

# Early Loading of Nonsubmerged Titanium Implants with a Sandblasted and Acid-Etched (SLA) Surface: 3-year Results of a Prospective Study in Partially Edentulous Patients

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**Purpose:** The aim of this study was to evaluate the success rate of ITI implants with the SLA surface that were loaded after 6 weeks of healing. **Materials and Methods:** In this prospective cohort study, a total of 104 implants were placed in posterior sites of 51 partially edentulous patients exhibiting bone densities of Class 1, 2, or 3. After a healing period of 6 weeks, all implants were functionally loaded with cemented crowns or fixed partial dentures. The patients were recalled at 3, 12, 24, and 36 months for clinical and radiographic examination. **Results:** One implant failed to integrate during healing, and 1 implant was lost to follow-up and considered a dropout. The remaining 102 implants showed favorable clinical and radiographic findings and were considered successfully integrated at the 3-year examination. This resulted in a 3-year success rate of 99.03%. **Discussion:** The peri-implant soft tissues were stable over time, as evidenced by no changes in the mean probing depths and the mean attachment levels during the follow-up period. None of the radiographs exhibited signs of continuous peri-implant radiolucency, which confirmed ankylotic stability of all 102 implants. The radiographic evaluation of the bone level at the implant indicated stability of the bone crest levels. **Conclusion:** The results of this prospective study demonstrated that early loading of ITI implants with the SLA surface after an unloaded healing period of 6 weeks provided successful tissue integration with high predictability, and that successful tissue integration was well maintained up to 3 years of follow-up in this study population. *INT J ORAL MAXILLOFAC IMPLANTS* 2003;18:659–666

**Key words:** clinical trial, dental implants, early loading, healing time, SLA surface

In recent years, the utilization of endosseous implants for the rehabilitation of completely or partially edentulous patients has become a standard of care in dentistry. This progress is based on the concept of osseointegration first described by the 2 research groups led by Brånemark<sup>1,2</sup> and Schroeder.<sup>3,4</sup> In the past 15 years, numerous prospective long-term studies have documented a high efficacy and predictability of osseointegrated implants.

Among the various implant systems, the best long-term documentation is available for 2 implant systems: the Brånemark System (Nobel Biocare, Göteborg, Sweden) and the ITI Dental Implant System (Straumann, Waldenburg, Switzerland). For both systems, prospective long-term studies have exhibited survival and success rates clearly exceeding 90% at 5 and 10 years of follow-up.<sup>5–14</sup> In the past 10 years, both implant types have been widely used with 1- and 2-stage healing modalities.<sup>15–17</sup>

In the late 1980s, a series of studies was initiated to evaluate alternative titanium surfaces. The goal was to develop a noncoated titanium surface that could replace the titanium plasma-spray (TPS) surface for clinical application in patients. A histometric study by Buser and coworkers<sup>18</sup> evaluated 5 different titanium surfaces in long bones of miniature pigs and demonstrated that bone apposition to a sandblasted and acid-etched surface (SLA) was better than that to the TPS surface and other fine-structured or electropolished surfaces. A parallel biomechanical study

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**Table 1** Indications for the Placement of 104 ITI Implants with the SLA Surface

Indication	No. of patients	No. of implants
Distal-extension situation in the mandible	19	44
Single-tooth gap in the mandible	17	21
Extended edentulous gap in the mandible	9	24
Single-tooth gap in the maxilla	4	4
Extended edentulous gap in the maxilla	5	11
Total	54	104

by Wilke and associates<sup>19</sup> tested removal torque values (RTV) of unloaded titanium implants with various surface characteristics in the tibiae of sheep. The SLA surface achieved RTVs exceeding 600 Ncm at 6 months of healing, while polished or fine-textured surfaces showed mean RTVs of 40 to 70 Ncm during the course of the study period. Both studies were carried out in the femora and/or tibiae of miniature pigs or sheep; hence, there was a need to examine this promising SLA surface in jawbone prior to clinical testing in patients.

The advantages of the SLA surface, in comparison to the TPS surface, during the initial healing period were then confirmed in a histometric study in the canine mandible<sup>20</sup> and in a biomechanical study measuring the RTV of 8-mm-long implants in the maxillae of miniature pigs.<sup>21</sup> The osteophilic properties of the SLA surface were also confirmed in a series of *in vitro* studies examining various titanium surfaces in tissue cultures with osteoblast-like cells.<sup>22–25</sup>

The biomechanical study by Buser and associates<sup>21</sup> demonstrated for the SLA surface a mean RTV approximating 140 Ncm at 4 weeks of healing. This value led to the possibility of reducing the standard healing period of 3 months that had been used with ITI implants in patients for more than 20 years. Thus, it was decided to test SLA implants in an international multicenter study with an initiation of loading as early as 6 weeks.

The present report documents the 3-year results of this prospective study at the University of Berne, where SLA implants were tested exclusively in posterior sites in partially edentulous patients. The tested hypothesis was that SLA implants would achieve a success rate similar to that reported in previous clinical studies for ITI implants with a TPS surface.

## MATERIALS AND METHODS

### Patient Selection

Between May 1997 and June 1999, 51 partially edentulous patients were consecutively admitted to the

study. Prior to the start of the study, the study protocol was approved by the standing ethical committee for clinical studies of the Medical Faculty, University of Berne. Patient selection excluded candidates with severe systemic health problems or local bone defects requiring augmentation, as well as heavy smokers. In these 51 patients, a total of 104 implants were placed. All implant sites exhibited a bone density of Class 1 to 3 as judged by the surgeon (DB) during surgery, allowing early loading after 6 weeks of healing according to the protocol. In the same period, 3 additional patients received 5 implants of the same type but demonstrated a bone density of Class 4 and required a healing period of 12 weeks. Because of the small number of patients, these implants were not included in the present analysis. The various indications for implant therapy are listed in Table 1. Three patients presented with multiple indications for implant therapy, such as a bilateral distal-extension situation or a single-tooth gap on one side and an extended edentulous gap on the contralateral side.

### Clinical Procedures

The surgical procedures were carried out under local anesthesia employing a low-trauma surgical technique. All patients received premedication with atropine (0.5 mg intramuscularly) and preoperative antibiotic prophylaxis 2 hours prior to surgery. A total of 104 ITI implants with a SLA surface were placed in various sites (Table 1). Of these, 89 implants were placed in the mandible and 15 were placed in the maxilla. All implants were placed using a standardized surgical procedure. Details on presurgical evaluation, surgical techniques, and postoperative treatment have been previously described in detail.<sup>17</sup> After a healing period of 6 weeks, free of masticatory function, solid abutments were connected with an insertion torque at 35 Ncm. Subsequently, the prosthetic rehabilitation was initiated. Thirty-nine implants were restored with a single crown, and 43 implants were restored with splinted single crowns. The remaining 21 implants served as abutments for 10 implant-supported fixed partial dentures. All restorations were cemented.

### Follow-up Protocol

The day of abutment connection was set as day 0. Thereafter, the patients were recalled at various intervals for clinical and radiographic examination. At 3, 12, 24, and 36 months, the following parameters were assessed as described for previously published long-term studies of ITI implants.<sup>26</sup>

- Modified Plaque Index (mPLI) at 4 aspects around the implants.<sup>27</sup> For each implant, the mPLI value was calculated based on the average

of the 4 obtained values: score 0 = no plaque detected; score 1 = plaque recognizable only by running a probe across the smooth marginal surface of the implant; score 2 = plaque visible to the naked eye; score 3 = abundance of soft matter.

- Modified Sulcus Bleeding Index (mSBI) at 4 aspects around the implants.<sup>27</sup> For each implant, 1 mSBI value was calculated based on the average of the 4 obtained values: score 0 = no bleeding when a periodontal probe is passed along the gingival margin adjacent to the implant; score 1 = isolated bleeding spot visible; score 2 = blood forms a confluent red line on margin; score 3 = heavy or profuse bleeding.
- Probing depth (PD, in mm) at 4 aspects around the implants. For each implant, the PD value was calculated based on the average of the 4 obtained values.
- The distance between the implant shoulder and the mucosal margin (DIM, in mm) at 4 aspects around the implants.<sup>26</sup> A submucosal implant shoulder was given a negative DIM value.
- Clinical attachment level (AL, in mm) at 4 aspects around the implants ( $AL = PD + DIM$ ).
- Mobility was tested manually and evaluated with the Periotest instrument (Siemens AG, Bensheim, Germany). The tip of the handpiece was applied perpendicular to the facial surface of the crown, which remained in place, if possible, at a distance of 3 mm from the implant shoulder, with the patient seated in a vertical position. The crowns were not removed when testing splinted implants and implants supporting fixed partial prostheses. For the record, the measurements were repeated until the same score was obtained 3 times.
- The distance between the implant shoulder and the first visible bone-implant contact (DIB) was measured (in mm) at the mesial and distal aspect of each implant using periapical radiographs with the long-cone technique.<sup>26,28</sup> All radiographs were examined by the same person (MMB). For each implant, 1 DIB value was calculated based on the average of the mesial and distal values. The 36-month DIB values were compared with the 3-month values to evaluate the crestal bone changes around the implants over the 33-month period between examinations ( $\Delta DIB_{36mo-3mo}$ ).

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 of implants in nonregenerated bone.<sup>26</sup>

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

First, all data were analyzed by descriptive methods using box plots (Systat 5.2; Systat, Evanston, IL). Since they were not normally distributed, a nonparametric test was performed. The Wilcoxon test was used for paired data (eg, comparison between 3, 12, 24, and 36 months). When multiple comparisons were employed, the *P* values were corrected using the Bonferroni adjustment procedure. The significance level chosen for all statistical tests was .05.

## RESULTS

### Healing Period

Following surgery, the patients reported no or only moderate discomfort at the surgical sites. During healing, 1 implant in the right mandible became unstable. Upon examination, a peri-implant infection with suppuration was present, and the implant was subsequently removed. Another implant was placed in the same region 3 months later and demonstrated complication-free tissue integration. The remaining 103 implants showed no signs of peri-implant infection or detectable mobility throughout the healing period, and periapical radiographs taken at that time showed no signs of continuous peri-implant radiolucencies. The implants exhibited favorable positions, which allowed the connection of abutments to initiate the prosthetic treatment. At abutment connection, 1 implant turned slightly and caused some discomfort to the patient. The implant, however, demonstrated no mobility. This implant was restored with a provisional crown that was splinted to another crown on an adjacent implant and placed into function (Fig 1a).

### Maintenance Period

During the maintenance period, clinical examinations at 3 months revealed that 2 implants had developed a local peri-implant infection caused by a failure to remove excess cement following cementation of the fixed restoration. The cement was removed, and in addition, local irrigation of the peri-implant sulcus with chlorhexidine digluconate (0.1% twice a day) was prescribed. With this treatment, the peri-implant infection was successfully treated in both patients.

The remaining implants were firmly anchored in bone and showed no signs of peri-implant infections and/or radiolucencies throughout the maintenance

**Table 2 Gingival Parameters of 102 Implants (Mean ± Standard Error of the Mean)**

Time	mPLI	mSBI	PD (mm)	DIM (mm)	AL (mm)
3 mo (n = 102)	10.49 ± 0.05	0.65 ± 0.05	4.29 ± 0.08	-1.12 ± 0.08	3.18 ± 0.04
1 y (n = 102)	0.28 ± 0.03	0.49 ± 0.04	4.47 ± 0.09	-1.24 ± 0.10	3.22 ± 0.03
2 y (n = 102)	0.24 ± 0.03	0.33 ± 0.03	4.32 ± 0.09	-1.12 ± 0.09	3.19 ± 0.04
3 y (n = 102)	0.28 ± 0.03	0.26 ± 0.03	4.23 ± 0.09	-1.09 ± 0.10	3.15 ± 0.04

Bars = Significant difference between values ( $P < .05$ ).

**Table 3 Periotest Values (PTV) of 102 ITI Implants (Mean ± Standard Error of the Mean)**

Time	PTV
3 mo	-2.08 ± 0.20
1 y	-3.57 ± 0.23
2 y	-4.08 ± 0.22
3 y	-3.17 ± 0.16

period, including the implant that had turned slightly at abutment connection. In addition, all patients were free of subjective complaints. One patient did not attend the 3- and 12-month follow-up visits. This patient, therefore, was considered a dropout and removed from the study analysis.

### Gingival Parameters

The patients performed good home care. The mean mPLI for the 3-month examination was 0.49. The mean mPLI scores decreased for the 12-, 24-, and 36-month examinations, with values of 0.28, 0.24, and 0.28, respectively (Table 2). The decrease of the mean mPLI score at the 3-year examination in comparison to the mean value at the 3-month examination was statistically significant ( $P < .05$ ). The peri-implant soft tissues revealed little tendency to bleed following probing and were clinically healthy. At the 3-month examination, the mean mSBI was 0.65, and at the 12-, 24-, and 36-month visits the mSBI scores decreased, with mean values of 0.49, 0.33, and 0.26, respectively (Table 2). The decrease in the mean mSBI score at the 3-year examination was statistically significant ( $P < .05$ ), in comparison to the mean value at the 3-month visit. At the 3-month examination, the mean PD was 4.29 mm. At the 1-, 2-, and 3-year examinations, the mean PD remained stable, with values of 4.47 mm, 4.32 mm, and 4.23 mm, respectively (Table 2). No statistically significant difference could be shown between the mean PD scores at the 3-month and 36-month examinations. The mean DIM score at the 3-month examination was -1.12 mm, indicating a subgingival implant shoulder. The mean values for the 1-, 2-, and 3-year examinations were -1.24 mm, -1.12 mm, and -1.09 mm (Table 2). There was no statistically

significant difference between the mean values found at the 3-month and 36-month examinations. The addition of PD and DIM resulted in the AL. The mean AL at the 3-month examination was 3.18 mm and remained stable for the 1-, 2-, and 3-year visits, with mean values of 3.22 mm, 3.19 mm, and 3.15 mm, respectively (Table 2). There was no statistically significant increase in the mean AL between the 3-month and the 36-month examinations.

### Implant Mobility

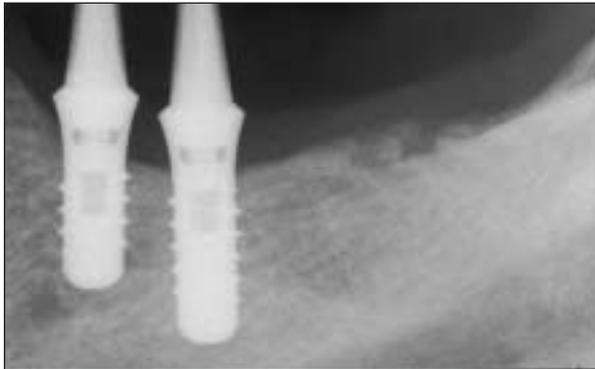
The Periotest scores for the 102 successfully integrated implants at the 3-month examination ranged from -8 to +2, with a mean value of -2.08. Over time, the scores showed a tendency to decrease, with mean values of -3.57 (range: -8 to +2), -4.08 (range: -8 to +1), and -3.17 (range: -8 to +3) at the 1-, 2-, and 3-year examinations, respectively (Table 3).

### Radiographic Findings

The radiographs obtained of each implant did not reveal any signs of continuous peri-implant radiolucencies throughout the observation period of 3 years, including the implant that turned slightly at abutment connection (Figs 1 and 2). At the 3-month examination, the mean DIB was 2.64 mm for the 102 implants. A mean value of 2.76 mm was found at the 1-year examination, 2.82 mm at the 2-year examination, and 2.72 mm at the 3-year examination (Table 4). The minimal increase in the mean DIB of 0.08 mm between the 3-month and the 3-year examination demonstrated overall stable bone crest levels and was not statistically significant. The frequency analysis exhibited for 72 implants a  $\Delta\text{DIB}_{36\text{mo} - 3\text{mo}}$  between -0.6mm and +0.6mm, which corresponds with a bone loss or bone gain of less than 0.2 mm per year (Fig 3). Twelve implants demonstrated a bone gain of more than 0.6 mm ( $\Delta\text{DIB}_{36\text{mo} - 3\text{mo}} < -0.6\text{mm}$ ), whereas 18 implants showed a bone loss of more than 0.6 mm ( $\Delta\text{DIB}_{36\text{mo} - 3\text{mo}} > +0.6\text{mm}$ ).

### Survival and Success Rates

At the end of the 3-year observation period, only 1 implant was lost (at 3 weeks, during the healing period). One patient dropped out of the study at the



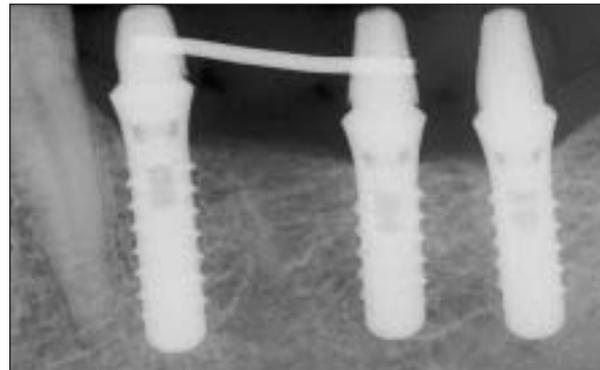
**Fig 1a** One implant in the first premolar position in the left mandible showed a slight turn at the time of abutment connection.



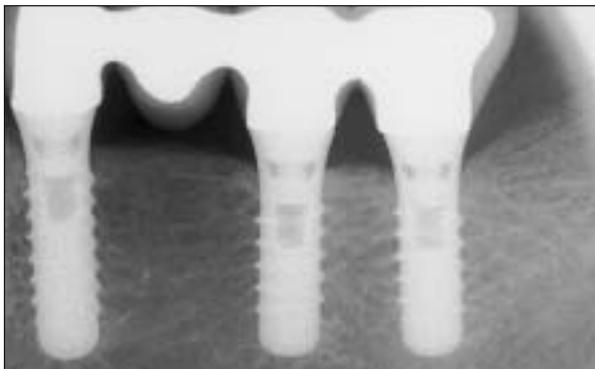
**Fig 1b** The implant was restored with a provisional crown made of acrylic resin and splinted to an adjacent implant that healed uneventfully. At 3 months following restoration, the implant demonstrated no signs of mobility, peri-implant infection, or peri-implant radiolucencies.



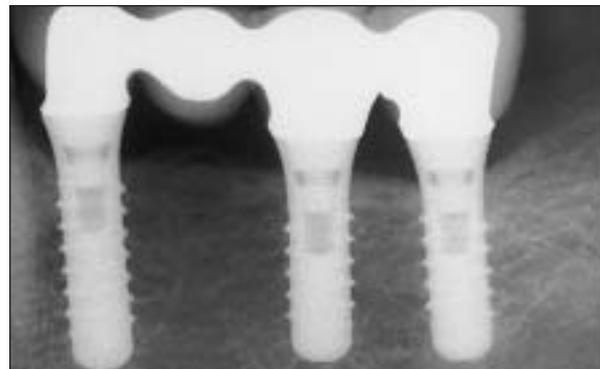
**Fig 1c** At the 3-year examination, both implants fulfilled the criteria of successfully integrated implants.



**Fig 2a** Radiographic documentation of 3 implants in the left mandible. After 6 weeks of healing, the implants were restored with a provisional fixed partial denture. The 3-month periapical radiograph demonstrates normal bone structures around the 3 implants without signs of peri-implant radiolucencies.



**Fig 2b** At the 1-year follow-up, the bone crest levels were stable and no signs of peri-implant radiolucencies were apparent.



**Fig 2c** At the 3-year examination, the periapical radiograph confirmed stable bone crest levels and no apparent signs of crestal bone loss.

3-month examination. This resulted in a 3-year survival rate of 99.03% (Table 5). Summarizing the clinical and radiographic results, 102 implants were considered successfully integrated at the 3-year examination using the well defined success criteria. This resulted in a success rate of 99.03% (Table 5).

## DISCUSSION

In recent years, numerous efforts have been made to improve the attractiveness of implant therapy to potential patients by simplifying clinical procedures. One of these efforts has been a general reduction of

the healing period by utilizing new titanium surfaces. Albrektsson and associates<sup>29</sup> recognized early that the implant surface is an important factor influencing osseointegration. In the late 1980s, several research groups started to examine new titanium surfaces and focused on subtractive surface techniques such as sandblasting and/or acid-etching procedures.<sup>18-20,30-33</sup> These experimental studies demonstrated better bone integration with these new titanium surfaces when compared with machined titanium surfaces. Documentation was provided by higher removal torque values or higher bone-to-implant contact (for review see Buser<sup>34</sup>). Based on these promising experimental data, clinical trials were initiated to test these new titanium surfaces in patients. Reduced healing periods were examined and compared with standard healing periods of 3 to 6 months, which had been used in clinical practice for almost 3 decades.<sup>5-14</sup>

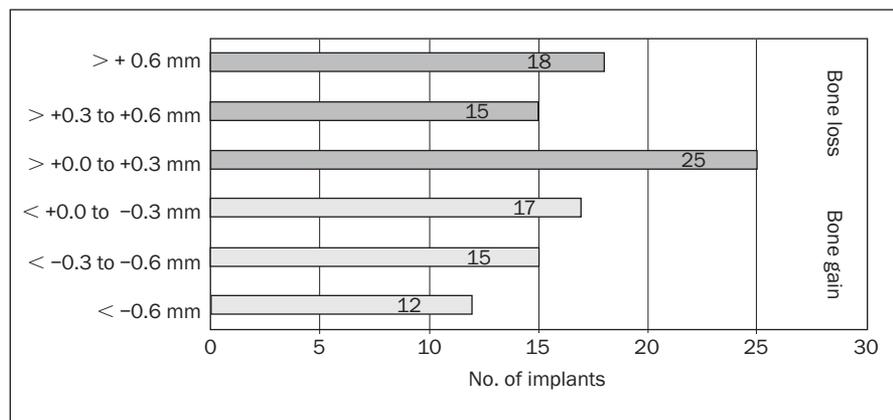
The examined gingival parameters demonstrated overall excellent gingival health during the 3-year observation period, as documented by low plaque and sulcus bleeding indices. The peri-implant soft tissues were stable over time, as shown by the fact that mean probing depths and mean attachment levels did not change during the follow-up period. The obtained mean values are comparable with previously published 3-year prospective studies of osseointegrated implants.<sup>35-38</sup> In addition, all implants revealed ankylotic stability in the jawbone throughout the observation period, and mobility was never detected when tested manually. The mean Periotest scores were negative with a trend to decrease over time, which is in accordance with previously published studies.<sup>37,38</sup>

In the present study, none of the implant sites exhibited signs of a continuous peri-implant radiolucency, which confirmed ankylotic stability of all 102 implants. However, for the long-term follow-up of implants, observation of bone crest levels is considered more important.<sup>39</sup> For ITI implants, the distance from the implant shoulder to the first bone-implant contact, called DIB, has been used in previous studies.<sup>26,28</sup> This method is appropriate to follow changes of peri-implant bone levels over time, since the  $\Delta$ DIB between 2 time points can be examined. In the present study, the mean  $\Delta$ DIB<sub>36mo-3mo</sub> was 0.08 mm, indicating stable bone crest levels. The value of

**Table 4 DIB Values (in mm) of 102 ITI Implants**

Time	Minimum	Maximum	Mean	SEM
3 mo	1.07	3.84	2.64	± 0.04
1 y	1.43	3.93	2.76	± 0.04
2 y	1.35	4.00	2.82	± 0.04
3 y	1.76	4.07	2.72	± 0.04

Bars = Significant differences between values ( $P < .05$ ).



**Fig 3** Frequency analysis of  $\Delta$ DIB<sub>36mo-3mo</sub> (n = 102 implants).

**Table 5 Success Rates of 104 ITI Implants with the SLA Surface**

Time (mo)	Implants at start of interval	Dropouts	Implants at risk	Implant failures	Interval success rate (%)	Cumulative success rate (%)
Healing period	104	0	104	1	99.03	99.03
0-3	103	1	102	0	100	99.03
3-12	102	0	102	0	100	99.03
12-24	102	0	102	0	100	99.03
24-36	102	0	102	0	100	99.03

Healing period = Time from implant placement to abutment connection (day 0).

the mean  $\Delta$ DIB, however, is limited, since implants exhibiting bone loss are compensated by implants with bone gain. This can be documented with a frequency analysis, which was done in the present study. This analysis demonstrated a  $\Delta$ DIB<sub>36mo-3mo</sub> between  $-0.6$  mm and  $+0.6$  mm for 72 implants. Twelve implants had a bone gain of more than 0.60 mm, whereas 18 implants yielded a bone loss of more than 0.6 mm. A similar pattern of the frequency distribution has been reported for 8-year data on 97 ITI implants in nonregenerated bone<sup>10</sup> and recently for 5-year data on 61 ITI implants in augmented bone.<sup>40</sup>

The present study resulted in a success rate of 99.03% after 6 weeks of healing and 99.03% after 3 years. It can therefore be concluded that in this patient population, ITI implants with the SLA surface achieved successful tissue integration with high predictability, even though the implants were put into function with early loading after 6 weeks of healing. These favorable results are even slightly better than the results of a prospective study with ITI implants with the TPS surface, which used the standard healing period of at least 3 months.<sup>38</sup> In that study, the 3-year survival rate was 98.1% and the 3-year success rate was 97.1%.

It has to be kept in mind that the present study was carried out under ideal clinical conditions using a strict selection of patients and excluding at-risk patients such as heavy smokers. In addition, the surgical procedures were all carried out by an experienced team with only 1 surgeon (DB). The obtained results compare well with published studies examining ITI implants with the SLA surface in various clinical situations for early loading at 6 weeks.<sup>41-43</sup> Cochran and coworkers<sup>42</sup> reported the results of an international multicenter study with up to 2 years of follow-up. Of 383 placed implants, 3 failed during the healing period, resulting in an early failure rate of only 0.78%. During follow-up, no additional implants failed or demonstrated signs of infection or implant mobility. These results indicate that, under defined conditions, early loading of ITI implants with the SLA surface after 6 weeks of healing can offer successful tissue integration with predictability. Based on these promising results, early loading of implants in posterior sites has the potential to become the standard of care in partially edentulous patients.

## CONCLUSION

The results of this prospective study of 104 implants placed in posterior sites of 51 partially edentulous patients demonstrated that early loading of ITI implants with the SLA surface after an

unloaded healing period of 6 weeks provided successful tissue integration with high predictability. Successful tissue integration was well maintained for up to 3 years of follow-up in this study population. One implant failed to integrate during the healing period because of peri-implant infection, whereas 1 implant was lost to follow-up and considered a dropout. The remaining 102 implants showed favorable clinical and radiographic findings and were considered successfully integrated at the 3-year examination based on strict success criteria. This resulted in a 3-year success rate of 99.03%.

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