abutment, Nobel Biocare AB) were connected to the implants. Final prosthetic abutments were connected to implants that were to be loaded the same day ($n = 24$). Flaps were closed with resorbable sutures.

TABLE 2 Number of Placed and Failed Implants with Regard to Type, Length, and Jaw

Implant Type	Length (mm)	Placed	Maxilla	Mandible
TiUnite, NP	10	2	2	0
	11.5	2	2	0
	13	1	1	0
	15	5	5	0
Total		10	10	0
TiUnite, RP	8.5	5	0	5
	10	7	1	6
	11.5	1	1	0
	13	14	9	5
	15	43	37	6
	18	29	28	1(1)
Total		103	76	27
TiUnite, WP	8.5	1	1	0
	10	2	0	2
	11.5	2	2	0
	13	3	1	2
Total		8	4	4
Grand total		121	90	31

Prosthetic Procedures

A total of 22 single, 23 partial, and 7 total restorations were delivered (Table 3). In the immediate loading group, an impression was taken after surgery for fabrication of a laboratory-made temporary construction. All temporary prosthesis was delivered within 5 hours after surgery. One to 3 months after implant installation, an impression was taken for manufacturing of a permanent prosthesis. The single-tooth replacements were cemented on individual titanium abutments (Procera®, Nobel Biocare AB). Twenty-eight partial and total

restorations were restored with porcelain on titanium frameworks (Procera® Implant Bridge, Nobel Biocare AB), and two frameworks were casted from gold alloy.

Clinical and Radiographic Examinations

Clinical and radiographic follow-up examinations for the study were carried out after 3, 6, 12 months, and thereafter annually. At these occasions oral hygiene was assessed as good, acceptable, or poor. Although annual checkup was the normal regimen, all patients participating in the study agreed to be enrolled in a strict and individually designed maintenance care program if needed. Thus, some patients were seen every 6 or every 3 months for professional cleaning and examinations. The suprastructures were not removed for examination. Assessments of bleeding were made by probing the mucosal lining around each implant at the 10th annual checkup visit. Any sign of bleeding was recorded but not graded; thus, only a bleeding/no bleeding score was used. Pockets were probed using a 0.2-N PDT Sensor Probe Type CP-12 (Zila Pharmaceuticals Inc., Phoenix, AZ, USA) for the presence of pus.

The marginal bone level was measured in intraoral radiographs taken after or within 10 days from surgery (immediate loaded group, $n = 24$) or within 10 days after second-stage surgery (baseline), 1 year, 5 years, and after 10 years. The distance from the implant/abutment junction (IAJ) to the first bone contact was measured at mesial and distal aspects of each implant by an independent radiologist. The width of the implant collar was measured in each radiograph for the purpose of calibration. Mean values of distal and mesial measurements for each implant and time point were calculated and calibrated. Pairs of baseline and follow-up bone levels were used to calculate bone loss after 10 years.

RESULTS

Clinical Observations

All 46 patients attended the 10th annual checkup. Twenty patients who showed good oral hygiene and healthy soft tissue conditions had been examined annually. Twenty-four patients with acceptable hygiene had been scheduled for professional cleaning and checkups every 6 months, and two patients (smokers) with poor oral hygiene every 3 months (Figure 1).

Few prosthetic complications were observed during the follow-up time. One patient showed multiple porcelain fractures of a full arch bridge (Procera Implant

TABLE 3 Number of Placed and Failed Implants and Type of Prosthetic Case

Type	Number of Constructions	Number of Implants
Partial mandible	6	21 (1)
Partial maxilla	15	40
Complete mandible	1	5
Complete maxilla	6	35
Single mandible	7	7
Single maxilla	15	15
Total	52	121 (1)

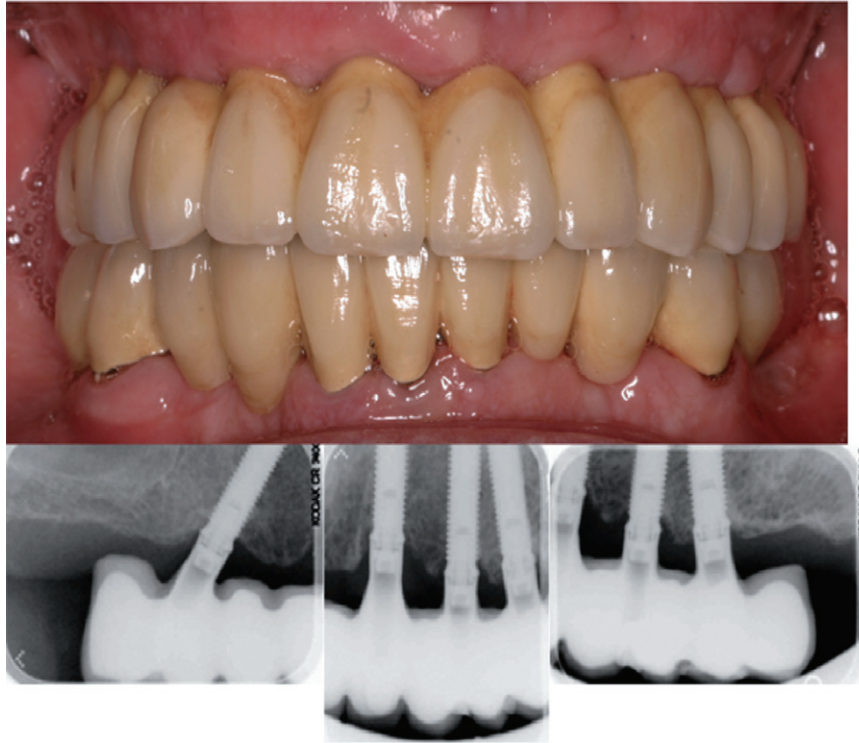


Figure 1 Showing clinical and radiographic status of a totally edentulous maxilla treated with a fixed full-arch bridge after 10 years of function.

Bridge), and a new porcelain had to be applied. One framework (Procera Implant Bridge) fractured after 7 years in function had to be replaced by a new bridge. A third patient presented with mucositis and marginal bone loss at three implants, which was diagnosed as a possible allergic reaction to the casted gold alloy framework. A new bridge on a titanium framework was manufactured where after the situation stabilized.

Implant Survival

All 121 implants were initially integrated and functionally restored. One implant was removed after 8 years, and the overall survival rate was 99.2% after 10 years (Table 4).

The removed implant had been positioned adjacent to a tooth that developed an endodontic lesion after 3 years. At this time, the implant showed radiolucency around the apex. The tooth was endodontically treated and the implant apex with lesion was surgically removed. However, the situation did not stabilize, and the implant was removed after 8 years due to progressive apical bone loss.

Radiographic Results

The marginal bone level was situated 0.9 ± 1.09 mm below the IAJ at baseline ($n = 110$), 1.3 ± 1.00 mm after

1 year ($n = 104$), 1.3 ± 1.04 mm after 5 years ($n = 97$), and 1.6 ± 1.24 mm after 10 years ($n = 115$) of loading (Table 5). Frequency distribution showed scattered bone levels at all time points (Table 5, Figure 2).

The marginal bone loss based on paired baseline and follow-up radiographs amounted to 0.4 ± 1.06 mm after 1 year ($n = 105$), 0.4 ± 1.10 mm after 5 years ($n = 90$), and 0.7 ± 1.35 mm after 10 years ($n = 106$) (Table 6).

Frequency distribution showed that 11.3% of the implants showed more than 2 mm and 4.7% more than 3 mm of bone loss after 10 years. The corresponding figures were 6.3 and 2.9% after 1 year and 10.0 and 3.3% after 5 years, respectively (Table 6).

TABLE 4 Life Table of Implant Survival

Interval	Number of Implants	Failures	Withdrawn	CSR (%)
Placement to 1 year	121	0	0	100
1 to 5 years	121	0	0	100
5 to 10 years	121	1	0	99.2
>10 years	120			99.2

TABLE 5 Mean and Frequency Distribution of Marginal Bone Level in Relation to the Implant/Abutment Junction at the Different Time Intervals

Time	BL	1 Year	5 Years	10 Years
Number of radiographs	110	104	97	115
Mean \pm SD (mm)	0.9 ± 1.09	1.3 ± 1.00	1.3 ± 1.04	1.6 ± 1.24
Frequency distribution, number of implants, mm (%)				
>0 mm	13 (11.8)	5 (4.8)	3 (3.1)	2 (1.7)
0–0.9 mm	43 (39.1)	32 (30.8)	35 (36.1)	33 (28.7)
1–1.9 mm	33 (30.0)	41 (39.4)	33 (34.0)	39 (33.9)
2–2.9 mm	18 (16.4)	23 (22.1)	19 (19.6)	30 (26.1)
>3 mm	3 (2.7)	3 (2.9)	7 (7.2)	11 (9.6)

A time/bone level plot of implants showing more than 2 and 3 mm bone loss after 10 years, showed the major changes had occurred during the first year in function, except for two implants (Figures 3 and 4)

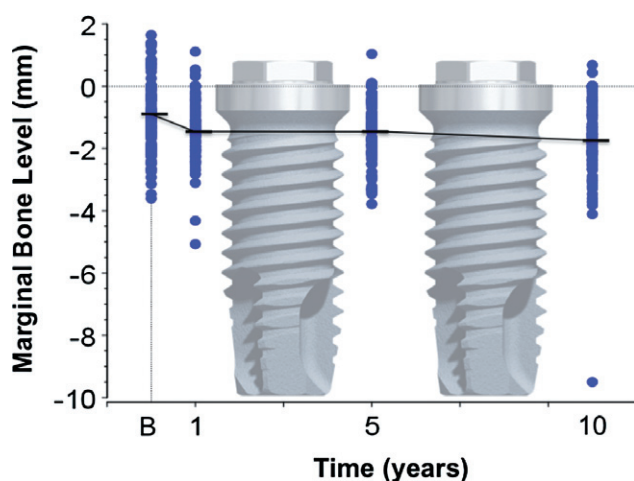


Figure 2 Diagram showing marginal bone levels (dots) and mean marginal bone level at baseline and after 1, 5, and 10 years of loading in relation to implant design.

Soft Tissue Health

A total of 11 sites (9.2%) showed bleeding on probing (BP) at the 10th annual checkup. Two sites showed pus when probing.

All implants with more than 3 mm bone loss after 10 years showed BP and two showed pus (Figure 5). The latter showed continuous bone loss from year one and five (Figure 4). All patients were smokers and had poor or acceptable oral hygiene.

DISCUSSION

The present study was undertaken to evaluate implant survival, marginal bone and soft tissue conditions at surface-modified, oxidized (TiUnite) titanium implants ad modum Brånemark after 10 years of function. The implants had been placed in consecutive patients with different needs of treatment and supported single-tooth replacements, partial bridges, and full-arch constructions in both jaws. A two-stage procedure was used for the majority of implants ($n = 97$), although some implants were loaded the same day ($n = 24$). Only one

TABLE 6 Mean and Frequency Distribution of Marginal Bone Loss Calculated from Paired Baseline and Follow-Up Radiographs after 1, 5, and 10 Years of Function

Time	BL to 1 Year	BL to 5 Years	BL to 10 Years
Number of paired radiographs	95	90	106
Mean \pm SD (mm)	0.4 ± 1.06	0.4 ± 1.10	0.7 ± 1.35
Frequency distribution, number of implants, mm (%)			
>0 mm	27 (28.4)	29 (32.3)	24 (22.6)
0–0.9 mm	47 (49.5)	40 (44.4)	43 (40.6)
1–1.9 mm	15 (15.8)	12 (13.3)	27 (25.5)
2–2.9 mm	4 (4.2)	6 (6.7)	7 (6.6)
>3 mm	2 (2.1)	3 (3.3)	5 (4.7)

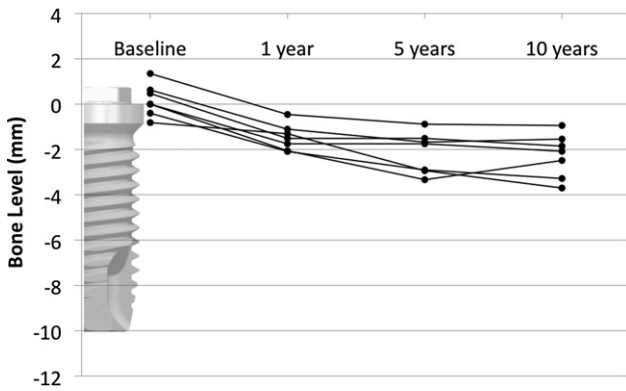


Figure 3 Diagram showing changes in bone level for seven implants showing 2–3 mm of bone loss after 10 years in relation to implant design.

implant was lost, giving a cumulative survival rate of 99.2% after 10 years. Two implants showed continuous bone loss and suppuration and were diagnosed to have a peri-implant infection. Few other and mainly prosthetic complications were experienced, such as fracture of one framework and fractures of porcelain teeth.

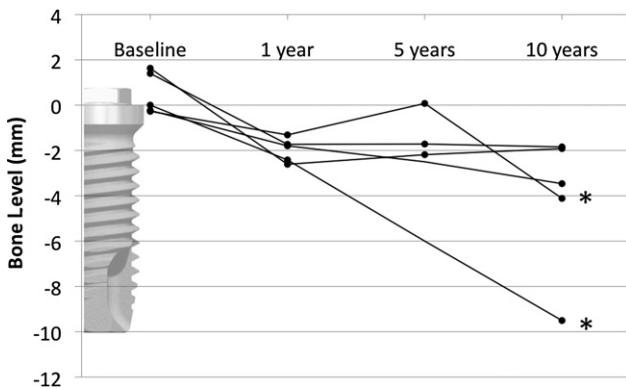


Figure 4 Diagram showing changes in bone level for five implants showing more than 3 mm of bone loss after 10 years in relation implant design. * = showing suppuration.

The average marginal bone loss was 0.7 mm after 10 years, which indicated stable marginal conditions for the patient group. The majority of baseline radiographs were taken after abutment surgery and about 20% after implant placement. This means that changes of the marginal bone during submerged healing are not encountered for in 80% of our radiographs, which may explain the small amount of bone loss. According to Åstrand and colleagues, 1.44–1.83 mm was lost for submerged Brånemark implants from placement to prosthetic connection.¹⁷ However, most studies on two-stage procedures have been using abutment or prosthesis connection as baseline.^{18–23} Another factor influencing the marginal bone loss calculations in the present study is the fact that positive bone levels, that is, above the IAJ had been registered by the radiologist. A thorough analysis of the radiographic data from the present study will be presented in a coming publication.

The results from the present study are in line with previous 5-year studies on the same implant design.^{18,19} Friberg and Jemt evaluated two patient groups and survival rates of 97.1 and 98.4% and mean marginal bone loss of 0.7 and 0.8 mm were reported.¹⁸ A more recent study on totally edentulous patients showed a survival rate of 97.3% and an average bone loss of 0.7 mm after 5 years.¹⁹ In a randomized study comparing early and delayed loading of two implants in the mandible with an overdenture, Turkyilmaz and colleagues²⁰ reported no implant losses and a mean marginal bone loss of 1.3 mm after 7 years of loading. Other long-term studies have used the same surface but different implant designs. For instance, Glauser²¹ reported a survival rate of 97.1% and a mean marginal bone loss of 1.5 mm after 7 years for tapered implants (MKIV) used in immediate loading. Calandriello and Tomatis²² evaluated the use of a wide



Figure 5 Baseline and 10-year follow-up radiographs of the worse implant in the study showing continuous bone loss, bleeding and suppuration. The implant had been connected to a natural tooth with a partial bridge in the posterior mandible.

platform-oxidized implant used for immediate loading of single molar reconstructions and showed a survival rate of 95% and an average marginal bone loss of 1.2 mm after 5 years of follow-up. In a 5-year study, Mura²³ experienced no failures and an average bone loss of 0.6 mm for a tapered implant design (Replace Select Tapered, Nobel Biocare AB). The results from the present and previous studies suggest that high survival rates and stable marginal bone levels can be achieved with oxidized two-piece implants.

Probing depth assessments and provoked bleeding have been proposed for diagnosing peri-implant inflammation/infection.²⁴ According to long-term follow-up studies, up to 86% of implant sites can show signs of bleeding and mucositis and seems to be a weak indicator of peri-implant marginal bone loss.^{12,15,25,26} In the present study, 9.2% of all sites showed bleeding, which is less than reported in other studies.^{12,15,25,26} The reason could be differences in probing technique, oral hygiene/maintenance, or other factors. The described high incidence of bleeding may be explained the fact that the implant interface consists of a scar tissue, which is different to the highly differentiated and specialized tissues that are part of the dento/gingival complex. From a classic pathological point of view, the long-term host response to a biomaterial can be classified as chronic inflammation, where the presence of inflammatory cells is a common finding also at biocompatible materials such as titanium.²⁷ Also probing depth measurements seems to be questionable at implants, as Dierens and colleagues and Koldslund and colleagues^{25,26} could not demonstrate any correlation with bone loss in the studies. This can be explained by that implants are placed at different depths in bone and at sites with different soft tissue thickness.

Frequency distribution of bone loss based on 106 readable pairs of radiographs of the 120 surviving implants in the present study revealed that 12 (11.4%) implants showed more than 2 mm, and five implants (4.8%) more than 3 mm of bone loss after 10 years. For the latter, all patients were smokers and had poor or acceptable oral hygiene, while no such correlation could be seen for the seven implants with 2–3 mm bone loss. All five implants with more than 3 mm bone loss showed BP and two (1.9%) of the implants showed pus. A time/bone level plot showed continuous bone loss over time for these two implants (Figure 3). Moreover, these implants were found in one smoking patient, in whom extensive oral hygienist resources had been

invested but with no improvement of oral hygiene. Smoking has been shown to be one of the prominent risk factors affecting the success rate and marginal bone loss of dental implants.¹⁴

Friberg and Jemt¹⁸ reported that 6.2% of 129 oxidized titanium implants showed more than 1.9 mm of bone loss after 5 years in function. Almost two-thirds of these (3.9% of all implants) showed this amount of bone loss already after 1 year, and thus, the progression of bone loss was low. In the present study, 4 of 12 implants with more than 2 mm bone loss were seen at the first and seven at the fifth annual checkup. Three of these implants had been placed in one patient who showed an allergic reaction and subsequent bone loss to the acrylic plastic. Moreover, because less pairs of readable radiographs were at hand after 1 year than after 10 years in the present study (95 vs 106), it is possible that more implants showed bone loss already after 1 year. Time/bone level plots of the implant with more than 2 mm bone loss after 2 years showed that the major changes had occurred during the first year in function (Figure 2). In a similar way, Glauser²¹ grouped all oxidized implants showing more than 2 mm bone loss during the first year and found small further changes for these implants over another 6 years in loading. Thus, these and the present study indicate small changes after the first year in function, that is, in the range 0.03–0.1 mm/year. The change of bone levels during the first year is most likely due to remodeling/adaptation rather than infection.

Our results agree with the findings from long-term studies on other implant surfaces and designs, where all patients have been followed for at least 10 years. For instance, a prospective 10-year study on sand-blasted large-grit acid-etched implants (SLA®, Straumann AG, Basel, Switzerland) supporting full-arch maxillary bridges revealed a survival rate of 95.1% and a mean marginal bone loss of 1.07 mm.¹⁵ In that study, 4.9% of the implants showed more than 3 mm bone loss over 10 years of loading. However, 86.9% of all examined sites showed BP but no implant site showed suppuration. In a study on titanium-blasted implants (TioBlast, AstraTech AB, Mölndal, Sweden) used for single-tooth restorations, all 20 implants had survived after 10 years of loading.¹² The mean marginal bone loss amounted from 0.64 to 0.86 and 40% of the implant sites showed BP at the 10th annual checkup.

We have previously reported on extensive marginal bone loss around one-piece implants used for

immediate loading and placed in contact with the oxidized surface in contact with mucosa, which was believed to result in “soft tissue integration.”²⁸ Catastrophic results were experienced and although many sites showed classic signs of “peri-implantitis,” that is, crater-formed defects, BP, and sometimes pus, the rapid breakdown of marginal bone from 3 to 6 months after placement suggested other explanations than just surface-mediated infection as the primary cause. When analyzing the one-piece implant results, it was evident that the combination of factors such as immediate loading, dense bone, and splinted implants resulted in bone loss and implant failures. Moreover, the one-piece implants had to be prepared in situ with high-speed drills in order to fit crowns and bridges. Together, the data suggest unfavorable healing and loading conditions as a plausible explanation for marginal bone loss where some site became infected. Clinical studies using a more conservative approach have reported acceptable results with the same one-piece implants.²⁹ The present study shows that most implants have the oxidized surface exposed to the soft tissue interface after 1 year in function. In spite of this, no negative effects were seen on marginal bone loss. Having said this, it is probably not a good idea to intentionally place the rough surface in contact with soft tissue, where the formation of a contact epithelium is expected, that is, near the mucosal margins.

It is concluded that good long-term clinical outcomes can be obtained with oxidized titanium dental implants. Only 1.9% of examined implants showed significant marginal bone loss together with bleeding and suppuration after 10 years of function.

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