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**Publication Date**

2015

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UNIVERSITY OF CALIFORNIA  
Los Angeles

The Effect of Implant Thread Design  
on Implant Stability in the Early  
Post-operative Period

A thesis submitted in partial satisfaction of the  
requirements for the degrees of Master of  
Science in Oral Biology and Certificate in Periodontics

by

Jeffrey McCullough

2015



## ABSTRACT OF THE THESIS

### The Effect of Implant Thread Design on Implant Stability in the Early Post-operative Period

By

Jeffrey McCullough

Master of Science in Oral Biology

University of California, Los Angeles, 2015

Professor Perry Klokkevold, Chair

Available literature suggests that there is a transient drop in implant stability from approximately week 0 to week 3-4 as a result of bone remodeling around the implant as it transitions from a primary, mechanical stability to a secondary, biologic stability. Minimal research has been conducted investigating the potential influence of macrothread design on this process. **Objective:** to determine the role of macrothread design on implant stability in the early post-operative healing period through the use resonance frequency analysis (RFA). **Methods:** 7 patients, each missing at least two posterior teeth in the same arch, were included in the study, resulting in 10 matched pairs available for analysis. All sites were healed sites (> 6 months post-extraction) with sufficient bone volume for implant placement and no history of prior augmentation. Each site in a matched pair was randomly selected to receive either the control implant (Megagen EZPlus Internal) or the test implant (Megagen AnyRidge). The test implant

incorporates a novel thread design which includes rounded, non-cutting edges, wide thread depth, and increased thread pitch compared to a conventional thread design. Implants were placed using a standardized drilling protocol. 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:** Surgical placement of implants and subsequent healing was uneventful in all cases. At insertion, implants consistently achieved a relatively high insertion torque (30-45 Ncm-1) 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. A general pattern of mean stability in mean ISQ values from baseline across all eight follow-up evaluations was seen for the test implant. A pattern of decreasing ISQ values was seen across the follow-up evaluations for the EZ implant up to week four, where the value plateaued. There was a statistically significant main effect due to implant type ( $p < 0.01$ ). The main effect for time was not statistically significant ( $p = 0.21$ ). However, there was 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, macrothread design does appear 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.

The dissertation of Jeffrey McCullough is approved.

Renate Lux

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University of California, Los Angeles

2015

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## **Acknowledgements**

This project would not have been possible without the support of numerous individuals. Many thanks to my advisor, Dr. Perry Klokkevold, who dedicated significant time and effort in helping me to develop this project from the ground up. Thank you to my committee members, Dr. Renate Lux and Dr. Takahiro Ogawa, for their guidance and support throughout this process. I would also like to thank Dr. Kwang-Bum Park, Dr. Thomas Han, and all of the individuals at Megagen Co. who helped make this project possible through their generous donation of the necessary surgical components. Finally, I would like to express my sincere gratitude to Dr. Neal Garrett for donating his time and substantial expertise in helping me to complete the statistical analyses for this project.

## **Introduction, Background, and Significance**

Dental extractions are among the most common surgical procedures performed. While precise statistics are unavailable, it is estimated that over 20 million teeth are extracted every year in the United States [1, 2], and dental implants are being utilized in ever-increasing proportions as replacements for missing teeth; and rightly so, as implants have proven to be a predictable treatment option for replacing teeth and restoring fully and partially edentulous patients, achieving five and ten-year survival rates of approximately 95% and 90%, respectively, when placed into healed sites (i.e. delayed placement) [3].

It has been over forty years since the first reported use of a dental implant to replace a missing tooth in a human [4], thus marking the start of a new era in dentistry. The field of implantology has evolved much over the last four decades, and it will continue to do so into the foreseeable future, for while much has been learned, many questions remain.

One such question centers around the topic of what happens to the bone surrounding an implant 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 [5, 6, 7, 8, 9]. This, along with histologic studies [10] 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 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. Consequently, immediate loading of prostheses is not done routinely at this time due to the inability to predict implant stability in the early healing period.

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 (Figure 1).

While implant thread design has been studied in varying contexts, including how it will affect primary stability [11] and osseointegration [12], its effect on bone remodeling shortly after placement has not been examined sufficiently. In addition, the majority of studies using resonance frequency analysis 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 examined the potential effect of macrothread design.

The benefits to identifying factors that affect bone remodeling around implants are significant. It will enable dental professionals to choose (or design) an implant, which reduces or eliminates the decrease in implant stability during the 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. The ultimate benefit of implant therapy to patients comes from providing a functional restoration supported by a stable dental implant and not simply the placement of the dental implant in bone.

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 because, although there may be an increase in the amount of bone-to-implant contact (BIC), it goes against the biologic limitation of the bone healing timeline. In this study, we will examine whether the level of the primary implant stability in the early healing period can be altered by a macroscopic change in the implant geometric design. Information gathered from this study can be used as a foundation for further research, with the ultimate goals of optimizing implant macrothread design and determining if ISQ values can be correlated to immediate loading success rate.

## **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 criteria outlined below. The study site for this project was the UCLA Postgraduate Periodontics and Implant Surgery Clinic. All implant surgeries and follow-up evaluations were performed by a third-year postgraduate periodontal resident of this program.

### 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 simultaneous 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 & 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) (Figure 2). Both implants are currently available on the market. The EZ Plus fixture features a conventional V-shaped macroscopic thread design with self-tapping threads with four cutting edges. The AnyRidge fixture features a unique knife-edge thread design (Figures 3, 4). The company claims this thread design results in “maximum bone to implant contact, maximized compressive force resistance and minimized shear force production,”[13] thereby preventing a drop in stability in the immediate post-placement healing period. Both fixtures are manufactured with the same material (commercially pure, grade 4 titanium, standard ASTM F67-06) and surface (Super RBM – sand-blasted, large-grit, acid-etched (SLA)-type surface) (Figure 16). While the differences in macrogeometries of the test and control implants may result in slightly different microsurface topographies (e.g. the results of the sandblasting process for a V-shape thread may be minutely

different compared to a knife-edge thread), however 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.

Treatment for patients selected for this study was conducted according to the following workflow:

- Visit 1: Screening appointment or comprehensive exam
- Visit 2 (if needed): Comprehensive exam (if not completed at visit 1)
- Restorative DDS visit (if not already completed)
- Cone beam computed tomography (CBCT) scan visit (if not already completed)
- Visit 3: Implant surgery & baseline ISQ measurements
- Visit 4-11: Weekly follow-up evaluations and ISQ measurements for 8 weeks

Seven patients, each missing at least two posterior teeth in the same arch, were enrolled in and completed the study (0% dropout rate), resulting in 10 matched pairs available for analysis. All sites were healed sites (> 6 months post-extraction) with sufficient bone volume for implant placement without simultaneous grafting and no history of prior augmentation. Pre-operatively, each participant received a loading dose of an antibiotic (2g amoxicillin, or 600mg clindamycin if allergic to penicillin) and rinsed



with chlorhexidine gluconate 0.12% for one minute. No post-operative antibiotics were prescribed.

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.. Implants were placed using a standardized drilling protocol. Osteotomies for the test and control implants were prepared in an identical fashion according to the manufacturer's recommended drilling sequence. All implants measured 4mm in diameter and 10mm in length. Insertion torque was estimated to the nearest 5 Ncm-1 using a manual torque wrench. Immediately following implant placement, an Osstell Smart Peg (Osstell, Osstell AB, Gothenburg, Sweden) was connected to the fixture at 5 Ncm-1 using an electric handpiece and initial ISQ measurements were taken using a Mega ISQ Osstell meter (Figure 5). The Smart Peg 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 Ncm-1 using an electric handpiece in order 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 a gauze. The Smart Peg was inserted into the fixture at 5 Ncm-1, and the ISQ measurements were taken. The peg was then removed and the healing abutment replaced at 5 Ncm-1 (Figure 6).

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 dimension. 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 Collection*

Data were collected in a standardized, coded fashion according to Appendix 1.

#### *Data Analysis*

Data analyses were conducted using the SAS System (SAS Institute Inc., North Carolina, USA). 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 were used as the primary outcome measure for subsequent analyses. Mean ISQ values and standard deviations were calculated for the test and control implants for the baseline (T0) and the eight weekly follow-up evaluations (T1-T8). 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)

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 \* time interval) repeated measure analysis of variance (rANOVA) was conducted in order to compare the test and control implants across time (baseline + four intervals). 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. T-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 submitted to and approved by the UCLA Human Research Protection Program (HRPP). IRB#13-001878.

## **Results**

Surgical placement of implants and subsequent healing was uneventful in all cases. At insertion, implants consistently achieved a relatively high insertion torque (ranging from 30-45 Ncm-1) and high initial ISQ value (79.8 +/- 1.49).

As can be seen in Figure 7, similar baseline ISQ values were found for the test (AR; 79.55 +/- 1.61) and control (EZ; 80.05 +/- 1.37) implants. A general pattern of mean stability in mean ISQ values from baseline across all eight follow-up evaluations was seen for the test implant. A pattern of decreasing ISQ values was seen across the follow-up evaluations for the control implant up to week four, where the value plateaued.

Primary analysis (rANOVA) 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 (Figure 8, 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 ( $p = 0.21$ ), 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 the changes in ISQ values for 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 ( $p < 0.005$ ).

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 across time due to the greater variability in the performance of the control implant (Figures 8, 9, Table 2).

## **Discussion**

Resonance frequency analysis has been used in the field of dental implantology since its introduction in 1996 [14]. In its original form, an L-shaped transducer was attached to the fixture and subsequently excited over a range of frequencies (typically 5-15 kHz) (Figure 10). Excitation of the transducer creates a microscopic bending force, which is the most common type of loading for a dental implant [15]. The response of this excitation is a flexural resonance of the L-shaped beam, which manifests as a change in amplitude and phase of the received signal and is measured by a frequency response analyzer. More modern RFA equipment employs wireless technology, making units much less cumbersome and more portable and convenient to use. Here, an aluminum peg (e.g. Smart Peg) is excited by magnetic pulses and the resonance frequency is expressed electromagnetically as ISQ units and is calibrated on a scale of 1-100 [15].

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 [15]. Other methods of assessing the stability of an implant include pullout,

pushout, 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, [45, 46] they are usually only applied to pre-clinical scenarios, as they are potentially destructive to the implant and surrounding tissues. For example, reverse torqueing may cause failure of an implant that is in the process of osseointegrating, albeit it slowly. Also, reverse torqueing does not emulate normal loading of an implant in function in the mouth [16]. Thus, RFA has the advantage of providing a simple, non-invasive way of evaluating the stiffness of the implant-bone interface 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, and, more importantly, 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 co-workers [17] 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, malalignment, psychological, etc.). The implants were in place for 6 months prior to removal. Implants were removed *en bloc* using a trephine bur. Prior to removal, ISQ readings were taken. The specimens were then sectioned and prepared for histomorphometric analysis. Results of the study demonstrated a direct correlation between ISQ and BIC (Figure 11).

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 this study are supported by numerous human cadaver [18, 19], in vitro [20] and animal [21, 22] studies which also reported a direct correlation between ISQ and BIC.

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 torque ( $p < 0.01$ ) [23]. 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, etc.). An example of this is shown in Figure 12. Other investigators have found no correlation between insertion torque and ISQ value [44], and this could be a possible explanation as to why no correlation was seen.



It is essential to realize that a high primary stability and high initial ISQ provides little predictive value in and of themselves. The surgeon must always consider how s/he arrived at those values. Was the osteotomy significantly undersized? Did the implant have a very aggressive thread design? Consider the cross-sectional CBCT image shown in Figure 13. With a proper surgical approach and implant design, obtaining high primary stability is readily achievable through engagement of the dense cortical bone, yet it is apparent that this implant would be at higher risk compared to an implant placed in the site depicted in Figure 14, even though they may have similar initial insertion torques. In the first case, any significant remodeling of the cortex could result in complete loss of implant stability. 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.

The relationship between ISQ and bone density has also been studied. Methods of assessing bone density include both radiographic metrics (e.g. Hounsfield units) and clinical metrics (e.g. cutting resistance during osteotomy preparation). The correlation between ISQ and Hounsfield units ranges from moderate [24] to high [25] depending on the methodology used to determine the density of a given edentulous site. Studies calculating density based only on the trabecular bone arrive at a moderate correlation, while those using both the cortical and trabecular bone report high correlation coefficients [26]. It is clear that the thickness of the cortical plate is related to primary stability [26], thus it would seem more appropriate to include the cortical bone in the computation of Hounsfield units. Zix and co-workers [27] reported no correlation

between ISQ and bone density, however their method of assessment was a visual examination of a panoramic radiograph which is not a reliable method of determining bone density.

Overall, there is a substantial body of evidence in support of the correlation between ISQ and bone density [26]. 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 outline and explained. Studies meeting this 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 occurs. A healthy implant with an initially high ISQ, depending on the conditions under which it was placed, will tend to

experience either a slight increase in ISQ or persistence of the initial ISQ value [5, 28, 29, 30, 31].

In order to be useful, the technology must also be able to identify “ailing” implants, ideally at an early point in time so that measures can be taken to try to save the implant from complete failure. Vanden Boagerde and co-workers [32] demonstrated proof of principle of this concept by rescuing an immediately loaded implant based on RFA. From the time of placement to the 6 week post-operative visit, ISQ values decreased from 67 to 53. The implant was unloaded and allowed to heal for a period of several months, at which time the ISQ was measured to be 72. Similarly, Friberg and co-workers [28] demonstrated rescue of two implants being loaded by a denture and demonstrating decreasing ISQ values. Unloading via denture adjustment resulted in recovery of ISQ. Others have demonstrated decreasing ISQ values which correspond to loss of implant stability and eventual implant failure [8, 33, 34, 35]. Thus, lower or decreasing ISQ values may be a sign of developing instability, while increasing or persistently high ISQ values is a sign of a healthy implant. 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 [15].

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. 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 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 the necessary research and development of standardized protocols have not been completed 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 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, etc.) 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 “identical” conditions will respond differently. These factors must all be sufficiently studied before this technology can be used in a predictive fashion. Also, 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 (Figure 9), 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. macrothread design, micro/nanosurface topography, bone quantity, bone quality, surgical technique, operator skill, etc.), 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 macrogeometry.

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 macrothread 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 question becomes, can the test implant demonstrate the same degree of stability in loaded scenarios? As discussed previously, in order to have value, the answer to this question 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. By eliminating or minimizing the influence of as many confounding variables as possible, the basic question of, “all else being equal, what is the effect of macrothread design on implant stability?” can be most accurately answered. Preliminary calculations yielded a minimum of 10 matched pairs in order to achieve the desired statistical power. While this was met, it certainly would be beneficial to have a larger sample size, however this was not possible due to time constraints. Increasing the sample size would have also allowed for more than two macrothread designs to be evaluated. While many “conventional” macrothread designs are quite similar, there is enough variation in macrogeometry among commonly used implants to warrant their investigation using a similar study design. Also, as discussed previously, despite every effort to ensure identical microsurface 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, nonetheless, the potential role played by the microsurface cannot be ignored.

Another limitation is the fact that eight of the ten matched pairs were posterior mandibular sites. And, unusually, the patients providing the two matched pairs in the maxilla both had atypically dense bone for the maxillary premolar region. 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 4x10mm 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, etc. 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) (Figure 15).

Similarly, no provisionalization or immediate loading was done 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 [42] and improved peri-implant bone density [43]. 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 does appear 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. Research employing a greater number of macrothread designs placed in a variety of clinical scenarios would be beneficial towards the goals of optimizing implant macrothread design and determining if RFA technology holds predictive value in immediate loading success rates.



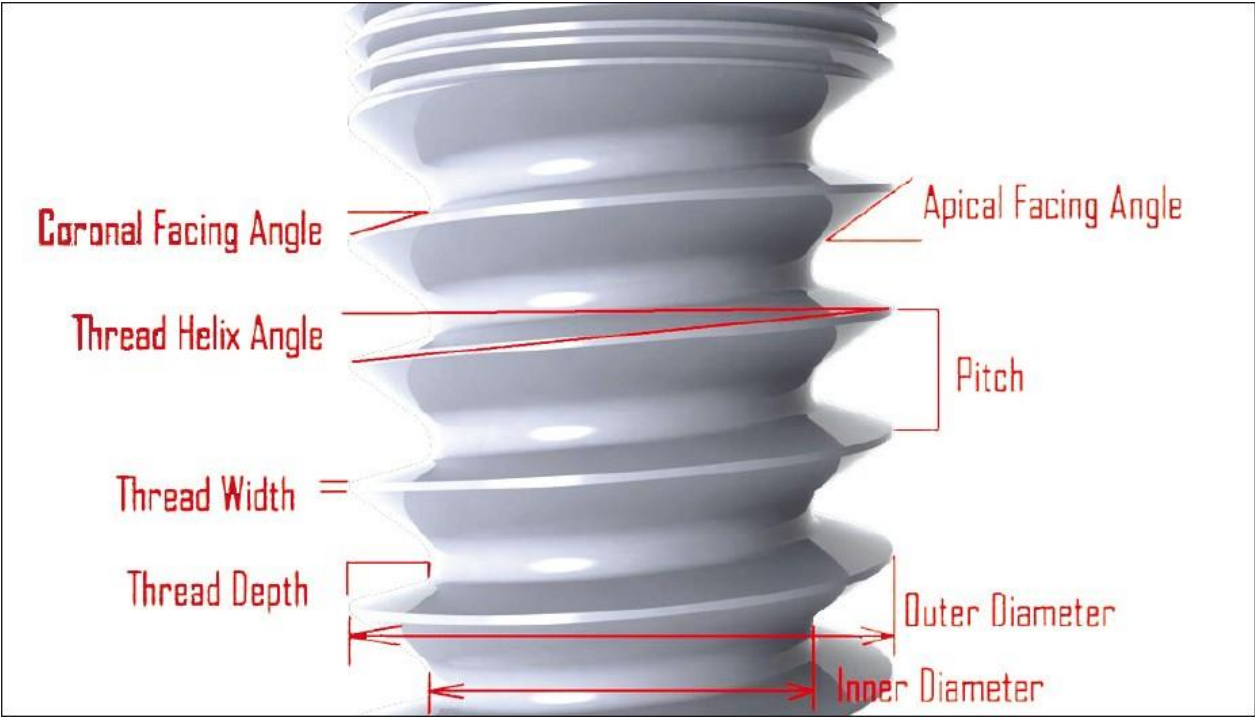


Figure 1. Parameters of implant thread design [36].



Figure 2. Megagen EZ Plus Internal (left; control implant) and AnyRidge (right; test implant) dental implants [37, 38].

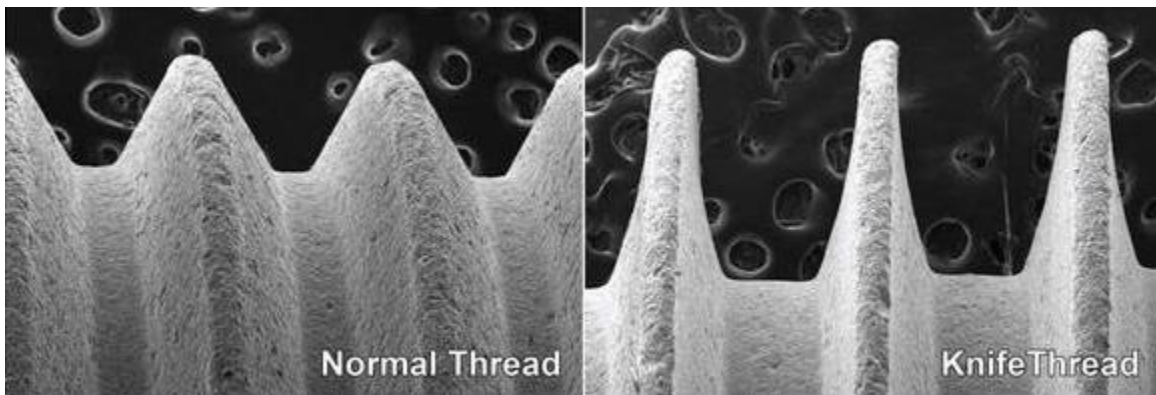


Figure 3. Microscopic view of a standard V-shape thread design (EZ Plus Internal; left) and the novel knife thread design (AnyRidge; right) [39].

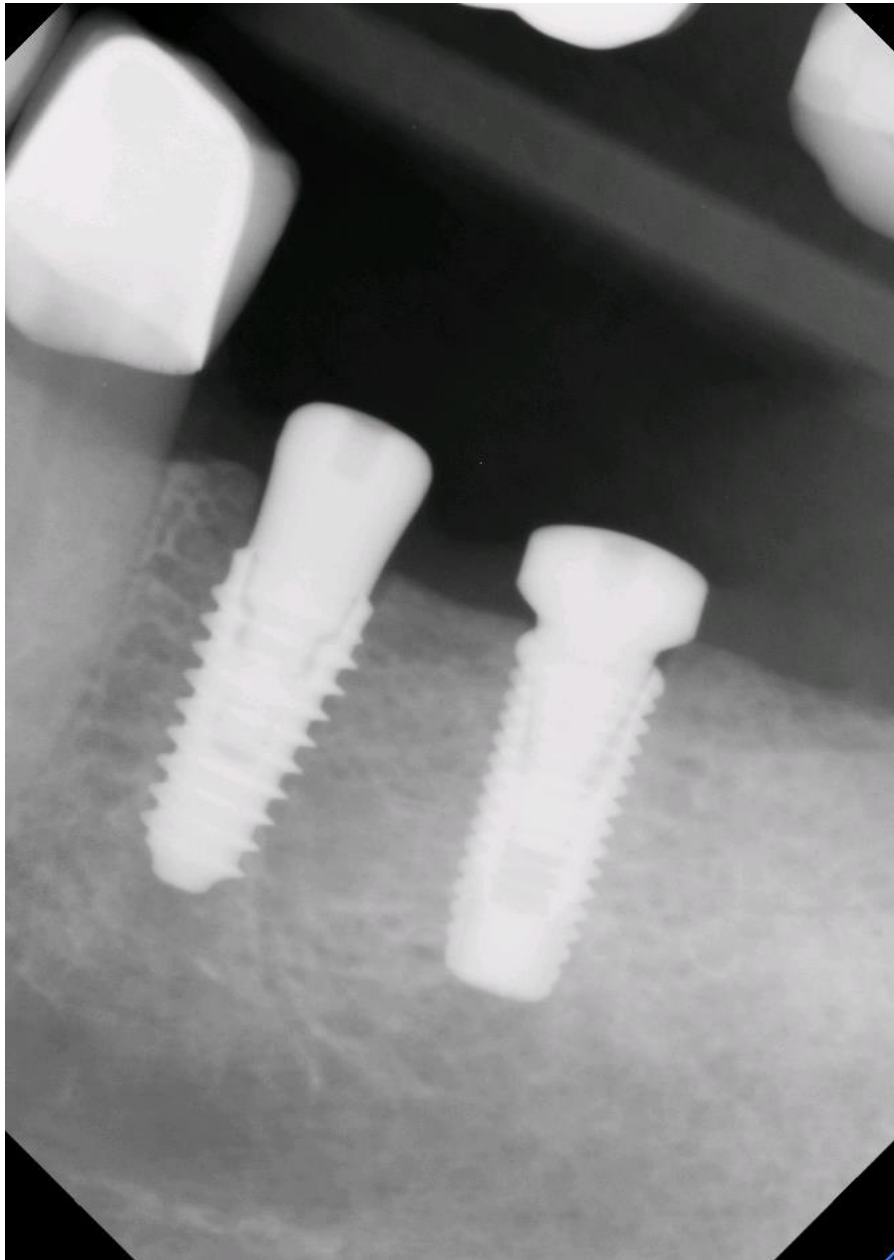


Figure 4. Radiographic appearance of test (left) and control (right) implants. Study case.



Figure 5. Osstell Smart Pegs (upper left), Megagen electric handpiece (upper right), Mega ISQ Osstell meter (bottom center).



Figure 6. Clinical case photos showing Smart Pegs attached to fixtures in preparation of ISQ measurements.

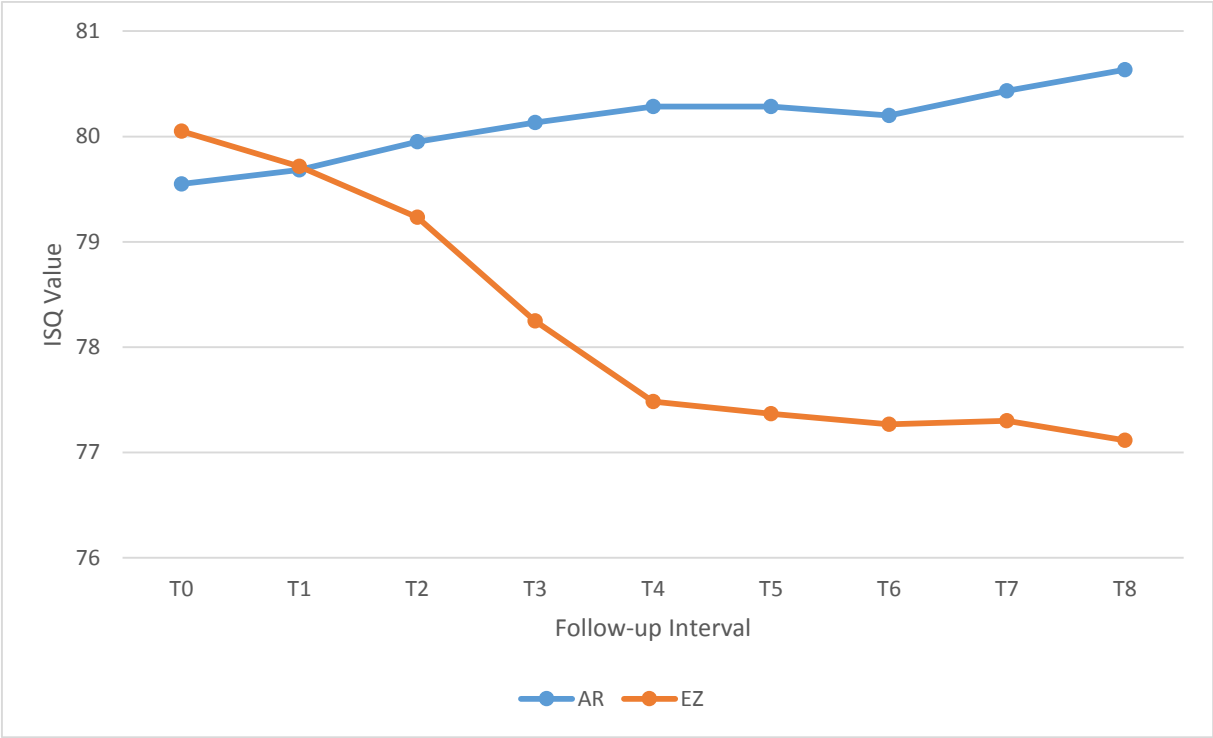


Figure 7. Mean ISQ at baseline (T0) and 8 weekly follow-up evaluations

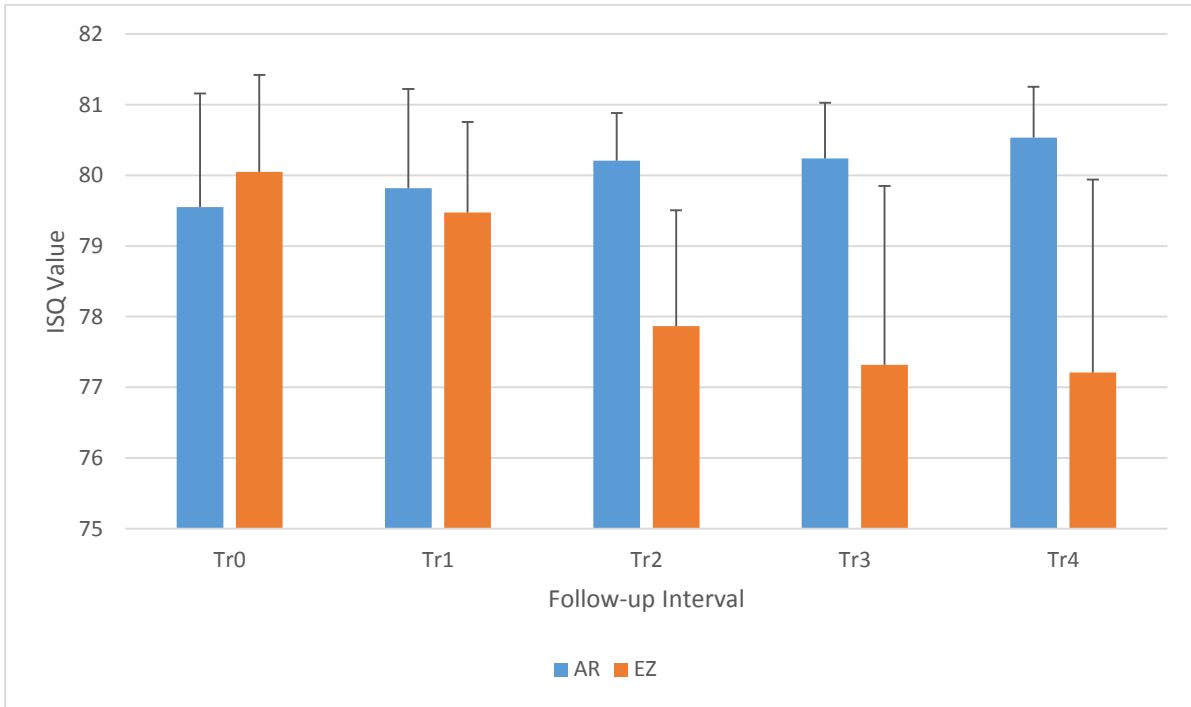


Figure 8. Mean (SD) ISQ at baseline (Tr0) and 2-week combined follow-up (Tr1-4) intervals.

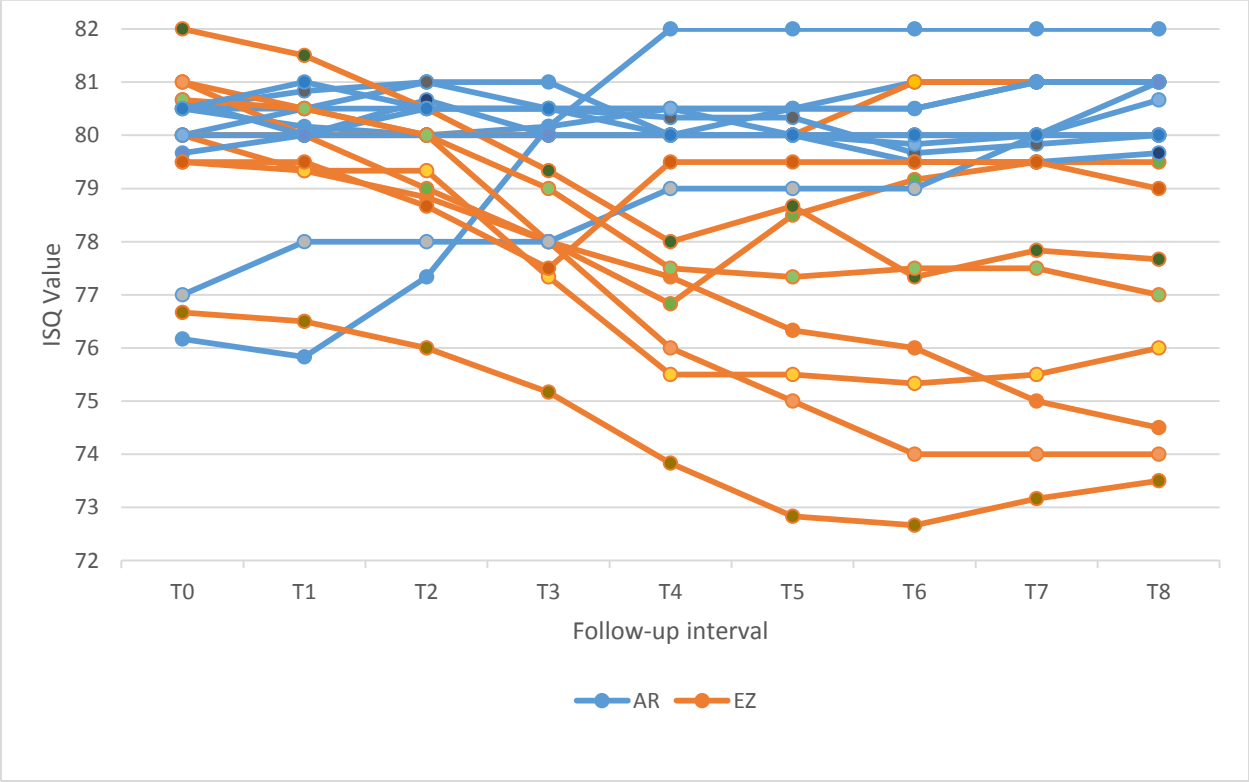


Figure 9. Individual implant ISQ trajectories.



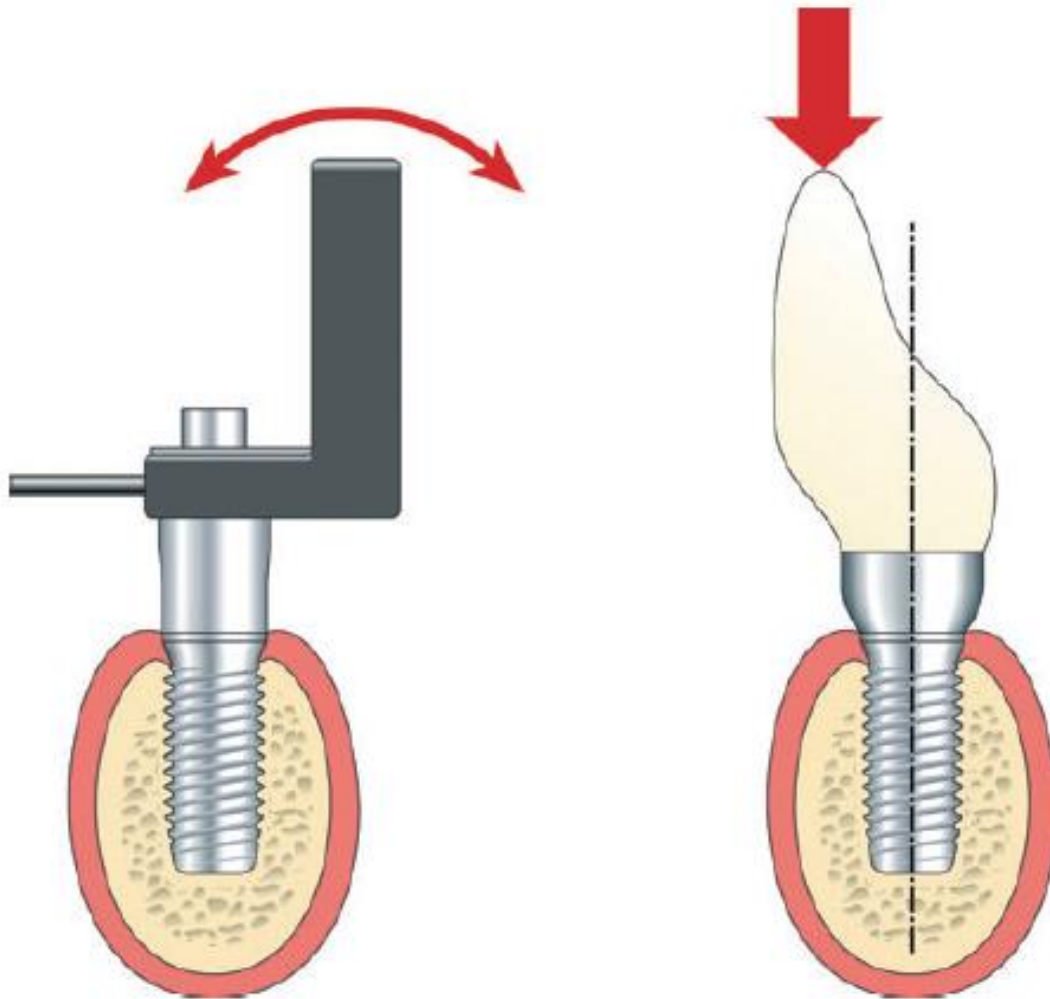


Figure 10. Adapted from Sennerby et al. [16]. Schematic representation of original RFA technology utilizing an L-shaped transducer. The cantilever offset of the transducer transmits a microscopic bending force to the fixture, which mimics the type of force experienced by a dental implant in function (albeit in a much smaller magnitude).

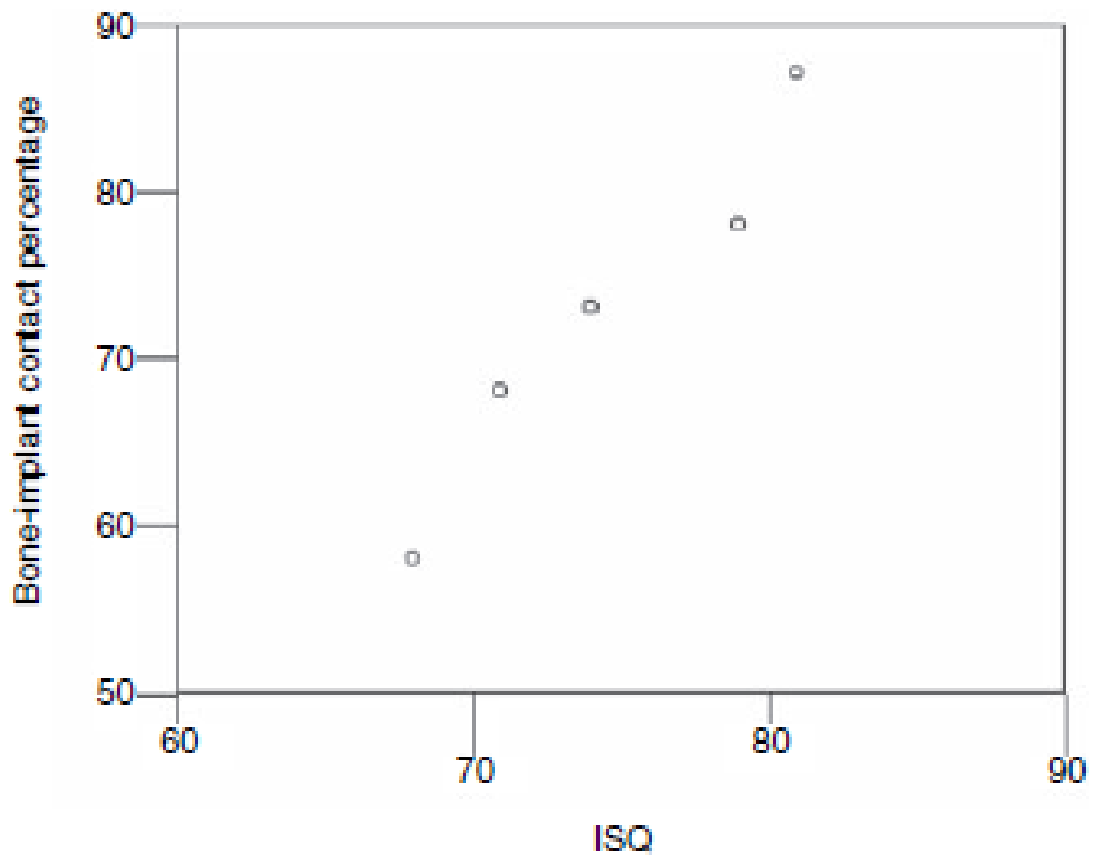


Figure 11. Adapted from Scarano et al. [17]. Data from the study demonstrating a direct correlation between BIC and ISQ values.

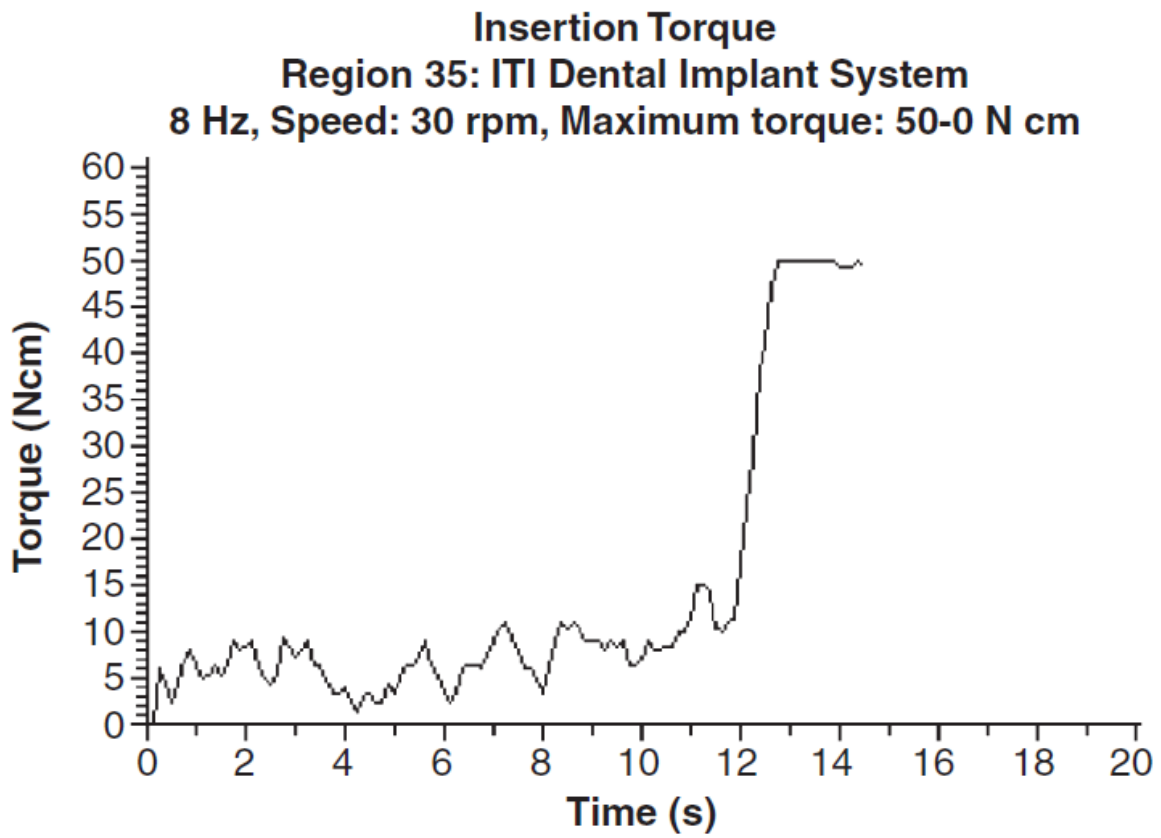


Figure 12. Adapted from Park et al. [23]. Example of an insertion torque graph.

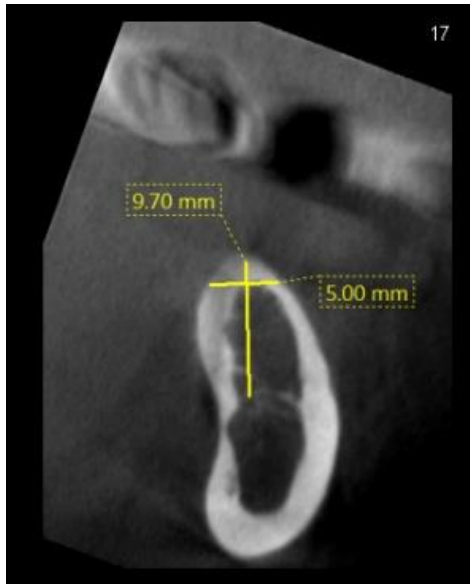


Figure 13. Cross sectional CBCT image showing trabecular bone of very poor density surrounded by thick, high density cortical bone. Note: not a study case.

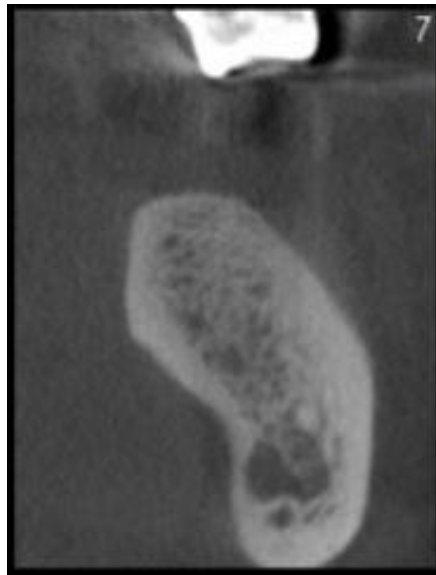


Figure 14. Cross sectional CBCT image showing dense trabecular bone throughout the entire body of the mandible. Note: not a study case.

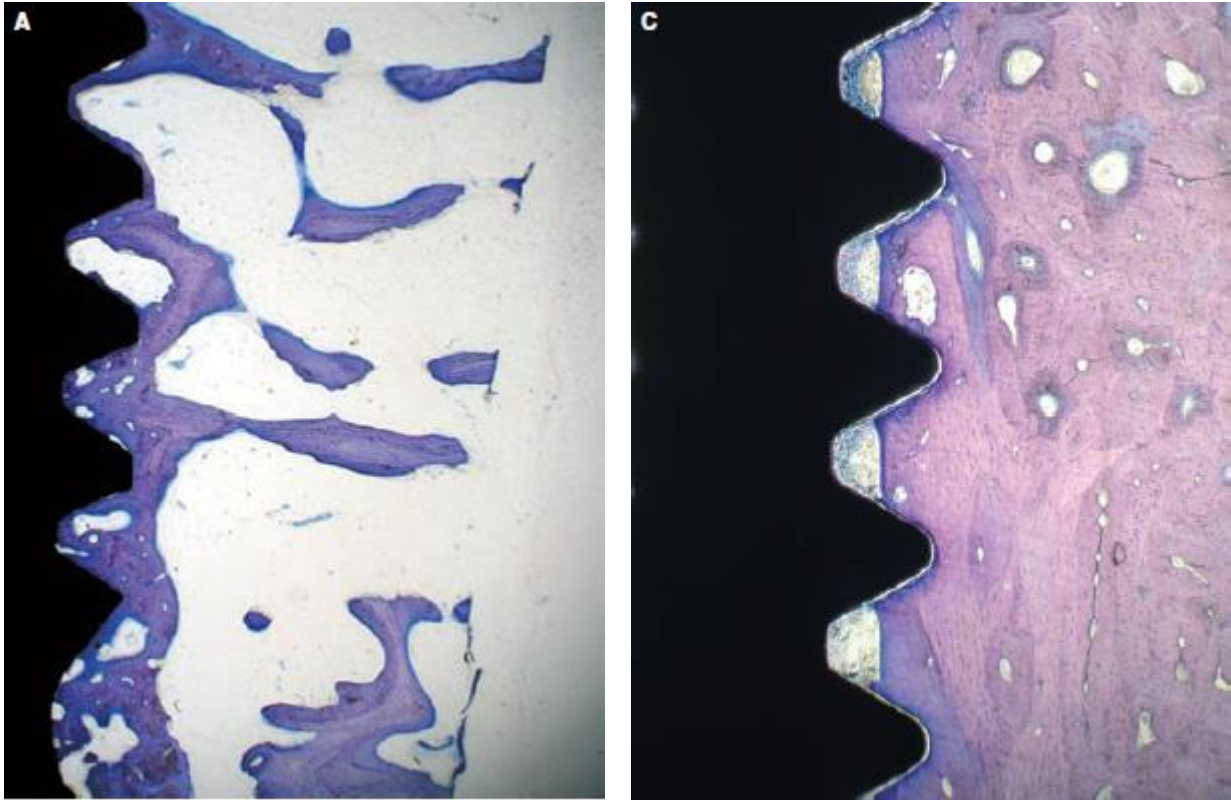


Figure 15. Adapted from Sennerby et al. [16]. Comparison of an implant placed in soft, trabecular bone (left) and dense, cortical bone (right) immediately post-insertion.

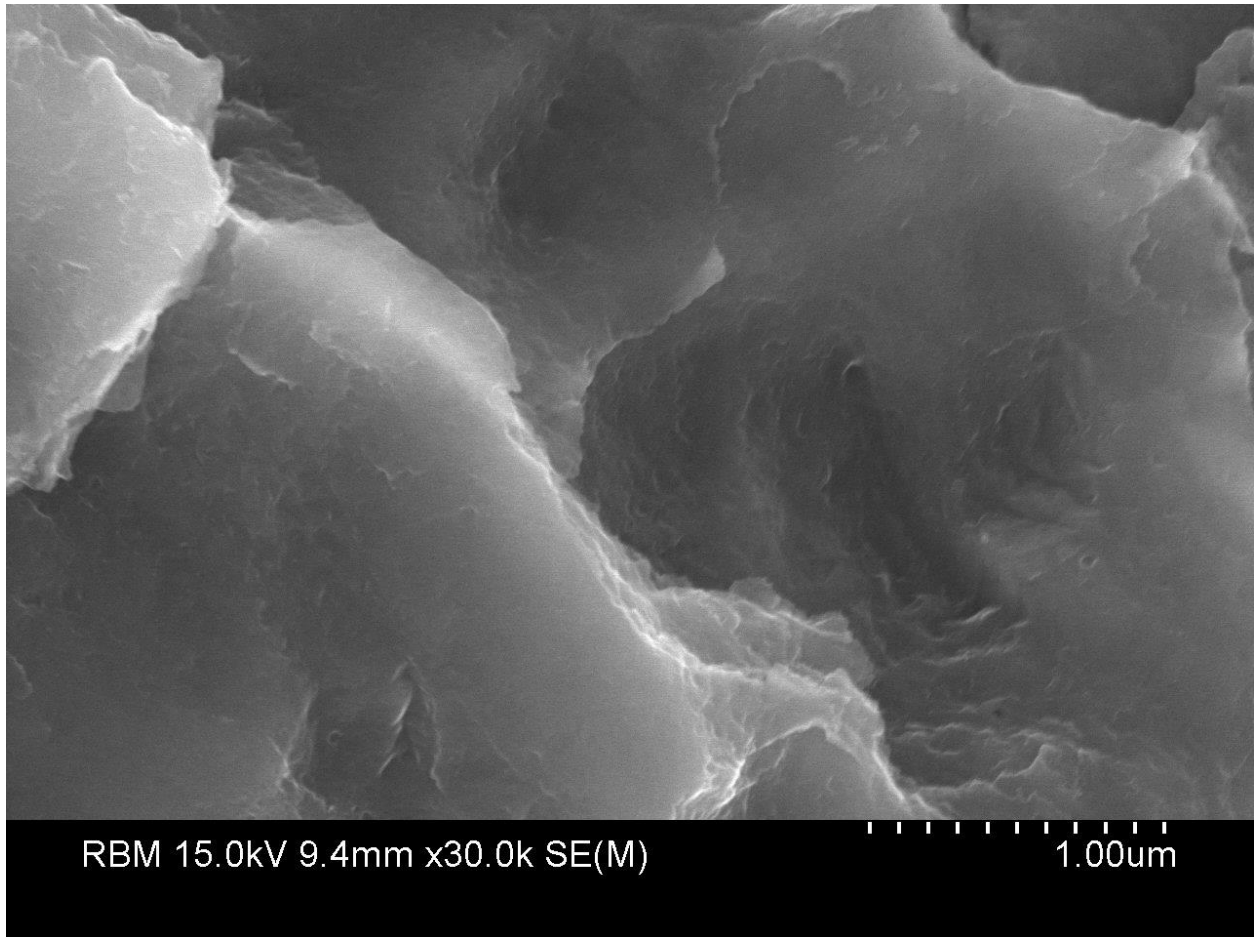


Figure 16. High-magnification scanning electron microscope image of Super RBM microsurface topography (company data).

	<b>T0</b>	<b>T1</b>	<b>T2</b>	<b>T3</b>	<b>T4</b>	<b>T5</b>	<b>T6</b>	<b>T7</b>	<b>T8</b>
<b>AR</b>	79.6	79.7	80.0	80.1	80.3	80.3	80.2	80.4	80.6
<b>SD (AR)</b>	1.61	1.58	1.26	0.81	0.75	0.75	0.85	0.77	0.71
<b>EZ</b>	80.1	79.7	79.2	78.3	77.5	77.4	77.3	77.3	77.1
<b>SD (EZ)</b>	1.37	1.31	1.29	1.41	2.03	2.41	2.70	2.74	2.73

Table 1. Mean ISQ values and standard deviations at baseline (T0) and 8 weekly follow-up evaluations.

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

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

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

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



**Appendix 1**  
Data Extraction Form

ID # \_\_\_\_\_

Site	PI	GI	Implant type	Insertion torque	ISQ Wk 0	ISQ Wk 1	ISQ Wk 2	ISQ Wk 3	ISQ Wk 4	ISQ Wk 5	ISQ Wk 6	ISQ Wk 7	ISQ Wk 8

Site = tooth #

PI = plaque index (Silness & Loe) [40]

GI = gingival index (Silness & Loe) [41]

Implant type = AR (test) or EZ (control)

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