

Jeffrey J. McCullough
Perry R. Klokkevold

The effect of implant macro-thread design on implant stability in the early post-operative period: a randomized, controlled pilot study

Authors' affiliations:

Jeffrey J. McCullough, Section of Periodontics,
UCLA School of Dentistry, Los Angeles, CA, USA
Perry R. Klokkevold, Postgraduate Periodontics
Residency Program, Section of Periodontics, UCLA
School of Dentistry, Los Angeles, CA, USA

Corresponding author:

Perry R. Klokkevold, DDS, MS, FACD
Postgraduate Periodontics Residency Program
63-022 CHS-Dental, Section of Periodontics
UCLA School of Dentistry
Los Angeles, CA 90095-1668, USA
Tel.: +310 825 1927
Fax: +310 825 1903
e-mail: pklokkevold@dentistry.ucla.edu

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Abstract

Introduction: Available literature suggests there is a transient drop in implant stability from approximately week 0 to week 3–4 as a result of peri-implant bone remodeling as it transitions from a primary, mechanical stability to a secondary, biological stability. Research investigating the influence of macro-thread design on this process is scant.

Aim: The specific aim of this study was to evaluate the role of macro-thread design on implant stability in the early post-operative healing period using resonance frequency analysis (RFA).

Material and methods: Seven patients, each missing at least two posterior teeth in the same arch, were included in the study. Three patients qualified for four implants resulting in a total of 10 matched pairs. All sites were healed (>6 months), non-grafted sites with sufficient bone to place implants. Each site in a matched pair was randomly assigned to receive either a control (Megagen EZ Plus Internal; EZ) or test (Megagen AnyRidge; AR) implant. The test implant incorporates a novel thread design with a wide thread depth and increased thread pitch. RFA was used to determine implant stability quotient (ISQ) values for each implant at the time of placement and weekly for the first 8 weeks.

Results: Implants consistently achieved a relatively high insertion torque (30–45 N/cm) and high initial ISQ value (79.8 ± 1.49). Baseline ISQ values for test (AR; 79.55 ± 1.61) and control (EZ; 80.05 ± 1.37) implants were similar. A general pattern of stability from baseline through all eight follow-up evaluations was observed for the test implants. A pattern of decreasing ISQ values was observed for the control implants across the early follow-up evaluations up to week four, where the value plateaued. There was a statistically significant main effect due to implant type ($P < 0.01$) and a statistically significant interaction between implant type and time ($P < 0.01$), indicating that the test and control implants performed differently at certain time points.

Conclusions: Within the limitations of this study, macro-thread design appears to play a role in implant stability in the early post-operative healing period as assessed by RFA. These findings may have important implications related to immediate or early loading protocols.

Dental implants are being utilized in ever-increasing proportions as replacements for missing teeth with proven predictability achieving 5- and 10-year survival rates of approximately 95% and 90%, respectively, when placed into healed sites (i.e., delayed placement) with conventional loading protocols. (Pjetursson et al. 2004) Recent trends have challenged these tested protocols by loading implants early, and in some cases, immediately after implant placement.

An important question that remains to be answered relative to immediate loading is what happens to the bone supporting an

implant in the early period immediately after it is placed. Studies using resonance frequency analysis (RFA) have reported a drop in implant stability quotient (ISQ) values from week 0 to week 3–4 following implant placement (Barewal et al. 2003; Ersanli et al. 2005; Raghavendra et al. 2005; Huwiler et al. 2007; Boronat Lopez et al. 2008). This, along with histologic studies (Cochran et al. 1998), provides strong evidence for the idea that there is a period of bone remodeling following implant placement that results in a transient decrease in implant stability. In cases of conventional loading (>2 months after

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implant placement), this phenomenon is likely to be of little consequence, as the implant has time to recover from this loss of stability prior to placing it into functional loading. However, largely due to patient demand, there is a desire for early or even immediate prosthetic loading of implants. In these cases, a small drop in stability in the early phases of healing could have a significant negative impact on treatment outcomes. It is primarily for this reason that immediate loading is not yet a routine practice.

There are numerous factors that could potentially influence the extent and duration of bone remodeling in the post-operative period, many of which have not been adequately studied. One possible factor is implant thread design, of which there are numerous parameters including thread pitch, depth, and shape (e.g., V-shape, reverse buttress, block).

While implant thread design has been studied in varying contexts, including how it will affect primary stability (Park et al. 2009) and osseointegration (Abuhussein et al. 2010), its effect on bone remodeling shortly after placement has not been examined sufficiently. In addition, the majority of studies using RFA focus only on stability at time of placement (primary stability), with some making an additional measurement after integration has occurred, therefore overlooking and not accounting for the temporary drop in stability during the first few weeks after placement. Among the studies that do evaluate ISQ values in the early healing period, none have focused on the potential effect of macro-thread design.

The benefits to identifying factors that affect bone remodeling around implants are significant. It will enable clinicians to choose (or design) an implant, which reduces or eliminates the decrease in implant stability during the early period of bone remodeling, thus allowing for a greater number of cases to be candidates for immediate or early loading while maintaining a high degree of predictability and successful treatment outcomes.

There have been many attempts by industry to decrease loading time by altering the secondary integration through surface modifications. However, implant surface modifications have not yet provided any practical advantage in the context of immediate loading because, although there may be an increase in the amount of bone-to-implant contact (Ersanli et al. 2005) after integration, at this time, micro-/nano-surface modifications cannot overcome the biologic limitation of the bone healing timeline. This study

aimed to evaluate whether the level of the implant stability achieved at placement can be maintained during the early healing period by the macroscopic features of a new implant geometric design.

Materials and methods

Study design/sample

This study was a prospective, randomized, controlled, within mouth study. The study population was derived from patients presenting to the study site in need of at least two dental implants and who satisfied the inclusion criteria. The study site for this project was the UCLA Postgraduate Periodontics and Implant Surgery Clinic. In addition to the recruitment of subjects from the clinic, IRB-approved study flyers were posted on bulletin boards in the UCLA School of Dentistry and the adjacent Center for the Health Sciences building. Subjects with missing teeth who were seeking replacement with implant(s) were screened to determine eligibility for this study. Those who were deemed eligible were provided with study information and invited to participate. All patient enrollment, implant surgeries, and follow-up evaluations were performed by a single operator (JJM).

Inclusion criteria

- 18 years of age or older (male or female)
- Healthy without diseases or conditions that will compromise bone healing
- Missing two or more teeth with a desire to receive an implant-supported or implant-assisted tooth replacement
- Healed maxillary or mandibular edentulous site for implant placement
- Sufficient bone volume in the site to allow implant placement without the need for bone augmentation

Exclusion criteria

- Systemic disease, medication, or habit known to negatively influence bone healing and/or dental implant success
 - Poorly controlled diabetes (HbA1c > 8%)
 - History of bisphosphonate use
 - History of head and neck radiation therapy affecting the proposed implant site
 - History of smoking >10 cigarettes/day (within past 12 months)
 - Current use of medications that adversely affect healing (e.g., corticosteroids, chemotherapeutic drugs)

- Immune-compromised condition (resulting from disease or treatment)
- Insufficient bone volume for dental implant placement
- Otherwise contraindicated to undergo periodontal / oral / implant surgery

The implants tested in this study were Megagen EZ Plus Internal and Megagen AnyRidge (Megagen Implant Co., Ltd, Seoul, South Korea) (Fig. 1). Both implants are currently available on the market. The EZ Plus implant features a conventional V-shaped macroscopic thread design with self-tapping threads with four cutting edges. The AnyRidge implant features a unique knife-edge thread design (Figs 2 and 3). The company claims this thread design results in “maximum bone-to-implant contact, maximized compressive force resistance, and minimized shear force production,” thereby maintaining stability in the immediate post-placement healing period. Both implants are manufactured with the same material (commercially pure, grade 4 titanium, standard ASTM F67-06) and surface characteristics (Super RBM – sand-blasted, large-grit, acid-etched [SLA]-type surface). While the differences in macro-geometries of the test and control implants may result in slightly different micro-surface topographies (e.g., the results of the sandblasting process for a V-shaped thread may be minutely different compared to a knife-edge thread), these small differences are likely to be insignificant with regard to the objective of this study. Therefore, the only difference between the two implants is the macroscopic thread design.

Seven healthy subjects (7 males, 0 females) ranging in age from 47 to 72 years (mean 60.4 years) were included in the study. Each subject was missing at least two posterior teeth in the same arch. Three of the subjects had a history of chronic periodontitis and therefore underwent periodontal therapy (two patients required non-surgical therapy only, one patient required both non-surgical and surgical therapy) prior to proceeding to implant therapy. All seven subjects enrolled in and completed the study (0% dropout rate). All sites were healed sites (>6 months post-extraction) with sufficient bone volume for implant placement without the need for grafting and no history of bone augmentation. Each subject received pre-operative antibiotics (2 g amoxicillin, or 600 mg clindamycin if allergic to penicillin) and rinsed with chlorhexidine gluconate 0.12% for 1 min. Post-operative antibiotics were not prescribed or dispensed.



Fig. 1. Macroscopic view of EZ Plus and AnyRidge dental implants.

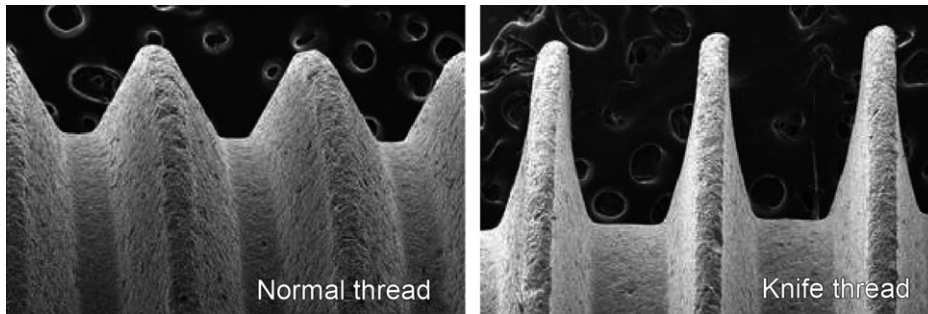


Fig. 2. Microscopic view of a standard V-shaped thread design (EZ Plus) and the novel knife thread design (AnyRidge).

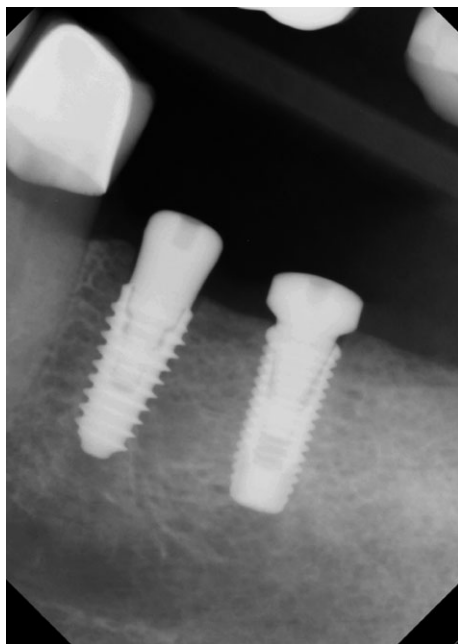


Fig. 3. Radiographic appearance of test (left) and control (right) implants.

Each site in a matched pair was randomly selected to receive either the control implant (Megagen EZ Plus Internal) or the test implant (Megagen AnyRidge), thereby allowing each enrolled participant to serve as an internal control and minimizing or eliminating variations due to oral hygiene, oral flora composition, bone quality, etc. Simple randomization was achieved using a coin flip method wherein the type of implant (test or control) to be placed in the first site of matched pair was determined by coin flip, performed by the operator (JJM), on the day of surgery. The second site of the matched pair would then automatically receive the other type of implant. Three patients received four implants each (two control with two matched test implants), thus resulting in a total of ten matched pairs of implants included in the study. Implants were placed using a standardized drilling protocol. Osteotomies for the test and control implants were prepared according to the manufacturer's recommended drilling sequence. All implants

measured 4 mm in diameter and 10 mm in length. Insertion torque was estimated to the nearest 5 N/cm using a manual torque wrench (MegaGen Implant Co., Ltd). Immediately following implant placement, an Osstell SmartPeg (Osstell; Osstell AB, Gothenburg, Sweden) was connected to the implant at 5 N/cm using an electric handpiece (MegaTorq; MegaGen Implant Co., Ltd) and initial ISQ measurements were taken using an ISQ meter (MegaISQ; MegaGen Implant Co., Ltd). The SmartPeg was then removed and a healing abutment placed. The height of the healing abutment was selected such that it protruded through the gingiva but remained out of occlusion. Healing abutments were placed at 5 N/cm using an electric handpiece to allow for controlled placement and removal of the healing abutments at each visit. No provisional prosthesis was used in any case.

At each follow-up evaluation, the healing abutment was removed and cleaned with gauze. The SmartPeg was inserted into the implant at 5 N/cm, and the ISQ measurements were taken. The peg was then removed and the healing abutment replaced at 5 N/cm (Fig. 4).

A total of 6 ISQ measurements were taken per implant per time point: three from the buccal-lingual direction, and three from the mesial-distal direction. Multiple measurements allowed for assessment of the reproducibility of the ISQ instrument, which was found to be highly consistent and reproducible in all cases.

Data analysis

Data analyses were conducted using the R environment (R Core Team, Vienna, Austria). Comparisons of the mean ISQ values in the buccal-lingual and mesial-distal orientations were made using a paired *t*-test. No significant difference was found ($P > 0.1$); therefore, the average of the mesial-distal and buccal-lingual measurements was used as the primary outcome measure for subsequent analyses. Mean, standard deviation, median, minimum, and maximum ISQ values were calculated for the test and control implants for the baseline (T0) and the eight weekly follow-up evaluations (T1–T8) (Table 1). Due to the high number of intervals relative to the number of observations, data were combined to reduce the number of intervals for analysis purposes. Data from intervals were combined as follows:

Tr0 = T0 (baseline, unchanged)

Tr1 = Average of follow-up week 1 (T1) and follow-up week 2 (T2)



Fig. 4. SmartPegs attached to implants in preparation of implant stability quotient measurements.

Table 1. Mean, standard deviation, median, minimum, and maximum ISQ values at baseline (T0) and 8 weekly follow-up evaluations

	T0	T1	T2	T3	T4	T5	T6	T7	T8
Mean (AR)	79.6	79.7	80.0	80.1	80.3	80.3	80.2	80.4	80.6
SD (AR)	1.61	1.58	1.26	0.81	0.75	0.75	0.85	0.77	0.71
Median (AR)	80.3	80.0	80.5	80.3	80.2	80.2	80.0	80.0	80.8
Min (AR)	76.2	75.8	77.3	78.0	79.0	79.0	79.0	79.5	79.7
Max (AR)	80.7	81.0	81.0	81.0	82.0	82.0	82.0	82.0	82.0
Mean (EZ)	80.1	79.7	79.2	78.3	77.5	77.4	77.3	77.3	77.1
SD (EZ)	1.37	1.31	1.29	1.41	2.03	2.41	2.70	2.74	2.73
Median (EZ)	80.0	80.0	79.7	78.0	77.3	77.9	77.3	77.7	77.3
Min (EZ)	76.7	76.5	76.0	75.1	73.8	72.8	72.7	73.2	73.5
Max (EZ)	82.0	81.5	80.5	80.0	80.0	80.0	81.0	81.0	81.0

ISQ, implant stability quotient.

Tr2 = Average of follow-up week 3 (T3) and follow-up week 4 (T4)

Tr3 = Average of follow-up week 5 (T5) and follow-up week 6 (T6)

Tr4 = Average of follow-up week 7 (T7) and follow-up week 8 (T8)

Mean ISQ values and standard deviations were calculated for the test and control implants for baseline (Tr0) and the four combined follow-up intervals (Tr1–Tr4).

A two-factor (implant type $\times$ time interval) nonparametric analysis for longitudinal data (Brunner et al. 2002) was conducted to compare the test and control implants across time (baseline + four intervals). The R package “nparLD” was used (Noguchi et al. 2012). Data were analyzed for main effects

due to implant type and time, and for the interaction between implant type and time. Contrasts were planned between the baseline interval and each of the four follow-up intervals. Nonparametric Wilcoxon signed-rank tests with Bonferroni corrections were used for comparisons of mean ISQ between implant types at the specified time intervals, and within each implant type between baseline and each follow-up interval.

Human subjects and privacy

This study was conducted in full accordance with ethical principles. All subjects signed a written informed consent to participate in the study. The UCLA Human Research Protection Program (HRPP) approved the study protocol. IRB#13-001878.

Results

Surgical placement of implants and subsequent healing were uneventful in all cases. At insertion, implants consistently achieved a relatively high insertion torque (ranging from 30 to 45 N/cm) and high initial ISQ value (79.8 ± 1.49).

Similar baseline ISQ values were found for the test (AR; 79.55 ± 1.61) and control (EZ; 80.05 ± 1.37) implants (Fig. 5a, Table 1). A general pattern of stability in mean ISQ values from baseline across all eight follow-up evaluations was seen for the test implant. A pattern of decreasing mean ISQ values was seen across the follow-up evaluations for the control implant up to week four, where the value plateaued.

Primary nonparametric analysis of the mean ISQ values for the test (AR) and control (EZ) implants across baseline (Tr0) and the four combined follow-up intervals (Tr1–Tr4) indicated that there was a statistically significant main effect due to implant type (Fig. 6a, Table 2; $P < 0.01$). Control (EZ) implants had overall lower mean ISQ values compared to test (AR) implants. The main effect for time (baseline and four follow-up intervals) was not statistically significant ($P = 0.11$), indicating that there was not a change in ISQ across time for the combined AR and EZ implants. This is primarily due to the very stable ISQ values for the test implant over the follow-up intervals along with changes in ISQ values for the control implants that were not large enough to produce an overall average reduction across the follow-up intervals. However, there was a statistically significant interaction between the main factors of implant type and time ($P < 0.01$), indicating that the test and control implants performed differently at certain time points. The post hoc tests indicated there were statistically significant differences between the test and control implants at Tr2 (post-operative weeks 3–4; $P < 0.01$), Tr3 (post-operative weeks 5–6; $P < 0.01$), and Tr4 (post-operative weeks 7–8; $P < 0.01$). There was no significant difference in ISQ between implant types at baseline (Tr0; $P = 0.46$) or Tr1 (post-operative weeks 1–2; $P = 0.58$).

Comparisons of mean ISQ values within each implant type between baseline and each follow-up interval demonstrated that there was no significant difference in ISQ values in the test implant at any point in the study period ($P > 0.05$). There were statistically significant differences in ISQ values in the control implant at each interval (Tr1–Tr4) compared to baseline ($P < 0.005$).

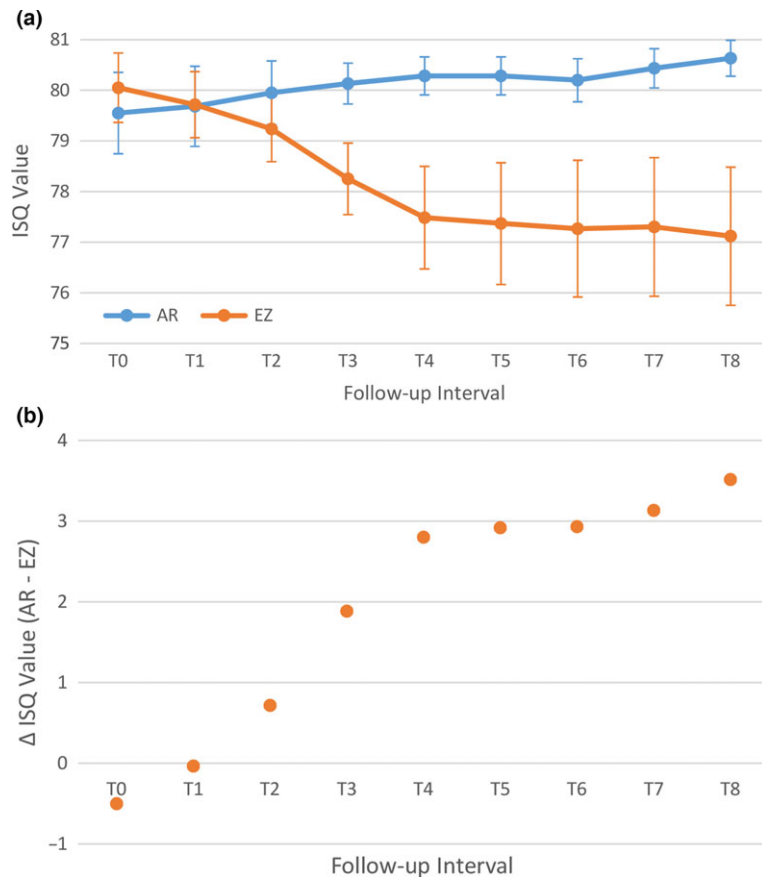


Fig. 5. (a) Mean implant stability quotient (ISQ) at baseline (T0) and 8 weekly follow-up evaluations; (b) difference in mean ISQ values (AR – EZ) at each time interval.

The standard deviation of the test implant decreased from Tr0 to Tr2, after which it remained relatively stable. In contrast to this, the standard deviation of the control implant tended to increase over time due to the greater variability in the performance of the control implant (Figs 6a and 7, Table 2).

Discussion

Resonance frequency analysis has been used in the field of dental implantology since its introduction in 1996 (Meredith et al. 1996). Modern RFA equipment employs wireless technology, making units much less cumbersome and more portable and convenient to use. An aluminum peg (e.g., SmartPeg, Osstell) is excited by magnetic pulses, and the resonance frequency is expressed electromagnetically as ISQ units and is calibrated on a scale of 1–100 (Aparicio et al. 2006).

It is a commonly held belief that the development of a firm implant–bone interface is a requirement for the long-term success of a functional dental implant. Therefore, it is advantageous to develop and evaluate

technology, which enables a quantitative assessment of this interface. Insertion torque is an often-cited quantitative measurement of primary stability, yet it only provides information about the implant at the time of installation (Aparicio et al. 2006). Other methods of assessing the stability of an implant include pullout, pushout, pushin, and reverse torque techniques. While these are useful techniques capable of providing valuable information about the implant–bone interface and how it is influenced by various parameters (Klokkevold et al. 1997, 2001), they are usually only applied to pre-clinical scenarios, as they are potentially destructive to the implant and surrounding tissues. For example, reverse torquing may cause failure of an implant that is in the process of osseointegrating. Also, reverse torquing does not emulate normal loading of an implant under function in the mouth (Sennerby & Meredith 2008). Thus, RFA has the advantage of providing a simple, non-invasive way of evaluating the stiffness of the implant–bone interface by applying a clinically relevant bending force without risking damage to the implant or surrounding tissues.

While there are now over 600 publications in the dental literature on ISQ, questions persist regarding how and when to apply this technology. Perhaps more importantly is the question of what conclusions can actually be drawn from the data provided. Establishing the validity of RFA is a pre-requisite for employing its use as a clinical tool upon which clinicians rely to make treatment decisions. To this end, numerous studies have been conducted in an effort to decipher what information can be drawn from ISQ values and how this value correlates to other metrics used in implant dentistry.

For obvious reasons, human cadaver and *in vitro* and *in vivo* animal studies are the predominant models used in investigating correlations between ISQ and BIC on a histologic level; however, there is one human *in vivo* study in the literature. In 2006, Scarano and coworkers (Scarano et al. 2006) published a study of 7 sand-blasted, large-grit, acid-etched (SLA) implants placed in the posterior mandible which required removal for a variety of reasons (e.g., nerve pathology, misalignment, psychological). The implants were in place for 6 months prior to removal. ISQ measurements were obtained prior to removal. The specimens were then sectioned and prepared for histomorphometric analysis. Results of their study demonstrated a direct correlation between ISQ and BIC.

While there are certainly limitations to the study as related to sample size, the results do provide direct evidence to support the notion that there is a correlation between ISQ values and BIC for an osseointegrated implant. The findings of that study are supported by numerous human cadaver studies (Nkenke et al. 2003; Gedrange et al. 2005), *in vitro* studies (Huang et al. 2013), and animal (Meredith et al. 1997; Park et al. 2011) studies, which also reported a direct correlation between ISQ and BIC. However, others have found no correlation (Meredith et al. 1997; Akca et al. 2006; Ito et al. 2008). One possible explanation for these conflicting results is that the rigidity of the implant–bone interface is not dependent solely upon the degree of bone contacts and the amount of bone in contact with the implant surface does not necessarily reflect the density of the surrounding bone (Sennerby & Meredith 2008).

The relationship between ISQ value and insertion torque has also been examined in the literature. In 2012, a study of 81 implants placed in 41 patients found a direct correlation between ISQ and maximum insertion

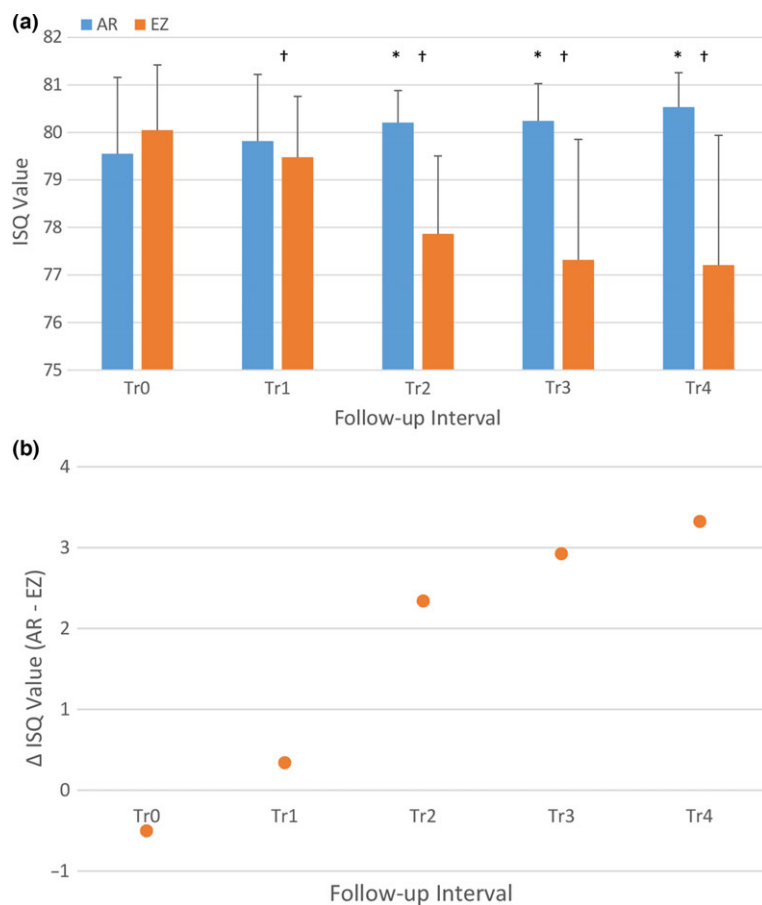


Fig. 6. (a) Mean (SD) implant stability quotient (ISQ) at baseline (Tr0) and 2-week combined follow-up (Tr1–4) intervals. (*) indicates statistical significance between test and control implants at Tr2, Tr3 and Tr4 ($p < 0.01$). (†) indicates statistical significance in the control implant ISQ values at each interval (Tr1–Tr4) compared to baseline ($P < 0.005$); (b) difference in mean ISQ values (AR - EZ) at each combined time interval.

Table 2. Mean ISQ values and standard deviations at baseline (Tr0) and 2-week combined follow-up (Tr1–4) intervals

	Tr0	Tr1	Tr2	Tr3	Tr4
AR	79.6	79.8	80.2	80.2	80.5
SD (AR)	1.61	1.40	0.67	0.79	0.72
EZ	80.1	79.5	77.9	77.3	77.2
SD (EZ)	1.37	1.28	1.64	2.54	2.73

ISQ, implant stability quotient; AR, mean ISQ values for test implants; SD (AR), standard deviation for test implants; EZ, mean ISQ values for control implants; SD (EZ), standard deviation for control implants.

torque ($P < 0.01$) (Park et al. 2012). It is important to keep in mind that insertion torque is a dynamic measurement. The profile of this non-uniform measurement will vary depending on a variety of factors (e.g., implant design, bone density, drilling protocol). Other investigators found no correlation between insertion torque and ISQ value. (Gonzalez-Garcia et al. 2011) The non-uniform nature of insertion torque measurements and fact that insertion torque measures resistance to shear force while RFA measures resistance to lateral micro-movement are possible explanations as to why no correlation was seen.

It is essential to realize that a high primary stability and high initial ISQ provide little predictive value in and of themselves. The surgeon must always consider how he or she arrived at those values. Was the osteotomy significantly undersized? Did the implant have a very aggressive thread design? To this point, a large prospective study of over 4000 implants (Rodrigo et al. 2010) found that, while there was a good correlation between initial RFA values and the clinical classification of primary stability, initial RFA values were unable to predict implant survival. Unfortunately, the correlation between maximum insertion torque and baseline ISQ value

could not be examined statistically in the present study due to the narrow range of both values.

Overall, there is a substantial body of evidence in support of the correlation between ISQ and bone density (Marquezan et al. 2012). It is important to keep in mind that other factors, such as implant design, drilling protocol, and precision of the osteotomy preparation, will play a significant role in whether or not this correlation is seen. For example, imprecise osteotomy preparation in type I bone could result in an unstable implant and a corresponding low ISQ value compared to a precisely prepared osteotomy in type III bone. This highlights the need for well-controlled studies that employ standardized protocols, which are clearly outlined and explained. Studies meeting these criteria are uncommon in the literature on RFA.

The real value in taking multiple ISQ measurements of an implant over time is being able to track the dynamic changes occurring around an implant after installation and also after restoration and use that information to aid in clinical decision-making such as whether or not to immediately load an implant or when to transition from a provisional restoration to a definitive restoration. After the transient decrease in implant stability described previously, a healthy implant with an initially low ISQ value will tend to display a marked increase in ISQ over time as osseointegration increases. A healthy implant with an initially high ISQ will tend to experience either a slight increase in ISQ or persistence of the initial ISQ value (Frigberg et al. 1999; Barewal et al. 2003; Olsson et al. 2003; Nedir et al. 2004; Becker et al. 2005). Lower or decreasing ISQ values may be a sign of developing instability. Future research should focus on the prognostic value of RFA in predicting future improvement, constancy, or loss of implant stability, as threshold ranges for different implant systems have not been established at this time; thus, there is little prognostic capability (Aparicio et al. 2006).

On the whole, the body of available literature supports the use of RFA as a clinical tool in implant dentistry capable of providing a non-invasive, quantitative assessment of the stiffness of the bone-implant interface (i.e., bone support). However, it is important to understand the limitations. The real value in RFA lies in having multiple (minimum of two) measurements across time that can be compared. A single reading at any given time point, whether it is at the time of implant placement, the time of the osseointegration

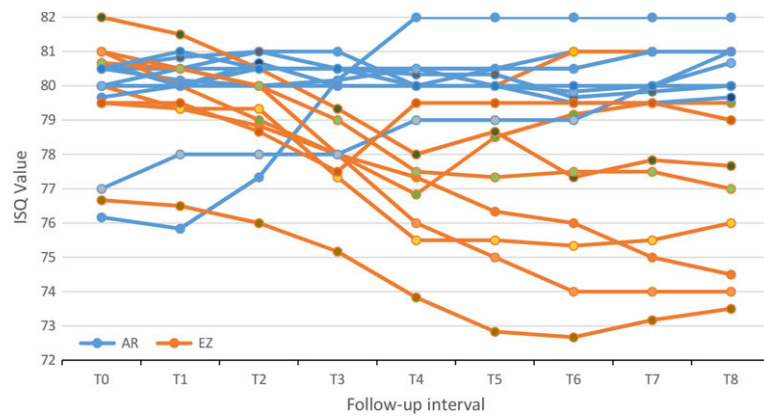


Fig. 7. Individual implant ISQ trajectories.

check, or after the implant is restored, is of little value and potentially can be misleading. Also, this technology should not be used in isolation, but rather as a supplement to other methods of implant assessment, including a thorough clinical and radiographic examination of the area. It is possible that, in the future, this technology may be used as the primary means of determining whether or not an implant can be immediately provisionalized or loaded, but current research and protocols do not support it at this time.

Due to the complexity of implant surgery and the subsequent bone remodeling it induces, establishing the predictive ability of this technology will require large, well-controlled trials utilizing standardized protocols. It is likely that surgical placement of identical implants placed under slightly different conditions (e.g., different bone densities, different drilling protocols, different drill wear) will result in different trajectories in the early healing period. It is also likely that, as was shown in the current study, different implants placed under “nearly identical” conditions will respond differently. These factors must all be sufficiently studied before this technology can be used in a predictive fashion. One must remain open to the possibility that RFA will not be capable of providing high positive predictive value for immediate loading success rates.

In the present study, the control implant displayed a clear pattern of decreasing mean ISQ value across the follow-up evaluations up to week four, after which the mean value plateaued. However, when individual implant trajectories are examined (Fig. 7), it becomes apparent that there was significant variability in the behavior of the control implant beyond week 4. This is evidenced numerically by the increasing standard deviation of the control implant as a function of time. Some implants continued to experience a decrease in ISQ,

while others remained steady or even showed increased ISQ values. Those that increased in ISQ beyond week 4 did so to varying degrees.

This finding highlights a key concept in implant dentistry – the inability to predict the extent and duration of bone remodeling – and thus, implant stability – in the early healing period. While this is a complex phenomenon potentially influenced by a variety of factors (e.g., macro-thread design, micro-/nano-surface topography, bone quantity, bone quality, surgical technique, operator skill), the data from the test implant support the notion that, to a certain extent, the influence of some of these factors can be eliminated or minimized by selecting an implant with an optimized macro-geometry. While this is encouraging, it must be recognized that there are factors that remain out of our complete control. One example of major importance is the host response to the surgically induced trauma of implant surgery. We have much to learn about the biologic reactions that take place in the initial healing period and how systemic and environmental factors such as diabetes, periodontitis, smoking may influence these processes.

A key question that cannot be answered with certainty is whether the stable ISQ measurements for the test implant throughout the study period are the results of a primary (e.g., mechanical) effect, or a secondary (e.g., biologic) effect. In other words, does the design of the test implant reduce the magnitude of the bone remodeling response (secondary effect), or is it simply that the macro-thread design of the test implant is capable of achieving sustained stability in the presence of a bone remodeling response equal in magnitude to that experienced by the control implant (primary effect)? In either scenario, the next obvious question becomes, can the test implant demonstrate the same degree of stability in loaded scenarios? Can the test

implant demonstrate the same degree of stability in various bone densities? To have value, the answer to these questions must be “yes”.

Limitations

There are numerous limitations to this study, which is, in part, a reflection of the stringent inclusion and exclusion criteria employed in an effort to produce a well-controlled study with a narrow focus. Eliminating or minimizing the influence of as many confounding variables as possible can most accurately answer the basic question. Assuming all else being equal, “what is the effect of macro-thread design on implant stability?” Preliminary calculations yielded a minimum of 10 matched pairs to achieve the desired statistical power. While this was met, it certainly would be beneficial to have a larger sample size. An increase in the sample size would also allow for more than two macro-thread designs to be evaluated. While many “conventional” macro-thread designs are quite similar, there is enough variation in macro-geometry among commonly used implants to warrant their investigation using a similar study design. Also, as discussed previously, despite every effort to ensure identical micro-surface topography, there is the possibility of minute differences in the surface. While it is very unlikely that this would have a significant effect on the outcome of the study, the potential role played by the micro-surface topography cannot be ignored.

Another limitation is the fact that eight of the ten matched pairs were posterior mandibular sites. The other two matched pairs were posterior maxillary premolar sites with atypically dense bone. Thus, bone density was quite high (mostly type II bone) and resulted in a narrow range of maximum insertion torque and baseline ISQ values. All sites were native, healed sites at least 6 months post-extraction with sufficient bone volume to place a 4 × 10 mm implant without requiring simultaneous bone grafting. The reason behind this choice was to study the effect of thread design under “ideal” conditions before moving onto more complex clinical scenarios. Thus, conclusions from this study should not be extrapolated to cases involving poor bone density, immediate implant placement, previously grafted sites, sites requiring simultaneous grafting. It is likely that the effect due to thread geometry observed in the present study would be magnified in situations involving poor bone density, as one would expect greater remodeling

around an implant placed mostly in trabecular bone (e.g., type III/IV bone).

Similarly, no provisionalization or immediate loading was carried out in this study. It is critical to understand how these factors will affect the ISQ trajectory of an implant, yet little research on this topic exists. What manifests as a small, perhaps transient, drop in ISQ in an unloaded implant could be detrimental to a loaded implant, resulting in failure. On the other hand, there are data from animal models to suggest physiologic loading of an implant during the integration period results in improved BIC (Piattelli et al. 1997)

and improved peri-implant bone density (Romanos et al. 2002). The bottom line is that there are many details about which little is known. This study was intended to serve as a first step towards finding answers to these questions.

Conclusions and future direction

Within the limitations of this study, macrothread design appears to play a role in implant stability in the early post-operative healing period as assessed by RFA. These

findings may have important implications related to immediate or early loading protocols. Further research is needed to expand upon the results of this study.

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Supporting Information

Additional Supporting Information may be found in the online version of this article:

Appendix S1. CONSORT 2010 checklist of information to include when reporting a randomised trial.