Clinical Assessment of Primary Implant Stability Parameters Using

a Stereolithographic Surgical Guide

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THESIS
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LIST OF ABBREVIATIONS

$BaSO_4$	Barium Sulfate
BIC	Bone-implant Contact
BMD	Bone Mineral Density
CAD	Computer Aided Design
CAM	Computer Aided Manufacturing
CSR	Cumulative Survival Rate
CT	Computed Tomography
DICOM	Digital Imaging and Communications File in Medicine
EIL	Effective Implant Length
HU	Hounsfield Units
ISQ	Implant Stability Quotient
ITV	Insertion Torque Value
Ncm	Newton-centimeters
PTV	Periotest Value
RCT	Randomized Control Trials
RF	Resonance Frequency
RFA	Resonance Frequency Analysis
SLA	Stereolithographic

SUMMARY

Purpose: The objective of this investigation was to determine if there was a correlation between the circumferential mean bone density calculated quantified using computed tomography (CT), maximum applied insertion torque value, and the implant stability quotient (ISQ).

Materials and Methods: Medical grade CT was utilized in conjunction with rapid prototyping to fabricate a stereolithographic (SLA) surgical guide. Nineteen self-tapping dental implants (OsseospeedTX TX™) with a length ≥ 11mm were placed in eight patients using a SLA surgical guide, either tooth-mucosa supported or bone-supported. The circumferential mean bone density was quantified pre-operatively using CT in Hounsfield (HU) units using Facilitate™ computer-guided implant software. The maximum applied insertion torque value was recorded using a W&H ImplantMed™. Primary stability was quantified in ISQ values with the wireless Ostell™ Mentor instrument using resonance frequency analysis (RFA) at the time of dental implant placement. Three measurements were taken from the buccal and lingual for a total of six measurements for each dental implant using RFA. The Pearson correlation coefficient was implemented to determine the presence of positive correlations between the parameters of circumferential mean bone density calculated using CT; the mean bone densities calculated using CT at the coronal, midcrestal, apical regions; maximum applied insertion torque value, and the implant stability quotient (ISQ). The linear regressions for the Pearson correlation coefficient were converted to p-values using biostatistics software (Systat™ software 13;Systat Software, Inc., Chicago, IL). A positive correlation amongst the parameters was reported when p-value < 0.05.

Results: There was a positive correlation found between the circumferential mean bone density and the maximum applied insertion torque values for all implants ($r = 0.862$, $p < 0.001$). No correlation was found between circumferential mean bone densities and the mean ISQ values ($r =$

0.275, $p > 0.05$). No correlation was found between the measurements of mean ISQ values and the maximum applied insertion torque values ($r = 0.056$, $p > 0.05$).

Conclusion: The mean maximum applied insertion torque value of 33.2 Ncm for all dental implants was correlated with the circumferential mean bone densities calculated using CT pre-operatively. Since no correlation was found between circumferential mean bone density and the mean ISQ vales or between maximum applied insertion torque and the ISQ values. It seems rationale to conclude that the high mean ISQ value of 72 ± 2.80 for all dental implants was a result of the surgical approach implemented using computer-guided implant software to maximize the length of a potential implant site to $\geq$ 11mm.

I. INTRODUCTION

A. Overview

The osseointegration process for dental implants described by Per-Ingvar Brånemark and colleagues has been one of the most significant contributions to modern dentistry. Dental implants are routinely used for the rehabilitation of lost teeth in patients presenting with complete and partial edentulism. The success of the osseointegration process associated with endosseous dental implants and implant-supported prostheses is based on scientific data. Today, the focus of dental implant rehabilitation has shifted to surface nanoscale technology, esthetics, and immediate/early loading protocols.

The dynamics of implant-supported restorations has changed rapidly with the advent of computed tomography and computer-aided design/computer-aided manufacturing (CAD/CAM). Computer-guided implant software has been incorporated into the treatment planning process to enhance esthetics, develop proper occlusal loading schemes for implant-supported prostheses, enhance primary stability, and decrease the healing period for an implant-supported prosthesis. This thesis evaluates the use of computer-guided implant therapy and the methods used to determine primary implant stability.

B. Specific Aims

The primary stability of a dental implant at the time of placement and the healing process associated with the osseointegration process are two important aspects effecting the survival of implant-supported prostheses. A quantifiable means of assessing the primary stability of a dental implant at the time of initial placement is crucial for early and immediate loading procedures.

The purpose of this study is to determine if there is a correlation between the circumferential mean bone density calculated using computed tomography (CT), the implant

stability quotient (ISQ) using resonance frequency analysis (RFA), and the maximum applied insertion torque value. This investigation implemented a specific protocol to determine if RFA and insertion torque value (ITV) are valid means of assessing primary implant stability at the time of dental implant placement.

Another aspect of this prospective clinical study is to determine if there is a correlation between the mean bone density calculated in Hounsfield (HU) units using CT at three different regions of the implant fixture (coronal, midcrestal, and apical region) with the primary implant stability parameters of maximum applied insertion torque value and ISQ. All mean bone densities were quantified pre-operatively using computer-guided implant software and compared to the primary implant stability parameters. The stability parameters of maximum applied insertion torque value and ISQ were collected immediately following the placement of all dental implants included in this investigation. The data collected for the mean bone densities, maximum applied insertion torque, and ISQ was organized into the four anatomical regions (anterior mandible, anterior maxilla, posterior mandible, and posterior maxilla). The purpose of this study was to determine if there was a correlation between the mean bone densities quantified using CT and the primary implant stability parameters.

C. Hypotheses

1. A positive correlation exists between the circumferential mean bone density quantified using CT and the implant stability quotient (ISQ).

2. A positive correlation exists between the circumferential mean bone density quantified using CT and the maximum applied insertion torque value.

3. A positive correlation exists between maximum applied insertion torque value and the ISQ value.

4. A positive correlation exists between the mean bone densities quantified using CT at the different regions of the dental implant (crestal, midcrestal, and apical) and the ISQ value.

5. A positive correlation exists between the mean bone densities calculated using CT at different regions of the dental implant and the maximum applied insertion torque value.

6. A positive correlation exists between the anatomical region of dental implant placement and the circumferential mean bone density quantified using CT.

D. **Clinical Significance**

The ability to quantify the bone density of a potential dental implant site using CT pre-operatively allows the clinician to select potential implant positions in a prosthetic driven manner based on bone quality and bone quantity using computer-guided implant software. The quantification of primary stability for a dental implant using maximum applied insertion torque value and ISQ value as a means of assessment allows the clinician to determine whether to implement immediate or early loading protocols. A positive correlation between the pre-calculated circumferential bone density calculated using CT and the primary stability parameters of insertion torque and the ISQ could give the clinician predictable insight into the primary stability of a potential dental implant site prior to surgical placement. Implementation of computer-guided implant software for surgical placement of a dental implant can provide preoperative information that could be used to determine if immediate loading protocols are feasible through the critical selection of potential implant sites with high bone density which may result in greater insertion torque or higher ISQ values dependent on the surgical technique implemented.

II. REVIEW OF THE LITERATURE

A. Osseointegration

1. Overview

The concept of osseointegration is based on research that began in 1952 with microscopic studies of a titanium chamber placed into a rabbit's fibula. Upon retrieval a rigid connection between the titanium surface and bone was discovered (1). This phenomenon was termed 'osseointegration' and the original definition was based on the microscopic findings that Brånemark defined as "a direct structural and functional connection between ordered, living bone and the surface of a load-carrying implant" (1). Albrektsson et al further clarified the osseointegration process as the direct contact between a loaded implant surface and bone at the light microscopic level free of interposed fibrous tissue at bone-implant interface (2). This term has also been defined from a clinical standpoint as "a process whereby clinically asymptomatic rigid fixation of alloplastic materials is achieved and maintained in bone during functional loading" (3).

Albrektsson et al. (2,4) suggested that successful osseointegration is dependent on the inter-relationship of various parameters including: material biocompatibility, proper dental implant design (macrostructure) & implant surface (microstructure) (5-7), good health of implant bed & good bone quality, atraumatic surgical technique (8), an undisturbed healing phase, and proper long-term prosthetic loading techniques to achieve esthetic success (9-11). Albrektsson and Zarb, et al. (4) suggested the following criteria for successful osseointegration for machine turned dental implants: the implant is not mobile when tested clinically, there is no evidence of peri-implant radiolucency around the implant fixture, the vertical bone loss is $\leq$ 1.5mm after the first year and less than 0.2 mm following the implant's first year of service, and there are no

signs of paresthesia, no pain, no suppuration, no mobility or ongoing infection. Lastly, a successful dental implant meets the above criteria listed above by 85% at the end of a 5 year observation period and an 80% at the end of a 10 year observation period (4).

2. Bone Healing, the Osseointegration Process, and the Implant Surface

Titanium is an excellent biocompatible material that rarely causes foreign body reactions (12). The preparation of an osteotomy and insertion of a dental implant initiates a sequence of healing events comprised of three periods: healing period (implant insertion to 12 months), remodeling period (3 to 12 months), and a dynamic equilibrium period (13). The pitches of a threaded dental implant after placement have close contact with the surrounding bone; the mechanical stability achieved by the macro-retentions of the implant thread will be replaced by the direct bonding of newly formed woven bone onto the surface (14). This starts with hematoma formation in the cavities found between the pitches of the dental implant as early as the first week after implant placement and continues for the first three months of the healing period (14).

The bone formation seen at the bone-implant interface has been organized into the following cascade of cellular events: clot formation, recruitment-attachment-proliferation-differentiation of osteoblastic cells, mineralization of a collagen-rich matrix called woven bone, transformation of woven bone to lamellar bone, and bone remodeling after loading of implant-supported prosthesis (15). Davies et al. organized the cascade of cellular events associated with osseointegration at the bone-implant interface into the following three phases: osteoconduction, de novo bone formation, and bone remodeling (16-19). Following placement of a dental implant a series of bone remodeling steps take place, the integration of an implant is characterized by a series of biological reactions that start with bone turnover at the implant-bone interface (a

process of localized necrosis) followed by rapid repair (20). Following placement, the surrounding bone undergoes initial necrosis followed by bone resorption and replacement, initially with a woven-like cell rich bone that is replaced through remodeling with mature haversian bone (20-23).

Osteoconduction acts as a scaffold or matrix (i.e. hydroxyapatite coatings) that provides a proper environment for direct bone formation by bone forming osteoblasts (19,24). Osteoinduction refers to the properties of a material that induce the recruitment and differentiation of undifferentiated mesenchymal cells into bone forming osteoblasts (i.e. bone morphogenic proteins) (19,24). Osteogenesis refers to the stimulation of osteoprogenitor cell proliferation and encouragement of osteoblast biosynthetic activity (15). Two different phenomena are associated with osteogenesis were described by Osborn and Newesley termed distance osteogenesis and contact osteogenesis. (25). In distance osteogenesis, new bone is formed on old bone present at the bone-implant interface (18,19,25,26). In contact osteogenesis, new bone forms first on the implant surface and is dependent on the migration of differentiating osteogenic cells to the implant surface (18,19,25,26).

Undifferentiated mesenchymal cells migrate to the surface of a dental implant, attach, differentiate, and proliferate (18,19,26). The cellular physiology of an osteoblast can be targeted to improve bone formation at the implant surface by controlling osteoblastic recruitment, osteoblast attachment, osteoblast proliferation and osteoblast differentiation (15). *In vitro* studies, have demonstrated that the surface topography of 'moderately rough' dental implants enhance the cellular activities of undifferentiated mesenchymal cells such as proliferation, differentiation, and bone formation by osteoblasts (27-32,37-40). Almost all modern dental implants have a surface topography that is 'moderately rough', the original Brånemark implant

was a machine turned screw with a 'minimal roughness' surface (33,34). The surface roughness of a dental implant has been defined using the Sa value, defined as the average roughness of the dental implant surface. The following is a classification for the surface roughness of a dental implant: 'smooth' surface has a Sa value < 0.5μm, 'minimally rough' surface has a Sa value equal to 0.5 – 1.0μm, 'moderately rough' surface has a Sa value equal to 1.0 to 2.0μm, and 'rough' surface has a Sa value > 2.0μm (35,36). *In vitro* studies, indicate that 'moderately rough' surface implants with a Sa value of about 1.5 μm and an Sdr of about 50% show stronger bone responses than all other surfaces (27,37-40). The developed surface ratio (Sdr) is a measurement that provides information regarding surface enlargement if the surface were to be flattened out, taking into consideration the number and the height of peaks of a given surface (35,36,40).

Recent developments in the nano-scale surface topographies of dental implants have focused on improving the bone healing response through surface modification of the oxide surface, precise nano-scale technologies to alter the cellular response to promote active biologics (21). An important biological principal of bone is that it responds favorably to compressive loading but not shear forces, thus screw thread implant designs have been adapted to achieve compressive loading of the surrounding bone (21,41). Current strategies used to modify the surface of a dental implant include: an attempt to enhance the in-migration of new bone cells or osteoconduction through changes in the surface topography (i.e. surface roughness) (37-40), modifications to alter the biological response to manipulate the type of cells that grow onto the surface (15,21), and the utilization of the dental implant as a vehicle for the delivery of bioactive technology (i.e. adhesion matrix or growth factor such as BMP-2) (42,43) .

Other surface modifications have focused on platelets which release growth factors (i.e. PDGF, TGF-Beta, PDEGR, IGF-1) that accelerate the wound healing process through the

recruitment and differentiation of mesenchymal cells critical to establishing bone formation at the implant-bone interface (44). Titanium surfaces that were modified through a controlled etching process have been show to alter whole blood derived platelet adhesion and generated thrombin-antithrombin complexes (45). Platelet adhesion and activation was compared on machined versus blasted/etched titanium surfaces, the smoother machined surfaces demonstrated higher adhesion of platelets but reduced activation while the rougher surfaces demonstrated reduced platelet adhesion but near 100% platelet degranulation (46).

Various studies have focused on surface roughness through various means of grit blasting followed by surface etching or coating procedures (21). This has included titanium plasma spray (47), abrasion (TiO_2 blasting or soluble abrasives) combinations of blasting and etching (i.e. Al_2O_3 with H_2SO_4/HCL) (47), thin hydroxyapatite coating (48), and sintered beading (49). Roughened surfaces using large grit blasted and acid etched surfaces have laboratory and clinical evidence of elevated cumulative success rates in the posterior maxilla where low bone quality has been identified (50-52). *In vitro* studies using mesenchymal cell culture models demonstrated a rapid increase in expression of key genes involved in the differentiation of bone unique to fluoride modified and etched titanium surfaces, this was not evident on blasted surfaces alone or a comparison group of large grit/dual acid etched surfaces (53,54). A follow-up study, demonstrated that the same titanium surfaces also increased the expression of bone forming cell adhesion leading to an increase in the expression of bone sialoprotein, osteopontin, and other bone-specific proteins critical to the acceleration for bone adaptation to the implant surface (55).

3. Timing of Implant Loading

To minimize the risk of fibrous tissue encapsulation of a dental implant and infection, the original loading protocol proposed by Brånemark was a two-stage protocol with a healing period of 3 to 4 months in the mandible and 6 to 8 months in the maxilla prior to loading with a definitive prosthesis (4,56,57). The terminology for the timing of dental implant loading protocols (i.e. immediate, delayed/early, and conventional) varied among several consensus conferences reports (58-62). Numerous studies report long-term cumulative survival rates with high success rates using conventional loading protocols (63-65). A study by Schmitt et al. reported predictable success rates using conventional loading techniques for implant-supported single crown replacement (66). Similar studies by Zarb et al. reported high success rates for implant-supported fixed partial dentures in the anterior and posterior regions of the maxilla and mandible arches (67,68). In 2002, the McGill Consensus reported that mandibular two-implant overdentures using conventional loading protocols as the first choice of care for edentulous patients based on randomized controlled trials with conventional denture patients (69).

The first longitudinal clinical investigation on immediate loading was reported by Schnitman et al, the study reported an immediate fixed implant-supported cross arch provisional prostheses loading protocol for the edentulous mandible using machine milled dental implants (70,71). The study reported a 10-year cumulative success rate (CSR) of 93.4% for 28 implants placed into immediate function and 35 submerged dental implants, no implants submerged after placement were lost for a CSR of 100%, and four implants placed into immediate function were lost over a 10-year time span for a CSR of 84.7% (70,71). A study by Tarnow et al. reported on 10 edentulous arches (6 mandible and 4 maxilla) using 106 implants concluding that the delivery of a fixed provisional immediate prosthesis rigidly splinted around a completely edentulous arch is a viable treatment modality (72). High cumulative success rates have been reported for

immediate implant retained mandibular overdentures (73). High cumulative implant survival rates have been reported for immediate loading protocols using fixed interim prosthesis for fixed implant-supported complete dentures in the mandibular arch (70,71,74-76).

A systematic review published by the Cochrane Collaboration (Esposito el al.), reported treatment outcomes of immediately or early loaded implants versus conventionally loaded implants using 22 randomized control trials (RCTs) having a follow up of 4 months to 1 year (58). The systematic review showed that there were no statistically significant differences between the loading regimens for any of the meta-analyses which included prostheses failures, implant failures, and marginal bone level changes (58). The authors of the systematic review had the following conclusions: it is possible to successfully load implants immediately or early after implant placement in selected patients but not all clinicians may be able to achieve optimal results, the risk of failure for immediately loaded implants seemed to be higher than those conventionally loaded but less common than early loaded implants, and a high degree of primary implant stability (insertion torque value) seems to be one of the prerequisites for successful immediate/early loading protocols (58).

B. **Means of Assessing Osseointegration**

1. **Invasive Methods**

The degree of osseointegration of an implant fixture has been evaluated using histologic and histomorphometric techniques (77-81). Histological ground sections are typically used in conjunction with light microscopy in these methodologies and are considered to be a true means of quantifying the bone to implant contact (BIC) percentage (77-81). These techniques require meticulous specimen preparation, render a few sections per implant via ground-sectioning, and are a destructive means of measuring implant stability (82). Due to a limited number of sections

obtained via histomorphometric techniques, an accurate overview of the overall osseointegration process of the entire implant specimen may not be obtainable (83).

Removal torque analysis is another method of evaluating the osseointegration process by slowly increasing a force to disrupt the implant-bone interface (81,84-87). Removal torque analysis is a measurement of the interfacial shear strength present at the bone-implant interface and is dependent on the implant fixture morphology and surface topography (78,87). This method utilizes either a manual torque instrument called a tohnichi torque gauge or a more accurate electronically controlled loading device to apply a counter-clockwise (reverse) torque (81,84). A correlation has been found between the bone-implant contact measured from histomorphometric analysis and removal torque measurement. This correlation states that an increase in the bone-implant contact percentage is directly related to an increase in removal torque values (81,84-87).

2. **Non-invasive Methods**

Traditional radiographic techniques are often used in comprehensive dental implant therapy during the treatment planning phase to evaluate the osseointegration process and confirm the accuracy of the abutment-implant connection (82). Radiographic analysis is a valuable tool for the clinician to detect peri-implant radiolucencies and marginal bone loss around an implant fixture using the implant threads as a dimensional reference (82). It has been reported that 1.5mm of radiographic crestal bone loss can be expected in the first year following loading with 0.1 mm subsequent annual bone loss with machine turned dental implants with a minimally rough surface (4). Radiographic monitoring of the marginal bone loss around a dental implant overtime cannot be standardized without the construction of a custom radiographic film holding device but its construction can be time consuming (88). A study to evaluate the accuracy and

precision of dental radiographs to determine the clinical instability of dental implants concluded that implant instability from radiographic examination was low in populations with low prevalence of implant instability (89). A simple noninvasive method to assess implant stability is the percussion or tapping test which may involve the tapping of a mirror handle against the implant carrier (82,90). This test is designed to elicit a ringing sound from the implant an indication of good stability or osseointegration (82,90).

The Periotest ™ (Siemens, Bensheim, Germany) is a noninvasive and objective diagnostic method to detect the subclinical mobility at the bone-implant interface or to check the clinical mobility of a tooth (82,91,92). The Periotest™ is an electric instrument designed to perform quantitative measurements of the damping effect at the tissue-implant interface and assigns a value based on the biomechanical characteristics at this interface (82,91,92). The instrument contains an electronically controlled rod inside a handpiece that hits the tooth or implant-abutment surface four times per second to achieve 16 defined and reproducible impacts (93). The rod deceleration after the impact is recorded by an accelerometer and analyzed as deceleration time to produce a numeric value known as Periotest™ values (PTV) (93). The greater the damping effect at the bone-implant interface the faster the deceleration and the greater the negativity of the PTV value (93,94). The PTV values are displayed visually and audibly ranging from -8 to +50, the lower the PTV the greater is the stability of the implant (94). PTV for good osseointegration for implants falls into a relatively narrow zone of -8 to 0, this may falsely be interpreted as having a small standard deviation or good accuracy (91,92,94). A dental implant with a PTV of +10 to +50 should not be loaded and is an indicator of insufficient osseointegration (91,92,94).

A high degree of interexaminer reliability and repeatability has been demonstrated when the Periotest™ was used to determine implant stability *in vitro* and *in vivo* (95-97). Clinical studies using various implant fixtures have demonstrated lower PTVs for the mandibular region and higher PTVs for the maxillary region (92,93,98). Osseointegrated implants with cortical bone contact at the apical and coronal position exhibited significantly lower PTVs compared with those without cortical contact (99). Studies have shown that longer abutments produce greater PTVs due to the leverage effect during the measurements, follow-up measurements should always involve the same abutment length and level of impact if values are to be compared (91,92,98,99). The accuracy of the Periotest to measure implant stability can be affected by the vertical position at which the handpiece strikes the abutment in relationship to the crestal bone level, the angulation of the handpiece, and the duration of contact time between the handpiece and abutment (82,100,101).

3. **Resonance Frequency Analysis**

Resonance frequency (RF) has been used in orthopedics to identify the *in vivo* vibration modes of early fracture healing in the human tibiae and make a quantitative assessment of the fracture healing in long bones to determine the torsional stiffness of long bones (102-105). In 1996, Meredith et al. described a noninvasive method for using RF to make quantitative measurements of the stability of a dental implant at the tissue-implant interface (106). This *in vitro* study, modeled the change of stiffness observed in the bone surrounding an implant during the healing process using a self-curing polymethylmethacrylate and measuring the RF at different periods during the polymerization process (106). The technique originally proposed by Meredith et al., used an L-shaped transducer directly attached to the implant fixture or its abutment in rabbit tibia (106,107). The transducer was excited over a range of frequency

ranging from 5 to 15 kHz with a peak amplitude of 1 V from a hand held probe (82). A frequency response analyzer calculates the response of the frequency beam transmitted from the hand held probe, the RF of the transducer/implant system is calculated from the peak amplitude of the signal (82). The RF technique is a bending test of the implant-bone complex where a transducer applies an extremely small bending force to mimic the clinical loading condition; the RF is determined by the stiffness of the bone-implant interface and by the distance from the transducer to the first bone-implant contact (90). The literature on resonance frequency published prior to 2003 (106-117) is difficult to compare with recent studies due to several factors including: early studies on resonance frequency used prototype instruments with different types of transducers, each transducer had its own unique resonance frequency, different transducers had to be calibrated using a standard before measurements were comparable, and early studies reported findings in Hz not the implant stability quotient making conversion/comparison difficult (90,108).

First and second generation resonance frequency analysis (RFA) systems were used in early studies, the first commercial system for RFA system was Ostell™ (Integration Diagnostics, Sävedalen, Sweden), consisting of L-shaped transducers that were pre-calibrated from the manufacturer (90). This RFA system calculates resonance frequency with the implant stability quotient (ISQ) not the measurement unit of Hertz. The ISQ value is based on a numerical scale used to quantify the stability of an implant using the RFA technique, it is an algorithm derived assessment of the damping effect of the harmonic frequency relative to the type of implant or abutment in which it is connected (90). The ISQ value is a numerical measurement ranging from 1 to 100 that quantifies the stiffness or stability at the bone-implant interface, a high value indicates greater stability whereas a low value indicates instability (90). The third generation

RFA instrument has been modified to a wireless system called the Ostell Mentor™ (Integration Diagnostics, Sävedalen, Sweden), this device substitutes the L-shaped transducer with an aluminum SmartPeg™ (Integration Diagnostics, Sävedalen, Sweden) attached to the implant that is excited by signals from a contact-free probe and has computer software available to organize data collection.

A linear relationship was found between effective implant length (EIL) and the level of resonance frequency with a correlation coefficient of r = -0.94 *in vitro* and r = -0.78 *in vivo*, indicating that marginal bone loss and abutment height influences resonance frequency (82,106). EIL was defined as the amount of exposed implant threads plus the length of each abutment within an aluminum block (82,106). Other studies have concurred with this finding (107,110,111,113,118,). Meredith et al. concluded that the following factors influence primary stability and RFA: the stiffness of the implant components (length, diameter, composition, tightness of components when joined together), the stiffness of the implant-tissue interface which is dependent on the bond between the surface of the implant and surrounding bone, and the stiffness of the bone determined by the ratio of cancellous to cortical bone or bone density (82,106). Atsumi et al. reported the factors that influence RFA include: primary stability, secondary stability, constants (implant length, implant diameter, implant geometry/implant system, implant surface characteristics, placement position, abutment length), and variables (bone quality, bone quantity, damping effect of marginal mucosa, bone-implant contact, EIL, connection of transducer) (119).

A positive correlation has been reported for insertion torque and RF measurements at the time of placement (112,120,121). The Ostell™ technique has demonstrated higher implant stability values in mandibular bone than maxillary bone (122-127). In an *in vitro* study of human

bone, reported positive correlations for resonance frequency analysis, insertion torque, and bone density calculated using computed tomography (128). Primary stability evaluated using RFA in maxillary implants showed higher stability in male patients than in female patients (129).

Studies have concluded that dental implants placed in soft, medium, and dense bone show a slight decrease in stability probably as a result of bone remodeling but reach similar resonance frequency values after 1 year of loading irrespective of initial stability at the time of placement (109,112,116,124,130-133). Immediately loaded implants have demonstrated an initial decrease of implant stability using RFA during the first 3 months followed by an increase in implant stability (112,124,134-136). The initial decrease or drop in ISQ values following initial placement is most likely related to the healing response, resulting in a decreased stiffness at the bone-implant interface due to early bone resorption and extensive bone remodeling adjacent to the implant fixture (79,112,135). Implementation of an immediate loading protocol using RFA showed a decrease in implant stability for machined implants versus oxidized implants during the first 3 months after loading (137).

The prognostic value of using RFA in predicting the loss of implant stability was confirmed in a study by Fridberg et al. using 75 one-stage implants in the edentulous mandible (113). One implant showed a decreasing stability from 2 to 15 weeks and was found to be clinically mobile at the end of this period. Another patient within the same study presented with three of five implants with a marked decrease in stability from 2 to 6 weeks when the implants were loaded with a relined denture. Unloading of these implants subsequently resulted in the implant stability to increase for two implants and the implant stability was maintained at the same level for one implant (113). In another study by Friberg et al., nine patients with 56 implants in the maxilla showed an increase in implant stability from the time of placement to

abutment connection for all but two failing implants (112). The results seem to indicate that RFA can identify the loss of implant stability over time and identify an increase of stiffness at the implant-bone interface over time. Huang et al. reported that resonance frequency can be used for an early diagnosis of primary stability and provide useful information regarding the secondary stability of the implant (138).

RFA may be useful tool for assessing immediate loading protocols for dental implants and during various stages of comprehensive dental implant therapy. In a retrospective longitudinal study on immediate loading by Glauser et al. RFA was performed on 81 implants from the time of placement to 1 year in function (135). All implants showed a high degree of initial stability (ISQ = 70) but the failed implant showed a continuous decrease in implant stability. A total of nine implants failed during the 1 year observation period, these implants showed a continuous decrease in ISQ values until clinical failure was evident (mean ISQ = 52). This study concluded that the lower the ISQ value after 1 month of immediate loading the higher the risk for future failure, ISQ values of 49 to 58 were associated with an 18.2% risk of failure (135). In a study by Sjöström et al. using RFA to determine implant stability in grafted maxillae, reported lower primary stability for 17 implants (ISQ = 54.6) that failed during the first year of function compared with 195 implants (ISQ = 62.0) that were successful (133). Östman et al. reported low failure rates when using ISQ value of 60 as the inclusion criteria for immediate loaded implants in the totally edentulous maxillae and posterior mandibles (139,140).

Low or decreasing RFA values can identify failing implants prior to complete loss and determine whether or not an implant is at risk for complications but the exact resonance frequency analysis threshold values have yet to be identified (90,135). ISQ values ranging from 60 to 65 indicate good primary stability and may be suitable for immediate loading procedures

while ISQ values below 40 may be more prone to failure or indicative of an ongoing failure (90). Implant stability above 65 ISQ should be regarded as optimal, whereas ISQ values of 50 to 60 are seen in softer bone, ISQ values of 60 to 80 have been correlated with denser bone, and an ISQ value below 45 should be seen as a warning sign to take measures to increase implant stability (141). Balleri et al. concluded that ISQ values for successful osseointegration range from 57 to 82 with an average of 69 ISQ after one year of loading (122). An unloaded period of 6 weeks or longer for an implant that shows signs of risk or failure using RFA to assess implant stability may give the implant sufficient time to regain stability (90).

C. **Bone Density**

1. **Overview**

The two most important predictors for successful osseointegration of a dental implant which affect the surgical technique utilized, healing time, and loading protocols are bone quantity and bone quality (90,108,125,126,138,142-150). It is important to note that bone density is a component of bone quality, other contributing factors of bone quality include: bone metabolism, cell turn over, mineralization, maturation, intercellular matrix, and vascularity (136). The distribution of bone quality in patients receiving 2,839 endosseous dental implants was reported to be the densest in the anterior mandible, followed by the posterior mandible, anterior maxilla, and posterior maxilla (151). Two studies report a slightly different distribution of bone density quantified using computed tomography (CT) to be the densest in the anterior mandible, followed by the anterior maxilla, the posterior mandible, and posterior maxilla (152,153). Bone density is of great importance on primary stability and the long-term success of an implant-supported prosthesis, cumulative survival rates as high as 99% for a fixed prostheses followed over 12 to 15 years have been reported for the mandibular arch (154) and other studies

report high implant cumulative survival rates for implant-supported prostheses in the mandibular arch (155-157) . Several clinical studies report higher implant cumulative survival rates for implant-supported prostheses in the mandibular arch versus the maxillary arch (158-161). The highest failure rates for implant-supported prostheses have been reported in the posterior region of the maxilla, this region has low bone quantity and the poorest bone quality/bone density (144-147,162,163).

2. **Classifications**

An accurate analysis of the bony architecture for a potential implant site is a fundamental prerequisite prior to the surgical placement of a dental implant and several classification systems have been introduced to evaluate the available bone present. The first classification system for bone density was introduced by Linkow in 1970 (164). This classification was divided into three categories: 'Class I' bone is ideal bone for implant procedures and consists of spaced trabeculae with small cancellous spaces, 'Class II' bone has slightly larger cancellous spaces with less uniformity of the osseous pattern than Class I bone but is still satisfactory for implantation, and 'Class III' is the least desirable for all endosseous implant procedures, has large marrow-filled spaces between bone trabeculae, and results in loose fitting implants (164). Linkow stated that on the basis of vascular-connective tissue bone can be divided into three main varieties: compact, coarse cancellous, and fine cancellous; the adult human is characterized by compact and coarse cancellous bone composed mostly of lamellar bone and a human fetus is characterized by fine cancellous bone (164).

In 1985, the most widely accepted pre-assessment of bone quality was introduced by Lekholm and Zarb. This classification is based on the amount of cortical versus trabecular bone viewed radiographically (142). Type 1 bone is "almost the entire jaw is comprised of

homogenous bone", Type 2 bone is "a thick layer of cortical bone surrounds a core of dense trabecular bone", Type 3 is "a thin layer or cortical bone surrounds a core of dense trabecular bone of favorable strength", and Type 4 is "a thin layer or cortical bone surrounds a core of low density trabecular bone" (142). In a study by Lindh et al, the accuracy of this classification system could not be verified by seven clinicians using mandibular specimens, concluding that this classification system is mainly based on personal experience and the opinion of the clinician which might be subjective (165).

In a multi-center study by Truhlar et al., the Lekholm and Zarb classification was modified to include tactile sensation during drilling (151). This study of 2,839 endosseous implants concluded that the bone quality for Types 1 and 4 occur less often than Types 2 and 3, Type 2 bone predominates in the mandible, and Type 3 bone is more prevalent in the maxilla. The anterior region of the mandible had the densest bone followed by the posterior mandible, anterior maxilla, and posterior maxilla (151).

Another bone density classification proposed by Misch relates the clinical hardness of bone perceived during drilling with materials of different resistance. This classification describes D1 bone as dense cortical or 'oak or maple-like', D2 as porous cortical with coarse trabecular or 'spruce or white pine wood', D3 as porous cortical with fine trabecular or 'compressed balsa wood', and D4 as fine trabecular or 'styrofoam' (166). In a study by Trisi et al., the Misch classification which includes tactile sensation during drilling was correlated with the bone density quantified from histomorphometric analysis of human trephine core biopsies (167). They concluded that the D1 and D4 classes had the highest and lowest histomorphometric density or trabecular bone volume, respectively, while D2 and D3 presented with similar densities (167). This study demonstrated that tactile sensation can be utilized to distinguish

between D1 and D4 bone with statistically significant confidence but differentiation between D2 and D3 bone cannot be distinguished (167). Other methods for assessing bone quality have included densitometry (168), digital image analysis of microradiographs (83,169), and ultrasound (170).

Norton and Gamble applied computed tomography (CT) to determine an objective means for quantifying bone density pre-operatively by comparing CT bone density values to the Lekholm and Zarb classification system (152). This clinical study assessed 139 implant sites on 32 patients using Simplant™ software (Materialise Dental, Glen Burnie, MD, USA), the mean bone density for each implant site was measured using an 11 x 3.5 mm dimension. The results demonstrated an objective means for measuring CT bone density pre-operatively based on the Hounsfield scale (152). The Hounsfield scale ranges from -1500 to +4000 HU, within this range the density of air is equal to -1000 HU, the density of water at 25°C is equal to 0 HU, and cortical bone shows higher HU values compared to trabecular bone (152,171). This *in vivo* study calculated a mean bone density of 682 HU for 25 anterior mandible sites, 45 posterior mandible sites, 42 anterior maxillary sites, and 27 posterior maxillary sites (152). A strong correlation between bone density and the four regions of the mouth was reported, the anterior mandible had a mean bone density value of 970.0 HU > anterior maxilla, 696.1 HU > posterior mandible, 669.6 HU, and posterior maxilla, 417.3 HU (152).

In a study by Turkyilmaz et al., 131 endosseous implant sites were evaluated on 72 patients using CT to quantify the bone density in the designated implant sites (153). The recorded bone density values measured using CT showed a strong correlation between the four regions of the mouth similar to the results in Norton and Gamble study. The mean bone density for the 131 endosseous dental implants was 766.5 ± 265 HU which was higher than that reported

by Norton and Gamble (153). The mean bone density values were reported as follows: anterior mandible, 944.9 ± 207 HU > anterior maxilla, 715.8 ± 190 HU > posterior mandible, 674.3 ± 227 > posterior maxilla, 455.1 ± 122 HU (153). Comparing this study with the Norton and Gamble study, a significantly higher mean bone density for all implants and a lower mean bone density for the anterior mandibular region was obtained. This was attributed to the variations in age and gender of patients between the studies (152,153).

3. **Implant Stability**

Many authors agree that primary stability is important for the success and longevity of an osseointegrated dental implant (2,82,90,106,112). The lacks of micro-movement and primary stability are considered two factors necessary for the achievement successful osseointegration of an endosseous dental implant (2). A successful fully integrated dental implant has direct bone-implant contact but in the presence of micro-movement a soft tissue interface can encapsulate the dental implant leading to failure (172,173). A stress free healing period encourages a direct bone-implant interface, when occlusal loads are applied prematurely to an implant-retained prosthesis the primary stability can be jeopardized (172,173). Brunski et al. concluded that a micro-movement greater than 100 μm will cause the healing process to undergo fibrous repair rather than the desired osseous regeneration (172,173). The stability of an osseointegrated implant is determined by the mechanical properties of the surrounding bone which is dependent on bone quality/bone quantity and the fixation between the implant surface and bone (83,90). The mechanical properties of bone consist of its mineral contents, structural composition, and ratio of cortical to cancellous bone (160).

A correlation has been found between the bone-implant contact quantified from histomorphometric analysis and removal torque measurements, this correlation states that an

increase in the bone-implant contact percentage is directly related to an increase in removal torque values (81,84--87). Studies have shown that the structural and geometrical arrangement of bone in contact with the implant surface influences the removal torque values (78,175) and the RFA measurements of osseointegrated implants (82,90,106,112,119).

Primary stability occurs at the time of placement and is related to the level of primary bone contact (176). Primary stability is influenced by the local bone quality/quantity, the geometry of the implant (length, diameter, and type), and the surgical placement technique implemented (i.e. the drill size in relation to implant) (82,90,106). Primary stability can be improved by modifying the surgical technique through the selection of a wider, longer or taper implant (90). Primary stability is influenced by the amount of bone-implant contact and the compressive stresses at the implant-tissue interface (82). Using a drill that is smaller in diameter than the implant placed can result in compressive stresses at the bone-implant interface enhancing the stability of the implant but high levels of such stresses can lead to necrosis and localized ischemia at the implant-tissue interface (82). The condensing osteotome technique was introduced to enhance bone quality for implant placement in the posterior maxilla through the use of lateral compression to increase bone-implant contact leading to enhanced primary stability (177)

Secondary stability is the result of peri-implant bone formation through gradual bone remodeling and osteoconduction at the implant-bone interface (18,19). During the bone healing process at the implant-bone interface the primary stability declines and the secondary stability increases as a result of bone remodeling (176). Raghavendra et al. proposed that measurement of osseointegration be approached in a quantitative manner, as primary and secondary stability are in an inverse relationship (178). Surface roughness has been shown to effect the secondary

stability, indicating that roughened titanium surfaces generally exhibit greater contact with the bone and/or higher removal torque values than smoother implant surfaces such as turned, machined or polished titanium surfaces (7,27,32,37-40,47,179). Surfaces with a mean roughness of 1.0 to 1.5 µm exhibit stronger bone responses than smooth, minimally rough or rough implant surfaces (27,32,37-40). Current implant surface topographies have been modified to make placement easier, reduce trauma, reduce surgical time, and enhance the potential to improve primary and secondary stability (15,21,32,40,46,82,106).

The measurement of the cutting resistance has been termed insertion torque and is calculated in newton-centimeters (Ncm). A Ncm is the torque generated by a force of 1 N acting on a lever of 1 cm in length and cannot be measured pre-operatively in the surgical planning phase for endosseous dental implant placement (82,112,174,180-182). The insertion torque value (i.e. cutting resistance) reflects the mechanical properties of bone and is accepted as an indicator of primary implant stability (58,112,180-182). A systematic review stated that a high degree of primary implant stability measured with insertion torque is a prerequisite for successful immediate or early loading protocols (58). Several studies have noted a statistically significant correlation between insertion torque values and mean bone density quantified from CT (128,153,182-188-190). Several studies have noted a statistically significant correlation between mean bone density and ISQ values recorded using RFA (128,153,184-186,190). Several studies have noted a statistically significant correlation between insertion torque and ISQ values recorded using RFA (112,128,153,184-186,190-192).

High insertion torque values can lead to a discontinuation of the microcirculation due to compression at the implant-bone interface, this phenomenon has only been observed in cortical bone (193,194). Khayat et al. presented a study with implants placed at 176 Ncm, the implants

were followed for one year and no signs of pressure necrosis, crestal change or compromised healing were noted compared to the control group (195). In a histomorphometric study using sheep mandible by Trisi et al., implants were placed with insertion torque of up to 150 Ncm with a mean of 110 Ncm, the high torque value group did not induce adverse outcomes or necrosis but demonstrated accelerated bone remodeling compared to the low insertion torque group (196). A wide range of insertion torque values between 30 to 60 Ncm have been suggested as acceptable threshold levels for primary stability when immediate loading protocols are implemented (197-203). Testori et al. suggested that implants be inserted with an insertion torque value of at least 30 Ncm for immediately loaded full-arch prostheses in the mandible or partial prostheses in either arch (197,198). Wöhrle reported 100% survival for immediately loaded single tooth implants in the esthetic zone with a minimum ITV of 45 Ncm (199). A recent retrospective study by Norton included 61 patients with 68 implants immediately placed after extraction and provisionalized, all implants included in this study had an insertion torque value of $\leq$ 25 Ncm, and the overall survival rate for all implants was 95.5% for a period of 1.25 to 9.5 years (204). A threshold for primary stability measured with maximum applied insertion torque for immediate loading protocols has not been agreed upon or identified in the literature.

D. Computer-Guided Implant Software

1. Overview

In the past, the long-term success of an implant-supported prosthesis was thought to be achieved by placing an endosseous dental implant where the greatest amount of bone was present to ensure stability. The intimate contact of a dental implant to bone is unquestionably important for the long-term success of an implant-supported prostheses but disregarding the prosthetic considerations can lead to peri-implant bone loss, implant failure, poor soft tissue esthetics (205-

214), or compromised prostheses with improper occlusal schemes, poor esthetics, and unfavorable biomechanics (215-224). Today the standard philosophy for the surgical placement of an endosseous dental implant is prosthodontically driven incorporating diagnostic casts with full contour wax-ups of the final prostheses to guide the positional planning of the proposed/potential dental implant sites (225-229).

The utilization of computer-guided implant therapy requires a comprehensive knowledge of the diagnosis and treatment planning process. Numerous aspects of this process need to be understood and completed for proper utilization of computer-guided implant techniques including: proper medical/dental histories, detailed intra-/extra-oral examinations, proper radiographs using conventional techniques (intraoral, panoramic, cephalometric), a correct diagnosis for partially or complete edentulism using the American College of Prosthodontics classification, proper assessment of the bone quality/bone quantity, articulated casts with full contour diagnostic wax-ups, implementation of an accurate conversion technique to transfer the diagnostic setup to the future surgical field using a radiographic prosthesis in conjunction with computed tomography, understanding of medical grade CT for administration procedures, surgical planning using computer-aided design (CAD) to determine ideal implant positions, fabrication of a stereolithographic guide using rapid prototyping or computer-assisted manufacturing (CAM), and surgical execution (230-235).

Traditional radiographic techniques (intraoral/plain film, panoramic, cephalometric tomography) are useful but have diagnostic limitations including distortion, magnification, overlapping, limited area of interest, poor resolution of crucial anatomical structures, and do not provide an accurate cross-sectional reproduction of residual alveolar ridge (236-240). In 1982, computerized axial transverse scanning which is commonly referred to as computed tomography

was introduced to the medical field by Godfrey Hounsfield (241). In 1987, computed tomography (CT) was introduced for dental implementation allowing the clinician to view an accurate three-dimensional reconstruction of the patient's craniofacial structures (242,243). Prior to this time period the surgical placement of an dental implants was performed using customized radiographic/surgical stents or 'dual-purpose' templates with various radiopaque markers (i.e. ball bearings, gutta percha, barium sulfate, cylinders, etc.) of known dimension incorporated into the template. Based on the magnification factor of the known dimension of the object within the template the potential implant sites were then planned for depth, width, and orientation. These surgical/radiographic stents were used in conjunction with computed tomography and traditional radiographic techniques but the clinical outcomes were often unpredictable, time consuming, only used for the pilot drill or initial osteotomy, and sometimes deviated from the ideal prosthodontic location determined pre-operatively (225,244-249).

Computed tomography (CT) is used to obtain cross-sectional images of the jawbones and alveolar processes through the use of multiplanar reformatting of volumetric data sets from axial, coronal, and sagittal cuts (242,243). The most important advantages of CT are its high level of accuracy, ability to assess bone density, and gives the clinician an accurate representation of the bone width/cross sectional for potential dental implant sites (240). CT is a helpful tool in complex implant cases with anatomic limitations, cases with reduced bone volume, and in cases with poor bone density present (250,251). In 1993, the first computer-aided design/computer-assisted manufacturer (CAD/CAM) or three-dimensional (3D) virtual planning software program Simplant™ (Materialise Dental, Glen Burnie, MD, USA) was introduced allowing the clinician to simultaneously interact with the bony architecture from the CT scan data and radiographic marker of the proposed prosthesis (252). CAD/CAM virtual planning software allows the

clinician to ideally position the implants in a prosthodontic-driven manner with respect to vital anatomical structures including but not limited to the naso-palatine canal, maxillary sinus, inferior alveolar nerve, mental foramina, and roots of adjacent teeth (240,253-256).

The CAD/CAM software allows the clinician to transfer the ideal pre-determined implant positions to the surgical field through the use rapid prototyping technology that generates a stereolithographic surgical guide (254-256). There are two types of computer-assisted implant surgery, imaged guided stereolithographic (SLA) type surgical techniques and navigation type which utilize optical bur tracking (254-257). Computer-guided implant surgery using a SLA surgical guide is considered 'static' meaning the surgical guide is reproduced from the virtual implant position directly from CT data and does not allow for intraoperative modification (254-259). Computer-navigated implant surgery utilizes an optical bur-tracking system, this type of technology is considered 'dynamic' meaning the surgical navigation system reproduces the virtual drill position directly from CT data in real time on a monitor in all dimensions (x, y, and z) and allows for real time intraoperative changes in implant position or trajectory (254-257,260-262). Ruppin et al evaluated the accuracy of 2 optical tracking systems and 1 SLA guide system *in vitro* using human mandibles and found no statistically significant difference in the accuracy between the three systems (263).

There are several advantages of computer-guided implant therapy. This technology allows for the utilization of a minimally invasive approach not requiring the elevation of a flap which has been associated with decreased surgical time (264) and a reduction in patient morbidity (265-268). The final prostheses design can be incorporated into the surgical planning resulting in predictable prosthetic outcomes with increased esthetics, the fixed provisional prostheses can be fabricated prior to surgical placement to facilitate immediate loading protocols

(258,269-274). Computer-guided implant surgery allows for the simplification of an operator dependent and technique sensitive surgical procedure (259). The available bone can be fully utilized allowing for longer implants allowing for simultaneous grafting procedures or can omit bone grafting procedures (275-277). Computer-guided implant therapy has some disadvantages including increased cost associated with instruments/software/fabrication of SLA guide, requires more effort (fabrication of radiographic marker, CT imaging, surgical planning using CAD/CAM software), and higher radiation dose compared to traditional surgical techniques (254-256,262,278).

Computer-guided implant therapy using a static approach or SLA surgical guide (tooth-mucosa supported or mucosa-supported) allows for the utilization of a flapless surgical approach. A flapless surgical approach has several advantages including: reduction of complications associated with patient morbidity, reduction in intraoperative bleeding, reduction in surgical time, reduces the likelihood of complicated suturing, preserves the integrity of the hard/soft tissues, and maintains an intact blood supply (279). Despite the advantages listed, a flapless surgical approach using computer-guided therapy and a SLA surgical guide has several potential shortcomings including: inability to visualize anatomical landmarks or vital structures, potential for bone trauma as a result of overheating due to limited external irrigation during osteotomy preparation, inability to evaluate depth of implant placement with respect to the coronal aspect of residual alveolar ridge, difficulties with internal sinus augmentation, and inability to manipulate the soft tissue to idealize keratinized tissue around the implant (279).

2. **Accuracy**

Clinical studies for computer-guided implant therapy have reported outcomes on accuracy but not all clinical studies can be compared due to the lack of uniformity and reported

outcomes. Careful distinction between the accuracy achieved at the point of entry and at the apex for the dental implant placement is necessary, the accuracy at the apex is considered more crucial as the apex is situated in the vicinity of vital anatomic structures (254-256). An *in vitro* study by Sarment et al included 50 implants placed into five epoxy resin edentulous mandible models, each mandible had 5 implants placed using a conventional surgical guide and 5 implants using a SLA surgical guide (259). Significant accuracy was reported with the SLA surgical guides versus the conventional guides, the study concluded that SLA surgical guides should be utilized when multiple parallel distant implants are required or where the degree of accuracy for obtaining a single prosthetic path of insertion is indicated (259).

Two human cadaver studies aimed to determine the magnitude of error in transferring the planned position of implants using CAD from CT scans to the fabrication of a surgical guide. Van Assche et al. inserted 12 implants in four formalin fixed cadaver jaws, upon comparison with the planned implants the investigators reported an average angular deviation of 2 ± 0.8 degrees, a mean linear deviation of 1.1 ± 0.7 mm at the neck, and a 2 ± 0.7 mm at the apex (280). Another human cadaver study by van Steenberghe et al. included 6 zygoma implants with SLA surgical guides based on CT data, researchers reported that the angular deviations in the axis for 4 planned placed implants were less than 3 degrees, whereas 1 implant showed 3.1 degrees, and the last one showed 6.9 degrees of angular deviation (281).

The first *in vivo* study on accuracy for a SLA surgical guide was by Di Giacomo et al, this study inserted 21 implants in 4 patients using 6 SLA surgical guides and measured the deviation between planned and inserted implants. Investigators noted an average angular deviation of 7.25 ± 2.67 degrees between planned and inserted (282). Another *in vivo* study by Ozan et al. placed 110 implants using SLA surgical guides, the mean angular deviation of all

placed implants was 4.1 ± 2.3 degrees with a mean linear deviation of 1.11 ± 0.7 mm at the implant neck and 1.41 ± 0.9 mm at the implant apex (283). The angular deviations of the placed implants compared with the planned implants were 2.91 ± 1.3 degrees, 4.63 ± 2.63 degrees, and 4.51 ± 2.1 degrees for tooth-supported, bone-supported, and mucosa-supported SLA surgical guides respectively (283). The investigators concluded that tooth-supported guides were more accurate than bone- or mucosa-supported SLA surgical guides (283). An *in vivo* study by Cassetta et al. placed 116 implants using SLA surgical guides, the researchers reported a mean linear deviation of 1.47 mm at the coronal aspect of the implant and a 1.83 mm deviation at the apical aspect with a mean angular deviation of 5.09 degrees. The study concluded that a safety zone of at least 2 mm is necessary to avoid critical anatomical structures when using a SLA surgical guide (284).

In a systemic review by Jung et al, the accuracy for 'static' and 'dynamic' computer-guided implant systems was assessed with clinical studies that reported findings with the following four parameters: deviation error in a horizontal direction at the entry point of the drill or implant, deviation error in a horizontal direction at the apex of the drill or implant, deviation of height in the vertical direction, and deviation of the axis of the drill or implant (255). A meta-analysis for the first two parameters (error at entry point and apex) was completed using nineteen articles published from 2001 to 2007, resulting in an overall mean error at the entry point of 0.74 mm (maximum of 4.5 mm) and a mean error at the apex of 0.85 mm (maximum of 7.1mm) (255). In the same study, a meta-analysis could not be performed for the error in height or error in angulation due to insufficient data (255). The researchers concluded that dynamic systems showed 2.2 times higher incidence of complications than static systems (255). This systematic review by Jung et al. reported a cumulative implant survival rate of 96.6% after 12 months of

observation for 506 dental implants (255). This study included only one study with an observation period greater than 2 years, reporting a cumulative implant survival rate of 95.1% for 183 dental implants placed using a static surgical guide with prefabricated fixed provisional prostheses that were immediately loaded (250).

Another systematic review was completed by Schneider et al to assess the accuracy of computer-guided implant surgery using 'static' surgical guides in human, cadaver, and model (256). Eight studies comprised of 321 implant sites met the inclusion criteria for accuracy at the entry point, reporting a mean deviation of 1.07mm. Seven studies comprised of 281 implant sites met the inclusion criteria for accuracy at the apex, reporting a mean deviation of 1.63 mm. Eight studies comprised of 321 implant sites met the inclusion criteria for accuracy, reporting an error in angulation of 5.26 degrees (256). Two studies comprised of 88 implant sites met the inclusion criteria for accuracy in height, reporting a mean error in height of 0.43 mm. No statistical difference for accuracy was found regarding the method of template production or template stabilization method (tooth-mucosa supported, mucosa-supported, bone-supported) (256).

The same systematic review by Schneider et al, reported early surgical complications using computer-guided implant therapy in eight studies (428 patients, 1581 implants) (256). The most common early surgical complication was limited access in the posterior regions (10 patients, 2.3% of the patients or 25.6% of complications) followed by need for primary bone augmentation (8 patients, 1.9% of patients or 20.5% of complications). This systematic review for computer-guided implant placement reported early prosthetic complications for immediate loading procedures using three studies (69 patients, 438 implants) (269,285,286). The most common early prosthetic complication was misfit of abutment to bridge (5 patients, 7.2% of

patients or 38.5% of complications) followed by extensive adjustments of occlusion (3 patients, 4.3% of patients or 23.1% of complications), and incomplete seating of prosthesis (2 patients, 2.9% of patients or 15.4% of complications) (256,269,285,286). This systematic review by Schneider et al, reported a cumulative implant survival rate of 91-100% which included an observation time of 12-60 months for 6 clinical trials with 537 dental implants mainly restored immediately using flapless procedures (256).

3. **Immediate Loading**

Immediate loading protocols for dental implants was first proposed by Schnitman, Tarnow, and coworkers (71,72). Early immediate loading protocol using cross-arch splinting in the anterior mandibular region for fixed immediate provisional prostheses resulted in predictable clinical outcomes similar to two-stage surgical approaches (70,71,74-76). Success with immediate loading techniques in the mandible has resulted in the expansion of loading protocols to the edentulous maxillae for fixed provisional prostheses (72,287), implant single crown situations (204,288,289), partially edentulist regions (198,290-292), implementation of fewer implants for fixed implant complete dentures (202,293,294), and immediate loading esthetic scenarios (199,203,295).

The incorporation of computer-assisted implant software for prefabrication of provisional prostheses to facilitate immediate loading protocols using a flapless surgical approach with a static surgical guide has resulted in high cumulative implant survival rates (258,270,296). Computer-guided implant therapy allows for the placement of multiple implants with the delivery of a prefabricated provisional prosthesis for complex restorative procedures (274). The utilization of computer-guided implant placement allows for the final prostheses design to be incorporated into the surgical planning resulting in predictable prosthetic outcomes with

increased esthetics and the fixed provisional prostheses can be fabricated prior to surgical placement to facilitate immediate loading protocols (258,269-274).

III. MATERIALS AND METHODS

A. Patient Selection and Diagnostic Assessment

This study was approved by the UIC Institutional Review Board (Research Protocol #2008-1212). A total of eight patients (7 female,1 male with a mean age 61.4) were treated with computer-guided implant therapy using a stereolithographic guide in the Advanced Prosthodontics department at the University of Illinois at Chicago. Implants were surgically placed by UIC prosthodontic residents from August 2010 to April 2011. An informed written consent was obtained from all subjects following the approved IRB guidelines for clinical research. All subjects used in this investigation were either partially or fully edentulous with an agreed upon comprehensive treatment plan for an implant-supported prosthesis.

Comprehensive treatment planning was completed on every subject prior to implementation of computer-guided implant placement to ensure optimum definitive prosthesis design. The diagnosis and treatment planning phase included the following: medical/dental histories, intra-/extra-oral examinations, proper radiographs using conventional techniques, a correct diagnosis for partial or complete edentulism using the American College of Prosthodontics classification, proper assessment of the bone quality/bone quantity, articulated casts with full contour diagnostic wax-ups, implementation of an accurate conversion technique to transfer the diagnostic setup to the future surgical field using a radiographic prosthesis in conjunction with computed tomography, surgical planning using computer-aided design (CAD) to determine ideal implant positions, and fabrication of a stereolithographic guide using rapid prototyping or computer-assisted manufacturing (CAM).

Patients that were excluded from this investigation included the following: those that presented with an uncontrolled systemic disease (diabetes, hematologic disorder, metabolic bone disorder), an uncontrolled dental disease, a history of radiation treatment to the head/neck region,

a history of IV or oral bisphosphonates, suspected pregnancy, history of tobacco use within the past 6 months, or need for simultaneous bone augmentation procedures. Dental implant failure was defined as any implant that required removal.

B. **Pre-surgical Protocol**

Medical grade computed tomography (CT) was utilized in conjunction with rapid prototyping or stereolithography to fabricate a SLA surgical guide for the placement of all dental implants included in this investigation. The topography of the bone model is determined by the CT scan and this model along with the radiographic prosthesis is used in conjunction with the computer guided implant Facilitate™ software (Astra Tech Inc., Waltham, MA) based on SimPlant™ by Materialise™ (Materialise Dental Inc., Glen Burnie, MD) to fabricate a stereolithographic (SLA) surgical guide.

A radiographic prosthesis was fabricated for all patients included in this study prior to the administration of medical grade CT. The radiographic prosthesis or radiographic marker was fabricated from a diagnostic wax-up replicating ideal tooth position, occlusion, and gingival emergence profile. To mimic the ideal tooth position, a mixture of 20 g barium sulfate ($BaSO_4$) (E-Z-HD Barium Sulfate for Suspension, E-Z-EM Canada, Inc., Westbury, NY) and 80 g of clear autopolymerizing acrylic resin (Orthodontic Resin, Dentsply/Caulk, Milford, DE) was used. To mimic the ideal contours for soft tissue architecture, a 10 g $BaSO_4$ and a 90 g clear autopolymerizing acrylic mixture was implemented. After the fabrication of the radiographic prosthesis, the radiographic marker was seated intra-orally to verify accuracy and comfort. A radiolucent polyvinylsiloxane bite registration material (Regisel™, Dentsply Caulk, Milford, DE) was used to fabricate a registration to properly position the radiographic prosthesis during the administration of medical grade CT. This registration was also used to capture a

maxillomandibular relationship and clearly separate the opposing jaws during the administration of radiation to facilitate proper radiographic analysis.

The bone density for potential dental implant sites was assessed with CT from a Somatom® Sensation helical 64 CT spiral scanner (Siemens AG, Erlangen, Germany) located at Loyola University Medical Center -3D Imaging Center (Maywood, IL). The radiation dosage was delivered according to the Facilitate™ software by Materialise™ recommended settings of 140 kV tube voltage, 100 mA tube current, with a rotation time of 1.0 s, 205mm field of view, 1.0 mm slice thickness, and 1.0 mm slice intervals. The coronal, axial, cross-sectional images for each maxilla and mandible used in this study were obtained from a medical CT scan after software formatting following Facilitate™ manufacturer recommendations. Image reconstruction was completed using standard dental and evaluation software programs supplied with the scanner. After reconstruction of the CT scan to reduce artifacts and metal scatter, a digital imaging and communications in medicine (DICOM) file was then sent to the clinician. Facilitate™ software by Materialise™ was used to orientate the dental implants in the most ideal prosthetic position based on the radiographic prosthesis to maximize the length of the dental implant.

A stereolithographic surgical guide was fabricated based on the type of support needed to accurately complete the surgical procedure by the clinician. The design of the SLA surgical guide was selected by the clinician. The selection of either a tooth-mucosa supported, mucosa-supported, or bone supported stereolithographic surgical guide was based upon the clinician's preference and patient indication. No mucosa-supported SLA guides were implemented in this investigation. Rapid prototyping technologies were used to fabricate the surgical guide based on

computer-aided design specifications completed using Facilitate™ Pro software, a master cast was sent with design specifications to the manufacturer for tooth-mucosa supported guides.

Using the Facilitate™ by Materialise™ software the total circumferential mean density value and standard deviation was calculated in Hounsfield units for the circumferential aspect of all dental implants prior to surgery. This value represented the total mean bone density surrounding the entire dental implant fixture that was in contact with the virtual implant site found within the design software.

The mean bone densities for each dental implant (OsseospeedTX™, Astra Tech, Waltham, MA) was then evaluated in six specific locations along the virtually planned implant. The unique macro-structure of the OsseospeedTX™ dental implant allowed the clinician to identify the six specific locations around each of the dental implant (Figure 1).

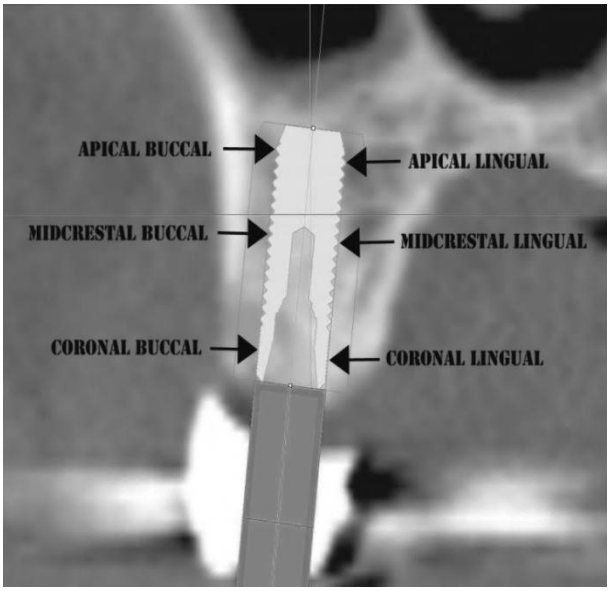

Figure 1. Quantification of Mean Bone Density using CT at the coronal, midcrestal, and apical regions of the dental implant.

In the cross-sectional view of the computer-guided implant software, the *coronal buccal* and *coronal lingual* locations were found by identifying the midpoint of the total length or distance of the micro-threading found at the coronal aspect of the dental implant using the measurement ruler found in the menu bar of the software. The *midcrestal buccal* and *midcrestal lingual* locations were found by identifying the midpoint of the total length of the macro-threading. The length of the macro-threading was found by measuring the distance from the outside circumference of the most coronal and most

apical thread edge using the measuring tool found within the software. The *apical buccal* and *apical lingual* locations were found by identification of the last macro-thread, this is the point where the apical region of the dental implant fixture begins to taper.

After identification of the six regions seen in Figure 1, the mean bone density was calculated for the region of interest using a 0.50 mm^2 elliptical radius bone density measurement tool located in the menu bar of the computer-guided implant software. Three bone density measurements with standard deviations were taken for each region of interest described above for a total of 18 mean bone density measurements for each dental implant used in this prospective study. A total of 19 dental implants were evaluated, the total mean bone density with standard deviation was calculated for the coronal, midcrestal, and apical regions of the implant fixture.

C. **Surgical Protocol**

All surgical procedures were completed under local anesthesia using a sterile technique by residents in the Advanced Prosthodontics clinic at the University of Illinois at Chicago, under the direct supervision and assistance of the postgraduate program director. A total of eight patients (7 female,1 male with a mean age 61.4) were treated using computer-guided implant software to facilitate the fabrication of a stereolithographic guide for the placement of 19 dental (OsseospeedTX™, Dentsply, Waltham, MA, USA) implants from August 2010 to April 2011.

Full thickness mucoperiosteal flaps were elevated as necessary on all patients included in this study. Meticulous attention was implemented to ensure that all soft tissue was handled atraumatically and reflected appropriately to allow for complete seating of the stereolithographic guide. For the tooth-supported surgical guides implemented in this study, crestal incisions and full mucoperiosteal flaps were elevated on either side of the edentulous span. This allowed for

better visibility of the surgical site and to verify complete seating of the implant fixture after placement with the SLA surgical guide. After initial reflection the surgical guide was verified for stability, proper position/orientation, and complete seating.

Preparation of the osteotomies was completed following manufacturer drilling and installation protocol for Facilitate™ (Astra Tech Inc., Waltham, MA). Osteotomies were prepared using profuse saline irrigation. Meticulous attention from all clinicians was directed towards maintaining the stability of the surgical guide during the osteotomies to ensure proper osteotomy depth and angulation accuracy. The indicated implant holder was used to properly install and vertically seat the dental implant. Vertical seating of the dental implant was deemed complete when the seating portion of the implant holder came into light contact with the cylinder of the surgical guide.

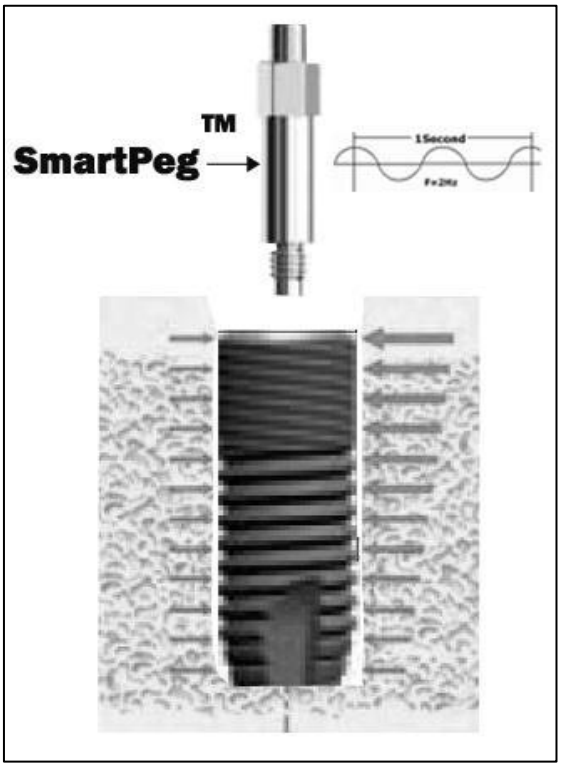

Figure 2. Smartpeg™ - Quantification of the lateral movement of a dental implant using RFA.

After the placement of each dental implant, the maximum applied insertion torque value was recorded using a W&H ImplantMed™ motor (W&H Impex Inc., Windsor, Ontario). During implant placement the measurement for the maximum applied insertion torque value was started at 10 Ncm. The insertion torque value was increased at intervals of 5 Ncm when the rotation of the implant driver was stopped due to friction during implant placement. The maximum applied insertion torque value was recorded using one of the following increments: 15 Ncm, 20 Ncm, 25

Ncm, 30 Ncm, 32 Ncm, 35 Ncm, 40 Ncm, 45Ncm and 50 Ncm. If the final implant torque value was ≥ 50 Ncm, and additional torque with a manual torque wrench was needed to complete seating of the dental implant, the final seating torque was recorded at 50 Ncm.

After the maximum applied insertion torque values were obtained a disposable SmartPeg™ transducer (Integration Diagnostics, AB, Sävaedalen, Sweden) was attached to the dental implant using light finger pressure, approximately 4-5 Ncm of hand torque, with the aid of a mount (Figure 2). RFA measurements were taken using a wireless handheld probe attached to the Ostell Mentor™ **(**Integration Diagnostics, AB, Sävaedalen, Sweden). The handheld probe from the RFA unit was put into close proximity to the SmartPeg™ transducer**.** Six resonance frequency measurements were taken for each implant fixture. The RFA measurements were recorded using ISQ values ranging from 1 to 100. Three of the measurements were taken from either the facial or buccal aspect and three were taken perpendicular to the first measurement from either the mesial or distal. The full thickness mucoperiosteal flap was then closed to allow healing.

D. **Statistical Analysis**

The modified Albrektsson and Zarb bone classification (142) was used to organize the dental implants into the following anatomical regions: anterior mandible, anterior maxilla, posterior mandible, and posterior maxilla. The power of a statistical test, sometimes referred to as π, is the probability of not committing Type II error or making a false negative decision (297). As the power of statistical test increases, the chances of a Type II error occurring decreases or referred to as a false negative rate (β) (297). The hypotheses in the present study were based on a sample of 19 dental implants, their statistical power analysis was completed *post hoc* and is at least 80% (π = 0.80) to detect a correlation coefficient amongst the parameters measured with a

Type I error equal to 0.05 ($\alpha = 0.05$) or Type II error equal to 0.20 ($\beta = 0.20$) (Systat™ software, version 13; Systat Software, Inc., Chicago, IL).

Most researchers assess the power of their tests using $\pi = 0.80$ as the standard for accuracy, this convention implies a 4-to-1 trade between β-risk (Type II) to α-risk (Type I), Type I error denotes a false positive and Type II error denotes a false positive (297). Descriptive biostatistic software was implemented to determine the mean values with standard deviation for the circumferential bone density quantified using CT, maximum applied insertion torque value, and the mean implant stability quotient (Excel™, Microsoft Corp., Redmond, WA). Biostatistic software was implemented to determine the presence of positive correlations amongst the parameters of circumferential bone density quantified using CT, maximum applied insertion torque value, and the mean implant stability quotient (Systat™ software, version 13; Systat Software, Inc., Chicago, IL).

The implant cumulative survival rates for the 19 implants placed using a stereolithographic surgical guide was measured at 100% with an observation time since implant placement of 0 to 24 months. No prosthetic complications have been reported. The Pearson correlation coefficient test was used to determine if there was a positive correlation amongst the measurements of mean circumferential bone density calculated using CT, maximum applied insertion torque value, and the mean ISQ value. The Pearson correlation coefficient test is a measure of the linear dependence between two variables calculated using mean values and standard deviations. It is the measure of two variables divided by the product of their standard deviations, often denoted by p or r values which measure the degree of correlation (298,299). Scatterplots can evaluate the regression line showing the Pearson's correlation coefficient, the r correlation coefficient ranges from 0 to 1.0, with 0.5 to 1.0 representing a strong positive

correlation (298,299). Refer to the scatterplots showing the linear regression lines and *r* correlation coefficients for the parameters of circumferential mean bone density calculated using CT, maximum applied insertion torque value, and the mean ISQ value (Figure 3-5).

The lower the *r* value for the linear regression the lower the statistical correlation, the Pearson's correlation coefficient is +1 for strong positive correlations or increasing linear relationships whereas -1 represents weak negative correlations or decreasing linear relationships (298,299). There was no correlation found between the mean ISQ values and circumferential mean bone density calculated using CT (r = 0.275), the variance for the Y variable is closer to zero (Figure 3). There was no correlation found between the implant stability quotient and insertion torque value (r = 0.056) (Figure 4). A positive correlation was found between mean bone density calculated using CT and insertion torque value (r = 0.862) (Figure 5). The *r* values for the Pearson's correlation coefficient were converted to p-values using statistical software to test the hypotheses for positive correlation coefficients using p-value is equal to 0, based on the value of the sample correlation coefficient *r* (Systat™ software, version 13; Systat Software, Inc., Chicago, IL). The p-values for the Pearson's correlation coefficient for all possible parameter pairings are listed in Table I, a positive correlation was considered when p-value < 0.05.

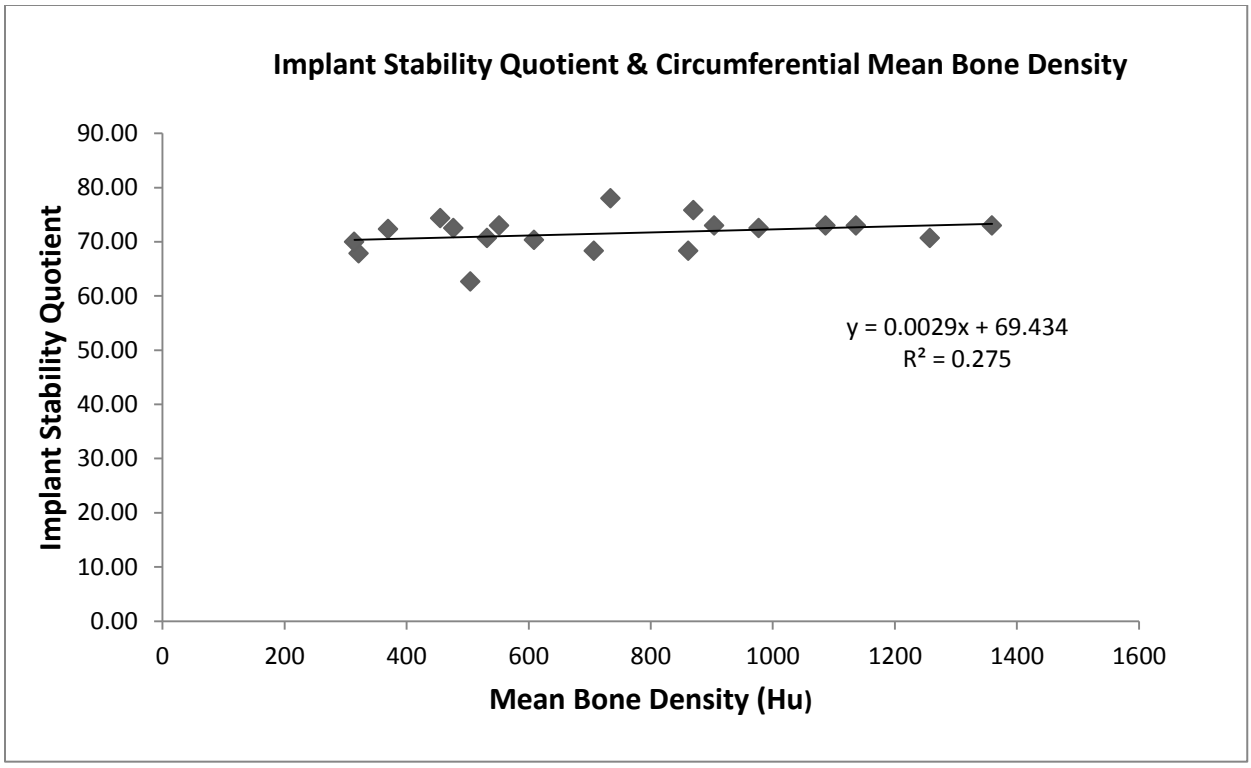

Figure 3. Scatter plot graph with linear regression line for the implant stability quotient and circumferential mean bone density.

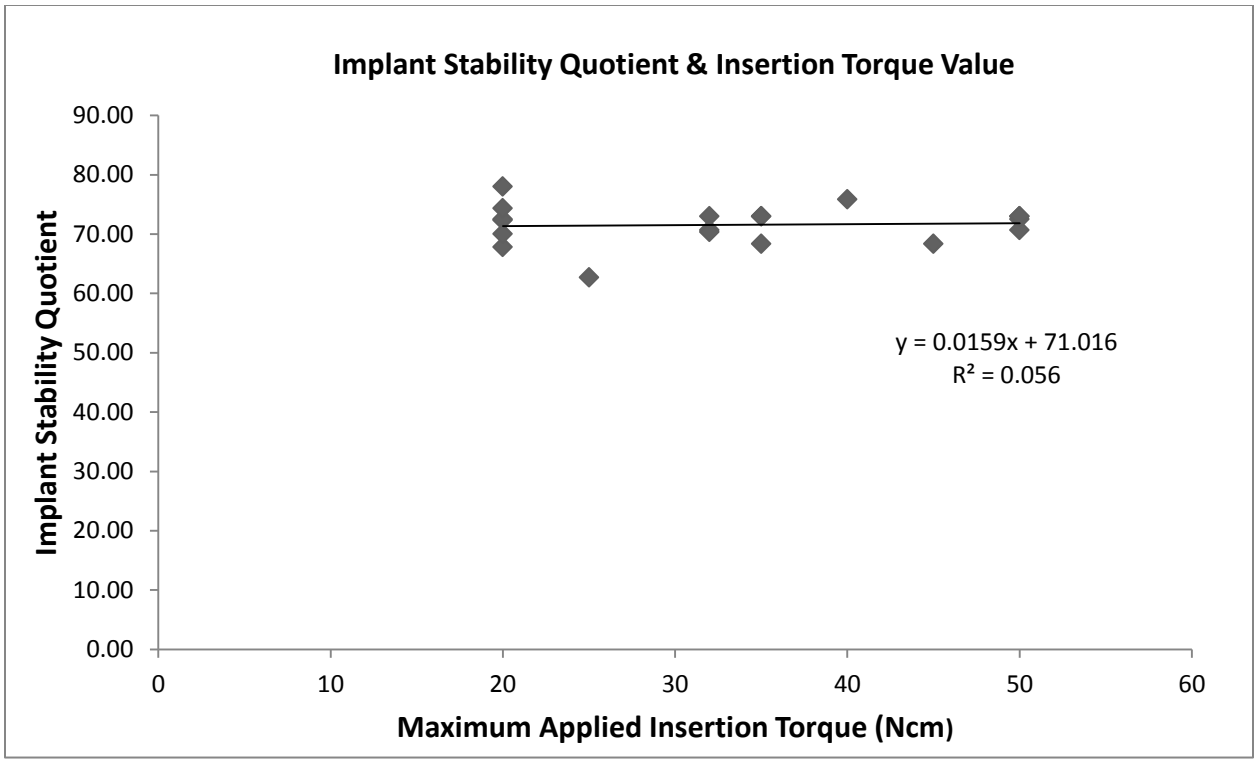

Figure 4. Scatter plot graph with linear regression line for the implant stability quotient and maximum applied insertion torque value.

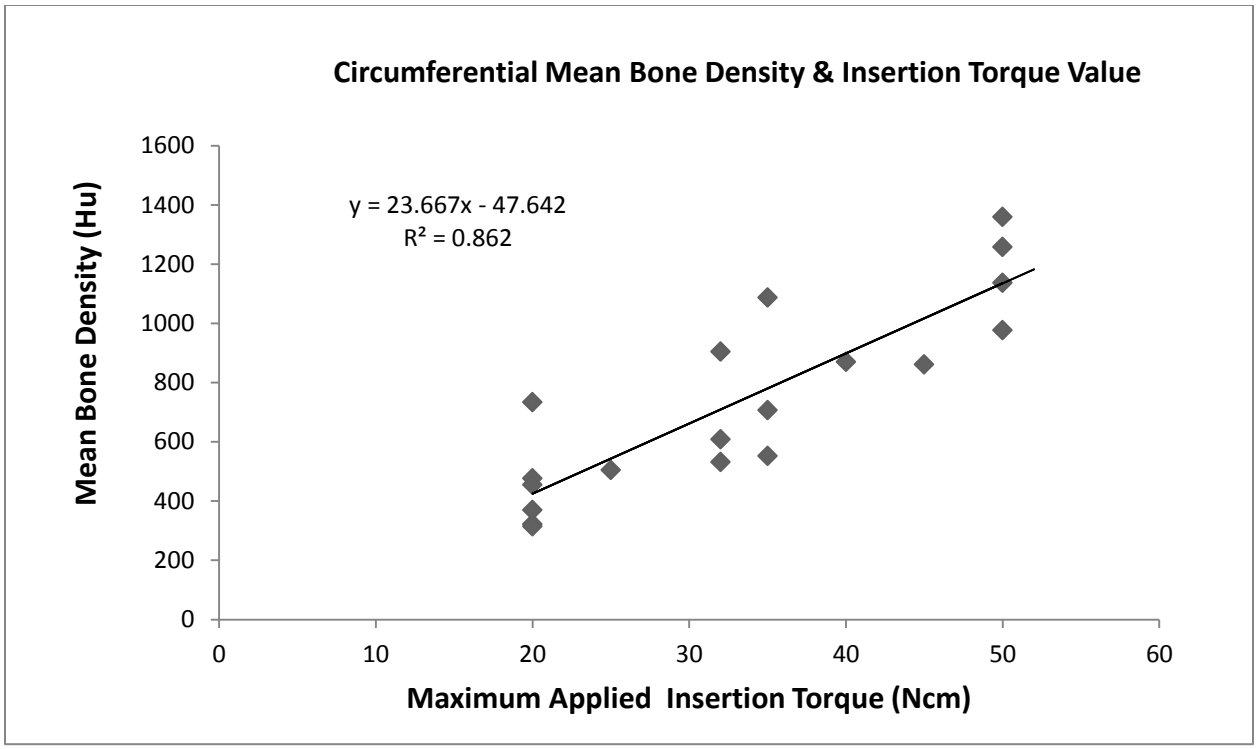

Figure 5. Scatter plot graph with linear regression for circumferential mean bone density calculated using CT and maximum applied insertion torque value.

TABLE I

P-VALUES FOR PEARSON'S CORRELATION COEFFICIENT

	DBC	DBM	DBA	DLC	DLM	DLA	MBD	ITV	ISQ
DBC	0.000								
DBM	0.201	0.000							
DBA	0.403	0.000*	0.000						
DLC	0.300	0.000*	0.002*	0.000					
DLM	0.045*	0.002*	0.000*	0.005*	0.000				
DLA	0.009*	0.139	0.067	0.062	0.000*	0.000			
MBD	0.025*	0.000*	0.000*	0.000*	0.000*	0.001*	0.000		
ITV	0.002*	0.003*	0.001*	0.000*	0.000*	0.001*	0.000*	0.000	
ISQ	0.267	0.039*	0.012*	0.453	0.241	0.438	0.255	0.821	0.000

(*) denotes that the p-value < 0.05 reflecting a statistically significant correlation between parameters, if p-value equals 0 then $p < 0.01$.

DBC - mean bone density buccal coronal
DBM - mean bone density buccal midcrestal
DBA - mean bone density buccal apical
DLC - mean bone density lingual coronal
DLM - mean bone density lingual midcrestal
DLA - mean bone density lingual apical
MBD - total circumferential mean bone density
ITV – maximum applied insertion torque value
ISQ – mean implant stability quotient

Note: all bone density values were calculated using CT

IV. RESULTS

A total of eight patients (7 females and 1 male with a mean age 61.4) received 19 self-tapping dental implants (OsseospeedTX™, Astra Tech, Sweden) placed using computer-guided implant software and a stereolithographic surgical guide. All implants used in this study were ≥ 11mm in length with either a 3.5 mm or 4.0 mm diameter (Table II). The different types of prostheses included in this study consisted of 1 implant fixed complete denture, 1 implant overdenture, 4 implant fixed partial dentures, and 4 implant single crowns. A 100% cumulative implant survival rate has been reported after two years of follow-up and no prosthetic complications have been reported.

As shown in Table II, the circumferential mean bone density quantified using CT with correlating standard deviations for all implants was 738.34 ± 155.08 HU. The circumferential mean bone density for all implants ranged from 322 HU to 1360 HU. The maximum applied insertion torque value for all implants used in this study was 33.2 Ncm and the total mean ISQ value was 71.54 ± 2.80 (Table II).

As shown in Table III, the mean bone density was found to be the highest at the midcrestal region for all 19 dental implants at 876.14 ± 24.39 HU, > coronal 865.88 ± 16.78 HU, > apical 811.58 ± 19.93 HU. Refer to Figure 1 in the Materials and Methods section for the description of regions found around the dental implants.

Refer to Table IV for the mean bone densities based on anatomical region and anatomical location. In the anterior mandibular region, the mean bone density was found to be the highest in the midcrestal region at 1346.35 ± 22.84. In the posterior maxilla, the mean bone densities were found to be highest at the midcrestal region of the dental implant at 460.24 ± 5.680. In the

anterior maxilla and posterior mandible, the mean bone densities were found to the highest at the coronal aspect of the implant at 808.73 ± 19.06 and 637.95 ± 21.92, respectively.

A total of 19 implants were included in this study: 7 anterior mandibular, 7 anterior maxillae, 2 posterior mandible sites, and 3 posterior maxillae. As shown in Table V, the mean bone densities quantified using CT with correlating standard deviations based on anatomical region was the highest in the anterior mandible 1055 ± 169 HU, > anterior maxilla 671 ± 112 HU, > posterior mandible 413 ± 140 HU, > posterior maxilla 380 ± 110 HU. A traditional box plot graph is depicted in Figure 6, showing the maximum, minimum, 25^{th}, 50^{th}, and 75^{th} percentiles for the circumferential mean bone density calculated using CT organized by anatomical region.

As shown in Table V, the maximum applied insertion torque value for each anatomical region was found to be the highest in the anterior mandible at 45 Ncm, > anterior maxilla 30 Ncm, > posterior mandible 23 Ncm, > posterior maxilla 20 Ncm. The mean ISQ values with correlating standard deviations based on anatomical region was found to be the highest in the anterior maxilla 74.17 ± 1.47, > anterior mandible 71.26 ± 3.77, > posterior maxilla 71.17 ± 1.33, > posterior mandible 65.25 ± 2.41.

Sixteen implants were placed in female patients and three in male patients. For females, the mean bone density was 776 ± 160 HU. The mean bone density quantified using CT for males was calculated to be 539 ± 131 HU. The mean insertion torque value was found to be lower in males at 28 Ncm. The mean insertion torque value for the 16 implants in female patients was calculated to be 34 Ncm. The mean ISQ value calculated using RFA was almost identical for both sexes, the mean ISQ value for females and males was calculated to be 72 ± 3 and 71 ± 3, respectively.

Pearson correlation coefficient was used to evaluate the presence or absence of a positive correlation among the parameters of mean bone density calculated using CT, insertion torque value, and the implant stability quotient. Pearson correlation coefficient is a measure of the linear dependence between two variables calculated using mean values and standard deviations. It is the measure of two variables divided by the product of their standard deviations, often denoted by *p* or *r* values which measure the degree of correlation (298,299).

Refer to the scatterplots showing the linear regression lines and *r* correlation coefficients for the parameters of circumferential mean bone density calculated using CT, maximum applied insertion torque value, and mean ISQ value (Figure 3-5). The *r* values for the Pearson's correlation coefficient were converted to p-values using statistical software to test the hypotheses for positive correlation coefficients using p-value is equal to 0, based on the value of the sample correlation coefficients *r* (Systat™ software, version 13; Systat Software, Inc., Chicago, IL). The p-values for the Pearson's correlation coefficient for all possible parameter pairings are listed in Table I, a positive correlation was considered when p-value < 0.05.

Please refer to Figures 3 to 5 and Table I for the results of the Pearson's correlation coefficient. A positive correlation was detected between the circumferential mean bone density and maximum applied insertion torque value for all implants ($r = 0.862$, $p < 0.001$). No correlation was found between circumferential mean bone density and the ISQ ($r = 0.275$, $p > 0.05$). No correlation was found between the ISQ and maximum applied insertion torque value ($r = 0.056$, $p > 0.05$). A positive correlation was detected between the all mean bone densities calculated at the different regions of the dental implant (crestal, midcrestal, apical) and the maximum applied insertion torque value ($p < 0.01$).

TABLE II

DATA SUMMARY FOR ALL IMPLANTS

No.	REGION	DIMENSION (mm)	MEAN BONE DENSITY (Hu)	INSERTION TORQUE (Ncm)	MEAN ISQ
1	ANT MAND	3.5 x 13	707.14 ± 203.71	35	68.33 ± 2.66
2	ANT MAND	3.5 x 13	861.47 ± 268.33	45	68.33 ± 2.36
3	POST MAND	4.0 x 11	321.78 ± 181.87	20	67.83 ± 0.41
4	POST MAND	4.0 x 11	504.48 ± 98.92	25	62.67 ± 4.41
5	ANT MAX	4.0 x 13	734.02 ± 44.83	20	78.00 ± 0.00
6	ANT MAX	4.0 x 13	870.06 ± 106.04	40	75.83 ± 4.36
7	ANT MAX	3.5 x 11	904.11 ± 347.76	32	73.00 ± 2.19
8	ANT MAX	3.5 x 11	551.84 ± 184.52	35	73.00 ± 3.29
9	ANT MAX	4.0 x 11	531.66 ± 118.49	32	70.67 ± 0.52
10	ANT MAX	4.0 x 11	476.50 ± 96.96	20	72.50 ± 4.93
11	ANT MAX	4.0 x 11	608.75 ± 178.16	32	70.33 ± 2.94
12	POST MAX	3.5 x 11	369.91 ± 119.16	20	72.33 ± 2.66
13	POST MAX	3.5 x 11	455.16 ± 107.96	20	74.33 ± 1.03
14	POST MAX	3.5 x 11	314.32 ± 102.91	20	70.00 ± 0.00
15	ANT MAND	4.0 x 11	1086.63 ± 213.45	35	73.00 ± 3.29
16	ANT MAND	3.5 x 11	976.86 ± 110.71	50	72.50 ± 3.83
17	ANT MAND	3.5 x 11	1257.62 ± 142.80	50	70.67 ± 5.54
18	ANT MAND	3.5 x 11	1359.48 ± 142.94	50	73.00 ± 3.29
19	ANT MAND	3.5 x 11	1136.65 ± 177.04	50	73.00 ± 5.48
TOTAL	**7:7:2:3**	**3.5/4.0 ≥ 11mm**	**738.34 ± 155.08**	**33.21**	**71.54 ± 2.80**

TABLE III

MEAN BONE DENSITY AT THE CORONAL, MIDCRESTAL, AND APICAL REGIONS FOR ALL DENTAL IMPLANTS

No.	REGION	MEAN BONE DENSITY CORONAL	MEAN BONE DENSITY MIDCRESTAL	MEAN BONE DENSITY APICAL
1	ANT MAND	972.80 ± 38.69	664.73 ± 48.15	838.71 ± 2.93
2	ANT MAND	1000.76 ± 14.82	941.20 ± 53.34	1219.61 ± 5.98
3	POST MAND	613.82 ± 29.98	328.59 ± 7.69	166.85 ± 6.80
4	POST MAND	662.08 ± 13.85	258.34 ± 27.16	624.44 ± 63.69
5	ANT MAX	566.03 ± 14.95	1046.63 ± 65.30	1042.40 ± 36.43
6	ANT MAX	859.53 ± 20.55	1072.06 ± 107.48	829.17 ± 0.00
7	ANT MAX	1124.07 ± 13.97	772.17 ± 14.15	380.33 ± 3.75
8	ANT MAX	765.10 ± 18.25	406.80 ± 30.83	838.93 ± 24.01
9	ANT MAX	849.37 ± 3.50	692.23 ± 12.12	485.10 ± 4.68
10	ANT MAX	569.73 ± 61.30	789.83 ± 3.75	443.10 ± 11.26
11	ANT MAX	927.27 ± 0.92	474.77 ± 18.07	429.47 ± 74.32
12	POST MAX	381.33 ± 0.00	413.95 ± 13.95	280.83 ± 3.18
13	POST MAX	414.72 ± 1.54	548.50 ± 0.00	415.67 ± 10.87
14	POST MAX	403.00 ± 0.00	418.28 ± 3.08	457.83 ± 35.80
15	ANT MAND	741.80 ± 11.26	1189.23 ± 0.92	1227.40 ± 0.00
16	ANT MAND	1378.61 ± 12.31	1515.45 ± 22.04	1367.82 ± 79.05
17	ANT MAND	1591.09 ± 19.52	1697.08 ± 22.07	1398.21 ± 2.89
18	ANT MAND	1395.59 ± 2.99	1797.51 ± 10.38	1650.76 ± 8.48
19	ANT MAND	1235.09 ± 27.16	1619.24 ± 2.97	1323.47 ± 4.67
TOTAL	**7:7:2:3**	**865.88 ± 16.78**	**876.14 ± 24.39**	**811.58 ± 19.93**

TABLE IV

MEAN BONE DENSITY AT THE CORONAL, MIDCRESTAL, AND APICAL REGIONS FOR ALL DENTAL IMPLANTS ORGANIZED BY ANATOMICAL REGION

REGION	MEAN BONE DENSITY CORONAL	MEAN BONE DENSITY MIDCRESTAL	MEAN BONE DENSITY APICAL
Anterior Mandible	1187.96 ± 18.11	1346.35 ± 22.84	1289.43 ± 14.86
Anterior Maxilla	808.73 ± 19.06	750.64 ± 35.96	635.50 ± 22.06
Posterior Mandible	637.95 ± 21.92	293.46 ± 17.43	395.64 ± 35.25
Posterior Maxilla	399.68 ± 0.51	460.24 ± 5.68	384.78 ± 16.61

TABLE V

DATE SUMMARY BY ANATOMICAL REGION

REGION	Implant No.	MEAN BONE DENSITY (Hu)	INSERTION TORQUE (Ncm)	MEAN ISQ
Anterior Mandible	7	1055.12 ± 179.85	45	71.26 ± 3.77
Anterior Maxilla	7	671.39 ± 111.50	30	74.17 ± 1.47
Posterior Mandible	2	413.13 ± 140.40	23	65.25 ± 2.41
Posterior Maxilla	3	379.80 ± 110.01	20	71.17 ± 1.33

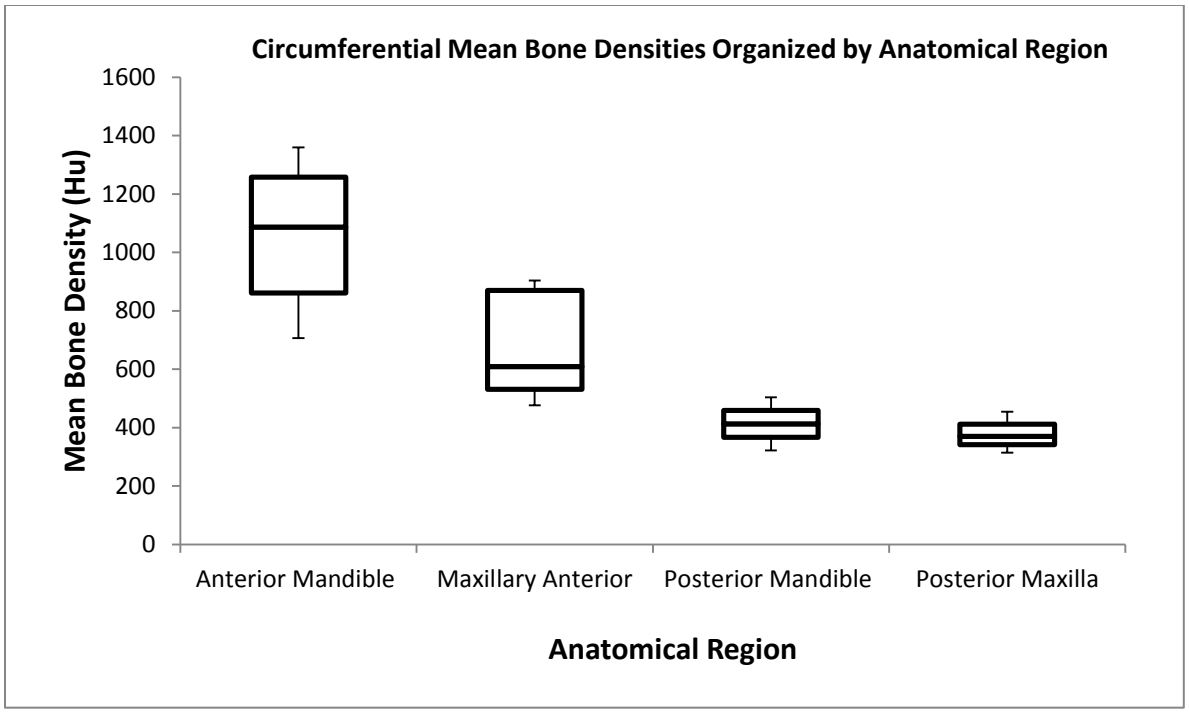

Figure 6. Box plot graph for the circumferential mean bone density calculated using CT organized by anatomical region.

V. DISCUSSION

A. Overview

There was correlation found between the circumferential mean bone density and maximum applied insertion torque values for all implants ($r = 0.862$, $p < 0.001$). No correlation was found between the circumferential mean bone density calculated using CT and the ISQ values ($r = 0.275$, $p > 0.05$). No correlation was found between the ISQ values measured using RFA and insertion torque values ($r = 0.056$, $p > 0.05$). There was a positive correlation found between the mean bone densities calculated at the different regions of the dental implant (coronal, midcrestal, apical) and insertion torque values ($p < 0.01$). The results of this study are consistent with the conclusions of Molly et al (150), bone density quantified using CT as a predictor of insertion torque value was substantiated. Bone density as a predictor of ISQ to measure the primary stability of a dental implant was not substantiated. The hypotheses that assessed correlation between bone density and ISQ, and ISQ with insertion torque value were not supported by the results in this study.

Controlling the surgical approach using computer-guided implant software allows the clinician to maximize the length of a dental implant in relationship to vital structures. All dental implants used in this study were ≥ 11 mm with a diameter or 3.5 mm or 4.0 mm. No correlation was found between the circumferential bone density calculated using CT and the mean ISQ values ($r = 0.275$, $p > 0.05$) or ISQ values and the maximum applied torque values ($r = 0.056$, $p > 0.05$). The mean ISQ value for all implants was relatively high measured at 71.54 ± 2.80 and only one implant in this study had a mean ISQ of ≤ 65 ISQ (Table II). ISQ values ranging from 60 to 65 indicate good primary stability and may be suitable for immediate loading procedures while ISQ values below 40 may be more prone to failure or indicative (90). Regardless of the

bone quality or bone density calculated using CT pre-operatively, all implants achieved good primary stability measured using RFA with a mean ISQ value ≥ 63 in this study. An explanation for the relatively high primary stability measurement of mean ISQ value of 72 ± 2.80 might be related to the length of the dental implants used in this study ≥ 11 mm.

As shown in Table V, the circumferential mean bone densities quantified using CT with correlating standard deviations based on anatomical regions was the highest in the anterior mandible 1055 ± 169 HU, > anterior maxilla 671 ± 112 HU, > posterior mandible 413 ± 140 HU, > posterior maxilla 380 ± 110 HU. The findings from this study are comparable to the results disclosed in studies by Norton et al (152) and Turkyilmaz et al (128) with the exception of the posterior mandible. The results from the Norton et al study found the mean bone densities quantified using CT for 139 dental implants to be anterior mandible 970 ± 269 HU, > anterior maxilla 696 ± 244, > posterior mandible 669 ± 249 HU, > posterior maxilla 417 ± 227 (152). In the study by Turkyilmaz et al which included 300 dental implants, the mean bone densities quantified using CT were anterior mandible 846 ± 234 HU, > anterior maxilla 591 ± 176 HU, > posterior mandible 526 ± 107 HU, > posterior maxilla 403 ± 95 HU (128). In this study, the circumferential mean bone density in the posterior mandibular region was found to be 413 ± 140 HU. This low circumferential mean bone density value might be attributed to the low number of dental implants placed in the posterior mandibular region which consisted of only two dental implants.

In this study, a positive correlation was found between circumferential mean bone densities and the maximum applied insertion torque values using the Pearson correlation coefficient ($r = 0.862$, $p < 0.001$). This is similar to *in vitro* studies on cadaver mandibles and maxillae which have found positive correlations between bone density quantified with CT and

insertion torque (182,185,187,189). *In vivo* studies have reported positive correlations between bone density calculated using CT and insertion torque (128,153,183,184,186,188,190). This relationship between bone density calculated using CT and insertion torque allows the clinician to predict the primary stability of a dental implant prior to placement based on preoperative bone density using CT. This preoperative information could possible be used to determine if immediate loading protocols are feasible through the critical selection of potential implant sites with high bone density which may result in greater insertion torque depending on the surgical technique implemented.

In this study, no correlation was found between the circumferential mean bone density values calculated preoperatively using CT and the ISQ values ($r = 0.275$, $p > 0.05$). In addition, the mean bone density calculated at the crestal aspect of all dental implants included in this this study did not have a statistically significant correlation with the mean ISQ values recorded using RFA at the time of placement ($p > 0.05$) . The results of this study are consistent with other i*n vitro* and *in vivo* studies that have reported no correlation between bone density and ISQ values recorded using RFA (127,300,301). Other *in vivo* studies have reported a positive correlation between bone density and ISQ values recorded using RFA (128,153,184,186,190). In this study, no correlation was found between the insertion torque values and the mean ISQ values recorded using RFA at the time of dental implant placement ($r = 0.056$, $p > 0.05$). Several studies have found no correlation between insertion torque values and ISQ values using RFA at the time of placement (127,302,303). Other studies have reported a positive correlation between insertion torque and the ISQ recorded using RFA (112,128,153,184-186,190-192). Bone density as a predictor of ISQ to measure the primary stability of a dental implant was not substantiated. The

hypotheses that assessed correlation between bone density and ISQ, and ISQ with insertion torque value were not supported by the results in this study.

B. **Clinical Implications**

Computer-guided implant placement allows the clinician to critically select potential implant sites within appropriate dimensions within the confinements of the residual alveolar or basal bone to maximize primary stability of a dental implant at the time of placement. This could be accomplished in a prosthetic-driven manner through the selection of potential implant sites with high bone density calculated in HU pre-operatively leading to high maximum applied insertion torque value at the time of placement. Critical selection of these sites through bone density assessment in cross sectional views using computer-guided implant software may be helpful in identifying the best potential implant site with proper position and angulation in relationship to the radiographic prosthesis. The results of this study are consistent with the conclusions of Meredith and Sennerby, that the primary stability is influenced by the local bone quality/quantity, the geometry of the implant (length, diameter, and type), and the surgical placement technique implemented (82,90).

One dental implant initially selected for the study was not included in the statistical analysis because simultaneous internal sinus lift was performed at the time of placement to achieve the clinical outcome. Three other implants were placed using the same stereolithographic surgical guide and were included in the statistical analysis. An ISQ value of 74.67 ± 0.52 and an insertion torque value of ≤ 25 Ncm was recorded at this time of placement for this dental implant not included in the statistical analysis. The mean ISQ recorded for this dental implant would have been the third highest out of the 19 implants included in this study. A

mean circumferential mean bone density of -53 ± 359 Hu was quantified for this dental implant using Facilitate™ Pro software pre-operatively.

The negative value for the mean bone density and high standard deviation for this dental implant was most likely a result of the extremely low mean bone density recorded in the apical region of this dental implant quantified at -629 ± 47 Hu. Pre-surgical planning using Facilitate™ software provided pertinent information to maximize the implant length to achieve proper implant stability of the dental implant in an area with poor bone quantity and quality. This example illustrates how the surgical approach can be modified using computer-guided implant software to maximize the length of a dental implant to increase the primary stability. The rationale for not including this implant into the statistical analysis was to standardize the surgical approach when measuring the implant stability parameters after placement using a stereolithographic surgical guide.

Comprehensive prosthetic planning using computer-guided implant software allows for an accurate preoperative assessment of the patient's craniofacial structures to properly select potential dental implant sites. This allows the clinician to position implants in an ideal prosthetic position to properly distribute loading forces, maximize implant length, and increase the primary stability. Increasing the primary stability can facilitate immediate loading protocols and may be accomplished by assessing the bone density of potential implant sites preoperatively. The critical evaluation of the bone density using CT and bone quantity using CT pre-operatively allows the clinician to determine whether or not bone grafting procedures are needed prior to placement or can be completed during implant placement. Another benefit of computer-guided implant planning is to eliminate potential errors associated with manual implant placement such as perforation, incorrect alignment, and incorrect depth.

A critical factor in the comprehensive diagnosis and treatment planning process for computer-guided implant therapy is the conversion of the final prostheses wax-up to the radiographic prosthesis. An accurate transfer from the wax-up to the conversion of the radiographic prosthesis can be accomplished through a sequence of steps which includes: proper articulation of all models using a semi-adjustable articulator, knowledge of dental materials, proper dental stone technique, meticulous full contour wax-ups, accurate duplication of the wax-up, accurate fabrication of the barium sulfate radiographic marker, adjustment of the radiographic prosthesis after patient try-in, and stabilization of the radiographic prosthesis during CT with a radiolucent bite registration. Without the proper execution of these critical planning steps, definitive implant placement can be errant and the final prosthetic result may be compromised.

The assessment of primary stability after placement of a dental implant is a crucial component in the decision making process to determine whether immediate or early loading protocols can be implemented. Insertion torque value and the use of RFA to measure the ISQ value have been deemed acceptable modes of measurement to quantify the primary stability after dental implant placement (82,90,150,112,113,180-182). The secondary stability of the dental implants used in this study was not evaluated. Monitoring a dental implant after placement using RFA has been used to evaluate successful osseointegration, identify a non-rigid connection at the bone-implant interface, identify instances where a longer healing period is indicated, or identify loading conditions that need to be re-assessed due to consecutively low ISQ values recorded over a specific amount of time (82,90).

Using RFA as a stability determinant during immediate or early loading protocols may not be indicated due to the wide range of acceptable ISQ values based on the specific implant

geometry and surgical technique reported in the current literature (90,122,141). Studies have concluded that dental implants placed in soft, medium, and dense bone show a slight decrease in stability probably as a result of bone remodeling during the first 1 to 12 weeks but reach similar resonance frequency values after loading irrespective of initial stability at the time of placement (109,112, 116,124,130-133,135,304). The decrease of the ISQ value after dental implant placement as a result of the inverse relationship between primary and secondary healing could limit the use of RFA as a quantifiable predictor of determining whether or not to implement implant loading protocols at the time of placement. A quantified threshold for immediate loading procedures based on ISQ values using RFA has not been established for immediate or early loading procedures in the current literature, RFA is most reliable in the determination of successful osseointegration.

In summary, the results from this study suggest that Facilitate™ may be used in cross sectional views to assess bone density in Hounsfield units pre-operatively for potential implant sites in the coronal, midcrestal, and apical regions. When multiple measurements are made in a specific area of a potential dental implant site, the mean bone density in that area may be used to identify the relative probability of achieving primary stability in relation to the maximum applied insertion torque. If greater insertion torque value is correlated with primary stability, greater mean bone density particularly in the coronal and midcrestal regions could be predictive of implant stability at the time of placement.

C. **Limitations**

A critical limitation in this study was the low number of patients and dental implants included along with a short observation period of 2 years. The measurements for the ISQ using RFA was not utilized on any of the dental implants after surgical placement and ISQ values have

been found to decrease then increase after placement. An assessment of implant stability using RFA could be recorded in follow-up studies after placement to include other time intervals (2-, 4-, 8-, 12-, 16, and 24-weeks) to achieve a better understanding of the osseointegration process or secondary healing response using ISQ values measured with RFA as a means of quantification.

The accuracy for the placement of the dental implants in this study using a stereolithographic surgical guide with the methodologies described in this investigation has not been determined. As a result, the circumferential mean bone densities used to determine whether or not a positive correlation exists between insertion torque and the implant stability quotient can be questioned. Future studies involving the assessment of correlations between circumferential mean bone density, maximum applied insertion torque, and the implant stability quotient using computer-guided implant software will encounter similar predicaments. A determination will need to be made by the principal investigators in future studies whether or not the amount of radiation administered for a second medical grade CT after surgical placement to evaluate the accuracy of placement is relevant. The majority of the current literature to evaluate the accuracy of dental implants placed using a SLA surgical have been completed *in vivo* through the use of human cadavers to eliminate this obstacle. The methodologies of these studies raise other limitations associated with the results due to the use on non-vital craniofacial structures incorporated. Future studies involving computer-guided implant surgery using a stereolithographic surgical guide need to implement stringent protocols to validate correlations between circumferential bone density, insertion torque, and ISQ using RFA.

D. **Future Research**

This study could be utilized as a template for the creation of a comprehensive database for all patients seeking dental treatment using computer-guided implant placement in the Advanced Prosthodontics clinic at University of Illinois at Chicago. Similar spreadsheets and statistical analysis could be incorporated in the postdoctoral program to determine long-term correlations between mean bone density, insertion torque, and ISQ values using RFA. In this study, RFA recordings were only taken immediately following implant placement but future protocols could be implemented to evaluate ISQ values at 2 weeks, 4 weeks, 8 weeks, 12 weeks, and 6 month intervals. This data could identify secondary implant stability trends using RFA prior to and after the loading of an implant-supported prostheses with implants placed using a SLA surgical guide.

A second study could be conducted to follow-up CT scans of the patients included in this investigation to determine the accuracy of the protocols, instruments, and software utilized in this investigation. Further retrospective study on all patients treated with a stereolithographic surgical guide in the Advanced Prosthodontics department at the University of Illinois at Chicago could provide an opportunity to evaluate success or survival rates based on the type of prostheses. *Post hoc* measurements of the circumferential mean bone density calculated using CT could be incorporated into the database to determine trends.

A database of patients treated with a stereolithographic surgical guide can be collected overtime to provide an opportunity for long-term statistical analysis of the implant stability parameters discussed in this investigation. A properly organized database could determine if correlations are present between circumferential mean bone density, anatomical position, implant dimension/length, maximum applied insertion torque, and ISQ values. This data could be used

to determine proper thresholds that have not been established in the current literature for conventional or early loading procedures.

IV. CONCLUSION

Under the conditions of this study, the following conclusions regarding bone density, maximum applied insertion torque value, and the implant stability quotient may be drawn:

1. A positive correlation was detected between circumferential mean bone density quantified using CT and maximum applied insertion torque value for all implants ($r = 0.862$, $p < 0.001$).

2. No correlation was found between circumferential mean bone density quantified using CT and the mean ISQ values ($r = 0.275$, $p > 0.05$).

3. No correlation was found between mean ISQ and maximum applied insertion torque value ($r = 0.056$, $p > 0.05$).

4. A positive correlation was detected between mean bone density measured at the different regions of the dental implant (crestal, midcrestal, apical) and maximum applied insertion torque values ($p < 0.01$).

5. The highest mean bone density was found in the midcrestal region for all implants measured at 877 ± 24 HU, > coronal 865.88 ± 16.78 HU, > apical 811.58 ± 19.93 HU.

6. The circumferential bone density quantified using CT was the highest in the anterior mandible measured at 1055 ± 169 HU, > anterior maxilla 671 ± 112 HU, > posterior mandible 413 ± 140 HU, > posterior maxilla 380 ± 110 HU.

7. The high mean ISQ value of 72 ± 2.80 after dental implant placement relates to the surgical approach implemented using computer-guided implant software to maximize the length of a potential implant site to ≥ 11mm.

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