Retrospective Analysis of Long-Term (up to 12 years) Clinical and Radiologic Performance of Anodized-Surface Implants

Giuseppe Luongo, MD, DDS1,2
Antonio Cipressa, DDS1
Fabrizia Luongo, DDS, MS2

To accurately assess the long-term performance of anodized-surface implants, more data monitoring is needed outside of clinical evaluations. This retrospective study evaluated long-term implant survival and bone remodeling after up to 12 years of function. Data from 195 implants placed in 60 patients over a follow-up period ranging from 0.6 to 12.1 years were included. The implant-level survival rate was 99.0%. Marginal bone loss remained low across all follow-up cohorts. The data show that anodized-surface implants are a safe, reliable option with high implant survival rates and low levels of bone loss. Int J Periodontics Restorative Dent 2018;38:533–539. doi: 10.11607/prd.3350

The use of moderately rough surfaces on dental implants is shown to support osseointegration and clinical outcomes by enhancing the osteoconductive properties of the implant. Evidence from animal and human histologic studies supports increased bone-to-implant contact during the healing process.1–3 One such surface is generated by anodizing a commercially pure titanium implant to create a thickened, moderately rough oxide layer with a phosphate-rich microporous surface (TiUnite, Nobel Biocare). Numerous studies of anodized-surface implants reported primary stability maintenance during the healing phase and faster osseointegration.4–8

However, limited data are available on the long-term performance of these anodized implants outside of clinical evaluations.6,7,9–12 Most trials use highly selective inclusion criteria, such as patients with ideal bone conditions and high hygiene compliance, that improve the probability of success.13,14 As a result, the clinical outcomes of dental implants in the literature could be skewed in favor of success. Thus, there is a critical need for data on the long-term performance of implants under real-world clinical conditions.

This retrospective investigation evaluated the clinical and radiologic performance of anodized-surface implants placed in healed sites for
any indication. The objective of this study was to assess long-term implant survival and bone remodeling around implants for up to 12 years of function.

Materials and Methods

Study Design and Selection Criteria

In this retrospective study, charts were reviewed for patients who received implants between November 10, 2000, and August 31, 2011, at two private practice clinics in Italy. Data are reported in compliance with the STROBE statement version 4.15 Data from patients who received at least one Brånemark System Mk III or Mk IV implant with anodized surface (TiUnite, Nobel Biocare) were selected and deidentified. Any completely or partially edentulous patient who received at least one anodized-surface implant was included. Patients with controlled periodontitis or controlled diabetes were also included. Patients were excluded if they had recently undergone radio- or chemotherapy treatments or had a diagnosis of psychosis. Any patient who failed to attend follow-up visits was also excluded.

The outcomes investigated in this study were implant survival rate, bone remodeling, implant stability, probing pocket depth (PPD), and presence of plaque.

Surgery and Prosthetic Placement

The number of implants placed, type and dimension of implants, loading protocol, and use of provisional restorations were selected on a case-by-case basis. All implants were placed in healed sites, and all patients received fixed final prostheses. The general surgical protocol was as follows. At 1 hour prior to surgery, 2 g amoxicillin (if allergic, erythromycin was substituted) was administered to patients as a prophylactic antibiotic. A local anesthetic (articaine) was administered, and full-thickness flaps were raised. Implants were placed according to the manufacturer’s instructions. No bone- or soft-tissue grafting was performed. After surgery, patients were instructed to rinse twice daily with 0.12% chlorhexidine for 10 days. Implants were loaded within 48 hours of implant insertion (immediate loading, n = 12) or following a 3- to 6-month healing period (delayed loading, n = 183).

Implant Survival

The implant survival rate was calculated as number of surviving implants divided by total implants multiplied by 100.

Bone Level and Remodeling

Digital radiographs were collected at implant placement and the at last follow-up. As this was a retrospective study, radiographs were not collected according to specific time intervals or specialized imaging protocols between baseline and follow-up. In three cases, the final radiograph was collected up to 5 months after the clinical follow-up visit. Deidentified radiographs were analyzed by an independent radiologist at the University of Gothenburg. Bone-level measurements were performed in Adobe Illustrator using the implant-abutment junction as the reference point and calibrated to the implant diameter to an accuracy of 0.1 mm. The bone levels presented are the average of separate mesial and distal measurements. Negative values indicate bone levels apical to the reference point.

Marginal bone remodeling was calculated for paired radiographs. Radiographs taken at implant insertion were used as the baseline. The mesial and distal bone remodeling was calculated separately, and data presented are the average of mesial and distal remodeling values. Negative numbers indicate bone loss.

Other Measurements

Implant stability was performed by tapping or rocking. PPD was measured at the last follow-up using a periodontal probe. Plaque was measured by scraping the tooth with a manual probe. Implants were categorized as “no plaque” or “plaque present” according to the modified Mombelli plaque index.
Statistical Analysis

Analysis of implant survival, implant stability, PPD, and presence of plaque included data from all patients (n = 195 implants). Analysis of marginal bone levels and remodeling included patients with at least 4 years of follow-up (n = 108 implants). Radiographs were clustered into four follow-up cohorts as follows: 4 to 6 years, 6 to 8 years, 8 to 10 years, and 10 to 13 years of follow-up. Descriptive statistics were used to evaluate bone remodeling. Statistics were performed in SPSS version 22 (IBM).

Results

Patients

Overall, data for 195 anodized-surface implants (96.4% Mk III, 3.6% Mk IV) placed in 60 patients were included in the analysis. Of those, 19 patients (81 implants) were from center 1, and 41 patients (114 implants) were from center 2. The mean follow-up period was 7.6 years (range: 0.6 to 12.1 years). Among the 60 patients, 33.3% received single-tooth restorations, 60% partial restorations, and 6.7% full-arch restorations. Implants were placed using a one-stage (n = 16) or two-stage (n = 179) surgical procedure. While 16 implants were placed using one-stage surgery, only 12 implants were immediately loaded. The remaining 183 implants were loaded after a healing phase of 3 to 6 months. Patient demographics, implant characteristics, and treatment protocols are shown in Table 1. Implant dimensions and implant positions are provided in Tables 2 and 3, respectively. A representative case of successful implant placement with minimal observed marginal bone loss after 12 years of follow-up is shown in Fig 1.

Survival and Adverse Events

Over the course of the study period, two implants in two patients failed. The first was a 3.75-mm-diameter, 8.5-mm-length Mk III implant placed at the position of the maxillary right second premolar using a two-stage
The implant failed approximately 1 month after placement due to failure to osseointegrate. The second implant was a 4.00-mm-diameter, 10-mm-length Mk IV implant placed at the position of the mandibular right canine using a two-stage protocol. This implant failed 7 years after placement due to peri-implantitis. Thus, the total survival rate was 99.0% at the implant level and 96.7% at the patient level. No adverse events were reported during the study period.

**Bone Levels and Remodeling**

Patients were separated into cohorts based on the length between implant placement and final follow-up. Patients with < 4 years of follow-up were excluded. The mean marginal bone level at implant placement (baseline) was $-1.62 \pm 0.87$ mm ($n = 135$); at 4 to 6 years of follow-up, $-1.58 \pm 1.48$ mm ($n = 12$); at 6 to 8 years, $-1.69 \pm 0.45$ mm ($n = 12$); at 8 to 10 years, $-1.99 \pm 1.17$ mm ($n = 52$); and at 10 to 13 years, $-2.94 \pm 2.19$ mm ($n = 44$). Marginal bone remodeling calculated from paired radiographs at baseline and the last follow-up showed low bone remodeling for all cohorts (Table 4).

**Implant Stability and Soft Tissue Outcomes**

With the exception of the two failed implants and one implant that was not assessed, all measured implants remained stable throughout the follow-up period. PPD was good at the last follow-up, with 85.6% of implants having a PPD of 2 to 3 mm, 7.7% having a PPD of 4 mm, and 6.7% having a PPD > 4 mm. Regarding plaque accumulation at the last follow-up, 60.5% of implants had plaque present, 33.8% had no plaque, and 5.6% were not reported.

**Discussion**

Clinical investigations provide invaluable information on implant performance. However, they may not always reflect performance under real-world conditions. Studies have shown that experimental design, surgeon experience, and the patient’s socioeconomic background, education, and oral hygiene can affect implant outcomes. Clinicians...
must understand how implants perform over the long term under less than ideal conditions to provide patients with the best care. Therefore, this study included multiple indications, surgical protocols, and loading protocols and followed patients for up to 12 years. The implant-level survival rate observed in this study was 99%. The survival rate of anodized implants has been previously investigated. A retrospective study by Arnhart et al\(^7\) reported a survival rate of 98.5% at approximately 80 months. A retrospective study by Polizzi et al\(^12\) observed a 96.6% cumulative survival rate after up to 10 years of follow-up. A randomized open-ended trial by Rocci et al\(^6\) observed a 95.5% cumulative survival rate at the 9-year follow-up. A retrospective study by Mozzati et al\(^10\) and an open prospective cohort study by Glauser\(^9\) both observed a 97.1% cumulative survival rate at the 12-year and 11-year follow-ups, respectively. Due to the nonconsecutive nature of this study, cumulative survival rate was not calculated. Given this study’s extended follow-up length and the fact that cumulative survival rate is typically lower than survival rate, the survival rate observed in this study is consistent with the above cumulative survival rates.

**Fig 1** A 51-year-old man presented with a traumatic fracture of his maxillary right lateral incisor. (a, b) The tooth was carefully extracted, and a Brånemark System TiUnite Mk III RP 3.75 × 13-mm implant was placed. (c) The implant was immediately loaded with a temporary crown followed by (d) final crown placement 3 months later. Patient follow-up was performed every 6 months for 12 years. Analysis of radiographs taken at (e) the time of implant placement and (f) the 12-year follow-up show excellent integration and no observable marginal bone loss.
In addition to survival rate, bone remodeling in this study was low, ranging from $0.26 \pm 1.38$ mm in the 4- to 6-year cohort to $-1.28 \pm 2.23$ mm in the 10- to 13-year cohort. Among long-term studies of anodized surface implants, Polizzi et al\textsuperscript{12} reported bone remodeling of $-1.55 \pm 1.75$ mm at 80 months, Rocci et al\textsuperscript{6} reported $-0.1 \pm 0.4$ mm at 9 years, Mozzati et al\textsuperscript{10} reported $-0.60 \pm 1.17$ mm at 11 years, and Glauser\textsuperscript{9} reported $-1.66 \pm 0.98$ mm at 11 years. Therefore, the bone remodeling in this study was consistent with previous studies.

When looking at secondary outcome measures, 98.9% of implants in the present study were stable at last follow-up. This is comparable to the 98% implant stability at 11 years reported by Mozzati et al\textsuperscript{10}. The PPD at last follow-up in the present study was good, with 85.6% of implant sites having a PPD of 2 to 3 mm. These values were similar to those of Arnhart et al\textsuperscript{7}, who reported a mean PPD of 3.13 mm at 80 months, and Polizzi et al\textsuperscript{12}, who reported mean PPDs of 2.53 and 2.79 mm in the vestibular and palatal/lingual direction, respectively. However, they are not as good as those of Mozzati et al, who reported a mean PPD of 1.65 mm. In this study, plaque was observed on 60.5% of implant sites. This value is similar to Arnhart et al\textsuperscript{7}, who observed plaque at 61.8% of implant sites. However, it is substantially higher than the 14.9%, 15.5%, and < 40% plaque-positive implants reported by Polizzi et al\textsuperscript{12}, Mozzati et al\textsuperscript{10}, and Glauser\textsuperscript{9}, respectively.

Anodized-surface implants demonstrated excellent long-term outcomes for all indications in this study, which is consistent with previous studies for single-tooth, partial, and full-arch applications\textsuperscript{9,10,12}. Under both ideal and less than ideal conditions, anodized-surface implants represent a good all-purpose implant.

### Table 4 Marginal Bone Remodeling (in mm) Based on Years of Follow-up

<table>
<thead>
<tr>
<th>Cohort 1: Baseline to 4-6 y</th>
<th>Cohort 2: Baseline to 6-8 y</th>
<th>Cohort 3: Baseline to 8-10 y</th>
<th>Cohort 4: Baseline to 10-13 y</th>
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<td>Maximum</td>
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<tr>
<td>Minimum</td>
<td>-1.35</td>
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<th>%</th>
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<td>100</td>
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There were several limitations to this study. First, the study was retrospective and therefore had a high risk of patient- and treatment-selection bias and missing information. Notably, only patients with follow-up visits were included. Patients who regularly follow up could be more likely to comply with care instructions. Second, there was no standardized method for collecting radiographs (eg, fixed time intervals, standardized bitewings). The lack of standardization limits the precision of radiographic measurements and may account for the larger standard deviations observed for bone remodeling. The third limitation is the lack of consecutive measurements, which prevents the calculation of cumulative statistics.

Conclusions

Overall, the results from this long-term retrospective investigation show that anodized surface implants are a safe, reliable option for implant-supported prostheses. Over the long term, these implants had high survival rates and demonstrated low bone remodeling.

Acknowledgments

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References