

**An *in-vitro* evaluation of Periotest™ implant stability
measurements taken on implant retained crowns and
healing abutments.**

**A thesis submitted to the University of Dublin in partial fulfilment of the degree of
Doctorate in Dental Surgery D.Ch.Dent. (Periodontology)**

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Summary

This *in vitro* study aimed to assess the reliability of implant stability measurements recorded with the Periotest™ device and to investigate the differences in values when these measurements were taken on implant retained crowns and healing abutments. To achieve our aims, implant stability measurements previously recorded by Naughton et al. (2023) for the same group of implants by using the ISQ Osstell® device, were used as a control and an attempt was made to correlate the PTVs to the ISQ values. The optimal position for placement of the Periotest™ hand-piece on the implant abutment and crowns was also assessed. Finally, we sought to determine differences in implant stability for different implant systems and their possible effects on the Periotest™ measurements.

Seven different types of implants of similar length and width were placed in resin polyurethane blocks representing the four different bone densities (D1, D2, D3 and D4). Two blocks of each type of bone density were included in the study, resulting in a total of 56 implants of various design and connection type being placed in eight bone blocks. Implant abutments correlating to the implant manufacturer and connection type were attached to the implants to facilitate measurement of the implant stability and torqued to 5 N cm using a calibrated torque wrench. The Periotest™ device was used to assess the implant stability at three different sites on the implant abutments – coronal, mid- and implant-head – with measurements repeated in triplicate. Screw-retained implant crowns designed to replicate an average central incisor were fabricated for each type of implant. The implant stability assessment was repeated on the implant-retained crowns

following the same method of recording PTVs in triplicate, at three different heights on the crown. All measurements were repeated by a second operator and a total of 2,016 PTVs were recorded.

Descriptive statistics were used to describe the PTVs recorded for the different implants in the bone blocks of different bone density. The PTVs obtained were compared to the ISQ values previously recorded by Naughton et al. (2023). The intraclass correlation coefficient (ICC) was used to determine the relationship between the PTVs recorded on the implant abutments and implant crowns. Further analysis involved plotting Blant Altman plots and the Wilcoxon Signed-Rank test. Spearman's rank test was used to assess the relationship between the PTVs recorded on implant abutments and ISQ values recorded for the same implants by Naughton et al. (2023). These analyses were repeated with D4 bone excluded. The ICC between operators was also calculated. Moderation analysis was used to investigate the effect of bone density and implant type on the implant stability measurements recorded.

The range of PTVs was found to differ significantly in D4 bone blocks compared to bone blocks of D1-D3 bone density. The mean PTVs recorded when all bone densities were included was 5.32 +/- 11.493 PTV at the mid-abutment site and 11.96 +/- 12.264 at the mid-crown site. When D4 bone was excluded the mean PTVs were -0.82 +/- 3.050 at the mid-abutment site, and 5.36 +/- 3.843 at the mid-crown site. When compared to the Osstell® device, the Periotest™ device was found to be reliable at assessing implant stability in all bone densities. A difference of 6 PTVs less stability (+ 6 PTV) for measurements recorded on implant crowns was found when compared to

measurements recorded on implant abutments. This difference was found to be less consistent in D4 bone density. The intraclass correlation coefficient between operators was good to excellent when assessing implant stability with the Periotest™ device (ICC ranged from 0.776 to 0.938 for D1-D4 bone density, $p < .001$). The mid-abutment implant site was found to have the best correlation to the ISQ values ($r_s = -.482$, $p < .001$) indicating that the mid-abutment site facilitated the most accurate assessment of implant stability using the Periotest™ device. The results demonstrated that PTVs in the range of -5 to +5 correlated with ISQ values ≥ 60 . For implants placed in good quality bone, some differences in implant stability measurements based on the different types of implants were identified.

These results demonstrate that Periotest™ is a reliable tool for the assessment of implant stability in all bone types. Measurements should be recorded at the mid-abutment site. The range of clinically acceptable implant stability for the Periotest™ and Osstell® devices correlate well and there is a mean difference of about 6 PTV between measurements recorded on implant crowns compared to implant abutments for all bone densities. Finally, there were some differences in the implant stability measurements for different implant systems when these were placed in good quality bone. These differences didn't seem to have an effect on the reliability of Periotest™ measurements.

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List of Abbreviations

BIC.....Bone Implant Contact

CBCT..... Cone Beam Computerised Tomography

CT..... Computerised Tomography

DCA..... Damping Capacity Assessment

FBIC..... First Bone to Implant Contact

HU..... Hounsfield Units

ITV..... Insertion Torque Value

ISQ.....Implant Stability Quotient

PDL..... Periodontal Ligament

PTV.....Periotest value

RFA..... Resonance Frequency Analysis

1. Literature Review

Introduction

Osseointegrated dental implants have had a significant impact on the prosthetic options available for the rehabilitation of patients who present with different types of edentulism (Jung et al., 2012). Excellent survival rates have been reported for the implants and their single and multiple unit implant-supported prostheses (Pjetursson et al., 2018, Sailer et al., 2018). The high success rate of dental implants has been influenced by improvements in prosthetic materials and implant surface design, as well as the advent of digital planning programs and adapted surgical techniques (Aiquel et al., 2021, Buser et al., 2017). Contemporary implant concepts aim to provide the patient with optimal implant-supported restorations efficiently, which has led to diversity in the protocols for implant placement and loading (Aiquel et al., 2021). Proper patient selection and treatment planning are required to maintain high implant success rates when using a reduced treatment time protocol (Gallucci et al., 2018). The authors also recommended that the implant-prosthesis complex and the relevant implant placement and loading protocol used be considered as a single denominator for survival and success (Gallucci et al., 2018). Treatment protocols are significantly affected by the primary stability of the implant – which in turn is influenced by the biological environment, implant design, and mechanical forces applied (Monje et al., 2019). Therefore, pre-operative prediction and accurate intra-operative assessment of the primary stability of an implant allows the surgeon to adapt planned loading protocols to

the clinical situation and thereby improve the patient experience and outcomes (Merheb et al., 2018).

There are numerous ways of testing implant stability, including insertion torque, resonance frequency analysis (RFA), or damping capacity assessment (DCA). The latter two are novel advances that allow the use of technology to accurately assess this stability. The aim of this research is to carry out an *in-vitro* investigation into the stability of different dental implants, placed into polyurethane blocks of varying density measured using the Periotest™ device, and to correlate them with stability measurements taken using the Osstell® device.

This literature review will focus on the stability of dental implants – the current scientific understanding of primary and secondary stability, its impact on clinical implant dentistry, and different methods of assessing the stability of an implant, with particular attention paid to the Periotest™ and Osstell® devices.

1.1 Implants

The 1982 conference on Osseointegration in Clinical Dentistry was a seminal event that presented the findings from the laboratory of P-I Brånemark and sparked academic interest in the field of dental implants (Albrektsson et al., 1986). This interest has not waned since, with the Brånemark implant having been adopted into general use, and dental implants now making up 15% of the overall dentistry market. (AG, 2018).

The Brånemark implant was shaped like a screw and made of commercially pure titanium (Albrektsson et al., 1986). It was machined and had a relatively smooth surface, however clinical research has led to implants now being available with varying degrees of roughness and enhanced surface characteristics. (Stavropoulos et al., 2021).

Chemically, implants can be made out of metals, ceramics or polymers (Osman and Swain, 2015). Titanium is the gold standard material, with zirconia ceramic implants presenting the option for metal-free, more aesthetic implants, although not without their limitations (Osman and Swain, 2015).

1.1.1 – Osseointegration

The success of an implant is determined by its ability to biologically bond to the bone. The term for this coined by Brånemark in 1977 was “osseointegration” (Albrektsson T, 2017). Osseointegration has been defined as “A direct structural and functional connection between ordered, living bone and the surface of a load-carrying implant” (Brånemark, 1985). The original prerequisites for osseointegration consisted of “1)

infliction of minimal trauma during surgery, 2) establishment of primary implant stability and 3) avoidance of infection and micro-motion during healing” (Berglundh et al., 2003).

Infliction of minimal trauma during surgery includes preventing a rise in the temperature of the bone above 47 degrees for more than one minute when preparing the osteotomy site as this has been shown to cause bony necrosis (Eriksson and Albrektsson, 1983).

Primary implant stability is achieved through the mechanical interlocking of the implant in the existing bone (Sennerby and Meredith, 1998). Primary implant stability is dependent on the quality and quantity of bone available at insertion of the implant, as well as the surgical technique employed and implant design (Misch, 2008).

Osseointegration is established by virtue of a dynamic healing process that involves the remodelling and regeneration of old bone and *de novo* bone formation around an implant (Abrahamsson et al., 2004, Berglundh et al., 2003). This healing process develops a bone-implant interface that is chemically and mechanically stable (Skripitz and Aspenberg, 1998). Secondary implant stability refers to implant stability after primary healing has occurred (Sennerby and Meredith, 1998). Two mechanisms for the juxtaposition of bone growth on an endosseous implant were described by Osborn and Newsley in 1980 – distance and contact osteogenesis (Davies, 1998, Davies, 2003). In distance osteogenesis, the remodelling of the damaged existing bone leads to bone growth towards the implant (Davies, 2003). The bone is deposited in an appositional fashion on the existing bone and is seen in cortical bone healing (Davies, 2003).

Conversely, contact osteogenesis involves the deposition of new or *de novo* bone on the implant surface by differentiating osteogenic cells (Davies, 2003). This is achieved by the

migration of osteogenic cells through the fibrin-based blood clot to reach the implant surface where deposition of extracellular matrix can begin that is subsequently mineralised to form new bone (Davies, 2003).

This process of wound healing around an implant that results in osseointegration was studied in the canine model by Berglundh and Abrahamsson (Berglundh et al., 2003, Abrahamsson et al., 2004). They adapted the ITI® Straumann dental implant to create a wound chamber between the implant threads and placed these in the mandible of dogs. They then carried out histological analysis of the specimens over a period of 12 weeks and demonstrated that woven bone developed on the implant surface in the wound chamber following an initial blood clot, representing contact osteogenesis, and distance osteogenesis was evident in the area of the threads where remodelling, resorption and apposition were seen.

Osseointegration has subsequently been studied in the human model and documented in a series of publications (Lang et al., 2011, Bosshardt et al., 2011, Donos et al., 2011, Ivanovski et al., 2011). This involved the placement of 2.8 x 4mm implant devices for submerged healing in the retromolar region of volunteers who were lacking their third molar teeth. These implants were then removed by an explantation trephine drill at different stages of the healing period. Some of the findings of the study are outlined below (Lang et al., 2011, Bosshardt et al., 2011).

7 days – There was a deposit of osteoid lined by osteoblasts on the implant surface.

Bone debris particles were present on the implant surface, with and without the

apposition of new bone. The major area between old bone and implant consisted of a primitive matrix with bone debris particles contained within.

14 days – Bone formation was seen on old bone surfaces and extended onto the implant surface in areas. Large surface areas of the implant showed apposition of new bone. Resorption was seen on the surface of the old bone, but did not seem to affect the bone debris.

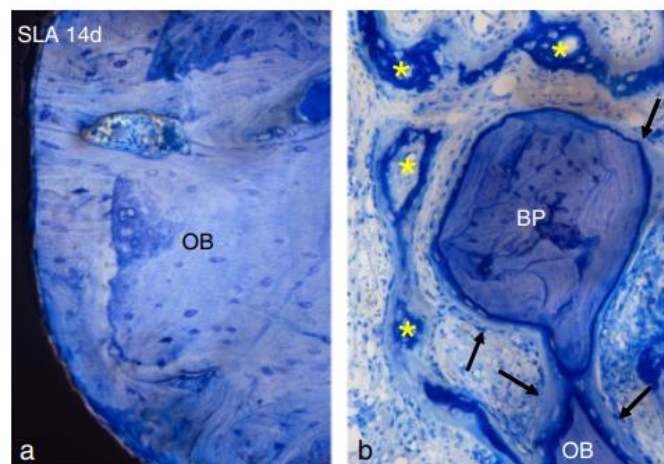


Figure 1: 14-day healing of tissue at an SLA implant.

The image above shows 14-day healing of tissue at an SLA® implant: a) shows the bone-implant interface and peri-implant tissues where compact old bone (OB) is present and in direct contact with the implant surface. b) demonstrates a region further away from the implant where bone particles (BP) are surrounded by soft tissue matrix with new bone formation occurring on their length (arrows) and new trabeculae forming of woven bone

() (Bosshardt et al., 2011).*

28 days – Bone-implant contact had increased significantly at this point to 32.4 – 48.3%.

The bone debris fragments were embedded in bone matrix, and new mineralised bone trabeculae extended from the parent bone to the new matrix.

42 days – Bone maturation was advanced, with a bone implant contact of 62%. Primary osteons had formed away from the implant surface, and secondary osteons were visible where remodelling of old bone had occurred. Bone debris was virtually indistinguishable from the mineralised bone matrix.

The growth of bone on and around the implant results in osseointegration. Bone implant contact, contact between trabeculae and the bone coating the implant surface, the density of the surrounding bone, and the thickness of the bone coating may all contribute to mechanical retention and subsequent implant stability (Lang et al., 2011).

André Schroeder and co-workers (1978, 1981, 1976) were the first to show histological evidence of the bone-implant-contact in 1976 and termed the union “functional ankylosis” (Salvi et al., 2015).

More recently, a new definition of osseointegration was proposed by Albrektsson et al. (2017): “Osseointegration is a foreign body reaction where interfacial bone is formed as a defence reaction to shield off the implant from the tissues”. This proposal resulted from research demonstrating a characteristic foreign body response around titanium dental implants by Albrektsson (Albrektsson T, 2017, Albrektsson et al., 2014, Albrektsson et al., 2016) and was first suggested by Donath (Donath, 1992, Donath et al., 1992). Regardless of the definition, the fact remains that dental endo-osseous implants

embedded in bone provide excellent platforms for the retention of dental prostheses (Pjetursson et al., 2014).

1.1.2 – Survival and Success of dental implants

The survival of an implant has been defined as both the implant and fixed prosthesis being present in the mouth despite biological and/or technical complications (Smith and Zarb, 1989, Simonis et al., 2010). Survival rates report on “prostheses that remained in clinical service for a defined follow-up period” (Pjetursson et al., 2014). Biological complications can be multifactorial and are generally patient-related (Pjetursson et al., 2014), or due to poor access for oral hygiene techniques (Serino and Ström, 2009). Technical complications are influenced by the materials used and component design (Pjetursson et al., 2014). In a systematic review of the literature to assess the 5-year survival and complication rates of implant-supported single crowns, Jung and colleagues found that the survival rate for implants supporting single crowns was 96.8% while the survival rate for single crowns supported by implants was 94.5% (Jung et al., 2008). A later review by Jung et al. (2012) found the 10-year survival of implants supporting single crowns to be 95.2%, and the 10-year survival of implant-supported single crowns to be 89.4%. However, the cumulative soft tissue complication rate was 7.1%, and there was a 5.2% complication rate for implants with bone loss >2mm (Jung et al., 2012). The cumulative aesthetic complication rate over 5 years was 7.1% and technical complication rate ranged from 0.18% for implant, abutment, or screw fractures to 8.8% for screw loosening over a 5-year period (Jung et al., 2012). Therefore, while survival of

an implant and its prosthesis are of interest when discussing treatment options with the patient, there are a number of complications that may occur and need to be expected (Jung et al., 2012).

In contrast, the success of the implant is determined in the absence of these complications. The success criteria of a dental implant as proposed by Albrektsson et al. (1986) is displayed in figure 2 below.

| Proposal by Albrektsson, Zarb, Worthington, and Eriksson, 1986 |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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 2: Success criteria proposed by Albrektsson et al.(1986).

Much research has been done to determine the success rates of dental implants, alone, in the context of their placement in patients with specific disease, and regarding the use of certain materials or surface characteristics. A systematic review by Moraschini et al. (2015) found that seven studies applied the success criteria as outlined by Albrektsson et al. (1986) resulting in “a cumulative mean success rate of 89.7%”. The mean follow-up

period was 15.7 years. Paradoxically, the same systematic review found that 23 studies published their survival rates resulting in a cumulative mean value of 94.6% for a total of 7711 implants placed, with results varying between individual studies from 73.4% to 100% (Moraschini et al., 2015). The follow up-period was up to 20 years.

Linkevičius (2019) has recently challenged this success criteria – in particular the acceptance of 1.5mm of bone loss in the first year, and 0.2mm per year thereafter – as being insufficiently ambitious in light of the advances of surface and design characteristics of contemporary implants. The progress in endo-osseous implant dentistry since the first implant was placed in 1965 is reflected in the systematic review by Pjetursson et al. (2014) which found that overall there were higher rates of survival and lower rates of complications for implant supported prostheses in studies carried out after the year 2000: 97.1% after 2000 vs 93.5% before. Whilst there are many factors that can affect the implant-supported prosthesis (Pjetursson et al., 2014), the pre-requisites for osseointegration as outlined by Albrektsson et al. (1981) are: 1. Implant material; 2. Implant design; 3. Implant finish; 4. Status of bone; 5. Surgical technique; 6. Implant loading conditions. Together these factors have an impact on the stability of the implant and its long-term success. As such, reliable and reproducible methods that allow clinicians and researchers to assess the stability of an implant, and therefore its degree of osseointegration, are key in determining the success of the dental implant.

1.1.3 – Types of Bone

A number of different factors that affect implant stability relate to the status of the bone. The strength of the bone, its modulus of elasticity, and the percentage of bone-implant contact that can be achieved are all related to the density of the cortical and trabecular bone present (Misch, 1990). These in turn have an impact on treatment planning and implant success (Misch et al., 1999).

Goldstein (1987) carried out a review of the literature analysing the physical properties of trabecular bone based on their physical location. One of the most striking findings of the review was the large variation in modulus and strength reported, which were shown to be a function of the “anatomic position, loading function, methods of storage and testing conditions” (Goldstein, 1987). The findings regarding the correlation between the physical properties of the trabecular bone and the anatomic position tested are in keeping with Wolff’s Law (1892) which states that function has a direct influence on the physical structure and strength of bone (Misch et al., 1999).

In 1985, four types of bone quality were described by Lekholm and Zarb based on radiographic appearance of the bone and the feeling of resistance on insertion of an implant (Choi et al., 2011). Quality 1 consisted of homogenous compact bone. Quality 2 had a thick outer layer of compact bone that surrounded a dense trabecular core. Quality 3 was mostly trabecular bone of favourable strength surrounded by a thin layer of cortical bone. Quality 4 consisted of low-density trabecular bone surrounded by a thin layer of cortical bone (Lekholm and Zarb, 1985).

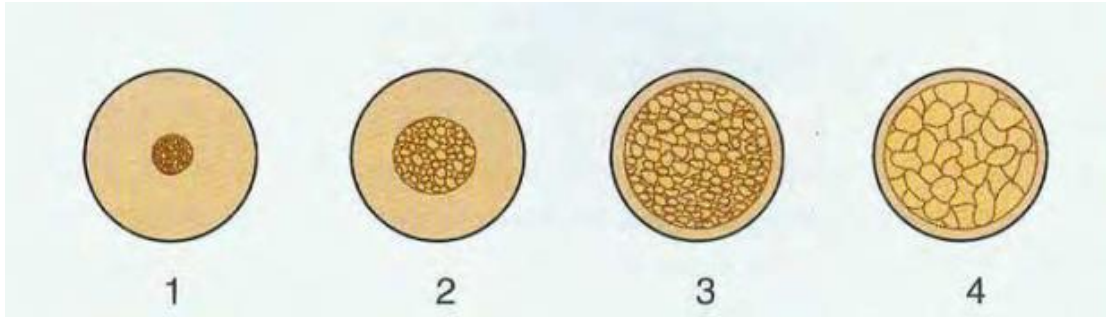


Figure 3: The grading system for assessment of bone quality per Lekholm and Zarb (1985).

In 1988, Misch developed another classification of bone density and reported on the usual anatomic location where each type of bone was found. The bone densities described were: D1 – Mainly dense cortical bone, D2 – Porous cortical with coarse trabecular bone, D3 – Thin, porous cortical and fine trabecular bone, and D4 – fine trabecular bone with minimal to no cortical bone. Misch also recommended that the implant surgery protocol should be adapted depending on the type of bone that is present at the edentulous site (Misch, 1988).

1.1.3.1 Radiographic Assessment of Bone Density

Bone density can be assessed using plain film radiography, e.g. peri-apical, panoramic or lateral cephalometric radiographs, however, the detail that can be obtained from these

images is poor because the lateral cortical plates obscure the trabecular bone density (Misch, 2008). These “planar imaging modalities” produce a 2D image, however the nature of the projective view results in an image that is the “sum (or integral) of tissue density in the projection direction” (Zanetti et al., 2018). The resulting commonly accepted limitation of these 2D images and their associated magnification and distortion errors is that only variations in bone density of more than 40% can be detected (Zanetti et al., 2018). The introduction of computerised tomography to implant dentistry has allowed a more thorough pre-operative assessment of the edentulous site which enables the clinician to plan more precisely (Merheb et al., 2018).

Computerised tomography (CT) was developed by G. N Hounsfield in 1973 – who subsequently received a Nobel Prize in 1980. Computerised tomography measures the attenuation of the x-ray beam that passes through the area of interest from a multitude of axial angles, and then reconstructs a 3-D image based on the axial images or “slices” (Hounsfield, 1980, Misch, 2008). Each CT “slice” has 260,000 pixels, and each pixel is given a CT number or “Hounsfield Unit” (HU) based on the density of the tissues within the pixel (Misch, 2008). Therefore, bone density can be measured radiographically using Hounsfield Units on a medical CT machine (Mah et al., 2010). However, as cone-beam computerised tomography (CBCT) systems use the arbitrary grey scale they do not allow for accurate assessment of the bone density (Mah et al., 2010). Algorithms have been developed to convert CBCT grey scale to Hounsfield Units with limited results to date (Mah et al., 2010, Merheb et al., 2018). The development of a CBCT machine (WhiteFox CBCT, de Götzen Srl, Olgiate Olona, Italy) that incorporates a “bone density examination (BDE) protocol” now allows highly accurate measurement of the bone density in

Hounsfield Units (Sennerby et al., 2015). This study, also demonstrated a significant correlation between the bone density as measured in HU on the CBCT pre-operatively, and the peri-operative assessments of primary implant stability.

1.2 Implant Stability

The absence of mobility is the first criterion of success listed by Albrektsson et al. (1986) and is determined as an important criterion for the success of the implant (Smith and Zarb, 1989). Stability is defined as ‘a measure of the difficulty of displacing an object or system from equilibrium’ (Molly, 2006) and implant stability can be defined as “the absence of clinical mobility” (Sennerby and Meredith, 2008). Implant stability is essential for two reasons: 1) to allow undisturbed healing and bone formation around the implant on insertion, and 2) to allow “optimal stress distribution from masticatory and occlusal functional loads through the implant tissue interface” (Meredith, 1998). Movement of the implant in the surrounding bone during the early healing phase is a high risk factor for early implant loss because osseointegration fails to occur (Raghavendra et al., 2005). The nature of the mechanism that provides stability to an implant is different during healing to that present during function (Berglundh et al., 2003). The development of the implant-bone interface is complex, and many factors are involved (Raghavendra et al., 2005). In a paper titled “Mechanisms of Endosseous Integration” Davies (1998) described three biological tissue responses that are separate to distance osteogenesis and function to facilitate osseointegration of an implant

through contact osteogenesis– osteoconduction, de novo bone formation, and bone remodelling.

Raghavendra et al. (2005) discussed in their review of 50 pertinent articles, that one of the most critical factors for successful osseointegration of an implant is implant stability in the bone at time of placement, or primary stability. Expanding on the findings of Berglundh et al. (2003) they deduce that there is a period of time during healing where the osteoclastic activity has decreased the mechanical or primary stability of the implant, but new bone formation has not yet occurred to the level that is sufficient to equal the initial mechanical implant stability. i.e. secondary or biologic stability has not yet fully developed. Berglundh et al. (2003) mention that despite the resorption of bone immediately lateral to the “pitch” of the implant thread, and “the temporary loss of hard tissue contact” the clinical stability of the implants was unaffected in the canine model. This means that even in the first weeks of healing the biological reactions described by Davies (1996, 1998) and Schenk et al. (1994) provided sufficient “de novo” bone formation to stabilise the implant clinically. Below, figure 4. depicts this change in the source of implant stability which tends to occur around week 3 after implant insertion in humans (Raghavendra et al., 2005). Where good primary stability was achieved, there may be a drop in stability that can occur as mechanical stability is lost and biological stability is still developing which has since been termed the ‘stability dip’ (Simunek et al., 2012).

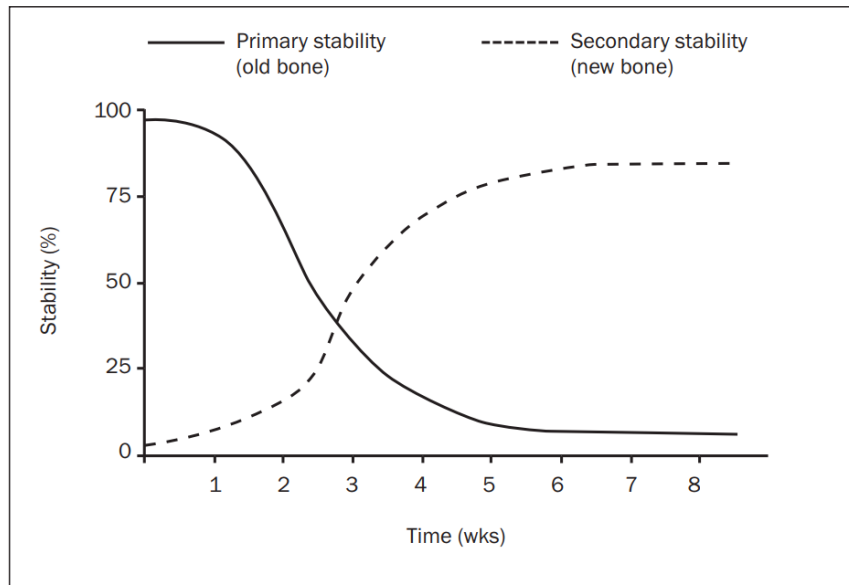


Figure 4: Implant Stability Graph

Graph depicting the decrease in primary stability and increase in secondary stability that occurs after implant placement owing to the resorption of old bone, deposition of new bone and remodelling that occurs in humans (Raghavendra et al., 2005).

As demonstrated by Davies (1996) the remodelling of the bone facilitates the gradual replacement of the peri-implant old compact bone with de-novo bone formation at the implant surface which provides the implant with the means to be stable once again.

Osseointegration is a dynamic process during both its establishment where the bone-implant interface is developed, and its maintenance where there is continuous remodelling and adaptation of the bone to function as described by Wolff's law (Berglundh et al., 2003). Implant stability can therefore be subdivided into primary (mechanical) and secondary (biological) stability (Meredith, 1998).

1.2.1 Primary Stability

Primary stability is obtained by achieving mechanical interlocking of the implant threads with the surrounding bone (Berglundh et al., 2003), and is a pre-requisite for the development of secondary stability (Davies, 1998). Primary stability is mainly influenced by the bone quantity and quality, implant geometry, and the surgical technique used for implant placement (Javed et al., 2013). Where a lack of primary stability is achieved, excessive micromovements of the implant can result in implant failure owing to fibrous encapsulation rather than osseointegration (Monje et al., 2019). Conversely, if excessive force is used on insertion of the implant with a view to increasing primary stability, increased microfracture and resorption of the bone may result which can also compromise primary stability (Monje et al., 2019). Primary stability can be defined as “bone-to-implant biomechanical engagement with a micromotion lower than 150 µm” and is considered essential for both osseointegration and to determine when implants may be loaded (Bergamo et al., 2021). Much research has focused on the timing of both implant placement and implant loading – with specific timelines being defined for immediate, early, or delayed protocols (Aiquel et al., 2021, Gallucci et al., 2018, Siebers et al., 2010). The consensus reached by the 6th EAO Consensus Conference 2021 was that “there were no differences in survival rates and marginal bone levels” when immediate and delayed loading of implants placed on a delayed protocol were compared with regard to the restoration of implant-supported multiple-unit fixed dental prosthesis (Donos et al., 2021). Similarly, the group concluded that there were high

implant survival rates for up to 10 years of follow up with similar amounts of marginal bone loss found in implants placed using an immediate and delayed protocol for the different loading protocols (Donos et al., 2021) The restoration of an implant at the time of implant placement allows restoration of aesthetics, improvement in patient comfort, and reduction in the number of dental visits required (Francisco et al., 2021). Achieving primary stability of the implant is imperative for both immediate and delayed loading protocols (Zhou et al., 2009), whilst assessment of the primary stability contributes to the clinician's decision of which loading protocol is most appropriate.

Histological analysis of the bone-to-implant contact (BIC) of implants placed in monkeys that were left unloaded (group A), delayed loading protocol (group B) and immediately loaded (group C) showed a significant difference in the implant-bone interface (Romanos et al., 2003). All implants achieved osseointegration, however Group A implants were surrounded by cancellous bone with loose fatty tissue present and had a significantly lower BIC than Group B and C ($P < 0.05$). There was a higher quantity of mineralised bone tissue found apical to the delayed implants compared to the immediate implants ($P < 0.05$), while the immediate implants had a higher BIC value within the threads of the implant ($P < 0.05$). The authors concluded that implant loading may have had a positive influence on bone formation and that the immediately loaded implants osseointegrated in a similar fashion to implants restored with delayed protocols (Romanos et al., 2003).

Recently, there has been a paradigm shift in implant site preparation with the use of osseodensification burs during implant osteotomy (Bergamo et al., 2021). This technique

ultimately increases the primary stability of the implant. The osseodensification burs cause “lateralisation of autogenous bone into the surrounding cancellous structure and expands the surrounding osseous environment” where the spring back effect of the autogenous bone results in gentle compressive forces on the implant thereby increasing the mechanical interlocking and primary stability (Bergamo et al., 2021). The substantial amount of research that has been undertaken concerning factors that affect the primary stability of implants and ways in which it can be improved demonstrate the determining nature of primary implant stability in the success and survival of dental implants.

1.2.2 Secondary Stability

Secondary stability or biological stability results when new bone has formed along the implant surface (Greenstein and Cavallaro, 2017). For an implant that has achieved osseointegration, its ongoing stability is the result of the biological events of bone turnover (Simunek et al., 2012).

A study to assess the changes that occur in implant stability in the early healing phase and the impact that different bone densities have on this transition from primary to secondary stability was carried out using RFA (Barewal et al., 2003). Twenty patients had between 1-4 ITI SLA implants of 10-12mm in length placed in the posterior maxilla and mandible. The bone quality was categorised at the implant insertion surgery per Lekholm and Zarb (1985), and the ISQ values were recorded weekly for 0-6 weeks, and then at 8 weeks and 10 weeks post-placement. The lowest mean stability measurement for all bone types was at 3 weeks after implant insertion. In Type 4 bone, there was an

8.6% decrease in implant stability at 3 weeks and a 15.8% increase in stability then occurred between 3 to 10 weeks. A similar pattern of change in stability occurred in bone type 1, 2 and 3, however with much smaller differences detected (Barewal et al., 2003).

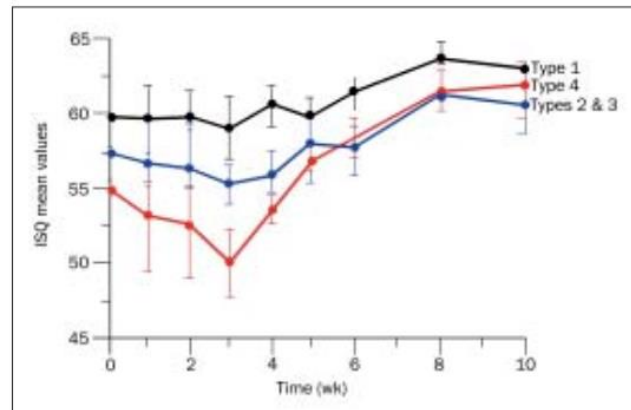


Figure 5: Graph depicting the changes in implant stability relative to the type of bone over a period of 10 weeks post-implant placement (Barewal et al., 2003)

The authors found that there was no difference in the RFA measurements obtained at 6 weeks compared to 10 weeks across all bone types, however they recommend caution when considering loading of implants in type 4 bone at this time due to the potential detrimental effects of occlusal forces in this early healing phase (Barewal et al., 2003).

The result of this clinical study on the progression of primary to secondary implant stability, is similar to the findings of a much earlier study in a rabbit model by Roberts (1988), although the loading time recommended by the author was 18 weeks. The author noted that bone-implant contact was approximately 50% for “clinically successful” implants, and that full maturation of the bone-implant interface took 1 year

(Roberts, 1988). In a prospective clinical trial, Simunek et al. (2012) investigated the development of implant stability in immediately loaded implants. When assessed using RFA, a statistically significant dip in the stability was found during the early healing period. In contrast to the results of Barewel et al. (2003) the most pronounced decrease in ISQ values occurred 1 week after implant placement, rather than after 3 weeks as in the delayed loaded implants seen in the study by Barewel et al. (2003). In line with the findings of the study in delayed implant loading, the ISQ values increased for 3 weeks after this dip, whereupon they continued to increase but without statistical significance (Simunek et al., 2012). Thus, the development of secondary stability in immediately loaded implants appears to follow a similar pattern to that of delayed loaded implants.

1.3 Assessment of Implant Stability

Assessment of implant stability is essentially an assessment of the implant-bone interface and percentage of bone-to-implant contact present to hold the implant in a fixed position (Alsaadi et al., 2007). Therefore, factors such as bone density (Alsaadi et al., 2007, Truhlar et al., 1997a), implant length, and the surface characteristics of the implant (Ochi et al., 1994), and the patient's healing capacity have an impact on the implant stability that can be achieved (Aparicio et al., 2006). It is important for both clinical and research practice to be able to assess the implant stability objectively.

Friberg et al. (1999a) reported the failure of one implant out of 75, where the resonance frequency value at six weeks post-surgery was substantially lower than that recorded at the time of surgery. Several weeks later implant mobility was detected clinically and the implant was removed. Conversely, a second patient presented at six weeks post-surgery with three implants showing decreased resonance frequency values (Friberg et al., 1999a). The implants were relieved of pre-loading from the removable prosthesis, and followed closely until they were found to be asymptomatic and clinically stable, with improved resonance frequency values reported at 15 weeks (Friberg et al., 1999a). This demonstrates how accurate assessment of implant stability can aid clinical decision making and thereby improve patient outcomes. As discussed by Lachmann et al. (2006a), it is imperative that diagnostic procedures such as this are predictable and reliable.

A number of methods exist to assess implant stability – some less invasive, and with more diverse applications than others. Historically, percussion testing was the most

common and simplest test of implant stability (Meredith, 1998). The sound created by tapping a dental instrument against the fixed mount or abutment of an implant can indicate whether the implant is stable or not. However, limitations of this technique are its subjectivity and lack of ability to distinguish between stabilities (Meredith, 1998). The non-destructive intra-oral testing methods include insertion torque measurements, resonance frequency analysis (RFA) and PTV. The destructive methods have limited clinical application but are useful for pre-clinical research purposes and include removal torque assessment, and pull-out and push-out techniques (Aparicio et al., 2006).

1.3.1 Insertion Torque Measurements

Johansson & Strid (1994) were the first to describe the use of cutting resistance measurements during implant surgery to assess bone density (Molly, 2006). This developed into measurement of the torque created when cutting a thread in an implant osteotomy site based on the current drawn by the electric motor (Molly, 2006). Insertion torque has since been measured in N cm when placing implants in pre-tapped sites (Ueda et al., 1991), or when placing self-tapping implants (Friberg et al., 1999a, Friberg et al., 1999b, Friberg et al., 2003, Johansson et al., 2004, Molly, 2006). The insertion torque at pre-tapped sites differs from the thread-cutting forces, and when the latter are excluded then insertion torque is “a function of the compressive stresses applied locally to the surrounding bone and friction at the implant-bone interface” (Molly, 2006). Peak insertion torque has been used by many investigators as an indicator of primary implant stability (Molly, 2006). O’Sullivan and colleagues (2000) demonstrated that the peak insertion torque occurs at different times for parallel and

tapered implants. Where parallel implants achieve peak insertion torque when the implant head is fully seated, while for tapered implants a continuous increase of insertion torque occurs owing to lateral compression during insertion of the implant (O'Sullivan et al., 2000, Molly, 2006). Roca-Millan and colleagues recently carried out a systematic review and meta-analysis to assess the relationship between insertion torque and marginal bone loss (Roca-Millan et al., 2020). They found no association between marginal bone loss around the implants and insertion torque values above or below 50 N cm up to 15 months. Normally, a high insertion torque would be associated with good implant stability. Norton et al. (2017) found that whilst the primary stability of implants with low insertion torque was low when measured with RFA, almost three-quarters of the implants had no marginal bone loss and the survival rate for the implants was 100% at 1 year. Greenstein and Cavallaro (2017) reviewed the literature and found that whilst primary stability is important, the lack of micromotion is a key factor in achieving predictable implant osseointegration. This was demonstrated by Sivoletta et al. (2012) in a canine model where implants were placed into oversized osteotomies and passively fixed with plates. All implants achieved osseointegration successfully (Sivoletta et al., 2012).

The lowest insertion torque required to establish primary stability has not yet been determined (Greenstein and Cavallaro, 2017). However, it has been said that insertion torque values above 40-45 N cm cause disturbance in the local microcirculation, which leads to necrosis of osteocytes and subsequent bone resorption (O'Sullivan et al., 2000). To investigate high versus low insertion torque values, Trisi et al. (2011) placed 40 implants in the mandible of sheep and carried out histologic, histomorphologic and

biomechanical evaluation at 1, 2, 3, 4 and 6 weeks. In each sheep, four implants were placed at 10 N cm on one side and on the contralateral side four implants were placed at 110 N cm. The authors found that the stability of the high torque implants was consistently better than that of the low torque implants. Microfractures were noted in the cortical plate surrounding the implants placed at high torque. These sites showed significant resorption at 2 weeks, however at 4 weeks up to 30% of the cortical wall had been replaced with new composite bone, and at 6 weeks this was at 40% (Trisi et al., 2011). Conversely, the implants placed at 10 N cm were not well adapted to the bone at 1 week and there were no cracks visible in the cortical plate. It took until 4 weeks for the gap between the cortical bone and the implant to be almost completely filled with new composite bone. The % BIC increased from 22.61 +/- 17.51 at 3 weeks to 50.46 +/- 4.17 at 4 weeks in the low torque implants. This is significantly lower than the % BIC of 64.90 +/- 5.55 for high torque implants ($P < .0001$). The authors concluded that the higher insertion torque was not associated with deleterious effects, but instead accelerated bone remodelling when compared to the low insertion torque implants and improved the primary stability of the implants (Trisi et al., 2011). However, further studies were recommended by the authors to confirm these results in humans. Khayat et al. (2013) carried out a prospective clinical trial in 48 patients to this end where 42 implants were placed with insertion torque > 70 N cm, and compared to 9 implants placed with insertion torque of 30-50 N cm. There were no statistically significant differences detected between the two groups for both bone stability and implant success rate after 2-3 months of non-submerged healing. The authors concluded that the use of high

insertion torque did not prevent osseointegration or negatively impact marginal bone resorption around tapered multi-threaded implants (Khayat et al., 2013).

With regard to immediate loading of implants, Papaspyridakos et al. (2014) carried out a systematic review on implant loading protocols for fixed prosthesis in edentulous patients and reported a minimum requirement of 30 N cm insertion torque.

1.3.2 Resonance Frequency Analysis

Resonance frequency analysis (RFA) is a technique developed for clinical measurement of implant stability and osseointegration first presented by Meredith and colleagues in 1996. The original method involved using an L-shaped transducer that was screwed into an implant or its abutment and then vibrated over a range of frequencies, generally from 5-15 kHz (Meredith, 1998). The vertical beam of the transducer contained two piezoceramic elements that were attached to a computer, a frequency response analyser and dedicated software. The first flexural resonance frequency of the beam was identified as a peak from plotting the amplitude (V) against the frequency (Hz). The resonance frequency of the implant is determined by the stiffness of the bone-implant interface and the distance from the transducer to the first bone-implant contact (Meredith, 1998). The prototype instruments gave the results in Hz, however by the time the first commercial version of the RFA technique (Osstell®, Integration Diagnostic AB, Goteberg, Sweden) became available the results were expressed as the implant stability quotient (ISQ) (Aparicio et al., 2006). The Osstell® was calibrated by the manufacturer, however the implant length had to be registered as a linear relationship

had been found in earlier studies regarding abutment length and the resonance frequency (Meredith et al., 1996). The implant stability quotient ranges in value from 1-100, where a high ISQ value indicates high implant stability and a low ISQ value indicates low stability. The ISQ values are based on the stiffness of the implant bone system and the calibrated resonance frequency of the transducer used (Turkyilmaz et al., 2009, Aparicio et al., 2006).

Factors that affect the resonance frequency analysis include the stiffness of the bone-implant interface, and the height of the abutment exposed. Meredith et al. (1996) showed that the vertical position of the implant, the marginal bone level and the abutment height all influenced the resonance frequency. In an initial study, Friberg and colleagues (Friberg et al., 1999a) assessed the placement of implants in a one-stage technique in the anterior mandible and found only minor changes occurred in the resonance frequency over the healing period for the majority of implants placed in dense bone of good volume. These findings are in contrast to the results of Rasmusson et al. (1998) who found a statistically significant increase in implant stability during the study period when implants were placed in rabbit tibia. They are also in contrast to the results of Friberg et al. (1999b) where implants were placed in the maxilla in a two-stage surgical procedure and followed for 20 months. In this study, the sites were grouped based on bone density (poor, medium and high) and the implant stability was measured with RFA at implant insertion, abutment connection, and 1-year follow up. Implants inserted into poor density bone showed greater changes in resonance frequency values in comparison to those inserted into medium- and high-density bone (Friberg et al., 1999b). This provides evidence for the impact of the implant-bone interface on the

stiffness of the implant – where less dense bone is more heavily influenced by the osseointegration that occurs during the healing process, as demonstrated by the increase in the resonance frequency values detected in implants placed in soft bone after healing (Friberg et al., 1999a, Friberg et al., 1999b).

1.3.3 Periotest™

The Periotest™ (Gulden-Medizintechnik, Bensheim an der Bergstrasse, Germany) was originally developed by Schulte and co-workers (1983) in order to dynamically measure the reaction of the periodontium to a defined impact load (Olivé and Aparicio, 1990, Aparicio et al., 2006). The periotest value (PTV) indicates the periodontal damping capacity and was designed to assess tooth mobility. The Periotest™ has since been used to assess implant stability, however the range is narrower owing to the fact that a stable implant with an implant-bone interface has more stiffness than a tooth surrounded by periodontal ligament (Aparicio et al., 2006).

The Periotest™ consists of an electronically controlled handpiece that contains an 8g metal rod that is accelerated by an electromagnet towards the tooth or implant. The rod is decelerated when it touches the tooth or implant, and then recoils. The more solid the tooth or implant is, the higher the deceleration, which is manifested as a higher recoil. The increased deceleration and quicker recoil time indicate increased damping capacity of the surrounding tissues (Olivé and Aparicio, 1990, Aparicio et al., 2006). The measurement of the damping capacity is given audibly and displayed digitally as a Periotest Value (PTV) on a scale of –8 to +50, where the lower value indicates lower

mobility or increased stability (Aparicio et al., 2006). In a preliminary study, Olivé and Aparico (1990) determined that the normative range for implants might lie between –5 to + 5 PTV. However, they outlined that large scale studies with follow up of 1-3 years of loaded function were required before the normal range of an osseointegrated implant could be determined. Truhlar et al. (1997a) reported on the data gathered from a veteran study across 31 centres where the PTV of 2,212 implants were measured at the surgical uncovering of the implant after a submerged healing protocol of 4-6 months. The mean PTV was –3.75, and 92.2% of the implants had a PTV of 0 or less. Truhlar et al. (1997a) found that the mean PTV differed for different bone densities and different areas of the jaw. The mean PTV of mandibular implants was lower than the mean PTV of maxillary implants (-4.14 vs -3.24 PTV). This is in line with the distribution of bone density, where the maxilla tends to have less dense and more trabecular bone, while the mandible has more dense cortical bone (Truhlar et al., 1997b). The relationship of the bone quality to the periotest value of the implant was also assessed in this study. Implants in Quality 1 bone had the lowest mean PTV (-4.13), closely followed by quality 2 (-4.00 PTV) quality 3 (-3.58 PTV) and quality 4 bone had a mean PTV of –2.64 It can further be concluded that factors that affect the PTV reading include the position of the implant in the jaw and the density of the bone.

A linear relationship has been noted for the contact time of the rod on the implant and the PTV which gives an indication of the robustness of the instrument (Meredith et al., 1996, Meredith, 1998, Aparicio et al., 2006). The positioning of the Periotest™ rod on the implant in relation to the first bone-implant contact has been shown to have a linear relationship with the PTV recorded in both *in vitro* and *in vivo studies* (Chai et al., 1993,

Meredith et al., 1996, Haas et al., 1995, Aparicio et al., 2006). Faulkner and colleagues (2001) carried out an *in vitro* experiment to attempt to better understand the clinical variables and physical parameters that have an impact on the Periotest™ instrument. As discussed above, they found that variation of 1mm height can have an impact of 1-2 PTV. They also suggested that the rim of the abutment should be used as the standard positioning for the rod, such that a small angle deviation from the perpendicular can be used to make the result more reproducible. A deviation in angulation on the abutment cylinder was found to result in a change in the point of contact of up to 2mm (the diameter of the rod) and had the effect of changing the reading by 2.5-4 PTV (Faulkner et al., 2001).

Therefore, it is understood that the vertical positioning of the implant, the abutment height, the level of the marginal bone and the striking position of the rod on the implant or implant abutment are critical factors for accuracy and reproducibility of results (Aparicio et al., 2006). The results for the correlation of implant length on the PTV postulated by Van Steenberghe et al. (1995) are contradictory with some authors finding no impact (Haas et al., 1995, Tricio et al., 1995) and others finding a correlation for the maxilla only (Olivé and Aparicio, 1990). It has been noted in several studies that lower PTVs are recorded for later follow up appointments. This implies that time elapsed since implant installation may influence the implant stability (Aparicio et al., 2006). Van Steenberghe and colleagues (1995) found decreasing PTVs up to the fifth year of follow up for 213 mandibular implants and reasoned that this was on account of ongoing remodelling at the implant-bone interface resulting in further stiffening.

1.3.4 Factors That Affect Implant Stability Assessment

1.3.4.1 Bone Quality and Bone Density

Bone density has been equated to bone quality in the literature, however this is not accurate as there are many factors aside from density which affect bone quality. These include the “bone metabolism, cell turn over, mineralisation, maturation, intercellular matrix, and vascularity” amongst others (Molly, 2006). Each of these factors may influence the implant outcome. Esposito et al. (1998) concluded that surgical trauma and anatomical conditions are the most pertinent factors for early loss of an implant, whilst bone quality, bone quantity and overloading of the implant are important influencing factors for late implant failures. (Truhlar et al., 1997b) investigated the distribution of different bone qualities in different anatomical positions of the jaw when placing 2,839 implants in a large-scale, multicentre study. They classified the bone quality according to Lekholm and Zarb (1985) and reported quality 2 and 3 bone to be present most commonly, with quality 1 and quality 4 found in a minority of cases. Quality 2 bone was most often present in the mandible, whilst quality 3 bone was found most often in the maxilla. These findings are demonstrated in the bar chart below.

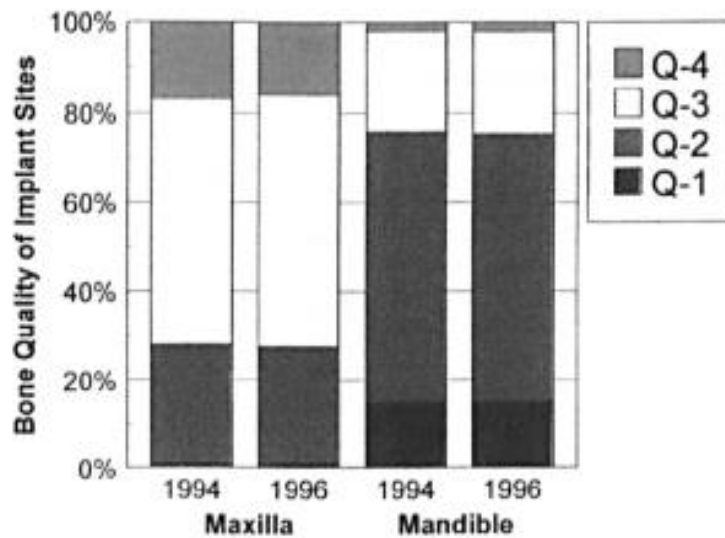


Figure 6: Comparison of the data on bone quality from the DICRG trial (Truhlar et al., 1997b). Implants were placed in 1994 (774 maxillary, 1,161 mandibular) and in 1996 (1,237 maxillary, 1,602 mandibular).

Truhlar et al. (1997b) also reported on the relationship between implant mobility at placement and the bone quality present. There was a much higher percentage of mobile implants on placement in quality 4 bone (6.8%) in comparison to the others (2.8%, 2.3% and 3.6% for qualities 1,2 and 3, respectively). This data is of use to both the clinician and the industry, as alterations in implant design and surgical technique have been forwarded to minimise the impact of the effect of poor-quality bone on implant stability (Truhlar et al., 1997b).

A meta-analysis by Chrcanovic et al. (2017) reports on the failure rate of dental implants placed in sites of different bone quality and quantity per the Lekholm and Zarb (1985) classification. Bone quality is divided into four groups based on the ratio and structure of compact and trabecular bone present. Bone quantity is divided into five groups

depending on the residual architecture after tooth extraction (A-E) (Lekholm, 1985, Chrcanovic et al., 2017). These five groups or shapes of bone relate to five stages of jaw bone resorption and the impact of each on the placement of Brånemark fixtures. (Lekholm, 1985). They do not necessarily describe the resorption process in chronological order, but describe the different shapes of residual bone with which a patient may present. In the mandible, resorption is only described in terms of loss of height, whilst in the maxilla there is bone resorption in both the horizontal and vertical planes. Shape A represents a healed alveolar ridge that has only recently undergone extraction and therefore is of normal height and width. Shape E by contrast demonstrates a severely atrophic ridge where almost no alveolus remains.

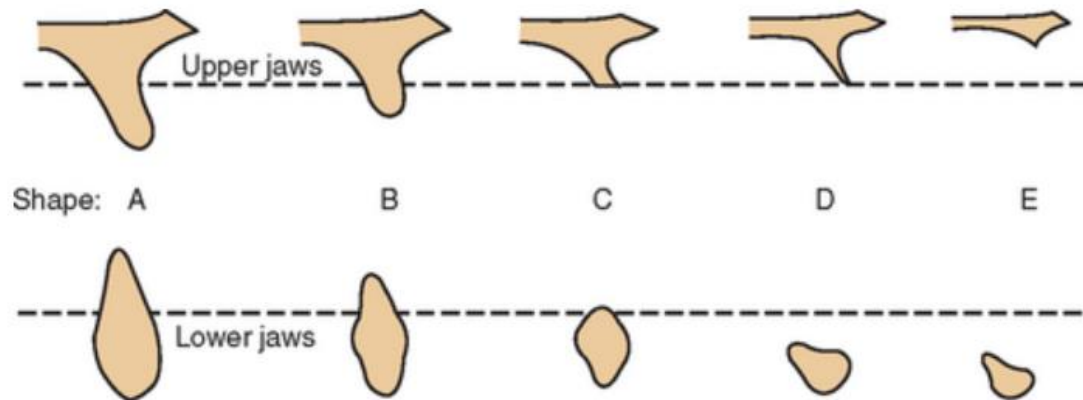


Figure 7: Bone quantity Classification as presented by Lekholm and Zarb (1985).

In the maxilla, the bone resorbs in the horizontal and vertical plane while in the mandible bone resorption is presented as loss of height only. Shapes A-E present various stages of the process, each with their own management considerations prior to implant placement.

Whilst these classifications are not perfect due to the subjectivity involved, they are routinely used in reports throughout the literature (Chrcanovic et al., 2017). The implant survival rates of a total of 39, 252 implants were assessed in relation to bone quality in 94 studies. The failure rate for implants placed in type 4 bone was significantly higher (8.06%) in comparison to the failure rates for the other types of bone quality (3.38% for type 1, 3.13% for type 2, and 4.27% for type 3 bone). Similarly, the survival rates for 17,333 implants placed in bone quantities A-E across 55 studies were analysed and a much higher failure rate was reported for quantity D and quantity E (8.74% and 18.98%, respectively) in comparison to the failure rates for quantities A, B and C (3.98%, 3.75% and 4.74%, respectively) (Chrcanovic et al., 2017).

| Quantity | RR (CI) | P |
|-------------------|-------------------|----------|
| Q A-B | 1.45 (0.87, 2.17) | .07 |
| Q A-C | 1.29 (0.95, 1.74) | .10 |
| Q A-D | 0.74 (0.51, 1.08) | .11 |
| Q A-E | 0.25 (0.14, 0.44) | < .00001 |
| Q B-C | 0.74 (0.58, 0.94) | .01 |
| Q B-D | 0.47 (0.36, 0.61) | < .00001 |
| Q B-E | 0.18 (0.14, 0.24) | < .00001 |
| Q C-D | 0.57 (0.42, 0.78) | .0005 |
| Q C-E | 0.25 (0.19, 0.33) | < .00001 |
| Q D-E | 0.43 (0.31, 0.59) | < .00001 |
| F/T (%) QA | 92/2,311 (3.98) | |
| F/T (%) QB | 274/7,302 (3.75) | |
| F/T (%) QC | 268/5,651 (4.74) | |
| F/T (%) QD | 155/1,774 (8.74) | |
| F/T (%) QE | 56/295 (18.98) | |
| Number of studies | 55 | |

CI = confidence interval; F/T (%) = failed implants/total number of inserted implants (% of implants that failed); Q = bone quantity.

Figure 8: Table from Chrcanovic et al. (2017) comparing the risk ratios (RR) between implants inserted in bone of different quantities according to the Lekholm and Zarb Classification (1985) (A-E).

Furthermore, a sensitivity analysis was performed to assess whether the implant surface had an impact on the survival rate for different bone qualities and quantities. The results showed a trend for implants with oxidised and sandblasted/acid-etched surfaces to reduce the significant failures when compared to turned implants in bone qualities 1 and 2, and 1 and 3, but not for quality 1 and 4 bone (Chrcanovic et al., 2017). The authors conclude that within the limitations of the study, “sites with poorer bone quality and lack of bone volume may statistically affect implant failure rates,” and that the implant surface may influence the failure rate of implants in different bone qualities (Chrcanovic et al., 2017).

In a mathematic model of the Periotest™ impacting the abutment or implant, it was seen that the contact time depended not only on the positioning of the rod, but also on the thickness, the stiffness and the damping provided by the supporting tissues (Faulkner et al., 2001). The impact of the alveolar bone design and form is therefore significant when assessing implant stability. When treatment planning, a pre-surgical assessment of the bone density could contribute to improving the primary stability of the implant by modifying the surgical technique, the loading protocol or the type of implant placed in order to account for the particular characteristics of the bone at that site (Molly, 2006).

1.3.4.2 Surgical Protocol

The surgical protocol used is one factor that can have a significant impact on implant stability. A 20% reduction in the failure rate of single implants was reported by Ottoni et al. (2005) for every 9.8 N cm increase in the insertion torque value. Under preparation of the osteotomy is one method that is used to increase the insertion torque value and therefore the primary stability of the implant (Elsayyad and Osman, 2019). One group published a 10% improvement in the primary stability of implants placed in bovine bone when one drill size smaller was used for the osteotomy (Degidi et al., 2015). However this may reduce the size of the healing chamber present between pristine bone and the implant surface, therefore decreasing the speed of woven bone formation and establishment of secondary stability (Elsayyad and Osman, 2019). The use of osteotomes for preparation of the implant osteotomy is a surgical method used to augment the

properties of the surrounding bone. Summers (1994) describes how the use of osteotomes may conserve osseous tissue rather than the more common subtractive drilling procedure. The principle of bone compaction at the osteotomy site was investigated further and in 2000 resulted in the development of a sinusoidal thread implant design (LaminOss; Implants Ltd., Holliswood, NY) (Elsayyad and Osman, 2019). More recently, a technique based on osseodensification drilling was introduced using a bur specifically designed for the purpose called a Densah Bur (Versah, Jackson, MI) (Elsayyad and Osman, 2019). The osseodensification technique uses non-subtractive drilling with a reverse cutting bur to compress autografts against the periphery and the apex of the osteotomy site (Elsayyad and Osman, 2019). Osseodensification is reported to increase the primary stability, the bone mineral density and the bone-implant contact ratio (Huwais and Meyer, 2017). Adapted surgical methods can have an impact on the osseointegration process and therefore the stability of the implants when assessed by the clinician.

1.3.4.3 Implant Characteristics and Loading

Ochi et al. (Ochi et al., 1994) analysed the periotest values of implants placed by the Dental Implant Clinical Research group at second stage surgery in relation to the type, material, coating, diameter and length of the implant. They found that hydroxyapatite-coated implants and implants of increased diameter and length resulted in lower PTVs, i.e. indicated increased stability. The hydroxyapatite-coated cylinder implants gave the most favourable PTV reading, and the commercially pure titanium screws gave the least

favourable. Walker et al. (1997) evaluated the periosteal values for the same cohort of patients two years after the second stage surgery had been performed. The authors found that the mean PTV for the uncoated implants had decreased gradually over the 24 months until the values were almost identical.

Furthermore, Walker et al. (1997) Found that while the PTVs of implants placed in quality 3 bone did not alter greatly over the 24 months, the PTVs of implants placed in bone of qualities 1 and 2 decreased (i.e. became more stable), while the PTV of implants placed in quality 4 bone became more positive, indicating a reduction in stability. The improved PTVs over time found in this study are consistent with the literature regarding bone maturation and remodelling (Walker et al., 1997), where the close relationship of the implant to the bone allows the transfer of stress to the supporting bone to encourage modelling and remodelling. Lian et al. (2010) reported that where the bone-to-implant contact initially was 25-100%, the final outcome of 58-60% bone-to-implant contact was expected once equilibrium was achieved after bone remodelling.

1.3.5 Clinical Applications

1.3.5.1 Clinical Applications of Implant Assessment with RFA

The clinical applications of the resonance frequency analysis technique include measuring the primary stability of implants in order to determine whether immediate loading is possible, as well as monitoring the stability over time to assess the level of

integration of the implant before proceeding with the next stage of implant restoration. It may be that the RFA technique could be useful as a predictor of implant failure, although further research on this subject is required. One implant out of the 75 implants placed in the anterior mandible in the study by Friberg and team (1999a) became clinically mobile and required removal. At six weeks post-operatively, this implant showed radiographic evidence of marginal bone loss but was otherwise stable and asymptomatic. However, the RF value of the implant at this appointment was 2,000 Hz lower than the RF value recorded on insertion of the implant. At 15 weeks, clinical mobility of the implant was detected, along with a RF value 300 Hz lower again (Friberg et al., 1999a). Therefore, it may be that the RFA technique allows for early prediction of implant failure through early detection of low or decreasing implant stability. In a second patient in the study by Friberg et al. (1999a), the RF values dropped significantly for 3 implants between 2-6 weeks. Appropriate intervention was undertaken and the RF values stabilised and increased slightly up to attachment of the fixed device. Therefore, not only does the RFA technique identify failing implants, but it also allows for timely intervention and subsequent monitoring of the implant until implant stability is once again achieved.

Immediate implant placement has received heightened interest in recent years. A systematic review by Gotfredsen et al. (2021) on patient's perception of timing concepts in implant dentistry found some evidence that patients rehabilitated with implant-supported full-arch fixed dental prostheses were more satisfied when an immediate loading protocol was used in comparison to an early or delayed protocol. However, the difference for this cohort of patients was not clear after 1 year. The evidence for patient

satisfaction regarding implant placement or loading protocols is otherwise lacking (Gotfredsen et al., 2021). While patient satisfaction and aesthetic outcomes play a role in therapeutic success nowadays, the long-term implant survival and biologic success regarding marginal bone stability are still imperative to achieve a successful result (Pommer et al., 2021). The resonance frequency analysis technique has therefore been investigated to as a method to assess the primary stability of implants placed immediately into fresh extraction sockets, and the correlation between the peri-implant bone levels and implant stability. Turkyilmaz and co-workers (2009) carried out a cadaver study on six mandibles to this end and measured the insertion torque and resonance frequency values for 14 implants immediately placed at 5 different depths in the same extraction sockets. A statistically significant correlation was found for the mean insertion torque (28.9 ± 7 Ncm) and RFA values (65.6 ± 9 ISQ) for these implants. There was also a statistically significant decrease in the mean insertion torque and ISQ value for each millimetre increase in the peri-implant vertical bone defect. This study demonstrated that the RFA technique is sufficiently sensitive to detect marginal bone defects at implants placed in fresh extraction sockets. The decrease in ISQ per millimetre was similar to that expected by the manufacturers for implants placed at different heights in the same bone density, and highlights impact that the distance from the abutment to the first implant-bone- contact has on the reading of resonance frequency readings (Turkyilmaz et al., 2009)

Clinical limitations of the RFA technique include the fact that it cannot be used on implants with cemented restorations or implants that are no longer in production (Lachmann et al., 2006a). Variations in the length of the abutment and distance to the

marginal bone crest also have an impact on the ISQ recorded (Sennerby and Meredith, 2008). The orientation at which the transducer is held in relation to the implant has also been shown to have an impact on the ISQ recorded, where Fischer et al. (2008) found that mesial-distal measurements had higher RFA values recorded than buccal-palatal ones for all implants.

1.3.5.2 Clinical Applications of Implant Assessment with Periotest™

Drago (2000) discusses how the Periotest™ may be used to assess in conjunction with other methods for early detection of whether an implant has osseointegrated, or not. An ability to determine whether an implant has failed to osseointegrate prior to commencing with costly restoration stages would concurrently reduce the cost of the failed implant, and reduce the treatment time if the failed implant was removed as soon as it was detected. Drago (2000) reports on an *in-vivo* results for the predictive value of the Periotest™ instrument, and found the positive predictive value to be 64%, and negative predictive value to be 99%. This means that in this study, the Periotest™ predicted non-integration of implants 64% of the time, and correctly predicted integration of the implants 99% of the time. Drago (2000) draws attention to the fact that this means that 1% of the predictions were false – where integrated implants were evaluated by the Periotest™ as being non-integrated – and therefore, adjunctive methods such as radiographs and clinical judgement should be used when assessing implants for osseointegration at 2nd stage surgery. Drago (2000) also discusses that the negative predictive value for implants with a PTV greater than or equal to +5 at time of

second stage surgery and occlusal loading were not significant. This is in line with the findings of Olivé and Aparicio (1990) who left implants with a PTV of +4 or more unloaded for an additional period of time and successfully restored these implants once lower PTVs had been recorded.

Faulkner et al. (2001) also draw attention to the fact that the ultimate use of the Periotest™ is not in assessing the absolute value of the PTVs, but in comparing the PTVs over a period of time to evaluate the integrity of the bone-implant interface in a non-destructive manner. Truhlar et al. (1997a) also discusses the Periotest™ being used in this fashion which would allow an assessment of the implant-bone interface whilst the implant is functioning under a prosthetic load. Accurate records of consecutive PTVs could help identify the point at which pathological processes may have begun (Truhlar et al., 1997a).

The clinical limitations of the Periotest™ device include the greater measurement error when used *in vivo* compared to *in vitro* experiments (Meredith et al., 1998). The different superstructures and their attachment mode has also been shown to have an impact on the PTV result (Gomez-Roman and Lukas, 2001). Furthermore, as demonstrated by Meredith et al. (1998) there is an increase in PTV by 1.5 units for each millimetre away from the marginal bone. Therefore, the superstructure upon which the reading is made has a significant impact on the resultant PTV. The manufacturers also recommend that the Periotest™ handpiece be positioned in a particular manner in order to obtain valid and reproducible readings (Medizintechnik-Gulden, 2015). Ideally the handpiece is held horizontally at 90° to the implant abutment with a range of 65° - 115°

being accepted in the vertical plane. The angle between the Periotest™ handpiece and the implant abutment should be 90° to gain the most accurate reading. Deviations up to 45° are acceptable, e.g. in the molar region where direct access is difficult, however the PTV recorded may differ by 1 PTV owing to the altered contact angle between the piston and the abutment (Medizintechnik-Gulden, 2015). Another operating limitation is the required distance between the handpiece and the abutment when measuring the damping capacity of the implant. Distances outside the range of 0.6-2.5mm will not give a valid reading and achieving this clinically can be difficult (Medizintechnik-Gulden, 2015).

1.3.5.3 Correlation between the different methods to assess implant stability

Lachmann et al. (2006a) set out to assess the measurement accuracy of the Periotest™ and the Osstell® devices in a bovine bone model independently to assess the reliability of each, and then to compare the results in order to furnish clinicians with knowledge that could aid their choice regarding which device may be of use in clinical practice. The reliability of each tool was investigated firstly by comparing measurement errors in repeated measurements by calculating the within-experiment standard deviations, and secondly by using the approach suggested by Bland & Altman (1996) to calculate repeatability. The results demonstrated no difference more than 2 standard deviations in the variations in the results, and both methods were found to be reliable. Previous studies had outlined that the reliability of Periotest™ would be +/- 1 PTV around the

“true” value, and +/- 2 PTV where a high level of mobility was present (Lachmann et al., 2006a, Teerlinck et al., 1991, van Steenberghe and Quirynen, 1993). The results of the study by Lachmann et al. (2006a) indicate that the difference between two measurements with the Periotest™ under the same conditions would differ by less than 1 PTV in 95% of observations. With regard to the repeatability of the RFA technique, this study confirmed the earlier findings of Meredith et al. (Meredith et al., 1996, Meredith et al., 1997) where the repeatability of less than 1% was reported. Lachmann and colleagues (2006a) concluded that the measurement error of both techniques should not have an impact on the diagnosis of implant stability or therapeutic decision making.

The implant stability values of implants placed adjacently in the same bone block, and in separate bone blocks were also compared. The bovine bone blocks used were of Class 1 and Class 2 bone per the Lekholm and Zarb Classification (Lekholm, 1985). It was found for both the Periotest™ and the RFA technique that there was a statistically significant difference in the results between the two bone blocks, and between adjacent implants in the softer bone model. The condition of the bone was the only variable that significantly affected the primary implant stability measurement in this study (Lachmann et al., 2006a).

This team went one step further and attempted to correlate the RFA technique to the Periotest™ by successively removing millimetre increments of marginal bone in order to simulate peri-implant defects of various heights. The resulting recorded ISQ and PTV in this bovine bone model were then compared and analysed using linear regression. The results are displayed below.

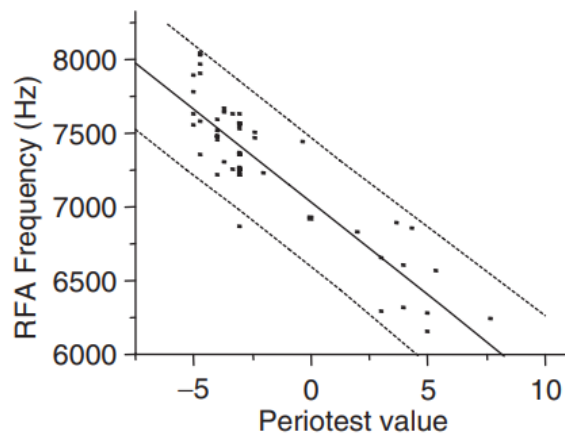


Figure 9: Comparison between Osstell® and Periostest™ devices (Lachmann et al. 2006a)

Method comparison of the Osstell® and Periostest™ devices in bovine bone where peri-implant bone loss was simulated. Linear regression analysis was carried out: n= 52 measurement means, $R^2 = 0.8$, $P < 0.0001$ (Lachmann et al., 2006a).

The authors found a statistically significant linear correlation between the Osstell® and Periostest™ measurements. They developed equations to transfer the Periostest™ readings into Osstell® frequency and ISQ where “Frequency = $7038 - 125 \times \text{PTV}$, and ISQ = $76 - 2 \times \text{PTV}$ (Lachmann et al., 2006a).

In a follow up study, the same team assessed the implant stability of implants with increasing peri-implant bone defects (0-9mm) in acrylic blocks using both the Periostest™ and Osstell® devices (Lachmann et al., 2006b). The repeatability of both methods was comparable, and the analysis of variance demonstrated that both methods of implant stability assessment were significantly affected by the peri-implant bone loss. The Periostest™ device detected a statistically significant difference in differences of 4mm of bone height for all machined Brånemark implant lengths, but was more precise in

shorter implants where differences were detected in 2mm differences in bone height. Interestingly, the Osstell® device was found to be more precise, detecting a difference of 2mm of bone height regardless of the length of the Brånemark implants assessed. A similar result was found when the implant stability of various diameters of Friault-2 implants was assessed, again with the Osstell® device being more precise than the Periotest™ device. Linear regression analysis of the two methods for measuring implant stability showed a statistically significant linear association between the ISQ and PTV readings. It was found that “each Periotest™ value may be assigned to an ISQ value with a range of +/- 7 ISQ units and each ISQ value can be assigned a PTV with a range of +/- 3 PTV units” (Lachmann et al., 2006b).

Zix et al. (2008) carried out a clinical trial to "evaluate the presumed correlation the RFA technique and the damping capacity assessment of Periotest™". This was the first direct comparison of both techniques *in vivo*. They measured the implant stability of 213 unloaded and loaded clinically stable Straumann implants placed using a non-submerged, single stage technique in 65 edentulous patients. The authors found that the results of both measurement techniques to be similar where the correlation of both techniques were – 0.64 (Pearson) and – 0.65 (Spearman). However, the correlation coefficients seen in this clinical study were less than those recorded by Lachmann et al. (2006a, 2006b) which indicates the limitations presented by the clinical environment such as accessibility, space and patient compliance (Zix et al., 2008).

The single-measure intraclass correlation coefficient was 0.99 for ISQ, and 0.88 for the PTV (CI 95%) (Zix et al., 2008). This demonstrates a poorer reproducibility for the

Periotest™ device than for the Osstell® device. There was no significant impact of implant length on the PTV or ISQ value recorded, however there was a statistically significant correlation between the RFA and PTV recorded regarding the implant diameter.

With regard to the distribution of the values, the RFA values were found to be almost linear to the normal distribution while the Periotest values differed more from the normal distribution (Zix et al., 2008). The authors concluded that while both measuring techniques were applicable in assessing implant stability, the Osstell® device was more precise than the Periotest™, which appeared to be more susceptible to the clinical conditions (Zix et al., 2008).

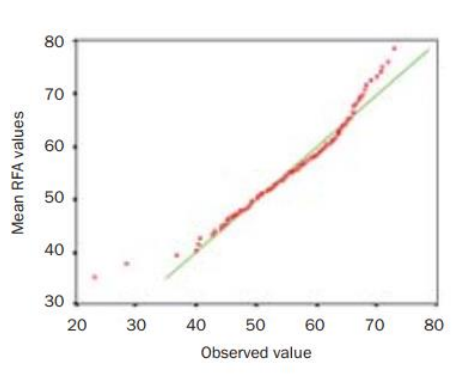


Fig 6 Quantile-quantile plots of ISQs.

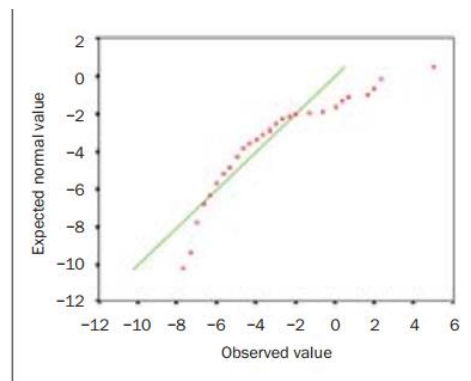


Fig 7 Quantile-quantile plots of Periotest values.

Figure 10: Quantile-quantile plots of the ISQ and Periotest™ values recorded in the clinical trial by Zix et al. (2008).

A meta-analysis of the methods used to quantify implant stability was carried out by Cehreli et al. (2009) with a secondary aim of identifying correlations between the

techniques. A total of 47 articles were found to fulfil the inclusion criteria – 11 human cadaver studies, 15 clinical studies, 15 animal studies and 5 in vitro studies. Six studies provided the *P* value for comparative evaluation of cutting torque or insertion torque and RFA where, using the Fisher method, it was found that the correlation between cutting torque/insertion torque and RFA was statistically significant ($p = 0.0022$). One study provided a *P* value for comparison of cutting torque/insertion torque and Periotest™ and RFA, where the correlation between Periotest™ and cutting torque/insertion torque was found to be significant ($P = 0.015$) while the correlation between Periotest™ and RFA was found to be insignificant ($P = 0.28$) (Nkenke et al., 2003).

Nine of the 47 articles provided *r* values. The forest plots and funnel plots of these studies are displayed below.

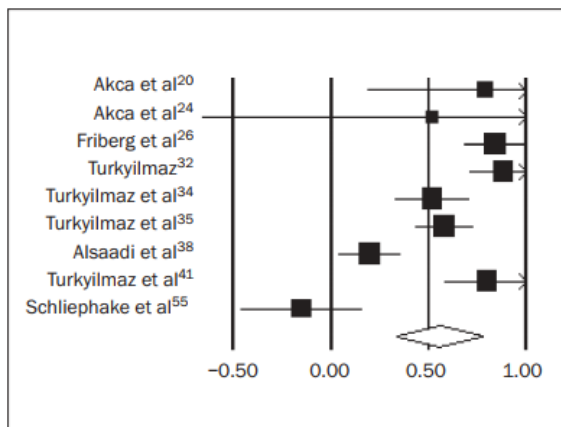


Fig 1 Forest plot of nine studies that included *r* values (point estimate and 95% confidence intervals).

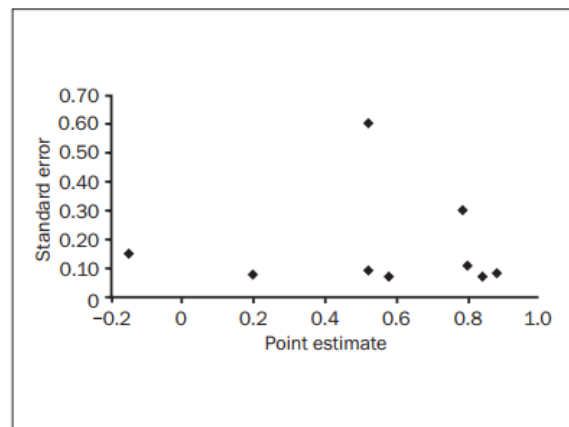


Fig 2 Funnel plot of nine studies including *r* values.

Figure 11: Forest plot and funnel plot of the nine studies that included *r* values to allow comparative analysis of cutting torque/insertion torque and RFA (Cehreli et al., 2009).

Two studies (Akça et al., 2007, Schliephake et al., 2006) found no statistically significant correlation between cutting torque/insertion torque and RFA, whilst the other seven studies (Akca et al., 2006, Akça et al., 2007, Friberg et al., 1999b, Turkyilmaz, 2006, Turkyilmaz et al., 2006, Turkyilmaz et al., 2007, Alsaadi et al., 2007, Schliephake et al., 2006) found a statistically significant correlation that was unaffected by publication bias. When sensitivity analysis was carried out on these studies, there was no change in the results. A statistically significant relationship was found for cutting torque/insertion torque and RFA when all studies were assessed, and when cadaver studies were assessed separately to the other studies ($r = 0.554$, $r = 0.726$ and $r = 0.629$ respectively, $P = .000$ for all) (Cehreli et al., 2009).

In contrast to the results of Zix et al. (2008) who found the Periotest™ less reliable than the Ostell® device, Schnitman and Hwang (2011) concluded that the PTV was “the most reliable predictor at implant placement of failure to osseointegrate” when compared to insertion torque and resonance frequency analysis. The authors undertook a retrospective study of 18 patients to assess the “predictive usefulness of preoperative CT bone density and the intraoperative implant stability measurements” of insertion torque, RFA and PTV in order to develop an evidence-based algorithm to determine whether an implant was suitable for immediate loading or exposure, or required submerged healing (Schnitman and Hwang, 2011). Preoperative CT bone density (measured in Hounsfield Units) correlated with all methods used to assess primary stability. Analysis of the correlation between insertion torque, PTV and RFA was also

completed, with the strongest correlation found between PTV and RFA ($r = 0.78$). Correlation between insertion torque and PTV or RFA was not as strong ($r = 0.64$ and $r = 0.59$, respectively) however RFA was only used to assess implant stability in the latter half of patients included in the study (Schnitman and Hwang, 2011). Based on the significant difference between the PTV for the implants that failed and were successful overall, and those that were successful and failed from the submerged protocol only, the authors determined that the Periotest™ was the “most reliable of the intraoperative technologies” used in this study to predict failure at time of implant placement.

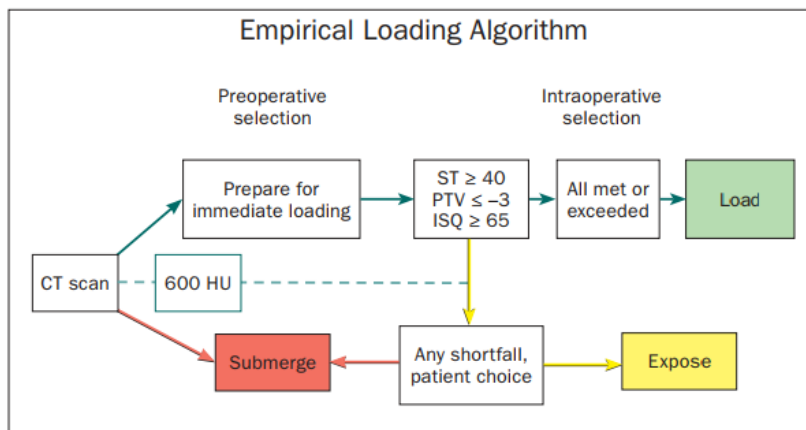


Figure 12: Empirical Loading Algorithm to determine whether an implant can be immediately loaded, exposed or submerged (Schnitman and Hwang, 2011).

The figure above shows the conservative algorithm composed by the authors to determine the immediate course of action after implant placement. The authors highlight that the data were skewed because 12 implants in seven patients were grouped according to parameters other than those indicated by the intraoperative stability measurements e.g. patient wishes, one implant among a group not meeting the

immediate loading or exposure criteria. They also recognise that the values seen in this study group of 18 patients may not be transferable to other implant designs of computerised tomography procedures, but within the limitations of the study found the PTV and ISQ values to correlate to each other well, and for the PTV to be the most reliable predictor at implant placement for failure of an implant to osseointegrate (Schnitman and Hwang, 2011).

The linear correlation between the RFA and Periotest™ that was discussed in Lachmann et al. (2006a, 2006b) was further corroborated in a clinical study by Oh and Kim (2012) who assessed a total of 211 dental implants in 162 patients. The quality of the bone was determined using the Lekholm and Zarb classification (1985) based on radiographic assessment and the drilling resistance that was felt by the operator carrying out the osteotomy. The Osstell® Mentor and Periotest™ devices were used to assess implant stability immediately after implant installation. The PTV was recorded with the handpiece positioned at the connection point of a 4mm abutment. The ISQ was recorded after installing a Smartpeg. Readings were taken from both the buccal and lingual aspects on both accounts.

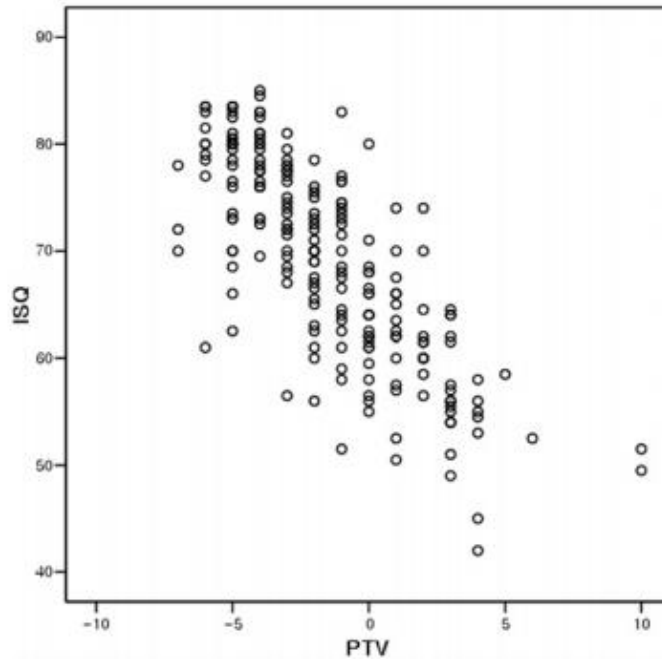


Figure 13: Scatter plot of the Periotest™ values and ISQ values recorded by Oh and Kim (2012).

The results of this study found that implants placed in the mandible were more stable than those placed in the maxilla, with no statistically significant difference between their anterior and posterior sites. The authors found a statistically significant correlation of -0.777 between the ISQ value and the PTV ($P < 0.01$). The relationship between the ISQ and PTV is visually depicted in the scatter plot above (Oh and Kim, 2012).

Marquezan et al. (2012) carried out a systematic review to assess the influence of bone mineral density on primary implant stability. They set out to use HU, ITV, ISQ and PTV as the parameters, however no results for PTV were found. There was correlation of 0.46 found in one study, and a number of studies found the bone density of the mandible to be greater than that of the maxilla, and greater in men than in women. The authors

concluded that despite the weak to moderate methodological quality and differences present between studies, all articles assessed demonstrated a positive association between primary implant stability and bone density (Marquezan et al., 2012).

In a laboratory-based study, Hsu and colleagues (2013) combined cortical shells of various thickness with polyurethane foam blocks of different elastic moduli in order to represent the various qualities of bone that are presented to the implant surgeon.

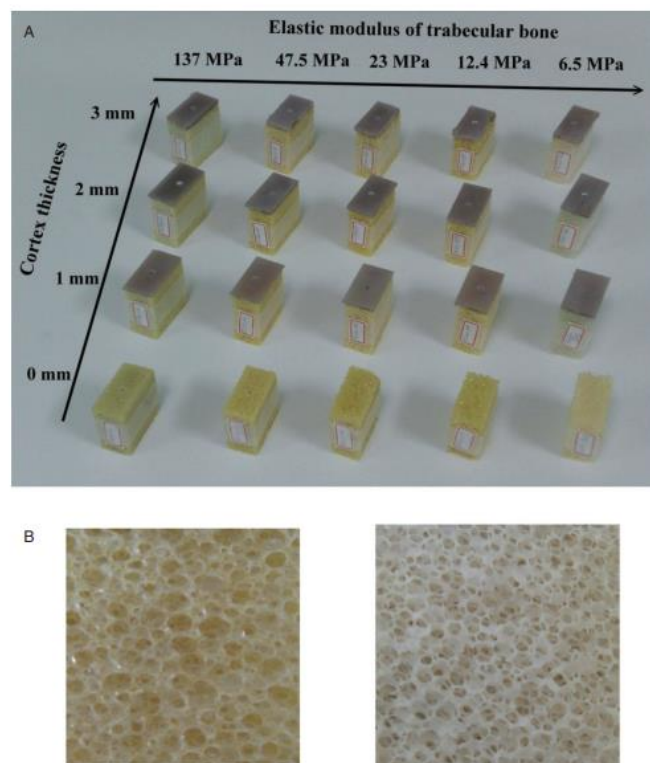


Figure 14: Foam blocks used in study by Hsu et al. (2013)

Image demonstrating A) the foam blocks of different cortical thickness and decreasing elastic modulus of trabecular bone region, and B) the close-up images of the trabecular bone for healthy bone (left) and osteoporotic bone (right) (Hsu et al., 2013).

A self-tapping 3.75 x 13mm implant was inserted into each block, and the insertion torque value, PTV and ISQ of each implant were recorded. All implant stability measurements varied significantly with the thickness of the cortical shells and the elastic modulus of the trabecular bone ($p < 0.005$). Models with thicker cortical plates had higher ITV and ISQ values, and lower PTV. A similar result was found for models with higher elastic modulus of trabecular bone, except for the models with an elastic modulus of 47.5 MPa and 137 MPa. The ITV values increased in a linear fashion with the elastic modulus, however there was a higher variation in the PTV and ISQ values when the elastic modulus was lower. The results of a second order regression analysis demonstrated that both ISQ and PTV methods had strong relationships to cortical bone thickness ($R^2 > 0.92$), and to the elastic modulus of the trabecular bone ($R^2 > 0.9$ and $R^2 > 0.7$ for ISQ and PTV, respectively) (Hsu et al., 2013). This study used the ITV, PTV and ISQ to assess the stability of implants in bone models of different presentations with varying trabecular structures and cortical thickness, including that of osteoporotic bone. The authors concluded that the implant stability was affected by the strength of the trabecular bone and the thickness of the cortical plate, but these factors were non-linearly correlated to the ITV, PTV and ISQ (Hsu et al., 2013). They also found that the ITV and PTV were of more use in identifying primary implant stability in osteoporotic bone than the ISQ (Hsu et al., 2013). This is of interest as it may be that the different technologies are more appropriate in different environments.

Pommer et al. (2014) carried out a study on 11 cadaveric specimens of human maxillae “to investigate the impact of residual bone height, bone density, and implant diameter on primary stability of implants placed in the atrophic maxillary sinus floor”. The study

consisted of NobelActive™ implants (NA Internal, TiUnite, Nobel Biocare AB, Goteborg, Sweden) of 10mm length and of 3 varying diameters being placed in 22 maxillary sinus floors according to the manufacturer’s instructions for implant placement in type IV bone. Conventional computerised tomographic scans were obtained of each specimen prior to implant placement to assess the bone density. The primary implant stability was assessed by cutting resistance measurement (ITV), Periotest™ (PTV), and resonance frequency analysis (ISQ). The mean residual alveolar ridge height measured 4.0 +/- 1.4 mm at the implant sites. Mean radiographic bone density was 110 +/- 51 HU. Details of the implant diameters, residual ridge heights, and implant stability measurements are shown in the table below.

| | Residual alveolar bone height | | | |
|------------|-------------------------------|-------------|-------------|------------|
| | 2.0–2.9 mm | 3.0–3.9 mm | 4.0–4.9 mm | 5.0–6.0 mm |
| ITV | | | | |
| 3.5 mm | 19 ± 12 Ncm | 16 ± 8 Ncm | 16 ± 7 Ncm | 20 ± 9 Ncm |
| 4.3 mm | 19 ± 5 Ncm | 14 ± 10 Ncm | 16 ± 6 Ncm | 14 ± 8 Ncm |
| 5.0 mm | 16 ± 9 Ncm | 17 ± 6 Ncm | 19 ± 13 Ncm | 16 ± 7 Ncm |
| PTV | | | | |
| 3.5 mm | 8 ± 6 | 8 ± 8 | 6 ± 6 | 2 ± 3 |
| 4.3 mm | 7 ± 6 | 11 ± 12 | 12 ± 9 | 5 ± 4 |
| 5.0 mm | 14 ± 16 | 7 ± 5 | 8 ± 7 | 9 ± 6 |
| ISQ | | | | |
| 3.5 mm | 45 ± 19 | 45 ± 22 | 50 ± 11 | 61 ± 8 |
| 4.3 mm | 34 ± 7 | 37 ± 12 | 42 ± 6 | 46 ± 5 |
| 5.0 mm | 42 ± 4 | 45 ± 9 | 37 ± 16 | 46 ± 3 |

Table 1: Table showing the primary implant stability measurements and residual ridge heights for the three different diameters of 10mm NobelActive™ implants placed in the cadaveric study by Pommer et al. (2014).

The mean primary implant stability measurements recorded were; ITV 17.0 +/- 7.8 Ncm (range 5-38 N cm), 8+/-7 PTV (range -2 to 27 PTV), 44 +/-12 ISQ (range 8-70 ISQ). The authors found that correlations among the outcome measures (ITV vs. PTV: $r_s = -0.58$,

ITV vs. ISQ: $r_s = 0.52$, PTV vs. ISQ: $r_s = 0.73$) were all highly significant ($P < 0.001$) (Pommer et al., 2014). Only the radiographic bone density recorded had a statistically significant correlation to all three methods of assessing primary implant stability ($P < 0.001$). The highest degree of correlation was found between the radiographic bone density and ITV ($r_s = 0.64$). As a lower number on the PTV scale indicates higher implant stability, an inverse correlation was found between bone density and the PTV ($r_s = -0.44$). Of interest, is the fact that the correlation between the bone density and ISQ values was lower ($r_s = 0.39$), but still highly significant. The correlations recorded in this study are similar to that of Hsu et al. (2013) who found the Periotest™ of more use in osteoporotic bone types, and to the results of Schnitman and Hwang (2011) who found the Periotest™ to be the most reliable measure, but in contrast to the results of Zix et al. (2008) who found the Osstell® device more reliable. The authors concluded that bone density is a major determinant of primary stability in maxillary sinus augmentation with simultaneous implant placement, or the placement of short implants, and recommend pre-operative bone density assessment to help avoid stability-related complications during implant surgery (Pommer et al., 2014).

Romanos et al. (2014) used the Periotest™ and Osstell® devices to assess the primary stability of three types of Straumann implants placed in fresh bovine bone blocks. The authors reported the mean ISQ and PTV recorded for each type of implant macrodesign. Of interest, is the impact that the implant design had on the primary stability recorded with both the Osstell® and Periotest™ devices, indicating that the tapered implants had superior primary stability when compared to the straight implants in the study

(Romanos et al., 2014). No attempt was made to correlate the PTV to the ISQ values recorded.

In another study using fresh bovine ribs to model the edentulous human mandible, 30 implants in total were placed in type III bone per the Lekholm and Zarb classification, and the primary stability of the implants was assessed using insertion torque, RFA and Periotest™ (Bilhan et al., 2015). The aim of this *in vitro* study was to investigate the reliability of Periotest™ in measuring implant stability and to assess the relationship between 3 common clinical objective methods of testing implant stability. Therefore, the primary researcher carried out all implant stability measurements first, and then the Periotest™ measurements were repeated twice by three more examiners at 2-hour intervals, with measurements being recorded from both the buccal and mesial aspect of the implants in all cases. With regard to the intra-observer reliability, the ICC values for all buccal measurements for all examiners were excellent. For the mesial measurements, examiner 1 was deemed to have taken fair measurements (95% CI IC 0.567; -0.752), however all other examiners were deemed to have taken poor mesial measurements. Similarly, the inter-observer reliability assessment of buccal PTVs was found to be excellent, however the mesial measurements were evaluated as poor for all four examiners (Bilhan et al., 2015). In terms of the relationship between the different methods of assessing implant stability, the authors found no correlation between the PTV and the IT values ($P = .803$), however there was a significant correlation of 47.1% detected between the IT values and ISQ values ($P = .009$). A 30.3% negative correlation was detected between the PTV and ISQ values, however it was not statistically significant ($P = .104$). The authors concluded that in order to achieve good intra- and

inter-observer reliability measurements should be recorded from the buccal aspect when using the Periotest™ device. Furthermore, they concluded that there was no strong correlation between the PTVs and the ISQ or IT values recorded, however it is worth noting the limitation of half of the Periotest™ measurements used for comparison in this study were recorded from the mesial aspect of the implant (Bilhan et al., 2015).

More recently, Merheb et al. (2018) used stereolithographical guides to allow maximum precision in a prospective clinical study to investigate the relationship between implant stability and bone and implant features. Methods of assessing implant stability included assessment of implant damping capacity with the Periotest™ device, and assessment of RFA using the Osstell® device, with measurements taken in both the bucco-lingual and mesio-distal direction for both devices. Bone density was assessed using Hounsfield units after a computerised tomographic scan was taken with the patient wearing their prosthesis, and a CBCT of the prosthesis alone was also recorded. From this, stereolithographic guides were made to control implant placement in relation to the prosthesis and based on the available bone volume. Regions of interest around the planned implant were identified to allow analysis.

| Region of interest | Hounsfield values | | | | | Implant placement | | | | Prosthetic phase | | | |
|--------------------|-------------------|---------|--------|-------------|--------------|-------------------|---------|-------|---------|------------------|---------|-------|---------|
| | Mean | Median | SD | 2.5th perc. | 97.5th perc. | RFA | P value | PTV | P value | RFA | P value | PTV | P value |
| Inside | 593.33 | 590.21 | 193.64 | 244.42 | 971.97 | 0.43 | <.01 | -0.32 | <.01 | -0.09 | .65 | 0.17 | .31 |
| Outside | 672.84 | 682.87 | 207.53 | 288.48 | 1071.32 | 0.51 | <.01 | -0.25 | <.01 | 0.18 | .38 | 0.13 | .51 |
| Cortex | 1286.8 | 1319.66 | 355.76 | 580.41 | 1826.64 | 0.37 | <.01 | -0.41 | <.01 | 0.5 | <.01 | -0.32 | .11 |
| First 3 mm | 670.62 | 654.32 | 288.53 | 186.06 | 1253.24 | 0.38 | <.01 | -0.21 | .01 | 0.13 | .52 | 0.13 | .53 |
| Spongious | 522.26 | 500.22 | 123.36 | 353.26 | 835.02 | 0.64 | <.01 | -0.33 | <.01 | -0.13 | .54 | 0.33 | .05 |
| Cortical thickness | 1.31 | 1.24 | 0.31 | 0.82 | 2.07 | 0.58 | <.01 | -0.35 | <.01 | 0.28 | .17 | -0.27 | .11 |

Abbreviations: perc.: Percentile; PTV: periotest values; RFA: resonance frequency analysis; SD: standard deviation.

Table 2: Table showing the correlation between the different bone indices in the region of interest and the implant stability as found by Merheb et al. (2018).

The authors found that the average implant stability recorded at abutment phase was lower than that recorded at implant surgery. This was true for both the PTV and the RFA values recorded, and it was noted that there was a significant correlation detected between the mean RFA values and the mean PTV values ($r = 0.42$, $P < 0.1$) at implant placement. Implant stability was found to correlate strongly and significantly with the bone density in the previously identified region of interest (Merheb et al., 2018). For the most part, the correlation between the region of interest and RFA ($r = 0.37$ to 0.64) was better than that seen with PTV ($r = -0.21$ to -0.41). Interestingly, the RFA showed the highest correlation with the spongy bone ($r = 0.64$) while the coronal cortical bone had the highest correlation with PTV ($r = -0.41$). The measurements were repeated at the beginning of the prosthetic phase, where it was found that correlations between HU and RFA decreased and became statistically insignificant, except for the correlation with cortical bone density ($r = 0.40$, $P < .01$). The correlation between HU and PTV also decreased and lost significance ($P > .05$). The authors developed a formula based on radiological information to attempt to predict primary implant stability in ISQ using the factors that appeared to have the most influence: HU outside, HU spongy, and cortical thickness. This formula was found to predict 96.92% of RFA measurements within 10 ISQ units, and 78.46% of RFA measurements within 5 ISQ units (Merheb et al., 2018). The authors concluded that analysis of the bone characteristics pre-operatively could be used to predict implant stability.

Romanos et al. (2020) carried out a further *in-vitro* study to assess the primary stability of implants with multiple condensing thread design (MCTD) placed in type IV density bone blocks using three different techniques that combined the use of conventional drilling with or without the use of osteotomes of different dimensions. Primary stability was assessed using RFA (Penguin, Integration Diagnostics Ltd. Goteborgsvagen, Sweden) and the Periotest™ device. Each handpiece was held perpendicular to and approximately 2mm from the implant to be tested. There was no statistically significant difference between the ISQ values or PTV recorded for each group. The authors concluded that there was no difference in the primary stability achieved with the addition of osteotomes when MCTD implants were placed (Romanos et al., 2020). No attempt was made to attempt to correlate the ISQ to the PTV recorded for each implant.

1.4 Aims and objectives of the study

The main aim of the study herein was to assess the degree to which the results of implant stability measurements taken in-vitro by the Periotest™ device can be dependent on to be accurate.

A secondary aim was to investigate the differences between Periotest™ measurements taken on implant retained crowns and those taken on healing abutments for the same group of implants.

Our objectives were to determine the optimal position for the Periotest™ hand piece when using it on either abutments or crowns

To correlate the readings recorded by two operators using the same Periotest™ device to the ISQ readings previously recorded using the Osstell® device for these same implants.

Finally, there was also an attempt to determine implant stability differences between different implant systems and possible effects on the Periotest™ measurements.

2. Materials and Methods

2.1 Ethical Approval

Owing to the use of non-biologic materials in this study, ethical approval was not required as per Dublin Dental University Hospital Research Ethics Committee guidelines.

2.2 Study Design

This *in vitro* study involved the use of the Periotest™ device to record the damping capacity of a number of implants placed in synthetic bone blocks of varying density. An apparatus was employed to support the Periotest™ handpiece at different levels for each implant on each block.

The seven implants placed in each bone block were:

1. Standard 4.1 x 10mm SLA (Institute Straumann AG®, Basel, Switzerland)
2. Standard Plus 4.1 x 10mm SLA (Institute Straumann AG®, Basel, Switzerland)
3. Tapered Effect 4.1 x 10mm SLA implant (Institute Straumann AG®, Basel, Switzerland)
4. Standard 4.8 x 10mm SLA (Institute Straumann AG®, Basel, Switzerland)
5. BNST 4.0 x 10mm internal hexagonal connection implant (Zimmer Biomet®, Barcelona, Spain)
6. BOET 4.0 x 10mm external hexagonal connection (Zimmer Biomet®, Barcelona, Spain)
7. Ankylos C/X 3.5x11mm (Dentsply® Sirona, Hanau, Germany).

The synthetic bone blocks were composed of resin polyurethane (BoneModels, Castellón de la Plana, Spain) and each individual block constituted an example of bone of density D1, D2, D3 or D4. Two blocks of each density were used resulting in a total of eight bone blocks. Each bone block had seven implants placed at uniform distance from each other according to the manufacturer's protocols. The osteotomies in the D1 bone blocks required the use of a bone tap prior to implant placement, while the osteotomies in the D4 synthetic bone blocks were undersized to enable placement of an implant that was stable. Therefore, there was a total of 56 implants used in this study. All implants were placed according to the implant manufactures' protocols using the official method for each system drills.

The apparatus to support the Periotest™ pen was an articulated gauging arm [Fisso, Strato Line Model: S-20 Arm (Length L 200mm)] sourced from MAPRA Technik (figure 15).

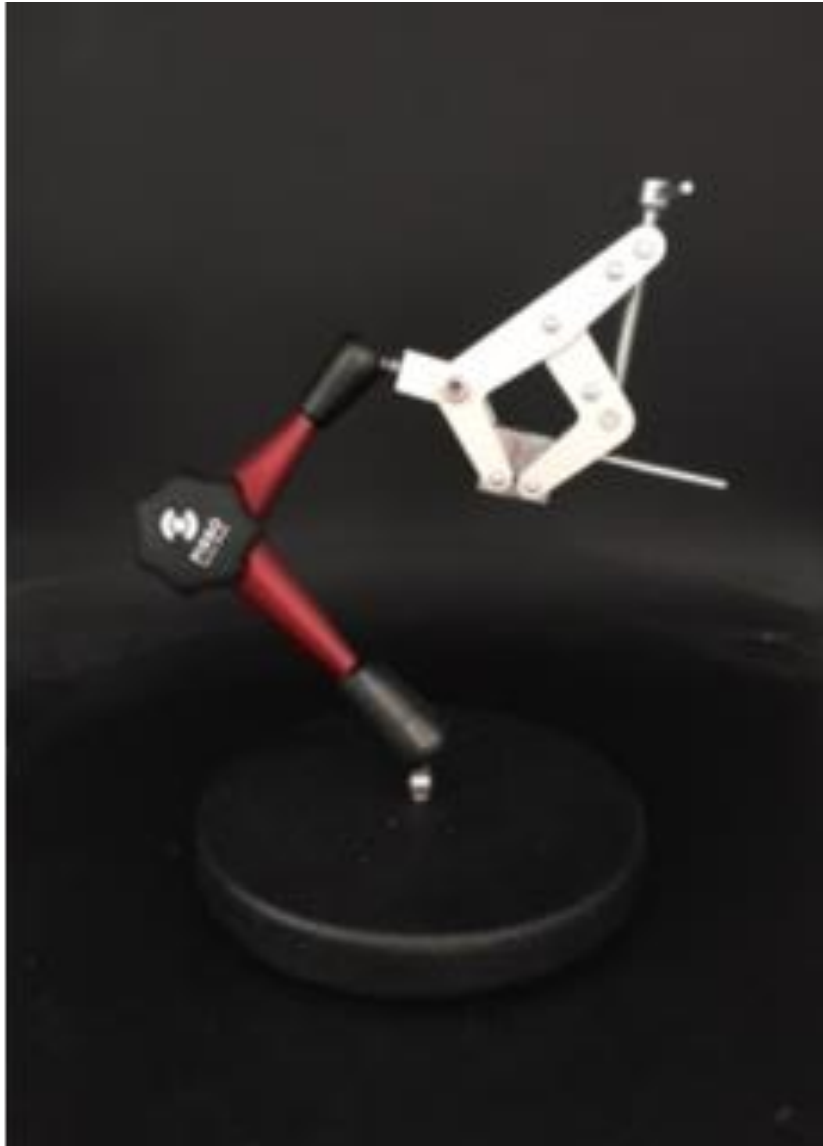


Figure 15: Articulated arm and clamp with steel base [Mapra Technik].

The articulated arm involved two struts connected by a joint, and a joint at the end of each arm also which allowed various positioning of the arm to be achieved. One end of the arm was connected to a steel base (weight 2.2kg), whilst at the other joint a clamp [KT2 Alu quick clamp] was connected to hold the Periotest™ handpiece. Furthermore, the precise microfine adjustment could be locked using the central tightening knob which

meant that once the correct position was achieved, it could be locked in place and easily adjusted as required.

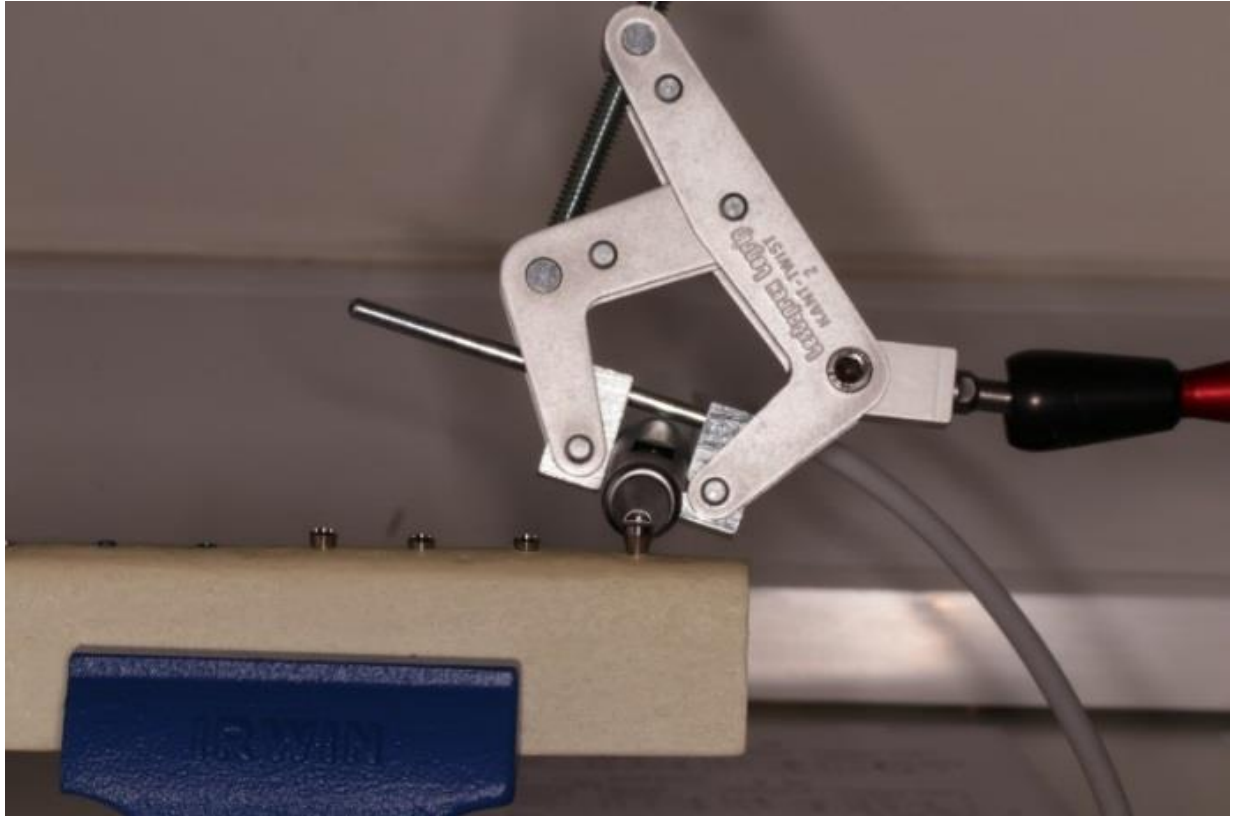


Figure 16: Articulated gauging arm [Fisso, Strato Line Model: S-20 Arm (Length L 200mm)] connected to a clamp [KT2 Alu quick clamp] which held the Periotest handpiece in position.

The Periotest™ machine used was the Periotest™ classic (Medizintechnik Gulden e.K. Eschenweg 3, 64397 Modautal, Germany). It consisted of a base unit computer with a display, and an attached handpiece that could be positioned to assess the damping capacity of teeth or implants. A test sleeve was provided with the machine to allow a

functional test to be carried out to verify the correct function and readings of the Periotest™ classic each time that the unit was switched on.

A number of healing abutments and temporary crowns were used in this study.

The healing abutments used were:

- Straumann 4mm x 4.5mm healing abutments
- Straumann 4 x 3mm healing abutments
- Zimmer Biomet® EP one piece 4.1 x 4 x 6mm healing abutment (internal hexagonal connection)
- Zimmer Biomet® EP one piece 4.1 x 4 x 6mm healing abutment (external hexagonal connection)
- Ankylos® standard C/ sulcus former – 6mm height.

The healing abutments were matched to the implant manufacture type and of a height to allow approximately 6mm of the implant-abutment complex to be supra-crestal to the synthetic bone blocks. Therefore, the Straumann 4.5mm height healing abutments with the Straumann Standard Plus implant which had an implant collar height of 1.8mm, thereby giving a supra-crestal implant-abutment complex of 6.3mm height. Similarly, the Straumann 3mm height healing abutments were used in conjunction with the Straumann Standard implants (2.8mm collar) such that they created a supra-crestal implant-abutment complex of 5.8mm height. The temporary crowns were manufactured in-house using Elos Accurate® Tibase and PMMA milled crowns, all made to the same to the dimensions of an average central incisor (width 9mm and length 12mm). The healing

abutments and crowns were all torqued to 5 N cm using a calibrated torque wrench (Tohnichi®). The National Metrology Laboratory calibrated the device (figure 17).



Figure 17: Calibrated torque wrench ((Tohnichi®.)

As the supra crestal implant abutment complex was always the same for the abutments, the sites chosen were the most coronal aspect, the mid-point of the abutment and the implant-head so the measurement points were approximately 2mm apart. For crowns,

the sites chosen were the implant head and the rest of the sites were approximately 3mm apart moving coronally. Taking into consideration that the width of the metal rod is 2mm these distances are estimates.

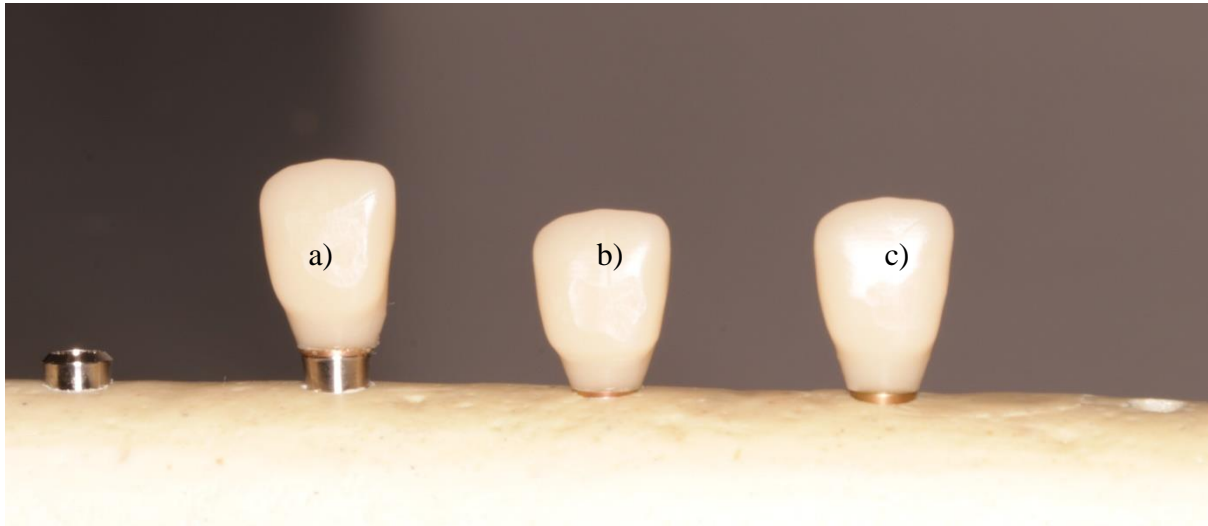


Figure 18: PMMA Temporary crowns in situ torqued to 5Ncm on a) Straumann Standard Plus (4.8mm x 10mm) and b) Zimmer Biomet Certain (internal hex, 4mm x 10mm) and c) Zimmer Biomet (external hex, 4mm x 10mm) implants placed in the synthetic bone block.

The bone blocks were immobilised on a benchtop using a standard benchtop vice (figure below).

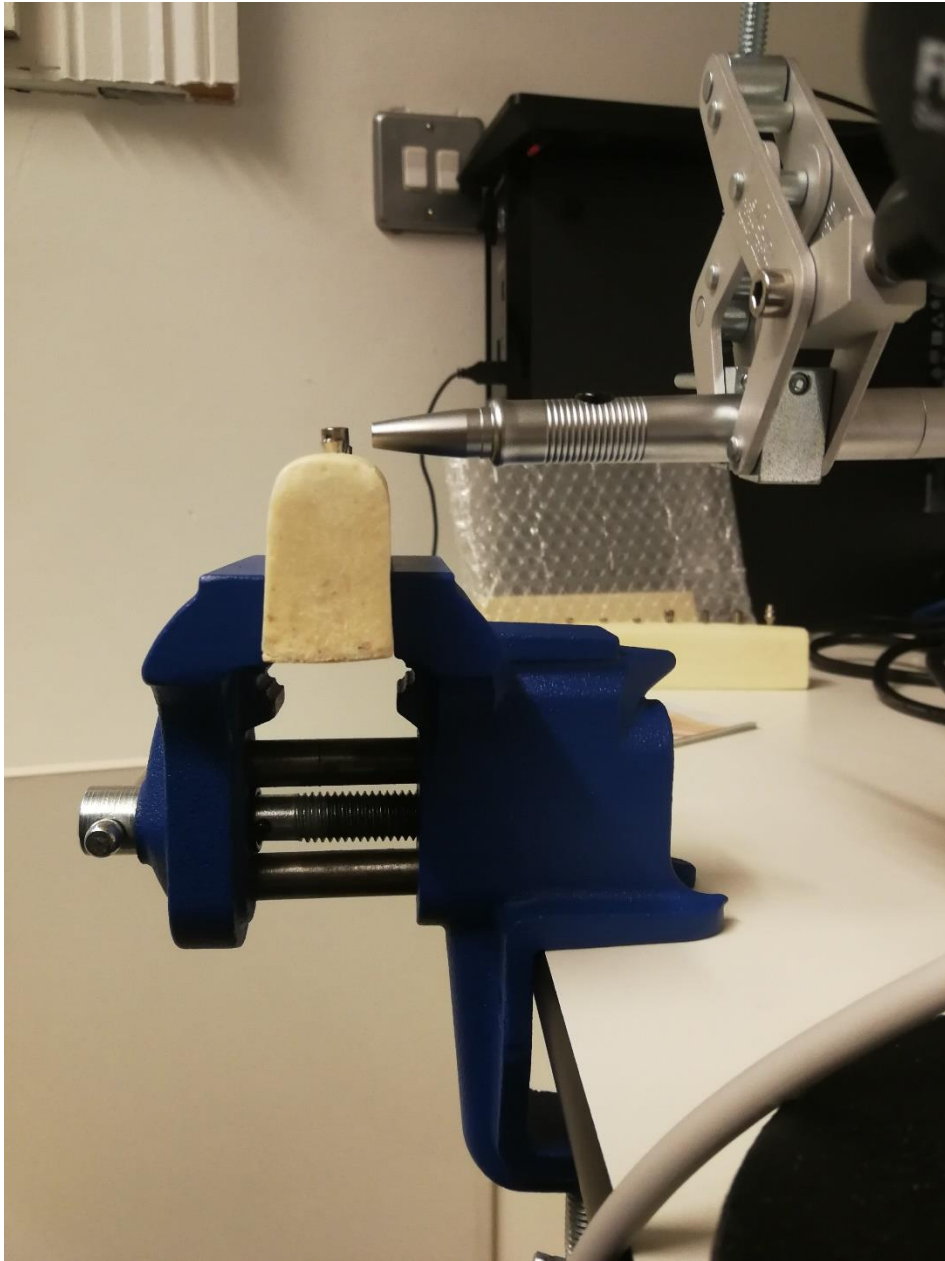


Figure 19: Vice holding the synthetic bone block, with the Periotest™ handpiece held in position by KT2 Alu quick clamp.

The Periotest™ classic machine and Fisso articulated arm were set up alongside, such that the handpiece of the Periotest™ could be positioned in relation to each implant at a distance of 0.6-2.5mm to facilitate a reading of the PTV of each implant to be taken.

A pilot study was carried out on eight randomly selected implants (one from each bone block) to assess whether there was a difference between the PTVs measured when the handpiece was positioned at each end of the recommended range i.e. 0.6-1.5mm or 1.5-2.5mm distance from the implant abutment. A calliper was used to create three blocks made of card that measured 0.6-1.5mm, 1.5-2.5mm and 1-1.5mm in width. These were then positioned between the implant abutment or temporary crown and the Periotest™ handpiece to standardise the measurements taken at each site, depending on the phase of the experiment. The 0.6-1.5mm and 1.5-2.5mm blocks were used in the pilot study. No differences were identified in the PTVs recorded by changing the distance within the recommended range. Therefore, a distance of 1-1.5mm was chosen for the study protocol and the 1-1.5mm block was used to standardise the distance in the study proper. Measurements of the PTV were taken in triplicate at each height and the mean PTV was recorded in an Excel (v16.55) spreadsheet. The experiment procedure was repeated by a second operator using the same equipment.

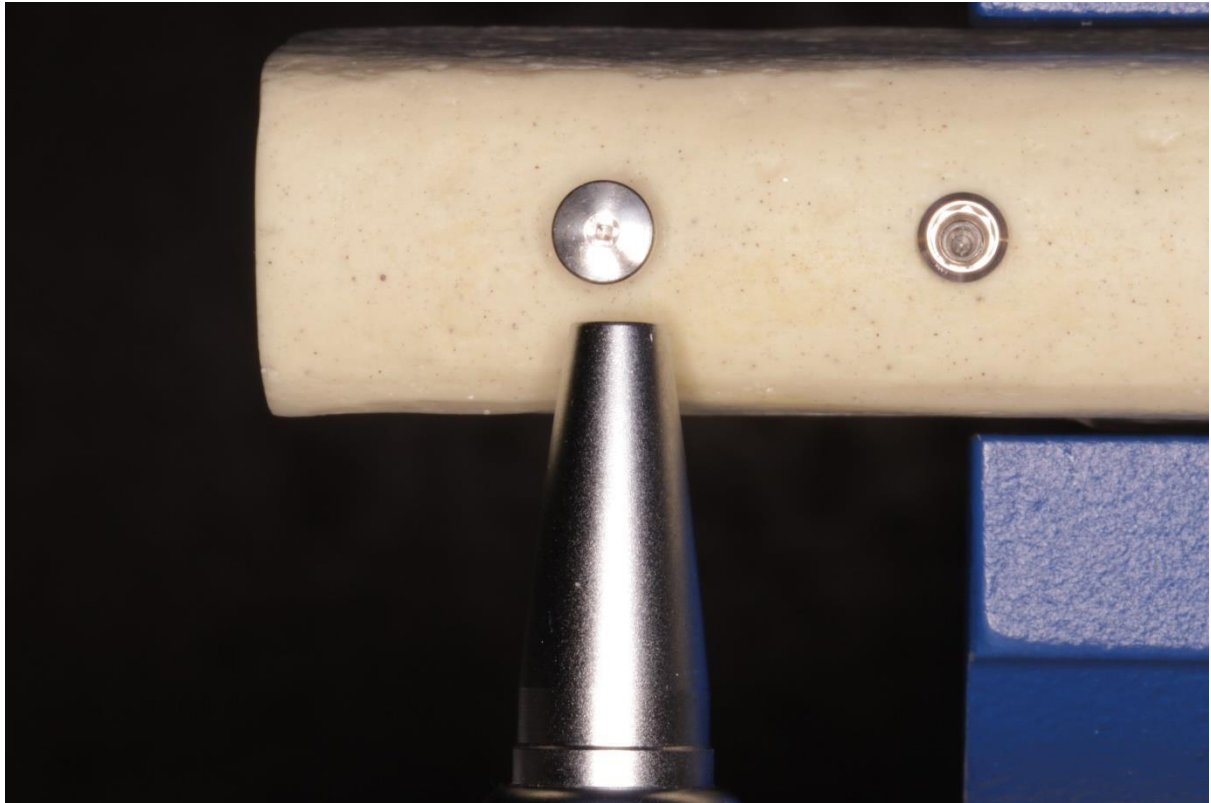


Figure 20: Periotest™ handpiece tip positioned 1.5mm distance from the implant abutment, and the synthetic bone block immobilised in a vice.

The experiment protocol was as follows:

1. Once bone block is in clamp, attach abutment to implant. Torque to 5 Ncm using calibrated torque wrench.
2. Turn on Periotest™.
3. Test Periotest™ machine using test sleeve. Should be between 9-11 PTV.
4. Use 1-1.5mm width block to position Periotest™ at correct distance from the abutment at the coronal aspect ensuring that it is 90 degrees to the abutment (allowance for +/- 25 degrees per manufacturers guidelines). Ensure that the Periotest™ handpiece is not resting on the bone block as this might alter the readings.

5. Press the button to record the PTV. Record the PTV in notes/spreadsheet.
6. Repeat Step 5 twice more to give a total of 3 readings of implant stability per position.
7. Repeat Steps 5-6. for the mid and implant head positions. *Note: Actual implant head is not possible to record because of size the Periotest™ handpiece. However, want the pen to be as close to the base of the implant abutment as possible without it touching the bone block.*
8. Move to the next implant.
9. Torque abutment to 5Ncm using calibrated torque wrench. Position the Periotest™ handpiece at the implant abutment checking correctly positioned (1-1.5mm from abutment, at 90 degrees). If the Periotest™ machine stays on, can proceed with measurement. If Periotest™ machine turns off due to being unused for a period of time, then it is necessary to turn the machine back on and re-record the test value (black test sleeve, 9-11 PTV) and then re-position the Periotest™ handpiece.
10. Record PTVs in triplicate at the coronal aspect, mid aspect and implant head as above.
11. Repeat Steps 9-10. per implant on the block.
12. Move to the next block and repeat Steps 2-11 per bone block.
13. Repeat entire experiment above using the facial surface of the temporary crowns instead of abutments on the implants to record the PTVs. The implant head site was recorded first, and then 3mm above that site equated to the mid site on the

crown, while 3mm above the mid-site equated to the coronal aspect of the crown (i.e. Repeat Steps 2-13 using temporary crowns – facial surfaces).

Notes:

- a) Where the Periotest™ machine turns off, the test PTV must be checked each time using the test sleeve.
- b) The Periotest™ handpiece needs to be at a 90-degree angle to the abutment or crown face, not perpendicular to the bone block which is tapered and can be at a slight slant in the clamp.



Figure 21: Experiment Set up: Fisso Articulated Arm holding the Periotest™ handpiece at the correct distance to enable measurement of the stability of the individual implants placed in the synthetic bone block that is immobilised in the vice.

2.3 Null Hypothesis

There are no statistically significant differences between the PTVs recorded on implant abutments and the PTVs recorded on implant-retained crowns for the same group of implants.

2.4 Statistical Analysis

Descriptive statistics were used to display the PTVs at the different heights on the implant abutments and implant crowns. Frequency distributions and boxplots were used to display the data. The means for each site were calculated, and the distribution of the data was assessed using the Kruskal Wallis test. The interclass correlation coefficient (ICC) was used to determine the relationship between the PTVs recorded on the implant abutments and implant crowns. Further analysis involved plotting Bland Altman plots and the Wilcoxon Signed-Rank test. “Investigative statistics” such as Spearman’s rank test was used to assess the relationship between the PTVs recorded on implant abutments and ISQ values recorded for the same implants by Naughton et al. (2023). Descriptive statistics were also used to assess the impact of the bone density and implant type on the PTVs recorded. These analyses were repeated with D4 bone excluded. The ICC between operators was also calculated. Moderation analysis was used to investigate the effect of bone density and implant type on the implant stability measurements recorded. Assessment of the agreement between PTV and ISQ values in determining implant

stability for this cohort of implants was completed using a scatter plot that facilitated analysis of the data for all bone types, and when D4 bone was excluded.

2.5 Power Calculation

To our knowledge, this is the first *in vitro* study comparing the PTVs recorded on implant abutments to those recorded on crowns for the same implants.

A previously published *in vivo* work by Gomez-Roman and Lukas (2001) compared the PTVs recorded on crowns to those recorded at the same time point on a gingival former/abutment. Limited information was given by the authors about the materials and methods used and to this effect, the results were difficult to interpret. Still, a power calculation was done based on the available information. Prior data indicated that the difference in the response of matched pairs was normally distributed with standard deviation of 2.51. If the true difference in the mean response of matched pairs was 3.5, we would need to study 6 pairs of subjects to be able to reject the null hypothesis that this response difference is zero with probability (power) 0.8. The Type I error probability associated with this test of this null hypothesis was 0.05.

2.6 Funding

The funding of all materials for this research project was provided by the postgraduate research budget of Dublin Dental University Hospital.

3. Results

3.1 Part One - All four types of bone included as classified according to quality (D1, D2, D3, D4).

Seven implants in eight bone blocks (n=56 implants) were used to carry out implant stability measurements by using the Periotest™ (PTV) device. Measurements were performed at three different areas on the implant abutments and, subsequently, at three different areas on implant-retained temporary crowns. These measurements were taken in triplicate by two different operators, and the mean PTV for each site was recorded. Therefore, while a total of 2,016 PTVs were measured, 672 of these inform the data analysis.

The mean PTV recorded across all sites was 5.57 +/- 11.643 on the implant abutments, and 12.27 +/- 11.735 on the temporary crowns. The highest mean value (lowest stability) was at the most coronal test area and the lowest mean value (highest stability) was at the area closest to the implant head for both abutments and crowns (Tables 3 and 4).

| PTV | Mean, SD |
|-----------------------|-----------------|
| Coronal Abutment | 7.12 +/- 11.831 |
| Mid Abutment | 5.32 +/- 11.493 |
| Implant-head Abutment | 4.28 +/- 11.526 |

Table 3: Mean PTVs recorded by Periotest™ at the three different areas of the healing abutments.

| PTV | Mean, SD |
|--------------------|------------------|
| Coronal Crown | 14.32 +/- 11.829 |
| Mid Crown | 11.96 +/- 12.264 |
| Implant-head Crown | 10.54 +/- 10.860 |

Table 4: Mean PTVs recorded by Periotest™ at on the three different areas of the temporary crowns.

The distribution of the PTVs recorded at the coronal, mid- and implant-head on the implant abutments and implant crowns were all similar (figure 22). The ISQ values recorded previously by Naughton et al. (2023) for the same 56 implants, present the reverse distribution (figure 23).

Figure 22: Frequency Distribution of mean PTVs measured at Coronal, Mid and Head of Implant Abutments and Implant-retained Temporary Crowns when torqued to 5 N cm.

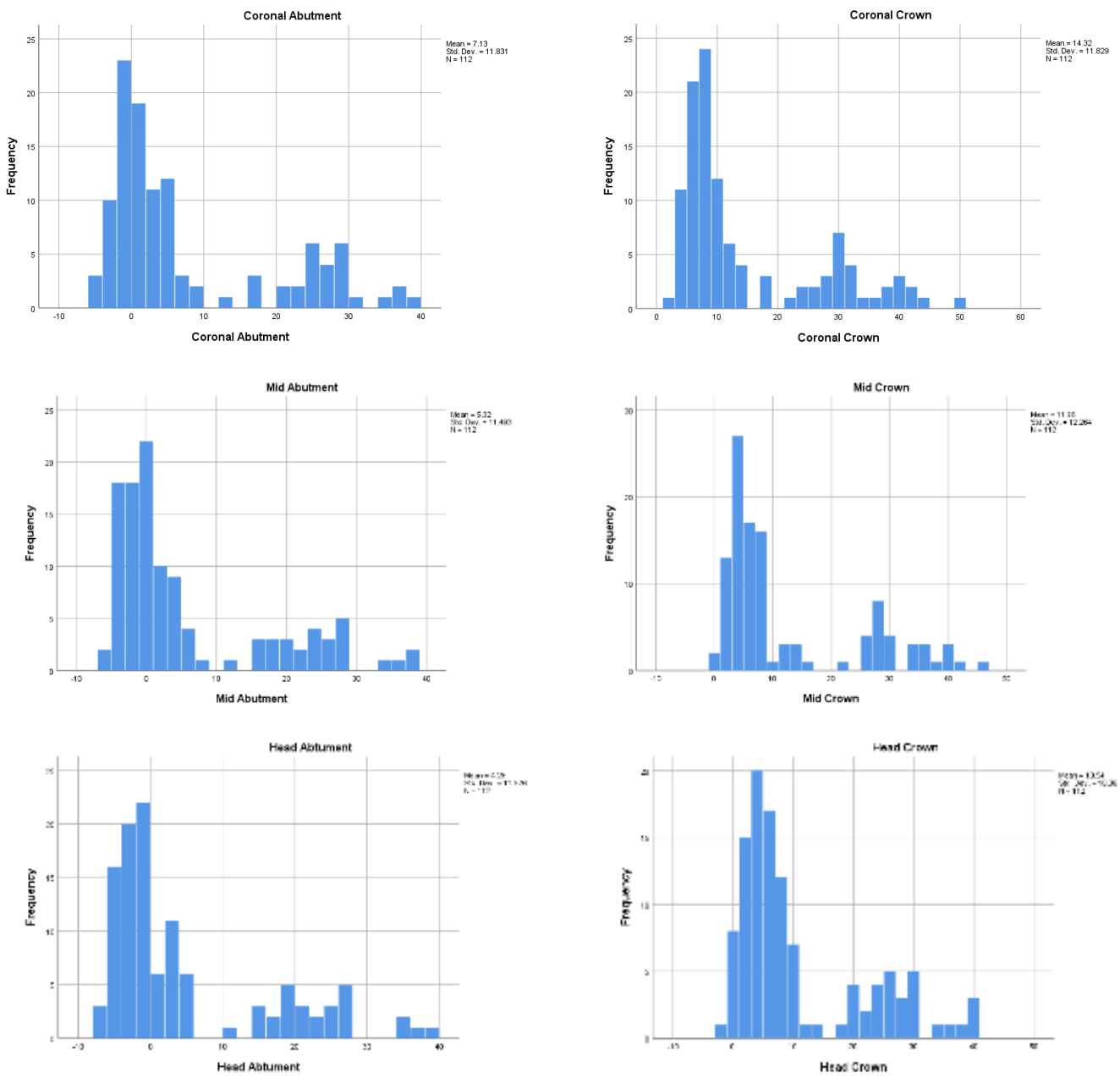
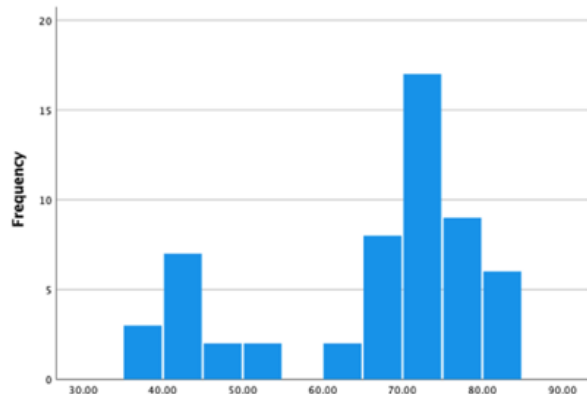


Figure 23: Frequency distribution of mean ISQ values for implant abutment assessed with Osstell® device when torqued to 6 N cm. (Naughton et al. 2023).



The inclusion of implants placed in bone blocks of D4 density account for the outliers of low stability. The PTV data shows a positive skew, while the ISQ data shows a negative skew. The PTVs recorded range from -7 to 38 PTVs on the abutments, and from -2 to 41 PTV on the temporary crowns. The range of the Periotest™ device is from -8 to +50, with -8 being most stable and +50 being the least stable. Conversely, the ISQ measurements range from 0- +100, with 0 being least stable and +100 being most stable. Based on existing literature and the number of articles published using the Osstell® device for measuring implant stability, RFA would generally be considered as the gold standard device. As a result, we used the RFA measurements recorded by Naughton et al. (2023) for the same cohort of implants as a control against which the PTVs measurements would be compared.

The non-normal distribution of the PTVs recorded on the abutments and crowns placed in bone blocks D1-D4 was assessed and confirmed with the Kolmogorov-Smirnov test which had a significance value of <0.001. The quantile-quantile (Q-Q) plot below demonstrates this deviation from normal graphically (figure 24- 25).

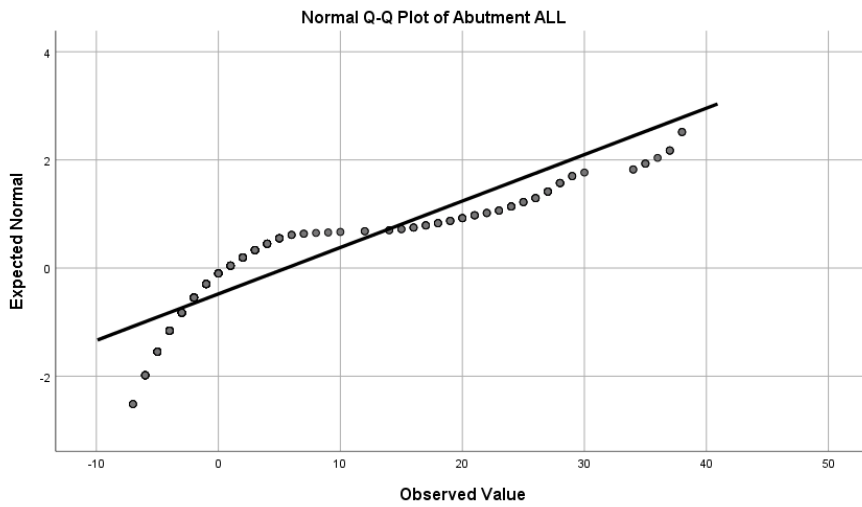


Figure 24: Q-Q plot displaying non-normal distribution of PTVs recorded on implant abutments.

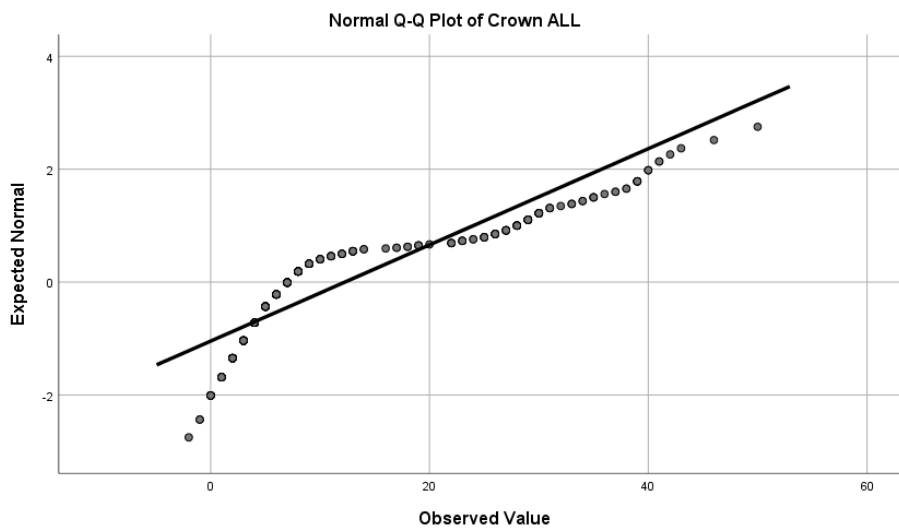


Figure 25: Q-Q plot displaying non-normal distribution of PTVs recorded on implant crowns.

The results of Naughton et al. (2003) demonstrate that the ISQ values recorded on implants across all bone types were also not of normal distribution. When tested with

the Kolmogorov-Smirnov test the significance was <0.001 . This is displayed on the Q-Q plot below (figure 26).

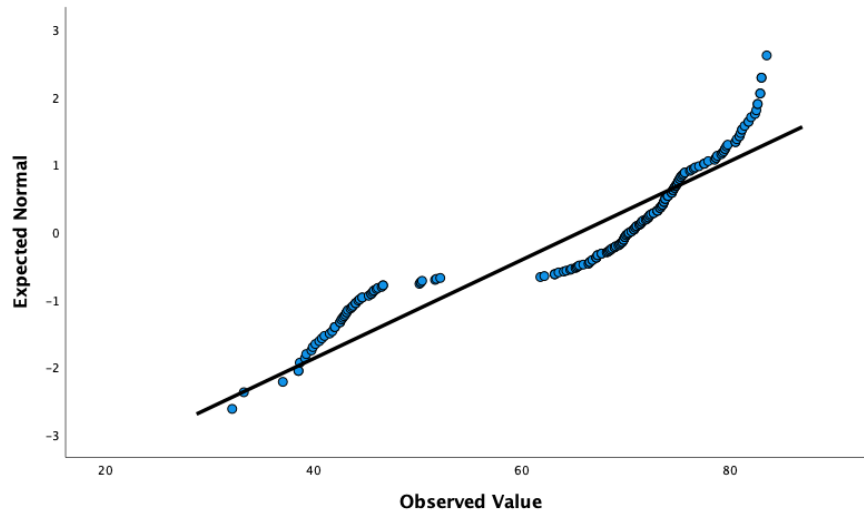


Figure 26: Q-Q plot showing the non-normal distribution of the ISQ data (Naughton et al. 2023).

The range and interquartile range demonstrated by the PTVs recorded on the abutments and crowns was similar (figure 27). However, a number of outliers are present. This is similar to the range of ISQ values recorded by Naughton et al. (2023) when the Osstell[®] smart-pegs were torqued to 6 N cm (figure 28). Outliers were also present in the ISQ data. This is visually displayed by the boxplot below. Again, the presence of outliers is not unexpected owing to the inclusion of D4 bone blocks in the experiment, where implant stability would be substantively less when compared to the primary stability that can be achieved in D1 bone blocks.

Figure 27: Boxplots showing the median PTVs for the Coronal, Mid and Implant Head measurements on the Implant Abutments and Implant-retained Temporary Crowns when torqued to 5 N cm across all bone densities and for all implant types.

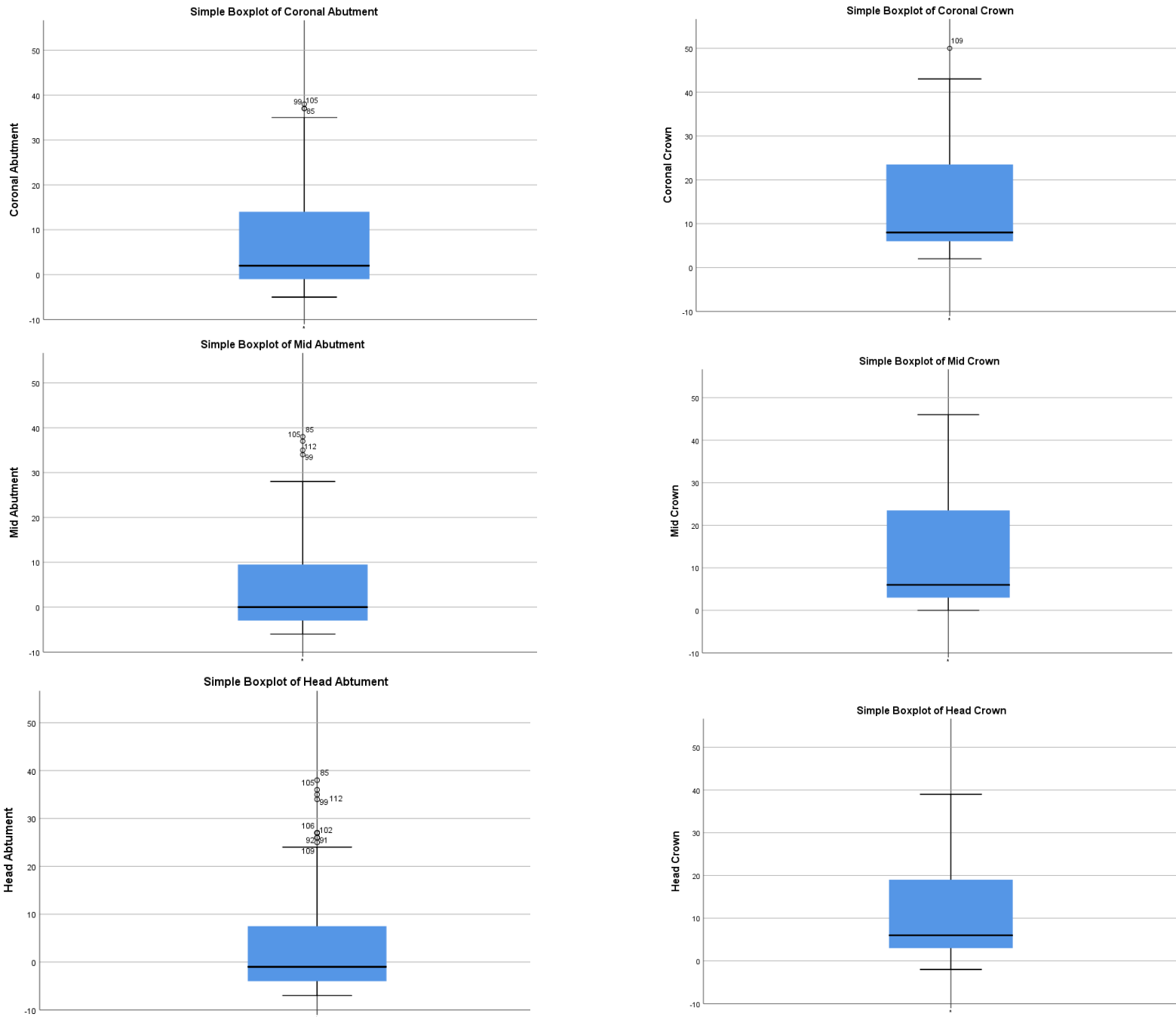
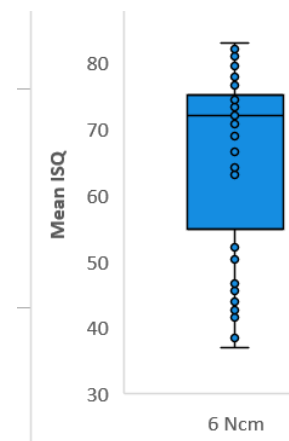


Figure 28: Median ISQ value when Implant Abutment Assessed with Osstell® device, when smartpeg was torqued to 6Ncm (Naughton et al. 2023).



The substantial difference between the range of PTVs recorded on the implant abutments and temporary crowns in D1-D3 bone and D4 bone is evident when the recorded measurements are displayed based on bone density (figure 29). The PTVs recorded in D1-D3 bone density demonstrate a much higher degree of implant stability. The implant stability recorded for implants in D4 bone is poor. This is true for all sites of measurement on the abutments and crowns.

The ISQ measurements recorded by Naughton et al. (2023) demonstrate a similar picture, but on an inverse scale (figure 30). The ISQ values recorded in D1-D3 bone show excellent implant stability, while the implant stability recorded in D4 bone is again poor. The boxplots below show the ISQ values recorded based on bone density. The inverse of the PTV data is seen owing to low values on the ISQ scale indicating poor implant stability, and high values indicating good implant stability.

Figure 29: Box Plots of median PTVs displayed by position of measurement on Implant Crown or Abutment based on Bone Density.

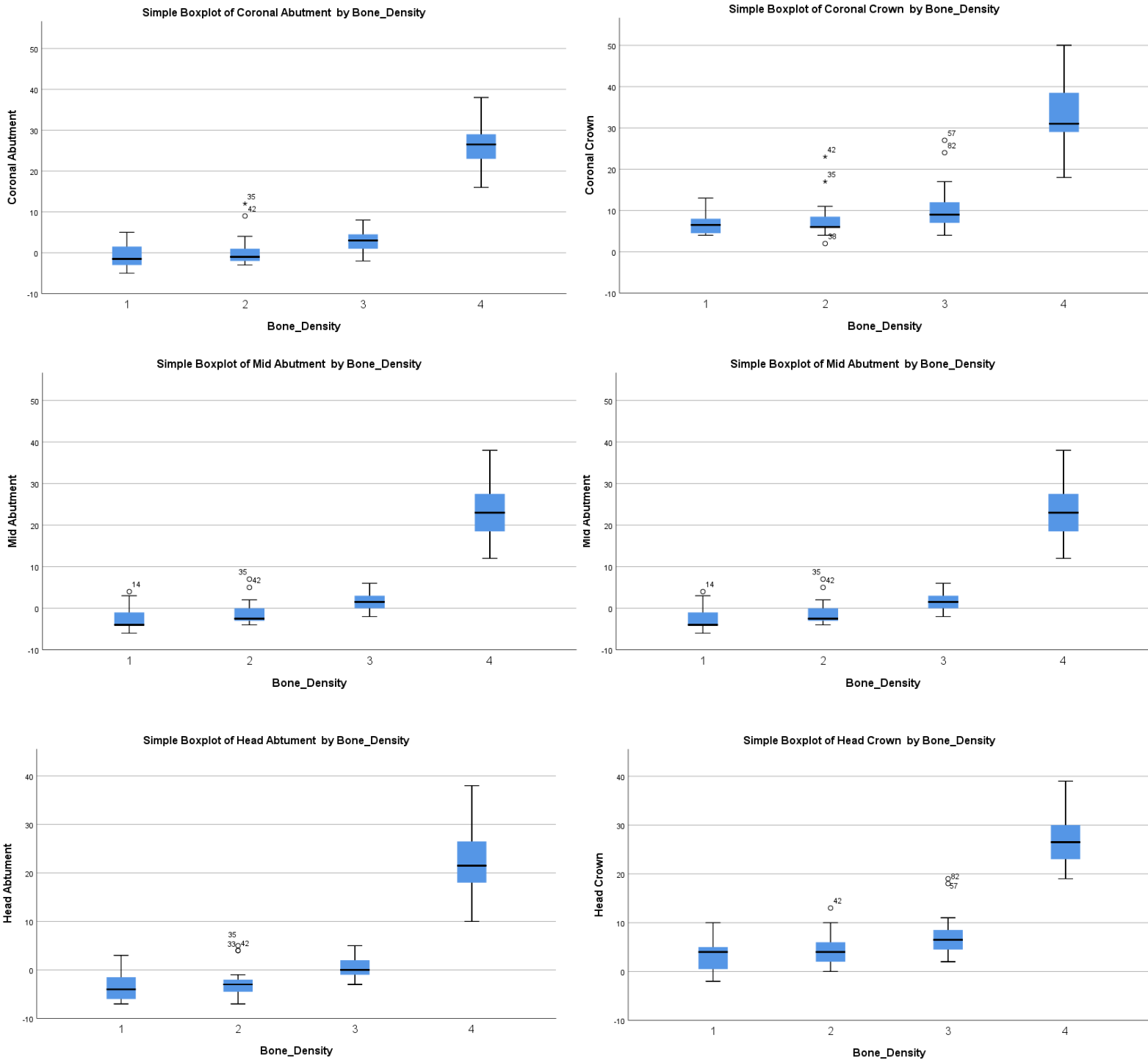


Figure 30: Boxplot of mean ISQ values by Bone Density (Naughton et al.2023).

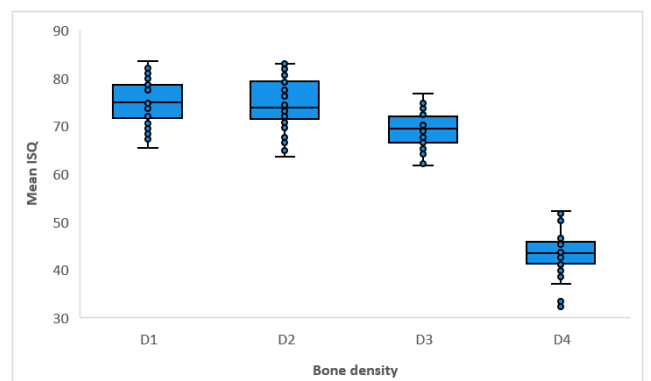


Figure 12 Boxplot of ISQ values by bone density

Considering the inverse relationship that can be observed on the graphical depictions above, the relationship between the ISQ and the PTVs recorded at each site on the implant abutments was assessed using Spearman's rank correlation coefficient. A statistically significant negative correlation was found between the ISQ data and the PTVs recorded on the coronal abutment ($r_s = -.305, p = .022$), and the mid-abutment ($r_s = -.482, p < .001$), but not to the implant-head abutment readings ($r_s = -.232, p = .085$).

The correlation between the ISQ values and the mid abutment PTV value is of moderate strength (Dancey and Reidy, 2004) and from this, we concluded that the mid-abutment position should be used to gain the most accurate measurement when using the Periotest™ device to assess the stability of an implant.

To assess the impact of using the Periotest™ device on an implant crown instead of an abutment to assess the implant stability, an intraclass correlation coefficient (ICC) was calculated for the mid-abutment to each site on the implant-retained temporary crowns. The ICC was moderate for the coronal crown, and good for the mid-crown and implant-head crown sites. The ICC for the coronal crown was lowest at 0.700, for the mid-crown was 0.810, and highest for the implant-head crown was 0.847. All results were statistically significant ($p < .001$).

The difference between the intraclass correlation coefficient for the mid-crown and implant-head crown to the mid-abutment was negligible (0.810 vs 0.847). Taking measurements at the implant head position on implant-retained crowns can be extremely challenging for the clinician owing to the presence of soft tissue and the

emergence profile of the restoration. Owing to the negligible difference between the ICC for the mid and head positions, and the ease with which mid-crown measurements can be taken, the mid-crown is of more interest to researchers and clinicians in establishing a correlation between the PTVs recorded on implant-retained crowns and implant abutments.

The Blant Altman Plots below (figure 31- 33) display the distribution of the difference vs the mean for the mid-abutment to coronal crown, mid-abutment to mid-crown and mid-abutment to implant-head of crown. A similar distribution is seen for each of these crown sites in relation to the mid-abutment, with a number of outliers present outside of the interquartile range for each.

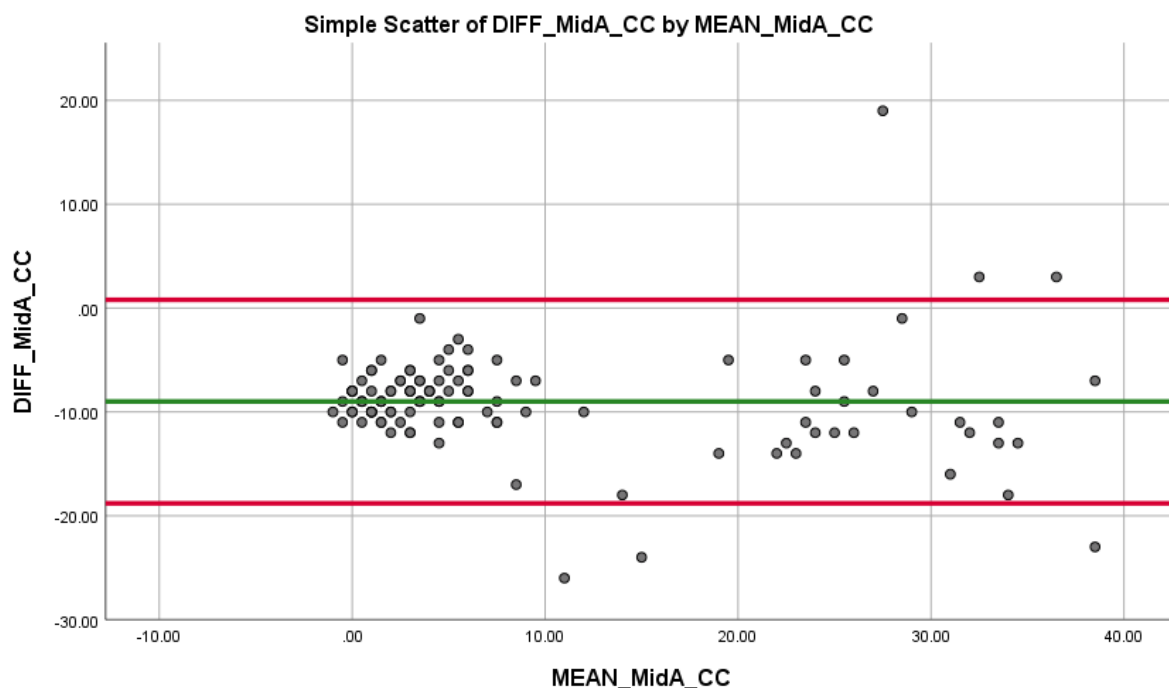


Figure 31: Blant Altman Plot for difference vs mean of mid-abutment vs coronal crown in all bone densities.

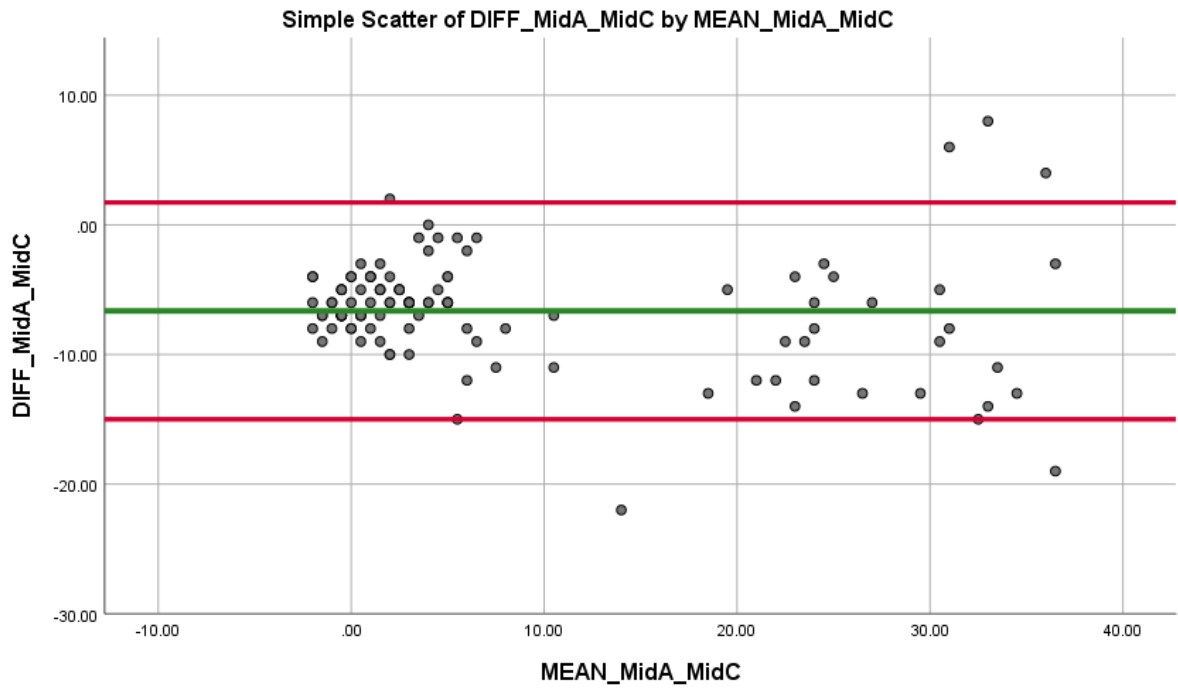


Figure 32: Blant Altman Plot for difference vs mean of mid-abutment vs mid crown in all bone densities.

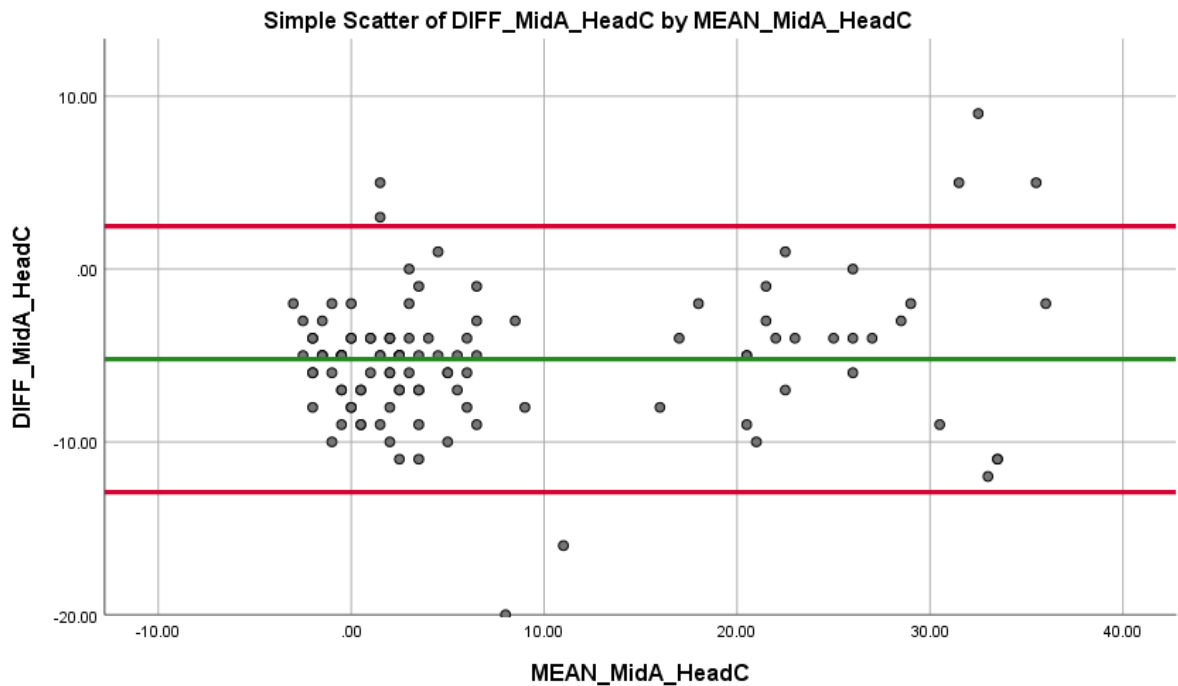


Figure 33: Blant Altman Plot for difference vs mean of mid-abutment vs implant-head of crown in all bone densities.

The distribution of the values seen on the Blant-Altman plots above are similar for each of the three crown heights in relation to the mid-abutment. When the distribution of the PTVs recorded at mid-abutment and mid-crown were individually assessed using the Kolmogorov Smirnov test, a non-normal distribution was detected for both the mid-abutment and mid-crown PTVs ($p < .001$). This is not unexpected considering the inclusion of the D4 values and the substantial differences in the PTVs recorded at D1-D3 bone versus those recorded in D4 bone, as seen on the boxplots previously.

Further analysis using the Wilcoxon Signed-Rank test showed that there was a statistically significant difference between the PTVs recorded at the mid-abutment level when compared to the mid-aspect of the crown ($Z = 8.715, p < .001$).

It would appear that for all implant types assessed in this study across all bone types, there is a statistically significant difference between the PTVs recorded on crowns when compared to the mid-abutment reading.

As can be seen from the data thus far, there are substantial differences in implant stability recorded by both the Periotest™ and the Osstell® devices in D1-D3 bone densities versus the stability recorded in D4 bone density. Furthermore, there is a non-normal distribution of the data when all bone densities are included. Both the PTVs recorded at mid-abutment and mid-crown, and the ISQ values previously recorded by Naughton et al. (2023) demonstrate a number of outliers in the data, which are likely to be owing to the inclusion of D4 bone. Considering that D4 bone does not commonly present to the implant surgeon, and the number of outliers presented, it is therefore of

interest to exclude D4 and continue analysis of this dataset with D1-D3 bone density only.

Finally, the intraclass correlation coefficient between operator 1 and operator 2 was calculated. The ICC between operators was good to excellent when measurements were recorded with the Periotest™ device on the implant mid-abutment site for all bone types. Excellent inter-operator intraclass correlation coefficients were recorded for the mid-abutment site for D2 and D3 bone (ICC = .922, $p < .001$, ICC = .938, $p < .001$, respectively), and good inter-operator intraclass correlation coefficients were recorded for D1 and D4 bone (ICC = .814 $p < .001$, ICC = .776, $p < .001$, respectively) (table 5). This differs to the results of Naughton et al. (2023) where excellent inter-operator intraclass correlation coefficients were reported for measurements taken using the Osstell® device for D1-D3 bone, but not for D4 bone. In fact, the inter-operator ICC reported for the ISQ values recorded in D4 bone was very poor (ICC = 0.039) (table 6).

| Bone Density | ICC Mid Abutment PTV values |
|--------------|-----------------------------|
| D1 | 0.814 $p < .001$ |
| D2 | 0.922, $p < .001$ |
| D3 | 0.938, $p < .001$ |
| D4 | 0.776, $p < .001$ |

Table 5: ICC between operators when measurements were recorded using the Periotest™ device at the mid-abutment site across all bone types with abutments torqued to 5 N cm.

| Bone Density | ICC ISQ values |
|--------------|-------------------|
| D1 | 0.944, $p < .001$ |
| D2 | 0.983, $p < .001$ |
| D3 | 0.803, $p < .001$ |
| D4 | 0.039, $p = .410$ |

Table 6: ICC between operators when measurements were recorded using the Osstell® device with the SmartPeg torqued to 6 N cm.

The ICC between operators was somewhat more mixed when measurements were recorded on the mid-crown site of the implants (table 7). While the ICC between operators was excellent for recordings in D2 bone (ICC = .897, $p < .001$) and moderate for D4 bone (ICC = .675, $p = .004$), the ICC for D1 and D3 bone was poor (ICC = .494, $p = .020$)

and (ICC =.360, $p = .094$) respectively. The variation in the results recorded at the mid-crown for the different bone densities is of interest, particularly considering the moderate result for the ICC recorded in D4 bone.

| Bone Density | ICC Mid Crown |
|--------------|------------------|
| D1 | .494, $p = .020$ |
| D2 | .897, $p < .001$ |
| D3 | .361, $p = .094$ |
| D4 | .675, $p = .004$ |

Table 7: ICC between operators when measurements were recorded using the Periotest™ device at the mid-crown site of the implants across all bone types.

As the ICC for both the ISQ values and mid-abutment PTVs recorded in D4 bone density were worse than those recorded in D1-D3 bone, it is of interest to analyse this dataset using the implant stability measurements recorded in D1-D3 bone only.

3.2 Part Two – D1-D3 bone density only.

As previously mentioned, the substantial variance in the PTVs and ISQ values recorded for D4 bone density when compared to those recorded in D1-D3 bone density, indicate that further analysis of the implant stability measurements when D4 bone is excluded is of interest.

The mean PTV recorded across all sites when D4 bone was excluded was -0.82 ± 3.050 on the implant abutments, and 5.36 ± 3.843 on the temporary crowns. The standard deviations recorded for the means when D4 bone is excluded are narrower, and as expected, the mean stability is higher when D4 bone is excluded. The highest mean value was at the coronal aspect (lowest stability) and the lowest mean value (highest stability) was at the implant head. This was true for measurements taken on both abutments and crowns.

| PTV Site (D1-D3 bone) | Mean, SD |
|-----------------------|-----------------|
| Coronal Abutment | 0.74 +/- 3.359 |
| Mid Abutment | -0.82 +/- 3.050 |
| Implant-head Abutment | -1.85 +/- 3.153 |

Table 8: Mean PTVs recorded by Periotest™ at different heights on implant abutments in D1-D3 bone density.

| PTV Site (D1-D3 bone) | Mean, SD |
|-----------------------|----------------|
| Coronal Crown | 8.18 +/- 4.327 |
| Mid Crown | 5.36 +/- 3.843 |
| Implant-head Crown | 4.82 +/- 3.761 |

Table 9: Mean PTVs recorded by Periotest™ at different heights on temporary crowns in D1-D3 bone density.

Fewer outliers were observed in the distribution of the PTVs recorded at each site on the implant abutments and temporary crowns when D4 bone was excluded (figure 34). The ISQ values recorded previously by Naughton et al. (2023) also show fewer outliers and the inverse of the distribution presented by the PTVs again (figure 35).

Figure 34: Frequency Distribution of mean PTVs in D1-D3 bone measured at Coronal, Mid and Head of Implant Abutments and Implant-retained Temporary Crowns when torqued to 5 N cm.

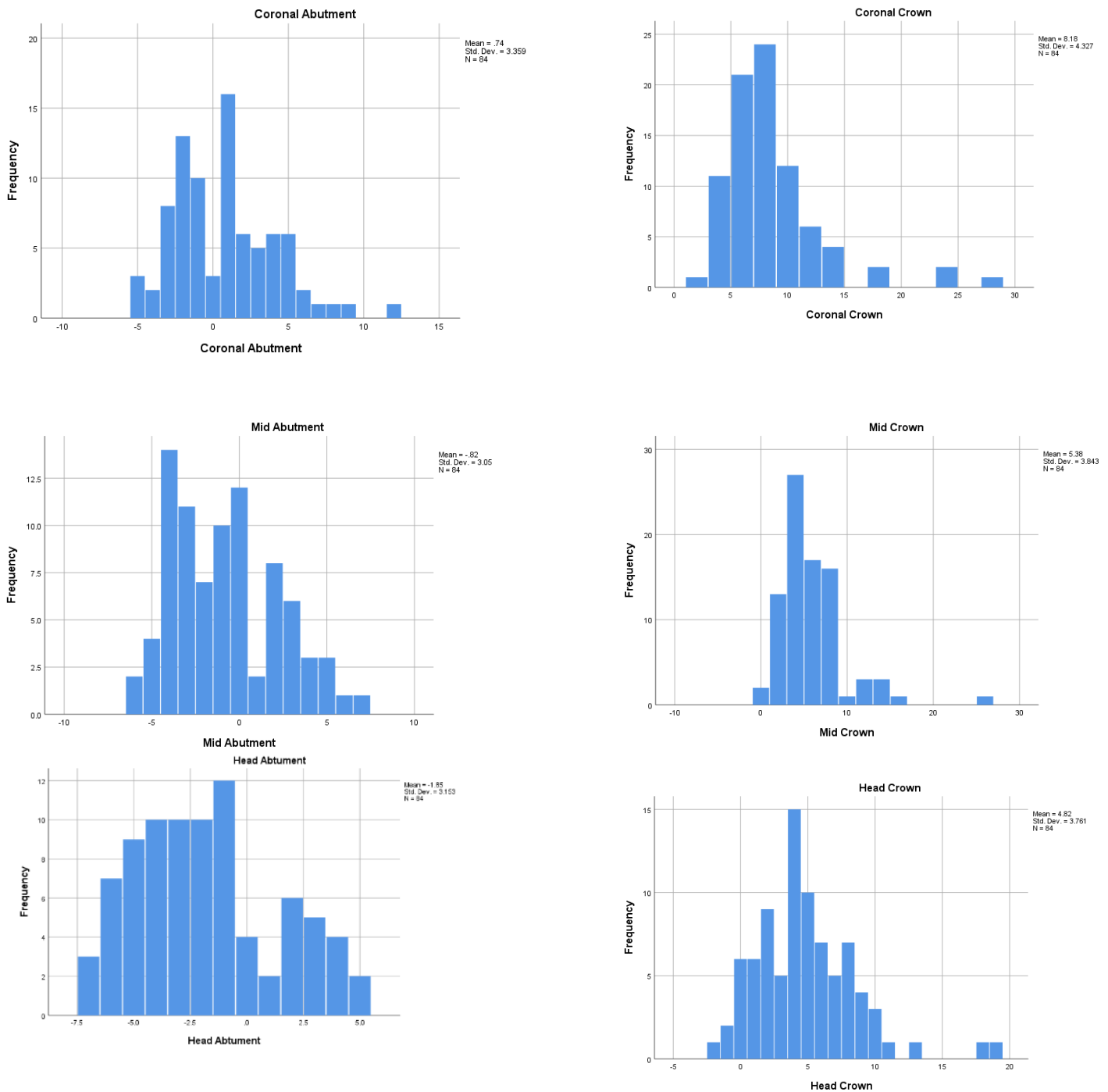
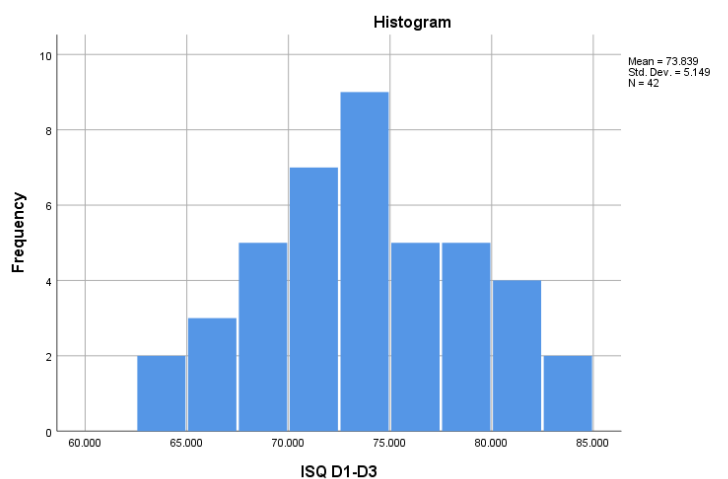


Figure 35: Frequency distribution of mean ISQ values in D1-D3 bone when assessed with Osstell® device when torqued to 6 N cm. (Naughton et al. 2023).



Analysis of the distribution of the PTVs and ISQs recorded in D1-D3 bone only was carried out using the Kolmogorov-Smirnov test, which demonstrated a gaussian distribution for the PTVs and ISQs recorded when D4 bone was excluded ($p > 0.001$). The quantile-quantile (Q-Q) plot below demonstrates this normal distribution graphically (figures 36-38).

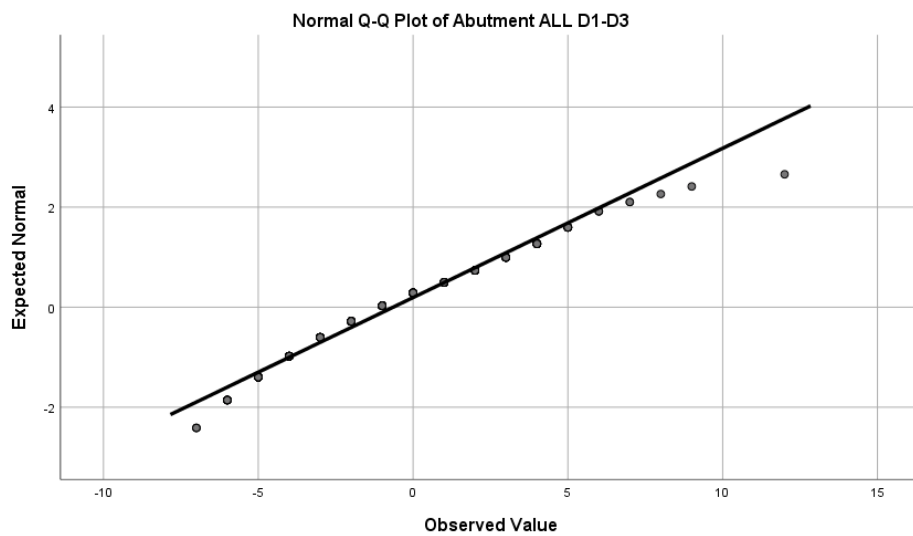


Figure 36: Q-Q plot showing the normal distribution of the PTVs recorded on the implant abutments in D1-D3 bone density.

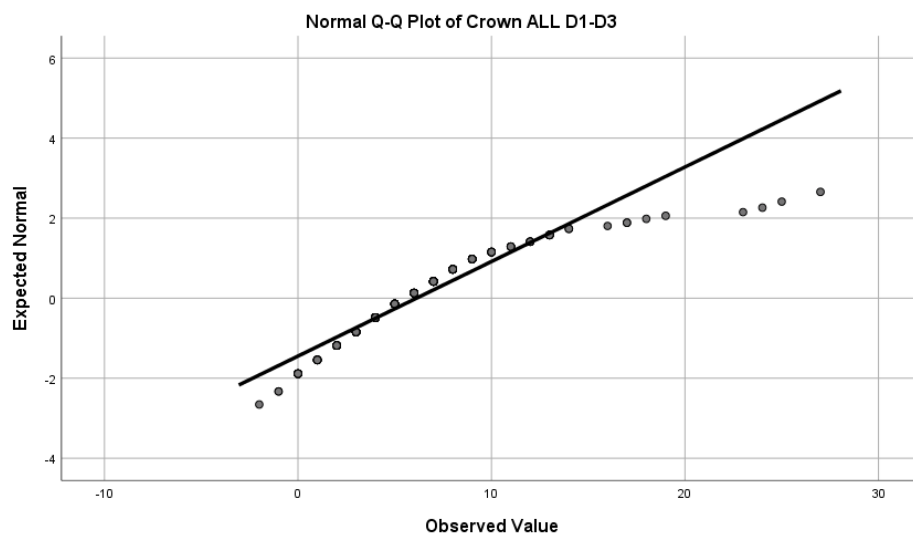


Figure 37: Q-Q plot showing the normal distribution of the PTVs recorded on the temporary crowns in D1-D3 bone density.

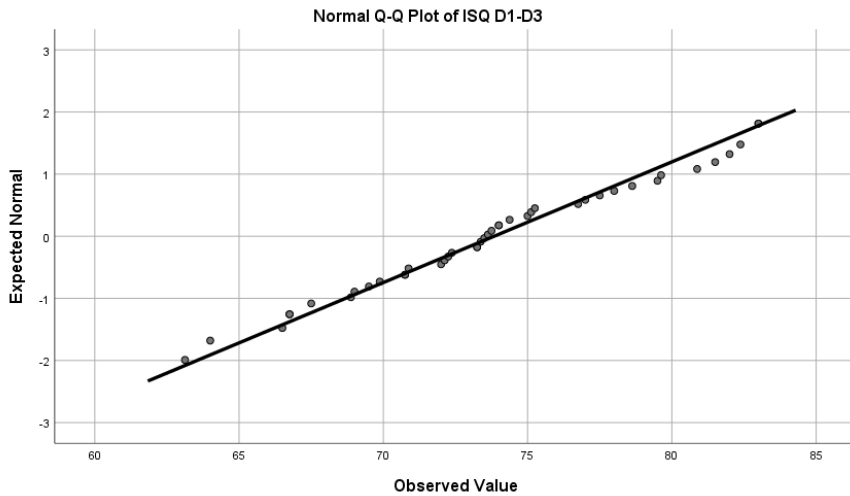


Figure 38: Q-Q plot showing the normal distribution of the ISQ data recorded in D1-D3 bone density (Naughton et al. 2023).

The boxplots for the range of values recorded on the implant abutments and temporary crowns by the Periotest™ and Osstell® device are displayed below (figures 39 – 41). A much narrower range of PTVs was observed for the implant abutments in D1-D3 bone compared to when all bone densities were included. The inter-quartile range of PTVs recorded on the temporary crowns much narrower again, however there were a number of outliers recorded for the PTVs recorded on the crowns in D1-D3 bone. The ISQ data reported by Naughton et al. (2023) demonstrates a reduced range of values when the D4 bone density is excluded, with no outliers reported. This is considerably different to the range of values recorded with the Osstell® device when all bone densities were included.

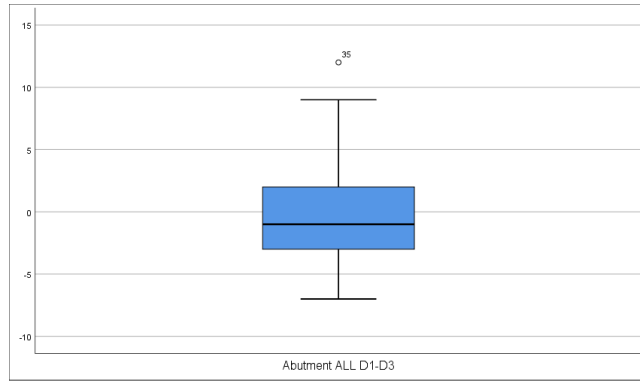


Figure 39: Boxplot of PTVs recorded on the implant abutments in D1-D3 bone density.

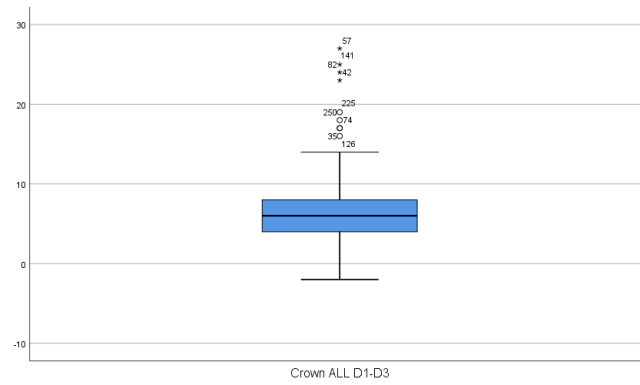


Figure 40: Boxplot of PTVs recorded on the temporary crowns in D1-D3 bone density.

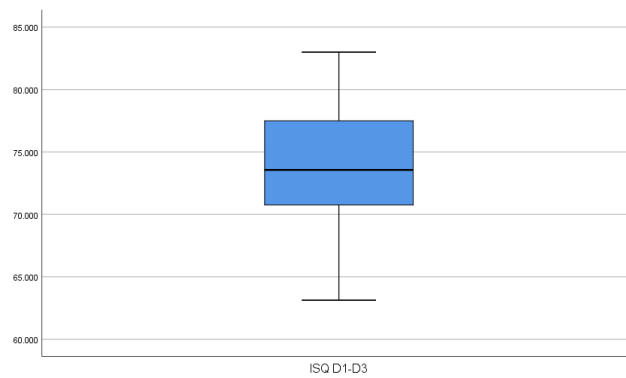
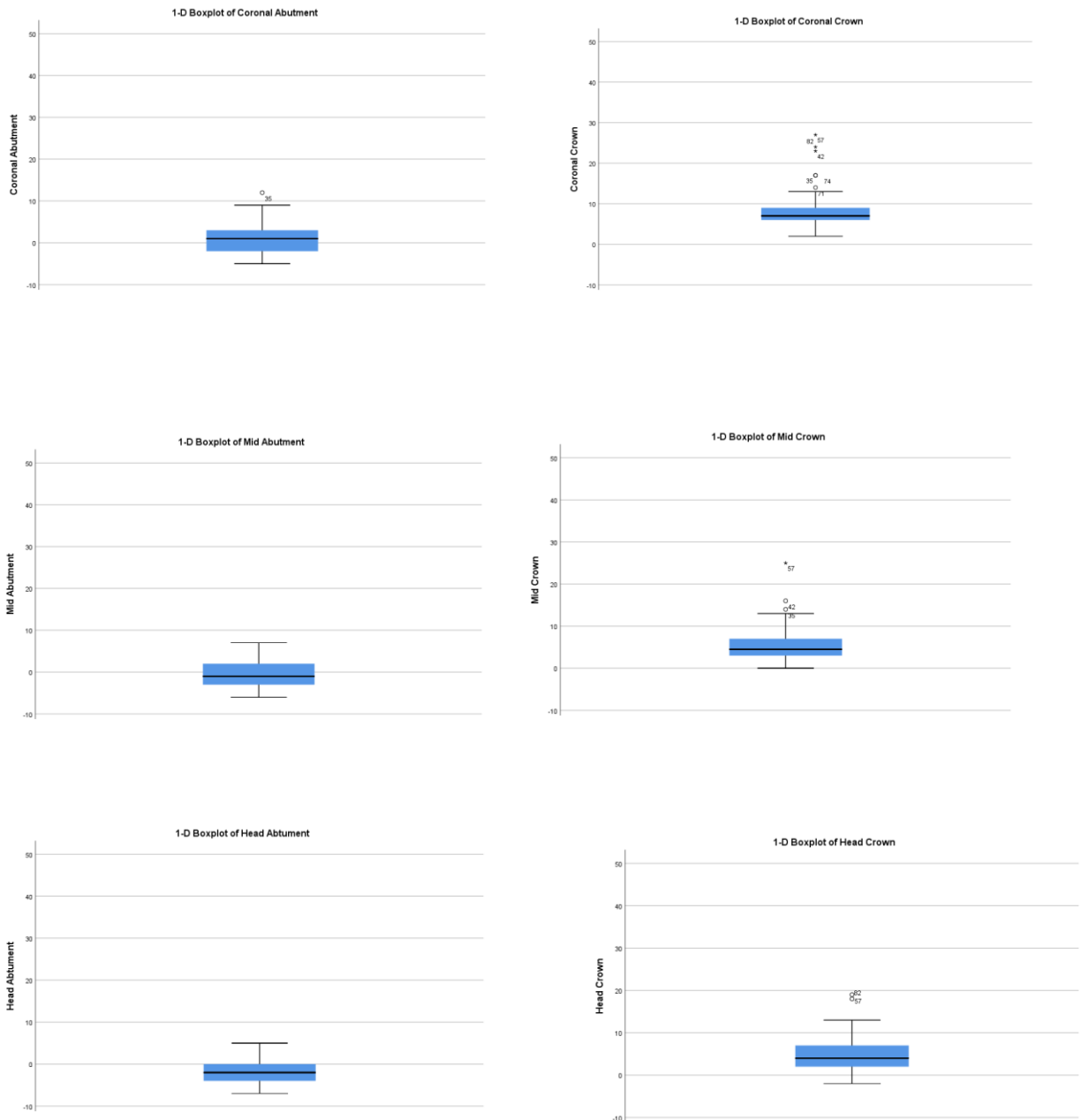


Figure 41: Boxplot of ISQs recorded on in D1-D3 bone density (Naughton et al. 2023).

When this data is analysed based on the position on the implant abutment or temporary crown at which the PTV was recorded, the differences in PTVs recorded at the different sites is evident. A number of outliers were present for all measurements taken on the temporary crowns, and for the PTVs recorded at the coronal aspect of the implant abutment. The boxplots below demonstrate this data (figure 42).

Figure 42: Boxplots showing the median PTVs for the Coronal, Mid and Implant Head measurements on the Implant Abutments and Implant-retained Temporary Crowns when torqued to 5 N cm in D1-D3 bone only.



Spearman's rank correlation coefficient was used to assess the relationship between the ISQ readings with the PTVs recorded at the different sites on the implant abutment in D1-D3 bone only. The results show that the ISQ readings have a significant moderate negative correlation with the coronal abutment ($r_s = -.537, p < .001$), the mid-abutment ($r_s = -.685, p < .001$), and the head of the implant abutment ($r_s = -.508, p = .001$) (Dancey & Reidy 2004). The Spearman's rank correlation coefficient test showed that the best correlation to the ISQ values recorded by Naughton et al. (2023) was found for the PTVs recorded at the mid-abutment site ($r_s = -.685, p < .001$).

The intraclass correlation coefficient was then assessed for the mid-abutment PTVs to the different sites on the temporary crowns when D4 bone was excluded. The results show a generally poor correlation between the PTVs recorded at the mid-abutment site and all sites on the temporary crowns in D1-D3 bone density. The ICC for mid-abutment to the different sites on the temporary crowns was much lower when D4 bone was excluded. The highest ICC was between the mid-abutment PTV and the mid-crown PTV (ICC = .221, $p < .001$) when compared to the ICC for the coronal crown (ICC = .138, $p < .001$) or the head crown (ICC = .212, $p < .001$). This differs to the results recorded for the intraclass correlation coefficient calculated across all bone densities where the ICC between mid-abutment and mid-crown was 0.810 ($p < .001$).

The Blant Altman Plots below (figures 43 - 45) display the distribution of the difference vs the mean for the mid-abutment to coronal crown, mid-abutment to mid-crown and mid-abutment to implant-head of crown when D4 bone is excluded. A similar distribution is seen for each of these heights. A few outliers are present on each plot, however the majority of points lie within one standard deviation of the mean value.

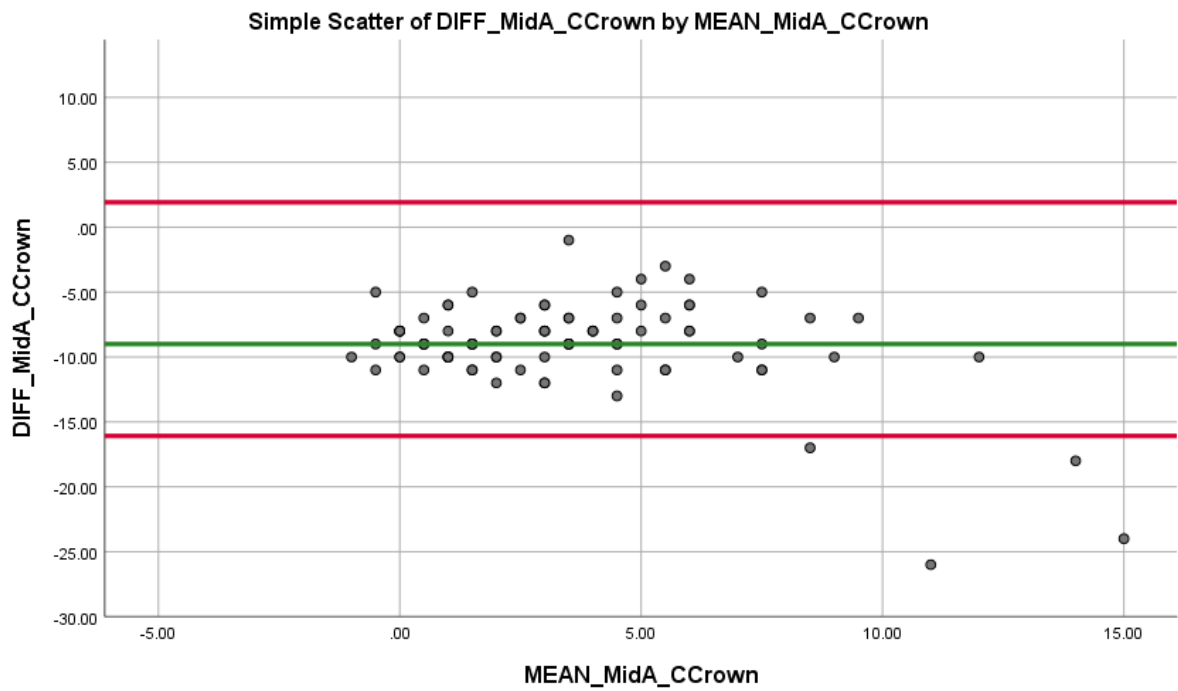


Figure 43: Blant Altman Plot for difference vs mean of mid-abutment vs coronal crown in D1-D3 bone density.

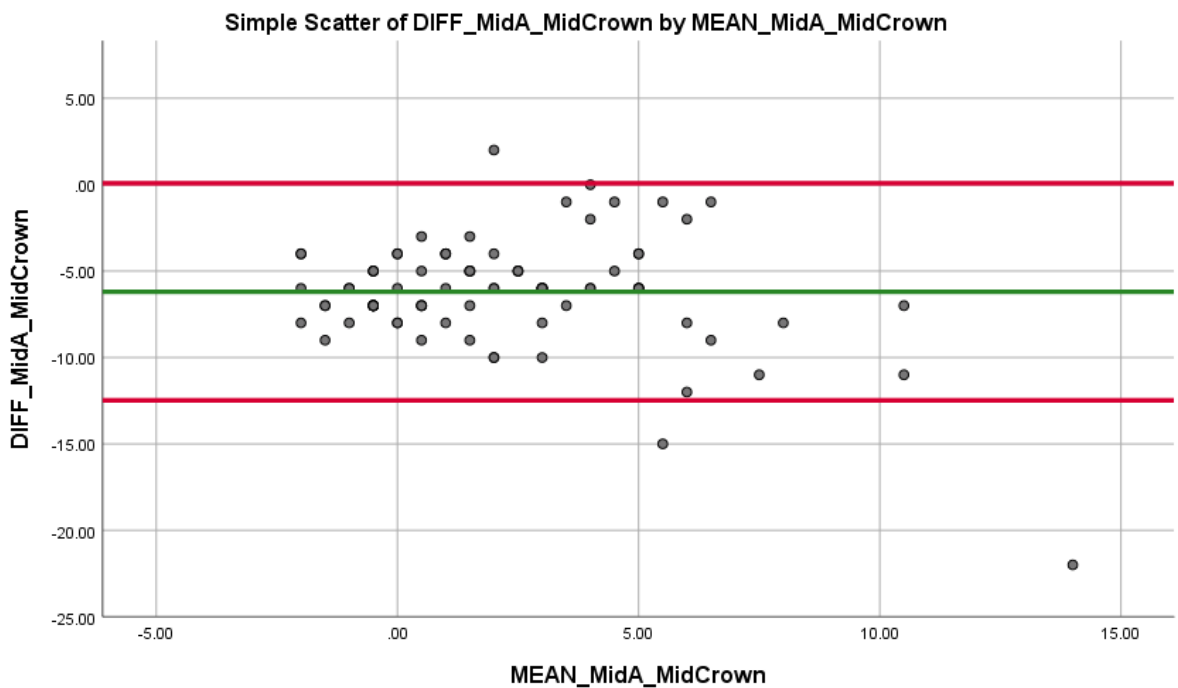


Figure 44: Blant Altman Plot for difference vs mean of mid-abutment vs mid-crown in D1-D3 bone density.

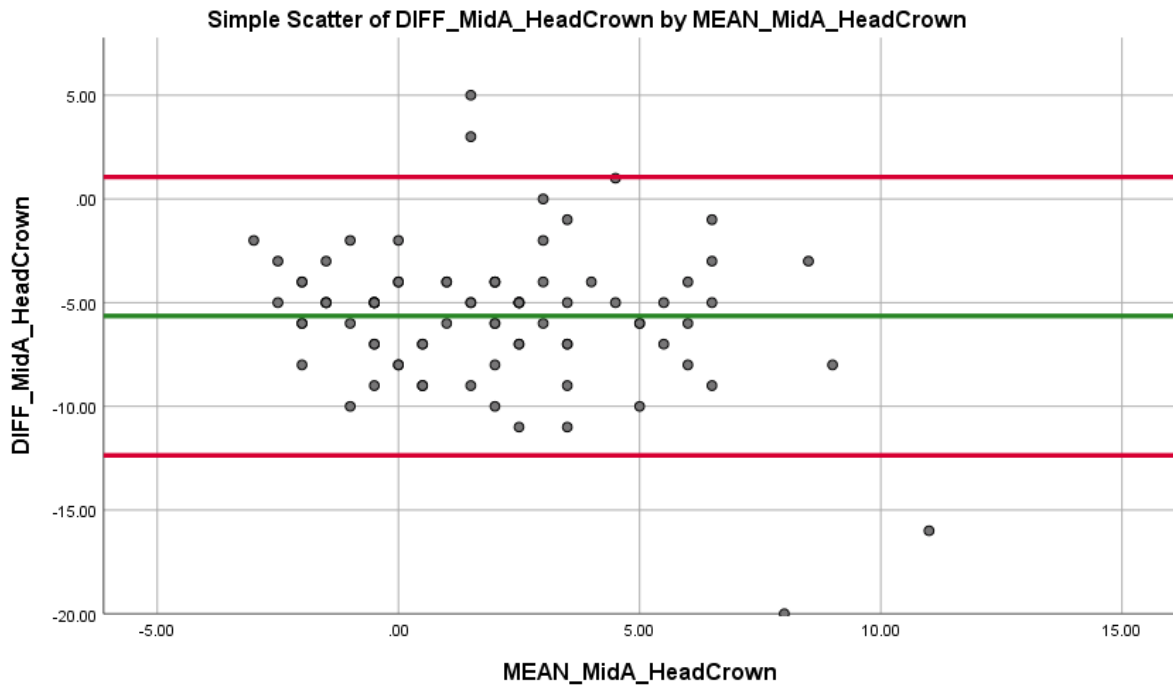


Figure 45: Blant Altman Plot for difference vs mean of mid-abutment vs implant-head position on the temporary crown in D1-D3 bone density.

Further analysis using the Wilcoxon Signed-Rank test showed that there was a statistically significant difference when D4 bone density was excluded in the PTVs recorded at the mid-abutment level compared to the mid-aspect of the crown ($Z = 7.907$, $p < .001$). This finding is similar to the result of the Wilcoxon Signed Rank test when the PTVs recorded at the mid-abutment and mid-crown were compared across all bone types, resulting in a significant difference ($Z = 8.715$, $p < .001$). Whilst the Wilcoxon Signed-Rank test demonstrates that there is significant difference between the PTVs recorded at the mid-abutment and mid-crown sites across all bone densities and when D4 bone is excluded, further calculations are required to determine the difference in PTVs that the clinician should expect.

The impact of excluding D4 bone when analysing the difference between the mid-abutment and mid-crown PTV was analysed. This was required prior to defining a set value for the difference in PTV that clinicians should expect when implant stability measurements are recorded on an implant abutment compared to an implant crown. The mean mid-abutment PTV recorded across all bone densities was 5.32 +/- 11.49, while that recorded when D4 bone was excluded was 0.82 +/- 3.050. Similarly, the mean mid-crown PTV recorded across all bone densities was 11.96 +/- 12.264, while that recorded when D4 bone was excluded was 5.38 +/- 3.843. An Independent Sample Test compared the mean PTVs recorded across all bone densities and when D4 bone was excluded. The results demonstrated that PTVs did not differ significantly based on whether D4 bone was included or not when assessed at both the mid-abutment sites ($p = 0.439$) and mid-crown sites ($p = 0.421$). Therefore, although there was a difference in the mean values reported when D4 bone was excluded compared to all bone densities, the Independent Sample Test demonstrated that the inclusion of values recorded in D4 bone did not have a significant impact on the differences.

The difference in implant stability recorded at the mid-abutment site compared to when the measurement was taken at the mid-crown site was found to be 6.63 +/- 4.27 PTV, when all bone densities were included. The difference between the mid-abutment and mid-crown sites were also assessed when D4 bone was excluded, and was found to be 6.20 +/- 3.20 PTVs. Therefore, when assessing the stability of an implant with the Periotest™ device, the clinician should expect a difference of approximately 6 PTVs between measurements taken on an abutment and measurements taken on a crown, when the mid-points of each are used. This translates to the PTV recorded on an implant

crown being approximately 6 PTVs higher than the PTV recorded on the implant abutment, at the same time, for the same implant.

The difference in PTV recorded at mid-abutment compared to mid-crown was analysed further for variance based on the type of bone density in which the implant was placed.

Table 10 below demonstrates some variations in the difference in PTVs between mid-abutment and mid-crown sites for the same implant.

| Bone Density | Difference in PTV recorded at mid-crown compared to mid-abutment: |
|--------------|-------------------------------------------------------------------|
| D1 | 6.107 +/- 2.859 |
| D2 | 6.179 +/- 1.887 |
| D3 | 6.321 +/- 4.448 |
| D4 | 7.929 +/- 6.400 |

Table 10: Difference in PTVs recorded at mid-crown compared to mid-abutment based on bone density.

As can be seen from the table above, there was a reliable difference of 6 PTVs between mid-abutment and mid-crown readings in D1 and D2 bone, however the readings became less reliable in D3 and D4 bone where the standard deviations were almost equal to the means.

3.3 Part Three – Impact of Type of Implant

Seven different implants were used in this study. The seven implants placed in each bone block were:

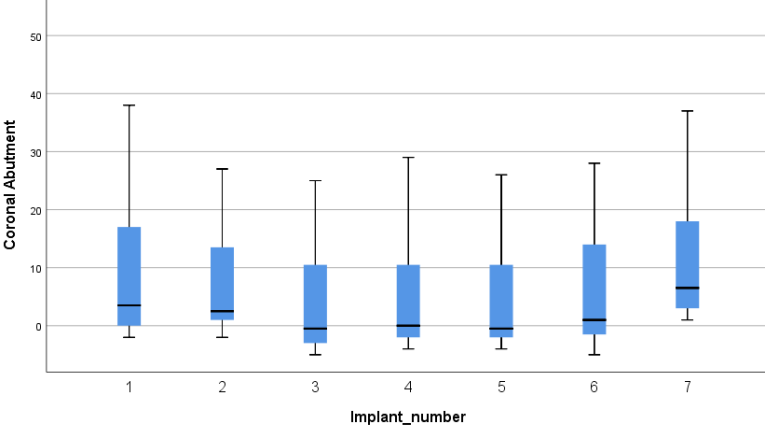
1. Standard 4.1 x 10mm SLA (Institute Straumann AG®, Basel, Switzerland)
2. Standard Plus 4.1 x 10mm SLA (Institute Straumann AG®, Basel, Switzerland)
3. Tapered Effect 4.1 x 10mm SLA implant (Institute Straumann AG®, Basel, Switzerland)
4. Standard 4.8 x 10mm SLA (Institute Straumann AG®, Basel, Switzerland)
5. BNST 4.0 x 10mm internal hexagonal connection implant (Zimmer Biomet®, Barcelona, Spain)
6. BOET 4.0 x 10mm external hexagonal connection (Zimmer Biomet®, Barcelona, Spain)
7. Ankylos C/X 3.5x11mm (Dentsply® Sirona, Hanau, Germany).

It is of interest to see the variation between the PTVs recorded on the different implants in the different bone densities. The boxplots below show the PTVs recorded by implant type across all bone densities (figure 46).

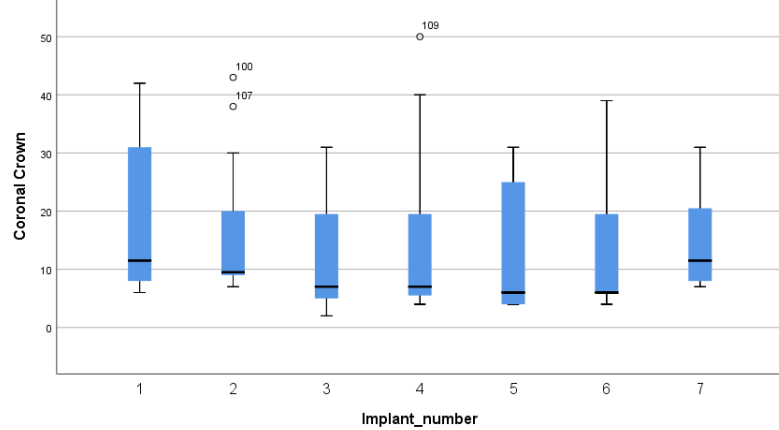
Figure 46: Boxplot of median PTVs by Implant Type across All Bone Densities.

1= Straumann Standard, 2= Straumann Aesthetic Plus, 3= Straumann Tapered Effect, 4= Straumann wide body, 5= Zimmer Biomet internal connection, 6= Zimmer Biomet external connection, 7= Ankylos.

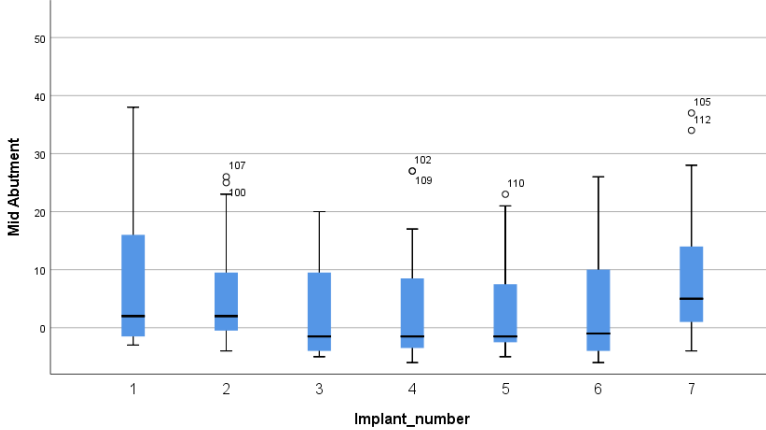
Simple Boxplot of Coronal Abutment by Implant_number



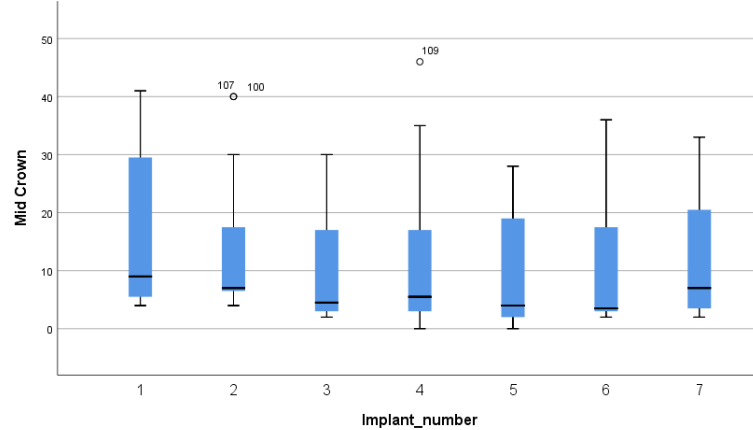
Simple Boxplot of Coronal Crown by Implant_number



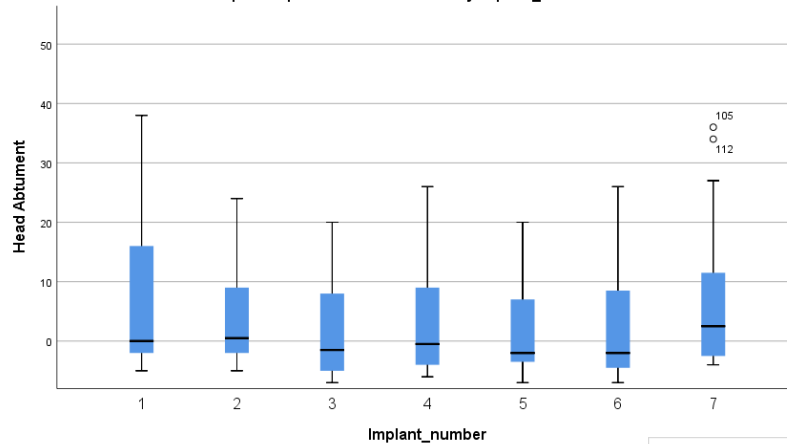
Simple Boxplot of Mid Abutment by Implant_number



Simple Boxplot of Mid Crown by Implant_number



Simple Boxplot of Head Abutment by Implant_number



Simple Boxplot of Head Crown by Implant_number

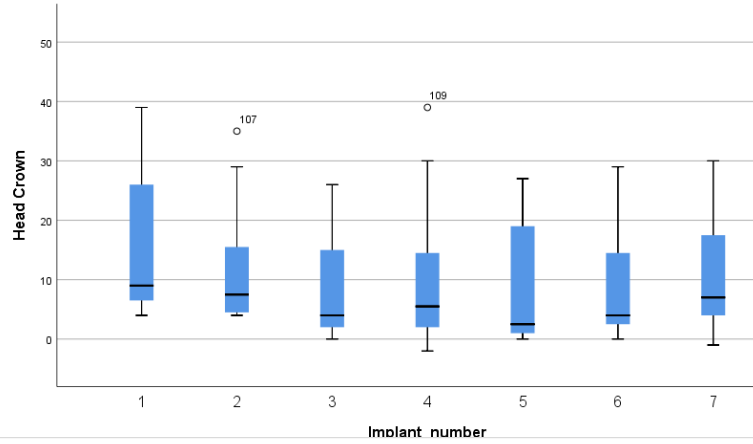
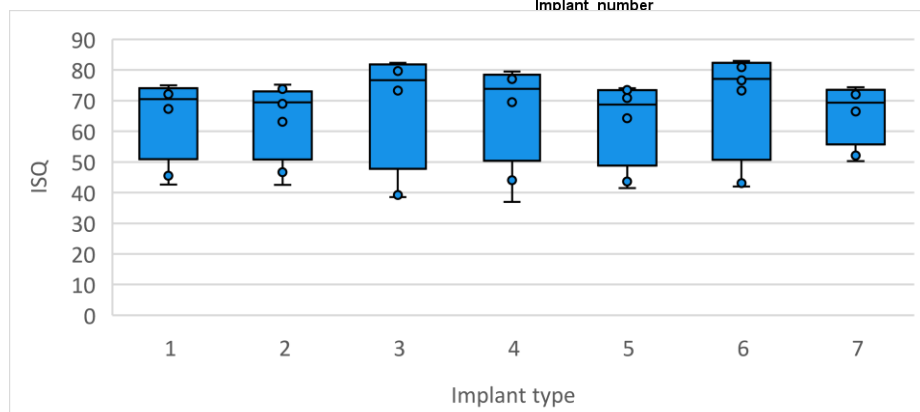


Figure 47: Median ISQ value by Implant Type across All Bone Densities (Naughton et al. 2023).



On examination, while the general pattern of distribution appears similar for all heights on both abutments and temporary crowns across all implant types, there is a slight discrepancy in the results from the coronal and implant-head level measurements on the temporary crown. Furthermore, as would be expected after the evident difference in PTVs based on bone density, there is a large range of values recorded for each implant with a number of outliers affecting a number of different implants. Outliers are quite consistently recorded for implant 2 (Straumann Standard Plus 4.1 x 10mm SLA) and 4 (Straumann Standard 4.8 x 10mm SLA).

While the spread of ISQ measurements based on implant type across all bone densities is not dissimilar to that of the PTVs, the pattern of distribution is somewhat different (figure 47). The boxplots sit much higher on the graph and appear to have a shorter range of values.

A one-way-ANOVA with post-hoc Tukey test was carried out for the implant types across all bone densities. There were no statistically significant differences detected in the mid-abutment readings between the different types of implants when all bone densities were included. This is similar to the findings of Naughton et al. (2023) where there was no statistically significant difference in the ISQ values recorded for the different implants when all bone densities were included ($p = .361$).

Owing to the difference between the values of implant stability recorded in D4 bone compared to those recorded in D1-D3 bone density, further analysis based on the type of implant in D1-D3 bone density only is of interest. The boxplots below show the PTVs recorded by implant type across bone densities D1-D3 (figure 48). Again, the patterns of

distribution across the different implants for different level readings on abutment and crown are similar, however the range of values is much less than when D4 bone was included in the analysis. A not dissimilar pattern is seen in the in the ISQ values recorded using the Osstell® device (figure 49). In fact, the flow of the pattern is almost exactly the inverse of the PTVs based on implant type.

Figure 48: Boxplot of PTVs by Implant Type across D1, D2, D3 Bone Densities.

1= Straumann Standard, 2= Straumann Aesthetic Plus, 3= Straumann Tapered Effect, 4= Straumann wide body, 5= Zimmer Biomet internal connection, 6= Zimmer Biomet external connection, 7= Ankylos.

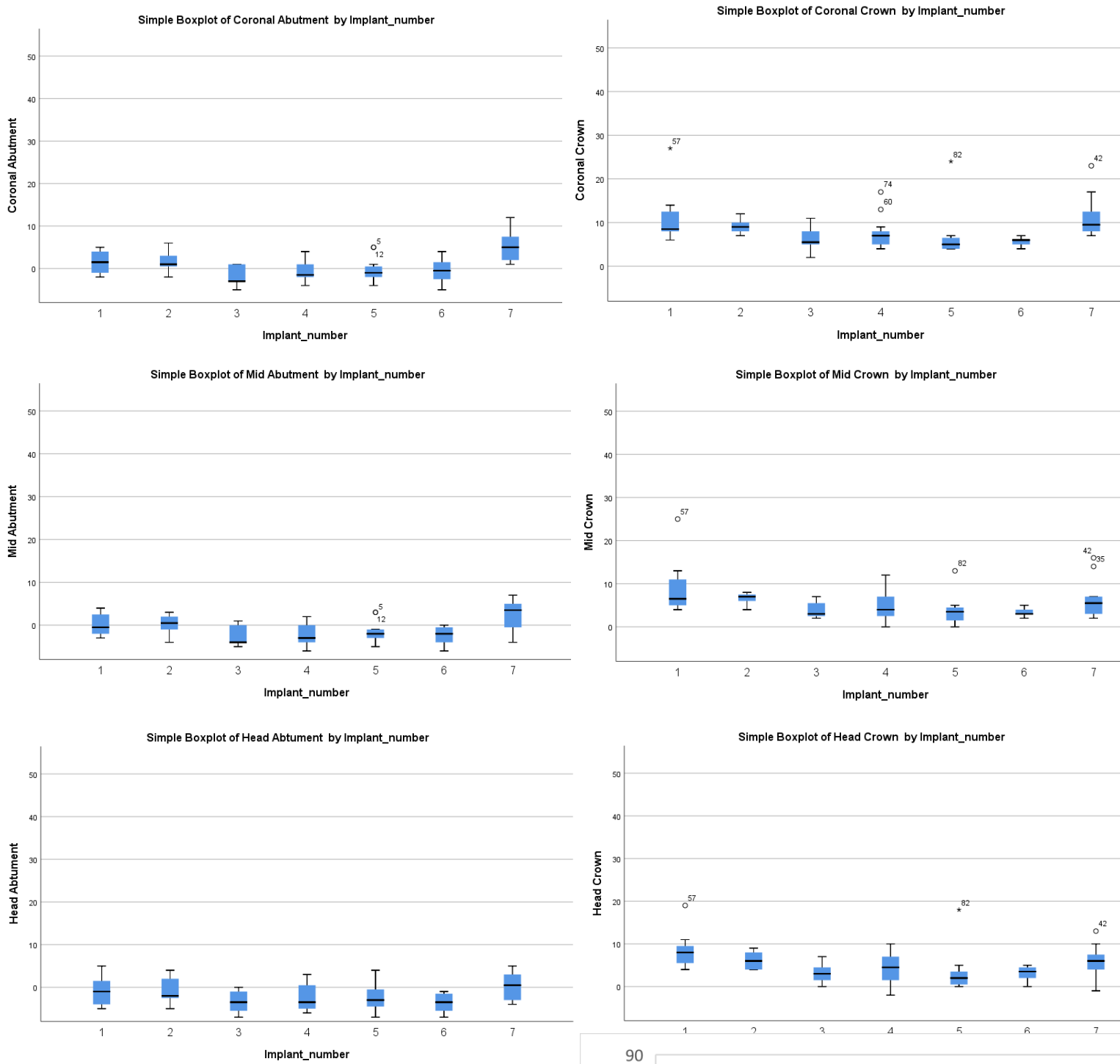
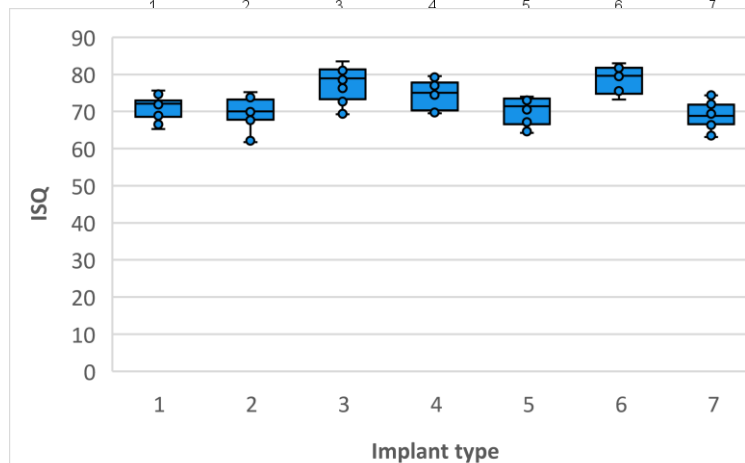


Figure 49: ISQ value by Implant Type across D1, D2 and D3 Bone Densities (Naughton et al.2023).



Analysis of the implant stability using the PTVs and ISQ values recorded for D1-D3 bone based on implant type was done using a one-way ANOVA. This revealed statistically significant differences between the PTVs and ISQs recorded for the different implants ($p < .001$). Post-hoc analysis with the Tukey test demonstrated which implants differed significantly from one and other.

As can be seen from table 11 below, a statistically significant difference was noted between implant 7 (Ankylos 3.5 x 11mm, Dentsply®) and several of the other implants. There were no statistically significant differences detected between the PTVs recorded for all other implants.

| Differences between implant stability measurements recorded with the Periotest™ device (PTV) for different implant types across bone density D1-D3. | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|
| Implant 7 | Implant 3 (mean difference 5.167, $p < .001$) |
| | Implant 4 (mean difference 4.667, $p = .001$) |
| | Implant 5 (mean difference 4.083, $p = .004$) |
| | Implant 6 (mean difference 4.917, $p < .001$) |

Table 11: Difference in PTVs between Implant 7 and implants 3,4,5 and 6.

A similar analysis was computed for the ISQ data. This is demonstrated in table 12 below. Implant 3 (Straumann, Tapered Effect 4.1 x 10mm SLA) and implant 6 (BOET, 4 x 10mm external hexagonal connection, Zimmer Biomet®) differed to a number of the other implants.

Differences between implant stability measurements recorded with the Osstell® device (ISQ) for different implant types across bone density D1-D3.

| | |
|------------------|------------------------------------------------|
| Implant 3 | Implant 2 (mean difference 8.438, $p = .012$) |
| | Implant 5 (mean difference 8.354, $p = .013$) |
| | Implant 7 (mean difference 7.708, $p = .026$) |
| | |
| Implant 6 | Implant 1 (mean difference 7.229, $p = 0.44$) |
| | Implant 2 (mean difference 8.771, $p = .008$) |
| | Implant 5 (mean difference 8.688, $p = .009$) |
| | Implant 7 (mean difference 8.042, $p = .018$) |

Table 12: Table demonstrating difference in ISQ values between Implant 3 and implant 6, and a number of the other implants.

3.4 Part Four – Association between mid-crown and mid-abutment PTVs

The effect of the implant and the bone density on the correlation between mid-abutment and mid-crown was assessed using moderation analysis. This allowed examination of whether the variables of bone density and implant type changes the strength of the relationship between the mid-abutment and mid crown PTVs.

First, the distribution of the mid-abutment and mid-crown data were plotted (figure 50).

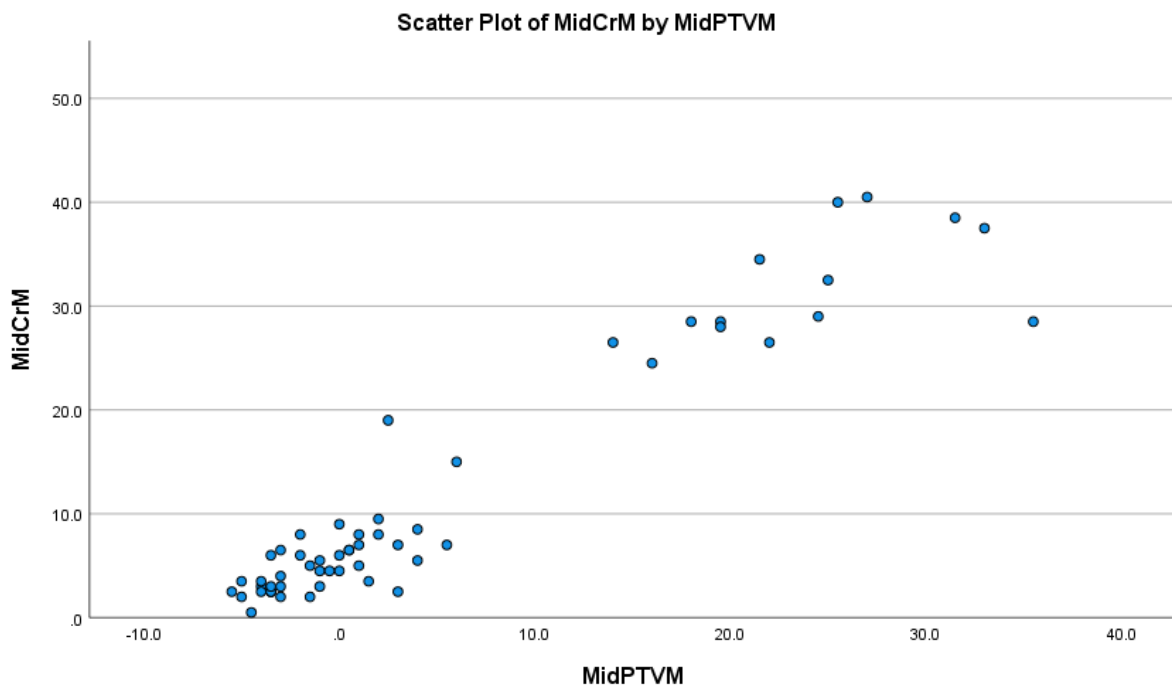


Figure 50: Scatter plot of mid-abutment and mid-crown PTVs.

The correlation between the mid-abutment and mid-crown PTVs were then assessed using the Pearson test and the correlation was found to be excellent ($r = 0.954$, $p < .001$).

The relationship between the mid-abutment and mid-crown was examined using moderation analysis with bone as the moderator, which resulted in a statistically significant result ($p = 0.041$).

Further analysis of these results was carried out using the Pearson test to assess the relationship between the mid-abutment and mid-crown based on each individual type of bone density. The results are displayed in table 13 below.

| Bone Density | Relationship between mid-abutment PTV and mid-crown PTV as assessed using the Pearson test. |
|--------------|---------------------------------------------------------------------------------------------|
| D1 | $R = 0.404, P = .152$ |
| D2 | $R = 0.857, P < .001$ |
| D3 | $R = 0.237, P = .414$ |
| D4 | $R = 0.586, P = .028$ |

Table 13: Relationship between bone density and mid-abutment and mid-crown PTVs.

From the above table, it can be seen that the correlation between the mid-abutment and mid-crown changes based on the bone density, with a significant correlation for D2 and D4 bone, and a non-significant correlation for D1 and D3.

The scatter plot below (figure 51) shows the variation/significance of the correlation coefficient between mid-abutment and mid-crown PTVs for different bone densities that indicate the significance of moderation effect of the bone types.

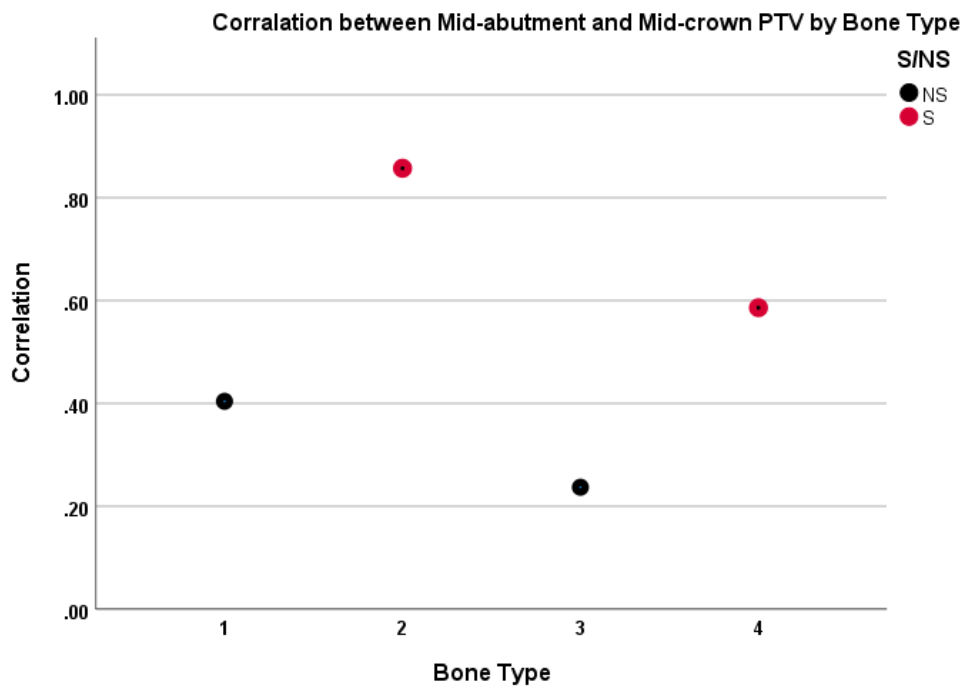


Figure 51: Correlation between mid-abutment and mid-crown PTV by bone type.

Analysis of the relationship between the mid-abutment and mid-crown PTVs based on the impact of the implant was also assessed using moderation analysis, with the implant set as the moderator (figure 52). The moderation analysis found that that the implant had no significant impact on the relationship between the mid-abutment and mid-crown PTV differences ($p = 0.814$). This result indicates that the type of implant does not have an effect on the difference in PTVs that can be expected when implant stability measurements are taken on the implant abutment versus on the implant-retained crown.

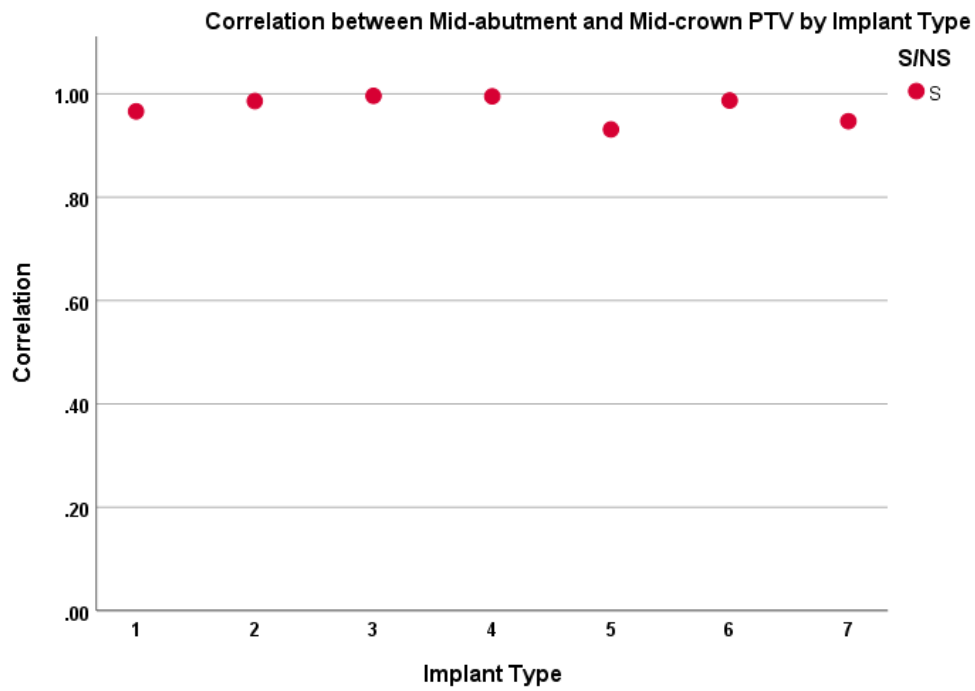


Figure 52: Correlation between mid-abutment and mid-crown PTV by implant type.

The results of the correlation analysis based on each implant type (1-7) are displayed in table 14 below. They demonstrate that the relationship between the mid-abutment and mid-crown PTVs is not moderated by the presence of the implant.

| Implant Type | Relationship between mid-abutment PTV and mid-crown PTV as assessed using the Pearson test. |
|--------------|---------------------------------------------------------------------------------------------|
| 1 | $R = 0.966, P < .001$ |
| 2 | $R = 0.986, P < .001$ |
| 3 | $R = 0.996, P < .001$ |
| 4 | $R = 0.995, P < .001$ |
| 5 | $R = 0.931, P = .001$ |
| 6 | $R = 0.987, P < .001$ |
| 7 | $R = 0.947, P < .001$ |

Table 14: Relationship between mid-abutment and mid-crown PTV based on implant type.

3.5 Part Five - Investigation into correlation between PTVs & ISQ values.

The effect of the implant and the bone density on the correlation between PTVs and ISQs values was also assessed using moderation analysis. This allowed examination of whether the variables of bone density and implant type changes the strength of the relationship between the mid-abutment PTV and the ISQ values for the same implants.

Again, the scatter plot of the mid-abutment and ISQ data were plotted first (figure 53).

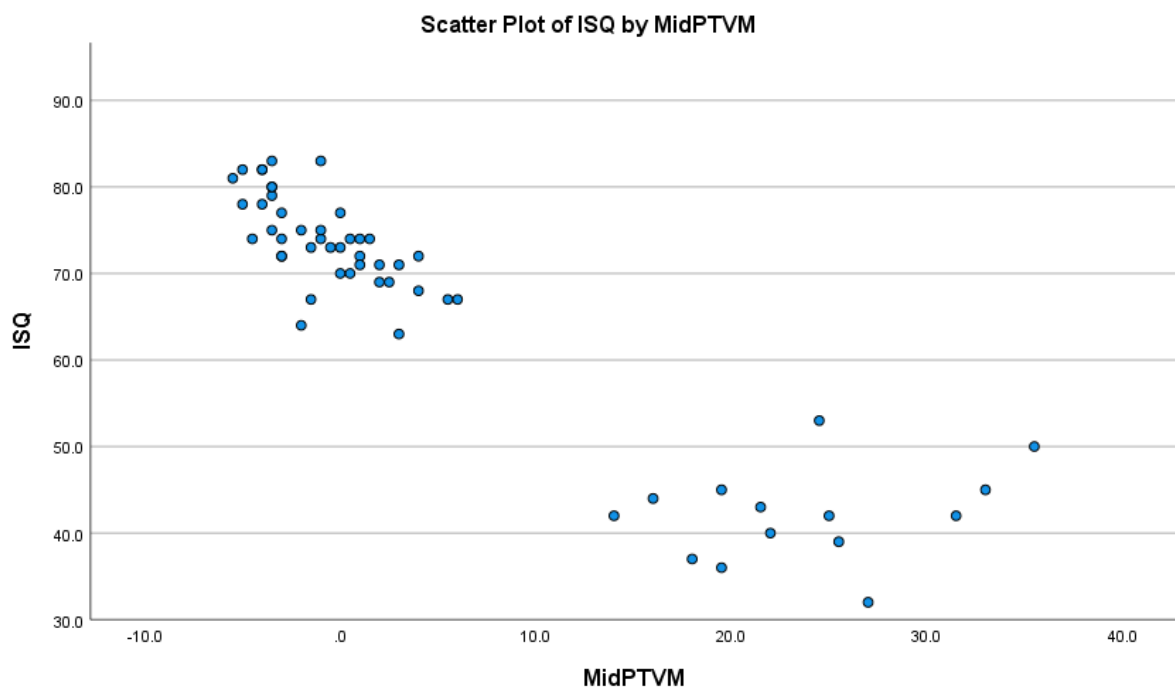


Figure 53: Scatter Plot of mid-abutment PTV and ISQ values.

The correlation between the PTVs and ISQ values were then assessed using the Pearson test and the correlation was found to be excellent ($r = 0.912, p < .001$). The relationship between the PTVs and ISQ values was examined using moderation analysis with bone as the moderator. The results demonstrated that there was no significant impact of the type of bone density on the relationship between the PTVs and ISQ values recorded for the same implants ($p = 0.063$), when all bone types were included in the analysis.

However, the moderation effect is significant in significance level of 10%, (i.e. where the p value is set to ≤ 0.10 instead of ≤ 0.05).

However, when the impact of each type of bone density on the relationship between the PTVs and the ISQ values recorded was assessed, the moderation analysis showed that D1 ($r = -0.731, p = .003$) and D2 ($r = -0.716, p = .004$) bone types showed different/significant correlation between PTVs and ISQs. However, D3 ($r = -0.166, p = .569$) and D4 ($r = 0.265, p = .359$) bone densities did not. These results are displayed in table 15 and figure 54 below.

| Bone Density | Relationship between mid-abutment PTV and ISQ value as assessed using the Pearson test. |
|--------------|-----------------------------------------------------------------------------------------|
| D1 | $R = -0.731, P = .003$ |
| D2 | $R = -0.716, P = .004$ |
| D3 | $R = -0.166, P = .569$ |
| D4 | $R = 0.265, P = .359$ |

Table 15: Relationship between PTV and ISQ based on bone density.

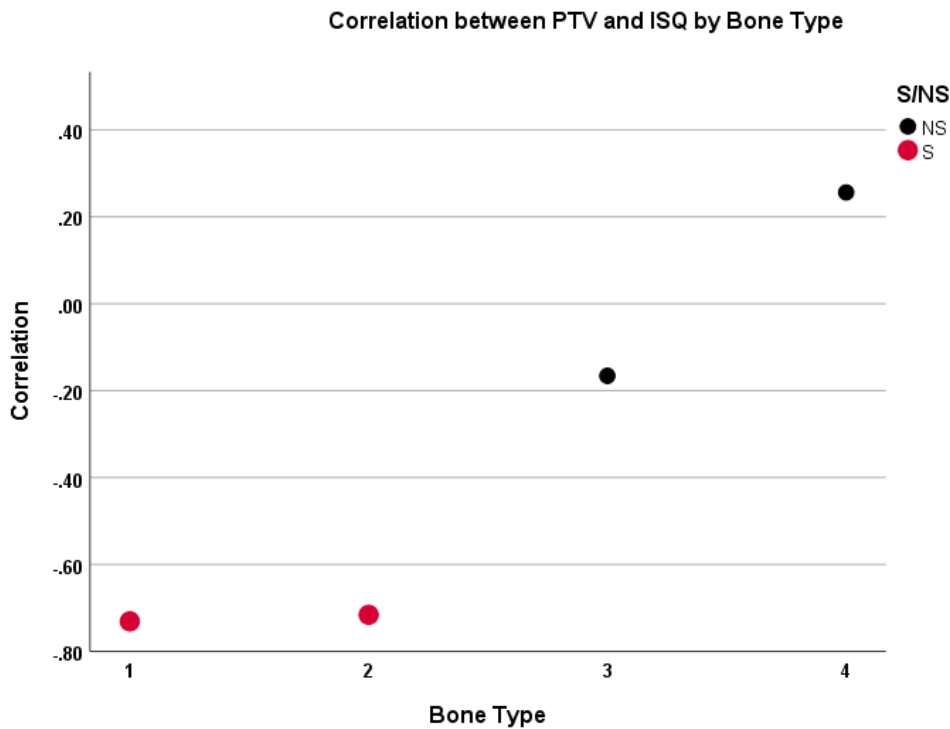


Figure 54: Correlation between PTV and ISQ based on bone density.

Analysis of the relationship between the PTVs and the ISQ values based on the impact of the implant type was also assessed using moderation analysis, with the implant set as the moderator. The moderation analysis found that that the implant had no significant impact on the relationship between PTVs and ISQ values recorded ($p = 0.745$). This result indicates that the type of implant does not have an effect on the relationship between PTVs and ISQ values.

The results of the moderation analysis based on each implant type (1-7) are displayed in the figure below.

They demonstrate that the relationship between the mid-abutment and mid-crown PTVs is not moderated by the type of implant.

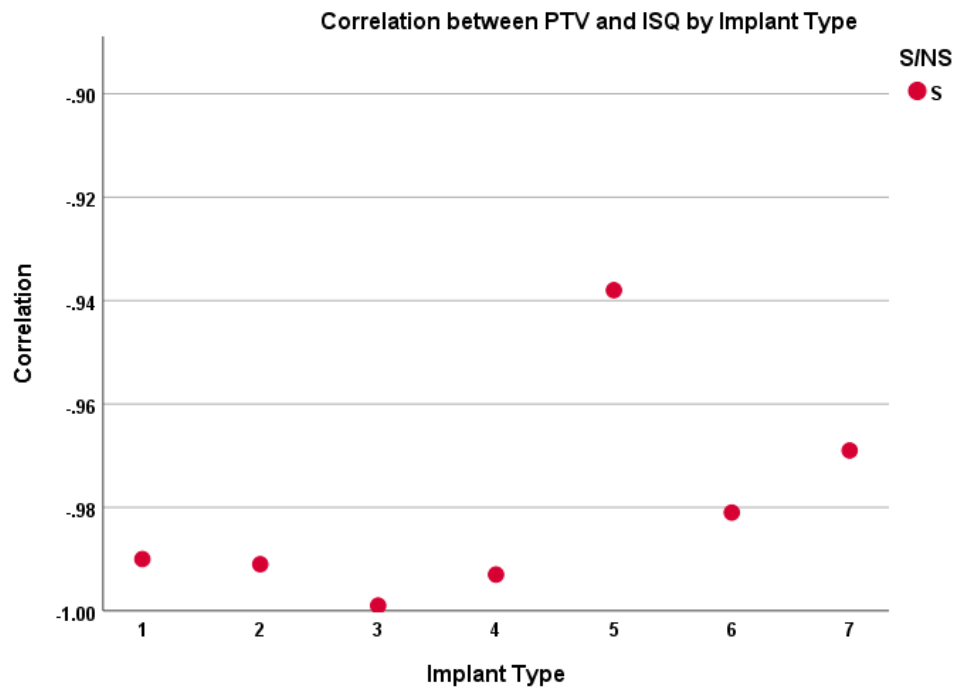


Figure 55: Correlation between PTV and ISQ by implant type.

| Implant Type | Relationship between mid-abutment PTV and ISQ as assessed using the Pearson test. |
|--------------|-----------------------------------------------------------------------------------|
| 1 | $R = -0.990, P < .001$ |
| 2 | $R = -0.991, P < .001$ |
| 3 | $R = -0.999, P < .001$ |
| 4 | $R = -0.993, P < .001$ |
| 5 | $R = -0.938, P = .001$ |
| 6 | $R = -0.981, P < .001$ |
| 7 | $R = -0.969, P < .001$ |

Table 16: Relationship between PTV and ISQ values as assessed using the Pearson test.

3.6 Part Six – Correlation between PTV and ISQ values for implant cohort included in investigation

As previously discussed, the Spearman's rank test demonstrated a statistically significant moderate negative correlation between the mid-abutment PTV and the ISQ readings, across all bone densities ($r_s = -.482, p < .001$), and when D4 bone was excluded $r_s = -.685, p < .001$).

Olivé and Aparicio (1990) previously stated that an implant can be considered to have good stability where the PTVs recorded for the implant lie in the range of -5 to +5. Similarly, it is commonly accepted in the literature, that an ISQ value ≥ 60 indicates good implant stability, and that the implant is suitable for loading, etc.

Therefore, a scatter plot was constructed to attempt to correlate the "good stability" measurements for the PTV to the ISQ values recorded for the implant cohort included in this investigation and that of Naughton et al. (2023). This scatter plot is displayed below and demonstrates excellent agreement between the mid-abutment PTVs and ISQs recorded for each implant across all bone densities (figure 56).

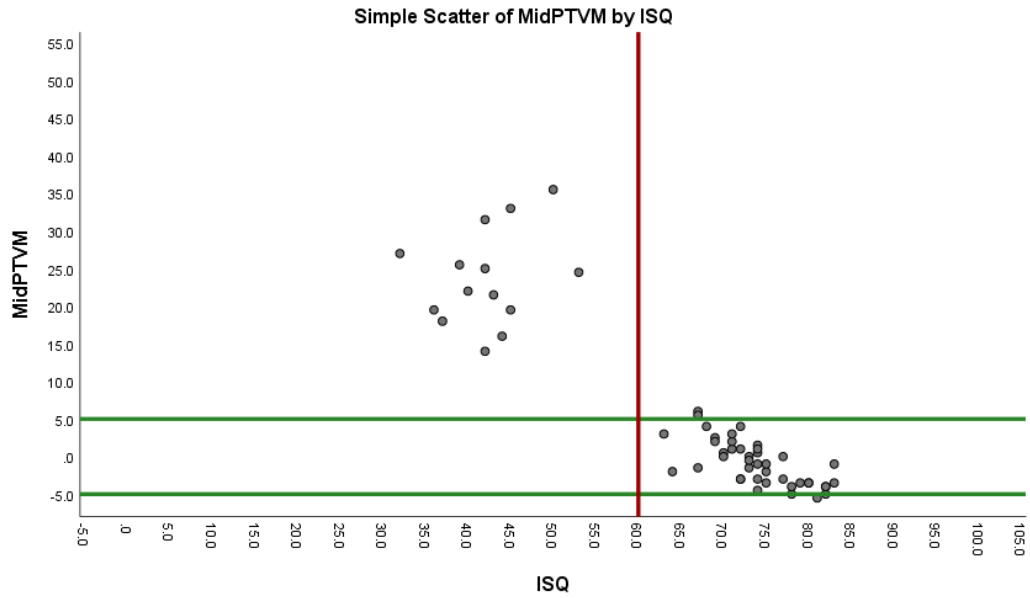


Figure 56: Scatter plot of PTVs and ISQ values recorded across all bone densities.

Where D4 bone is excluded, it can be seen that the implant stability was clinically acceptable (i.e. within the range of -5 to +5 PTVs, or ≥ 60 ISQ) for the majority of the implants (figure 57).

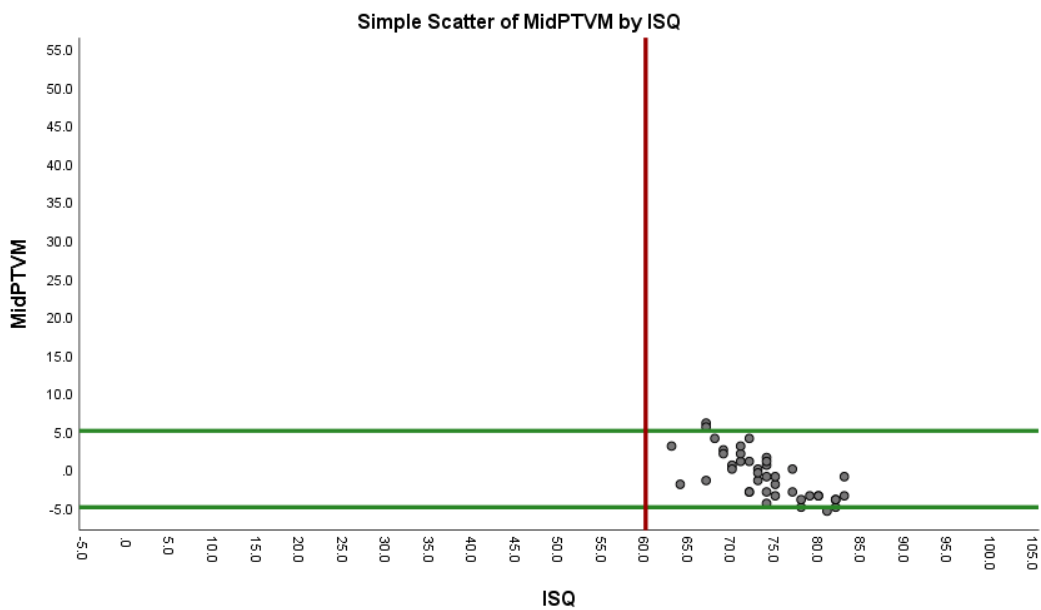


Figure 57: Scatter plot of PTV and ISQ values in D1-D3 bone densities only.

4. Discussion

The main aim of the study herein was to assess the degree to which the results of implant stability measurements taken *in-vitro* by the Periotest™ device can be depended on to be accurate.

A secondary aim was to investigate the difference between Periotest™ measurements taken on implant retained crowns and those taken on healing abutments for the same group of implants.

To achieve these goals, we tried to correlate the readings recorded by two operators using the same Periotest™ device to the ISQ readings previously recorded using the Osstell® device for these same implants. Additionally, we tried to determine the optimal position for the Periotest™ hand piece when using it on either abutments or crowns.

Finally, there was also an attempt to determine implant stability differences between different implant systems and possible effects on the Periotest™ measurements.

The Periotest™ device was originally designed to measure the damping capacity of the periodontium surrounding natural teeth (Schulte, 1988). It was almost a decade later before Aparicio (1997), building on the growing literature regarding assessment of implant stability with the Periotest™ device, proposed the Periotest™ to be used for determining the initial success of the implant. The results of this eight-year longitudinal study indicated a strong correlation between the PTV recorded and the degree of

osseointegration of an implant (Aparicio, 1997). It has since been used in many studies evaluating implant stability – both pre-clinical and clinical in nature. Olivé and Aparicio (1990) reported a normative range of -5 to +5 PTVs. The PTVs reported for implants are lower than those obtained from natural teeth owing to the lack of PDL and the stiffness of the surrounding bone (Meredith, 1998). In the original article by Aparicio (1997), the author reported a range of PTVs recorded at the second stage surgery that were associated with clinically successful implants, and a separate range of values for implants that failed to achieve osseointegration. He also reported that the range of PTVs recorded when assessing implant stability differed based on the density of the bone, but different types of implants that failed to osseointegrate had similar PTVs. The conclusion was that the Periotest™ was a useful diagnostic tool for the assessment of implant stability (Aparicio, 1997). Much of the literature around the Periotest™ device has investigated its usefulness for assessing implant stability at different times during the surgical and restorative phases, as well as analysing its predictive value for success or failure of an implant. However, inconsistencies in the ability of the Periotest™ to assess implant stability have been reported, where the position of the rod, the angulation of the handpiece and the physiological environment have been shown to have an effect (Faulkner et al., 2001, Derhami et al., 1995, Haas et al., 1995, Aparicio, 1997). This has led to questions regarding the reliability of the Periotest™ device in assessing implant stability.

Monje et al. (2019) performed a systematic review of the relationship between primary/mechanical and secondary/biological implant stability. As part of their assessment, they analysed the tools and methods with which implant stability may be

assessed, and determined that Periotest™ had low reliability and low feasibility. An *in vitro* study on cow ribs to evaluate the reliability of the Periotest™ for implant stability measurements concluded that the Periotest™ device was less reliable than resonance frequency analysis for assessing implant stability (Bilhan et al., 2015). While inter-operator and intra-operator reliability was assessed, little information was given whether the cow bone was fixed during measurement, or at what vertical position on the sulcus former measurements were taken. It would also appear that no abutment was used when assessing implant stability with the Periotest™ device (Bilhan et al., 2015). Therefore, the angulation of the handpiece may have been affected by the proximity of the bone crest. In contrast, our results indicated that the Periotest™ has good inter-operator reliability when the positioning of the handpiece is standardised. Additionally, we have observed that measurements at the implant-abutment junction can be difficult to take owing to interference from the bony crest. Therefore, handheld measurements taken on the implant platform may have also been difficult to take and as a result influenced the interpretation of the reliability of the Periotest™ device. Conversely, Hsu et al. (2013) and Schnitman and Hwang (2011) are amongst some of the authors who found the Periotest™ more reliable than the Osstell® device in assessing implant stability.

Many authors have investigated the use of the Periotest™ in predicting the success of an implant, however there is a lack of standardisation across the literature in the positioning of the Periotest™ handpiece on the implant suprastructure. Some authors do not report on the details of how the Periotest™ handpiece was positioned or how many measurements were taken. One such study was that of Nogueroles et al. (2006) who

investigated the predictive value of the Periotest™ device in a 10-year retrospective cohort study of 1084 Brånemark implants.

Teerlinck et al. (1991) set out to identify the borderline values for implant osseointegration by measuring the PTV of clinically successful implants. The authors found the PTVs recorded for intraforaminal implants ranged from -4 to +2. In this study, four abutments of different heights were used: 3mm, 4mm, 5.5mm and 7mm. The authors reported that measurements were taken just below the coronal edge of the abutment. Therefore, the position of the Periotest™ device in relation to the crest of the alveolar bone changed depending on the abutment length. The authors concluded that the type of bone, the peri-implant tissue, and the abutment length are the determining factors for the PTVs recorded for an implant (Teerlinck et al., 1991). Where Schulte et al. (1983) reported that changes in the height of the position of the Periotest™ handpiece would alter the PTV, it may be that the range of PTVs obtained in the study by Teerlinck et al. (1991) was influenced by the abutment height.

More recently, Oh and Kim (2012) found an average range of -5 to + 5 PTVs for Straumann implants when evaluating the relationship between implant stability and bone quality. The results of this clinical study indicated a significant correlation between bone quality and PTVs, where the PTVs recorded in type 4 bone density were significantly higher than those recorded in type 1 to 3 bone ($p < .01$). Oh and Kim (2012) draw attention to the standard use of a healing abutment of 4mm height in this study in order to reduce errors associated with PTVs based on the site of measurement.

Standardisation of the method of using the Periotest™ device provides robustness to

that study, however until there is a standardised method of assessment used across the literature, comparison of PTVs obtained in different studies is of questionable value.

While it is common for investigators to repeat PTV measurements until a number of similar PTVs are obtained for an implant (Zix et al. 2008), different studies record measurements at different points on the implant abutments. Similar to Oh and Kim (2012), Schnitman and Hwang (2011) elected to standardise the position of the Periotest™ handpiece at 4mm coronal to the implant platform in their study. As discussed above, Teerlinck et al. (1991) positioned the Periotest™ handpiece just below the coronal aspect of the abutment, regardless of the height of the abutment. Other studies placed the Periotest™ handpiece just coronal to the soft tissue (Walker et al., 1997, Truhlar et al., 1997a). The literature investigating the reliability and predictive value of the Periotest™ device suffers from the lack of standardisation in the position of the Periotest™ handpiece when implant stability is being assessed. Khalaila et al. (2020) chose to position the Periotest™ device 2 mm coronal to the implant-transfer coping connection point. They reported significant correlations between the PTVs recorded over a 3 year follow up period. The position that they chose would approximately be just below the mid-point of the abutments used in our study. Variables that may have had an impact on their results include marginal bone loss and the fact that readings were taken at different time points (Khalaila et al., 2020). The authors concluded that the Periotest™ device was a reliable method for assessing implant stability and predictive information regarding marginal bone changes around an implant.

Previous studies had outlined that the reliability of Periotest™ would be +/- 1 PTV around the “true” value, and +/- 2 PTV where a high level of mobility was present (Teerlinck et al., 1991, van Steenberghe and Quirynen, 1993). A laboratory-based study by Lachmann et al. (2006a) also reported a variation of 1 PTV around the “true” value when describing the reliability and precision of the Periotest™ device.

In our study, three sites on the implant abutments and implant crowns were chosen to record the implant stability with the Periotest™ device to allow us to investigate which site facilitated the most consistent and reliable reading of the stability of the implant. Both abutments and crowns were torqued to 5 N cm. For abutments, the sites chosen were the most coronal aspect, the mid-point of the abutment and the implant-head so the measurement points were approximately 2mm apart. For crowns, the sites chosen were the implant head and the rest of the sites were approximately 3mm apart moving coronally. The implant head was set as the most apical position of the abutment or crown possible whilst ensuring that the Periotest™ handpiece did not touch the bone block in which the implant was placed, i.e. approximately 1.5mm from the implant-abutment or implant-crown interface.

In an earlier work by Derhami et al. (1995) using a cadaver bone specimen the Periotest™ handpiece was positioned at five different vertical positions measuring 0.5mm apart between the most coronal extremity and the midpoint of the abutment. The horizontal distance was set to a maximum of 1.5-2mm from the implant. Implant stability measurements were recorded mechanically at 5 sites, and by hand at 3 sites. The authors reported a significant difference between the PTVs recorded at the most

coronal aspect compared to the mid-abutment level of approximately 3 PTVs ($p < .001$). This difference in PTVs is attributed to the variation in the length of the leverage arm that occurs when the point of measurement was further away from the bony crest (Derhami et al., 1995). In the cadaver study a pin was mounted on the tip of the handpiece to ensure the correct distance between the handpiece and the implant abutment (Derhami et al., 1995). In our study, a card block measuring 1-1.5mm in thickness was used to ensure a standard distance between the tip of the handpiece (rod) and the implant.

Derhami et al. (1995) reported five points of uncertainty regarding the positioning of the Periotest™ device, namely: 1) vertical point of measurement; 2) the interoperator variability; 3) variation between fixed and hand-held measurements; 4) the correct angulation of the handpiece, and 5) the horizontal distance between the handpiece and the abutment surface. Of these five uncertainties, the authors report that they investigated the first three. In this investigation, we have also addressed three of these points (1, 2 and 5), in addition to considering the difference between PTVs recorded on implant abutments and implants crowns for the same implant.

While histological measurements remain the gold standard for the assessment of implant osseointegration (Molly, 2006), resonance frequency analysis is the most common technique used to measure implant stability (Hériveaux et al., 2021).

Therefore, in order to determine the most appropriate vertical site in which to position the Periotest™ handpiece, the ISQ values previously recorded by Naughton et al (2023) for this cohort of implants were used as the gold standard against which the PTVs would

be evaluated. A major advantage is that in this study the Osstell® smart pegs used for the measurements were all tightened to 6 Ncm by a previously calibrated torque wrench. The same torque wrench was used to tighten the healing abutments and crowns. The correlation between the ISQ values and the PTVs recorded at each of the three sites on the implant abutment (coronal, mid and implant-head) was explored using Spearman's rank correlation coefficient. When all bone densities were considered, a statistically significant negative correlation was found for the ISQ value and the PTVs recorded at the coronal abutment site ($r_s = -.305, p = .022$), and the mid-abutment site ($r_s = -.482, p < .001$). The correlation between the ISQ value and the implant-head abutment reading was not statistically significant and of poor strength ($r_s = -.232, p = .085$). When D4 bone was excluded, the Spearman rank correlation coefficient revealed a significant moderate negative correlation with all three sites on the implant abutment (coronal abutment: $r_s = -.537, p < .001$; the mid-abutment: $r_s = -.685, p < .001$; head of the implant abutment: $r_s = -.508, p = .001$). In both situations, the correlation was best for the relationship between the ISQ and the mid-abutment site PTV readings. Therefore, based on the results of our investigation, the site that can be recommended for assessing implant stability with the Periotest™ device is the mid-abutment site. Healing abutments of about 6mm height were used in this investigation, therefore this corresponds to the Periotest™ handpiece being positioned approximately 3mm from the bone crest. .

One putative advantage that the Periotest™ device might have over competitors, is that for single implants, the implant crown might not need to be removed to facilitate implant stability assessment (Bilhan et al., 2015). Therefore, one of the aims of our study included assessment of the positioning of the Periotest™ handpiece on implant-

supported crowns also. While positioning of the Periotest™ handpiece is sporadically reported in detail, few studies have analysed differences in PTVs based on the type of suprastructure and the impact this may have on the PTV recorded. A clinical study by Gomez-Roman and Lukas (2001) investigated the differences in PTVs recorded based on whether the implant stability was assessed on a sulcus former, a crown abutment, or a single crown. The authors reported that “the Periotest™ measurement was performed at the center of the visible labial or buccal surface of the gingiva former, crown abutment or crown.” The results of their study demonstrated a difference between the PTVs recorded on the abutments and crowns at the same timepoint. The average individual change between the single crown and the sulcus former was -3.5 PTVs, and between the crown abutment and the single crown was -1.7 PTVs (Gomez-Roman and Lukas, 2001). The implants used in their study were Frialit-2 implants (Friadent). As this was a clinical study where the bone quality and quantity were not controlled, the mean differences in recorded PTVs may be interpreted with caution. Furthermore, while measurements were taken at the centre of the gingival sulcus former, crown abutment or single crown, these components all significantly vary in height which may have had an impact on average individual change for each implant. Faulkner et al. (2001) demonstrated that variation in height of 1mm can alter the implant stability measurement by 1-2 PTV. Further discrepancies may have occurred owing to different torque values used for each of the components, where the authors reported that the healing abutment was torqued to 8 N cm and the crown was torqued to 18 N cm (Gomez-Roman and Lukas, 2001). In our study, a standardised torque of 5 N cm was used on both the implant abutments and crowns. The authors concluded that the

different superstructures and their attachment mode had an impact on the PTV result (Gomez-Roman and Lukas, 2001).

In our study, where the mid-abutment PTV had been found to have the closest correlation with the resonance frequency analysis results, the correlation between the mid-abutment PTV and the PTVs recorded at the different sites on the implant-supported crowns was explored. The intraclass correlation coefficient (ICC) for the mid-abutment to the coronal crown was 0.700, while the ICC for the mid-abutment to the mid-crown and implant-head crown were 0.810 and 0.847, respectively ($p < .001$). The difference between the mid-crown and mid-abutment results was considered very small, and owing to the clinical difficulties that can be anticipated from attempting to measure implant stability juxta-gingivally, the mid-crown site is to be recommended for implant stability assessment with the Periotest™ device.

Further investigation of the relationship between the mid-abutment PTV and mid-crown PTV naturally developed as consistent differences were recorded. This was to be expected, as Gomez-Roman and Lukas (2001) had previously shown that the type of abutment had an impact on the PTV reported for a given implant at the same time point. The authors highlighted the importance of standardised measurements in order to reliably assess implant stability. Correlation of the relationship between PTVs recorded on the abutment to those recorded on the crown for the same implant would allow the clinician better information when analysing implant stability changes at the different stages between implant placement and restoration.

We deduced that analysis of the above information could be used to provide a guide for clinician's as to what difference in PTVs to expect when assessing implant stability using an implant abutment vs on an implant crown, with all other factors being equal.

Khalaila et al. (2020) had previously shown that the Periotest™ device was a reliable tool for assessment of implant stability and predictive bone level changes around implants. The PTVs recorded at baseline and at follow-up correlated significantly with the bone loss detected at follow up. The variation in PTVs here is controlled by use of the transfer coping to record all implant stability measurements. However, for implants with a cement retained restoration where placement of a standard abutment is challenging, the clinician may be uncertain as to whether higher PTV values recorded on crowns versus those previously recorded on abutments is due to marginal bone loss or simply on account of the longer lever. Cemented implant restorations may be used for aesthetic reasons (Palmer et al., 2003), or in situations of expected high occlusal load as they have been shown to have greater resistance to high loads than screw-retained restorations (Cicciu et al., 2014).

Therefore, we aimed to find the mean difference in PTV for implant stability measurements recorded at the mid-abutment site versus the mid-crown site of our cohort of implants. ICC of mid-abutment and mid-crown measurements demonstrated a good agreement (0.810). Statistical analysis of the data revealed a difference of 6 PTVs between measurements recorded on the implant abutment versus on the implant crown, all other factors being equal. As the PTV scale runs from -8 to +50 where the lower value indicates increased stability, the crown measurement would be 6 PTVs

higher (lower stability) than the measurement recorded on the abutment. Where the mid-abutment site had been shown to have the best correlation with the ISQ values, and the mid-crown site had been shown to have excellent correlation with the mid-crown site and be feasible for clinicians to access, this difference was deemed to be of interest to the clinician. Interestingly though, when the D4 bone measurements are excluded the ICC between the mid-abutment and mid-crown measurements demonstrated low agreement (0.221).

Furthermore, the difference in PTVs between the mid-abutment and mid-crown sites was investigated based on the bone density. Results demonstrated that the difference in PTVs that can be expected when measuring the implant stability using the Periotest™ device on an implant-retained crown compared to on the implant abutment is around 6 PTVs. Times when this may be clinically relevant, include immediate restoration of an immediately placed implant; provision of a temporary restoration at the second stage surgery; when delivering the final prosthesis, and at subsequent maintenance visits.

When assessed, the correlation (Pearson's) between the mid-abutment and mid-crown PTVs was found to be excellent ($r = 0.954$, $p < .001$). This relationship was also examined using moderation analysis with bone as the moderator, which resulted in a statistically significant result ($p = 0.041$). Implant type was found not to moderate the correlation between the mid-abutment and mid-crown PTVs. No significant impact was detected when an attempt was made to include both bone density and implant type as moderators for the relationship between mid-abutment and mid-crown PTVs. This may be because of an insignificant effect, or may be because of insufficient power to run this analysis.

In the study herein, the Osstell® device was used as the gold standard to facilitate assessment of the accuracy of the Periotest™ device. The implant stability measurements as recorded with the Periotest™ device were compared to those previously recorded by Naughton et al. (2023). Analysis of the correlation between the two methods allowed us to determine the accuracy of the Periotest™ device at assessing implant stability *in vitro*.

The bar charts and boxplots depicted in our results facilitate clear visualisation of the inverse relationship between the PTVs and ISQ values recorded for the same cohort of implants in this study and the investigation by Naughton et al. (2023). This was true for all bone types and when D4 bone was excluded. The relationship between the different sites on the implant abutment and the ISQ value previously recorded by Naughton et al. (2023) was explored using Spearman's rank correlation coefficient. As previously discussed, the results of our analysis demonstrated the best correlation was between PTV recorded at the mid-abutment site and the ISQ. This was true across all bone types, and when D4 bone was excluded ($r_s = -.482, p < .001, r_s = -.685, p < .001$, respectively).

Many authors have previously commented on the relationship between the implant stability measurements gained using the Periotest™ and the Osstell® devices. In an *in vitro* study, Lachmann et al. (2006a) were the first to assess the reliability of both devices and attempt to create a method of comparison. Bovine bone of D2 and D3 quality per Lekholm and Zarb (1985) were used to house four implants each. The authors reported that both methods were reliable for assessment of implant stability. A linear, high statistical correlation was reported between the Osstell® and Periotest™

measurements ($n = 52$ observations, $R^2 = 0.8$, $p < 0.0001$) (Lachmann et al., 2006a). This is in line with the results of our study where an inverse relationship between the two methods of assessing implant stability has been reported. Lachmann et al. (2006a) also developed equations to facilitate transfer of PTV values into ISQ, where “ $ISQ = 76 - 2 \times PTV$ ”. However, they are somewhat unwieldy for day-to-day clinical practice. Further research by the same group where the relationship between peri-implant defects and implant stability was assessed and corroborated their previous findings regarding a linear relationship between PTV and ISQ (Lachmann et al., 2006b).

In a cadaver study investigating the impact of residual bone height, bone density and implant diameter on the primary stability of implants placed in the atrophic maxillary sinus floor, Pommer et al. (2014) recorded the ITV, ISQ and PTVs obtained for each implant. The authors found the mean PTV was 8 ± 7 (range: -2 to 27 PTV), while the mean ISQ was 44 ± 12 (range: 8-70 ISQ). A highly significant negative correlation was found for the PTV vs ISQ ($r_s = -0.73$, $p < 0.001$). The significant negative correlation found by Pommer et al. (2014) is in line with the findings of our study. Interestingly, the bone density of the specimens used in this study (mean 110 ± 51 HU; range 34 – 239 HU) were all of D4 bone density or less according the Misch classification of D4 bone being 150-350 HU (Misch, 2004). The correlation between the ISQ and PTV reported by Pommer et al. (2014) for these implants placed in poor quality bone is somewhat better than that recorded in our study where D1-D4 bone densities were included ($r_s = -0.73$, $p < 0.001$ vs. $r_s = -.482$, $p < .001$) and similar to that recorded when D4 bone was excluded from the analysis ($r_s = -.685$, $p < .001$). This is interesting, as the results of previous

authors found that the Osstell® device functioned poorly in D4 bone density (Hsu et al., 2013, Naughton et al., 2023).

Bilhan et al. (2015) also found a 30.3% negative correlation between the PTVs and ISQs recorded for 30 implants placed in fresh bovine bone ribs of type 3 bone density, however it was not significant ($p = .104$). The authors concluded that no strong correlation existed between the PTV and ISQ or ITV measurements. However, it is worth noting that implant stability was assessed with the Periotest™ at both the mesial and buccal aspect of the implants in this study, with poor inter- and intra-operator reliability found for the mesial measurements (Bilhan et al., 2015). Therefore, poor measurement technique may have had an impact on the authors' ability to determine the correlation between the PTVs and the ISQ values.

The results of Bilhan et al. (2015) are similar to those reported by Zix et al. (2008) where the Osstell® device was found to be more reliable than Periotest™ in a clinical study involving the assessment of 213 dental implants placed in edentulous arches. Zix et al. (2008) reported a negative correlation ($r_s = -0.65$) between the Osstell® and Periotest™ devices but did not report whether it was of statistical significance. Zix et al. (2008) were the first to directly compare the two methods of implant stability assessment in the clinical setting, and highlight the difficulties encountered and reduced measurement accuracy obtained. While both the Osstell® and Periotest™ devices are sensitive to alterations in distance from the point of measurement to the alveolar crest, and soft tissue contact (Meredith, 1998), other variables relating to the use of the Periotest™ device are raised by Zix et al. (2008). Namely, the influence that the angle of the

handpiece, and the specific horizontal distance that must be maintained between the handpiece and the implant (Zix et al., 2008). Therefore, our investigation involved maintaining a standardised horizontal distance within the manufacturer's recommended range between the implant and the Periotest™ handpiece. The articulated arm was instrumental in facilitating this, as well as maintaining an angle of 90 degrees between the handpiece and the implant.

A canine study involving the placement of 48 commercially pure titanium implants in four mongrel dogs by Oh et al. (2009) concluded that a correlation was present between the Osstell® and Periotest™ devices. However, no statistical analysis was reported in this study. Histomorphometric analysis of the new peri-implant bone formation rate was also carried out. Interestingly, while the implant stability values recorded for the maxilla indicated less stability when compared to those recorded for the mandible, the rate of new peri-implant bone formation was higher in the maxilla than in the mandible (Oh et al., 2009).

More recently, a clinical study from our research group investigated the correlation between the Osstell® and Periotest™ devices over a three-year period with implant stability measurements being assessed at implant insertion (T1), implant uncovering (T2), and 3 years after implant placement (T3). They noted a weak to moderate correlation between the mean ISQ and PTVs at each time point (T1 $r_s = -0.26$, $p = 0.05$; T2 $r_s = -0.35$, $p < 0.01$; and, T3 $r_s = -0.28$, $p = 0.04$) when assessed with the Spearman's rank correlation. Interestingly, implant stability appeared to improve over the three-year period when assessed with both devices, with the ISQ and PTV range both narrowing.

The authors found that the Periotest™ device was more sensitive in highlighting differences in measurements affected by local conditions, such as the density of the bone and the presence or absence of marginal bone loss (Reynolds et al., 2023). This is in line with the results of the study herein, where the intraclass correlation coefficient between operator 1 and operator 2 were good to excellent for assessment of implant stability with the Periotest™ in all bone densities. Conversely, the ICC between operator 1 and operator 2 as reported by Naughton et al. (2023) was poor (ICC = 0.039) in D4 bone. Furthermore, it is worth noting that in the study by Reynolds et al. (2023) the correlation between the Periotest™ and Osstell® devices at implant insertion was weak ($r_s = -0.26$, $p = 0.05$). This differs to the results of our *in vitro* study where there was a significant moderate correlation found between the devices ($r_s = -.482$, $p < .001$) and improved when D4 bone was excluded from the analysis ($r_s = -.685$, $p < .001$). This is likely on account of the increased measurement error involved with positioning of the handpiece clinically, as discussed by Zix et al. (2008) or because both the Osstell™ transducers and the healing abutments were only hand torqued. A number of studies have demonstrated that there is a need for standardisation of the Smartpeg tightening forces in order to get accurate results (Geckili et al., 2015, Salatti et al., 2019, Naughton et al., 2023).

Olivé and Aparicio (1990) demonstrated that the normative range of PTVs for implant stability was from -5 to +5. In a study by Truhlar et al. (1997a) where the implant stability of 2,212 implants were assessed using the Periotest™, the authors reported the mean PTV for all implants to be – 3.5 PTV across all visits. The range of PTVs reported for all bone densities were in line with the normative range suggested by Olivé and Aparicio

(1990). Similarly, the literature accepts reasonable implant stability as assessed using resonance frequency analysis to be classed as ≥ 60 ISQ (Rodrigo et al., 2010, Stephan et al., 2007, Liddelow and Henry, 2007). In a prospective multi-centre prospective case study Rodrigo et al. (2010) followed more than 4000 SLA Straumann® implants over a 6- to 42-month period and reported that no implants with stability ≥ 60 ISQ failed.

Therefore, they set out to assess the correlation between the accepted normative values reported in the literature for the Periotest™ and Osstell® devices. In contrast to the work of Lachmann et al. (2006a) where a defined equation was computed to translate PTVs to ISQ values, we thought that assessing the correlation between the “healthy” range of implant stability measurements recorded with the Periotest™ and Osstell® devices would be of more use to the clinician in daily clinical practice.

To this end, a scatter plot was constructed to explore the correlation between the PTVs and ISQ values recorded for the cohort of implants included in this study. This scatter plot demonstrated excellent agreement between the mid-abutment PTVs and ISQs recorded for each implant. The majority of the implants that lie within the normative range follow a linear pattern. Where implants with a PTV 0 - 5 PTV have a lower ISQ (approx. 62-75 ISQ) while the implants reporting -5 to 0 PTVs have a higher ISQ value (range 70 to 85). The correlation between the PTVs and ISQ depicted here for all bone densities, and when D4 bone is excluded, provides the clinician with a range of values where the ISQ will correlate with the PTVs. This should foster confidence when clinician’s wish to compare the implant stability measurements gained with Periotest™ to those gained with Osstell®.

Moderation analysis of the relationship between the Periotest™ and Osstell® devices was carried out to analyse the impact that the bone density and implant type might have on the strength of the relationship between the mid abutment PTV and the ISQ values for the same implants. Overall, bone density did not have a significant impact on the relationship between the PTVs and ISQ values reported for the implants ($p = 0.063$). The implant type was also found to have no effect on the relationship between the PTV and ISQ values ($p = 0.745$).

Two operators were involved in assessing implant stability with the Periotest™ device in this study as well as with the Osstell® device, as reported by Naughton et al. (2023). The aim of having 2 operators was to ensure that there is a good degree of consistency amongst different operators when taking stability measurements for the same group of implants. The ICC between operators was calculated and found to be good to excellent for all bone types when implant stability was assessed with the Periotest™ device on the mid-abutment site. Interestingly, the ICC was better for D2 and D3 bone (ICC = .922, $p < .001$, ICC = .938, $p < .001$, respectively), than for D1 and D4 bone (ICC = .814 $p < .001$, ICC = .776, $p < .001$, respectively).

Regarding the better ICC for D2 bone compared to D1 bone, it is of note that the Periotest™ device was originally designed to assess tooth mobility and the damping capacity of the periodontium, and was therefore designed to work with some flexibility in the apparatus being assessed owing to the presence of the periodontal ligament and physiological tooth mobility (Lukas and Schulte, 1990). D1 bone is composed of a thick plate of cortical bone with little trabecular, while D2 bone is composed of a dense

trabecular structure with a moderate cortical plate (Lekholm, 1985). Hsu et al. (2013) demonstrated that the PTVs recorded for foam blocks of the same elastic modulus was influenced by increasing the thickness of the cortical plate, where the thicker cortical plate gave a lower PTV indicating increased implant stability. Therefore, it makes sense that the inter-operator results were more reliable when using the Periotest™ device in D2 bone compared to D1 bone. Interestingly, Naughton et al. (2023) demonstrated excellent ICC values between operator 1 and operator 2 in D1 and D2 bone (D1 ICC = 0.944, D2 ICC = 0.983) with the figure recorded for D2 bone being marginally better.

In D4 bone, the Periotest™ device demonstrated good ICC values between operators (D4 ICC = 0.776, $p < .001$). Therefore, implant stability assessed in D4 bone shows good inter-operator reliability and reproducibility, indicating that the Periotest™ device functions well in D4 bone density. This is in stark contrast to the results of Naughton et al. (2023) where an extremely poor inter-operator ICC of 0.039 was found when implant stability was assessed in D4 bone using the Osstell® device. Lack of cortical bone in the D4 bone might explain the finding. Similar findings were previously reported by Hsu et al. (2013) where the ITV and PTV were found to be more accurate than the ISQ values when assessing implant stability in osteoporotic bone. Where the Osstell® device was designed to “analyse the first resonance frequency of a small transducer attached to an implant fixture or abutment” (Sennerby and Meredith, 2008) and would therefore expect a higher degree of stiffness in the implant-bone complex. The poor inter-operator ICC reported by Naughton et al. (2023) for D4 bone indicates a poor reliability and reproducibility for the Osstell® device in D4 bone density. Therefore, we could conclude

that the Periotest™ functions satisfactorily across high and low bone densities and the Osstell® device functions well in high bone densities but very poorly in low density bone.

The inter-examiner reliability is of more interest than the intra-examiner reliability as this investigation was carried out *in vitro* using a number of devices to standardise the measurements recorded. An articulated arm held the Periotest™ handpiece in position in relation to the implants. The bone block in which the implants were placed, was housed in a bench-top vice in order to eliminate macro-movement of the implants when implant stability was being tested. Similar lab conditions were created for the investigation carried out by Naughton et al. (2023), except that the Osstell® handpiece was hand-held to facilitate ease of accurate ISQ recording. These standardised conditions were created such that the implant stability measurements recorded were reliable and reproducible.

Assessment of the inter-examiner reliability allows assessment of the methods of standardisation for data-collection and, therefore, confidence in the results presented. Furthermore, the inter-examiner reliability assessment has highlighted the impact that the different devices and different bone densities have on the recording of implant stability. This is of high clinical value as it is likely that different operators will want to assess the implant stability in the various stages from implant placement to provision of the implant-retained prosthesis, and during subsequent annual maintenance visits.

In an *in vitro* study, Hsu et al. (2013) set out to determine the correlation between bone quantity and quality, and primary implant stability by measuring the ITV, ISQ and PTV of implants placed in synthetic bone samples. The bone blocks used in the study herein

were composed of separate synthetic cortical and trabecular specimens. Cortical thickness varied from 0-3mm, while the elastic moduli of the trabecular bone ranged from 6.5 MPa to 137 MPa. Each of the specimens were combined to create 20 different synthetic bone blocks (Hsu et al., 2013). Each type of block was created in triplicate. This design of bone block differed somewhat to that used to house the cohort of implants under investigation in this study and that of Naughton et al. (2023). Our synthetic bone blocks were made of resin polyurethane of uniform density that represented either D1, D2, D3 or D4 bone (BoneModels, Castellón de la Plana, Spain). Faulkner et al. (2001) demonstrated that the thickness, stiffness, and damping capacity of the supporting tissues influenced the contact time of the rod of the Periotest™ handpiece on the implant, as did the positioning of the rod. The authors concluded that the alveolar bone design and form therefore had a significant impact on the results of the Periotest™ device in assessing implant stability. Similarly, Lachmann et al. (2006a) used blocks of bovine bone for their *in vitro* investigation. The authors reported that one block was of class II bone density and the other was class III density according to the Lekholm and Zarb classification (1985). The implants were placed 7mm apart in the bone blocks, and the blocks were immobilised in a vice to facilitate accurate assessment of the implant stability. Lachmann et al. (2006a) reported that there was a statistically significant difference in the mean implant stability values obtained for the implants in the different bone blocks with both the Periotest™ ($p < .0008$) and Osstell® ($p < .0001$) devices. Furthermore, there was a statistically significant difference detected for implant stability values between individual adjacent implants in the softer bone blocks when assessed with RFA. The authors concluded that the condition of the bone was the only variable

that significantly affected the primary implant stability measurement in this study (Lachmann et al., 2006a).

An early finding in analysis of the results of this research, was the significant discrepancy between the PTVs recorded in D4 bone compared to all other bone densities. This was true for implant stability measurements recorded on the implant abutments and implant-retained temporary crowns. In this regard, the results of this investigation mimicked those of the study by Naughton et al. (2023) using the same implant and bone block cohort.

D4 bone is not commonly encountered by the implant surgeon. Truhlar et al. (1997b) found that that D4 bone was rarely encountered in the mandible, and was present in the maxilla in <20% of cases when placing over 4000 implants between 1996-1997. D4 bone has been associated with higher incidence of implant failure (8.06%) compared to implants placed in D1-D3 bone density (implant failure rates of 3.13% - 4.27%) (Chrcanovic et al., 2017). D4 bone as described by Lekholm and Zarb (1985) consists of low-density trabecular bone surrounded by a thin cortical plate. This leads to lower bone-implant-contact initially which can reduce the primary stability of the implant, placing the implant at risk of micromotion exceeding 150µm and therefore increased risk of failure (Mathieu et al., 2014, Pilliar et al., 1986). Surgeons commonly alter their osteotomy preparation when placing in D4 bone, typically by undersizing the osteotomy or by using osteotomes to enhance the primary stability (Cavallaro et al., 2009). In accordance with this, the implant osteotomies performed in the D4 bone blocks in this study were undersized. For the reasons listed above, it was deemed of interest in this

investigation to exclude the measurements recorded in D4 bone blocks and continue analysis using the implant stability measurements recorded in D1-D3 bone density only.

Exclusion of D4 bone from the analysis led to interesting results. Firstly, the distribution of the data now followed a gaussian curve. This was demonstrated in the Q-Q plots and by assessment with the Kolmogorov-Smirnov test. The normal distribution of the PTVs recorded at implant abutments and implant-retained temporary crowns when D4 bone was excluded, was similar to the previous results of Naughton et al. (2023) where the ISQ values also followed a normal distribution when D4 bone was excluded.

Previous works in the literature have demonstrated that implant design can have an impact on the primary stability achieved (Romanos et al., 2014, Toyoshima et al., 2015, Sakoh et al., 2006). Friberg et al. (2003) reported on the results of a one-year prospective multi-centre study comparing the primary and secondary stability that could be achieved with two different types of implants. Both implants were of 4mm diameter, and threaded, with machined surfaces. The control implant was a standard non-round Brånemark implant. Meanwhile, the test implant was a prototype Mk IV, Brånemark system® by Nobel Biocare. The Mk IV implant differed to the control implant in that it was circular, had a tapered neck, and a portion of the threads were also tapered. The authors reported higher implant stability for the test implants compared to the controls when assessed with resonance frequency analysis ($p = .004$). They also found that higher insertion torque was necessary for the test implant. However, when the secondary stability of the implants was assessed, comparable results were found for both implants. The 1-year outcomes were similar for the test (93.1%) and the control (88.4%) implants

assessed in this study. From this study, it can be seen that the implant dimensions can affect the primary stability achieved.

Many of the *in vitro* investigations to date have only assessed one type of implant. Lachmann et al. (2006a) used 3.8 x 13mm Frialit Synchro screws (Friadent GmbH, Mannheim, Germany) in their investigation, while Hsu et al. (2013) used a 3.75mm x 13mm self-taping implant (ICE, 3i Implant Innovation, Palm Beach, Florida, USA). Bilhan et al. (2015) used 30 3.8 x 13mm implants from Trias Implant System (Servo-Dental GmbH & Co., Hagen, Germany). The advantage of using the same implants is to maintain a standard test condition (Bilhan et al. 2015). Where variables such as the implant type and bone density are standardised, the accuracy of the Periotest™ device can be more readily assessed.

In this study, variations in the implant stability achieved for the different types of implants were analysed using a one-way ANOVA. No variation in PTVs was detected when the implants were analysed with all types of bone density included. This is in line with the findings of Naughton et al. (2023) who did not detect any differences in implant stability based on implant type when assessing this cohort of implants with the Osstell® device.

However, when the implant stability measurements recorded on implants in D4 bone were excluded from the analysis, significant differences were detected for the implant stability measurements obtained for different implants with both the Periotest™ and Osstell® devices ($p < .001$).

Where our study aimed to assess the reliability of the Periotest™ device, we used different implant systems to see if their anatomical and connection differences would significantly affect the correlations between the ISQ and the PTV measurements as well as between the PTV's taken on crowns and abutments. No significant effects were detected. This is an important finding as nowadays, hundreds of different implant systems are in circulation. As a result, it is important for clinicians to know that the instrument they use measures what was designed to measure regardless of the type of implant examined.

Limitations of this study include the inability to include both implant type and bone as moderators when assessing the relationship between PTVs and ISQ values, and mid-abutment to mid-crown PTVs. This is possibly due to insufficient power.

Another limitation was the inclusion of only 2 operators. Although a calibrated torque wrench was used to torque each implant abutment and crown to 5 N cm, inclusion of more operators would allow better assessment of the reliability of the device.

A 6mm healing abutment was chosen to facilitate implant stability to be measured at different heights with the Periotest™ device, while the crowns were of approximately 12mm height. Differences in the height will have had an impact on the PTVs recorded for the crowns compared the abutments (Chai et al., 1993, Haas et al., 1995). However, discrepancies between the height, width and shape of both abutments and crowns are common in clinical practice, and impossible to standardise.

5. Conclusion:

Within the limitations of this study, it seems that the Periotest™ device can reliably measure the implant stability across all types of bone when the implant stability is assessed at about 3mm coronal to the implant platform for abutments and 4.5mm for implant supported single crowns.

Implant stability measurement appear to be more reliable when measured at healing abutments than at implant supported single crowns.

Clinicians should take PTV measurements both with the abutment and the crown at baseline. This way, they have a reference PTV number for comparison in the future review appointments. In cases where crown removal can become problematic, the difference of 6 PTVs in the relationship between the implant abutments and implant crowns can act as a guide for clinicians in the longitudinal follow up of their implants.

Finally, it seems that the anatomy of the implant and the nature of their connection, doesn't affect the reliability of the Periotest™ measurements.

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