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EVALUATION OF THE FACTORS AFFECTING THE CRESTAL BONE LEVEL IN IMPLANTS WITH DIFFERENT DESIGNS

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Ph.D. Dissertaion

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I hereby declare that all information/data presented in this graduation project has been obtained in full accordance with academic rules and ethical conduct. I also declare all unoriginal materials and conclusions have been cited in the text and all references mentioned in the Reference List have been cited in the text, and vice versa as required by the abovementioned rules and conduct.

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DEDICATION

Without the assistance and support of kind people in my life, only a few of whom may be specifically mentioned here, I would not have been able to complete this PhD thesis.

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ABSTRACT

EVALUATION OF THE FACTORS AFFECTING THE CRESTAL BONE LEVEL IN IMPLANTS WITH DIFFERENT DESIGNS

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OBJECTIVE: The aim of this study is to evaluate the amount of marginal bone loss (MBL) in implants with different macro-designs at the neck portion and, to evaluate the effect of patient related factors on MBL.

MATERIALS AND METHODS: Thirty-two subjects with single tooth loss in the posterior maxillary or mandibular sites were included and randomly assigned into test (n=16) or control (n=16) groups. Full-mouth clinical periodontal measurements consisting of probing pocket depth (PPD), clinical attachment level (CAL), bleeding on probing (BOP) and plaque indices were recorded. Also, vertical mucosal thickness (VMT) and keratinized tissue width (KTW) at the edentulous site were recorded at baseline. Implants with different macro-designs (DTI Power 4 or DTI-1 standard) were placed into the maxillary or mandibular posterior edentulous sites of the subjects in the test and control groups, respectively. MBL was evaluated by measuring the distances between implant shoulder (IS), the most coronal portion of the crest (C) and the first bone-implant contact (fBIC) on the standardized peri-apical radiographs which were taken at 10 days, 3 and 6 months following the one-stage implant surgery. Implant stability was evaluated by resonance frequency analysis (RFA) performed at the day of surgery and at 3rd month. Inter- and intra-group comparisons at

different time points and the correlations between different variables were analyzed by non-parametric tests.

RESULTS: Radiographic measurement of IS-C and IS-fBIC distances were lower at 3rd and 6th month follow-ups compared to baseline in both control and test groups ($p<0.01$), however no differences were found between the groups in terms of MBL amount ($p>0.05$). Stability of the implants in both groups were higher at 3rd month in comparison to baseline ($p<0.05$), with no statistically significant differences between the groups ($p>0.05$). There was positive correlation between VMT, KTW and IS-C-d distance at 3rd and 6th months in the control group. KTW and IS-C-m distance were positively correlated at 6th month in the test group.

CONCLUSION: MBL is a multifactorial phenomenon that may be controllable, however, implant macro-design does not seem to affect MBL. Long-term studies should be conducted to observe the impact of implant and patient related factors on MBL.

Keywords: Marginal Bone Loss, Implant Macro-design, Vertical Mucosa Thickness, Keratinized Tissue Width, Implant Shoulder.

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ABBREVIATIONS

MBL	:	Marginal Bone Loss
AH	:	Abutment hEight
PEEK	:	Polyetheretherketone
SLA	:	Sandblasted, Large-Grit and Acid-Etched
TiO2	:	Titanium Dioxide
STI	:	Soft Tissue Integration
PS	:	Platform Switch
PT	:	Placement Torque
RFA	:	Resonance Frequency Analysis
PTV	:	Periotest Value
ISQ	:	Implant Stability Quotient
RCT	:	Randomized Controlled Clinical Trial
ASA	:	American Society of Anesthesiologists
FMPS	:	Full Mouth Plaque Score
KMW	:	Keratinized Mucosa Width
PPD	:	Probing Pocket Depth
CAL	:	Clinical Attachment Level
CEJ	:	Cemento-Enamel Junction
BOP	:	Bleeding on Probing
PI	:	Plaque Index
fBIC	:	First Bone Implant Contact

IS : Implant Shoulder

C : Crest

VMT : Vertical Mucosal Thickness

1. INTRODUCTION

In contemporary dentistry, the dental implant therapy is considered as a safe and effective option for the rehabilitation of partial or fully edentulous patients. In implant therapy, it is aimed to attain the long-term functional, aesthetic, and phonetic requirements of patients. Therefore, researchers emphasize the importance of success rates in both surgical and prosthetic aspects of the therapy (Albrektsson, Zarb, Wothington, Eriksson, 1986).

In recent years, implantology studies have shifted their priority from implant survival rates to the quality of survival rates, which are determined as success rates. The long term cumulative mean implant survival and success rates for dental implants are reported to be 94.6% ± 6% and 89.9% ± 10.2% after mean post functional loading periods of 13.4 years and 15.7 years, respectively (Moraschini, Poubel, Ferreira, Barboza, 2015). Stabilization and long-term preservation of peri-implant hard and soft tissues are of primary importance in achieving success. According to success criteria defined by Albrektsson et. al, 1986 detection of marginal bone loss (MBL) less than 2 mm within the first year of functional loading, followed by 0.1–0.2 mm of MBL in each subsequent year has been considered as a natural process. Also, it is reported that following implant placement and functional loading crestal bone height is reduced because of remodelling of the bone (Araujo, Lindhe, 2018). Although there is no consensus, there are number of factors that are suggested to play role on MBL levels such as macro and micro designs of the implants, apico-coronal positioning of the implant in relation to bone crest (Valles, Rodríguez-Ciurana, Clementini, Baglivo, Paniagua, Nart, 2018; Valles, Rodriguez-Ciurana, Muñoz, Permuy, Lopez, Nart, 2018) vertical tissue thickness (Suarez-Lopez Del Amo, Lin, Monje, Galindo-Moreno, Wang, 2016), surgical trauma (Blanco, Pico, Caneiro, Novoa, Batalla & Martín, 2018; Albrektsson, Chrcanovic, Östman, Sennerby, 2017), occlusal overload, microleakage, biological width formation (Oh, Yoon, Misch, Wang, 2002; Hermann, Lerner, Palti, 2007; Hermann, Buser, Schenk & Cochran, 2000), location of the implant–abutment micro gap (Schwarz, Hegewald, & Becker, 2014; Strietzel, Neumann , Hertel, 2015), number of abutment disconnections/reconnections (Atieh, Tawse-Smith, Alsabeeha, Ma, Duncan, 2017), and abutment height (AH) (Galindo-Moreno, Leon-Cano, Monje, Ortega-Oller, Valle, Catena, 2016). Regarding the effect of macro design, various modifications are made in the implant-abutment connection and in the neck portion of implants, in order to reduce the stress in the

coronal region of the implant and to prevent MBL that may occur in short and long term (Derks, Schaller, Hakansson, 2016). Thickness of the bone at the time of implant placement influences the initial bone resorption around implants and in the literature, it is recommended to have minimum 2 mm of bone thickness in order to achieve stability of peri-implant bone and mucosa (Aizcorbe-Vicente, Javier, 2020). Implant macro design which allows to have increased bone thickness in the marginal portion of an implant may have beneficial effects in order to avoid MBL at the initial phase of the healing.

Predictable success rates for dental implants can only be achieved with a careful combination of clinical and radiographic evaluations (Yepes, Al-Sabbagh, 2015). Radiographic monitoring with the use of long-term standardized radiographs is essential for the accurate determination of changes in the marginal bone level (Payne, Solomons, Lownie, 1999; Parashis, Andronikaki-Faldami, Tsiklakis, 2004; Tsitoura, Tucker, Suvan, Laurell, Cortellini, Tonetti, 2004). The standard method for measuring marginal bone levels around implants is scanned and digitized conventional periapical radiography (Batenburg, Meijer, Geraets, Stelt, 1998; Bittar-Cortez, Passeri, Almeida, Haiter-Neto, 2006).

In the light of these information, it is hypothesized that the use implants with a macro design of reduced diameter in the most coronal portion, may lead to have increased bone thickness around the implants which in turn may cause less MBL.

The purposes of the current study are:

a. to evaluate the amount of MBL in implants which have different macro designs at the neck portion and,

b. to determine the effect of patient related factors such as smoking and mucosal thickness on crestal bone level changes around one-staged dental implants.

2. LITERATURE REVIEW

2.1 DENTAL IMPLANTS

2.1.1 Structural Properties of Dental Implants

Dental implant therapy has a high survival and success rates and Albrektsson et al. (1981) reported that the structural design features of implants have a direct impact on the survival and success rates. While classifying the designs of dental implants, two main factors come to the fore: the micro- and macrostructural features of the implants (Sykaras, Iacopino, Marker, Triplett, Woody, 2000).

Components in the microstructure:

a. Implant materials

b. Surface properties

Components in the macrostructure:

a. Implant body
b. Groove design
c. Design of the neck region

2.1.1.1 Microstructural features of dental implants

Implant materials

Titanium and its alloys are used almost exclusively for dental implants at the present time. As dental implant materials, various other metal alloy combinations, polymers, and ceramics have been proposed and/or considered. Polyetheretherketone (PEEK) and zirconia are two that deserve discussion.

PEEK is an organic synthetic polymeric material with excellent chemical resistance and biocompatibility. Young's modulus of unaltered PEEK material is 3.6 GPa, while carbon fiber-reinforced PEEK (CFR-PEEK) is close to bone (14 GPa) (Mishra, Chowdhary, 2019). PEEK exhibits less stress shielding when used in load-bearing situations compared to titanium and other metal alloys (Lee, Koak, Lim, Kim, Kwon, Kim, 2012). However, before this intriguing material could be used as a potential alternative to titanium dental implants , additional research is required.

In the past decade, zirconia has acquired considerable popularity in implant dentistry (Chopra, Jayasree, Ivanovski, 2022). As a replacement for aluminum oxide implants, zirconia ceramics with enhanced features are being used. The white, opaque color and findings of high biocompatibility and low bacterial plaque retention make zirconia an appealing biomaterial (Cionca, Hashim, Mombelli, 2017). Zirconia possesses a number of advantageous mechanical features, such as low thermal conductance and high strength of bending, favorable resistance to be fractured, and erosion and corrosion resistance. Zirconia's remarkable properties are the result of a phenomenon known as phase transformation toughening (Sanon, Chevalier, Douillard, Cattani-Lorente, Scherrer, Gremillard 2015).

A disadvantageous characteristic of zirconia is that it degrades at low temperature. When water is present, the weak transformation from tetragonal to monoclinic phase induces the gradual deterioration of the material via the slow development of roughness (Kelly, Denry, 2008).

Zirconia implants have several advantages over titanium implants, the gold standard. Their opaque color is advantageous for the aesthetics of the mouth. It has been reported that their soft-tissue integration is more favorable than that of titanium implants (Roehling, Schlegel, Woelfer, Gahlert, 2019). They have a lower affinity for bacterial plaque. In regard to osseointegration capacity, it has been shown that ZrO2 implants are equivalent to the 'gold standard' Ti implants (Janner, Bosshardt, Roehling, Milz, Higginbottom, Buser, Cochran, 2018).

Despite advances, there are still major concerns about mechanical stability and local cytotoxicity. Even in impaired patient conditions, zirconia implants will be manufactured with regulated bioactive features to expedite osseointegration (Chopra, Jayasree, Guo, Gulati, Ivanovski, 2022).

According to some investigators (Massa,Von Fraunhofer, 2021), titanium alloys are the mostly employed and preferred materials for dental implants. Ti6A14V and commercially pure titanium are used for endosseous implants. These alloys consist primarily of oxygen, titanium, and additional elements.

ISO standard 5832-2 classifies CP-Ti into four categories based on impurity content (such as carbon and oxygen). The primary distinctions between grades are oxygen content, corrosion resistance, flexibility, and endurance .

a. CP Grade I Titanium

b. CP Grade II Titanium

c. CP Grade III Titanium

d. CP Grade IV Titanium

At 0.4%, Grade IV CP-Ti contains the most oxygen. Nitrogen, carbon, hydrogen, and iron are also present, but their proportions do not vary significantly between grades; iron is added to increase corrosion resistance. Changes in the concentrations of these alloys' minor elements can significantly alter their mechanical and corrosion properties. Titanium is alloyed to improve its strength, corrosion resistance, and machinability, as well as to reduce its modulus of elasticity. In comparison to CPTi, Ti-6Al-4V has superior yield strength and fatigue properties, superior corrosion resistance, and a lesser modulus of elasticity (Liu, Chen, Tsoi, Matinlinna, 2017). However, the disadvantages of low wear resistance and low shear strength (Kong, Chen, Zhang, 2011) of Ti-6Al-4V alloy prevent its use as an implant or as a fastener. This phenomenon is known as the "stress shielding effect" (Niinomi, Nakai, 2011), and it is caused by the disparity in stiffness between implant material and surrounding bone. Appropriate surface treatments are suggested to enhance the situation.

Titanium, both as a pure metal and as an alloy, is easily passivated, forming a stable TiO2 (titania) surface oxide that makes the metal corrosion resistant. This oxide will repair itself instantaneously from damage such as that which might occur during the insertion of an implant (Guo, Gulati, Arora, Han, Fournier, Ivanovski, 2021a). The surface properties of implants are important for the biological response of the body to the materials (Guo, Gulati, Arora, Han, Fournier, Ivanovski, 2021b). Recently, Roxolid® (Straumann, Basel, Switzerland), a new alloy that can be used especially in bone conditions where a narrow-diameter implant needs to be placed, has been launched (Grandin, Berner, Dart, 2015; Karl, Krafft, Kelly, 2014). This alloy is made of 83–87% titanium and 13–17% zirconium; it consists of a combination of the two, and it is stated that it shows better tensile force resistance, fatigue resistance, and bone-implant integration than CPTi and Ti-6Al-4V (Gottlow, Dard, Kjellson, Obrecht, Sennerby, 2012).

Implant surface properties

It is known that the morphology, chemistry, electrical charge, and wettability of implant surface properties are important factors that are effective in achieving osseointegration. The modifications made to the implant surface properties play a role in the osseointegration process by affecting the adsorption of proteins, adhesion of osteoblastic cells, and cell-tissue formation at the bone-implant interface (Buser et al. 2004; Brett et al. 2004). Although titanium used in dental implants is a highly biocompatible material, it has been reported that it cannot stimulate bone attachment on its own. In order for early hard and soft tissue integration to occur, it also needs certain surface treatments of titanium to shorten the treatment time (Wiskott, Belser, 1999; Avila, Misch, Galindo-Moreno,Wang, 2009). During the last 30 years, many techniques related to surface topography, both physical and chemical, have been developed in order to improve osseointegration and increase stabilization (Coelho et al. 2009; Albrektsson 2004).

Implants with a rough surface of less than 1 m are classified as having a polished surface; those with a rough surface of 1 m and more than 1 m are classified as having a rough surface. According to a theoretical approach, it has been stated that for ideal roughness on the implant surface, it will be sufficient for the hemispherical dimensions of the microscopic cavities created to be 1.5 m deep and 4 m in diameter (Hansson, Norton, 1999).

Sandblasted, large-grit and acid-etched (SLA)

SLA surface is created by bombarding the implant surface with particles such as silicon, aluminum, titanium dioxide, and absorbable bio-ceramic at high speed. Following this process, implant surface is cleaned with acid etch. Also, to enhance hydrophilicity, implants are submerged in low pH isotonic solution. This process generates a hydrophile surface, referred to as SLA active (Agroya et al. 2020). Currently, the majority of implants utilize SLA technology to modify the surface.

Anodic oxidation

Anodic oxidation aims to thicken the TiO2 layer with to enhance the implant surface features (Anil, Anand, Alghamdi et al. 2011). The anodic oxide FLM is produced by the charge of the double electric layer at the interface between the metal and electrolyte. The process consists of dissolving an oxide layer sustained by an electric field and accelerated by

temperature. It additionally includes the production of an insoluble salt in an electrolytic bath.

Mild microrough surface increases bone-implant contact area and thickness of oxide layer. In a meta-analysis, it is reported that anodized implants supply more adhesion site for the cells which enhances osseointegration (Misch, Albrektsson, 2017).

Surface process with Laser

Implant surface process with lasers is growing as an option for the modification of the surface. Also, it may form a surface which is micro-rough with grooves on Ti surfaces that are distributed in a uniform or random way. This offers many advantages for mechanical treatments, such as production of fewer metal particles (Chen et al. 2017; Blázquez-Hinarejos et al. 2017).

In addition, unlike the aforementioned techniques, laser processing is primarily concerned with enhancing the soft tissue implant integration. Implant neck portion's surface which is micromachined with laser may contain microscale and nanoscale channels. These microchannels are thought to function as biological seal that elicits bone and connective tissue adhesion and prevents downgrowth of the epithelium (Nevins et al. 2010).

Titanium plasma spraying deposition

The technique entails igniting 40-m-sized titanium particles with a plasma flame and spraying them onto a titanium surface at high speed and temperature to ensure their fusion with the surface (Le Guéhennec, Soueidan, Layrolle, Amouriq 2007). Observations indicate that the irregularity formed around the entire implant in titanium plasma spraying (TPS) enhances tensile strength by increasing bone-implant surface area (Buser, Schenk, Steinemann, Fiorellini, Fox, Stich 1991). Utilizing the plasma made up of argon and hydrogen, particles of titanium hydride are sprayed to the surface at a speed of 3000 m/s and a temperature between 15000 and 20000°C. The obtained surface coating has a thickness of 20 to 30 m and a porosity depth of approximately 15 m (Leize, Hemmerle, 2000). In implants exposed to surface coating treatment with TPS, an enhancement in the bone-implant surface area, the emergence of a tight bond among the decking surface and the implant surface, and the circumference of the implant bone were observed. As a result of its benefits, including

the observation of an enhancement in its attachment, TPS is widely used in the coating of dental implants today.

2.1.1.2 Macrostructural features of dental implants

Generally, macro-scale changes affect primary stability and provide mechanical connection of implants and tissues, thereby prevent micro-motion that can be detrimental for osseointegration (Hyo-Sook, Cheol, Jong-Ho, 2014). Applying a macro design to expand the surface area and to prevent concentrated stress on bone is essential for osseointegration and implant survival (Barfeie, Wilson, Rees, 2015). Design of implant body, thread design, and thread distances are mechanical characteristics that are associated with implant macrodesign (Dagorne, Malet, Bizouard, 2015).

Implant body shape

Dental implants are classified as eposteal implants (above the bone), transosteal implants (along the bone), and endosteal implants (intra-bone) according to their location in the bone (Rasmusson, Kahnberg, Tan, 2001). Among the numerous implant configurations designed and created since the discovery of osseointegration, the most commonly used ones today are endosteal implants.

Endosteal implants are classified as blade, cylinder, and screw types according to the geometric shape of the main part remaining in the bone.

a. Blade implants: These are endosteal implants consisting of titanium, nickel, and vanadium. They contain prosthetic restoration designs that are cemented after a recovery period of several weeks following their surgical placement (Linkow LI, 1969). The most common complication observed in blade-type implants is necrosis on the bone surface in contact with the implant, which occurs with the fibrous soft tissue growth and the progression of this phenomenon (James, 1980).Cylinder implants:

b. Cylinder implants provide integration with bone thanks to the roughening and coating processes on their surfaces. The created surface and the friction force between the roughness and the bone surface provide the primary stabilization of the implant, which is the basis for osseointegration (Buser, Weber, Lang, 1990).

c. Screw-type implants: The threads along the body of screw-type implants increase the contact area of the bone with the implant, increasing the primary stabilization, expanding the implant surface area, and decoupling the stresses at the interface. It is the most frequently preferred implant design in today's implantology. It has been reported that differences in thread designs affect force distribution (Abuhussein, Pagni , Rebaudi, Wang, 2010).

Thread designs

The structure of the implant's macro threads increases its stability and facilitates implantation. In addition, it enhances the area of bone cells to attach and fosters osseointegration at later stage. Also, it optimizes tension distribution, influences occlusal force transmission, and enhance the implant stability at longer term. Typical thread types are standard V-shape, square, circular, sawtooth, anti-sawtooth shape, and spiral shapes (Figure 2.1). There may be just a single thread shape, or various thread shapes at different parts of an implant. For instance, an implant may contain micro threads with a small pitch at the neck portion, broad or double threads in the middle third; and a self-tapping thread is in the apical third.

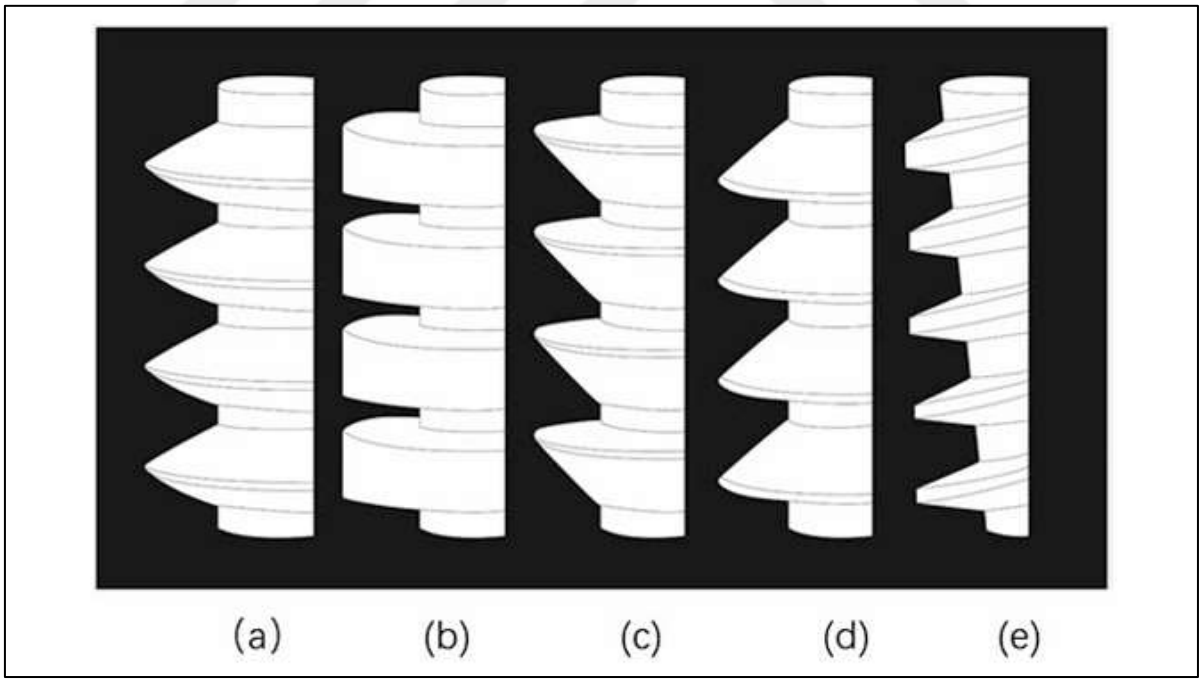


Figure 2.1: Different Thread Designs: a- Standard V, b- Square,c- Sawtooth, d- Anti-Sawtooth, e- Spiral.

Implant neck region design

The neck part of the implants is the area of the implant that provides a soft tissue transition area in contact with the oral cavity, which terminates in the body region that is completely within the bone. What makes the neck region designs different from other components is that the stresses that occur under function are observed most intensely around the crestal bone of the implant (Micsh, 2005). It's reported that the design of the implant neck region, together with the structure of the alveolar crest, the space width, and implant-abutment surface, play a primary role in tissue destruction (Oh, Yoon, Misch, Wang, 2002). Implant neck area or crest circle design also plays a crucial role in the long-term survival and success due to the effects on primary stabilization, the range of biological gaps, the consideration of loading conditions, and the protective surface (Hermann, Lerner, Palti, 2007).

Implant neck region design is evaluated in four main categories (Aparna, Dhanasekar, Lingeshwar, Gupta, 2012).

a. Form
b. Diameter
c. Surface properties
d. The existence of microthreads and microgrooves

Neck region form

Neck part of an implant may be designed as cylindrical, dish-shaped, or inverted dish-shaped. Several investigations have demonstrated that dish or reverse dish structure alter distribution of stress in the implants with cylindrical neck, thereby reduce cervical bone resorption (Rokn, Badri, Rasouli Ghahroudi, 2015;. Messias, Nicolau, Guerra, 2019). Microthreads can also be constructed to reduce neck stress and enhance the bone cell attachment area (Bateli, Att, Strub, 2011).

It has been stated that implants with a conical neck area with a rough surface have a greater bone to implant contact area than flat surfaced implants and a parallel neck design (Misch, Strong, Bidez, 2008). They predicted that as a result of the taper inclination making an angle of more than 20° with the outer axis of the implant body, the resistance to pressure and tension will increase and the MBL will be less. Studies reporting that the amount of stress in the neck region is affected by the form of this region have also reported that the conical neck

region has the most surface area with bone and shows the least stress formation (Shen, Chen, Hsu, 2010).

In addition to studies predicting that the conical type of neck region shape will reduce the amount of MBL, there are also studies indicating that, conical designs perform stress distribution around the implant more appropriately (Kong et al. 2008). Pozzi et al. (2012) have comparatively examined the MBL values in implants whose neck design has a reverse conical slope of 12° and has a parallel neck region form design. The authors claimed that the mean MBL of the reverse conical-shaped implants were measured as 0.68 mm and the mean MBL values of parallel-shaped implants were measured as 1.15 mm at first year and the difference was statistically significant.

Neck region diameter

It has been reported that the neck region which is diametrically wider than the outermost thread of the implant will create a plug effect at the osteotomy site during the surgical operation and reduce stress to the crestal region by increasing the surface area. It has been stated that this width of the diameter of the neck region prevents the progression of fibrous tissues with bacteria to the area during the healing period of the implant by acting as a barrier at the osteotomy site (Petrie, Williams, 2005).

In addition to the primary stability and intra-bone sealing advantages of the wider diameter of the neck region, the abutment provides a wider platform. In this way, it has been observed that it has prosthetic advantages by reducing the load on the prosthetic screw (Boggan, Strong, Misch, Bidez, 1999). Along with studies on the effect of increasing the diameter width on MBL formation in implants, there are also studies indicating that reducing the implant diameter thins the implant wall on the surface where the abutment-implant connection takes place and reduces its resistance to fractures (Schwarz, 2000).

Surface features of neck region

Surface morphologies of neck region designs of existing dental implants;

a. Flat/turned/polished structure
b. Modifications in continuity with the body surface properties of the implant in the rough structure

c. Existence of micro-beings.

Rough surfaces create a mechanical connection between the implant and the bone, creating the necessary stimulation for osseointegration (Wiskott, Belser, 1999). In studies comparing the flat or turned surface features of the neck region with rough neck areas (Bratu, Tandlich, Shapira, 2009; Nickenig et al. 2009), the authors reported that neck designs with a rough surface area caused less MBL at the crestal bone level. In an animal study, a total of 72 implants (4.1 mm diameter and 8 mm tall) were applied 36 flat or turned (2.8 mm high) neck areas, and MBL evaluation was performed at 1 year via periapical radiographs. As a result of the follow-up period, MBL values in the flat/turned neck region group were reported as an average of 1 mm, and the MBL in the rough-surface neck region group was reported as an average of 0.11 mm (Valderrama, Jones, Wilson, 2010).

In addition to the advantages of the implant neck region containing modifications in continuity with the surface characteristics of the trunk at the crestal bone level, there are also advantages in terms of peri-implant soft tissue. Without treatment of the surface, collagen fiber bundles originating from the subepithelial connective tissue and periosteum develop parallel to the long axis of the implant in the connective tissue layer (Shioya, Sawada, Miake, 2009).

Presence of microgrooves

The presence of microgrooves in the neck region as a retaining element helps to maintain the marginal bone according to Wolff's law, a theory that reveals that the structure of bones exposed to intermittent force becomes stronger and adapts itself in a healthy living being (Wolff, 1986). Lee et al. (2010) reported that the average MBL observed in neck-area of implants containing microgrooves was lower in MBL measurements performed on dental implants that they followed for 3 years under functional occlusal loads compared to implants with rough and polished neck-area surfaces. In addition to maintaining the level of crestal bone, it has also been shown in experimental studies that the presence of microgrooves is more effective in ensuring and maintaining bone-implant contact compared to flat surfaces (Abrahamsson, Berglundh, 2006).

Along with the advantages of micro-grooved rough surfaces in the neck area for bone-implant integration by increasing the implant surface area, they may also carry risks in terms

of peri-implant mucosa and aesthetics. In cases where resorption is observed in the crestal bone due to poor bone quality or a lack of oral hygiene, rough micro-grooves are exposed to the oral environment and may form plaque accumulation (Quirynen, Bollen, Papaioannou, van Eldere, van Steenberghe, 1996). Implant surfaces that are rough and contain microfluids have more plaque retention than polished surfaces. The rough neck design is especially important for patients with a history of periodontitis. It has been stated that they can also cause the development of peri-implant mucositis and periimplantitis if they are exposed to the oral environment (Teughels, Van Assche, Sliepen, Quirynen, 2006).

Besides the presence of micro-fluids in the neck region, designs have emerged in recent years to increase the surface roughness and bone-implant contact area by opening micro-channels at the cellular level around the neck region using laser roughening (Figure 2.2).

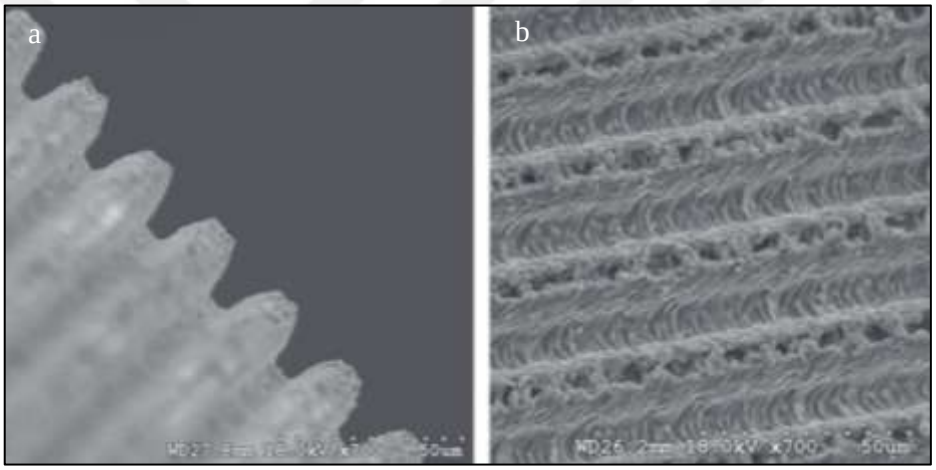


Figure 2.2: Scanning Electron Microscope Images of the Laser-Lok Surface Showing a Profile View of the Microchannels (a) and a Surface Picture of the Microchannels (b). Mag = 700x.

Platform switching concept

Since 2006, the platform switch (PS) concept has been defined as a long-term approach to reduce MBL in an effort to increase implant survival and success rates. The design feature of this concept is to bring the forces emanating from the abutment utilizing narrower diameter than the neck area of an implant which is closer to central axis than the crest module, where the most intense accumulation of stress is shown (Lopez-Mari, Calvo-Guirado, Martin-Castellote, 2009). It has been reported that with the medial positioning of the implant-abutment connection, the biological width is also provided horizontally, providing an additional barrier against bacterial leakage. PS concept allows to have an

additional area for soft tissue attachment, and it has been stated that it is effective in the stability of the hard and soft tissues around the implants and protection of the papilla, particularly in areas where aesthetics come to the fore (Atieh, Ibrahim, 2010).

2.2 PERI-IMPLANT TISSUES

Peri-implant tissue refers to the tissues that have accomplished osseointegration around the implant. The peri-implant tissue consists of both soft and hard tissues (Araujo, and Lindhe, 2018). The soft tissue section is known as "peri-implant mucosa" (Berglundh, Lindhe, 1996) and it is established during wound healing after abutment is connected (Tomasi, Tessarolo, Caola, Wennström, Nollo, Berglundh, 2014). Hard tissue section is the contact between bone and implant surface (Albrektsson, Brånemark, Hansson, Lindström, 1981). After 6 to 12 weeks of implant installation, the implant is approximately 60% surrounded by bone (Lang, Salvi, Huynh-Ba, Ivanovski, Donos, Bosshardt, 2011; Bosshardt, Salvi, Huynh-Ba, Ivanovski, Donos, and Lang, 2011; Donati, Botticelli, La Scala, Tomasi, and Berglundh, 2013). The primary function of the soft tissues is to protect the bone beneath implant's mucous membrane, while the hard tissue serves to support the implant. Damage to these tissues affects the implant's survival and success. (Derks, Tomasi, 2015).

2.2.1 Peri-implant Mucosa

The soft tissue surrounding a dental implant is called "peri-implant mucosa". Characteristics of peri-implant mucosa are developed following the closure of the mucoperiosteal flap in one-stage implant surgery or after the connection of healing cap in two-stage implant surgery.

There are significant distinctions between peri-implant mucosa and gingiva, despite the fact that they share many clinical and histological characteristics in common. In their study, Berglundh et al. (1991) compared the features of peri-implant mucosa and gingiva around tooth. Briefly, premolars in one side of the mandible were extracted, while the premolars in the contralateral site were left. Implants were installed and submerged after 3 months of healing following the extractions. After 3 months following the implant surgery, abutments were connected, and plaque-control regimen were applied. At 4^{th} month following the abutment installation, animals were sacrificed and biopsies from implant and tooth sites were taken. It was observed that both healthy gingiva and peri-implant mucosa were pink in color

and their consistency were firm. When radiographic analyses of tooth sites were performed, it was seen that alveolar bone crest was located approximately 1 mm apically to the cementoenamel junction (CEJ) of adjacent teeth. Bone crest in the implant sites were seen to be close the abutment and implant connection. Microscopically, gingiva and peri-implant mucosa were seen to share many features in common. In the gingiva, oral epithelium was keratinized, and the junctional epithelium facing the enamel ended at the CEJ. The dimension of the supra-alveolar connective tissue was 1mm and the width of periodontal ligament was 0.2-0.3 mm. Sharpey fibers were seen to extend from the root cementum into the hard tissues of periodontium. The peri-implant mucosa was also covered with keratinized epithelium which is continuous with a thin layer of junctional epithelium like barrier epithelium that is facing the abutment. The supra-alveolar connective tissue is in close contact with the implant surface. The collagen fibers that are originating from the periosteum are seen to extend parallel to the abutment surface. It was observed that the barrier epithelium ended at 1-1.5 mm distance from the bone. This portion is reported to be a biological attachment between connective tissue of peri-implant mucosa and the titanium surface of abutment. In other animal studies Abrahamsson et al. (2002) reported that mucosal attachment was formed in different types of implant systems, in either submerged or non-submerged implants.

Peri-implant tissues (Figure 2.3), unlike periodontal tissues, have no cement and no periodontal ligaments. In peri-implant tissues, the crestal bone and junctional epithelium are less vascularized than the periodontal connective tissue. (Tomasi, Tessarolo, Caola, Wennström, Nollo, Berglundh, (2014). Consequently, peri-implant tissues are more susceptible to disease than periodontal tissues (Araujo, Lindhe, 2018).

2.2.2 Transmucosal Attachment

The supra-crestal connective tissue located between the apical of the barrier epithelium and the bone surface is about twice the size of the tooth (1–1.5 mm). This supra-crestal connective tissue cannot be explained as a wound surface. It has been reported that titanium in the peri-implant mucosa of this feature has a significant effect on soft tissue defense against external irritations and adhesion to the abutment (Berglundh et al. 1991).

In their animal study, Berglundh et al. (2007) observed the improvement of the transmucosal connection around one-stage titanium implants. After 1 to 2 weeks of recovery, the first signs

of epithelial proliferation appeared, and the formation of mature barrier epithelium was completed after 6 to 8 weeks. Within 4 to 6 weeks of healing, collagen fibril regulation in the mucosa was complete.

In a preclinical in vivo study by Berglundh and Lindhe (1996), the location and the dimensions of transmucosal attachment were investigated. Two-staged implants were installed and at the 3rd month of healing, abutments were connected. While at one side of the mandible, the thickness of the mucosa was preserved, on the contralateral side, the mucosa thickness was surgically decreased to 2 mm or less and the flaps were closed. After 6 months, biopsies were taken, and it was observed that in all implant sites there was a barrier epithelium of 2 mm long and connective tissue attachment of 1.3-1.8 mm long with no exception. Moreover, at all sites with reduced mucosa thickness, marginal bone resorption was seen. The authors claim that marginal bone resorption occurred with an effort to establish a transmucosal attachment which includes both barrier epithelium and connective tissue compartments. The wound healing of peri-implant mucosa is a critical process which takes several weeks as the bone healing.

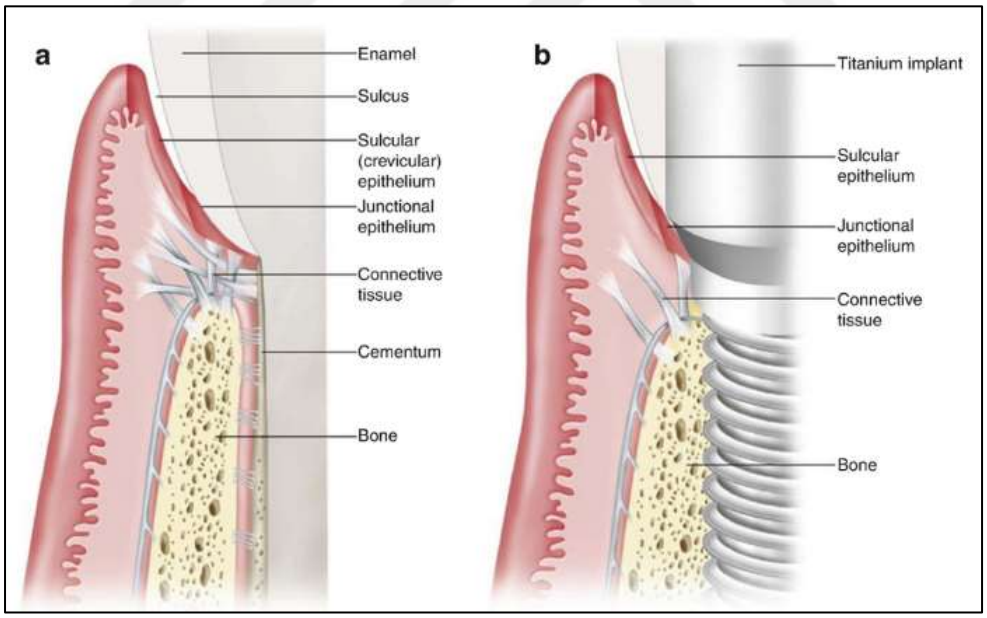


Figure 2.3: (a) The Hard and Soft Tissue Anatomy Surrounding a Natural Tooth (b) The Anatomy of Hard and Soft Tissues Surrounding an Implant.

[From Rose LF, Mealey BL: Periodontics: Medicine, surgery, and implants, St. Louis, 2004, Mosby]

2.3 OSSEOINTEGRATION

The term "osseointegration" was first introduced by Branemark (1985) and is defined as "the direct structural and functional connection at the light microscope level between the living bone and the load-bearing implant". Since, aforementioned definiton is a histological concept in which the contact between bone and implant can be determined by a light microscope; it is not clinically applicable. (Albrektsson, Sennerby, Wennerberg, 2008).

Therefore, Zarb and Albrektsson (1991) developed a new definition of osseointegration based on implant stability. According to these researchers, osseointegration is defined as a process that continues over a clinically asymptomatic and functional period, provided by the rigid fixation of alloplastic materials in the bone.

The main factors that are effective in achieving osseointegration (Misch, Perel, Wang, Sammartino, Galindo, 2008) are:

a. Biocompatibility of the implant material

b. The implant design

c. The implant surface characteristics

d. Transmission of the load

e. Surgical technique

f. Bone density

2.3.1 Bone-Implant Interface

This interface has a dynamic character with the potential to constantly reconstruct itself against forces (Elias, Brunski, Scarton, 1996). Two fundamental theories define the interface of bone and implants: osseointegration and fibro-osseous integration.

Numerous researchers over the years have supported the fibro-osseous integration theory, which states that integration cannot occur without a fibrous connective tissue consisting of organized collagen fibers between the implant and bone. In some cases, fibrous collagen tissue surrounds the implant before the integration of bone and implant during the healing phase. It has been determined that fibro-osseous integration can be organized at a certain

rate, but it cannot provide good support in the long term due to insufficient biomechanical capacity and is an indicator of failed osseointegration (Branemar, 2001).

With the advances in current implantology, this concept has also undergone modifications and is expressed as a direct connection between bone and implant (Mosby's, 2008).

2.3.2 Osseointegration Mechanism

Following the osteotomy stage, bone walls are flooded with blood, and hematoma formation is observed, just like in fracture healing. The first tissue that comes into contact with the implant is blood tissue (Marco, Milena, Gianluca, Vittoria, 2005). In the response that begins at the cellular level, erythrocytes transport oxygen, but they do not have an important role in early peri-implant tissue healing. Platelets are the most effective cells in the early period. Once the platelets are activated the degranulation of platelets is observed and the granular contents are released into the intercellular environment. Thus, many growth factors, such as platelet-derived growth factor (PDGF) and transforming growth factor beta (TGF-β), which play an important role in the wound healing process by triggering cell proliferation and migration, and vasoactive mediators such as histamine and serotonin, are ensured to be present in the environment.

Following the clot formation, adsorption of extracellular matrix proteins occurs from blood and tissue fluids to the implant surface. The orientations and compositions of these proteins vary according to the structural properties of the surface (Singhatanadgit, 2009). These proteins are responsible for the initiation of bone mineralization. Pro-callus, which consists of fibroblasts, fibrous tissues, and phagocytes, is formed within 1-3 days after implant installation. This structure turns into dense connective tissue and differentiates into mesenchymal cells, osteoblasts, and fibroblasts. Connective tissue that is rich in osteoblasts, called "callus", begins to be observed on the implant surface. Dense connective tissue forms a fibro-cartilogen callus that contains penetration of new bone and a new bone matrix and it is called "bone callus". At the implant-bone interface, bone trabeculae containing parallel fibrous, dense trabeculae, pronounced bone marrow cavities, and lamellar bone are monitored 28 days after the surgical procedure. At the 6th week, substantial amount of newly formed woven bone was present in close contact to implant surface along with lamellar bone and bone marrow. After 8–12 weeks, fully mature lamellar bone contacts implant surface histologically (Berglundh, Abrahamsson, Lang , Lindhe, 2003).

2.4 DENTAL IMPLANT STABILITY

Although the stability of dental implants depends on the nature of the contact between the bone and the implant surface, it is a prerequisite for achieving osseointegration and implant survival (Huang et al. 2011; Huang et al. 2010). Implant stability can be divided into two stages: primary and secondary stability (Jun et al. 2010). Primary stability is a mechanical parameter that exists between the cortical bone and the implant and is defined as the stability observed immediately following surgery. In primary stability, the implant is positioned rigidly within the bone cavity and lacks micromotion (Liu et al. 2012). However, despite their rarity, implants and bones are deformable structures due to functional forces. It is therefore inevitable that there will be micromovements between the implant and bone (Haïat, Wang, Brunski, 2014).

Since the density and hardness of cortical bone are higher than spongy bone, it also constitutes a more favorable mechanical retention for the primary stabilization. It has been stated that the reason for the higher implant loss rate observed in the posterior region of the maxilla is that primary stabilization cannot be achieved at the desired level due to low cortical bone density (Misch, 1999; Sennerby, Thomsen, Ericsson, 1992).

High primary stability assures the resistance of an implant against micromovements. For successful osseointegration, implants should not be subjected to micro-movements greater than 50-150m (Elias et al., 2012). A strong primary stability correlates positively with secondary stability (Davies, 1998).

Primary stability is necessary for implant healing, while secondary stability is necessary in reciprocating the functional forces in the long term (Cochran et al. 1996). Secondary stability is observed after the recovery period in the fourth week of healing. Until this time period, secondary stability remains at low values (Raghavendra, Wood, Taylor, 2005).

Factors affecting primary stability:

a. The amount of bone
b. Bone quality
c. Surgical technique
d. Implant macro-design

The factors affecting the secondary stability are:

a. Primary stability
b. Bone remodelling
c. Implant micro-design

While decrease in the secondary stability of an implant with high primary stability may be observed due to osteoclastic activity that may increase on the bone-implant interface during the healing period, secondary stabilization may increase as a result of bone attachment and remodelling in cases where primary stability cannot be ideally achieved (O'Sullivan, Sennerby, Jagger, Meredith, 2004).

2.4.1 Stability Measurement Methods

Implant stability measurement is essential for determining the extent of osseointegration during the recovery period, the time of implant loading, and for estimating the efficacy of implant systems. Reviewing the relevant literature shows that placement torque (PT), resonance frequency analysis (RFA), and Periotest® are most frequently used to evaluate the stability of implants. Nonetheless, histological examination, tension test, push-pull test, reverse torque test, shear torque analysis, percussion test, instrument test, and radiographic examination are also methods that are used to assess the implant stability.

2.4.1.1 Radiographic examination

Evaluation of radiographic techniques for stabilization is a method that can be applied at any stage of implant treatment. Traditional periapical radiographs are used for the evaluation of MBL in implants. However, it does not provide sufficient information in the evaluation of implant stability and in the evaluation of the MBL (Mall,Dhanasekar, Aparna, 2011).

2.4.1.2 Percussion test

The percussion test is performed using a metal blunt instrument. A clearly audible sound indicates a successful osseointegration, while a less intense blunt sound indicates the formation of a soft tissue capsule, and it is evaluated as an indicator of failure (Atsumi, Park, Wang, 2007).

However, it is a subjective method and is based on the experience of the examiner. Therefore, it cannot be used as a standard method in order to determine the implant stability (Park et al. 2011).

2.4.1.3 Placement torque

It is based on the principle of measuring the torque force required to open the groove in the slot when placing the implants at a low speed during implantation. PT was previously considered as a parameter to evaluate bone quality during surgical procedure (O'Sullivan, Sennerby, Jagger, Meredith, 2004; Meredith, 1998). However, many authors have recently stated that this measurement is an indicator of primary stability (Homolka et al. 2002; Trisi et al. 2009; Farré-Pagès et al. 2011).

Minimum pressure should be applied to the cortical bone during implant placement (Barone et al. 2016). There are studies in the literature showing that the torque values in the range of 25-45 Ncm may prevent negative micro movements during loading and allow the osseointegration process to occur (Trisi et al. 2009).

The limitation of PT is that the bone density, bone quality and the predicted primary stabilization cannot be obtained before the osteotomy (Friberg, Sennerby, Roos, Lekholm, 1995).

In an in-vitro study, it was reported that a high torque value will reduce the micro-movement between the implant and the bone (Trisi et al. 2011). However, it is believed that high torque values will cause excessive lateral forces and high mechanical stress in the bone, which in turn may have negative consequences on local micro-vascularization and cellular responses of the bone. This may lead to bone necrosis and consequently, delayed, or damaged osseointegration (Coelho et al. 2010).

2.4.1.4 Periotest

Periotest was originally designed to assess tooth mobility, periodontal tissue function, and the dynamic measurement of periodontium. Later, it began to be utilized for evaluating implant stability (Olivé, Aparicio, 1990). Periotest® evaluates the damping characteristics of the periodontium. It is designed to identify the damping capacity of a natural tooth or implant by measuring the contact time of an electronically used and electronically monitored rod

after percussion on the test surface. The results are obtained as a digital Periotest Value (PTV) and vary between +8 (low mobility) and -50 (high mobility). An osseointegrated implant is expected to have PTV within the range of -5 to +5. However, it has been stated that Periotest is not sensitive enough to determine the stability of the implant, and RFA provides more reliable results (Homolka et al. 2002; Turkyilmaz et al. 2006).

2.4.1.5 Resonance frequency analysis (RFA)

RFA is a non-invasive method developed by Meredith (Meredith, Alleyne, Cawley, 1996) in 1996 and it allows reliable and repeatable evaluation of both primary and secondary stability. This RFA system is commercialized as Osstell™ (Osstell AB, Gothenburg, Sweden). In RFA, bone density and stability are evaluated by vibration and structural analysis. The resonance frequency is measured by means of a small transducer that is screwed onto the implant or abutment with a force of 5-10 Ncm (Meredith et al. 1997; Aparicio, Lang, Rangert, Validity, 2006).

When the RFA technique was first developed, the resonant frequency values obtained as Hertz were converted into the 'Implant Stability Quotient (ISQ)' score with the development of the technique. A 1-unit change in the ISQ score is equivalent to 50 hertz in resonance. ISQ values range from 0-100 and low ISQ values are related to weak stability, while high ISQ values are indicator of strong stability (Friberg, Sennerby, Meredith, Lekholm, 1999; Lachmann et al., 2006).

Although the RFA method is a newer technology compared to other stabilization measurement methods, it can measure a complex system including shearing, tensile and compressive forces, changes in stability and elasticity at the implant-bone interface. Therefore, it has become a popular system to evaluate the stability and to distinguish between successful implants and clinical failures (Meredith et al. 1997). The main factors affecting the stabilization values measured with RFA are the surface properties, length, geometry and the position of the implant, abutment length, prosthetic loading time, gender, bone density and quality, three-dimensional bone-implant contact area and the connection of the transducer with the implant (Jackson et al. 2008; Zix, Kessler, Liechti, Mericske, 2005; Rompen, DaSilva, Lundgren, Gottlow, Sennerby, 2000; Pimentel Lopes, Oliveira, 2016; Glauser et al. 2001; Östman, Hellman, Wendelhag, Sennerby, 2006).

2.5 ONE STAGE AND TWO STAGE IMPLANT SURGERY

The healing following implant placement can take place in one or two stages depending on the position of the implant at the level of the crestal bone. When implants with two parts are placed and the mucoperiosteal flap is primarily closed, it is called 'two-stage implant surgery'. However, when the healing cap is connected at the time of implant surgery and the mucoperiosteal flap is closed around the healing cap, it is called 'one-stage implant surgery'. When the two-stage implant surgery is applied, second surgery is performed to connect the healing cap following the osseointegration period. Both techniques have their own advantages and disadvantages (Hermann, Buser, Schenk, Schoolfield, Cochran, 2001; Sclar, 2003).

2.5.1 Two-Stage Implant Surgery

Primary advantage of two-stage implant surgery is the osseointegration process occurs independently of oral hygiene or anaerobic bacteria infiltration. There are more prosthetic options in two-stage implants compared to one-stage implants and surgical errors may be corrected, and it allows to form nice emergence profile, especially in the anterior aesthetic region (Albrektsson, Zarb, 1993). Also, second surgery allows to evaluate facial-crestal region directly before prosthetic step (Qian, Wennerberg, Albrektsson, 2012). The disadvantage of the technique is that it requires a second surgery to expose the implant.

2.5.2 One-Stage Implant Surgery

The main advantage of one-stage surgery is the absence of second surgery. As the bone interface heals, the soft tissue healing, and maturation occurs simultaneously. This allows the soft tissue profile to be fully evaluated during restoration. In order to be able to place the implants in a single stage, the placement torque value should be above 35 N/cm. If primary stability cannot be achieved, the implant should be left for two-stage healing (Sclar, 2003).

2.6 MARGINAL BONE LOSS AND FACTORS AFFECTING MARGINAL BONE LOSS

Bone loss that occurs in the crestal bone in the early or later period after implant placement is called MBL. Implants in cases where the marginal bone level can be consistently monitored have been considered successful (Qian, Wennerberg, Albrektsson, 2012; Albrektsson, Zarb, 1993).

Early MBL is defined as the bone resorption around the neck portion of a dental implant from the time of implant surgery to one year following the functional loading. This definition is based on the implant success criteria proposed by Albrektsson et al. (1986), which state that 1.5 mm of bone loss during the first year of loading can be regarded as success if subsequent bone loss does not exceed 0.2 mm per year. This concept was derived from observations of the original Branemark implants; however, modern implants have superior designs and surfaces, resulting in greater success and bone stability. Consequently, some recent studies have questioned the generally accepted success criteria and claimed that it is feasible for implants to experience less bone loss after one year of function. According to these reports, implants with micro threads in the neck region and with a conical implant-abutment connection are predicted to experience only 0.33 to 0.56 mm of bone loss after 12 months of loading (Norton, 1998; Norton, 2006). However, on the contrary, in a cross-sectional study of 6129 implants performed in the United States, it was observed that 34% of patients and 21% of implants had radiographic bone loss of 2 mm or more at the end of 3.5 years of follow-up (Kordbacheh, Finkelstein, Papapanou, 2019).

In the consensus report by Berglundh et al. (Berglundh, Armitage, Araujo, Avila-Ortiz, Blanco, Camargo, Zitzmann, 2018), it was reported that in epidemiological studies, bone loss of 3 mm that is observed on radiograph taken at least one year after the first bone remodelling, is among the criteria for the diagnosis of peri-implantitis . However, in this report, it was stated that there is a need for studies with randomized selected patient groups and sufficient cohort size, in which marginal bone level changes are ideally evaluated.

According to Linkevicius (2019), the old implant dentistry standards that consider 1 mm of MBL around implants within the first year as normal, should no longer be considered valid. The bone may respond differently to the presence of implants. These responses are as follows;

a. Zero bone loss
b. Stable remodelling
c. Progressive bone loss
d. Bone demineralization and remineralization
e. Corticalization
f. Bone growth

2.6.1 Patient Related Factors

2.6.1.1 Age

As a consequence of aging, there are changes at the molecular, cellular, and systemic levels of wound healing (Bartold, Ivanovski, Darby, 2016). Age-related increase in fibroblast-secreted inflammatory mediators and a protracted inflammation phase may delay wound healing (Arancibia, Oyarzún, Silva, Tobar, Martínez, Smith, 2013). The delay in wound healing is believed to be a result of both aging and the increase in chronic systemic diseases observed in older adults. Recent studies have shown that older age is not a cause of premature implant loss. In addition to delayed wound healing in older patients, lack of the maintenance of adequate oral hygiene, limited access to supportive periodontal therapy, and difficulty in using removable prostheses are other limitations related to older age (Schimmel, Srinivasan, McKenna, Müller, 2018; Bertl, Ebner, Knibbe, Pandis, Kuchler, Ulm,Stavropoulos, 2019).

2.6.1.2 Gender

The fact that osteoporosis, which can be caused by the post-menopausal effect, affects older females more frequently than males has led to the investigation of this factor (Moy, Medina, Shetty, Aghaloo, 2005). There are studies in which failure rates in females are higher, however there are also other studies with controversial results. In the majority of studies (Smith, Berger,Dodson, 1992; Chuang, Wei, Douglass, Dodson, 2002; Derks, Schaller, Håkansson, Wennström, Tomasi, Berglundh, 2016) there is no significant difference between male and female in terms of dental implant success and MBL.

2.6.1.3 Systemic diseases and medication

In numerous experimental and clinical investigations, the effect of systemic diseases on the survival and success of dental implants has not been conclusively proved. It has therefore been not possible to conduct controlled investigations. While these factors may increase the risk of complications following implant surgery in the early period, they may affect long-term survival and success by affecting osseointegration and marginal bone stability (Bornstein, Cionca, Mombelli, 2009 ; Donos, Calciolari, 2014; Aghaloo, Pi-Anfruns, Moshaverinia, Sim, Grogan, Hadaya, 2019).

In systematic reviews and/or meta-analyses, it has been observed that diabetes and osteoporosis have detrimental effects on tissue healing and biology. Diabetes mellitus is an

insulin-dependent (Type 1) or insulin-independent (Type 2) disease systemically characterized by retinopathy, neuropathy, nephropathy, micro- and macro-vascular disorders, and a delay in wound repair. Xerostomia in the oral cavity increases the incidence of dental caries and the susceptibility to periodontitis (Bornstein, Cionca, Mombelli, 2009). Early failures have been observed in dental implant patients, particularly when there is no diabetic control (Schimmel, Srinivasan, McKenna, Müller, 2018). Osteoporosis is a disease characterized by decrease in bone mass and density and an increase in the incidence of bone fractures (Aghaloo, Pi-Anfruns , Moshaverinia, Sim, Grogan, Hadaya, 2019). Anti-osteoclastogenic medications containing active substances, such as bisphosphonate and denosumab, are used to prevent bone density loss. These medications also affect the bone surrounding the dental implant by increasing the risk of osteonecrosis in the bone and reduce implant success (Javed, Al-Hezaimi, Al-Rasheed, Almas, Romanos, 2010). It has been reported that patients who are under medication with higher doses of bisphosphonates administered intravenously for oncological treatment or orally for more than five years should not be treated with dental implants (Madrid, Sanz, 2009).

2.6.1.4 Smoking

It is believed that nicotine related vasoconstriction slows angiogenesis and alters bone cell proliferation, both of which may have negative effects on the implant bone connection, which is the basis of osseointegration (Pereira, Carvalho, Peres, Fernandes, 2010). Thus, smoking which is defined as a risk factor for periodontitis, has also been linked to the success of dental implants. Lindquist et al. (1997), evaluated MBL around osseo-integrated implants in 21 smoker subjects versus 24 non-smoker subjects in 10-year follow-up and, it is reported that smoker group presented substantially higher MBL compared to non-smoker group. Since, it is known that smoking may affect the healing process in peri-implant tissues, it is also believed that smoking may increase the susceptibility to peri-implantitis (Chrcanovic, Albrektsson, Wennerberg, 2015). Despite the fact that there are studies indicating that smoking raises the risk of implant failure, there are number of studies that cannot establish a significant correlation (Schwarz, Derks, Monje, Wang, 2018; Rakic, Grusovin, Canullo, 2016).

2.6.1.5 Periodontis

Periodontitis is characterized by clinical attachment loss, periodontal pocket formation, gingival bleeding, and alveolar bone loss that can be seen on radiography (Papapanou, Sanz, Buduneli, Dietrich, Feres, Fine, Tonetti, 2018). Chrcanovic et al. (2014) concluded that an increased susceptibility for periodontitis may also be related with an increased susceptibility of implant loss, peri-implant bone loss, and/or post-operative infection. In a comprehensive systematic review, it has been shown that there is a strong relationship between peri-implantitis and periodontitis (Schwarz, Derks, Monje, Wang, 2018).

2.6.2 Surgery Related Factors

Elevation of the full-thickness flap leads to temporary change in the blood circulation of the crestal bone. Because blood supply of cortical bone originates from the trabecular bone, it has been shown that trabecular bone volume and crestal bone loss are inversely proportional. In addition, crestal bone destruction is observed in two-stage implants after the second surgical phase. For these reasons, it has been concluded that the removal of the periosteum during surgery is associated with crestal bone loss (Pilliar, Deporter, Watson, Valiquette, 1991).

When the implant cavity is prepared, a devital bone area of about 1 mm is formed around the implant due to trauma in the bone. Some researchers have found that since there is no blood circulation in the crestal cortical bone, it is stated that there is early bone loss in this portion of the implant cavity (Moraschini, Poubel, Ferreira, Edos, 2015). However, there are also opinions in the literature that do not coincide with this. In one-stage implants, MBL begins immediately after implant surgery. However, in two-stage implants, the average loss of 1.5 mm within the first year occurs after the second surgery. Even in the implants placed sub-crestally or at the crestal level, bone formation was observed on top of the implant cover during the second surgery. Therefore, trauma related to the implant is not considered among the primary factors for early MBL (Misch, Perel, Wang, Sammartino, Galindo-Moreno, Trisi, Steigmann, Rebaudi , Palti, Pikos, Schwartz-Arad, Choukroun, Gutierrez-Perez , Marenzi , Valavanis, 2008).

2.6.3 Factors Related to The Implant Site and Implant

2.6.3.1 Bone volume and quality

The first step of dental implant therapy should be comprehensive clinical and radiographic examination of the implant site. (Misch, 1990). The quality and quantity of bone of the implant site determine the survival and success of the dental implant in the early and late stages (Klinge, Johansson, Albrektsson, Hallströ, Engdahl, 1995; Tolstunov, 2007).

There are significant differences in the amount of cortical and cancellous bone between the maxilla and mandible and also between the anterior and posterior regions of the jaws (Misch, 1990; Klinge, Johansson, Albrektsson, Hallströ, Engdahl, 1995). While cancellous bone is dominant in the maxillary posterior region, the amount of cortical bone increases in the anterior parts. Cortical bone is dominant throughout the mandible (Lindh, Petersson, Rohlin, 1996). As the amount of cortical bone increases, the primary stability of the implant increases (Friberg, Sennerby, Gröndahl, Bergström, Bäck, Lekholm, 1999). In cases with insufficient bone quality and quantity in the implant site, micro-movement resulting from inadequate primary stability may impair the early osseointegration. As occlusal forces are higher in the posterior region, insufficient stability may cause MBL (Barone, Orlando, Tonelli, Covani, 2011).

Vertical bone stability is related to the bone thickness around an implant at the time of implant surgery. Prior to surgery, it is recommended to have minimum 2 mm thickness of bone around the coronal portion of the implant. In a systematic review evaluating the effect of facial bone thickness on the bone remodeling, soft tissue changes and implant survival rate, bone thickness of 2 mm was reported to be related to less vertical bone resorption and soft tissue recession (Aizcorbe-Vicente et al. 2020).

2.6.3.2 Vertical soft tissue thickness

In their preclinical in vivo study, Berglundh & Lindhe (Berglundh, Lindhe, 1996) evaluated the transmucosal attachment formation. Submerged implants were installed at contralateral sides of mandible. At the time of second surgery, mucosa thickness was reduced to less than 2 mm at one side, while at the other side thickness of at least 4 mm was maintained. As a result, the authors reported that marginal bone resorption occurred at all implants with reduced mucosa thickness in the process of transmucosal attachment formation. However,

still there is no precise statistics on the minimum amount of vertical mucosa thickness that is crucial. If there is not sufficient vertical mucosal thickness, it is possible to experience bone loss in order to ensure the proper development of biological width consisting of barrier epithelium and supra-crestal connective tissue that serves as a seal to protect the implant from the oral environment. Therefore, it is necessary to know how crestal bone may respond to varying tissue thickness situations. Abrahamsson et al. (1997) discovered that implant sites with thin vertical tissue were more susceptible to angular defects around the implants after healing, whereas implant sites with thick mucosa were not associated with these defects.

Linkevicius et al. (2015) evaluated the effect of vertical soft tissue thickness in a group of 80 patients. The patients were assigned to two groups as patients with vertical soft tissue thickness below and above 2 mm. The findings of the study showed that implants in group 1 (thin tissue) experienced 0.76 mm of mean bone loss after two months. At one year, the mean bone loss was 1.18 millimeters. Implants in group 2 (thick tissue) demonstrated average bone loss of 0.17 mm after 2 months and 0.22 mm after 1 year.

2.6.3.3 Implant design factors

The implant neck and the implant-abutment connection are the most important factors that create design differences. Early crestal bone loss is definitely attributable to the polished implant neck. Historically, the neck of the implant was manufactured with a polished surface to reduce plaque accumulation if the implant became exposed to the oral environment due to alveolar bone loss. However, clinical trials examining bone levels around implants with polished neck have revealed that hard tissue in contact with machined surfaces tends to resorb (Alomrani, Hermann, Jones, Buser, Schoolfield , Cochran, 2005). All two-piece implants have a micro-gap at the implant-abutment interface. This is a crucial component of implant design that affects bone stability. In vitro studies demonstrating microbiologic contamination of the entire implant system due to micro-leakage at the implant-abutment interface demonstrate the significance of micro-gap size. The micro-gap can therefore be considered as a potential "gate" for the microorganisms (Gross, Abramovich, Weiss, 1999; Quirynen, Bollen, Eyssen, van Steenberghe, 1994). Locking taper implant systems with a micro-gap of only 0.5 pm were considered to have a "bacteria-free" connection because microorganisms are larger than 0.5 pm in diameter (Dibart, Warbington, Su, Skobe, 2005).

Stability of the implant-abutment connection is an additional factor that can influence bacterial contamination, as movement permits bacteria to escape and damage the bone; however, movement itself may be destructive to the crestal bone.

There are various connection types, such as external, flat, and internal connections, but a conical connection appears to be the most stable (Zipprich, Miatke, Hmaidouch, Lauer, 2016). It is believed that implant-abutment interface instability has a dual effect on bone loss. It has been hypothesized that when occlusal forces are applied to an implant with an unstable abutment connection, a pumping effect maintains a constant flow of bacteria from within the implant through the micro-gap to the peri-implant tissues (Hermann F, Lerner H, Palti, 2007). This action contributes to the formation of inflammatory cell infiltrate, which is the basis for bone loss caused by micro-gaps. According to a second theory, abutment micromotion itself can result with the resorption of nearby crestal bone.

At the implant-platform level, the concept of platform switching entails an abutment or supra-structure with a smaller diameter than the implant. This configuration results in a horizontal circumferential step, which enables horizontal expansion of the biologic width. The purpose of platform switching is to position the implant-abutment micro-gap away from the vertical bone-to-implant contact area. Compared to the standard restorative procedure of matching implant and supra-structure diameters, platform switching is recommended to prevent or reduce crestal bone loss (Lazzara, Porter, 2006; Gardner, 2005; Prosper, Redaelli, Pasi, Zarone, Radaelli, Gherlone, 2009).

2.6.4 Prosthesis Related Factors

Single-unit prostheses, multi-unit bridges (partial edentuolus), and all oral fixed prostheses (complete edentuolus) are different clinical conditions that differ in a variety of ways, including the number of implants to be used, restoration techniques, materials to be used, oral hygiene requirements, complications, and success rates (Sailer, Karasan, Todorovic, Ligoutsikou, Pjetursson, 2022). Therefore, it is anticipated that various types of prostheses will have different effects on peri-implantitis and MBL (Chrcanovic, Albrektsson, Wennerberg, 2014).

Implant-supported fixed prostheses are either cement-retained or screw-retained and the type of the prosthesis changes the mechanical structure of the prosthesis (Wittneben, Millen,

Brägger, 2014). Both types can be used in almost any indication, but it is reported that the choice is of critical importance given its advantages and disadvantages (Wittneben, Joda, Weber, Brägger, 2017). There was no significant difference between cement-retained and screw-retained implant supra-structures in terms of survival and success. The most obvious advantage of screw-retained systems are the absence of cement residue, easy removal, and the ability to shape the peri-implant mucosa. As for the advantage of cement-retained supra-structures, it is shown that passive adaptation can be achieved easier in cases, without screw gap. However, it is reported that the most important disadvantage is the residual excess cement (Linkevicius, Vindasiute, Puisys, Peciuliene, 2011) which is directly related to peri-implant diseases (Renvert, Quirynen, 2015; Sailer, Mühlemann, Zwahlen, Hämmerle, Schneider, 2012). In addition to a comprehensive systematic review (Staubli, Walter, Schmidt, Weiger, Zitzmann, 2017) stating that cement residue can initiate MBL in individuals predisposed to periodontitis, the presence of studies that cannot establish a relationship (Daubert, Weinstein, Bordin, Leroux, Flemmig, 2015) indicates that this issue should be investigated in the future (Schwarz, Derks, Monje, Wang, 2018).

It has been demonstrated that the abutment height causes MBL and that the use of a short abutment creates pressure on the mucosa (Galindo-Moreno, León-Cano, Monje, Ortega-Oller, O′ Valle, Catena, 2016) and inflammation due to biofilm accumulation in the micro-gap at the restoration- abutment junction (Hänggi, Schoolfield, Meyer, Cochran, Hermann, 2005). Later studies have also suggested that the abutment height may influence the bone levels at the margin (Galindo-Moreno, León-Cano, Ortega-Oller, Monje, Suárez, ÓValle, Catena, 2014).

The structures adjacent to the implant may affect the continuity of marginal bone levels around an implant (Tarnow, Cho, Wallace, 2000). An implant may be placed adjacent to a natural tooth, to another implant, or to an edentulous area. It is reported that having a natural tooth adjacent to the implant is advantageous in terms of maintaining the marginal bone level (Rocchietta, Fontana, Simion, 2008). This may explain the high success rate of single implant cases which are adjacent to the natural teeth at both sides (Zumstein, Billström, Sennerby, 2012).

As the number of implants applied per year increases exponentially, implant success rather than survival is of great importance. Maintenance of soft and hard tissue volume around an

osseo-integrated implant is the key factor for long term success. Recent advances in implantology research have led to a paradigm shift in the traditional success criteria. Previously, vertical bone loss that does not exceed 1-1.5 mm within the first year of functional loading of an implant was considered as a normal process. In recent years, several factors that may affect the MBL were studied extensively. Among these factors, facial bone thickness at the time of implant placement, vertical soft tissue thickness and keratinized tissue width are important factors however, in the literature there is no consensus regarding the impact of these factors on MBL. It is hypothesized that along with the horizontal dimensions of alveolar ridge, an implant with a macro-design which allows to have increased bone thickness around the neck portion may lead to less MBL in early healing phase.

Therefore, the aims of the current study are;

a. to evaluate the impact of implant macro-design,
b. to determine the effect of patient related factors such as age, gender,
c. to define the effect of surgical site related factors such as maxillary or mandibular arch, vertical soft tissue thickness, and keratinized tissue width, on MBL around bone-level, platform-switched implants with different macro-design.

3. MATERIALS AND METHODS

3.1 STUDY DESIGN

This study was planned as single-centered, randomized controlled clinical trial (RCT) in accordance with the Helsinki Declaration of 1975, as revised in 2013. Prior to the study ethical approval was obtained from Altınbaş University Clinical Research Ethics Committee (02.03.2023-46352).

3.2 STUDY POPULATION AND PATIENT SELECTION CRITERIA

Subjects with partial edentulism attending Altınbaş University, Faculty of Dentistry, Department of Periodontology were invited to participate in the study. After obtaining informed consent, patients were screened for eligibility based on the following inclusion criteria:

a. Male or female, >18 years old
b. Subjects with systemic conditions determined as type I or II according to the American Society of Anesthesiologists (ASA)
c. Patients who are periodontally healthy or with stable periodontitis after periodontal treatment
d. The need for rehabilitation with implant-supported restorations in maxillary or mandibular partially edentulous posterior sextants
e. Full Mouth Plaque Score (FMPS) less than 20%
f. Healed posterior sites with at least 2 months after tooth extraction
g. No indication of hard tissue augmentation before and after implant surgery
h. Minimum 2 mm of keratinized mucosa width (KMW).

Exclusion criteria were as follows:

a. Having endocrine and metabolic diseases
b. Pregnancy
c. Allergy to any metal component of the implant
d. Alcoholism
e. Tobacco consumption of >10 cigarettes per day
f. Severe bruxism and TMJ disorders
g. Presence of residual infection at the implant site.

A total of 32 individuals who fulfill the inclusion criteria were included in the study and assigned into test and control groups, randomly. DTI Power 4 SLA-ACT® or DTI-1 standard SLA-ACT® implants were placed into the maxillary or mandibular edentulous sites of the subjects in the test (n=16) and control (n=16) groups, respectively.

3.3 FEATURES OF THE IMPLANTS

Two different implants with different macro designs were used in the study (DTI® Istanbul, Turkey) (Figure 3.1). DTI-1 standart SLA Implant System implants are solid screw implants comprised of titanium grade 5 with a bone anchorage SLA surface that is large-grit sandblasted and acid etched. (Figure 3.2) Power4 aggressive implants are comprised of titanium grade 4 with a double helix thread and an angled neck region. Both implants are platform switched and have 11-degree Morse taper conical connection.

Figure 3.1: DTI Power4® (a), DTI-1 Standart® (b).

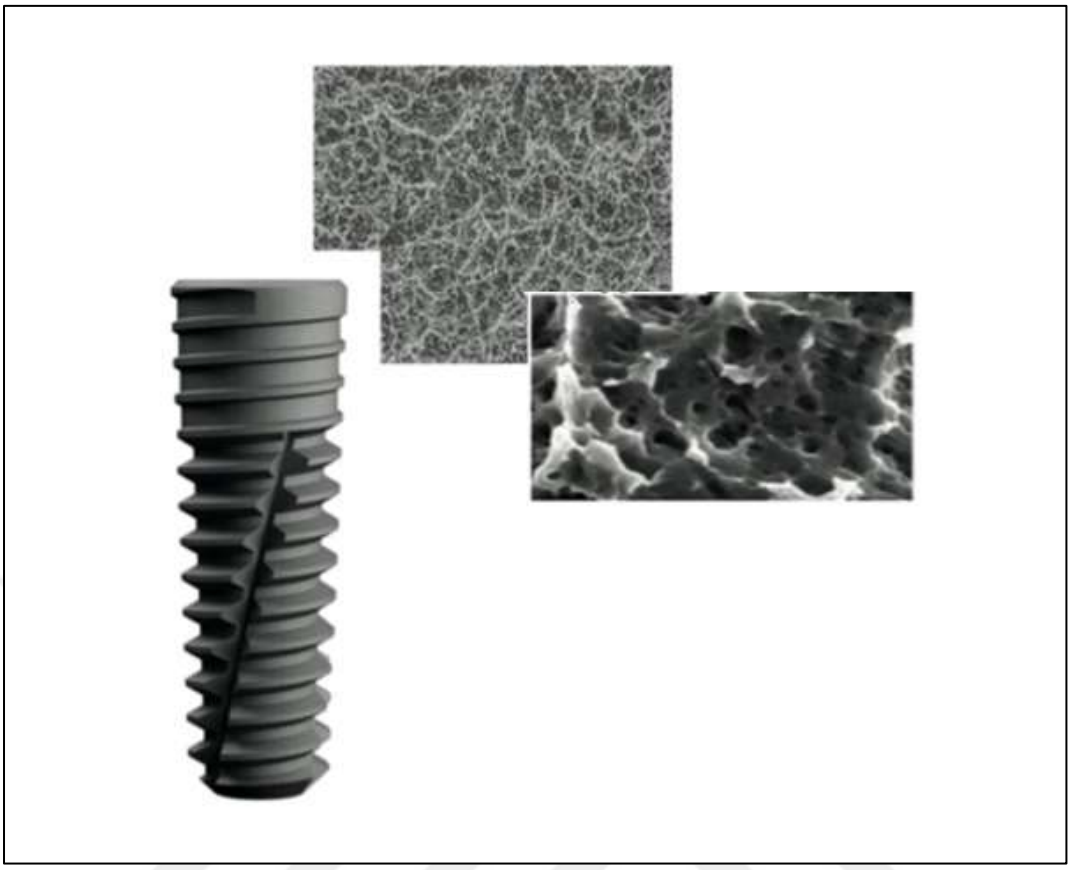


Figure 3.2: Scanning Electron Microscopy Image of SLA & ACT of DTI® Implant Surface.

3.4 PRE-OPERATIVE PROCEDURES

The patients who volunteered to participate in the study and signed the informed consent were examined clinically and radiographically for their eligibility according to the inclusion criteria.

3.4.1 Clinical Measurements

Periodontal clinical parameters consisting of probing pocket depth (PPD), and clinical attachment level (CAL) were measured from six sites per tooth (mesiobuccal, buccal, distobuccal, mesiooral, oral, diatooral) using PCP-15 UNC periodontal probe (Hu-Friedy, Chicago, IL, USA). Bleeding on probing (BOP) and plaque index (PI) were recorded at 6 sites per tooth and full mouth percentages of both scores were calculated.

The evaluation of vertical and horizontal bone volume was performed by cone beam computerized tomography. Keratinized tissue width, vertical mucosa thickness measurements at the implant sites were done. Prior to the examination, local anesthesia was

applied, and the vertical mucosal thickness was measured by inserting a spreader with stopper from the mid-crest to the bone (Figure 3.3).

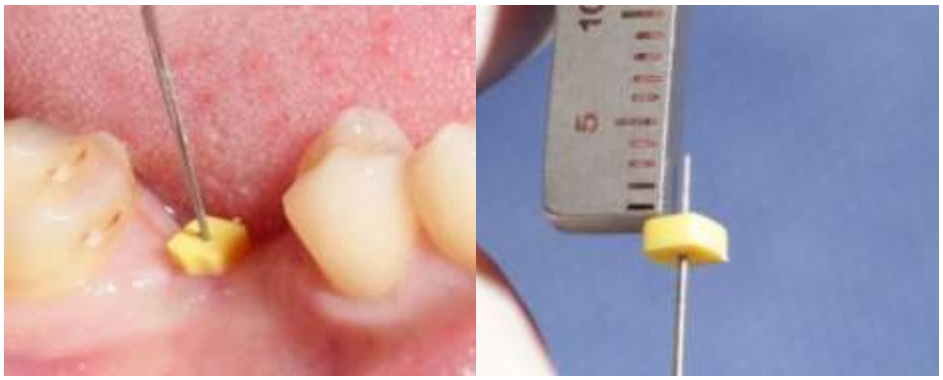


Figure 3.3: Measurement of Vertical Soft Tissue Thickness.

All subjects who fulfill the inclusion criteria were informed about oral hygiene practices including brushing and interproximal cleaning.

3.4.2 Pre-operative Radiographical Procedures

Pre-operative radiographs were taken by using parallel cone technique. In order to achieve standardization at different follow-up sessions, patient-specific silicone stents were prepared. Before implant placement, impressions were taken to obtain cast models. Then, a silicone-based impression material was applied on the cast model and the film holder was placed on the silicon material in a position that would allow to take standardized radiographs. The same standard film holders were used in all follow-up sessions (Figure 3.4).

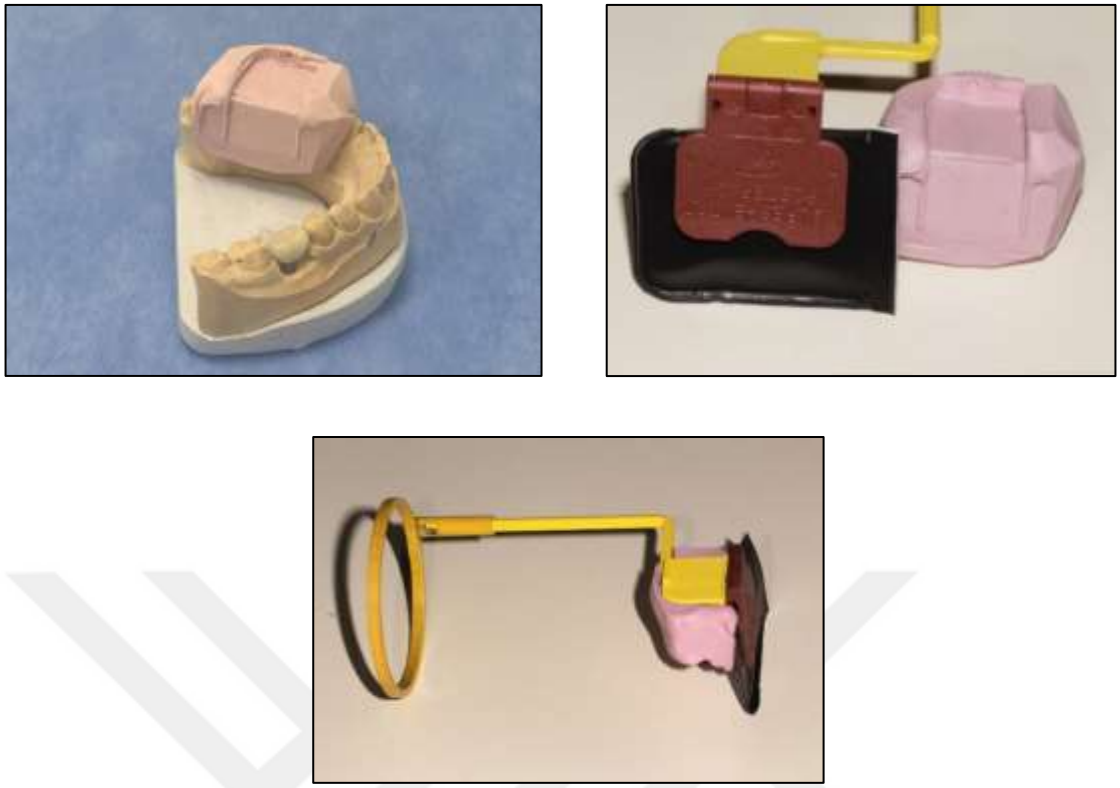


Figure 3.4: Radiographic Silicone Stent.

3.4.3 Randomization

Subjects were randomly assigned to either the test (DTI Power 4®) or control (DTI-1 Standard®) groups. The randomization list sequence was generated using the adaptive minimization method of the open-source software OxMaR (Oxford Minimization and Randomization, 2014).

3.4.4 Pre-operative Medication

Pre-operative prophylaxis including amoxicillin and potassium clavulanate (Augmentin-BID 1000 mg 14 film tablets (Glaxo Smith Kline ilaçlar San.Ve Tic.Aş.), was prescribed to each subject in every 12 hours 1 day prior to the surgery during 1 week.

3.5 OPERATION

Prior to surgery, subjects were asked to rinse with 0.2% chlorhexidine digluconate solution for 2 minutes and infiltrative local anesthesia was administered. A mucoperiosteal flap was elevated in the surgical area and the stages of the osteotomy procedure applied in line with

the company's recommendations (Figure 3.5-3.6). The implant cavities were prepared at 1500 rpm with pilot burs and at 750 rpm with conical drills under the irrigation of 0.9% NaCl solution. All implants were positioned 1.5 mm subcrestally from the most apical part of the bone crest (Figure 3.7).

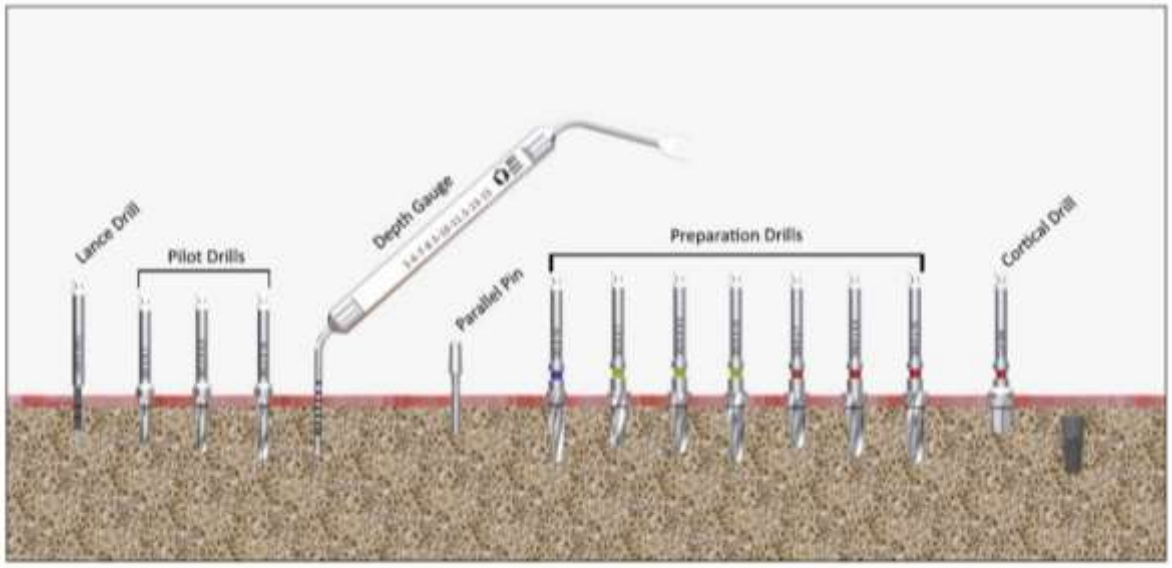


Figure 3.5: Preparation Set of DTI® Standard Implant System.

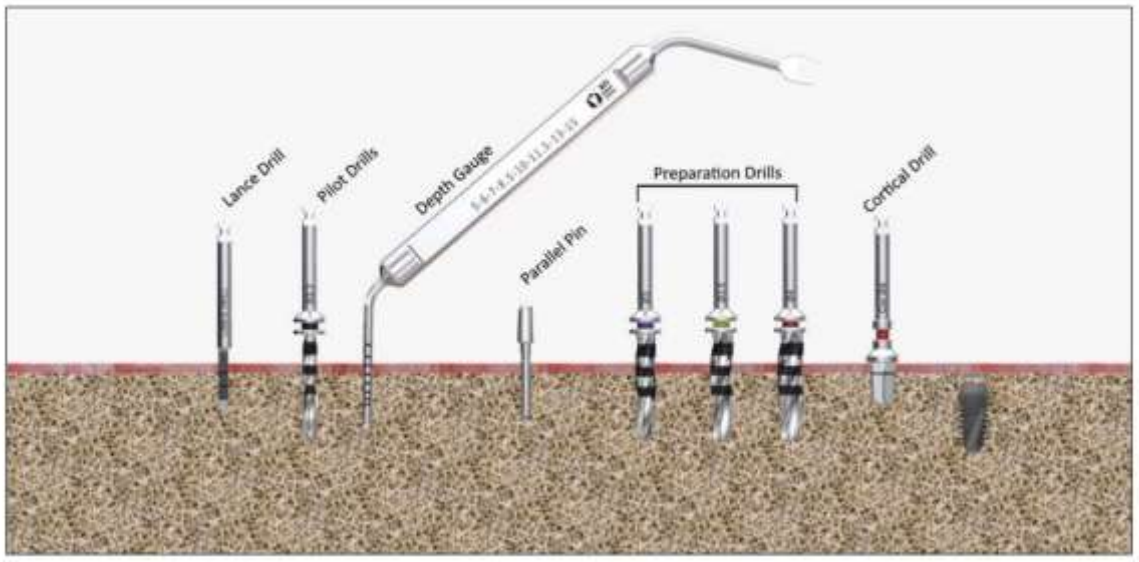


Figure 3.6: Preparation Set of DTI® Power 4 Implant System.

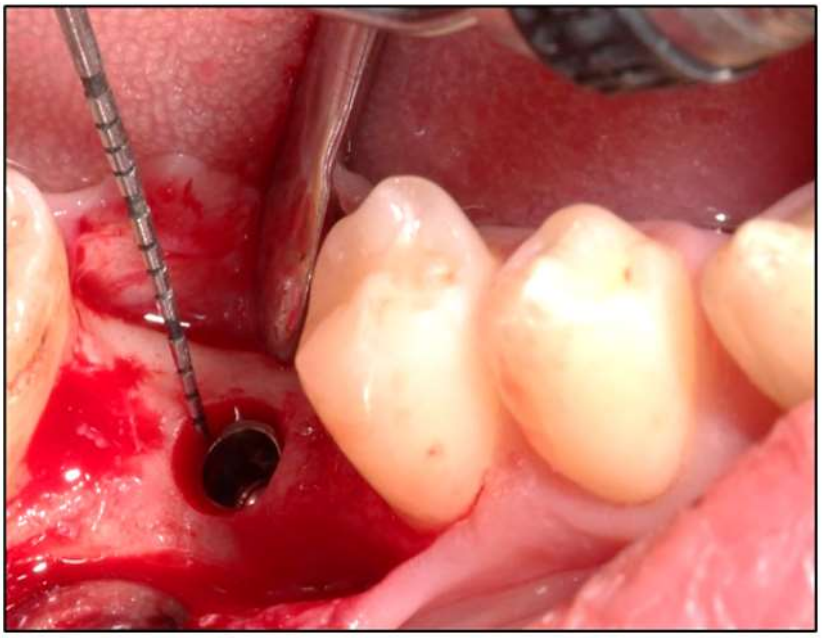


Figure 3.7: Subcrestal Placement of Implants.

The surgical procedure was performed as one-step surgery, and the healing caps with appropriate gingival height was connected and tightened at 25Ncm. The mucoperiosteal flaps were closed by interrupted sutures by using 5/0 polypropylene suture material. (Propilen® Doğsan,Trabzon, and Turkey) (Figure 3.8).

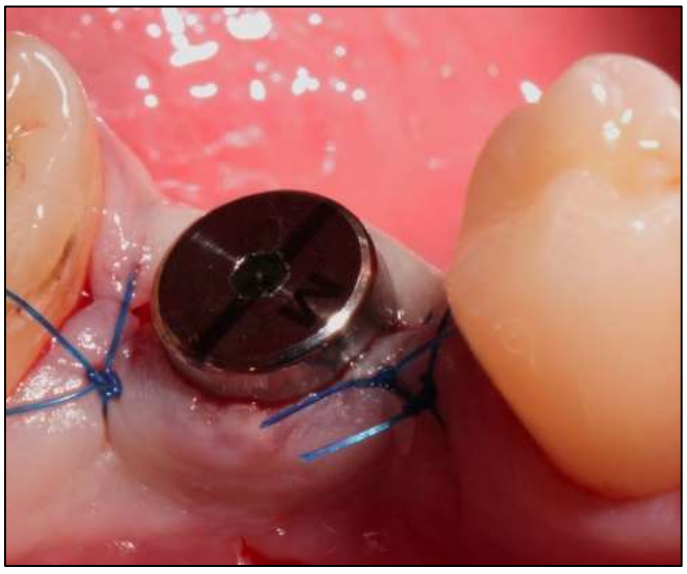


Figure 3.8: Healing Cap Placement and Flap Closure.

RFA was performed by using OSSTELL® IS3 (HIOSSEN Company, Pennsylvania,ABD) device. Transducers called SmartPeg® were used in the construction of RFA measurements. The first measurement of ISQ value was made during the surgical operation, before the healing caps were placed. The implant site was isolated and appropriate SmartPegs® were placed by applying finger pressure. The device was positioned at an angle of 90° with SmartPegs® in accordance with the company's instructions. Two values were taken from each implant's mesial and distal surfaces, and the mean value was calculated, which corresponds to a single ISQ value.

Post-operative prophylaxis including dexketoprofen (Arveles 25 mg Menarini İlaç Sanayi ve Ticaret AŞ,) (3x1), and benzidamine hydrochloride and %0.12 chlorhexidine gluconate mouthwash (Kloroben 120 ml (Drogsan ilaçlar SAN. VE TC.) (2x1) was prescribed. Each patient started taking the antibiotics one day prior to the surgery and were recommended to continue until the 7 day postsurgery. Daily oral hygiene practices including brushing and cleaning of healing caps with interdental brushes were recommended following suture removal.

3.6 POST-OPERATIVE DAY 10

The sutures were removed 10 days after the surgery and standardized radiographs were taken by using previously prepared silicon stents. Silicon stents were modified in order to create space for the healing cap by carving the silicone at the implant site with a #15 scalpel (Figure 3.9).

Figure 3.9 : Modification of the Silicon Stent.

3.7 THIRD MONTH FOLLOW-UP

Full mouth periodontal measurements including PPD, CAL, BOP and PI were performed. Standardized radiographs were taken and ISQ value measurements were done. Once the ISQ values were ≥ 65 after 12 weeks of healing, the prosthetic procedures were initiated to make cemented-retained restorations.

3.8 SIXTH MONTH FOLLOW-UP

Full mouth periodontal measurements were repeated, and standardized radiographs were taken.

3.9 RADIOGRAPHIC MEASUREMENTS

Radiographic measurements were done on standardized radiographs taken by paralleling cone technique using a patient-specific silicone radiographic stent. All radiographic measurements were taken to the nearest 0.1 mm at baseline and performed by a single calibrated examiner using ImageJ software (Java; National Institutes of Health, USA) at a magnification of 7x. The calibration was done by measuring the distance between bone crest (C) the and implant shoulder (IS) on the radiographs three times in 72-hour intervals to achieve intra-examiner reproducibility. All measurements were repeated 3 times and the mean value was recorded.

The most coronal portion of the C, IS, and the level of the first bone-to-implant contact (fBIC) at mesial and distal sites were chosen as reference points (Figure 3.10). Initially, the reference points were defined on the radiographs and the distances between these points were measured (Figure 3.11)

a. IS–C: the distance (mm) between the implant shoulder and the most coronal portion of the bone crest at the mesial and distal of the implants
b. IS–fBIC: the distance (mm) between the implant shoulder and the first bone-to-implant contact at the mesial and distal of the implants
c. C- fBIC: the distance (mm) between the bone crest and the first bone-to-implant contact at the mesial and distal of the implant.

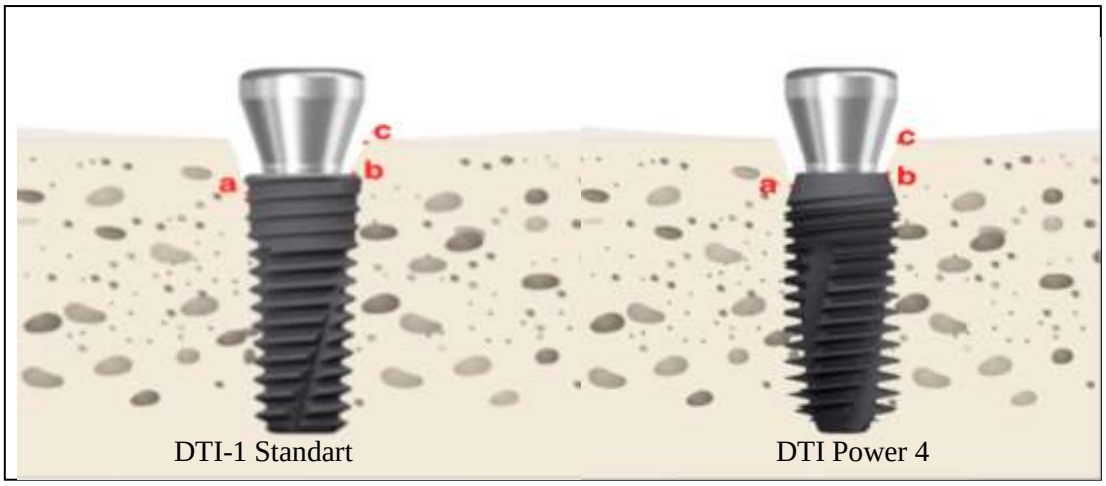


Figure 3.10: The Reference Points for Measurement of MBL First Bone Implant Contact (fBIC) (a), Implant Shoulder (IS) (b), Crest (C) (c).

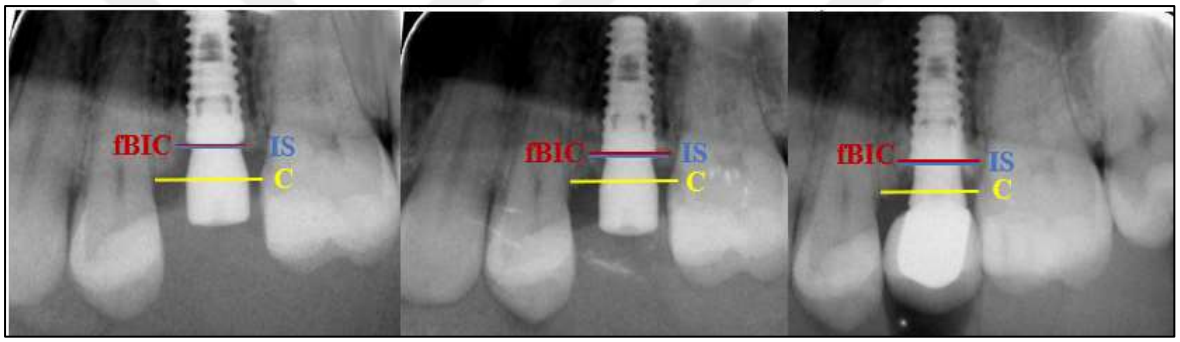


Figure 3.11: Measurement on Periapical Radiographs of IS-fBIC and IS-C at Baseline, 3rd and 6th Months.

3.10 STATISTICAL ANALYSIS

The number of patients was determined by power analysis. In the statistical power analysis, a total of 32 individuals, 16 in each group, were used to determine the 0.5 mm difference between the groups at 80% power and a 0.05 significance level by estimating that the standard deviations would be approximately 0.5, as planned. The SPSS (Statistical Package for the Social Sciences) 24.0 program was used for statistical analyses. Data were evaluated by descriptive statistical methods (Mean, Standard Deviation, Median, Minimum, and maximum). One-way ANOVA was used to evaluate the demographic data. The Mann-Whitney U test was used to compare the two groups. Repeated Measures and the Wilcoxon Signed Rank test were used for evaluation in follow-up measurements. Spermans'

Correlation analysis was used to evaluate the relation between MBL and clinical variables such as VMT and KWT. Significance was evaluated at $p<0.01$ and $p<0.05$ levels.

4. RESULTS

4.1 STUDY POPULATION, DEMOGRAPHIC DATA

Total number of 32 patients with single tooth loss were recruited in this study. Patients with the age range of 23-56 (40.75±11.13) were assigned into either control (n=16) or test groups (n=16), randomly. No adverse events requiring exclusion from the study were experienced during the study period and all patients attended 3rd and 6th month follow-up sessions. Total number of 32 patients completed the study. There were no differences between the test and control groups regarding age, gender distribution and smoking status (p>0,05) (Table 4.1).

Table 4.1: Demographic Data.

	Control Group (n=16)	**Test Group (n=16)**	
	Mean±Sd	**Mean±Sd**	***p***
Age	42.5 ±11.68	38.93 ±10.60	***0.365***
Age range	23-56	24-56	***0.828***
Gender (female/male)	10/6	7/9	***0.303***
Smoker / non-smoker	6/10	7/9	***0.729***

One-way ANOVA, p<0.05

4.2 CLINICAL PERIODONTAL PARAMETERS AT BASELINE

Clinical parameters including PPD, CAL, PI and BOP were recorded at baseline. Along with periodontal parameters VMT and KTW were also recorded. There were no statistically significant differences between the study groups in terms of periodontal clinical measurements at baseline (p>0.05) (Table 4.2).

Table 4.2: Clinical Characteristics of the Study Groups.

	Control Group (n=16)		Test Group (n=16)		p
	Mean±Sd	**Min-Max (Median)**	**Mean±Sd**	**Min-Max (Median)**	
PPD (mm)	1.49±0.37	1.1-2.1 (1.3)	1.53±0.4	1.1-2.3 (1.5)	***0.820***
CAL (mm)	1.57±0.34	2.2-1.1 (1.55)	1.5±0.29	1.9-1.1 (1.5)	***0.608***
PI %	1.25±1.39	0-3 (0.5)	1.38±1.36	0-5 (1)	***0.828***
BOP %	2.75±1.81	0-6 (3)	2.0±1.15	0-4 (2)	***0.211***
VMT (mm)	1.97±0.56	1-3 (2)	1.88±0.85	1-4 (1.75)	***0.351***
KTW (mm)	4.41±1.04	3-6 (4.5)	4.69±1.05	3-6 (4.75)	***0.455***

*Mann Whitney U test, *p<0.05*

PPD: Probing pocket depth CAL: Clinical attachment level PI: Plaque Index BOP: Bleeding on probing VMT: Vertical mucosa thickness, KTW: Keratinized tissue width.

4.3 INTRA-GROUP COMPARISONS OF RADIOGRAPHIC MEASUREMENTS AT BASELINE, 3RD, AND 6TH MONTHS

In the control group, the distance between IS and C revealed statistically significant decrease at 3rd month and 6th month follow-ups compared to the baseline (p=0.001) in both distal and mesial aspects. The distance between IS and C at mesial and distal sites was lower at 6th month compared to the 3rd month follow-up (p< 0,01). When intra-group comparison of IS to fBIC distances were performed, lower bone levels were found at both 3rd and 6th month follow ups compared to baseline at both mesial and distal aspects in the control group (p<0.01) (Table 4.3 - Graph 4.1, 4.2)

Table 4.3: Radiographic Measurements At Baseline, 3rd and 6th Months in the Control Group.

	Baseline	***3rd Month***	***6th Month***	
Distance (mm)	**Min-Max (Median)**	**Min-Max (Median)**	**Min-Max (Median)**	***p***
IS-C-d	1.5 (1.5-1.5)	0.9 (0.3-1.35)	0.7(-0.35-1.2)	***0.001***
IS-C-m	1.5 (1.5-1.5)	1.2 (0.71-1.43)	1.1 (0.44-1.41)	***0.001***
IS – fBIC-d	0 (0-0)	0 (-0.81-0)	-0.2 (-1.43-0)	***0.001***
IS – fBIC-m	0 (0-0)	0 (-1.03-0)	-0.09 (-1.3- 0)	***0.001***

Wilcoxon Test **p<0.05* ***p<0.01*

In the test group, radiographic, crestal bone level in relation to IS at mesial and distal sites were lower at 3rd and 6th month follow-ups compared to the baseline (p< 0.01). Also, there was statistically significant difference in IS-C-d and IS-C-m distances between 3rd month and 6th month follow ups (p<0.01). Intra-group comparison of IS-fBIC distance in the test group also, revealed statistically significant lower bone levels at 3rd and 6th month follow ups compared to baseline (p<0.01). Statistically significant difference was found in IS-fBIC distance at mesial and distal sites between 3rd and 6th month follow-up periods in the test group (p<0.01) (Table 4.4).

Table 4.4: Radiographic Measurements At Baseline, 3rd, and 6th Months in the Test Group.

	Baseline	***3rd Month***	***6th Month***	
Distance (mm)	**Min-Max (Median)**	**Min-Max (Median)**	**Min-Max (Median)**	***p***
IS-C-d	1.5 (1.5-1.5)	1.1 (-0.91-1.4)	0.9 (0.3-1.29)	***0,001***
IS-C-m	1.5 (1.5-1.5)	1.1 (0.71-1.42)	0.9 (0.02-1.2)	***0,001***
IS – fBIC-d	0 (0-0)	0 (-0.71-0)	-0.26 (-1.21-0)	***0,001***
IS – fBIC-m	0 (0-0)	0 (-0.93-0)	-0.34 (-1.15-0)	***0,001***

Wilcoxon Test **p<0.05 **p<0.01*

4.4 INTER-GROUP COMPARISONS OF RADIOGRAPHIC MEASUREMENTS AT BASELINE, 3RD, AND 6TH MONTHS

In both study groups implants were placed 1.5 mm subcrestally. Therefore, there were no differences at IS-C and IS-fBIC distances at baseline. Crestal bone level to implant shoulder distance (IS-C) at 3rd and 6th month follow-ups were lower compared to baseline in both control and test groups at mesial and distal sites ($p<0.01$), whereas no differences were found between the groups ($p>0.05$). The distance of IS-fBIC at mesial and distal sites revealed no statistically significant difference at 3rd and 6th month follow-up periods between the groups ($p>0.05$) (Table 4.5).

Table 4.5: Inter-group Comparison Of Radiographic Measurements at Different Time Points.

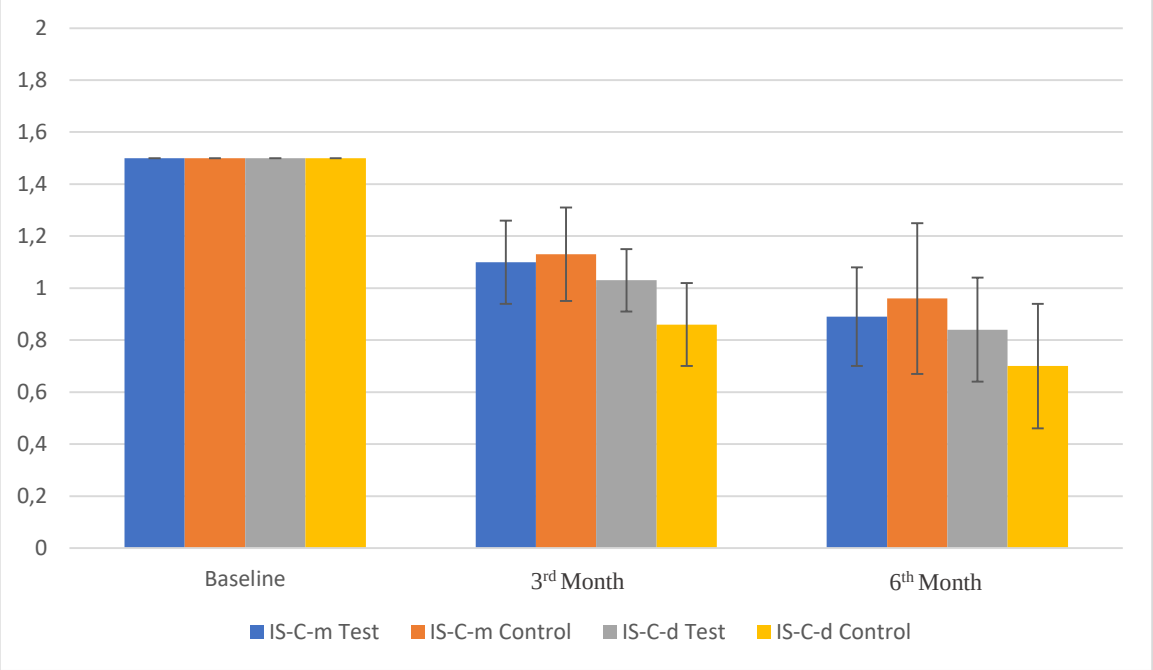
	Control Group (n=16)	**Test Group (n=16)**	***p***
	Median (Min-Max)	**Median (Min-Max)**	
Baseline			
IS-C-d (mm)	1.5 (1.5-1.5)	1.5 (1.5-1.5)	-
IS-C-m (mm)	1.5 (1.5-1.5)	1.5 (1.5-1.5)	-
IS – fBIC-d (mm)	0 (0-0)	0 (0-0)	-
IS – fBIC-m (mm)	0 (0-0)	0 (0-0)	-
3rd Month			
IS-C-d (mm)	0.9 (0.3-1.35)	1.1 (0.91-1.4)	***0.080***
IS-C-m (mm)	1.2 (0.71-1.43)	1.1 (0.71-1.42)	***0.462***
IS – fBIC-d (mm)	0 (-0.81-0)	0 (-0.71-0)	***0.124***
IS – fBIC-m (mm)	0 (-1.03-0)	0 (-0.93-0)	***0.722***
6th Month			

Table 4.5: Inter-Group Comparison of Radiographic Measurements at Different Time Points "Tables Continued".

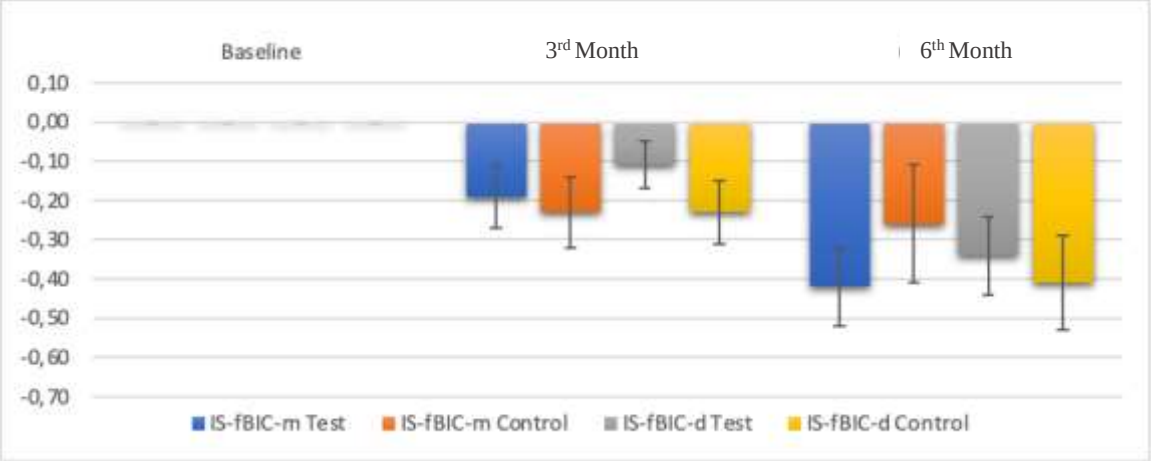
IS-C-d (mm)	0.7 (0.35-1.2)	0.9 (0.3-1.29)	***0.181***
IS-C-m (mm)	1.1 (0.44-1.41)	0,9 (0.02-1.2)	***0.396***
IS – fBIC-d (mm)	0.2 (0-1.43)	-0.26 (-1.21-0)	***0.985***
IS – fBIC-m (mm)	0.09 (-1.1-1.3)	-0.34 (-1.15-0)	***0.240***

*Mann Whitney U Test, *p<0.05 **p<0.01*

Charts 4.1: Comparison of IS and C Distance (mm) at Baseline, 3rd and 6th Months (mean ±sd).



Charts 4.2: Comparison of IS and fBIC Distance (mm) at Baseline, 3rd and 6th Months (mean ±sd).



4.5 COMPARISONS OF THE RESONANCE FREQUENCY ANALYSIS

When inter-group comparison of ISQ values at baseline and 3rd month was done, no statistically significant differences were found between the study groups. However, when intra-group analysis was done, in both test and control groups, ISQ values were found to increase (75.25±2.74 vs 76.94±2.11 and 77±2.76 vs 78.25±2.41, respectively) from baseline to 3rd month follow up ($p<0.01$) (Tables 4.6, 4.7- Graph 4.3).

Table 4.6: Inter-Group Comparison of ISQ Values.

	Control Group (n=16)		**Test Group (n=16)**		
	Mean±Sd	**Min-Max (Median)**	**Mean±Sd**	**Min-Max (Median)**	***p***
Baseline	77±2.76	78 (71-81)	75.25±2.74	74.5 (71-80)	***0.094***
3th Month	78.25±2.41	78.5 (73-82)	76.94±2.11	77 (73-81)	***0.098***

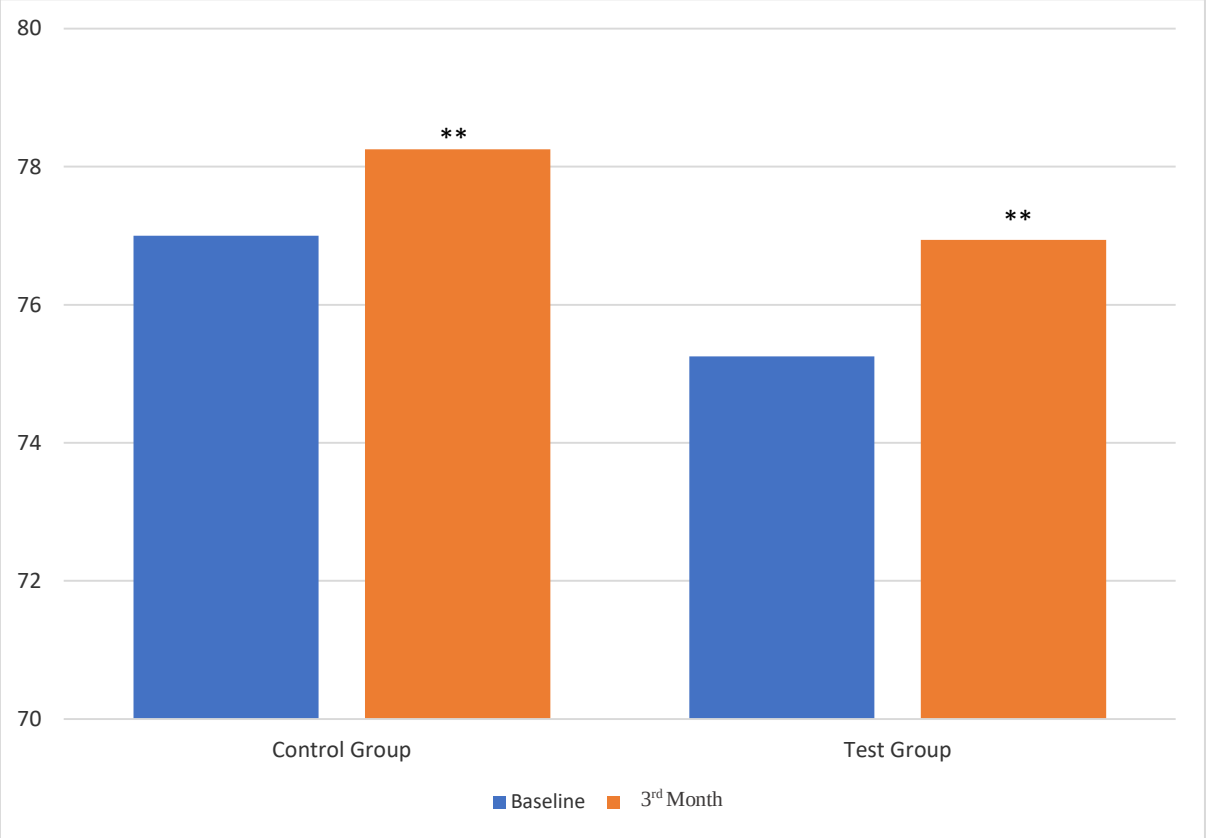
*Mann Whitney U Test **p<0.01*

Table 4.7: Intra-Group Comparison of ISQ Values at Baseline and 3rd Month.

	Baseline		***3th Month***		
	Mean±Sd	**Min-Max (Median)**	**Mean±Sd**	**Min-Max (Median)**	***p***
Control Group	77±2.76	78 (71-81)	78.25±2.41	78.5 (73-82)	***0.001*****
Test Group	75.25±2,74	74.5 (71-80)	76.94±2.11	77 (73-81)	***0.001*****

*Wilcoxon Test, **p<0.01*

Charts 4.3: Inter-Group Comparison of ISQ Values.



*Wilcoxon Test **p<0.01*

4.6 INTRA-GROUP COMPARISONS OF CLINICAL AND RADIOGRAPHIC MEASUREMENTS IN SMOKERS VERSUS NON-SMOKERS

When data of smoker and non-smoker subjects in the control group were compared, no statistically significant differences were found between the subgroups at either baseline, 3rd or 6th month follow-ups (p>0.05) (Table 4.8).

Table 4.8: Smoker vs Non-smoker Comparison of Clinical and Radiographic Measurements in the Control Group.

	Non-smoker (n=10)	**Smoker (n=6)**	
	Min-Max (Median)	**Min-Max (Median)**	***p***
Baseline			
PI %	0 (0-3)	2.5 (0-3)	***0.216***

Table 4.8: Smoker vs Non-smoker Comparison of Clinical and Radiographic Measurements in the Control Group "Tables Continued".

BOP %	2 (0-6)	3 (0-4)	***0.582***
VMT (mm)	2 (1-3)	2 (2-3)	***0.082***
KTW (mm)	5 (3-6)	4 (3-6)	***0.471***
ISQ	78 (71-81)	78 (74-79)	***0.825***
IS-C-d (mm)	1.5 (1.5-1.5)	1.5 (1.5-1.5)	-
IS-C-m (mm)	1.5 (1.5-1.5)	1.5 (1.5-1.5)	-
IS – fBIC-d (mm)	0 (0-0)	0 (0-0)	-
IS – fBIC-m (mm)	0 (0-0)	0 (0-0)	-
3rd Month			
PI %	2(0-7)	3.5 (0-8)	***0.411***
BOP %	2 (0-6)	4 (0-5)	***0.742***
ISQ	79 (73-82)	78 (75-80)	***0.548***
IS-C-d (mm)	0.94 (0.3-1.35)	1.12 (0.12 -1.29)	***0.386***
IS-C-m (mm)	1.17 (0.71-1.43)	1.26 (0.85-1.43)	***0.720***
IS – fBIC-d (mm)	0 (-0.76-0)	-0.07 (0- -0.81)	***0.803***
IS – fBIC-m (mm)	0 (-0.54-0)	0 (-1.03- 0)	***0.379***
6th Month			
PI %	1 (0-6)	3.5 (1-9)	***0.248***
BOP %	2.5 (0-5)	3.5 (2-6)	***0.302***
IS-C-d (mm)	0.65 (-0.35-1.23)	0.91 (0.21-1.11)	***0.129***
IS-C-m (mm)	1.02 (0.44-1.29)	1.17 (0.71-1.41)	***0.147***

Table 4.8: Smoker vs Non-smoker Comparison of Clinical and Radiographic Measurements in the Control Group "Tables Continued".

IS – fBIC-d (mm)	-0.24 (-1.43-0)	-0.2 (-1.19-0)	***0.957***
IS – fBIC-m (mm)	-0.05 (-1.11- -0.87)	-0.11 (-1.34-0)	***0.585***

Mann Whitney U Test

When clinical and radiographic data of smoker and non-smoker subjects in the test group were compared, no significant differences were found between the subgroups at baseline and 6th month follow-up ($p>0.05$). At 3rd month follow up, only IS-fBIC distance at distal aspect was found to be significantly lower in the smoker subgroup compared to non-smoker subgroup ($p<0.036$) (Table 4.9).

Table 4.9: Smoker vs Non-smoker Comparison of Clinical And Radiographic Measurements in the Test Group.

	Non-smoker (n=9)	**Smoker (n=7)**	***p***
	Min-Max (Median)	**Min-Max (Median)**	
Baseline			
PI %	1 (0-5)	1 (0-3)	***0,660***
BOP %	2 (1-4)	2 (0-4)	***0,584***
VMT (mm)	2 (1-4)	1,5 (1-2)	***0,353***
KTW (mm)	5 (3-6)	4,5 (3-5,5)	***0,361***
ISQ	75 (72-79)	74 (71-80)	***0,831***
IS-C-d (mm)	1,5 (1,5-1,5)	1,5 (1,5-1,5)	-
IS-C-m (mm)	1,5 (1,5-1,5)	1,5 (1,5-1,5)	-
IS – fBIC-d (mm)	0 (0-0)	0 (0-0)	-
IS – fBIC-m (mm)	0 (0-0)	0 (0-0)	-

Table 4.9: Smoker vs Non-smoker Comparison of Clinical And Radiographic Measurements in the Test Group "Tables Continued".

3rd Month			
PI %	1 (0-5)	1 (0-5)	***0,739***
BOP %	1 (1-3)	2 (0-4)	***0,261***
ISQ	77 (73-79)	76 (74-81)	***0,914***
IS-C-d (mm)	1,12 (0,93-1,28)	1,12 (-0,91-1,44)	***0,427***
IS-C-m (mm)	1,2 (0,74-1,42)	0,71-1,31 (1,12)	***0,138***
IS – fBIC-d (mm)	0 (0-0)	0 (-0,71-0)	***0,036****
IS – fBIC-m (mm)	0 (-0,93-0)	0 (-0,86-0)	***0,479***
6th Month			
PI %	1 (0-4)	1 (0-4)	***0,823***
BOP %	1 (0-3)	1(0-3)	***0,393***
IS-C-d (mm)	0,92 (-0,04-1,13)	0,94 (-0,31-1,29)	***0,491***
IS-C-m (mm)	1,01 (-0,02-1,26)	0,94 (0,58-1,13)	***0,491***
IS – fBIC-d (mm)	-0,1 (-0,38- 0)	-0,44 (-1,21-0)	***0,063***
IS – fBIC-m (mm)	0,28 (-1,15-0)	-0,4 (-1,04-0)	***0,559***

*Mann Whitney U Test *p<0,05*

4.7 INTER-GROUP COMPARISON OF CLINICAL AND RADIOGRAPHIC MEASUREMENTS IN SMOKERS

Inter-group comparison of clinical and radiographic measurements in smoker test and smoker control subgroups were performed. Baseline VMT was significantly higher in the smoker control subgroup compared to smoker test subgroup (p=0.019). Bleeding on probing % was found to be significantly lower in the smoker test subgroup compared to the smoker

control subgroup (p=0.029). There were no significant differences between the smoker subgroups in terms of radiographic measurements at any time point (p>0.05) (Table 4.10).

Table 4.10: Inter-Group Comparison of Clinical and Radiographic Measurements in Smokers.

	Smoker			**p**
	Control Group (n= 6)	**Test Group (n= 7)**		
	Median (Min-Max)		**Median (Min-Max)**	
Baseline				
PI %	2.5 (0-3)	1 (0-3)		***0.329***
BOP %	3 (0-4)	2 (0-4)		***0.266***
VMT (mm)	2 (2-3)	1.5 (1-2)		***0.019****
KTW (mm)	4 (3-6)	4.5 (3-5,5)		***0.558***
ISQ	78 (74-79)	74 (71-80)		***0.466***
IS-C-d (mm)	1.5 (1.5-1.5)	1.5 (1.5-1.5)		-
IS-C-m (mm)	1.5 (1.5-1.5)	1.5 (1.5-1.5)		-
IS – fBIC-d (mm)	0 (0-0)	0 (0-0)		-
IS – fBIC-m (mm)	0 (0-0)	0 (0-0)		-
3th Month				
PI %	3.5 (0-8)	1 (0-5)		***0.277***
BOP %	4 (0-5)	2 (0-4)		***0.165***
ISQ	78 (75-80)	76 (74-81)		***0.718***
IS-C-d (mm)	1.12 (0.12-1.29)	1.12 (0.91-1.44)		***0.319***
IS-C-m (mm)	1.26 (0.85-1.43)	1.12 (0.71-1.31)		***0.153***
IS – fBIC-d (mm)	-0.07 (-0.81-0)	0 (-0.71-0)		***0.877***

Table 4.10: Inter-Group Comparison of Clinical and Radiographic Measurements in Smokers "Tables Continued".

IS – fBIC-m (mm)	0 (-1.03-0)		0 (-0.86-0)	***0.872***
6th Month				
PI %	3.5 (1-9)	1 (0-4)		***0.077***
BOP %	3.5 (2-6)	1 (0-3)		***0.029****
IS-C-d (mm)	0.91 (-0.21-1.11)	0.94 (-0.31-1.29)		***0.668***
IS-C-m (mm)	1.17 (0.71-1.41)	0.94 (0.58-1.13)		***0.063***
IS – fBIC-d (mm)	-0.2 (-1.19-0)	-0.44 (-1.21-0)		***0.224***
IS – fBIC-m (mm)	-0.11 (-1.34-0)	-0.4 (-1.04-0)		***0.566***

*Mann Whitney U Test *p<0.05*

When inter-group comparisons were done in the non-smoker test and control subgroups, there were statistically significant difference between the groups in terms of clinical and radiographic measurements at baseline (p>0.05). At 3rd month follow up, IS-fBIC-d distance was found to be significantly lower in the non-smoker control subgroup (p= 0.039). There were significant differences in any of the clinical and radiographic measurements between the non-smoker subgroups at 3rd month follow-up (p>0.05). At 6th month follow-up, BOP was significantly lower at non-smoker control subgroup (p=0.039). There were no significant differences between the non-smoker subgroups in other clinical and radiographic measurements at 6th month follow-up (p>0.05) (Table 4.11).

Table 4.11: Inter-Group Comparison of Clinical and Radiographic Measurements In Non-smokers

	Non-smoker		***p***
	Control Group (n= 10)	**Test Group (n= 9)**	
	Min-Max (Median)	**Min-Max (Median)**	
Baseline			
PI %	0 (0-3)	1 (0-5)	***0.265***

Table 4.11: Inter-Group Comparison of Clinical and Radiographic Measurements In Non-smokers "Tables Continued".

BOP %	2 (0-6)	2 (1-4)	***0.423***
VMT (mm)	2 (1-3)	2 (1-4)	***0.672***
KTW (mm)	5 (3-6)	5 (3-6)	***0.453***
ISQ	78 (71-81)	75 (72-79)	***0.163***
IS-C-d (mm)	1.5 (1.5-1.5)	1.5 (1.5-1.5)	-
IS-C-m (mm)	1.5 (1.5-1.5)	1.5 (1.5-1.5)	-
IS – fBIC-d (mm)	0 (0-0)	0 (0-0)	-
IS – fBIC-m (mm)	0 (0-0)	0 (0-0)	-
3th Month			
PI %	2 (0-7)	1 (0-5)	***0.705***
BOP %	2 (0-6)	1 (1-3)	***0.240***
ISQ	79 (73-82)	77 (73-79)	***0.147***
IS-C-d (mm)	0.94 (-0.3-1.35)	1.12 (0.93-1.28)	***0.094***
IS-C-m (mm)	1.17 (0.71-1.43)	1.2 (0.74-1.42)	***0.775***
IS – fBIC-d (mm)	0 (-0.76-0)	0 (0-0)	***0.039****
IS – fBIC-m (mm)	0 (-0.54-0)	0 (-0.93-0)	***0.553***
6th Month			
PI %	1 (0-6)	1 (0-4)	***0.728***

Table 4.11: Inter-Group Comparison of Clinical and Radiographic Measurements In Non-smokers "Tables Continued".

BOP %	2.5 (0-5)	1 (0-3)	***0.039****
IS-C-d (mm)	0.65 (0.35-1.23)	0.92 (0.04-1.13)	***0.221***
IS-C-m (mm)	1.02 (0.44-1.29)	1.01 (0.02-1.26)	***0.870***
IS – fBIC-d (mm)	-0.24 (-1.43-0)	-0.1 (-0.38-0)	***0.228***
IS – fBIC-m (mm)	-0.19 (-1.11-0)	-0.28 (-1.15-0)	***0.806***

*Mann Whitney U Test *p<0.05*

4.8 INTRA-GROUP COMPARISON OF CLINICAL AND RADIOGRAPHIC MEASUREMENTS IN MAXILLA AND MANDIBLE

When the clinical and radiographic measurements of different arches (maxilla vs mandible) were evaluated, no significant differences were found in any of the parameters at baseline, 3rd, and 6th month follow-up periods between maxilla and mandible in the control group (p>0.05) (Table 4.12). Also, in the test group, comparison of clinical and radiographic measurements revealed no statistically significant difference between maxillary and mandibular arches (p>0.05) (Table 4.13).

Table 4.12: Maxillary vs Mandibular Comparison of Clinical and Radiographic Measurements in the Control Group.

	Maxilla (n=6)	**Mandible (n=10)**	***p***
	Min-Max (Median)	**Min-Max (Median)**	
Baseline			
PI %	1.5 (0-3)	0 (0-3)	***0.814***
BOP %	2 (1-6)	3 (0-6)	***0.700***
VMT (mm)	2 (1.5-3)	2 (1-2.5)	***0.208***

Table 4.12: Maxillary vs Mandibular Comparison of Clinical and Radiographic Measurements in the Control Group "Tables Continued".

KTW (mm)	5 (3-6)	4 (3-6)	***0.134***
ISQ	77 (71-79)	78 (73-81)	***0.269***
IS-C-d (mm)	1.5 (1.5-1.5)	1.5 (1.5-1.5)	-
IS-C-m (mm)	1.5 (1.5-1.5)	1.5 (1.5-1.5)	-
IS – fBIC-d (mm)	0 (0-0)	0 (0-0)	-
IS – fBIC-m (mm)	0 (0-0)	0 (0-0)	-
3th Month			
PI %	2 (1-5)	2 (0-8)	***0.622***
BOP %	1.5 (1-6)	3 (0-6)	***0.583***
ISQ	77.5 (73-80)	78.5 (75-82)	***0.251***
IS-C-d (mm)	1.11 (0.64-1.35)	0.94 (-0.3-1.29)	***0.329***
IS-C-m (mm)	1.17 (0.83-1.42)	1.22 (0.71-1.43)	***0.664***
IS – fBIC-d (mm)	0 (-0.42-0)	-0.25 (-0.81-0)	***0.084***
IS – fBIC-m (mm)	0 (-0.51-0)	-0.15 (-1.03-0)	***0.191***
6th Month			
PI %	1 (1-7)	2 (0-9)	***0.955***
BOP %	2.5 (1-6)	3,5 (0-6)	***0.562***
IS-C-d (mm)	1 (0.54-1.23)	0.65 (-0.35-1.11)	***0.181***

Table 4.12: Maxillary vs Mandibular Comparison of Clinical and Radiographic Measurements in the Control Group "Tables Continued".

IS-C-m (mm)	1.02 (0.44-1.29)	1.07 (0.44-1.41)	***0.870***
IS – fBIC-d (mm)	0.06 (0-1.1)	-0.32 (-1.43-0)	***0.480***
IS – fBIC-m (mm)	0.01 (-1.11-0.87)	-0.19 (-1.34- 0)	***0.220***

*Mann Whitney U Test, *p<0.05*

Table 4.13: Maxillary vs Mandibular Comparison of Clinical and Radiographic Measurements in the Test Group.

	Maxilla (3)	**Mandibula (13)**	***p***
	Min-Max (Median)	**Min-Max (Median)**	
Baseline			
PI %	1-5 (3)	0-2 (1)	***0.079***
BOP %	1-3 (2)	0-4 (2)	***0.945***
VMT (mm)	2-3 (2)	1-4 (1,5)	***0.127***
KTW (mm)	4-6 (6)	3-6 (4,5)	***0.246***
ISQ	72-74 (74)	71-80 (76)	***0.174***
IS-C-d (mm)	1.5 (1.5-1.5)	1.5 (1.5-1.5)	-
IS-C-m (mm)	1.5 (1.5-1.5)	1.5 (1.5-1.5)	-
IS – fBIC-d (mm)	0 (0-0)	0 (0-0)	-
IS – fBIC-m (mm)	0 (0-0)	0 (0-0)	-
3rd Month			
PI %	2 (1-4)	1 (0-5)	***0.397***

Table 4.13: Maxillary vs Mandibular Comparison of Clinical and Radiographic Measurements in the Test Group. "Tables Continued".

BOP %	2 (1-2)	1 (0-4)	***0.830***
ISQ	76 (73-76)	77 (74-81)	***0.69***
IS-C-d (mm)	1.04 (1.02-1.25)	1.12 (-0.91-1.44)	***0.736***
IS-C-m (mm)	1.17 (0.71-1.42)	1.14 (0.74-1.36)	***0.840***
IS – fBIC-d (mm)	0 (-0.71-0)	0 (-0.66-0)	***0.374***
IS – fBIC-m (mm)	-0.41 (-0.86-0	0 (-0.93-0)	***0.164***
6th Month			
PI %	1 (1-3)	1 (0-4)	***0.619***
BOP %	1 (0-1)	1 (0-3)	***0.218***
IS-C-d (mm)	0.91 (0.84-1.13)	0.94 (-0.31-1.29)	***0.946***
IS-C-m (mm)	1.05 (0.62-1.22)	0.94 (-0.02-1.26)	***0.459***
IS – fBIC-d (mm)	0.36 (0.02-0.85)	-0.2 (-1.21-0)	***0.544***
IS – fBIC-m (mm)	0.81 (0.28-1.04)	-0.25 (-1.15-0)	***0.157***

*Mann Whitney U Test, *p<0.05*

4.9 CORRELATION ANALYSIS OF BASELINE VERTICAL MUCOSAL THICKNESS AND KERATINIZED TISSUE WIDTH WITH RADIOGRAPHIC MEASUREMENTS

When the relation of radiographic measurements with baseline values of VMT and KTW were evaluated, in the control group IS-C-d distance at 3rd month showed positive correlation with VMT and KTW (p=0.021 and p=0.028, respectively). Also, positive correlation was found between IS-C-d distance and VMT in the control group at 6th month (p=0.002) (Table 4.14).

Table 4.14: Correlation of Baseline VMT & KTW with 3rd and 6th Month Radiographic Measurements in the Control Group.

		Baseline VMT	Baseline KTW
3rd Month			
IS-C-d	***r***	0.570*	0.548*
	p	**0.021**	**0.028**
IS-C-m	***r***	0.232	-0.086
	p	**0.387**	**0.752**
IS – fBIC-d	***r***	0.338	0.313
	p	**0.200**	**0.237**
IS-fBIC-m	***r***	-0.111	0.162
	p	**-0.682**	**0.550**
6th Month			
IS-C-d	***r***	0.701**	0.457
	p	**0.002**	**0.075**
IS-C-m	***r***	0.457	-0.044
	p	**0.075**	**0.873**
IS – fBIC-d	***r***	0.077	0.160
	p	**0.776**	**0.553**
IS-fBIC-m	***r***	-0.282	0.004
	p	**0.289**	**0.989**

*r=Spearman's Correlation *p<0.05. **p<0.01*

When the correlation of radiographic measurements with VMT and KTW were evaluated in the test group, no significant correlation was found other than positive correlation between KTW and IS-C-m distance at 3rd and 6th month follow-ups (p=0.038 and p= 0.049, respectively) (Table 4.15).

Table 4.15: Correlation of Baseline VMT & KTW with 3rd and 6th Month Radiographic Measurements in the Test Group.

		Baseline VMT	Baseline KTW
3rd Month			
IS-C-d	***r***	-0.210	0.090
	p	**0.434**	**0.741**
IS-C-m	***r***	0.167	0.523*
	p	**0.536**	**0.038**
IS – fBIC-d	***r***	-0.002	0.127
	p	**0.993**	**0.639**
IS-fBIC-m	***r***	-0.015	0.158
	p	**0.957**	**0.559**
6th Month			
IS-C-d	***r***	-0.126	0.251
	p	**0.642**	**0.349**
IS-C-m	***r***	0.291	0.049*
	p	**0.274**	**0.049**
IS – fBIC-d	***r***	-0.479	-0.210
	p	**0.060**	**0.436**
IS-fBIC-m	***r***	-0.348	-0.136
	p	**0.186**	**0.615**

*r=Spearman's Correlation *p<0.05 **p<0.01*

5. DISCUSSION AND CONCLUSION

Dental implants are considered as a safe and successful treatment option in the rehabilitation of edentulous patients. As the number of implants placed have increased exponentially in recent years, expectations of both the clinician's and patient's have gradually increased, and this has led to a paradigm shift in the success criteria of dental implant therapy. Maintenance of soft and hard tissues around an osseointegrated implant is of importance in the succession of dental implants. Prevention of crestal bone loss around implants is necessary to maintain the stability of soft tissue, which in turn affects the aesthetic outcomes of the therapy. Although still under debate, according to the success criteria defined, MBL up to 2 mm within the first year of functional loading is considered to be normal and it is accepted as a normal process of tissue remodeling (Araujo, Lindhe, 2018; Galindo-Moreno, Leon-Cano, Ortega-Oller, Monje, O'valle, Catena, 2015). MBL is a multifactorial phenomenon which is affected by biological, surgery related or implant related factors. In recent years, with the advances in implant research, different methods were proposed for the maintenance of marginal bone (Canullo, Iannello, Peñarocha, Garcia, 2012).

Our study is planned as a single-centered, randomized controlled clinical follow-up study, to investigate the effect of implant with a macro-design that allows to have increased bone thickness around the neck portion of the implant, on MBL. As secondary outcomes, the effect of patient related factors such as smoking status, VMT, KTW on MBL were evaluated. A total number of 32 systemically and periodontally healthy or stable subjects with single tooth loss in the posterior maxilla or mandible were included in the study and were assigned into test (n=16) and control groups (n=16). Either DTI-1 SLA® implants with cylindric design or DTI Power4® aggressive implants with angled neck design were placed in the edentulous maxillary or mandibular posterior sites of the subjects in control and test groups, respectively. Full mouth periodontal clinical measurements, VMT and KTW at the edentulous site are recorded at baseline. Implants in the test and control groups were placed by one-stage surgery. MBL was assessed by measuring the distances between IS, C and fBIC on standardized peri-apical radiographs which were taken at 10 days, 3 and 6 months following surgery. Implant stability was determined by RFA which is performed at the day of surgery and at the 3rd month follow-up. Inter- and intra-group comparisons at different

time points and the correlations between different variables were analyzed by non-parametric tests.

When demographic data is analyzed, there were no statistically significant differences in terms of age, gender distribution and smoking status between the study groups. The mean age was found to be 42.5 ±11.68 and 38.93 ±10.60 in the control group and test groups, respectively. Subjects included in our study is rather young, therefore we assume that the results were not affected by any possible negative impact of age. In the literature, it is discussed that decreased rate of wound healing as a consequence of aging could affect osseointegration and the ability to practice appropriate oral hygiene in a negative manner (Schimmel, Müller, Suter, Buser, 2017). In the vast majority of studies conducted in recent years, it has been reported that dental implant application will not present a disadvantage in terms of survival and MBL with the progression of age (Schimmel, Srinivasan, McKenna, Müller, 2018). In a retrospective cross-sectional study that assess the success of dental implant and MBL in subjects >65 years old at the time of implant placement, total number of 218 dental implants placed in 74 subjects, were evaluated for a follow-up period of at least 5 years, and it was found that advanced age did not affect the success of the dental implant or the risk of peri-implantitis (Etöz, Bertl, Kukla, Ulm, Ozmeric, Stavropoulos, 2021). However, it should be kept in mind, in spite of the fact that aging process itself may not jeopardize the implant success, the increased incidence of systemic diseases at advanced age and use of medications may interfere with osseointegration process and MBL in short and long term.

In the current study, female to male ratio were found to be similar in the study groups. In a systematic review by Chrcanovic et al. (2015), it was stated that the failure rate of dental implants is higher in male than in female. In another study by Mumcu et al. (2011), MBL was found to be similar in male and female subjects during the first 24 months. However, the authors reported that MBL was higher in female subjects at 36-month follow-up. Also, in other studies evaluating the implant success in a large cohort, gender was not considered as a potential risk factor for MBL (Kordbacheh Changi, Finkelstein, Papapanou, 2019; Derks, Schaller, Håkansson, Wennström, Tomasi, Berglundh, 2016).

In our study, periapical radiographs taken with the long-con parallel technique were used to evaluate MBL. Individualized silicone stents were prepared in order to obtain standardized

radiographs. Intra-oral radiograph is known as safe, simple, and reproducible diagnostic tool to determine MBL around implants and considered as the standard imaging method according to current guidelines. However, due to its 2-dimensional nature, intra-oral radiography does not provide information about buccal and lingual/ palatal bone. Cone-beam computed tomography (CBCT) is considered as an alternative to intra-oral radiography, as it may provide 3-dimensional images. However, CBCT also has limitations to be used as a standard diagnostic tool in the assessment of peri-implant bone defects. The quality of CBCT images is negatively affected by artefacts. Especially metal objects such as dental implants may cause artefacts such as beam-hardening, bright streaking, or scatter. In the literature, there are number of studies comparing the efficacy of imaging methods in the diagnosis of peri-implant bone loss (Carral, Flores- Guillén, Figuero, 2021; Dave, Davies, Wilson, Palmer, 2013). In an in-vitro study by Dave et al. (2013), accuracy of long-cone parallel periapical radiographs and CBCT in the detection of peri-implant defects were compared. Dental implants were placed in osteotomy sites that are prepared in different diameters in fresh bovine ribs. It was found that there were no differences between two methods in the detection of large defects, however periapical radiographs were found to be more accurate in the detection of small size defects. Sirin et al. (Sirin, Horasan, Yaman, Basegmez, Tanyel, Aral, Guven, 2012) compared conventional periapical radiography with panoramic radiography and CBCT, and it was reported that periapical radiographs were faster and more reliable when compared to the other methods in the evaluation of peri-implant bone. Since, the 6-month follow-up period in our study is rather short and minimal MBL was expected, intra-oral radiography was chosen as the imaging method for the detection of MBL.

The distance between the most apical portion of the C and IS and the distance between IS and fBIC were determined as the reference points on the radiograph in order to evaluate MBL. In both study groups, 1.5 mm subcrestal implant placement were done. The distances of both IS-C and IS-fBIC were chosen to be analyzed because when only IS-C distance is taken into consideration to evaluate MBL, the alteration as a consequence of tissue remodeling would cause misinterpretation of the data and false positive detection of MBL. Therefore, along with IS-C distance, IS-fBIC distance is also evaluated to detect whether the neck portion of the implant is exposed or not. When data is analyzed, in both study groups IS-C and IS-fBIC distances were lower at 3rd and 6th months compared to baseline. However, no significant differences were found between the groups. The macro-design of dental

implants is a well-studied topic in implantology. Although, there is not an ideal implant design or an ideal surface treatment, it has been shown that long-term implant success and healing process is affected by macro-design of the dental implant. The neck portion of the implant connects the implant body to the oral cavity via abutment, and it is crucial in determining the peri-implant health. In an implant under function, stress is mostly concentrated in the neck portion, therefore implant neck portion is distinguished from other components (Montemezzi, Ferrini, Pantaleo, Gherlone, Capparè, 2020; Spies, B.C.; Bateli, Ben Rahal, Christmann, Vach, Kohal, 2018; Ormianer, Matalon, Block, Kohen, 2016). In the literature there are studies that examine the effects of the different surface properties and thread design of neck portion on MBL. However, there are very few studies that examine the effect of geometric differences in the neck region. In their study, Montemezzi et al. (2020) compared rough wide-neck and rough reduced-neck implants in terms of survival rate, PPD, and MBL at 12 and 24 months. It was reported that in patients treated with rough wide-neck designed implants, PPD and MBL was lower than those who were treated with rough reduced-neck designed implants and it was concluded that reduced neck implants showed a greater tendency to bone loss over time when compared to wide neck implants. In a retrospective study by Carinci et al. (2009), survival and success rates of conventional and reverse tapered neck implants was examined in a total number of 234 implants in 86 patients. They hypothesized that reverse conical implants might provide the necessary vascular support to hard and soft tissues, especially in cases where the inter-implant distance is less and could reduce mechanical stresses by increasing the crestal bone volume, however no statistically significant differences were found between two groups in terms of MBL. Pozzi et al. (2012), performed a multicenter, randomized, controlled, split-mouth study to evaluate MBL in implants with a reverse tapered and parallel neck design. At the end of 1 year follow-up after loading, the authors reported that there were statistically significant differences between the groups in favor of reverse tapered neck design. However, in the aforementioned study not only the neck design but also the connection type of the implants was different. The implants with reverse tapered neck had built-in platform shifting with 12° internal conical connection, while implants with parallel neck had flat to flat implant-abutment interface with external hexagonal connection of 0.7 mm height. Therefore, the authors claim that the significant difference in MBL could also be due to the effect of platform shifting on biological width formation. Also, it is reported that significant

difference in MBL was seen between surgery and delivery of the prosthesis, while no significant difference was seen within 1 year following the functional loading. This finding may indicate that major amount of MBL occurs between surgery and functional loading as a result of tissue remodeling at the initial phase of healing. Shen et al. (2010), investigated the effect of divergent, convergent, and parallel implant neck designs on stress and tension distribution in the crestal bone. The authors declared that implants with divergent neck design caused lower stress and tension on the compact crestal bone. However, there is still no consensus on the implant design that provide optimal maintenance of soft and hard tissue in the cervical part (Carinci, Brunelli, Danza, 2009; Shen, Chen, Hsu, 2010). Implants included in the current study are both platform-switched and have 11-degree Morse taper conical connection, yet the macro-design at the neck portion of the implants were different. In the literature, conical connection is recommended to avoid micro-movement and micro-leakage, which are among the factors that causes MBL. In our study, implants in both groups were placed with one-stage surgery, and loaded with single unit, cement retained crowns at the end of 3 months of osseointegration period. Therefore, any difference between the study groups is not expected to be due to the differences in the implant- abutment connection type or surgical procedure but rather the implant design. However, since it is not a split-mouth design study, patient related factors that could affect MBL were not excluded. In order to overcome aforementioned issue, age matched, systemically and periodontally healthy subjects were included in the study and there were no differences between the groups in terms of female to male ratio and smoker to non-smoker ratio. In the current study, MBL were measured at 3rd and 6th months following the surgery. As, it is observed in the study by Pozzi et al. (2012), major amount of MBL occurs within the first months of healing. Therefore, 6 months of follow-up period may be considered long enough to observe any differences between the groups. We assume that the MBL at the initial healing phase is mostly due to the tissue remodeling and MBL at longer term may result from upper structure related or microbiological factors. Thus, longer term follow-up for the evaluation of MBL is also suggested.

Among the surgical factors affecting MBL, apico-coronal positioning of the implant plays an important role (Muñoz, Busoms, Vilarrasa, Albertini, Ruíz-Magaz, Nart, 2021). Implant-abutment connection is known as micro-gap and positioning of the implant at the vertical axis directly affects the location of micro-gap. In a study by Hermann et al. (2011), it was

observed that MBL was higher in platform matching implants that are placed subcrestally. In a systematic review about the effect of subcrestal placement on MBL, Valles et al. (2018) concluded that less MBL was seen in PS implants that are positioned subcrestally compared to those placed at the bone level. Similar to the findings of Hermann et al. (2011), it was shown that the more MBL was seen when platform matching implants were placed at the subcrestal level (Valles et al. 2018). It has been proposed that PS implants provide space for the establishment of an appropriate biologic width around an implant and, which in turn causes junctional epithelium to extend less towards the apical direction. However, there are some studies showing that subcrestal positioning of PS implants resulted with significantly larger junctional epithelium and peri-implant soft tissue compared to implants that are placed in equicrestal position (Schwarz, Mihatovic, Golubovich, Schar, Sager, Becker, 2015; Huang, Meng, Zhu, Witek, Tovar, Coelho, 2015). In their systematic review, Valles et al. (2018) concluded that significantly less MBL was seen at subcrestally placed PS implants, however significant difference was seen in animal studies. In the current study, platform switch implants in both study groups were positioned at 1.5 mm subcrestal level. In their split-mouth designed study on dogs, Berglundh et al., 1996) have shown that when mucosa thickness was surgically decreased to 2 mm or less, MBL was seen with no exception due to the formation of transmucosal attachment around the implants. However, when mucosa thickness of 4 mm or more was preserved marginal bone was maintained. Our study did not have a split-mouth design, and in order to exclude the effect of VMT on transmucosal attachment formation, all implants were placed at the subcrestal position.

In our study, the RFA was used to monitor both primary and secondary stabilization. Some researchers consider RFA to be the gold standard for the assessment of implant stability. Numerous studies have demonstrated that RFA permits safe, user-friendly, dependable, and repeatable measurements to evaluate the primary and secondary stability of implants. High primary stability ensures that the implant is resistant to micromovements and for osseointegration to be successful, the implant should not be exposed to micro-movements which is greater than 50–150 m. The mechanical interaction between an implant and cortical bone is important for the determination of stability of the implant. Stability is affected by various parameters, such as the bone quantity and quality where the implant is placed, the surgical operation, and the length, diameter, and shape of the implant (Meredith, 1998). Ramakrisha and Nayar, (2007) indicated a suitable primary stability if ISQ values are above

65 and a weak primary stability if they are below 45. Sim and Lang, (2010), on the other hand, considered the clinical suitability of ISQ values above 55. There is no consensus on a threshold ISQ value for the success or failure of the implant. However, the idea of the higher the ISQ, the higher the primary stability, is generally accepted. In our study, ISQ values were found to be increased at 3rd month when compared to baseline in both study groups, however there were no significant differences between the study groups. Sanchez et al. (2019) evaluated whether there is correlation or not between RFA values and MBL in four different implant designs. The RFA was measured at baseline, the third, sixth, and twelve-month intervals. As a consequence, the measured values increased with time, but there was no correlation between implant design, stabilization, and MBL. According to Winter et al. (2010), there is a negative correlation between the primary stabilization values obtained by RFA and MBL in the finite element analysis that they conducted; they emphasize that increases in MBL are characterized by low primary stabilization values. Elsyad et al. (2014) evaluated 72 implants placed in the inter-foraminal region of 36 patients during a 12-month follow-up period and found no correlation between ISQ values and the amount of MBL in the results of their clinical investigations.

Surgical trauma is another factor affecting the MBL. Abrahamsson et al. (2021) evaluated the effect of implant geometry and osteotomy design on bone healing at early phase in their animal study. Two different types of implants were placed in osteotomy sites with regular or reduced diameter and both ISQ values and insertion torque values were recorded. The authors claimed that although no differences were detected by RFA, the insertion torque values were different between the study groups with higher insertion torque in the reduced diameter osteotomy group and at 6 weeks following the surgery, radiographic bone loss was positively correlated with insertion torque. Abrahamsson et al. (2021) suggested that increased stress at the cervical portion of the implant causes an increase in the bone tissue remodeling during early phase of healing. In order to control and standardize the stress in the most coronal portion, the implants in our study were placed in accordance with the manufacturer's recommendations and all implants were inserted with 30 Ncm torque value, and healing caps were screwed with the same torque value of 25 Ncm in both study groups.

Smoking is shown to have negative effect on outcomes of implant therapy, and it was also indicated that smoking is related with high risk of implant failure and increased MBL. The

mechanism underlying is explained by vasoconstriction caused by nicotine exposure. As a consequence, reduced blood flow and impaired supply of nutrients interferes with remodeling process (Chrcanovic, Albrektsson, Wennerberg, 2015; Mustapha, Salame, Chrcanovic, 2021). Also, it has been demonstrated bone remodeling process is impaired as a result of inhibition of the gene expression of the enzymes which take place in osteoblastic proliferation and differentiation. However, data on the smoking is still controversial. In a systematic review, Chranovic et al. (2015) reported that smoking is a risk factor for post-operative infection and MBL. However, the authors suggest that the results should be interpreted carefully because of the presence of uncontrolled and complex risk factors. In another meta-analysis by Mustapha et al. (2021) it was determined that the increase in MBL in smokers was statistically significant. In a cohort study (French, Ofec, Levin, 2021), smoking and MBL are found to be positively correlated. In another cohort study by the same study group, (French, Grandin, Ofec, 2019), it was concluded that smoking is a risk factor for periimplantitis. On the contrary, Koldsland et al. (2019) found that, no relationship was found between smoking and peri-implant bone loss. Derks and Tomasi, (2015), and Schwarz et al. (2018), claimed that adequate levels of evidence that support the negative role of smoking on peri-implant bone loss, have not been reached. In the current study, smokers were not excluded but the patients smoking less than 10 cigarettes per day were included. When data regarding smoker subjects in each group were compared, no significant differences were found between test and control groups in terms of clinical data and MBL. Also, comparison of smoker and non-smoker subjects were performed within the test or control groups and no significant differences were detected. We assume that small number of subjects in each sub-group may mask the effect of smoking. Another fact that should be kept in mind that the number of cigarettes smoked per day and pack year may affect the results since there is a dose dependent relationship between smoking and periodontitis.

Because the maxilla and mandible have different bone densities, they have been taken into consideration in implant survival studies. Cosano et al. (2021) investigated implant loss and MBL in their retrospective multi-center cross-sectional cohort study. The average annual MBL of maxillary implants was found to be significantly higher than those placed into the mandible. In addition, greater MBL was observed in implants that are placed in the anterior sites. Negri et al. (2014), examined the effect of age, insertion site and gender on MBL in their 3-year follow-up study and higher MBL in maxillary implants than mandibular

implants were seen. In a randomized prospective study (Peñarrocha-Diago et al. 2013) which was performed to examine MBL around implants with two different neck designs at 6- and 12-month follow-ups, no significant differences were found between maxilla and mandible. Ravald et al. (2013), in a long-term study in which they compared two different implant systems, could not find significant difference between the maxilla and the mandible in terms of bone loss. The result of our study is in accordance with the previous studies in terms of maxillary and mandibular comparisons. In both intra-group and inter-group comparisons of maxilla and mandible, no significant differences were seen in terms of MBL. However, the number of implants placed in the maxilla was rather higher than the implants placed in mandible. Therefore, it would be more accurate to evaluate the outcomes if the quantities of observations for the maxilla and mandible were approximately equal.

When the correlation between baseline VMT, KTW measurements and MBL were analyzed, IS-C-d distance at 3rd month showed positive correlation with VMT and KTW ($p=0.021$ and $p=0.028$, respectively) in the control group. Also, positive correlation was found between IS-C-d distance and VMT in the control group at 6th month. Whereas, in the test group no significant correlation was found other than positive correlation between KTW and IS-C-m distance at 3rd and 6th month follow-ups. In their study, Munoz et al., (2021) evaluated the bone loss around implant with different abutment height and the effect of mucosal thickness and no correlation was found between mucosa thickness and MBL changes. On the contrary, in a meta-analysis (Suarez-Lopez Del Amo, Lin, Monje, Galindo-Moreno, Wang, 2016), it is reported that implants with VMT > 2 mm revealed less MBL in comparison to the implants with VMT<2 mm. As it is previously mentioned, in the animal study by Berglundh et al. (1996), MBL was seen in the group where mucosa thickness was reduced to 2 mm or less and it was related to the formation of transmucosal attachment during initial phase of healing. It is thought that subcrestal placement of the implants may avoid MBL due to the process of transmucosal attachment formation by compensating thin VMT.

As a conclusion, within the limits of this study there were no differences between implants with standard design and angled neck design in terms of MBL. It was hypothesized that increased bone thickness around the neck portion of a dental implant might avoid MBL at the initial phase of the therapy. However, it is not supported by the findings of current study. Although MBL up to 1-1.5 mm within the first year of functional loading is considered

normal, it should be kept in mind that MBL is multifactorial and may be controllable. Implant abutment connection type and location of implant abutment interface in relation to the bone are important implant related factors in order to reduce MBL. In this context, use of platform switched implants with internal conical connection is recommended. One of the reasons of relatively less MBL compared to the amount of MBL expected according to the traditional criteria in both study groups may be due to the use of PS implants with conical connection. Other reasons may be less surgical trauma, standardized insertion torque values and subcrestal placement of the implants and inclusion of the subjects with no systemic diseases and with excellent plaque control. Longer term studies with larger study population are needed in order to evaluate the factors affecting the MBL around implants.

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APPENDIX A

ETHIC COMMITTEE APPROVAL

Evrak Tarih ve Sayısı: 02.03.2023-46352

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ALTINBAŞ ÜNİVERSİTESİ
KLİNİK ARAŞTIRMALAR ETİK KURULU

Sayı: 171 **Tarih: 02.02.2023**
Konu: Dt. Tümer Tekin

Sayın Dt. Tümer Tekin
Altınbaş Üniversitesi Diş Hekimliği Fakültesi

İlgi: Altınbaş Üniversitesi Diş Hekimliği Fakültesi, Periodontoloji ABD Başkanlığının 27.09.2022 tarihli yazısı ile Altınbaş Üniversitesi Klinik Araştırmalar Etik Kurulunun 2022/173 sayılı yazısı

Sorumlu araştırıcılığını üstlendiğiniz **2022/173** dosya numaralı "**Farklı tasarıma sahip implantlarda, krestal kemik seviyesine etki eden faktörlerin değerlendirilmesi**" başlıklı çalışma, kurulumuzun **02 Şubat 2023 tarih ve 4 sayılı toplantısında** görüşülerek etik yönden uygun bulunmuş olup, tutanaklar ekte sunulmuştur.

Bilgilerinize sunarım.

Prof. Dr. Mustafa Aydın BARLAS
Altınbaş Üniversitesi Klinik Araştırmalar
Etik Kurul Başkanı
E-İmzalıdır

Ekl: Altınbaş Üniversitesi Klinik Araştırmaları Etik Kurulu Karar Formu

Evrak Tarih ve Sayısı: 02.03.2023-46352

ETİK KURUL BİLGİLERİ	ETİK KURULUN ADI	**ALTINBAŞ UNIVERSITESI KLINIK ARAŞTIRMALARI ETIK KURULU KARAR FORMU**
	AÇIK ADRESİ:	**Kartaltepe Mah. İncirli cad. No:11 Bakırköy / İstanbul**
	TELEFON	**(0 212) 709 45 28**
	FAKS	**(0 212) 445 81 71**
	E-POSTA	etikkurul@altinbas.edu.tr

BAŞVURU BİLGİLERİ	ARAŞTIRMANIN AÇIK ADI	**"Farklı tasarıma sahip implantlarda, krestal kemik seviyesine etki eden faktörlerin değerlendirilmesi "**			
	ARAŞTIRMA PROTOKOL KODU	**2022/173**			
	KOORDİNATÖR/SORUMLU ARAŞTIRMACI UNVANI/ADI/SOYADI	**Dt. Tümer Tekin**			
	KOORDİNATÖR/SORUMLU ARAŞTIRMACININ UZMANLIK ALANI	**Periodontoloji**			
	KOORDİNATÖR/SORUMLU ARAŞTIRMACININ BULUNDUĞU MERKEZ	**Altınbaş Üniversitesi Diş Hekimliği Fakültesi**			
	DESTEKLEYİCİ	---			
	DESTEKLEYİCİNİN YASAL TEMSİLCİSİ	---			
	ARAŞTIRMANIN FAZI	FAZ 1	☐		
		FAZ 2	☐		
		FAZ 3	☐		
		FAZ 4	☐		
	ARAŞTIRMANIN TÜRÜ	Yeni Bir Endikasyon	☐		
		Yüksek Doz Araştırması	☐		
		Diğer ise belirtiniz: Bilimsel Araştırma			
	ARAŞTIRMAYA KATILAN MERKEZLER	TEK MERKEZ ■	ÇOK MERKEZLİ ☐	ULUSAL ■	ULUSLAR ARASI ☐

Evrak Tarih ve Sayısı: 02.03.2023-46352

ALTINBAŞ ÜNİVERSİTESİ KLİNİK ARAŞTIRMALARI ETİK KURULU KARAR FORMU

ARAŞTIRMANIN AÇIK ADI	"Farklı tasarıma sahip implantlarda, krestal kemik seviyesine etki eden faktörlerin değerlendirilmesi"

DEĞERLENDİRİLEN BELGELER	Belge Adı	Tarihi	Versiyon Numarası	Dili
	ARAŞTIRMA PROTOKOLÜ	■		Türkçe ■ İngilizce ☐ Diğer ☐
	BİLGİLENDİRİLMİŞ GÖNÜLLÜ OLUR FORMU	■		Türkçe ■ İngilizce ☐ Diğer ☐
	OLGU RAPOR FORMU	☐		Türkçe ■ İngilizce ☐ Diğer ☐
	ARAŞTIRMA BROŞÜRÜ	■		Türkçe ■ İngilizce ☐ Diğer ☐

DEĞERLENDİRİLEN DİĞER BELGELER	Belge Adı		Açıklama
	TÜRKÇE ETİKET ÖRNEĞİ	☐	
	SİGORTA	☐	
	ARAŞTIRMA BÜTÇESİ	■	
	BİYOLOJİK MATERYEL TRANSFER FORMU	☐	
	HASTA KARTI/GÜNLÜKLERİ	☐	
	İLAN	☐	
	YILLIK BİLDİRİM	☐	
	SONUÇ RAPORU	☐	
	GÜVENLİLİK BİLDİRİMLERİ	☐	
	DİĞER:	☐	İndex, Başvuru Formu, Bütçe, Akademik Kurul Kararı, Taahhütname, Özgeçmişler, Literatür Örneği, Onam Formu incelenmiştir.

KARAR BİLGİLERİ		
	Karar No:4	**Tarih: 02.02.2023**
	Yukarıda bilgileri verilen araştırma başvuru dosyası ile ilgili belgeler araştırmanın gerekçe, amaç, yaklaşım ve yöntemleri dikkate alınarak incelenmiş, gerçekleştirilmesinde **etik ve bilimsel sakınca bulunmadığına** toplantıya katılan Etik Kurul üye tam sayısının salt çoğunluğu ile karar verilmiştir.	

ALTINBAŞ ÜNİVERSİTESİ KLİNİK ARAŞTIRMALARI ETİK KURULU

ÇALIŞMA ESASI	**19.08.2011 tarihli, 28030 sayılı Resmi Gazetede yayınlanan Klinik Araştırmalar Hakkındaki Yönetmelik**
BAŞKANIN UNVANI / ADI / SOYADI:	**Prof. Dr. Mustafa Aydın BARLAS**

Unvanı/Adı/Soyadı	Uzmanlık Alanı	Kurumu	Cinsiyeti		Araştırma ile İlişki *		Katılım **		İmza
Prof. Dr. Mustafa Aydın BARLAS	**Farmakoloji**	**Altınbaş Üniversitesi (Etik Kurul Başkanı)**	E ■	K ☐	E ☐	H ■	E ■	H ☐	e-imzalıdır
Prof. Dr. Hatun Hanzade Doğan	**Tıp Etiği**	**Altınbaş Üniversitesi (Etik Kurul Üyesi)**	E ☐	K ■	E ☐	H ■	E ■	H ☐	e-imzalıdır
Doç. Dr. Soner Şişmanoğlu	**Restoratif Diş Tedavisi**	**İstanbul Üniversitesi-Cerrahpaşa (Etik Kurul Bşk. Yrd.)**	E ■	K ☐	E ☐	H ■	E ■	H ☐	[redacted]
Dr. Öğr. Üyesi Gülkızılca YÜRÜR	**Tıp Etiği**	**Altınbaş Üniversitesi (Etik Kurul Üyesi)**	E ☐	K ■	E ☐	H ■	E ■	H ☐	e-imzalıdır
Dr. Öğr. Üyesi Emir RUŞEN	**Nöroloji**	**Altınbaş Üniversitesi (Etik Kurul Üyesi)**	E ■	K ☐	E ☐	H ■	E ■	H ☐	e-imzalıdır
Dr. Öğr. Üyesi Mehmet Görgülü	**Genel Cerrahi**	**Altınbaş Üniversitesi (Etik Kurul Üyesi)**	E ■	K ☐	E ☐	H ■	E ■	H ☐	e-imzalıdır
Dr. Öğr. Üyesi Gaye HAFEZ	**Farmakoloji**	**(Bildirimin Değerlendirilmesinde Görev Alacak Üye)**	E ☐	K ■	E ☐	H ■	E ■	H ☐	e-imzalıdır

* Araştırma ile İlişki
** Toplantıda Bulunma

Sayfa 2