Survival Rates and Bone Level Changes around Porous Oxide-Coated Implants (TiUnite™)

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ABSTRACT

Purpose: This prospective study evaluated implant survival rates and crestal bone changes for porous oxide-coated (TiUnite, Nobel Biocare AB, Gothenburg, Sweden), parallel-walled implants.

Materials and Methods: All patients receiving TiUnite (porous oxide-surfaced implants [POS]) implants were entered into a database (Triton Tracking System) starting February 1999. Survival rates were calculated from the date of implant placement and related to surgical method of placement (two-stage buried, flapless, immediate placement, immediate placement flapless, one stage), bone quality, and implant characteristics. Failed and nonfailed implants were compared with respect to changes in mean proximal bone levels and the presence of radiolucent areas around the implant apex (shadows).

Results: Four hundred nine patients received 817 porous oxide-coated implants, of which 38 failed. Using the last office visit as the censoring date, the cumulative survival date was 93%. The failure rate was independent of bone quality or quantity; implant diameter or length; and surgical method. For the 102 surviving implants, there was no significant change in the average crestal bone loss (+0.13 mm with a standard error, 0.17). For the 17 failing implants, the average crestal bone loss was −4.14 mm (standard error, 0.55). This difference between bone levels of failing and nonfailing implants was highly significant ($p < .0001$). There was no difference in the prevalence of radiographic shadows around failing and nonfailing implants at time of placement ($p < .16$).

Conclusion: Results from this prospective clinical study indicate that 7% of TiUnite surfaced implants failed for unknown reasons. Failing implants were characterized by significant bone loss but not by the presence of shadows.

KEY WORDS: bone, implant, survival rate

INTRODUCTION

Branemark and colleagues demonstrated the need for long-term follow-up studies for patients receiving dental implants and provided 10-year implant survival data for rehabilitation of fully edentulous patients.[1,2] More importantly, they provided criteria for evaluating patients over time, including survival rates and changes in crestal bone levels.[3] Adell and colleagues,[4] during a 15-year period, installed 2,768 fixtures in 191 upper and 219 lower consecutive jaws in 371patients. Marginal soft tissue reactions were mild and marginal bone loss was less than 1.0 mm during the first year and thereafter only 0.05 to 0.07 mm annually. Dental implants with a porous oxide surface (Nobel Biocare, Yorba Linda, CA, USA) have been extensively studied and have been described as having excellent clinical outcomes.[5–8] Friberg and Jemt reported on rehabilitation of edentulous mandibles with TiUnite implants.[9] Three hundred implants were placed in 75 patients. One-year results demonstrated a cumulative survival rate (CSR) of 98.5%, with 0.3 mm marginal bone resorption during the first year. A prospective study was undertaken to assess the 10-year performance of porous oxidized surfaced implants supporting fixed prostheses placed with an immediate loading approach in postextractive and

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healed sites.[10] Two hundred ten implants were placed in 59 patients and followed up for an average of 10 years. The survival rate was 97%. Implants placed in healed and postextraction sites, respectively, achieved a 98% and a 97% CSR. A recent 7-year follow-up study reported on porous oxide-surfaced (POS) implants placed within soft bone.[11] There was a 97.1 survival rate with an average of 1.51 mm of marginal bone resorption. There was greater bone remodeling for sites augmented with barrier membranes and regenerative procedures.

MATERIALS AND METHODS

Dental implants placed since 1986 have been entered into a database (Triton System based on Microsoft Access software). The database program was designed to track reasons for dental extraction (if applicable), implant location, bone quality and quantity, type of implant surgeries, graft types if utilized, dates of implant placement, second stage, and dates of follow-up and implant types and sizes. Data from this system have been used to report results from other long-term studies.[12,13] The current report focuses on all POS implants placed starting in 1999 and ending in 2009.

Exclusion criteria were presence of poorly controlled diabetes, recent history of coronary heart disease, heavy smokers (more than five cigarettes per day), and history of cerebral vascular accident within the previous 6 months. Patients receiving radiation to the head and neck were excluded. Patients with a history of taking intravenous bisphosphonates were excluded from this study. Patients received a comprehensive periodontal evaluation, complete radiographic series including a panogram, study casts, and were either partially or fully edentulous. Computerized scans were taken on an individual basis when bone width or mandibular nerve or maxillary sinus floor could not be clearly discerned. Bone quality and quantity was determined according to the classification described by Lekholm and Zarb.[14] Patients signed informed consent forms and treatment was performed within the guidelines of the Helsinki Agreements.[15]

Surgery

One hour prior to surgery, patients took 2 g of oral amoxicillin, or if allergic, 600 mg of clindamycin. Patients were treated using intravenous conscious sedation and were given an appropriate local anesthesia. Prior to surgery, sites were scrubbed with povidone iodine. Implants were placed using one of five protocols: two-stage buried,[1] one stage,[16] immediate with flap,[17] immediate flapless,[18] and flapless.[19] Individual patient jaw shape and quality was determined from radiographs, and final determination was made at surgery.[14] None of the patients received sinus elevations, barrier membranes, xenogenic or allograft implants. The average healing period for maxillary and mandibular implants was 4.5 months. At implant evaluation, prior to the restorative phase, a periapical long-cone periapical radiograph was taken and assessed for radiolucencies adjacent to the implants. Cover screws or healing abutments were removed, an impression coping was placed, and light pressure was placed on the coping. In the absence of pain on pressure, and or radiographic peri-implant abnormalities, the implants were considered to have integrated.

Radiographic Evaluation

All patient charts were evaluated for the presence of radiographs at both time of implant placement (1999) and last visit (2009). Paired radiographs taken at second stage and last examination were scanned (Epson Perfection V700 Photo, Epson Corporate Office, Long Beach, CA, USA) and saved at 300 dots per inch in a personal computer. Measurement changes were made from second stage to longest follow-up time for failed and nonfailed dental implants. Using NIH ImageJ[20] and knowledge of implant length and width, radiographs were measured from the bottom of the prosthetic table to the first mesial and distal bone to implant contacts. For each implant, mesial–distal bone level measurements were averaged. Further, during evaluation of failed implants, dark shadows were noted around the apical aspect of some implants at time of implant placement. In order to determine measurement error, 28 radiographic pairs were randomly selected and remeasured by an outside examiner (PW).

Statistical Analyses

Kaplan–Meier survival probabilities were estimated using proc lifereg (SAS, version 9.3) (Figure 1). Logistic regression models for correlated data were employed to relate surgical method, bone type and quality, implant diameter, and length to failure rates (SAS Proc genmod). Generalized estimating equations with an exchangeable correlation structure were used to accommodate the

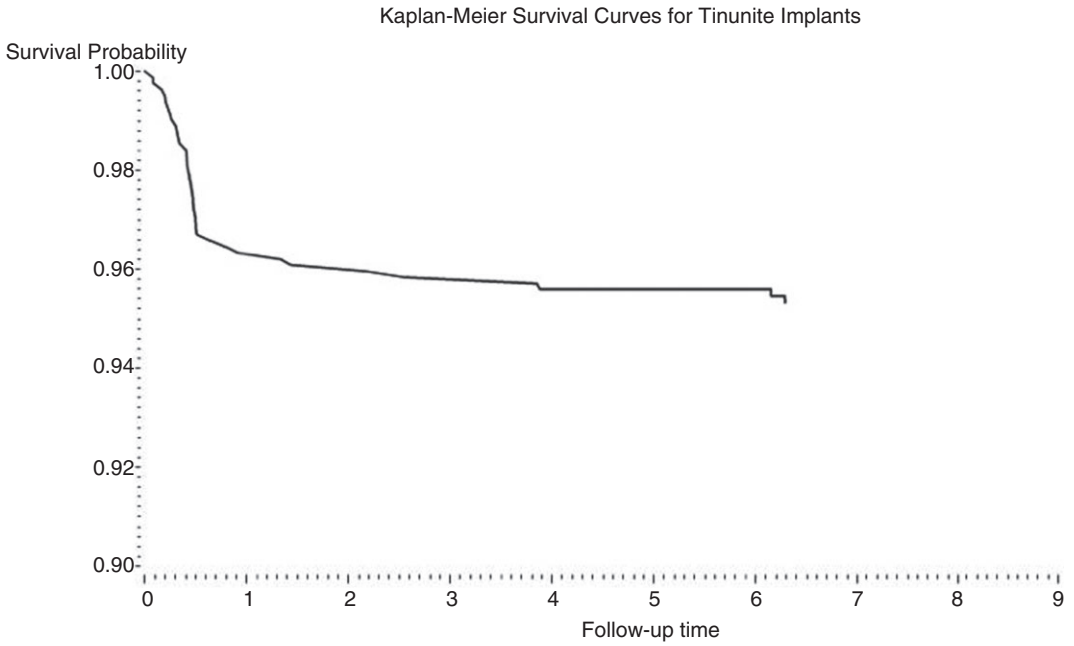

Figure 1 Kaplan–Meier survival curves for TiUnite implants under the assumption of perfect follow-up.

within-patient correlation of implant failures. Testing of the null hypothesis was performed using the Wald test. In one set of analyses, it was assumed that all patients with failures returned to the dental office and that none of the patients died (i.e., perfect follow-up). This assumption is most likely false and leads to an underestimation of the failure rates. In another set of analyses, the last visit date was used as the censoring date. The mean bone level changes and differences were estimated using generalized linear models with an identity link and a Gaussian error taken into account the clustering of dental implants within patients (proc genmod). The differences in the prevalence of shadows were estimated using generalized linear models with a logit link and a binomial error, taking into account the clustering of dental implants within patients (proc genmod). All statistical analyses were performed using SAS software.

RESULTS

Four hundred nine patients received 817 porous oxide-coated implants, 38 of which failed. There were 172 males (range 17–87 years) and 237 females (range 17–93 years). The majority of implants placed were in the maxillary incisor/canine areas (Table 1). In terms of bone quality and quantity, 743 implants (91%) were placed in Type 2 bone quality, while the majority of implants were in Type A bone shape (72%) (Table 2). Six hundred ninety-seven implants (85%) were 3.75 mm wide, while 294 were 13 mm in length (36%). The majority of implants were placed in one stage.

Survival Analysis

Of the 409 patients originally entered into the study, as of July 1, 2013, 242 remain in active patient recall. Fifteen patients are deceased, 14 moved, 138 are inactive and could not be located by telephone after two unsuccessful tries, and one additional implant was reported lost. When the last office visit was used as the censoring date, the cumulative survival estimate was 93.0%. The overall survival probability assuming perfect follow-up was 95.3%. The CSR for maxillary and mandibular implants was 94.8% and 96.0%, respectively. Numbers of implants lost according to the surgical procedure of placement were evaluated, and there were no significant differences between procedures in terms of implant failure rates. Bone type, bone quality, implant length, and implant diameter were similarly not related to survival probability (Table 2).

Reliability of Bone Level Changes

The correlations coefficients on bone level measures between two clinicians were larger than 0.95. There were no significant differences between the two clinicians on mean bone level measures (0.13 mm at baseline and 0.26 mm at follow-up).

TABLE 1 Descriptive Statistics on the Tooth Position Where Implant Was Placed, the Bone Shape and Quality, the Implant Length and Diameters, and Surgical Method of Placement

		Frequency	Percent
Anatomical area	Maxillary molars	38	4.65
	Maxillary premolars	193	23.62
	Maxillary incisors/cuspids	233	28.52
	Mandibular molars	90	11.02
	Mandibular premolars	133	16.28
	Mandibular incisors/cuspids	130	15.91
Bone shape	Immediately after extraction	588	71.97
	Slight resorption	173	21.18
	Significant bone loss	56	6.85
Bone quality	Primarily cortical bone	9	1.10
	Cancellous core surrounded by cortical bone	743	90.94
	Slight amount of cortical bone, mostly cancellous bones	65	7.96
Implant diameter (mm)	3.3	26	3.18
	3.75	697	85.31
	4	69	8.45
	5	24	2.94
	5.5	1	0.12
Implant length	7	20	2.45
	8.5	56	6.85
	10	239	29.25
	11.5	43	5.26
	13	294	35.99
	15	165	20.20
Surgical method	Flapless	137	16.77
	Flapless immediate	49	6.00
	Healing abutment	350	42.84
	Immediate healing abutment	198	24.24
	Standard	83	10.16

Marginal Bone Level Changes for Surviving and Failed Implants

One hundred two paired radiographs on surviving implants were available for crestal bone loss evaluation. The number of days between radiographic measurements (second stage and longest follow-up) for nonfailing implants was 2,628. Seventeen paired radiographs on failing implants were available for crestal bone loss evaluation. The number of days between radiographic measurements (second stage and longest follow-up) was 125. For the 102 surviving implants, there was no significant change in the average crestal bone loss (+0.13 mm with a standard error, 0.17). For the 17 failing implants, the average crestal bone loss was –4.14 mm (standard error, 0.55). This difference between bone levels of failing and nonfailing implants was highly significant ($p < .0001$).

Relationship of Darkened Areas Adjacent to Failing Implants and Surviving Implants

The presence of darkened shadows around failing and nonfailing implants was assessed for 38 failed implants and 54 successful implants (PW). There were 21% of failed implants (8/38) and 35% of nonfailed implants (19/54) that had the darkened shadow. The difference was not significant ($p < .16$).

DISCUSSION

This paper describes results of a longitudinal prospective study evaluating porous oxidized-coated implants

TABLE 2 Odds Ratio for Implant Failure Associated with Anatomical Area, Bone Shape and Quality, Implant Diameter and Length, and Surgical Method of Placement

Variable	Level	Odds Ratio	Lower 95% Confidence Limit	Upper 95% Confidence Limit	*p* Value
Anatomical area	Maxillary molar	0.47	0.08	2.74	0.399
	Maxillary premolar	0.73	0.19	2.84	0.650
	Maxillary incisor/cuspid	0.61	0.15	2.41	0.478
	Mandibular molar	0.68	0.14	3.38	0.634
	Mandibular premolar	0.69	0.17	2.79	0.605
Bone shape	Primarily cortical bone	0.54	0.10	2.88	0.473
	Cancellous core surrounded by cortical bone	0.68	0.12	3.79	0.662
Bone quality	Immediately after extraction	0.14	0.02	1.03	0.054
	Slight resorption	1.07	0.30	3.77	0.916
Implant diameter		0.61	0.18	2.06	0.431
Implant length		1.08	0.89	1.32	0.418
Surgical method	Flapless	2.09	0.51	8.61	0.306
	Flapless immediate	0.75	0.15	3.82	0.731
	Healing abutment	1.24	0.46	3.30	0.669
	Immediate healing abutment	0.83	0.27	2.61	0.754

in a private practice setting. The study included 409 patients with 817 implants. The CSR was 95.30%. The mean bone loss for 102 paired radiographs adjusted for time and taken at second stage and last office visit was 0.13 mm per year. Friberg and Jemt[9] reported 1-year survival and marginal bone changes for 300 TiUnite implants in 300 patients. The CSR was 98.5% with the average 1-year crestal bone change of 0.3 mm and 0.5 mm, respectively, for mesial and distal surfaces. The marginal bone changes are comparable with those reported in this study. A 5-year cross-sectional study of 81 TiUnite implants reported a mean marginal bone loss of 0.6 mm to 0.8 mm.[21] Another study compared implant survival at 5 years for turned and TiUnite-surfaced implants.[22] All implants followed a one-stage protocol with early loading. Survival rates for turned and TiUnite implants were, respectively, 94.7% and 99.4%. The mean marginal bone level was 1.8 mm for turned implants and 2.0 mm for porous oxide-coated implants. Differences in crestal bone loss were not statistically significant.

Results from this long-term study indicate that TiUnite-surfaced implants have 95% survival rates with minimal crestal bone loss when perfect follow-up is assumed. Of the 409 patients originally entered into the study, 242 remain in active patient recall. Fifteen patients are deceased, 14 moved, 138 are inactive and could not be located by telephone after two unsuccessful tries. Future long-term implant studies should account for all patients enrolled in the study, and the CSR should reflect patient drop outs. These results in terms of CSRs and crestal bone loss are comparable with other reported studies with this implant surface. To our knowledge, this is the first study to compare bone loss between surviving and failed implants. Differences in bone loss between surviving and failed implants were statistically and clinically significant. In this study, probing depth and gingival indices were not recorded; however, failed implants, for unknown reasons, lost integration and did not present classic clinical symptoms of "so called" peri-implantitis (bleeding, suppuration). One multicenter study reported on the TiUnite-surfaced implants consisted of 187 patients receiving 478 implants and followed for up to 1 year in function.[23] Five implants were lost up to the 1-year follow-up, revealing an implant CSR of 98.6%. The average marginal bone loss as measured from abutment connection to the first annual evaluation was 1.4 mm. Differences between survival rates and bone loss in the present study and the aforementioned studies may be related to bone quality and quantity into which implants were placed, and time intervals from which measurements were made. In our study, the majority of implants were placed in one stage; however, multiple methods of implants were utilized.

Other factors affecting survival of implants not studied here may be related to use of guided bone regenerative and bone grafting procedures. In the present study, no implants were placed in bone quality 4, while 3.8% of implants in the previous study were in relatively soft bone (quality 4). During the first year, there was an average marginal bone loss of 0.68 mm. A subsequent study reported 10-year follow-up results from 41 patients receiving 121 porous oxide-coated implants.[24] At 10 years, one implant was lost, yielding a 99.2% survival rate. At 7 years, the mean marginal bone loss was –1.51 mm (SD 1.00, $n = 73$). Differences between studies may be due to several factors. In the Glauser study, 76% of the implants were placed in soft bone, and 66 sites at implant installation had exposed threads, requiring guided bone regeneration and autologous bone grafting. In the present study, the majority of implants (90.74%) were placed in bone quality 2 (dense trabecular bone) and bone augmentation procedures were not performed. Others treated 46 patients with 121 TiUnite Branemark implants.[24] Twenty-four were immediately loaded and 97 were placed using a two-stage procedure. At 8 years, the survival rate was a surprisingly 99.2%, indicating the loss of one implant. The average crestal bone loss was 0.7 mm.

CONCLUSION

Results from this prospective clinical study indicate that within study limits, TiUnite-surfaced implant have high CSR rates with no clinically significant marginal bone loss. When comparing results from our study with others reporting on TiUnite-surfaced implants, it becomes apparent that this implant surface has survived in multiple clinical situations with high survival rates, minimal postoperative complications, and with clinically insignificant crestal bone loss over extended periods of time.

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