CLINICAL ORAL IMPLANTS RESEARCH

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The prognostic accuracy of resonance frequency analysis in predicting failure risk of immediately restored implants

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Abstract

Objectives: It is of imperative clinical significance to define a safe threshold for planned immediate implant restoration. The aim of this report was to evaluate the prognostic accuracy of resonance frequency analysis (RFA) measurements recorded at two different times (implant placement and 8-week post-implant placement) and to determine the optimal threshold value for predicting failure risk of immediately restored/loaded implants.

Material and methods: Twenty-eight 8- or 9-mm-diameter implants were placed in either a fresh molar extraction socket or a healed site. An electronic RFA device was used to record the implant stability quotients (ISQs) at implant placement surgery, 8 weeks and 1 year. Receiver operating characteristic (ROC) analysis was used to identify the optimal cut-off level. Sensitivity and specificity were also determined at the selected cut-off value.

Results: The area under the ROC curve for RFA at 8 weeks was 0.93 with a significant *P*-value ($P = 0.001$). The optimum cut-off value for detecting implant stability was 60.5 ISQ measured at 8 weeks, with sensitivity and specificity of 95.2% and 71.4%, respectively.

Conclusions: The implant stability measurements after 8 weeks showed a better accuracy in predicting implants that were at risk of failure than those taken at the time of implant placement.

Implant stability is considered an indicator for and a measure of osseointegration (Meredith et al. 1996, 1997) that could be defined at the primary and secondary level. Primary stability reflects the degree of mechanical interlocking between the implant and the surrounding bone at the time of placement (Abrahamsson et al. 2004; De Smet et al. 2005). It is often related to the degree of bone compression and could therefore be influenced by bone quality and quantity, the surgical technique, and implant design and characteristics (Sennerby & Roos 1998). Secondary stability, on the other hand, is a biologically induced mechanism (Huwiler et al. 2007) involving complex processes of bone formation, maturation and remodelling at the implant–bone interface (Davies 1998; Rasmusson et al. 1999).

Over the last decade, outcomes of immediate loading protocols have been facilitated with the introduction of implants of modified surface characteristics and by modifications of the surgical techniques. The rationale was to promote improved primary implant stability as a prerequisite for successful osseointegration (Albrektsson et al. 1981; Albrektsson & Zarb 1993). Immediate loading of implants was thought to result in implant micromobility leading to fibrous encapsulation instead of osseointegration (Roberts 1988; Pilliar 1991). A critical micro-mobility threshold of 100 μm was thereafter proposed, above which implant failure would ensue (Soballe et al. 1992; Brunski 1993). Ledermann (1977, 1979), however, showed that the micro-mobility at the bone–implant interface remains below this critical threshold; hence, successful osseointegration of immediately loaded implants could be achieved, albeit, specifically for mandibular implant overdentures.

Subsequently, several methods for the assessment of implant stability at different clinical time points have been described (Meredith et al. 1996; Atsumi et al. 2007). Percussion test, in which a stable implant would exhibit a high-pitched tone when tapped with a mouth mirror handle, was one early method used (Adell et al. 1985). Another standard method was radiography by which bone-level changes around implants could be determined as a measure of successful osseointegration and hence stability (Adell et al. 1986). Both methods, however, are of limited value as they fail to objectively quantify implant stability. Other methods have been the direct evaluation of the bone-implant contact (BIC) using electron microscopy (Kim et al. 2002), removal torque analysis (Carlsson et al. 1988; Sullivan et al. 1996), and pushout and pullout tests (Dhert et al. 1992). These methods are apparently invasive, lack accuracy or impractical to use clinically. Alternative non-invasive quantitative methods such as the resonance frequency analysis (RFA) are now extensively used as surrogate measures for osseointegration with claims to predict optimum time for loading (Olive & Aparicio 1990; Meredith et al. 1997).

The electronic RFA device (Osstell, Integration Diagnostics AB, Göteborg, Sweden) measures implant stiffness as a determinant of implant stability (Meredith et al. 1996; Sennerby & Meredith 1998) and is thought to be an accurate and precise tool that progressively replaced other methods in implant research (Zix et al. 2008). Several factors specific to the surgical site, patient characteristics or implant surface design were thought to influence RFA measurements. Extensive research has been carried out to determine the correlation between these factors and RFA measurements. The findings, however, were highly variable. For example, several authors (Bischof et al. 2004; Balshi et al. 2005; Ostman et al. 2006; Alsaadi et al. 2007; Sim & Lang 2010) showed that implant stability quotient (ISQ) values correlated well with bone quality as defined by Lekholm & Zarb (1985). Others (Zix et al. 2005; Degidi et al. 2010) demonstrated a weak correlation between bone quality and operator received primary stability on the one hand and ISQ values on the other. Lack of significant correlation between ISQ values and microcomputer tomographic analysis of bone volume density or trabecular connectivity was also observed (Huwiler et al. 2007). RFA measurements also failed to correlate with the insertion torque (O'Sullivan et al. 2000; Nkenke et al. 2003; da Cunha et al. 2004; Akkocaoglu et al. 2005; Bardyn et al. 2009; Dos Santos et al. 2009) but correlated well with cortical bone thickness (Merheb et al. 2010) and the cutting resistance at the time of implant placement (Friberg et al. 1999). Implant surface chemistry and finishing did not seem to influence the ISQ values (Valderrama et al. 2007; Dos Santos et al. 2009; Han et al. 2010) nor did the implant diameter (Bischof et al. 2004; Han et al. 2010). Implant length, by contrast, was found to enhance the primary implant stability as longer implants provided more BIC area (Langer et al. 1993; Renouard et al. 1999; Polizzi et al. 2000; Sim & Lang 2010).

Clinically, RFA could be more useful in monitoring implant stability over a period starting from the time of implant placement and throughout the healing phase. Repeated measurements at separate intervals following implant insertion were thought to determine the appropriate time of loading (Glauser et al. 2004) and to predict early signs of clinical failure (Meredith et al. 1997). Although an ISQ value falling within a wide range between 57 and 74 has been considered normal during implant placement (Balleri et al. 2002; Bischof et al. 2004; Huwiler et al. 2007), a consensus regarding a normative ISQ value range has not been established (Hobkirk & Wiskott 2006; Javed & Romanos 2010).

The controversy of the variable literature on RFA becomes compounded when it is applied to immediate restoration/loading protocols by clinicians (Atieh, et al. 2012a). With immediate restoration/loading protocol, the only RFA measurement taken prior to loading is the one recorded at the time of implant placement. It is of imperative clinical significance therefore to define a safe ISQ threshold for planned immediate loading. This threshold could identify implants that are amenable to immediate loading and predict those at a higher risk of failure. In an animal study, Al-Nawas et al. (2006) have suggested that an ISQ threshold value of 65.5 at implant placement, with a sensitivity of 83% and a specificity of 61%, may predict implant loss. Other clinical studies suggested that implants with ISQ values above 65 at time of placement were suitable for immediate loading (Meredith et al. 1997; Heo et al. 1998; Glauser et al. 2003; Lindeboom et al. 2006). On the other hand, ISQ values of ≥ 42 (Nedir et al. 2004), 60 (Ostman et al. 2005, 2008; Degidi et al. 2006) or 62 (Cornelini et al. 2006) at implant placement have also been suggested as threshold values for immediate loading. These conflicting results across the different clinical studies utilizing RFA have perplexed the profession with regard to the acceptable normative ISQ values for immediate restoration/loading.

The objectives of the current investigation were therefore, firstly, to determine the prognostic accuracy of RFA measurements recorded at two different times (implant placement and 8-week post-implant placement) and secondly to determine the optimal ISQ threshold value for predicting failure risk of immediately restored/loaded wide-diameter implant in molar sites.

Material and methods

Study design and participants

The study was conducted according to the Standards for the Reporting of Diagnostic accuracy studies (STARD) statement for reporting studies of diagnostic accuracy, where applicable (Bossuyt et al. 2003). The study protocol was approved by the Lower South Regional Ethics Committee (LRS/08/08/034) and the Ngai Tahu Research Consultation in New Zealand. Further, it was registered as a prospective controlled clinical trial with the Australian New Zealand Clinical Trial Registry (ACTRN12608000569303).

From November 2008 to December 2009, a total of 35 participants, requiring extraction of single molar tooth or having a missing single molar tooth in the mandible, were recruited prospectively and consecutively at the School of Dentistry, University of Otago, New Zealand. Of those recruited, only 28 met the inclusion criteria of the present diagnostic study. Prerequisites for inclusion were good general health, controlled oral hygiene, adequate bone quality (Type I–III), adequate sub-apical alveolar bone for immediate placement, presence of ≥ 2 mm of keratinized tissue to allow soft tissue manipulation and absence of medical risk factors (e.g. infectious disease, diabetes and osteopathy). Bruxers, smokers and those who had severe limitation of mouth opening were excluded. All the eligible participants attended a surgical and prosthodontic consultation sessions and were informed about the benefits and possible risks of the proposed research. An informed consent was obtained in compliance with the revised Declaration of Helsinki (Edinburgh, Scotland, October 2000).

Surgical and prosthodontics protocols

A single dose of appropriate antibiotic (2-g amoxicillin or 600-mg clindamycin if allergic to penicillin) was administered one hour before surgery, and participants were instructed to rinse twice for one minute with 0.2% chlorhexidine gluconate (Savacol, Colgate, New York, NY, USA). All the participants received a single 8- or 9-mm-diameter implant (MAX Southern Implants, Irene, South Africa) in the posterior mandible. In case of immediate implant placement, the mandibular molar was extracted atraumatically without raising a flap to minimize any injury to the surrounding soft and hard tissues. The extraction site was then prepared using the implant tapered drills (D-60TP and D-80TP MAX Southern implant tapered drills, Irene, South Africa) followed by pre-tapping. In the presence of a healed molar site, the implant installation followed the manufacturer's instructions. An insertion of torque of ≥45 Ncm was used to insert the most of the implants.

Following the surgical procedure of implant placement, a bone-level impression using polyvinyl siloxane impression material (Exaimplant, GC, Tokyo, Japan) was taken and a healing abutment was placed followed by suturing with polyglycolic, polylactic acid polymer-derived sutures (3/0 or 4/0 Vicryl Rapide, Ethicon Inc, Somerville, NJ, USA). Regardless of the implant placement protocol, an acrylic provisional crown with platform-switched design (Atieh et al. 2010a) was placed out of occlusion within 48 h and tightened to 20 Ncm. At 8 weeks, the provisional crown was replaced with permanent screw-retained zirconia-ceramic crown.

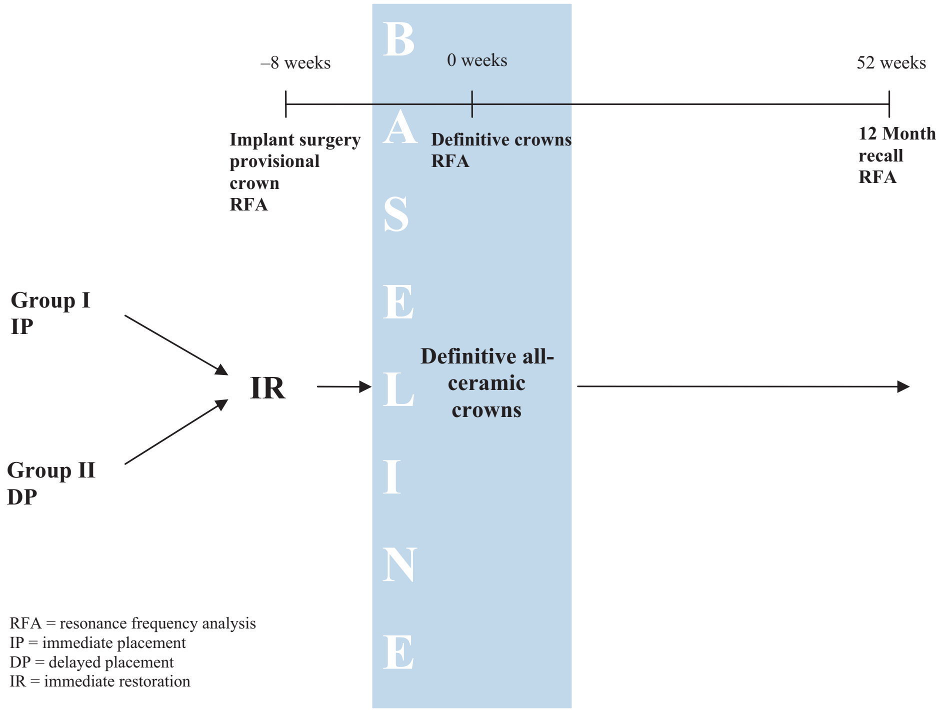

Fig. 1. Outline of the study.

RFA measurements

The electronic RFA (Osstell, Integration Diagnostics AB, Göteborg, Sweden), often referred to as the third generation (Sennerby & Meredith 2008), was used to measure the implant stability at implant placement surgery, 8 weeks and 1 year (Fig. 1). This device utilizes RFA to measure the implant stiffness (Meredith et al. 1996; Sennerby & Meredith 1998; Friberg et al. 1999) and consists of a calibrated L-shaped transducer that is wired to resonance frequency analyser (Fig. 2). The transducer, which is connected to the implant, produces a minute lateral stress that increases in frequency until the implant vibrates. The resonance frequency in Hertz is then converted to ISQ unit by computer software. The ISQ scale ranges from 0 to 100, with a higher value indicating a more stable implant.

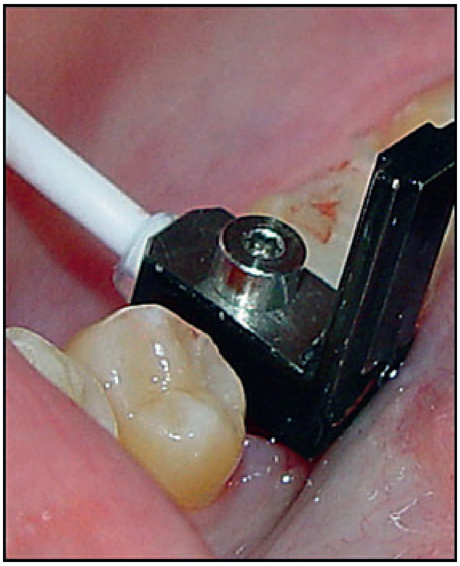

Fig. 2. L-shaped transducer attached to the wide-diameter implant at surgery.

Statistical analyses

The analyses were performed using statistical software (SPSS 17.0, SPSS Inc., Chicago, IL, USA). The continuous data (ISQ values) were presented as mean ± SD. Receiver operating characteristic analysis was used to assess the sensitivity and specificity of RFA measurements at specific time points and to identify the optimal threshold value with the highest accuracy for detecting implant failure risk. The ROC is constructed by plotting the sensitivities against the corresponding false-positive rates (1-specificity). The optimal threshold value is determined by the point on the ROC curve farthest from the diagonal line, which yields the maximum sum of sensitivity and specificity and optimizes the rate of true positives whilst minimizing the rate of false positives. The survival rate of immediately restored/loaded implants after a follow-up period of 12 months was used as a surrogate reference standard. The positive reference standard was failure of immediately restored/loaded implant to osseointegrate.

The area under the curve (AUC) measures the overall capacity of the test to discriminate between participants with high risk of implant failure and those without it. An AUC of 0.5–0.7 indicates poor accuracy, 0.7–0.9 is moderate, 0.9–0.99 is very good and an area of 1.0 indicates a perfect predictive ability (Akobeng 2007). The sensitivity and specificity were calculated from 2 × 2 contingency tables for optimal threshold value. Another important diagnostic measure is the likelihood ratio (LR), which is reliable in measuring the discriminating ability of diagnostic and prognostic tests as they are roughly less dependent on the prevalence rate. The LR+ was calculated using the formula (sensitivity/1-specificity) and the LR- was calculated using the formula (1-sensitivity/specificity). A LR+ of 2.0 and a LR- of 0.5 are the minimum values for a satisfactory discriminating diagnostic and prognostic performance (Jaeschke et al. 1994).

Results

All the participants completed all the follow-up measurements. The overall implant survival rate after 1 year of service was 78.6%. Out of the six failed implants, four implants lost their osseointegration within the first 3 months, and the remaining two implants were lost by the end of the 1-year observation period. All the failed implants exhibited signs of mobility without inflammatory signs apart from the one lost after 1 year, which showed tenderness, mobility and signs of peri-implant mucositis. The 1-year implant survival rates for the immediate and delayed placement were 71.4% and 85.7%, respectively. The participant demographics and implant characteristics are summarized in Table 1.

Prognostic value of RFA

The RFA measurements recorded at surgery, 8 weeks and after 1 year are summarized in Table 2. The mean values of RFA measurements for the survived implants at the different time points are given in Fig. 3. No significant differences in the implant stability measurements were observed between immediate and delayed implant placement groups at surgery, 8 weeks and 1 year ($P > 0.05$).

The AUC for RFA at surgery was 0.45 with a non-significant P-value of 0.70, whereas the AUC at 8 weeks was 0.93, with significant P-value ($P = 0.001$). According to ROC coordinates, the optimal threshold value for detecting implant stability was 60.5 ISQ measured at 8 weeks, with sensitivity and specificity of 95.2% and 71.4%, respectively (Fig. 4). The LR for positive test result was 3.33 and the LR for negative test results was 0.07 at a threshold of 60.5 ISQ. According to the Bayes' theorem (Deeks & Altman 2004), the post-test probability was calculated, which showed that 52.0% of immediately restored single implants in posterior mandible with an ISQ value of <60.5 ISQ at 8 weeks will be at risk of failure.

Table 1. **Summary of participant and implant characteristics**

	Total (n = 28)	Failed implants (n = 6)
Age (years) Mean (SD)	50.3 (13.5)	
Gender (n)		
Male	10	5
Female	18	1
Implant location (n)		
Right first molar	15	2
Left first molar	11	3
Right second molar	1	0
Left second molar	1	1
Bone quality (n)		
Type II	21	4
Type III	7	2
Implant diameter (mm)		
8	17	3
9	11	3
Implant length (mm)		
7	1	0
9	9	1
11	18	5
Insertion torque (Ncm) (n)		
>45	19	5
≤45	9	1

Table 2. **Summary of resonance frequency analysis measurements at different time points**

Implant no	Resonance frequency analysis at different time points (ISQ)		
	Surgery	8 weeks	1 year
1	80	78	81
2	88	86	64
3	82	82	87
4	83	85	83
5	67	66	68
6	78	59	*
7	83	77	*
8	77	80	81
9	83	85	88
10	78	50	*
11	81	50	*
12	81	59	61
13	73	81	79
14	79	53	*
15	83	88	85
16	80	80	82
17	74	83	86
18	83	73	*
19	77	80	82
20	78	80	82
21	80	62	87
22	83	85	86
23	82	84	85
24	74	72	85
25	78	66	54
26	81	83	87
27	80	80	81
28	80	50	*

ISQ, Implant Stability Quotient.
*Failed implant.

Discussion

The STARD guidelines (Bossuyt et al. 2003) were followed in reporting the prognostic accuracy of RFA, as a predictor of single implant failure in immediate restoration/loading conditions in molar sites. Two implant stability measurements, at implant surgery and 8-week post-implant placement, were investigated, and the clinical outcome (implant survival versus failure) was considered to be the reference standard. One of the main findings of the present research was that the AUC for RFA measurements at surgery was 0.45 with non-significant P-value. The AUC was not significantly different from the area under the reference (diagonal) line of ROC. This indicated that the RFA measurements taken at the time of surgery were not a significant predictor of the failure risk of immediately restored/loaded single implants in the posterior mandible. In contrast, the RFA measurements at 8 weeks were more effective in detecting the implant failure risk. The RFA measurements at 8 weeks have an AUC that was significantly greater than the diagonal line of ROC and therefore showed a significantly better prognostic accuracy than the RFA measurements taken at surgery. Similar observation was noted by Glauser et al. (2004), who measured the implant stability of 81 immediately loaded implants and showed that the risk of failure increased with decreased ISQ value at 1 month of loading. This is also in agreement with the results of a recent systematic review and meta-analysis that showed poor prognostic accuracy of the RFA measurements at surgery in detecting failure risk of immediately loaded implants (Atieh et al. 2012a).

The optimal value that would allow the use of RFA as a prognostic tool is where the rate of true positives (sensitivity) is maximized, whilst optimizing the specificity. An optimal ISQ threshold value of 60.5 recorded at 8 weeks was able to attain a high sensitivity of 95.2% and a specificity of 71.4%. It is important to note that previous studies proposed similar ISQ threshold values for immediate loading (Ostman et al. 2005, 2008; Degidi et al. 2006) but based on clinical experience rather than scientific evidence. Others, however, suggested different ISQ thresholds (Meredith et al. 1997; Heo et al. 1998; Glauser et al. 2003; Nedir et al. 2004; Lindeboom et al. 2006). The variability of the ISQ threshold values reported in literature could be attributed to different implant designs. Mean ISQs of 68.1, 67.4 and 57.4 were recorded for Neoss (Bogaerde et al. 2010), Brånemark (Ostman et al. 2006) and Straumann implants (Bischof et al. 2004), respectively. To date, no attempt has been made to evaluate the diagnostic accuracy of RFA and determine the optimal ISQ threshold for different implant systems using ROC curve.

The limitations of using the RFA as a prognostic tool for immediate restoration/loading are not only related to jaw location or implant system. It is also the ambiguity of what biologic parameters are exactly measured by RFA at the time of implant placement. Huwiler et al. (2007) described an ISQ range of 57–74 as being normal during implant placement, but showed that RFA failed to reflect the changes in BIC area and questioned the predictive ability of the RFA. Despite improvement in hardware, it appears that RFA testing can merely indicate that the inserted implant is clinically stable at the time of measurement and hence may provide a false sense of assurance for both clinicians and patients contemplating on immediate implant restoration.

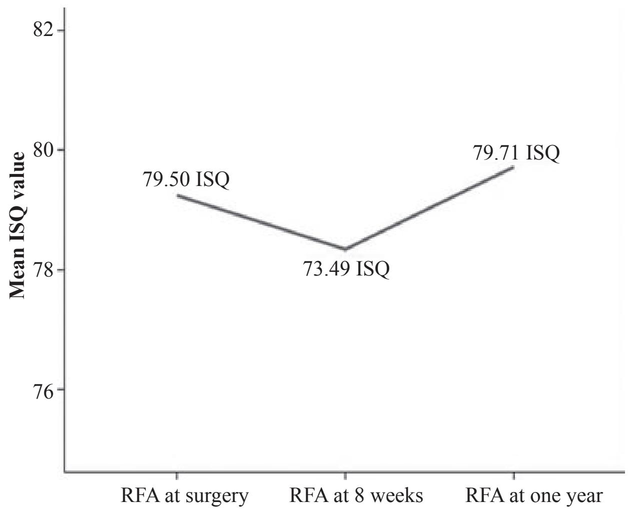

Fig. 3. Mean implant stability quotient (ISQ) recorded at surgery, 8 weeks and after 1 year.

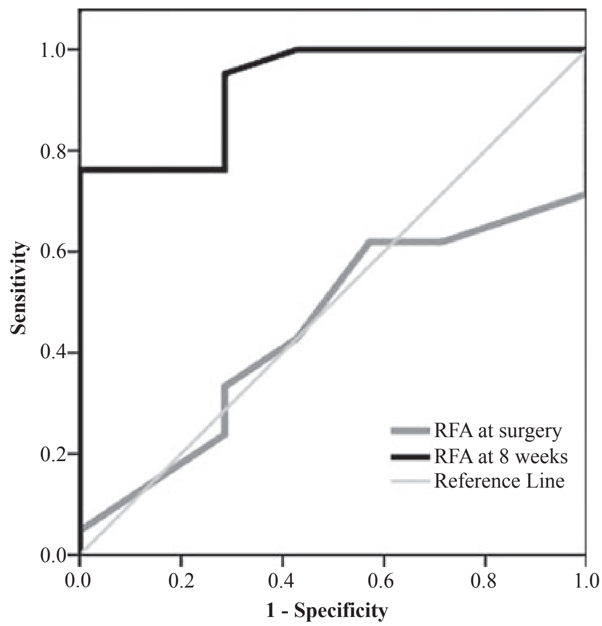

Fig. 4. Receiver operating characteristic curve showing sensitivity versus 1-specificity to detect cases considered as having a high risk of implant failure.

To overcome the low sensitivity of RFA as a prognostic tool for immediate restoration/loading at the time of implant placement, a combination of clinical parameters, RFA, radiographic evaluation and insertion torque should be considered before immediate restoration/loading. Moreover, an immediate restoration rather than loading is proposed in the first 8 weeks followed by RFA assessment prior to definitive loading. Any drop in the ISQ value below a threshold limit of 60.5 ISQ may indicate a tendency to failure, and in this instance, the implant can be unloaded until it regains its stability and reaches a safe ISQ level prior to final restoration. Such a cautious and conservative approach in implementing immediate loading protocols was recommended in previous studies (Rao & Benzi 2007; Sennerby & Meredith 2008).

It might be worth noting that the reported failure rate was relatively high compared with those reported in the anterior (Atieh et al. 2009a,b) and molar sites (Vandeweghe et al. 2012; Atieh et al. 2010b). This is partly due to the strongly tapered body of the used implant (MAX Southern Implants, Irene, South Africa; Atieh & Shahmiri 2011; Atieh et al. 2012b), which may have caused excessive stress at the cortical bone during placement and subsequently early implant failure (Ueda et al. 1991; Oh et al. 2002; Atieh et al. 2012c). In addition, none of the studies that reported high survival rates combined both the immediate placement and restoration protocols.

The present study had several limitations such as the small number of participants, the short follow-up period, the use of one implant system and the use of one anatomical site (posterior mandible). Moreover, the determination of a reliable and accurate cut-off value requires a larger sample size. The inclusion of both groups in the analysis, albeit no significant difference in the failure rates between the two groups, may have confounded the results in the present study. Nevertheless, the current research has also its own merits as it evaluated the accuracy of RFA in predicting implants at high risk of failure and questioned the reliability of RFA as an objective measuring tool at the time of implant placement. In addition, given the lack of generally accepted ISQ thresholds for immediate loading of different implant systems, the current research provided an ISQ threshold value that may help clinicians in predicting MAX Southern Implants that are at a higher risk of failure prior to immediate loading in the posterior mandible. Further studies with larger numbers of participants are still needed to confirm the applicability of the stated RFA threshold values for wide-diameter implants to other jaw locations.

Within the limitations of this study, the implant stability measurements after 8 weeks showed a better accuracy in predicting implants that were at risk of failure than those taken at the time of implant placement.

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