

Immediate Restoration of Nonsubmerged Titanium Implants with a Sandblasted and Acid-Etched Surface: Five-Year Results of a Prospective Case Series Study Using Clinical and Radiographic Data



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The aim of this study was to evaluate the survival and success rates of immediately restored implants with sandblasted, large-grit, acid-etched (SLA) surfaces over a period of 5 years. Twenty patients (mean age, 47.3 years) received a total of 21 SLA wide-neck implants in healed mandibular first molar sites after initial periodontal treatment. To be included in the study, the implants had to demonstrate primary stability with an insertion torque value of 35 Ncm. A provisional restoration was fabricated chairside and placed on the day of surgery. Definitive cemented restorations were inserted 8 weeks after surgery. Community Periodontal Index of Treatment Needs (CPITN) indices and the radiographic distance between the implant shoulder and the first visible bone-implant contact (DIB) were measured and compared over the study period. The initial mean CPITN was 3.24, and decreased over the study period to 1.43. At the postoperative radiographic examination, the mean DIB was 1.41 mm for the 21 implants, indicating that part of the machined neck of the implants was placed slightly below the osseous crest. The mean DIB value increased to 1.99 mm at the 5-year examination. This increase proved to be statistically significant ($P < .0001$). Between the baseline and 5-year examinations, the mean bone crest level loss was 0.58 mm. Success and survival rates of the 21 implants after 5 years of function were 100%. This 5-year study confirms that immediate restoration of mandibular molar wide-neck implants with good primary stability, as noted by insertion torque values of at least 35 Ncm, is a safe and predictable procedure. (Int J Periodontics Restorative Dent 2012;32:39–47.)

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The use of dental implants to rehabilitate partially and completely edentulous arches has become the standard of care over the past quarter century.^{1–3} Long-term prospective studies have shown survival of dental implants in excess of 90% at 5 and 10 years posttreatment for a conventional loading protocol (prosthesis attached in a second procedure after a healing period of 3 to 6 months).^{4–11} The new treatment concepts of early loading (restoration in contact with the opposing dentition and placed at least 48 hours after implant placement but no later than 3 months afterward), immediate loading (restoration in occlusion with the opposing dentition inserted within 48 hours of implant placement), and immediate restoration (restoration inserted within 48 hours of implant placement but not in occlusion with the opposing dentition) have shortened treatment times, improving patient acceptance of treatment with a significant reduction in the number of office visits, allowing the patient to receive the definitive restoration in a significantly reduced

Table 1 Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
<ul style="list-style-type: none"> • At least 21 years old • In need of a single molar restoration • Sufficient alveolar ridge height, width, and mesiodistal space to accept a 4.8-mm-wide implant with a 6.5-mm prosthetic neck and a minimum length (apicocoronal) of 8 mm • A healed site (at least 3 months postextraction) without bone deficiencies or socket preservation procedures • ≥ 35 Ncm insertion torque value at implant placement • Willingness to sign informed consent 	<ul style="list-style-type: none"> • History of alcoholism or drug abuse • Pregnancy • Medical contraindications that would affect bone/soft tissue healing (ie, uncontrolled diabetes, blood disorders, intravenous bisphosphonates, etc) • Need for bone grafting procedures during implant insertion • History of cervicofacial radiation therapy • History of a severe bruxing habit • Heavy smokers (> 20 cigarettes per day)

time period.^{12–16} Today, these approaches are frequently used in different clinical situations, ranging from posterior to anterior sites and in cases with and without bone augmentation.^{15–22}

The purpose of this 5-year prospective study was to evaluate the survival and success rates of wide-neck implants with sandblasted, large-grit, acid-etched (SLA) surfaces immediately restored with nonfunctionally loaded cemented restorations. The hypothesis to be tested was that immediately restored, nonfunctionally loaded implants in the mandibular molar region in patients with a history of periodontitis could be as predictable over an extended period of time as implants placed in healthy patients with a conventional or early loading protocol.

Method and materials

Patient population

All patients were referred by their restorative dentists to the first author's private periodontal practice for replacement of their mandibular first molar with a dental implant. All patients were examined with a standardized procedure, including initial medical and dental histories, periodontal and occlusal examination, and any necessary digital periapical or panoramic radiographs. Initial periodontal health status was assessed using the Community Periodontal Index of Treatment Needs (CPITN).²³ Oral hygiene instructions and nonsurgical periodontal therapy were given to all patients according to their initial status. All patients recruited for the study

were consecutively selected during the year 2002 and met strict inclusion and exclusion criteria (Table 1).

Surgical procedure

All surgical procedures were performed under local anesthesia under aseptic conditions in a private practice setting. Patients received oral perioperative antibiotic prophylaxis (amoxicillin or clindamycin) 1 hour prior to surgery. All implants were placed by the same experienced surgeon with the help of a custom-made surgical guide template. Full-thickness flaps were raised to gain access to the osseous crest, and the prospective implant beds were prepared to allow at least 1 mm of cortical bone on the buccal and lingual sides of the

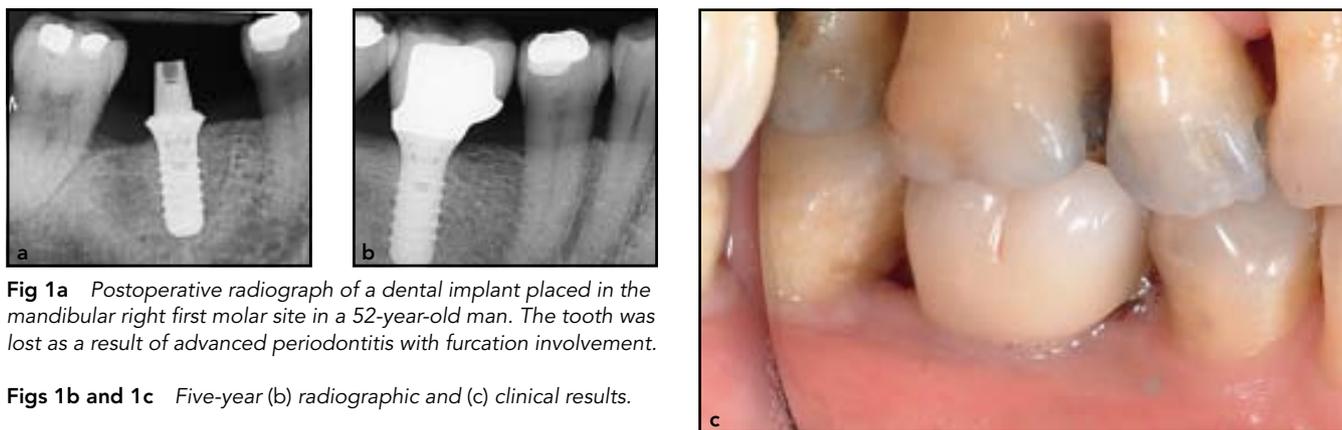


Fig 1a Postoperative radiograph of a dental implant placed in the mandibular right first molar site in a 52-year-old man. The tooth was lost as a result of advanced periodontitis with furcation involvement.

Figs 1b and 1c Five-year (b) radiographic and (c) clinical results.

alveolar crest after final implant placement. All patients received implants with a wide-neck configuration (diameter, 6.5 mm) and an SLA surface (Straumann). Implants were inserted by hand using the manufacturer's torque wrench device to depth, and the border of the SLA surface was positioned slightly below the osseous crest, with a portion of the machined neck (all implants, 1.8 mm) in the transmucosal area (Fig 1a). Details of the presurgical evaluation, surgical techniques, and postoperative treatment were published previously.²⁴⁻²⁶

Immediate restoration

After insertion of the dental implant, either a 4.0- or 5.5-mm wide-neck solid abutment (Straumann)

was tightened to the manufacturer's recommended 35 Ncm based on interarch space. None of the implants placed in the consecutively enrolled patients rotated upon abutment insertion. A provisional cementable coping for wide-neck solid abutments was used to capture the margins of the implant shoulder, and a provisional restoration was fabricated over this coping in the laboratory using an abutment analog. The immediate, nonocclusally loaded provisional was checked clinically to ensure no occlusal contacts in working, nonworking, and centric occlusion and was then cemented with temporary cement. All excess cement was removed, and the flaps were sutured. A digital periapical radiograph was taken using the long-cone technique before the patient was discharged.

Follow-up

Each patient was followed with postoperative appointments at 2, 4, and 8 weeks, when the cemented provisional was removed and the definitive restoration was inserted. Further follow-up preventive periodontal maintenance schedules were determined for each patient based on their needs and coordinated with their general dentist. All patients were scheduled for a follow-up visit 5 years after implant insertion to assess the following parameters (Figs 1b and 1c).

CPITN

The CPITN was assessed initially, after periodontal treatment/before implant insertion, and during the follow-up visit 5 years after implant placement. The score (per patient) was based on the following:

- 0 = no need for further treatment/no signs of periodontal disease in any sextant
- 1 = need to improve personal oral hygiene/gingival bleeding after gentle probing in any sextant
- 2 = need for professional cleaning of teeth and improvement in personal oral hygiene/supra- and subgingival calculus in any sextant
- 3 = need for professional cleaning of teeth and improvement in personal oral hygiene/pathologic pockets of 4 to 5 mm in any sextant
- 4 = need for more complex treatment to remove infected tissue/pathologic pockets ≥ 6 mm in any sextant

Distance between implant shoulder and first visible bone-implant contact (DIB)

DIB was measured (in mm) at the mesial and distal aspects of each implant using periapical radiographs with the long-cone technique.²⁷ All radiographs were examined by the same experienced examiner not involved in the surgical or prosthetic rehabilitations of the patients. For each implant, one DIB value was calculated based on the mean of the mesial and distal values. The

60-month DIB values were compared with the values at implant insertion to evaluate crestal bone changes around the implants over the 5-year period ($\Delta\text{DIB}_{60\text{ mos} - 0\text{ mos}}$).

Based on clinical and radiographic findings, each implant was classified as either successful or unsuccessful using the same success criteria as in previous prospective studies.^{17,24} Success was defined as follows: absence of persistent subjective complaints, such as pain, foreign body sensation, and dysesthesia; absence of peri-implant infection with suppuration; absence of mobility; and absence of continuous radiolucency around the implant.

Statistical analysis

Descriptive statistical analysis was complemented with inferential statistics. The Friedman test was used to test for overall differences in CPITN scores between three consecutive time periods (before implant placement, after implant placement, and after 5 years). The Wilcoxon signed rank test was used to compare between-group differences and to compare DIB values at baseline and after 5 years. In addition, 95% confidence intervals of the mean DIB were calculated for each time period. Univariate and multivariate linear regression models were used to test for potential associations between age, smoking status, and implant length (independent variables) and DIB values (dependent variable) after 5 years.

The statistical software package S-Plus Professional (version 6.2, Insightful Software) was used for all analyses.

Results

During the recruitment phase, 20 partially edentulous patients (8 women, 12 men) ranging in age from 31 to 71 years (mean, 47.3 years) were enrolled. The opposing maxillary arches for all patients consisted of natural teeth or crown and fixed partial denture restorations. The reasons for loss of the mandibular first molar included nonrestorable root fracture ($n = 13$), nonrestorable caries ($n = 5$), advanced periodontitis ($n = 2$), and endodontic failure ($n = 1$). Two patients were smokers (between 1 and 20 cigarettes per day), 2 were former smokers, and 16 patients were nonsmokers.

Implant surgery and healing period

Of the 21 implants inserted, 10 were placed at the site of the mandibular left first molar and 11 at the mandibular right first molar. All implants had a diameter of 4.8 mm, a smooth neck section of 1.8 mm, a shoulder diameter of 6.5 mm, and lengths varying from 8 to 13 mm (8 mm, $n = 1$; 9 mm, $n = 3$; 11 mm, $n = 11$; 12 mm, $n = 4$; 13 mm, $n = 2$). Following surgery, patients reported no to minimal postoperative discomfort at the surgical site.

Table 2 CPITN values over the study period for the 21 implants inserted*

Score	Initial visit (%)	Implant placement (%)	5-year follow-up (%)
0	0 (0)	1 (5)	4 (20)
1	0 (0)	1 (5)	7 (33)
2	4 (19)	12 (57)	7 (33)
3	8 (38)	7 (33)	3 (14)
4	9 (43)	0 (0)	0 (0)

CPITN = Community Periodontal Index of Treatment Needs.

*The Friedman test (comparing all three groups: $P < .0001$) and Wilcoxon signed rank test (initial visit – implant placement: $P < .0001$, implant placement – 5-year follow-up: $P = .0015$) were used for comparisons.

During provisionalization, there were no biologic complications. One provisional single crown became decemented during this period and was lost. Upon delivery of the definitive restoration at 8 weeks, no cases of implant mobility, spinning, or patient discomfort were noted. During the follow-up period of 5 years, no further biologic or prosthetic complications were recorded for the 20 patients included, and all patients attended the 5-year follow-up visit.

Clinical and radiographic follow-up

When the patients were examined initially, a mean CPITN of 3.24 was calculated. After a phase of intensive periodontal treatment, including extraction of the mandibular molar that was scheduled for replacement with a dental implant, the CPITN was reduced to a mean 2.19. This reduction proved to be statistically significant compared to baseline values ($P < .0001$, Table 2).

Table 3 DIB values (mm) at implant insertion and after the study period for the 21 implants inserted

	Mean (95% CI)	Minimum	Maximum
Implant placement	1.41 (1.29–1.54)	1.05	1.87
5-year follow-up	1.99 (1.76–2.22)	1.15	3.13

DIB = distance between the implant shoulder and first visible bone-implant contact; CI = confidence interval.

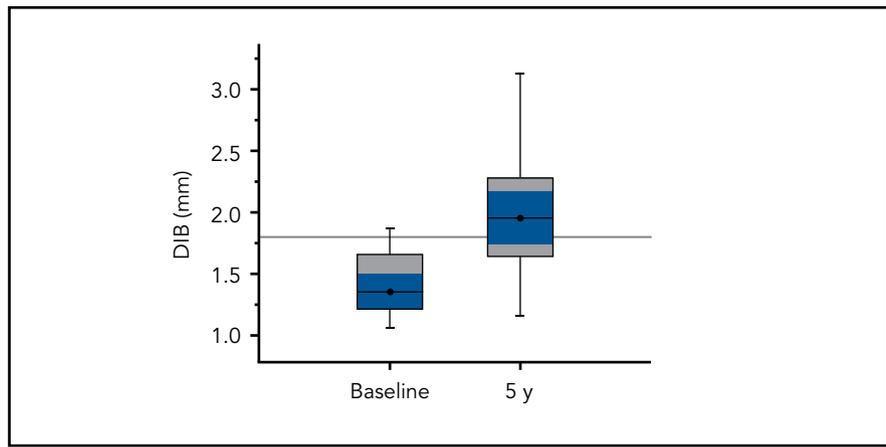


Fig 2 Box plot of DIB values at implant insertion and after a follow-up period of 5 years. Blue bands indicate the 95% confidence intervals of the median.

Oral hygiene was well maintained by all patients after implant placement and during the follow-up period. After 5 years, the mean CPITN decreased even further to 1.43 ($P = .0015$, Table 2).

The periapical radiographs taken at baseline and 5 years after surgery for all implants revealed no signs of continuous peri-implant radiolucency. At the postoperative radiographic examination, the mean DIB was 1.41 mm for the 21 implants, indicating that part of the machined neck of the implants was placed slightly below the osseous crest. The mean DIB value in-

creased to 1.99 mm at the 5-year examination ($P < .0001$; Table 3 and Fig 2). Between the baseline and 5-year examinations, the bone crest level demonstrated a mean loss of 0.58 mm. There were no statistically significant associations between age, smoking status, and implant length (independent variables) and DIB measurements (dependent variable) after 5 years.

At the end of the 5-year follow-up period, all 21 implants fulfilled the strict success criteria. Consequently, the 5-year survival and success rates were 100%.

Discussion

In the literature, several different loading protocols exist, which makes direct comparison of studies applying different healing periods for nonrestored dental implants difficult. At the Consensus Conference of the European Association for Osseointegration in 2006, the group accepted three different definitions and loading principles. Besides immediate loading and conventional loading, nonfunctional immediate loading and immediate restoration was defined as a prosthesis being fixed to dental implants within 72 hours after insertion without achieving full contact with the opposing dentition.²⁸ No such distinction between occlusal and nonocclusal loading was made in a recent systematic review by Esposito et al.²⁹ The distinction between nonfunctional immediate loading and immediate loading with implants in direct occlusion with the opposing dentition was also not further upheld in the proceedings of the most recent ITI Consensus Conference, held in 2008 in Stuttgart, Germany.³⁰ The present prospective clinical case series study demonstrated favorable results for titanium implants with an SLA surface when immediately restored without achieving full occlusal contact with the opposing dentition. All 21 inserted implants could be definitively restored after 8 weeks, and were still considered successfully integrated after 5 years of function.

The favorable results seen in the present study are comparable to data published in the literature analyzing immediate loading of dental implants with or without occlusal contacts. Cornelini et al¹⁸ reported results at 12 months for 30 single-tooth implants in the mandibular first molar site. As an inclusion criterion, the authors used resonance frequency analysis to monitor primary stability, including only implants with an implant stability quotient greater than 62. After 12 months of function, only one early failure resulting from acute infection occurred, resulting in a survival/success rate of 97%. Calandriello et al^{31,32} performed a study focusing on immediate loading with occlusal contacts in centric relation with single crowns and fixed dental prostheses on 50 machined implants inserted in the maxilla and mandible. For the 21 dental implants placed in partially edentulous posterior mandibles, the survival rate was 100% after a follow-up period of 12 to 24 months.^{31,32} Several other studies have also reported survival rates of 100% for immediately loaded/restored implants in the mandible, using different implant surfaces and follow-up periods ranging from 1 to 2 years.^{22,33-35} To the best of the authors' knowledge, the present paper is the first in the literature reporting long-term data from a 5-year follow-up period for immediately restored dental implants.

In the present study, all implants had an endosteal implant diameter of 4.8 mm and a shoul-

der diameter of 6.5 mm (wide-neck configuration). The success and survival rate of the 21 included implants after 5 years of follow-up was 100%. In a multicenter study by Levine et al,³⁶ 499 wide-neck implants were restored in 410 patients, and a survival rate of 99.2% for the 359 mandibular molars placed (mean loading period, 23 months) was reported. The overall cumulative survival rate of all implants was 98.4%. This is similar to the data from Bischof et al,³⁷ who evaluated 263 wide-neck implants in 212 patients and found a 5-year cumulative survival rate of 97.9%.

For the long-term follow-up of implants, the observation of bone crest levels is considered more important than mere success or survival percentages.⁵ DIB has been used in previous studies on dental implants with a titanium plasma-sprayed or (modified) SLA surface.^{7,17,24,38,39} This value is appropriate to follow changes in peri-implant bone levels over time by examining Δ DIB between two time points. In the present study, the mean Δ DIB_{60 mos - 0 mos} was 0.58 mm, indicating a mean bone loss of approximately 0.12 mm per year. A prospective 5-year follow-up study of implants with an SLA surface restored with an early loading protocol after 6 weeks demonstrated a mean crestal bone loss of 0.15 mm over the study period.¹⁷

In the present study analyzing immediately restored implants in the posterior mandible, the mean crestal bone loss after the follow-up period of 5 years was slightly

higher (0.58 mm) than in the studies mentioned previously. This difference in bone loss over time could be a result of two main factors in connection with patient inclusion criteria and the loading protocol applied. First, patients included in this study had a history of periodontal disease, emphasized by the initial mean CPITN of 3.24. Implants inserted in patients with a history of periodontitis having an increased risk of marginal bone loss and peri-implantitis (odds ratio, 3.1 to 4.7) was reported in a recent systematic review.⁴⁰ Nevertheless, implants in patients with treated periodontitis still achieve success rates well over 90% over a period of 3 to 16 years. The second factor influencing DIB values could be the loading protocol used for the present implants. In studies reporting outcomes of immediate loading with or without occlusal contact, crestal bone resorption rates from 0.03 to over 1 mm have been reported for follow-up periods of 1 to 2 years.^{18,31,35,41}

Based on these promising results, immediate restoration of mandibular molar wide-neck implants with good primary stability, as noted by insertion torque values of at least 35 Ncm, is a safe and predictable procedure, and one that can be recommended under clearly defined clinical conditions for standard sites without bone defects. In the present study, the implants were restored with provisional restorations to allow loading on the day of surgery. In daily practice, this approach is not recommended for implants in the posterior mandible

since this causes unnecessary expense for the patient. For immediate restoration, a definitive crown or fixed dental prosthesis should be provided within the first 48 hours to offer the patient a cost-effective treatment option.

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