Long-Term (9–12 Years) Outcomes of Titanium Implants With an Oxidized Surface: A Retrospective Investigation on 209 Implants

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The aim of this paper is to retrospectively assess the long-term clinical and radiological results in a group of patients treated with Brånemark TiUnite implants supporting mostly single-tooth and partial restorations. The clinical records of 90 consecutive patients (mean age 55.9 years; range 21–82 years), treated with 209 Brånemark System MkIII or MkIV TiUnite implants (72 maxillary/137 mandibular; 26 anterior intercanine/183 posterior sites), were analyzed. Indication types were single tooth (n = 21 implants), partial (n = 180) and full arches (n = 8). A delayed loading protocol was applied in 128 implants, while 81 were immediately loaded. Cumulative survival rate and marginal bone remodeling were evaluated. Marginal bone level was evaluated by an independent radiologist from periapical radiographs taken at implant insertion and at long-term follow up. Plaque, probing pocket depth and peri-implant mucosa conditions were also assessed. The results showed the mean follow-up duration was 11.0 years (range 9.6–12.4 years): 181 implants (90.5%) reached at least 10 years follow-up, 100 implants 11 years, and 17 implants 12 years. Overall, 6 implants failed in 4 patients (5 during the first year and 1 after 2 years) resulting in a 97.1% survival rate after 12 years. Mean bone levels at implant insertion and at the last follow up were −0.90 ± 1.16 mm (mean ± SD; n = 169) and −1.49 ± 0.95 mm (n = 195), respectively. Mean marginal bone remodeling from implant insertion to the last follow-up was −0.60 ± 1.17 mm (n = 168). At the last available follow-up, mean pocket depth was 1.65 ± 0.84 mm. Peri-implant mucosa was normal for the majority (97%) of implants. In conclusion, this retrospective long-term study showed excellent survival rate of TiUnite implants as well as favorable marginal bone response and soft tissue conditions.

Key Words: dental implants, oxidized surface, long-term survival, marginal bone loss, TiUnite

INTRODUCTION

Implant-supported prosthetic rehabilitation is a well-described and validated treatment alternative for partial or complete edentulism.[1–3] A number of studies reported high success rates for such rehabilitations both in cases of single edentulism or multiple tooth loss.[2,3] However, both technical and biologic complications could affect the success of implant-supported rehabilitation, leading to partial or complete failure of osseointegration.[4–11] Biological complications affect the bone-to-implant interface and the peri-implant soft tissues, and are mostly caused by bacterial infection that can occur early during the healing phase, immediately after the surgical intervention, or later, after prosthesis placement. Peri-implant mucositis, which is reversible and does not affect the marginal bone, and peri-implantitis are the two clinical biological complications occurring on peri-implant soft and hard tissues, respectively.[4,5,11,12] Technical complications related to the prosthetic device most frequently involve screw loosening, and less commonly, fracture of the fixture itself.[5–8]

Success of implant-prosthetic procedures is evaluated as the complete absence of any complication (either biological or technical). There exists controversy regarding the criteria to scientifically define implant restoration success. Classically, Albrektsson et al defined "success" as the absence of complications, and a marginal bone resorption <1.5 mm over the first year and <0.2 mm for each following year.[13] More recently, a consensus report defined "implant success" as the absence of any complication and of a bone loss <2 mm in all follow-up visits, highlighting that limited bone resorption is a viable marker of successful osseointegration.[14]

The role of implant surfaces on implant prognosis has been deeply investigated in the scientific literature. Implant surface macroscopic and microscopic characteristics can be important factors in determining and maintaining successful osseointegration, by allowing osteoblasts migration over implant surfaces and forming bone bridges between the native bone and the fixture.[15–22] Many studies reported higher bone-to-implant surface contact in the early healing phase and better success and survival rates using moderately rough (as compared to machine-smoothed) implant surfaces.[20–26] More-

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Table 1

Implant positions

Maxilla																			
Position	18	17	16	15	14	13	12	11	21	22	23	24	25	26	27	28	Ant.	Post.	Total
Total	0	1	4	7	11	0	3	3	5	3	2	14	11	8	0	0	16	56	72
Mandible																			
Position	48	47	46	45	44	43	42	41	31	32	33	34	35	36	37	38	Ant.	Post.	Total
Total	0	6	23	18	13	2	3	1	0	2	2	9	22	28	8	0	10	127	137

over, greater torque is necessary for removing moderately rough versus machined implants, as reported in several papers.[24–28]

Moderately rough surfaces with a highly crystalline, phosphate-enriched titanium layer were proposed to obtain successful and long-lasting osseointegration.[29,30] Bone-to-implant contact, as well as osteoconductive properties of this surface, have been widely described by animal studies and human clinical trials.[29–32]

Short-term clinical studies (6–36 months follow-up) reported the success of oxidized implants in different clinical situations and under different loading protocols, showing safety and effectiveness of these implants. Implant survival rates ranging from 96–100% have been reported for early- or immediately loaded implants, as well as for compromised clinical situations such as atrophic bone, low density bone, or concomitant grafting procedures.[33–36]

Although several studies reported long-term (about 5 years) clinical outcomes of moderately rough-surfaced implants, little is known about the tissue responses to oxidized-surface implants beyond this period of function.[37–42]

Thus, the aim of this retrospective report was to evaluate long-term success and survival rates of rehabilitations supported by oxidized-surface implants used for treating single and multiple edentulous ridges.

Materials and Methods

The present retrospective study was based on the analysis of clinical records of patients that underwent implant surgery between April 2000 and December 2002. Patients were treated in accordance with the principles of the Helsinki Declaration of 1975, as revised in 2000.[43] Patient recruitment, surgeries and prosthetic rehabilitations were performed in a single dental clinic. The same surgeon (MM), with long experience in implant surgery and prosthetic procedures, performed all interventions. Patients were informed about possible treatment alternatives and potential complications before surgery and provided written informed consent. Patients were selected for surgery according to the conventional prerequisites for implant surgery and rehabilitation (American Society of Anesthesiologists class I or II).

The selection of the patients' clinical records was based on the following inclusion criteria: (1) patients with prosthetic rehabilitations supported by one or more implant; (2) implants with a phosphate-enriched titanium oxide superficial layer, with a microstructured surface with 1–10 micron pores (TiUnite [R], Nobel Biocare AB, Zurich, Switzerland); (3) immediate or delayed prosthetic loading protocol; (4) attendance at all scheduled follow-up visits; and (5) availability of radiographic documentation at both implant insertion and long-term follow-up. Presurgical clinical assessment of the edentulous region included periapical radiographs, panoramic radiographs, or computed tomography.

Exclusion criteria were: (1) patients with incomplete demographic (age, gender) or clinical data reporting (eg, implant outcomes, smoking status, implant size); (2) patients who underwent concomitant grafting procedures; (3) immediate postextraction implants.

The primary outcomes to be determined were: (1) implant cumulative survival rate (CSR), defined as the presence of the implant in mouth, supporting a prosthetic restoration; (2) marginal bone levels in relation to the implant-abutment connection; (3) marginal bone remodeling calculated as the average between the mesial and the distal values, measured by a blinded examiner.

Digital periapical radiographs were taken using standardized holders at implant insertion and at the longest follow-up postsurgery. Each radiograph was calibrated by using the known implant thread distances in the image as the reference (for Brånemark Mk III and MkIV, the thread distance is 0.6 mm). After calibration, bone levels were measured at the mesial and distal aspects of each implant using the implant shoulder as the reference point for the first coronal bone-to-implant contact. Image calibrations and measurements were performed using ImageJ version 1.43u public domain software (US National Institutes of Health, Bethesda, Md). Bone level change was estimated by calculating the difference between baseline and follow-up values.

The secondary outcomes assessed included: (1) implant stability, clinically evaluated by applying force to the implant-abutment structure with two metallic instruments—implants were recorded as not stable if visible movement was observed; (2) bleeding of the peri-implant mucosa (0: no bleeding, 1: bleeding on probing, 2: spontaneous bleeding); (3) plaque (considered dichotomously as absence or presence of plaque); (4) probing pocket depth (PPD) recorded as the average of 6 values retrieved probing the implant in all sextants. Causes and times of implant failure were also recorded to perform a cumulative survival rate analysis. Other outcomes were reported narratively.

Descriptive statistical analysis was performed using Origin Pro 8.5.1 (OriginLab Corporation, Northampton, Mass); data are expressed as mean ± standard deviation for quantitative variables, and as absolute or relative frequencies for qualitative variables.

Table 2

Implant dimensions

Diameter	Length	Implant Type MkIII TiUnite	Implant Type MkIV TiUnite
3.75 mm	8.5 mm	2	0
	10 mm	26	0
	11.5 mm	16	0
	13 mm	58	0
	15 mm	32	0
	Total	134	0
4.0 mm	10 mm	0	4
	11.5 mm	0	4
	13 mm	0	24
	15 mm	0	37
	18 mm	0	1
	Total	0	70
5.0 mm	10 mm	5	0
	Total	5	0
Grand total		139	70

Results

Data from 209 implants placed in 90 patients were analyzed in this report. Mean patient age was 55.9 ± 12.2 years, including 49 females (54%) and 41 males. Thirty-three patients (37%) were smokers.

Implant position and dimensions are shown in Tables 1 and 2, respectively. One-hundred thirty-seven implants were mandibular and 72 were maxillary. Regard the clinical indication, 180 implants (86.1%) supported partial multiple-tooth restorations, 21 (10.0%) single-tooth, and 8 (3.9%) were full-arch restorations. Most implants (n = 128; 61.2%) were restored following a two-stage procedure with a delayed loading protocol, while 81 (38.8%) were placed with a one-stage protocol and immediately loaded. Characteristics of the provisional and definitive prosthesis are presented, respectively, in Tables 3 and 4. The opposing dentition was natural teeth in 153 cases (73.2%) and ceramic/crown bridge in 56 cases (26.8%).

The implant CSR was 97.1% up to 12 years follow-up (mean follow-up 11.0 ± 0.7 years; range 9.6–12.4 years) (Table 5). Six implants (2.9% of total), all mandibular (4.4% of mandibular), failed in four patients. Five implants failed within 5 months from loading while 1 was removed after 2 years. The features of the failed implants are presented in Table 6. Two patients, accounting for 3 implants, died during the study and were excluded from the analysis. One hundred ninety-six (98.0%) of the 200 long-term surviving implants showed clinical stability at the longest follow-up, while 4 of them were mobile at the clinical inspection.

Table 3

Characteristics of the provisional prosthetic restoration

	n	%
Cement retained	119	56.9
Screw retained	81	38.8
No provisional restoration/no information	9	4.3
Total	209	

Table 4

Characteristics of the definitive prosthetic restoration

	n	%
Cement retained – ceramic	109	52.2
Screw retained – ceramic	88	42.1
Screw retained – acrylic	3	1.4
No restoration/no information	9	4.3
Total	209	

The mean marginal bone levels at implant insertion and at the last follow up were 0.90 ± 1.16 mm (n = 169) and −1.49 ± 0.95 mm (n = 195), respectively, as shown in Table 7. Table 8 details the results of estimated marginal bone remodeling, which averaged −0.60 ± 1.17 mm (n = 168). Figures 1 through 4 show 2 clinical cases displaying limited marginal bone loss after 10 years of function.

At the last available follow-up, the mean PPD was 1.65 ± 0.84 mm (n = 200), with 6 implants displaying a PPD of 4 to 6 mm. A healthy, noninflamed peri-implant mucosa was observed at the large majority (97.0%) of implants. At the 10-year follow-up, 31 implants (15.5%) were assessed as positive for plaque, while plaque was not detected on 169 implants (84.5%). The bleeding score was 0 in 157 cases (78.5%), 1 in 37 cases (18.5%), and 2 in 6 cases (3.0%).

Discussion

Although many short-term clinical reports have shown favorable results for implants with anodized surfaces,[33–42] scarce documentation exists on the long-term success of these implants. The present retrospective study, performed with 90 patients, suggested that single-tooth and fixed partial restorations supported by implants with TiUnite surface achieve excellent clinical performance up to 12 years of function.

In 1986, Albrektsson and colleagues proposed implant success criteria that are still referred to by most clinicians. These criteria include implant stability, absence of peri-implant radiolucency, peri-implant bone loss not exceeding 1.5 mm after the first year of loading and <0.2 mm for each subsequent year.[13] In addition, an implant system should be considered

Table 5

Implant cumulative survival rate

Time Period	Implants	Failed	Not Followed	CSR (%)
Insertion–1 year	209	5	0	97.6
1–2 years	204	0	0	97.6
2–3 years	204	1	0	97.1
3–4 years	203	0	0	97.1
4–5 years	203	0	1	97.1
5–6 years	202	0	0	97.1
6–7 years	202	0	2	97.1
7–8 years	200	0	0	97.1
8–9 years	200	0	0	97.1
9–10 years	200	0	19	97.1
10–11 years	181	0	81	97.1
11–12 years	100	0	83	97.1
12 years	17	0	0	97.1

Table 6

Specification of failed implants (n = 6)

Patient	Implant Position	Dimensions	Time to Failure (yrs)	Smoker	Type of Restoration	Loading Protocol
AM	35	MkIII 3.75 × 10 mm	0.4	No	Partial	Delayed
	36	MkIII 3.75 × 10 mm	0.4	No	Partial	Delayed
	37	MkIII 3.75 × 10 mm	0.4	No	Partial	Delayed
AP	46	MkIII 3.75 × 11.5 mm	2.0	No	Partial	Delayed
EM	46	MkIV 4.0 × 11.5 mm	0.2	Yes	Single	Delayed
GM	44	MkIII 3.75 × 15 mm	0.2	Yes	Single	Delayed

successful if 85% of the implants meet such criteria under loading for at least 5 years and 80% after 10 years.[13] In 1991, Buser et al proposed similar criteria for implant success but did not specify the tolerated marginal bone loss over time.[44] Their criteria consisted of absence of disturbances, pain, foreign body sensation or altered sensitivity; absence of recurrent peri-implant infection with suppuration; absence of mobility; and absence of persistent radiolucency along the implant profile.[44] In the present study, apart from the 6 failures, 98.2% of the implants radiographically evaluated in the long term met the success criteria established by Albrektsson et al[13] In fact, only 3/168 implants displayed peri-implant bone remodeling exceeding 3 mm after ≥10 years of placement. The present longitudinal data, based on a sample size of approximately 200 implants, showed favorable long-term results of the TiUnite surface.

The outcomes of the present study are in line with other studies with ≥5 years of follow-up that investigated the clinical performance of implants with the TiUnite surface. For example, Calandriello and Tomatis evaluated the clinical and radiological performance of 38 Brånemark System TiUnite Wide Platform immediately loaded implants supporting single crowns in the mandibular molar region.[45] They treated 33 patients, achieving a cumulative success rate of 95%, with a mean marginal bone loss of 1.17 mm after 5 years. In another retrospective study, Friberg and Jemt compared 280 implants with the TiUnite surface to 110 machined implants in 111 patients.[37] They found a similar CSR of 98.2% for TiUnite implants and 99.1% for machined implants, and a similar mean marginal bone loss after 5 years of 0.75 and 0.6 mm, respectively. Additionally, the prevalence of bone defects >2 mm around the implants was very low for both implant types.[37]

The long-term bone loss data observed in the present study is in agreement with those reported by other studies that evaluated different rough-surfaced implants.[38,39,46–49] Rasmussen et al investigated TiO_2-blasted roughened implants for 10 years and reported no increase in progressive bone loss or peri-implantitis.[49] Glauser et al published 5- and 7-year results of a study on 38 patients, demonstrating excellent long-term performance of TiUnite implants submitted to an immediate loading protocol.[38,39] Fifty-one fixed prostheses (30 partial dentures, 20 single crowns, and 1 mandibular complete denture) were loaded the same day of intervention. The prostheses were supported by 102 implants placed largely in the posterior regions of the jaws and mostly in soft bone quality. Guided bone regeneration was performed in 66 sites (64.7%) that displayed exposed implant threads. After 8 weeks from placement, 3 maxillary implants had to be removed in 1 patient due to infection close to a guided bone regeneration site. The resulting overall implant CSR was 97.1%.[38,39] Very few complications were reported over time. The mean peri-implant bone loss was 1.51 ± 1.00 mm after 7 years.[39] This value is a bit higher than observed in the present study but the shorter loading time should be taken into account.

The predictability of the TiUnite surface in the long term is further confirmed by 3 recent articles reporting excellent performance of implants with the TiUnite surface.[41,42,50] Degidi

Table 7

Marginal bone levels*

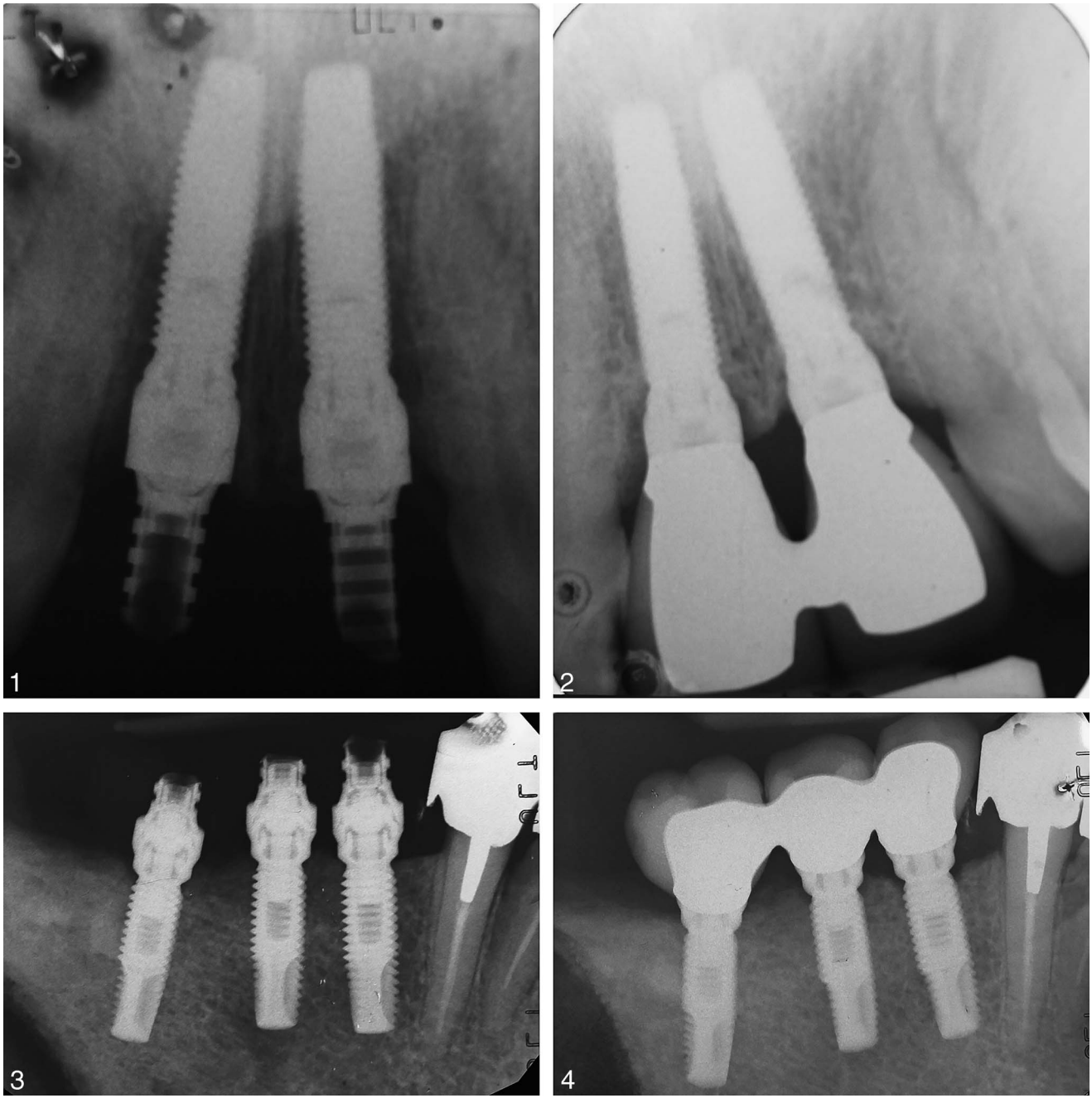
	Implant Insertion		Follow-up	
Mean	−0.90		−1.49	
SD	1.16		0.95	
n	169		195	
	n	%	n	%
1.1–2.0	4	2.4	0	0
0.1–1.0	13	7.7	2	1.0
0	29	17.2	7	3.6
−1.0–−0.1	62	36.7	53	27.2
−2.0–−1.1	42	24.9	96	49.2
−3.0–−2.1	13	7.7	24	12.3
−4.0–−3.1	3	1.8	6	3.1
<−4.0	3	1.8	7	3.6

*Bone levels presented as averages, (mesial + distal)/2. Negative numbers indicate bone levels apical to the reference point. Reference points used: Implant-abutment junction (= top of implant).

Table 8

Marginal bone remodeling

	Implant Insertion to Follow-up	
Mean	−0.60	
SD	1.17	
n	168	
	n	%
>3.0	2	1.2
2.1–3.0	2	1.2
1.1–2.0	3	1.8
0.1–1.0	33	19.6
0	6	3.6
−1.0–−0.1	67	39.9
−2.0– −1.1	39	23.2
−3.0–−2.1	13	7.7
−4.0–−3.1	2	1.2
<−4.0	1	0.6



Figures 1–4. Figure 1. Two implants supporting a maxillary fixed prosthesis at baseline (prosthetic phase). **Figure 2.** The two implants of Figure 1 after 10 years of loading. The peri-implant bone loss was very low. **Figure 3.** Three implants supporting a fixed bridge in the posterior mandible. **Figure 4.** After 11 years of function, there was a very small peri-implant bone loss.

et al reported 97.6% of implant CSR after 10 years of follow-up on 210 immediately loaded implants placed in 59 patients.[41] Ostman et al found 99.2% implant CSR with 121 implants (20% were immediately loaded) in 46 patients after 10 years.[42] Gelb et al found 100% of implant CSR and success after 7 to 8 years of follow-up in a cohort of 52 patients encompassing 107 implants.[50] In this last study, the mean marginal bone loss at the long term follow-up as compared to baseline was 1.49 $\pm$ 1.03 mm.

In the present study, most of the implants had a normal peri-implant mucosa, while only 6 implants (3.0%) displayed spontaneous bleeding of the peri-implant mucosa. The long-term outcomes of the current study suggest that the anodized TiUnite surface has a similar effect on peri-implant tissues over time as the machined surface. The present results are in agreement with other long-term studies that investigated the response of peri-implant tissues around moderately rough-surfaced versus machined implants. Vroom et al evaluated long-term differences in peri-implant health in patients that received both TiO_2-blasted and machined implants.[28] After 12

years, no significant differences were found between the rough-surfaced and machined-surface implants regarding marginal bone loss and soft tissue health, including plaque, calculus, bleeding and probing pocket depth. Astrand et al reported that after 3 years of loading, machined-surface implants were less susceptible to peri-implantitis than were rough-surfaced titanium plasma-sprayed implants inserted in the same patient.[51] A study by Karoussis et al compared biological complications of 3 different International Team for Implantology implants.[52] Along a 10-year period, the three implant types showed peri-implantitis incidences ranging from 10–29% when including strict radiographic and clinical parameters.[52] Those values were slightly worse than those found in the current study using oxidized implants.

The proposed risk of rough-surfaced implants for developing peri-implantitis is their potential to accumulate more plaque than machined-surface implants. Some studies have suggested that rough surfaces promote more plaque accumulation and subsequent bone loss than machined surfaces. Quirynen et al performed a literature review that focused on the relationship between implant surface roughness and peri-implantitis.[53] They stated that implants with a rough surface were more susceptible to late implant loss or marginal bone loss in patients with a history of periodontitis as compared to implants with a smoother surface.

Despite the early general concerns for higher plaque accumulation on moderately rough-surfaced implants versus machined implants, the present study showed low levels of plaque and peri-implant bone loss around implants with an anodized surface. The stable peri-implant mucosa health found in the present study may be attributable to the low plaque levels found in the majority of the anodized implants in our patient population.

Conclusion

Clinical and radiographic outcomes of this retrospective report showed high implant survival rates, excellent peri-implant bone response, and healthy soft tissues through up to 12 years of follow-up. Further studies with a prospective design are needed to confirm the observations of this report and investigate if anodized surface-implants are associated with a minimal risk for peri-implantitis, as the present long-term results might suggest.

Abbreviations

CSR: cumulative survival rate
PPD: probing pocket depth

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