Measurement of dental implant stability by Osstell® and Periotest™ at three different time points: Correlation between the two devices and comparison with clinical characteristics

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in partial fulfilment of the requirements of the degree of
Doctorate in Dental Surgery (Periodontology)

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Declaration

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Summary

This prospective cohort study was undertaken to elucidate our knowledge of two different implant stability measurement devices, the Osstell® mentor which is based on resonance frequency analysis technology and the Periotest™ device based on damping capacity assessment technology. The primary purpose of this study was to determine if there is a correlation between the values produced by the two devices at implant insertion, following integration of the fixture and loading of the implant. Secondly we investigated if certain clinical or other patient characteristics can affect the values produced by the two devices at these three time-points. Thirdly we sought to identify a normative range for Zimmer Biomet implants with an Osseotite® surface.

To achieve our aims, stability measurements were recorded at implant placement (T1), implant exposure (T2) and implant loading (T3). Stability measurements were recorded as implant stability quotient (ISQ) values with a range of 1-100 for the Osstell® and Periotest (PT) values with an inverse scale of 50 to -8 for the Periotest™ device. A range of clinical data was collected including details of the patient demographics, implant surgery, implant site and fixture features.

Data collection was performed from September 2018 to July 2020. Stability measurements and clinical characteristics were recorded for 29 patients and 68 dental implants at T1, subsequent stability measurements were recorded for 67 implants at T2 and 42 implants at T3. Statistical analysis was performed with IBM® SPSS software

V26. Data analysis included descriptive statistics and a Spearman's Rho test to evaluate correlation between values obtained with the measurement devices. A Mann-Whitney or Krushal Wallis test was performed to compare stability measurements with clinical characteristic groups. The mean ISQ value was 70.8 (SD 7.40) at implant placement, 70.2 (SD 8.51) at implant exposure and 72.4 (SD 5.42) at implant loading. The mean Periotest value was -3.79 (SD 4.65) at implant placement, -4.60 (SD 2.98) at implant exposure and -5.55 (SD 2.14) at implant loading. The range of ISQ values observed was 30-89 ISQ at implant placement and 61-82 ISQ at implant loading. The Periotest values ranged from 29 to -8 at 1st stage surgery and -2 to -8 at implant loading. A weak/moderate correlation was observed between mean ISQ and Periotest values at T1, T2 and T3, (r = -0.279, *p=0.021*), (r = -0.368, *p=0.002*) and (r = -0.342, *p=0.026*) respectively. A single dental implant failed shortly after 2nd stage surgery for an overall success rate of 98% during the study timeline. The failed implant had a mean ISQ of 49 and Periotest value of 3 at 2nd stage surgery. There were no radiographic or clinical signs to indicate implant failure at this stage.

Based on the results of this study there is a weak/moderate level of correlation between values recorded with these measurement devices at implant placement, implant exposure and implant loading. For both the Osstell® and Periotest™ a narrowing of stability values is observed from implant placement to fit of prosthesis. The stability values observed in the mandible are higher with the Osstell® and lower with the Periotest™ indicating greater implant stability in the mandible compared to the maxilla. Beyond this finding no clinical characteristic demonstrated a substantial influence on stability measurements of either device. Based on the findings of this

research and despite the weak correlation between the values generated by the two instruments, we would suggest that these devices may be beneficial as adjuncts to standard clinical practice and as instruments that can predict future implant failure. Finally, we propose a normative range of 61-82 ISQ as measured by the Osstell® mentor device for osseointegrated Zimmer Biomet dental implants with an Osseotite® surface. In conclusion this study has contributed to the body of evidence in this field of implant dentistry however further well-structured research should be undertaken to elaborate and validate the themes explored in this study.

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First and foremost, I wish to thank my wife Emma for her kindness, support and encouragement throughout the past several years and her unwavering commitment to my educational and career ambitions. I would like to specially thank my parents and siblings for instilling a strong sense of discipline and work ethic from an early age. These life skills have served me well to advance this doctorate with passion and determination. I would like to warmly thank my research supervisor Dr. Polyzois for his wisdom, guidance and patience throughout the entire research process. Furthermore I wish to extend my thanks to all the faculty members of the periodontal department of Dr. Harrison, Dr. Winning, Dr. Corcoran, Dr. Byrne and Dr. Allen. I also wish to extend my appreciation and best wishes to all the staff of the Dublin Dental Hospital that have helped to facilitate many aspects of this clinical research. Finally I want to sincerely thank my postgraduate colleagues in the periodontal and prosthodontic department for their support and patience Dr. Nolan, Dr. Aljudaibi, Dr. Naughton, Dr. Madeley, Dr. Agkhre and Dr. Moorthy. On many occasions while gathering measurements and data, I have eroded their valuable clinical time. On every occasion they facilitated my actions and supported my research endeavours. To conclude, I have learned many new skills over the past three years and developed great professional and personal friendships that will last for a lifetime. Thank you all.

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List of Abbreviations

BIC	Bone to Implant Contact
Buc	Buccal
CT	Computed Tomography
DCA	Dampening Capacity Assessment
Fig	Figure
G	Group
HU	Hounsfield Units
ICC	Intra Class Co-efficient
IQR	Interquartile Range
ISQ	Implant stability quotient
IT	Insertion Torque
ITI	International Team for Implantology
ITV	Insertion Torque Value
Ling	Lingual
Mg	Magnesium
MK	Mark
MRFA	Magnetic Resonance Frequency Analysis
Ncm	Newton Centimetres
Pg	Page
PPI	Proton Pump Inhibitor
PT	Periotest
PTV	Periotest value
RCT	Randomised Control Trial
RFA	Resonance Frequency Analysis
SD	Standard Deviation
SSRI	Selective Serotonin Reuptake Inhibitor
T1	Timepoint One
T2	Timepoint Two
T3	Timepoint Three
UNC	Universal Naming Convention

1. Literature Review

1.1 Introduction

Rehabilitation of the complete and partially edentulous patient with dental implants is now a well-established and recognised treatment modality in the field of dentistry. This is evidenced by the rapid increase in prevalence of dental implants to replace missing teeth in the past 20 years (Elani et al., 2018). More importantly the predictability of implant therapy in the form of single or multiple fixtures placed in the mandible or maxilla is broadly supported in the literature through a plethora of classic and more contemporary studies (Adell et al., 1990, Pjetursson et al., 2004, Jung et al., 2008, Balshi et al., 2015).

Table 1.1 Compilation of implant success rates (Beaumont et al., 2016).

Table 1 Summary of success and survival for different types of prostheses. Compiled from data reported in Pjetursson *et al.*[1]

Type of prosthesis	Estimated survival at 5 years	Estimated survival at 10 years	Estimated success at 5 years
Implant supported single crowns	95.50%	89.40%	
Implant supported fixed dental prostheses	96.80%	86.70%	61.30%
Conventional fixed dental prostheses	94.40%	89.20%	84.30%
Cantilever fixed dental prostheses	90.50%	80.30%	79.40%
Combined implant and tooth-borne fixed dental prostheses	93.40%	77.80%	

Implant stability is a fundamental concept of implantology however traditional methods used to evaluate implant stability have been invasive, destructive or subjective with little quantifiable value (Sennerby and Meredith, 2008). A new generation of instruments has been developed to respond to this demand for non-invasive quantifiable methods of measuring implant stability. The purpose of this study was to elucidate our knowledge of two such devices, the Osstell® Mentor (Integration Diagnostics, Gothenburg, Sweden) and Periotest™ (Medizintechnik Gulden, Benheim, Germany). Extensive research has been performed in the past few decades to evaluate the validity of these instruments and determine their true value as measurement apparatus in the clinical environment (Mistry et al., 2014). The primary purpose of this study was to evaluate correlation in stability measurements between these two devices and the secondary aim was to investigate factors that may influence stability measurements. Thirdly we sought to establish a normative range for Zimmer Biomet dental implants with an Osseotite® surface. In order to address these clinical questions a prospective cohort study was undertaken at Dublin Dental University Hospital.

This literature review discusses relevant themes such as osseointegration, implant success criteria, implant stability and primarily focuses on these two new generation quantitative devices that have been developed to evaluate implant stability. Although these instruments are applied for the same purpose of measuring implant stability, their mode of operation is completely different and this is discussed in detail. Based on the available literature, specific aspects

are elaborated upon such as the mechanism of action and evolution of both devices. Furthermore, factors that may influence clinical measurements and the potential prognostic applications of the Osstell® Mentor and Periotest™ are discussed comprehensively in subsequent sections. The final part of this literature review outlines and scrutinizes the available scientific evidence that explores the correlation of measurements between these two devices.

1.1.1 Osseointegration

The concept of osseo-integration is central to the viability of dental implant placement and was proposed by Albrektsson in 1981 as a direct structural and functional connection between ordered living bone and the surface of a load carrying implant (Albrektsson et al., 1981). This was based on an analysis of radiographs, scanning electron microscopy, transmission electron microscopy and histology at the implant-tissue interface. This concept was further elaborated upon by Davies in 1998 (Davies, 1998) who further elucidated the process of osseointegration at a histological level. In this research mechanisms that occur at the bone to implant level such as osseo-conduction, de novo bone formation and bone modelling where further delineated. Thus, these articles laid the foundation for a core aspect of implant dentistry. Subsequently a series of experimental dog studies by Berglundh, Davies and Abrahamsson (Abrahamsson et al., 2004, Davies, 2003, Berglundh et al., 2003) comprehensively described the stages of bone formation and osseointegration. They evaluated implants placed in the mandible of dogs at various stages of the osseointegration process and performed histological analysis on samples

ranging from 2 hours – 12 weeks in the healing process. This sequence of studies demonstrated that osseointegration is a dynamic process through establishment to maintenance and that a complex process of bone resorption and new bone formation in direct contact with the implant occurs over time with a gradual change in percentage composition of the implant-tissue interface from soft tissue, old bone and bone debris to new bone.

More recently a series of human studies was performed that closely examined the process of osseo-integration over a period of time (Bosshardt et al., 2011, Lang et al., 2011, Donos et al., 2011). In these studies moderately rough Straumann® implants were placed in the retromolar region of the mandible and submerged healing occurred. The implants were then removed with surrounding tissue by trephine drilling at 1,2,4 and 6 weeks. The samples were then evaluated by histology and morphometric measurements. This series of literature demonstrated the activity and physiological mechanisms occurring at the following stages in osseointegration.

Early wound – A substantial amount of residual bone is directly in contact with the implant surface reflecting the initial mechanical stability in successful implant placement.

1 week- A significant proportion of old bone still in contact with the implant surface reflecting primary implant stability, areas of bone resorption are also visible in areas adjacent to the tissue wound. There is a combination of hard tissue resorption & apposition characterising this early healing phase.

2 weeks – Partial remnants of residual bone still present and small areas of woven bone now visible adjacent to the implant surface.

4 weeks – Significant remodelling and modelling bone activity.

6 weeks – Large amounts of newly formed woven bone including lamellar and marrow are present in proximity to the implant surface thus creating a stable bone-implant contact or osseointegration**.**

The pattern of healing at the tissue-implant interface closely reflects that of the animal studies by Berglundh and co-workers and Abrahamsson and team (Berglundh et al., 2003, Abrahamsson et al., 2004) whereby as part of the osseointegration process a gradual transition in composition of the tissue-implant interface occurs. These morphometric changes are succinctly visualised in the histogram below.

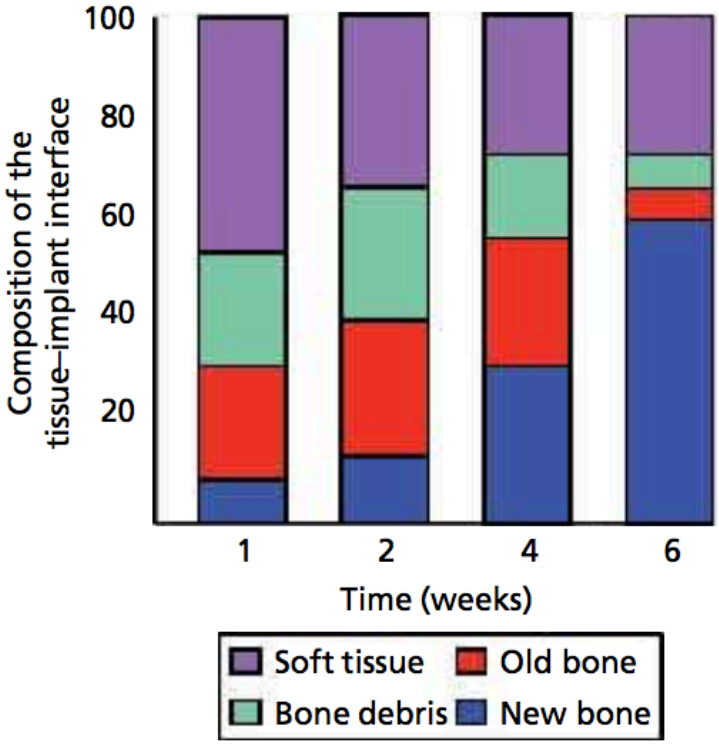


Figure 1.1 Barchart of composition of implant-tissue interface (Pg 108 Lang and Lindhe, 2015).

1.1.2 Implant Success Criteria

As research in implantology advanced, features that correspond with dental implant success were proposed by Albrektsson 1986, Buser 1997 and Cochran 2002 (Albrektsson et al., 1986b, Buser et al., 1997, Cochran et al., 2002). As part of success criteria these authors discussed the importance of implant immobility or the absence of clinically detectable mobility. The table below from the seminal Albrektsson paper elucidates the accepted characteristic features of implant success at the time (Albrektsson et al., 1986a).

1. That an individual, unattached implant is immobile when tested clinically.
2. That a radiograph does not demonstrate any evidence of peri-implant radiolucency.
3. That vertical bone loss be less than 0.2 mm annually following the implant's first year of service.
4. That individual implant performance be characterized by an absence of persistent and/or irreversible signs and symptoms such as pain, infections, neuropathies, paresthesia, or violation of the mandibular canal.
5. That, in the context of the above, a successful rate of 85% at the end of a five-year observation period and 80% at the end of a ten-year period be a minimum criterion for success.

Figure 1.2 List of success criteria for dental implants (Albrektsson et al., 1986a).

The criteria applied for implant success has evolved with the evolution of implant therapy. This is reflected in the transition of focus from merely predictable osseointegration of the implant fixture to optimal outcome for the peri-implant soft tissues and implant supported prosthesis. This was elaborated upon in a systematic review by Pjetursson and co-workers that examined the success and survival of different forms of implant prosthesis (Pjetursson et al., 2007). The research indicated that although implant supported fixed dental prostheses had a survival rate of 96.8% over 5 years, in 38.7% of those cases there was some form of biological or technical complication. This high proportion reflects factors such as fracture of porcelain, loosening of a screw fixture or pathology related to the soft tissues.

An investigation of the key parameters that are now considered for success in

modern implant dentistry include not only implant level factors but also peri-implant soft tissues, prosthesis complications and patient satisfaction with outcome (Papaspyridakos et al., 2012). This is a significant expansion on the criteria put forth by Albrektsson in his original paper discussing implant success (Albrektsson et al 1986).

The consistency of the term implant immobility in all classification systems has been a universal theme in the evolution of dental implant success criteria. This is supported by the findings of a recent review by Papaspyridakos and colleagues that explored the most frequently used criteria to define treatment success in implantology. This article identified implant mobility as the most frequently reported feature of implant success in all the selected studies at both implant level and as part of all the clinical parameters measured. The publication reported that 12 of the 14 studies evaluating success criteria for single implant crowns included implant mobility while 10 of the 12 studies assessing fixed partial dentures reported on implant mobility (Papaspyridakos et al., 2012).

1.1.3 Implant stability

Implant stability is fundamental to the concept of osseointegration and more specifically can be described as primary or secondary stability. Sennerby & Meredith eloquently and succinctly described primary stability as a mechanical

phenomenon that develops into secondary stability as part of the osseointegration process. This mechanical mechanism is related to the physiological process of bone remodeling and resorption that occurs at the tissue-implant interface (Sennerby and Meredith, 1998).

As described above, primary stability is considered a mechanical feature which is dictated by the stiffness of the object or in clinical terms the rigidity of the dental implant in the osteotomy site. Stiffness is defined as the extent to which the implant resists deformation in response to an applied force. The two main factors that influence primary stability are 1) the mechanical properties of the bone at the site of implant placement 2) how well the fixture is engaged with the osseous tissue as determined by surgical technique and implant geometry (Sennerby and Meredith, 2008).

Secondary stability is established gradually as bone resorption and remodeling occurs at the implant-tissue interface. The main determinants of secondary stability are primary stability, bone remodeling and implant topography (Esposito et al., 1998, Meredith et al., 1998).

Implant stability has also been proposed as the absence of mobility and defined as the ability to support an axial, lateral or rotational load. Thus, implant stability is now accepted as an integral feature of successful osseo-integration and evaluation of implant stability is an essential component of implant therapy (Sennerby and Meredith, 2008).

1.1.4 Measurement of implant stability

Despite this reinforcement of osseointegration and implant stability as the keystone feature of successful implantology, the diagnostic methods available to clinicians to objectively evaluate implant stability have failed to progress commensurately with other aspects of research in implant dentistry. The ability to measure implant stability can provide valuable information to support clinical decision making in implant therapy, improve communication, case documentation and trust between clinicians and patient (Mistry et al., 2014).

However, the traditional methods available in practice are invasive, subjective or of limited quantifiable value such as clinical perception, removal torque assessment, percussion testing of the implant with a blunt instrument or reverse torque testing (Sennerby and Meredith, 2008, Sullivan et al., 1996, Friberg et al., 1995).

The ideal characteristics of a device applied to measure implant stability should include all the features listed below.

- Objective
- Reproducible
- Quantifiable

- User-friendly
- Non-invasive
- Non-traumatic
- High sensitivity & specificity
- Provide accurate prognostic data

To address the limitations of traditional approaches, new quantitative, non-invasive methods and devices have been developed to evaluate implant stability based on magnetic resonance frequency and damping capacity analysis technology (Atsumi et al., 2007).

As part of the research undertaken in fulfillment of this doctorate, two measuring devices that apply this technology were evaluated, the Osstell® Mentor (Integration Diagnostics AB, Gothenburg, Sweden) and Periotest™ (Medizintechnik Gulden, Benheim, Germany).

Fig 1.3 Photograph of Osstell® Mentor (Integration Diagnostics AB, Gothenburg, Sweden).

Fig 1.4 Photograph of Periotest™ machine (Medizintechnik Gulden, Benheim, Germany).

1.2 Resonance Frequency Analysis

1.2.1 Background

(Osstell® Mentor Device)

The Osstell® Mentor is founded on resonance frequency analysis (RFA) technology and is the fourth generation of this technology. It consists of a metal rod termed a Smartpeg which is attached to an implant and a separate wireless frequency response analyser as seen in the images below.

Fig 1.5 (Image of smartpeg attached to dental implant in bone) retrieved from Osstell company website https://www.osstell.com/smartpeg-functionality/

Fig 1.6. (Image of Osstell® Mentor device) retrieved from Osstell company website https://www.osstell.com/osstell-isq-resource-page/

The Smartpeg contains a magnet that receives magnetic pulses generated by the frequency of the response analyser. The vibration results range in frequency from 5 to 15 kHz and are converted into an arbitrary scale of 1-100 ISQ described as the implant stability quotient (Oh and Kim, 2012). Based on the guidance of the manufacturer an ISQ of over 70 represents 'high stability', from 60 to 69 indicates 'medium stability' and below 60 signifies 'low stability' (Andreotti et al., 2017). Two ISQ values per implant are supplied as the vibration occurs in the direction of the highest resonance frequency and the lowest. For example, an implant which has exposed threads on the buccal aspect may give one low value, representing the lack of bone bucco-lingually, but one high value, demonstrating good bone support mesio-distally (Sennerby and Meredith,

1998).

Implant stability is considered a fundamental concept of implant success and has also been proposed as an alternative term to define osseointegration (Sennerby and Meredith, 1998). As dental implant therapy has advanced, the demand for shorter treatment times and reduced aesthetic inconvenience has driven research toward immediate implant placement and early loading of the implant fixture. However, with these modern protocols it has been proven that a high degree of primary stability is necessary to achieve success (Esposito et al., 2007). The limitations of traditional methods applied to evaluate implant stability drove the development of non-invasive and quantitative techniques to accurately determine the level of primary stability and ensure the predictable delivery of complex implant dentistry.

The RFA device was developed to meet this demand and it essentially applies a bending load to the implant that mimics clinical direction and force and provides information regarding the stiffness of the implant-bone interface (Sennerby and Meredith, 2008).

The original 1st generation RFA device consisted of a transducer which was attached to the implant with a cable extending to a large desktop computer and oscilloscope. The setup of the transducer attached to an implant is outlined in the image in (Figure 1.7).

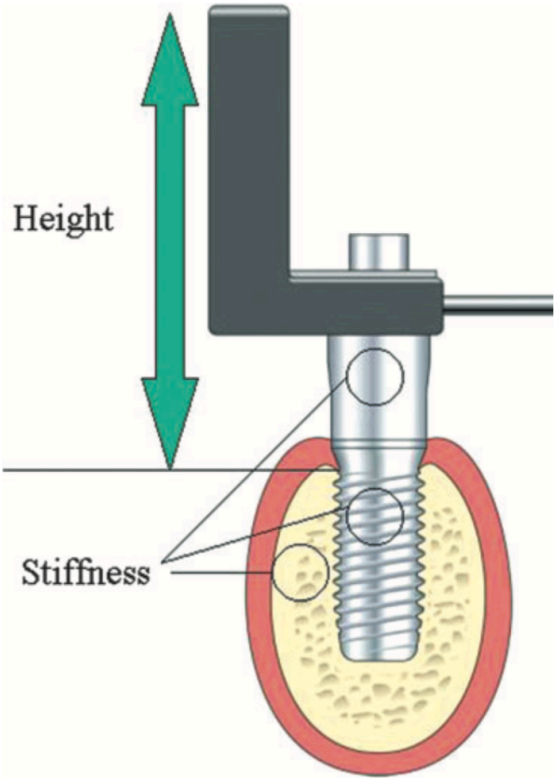


Fig. 5. A schematic showing the principles of resonance frequency analysis. The stiffness of the transducer, implant and bone influences the outcome as well as the effective length of the implant above the bone crest (length).

Fig 1.7. Transducer attached to implant in bone (Sennerby and Meredith, 2008)

Obvious disadvantages of the 1st generation device included the cost, bulk and difficulty of clinically applying the device. The second generation RFA device had a customized frequency response analyser that addressed some of the limitations of the previous machine, however a major disadvantage of the 1st and 2nd iteration of RFA units was the requirement for the transducer to be calibrated prior to each use as each transducer had a unique fundamental

resonance frequency. The 3rd generation device known as an Osstell® addressed this drawback in the technology through the development of a customized frequency response analyser and new generation transducer that was calibrated by the manufacturer prior to delivery for clinical application.

Most recently, the 4th generation device known as an Osstell® Mentor which is applied in this study is a wireless system consisting of a smart peg that contains a magnet at the top and separate micro-computer that emits an electromagnetic pulse and contains a frequency response analyser. The company Integration Diagnostics AB manufacture two versions of the Osstell® Mentor, a standard model and touch screen model, other than this aspect both machines operate with exactly the same functionality.

Fig 1.8 (Image of touchscreen version of Osstell® Mentor) retrieved from Osstell company website https://www.medicalexpo.com/prod/osstell-ab/product-73564-666834.html

A key proof of concept study undertaken by Meredith and co-workers in 1996 established the potential merit of resonance frequency analysis technology in the field of implant dentistry. The purpose of the study was to evaluate the stability of the implant-tissue interface in-vitro and in-vivo. Implants were embedded at different heights in aluminium blocks and an RFA transducer was attached to the implants. Measurements were recorded and a strong correlation ($r = 0.94$, $p < 0.001$) was observed between the RFA value and the height of implant fixture exposed. The greater the height of implant fixture exposed, the lower the resonance frequency value registered. Implants were then embedded in self-cured polymethylmethacrylate and the RFA measurements were taken at different stages of the polymerisation process. This experiment was undertaken to replicate the changes in stiffness observed in the bone surrounding an implant during osseointegration. As anticipated a statistically significant increase in RFA values was observed through the polymerisation process to reflect increase in stiffness. Measurements were also recorded of implants in situ with the RFA device and these results correlated well with the in-vitro findings (Meredith et al., 1996). Thus there was sufficient evidence to support further research in this area and to conclude that RFA technology may provide some clinical benefit in implant dentistry.

1.2.2 Factors that affect RFA

Over the past 25 years a multitude of laboratory and clinical studies have examined the factors that may influence implant stability and how these factors affect measurement values obtained with a resonance frequency analysis device.

Some of the earliest work on RFA technology by Friberg and co-workers was produced in the form of two scientific papers in 1999 (Friberg et al., 1999a, Friberg et al., 1999b). The first study evaluated stability of one stage Branemark® turned surface implants from placement to connection of the definitive prosthesis. 75 implants were placed in 15 edentulous mandibles. This publication found that ISQ values slightly decreased overall from placement to fit of prosthesis and therefore concluded that implants were as stable at initial placement as 3-4 months post-surgery. Another important outcome from this study was that one of the implants failed during the osseointegration process, the ISQ value of this implant had decreased significantly from placement, however interestingly, the mobility of the implant was not clinically diagnosed until several weeks after this reduced ISQ value was recorded. Thus this finding supported the proposal that very low ISQ values may provide diagnostic value as a predictor of early implant failure (Friberg et al., 1999a).

The subsequent publication by Friberg and co aimed to evaluate MK II Branemark® turned surface implants placed in the maxilla of nine patients, a

total of 61 implants were surgically inserted. Bone quality was determined based on the value of the cutting torque and assigned into three groups as 1) soft 2) medium and 3) dense bone. RFA measurements were recorded at placement, second stage surgery and one-year follow-up. The mean ISQ value was then compared against the mean value of each group 1,2 and 3. The study identified statistically significant differences between group 1 and 2 ($p = 0.047$) and group 1 and 3 ($p = 0.002$). No significant differences were present between groups at 2nd stage surgery or at further 1-year follow-up. Therefore, the study indicated that primary stability is influenced by bone quality and ISQ values vary at implant insertion based on the density of bone. Another important outcome from the study was that although ISQ values may vary substantially at baseline implant placement, ISQ values tend to stabilize towards a higher and narrower range on completion of osseointegration. Thus, implants initially placed into softer bone demonstrate lower ISQ values than implants placed into dense bone but by 2nd stage surgery these values tend to coalesce (Friberg et al., 1999b).

A clinical study completed by Balleri and co in 2002 set out to establish normative ranges for ISQ values and identify factors that affect implant stability and ISQ values. The study consisted of 14 partially edentulous subjects that received 45 Branemark® type implants, subsequently radiographic and RFA measurements were performed after one year of loading. The results of this study found that all 45 implants were stable and the implant stability levels ranged from 57 to 82 in implant stability quotient and the mean ISQ was 69 +/- 6.5. Analysis of data collected also determined that mandibular implants were

more stable than maxillary and there was no difference between anterior and posterior implants. No correlation was found between implant length and stability (Balleri et al., 2002).

Another clinical study that investigated RFA and the Osstell® device and in particular factors that affect ISQ values was performed by Bischof and co in 2004 (Bischof et al., 2004). The study included 36 subjects and 106 SLA Straumann® implants, ISQ measurements were recorded at implant placement and on multiple occasions up to 12 weeks. The results of the study indicated that ISQ values and thus primary stability were influenced by jaw and bone type. The ISQ values were lower in the maxilla 55.0 +/- 6.8 compared to the mandible 59.8 +/- 6.7. The ISQ was significantly higher in Type I bone 62.8 +/- 7.2 than in type III bone (56.0 +/- 7.8). Factors such as implant position, implant length, implant diameter and implant deepening did not seem to affect primary stability and as such implant stability (Bischof et al., 2004).

Extensive work by Ostman et al in 2006 aimed to determine how factors such as surgical technique, implant design and patient characteristics would affect ISQ values when measuring primary stability. 905 Branemark® implants placed in 267 patients had ISQ measurements at the time of implant placement. The results of the study determined a mean implant stability quotient of 67.4 (SD 8.6) for all implants placed. Based on a univariate analysis at both a patient and implant level, the following factors were determined to influence ISQ values - gender, jaw position, bone quality and implant diameter. ISQ values were

shown to be higher in men than women, mandible compared to maxillae, dense bone compared to trabecular bone and in wide implants compared to standard or narrow platform implants (Östman et al., 2006).

Huwiler and co-workers evaluated RFA measurements in relation to jawbone characteristics at baseline and on multiple occasions over 12 weeks. 17 standard platform and 7 wide platform Straumann® implants with an SLA surface were placed and ISQ values recorded at baseline, 1,2,3,4,5,6 and 12 weeks. Results of the study determined that baseline ISQ varied between 55-74 with a mean of 61.4 for 4.1mm diameter implants placed and ISQ between 57-70 and a mean of 63.3 ISQ for wide diameter 4.8mm implants. Implant stability quotient values tended to decrease at 2-3 weeks and gradually increase thereafter up to the 12-week measurement. The main conclusions from this study determined that Straumann® implants have a normative range of 57-70 when measuring implant stability with the Osstell® device (Huwiler et al., 2007).

Another study that applied the RFA device to evaluate implant stability focused on the potential influence of implant design on ISQ values. This clinical study assessed the clinical outcomes of SLA Straumann® implants with different morphology, placed immediately into extraction sockets. Cylindrical and tapered transmucosal implants were inserted and ISQ values were measured at placement and at 3 months. The study found ISQ values were higher for tapered compared to cylindrical implants. At baseline mean ISQ was 55.8 for the cylindrical compared to 56.7 for the taper implants. Similarly, at 3 months

follow-up the mean reading was 59.4 for cylindrical compared to 61.1 for tapered dental implants (Lang et al., 2007). Interestingly both the previously mentioned studies demonstrated nearly identical ISQ values at 3 months with mean values of 61.4 and 61.1 respectively (Huwiler et al., 2007, Lang et al., 2007).

Contrasting evidence published in 2010 by Han and co-workers did not show any correlation between RFA and implant diameter or implant surface modification. As part of the study 25 Straumann® implants were placed, 17 SLA surface and 8 SLActive surface implants. Implant stability quotient values were recorded at 4 days, 1,2 3, 4, 6, 8 and 12 weeks after surgery. There was no statistically significant difference for mean ISQ values at any measurement point for the different implant surfaces or implant diameters. The article did however demonstrate a slight decrease in RFA values after implant installation up to 3 weeks and gradual increase thereafter. This particular finding is consistent with earlier work by Huwiler and co-workers that identified a similar trend in ISQ values following implant installation (Huwiler et al., 2007, Han et al., 2010).

A more recent prospective clinical study by Guler and co-workers (Guler et al., 2013) also aimed to determine factors that may affect primary stability and ISQ values. In this research 208 Straumann® implants were placed, a combination of 164 sandblasted, large grit, acid-etched (SLA) and 44 SLActive surface implants. ISQ values were recorded at placement and during the healing period. Similar to the findings of the previous studies, ISQ values were significantly higher for wide

compared to narrow platform implants and in men compared to women. However, in contrast to the previously mentioned studies, there was no significant difference in ISQ values for implants placed in various regions such anterior or posterior area or mandible and maxilla. The mean ISQ value at implant placement was 64.3 (SD 7.9) and this increased to a mean of 70 (SD 6.2) by the final measurement which was taken before the prosthetic phase of treatment.

A randomised case series that sought to investigate the effect of implant surface on implant stability compared implants with identical macro design but different surface roughness. In this study 11 patients had 22 Neoss® implants placed in fresh extraction sockets applying an immediate placement protocol, 11 fixtures were minimally rough and 11 moderately rough. The ISQ value was measured at baseline, 2,4,6 and 12 weeks. Both implant types showed similar ISQ values at placement however at 12 weeks the moderately rough surface implants displayed significantly more stability compared to the minimally rough surface implants. Overall the study demonstrated that ISQ values dip after 2 weeks and subsequently increase progressively up to 12 weeks. The authors concluded that this reflects the biological mechanisms occurring during the process of osseointegration (Vanden Bogaerde and Sennerby, 2016).

Several studies have included jaw position as part of their outcome measures when evaluating factors that influence ISQ values and primary stability. As the primary focus, a study published in 2008 (Seong et al., 2008) sought to

investigate this aspect of implant stability. Seong and team measured implant stability with an Osstell® device and Periotest™ on implants placed in four pairs of edentulous maxillae and mandibles of human cadavers. Biomet 3i oral implants were evenly distributed between maxilla & mandible and anterior & posterior. The study demonstrated a statistically significant difference for ISQ and Periotest™ values between the maxilla and mandible however only the Periotest™ demonstrated significant differences between anterior and posterior region.

An experimental study by Cehreli and co-workers in 2009 sought to evaluate the relationship between bone density and RFA measurements. 40 dental implants were placed in femoral heads of fresh human male cadavers. Bone density was evaluated by cutting torque values measured with a manual torque wrench and analysis of computed tomography scans of the bones. Based on the results of the study the authors concluded no correlation could be found between ISQ values and bone density. (Çehreli et al., 2009)

A systematic review produced by Marquezan and team in 2012 (Marquezan et al., 2012) sought to evaluate the influence of bone mineral density on the primary stability of dental implants, bone density was assessed through cone beam computed tomography and Hounsfield unit (HU) values. After a comprehensive search of the literature and relevant databases, seven studies met the inclusion criteria. The correlation coefficient between ISQ values and Hounsfield units ranged from 0.46 (moderate correlation) to 0.882 (strong

correlation) and overall the study concluded there was positive association between implant stability and bone density. This publication supports the association between implant stability measurements and bone density but it is important to acknowledge that the methodological quality of the studies was classified as low to moderate indicating the need for further high-quality clinical studies to truly validate the argument (Turkyilmaz and McGlumphy, 2008).

Recent research has aimed to establish what optimum torque level is required when attaching the transducer (smartpeg) to the implant to ensure an accurate measurement of implant stability with an Osstell® Mentor device.

Research performed by Geckili and co-workers in 2015 suggested that a force of 5-8Ncm was required to achieve a reliable and objective RFA measurement. As part of this study 30 dental implants were inserted in three cow ribs. Four different examiners measured the ISQ value after hand tightening the smartpegs, ISQ values were recorded after smartpegs were inserted at 1,3,4,8,9,10 and 11Ncm and results analysed to produce the finding above (Geckili et al., 2015).

However later work by Barella and team on the same topic suggested alternative forces for tightening of the smartpeg, as part of the study methodology, one hundred 4 x 11mm screw shaped titanium implants were inserted into a uniform polyurethane block, implants were distributed in 10 groups of 10. Group one (G1) implants were attached by a female operator,

group two (G2) by a male operator and both used the manual connecter provided by the manufacturer. For the remaining groups (G3-G10) a connector adapted to a digital torque wrench with different torque settings ranging from 3Ncm to 20Ncm was applied. Stability measurements were recorded for all groups with the Osstell™ device. The results were homogenous for G7, G8, G9 and G10 however when torque of 20Ncm was reached the connection between the implant and transducer failed. Based on the findings of this in vitro model experiment, tightening of the transducer by applying torque force between 10Ncm and 17Ncm is recommended for accurate measurement of implant stability ensuring more precise comparison and importantly preventing damage to the prosthetic connection of the implant. (Barella Salatti et al., 2019).

Further research published by Kastel et al suggest that manual tightening of the smartpeg through finger pressure is adequate to achieve an objective and reliable determination of ISQ values from an RFA device (Kästel et al., 2019). In this experiment 30 self-tapping Dentsply Sirona implants were inserted in three cow ribs. RFA measurements were recorded in the buccal and mesial direction after tightening the corresponding smartpeg with a mechanically defined force of 5Ncm, 4 different researchers then measured the RFA value after hand tightening the smartpegs and the results were compared. The values ranged from 2 to 11Ncm by hand tightening and from 2 to 6 Ncm by machine tightening. The comparison of machine and hand tightening of the smartpegs indicated only minor differences in the mean ISQ values with low standard deviations. No statistically significant difference was revealed for RFA values

between the manual and machine method in the mesial (*p = 0.343*) and buccal direct (*p = 0.890*) (Kästel et al., 2019). These finding demonstrate the inconsistency of results between studies and the conflicting evidence available on this subject.

Although this thesis focuses on magnetic resonance frequency analysis technology and more specifically the Osstell® mentor, it is important to acknowledge from the literature that direct comparison of measurements is not possible between iterations of these devices.

In 2007 Valderrama and co performed a longitudinal prospective study that compared the 3rd generation electronic resonance frequency analysis (eRFA) device to the more recent 4th generation magnetic resonance frequency analysis (mRFA) device (Valderrama et al., 2007).

The aim of the study was to evaluate the ability of the magnetic RFA device to detect changes in stability during early healing following implant placement and to determine whether the implant stability quotient (ISQ) values obtained correlate with those of the electronic device. RFA values were recorded with the eRFA & mRFA machine on 34 Straumann® implants of 4.1mm diameter placed in 17 subjects. ISQ values were recorded at baseline, 1,2,3,4,5,6 weeks and 12 weeks. 3 measurements were taken each time and the average obtained to provide a single value for analysis.

At baseline the mean ISQ value obtained with the eRFA device was 61.9 and this value increased to 63.2 by 12 weeks. At baseline mean ISQ value obtained with the mRFA machine was 70.6 and this value increased to 75.9 by 12 weeks. Both devices demonstrated a pattern of decreased stability from week 1-3 and a gradual statistically significant increase to week 12. The values for both devices correlated significantly (r = 0.52; $p < 0.001$) but only to a moderate level, while there was no statistically significant correlation at 12 weeks, mRFA values were consistently higher than eRFA values throughout the study in the order of approximately 8-12 ISQ points, therefore the study concluded that measurements between different iteration of devices cannot be compared directly (Valderrama et al., 2007).

Another relevant finding from the Valderrama paper was the dip in stability values from week one to three and gradual increase up to 12 weeks which is consistent with the findings of comparable literature (Valderrama et al., 2007).

The findings of the previously mentioned study are strongly reinforced by those of a publication produced nearly a decade later by Grognard and co (Grognard et al., 2017). This article aimed to evaluate the secondary implant stability of two different implant systems, Ankylos® implants and Struamann® implants. The results of the study identified notable differences between the older generation cabled RFA device and new generation Osstell® Mentor instrument. The study demonstrated that the cabled Osstell® device produces differing ISQ

values of between 9.7-14.7 when compared with the wireless Osstell® machine. These findings support the argument that implant stability quotient values cannot be compared between different model of RFA device and that reviews that have included data from different iteration of RFA device should be interpreted with caution. The study also demonstrated statistically significant differences for RFA measurements between implant types with Ankylos® dental implants on average producing higher stability measurements than Straumann® implants 4.8 ISQ (*p-value 0.028*) (Grognard et al., 2017).

Overall the literature would indicate that a multitude of factors can affect implant stability and in turn measurements of RFA devices. These findings support the scientific plausibility of applying this technology in a clinical setting to yield clinical benefit. As a surrogate marker the evidence suggests these devices are responsive to clinical changes in implant stability however this does not establish correlation to the biological process of osseointegration.

1.2.3 Histometric Correlation

It is important to acknowledge the negative literature with regard to RFA technology that demonstrates the absence of correlation between RFA measurements and histological assessment of osseointegration.

Work undertaken by Ito et al in 2007, on mini-pigs demonstrated that there was

no correlation between ISQ values and bone-implant contact when measured by histological methods (Ito et al., 2008). These findings were confirmed by Al-Nawas and co-workers through evaluation of six different implant types that demonstrated minimal correlation between implant-bone contact and RFA values (Al-Nawas et al., 2008).

An vivo study around this period that investigated the relationship between jawbone characteristics and RFA, analysed central bone cores using micro computed tomography and found no statistically significant correlation between ISQ and bone volume density or bone trabecular connectivity (Huwiler et al., 2007).

Similarly, a comprehensive animal study performed by a research group in Gothenburg, Sweden during the same period evaluated the relationship between RFA and osseointegration and more specifically sought to determine the degree of correlation between RFA measurements and bone-implant contact (BIC). The results of this study identified no correlation between histological parameters of osseointegration and ISQ values. Over the 12-week monitoring period the RFA values obtained did not reflect marginal bone level changes, differences in BIC% or bone density at any time period. The conclusion of this study questioned the validity of the RFA device as a diagnostic tool to predict implant stability or as a useful predictor for the optimum time to functionally load dental implants (Abrahamsson et al., 2009).

In contrast to the scientific evidence outlined above an experimental study by Chen and co (Chen et al., 2017) did identify correlation between RFA and Periotest measurements and BIC. This study was based on 24 dental implants inserted in the femoral condyles of rabbits. The animals were sacrificed immediately after implant insertion and relevant values recorded at placement, 14, 28 and 56 days after surgery. Significant correlations were revealed between PTV and BIC% ($r = -0.637, p < 0.05$) and between ISQ and BIC% ($r = 0.701, p < 0.001$) when BIC% at different time points was compared with corresponding ISQ and PT values. Significant correlation was also identified between ISQ and PT values ($r = -.068, p < 0.05$). A relevant difference in the methodology of this study compared to those above was the use of rabbits as opposed to dogs and femoral condyles instead of jaws.

1.2.4 Prognostic Capacity of Magnetic RFA

A literature review by Aparicio et al in 2006 discussed the key principles necessary to establish and validate a prognostic measurement and the requirement for the following features to be definitively established in order to validate this measurement (Aparicio et al., 2006).

- Sensitivity
- Specificity
- Reliability
- Accuracy
- Normative range

These fundamental features are defined as followed:

Sensitivity is the ability of a test to correctly identify those with the disease (true positive rate).

Specificity is the ability of the test to correctly identify those without the disease (true negative rate).

Reliability is the degree to which the result of a measurement, calculation, or specification can be depended on to be accurate.

Precision refers to how close estimates from different samples are to each other. For example, the standard error is a measure of **precision**. When the standard error is small, estimates from different samples will be close in value; and vice versa.

Reproducibility is one component of the precision of a measurement or test method. The other component is **Repeatability** which is the degree of agreement of tests or measurements on replicate specimens by the same observer in the same laboratory.
(Baratloo et al., 2015).

In the publication by Aparicio and team, the conclusions from the study highlighted the paucity of prospective cohort studies and RCTs in the available literature that validate the Ostell® and Periotest™ device applied as implant stability measurement methods (Aparicio et al., 2006).

A prospective cohort study reported on RFA as a prognostic indicator in implant dentistry. This research aimed to evaluate RFA values over a 12-month period in 23 patients. Implants were placed applying an immediate/early loading protocol and the secondary objective was to identify differences between failing and successful implants.

As part of the materials and methods, 81 Branemark® implants were placed in 23 patients for immediate/early occlusal loading in all jaw regions. 30 implants were placed in extraction sockets and 62 were subjected to guided bone regeneration procedures. RFA measurements were taken at placement, prosthesis connection and after 1-3 months, 6 and 12 months.

Tabulation of results revealed that 9 implants failed (11.2%). RFA demonstrated a distinctly different pattern for implants that were lost compared to implants that remained stable. Implants that failed during the study showed a significantly lower stability after only 1 month.

The authors concluded that low RFA values after 1-2 months may act as a prognostic indicator for greater risk of future implant failure. Low ISQ values may guide timing of implant loading and indicate need to unload implant prosthesis (Glauser et al., 2004).

A prospective clinical study by a research group based in Switzerland was one of the first to investigate RFA as a predictive tool for osseointegration. The purpose of this clinical study was to 1) evaluate the Osstell® as a diagnostic tool capable of discriminating between stable and mobile ITI implants 2) establish a threshold ISQ value at implant placement that may act as a predictor of osseointegration when assessed after one year of functional loading 3) compare the predictive ISQ values of immediate loaded and delay loaded implants.

As part of the study, 18 subjects received 63 immediately loaded implants and 18 subjects received 43 delay loaded implants. RFA measurements were taken at baseline, 1,2,4,6,8,10 and 12 weeks.

One implant failed in the immediate group with an ISQ of 53 at placement and one implant failed in the conventional group with an ISQ of 48 at baseline. Despite the limitations of the study, this was one of the first articles to propose a cut-off ISQ value as a predictor of implant stability and osseointegration after 1 year of loading. Based on the findings of the study, Nedir and co-workers determined that applying a cut-off ISQ of 47 for implant stability yielded a sensitivity of 100% and a specificity of 97% (Nedir et al., 2004).

A clinical study by Huwiler and co-workers followed 24 implants for 12-weeks after placement. ISQ measurements were taken at baseline, 1,2,3,4,5,6 and 12 weeks. One implant failed after three weeks and the ISQ value had dropped from 68 to 45 however this change was identified after the clinical diagnosis of implant instability therefore the study concluded that no predictive value for loss of implant stability could be attributed to RFA measurements (Huwiler et al., 2007).

Overall much of the available literature on resonance frequency analysis as a measurement tool for dental implant stability has been surmised succinctly in a

number of systematic reviews on the topic published between 2005 and 2010 (Aparicio et al., 2006, Quesada-García et al., 2009, Javed and Romanos, 2010). These reviews conclude that there is certainly potential clinical benefit to RFA technology but pertinently acknowledge that this device evaluates mechanical properties of primary stability in the form of stiffness rather than histological findings and there is minimal scientific evidence to support a relationship between ISQ values and histological changes around dental implants.

As elaborated on in this literature review, RFA measurements would seem to be influenced by several clinical factors such as bone quality, implant diameter, topography and insertion depth. Single cross-sectional readings would seem to be of minimal clinical value and again normative values between and within implant systems have yet to be truly established. The research has tacitly sought to extend the scope of RFA technology by proposing predictive ISQ values that act as prognostic indicators for implant stability, loading protocols and failure (Nedir et al., 2004) but further well-structured prospective clinical studies are necessary to validate these values and importantly to determine if these values differ between the various implant systems and designs. Overall the research to date has established a foundation for this device to be applied clinically, the challenge is to determine the best manner in which to apply this device to achieve the optimum clinical benefit.

1.2.5 Other Clinical Applications

Resonance frequency analysis technology has also been applied in less conventional aspects of implant dentistry such as palatal implants and mini implants utilised in orthodontics for temporary anchorage.

A laboratory study by Nienkemper and co undertook proof of concept research in 2013 to validate the use of RFA to determine stability of mini-implants utilised in orthodontics. For the purpose of the study, smartpegs were modified to fit the inner screw thread of the orthodontic mini-implants. 110 mini-implants were then inserted into porcine pelvic bone. RFA measurements where then performed parallel and perpendicular to the bone fibres. A suitability test applying the Periotest™ device was also applied in the same directions. Statistical analysis included correlation tests and linear regression analysis. The results of the research demonstrated a mean ISQ value of 36.36 +/- 2.67 and the Periotest™ provided a mean value of -2.10 +/- 1.17. The differences between the two directions of measurement was statistically significant. There was high correlation between the RFA and Periotest™ ($r = -0.90$). Overall the study indicated that RFA may be feasible as a method to measure orthodontic mini-implant stability (Nienkemper et al., 2013).

More recently RFA technology has been applied to evaluate stability of palatal implants. A prospective randomised control trial performed by Wieczorek et al sought to determine the diagnostic value of RFA in predicting palatal implant

loss. 32 patients were split into two groups and had palatal implants inserted, group one implants were conventionally loaded after 12 weeks healing while group two had immediate loading after 1 week of implant insertion. RFA measurements were taken at implant placement, one week, and 12 weeks.

14 palatal implants were loaded conventionally and 18 loaded immediately. Differences between groups were not statistically significant at baseline but were significant from placement to 12 weeks. Consistent with the findings of similar literature, a decrease in ISQ values at 1 week and increase by 12 weeks was revealed.

In conclusion the general decrease after primary stability and increase with secondary stability gives support for specificity, however RFA had no sensitivity for prediction of stability. Within the limits of the study, the diagnostic value of RFA identifying stable palatal implants could be confirmed (Wieczorek et al., 2019).

1.3 Damping Capacity Analysis

1.3.1 Background

(Periotest™ Device)

Fig 1.9. (Image of Periotest™ device) retrieved from Medizintechnik company website https://www.medicalexpo.com/prod/medizintechnik-gulden/product-72414-664208.html

The Periotest™ device is based on the principle of damping capacity assessment (DCA) and was originally developed to evaluate the damping capacity of the periodontal ligaments surrounding teeth and to provide an objective quantitative value for tooth mobility (Schulte et al., 1992). Around the same period it was proposed that the device could be used to measure the damping characteristics of the implant tissue interface (Olive and Aparicio, 1990, Teerlinck et al., 1991) and in recent years has evolved as an instrument for

measuring implant mobility (Oh and Kim, 2012).

The machine consists of a microcomputer connected to a handpiece with an 8-g tapping pistil inside. The tapping pistil driven by an electromagnetic accelerator strikes the implant 16 times in 4 seconds at a velocity of 0.2m/s. As the tapping rod strikes a solid object it decelerates and this breaking time ranges from 0.3 to 2.3 milliseconds. The contact time between the implant and the tapping rod is recorded and converted by the internal computer into Periotest values (PTV). The PTV ranges from -8 for maximum stability to +50 for clinical mobility (Lukas et al., 1992, Zix et al., 2008).

This broad range of values however reflects the damping capacity of the attachment apparatus around natural teeth. The following range of PTVs was suggested to reflect grades of tooth mobility (Winkler et al., 2001). The PTVs are compared against the tooth mobility values of the Miller Mobility Index (Miller, 1950).

Table 1.2 Table of Periotest values related to tooth mobility.

Periotest Value	Grade of Tooth Mobility
-8 to +9	0
+10 to +19	1
+20 to +29	2
+30 to +50	3

Dental implants in contrast to natural teeth exhibit minimal clinical mobility. This is an important concept when applying the Periotest™ device to dental implants as based on the anatomy and physiology of the tooth-tissue and implant-tissue interface it would be expected that the range of PTVs for dental implants would be lower and narrower compared to natural teeth.

Early research on the Periotest™ by Truhlar et al assessed implant stability at second stage surgery on 1838 root form implants. This investigation sought to establish normative ranges for the Periotest™ and to correlate the device with various bone densities. The mean PTV for osseointegrated and non-integrated implants was -8 to +25 and more specifically for stable implants at 2nd stage surgery the mean Periotest value was -3.37 +/- 3.25. The study identified the influence of bone quality on PTVs with implants inserted in dense cortical bone displaying a lower mean PTV of -3.82 +/- 3.04 in contrast to implants placed in softer trabecular Type IV bone having a mean PTV of -1.29 +/- 3.57 (Truhlar et al., 1994).

This is supported in the literature by Winkler and co-workers that evaluated 2623 implants at second stage surgery and followed up on multiple occasions over 60 months, 975 natural teeth acted as control in the study. The research identified that the average PTV for teeth was +1.8 and the average PTV for implants was -3.4 (Winkler et al., 2001).

Further studies confirm these findings with Truhler and team identifying an

average PTV of -3.5 in their study that evaluated the stability of the bone implant complex over 60 months with the Periotest™ machine (Truhlar et al., 2000).

While early research by Teerlinck et al applying the Periotest™ to dental implants found a range of Periotest values between -4 and +2 (Teerlinck et al., 1991). A more recent study from 2012 that was evaluating the relationship between implant stability and bone quality with the Periotest™ device identified an average range of -5 to +5 for PTVs (Oh and Kim, 2012).

1.3.2 Factors that affect Periotest™

Early research on the Periotest™ device aimed to evaluate the reliability of this machine in clinical practice and specifically the factors that may affect Periotest values. Preliminary investigations by Teerlinck and co (Teerlinck et al., 1991) on the Periotest™ device recorded PTVs of implants placed in the mandible of 30 consecutive patients. The study identified abutment length and characteristics of the mandible as influencing factors on Periotest values. A subsequent clinical study by Derhami et al in 1995 applied the Periotest™ to measure stability of 15 Branemark® implants with a 5.5mm abutment connected. PTVs were recorded on each abutment by three different operators using 3 different Periotest™ devices of the same model, measurements were recorded at different vertical positions of the healing abutment. Variability of operator or instrument did not

influence PT values however the vertical point of measurement on the healing abutment did influence Periotest™ recordings. Therefore, the authors concluded that the contact point of the implant-abutment assembly may significantly influence Periotest values (Derhami et al., 1995).

Another early clinical study by Mericske-Stern and co (Mericske-Stern et al., 1995) followed 30 edentulous patients with 60 ITI implants placed in the mandible and investigated the impact of functional loading on Periotest values after 3 months of healing and after 12 months of functional loading. At 3 months PTVs ranged from -1 to -8 with an average of -4.08 and after one year of functional loading the PTVs ranged from -2 to -8 with an average of -4.97. Another finding of this study identified no correlation between Periotest values and bone density.

A combined in vitro and in vivo study performed by Meredith and team in 1998 (Meredith et al., 1998) evaluated the Periotest™ device. The purpose of this study was to determine the relationship between contact times and PTVs and to assess the influence of striking height of the Periotest™ handpiece and the length of the implant abutment on measurements.

As part of the materials and methods the accelerometer signal from a Periotest™ instrument was recorded and compared against the resulting Periotest values. In vitro measurements were recorded against a 3mm abutment that was attached to a 15mm implant that had been luted into an

aluminium block. These measurements were then repeated on abutments attached to six implants in the maxilla of the same patient. The abutment lengths ranged from 3mm to 7mm.

The data gathered from the study indicated that there was a linear relationship between PTV and contact time for implants measured in vivo and vitro. Greater scatter of the vivo data was attributed to variables such as striking position, distance and damping as a consequence of soft tissue presence. The authors concluded that the clinical variables of striking height and handpiece angulation influence measurements of the Periotest™ to such an extent that clinical application of the device would be limited (Meredith et al., 1998).

The individual findings of the studies described above were collated by a narrative review performed in 2006 by Carlos Aparicio and his fellow researchers that evaluated the available literature on the Periotest™ machine. In the summary section the author concluded that factors such as jaw location or striking position of the tapping pistil can influence PTVs (Aparicio et al., 2006).

A series of studies by Manz et al in the early 90s demonstrated that the Periotest™ device when applied to dental implants produced a high level of inter-examiner and intra-examiner reliability. A number of different Periotest™ models and devices were also tested for inter and intra-instrument reliability and similarly demonstrated a high degree of repeatability and reliability (Manz

et al., 1992a, Manz et al., 1992b).

These findings were corroborated by the results of an in vivo study that evaluated the damping characteristics of various bone-to-implant interfaces of Branemark® implants (Van Steenberghe et al., 1995).

Another laboratory study sought to determine the reliability of Osstell® compared to the Periotest™, this study was performed by Lachmann and team from the University of Tubingen. The purpose of the research was to determine reliability of the Osstell® and Periotest™ machines in the assessment of implant stability and to compare the two devices. Eight 13mm x 3.8mm diameter implants were inserted in two blocks of bovine bone and repeated measurements were taken with both devices. Both methods demonstrated high reliability with an intra-class co-efficient (ICC) of 0.99 and 0.86 for the Osstell® and Periotest™ respectively (Lachmann et al., 2006a).

More recent research by Bilhan and co in 2015 also proposed to investigate the reliability of the Periotest™ in implant stability measurements. This paper concluded that the Periotest™ had poor intra and inter reliability in contrast to the findings of earlier studies. More specifically, the Bilhan study recorded PTVs in two orientations buccal and mesial in comparison to the previous studies that only evaluated measurements from a single orientation.

As part of this research 30 implants were inserted into 3 bovine ribs. Periotest values were recorded by 4 different operators, measurements were repeated twice in both the buccal and mesial direction for each implant at 2 hour intervals. The intra and inter reliability of the measurements was then analysed applying an interclass correlation co-efficient. Results showed that the intraobserver reliability of the Periotest™ was excellent for the buccal PTVs but fair to poor for the mesial PTVs. Similarly the interobserver reliability of the Periotest™ was excellent for the buccal PTVs but poor for the mesial PTVs (Bilhan et al., 2015).

1.3.3 Prognostic Capacity of Periotest™ device

An interesting retrospective cohort study undertaken by Noguerol et al in 2006 sought to evaluate the prognostic capacity of the Periotest™ to evaluate early implant failure. The main objectives of the study were to determine the accuracy of Periotest™ to monitor primary stability at first-stage surgery and to compare the Periotest™ against radiographic assessment in the diagnosis of implant stability at second-stage surgery. Finally to determine the accuracy of Periotest™ at first stage surgery to predict early implant failure.

Measurements were evaluated on 1084 Branemark® implants placed in 316 patients.

The results of the study concluded the following; 1) PTVs at first stage surgery were independently related to early implant failure (OR + 3.01; 95% CI, 1.5-6.02) 2) Based on a PTV of -2 as the cut-off point for implant failure (84% sensitivity and 39% specificity). The main conclusions surmised from this study were that the Periotest™ with a selected cut off point of -2 at first stage surgery offers high sensitivity in the prognosis of early implant loss and shows greater ability to assess stability during the osseointegration period when compared with radiographic assessment (Noguerol et al., 2006).

1.4 Correlation between Osstell® & Periotest™

1.4.1 Factors that influence RFA & DCA

1.4.1.1 Implant Topography

Much literature and research effort has been devoted to investigating the effect of implant surface on implant stability, osseointegration and ultimately implant success. Multiple studies have applied resonance frequency analysis and damping capacity assessment technology to act as a quantitative method to evaluate these factors.

One example of this body of work was a retrospective cohort study performed by Al-Nawas and co in 2007. The purpose of this study was to compare two implants with identical morphology but different topography, the first implant

system was MK II™ turned and machined surface implants from Nobel™ Biocare and the other system were etched implants from Biomet 3i of the same macro design. The study identified no statistically significant difference between implant systems despite the contrasting surface design, for RFA the values were 64 ISQ +/- 8.6 and 63 ISQ +/- 9.7 for the etched and turned implants respectively, for Periotest™ the values were -2 +/- 3.3 and -1 +/- 5.1 respectively. Overall the study indicated that although there is some difference in RFA and DCA measurements between turned and etched implants, there is no statistically significant difference between them (Al-Nawas et al., 2007).

1.4.1.2 Bone Quality

A study undertaken in 2007 through the Periodontology Department at the University of Leuven sought to evaluate the validity of subjective jaw bone quality assessment. TiUnite Branemark™ dental implants were inserted and a subjective bone quality assessment was completed based on radiographs and the tactile sensation of the surgeon, as part of the study a subset of 71 patients and 153 implants had RFA measurements recorded and 22 subjects and 44 implants had DCA readings recorded. The study applied the Lekholm and Zarb grading system for bone quality assessment, Grade 1 representing thick cortical and dense trabecular bone with Grade 4 representing thin cortical and poor trabecular bone (Lekholm, 1985).

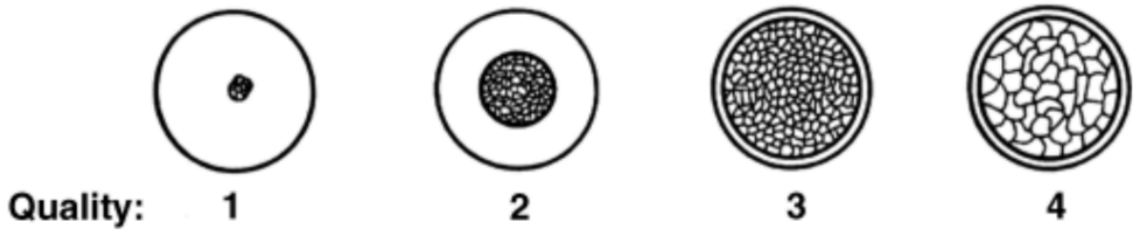


Fig 1.10 Grading system for bone quality assessment (Lekholm & Zarb 1985).

Of relevance to this literature review, the study found that subjective assessment of bone quality based on the Lekholm and Zarb classification system was related to PTV and ISQ. For Grade 1 bone quality the mean PTV was -5.3 and mean ISQ 73.3 while for Grade 3 or 4 the mean PTV was -1.6 and mean ISQ 55 (Alsaadi et al., 2007).

A subsequent study from the same institute two years later similarly sought to explore the relationship between bone quality and primary implant stability measurements. This article however applied more objective methods to evaluate bone quality based on bone density in Hounsfield Units and coronal cortical thickness at the osteotomy site as measured from pre-surgery computerized tomography scans (Merheb et al., 2010). In this clinical work, 24 participants received 136 Straumann® implants, RFA values were recorded at implant insertion then RFA and Periotest values were recorded at implant loading. Significant linear correlation was found between cortical bone thickness ($p<0.05$) and HU values ($p < 0.05$) when compared with ISQ or PTV

measurements at implant placement and loading. Based on these results the RFA and DCA methods can be applied to accurately predict bone quality.

Advancing on this basis, other research investigated the prognostic capacity of computed tomography, IT, PTV and ISQ compared and correlated to predict and plan implant loading. Schnitman and team (Schnitman and Hwang, 2011) through clinical research sought to determine the predictive benefit of pre-operative bone density measurements with CT, IT, PTV and RFA for decisions on timing of implant loading. 58 implants were retrospectively analysed from 18 patients. Seven implants failed for a survival rate of 88%. Overall the study concluded, based on the results of this patient cohort that objective measures of bone density through CT, IT, PTV and ISQ correlated with each other and may provide clinical benefit as part of a decision tree for loading protocol of dental implants. As an additional point the article indicted that the Periotest™ device provided the greatest reliability in predicting implant failure based on primary stability measurements.

Subsequent to this a laboratory study by Pommer et al in 2014 (Pommer et al., 2014) investigated the influence of residual bone height, bone density and implant diameter on primary stability of implants placed in an atrophic sinus floor. In this study 66 Nobel™ Active implants were surgically placed in the sinus floor of fresh human cadaver maxillae. Of interest in this study was the similar trend identified to the research above with statistical analysis determining a

highly significant correlation between insertion torques, Periotest values and ISQ measurements ($p < 0.001$).

Incongruous with the findings above, an article produced by Hsu and team (Hsu et al., 2013) demonstrated absence of correlation between IT, PTV and ISQ measurements. This was in an in vitro study published in the journal of clinical implant dentistry and related research that investigated how primary stability of dental implants as recorded by insertion torque, damping capacity analysis and resonance frequency analysis was affected by varying thickness of cortical bone and strength of trabecular bone. The results of the study revealed that insertion torque values, Osstell values and Periotest values differed significantly ($p < 0.05$).

1.4.1.3 Prognostic indicator of peri-implant bone loss

With the gradual acceptance of RFA and DCA technology in implant dentistry. Research focus has turned to the potential of these devices to detect and identify peri-implant bone loss and to act as a diagnostic tool in the management of peri-implantitis. One example of this new aspect of research was undertaken by Choi and co (Choi et al., 2014) to support proof of concept of these devices based on a laboratory study similar to the initial research performed by Meredith and his fellow researchers in 1996 (Meredith et al., 1996).

The purpose of this recent experimental study was to determine the reliability of the Osstell® Mentor and Periotest™ in assessment of peri-implant vertical and circumferential bone loss.

16 dental implants were embedded in acrylic resin units and resin around the implant neck was progressively removed to reflect advancement of peri-implant bone loss in a vertical and circular pattern. ISQ and Periotest values were then recorded and analysed against increasing loss of acrylic.

Both devices were capable of discriminating between differences in circular bone loss. However, both devices were limited in their ability to discriminate buccal bone loss. As the level of acrylic around the implants decreased, there was a significant correlation of PTV and ISQ values. The study concluded that both instruments may provide some benefit in detecting circumferential bone loss however sensitivity may be limited around implants with mild to moderate bone loss.

1.4.1.4 Prognostic Indicator for immediate loading of dental implants

A retrospective study by Wentaschek and co (Wentaschek et al., 2015) aimed to determine the most suitable stability parameter from the choice of insertion torque values, resonance frequency analysis and damping capacity assessment to predict non-osseointegration of immediately loaded splinted maxillary implants. Measurements recorded for each parameter were analysed from 11 edentulous and 8 partially edentulous maxillae treated 105 dental implants. The IT stability parameter demonstrated the highest level of specificity at a high sensitivity of 1 in contrast to the Periotest™ and Osstell®. The Periotest values for osseointegrated implants were significantly different to failed implants with PTV of -1.5 +/-3.0 and +2.7 +/- 3.0 respectively. This was also the case with ISQ values of 62.6 +/- 6.7 and 54.7 +/- 6.2 respectively.

1.4.1.5 Correlation Studies

The progression of research into the Osstell® and Periotest™ devices gradually evolved to investigate the potential comparison between these machines and more specifically correlation between measurements of both instruments. As mentioned earlier, preliminary research on this topic was performed by Lachmann and co in the form of two consecutive laboratory studies. The primary aim of the first study was to assess reliability of both devices and determine the extent of correlation between ISQ and Periotest values. The methodology involved insertion of eight 13mm Frialit™ Snychro dental implants into bovine rib segments of different anatomical origins and densities. Repeated implant stability measurements were then performed with the Osstell® and Periotest™. Based on statistical analysis applying a linear regression model a high level of correlation was demonstrated between the Osstell™ and Periotest™ readings ($n = 52, R^2 = 0.8, p < 0.0001$) (Lachmann et al., 2006a).

The subsequent in vitro study by Lachmann and team examined machined surface Branemark™ and Frialit™ Synchro dental implants that were polymerized in rows into blocks of auto-cured acrylic material. Similar to the previously mentioned study, this paper demonstrated statistically significant linear association between both methods of measurement device ($R^2 = 0.89, p < 0.0001$) (Lachmann et al., 2006b).

Consistent with these findings another laboratory based study from Chapel Hill University compared RFA and DCA devices and identified a similarly high correlation of (r = -0.852) (Seong et al., 2008). Equivalent findings were elucidated in a clinical study produced by Merhab and co that evaluated stability measurements and bone quality. As part of this research, 24 patients received a total of 136 Straumann® SLActive implants and stability values were recorded at fixture loading stage. The study produced the following result ($r = 0.52, p < 0.001$) and demonstrated correlation between the RFA and PTV scores (Merheb et al., 2010).

Although correlation between the Osstell™ and Periotest™ was identified by Merhab and his team, the results were weaker than those outlined in the previously mentioned studies. A number of potential reasons for this discrepancy have been proposed in the literature. Firstly, measurements from different iteration of Osstell® machine cannot be compared directly (Valderrama et al., 2007). Secondly there is potential for bias to be introduced when comparing two measurement devices at different surgical stages (Merheb et al., 2010) . Finally, application of the two machines in contrasting laboratory and clinical settings may influence access, direction and orientation of the instruments. This has been observed in the literature as a factor that can effect measurements and subsequently may effect correlation between devices (Mistry et al., 2014).

During this period of publication, a prospective clinical study was reported by Zix and Co (Zix et al., 2008). This research focused on correlation between RFA and DCA instruments and built on the accumulated literature of implant stability measurement devices. As part of the investigation 65 patients with 213 Straumann® dental implants were assessed and implant stability values recorded in triplicate with the RFA device and Periotest™. Extensive statistical analysis was performed to determine the level of correlation between RFA and DCA instruments. The correlation of both devices was *-0.64* based on Pearson's test and *-0.65* based on Spearman's test representing a moderate to strong level of correlation.

The findings of Zix and colleagues corroborates the results of the previous in vitro and in vivo studies discussed above. The weaker correlation reported in the Zix article in comparison to similar literature is acknowledged in the discussion section of the study and corresponding factors of access, space and patient compliance are suggested to explain the lower strength of correlation. Final conclusions from this article suggest that the Osstell® device is more precise compared to the Periotest™ due to the narrower standard deviation and higher intraclass correlation coefficient (Zix et al., 2008).

During this period a meta-analysis was also undertaken to assess correlation between different methods applied to evaluate implant stability and the article was published in 2009 in the International Journal of Oral & Maxillofacial Implants. The systematic review included the following methods for analysis;

Periotest™, cutting torque/insertion torque, reverse torque testing and resonance frequency analysis measurements. The literature review was completed from 1998 up to April 2008 and 47 articles fulfilled the inclusion criteria and consisted of 5 in vitro, 15 animal, 11 human cadaver and 16 clinical studies. Despite the extensive literature search only one study could be included to evaluate correlation between the Periotest™ and resonance frequency analysis method and importantly this was found to be non-significant (*p = 0.28*) (Cehreli et al., 2009). Therefore, this study added little to the evidence base supporting the argument for correlation of Periotest™ and RFA devices as only a single study with a negative finding was available in the literature but rather it emphasized the need for further well-structured clinical studies to build the available knowledge base. The paucity of clinical studies and high proportion of laboratory and animal studies in this meta-analysis reflect the conclusion of Aparicio and co in their narrative review of RFA and Periotest™ methods that further prospective and randomised clinical studies were required to truly determine the degree of correlation between these instruments and establish their clinical validity (Aparicio et al., 2006).

1.4.1.6 Correlation with clinical characteristics

In the past decade research has sought to evaluate correlation between ISQ and PTV values and clinical characteristics. A recent systematic review and seminal publication by Andreotti and co-workers (Andreotti et al., 2017) aimed to investigate correlation between the RFA and DCA techniques and to determine if both methods provide similar implant stability findings in the same clinical case. Six studies met the inclusion criteria and the table from the published article below provides a summary of the individual study characteristics. The studies outlined had the purpose of examining different implant types, implant surfaces, bone density and surgical techniques.

Table 1.3 Demographic & implant data of selected studies (Andreotti et al 2017).

Author and Year	Location	Type of Study	Number of Patients	Implant Type	Dimensions (mm)	Number of Implants	Insertion Region
Cannizzaro et al., 2013[19]	Italy	Prospective randomized controlled	37*	Implant 1†	Diameter: 3.7, 4.7, and 6 Length: 8, 10, 13, and 16	76*	Posterior maxilla
Cannizzaro et al., 2007[22]	Italy	Prospective single-masked controlled	40	Implant 2‡	Diameter: 3.25, 3.75, and 4 Length: 10, 11.5, 13, and 15	104	Posterior maxilla
Oh and Kim, 2012[3]	Korea	Prospective	162	Not reported	Diameter: 3.8 to 5.0 Length: 8 to 13	211	Varied regions
Palanie et al., 2012[5]	Germany	Prospective	124	Implant 3§	Diameter: 3.3, 3.75, 4.2, and 4.7 Length: 6, 8, 10, 11.5, 13, and 16	311	Varied regions
Pang et al., 2014[14]	Korea	Prospective	40	Implant 4‖ and implant 5¶	Diameter: 4.0 Length: 10.0	54	Posterior mandible
Park et al., 2010[26]	Korea	Prospective	53	Implant 6# and implant 7**	Diameter: 4.1 Length: 10.0	71	Posterior mandible

* Value calculated by the authors of this review; only raw values were provided by the study selected.
† Tapered Screw-Vent MP-1 HA Dual Transition Selective Surface Implants, Zimmer Biomet, Warsaw, IN.
‡ Zimmer Spline crystalline MP-1 hydroxyapatite (HA)-coated cylinders, Zimmer Biomet.
§ Alfa Gate Bioactive, Alfa Gate Dental Implants, Kafar Qara, Israel.
‖ Mg-incorporated oxidized implants, M Implant System, Shinhung, Seoul, Korea.
¶ Blasted magnesium incorporated implants, M Implant System, Shinhung.
# Osstem SSII Implant, Osstem Implant, Leatherhead, U.K.
** Standard Straumann Dental Implant, Institut Straumann, Basel, Switzerland.

The results of the systematic review indicated there was significant numerical correlation between both stability measurement methods however only 46% of cases demonstrated coincidence in relation to implant stability classification. Overall the study concluded that both devices may provide reliable results but there is inadequate agreement between them in clinical application. Therefore they recommended a clinician choose their preference of device and follow-up all measurements with this same device (Andreotti et al., 2017).

Several studies have explored the association between the RFA device, Periotest™ and bone density in the form of in vitro and vivo research. Work performed by Alsaadi and team aimed to examine the validity of jaw bone quality assessment on implant therapy. As part of this research 22 patients and 44 implants had PTV and ISQ measurements recorded at implant placement and abutment surgery. Following statistical analysis, they identified a significant relationship between ISQ, Periotest values and cortical bone grades (*p = 0.02 & p = 0.0001* respectively) (Alsaadi et al., 2007).

A laboratory study by Hsu and colleagues also identified correlation between ITV, PTV, ISQ and features of bone density. This study involved stability measurements of 60 implants placed in synthetic bone models. The results of this experiment showed strong correlation between insertion torque, ISQ and Periotest values and thickness of cortical bone ($R^2 > 0.9$) and elastic modulus of trabecular bone (R^2 = 0.74-0.99) (Hsu et al., 2013).

During this period Schnitman and co-workers performed two similarly themed studies that evaluated correlation between resonance frequency analysis and damping capacity assessment. The purpose of the first study was to assess the predicative value of pre-operative implant stability in the form of insertion torque (IT), PTVs and ISQ when planning for one-stage surgery or implant loading protocols. The study concluded that computed tomography, insertion torque, PTV and ISQ correlated with each other (Schnitman and Hwang, 2011).

The subsequent publication produced a number of years later by Schnitman et al was a retrospective analysis of 80 dental implants in 27 patients that was investigating computer assisted guided surgery and bone quality in implant surgery. The analysis of the data demonstrated correlation between the operative measurements of ISQ and PTV when performed on the 80 implants. Based on a Spearman rank-based statistical test, PTV and ISQ were significantly correlated with the coefficient ($r = -0.33$, $p < 0.0001$) (Schnitman et al., 2014).

A prospective clinical study by OH & Kim from 2012 which was included in the Andreotti systematic review evaluated 162 patients and 211 implants .This publication assessed the relationship between ISQ and PTV measurements and bone quality. The study identified statistically significant correlation between bone quality type, ISQ and PTVs. A significant negative correlation between RFA values and Periotest values was observed ($r = -0.777$, $p < 0.01$). The article

concluded that these measurements seem to be useful in predicting implant placement prognosis and in determining loading protocols (Oh and Kim, 2012).

Earlier work by Oh & Kim produced in 2009 also concluded there was strong correlation between the Periotest™ & Osstell® Mentor when recording implant stability, this finding was based on the results of an experimental animal study in which 48 titanium implants were placed in the mandible and maxilla of four mongrel dogs and stability values recorded at implant insertion, 3 and 6 weeks post insertion (Oh et al., 2009).

Although considerable literature has been published in the area of implant stability measurements and bone density, much of the evidence has significant limitations and significant methodological heterogeneity leading to quite contrasting statistical results and therefore making definitive conclusions on this subject quite difficult.

A number of studies also included in the Andreotti review scrutinised implant stability measurements and various surgical techniques. Two studies published by Cannizzaro and co sought to investigate aspects of ridge and sinus augmentation. The earlier paper produced in 2007 was a prospective single-masked controlled trial with 40 patients 104 implants and a 12 month follow-up (Cannizzaro et al., 2007). This study evaluated augmentation of the atrophic edentulous maxilla with implants placed in the ulna compared to sites treated with conventional particulate bone grafts. Implant stability was measured using

Osstell® and Periotest™ devices at baseline, 6 and 12 months. Both treatment groups demonstrated significant increases in implant stability at 6 and 12 months There were no differences between the 2 groups at any time point in implant stability.

Several years later Cannizzaro and team published a prospective RCT with 37 subjects and 76 implants followed up over five years. This study compared the difference between 1-stage lateral sinus lift versus crestal sinus lift and 8mm hydroxyapatite coated implants. Osstell® and Periotest™ devices measured implant stability and there was no difference between groups at any time point. As would be expected ISQ values increased and Periotest values decreased over time (Cannizzaro et al., 2013).

Further work has investigated correlation between implant stability measurements and different types or surface design of dental implant. A randomised clinical trial performed by Park et al compared the implant stability of two types of non-submerged implants that had different thread designs and surface treatments. 75 implants were placed in 56 subjects consisting of Osstem SSII implants in the experimental group and standard Straumann® implants in the control group. Peak insertion torque, ISQ and PTVs were evaluated at time of surgery, 4 and 10 weeks post-surgery. The study demonstrated statistically significant differences between the two groups with ISQ values ($p = 0.003$) but interestingly not in Periotest values ($p = 0.097$) (Park et al., 2010).

Subsequent research by Palarie and co evaluated implant topography through a prospective clinical study of 124 participants and 311 implants. This paper evaluated the early outcome of a dental implant with bioactive calcium-phosphate (CaP) coating placed in partially edentulous patients with a 1-year follow-up. Mean ISQ values after 6 months were higher than those recorded after placement. Periotest values increased in the first 6 months and after that remained constant (Palarie et al., 2012).

Similarly an article by Pang et al in 2014 also researched implant surfaces of 54 dental fixtures placed in 40 patients. This study evaluated implant stability of magnesium incorporated oxidised implants (Mg titanite) and compared them to blasted magnesium-incorporated oxidised implants (blasted Mg titanite). Immediately after surgery and at 2 months, ISQ and PTV showed strong correlation however at 3 and 15 month follow-up this correlation was weaker. There was no significant correlation between the two implant systems at 15 months based on stability measurements, ISQ ($p = 0.988$) and PTV ($p = 0.935$)(Pang et al., 2014).

1.5 Conclusion

Overall a substantial body of evidence has now been accumulated in this field of implant dentistry. A range of studies have investigated the basis for correlation between ISQ values and Periotest values, and more specifically the association with clinical characteristics. Most studies have demonstrated some degree of correlation of varying strength between the Osstell® and Periotest™ device. Several studies have identified some degree of association between some clinical characteristics and these quantitative measurement devices (Alsaadi et al., 2007, Oh and Kim, 2012, Hsu et al., 2013), however other publications have produced conflicting results (Cehreli et al., 2009). It is also important to highlight the limitations of much of the literature with a trend for strong correlation in laboratory studies and weaker to no correlation in clinical studies. This may be due to methodological deficiencies or heterogeneity of the available literature. In conclusion further robust and well-structured research is essential to clarify this aspect of implant dentistry and enhance our armamentarium in the clinical management of implantology. Based on our assessment of the literature the following aims and objectives were established to further investigate these measurement devices. The primary purpose of this study was to evaluate correlation in stability measurements between these two devices and the secondary aim was to investigate factors that may influence stability measurements. Thirdly we sought to establish a normative range for Zimmer Biomet dental implants with an Osseotite® surface.

2. Materials & Methods

2.1 Study Design

This study was a prospective clinical study that evaluated the stability of dental implants at three different time points employing two different measurement devices. It primarily tested how the output values from the two devices correlated with each other. It also investigated the relationship between the output values and selected clinical characteristics.

2.2 Ethical Approval

Ethical approval was granted by the Research ethics committee of Dublin Dental University Hospital and the Joint Research Ethics Committee in St. James' Hospital (Reference number 2018-08) Appendix I.

2.3 Study Outline

After implant assessment on the department of Restorative Dentistry and Periodontology and subsequent recruitment into the study, a standard work-up and preparation for implant placement was performed. At the implant surgery appointment, data was collected based on the patient, site and surgery characteristics. Implant stability measurements were recorded by the Osstell® and Periotest device. ISQ values for the Osstell® device were collected in the bucco-lingual direction and the mesio-distal direction. The first set of stability measurements were recorded at implant placement using the RFA and DCA devices. Further implant stability

measurements were taken at second stage surgery and prior to the installation of the definitive prosthesis. A flowchart outlining the order of the study is presented in figure 2.1. A copy of the data collection form is available to view as appendix IV in the appendices section.

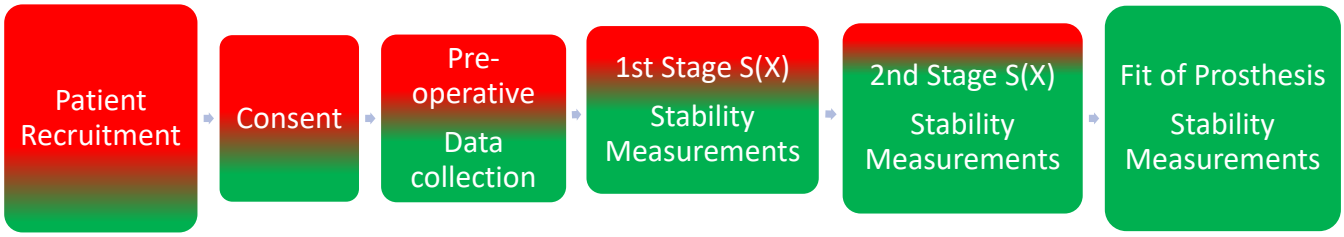


Fig 2.1 Study flowchart

2.4 Sample Population

2.4.1 Consent

The sample population was recruited from a cohort of patients referred to the periodontal department of Dublin Dental University Hospital for provision of dental implants.

This cohort of patients came from two pathways:

- Subjects that had been referred to Dublin University Dental Hospital from general practice or specialist practice for provision of dental implants.
- Subjects that had been referred from another department within the Dental Hospital for provision of dental implants.

On completion of a full assessment, patients that were deemed suitable for the study were provided with a patient information leaflet that outlined the purpose and process of the study. Patients that were enrolled in the study were required to sign a consent form. (Appendix II & III)

2.4.2 Inclusion Criteria

The following inclusion criteria were applied to the sample population:

- Male or female patients, 18 years old or over
- Planned for provision of dental implant(s) at Dublin Dental University Hospital

2.4.3 Exclusion Criteria

The following exclusion criteria were applied to the sample population:

- Pregnancy or lactation
- Those unable to provide consent

2.4.4 Sample Numbers

Based on the available evidence that has evaluated the correlation between the Osstell® and Periotest devices, a power calculation was performed to estimate the sample size required to achieve Power for the statistical analysis. This determination ensures a 95% chance of rejecting the null hypothesis when the projected population effect size is 0.6 and the alpha level for the test is 0.05. Based on this arithmetic 30 implants were required.

2.5 Stability Measurements

Osstell® Mentor device

The measurements for the RFA device were recorded after attaching the appropriate smartpeg to the implant and placing the probe tip of the Osstell® Mentor device close to the head of the smartpeg. Based on manufacturer guidance a suitable sized smartpeg was attached to the implant by tightening with finger pressure. Type 1 smartpegs were applied for external hex implants, type 15 for narrow and regular diameter internal hex dental implants and type 45 for wide diameter internal hex implants. Two measurements were taken from a mesio-distal and bucco-lingual direction. Three readings of each type taken and average of three readings used in the analysis. These readings were recorded as the implant stability quotient (ISQ).

Fig 2.2. Photograph of Osstell® Mentor (Integration Diagnostics AB, Gothenburg, Sweden).

Periotest™ device

Measurements for the Periotest™ device were recorded with the metal ‘slug’ tapped against the surface of a healing abutment connected to the dental implant. The head of the tapping pistol was directed as close as possible in a perpendicular direction towards the middle of the healing abutment. Two readings were recorded per implant fixture. For analysis the average of these two readings was taken as the Periotest value.

Fig 2.3. Photograph of Periotest™ device (Medizintechnik Gulden, Benheim, Germany).

Implant stability measurements (MRFA and DCA) were taken at the time of implant placement, second stage surgery and prior to fit of definitive prosthesis. Stability measurements were collected by two examiners, Dr. Ian Reynolds the lead investigator and Dr. Ioannis Polyzois the research supervisor.

2.6 Clinical Data

As mentioned previously all relevant data based on the patient, surgical site and surgical procedure was collected either prior to or during the surgery and recorded on a standardised data collection form. Specific clinical measurements including the tissue thickness and buccal, lingual, mesial and distal bone width were recorded to the nearest mm with a standard UNC 15 periodontal probe as seen in Appendix V. All dental implants installed were supplied by the manufacturer Zimmer Biomet. The design of dental implant was either parallel walled or tapered, non-platform switched Osseotite® dental implants. Choice of implant for each individual case was based on the clinical case and judgement of the surgeon. The diameter of the dental implants inserted were 3.25mm, 4mm and 5mm.

The length of the dental implants placed were 5mm,7mm, 8.5mm, 10mm, 11.5mm and 13mm. Fixtures were placed in the mandible and maxilla, anterior and posterior regions.

2.7 Statistical Analysis

During the study all data was entered into a Microsoft Excel spreadsheet. The data was then processed and transferred into IBM® SPSS software V26 for statistical analysis. Descriptive statistical analysis was initially performed on all of the accumulated data. The implant stability measurement data was evaluated by applying the Shapiro-Wilks test, Kolmogorov test and visible assessment of histograms. These investigations confirmed that the data was non-normally distributed. The correlation between Osstell® and Periotest™ values was determined by a Spearman's rho test.

Analysis of clinical factors and stability measurements was completed via Mann-Whitney or Krushal-Wallis test dependent on the number of groups in each variable.

3. Results

3.1 Introduction

As part of this prospective cohort study 29 subjects were consecutively recruited by convenience sampling and data was collected for 68 dental implants. As per the research protocol, clinical information was gathered and implant stability measurements were recorded by the following timeline.

Table 3.1 Data collection timeline for implant stability measurements

Timepoint	Clinical stage
T1	1st stage implant surgery
T2	2nd stage implant surgery
T3	Fit of prosthesis

The time period for T1 data collection ranged from the 17th September 2018 to 19th September 2019, T2 from the 12th February 2019 to 12th February 2020 and T3 from the 21st March 2019 to the 9th July 2020. At the 3rd timepoint data was gathered for 18 patients and 42 implants. Data collection was incomplete at the 3rd timepoint due to the impact of the Covid-19 pandemic and restrictions on clinical practice. One implant failed shortly after 2nd stage surgery, this resulted in an overall oral implant survival rate of 98%. Data collection included the following demographic factors; age, gender, ethnicity, smoking history and medication intake which was specifically bisphosphonates, selective serotonin re-uptake inhibitors (SSRIs) and proton pump

inhibitors (PPIs). Clinical measurements were categorized into implant position, site, surgery and fixture characteristics. Implant position was recorded by quadrant, jaw and anterior/posterior location. Implant site factors included bone thickness, tissue thickness, presence or absence of an adjacent tooth both mesially and distally, previous and simultaneous augmentation of the surgical site. Surgery factors consisted of timing of implant placement and apico-coronal positioning of the implant at placement. Finally implant characteristics included hex design, morphology, diameter and length of the implant. All these variables were categorical in nature and either nominal or ordinal excluding patient age which was quantitative and continuous.

3.2 Descriptive Results

3.2.1 Demographics

The mean subject age was 42.5 years with a range of 55 years from a minimum of 19 up to 74 years of age. There were 16 female and 13 male participants representing 55% and 45% of the patient cohort respectively. As a consequence of the small sample population ethnicity was classified as Caucasian or other and only one non-Caucasian subject was accounted in the study. Smokers were categorized as current, former or never smokers and the study cohort consisted of 10%, 14% and 76% respectively. At a patient level there was no intake of bisphosphonates, one case of SSRI intake and two cases of PPI.

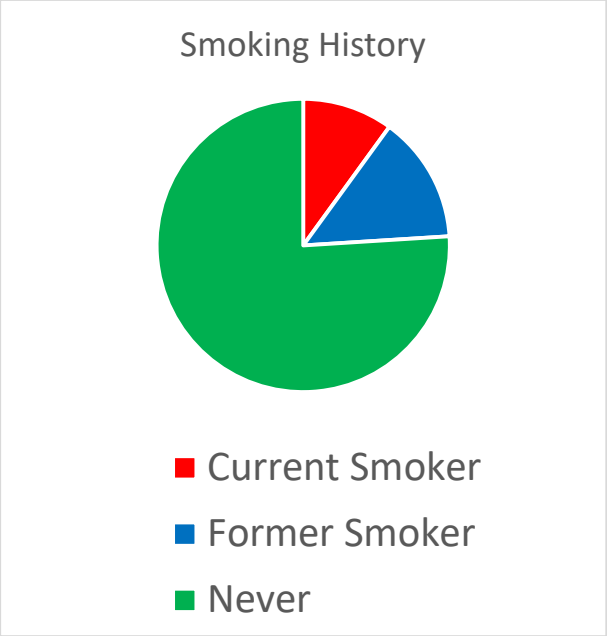


Figure 3.1 Pie chart of smoking distribution at a subject level

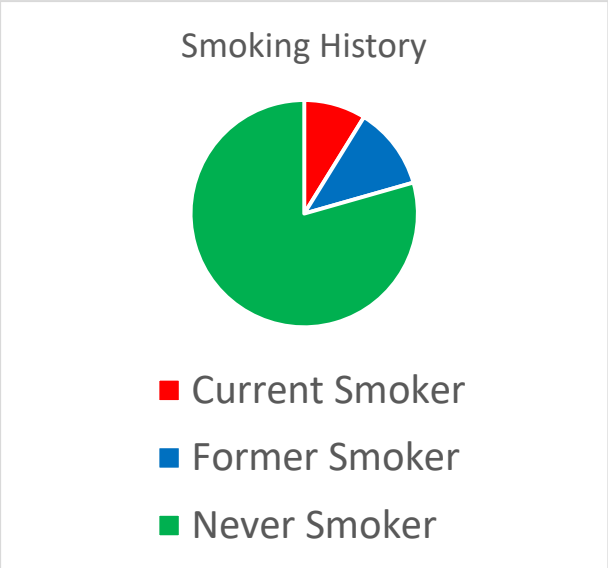


Figure 3.2 Pie chart of smoking distribution at implant level

3.2.2 Implant Position

41 of the dental implants were placed in the maxilla representing 60% of cases. 55 implants were placed in the anterior region representing 81% of cases. Anterior implant positioning was classified as premolar to premolar region while posterior positioning was regarded as any implant placement further back in the mouth. Implant placement by quadrant was distributed as follows; upper right quadrant 30%, upper left quadrant 31%, lower left quadrant 22% and lower right quadrant 22%.

Table 3.2 Characteristics of implant positions (Categorical Data)

Characteristic		Count	Percent (%)
Implant Position by Quadrant	Upper Right	20	30
	Upper Left	21	31
	Lower Left	15	22
	Lower Right	12	18
Implant Position by Jaw	Maxilla	41	60
	Mandible	27	40
Implant Position by Anterior/Posterior	Anterior	55	81
	Posterior	13	19

3.2.3 Implant Characteristics

59 of the dental implants placed had an internal hex design while the remaining 9 implants were of external hex design. The distribution of parallel and tapered implants was quite even at 33 and 35 respectively or 49% to 51% of the sample population. For implant diameter, 11 fixtures were 3.25mm wide, 44 were 4mm in width and 13 were 5mm in width. Implant length ranged from 5mm to 13mm with the majority of implants being 10mm or 11.5mm in length 23/68 and 31/68 cases respectively. To ensure adequate numbers for statistical analysis some of the implant lengths were aggregated into groups.

Table 3.3 Characteristics of implants (Categorical Data)

Characteristic		Count	Percent (%)
Implant Hex	Internal	59	87
	External	9	13
Implant Morphology	Parallel	33	49
	Tapered	35	51
Implant Diameter	3.25mm	11	16
	4mm	44	64
	5mm	13	19
Implant Length	5mm	2	3
	7mm	1	2
	8.5mm	8	12
	10mm	23	34
	11.5mm	31	45
	13mm	3	4
Implant Length (Collapsed Values)	≤8.5mm	11	16
	10mm	23	34
	≥11.5mm	34	50

3.2.4 Implant Site

The factors recorded with respect to the implant site included the bone thickness in the buccal and lingual aspect, presence or absence of an adjacent tooth, tissue thickness and previous or simultaneous ridge augmentation. The bone thickness and tissue thickness were measured free hand with a UNC-15 periodontal probe. Bone thickness was categorized as <1mm, ≥1mm and ≥2mm in both the buccal and lingual dimension. The majority of sites were ≥2mm, 36/68 in the buccal aspect and 34/68 in the lingual aspect. 13% of sites had a tissue thickness of ≥1mm while 87% of sites had a tissue thickness of ≥2mm. Presence or absence of an adjacent tooth was recorded dichotomously as Yes or No, 52% of sites had no adjacent mesial tooth and 56% of sites had no adjacent distal tooth. 50 sites had no previous augmentation, 10 sites had previously received lateral ridge augmentation and 8 sites had a previous maxillary sinus floor elevation procedure. Finally, 12 sites or 18% of cases had simultaneous ridge augmentation at implant placement.

Table 3.4 Characteristics of implant site (Categorical Data)

Characteristic		Count	Percent (%)
Buccal Bone Thickness	<1mm	4	6
	≥1mm	28	41
	≥2mm	36	53
Lingual Bone Thickness	<1mm	8	12
	≥1mm	26	38
	≥2mm	34	50
Tissue Thickness	≥1mm	9	13
	≥2mm	59	87

Adjacent Mesial Tooth	No	35	52
	Yes	33	48
Adjacent Distal Tooth	No	38	56
	Yes	30	44
Previously Augmented Site	No	50	74
	Yes- Lateral Ridge Augmentation	10	15
	Yes – Sinus Lift Procedure	8	11
Simultaneously Augmented Site	No	56	82
	Yes	12	18

3.2.5 Implant Surgery

For the timing of implant placement, 90% were by a delayed surgical approach and 10% were immediately placed. The apico-coronal parameter was recorded in a binary order as submerged or non-submerged, 37 implants were submerged below the bone crest and 31 implants were placed at crestal level.

Table 3.5 Characteristics of implant surgery (Categorical Data)

Characteristic		Count	Percent (%)
Timing of Implant Placement	Immediate	7	10
	Delayed	61	90
Apico-Coronal Positioning of Implant	Submerged	37	54
	Non-Submerged	31	56

3.3 Implant Stability Measurements

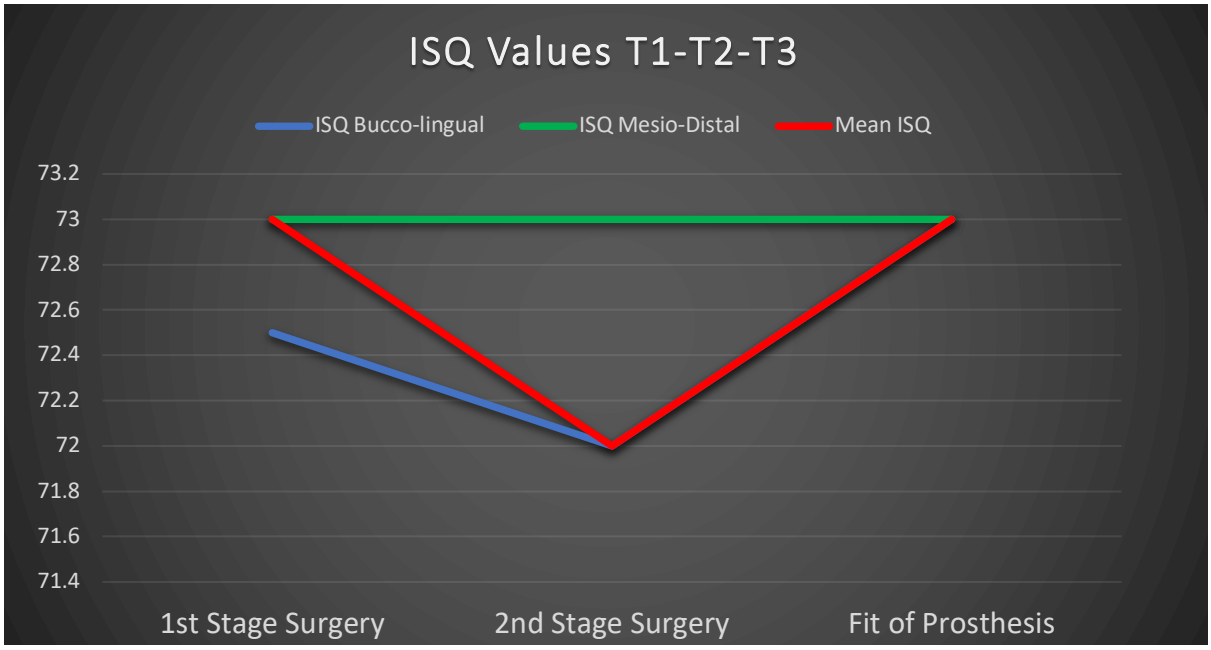


Figure 3.3 Graph of Median ISQ value from implant placement to fit of prosthesis

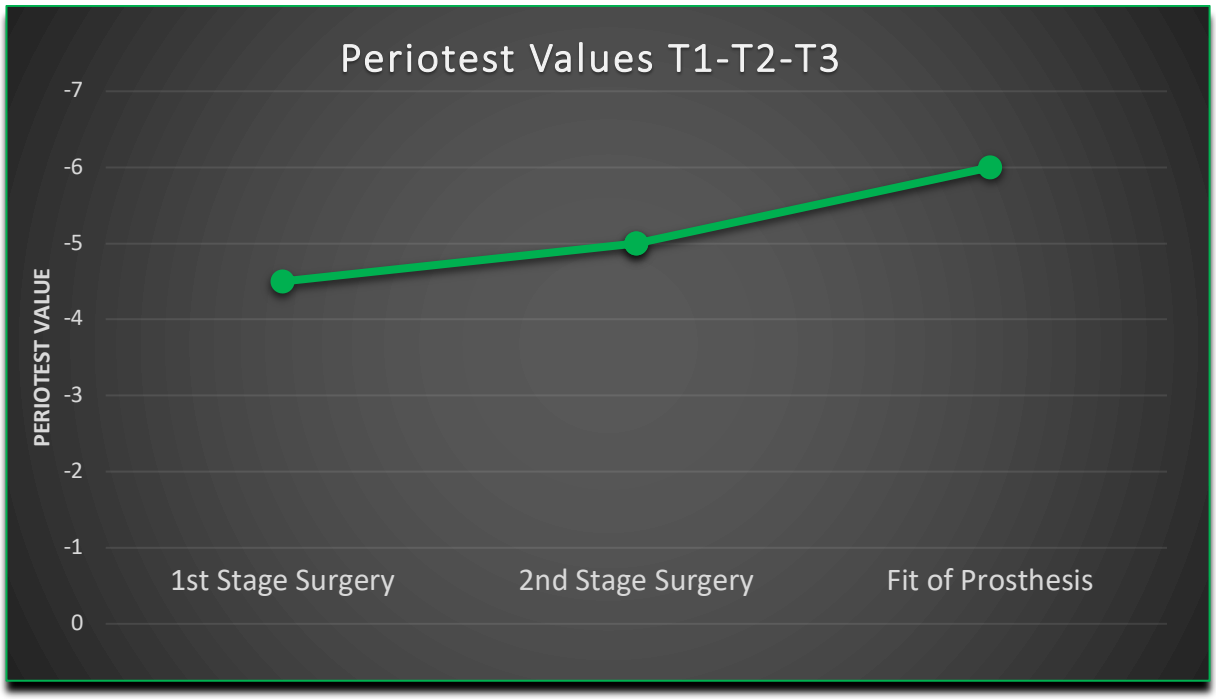


Figure 3.4 Graph of median PT value from implant placement to fit of prosthesis

In the histograms above the median ISQ in the bucco-lingual direction, mesio-distal direction and mean value for both directions is plotted at T1, T2 and T3. The mean ISQ value is 73 at implant placement, decreases to 72 by 2nd stage surgery and increases to 73 by fit of prosthesis. The histogram of Periotest values demonstrates a progressive decrease in PT value from -4.5 to -5 to -6 and inversely an increase of stability from implant placement to fit of prosthesis. Included below are comprehensive tables for the mean, median, standard deviation and interquartile range for implant stability quotient and Periotest values obtained at T1, T2 and T3.

Table 3.6 Summary of RFA and Periotest values over time (Median & Interquartile Range)

	1st Stage Surgery	2nd Stage Surgery	Fit of Prosthesis
Median $RFA_{buccolingual}$ Value (IQR)	72.5 (7.75)	72 (11)	73 (6)
Median $RFA_{mesiodistal}$ Value (IQR)	73 (8.75)	73 (9)	73 (5.5)
Median RFA_{M} Value (IQR)	73 (7.75)	72 (9)	73 (5.5)
Median Periotest Value (IQR)	-4.50 (4)	-5 (4)	-6 (5)

RFA_M = mean of $RFA_{buccolingual}$ + $RFA_{mesiodistal}$ = $RFA_{buccolingual}$ + $RFA_{mesiodistal}$ / 2

There was a statistically significant difference between mean Periotest values observed at T1, T2 and T3, $x^2(2) = 15.662$, $p = 0.000$. A Friedman test was performed to evaluate significant difference between the mean values for the three timepoints as the data was non-parametric. No statistically significant difference was observed for RFA values at different timepoints.

Table 3.7 Summary of ISQ and Periotest values over time (Mean & SD)

	1st Stage Surgery	2nd Stage Surgery	Fit of Prosthesis
Mean $RFA_{buccolingual}$ Value (SD)	70.7 (7.92)	69.6 (10.45)	73 (4.89)
Mean $RFA_{mesiodistal}$ Value (SD)	70.9 (7.58)	70.8 (7.89)	72.5 (5.55)
Mean RFA_M Value (SD)	70.8 (7.40)	70.2 (8.51)	72.4 (5.42)
Mean Periotest Value (SD)	-3.79* (4.65)	-4.60* (2.98)	-5.55* (2.14)

RFA_M = mean of $RFA_{buccolingual}$ + $RFA_{mesiodistal}$ = $RFA_{buccolingual}$ + $RFA_{mesiodistal}$ / 2

3.3.2 Range of RFA and DCA values

The range of ISQ values obtained, which can also be described as the difference between the lowest and highest ISQ value recorded was shown to decrease from T1 to T3, this was observed with ISQ values recorded in the bucco-lingual and mesio-distal direction and as a mean of ISQ values in both orientations. Overall the minimum ISQ value recorded in the study was 30 and the maximum was 90. From T1 to T3 in the bucco-lingual direction the range of ISQ values narrowed from 59 ISQ points at T1 to 19 at T3, in the mesio-distal direction the ISQ values narrowed from 41 at T1 to 21 at T3 (Figure 3.5).

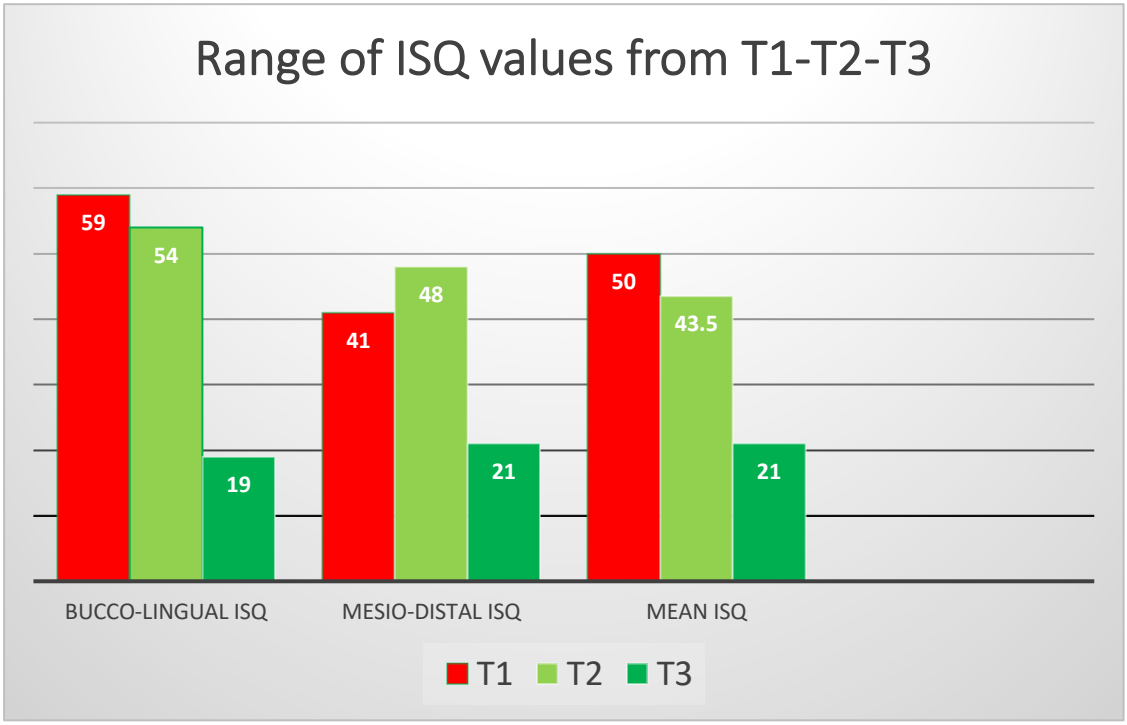


Figure 3.5 Bar chart of ISQ range at T1, T2 and T3

The range of Periotest values was 37 units at T1, 11 units at T2 and decreased to 6 units at T3 to reflect a narrowing of PT values from implant placement to fit of prosthesis. This is outlined in the histogram below. The maximum PT value recorded was 29 and the lowest -8.

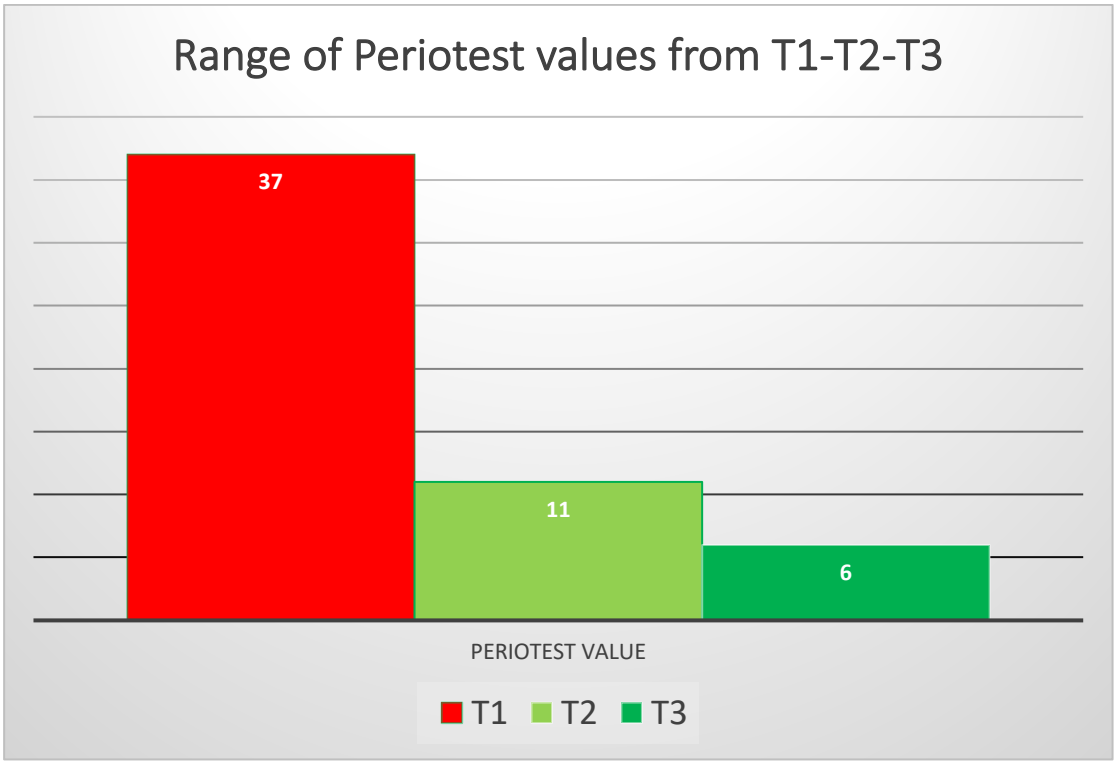


Figure 3.6 Bar chart of PTV range at T1, T2 and T3

3.4 Correlation between RFA and Periotest values

The relationship between ISQ values and PT values was evaluated at T1, T2 and T3. Statistical analysis was performed to identify correlation between Periotest values and ISQ values attained in the bucco-lingual direction, mesio-distal direction and the mean of the value in both directions. Correlation between the values for the Osstell® and Periotest™ was performed with a Spearman's Rho test after confirmation that the data was non-parametric.

Table 3.8 Spearman's Rho Correlations between ISQ and PT value at T1, T2 & T3

		1st stage surgery	2nd stage surgery	Fit of Prosthesis
Bucco-lingual ISQ vs PTV	Coefficient	-.180	-.312*	-.277
	Sig. (2-tailed)	.142	.010	.083
Mesio-distal ISQ vs PTV	Coefficient	-.347**	-.363**	-.287
	Sig. (2-tailed)	.004	.003	.065
Mean ISQ vs PTV	Coefficient	-.279*	-.368**	-.342*
	Sig. (2-tailed)	0.021	.002	.026

*. Correlation is significant at the 0.05 level (2-tailed)
**. Correlation significant at the 0.01 level (2-tailed)

The analysis identified a variable statistically significant negative correlation for the ISQ and PT values which was dependent on timepoint and direction of ISQ measurement. A weak to moderate level of statistically significant correlation was observed across timepoints for mean ISQ and Periotest values. The strongest relationship was demonstrated between the mean ISQ value and PT value at T2 with a

coefficient of -0.368** (*p = 0.002*). This is illustrated visually in the scatterplot below with RFA values in the Y-axis and Periotest values in the X-axis.

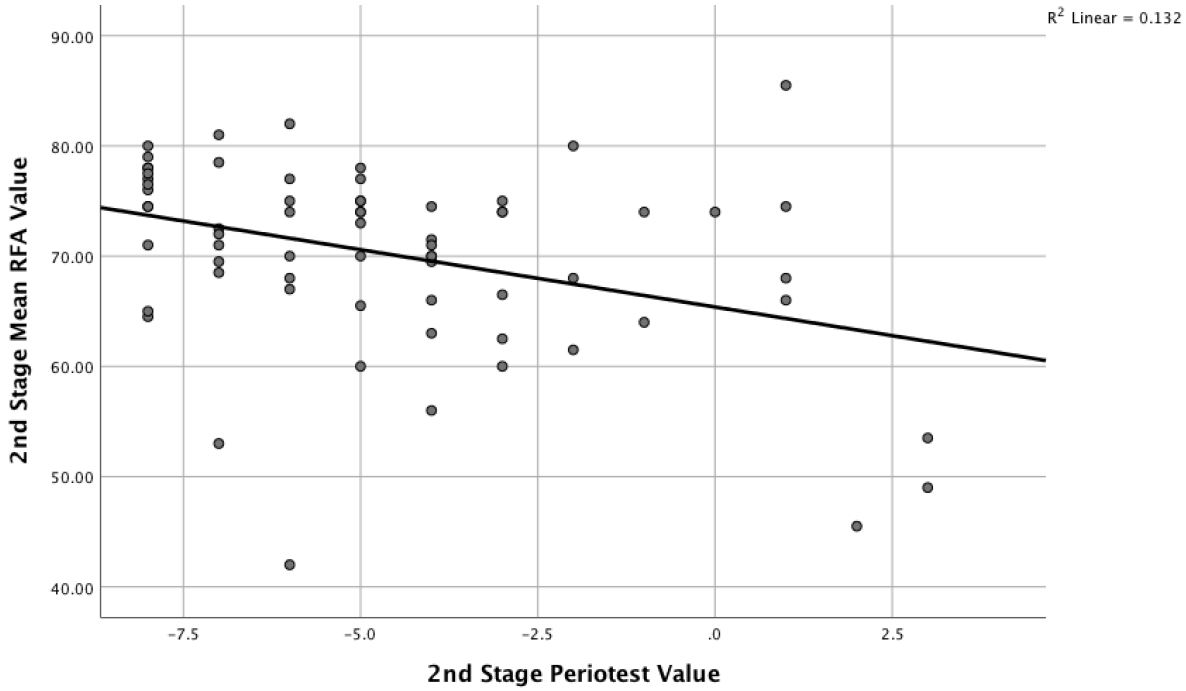


Figure 3.7 Scatterplot of Mean RFA value vs Periotest value at T2

3.5 Clinical Factors and Implant Stability Measurements

Clinical characteristics were evaluated and compared to mean implant stability measurements of the Osstell® and Periotest™ device at T1, T2 and T3. This was investigated by statistical analysis with a Mann-Whitney or Kruskal Wallis test. Choice of statistical test was determined by the number of groups in each variable. Demographic factors of ethnicity and medication intake were excluded from the statistical analysis due to the limited sample size. The majority of clinical factors that

were compared to mean ISQ and PT values demonstrated a statistically significant difference between groups of a clinical feature at specific timepoints rather than across all time points. In several cases, differences between groups within a clinical feature and mean ISQ values were identified but this was not consistent for bucco-lingual ISQ, mesio-distal ISQ and the mean ISQ values. The Periotest™ device demonstrated a similar trend with most clinical factors demonstrating some significant difference at one time point but not across all time points. Several clinical characteristics when compared to mean ISQ and Periotest stability measurements did not display any statistically significant difference between groups. These clinical features are listed below.

1. Anterior/posterior implant position
2. Immediate/delayed implant placement
3. Submerged or non-submerged implant placement
4. Previous ridge augmentation
5. Simultaneous ridge augmentation

The single clinical feature that did demonstrate a consistent trend across all timepoints and with both devices was implant position and more specifically difference between the maxilla and mandible. At T1 and T2 the mean ISQ and Periotest values were significantly different between the upper and lower jaw. Higher ISQ values and lower PT values were indicated in the mandible compared to the maxilla. These results are visualized in the boxplots outlined below that show the difference between implant position by jaw and stability measurements for the

Osstell® and Periotest™ device at implant placement and 2nd stage surgery. At T1 N=27 for the mandible while at T2 N=26 for the mandible while at T1 & T2 N=41 for the maxilla.

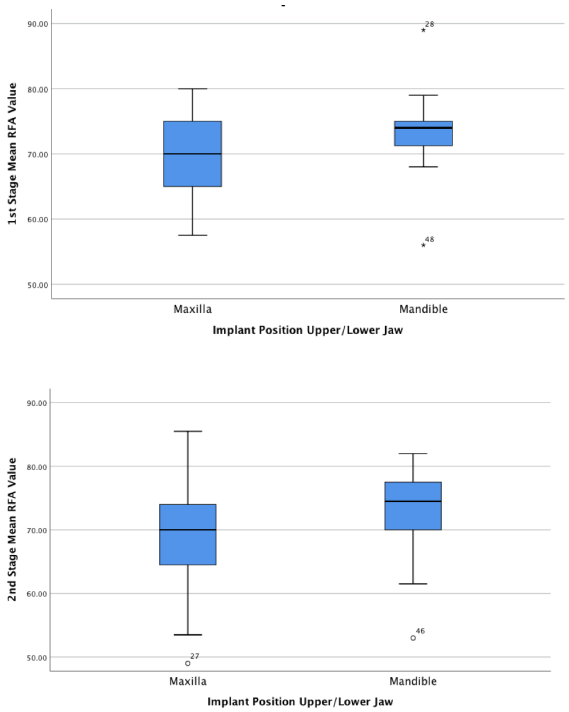


Figure 3.8 Boxplots of ISQ compared to implant position by jaw at T1 & T2

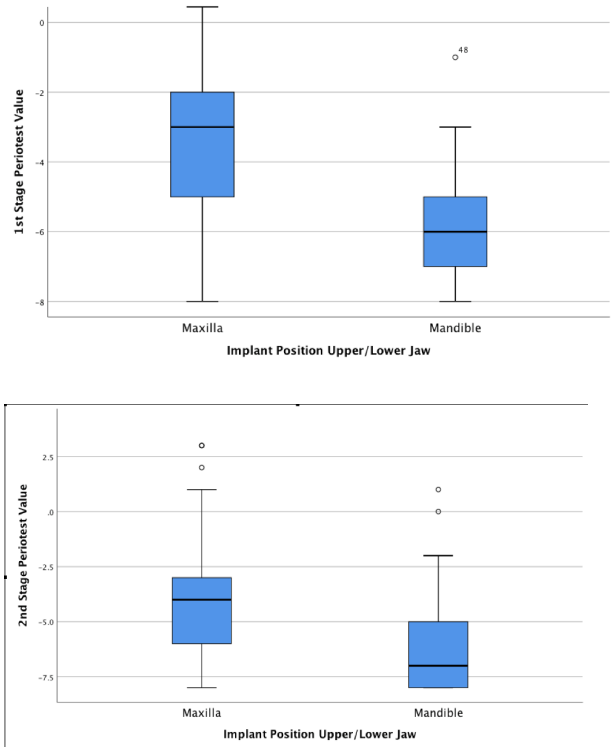


Figure 3.9 Boxplots of PTV compared to implant position by jaw at T1 & T2

Two extensive tables below illustrate the statistically significant differences that were identified between mean ISQ or Periotest values and groups in each clinical characteristic.

The tables delineate each clinical characteristic, their individual groups and numbers included for analysis. The tables also describe the timepoint, type of stability measurement and *p-value* obtained. Finally, there is a brief explanation of the clinical relevance of the result. The complete set of data can be seen in appendix VI & VII.

Table 3.9 Comparative analysis between clinical characteristics and implant stability measurements with Osstell® device

Clinical Characteristic	Timepoint	Measurement	*p-value*	Finding
Smoking History T3 N=42 Never smoker N=31 Former Smoker N=7 Current Smoker N=4	T3	ISQ Buc/Ling	*p = 0.045*	Never smokers have higher ISQ values than former or current smokers
Implant Position **T1 N=68** **Maxilla N=41** **Mandible N=27** **T2 N=67** **Maxilla N=41** **Mandible N=26**	**T1**	**ISQ Mes/Dis**	***p = 0.020***	**Higher ISQ values were observed for the mandible compared to maxilla**
		ISQ Mean	***p = 0.028***	
	T2	**ISQ Buc/Ling**	***p = 0.020***	
		ISQ Mes/Dis	***p = 0.015***	
		SQ Mean	***p = 0.010***	
Implant Position T3 N=42 Anterior N=34 Posterior N=8	T3	ISQ Mes/Dis	*p = 0.040*	Higher ISQ values observed in anterior compared to posterior Region
		ISQ Mean	*p = 0.045*	
Implant Hex T1 N=68 Internal Hex N=59 External Hex N=9 T3 N=42 Internal Hex N=35 External Hex N=7	T1	ISQ Buc/Ling	*p = 0.028*	Higher ISQ values were indicated for external hex compared to internal hex implants
		ISQ Mes/Dis	*p = 0.033*	
		ISQ Mean	*p = 0.025*	
	T3	ISQ Buc/Ling	*p = 0.007*	
Implant Diameter T3 N=42 3.25mm N=5 4mm N=29 5mm N=8	T3	ISQ Buc/Ling	*p = 0.016*	Wide diameter implants demonstrate higher ISQ values compared to standard & narrow diameter implants
		ISQ Mes/Dis	*p = 0.013*	
		Mean RFA	*p = 0.014*	
Implant Length	T1	ISQ Buc/Ling	*p = 0.044*	

T1 N=68 ≤8.5mm N=11 10mm N=23 ≥11.5mm N=34 T3 N=42 ≤8.5mm N=17 10mm N=22 ≥11.5mm N=3				Shorter length implants demonstrate higher ISQ values
		ISQ Mean	*p = 0.030*	
	T3	ISQ Buc/Ling	*p = 0.043*	
Apico-Coronal Implant Placement T2 N=67 Submerged N=37 Not Submerged N=30	T2	ISQ Buc/Ling	*p = 0.042*	Higher ISQ values observed for submerged compared to non-submerged implants
Buccal Bone Thickness T3 N=42 <2mm N=23 ≥2mm N=19	T3	ISQ Buc/Ling	*p = 0.015*	Higher ISQ values observed for thicker bone
Lingual Bone Thickness T3 N=42 <1mm N=8 ≥1mm N=15 ≥2mm N=19	T3	ISQ Buc/Ling	*p = 0.021*	Higher ISQ values observed for thicker bone
Mesial Adjacent Tooth T1 N=68 No N=35 Yes N=33 T3 N=42 No N=24 Yes N=18	T1	ISQ Buc/Ling	*p = 0.036*	The presence of an adjacent mesial tooth demonstrated higher ISQ values
		ISQ Mean	*p = 0.042*	
	T3	SQ Buc/Ling	*p = 0.001*	
		ISQ Mes/Dis	*p = 0.010*	
		ISQ Mean	*p = 0.006*	
Distal Adjacent Tooth T3 N=42 No N=25 Yes N=17	T3	ISQ Buc/Ling	*p = 0.000*	The presence of an adjacent distal tooth demonstrated higher ISQ values compared to absence of a tooth
		ISQ Mes/Dis	*p = 0.007*	
		ISQ Mean	*p = 0.004*	

Table 10.10 Comparative analysis between clinical characteristics and implant stability measurements with Periotest™ device

Clinical Characteristic	**Timepoint**	**Measurement**	***p-value***	**Finding**
Gender T3 N=42 Male N=21 Female N=21	T3	PTV	*p = 0.027*	Males demonstrate lower Periotest values (higher stability) compared to females
Smoking History T2 N=67 Never N=53 Former N=8 Current N=6	T2	PTV	*p = 0.023*	Former smokers have higher PT values (lower stability) than current or never smokers
Implant Position **T1 N=68** **Maxilla N=41** **Mandible N=27** **T2 N=67** **Maxilla N=41** **Mandible N=26**	**T1**	**PTV**	***p = 0.000***	**Lower Periotest values (higher implant stability) identified for mandible compared to maxilla**
	T2	**PTV**	***p = 0.002***	
Implant Position By Quadrant T1 N=68 Upper Right N=20 Upper Left N=21 Lower Left N=15 Lower Right N=12 T2 N=67 Upper Right N=20 Upper Left N=21 Lower Left N=15 Lower Right N=11	T1	PTV	*p = 0.000*	Lower Periotest values (higher stability) observed in the lower left and lower right quadrant
	T2	PTV	*p = 0.015*	

Implant Hex T2 N=67 Internal Hex N=58 External Hex N=9 T3 N=42 Internal Hex N=35 External hex N=7	T2	PTV	*p = 0.027*	Lower PTV values (higher stability) observed for external compared to internal hex
	T3	PTV	*p = 0.038*	
Implant Morphology T1 N=68 Parallel N=33 Tapered N=35 T2 N=67 Parallel N=32 Tapered N=35	T1	PTV	*p = 0.001*	Parallel implants demonstrate lower Periotest values (higher stability) than tapered implants
	T2	PTV	*p = 0.037*	
Implant Length T1 N=68 ≤8.5mm N=11 10mm N=23 ≥11.5mm N=34	T1	PTV	*p = 0.04*	Shorter length implants demonstrate lower Periotest values (higher stability)
Buccal Bone Thickness T1 N=68 <2mm N=32 ≥2mm N=36 T2 N=67 <2mm N=31 ≥2mm N=36	T1	PTV	*p = 0.024*	Greater bone thickness associated with lower Periotest values (higher implant stability)
	T2	PTV	*p = 0.002*	
Lingual Bone Thickness T1 N=68 <1mm N=8	T1	TV	*p = 0.021*	Greater bone thickness associated with lower Periotest values (higher implant stability)

≥1mm N=26 ≥2mm N=34 T2 N=67 <1mm N=8 ≥1mm N=26 ≥2mm N=34	T2	PTV	*p = 0.004*	
Distal Adjacent Tooth T3 N=42 No N=25 Yes N=17	T3	PTV	*p = 0.040*	Sites adjacent teeth demonstrated lower PTV values (higher stability)

3.6 Implant Failure

A single implant failure was reported during the study and this loss was observed four weeks after 2nd stage surgery. At a subject level the patient was a 56 years old Caucasian male and a former smoker. The individual also reported intake of proton pump inhibitor medication. A 4mm x 10mm tapered Osseotite® Zimmer Biomet dental implant was placed in an edentulous anterior maxilla site. The area had been previously developed by a lateral ridge augmentation procedure with a xenograft material. The ISQ values recorded at implant placement were 68 in the bucco-lingual direction and 69 in the mesio-distal direction while the Periotest value was -6. At implant exposure the bucco-lingual implant stability quotient value was 41 and the mesio-distal ISQ value was 57 while the PT value had increased to 3. At the 2nd stage surgery clinically and radiographically there were no obvious signs of implant failure.

4. Discussion

The fundamental purpose of this study was to expand our knowledge of the Osstell® and Periotest™ implant stability measurement devices. The main aim of this study was to determine if there is a correlation between the values produced by the two devices at implant insertion, following integration of the fixture and loading of the implant. Secondly we investigated if certain clinical or other patient characteristics can affect the values produced by the two devices at these three time-points. Thirdly we sought to identify a normative range for Zimmer Biomet implants with an Osseotite® surface. This was attempted by employing a prospective cohort study design. The selection of research methodology is supported in the literature and in particular in a narrative review by Aparicio and team (Aparicio et al., 2006). In their publication the researchers advocated for future controlled prospective studies to determine the prognostic value of these measurement instruments.

For the study herein, implant stability measurements were recorded at three time points with both the Osstell® and Periotest™ devices. The purpose of performing data collection at these specific time points was to reflect standard clinical practice in implant therapy and ensure the research findings could be extrapolated to real world clinical application. Much of the historical research published on this topic has recorded stability measurements at weekly intervals

commencing with implant placement (Huwiler et al., 2007, Nedir et al., 2004). The aim of those studies was to closely scrutinise the alterations in implant stability that occur during osseointegration. In contrast our study sought to elucidate knowledge that may be more directly applied to clinical practice.

A gradual increase in implant stability was recorded by the Periotest™ device over time. From implant placement to fit of prosthesis the median PT value depreciated from -4.5 to -6 and narrowed in range of values from T1 to T3. The PT value ranged from 29 to -8 at 1st stage surgery and -2 to -8 at fit of prosthesis. This narrowing of Periotest™ values is supported by the existing literature. The mean change in Periotest™ values was statistically significant over time however the mean PT value of -5.55 at fit of prosthesis stage would seem to be lower (higher stability) when compared to the findings of similar studies. Research by Winkler and team (Mean PTV -3.5) & Truhlar and colleagues (Mean PTV -3.4) demonstrated higher mean PT values than those identified in our study. We could postulate that this may be due to the implant system used in the study herein as other research has mainly examined implant stability with Straumann® and Nobel Biocare™ dental implant systems. This potential for difference between implant stability values and implant systems has been previously referenced in the literature specifically for RFA devices (Sennerby and Meredith, 2008).

A different trend was identified for the Osstell® device with a non-significant increase in mean RFA values identified over time. A median ISQ value of 73 was determined at implant placement, decreasing to 72 at 2nd stage surgery and returning to 73 by fit of prosthesis. This does not equate to the body of evidence available. However the RFA device did demonstrate a narrowing of values recorded from T1 to T3, 30-89 ISQ at implant placement and 61-82 ISQ at fit of prosthesis, which does correspond to the published studies. Research has suggested that a merging of high & low stability measurements to a narrower normalised range does occur over time and this process reflects the density of bone that the implant was placed into and the mechanism of osseointegration (Friberg et al., 1999b, Balleri et al., 2002). A normative range of 61-82 ISQ was identified in the study herein for Zimmer Biomet oral implants while in previous articles a normative range of 57-70 ISQ has been proposed for Straumann® fixtures (Huwiler et al., 2007) and 57-82 for Branemark oral implants (Balleri et al., 2002).

Previous evidence has confirmed the reliability of Periotest readings between operators with no need for calibration therefore this may mitigate the potential bias of multiple operators recording stability measurements. High intra and inter reliability was elucidated in the work published by Manz and team (Manz et al., 1992b, Manz et al., 1992a). In contrast Bilhan and co demonstrated poor intra and inter reliability of the Periotest™ device (Bilhan et al., 2015). The accuracy was excellent in the bucco-lingual direction but poor in the mesio-

distal direction, this may reflect the difficulty of access associated with an adjacent tooth. This has been acknowledged in previous literature and was the personal experience of the researchers in this study.

In respect of the RFA device the researchers in this study experienced difficulty on several occasions recording the bucco-lingual ISQ measurement of implants placed in the anterior maxilla. Numerous attempts were required to achieve a measurement and in two cases despite repeated efforts, it was not possible to record any ISQ value. This was curious as these implants did not present with any particular access issues or unusual clinical features. During the course of the study, this was the independent experience of both the lead researcher and research supervisor but interestingly this anomaly has not been reported in the literature. In contrast the published evidence has referenced the potential impact of access in the oral cavity, specifically presence of adjacent teeth as a factor that may hinder measurements in the mesio-distal direction (Mistry et al., 2014).

The results of this study demonstrated a weak/moderate level of negative correlation between Osstell® & Periotest™ measurements at T2 for all values and for mean ISQ values across all time points. There was a moderate level of correlation between the stability values recorded with RFA and Periotest instruments at 2nd stage surgery, this degree of correlation was similar for bucco-lingual, mesio-distal and mean ISQ values compared to PT values. Weak

to moderate correlation was also identified across all timepoints when the mean ISQ value was paired with the Periotest values. This correlation was weaker at T1 (r = -0.279, *p = 0.002*) and as expected, similar at T2 (r = -0.368, *p = 0.002*) and T3 (r = -0.342, *p = 0.026*) This result is consistent albeit weaker than those of Merhab and Co (*r = -0.52, p < 0.001*) and Zix and team (r = -0.650) (Merheb et al., 2010, Zix et al., 2008). Both of those studies demonstrated a moderate correlation between ISQ and PT values at implant placement and loading. The larger sample size and use of a different implant system may explain the stronger correlation observed in these studies. Similarly the statistical results of the study herein are weaker when compared with work by Seong and team as well as a series of studies by Lachmann and team (Lachmann et al., 2006a, Lachmann et al., 2006b, Seong et al., 2008). They identified a correlation of (r = -0.852), (R^2 = 0.8*, p < 0.0001)* and *(*R^2 = 0.89*, P < 0.0001)* respectively. These investigators performed laboratory based research on the devices in contrast to the clinical nature of our study. The easier access, direction and orientation when operating these machines in a non-clinical environment has been proposed as a reason for the higher level of correlation observed in an experimental study setting.

Another aspect to consider when comparing RFA and Periotest™ devices is the requirement for two measurements with the Osstell® machine in contrast to one reading with the Periotest™ machine. The importance of recording a bucco-lingual measurement and separate mesio-distal measurement with the Osstell™

is well documented through manufacturer guidance and in the literature, however most studies have only analysed the mean of the ISQ value recorded in both directions. This limited evaluation of the true functionality of the Osstell® may hide superiority of this device in comparison to the Periotest™ machine. From a clinical perspective bone deficiencies in the alveolar ridge are most prevalent in the bucco-lingual dimension rather than the mesio-distal. Single Periotest™ measurements may fail to reveal differences in implant stability as a direct relationship to bony deficiency in the bucco or lingual region. The findings of this study would seem to support these interpretations. This difference in values and correlation may be explained by the transition from primary to secondary stability. The discrepancy between bucco-lingual and mesio-distal stability measurements dissipates gradually during osseointegration and reflects the increased level of correlation between Osstell® & Periotest™ from implant placement to fit of prosthesis. In our study, weaker and statistically non-significant correlation was identified at T1 and T3 in the bucco-lingual direction values however a moderate correlation was demonstrated for the mesio-distal direction values at T1 & T2. As acknowledged above the smaller sample population available at T3 increases the potential for a Type II error and hinders scrutiny of this hypothesis. On this basis it may be beneficial for future research to explore the differences between RFA and Periotest readings when measurements are performed in multiple directions and investigate differences between the instruments.

As part of our analysis, the potential effect that a number of clinical factors as well as some other patient characteristics can have on the values produced by the two devices was comprehensively examined. Patient factors, implant features and surgical site characteristics were all investigated. A substantial limitation when evaluating these factors was the small sample size that could be applied for statistical analysis for each variable. In particular medication intake and gender were excluded from further investigation due to the absence of adequate numbers. The original plan to perform a logistic regression analysis was also deemed unfeasible following comparative analysis between variables and stability measurements. As outlined extensively in the results section many of the variable groups examined did not demonstrate a consistent statistically significant difference to mean stability measurements. Despite the computational analysis revealing a statistically significant difference for many variable groups the results were not uniform across timepoints or devices.

Statistically significant higher ISQ values were recorded from implants placed in the lower jaw when compared to the ISQ values recorded from implants placed in the upper jaw. Similarly, lower PT values were recorded in the mandible compared to the maxilla. These findings are in agreement with several other published articles in which higher RFA values and lower Periotest values were recorded in the mandible (Balleri et al., 2002, Bischof et al., 2004). Research by Seong et al specifically utilised Biomet 3i dental implants and evaluated the relationship between stability measurements and jaw position. In agreement

with the study herein, they reported significantly different mean stability values for the maxilla and mandible when measured by the Osstell® and the Periotest™ devices.

The literature has suggested that implant position, fixture height above bone level, implant width, implant topography and implant position between upper and lower jaw may influence ISQ values. For the Periotest™, evidence suggests striking position of the tapping rod and jaw location can influence values and jaw position may affect PT values. Although our study did not investigate all of the factors listed above, there is substantial ambiguity in the accumulated literature regarding implant stability measurements and clinical factors. I would surmise that beyond implant position and related bone density no other clinical factor has demonstrated an adequately strong and consistent association to implant stability measurements.

Simultaneous or previously grafted sites would be of particular interest to explore in the future with adequately powered studies. Intriguingly from our study, the two dental implants that demonstrated the lowest stability values were from augmented sites. One of the surgical areas received guided bone regeneration prior to implant placement and the other was simultaneously augmented at the time of implant placement. During the course of the study the implant placed in the previously grafted site was later reported as a failure. A

bucco-lingual ISQ value of 41 and mesio-distal ISQ value of 57 (Mean ISQ 49) was recorded several weeks prior to the clinical failure of the dental implant. These values were recorded at the time of implant exposure and in this period there were no associated clinical or radiographic signs that indicated future implant failure. The initial ISQ values at implant placement were 68 and 69 for bucco-lingual and mesio-distal direction respectively. The Periotest values demonstrated a similar trend with an initial value of -6 at implant insertion and an increased value of 3 at 2nd stage surgery. These changes in stability measurement values are reflective of reduced implant stability and support the argument that these devices may act as a prognostic indicator for implant failure. The measurement of a significantly reduced ISQ value in the absence of negative symptoms or implant mobility are consistent with the literature from Friberg and Co in which an implant failed several weeks after a significantly reduced ISQ value had been recorded despite the absence of any other negative clinical signs that would indicate potential future implant failure (Friberg et al., 1999a). Interestingly a study produced by Nedir and team proposed a cut-off ISQ value that would act as a predictor for implant stability. Based on the results of their study they proposed an ISQ of 47 and this yielded a sensitivity of 100%. The findings of the implant failure in our case correspond quite well with those of Nedir and colleagues (Nedir et al., 2004). Similarly research by Noguerol et al suggested a cut-off point of -2 for the Periotest™ as a prognostic indicator for implant loss (Noguerol et al., 2006). These results are approximate with those of our study and support the proposition that the RFA and Periotest™ devices may provide clinical value as prognostic indicators for implant failure.

The application of a clinical study model is a definite advantage to this study in contrast to much of the published evidence based on experimental and pre-clinical research. The use of a single implant system is an obvious strength of this study and to the best of the authors knowledge this is the first study of this type that has utilised Zimmer Biomet oral implants. The results of this research contribute to the establishment of normative ISQ and PT value range for Zimmer Biomet dental implants with an Osseotite® surface. As acknowledged before, the measurement of implant stability values at implant placement, 2nd stage surgery and fit of prosthesis is certainly a strength of the study. In comparison to much of the available literature, this allows the findings of our research to be extrapolated to a more general clinical environment as the procedures and timing are more compatible with normal clinical practice.

Due to the Covid-19 pandemic data collection was severely disrupted for the 2nd stage surgery and fit of prosthesis phase of data collection (T3). In particular recording of implant stability measurements at the 3rd timepoint was significantly affected as a consequence of reduced clinical access to research subjects. A smaller proportion of patients and implants were therefore included in the analysis for the 3rd timepoint. This may have skewed the results and findings of statistical analysis at the last stage. This limitation increases the potential for a Type 2 error as the sample size is reduced and the null hypothesis may be accepted when in fact it is false. Overall the small sample population was a significant impediment to effective analysis of the relationship between

stability measurements and clinical characteristics. A larger population size in future research would substantially improve the ability to evaluate this aspect of implant stability measurements and clinical factors in particular the ability to perform a logistic regression analysis. To a similar extent the assessment of correlation between Periotest™ and Osstell® measurements was also affected by reduced numbers specifically at T3.

Lack of calibration for clinical measurements specifically bone and tissue thickness may have introduced measurement errors to the study. The pooling of a large number of implants in a small number of patients is an obvious limitation to the study and increases risk of bias particularly when analysing clinical factors. Ideally single implants in individual participants would be a more favourable format for analyses of this type. Due to the challenge of case recruitment and time restrictions imposed by the Doctorate this was not feasible. These issues should be considered in future studies to improve the quality of research.

In our study hand tightening of smartpegs was performed, this is supported by some of the literature (Kastel et al 2019) however other studies dispute this recommendation. They suggest that a specific controlled force should be applied to tighten the smartpeg to the implant to ensure accurate readings (Geckili et al 2015, Barella et al 2019). The majority of studies that investigate RFA measurement devices have manually tightened the smartpegs and there is nominal reference to the use of controlled force. In the clinical environment it

would be reasonable to assume that hand tightening of the smartpeg is the standard practice.

An interesting avenue of future research would be the application of our study design to investigate osseodensification, a novel surgical method for osteotomy preparation. This drilling technique utilises a non-subtractive approach to the implant site in comparison to traditional techniques that apply a subtractive approach. These burs have been advocated to improve implant stability, bone density and bone to implant contact compared to standard subtractive techniques. It would be worthwhile to elucidate the ISQ and Periotest values obtained with this modern surgical technique and also to compare them to the values obtained with traditional drilling methods.
It would be interesting to investigate if techniques that claim to improve and accelerate osseointegration such as osseodensification actually do so by applying a similar research design.

This study has incrementally added to our understanding of implant stability measurement devices in particular the Osstell® and Periotest™. The findings of correlation between implant stability measurements and interrelation to implant position have strengthened and confirmed the consistency of previous publications. This paper has proposed a normative range for ISQ and PT values for Zimmer Biomet implants and supports the suggestion that a narrowing of stability measurement values develops from implant placement to fit of prosthesis. Finally this research has strengthened the proposal for these devices

to act as prognostic indicators for implant failure. Overall, the study design employed in our research addressed several limitations of previous studies. Future research should however aim to resolve the numerous methodological deficiencies outlined above to enhance the quality of evidence in this field.

5. Conclusion

The purpose of this study was to determine a level of correlation between the Osstell® mentor and Periotest™ implant stability measurement devices. As part of this study we also sought to evaluate the influence of clinical characteristics on values obtained from these measurement instruments. To answer these clinical questions a prospective cohort study was performed.

Based on the results of our analysis a weak/moderate level of correlation was identified between stability measurements recorded with both devices. This is a useful addition to the literature that will help to clarify an area of ambiguity in the available evidence. Further studies are required to definitively confirm the level of correlation between the values recorded with these devices and determine the clinical implications of those findings.

Beyond the effect of upper or lower jaw position on stability measurements our investigation of clinical characteristics yielded limited outcomes. These negative findings are worthwhile though as they reflect the spurious conclusions derived from previous studies on this subject. Ultimately it may demonstrate that most clinical characteristics have a nominal influence on stability measurements and future research efforts should be tailored to more specific clinical features. This focus of finite research resources may provide more beneficial clinical information.

The data gathered from the single implant failure observed in this study provides a useful contribution to the paucity of available evidence on this topic. Development of this research theme has the potential to provide substantial clinical benefit and improve outcomes for our patients. The clarification of these devices as a prognostic indicator for future implant failure is a worthwhile research endeavour.

Finally this study has contributed a novel advancement to the evidence base by proposing a normative range for Zimmer Biomet dental implants with an Osseotite® surface. Normative ranges have been recommended for other implant systems but to the best of this authors knowledge this is first time they have been proposed for Zimmer Biomet oral implants. Further investigation and validation of this suggested range is necessary.

6. Appendices

Appendix I: Ethical Approval

SJH/TUH Research Ethics Committee Secretariat
email: researchethics@tuh.ie

Tallaght University Hospital | Ospidéal Ollscoile Thamhlachta
An Academic Partner of Trinity College Dublin

Dr Ian Reynolds
Postgraduate Student in Periodontology
Dublin Dental Hospital
Lincoln Place
Dublin 2

14th August 2018

REF: A prospective clinical study investigating the relationship between implant stability measurements and clinical characteristics .A pilot Study

REC Reference: 2018-08 Chairman's Action (3)
(Please quote reference on all correspondence)

Dear Dr Reynolds

The REC is in receipt of your recent request to SJH/TUH Research Ethics Committee in which you queried ethical approval for the above named study.

The Chairman, Prof. Richard Dean, on behalf of the Research Ethics Committee, has reviewed your correspondence and granted ethical approval for this study.

Yours sincerely,

Secretary
SJH/TUH Research Ethics Committee

The SJH/TUH Joint Research and Ethics Committee operates in compliance with and is constituted in accordance with the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004 & ICH GCP guidelines.

Appendix II: Consent Form

Participant Consent form

Study Title: Measurement of dental implant stability by Osstell® and Periotest™ at three different time points: Correlation between the two devices and comparison with clinical characteristics

Patient Name: _____
Patient Number: _____

Staff conducting the research: Dr. Ian Reynolds

Dr. Ioannis Polyzois

What is informed consent?

You are being asked to participate in a research study. In order to make an informed judgement on whether you want to be part of this research study or not, you should understand its potential risks and benefits. This is called informed consent. This consent form gives you information about the research study which will be discussed with you. Once you understand the study, you will be asked to sign if you wish to participate.

Study Summary

Dental implants are a well-established and recognised method of replacing missing teeth or supporting full arch replacement of missing teeth in the mouth

The stability of the implant is a key aspect of successful treatment. Implant stability is understood to be the absence of mobility or the ability to support a load. In the past implant stability was evaluated subjectively by invasive methods with questionable clinical value. To meet the demand for a quantitative, non-invasive method of evaluating implant stability new methods and devices were developed based on magnetic resonance frequency and dampening capacity analysis technology.

Fig 1: The Osstell® Mentor machine

Fig 2: The Periotest™ Classic machine

Aims

This study aims to evaluate stability of dental implants placed in patients at Dublin Dental University Hospital using two different measuring devices and compare these findings to characteristics of the patient, site and implant**.** To evaluate correlation between the two devices, assess the accuracy of each device and determine their true clinical value.

Who can take part?

To participate in this study:

- Patients must be 18 years or over
- Planned for provision of dental implant(s) at Dublin Dental University Hospital

Who can't take part?

You cannot participate in this study if:

- You are unable to consent to assessment & treatment
- A pregnant or lactating mother

Benefits

- Your involvement will support scientific research in the field of implant dentistry with the aim of improving care for future patients.

Risks

- The measurement devices used in this study are routinely used in dental practice and dental research. The instruments are non-invasive and the risk extremely low.

Possible Alternatives

- You may choose not to participate in this study. Your decision not to partake will have no impact on any future treatment you have at Dublin Dental University Hospital.

What do we ensure?

- Your identity will remain confidential. Your name will not be published.
- This study is covered by standard institutional indemnity insurance.
- Nothing in this document restricts or curtails your rights.
- If you decide to participate in this study, you may withdraw at any time.
- If you decide not to participate, or withdraw, you will not be penalised and will not give up any benefits that you had before entering the study.
- You understand that the investigators may withdraw your participation in the study at any time without your consent.
- If the study team learns of important new information that might affect your desire to remain in the study, you will be informed at once.

If you have any questions or require further information about this study or your rights before electing to participate please do not hesitate to contact Dr. Ian Reynolds.

Contact Details:

Dr. Ian Reynolds

Periodontology Postgraduate,

Dublin Dental University Hospital,

Lincoln Place,

Dublin2.

Telephone: 01 6127200 extension 7305

E-mail: ian.reynolds@dental.tcd.ie

Participant signed consent to partake in study outlined above:

_____

Appendix III: Patient Information Leaflet

Participant information leaflet

Study Title: Measurement of dental implant stability by Osstell® and Periotest™ at three different time points: Correlation between the two devices and comparison with clinical characteristics

Just five minutes of your time at three of your planned implant therapy appointments will support scientific research

Introduction

Dental implants are a well-established and recognised method of replacing missing teeth or supporting full arch replacement of missing teeth in the mouth.

The stability of the implant is a key aspect of successful treatment. Implant stability is understood to be the absence of mobility or the ability to support a load. In the past

implant stability was evaluated subjectively by invasive methods with questionable clinical value. To meet the demand for a quantitative, non-invasive method of evaluating implant stability new methods and devices were developed based on magnetic resonance frequency and dampening capacity analysis technology.

This study aims to investigate two devices that have been developed to measure implant stability and to compare the measurements against several characteristics such as the length or width of the implant placed. These devices are all called an Osstell® Mentor and Periotest ™.

Fig 1: The Osstell® Mentor machine

Fig 2: The Periotest™ Classic machine

What your participation involves?

These devices are easy to use, measurements can be taken quickly and it is a non-invasive procedure. These devices are regularly used in dental practice during implant provision.

Your participation in this study will involve taking a number of measurements at each of the planned stages of implant provision. There are no extra appointments required beyond the routine visits necessary for implant placement and restoration. Simply put we require 5 extra mins of your time at three of the appointments you would normally have as part of your implant treatment.

Aims

This study aims to evaluate stability of dental implants placed in patients at Dublin Dental University Hospital using two different measuring devices and compare these findings to characteristics of the patient, site and implant**.** To evaluate correlation between the two devices, assess the accuracy of each device and determine their true clinical value.

Who can take part?
To participate in this study:

- Patients must be 18 years or over
- Planned for provision of dental implant(s) at Dublin Dental University Hospital

Who can't take part?

You cannot participate in this study if:

- You are unable to consent to assessment & treatment
- You are a pregnant or lactating mother

Benefits

- Your involvement will support scientific research in the field of implant dentistry with the aim of improving care for future patients.

Risks

- The measurement devices used in this study are routinely used in dental practice and dental research. The instruments are non-invasive and the risk extremely low.

Possible Alternatives

- You may choose not to participate in this study. Your decision not to partake will have no impact on any future treatment you have at Dublin Dental University Hospital.

What do we ensure?

- Your identity will remain confidential. Your name will not be published.
- This study is covered by standard institutional indemnity insurance.
- Nothing in this document restricts or curtails your rights.
- If you decide to participate in this study, you may withdraw at any time.
- If you decide not to participate, or withdraw, you will not be penalised and will not give up any benefits that you had before entering the study.
- You understand that the investigators may withdraw your participation in the study at any time without your consent.
- If the study team learns of important new information that might affect your desire to remain in the study, you will be informed at once.

If you have any questions or require further information about this study or your rights before electing to participate please do not hesitate to contact Dr. Ian Reynolds.

Contact Details:

Dr. Ian Reynolds

Periodontology Postgraduate,

Dublin Dental University Hospital,

Lincoln Place,

Dublin2.

Telephone: 01 6127200 extension 7305

E-mail: ian.reynolds@dental.tcd.ie

Appendix IV: Data Collection Form

IMPLANT RECORD CASE

Date of implant surgery: _____
Patient: _____
Restorative dentist: _____

IMPLANT PLACEMENT

Implant connection

Final Drill

Counter sink

ISQ:

PTV:

ABUTMENT CONNECTION

Date:

ISQ:

PTV:

Distance from Implant shoulder to CEJ of adjacent tooth:

FOLLOW-UP (ISQ/DCA) Final Restoration

Date:

ISQ:

PTV:

Distance from Prosthetic contact point to crest of alveolar bone:

SITE CHARACTERISTICS

Site Location:

Single-unit/multiple-unit:

Adjacent tooth present (1/2 sides):

Previously grafted:
Site dimensions (Buccolingual/Mesiodistal):
Reason for original extraction (if known):
Time since original extraction:(immediate/<3months/ 3-12 months/ 1-5 years />5years)
Tissue thickness:

P.T.O. – PAGE 1 OF 2

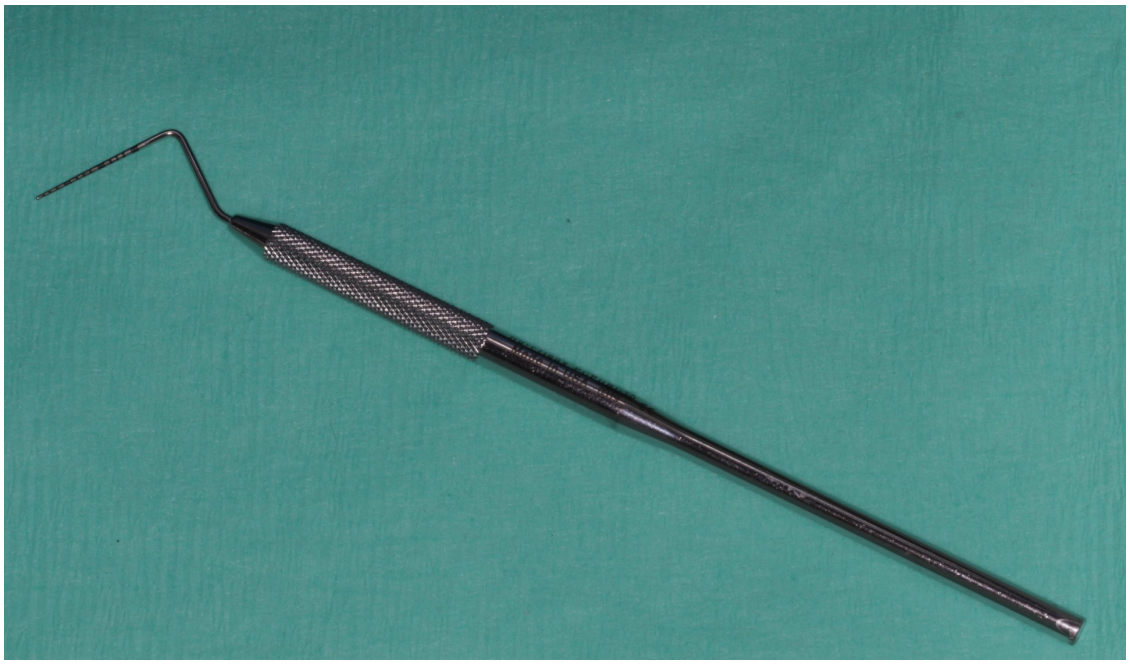
PATIENT CHARACTERISTICS

Age (group)
Gender
Ethnicity
Smoker
Anti-resorptive medications
Polymedication (e.g. ≥10 drugs)
Partially edentulous/Completely edentulous

PROCEDURE CHARACTERISTICS

Single implant / multiple implants placed during procedure
Flap elevated (Yes / No)
Immediate (Yes / No)
Implant system/type
Implant diameter
Implant length
One-stage/2 stage
Surgical stent utilised for osteotomy
Pre-op antibiotics (name)
Post-op antibiotics (name)
Simultaneous grafting (type)
Submerged (Yes / No)

Appendix V: Image of UNC-15 Periodontal Probe



Appendix VI: Complete set of data for comparative analysis between clinical characteristics and implant stability measurements with Osstell® device

Clinical Characteristic	Timepoint	Measurement	p-value	Finding
Gender T1 N=68 Male N=30 Female N=38	T1	ISQ Buc/Ling	*p = 0.264*	No statistically significant differences were identified across timepoints or measurements
		ISQ Mes/Dis	*p = 0.624*	
		ISQ Mean	*p = 0.488*	
T2 N=67 Male N=29 Female N=37	T2	ISQ Buc/Ling	*p = 0.388*	
		ISQ Mes/Dis	*p = 0.177*	
		ISQ Mean	*p = 0.352*	
T3 Male N=21 Female N=21	T3	ISQ Buc/Ling	*p = 0.186*	
		ISQ Mes/Dis	*p = 0.072*	
		ISQ Mean	*p = 0.054*	
Smoking History T1 N=68 Never N=54 Former N=8 Current N=6	T1	ISQ Buc/Ling	*p = 0.667*	***Never smokers have higher ISQ values than former or current smokers**
		ISQ Mes/Dis	*p = 0.629*	
		ISQ Mean	*p = 0.640*	
T2 N=67 Never N=52 Former N=8 Current N=6	T2	ISQ Buc Ling	*p = 0.860*	
		ISQ Mes/Dis	*p = 0.881*	
		ISQ Mean	*p = 0.911*	
T3 N=42 Never N=31 Former N=7 Current N=4	T3	ISQ Buc/Ling	****p = 0.045***	
		ISQ Mes/Dis	*p = 0.212*	
		ISQ Mean	*p = 0.194*	

Implant Position By Quadrant T1 N=68 Upper Right N=20 Upper Left N=21 Lower Left N=15 Lower Right N=12 T2 N=67 Upper Right N=20 Upper Left N=21 Lower Left N=15 Lower Right N=11 T3 N=42 Upper Right N=15 Upper Left N=15 Lower Left N=7 Lower Right N=5	T1	ISQ Buc/Ling	*p = 0.361*	No statistically significant differences were identified across timepoints or measurements
		ISQ Mes/Dis	*p = 0.073*	
		ISQ Mean	*p = 0.128*	
	T2	ISQ Buc/Ling	*p = 0.058*	
		ISQ Mes/Dis	*p = 0.099*	
		ISQ Mean	*p = 0.050*	
	T3	ISQ Buc/Ling	*p = 0.850*	
		ISQ Mes/Dis	*p = 0.729*	
		ISQ Mean	*p = 0.920*	
Implant Position T1 N=68 Maxilla N=41 Mandible N=27 T2 N=67 Maxilla N=41 Mandible N=26 T3 N=42 Maxilla N=30 Mandible N=12	T1	ISQ Buc/Ling	*p = 0.087*	**Higher ISQ values were observed for the mandible compared to maxilla**
		ISQ Mes/Dis	***p = 0.020**	
		ISQ Mean	***p = 0.028**	
	T2	ISQ Buc/Ling	***p = 0.020**	
		ISQ Mes/Dis	***p = 0.015**	
		ISQ Mean	***p =0.010**	
	T3	ISQ Buc/Ling	*p = 0.414*	
		ISQ Mes/Dis	*p = 1.00*	
		ISQ Mean	*p = 0.655*	
Implant Position	T1	ISQ Buc/Ling	*P = 0.833*	***Higher ISQ values observed**

T1 N=68 Anterior N=55 Posterior N=13 T2 N=67 Anterior N=55 Posterior N=12 T3 N=42 Anterior N=34 Posterior N=8		ISQ Mes/Dis	*p = 0.906*	**in anterior compared to posterior**
		ISQ Mean	*p =0.737*	
	T2	ISQ Buc/Ling	*p = 0.709*	
		ISQ Mes/Dis	*p = 0.937*	
		ISQ Mean	*p = 0.885*	
	T3	ISQ Buc/Ling	*p = 0.077*	
		ISQ Mes/Dis	***p = 0. 040**	
		ISQ Mean	***p = 0.045**	
Implant Hex T1 N=68 Internal Hex N=59 External Hex N=9 T2 N=67 Internal Hex N=58 External hex N=9 T3 N=42 Internal Hex N=35 External Hex N=7	T1	ISQ Buc/Ling	***p = 0.028**	**Higher ISQ values were indicated for external hex compared to internal hex implants**
		ISQ Mes/Dis	***p = 0.033**	
		ISQ Mean	***p = 0.025**	
	T2	ISQ Buc/Ling	*p = 0.124*	
		ISQ Mes/Dis	*p = 0.063*	
		ISQ Mean	*p =0.116*	
	T3	ISQ Buc/Ling	***p = 0.007**	
		ISQ Mes/Dis	*p = 0.332*	
		ISQ Mean	*p = 0.318*	
Implant Morphology T1 N=68 Parallel N=33 Tapered N=35 T2 N=67 Parallel N=32 Tapered N=35	T1	ISQ Buc/Ling	*p = 0.368*	No statistically significant differences were identified across timepoints or measurements
		ISQ Mes/Dis	*p = 0.707*	
		ISQ Mean	*p = 0.685*	
	T2	ISQ Buc/Ling	*p = 0.772*	
		ISQ Mes/Dis	*p = 0.263*	
		ISQ Mean	*p =0.455*	

T3 N=42 Parallel N=15 Tapered N=27	T3	ISQ Buc/Ling	*p = 0.086*	
		ISQ Mes/Dis	*p = 0.368*	
		ISQ Mean	*p = 0.188*	
Implant Diameter T1 N=68 3.25mm N=11 4mm N=44 5mm N=13 T2 N=67 3.25mm N=11 4mm N=43 5mm N=13 T3 N=42 3.25mm N=5 4mm N=29 5mm N=8	T1	ISQ Buc/Ling	*p = 0.579*	***Wide diameter implants demonstrate higher RFA values compared to standard & narrow diameter implants**
		ISQ Mes/Dis	*p = 0.907*	
		Mean RFA	*p = 0.635*	
	T2	ISQ Buc/Ling	*p = 0.739*	
		ISQ Mes/Dis	*p = 0.987*	
		Mean RFA	*p = 0.909*	
	T3	ISQ Buc/Ling	***p = 0.016***	
		ISQ Mes/Dis	***p = 0.013***	
		Mean RFA	***p = 0.014***	
Implant Length T1 N=68 ≤8.5mm N=11 10mm N=23 ≥11.5mm N=34 T2 N=67 ≤8.5mm N=11 10mm N=22 ≥11.5mm N=34 T3 N=42 ≤8.5mm N=17 10mm N=22 ≥11.5mm N=3	T1	ISQ Buc/Ling	***p = 0.044***	***Shorter length implants demonstrate higher RFA values**
		ISQ Mes/Dis	*p = 0.051*	
		Mean RFA	***p = 0.030***	
	T2	ISQ Buc/Ling	*p = 0.307*	
		ISQ Mes/Dis	*p = 0.589*	
		Mean RFA	*p = 0.372*	
	T3	ISQ Buc/Ling	***p = 0.043***	
		ISQ Mes/Dis	*p = 0.0245*	
		Mean RFA	*p = 0.139*	
Immediate Implant Placement T1=68	T1	ISQ Buc/Ling	*P = 0.301*	No statistically significant differences were
		ISQ Mes/Dis	*P = 0.435*	

No N=61 Yes N=7 T2=67 No N=60 Yes N=7 T3=42 No N=40 Yes N=2		Mean RFA	*P = 0.430*	identified across timepoints or measurements
	T2	ISQ Buc/Ling	*P = 0.203*	
		ISQ Mes/Dis	*P = 0.319*	
		Mean RFA	*P = 0.246*	
	T3	ISQ Buc/Ling	*P = 0.231*	
		ISQ Mes/Dis	*P = 0.557*	
		Mean RFA	*P = 0.307*	
<u>Apico-Coronal Implant Placement</u> T1 N=68 Submerged N=37 Not Submerged N=31 T2 N=67 Submerged N=37 Not Submerged N=30 T3 N=42 Submerged N=27 Not Submerged N=15	T1	ISQ Buc/Ling	*p = 0.595*	***Higher ISQ values for submerged compared to non-submerged implants**
		ISQ Mes/Dis	*p = 0.848*	
		Mean RFA	*p = 0.975*	
	T2	ISQ Buc/Ling	****p = 0.042***	
		ISQ Mes/Dis	*p = 0.159*	
		Mean RFA	*p = 0.080*	
	T3	ISQ Buc/Ling	*p = 0.400*	
		ISQ Mes/Dis	*p = 0.435*	
		Mean RFA	*p = 0.528*	
<u>Buccal Bone Thickness</u> T1 N=68 <2mm N=32 ≥2mm N=36	T1	ISQ Buc/Ling	*p = 0.381*	***Higher RFA values observed for thicker bone**
		ISQ Mes/Dis	*p = 0.057*	
		Mean RFA	*p = 0.119*	
	T2	ISQ Buc/Ling	*p =0.265*	

T2 N=67 <2mm N=31 ≥2mm N=36 T3 N=42 <2mm N=23 ≥2mm N=19				
		ISQ Mes/Dis	*p = 0.895*	
		Mean RFA	*p = 0.537*	
	T3	ISQ Buc/Ling	***p = 0.015***	
		ISQ Mes/Dis	*p = 0.143*	
		Mean RFA	*p =0.070*	
Lingual Bone Thickness T1 N=68 <1mm N=8 ≥1mm N=26 ≥2mm N=34 T2 N=67 <1mm N=8 ≥1mm N=14 ≥2mm N=19 T3 N=42 <1mm N=8 ≥1mm N=15 ≥2mm N=19	T1	ISQ Buc/Ling	*p = 0.842*	**Higher ISQ values Observed for thicker bone**
		ISQ Mes/Dis	*p = 0.860*	
		Mean RFA	*p = 0.823*	
	T2	ISQ Buc/Ling	*p = 0.755*	
		ISQ Mes/Dis	*p = 0.322*	
		Mean RFA	*p =0.638*	
	T3	ISQ Buc/Ling	***p = 0.021***	
		ISQ Mes/Dis	*p = 0.635*	
		ISQ Buc/Ling	*p = 0.397*	
Mesial Adjacent Tooth T1 N=68 No N=35 Yes N=33 T2 N=67 No N=24 Yes N=18 T3 N=42 No N=24 Yes N=18	T1	ISQ Buc/Ling	***p = 0.036***	***The presence of an adjacent mesial tooth was associated with higher ISQ values**
		ISQ Mes/Dis	*p = 0.090*	
		ISQ Mean	***p = 0.042***	
	T2	ISQ Buc/Ling	*p = 0.352*	
		ISQ Mes/Dis	*p = 0.542*	
		ISQ Mean	*p = 0.602*	
	T3	ISQ Buc/Ling	***p = 0.001***	
		ISQ Mes/Dis	***p = 0.010***	
		ISQ Mean	***p = 0.006***	
Distal Adjacent Tooth	T1	ISQ Buc/Ling	*p = 0.129*	***The presence of an adjacent distal tooth**

T1 N=68 No N=35 Yes N=33 T2 N=67 No N=24 Yes N=18 T3 N=42 No N=24 Yes N=18		ISQ Mes/Dis	*p = 0.176*	**demonstrated higher ISQ values compared to absence of a tooth**
		ISQ Mean	*p = 0.141*	
	T2	ISQ Buc/Ling	*p =0.995*	
		ISQ Mes/Dis	*p = 0.708*	
		ISQ Mean	*p = 0.667*	
	T3	ISQ Buc/Ling	***p = 0.000**	
		ISQ Mes/Dis	***p = 0.007**	
		ISQ Mean	***p = 0.004**	
Simultaneous Grafting T1 N=68 No N=56 Yes N=12 T2 N=67 No N=55 Yes N=12 T3 N=42 No N=31 Yes N=11	T1	ISQ Buc/Ling	*p = 0.545*	No statistically significant differences were identified across timepoints or measurement
		ISQ Mes/Dis	*p = 0.428*	
		ISQ Mean	*p = 0.473*	
	T2	ISQ Buc/Ling	*p =0.123*	
		ISQ Mes/Dis	*p = 0.290*	
		ISQ Mean	*p = 0.185*	
	T3	ISQ Buc/Ling	*p = 0.660*	
		ISQ Mes/Dis	*p = 0.554*	
		ISQ Mean	*p = 0.626*	
Tissue Thickness T1 N=68 ≥ 1mm ≥2mm T2 N=67 ≥ 1mm ≥2mm T3 N=42 ≥ 1mm ≥2mm	T1	ISQ Buc/Ling	*p = 0.806*	No statistically significant differences were identified across timepoints or measurement
		ISQ Mes/Dis	*p = 0.598*	
		ISQ Mean	*p = 0.935*	
	T2	ISQ Buc/Ling	*p = 0.971*	
		ISQ Mes/Dis	*p = 0.993*	
		ISQ Mean	*p = 0.993*	
	T3	ISQ Buc/Ling	*p = 0.240*	

		ISQ Mes/Dis	*p = 0.332*	
		ISQ Mean	*p = 0.314*	

Appendix VII: Complete set of data for comparative analysis between clinical characteristics and implant stability measurements with Periotest™ device

Clinical Characteristics	**Timepoint & Measurement**	**P-Value**	**Finding**
Gender T1 N=68 Male N=30 Female N=38 T2 N=67 Male N=29 Female N=37 T3 N=42 Male N=21 Female N=21	T1 PTV	*p = 0.965*	***Males demonstrate lower Periotest values (higher stability) compared to females**
	T2 PTV	*p = 0.557*	
	T3 PTV	****p = 0.027***	
Smoking History T1 N=68 Never N=54 Former N=8 Current N=6 T2 N=67 Never N=53 Former N=8 Current N=6 T3 N=42 Never N=31 Former N=7 Current N=4	T1 PTV	*p = 0.108*	***Former smokers have higher PT values (lower stability) than current or never smokers**
	T2 PTV	****p = 0.023***	
	T3 PTV	*p = 0.058*	
Implant Position T1 N=68	T1 PTV	****p = 0.000***	***Lower Periotest values (higher implant stability) identified for**

Maxilla N=41 Mandible N=27			**mandible compared to maxilla**
T2 N=67 Maxilla N=41 Mandible N=26	T2 PTV	***p = 0.002**	
T3 N=42 Maxilla N=30 Mandible N=12	T3 PTV	*p = 0.787*	
Implant Position By Quadrant T1 N=68 Upper Right N=20 Upper Left N=21 Lower Left N=15 Lower Right N=12	T1 PTV	***p = 0.000**	***Lower Periotest values (higher stability) demonstrated for lower quadrants compared to upper quadrants**
T2 N=67 Upper Right N=20 Upper Left N=21 Lower Left N=15 Lower Right N=11	T2 PTV	***p =0.015**	
T3 N=42 Upper Right N=15 Upper Left N=15 Lower Left N=7 Lower Right N=5	T3 PTV	*p = 0.947*	
Implant Position Anterior/Posterior T1 N=68 Anterior N=55 Posterior N=13	T1 PTV	*p = 0.777*	No statistically significant differences identified across timepoints or measurements
T2 N=67 Anterior N=55 Posterior N=12	T2 PTV	*p = 0.221*	

T3 N=42 Anterior N=34 Posterior N=8			
	T3 PTV	*p = 0.472*	
Implant Hex T1 N=68 Internal Hex N=59 External hex N=9 T2 N=67 Internal Hex N=58 External Hex N=9 T3 N=42 Internal Hex N=35 External hex N=7	T1 PTV	*p = 0.099*	***Lower PTV values (higher stability) observed for external compared to internal hex**
	T2 PTV	****p = 0.038***	
	T3 PTV	****p = 0.027***	
Implant Morphology T1 N=68 Parallel N=33 Tapered N=35 T2 N=67 Parallel N=32 Tapered N=35 T3 N = 42 Parallel N=15 Tapered N=27	T1 PTV	****p = 0.001***	***Parallel implants demonstrate lower Periotest values (higher stability) than tapered implants**
	T2 PTV	****p = 0.037***	
	T3 PTV	*p = 0.583*	
Implant Diameter T1 N=68 3.25mm N=11 4mm N=44 5mm N=13 T2 N=67 3.25mm N=11 4mm N=43 5mm N=13	T1 PTV	*p = 0.449*	No statistically significant differences identified across timepoints or measurements
	T2 PTV	*p = 0.572*	

T3 N=42 3.25mm N=5 4mm N=29 5mm N=8	T3 PTV	*p = 0.376*	
<u>Implant Length</u> T1 N=68 ≤8.5mm N=11 10mm N=23 ≥11.5mm N=34 T2 N=67 ≤8.5mm N=11 10mm N=22 ≥11.5mm N=34 T3 N=42 ≤8.5mm N=17 10mm N=22 ≥11.5mm N=3	T1 PTV	***p = 0.04***	***Shorter length implants demonstrate lower Periotest values (higher stability)**
	T2 PTV	*p = 0.057*	
	T3 PTV	*p = 0.322*	
<u>Immediate Implant Placement</u> T1N=68 No N=61 Yes N=7 T2 N=67 No N=60 Yes N=7 T3 N=42 No N=40 Yes N=2	T1 PTV	*P = 0.625*	No statistically significant differences identified across timepoints or measurements
	T2 PTV	*P = 0.764*	
	T3 PTV	*P = 0.232*	
<u>Apico-Coronal Implant Placement</u> T1 N=68 Submerged N=37 Not Submerged N=31	T1 PTV	*p = 0.064*	No statistically significant differences identified across timepoints or measurements

T2 N=67 Submerged N=37 Not Submerged N=30 T3 N=42 Submerged N=27 Not Submerged N=15	T2 PTV	*p = 0.954*	
	T3 PTV	*p = 0.233*	
<u>Buccal Bone Thickness</u> T1 N=68 <2mm N=32 ≥2mm N=36 T2 N=67 <2mm N=31 ≥2mm N=36 T3 N=42 <2mm N=23 ≥2mm N=19	T1 PTV	***p = 0.024***	***Greater bone thickness associated with lower Periotest values (higher implant stability)**
	T2 PTV	***p = 0.002***	
	T3 PTV	*p = 0.394*	
<u>Lingual Bone Thickness</u> T1 N=68 <1mm N=8 ≥1mm N=26 ≥2mm N=34 T2 N=67 <1mm N=8 ≥1mm N=14 ≥2mm N=19 T3 N=42 <1mm N=8 ≥1mm N=15 ≥2mm N=19	T1 PTV	***p = 0.021***	***Greater bone thickness associated with lower Periotest values (higher implant stability)**
	T2 PTV	***p = 0.004***	
	T3 PTV	*p = 0.168*	

Mesial Adjacent Tooth T1 N=68 No N=35 Yes N=33	T1 PTV	*p =0.877*	No statistically significant differences identified across timepoints or measurements
T2 N=67 No N=24 Yes N=18	T2 PTV	*p = 0.418*	
T3 N=42 No N=24 Yes N=18	T3 PTV	*p =0.287*	
Distal Adjacent Tooth T1 N=68 No N=35 Yes N=33	T1 PTV	*P = 0.746*	***Sites adjacent teeth demonstrated lower PTV values (higher stability)**
T2 N=67 No N=24 Yes N=18	T2 PTV	*p = 0.072*	
T3 N=42 No N=24 Yes N=18	T3 PTV	****p = 0.040***	
Simultaneous Grafting T1 N=68 No N=56 Yes N=12	T1 PTV	**** p = 0.045***	**Simultaneously grafted sites demonstrated higher Periotest values (Lower stability) compared to non-grafted sites**
T2 N=67 No N=55 Yes N=12	T2 PTV	*p = 0.222*	
T3 N=42 No N=31 Yes N=11	T3 PTV	*p = 0.559*	

Tissue Thickness T1 N=68 ≥ 1mm ≥2mm T2 N=67 ≥ 1mm ≥2mm T3 N=42 ≥ 1mm ≥2mm	T1 PTV	*p = 0.152*	No statistically significant differences were identified across timepoints or measurement
	T2 PTV	*p = 0.228*	
	T3 PTV	*p = 0.120*	

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