Early Loading after 21 Days of Healing of Nonsubmerged Titanium Implants with a Chemically Modified Sandblasted and Acid-Etched Surface: Two-Year Results of a Prospective Two-Center Study

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ABSTRACT

Purpose: The aim of this two-center study was to evaluate screw-type titanium implants with a chemically modified, sandblasted and acid-etched surface when placed in the posterior maxilla or mandible, and loaded 21 days after placement.

Material and Methods: All 56 patients met strict inclusion criteria and provided informed consent. Each patient displayed either a single-tooth gap, an extended edentulous space, or a distal extension situation in the posterior mandible or maxilla. Eighty-nine dental implants (SLActive®, Institut Straumann AG, Basel, Switzerland) were inserted according to an established nonsubmerged protocol and underwent undisturbed healing for a period of 21 days. Where appropriate, the implants were loaded after 21 days of healing with provisional restorations in full occlusion. Definitive metal ceramic restorations were fabricated and positioned on each implant after 6 months of healing. Clinical measurements regarding soft tissue parameters and radiographs were obtained at different time points up to 24 months after implant placement.

Results: Of the 89 inserted implants, two (2.2%) implants failed to integrate and were removed during healing, and two (2.2%) additional implants required a prolonged healing time. A total of 85 (95.6%) implants were therefore loaded without incident after 21 days of healing. No additional implant was lost throughout the study period, whereas one implant was lost to follow-up and therefore left unaccounted for further analysis. The remaining 86 implants all exhibited favorable radiographic and clinical findings. Based on strict success criteria, these implants were considered successfully integrated 2 years after insertion, resulting in a 2-year success rate of 97.7%.

Conclusion: The results of this prospective two-center study demonstrate that titanium implants with a modified SLA surface can predictably achieve successful tissue integration when loaded in full occlusion 21 days after placement. Integration could be maintained without incident for at least 2 years of follow-up.

KEY WORDS: chemically modified surface, clinical trial, dental implants, early loading protocol

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INTRODUCTION

The treatment of edentulous and partially edentulous patients with restorations supported by dental implants has become routine and is based on successful

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osseointegration or functional ankylosis of titanium implants.^{1–5} Periods of undisturbed healing in the range of 3 to 6 months have historically been central to protocols designed to ensure osseointegration and treatment success.^{6,7}

The period of undisturbed healing subsequent to implant placement has been a focus of research in implant therapy for some time. The microrough sandblasted and acid-etched (SLA) surface has been scientifically examined, and evidence has concluded that implants with this SLA surface can be successfully loaded between 6 and 8 weeks, with favorable survival and success rates up to 5 years of follow-up.⁸⁻¹⁴ In several experimental studies, a chemical modification of the SLA surface further improved the integration of the dental implant in the surrounding tissues by accelerating bone apposition during initial healing.¹⁵⁻¹⁸ The hydrophilicity, wettability, and surface charge, in addition to topography and chemistry, are integral to these observations. Factors such as these appear to indicate that a further reduction of undisturbed healing times with no increase in complications is possible.

A further reduction of the healing period required to complete therapy is beneficial to patients, simplifies clinical procedures, and may improve the acceptance of implant therapy by patients. Existing literature has firmly established that partially edentulous patients can be predictably restored with implant-supported crowns and fixed dental prostheses.^{4,5,8–14,19–24} Altering the period of undisturbed healing, and the method of load application to implants may reduce the likelihood of positive outcomes. Therefore, scientific validation of new treatment protocols that reduce healing times and improve treatment efficiency is vital prior to their routine use.

This prospective clinical two-center study in posterior sites of partially edentulous patients was designed to evaluate dental implant integration and tissue response to implants placed into full occlusal function 21 days after placement. The goal was to confirm the feasibility of this treatment protocol and hence determine the applicability of the SLActive® (Institut Straumann AG, Basel, Switzerland) surface for early loading protocols.

MATERIAL AND METHODS

Patient Selection

According to the requirements of each university (University of Bern, Switzerland, and University of Florida,

USA), the study protocol was evaluated by the institution's ethical committee and approved prior to patient selection. Fifty-six patients were subsequently enrolled in the study between December 2004 and June 2006. Each patient was at least 18 years of age and was able to understand and sign an informed consent.

All patients were partially edentulous in the posterior regions of the maxilla and/or mandible, displaying either a single-tooth gap, an extended edentulous space, or a distal extension situation. For all patients, the opposing dentition was characterized by natural or restored teeth or by implant-supported fixed restorations. All sites were required to have healed for a minimum of 4 months subsequent to tooth extraction and were considered capable of receiving a regular or wide neck implant of 10 to 12 mm length without augmentation at the time of placement.

Systemic exclusion criteria included routine use of prophylactic antibiotics or steroids, leukocyte dysfunction or deficiencies, bleeding disorders, radiation and/or chemotherapy, history of renal failure, bone or endocrine disorders, and physical handicaps capable of interfering with oral hygiene maintenance. The use of investigational drugs or devices in the 30 days prior to study commencement was also considered an exclusion factor, as was HIV infection. Additionally, moderate and heavy smokers (>10 cigarettes per day) were excluded. Local exclusion factors included unresolved periodontitis, mucosal and/or occlusal disease, the presence of osseous lesions, and/or unresolved extraction wounds (<4 months' healing). Inadequate bone at the time of surgery resulting in a need for guided bone regenerative methods and lack of implant stability were considered reasons for patient withdrawal from the study.

Clinical Procedures

Each patient was evaluated by the treatment team prior to therapy. Periodontal and restorative procedures were undertaken where necessary to establish a healthy oral environment. The prosthodontic needs relating to the missing teeth were determined, and patients were advised of treatment alternatives. Upon study inclusion, the requirements for three-dimensional, restorativedriven implant placement were identified.

One surgeon performed all surgical procedures for each institution (D.B. and J.R.). Preoperative antibiotic prophylaxis was provided 1 to 2 hours prior to surgery,

TABLE 1 Distribution of Inserted Dental Implants $(n = 89)$ According to the Federation DentaireInternational Classification									
Implants	0	4	1	3	2	1	1	0	12
Maxilla	17	16	15	14	24	25	26	27	Total
Mandible	47	46	45	44	34	35	36	37	Total
Implants	7	19	5	1	1	6	32	6	77

and all procedures were performed under local anesthesia. Where necessary, conscious sedation was used in conjunction with local anesthetic. Eighty-nine titanium dental implants characterized by a modified SLA (modSLA) surface were inserted in healed sites in the posterior maxilla or mandible. The distribution of implants by site is presented in Table 1. The implants were placed by using a standardized surgical procedure, with the border of the modSLA surface slightly below the alveolar crest, with a 2.8-mm machined neck in the transmucosal area. Prior to the placement of the healing cap, implants were indexed if practical to facilitate prefabrication of the provisional restoration prior to the 3-week loading appointment.

All implants were assessed after 21 days of healing and were loaded with provisional restorations if considered successfully integrated. The provisional restorations were fabricated in acrylic resin and were either prefabricated by using an altered cast-fabricated from the surgical index or fabricated by using an impression made of the implant at the 3-week follow-up appointment. All provisional restorations were supported by titanium abutments torqued to approximately 20 Ncm and were either cement retained or screw retained. Each provisional restoration was adjusted to ensure direct occlusal contact with the opposing arch. Direct occlusal contact was considered to be the holding of 20-µm shim stock foil with firm biting pressure.

Clinical and Radiological Follow-Up Protocol

The day of implant placement was defined as day 0. The soft tissues adjacent to the implants and provisional restorations were evaluated at each follow-up appointment (3, 6, 12, and 24 months), consistent with evaluations used for previous studies of this type.^{25–27} Soft tissue evaluations included

1. modified plaque index (mPLI) assessed at four sites around the implants (mesial, buccal, distal, and lingual),

- 2. modified sulcus bleeding index (mSBI) assessed at the same four sites adjacent to each of the implants, and
- 3. probing depths (PDs) measured in millimeters at the same four sites.

Periapical radiographs were obtained by using a long-cone parallel technique at days 0 and 3, 6, 12, and 24 months following implant placement. A single clinician evaluated the radiographs for all patients (J.W.). The distance from the restorative margin (or implant shoulder) to the first bone-to-implant contact (DIB) was noted for the mesial and distal of each implant at all time intervals. For each implant, a DIB value was considered to be the average of the mesial and distal measurements. The DIB values for each follow-up period were compared with those obtained at baseline (day 0) and the values obtained during the 3-month visit. Implant success was determined based on clinical and radiographic findings using previously published and validated criteria:^{11,13,21,25}

- 1. Absence of persistent subjective complaints, such as pain, foreign-body sensation, and/or dysesthesia
- 2. Absence of peri-implant infection with suppuration
- 3. Absence of mobility
- 4. Absence of continuous radiolucency around the implant

Statistical Analysis

All data were analyzed with descriptive methods using box plots. For the potential differences in the periimplant soft tissue parameters and DIB values over the study period to be analyzed, the Wilcoxon signed-rank test was used. For multiple testing situations to be compensated for, the p values for the testing blocks were corrected by using the Bonferroni–Holm adjustment procedure and compared with the alpha level of 0.05.

Wilcoxon signed-rank test was performed by using a software package (SAS 9.1, SAS Institute Inc., Cary, NC, USA). The Bonferroni–Holm adjustments were performed by using the internet-based R software package (http://www.r-project.org).

RESULTS

Healing and Loading Period

No patients reported adverse effects following dental implant placement. Two implants (2.2%; both lower second molars in two male patients) were considered

TABLE 2 Peri-Implant Soft Tissue Parameters of the Dental Implants Evaluated at the Follow-Up Visits (Mean ± Standard Error of the Mean)							
Exam	mPLI	mSBI	PD (mm)				
3 months $(N = 84)$	0.23 (±0.04)	0.22 (±0.03)	2.69 (±0.09) ^{a,b,c}				
6 months $(N = 84)$	0.27 (±0.05)	0.20 (±0.03)	2.93 (±0.10) ^a				
12 months ($N = 84$)	0.20 (±0.03)	0.15 (±0.02)	3.07 (±0.11) ^b				
24 months ($N = 84$)	0.32 (±0.04)	0.28 (±0.03)	3.21 (±0.11) ^c				

Statistically significant differences are marked with the same letters (alpha level of 0.05).

mPLI = modified plaque index; mSBI = modified sulcus bleeding index; PD = probing depth.

nonintegrated after the 21-day healing period and were removed without further complication. Two (2.2%) additional implants rotated slightly during healing cap removal, were considered to be "spinners" after the initial healing phase, and were not loaded according to the treatment protocol. These implants were given an additional 3 weeks of healing, after which provisional restorations were fabricated and delivered without additional complication. One implant in the first upperright premolar region in a 47-year-old female patient was lost to follow-up after the 6-month visit and therefore was left unaccounted for further statistical analysis. During the follow-up visits, no peri-implant soft tissue infections were noted, and each implant was considered successfully integrated. Each patient received instructions on the maintenance of oral hygiene and was advised to contact the investigators if any concerns arose.

Standard Peri-Implant Soft Tissue Parameters

Oral hygiene was well maintained by all patients throughout the follow-up period. The mean mPLI for

the 12-week examination was 0.23. A slight increase was observed for the measurement at the 2-year follow-up exam (0.32). The peri-implant soft tissues revealed little tendency to bleed following probing and were clinically healthy. At the 12-week examination, the mean mSBI was 0.22 and slightly increased over the follow-up period to 0.28 after 24 months. The mean PD at week 12 was 2.69 mm, also slightly increasing over the period of 2 years to 3.21 mm. The PD mean values were statistically significant higher for the 6, 12, and 24 months measurements than after 3 months (Table 2).

Radiographic Findings

The periapical radiographs taken at months 0, 3, 6, 12, and 24 for all implants revealed no signs of continuous peri-implant radiolucency, including the two implant "spinners." At the postoperative radiographic examination, the mean DIB was 2.37 mm for the 84 implants. During the follow-up period, the mean value increased up to 2.57 mm at the 24-month examination (Table 3 and Figure 1). Between the baseline and the 3-, 6-, and

TABLE 3 Radiographic Parameters (DIB) of the 84 Implants Analyzed over the Course of 2 Years							
Exam	0 Months	3 Months	6 Months	12 Months	24 Months		
Mean	2.37	2.57	2.63	2.60	2.57		
Median	2.37	2.57	2.62	2.58	2.54		
Maximum	3.91	3.54	3.85	3.73	4.125		
Minimum	0.89	1.30	1.62	1.58	1.56		
SEM	±0.06	±0.04	±0.04	±0.04	±0.05		
Significance	a,b,c	а	b	С			

Statistically significant differences between the radiographic parameter values are marked with the same letters.

DIB = distance from the restorative margin/implant shoulder to the first bone-to-implant contact; SEM = standard error of the mean.



Figure 1 Box plots of the mean DIB values (DIB values = distance from the restorative margin or implant shoulder to the first bone-to-implant contact) at day 0 (implant insertion) and at months 3, 6, 12, and 24.

12-month examinations, the differences of the DIB values were statistically significant (DIB_{3 months vs 0 months}, DIB_{6 months vs 0 months}, and DIB_{12 months vs 0 months p < .05). The difference between the DIB values at baseline and the values after 2 years did not reach the level of statistical significance (p = .069, see Table 3).}

In the frequency analysis for the 84 implants ($\Delta DIB_{24 \text{ months}-3 \text{ months}}$), two implants demonstrated a bone gain of more than 1.0 mm ($\Delta DIB_{24 \text{ months}-3 \text{ months}}$ < -1.0 mm), whereas no implant showed a bone loss of more than 1.0 mm ($\Delta DIB_{24 \text{ months}-3 \text{ months}} > 1.0 \text{ mm}$, Figure 2).



Figure 2 Gain and loss of bone around 84 implants using the $\Delta Ø$ DIB_{24 months-3 months} values (DIB = distance from the restorative margin or implant shoulder to the first bone-to-implant contact).

Survival and Success Rates

At the end of the 2-year observation period, two implants had been lost, one implant was lost to follow-up and considered as a dropout. The remaining 86 implants, including the two "spinners," fulfilled strict success criteria. Consequently, the 2-year survival and success rates were both 97.7%.

DISCUSSION

This prospective, two-center clinical study of implants with an SLActive surface, loaded after 21 days of healing, has demonstrated the applicability of the treatment protocol tested and the predictability of implant survival and success for a period of at least 2 years. The results during the healing period and the first 6 months of function for dental implants placed at the University of Bern (56 implants in 40 patients) were reported in a separate paper focusing on implant stability quotient values and peri-implant crestal bone changes.²⁸

Of the 89 implants placed in the present study, 86 remain successfully integrated and in function. Of the 86 functioning implants, 84 could be loaded without incident 21 days after placement. The two implants requiring additional healing time prior to loading (so called "spinners") remain in function and are successfully integrated. This observation further confirms the results obtained in other clinical studies,^{8,11,12} demonstrating that implants that rotate at the time of healing cap removal or abutment connection are not unconditionally associated with a loss of osseointegration or a negative treatment outcome when provided with additional healing time.

Throughout the follow-up period, no hard or soft tissue complications have been observed. Measurable peri-implant soft tissue parameters were comparable to those published in previous studies.^{9–11} All patients maintained satisfactory levels of oral hygiene, with the mPLI increasing only slightly throughout the 2-year follow-up period. Further, the results illustrate no tendency for increased bleeding on probing in the tissues surrounding the implants or restorations.

Systematic radiographic evaluation of the implants failed to identify continuous peri-implant radiolucency nor bone loss of greater than 1 mm associated with any of the implants throughout the observation period. The mean bone loss (0.2 mm) noted after 2 years in this study is similar to that reported for titanium implants with titanium plasma spray (TPS) and SLA surfaces for the first year of loading in nonregenerated bone^{11,13,29} and recently for 5-year data on implants in augmented bone²¹ after a staged approach with sinus floor elevation.³⁰

All implants capable of being loaded after 21 days of healing were provided with provisional restorations on abutments torqued to approximately 20 Ncm. This procedure did not result in any loosening or failure of components or provisional restorations during the study period and facilitated the noncomplicated removal of the provisional restoration and abutment for implant evaluation and definite prosthesis delivery. In daily practice, this is not recommended for implants in the posterior mandible because this causes unnecessary expenses to the patient. In daily practice, the restoration with a definitive crown or fixed dental prosthesis is routine to offer the patient a treatment with improved cost-effectiveness. For all implants used in this study, definitive abutments were, according to the manufacturer's recommendations, torqued to 35 Ncm.

An important characteristic of the modSLA surface reported in several experimental studies seems to be an enhanced bone apposition to this implant surface during the initial healing.^{16–18,31–37} These findings from experimental studies have been validated by three clinical studies reporting favorable implant stability measurements during the initial phase of healing using the implant stability quotient method.^{28,38,39}

Short-term results of a randomized, controlled multicenter trial comparing the performance of implants with an SLActive surface restored immediately or 28 to 34 days after insertion demonstrated favorable results for both treatment options.⁴⁰ After 5 months, implant survival rates were 98% in the immediate loading group and 97% in the early loading group. Mean bone level changes from baseline were 0.81 ± 0.89 mm in the immediate and 0.56 ± 0.73 mm in the early loading group. Similar results were obtained for the one-year follow-up data of the same study cohort.⁴¹

The slightly lower success rate (97.7%) after 2 years of follow-up reported in our present study when compared with studies reporting about early and long-term results of implants with an SLA surface^{8–13} might be a result of differences in the two centers performing the study. While both early implant failures occurred in one center (2 out of 33 inserted), no implant failed during the healing or follow-up period (56 implants) in the other center. Conversely, no "spinners" were noted in one center (University of Florida), while the two reported were associated with the other center (University of Bern). This may reflect a degree of subjectivity with regard to failing versus spinning implants. The routine use of resonance frequency analysis for all implants included in studies of this type should improve the objectivity and the consistency of evaluation.²⁸

As indicated with the present study, the concept of early loading of implants at 3 weeks after placement in the posterior mandible has a reasonably low risk for early failures (2.3%) when the defined inclusion criteria are met. These early failure rates are also in line with a recent systematic review of the incidence of biologic and technical complications in implant dentistry, reported in prospective longitudinal studies of at least 5 years, indicating that implant loss prior to functional loading is expected to occur in about 2.5% of all implants placed.⁴² The concept of early loading offers a straightforward treatment with definitive restoration after a 3-week healing period. Thus, this concept offers a good costeffectiveness. Additional studies with a larger sample size and longer observation periods are needed to further validate this treatment concept for implants in healed posterior sites.

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CONFLICT OF INTEREST

The authors report no conflict of interest related to this study.

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