Early Loading of Nonsubmerged Titanium Implants with a Chemically Modified Sand-Blasted and Acid-Etched Surface: 6-Month Results of a Prospective Case Series Study in the Posterior Mandible Focusing on Peri-Implant Crestal Bone Changes and Implant Stability Quotient (ISQ) Values

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ABSTRACT

Purpose: The aim of this prospective case series study was to evaluate the short-term success rates of titanium screw-type implants with a chemically modified sand-blasted and acid-etched (mod SLA) surface after 3 weeks of healing.

Material and Methods: A total of 56 implants were inserted in the posterior mandible of 40 partially edentulous patients exhibiting bone densities of class I to III. After a healing period of 3 weeks, all implants were functionally loaded with a screw-retained crown or fixed dental prosthesis. The patients were recalled at weeks 4, 7, 12, and 26 for monitoring and assessment of clinical and radiological parameters, including implant stability quotient (ISQ) measurements.

Results: None of the implants failed to integrate. However, two implants were considered "spinners" at day 21 and left unloaded for an extended period. Therefore, 96.4% of the inserted implants were loaded according to the protocol tested. All 56 implants including the "spinners" showed favorable clinical and radiographic findings at the 6-month follow-up examination. The ISQ values increased steadily throughout the follow-up period. At the time of implant placement, the range of ISQ values exhibited a mean of 74.33, and by week 26, a mean value of 83.82 was recorded. Based on strict criteria, all 56 implants were considered successfully integrated, resulting in a 6-month survival and success rate of 100.0%.

Conclusion: This prospective study using an early-loading protocol after 3 weeks of healing demonstrated that titanium implants with the modified SLA surface can achieve and maintain successful tissue integration over a period of at least 6 months. The ISQ method seems feasible to monitor implant stability during the initial wound-healing period.

KEY WORDS: chemically modified surface, clinical trial, dental implants, early-loading protocol, implant stability quotient (ISQ)

INTRODUCTION

The implant surface, including topography, chemistry, surface charge, and wettability, has been described as an important factor to influence osseointegration.[1] Several research groups have examined altered titanium surfaces and focused on subtractive production techniques such as sandblasting and/or acid etching.[2–8] Microrough titanium surfaces regularly exhibit a significantly increased percentage of bone-to-implant

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contact when compared with machined or polished titanium surfaces.[3,9–11]

Clinical trials using implants with sand-blasted and acid-etched (SLA) surfaces showed that healing periods with this surface were shorter (6–8 weeks) than conventional healing periods of 3 to 6 months, which had been the standard in clinical practice for almost three decades.[12–15] Clinical studies up to 5 years of follow-up demonstrated favorable results with the SLA implant surface, with survival and success rates of around 99%.[16–19]

In addition to surface roughness, the surface chemistry is an important factor for peri-implant bone apposition because it influences surface charge and wettability. Textor and colleagues concluded that a similarity of the clean hydrophilic titanium oxide surface to water can be assumed as a consequence of extensive hydroxylation/hydration of the oxide layer.[20] This leads to high wettability by water[21] and to an interaction of the surface with the water shell around biomolecules such as proteins. Such an interaction accelerates and enhances bone apposition to this hydrophilic titanium surface during the initial healing period as shown in an experimental study in miniature pigs.[22] In addition, this also increases removal torque values during this early healing phase.[23] Based on these preclinical studies, it could be speculated that this improved implant surface would allow a further reduction of the healing period of titanium implants.

The objective of the present prospective case series study was to assess the short-term clinical and radiographic performance of titanium screw-type implants with the modified SLA surface when inserted in the posterior mandible of partially edentulous patients. The tested hypothesis was that these implants, when loaded after 3 weeks of healing and monitored with the implant stability quotient (ISQ) method, would achieve a success rate similar to that reported for titanium implants with the a titanium plasma spray (TPS) coated or regular SLA surface in previous clinical studies with longer healing periods.

MATERIAL AND METHODS

Patient Selection

Between December 2004 and June 2006, 39 partially edentulous patients were consecutively admitted to the study. Prior to the start of the study, the standing ethical committee for clinical studies of the Medical Faculty, University of Bern, approved the study protocol (approval number CR 03/04). Patient selection excluded candidates with severe systemic health problems (classified by the Physical Status Classification System of the American Society of Anesthesiologists as P1 = a normal healthy patient; or P2 = a patient with mild systemic disease),[24] patients with local bone defects requiring local bone augmentation, and heavy smokers (>10 cigarettes per day).

TABLE 1 Distribution of Implant Sites ($n = 56$) according to the Federation Dentaire International Classification

Mandible	47	46	45	44	34	35	36	37	Total
Implants	5	14	5	0	1	4	25	2	56

A total of 56 titanium implants with a modified SLA surface (SLActive®, Institut Straumann AG, Basel, Switzerland) were placed in healed sites in the posterior mandible. If a tooth extraction in a potential implant site was necessary, a healing period of at least 4 months was required. All implant sites exhibited bone densities of class I to III,[25] allowing early loading after 3 weeks of healing, according to the protocol. The distribution of implants by site is presented in Table 1.

Clinical Procedures

The surgical procedures were carried out under local anesthesia by the same surgeon (D.B.). Preoperative antibiotic prophylaxis was provided 2 hours prior to surgery. All implants were placed by using a standardized surgical procedure, with the border of the modified SLA surface slightly below the alveolar crest, with a 2.8-mm machined neck in the transmucosal area. Details of presurgical evaluation, surgical techniques, and postoperative treatment have been previously described in detail.[26] The implant was indexed[27] prior to wound closure to allow fabrication of a provisional restoration using an altered cast technique, and implant stability was assessed by using resonance frequency analysis (RFA) (Osstell mentor, Institut Straumann AG, Basel, Switzerland). The mean of three consecutive ISQ values recorded was calculated and served for further statistical analysis.

After a healing period of 3 weeks, ISQ measurements were repeated, and screw-retained provisional restorations on titanium abutments were positioned and

torqued to 20 Ncm. When ISQ values lower than 65 were measured, single-tooth restorations were not fabricated. Forty-two implants were restored with occlusal contact to the opposing arch with a single crown, and 15 implants served as abutments for eight implant-supported fixed dental prosthesis, of which 6 included a cantilever unit. An occlusal contact was defined as contact at heavy biting that held a 20-μm shim stock foil. This would result in implant loading during mastication.

Following 1 week of loading, restorations were removed, and ISQ values measurements were examined again. When decreased ISQ values were noted, occlusal schemes were modified on each of the provisional restorations to provide 40-μm clearance, as determined using a metal matrix band. ISQ values were again recorded at weeks 7, 12, and 26. No further occlusal adjustments were made during the remaining time period. After the follow-up visit at 6 months, definitive cemented ceramo-metal prostheses were positioned on solid abutments torqued to 35 Ncm.

Clinical and Radiological Follow-Up Protocol

The day of implant placement was defined as day 0. ISQ values were recorded at placement, weeks 3 (provisional restoration), 4 (after 1 week of loading), 7 (4 weeks loading), 12, and 26.

At 12 and 26 weeks, the following clinical and radiographic parameters were assessed, as described for previously published long-term studies with dental implants:[19,28]

- *Modified plaque index* (mPLI) at four aspects around the implants[29]
- *Modified sulcus bleeding index* (mSBI) at four aspects around the implants[29]
- *Probing depth* (PD, in mm) at four aspects around the implants. For each implant, one PD value was calculated based on the average of the four obtained values.
- The *distance between the implant shoulder and the mucosal margin* (DIM, in mm) at four aspects around the implants. A submucosal implant shoulder was recorded with a negative DIM value.
- *Clinical attachment level* (AL, in mm) at four aspects around the implants (AL = PD + DIM).
- 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 taken with the long-cone technique at weeks 0, 12, and 26.[28,30] All radiographs were evaluated by the same experienced and calibrated examiner (C.N.H). For each implant, one DIB value was calculated based on the average of the mesial and distal values. The 26-week DIB values were compared with the DIB values at day 0 to evaluate the short-term crestal bone changes around the implants ($\Delta DIB_{26\ wks\text{-}0\ wks}$). Additionally, all biologic complications in the initial healing phase after implant placement, as well as during the follow-up period, were recorded.

Based on clinical and radiographic findings, each implant was classified as either successful or nonsuccessful, using the success criteria defined by Buser and colleagues in a previous clinical study of implants in nonregenerated bone.[28]

Statistical Analysis

All data were analyzed with descriptive methods by using box plots. To analyze potential differences in the peri-implant soft tissue parameters and DIB values over the time period, the Wilcoxon signed-rank test was used. To compensate for multiple testing situations, the *p* values for the testing blocks were corrected by using the Bonferroni adjustment procedure and compared with the alpha level of 0.05.

A linear regression model was initially chosen to assess how the ISQ values were affected by different parameters, including gender, implant length, and implant diameter. Because of the low number of cases available, a linear regression analysis was not possible, and a bivariate descriptive analysis was performed.

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

RESULTS

Healing and Loading Period

Following surgery, the patients reported no or only moderate discomfort at the surgical sites. Following the initial healing time of 3 weeks, deviations from the loading protocol were required in two patients. In one patient, removal of the healing cap of one implant was

TABLE 2 Detailed Peri-Implant Soft Tissue Parameters, ISQ and DIB Values of the Two "Spinners" during the Study Period

Parameter	"Spinner" 1	"Spinner" 2
Additional time of healing	6 weeks	3 weeks
$mPLI_{3\ months}$	0	0
$mPLI_{6\ months}$	0	0.5
$mSBI_{3\ months}$	0.25	0
$mSBI_{6\ months}$	0.5	0.5
$PD_{3\ months}$	2.75	3.75
$PD_{6\ months}$	2.75	3.75
$DIM_{3\ months}$	−0.5	−1.25
$DIM_{6\ months}$	−1.25	−1.5
$AL_{6\ months}$	2.25	2.5
$AL_{6\ months}$	2.25	2.25
$ISQ_{day\ 0}$	81	75
$ISQ_{3\ weeks}$		38
$ISQ_{4\ weeks}$		63
$ISQ_{7\ weeks}$	77	77
$ISQ_{12\ weeks}$	83	80
$ISQ_{26\ weeks}$	82	83
$DIB_{day\ 0}$	1.88	2.25
$DIB_{12\ weeks}$	2.79	2.47
$DIB_{26\ weeks}$	2.78	2.50

AL = clinical attachment level; DIB = distance implant to bone (radiographic); DIM = distance between the implant shoulder and the mucosal margin; ISQ = implant stability quotient; mPLI = modified plaque index; mSBI = modified sulcus bleeding index; PD = probing depth.

not possible because of slight implant rotation. In the same patient, the adjacent implant, which was also part of the study protocol, could be restored at day 21, as planned. At week 7, the healing cap could then be removed and ISQ values taken. An ISQ value similar to the adjacent implant at week 3 was determined, and, therefore, the screw-retained restoration was inserted. Regarding the second patient, also in one of two adjacent implants, a very low ISQ value (38) was recorded, and discomfort was reported by the patient on removal of the healing cap. The clinically stable implant was left unloaded for an additional 3 weeks, at which time an increase in the ISQ to 77 was noted, and the implant was restored. The restoration was splinted to the adjacent, already restored implant. Following restoration, both "spinning" implants developed further without any complications. Details of the clinical, radiographic, and ISQ parameters of these two implants are depicted in Table 2.

The remaining 54 implants showed no clinical signs of peri-implant infection or detectable mobility throughout the healing period. The following sections describe results of these 54 implants only.

Standard Peri-Implant Soft Tissue Parameters

Oral hygiene was well maintained by all patients. The mean mPLI for the 12-week examination was 0.23. A slight increase was observed for the measurement at week 26 (0.37). 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 0.23, and slightly increased at week 26 to 0.26. The mean PD at week 12 was 3.09 mm, also increasing at week 26 to 3.39 mm, which proved to be statistically significant ($p = .042$). The mean DIM score at the 12-week examination was −0.78 mm, indicating a submucosal implant shoulder. This mean value also increased to −1.03 by week 26, which also proved to be statistically significant ($p = .021$). The mean AL was 2.31 mm at 12 weeks and remained relatively stable, averaging 2.37 mm at week 26. For details, see Table 3.

Implant Stability

RFA was performed at weeks 0, 3, 4, 7, 12, and 26. The repeated ISQ value recordings were very consistent, not varying more than two units between the three measurements. At the time of implant placement, the range of

TABLE 3 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)	DIM (mm)	AL (mm)
3 months ($n = 54$)	0.23 (±0.06)	0.23 (±0.03)	3.09 (±0.10)[a]	−0.78 (±0.11)[b]	2.31 (±0.09)
6 months ($n = 54$)	0.37 (±0.07)	0.26 (±0.04)	3.39 (±0.11)[a]	−1.03 (±0.11)[b]	2.37 (±0.08)

Statistically significant differences are marked with the same letters.
AL = clinical attachment level; DIM = distance between the implant shoulder and the mucosal margin; mPLI = modified plaque index; mSBI = modified sulcus bleeding index; PD = probing depth.

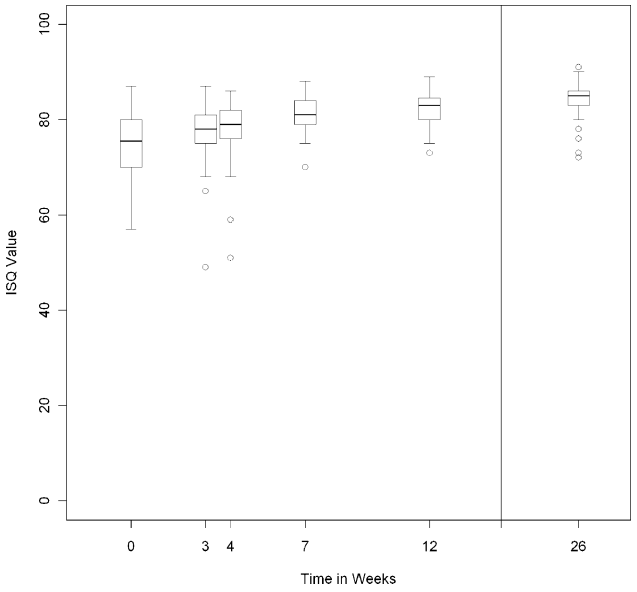

Figure 1 Box plots of the ISQ values at day 0 (implant insertion) and at weeks 3, 4, 7, 12, and 26. (ISQ = implant stability quotient.)

ISQ values was from 57 to 87 with a mean value of 74.33 (SD: 7.06). ISQ values ranged from 49 to 87 at week 3 (mean value: 77.67; SD: 5.95), from 51 to 86 at week 4 (mean value: 77.91; SD: 6.00), and from 70 to 88 at week 7 (mean value: 81.10; SD: 3.58). By week 12, the range had narrowed to between 73 and 89 ISQ units (mean value: 82.24; SD: 3.75), which were similar to the ISQ values at week 26 (range: 72–91; mean: 83.82; SD: 3.95) (see also Figure 1). The increase of the ISQ values over the study period was statistically significant for all time points tested (day 0 vs. 3 weeks: $p = .003$; day 0 vs. 4 weeks: $p = .003$; day 0 vs. 7 weeks: $p = .0001$; day 0 vs. 12 weeks: $p < .001$; day 0 vs. 26 weeks: $p < .001$).

Descriptive analysis of the ISQ values by patient sex and implant diameter and length demonstrated that implants with a wider diameter exhibited higher ISQ scores throughout the study period, whereas gender of the patient and length of the inserted implants did not similarly influence the ISQ values (Figure 2, A–C).

Radiographic Findings

The periapical radiographs taken at weeks 0, 12, and 26 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 2.43 mm (SD 0.33) for the 54 implants. The mean value increased to 2.55 mm (SD 0.32) at the 12-week examination and to 2.67 mm (SD 0.32) at the 26-week examination (Figure 3). Between the baseline and the 26-week examinations, the bone crest level demonstrated a mean loss of 0.24 mm, reaching statistical significance ($DIB_{26\,w\ vs.\ 0\,wks}$ and of $DIB_{12\,w\ vs.\ 0\,wks}$ $p < .01$).

Survival and Success Rates

At the end of the 6-month follow-up period, all 56 implants fulfilled strict success criteria. Consequently, the 6-month survival and success rates were 100%.

DISCUSSION

The present prospective clinical study has demonstrated favorable short-term results for titanium implants with a modified SLA surface when loaded after 3 weeks of healing using an early-loading protocol. Of all 56 inserted implants, 54 (96.4%) could be restored according to the study protocol at day 21. The two remaining implants were clinically stable at day 21 but spinned when rotational forces were applied. Consequently, both implants were left to heal for an additional healing period of 3 and 4 weeks, respectively. After that extended healing period, both implants could be restored and showed no further complications. This observation confirmed again that the phenomenon of implant "spinning" does not necessarily result in detrimental effects on the clinical outcome when such a clinical situation is properly handled. This has already been shown in a previous study by Roccuzzo and colleagues.[16]

At the 6-month follow-up examination, all 56 implants demonstrated ankylotic stability and no signs of peri-implant pathology. The obtained peri-implant soft tissue parameters were all in line with previous clinical studies evaluating the performance of the standard SLA surface during the initial months of loading.[18,31,32] Thus, all implants in the present study were considered successfully integrated at the 6-month follow-up examination, resulting in a survival and success rate of 100%.

It is speculated that the further reduction of the healing period of 6 to 8 weeks to 3 weeks was primarily made possible by the favorable properties of the utilized chemically modified SLA surface. This speculation in based on several experimental studies that confirmed an enhanced bone apposition to this implant surface during the initial healing period.[20–23,33–38] These promising results from experimental studies have been validated by two clinical studies. A randomized controlled

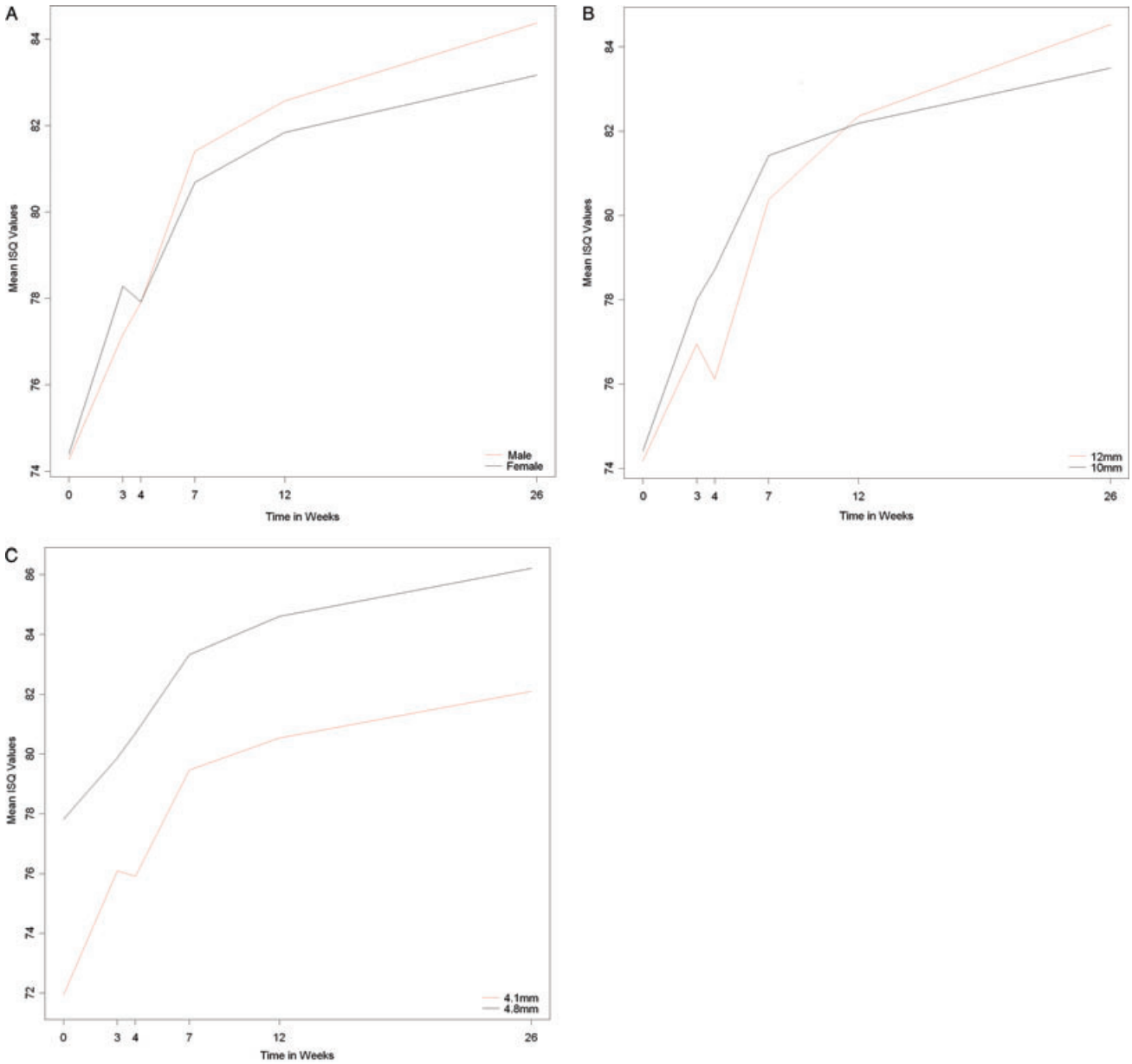

Figure 2 Box plots of the mean DIB values at day 0 (implant insertion) and at weeks 12 and 26. (DIB = distance implant to bone.)

pilot study in 31 patients, all receiving an SLA and a modified SLA implant, examined implant stability over the first 6 weeks after implant insertion.[39] Implant stability was measured on a weekly basis by using an RFA device. Implants with a modified SLA surface exhibited increased stability at an earlier stage, and the change from decreasing to increasing stability in the mandible occurred earlier with modified SLA implants, at 2 weeks compared with 4 weeks with conventional SLA implants. A similar pattern of ISQ values over the initial period of healing was demonstrated in a prospective study of implants placed in the posterior maxilla with sinus floor elevation using the osteotome technique.[40] The implants all had good primary stability (mean ISQ of 69) with a dip between 2 and 6 weeks in the stability curve (2 weeks: 65; 4 weeks: 57; 6 weeks: 64). After an observation period of 20 weeks, mean ISQ values of 70 had been recaptured.

The results from the present study showed that the mean ISQ values increased over the follow-up period, from 74.5 initially to 83.8 after 26 weeks, never exhibiting a decreasing trend. In contrast to the study by Oates and colleagues,[39] ISQ values were not taken on a weekly basis, and the first two measurements occurred on day

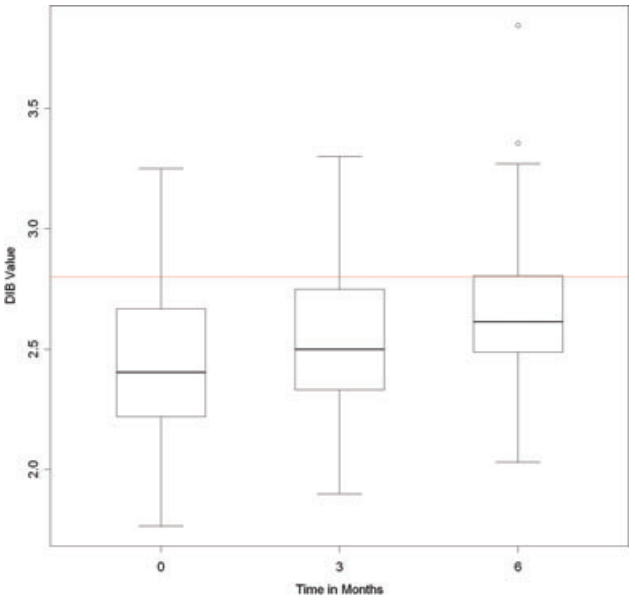

Figure 3 Descriptive analysis of the ISQ results by patient sex (A), implant length (B), and diameter (C). (DIB = distance implant to bone; ISQ = implant stability quotient.)

0 and week 3. Therefore, the reported change from decreasing to increasing implant stability could not be demonstrated in the present study.

An increase of ISQ values over the first month after implant placement with immediate and early loading in the partially edentulous maxilla has been reported in a recent study.[40] The change from baseline to the 1-year values was statistically significant. The ISQ values were generally lower than in the present study (baseline: 63.3; 12 months: 66.8), most likely as a result of the fact that Fischer and colleagues[41] only reported on implants placed in the maxilla, whereas all implants placed in our study were restricted to the posterior area of the mandible. In a recent prospective clinical study evaluating immediate loading of implants in the partially edentulous mandible, ISQ was measured at implant placement and after 6 months of loading, with values of 72.2 and 72.5, respectively.[42]

Short-term results of a randomized, controlled multicenter trial comparing the performance of implants with a modified SLA surface restored immediately or 28 to 34 days after insertion demonstrated favorable results for both treatment options.[43] After 5 months, implant survival rates were 98% in the immediate group and 97% in the early group. Mean bone level change from baseline were 0.81+/−0.89 mm in the immediate group and 0.56+/−0.73 mm in the early group.

A recent prospective controlled clinical trial evaluated the effects of two different early-loading times for solid screw titanium implants with a SLA surface applying clinical and radiographic parameters.[44] Two weeks (test) and 6 weeks (control) after implant placement, single-tooth crowns were cemented. After 1 year, implant survival was 100%. Two test and one control implants rotated at the time of abutment connection and were left unloaded for 12 additional weeks. Based on these findings, the authors concluded that loading of titanium implants with an SLA surface as early as 2 weeks did not appear to jeopardize the osseointegration healing process. Furthermore, implants rotating at 35 Ncm, if left unloaded for an additional 12 weeks, did not lead to a failure of the treatment. These results compare well with the findings in our present study, analyzing the early performance of implants with a modified SLA surface.

In the present study, radiographic bone level changes from day 0 to week 26 resulted in a mean bone loss of 0.24 mm. A similar bone loss distribution has been reported for titanium implants with TPS and SLA surfaces for the first year of loading in nonregenerated bone[18,19,45] and recently for 5-year data on implants in augmented bone[46] after a staged approach with sinus floor elevation.[47]

Based on these promising short-term results, early loading of titanium implants with a chemically modified SLA surface after 3 weeks of healing seems to be a valuable treatment option for the clinician, which can be recommended under clearly defined clinical conditions. One inclusion criterion for this approach is the site condition at the time of implant placement. In the present study, all implants were placed in healed sites without bone deficiencies. A second inclusion criterion is implant stability at time to loading. In the present study, all implants achieved good to excellent primary stability, which was documented by a high ISQ value (mean ISQ = 74.3). The threshold ISQ value for loading of the implants at day 21 was set at 65 for single standing implants. After 3 weeks, one of the "spinners" exhibited an ISQ value of only 38. For the other "spinner," ISQ measurement could not be performed because removal of the healing cap was not possible. Only one additional implant exhibited an ISQ value lower than 65 (49) at day 21. This implant was nevertheless restored because it could be splinted to the neighboring implant with an ISQ of 80, which was also

part of the study. In the literature, there are only limited data regarding ISQ values indicating a possible future failure of the implant if loaded at that stage. A threshold value of at least 60 has been mentioned as an indicator for sufficient stability to initiate the restoration of an implant.[40,43,48,49] Most of these implants have been splinted implants to support fixed dental prostheses. These studies support the ISQ/RFA method to be a useful tool for the clinician in daily practice, if the concept of immediate or early loading is applied. For early loading, a consecutive measurement of ISQ values seems important to compare the values at implant placement and at the day of anticipated loading. If the ISQ value at day to load is <65, an additional healing period is recommended, and the ISQ values is measured again 3 weeks later until the required level is reached. This approach is practical and well understood by patients.

In the present study, the implants were restored with provisional restorations to allow an exact loading at day 21 for all implants. 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 good cost-effectiveness. The concept of immediate loading of implants in the posterior mandible always requires a provisional restoration. In addition, the latest clinical studies demonstrated early failure rates between 1.6 and 5% for this treatment approach.[48–51] Therefore, immediate loading of implants in the posterior mandible of partially edentulous patients seems to be associated with a slightly increased early failure rate, in particular, for nonsplinted, single-standing implants. In addition, the mandatory provisional restoration during initial wound healing is a disadvantage from a cost-effectiveness point of view.

As indicated with the present study, the concept of early loading of implants at 3 weeks after placement in the posterior mandible has a low risk for early failures, when the defined inclusion criteria are met. The concept offers a straight restoration with definitive restoration after a 3-week healing period. Thus, the concept also offers good cost-effectiveness. Additional studies with a larger sample size and longer observation periods are needed to further validate this treatment concept for implants in healed sites in the posterior mandible.

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CONFLICT OF INTEREST

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