Development of Implant Stability Quotient values of implants placed with simultaneous sinus floor elevation – results of a prospective study with 109 implants

Keywords: autogenous bone grafts, Implant Stability Quotient, dental implant, deproteinized bovine bone mineral, early implant loading, resonance frequency analysis, SLActive, sinus floor elevation

Abstract

Objectives: In patients with implant placement and simultaneous sinus floor elevation (SFE), healing periods of 6 months have been the standard of care for more than 25 years. The primary objective of this prospective case series study was to determine what percentage of implants placed with SFE reach a threshold Implant Stability Quotient (ISQ) of ≥70 after 8 weeks of healing using Resonance Frequency Analysis (RFA).

Material and Methods: A total of 109 dental implants were placed in 97 patients. SFE was carried out with a lateral window approach and a mixture of autogenous bone chips and deproteinized bovine bone mineral (DBBM). Titanium screw-type, tissue-level implants with a chemically modified SLA surface were used. ISQ values were measured after implant insertion (ISQBL) and after 8 weeks of healing (ISQ8 wks). Patients showing ISQ8 wks ≥ 70 subsequently underwent restoration. Implants with an ISQ value < 70 were recalled at 2-week intervals.

Results: The ISQ at baseline had a mean value of 68.3 (SD ± 9.8). At 8 weeks, the mean ISQ value was 73.6 (SD ± 6.4). This increase was statistically significant (P < 0.001). An ISQ8 wks value ≥70 was observed for 91 implants (83%). One implant (0.9%) with a peri-implant infection and severe bone loss at 8 weeks was considered an early failure.

Conclusions: This study showed that 83% of implants reached the threshold level of ISQ ≥70 after 8 weeks, allowing an early loading protocol. The early failure rate was considered low with 0.9%. The RFA technology is a suitable method to objectively monitor implant stability longitudinally.

Current implant therapy provides predictable long-term results, as demonstrated by several 10-year studies with different implant systems (Buser et al. 2012; Degidi et al. 2012; Fischer & Stenberg 2012; Mertens et al. 2012). In the past 15 years, efforts have been made to make implant therapy more attractive for patients. Among other things, healing periods have been reduced when compared with the original healing protocols of the 1980s (Adell et al. 1981; Schroeder et al. 1981). Today, the clinician can choose between the concepts of immediate, early or conventional loading, depending on the anatomical, clinical and financial situation of the patient (Weber et al. 2009).

Progress in reduction of healing periods can mainly be attributed to improved titanium implant surfaces characterized by a micro-rough topography (Buser 1999; Wennerberg & Albrektsson 2009). One of these modern surfaces is the chemically modified sandblasted and acid-etched surface (SLActive®, Straumann, Basel/Switzerland), which has hydrophilic properties demonstrating enhanced bone apposition and increased removal torque values during early healing (Buser et al. 2004; Ferguson et al. 2006). Whereas immediate loading is well documented in fully edentulous patients (Papaspyridakos et al. 2014), the concept of early loading after 3–8 weeks of healing has been successfully used in partially edentulous patients. For standard implant placement without simultaneous bone grafting, early loading after 3 weeks of healing has demonstrated predictable treatment outcomes (Bornstein et al. 2010; Morton et al. 2010).
Eight weeks of healing has become routine for implant placement with simultaneous contour augmentation using guided bone regeneration (GBR), that is early implant placement in post-extraction sites (Buser et al. 2013a, Buser et al. 2013b). In the posterior maxilla, however, the placement of implants is much more demanding, as the bone height is frequently not sufficient for standard implant placement in premolar and molar sites (Nunes et al. 2013). To overcome this anatomical limitation, sinus floor elevation (SFE) has become a routine surgical technique used either simultaneously or prior to implant placement. A minimum residual bone height of 4–5 mm has been utilized as a threshold for a simultaneous SFE approach (Del Fabbro et al. 2013). In addition, a healing period of approximately 6 months has been the standard of care for implants placed with simultaneous SFE in the past 25 years (Checchi et al. 2010; Kahnberg et al. 2011; Rasmusson et al. 2012).

The goal of this prospective case series study was to investigate whether the concept of early loading with an 8-week healing period can also be applied for implants placed with a simultaneous SFE procedure utilizing the lateral window technique. This is the most frequently used surgical technique for SFE in our group (Engel Bruegger et al. 2015). Resonance frequency analysis (RFA) providing an “Implant Stability Quotient (ISQ)” has been used as a surrogate parameter to assess and monitor implant stability over time (Meredith et al. 1996, Sennery & Meredith 2008). The threshold level for prosthetic rehabilitation was defined as an ISQ value of 70 at 8 weeks. This value is based on a clinical study utilizing standard implant placement procedures in the posterior mandible (Bornstein et al. 2009). Several clinical studies have demonstrated the reliability of this method to determine the time point to initiate loading (Valderrama et al. 2007; Fischer et al. 2009, Bornstein et al. 2010; Sim & Lang 2010, Simunek et al. 2012). The primary objective of this study was to determine the percentage of implants placed with simultaneous SFE reaching this ISQ value of ≥70 after 8 weeks, in order to initiate prosthetic rehabilitation. The secondary objective was to identify the influence of residual bone height and crest width on the changes of ISQ values over time.

Material and methods

Participants and study design

This prospective case series study was conducted by the Department of Oral Surgery and Stomatology at the University of Bern. The Ethical Committee of the Canton Bern (#179/11) approved the protocol, and all participants enrolled provided written informed consent. Of 142 patients undergoing SFE procedures between January 2012 and December 2013, a total of 97 patients (68%) could be included and completed the prospective case series. Exclusion criteria were (i) patients <18 years; (ii) smokers (>5 cigarettes/day); (iii) patients with a chronic disease that would contraindicate an implant surgery (e.g. uncontrolled diabetes and hypertension, osteonecrosis of the jaw and head-neck radiation); (iv) bone height ≤3 mm; (v) pathology of the maxillary sinus; (vi) severe chronic periodontitis and (vii) lack of primary stability.

Cone-beam computed tomography (CBCT)

CBCT was performed with a 3D Accuitomo 170 (Morita, Kyoto, Japan) using a voxel size of 0.08 mm. Parameters were set at 5.0–7.0 mA and 80 kV, and exposure time was 17.5 s. A field of view of 4 × 4 cm, 6 × 6 cm or 8 × 8 cm was selected. The data were reconstructed with slices at an interval of 0.5 mm. CBCT images were analyzed using a Dell 380 Precision workstation (Dell SA, Geneva, Switzerland) and a 19-inch Eizo Flexscan monitor with a resolution of 1280 × 1024 pixels (Eizo Nanao AG, Wädenswil, Switzerland). Data analyses were performed with i-Dixel version 1.8 (Morita). Outcome measures were the average bone height in the sagittal and the coronal planes and the bone width in the area of future implant placement.

Surgical approach and RFA

Simultaneous SFE was performed using the lateral window technique under local anesthesia. Implants used in this study were tissue-level implants (Institut Straumann AG, Basel, Switzerland) with the following dimensions: regular neck (RN) Ø 3.3, 4.1 or 4.8 mm, wide neck (WN) Ø 4.8 mm, with implant lengths ranging from 8 to 12 mm. These tissue-level implants have a tulip shape and a machined implant surface in the neck area and a chemically modified sandblasted and acid-etched surface (SLActive®) in the endosseous portion. The surgical technique included the vertical positioning of the tapered tulip portion of the implant into the crestal portion of the alveolar process to improve primary stability during the initial wound healing phase. In consequence, the border between the machined and the micro-rough implant surface was positioned 1–2 mm subcrestally. For SFE, autogenous bone chips were locally harvested with a bone scraper (Hu-Friedy, Chicago, IL, USA) and mixed at an equal ratio with deproteinized bovine bone mineral (DBBM, Bio-Oss®, Geistlich Pharma AG, Wolhusen, Switzerland). Implant stability was assessed by resonance frequency analysis (RFA; Osstell mentor, Osstell AB, Göteborg, Sweden). ISQ values were recorded at baseline, immediately after implant insertion (ISQBL) and after 8 weeks of healing (ISQ8 wk). Implants not reaching the threshold level of ISQ 70 at 8 weeks were measured every 2 weeks until an ISQ value of ≥70 was reached. The ISQ value was measured twice from the buccal and the mesial aspects, and mean values were used for the analysis. Patients were then referred back to the dentist/clinic for prosthetic rehabilitation. Two typical case reports are shown in Figs 1 and 2.

Statistical analysis

The primary endpoint was the changes in ISQ values over 8 weeks depending on the primary stability at baseline (ISQBL). Secondary endpoints were the changes in ISQ values depending on the bone height and the bone width. The Pearson correlation coefficient was used to measure the degree of linear dependence between ISQBL and the delta ISQBL–8 wk. To calculate the slope of the relationship, a linear mixed model was fitted including time and potential confounders implant diameter and length as fixed effects, and nested factors implant ID and patient ID as random effects. For calculation, Wessa (2014) and R 3.2.2 [R Core Team 2015], and the nlme package [Pinheiro et al. 2015] for linear mixed model were used.

Results

Baseline and 8-week characteristics

A total of 109 dental implants placed in 97 patients (51 females and 46 males) were available for analysis. Patients had a median age of 63 years (min 34, max 91). Implant diameter was 3.3 mm (2 implants), 4.1 mm (25 implants) and 4.8 mm (82 implants). Most implants (70%) were positioned in area 16 or 26 (Table 1). Implant stability at baseline, as indicated by ISQBL, had a mean value of 68.3 ± 9.8 (min 31, max 84; median value 70.5). At baseline, a total of 50 implants (46%) had an ISQBL value below 70. During healing, one implant developed an infection with a fistula with clinical and radiographic bone loss on the buccal aspect. Although the implant showed an ISQ value of 81 at 8 weeks, the implant was later removed and...
replaced. This implant was considered an early failure (0.9%).

At 8 weeks, the mean ISQ k was 73.6 ± 6.4 (min 46.5, max 83.5; median value 75.0). The increase in mean ISQ value from baseline to 8 weeks was statistically significant (P < 0.001; Fig. 3a). Overall, 91 implants (83%) had an ISQ k ≥ 70, which allowed the initiation of prosthetic rehabilitation using an early loading protocol (Fig. 3b). Among those 91 implants, the ISQ8 wk increased in 68 implants (Fig. 4a), remained stable in 6 implants and decreased in 17 implants (Fig. 4b). The remaining 18 implants (17%) in 15 patients were below ISQ 70 at 8 weeks. They were allocated to an extended healing time (Fig. 4c). Patients were recalled at 2-week intervals: 12 of the 18 implants reached the threshold level within 16 weeks. Two implants were restored after 16 weeks with stable and rising ISQ values but not reaching the threshold level (Fig. 4c). Four implants <70 ISQ at 8 weeks underwent conventional loading after 6 months, as these patients were not available for repeated ISQ measurements. The results also demonstrated that implant length (P = 0.778) or implant diameter (P = 0.442) did not influence the ISQ values at baseline or after 8 weeks.

Correlation analysis of ISQ baseline and 8 weeks

There was a strong correlation [Pearson correlation coefficient r = −0.78] of the ISQBL and the ISQ8 wk−BL suggesting that the gain in implant stability is indirectly proportional to the ISQ value at baseline [Fig. 5]. The regression curve revealed the following formula: ISQBL = 44.3 + (−0.57 × ISQ8 wk−BL). No correlation with ISQ8 wk−BL was found for age [r = 0.078] or implant position [r = 0.081].

Correlation analysis considering bone height and width

Data on bone height and width were available for 68 implants placed in 66 patients. The reason for the lack of anatomical data with CBCT images in 31 patients was that the replaced tooth was still in place or a 3D examination had already been performed before the patient was referred. Median bone width was 8.48 mm (min 5.2; max 14.4). The median bone height, sagittal and coronal, was 5.8 mm (min 2.4; max 15.4) and 6.3 mm (min 3.1; max 14.1), respectively. Table 2 and Fig. 6 summarize the correlation analysis of ISQ values with anatomical parameters. Correlation of ISQBL and ISQ8 wk with the bone width gave r-values of −0.15 and 0.07, respectively. Correlation of ISQBL with sagittal

![Image](https://example.com/image1.jpg)

Fig. 1. Case report of a female patient in the left maxilla. (a) and (b) show the implant 26 placed with simultaneous SFE, which had ISQ values of 49 (from the buccal) and 55 (from the mesial) at baseline. After 8 weeks of healing, the implant had ISQ values of 69 and 72 (c). The periapical radiograph shows that bone healing around the implant has well progressed (d).

![Image](https://example.com/image2.jpg)

Fig. 2. Case report of a female patient in the right maxilla. Two implants have been inserted with SFE. Implant 16 shows low ISQ values of 44 (measured from the buccal) and 55 (from the mesial) at baseline. The corresponding radiograph demonstrates a borderline bone height distal to implant 16 (b). At 8 weeks of healing, the ISQ values have gained to 53 and 64 (c) requiring an extended healing period. At 12 weeks of healing, the gain in ISQ value has continued and reached the level of 71 (d).

Table 1. Distribution of implant sites

<table>
<thead>
<tr>
<th>Position</th>
<th>17</th>
<th>16</th>
<th>15</th>
<th>14</th>
<th>24</th>
<th>25</th>
<th>26</th>
<th>27</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implants</td>
<td>3</td>
<td>35</td>
<td>8</td>
<td>7</td>
<td>3</td>
<td>13</td>
<td>39</td>
<td>1</td>
<td>109</td>
</tr>
</tbody>
</table>
within 8 weeks of healing is indirectly proportional to the implant ISQ value at baseline. The high percentage of 83% implants with an ISQ value ≥ 70 has been favored by several factors. First, it was favored by the fact that roughly 50% of the inserted implant had an ISQ value of ≥ 70 at baseline indicating a good primary stability. The primary stability of an inserted implant is influenced by the mechanical anchorage of the implant at surgery. This mechanical anchorage depends on various factors present at implant surgery. Most important are the anatomical conditions at the implant site in the posterior maxilla, including the native bone height and the bone density. Other factors are the precision of the prepared implant bed and the shape of the inserted implant. The present study showed that bone height was crucial for primary stability, which was reflected in the measured ISQ values. Increased ISQ values at baseline were also favored by the shape of the tissue-level implants used, as the tapered tulip shape in the neck portion gives additional press fitting in the crestal area during initial healing (Da Costa Valente et al. 2015), as the borderline between the machined and micro-rough implant surface was intentionally positioned 1–2 mm below the crest to optimize primary stability.

After 8 weeks of healing, secondary implant stability mainly reflects the biological anchorage due to direct bone apposition onto the implant surface during the healing period. As demonstrated in preclinical studies, the primary bone-to-implant contact due to press fitting is reduced by osteoclastic activity and compensated by new bone apposition (Cochran et al. 1998; Schenk & Buser 1998). The reduction of implant stability during initial healing was also confirmed in a clinical study by Valderrama et al. (2007), in which ISQ values were measured in weekly intervals. The study showed a dip of the ISQ values with the lowest values between 3 and 4 weeks of healing. The speed and rate of new bone apposition to the implant surface during healing are mainly influenced by two factors: [i] the osteophilic properties of the utilized microrough implant surface and [ii] the osteogenic potential of the applied bone fillers for SFE. The measurement of the bone density would be an additional information, but this is not feasible with CBCT technology (Nackaerts et al. 2011).

In the present study, tissue-level implants with a chemically modified implant surface were utilized. This surface is produced by sandblasting and acid etching. This hydrophilic implant surface not only demonstrated enhanced bone apposition and increased

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**Table 2. Correlation analysis of ISQ values with anatomical parameters**

<table>
<thead>
<tr>
<th>Anatomical area</th>
<th>BWBL</th>
<th>BHSBL</th>
<th>BHSDBL</th>
<th>BHCMBL</th>
<th>BHCLBL</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISQBL (r value)</td>
<td>−0.15</td>
<td>0.25</td>
<td>0.14</td>
<td>0.09</td>
<td>0.05</td>
</tr>
<tr>
<td>P value</td>
<td>0.22</td>
<td>0.04</td>
<td>0.25</td>
<td>0.48</td>
<td>0.68</td>
</tr>
<tr>
<td>ISQ8 wk (r value)</td>
<td>0.07</td>
<td>0.16</td>
<td>0.17</td>
<td>0.09</td>
<td>0.05</td>
</tr>
<tr>
<td>P value</td>
<td>0.56</td>
<td>0.18</td>
<td>0.17</td>
<td>0.48</td>
<td>0.71</td>
</tr>
<tr>
<td>ISQ8 wk-ΔISQBL (r value)</td>
<td>0.24</td>
<td>−0.18</td>
<td>−0.04</td>
<td>−0.04</td>
<td>−0.03</td>
</tr>
<tr>
<td>P value</td>
<td>0.05</td>
<td>0.15</td>
<td>0.73</td>
<td>0.75</td>
<td>0.82</td>
</tr>
</tbody>
</table>

Bone width (BWBL) with bone height sagittal (mesial, distal; BHSBL, BHSDBL) and bone height coronal (medial, lateral; BHCMBL, BHCLBL).
removal torque values in standard implant sites without bone defects during early wound healing (Buser et al. 2004; Ferguson et al. 2006, Lang et al. 2011), but also improved bone formation in peri-implant bone defects (Schwarz et al. 2007, 2008).

A composite graft was used for SFE, with a 50 : 50 percent mixture of locally harvested autogenous bone chips and DBBM granules. This type of composite graft is commonly used for SFE procedures, as the two bone fillers have synergistic potential. Autograft chips have osteogenic potential, stimulating the rate of new bone formation during early healing, as demonstrated in preclinical studies in membrane-protected bone defects (Buser et al. 1998; Jensen et al. 2006) and in SFE defects (Jensen et al. 2013). The DBBM filler, on the other hand, has a low substitution rate, as shown by preclinical studies (Jensen et al. 2012, 2013), offering the advantage of improved vertical volume stability in SFE procedures.

In the present short-term study documenting the bone integration of implants in augmented SFE sites, the utilization of autografts is the important part of the composite graft. A recent histometric study has shown that the bone-to-implant contact of implants is significantly increased when autogenous bone grafts are mixed with DBBM (Jensen et al. 2013). This study also demonstrated no difference between autografts harvested in the iliac crest or in the mandible. This is an important finding from a clinical point of view, as locally harvested autograft chips – as used in the present study – reduce the morbidity for patients. A recent systematic review and meta analysis by Corbella et al. [2015] also confirmed that autogenous bone showed the highest possible new bone formation in maxillary sinus surgery. Autogenous bone chips have also been explored in recent in vitro studies (Miron et al. 2011, 2013; Cabrallé-Serrano et al. 2014). These studies confirmed the osteogenic potential of autograft chips, although more research is needed to fully understand these mechanisms.

Faster bone formation around implants offers the chance to reduce the healing period. There has been a trend to reduce healing periods in implant patients to make implant therapy more attractive for them (Gallucci et al. 2014). The original healing period of implants with simultaneous SFE has been 6 months or even longer (Blomqvist et al. 1996; Degidi et al. 2014). The early loading protocol with 8 weeks of healing for implants placed with SFE represents a significant progress for implant therapy in daily practice. For clinicians, the challenge is to identify those implants which are ready for loading at 8 weeks. Thus, an objective technique to measure implant stability to make the right decision is needed.

The threshold level of ISQ ≥ 70 after 8 weeks of healing and underwent an early loading protocol. The early failure rate was low, at 0.9%. The study also confirmed that using RFA to measure ISQ values is a suitable method to objectively monitor implant stability longitudinally.

Conclusions

In the present study, 83% of the implants reached the threshold level of ISQ ≥ 70 after 8 weeks of healing and underwent an early loading protocol. The early failure rate was low, at 0.9%. The study also confirmed that using RFA to measure ISQ values is a suitable method to objectively monitor implant stability longitudinally.

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Conflict of interest

There are no conflicts of interest.
References


