CORRELATION BETWEEN CORTICAL BONE THICKNESS AND IMPLANT STABILITY

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ABSTRACT

The objective of this research was to determine the relationship between cortical bone thickness measured by CBCT (cone beam computed tomography) and primary implant stability from RFA measurement (Resonance Frequency Analysis).

A total of 12 implants were placed in 8 patients at the posterior mandible sites. The crestal cortical bone thickness, buccolingual bone thickness at 5 mm. below the alveolar crest, and bone quality of implant recipient sites were preoperatively recorded using CBCT. RFA measurements (ISQ value) were taken using an Osstell ISQ immediately after implant placement. The correlation between crestal cortical bone thickness and primary implant stability and correlation between buccolingual bone thickness and primary stability were tested using Pearson's correlation with a P value of less than 0.05 considered statistically significant.

The results showed that mean crestal cortical bone thickness and buccolingual bone thickness at 5 mm. below the alveolar crest were 1.42 ± 0.65 mm. and 6.95 ± 1.37 mm., respectively. The bone at the implant sites was classified as bone quality type II and III. The mean ISQ value was 73.33 ± 6.14. No significant correlations were found between crestal cortical bone thickness and primary stability ($r = 0.171$, $P > 0.05$) and buccolingual bone thickness and primary stability ($r = 0.473$, $P > 0.05$).

With the limitations of this study, crestal cortical bone thickness and buccolingual bone thickness seem not to influence the primary implant stability. Further research is required to confirm the outcome.

KEY WORDS: IMPLANT STABILITY / CORTICAL BONE THICKNESS / RESONANCE FREQUENCY ANALYSIS

46 pages

ความสัมพันธ์ระหว่างความหนาของกระดูกทึบกับเสถียรภาพของรากเทียม

CORRELATION BETWEEN CORTICAL BONE THICKNESS AND IMPLANT STABILITY

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บทคัดย่อ

วัตถุประสงค์ เพื่อประเมินความสัมพันธ์ระหว่างความหนาของกระดูกทึบจากภาพเอกซเรย์คอมพิวเตอร์สามมิติ และเสถียรภาพของรากเทียมจากการใช้เครื่องวิเคราะห์คลื่นความถี่เรโซแนนซ์

วิธีทำ ผู้ป่วยที่มีการสูญเสียฟันหลังล่างบางส่วนจำนวน 8 คน ได้รับการคัดเลือกให้เข้าร่วมในการศึกษานี้ รากเทียมจำนวน 12 ราก ถูกนำมาฝังในผู้ป่วย ก่อนการฝังรากเทียม เครื่องเอกซเรย์คอมพิวเตอร์สามมิติถูกนำใช้วัดความหนาของกระดูกทึบบริเวณยอดสันกระดูก ความหนาของกระดูกในแนวด้านแก้ม-ลิ้นที่ระดับ ต่ำกว่ายอดสันกระดูก 5 มิลลิเมตร และประเมินคุณภาพของกระดูกในตำแหน่งที่จะฝังรากเทียม หลังการฝังรากเทียม เสถียรภาพของรากเทียมถูกประเมินโดยใช้เครื่องวิเคราะห์คลื่นความถี่เรโซแนนซ์ ความสัมพันธ์ระหว่างความหนาของกระดูกทึบบริเวณยอดสันกระดูกและเสถียรภาพของรากเทียมและความสัมพันธ์ระหว่างความหนาของกระดูกในแนวด้านแก้ม-ลิ้นที่ระดับต่ำกว่ายอดสันกระดูก 5 มิลลิเมตรและเสถียรภาพของรากเทียมถูกประเมินโดยใช้สถิติทดสอบค่าสัมประสิทธิ์สหสัมพันธ์เพียร์ซัน ที่ระดับนัยสำคัญทางสถิติที่ 0.05 เป็นเกณฑ์ในการยอมรับสมมติฐาน

ผลการวิจัย ค่าเฉลี่ยของความหนาของกระดูกทึบบริเวณยอดสันกระดูกและความหนาของกระดูกในแนวด้านแก้ม-ลิ้นที่ระดับต่ำกว่ายอดสันกระดูก 5 มิลลิเมตรเท่ากับ 1.42 ± 0.65 มิลลิเมตร และ 6.95 ± 1.37 มิลลิเมตรตามลำดับ กระดูกบริเวณที่จะฝังรากเทียมถูกประเมินคุณภาพเป็นชนิดที่ 2 และ 3 ไม่พบความสัมพันธ์ระหว่างความหนาของกระดูกทึบบริเวณยอดสันกระดูกและเสถียรภาพของรากเทียม (ค่าสัมประสิทธ์สหสัมพันธ์ = 0.171 ที่ระดับนัยสำคัญทางสถิติที่ 0.05) และ ความสัมพันธ์ระหว่างความหนาของกระดูกในแนวด้านแก้ม-ลิ้นที่ระดับต่ำกว่ายอดสันกระดูก 5 มิลลิเมตรและเสถียรภาพของรากเทียม (ค่าสัมประสิทธ์สหสัมพันธ์ = 0.473 ที่ระดับนัยสำคัญทางสถิติที่ 0.05)

สรุปผลการวิจัย เนื่องด้วยข้อจำกัดของการศึกษานี้ ความหนาของกระดูกทึบบริเวณยอดสันกระดูก และความหนาของกระดูกในแนวด้านแก้มลิ้นบริเวณที่จะฝังรากเทียมอาจจะไม่มีผลกับเสถียรภาพของรากเทียมหลังการฝัง จำเป็นต้องมีการศึกษาเพิ่มเติมเพื่อยืนยันผลการศึกษา

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CT	Computerized tomography
HU	Hounsfield units
CBCT	Cone beam computerized tomography
RFA	Resonance frequency analysis
ISQ	Implant stability quotient
FOV	Field of view

CHAPTER I
INTRODUCTION

1.1 Background and rationale

Nowadays the use of dental implants to restore missing teeth without affecting adjacent teeth has been increasingly accepted as a standard dental treatment. Many clinical studies have revealed favorable outcomes with implant treatment. [1-4] The success of any implant treatment depends on several factors, such as patient-related factor including general health conditions, surgical procedure, dental implant materials[5] and also quality and quantity of available bone.[6,7] High failure rates for implants placed in maxilla especially posterior maxilla have been seen in several studies [8,9] The primary cause of the higher failure rate may be associated with bone quality of maxilla because it has poorer bone quality than the mandible. [10] The success rate of dental implants is related to the volume and density of the local bone. Therefore, it is important to evaluate quantity and quality of the jawbone before implant placement. Several classification and procedures have been explained for bone quality evaluation.[11-13] The most widely used bone classification is introduced by Leckholm & Zarb.[12] They subjectively classified bone into four groups depending on the amount of cortical bone and trabecular bone according to radiographic examination and surgeon's tactile sensation during drilling at implant sites. However, this classification is subjective and is based on individual perception. Moreover, it cannot show bone quality of the entire jawbone. Because of poor reproducibility and objectivity, this bone quality measurement has recently been questioned. Johansson and Strid proposed a method that objectively measure the torque forces used during implant placement.[14] Studies have shown correlation between the cutting resistance during implant insertion and bone density as evaluated by microradiography.[15] This measurement may be useful to provide information on bone quality; however, it can be performed only after dental implants have already been placed. Therefore, in the past few years, the concept of using computerized tomography (CT), a more objective

method for assessing bone quantity and quality before implant placement, has been used and has gained popularity.[7,16] Bone density measurements from CT expressed in Hounsfield units (HU), ranges from -1000 to 3000. From CT image ,the density of structures can be quantitatively seen and tissue in each area can be distinguished by these values.(i.e.,muscle, 35-70 HU; fibrous tissue, 60-90 HU, cartilage,80-130 HU; bone 150-1800 HU) and differentiate bone quality (D1bone , >1250 HU; D2 bone, 850-1250 HU; D3 bone, 350-850 HU; D4 bone 150-350 HU)[17] However, a high radiation dosage is absorbed by patient during CT scan. Therefore, cone beam computerized tomography (CBCT) technique, espeacially designed for dental and maxillofacial imaging with high resolution, reduce radiation exposure, and costs compared with CT, was introduced.[18,19]

Primary stability of dental implant depends on several factors, such as implant design, surgical procedure, quantity and quality of available bone. When predicting implant stability, bone quality is the one of the most important factors to be considered. A good stability favors osseointegration of implant.[20] One of several methods that have been used in research for the last decade to assess the stability of implant is resonance frequency analysis (RFA). It is an objective method to assess implant stability and osseointegration. It is also a non-destructive method that does not destroy the surface between implant and tissue around implant. The measurement unit is the implant stability quotient (ISQ), ranges from 0 to 100 units.

Recently, with development in implant surfaces and clinical techniques, the initial healing time has significantly reduced and an early or even immediate loading of implant is possible. The successful outcome of immediate or early loading concept is dependent on level of primary stability of implant, which could be advantageous to the clinicians if they can predict the level of primary implant stability before implant placement.[21]

Several studies have shown the relationship between primary stability of dental implant and bone quality derived from CT and CBCT[7,19,22] However, in one study[23], found controversial correlations between CBCT derived gray values and CT-derived gray values. Therefore, using gray values derived from CBCT to determine bone density may not indicate the actual bone quality. Moreover, only

limited studies evaluated bone quality by cortical bone thickness measurement from CBCT and correlated with primary stability of implants.[22,24]

With this background, the purpose of this study was to find the correlation between cortical bone thickness measured from CBCT and implant stability measured by RFA.

1.2 Hypothesis

Cortical bone thickness significantly correlates with primary implant stability.

1.3 Objectives

The aim of this thesis was to find the correlation between cortical bone thickness and primary implant stability.

CHAPTER II
LITERATURE REVIEWS

2.1 Bone quality classification

The success rate of dental implants is related to the volume and local bone density. Therefore, evaluation of the bone quantity and quality of the jawbones before implant treatment is important. Several classifications and procedures have been described for bone quality evaluation.[11-13]

2.1.1 Leckholm & Zarb's bone quality classification

The most widely accepted bone classification is the one proposed by Leckholm & Zarb.[12] They subjectively classified bone into four groups based on the amount of cortical bone vs trabecular bone from radiographic examination and surgeon' s tactile sense while drilling at implant sites.

They classified bone into 4 types

Type I: homogeneous cortical bone in almost the entire jaw.

Type II: thick cortical bone with dense trabecular bone.

Type III: thin cortical bone with dense trabecular bone.

Type IV: thin cortical bone with low density trabecular bone.

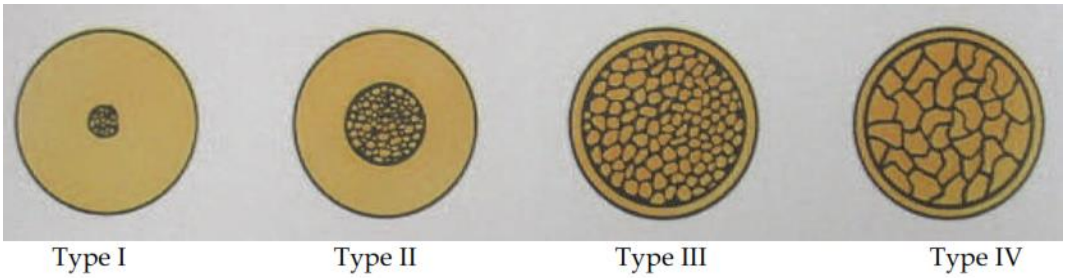

Figure 2.1 Bone quality index[25]

2.1.2 Misch's bone quality classification

The classification by Leckholm & Zarb closely resembles a more recent classification by Misch.[26] Misch classified bone in to four groups (D1, D2, D3, and D4) according to bone quality and volume and this classification also introduced a composition location, and a bone density measured in Hounsfield units for each type of bone.

D1 bone

D1 bone is located mainly in the anterior mandible, composed of almost all cortical bone. A Hounsfield unit reading over 1250 and above demonstrates D1 bone. Therefore, This bone type has the highest bone to implant contact (BIC) and initial implant stability. However, it has fewer intrinsic blood vessels and depends on a significant blood supply from the periosteum because of its density.

D2 bone

D2 bone is composed of a thick cortical bone with coarse trabecular. The area where this bone is mostly found is anterior and posterior mandible. A Hounsfield reading between 850 to 1250 units is an indicative of type D2 bone. This type of bone provides an excellent BIC and presents with rich intrinsic vascularization due to its coarse trabeculae.

D3 bone

D3 bone is composed of thin cortical bone and dense trabecular bone. This bone type can be primary found in the area of anterior and posterior maxilla but also in the posterior mandible. A Hounsfield reading between 350 and 850 units is representative of type D3 bone. The BIC is also less favorable in D3 bone. Due to the porous architecture, failure rate of implant may be increase when placing implant in this bone type. Therefore, a modified drill protocol during implant placement may be necessary.

D4 bone

D4 bone is composed of mainly low density trabecular bone with very thin cortical bone. The most common area for this type of bone is the posterior maxilla. A Hounsfield reading between 150 and 350 units is indicative of D4 bone. Due to the fine trabecular architecture and often absence of a cortical bone structure, D4 bone results in the primary stability of any implant design presents a surgical challenge.[27]

In implant dentistry, it has been considered that bone quality is comparable to bone mineral density [28] which can determine in endocrinology and traumatology by bone densitometry.[25]

2.1.3 Bone classification in Hounsfield unit from computerized tomography

For preoperative evaluation of implant treatment, several imaging modalities have been used to assess the quantity and quality of the local bone; the position of vital structures close to the future implant sites and the existence of disease at the surgical sites. Images from panoramic, periapical and cephalometric provide two-dimensional representations of three-dimensional structures and also have superimposition of structures. In an attempt to overcome this limitation, using CT for dental implant applications was available. This imaging technique creates the opportunity to increase more information than the conventional imaging methods. It produces accurate three-dimensional image that can help the clinician to visualize the alveolar ridges and adjacent structures in all three dimensions and guide the choice of implant site, number, size, and axial orientation of the implants. However, the limitation of CT such as high radiation expose, high cost and difficulty in accessibility associated with CT, CBCT was introduced in the field of dental and maxillofacial radiology. Patients significantly exposed lower radiation dose during scanning. The image created by CBCT provides the potential of enhanced diagnosis and treatment planning for a wide range of clinical applications in implant dentistry.

Producing multiplanar slices of an area of interest and reconstruct a three-dimensional image by using a cone beam x-ray by a series of mathematical algorithms is a principle of CBCT.[29] With the advancement of CBCT, it provide an opportunity to visualize image of maxillofacial skeleton , teeth and the location of vital structures

in all dimension. The application of CBCT in the field of dentistry is increasing exponentially because of the development of an equipment manufacturers and the widespread acceptance of this imaging modality. Generally, based on the field of view size (FOV), CBCT units can be classified into small, medium, and large volume which can be selected depend on each case. As the FOV decreases, the image resolution is higher due to decrease of x-ray noise. They are used to visualized only a quadrant to one jaw. Medium volume CBCT machines use to image both jaw. For orthodontic treatment and orthoganathic surgeries, large field of view is necessary to visualize complete facial structures and anatomical relationships prior treatment. [30]

Several clinical and experimental studies[24,28,31] show the reliability of preoperative bone quantity in implant treatment planning derived from CBCT. Furthermore, Using CBCT in presurgical implant treatment has the potential to assess the ridge form and localization of anatomical structures in more than two dimensions and to decide whether bone grafting is required for suitable prosthetic driven implant position. Another advantage of this imaging technique is, it can accurately measure the cortical bone thickness, walls of maxillary sinuses and the floor of the nasal cavity. Bone density assessment from CBCT has also been an area of increasing interest because it can provide an objective measurement of bone density.[27] However, bone density values derived from CBCT are not accurate values, like Hounsfields values which originated from medical CT. Until now, it has been obtained only predicted bone quality from CBCT. Several studies have been assessed the reliability of bone density measurements obtained from CBCT.[32] Study of Katsumata [33] shows that the Hounsfields value obtained from CBCT varied widely from a range of -1500 to over +3000 for different bone types. However, after calibration has been applied to grey scales of CBCT, the values are much similar to hounsfields value derived from medical CT. [34,35] On the other hand, in one study[36], found controversial association between gray values obtained from CBCT and CT. Therefore, using gray values derived from CBCT to determine bone density may not indicate the actual bone quality. Some studies have found that CBCT might has the ability to analyze cortical bone thickness and the structure of trabecular bone and also found a correlation between bone quality and dental implants primary stability.[19,22] Therefore, using

CBCT to quantify bone quality may be a possible diagnostic tool before implant treatment.[37]

2.2 Implant stability

Implant stability can be described as the lack of clinical mobility. It can be classified into primary stability and secondary stability.

Primary stability is the stability that occurs immediately after implant placement and obtains from mechanical interlock of dental implant to cortical bone. Bone quality and quantity, surgical technique and also implant design are the factors affecting primary stability. Primary stability has been considered as a requirement for osseointegration of dental implants especially when deciding to use early or immediate loading protocols. If an implant had poor stability at the time of placement, the micromotion may occur which will affect the bone healing process and fibrous tissue may form and finally, implant failure as a consequence. Primary stability influences the strength, rigidity and resistance to movement of the implant at the time of implant placement and increases gradually after bone healing. Primary stability must be evaluated immediately after insertion because the level of stability may change overtime due to bone remodeling at the implant–bone interface. A high primary stability of implant may reduce the overall treatment time of the patient because the clinician do not have to wait for the osseointegration of implant before prosthetic loading.[38]

Secondary stability is defined as the biological stability which is gradually obtained after a given a bone regeneration and remodeling period following primary stability. It is affected by bone modeling and remodeling, implant surface condition and primary stability. Secondary stability is provided by osseointegration and requires a direct contact between implant and bone without the interposition of connective tissue. Osseointegration is considered as a direct structural and functional connection between bone and dental implant surface.[39] The stability reduces in the early weeks, goes through a minimum and rises again when the osseointegration occurs.

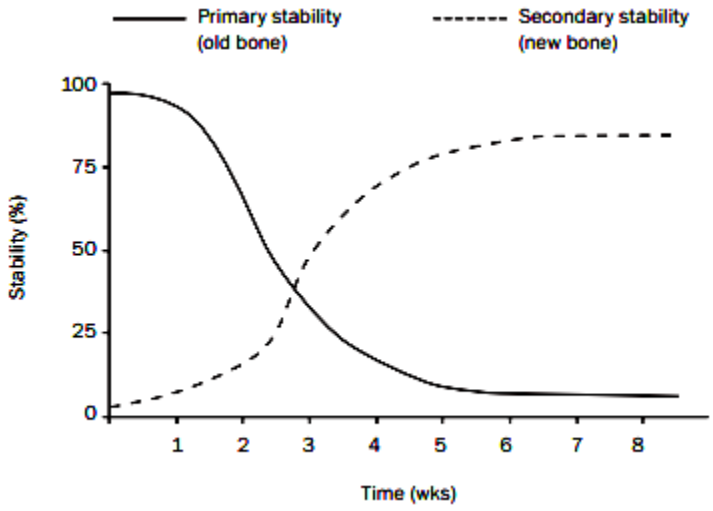

Figure 2.2 Changeover from primary stability created at the time of implant placement to secondary stability created by deposition of new bone (osseointegration) in humans.[40]

Long term implant stability is essential for successful osseointegration which will affect on the success of treatment outcome.[21] Consequently, implant stability measurement is a significant method for assessing the implant success. Functional loading time depends on the secondary stability. Therefore, quantification of implant stability at different time points is necessary for predictability of long term prognosis of implant treatment. [41]

2.3 Implant stability measurement

Nowadays, various techniques have been proposed to measure stability of implant such as histomophometric analysis, percussion test, radiographic method, cutting torque resistance analysis, reverse torque analysis, resonance frequency analysis and periotest.

2.3.1 Histomophometric analysis

This method has been used to quantify bone to implant contact in percentage from ground sections of implant under light microscope. It is used as a

gold standard as a quantitative method, however it is invasive method and cannot use in a daily clinical practice.[21,42]

2.3.2 Percussion test

A simple and non-invasive way to measure implant stability is to tap the implant with a metallic instrument immediately after implant placement, before or after the time of abutment connection. The purpose of this technique is to determine the ringing sound from percussion. However, it is non-specific method and cannot show the value of implant stability.[43]

2.3.3 Radiograph method

The most extensively used method for preoperative implant placement and also postoperative implant placement to assess osseointegration of implant placed is radiographic technique. The aim of this technique is to evaluate crestal bone and also peri- implant radiolucency. Although ,it is a good diagnostic method ,it is not easy to standardize and not specific to measure the stability of implant.[43]

2.3.4 Cutting torque resistance

Cutting torque resistance measurement used to assess bone quality which significantly correlated with implant stability has been proposed by Johansson and Strid. The principle of this technique is to measure the torque that created while preparation an implant osteotomy. It is one part of standard clinical procedure before placing implant into the bone. A torque gauge can also be used to measure implant insertion torque in N-cm. This method is later developed by Friberg, who measured cutting torque resistance in 31 sites of autopsy specimens, He found that maxilla has lower cutting torque resistance compared to mandible and there was a tendency that this value were higher in incisors regions than premolar regions. However, the main limitation of this technique is that it cannot use to predict bone quality before implant placement or after implant were placed. Moreover, the cutting torque resistance value may be depend on the sharpness of cutting instrument used and implant design.[43]

2.3.5 Reverse torque analysis

Reverse torque analysis is used to evaluate implant stability at the time of abutment connection. The principle of this technique is to measure a critical torque value where osseointegration of placed implant was destroyed and also give the indirect information about amount of bone to implant contact. However, it is a destructive technique which even at low level of torque can cause the risk of irreversible plastic deformation and resulted in implant failure. Additionally, the threshold values of reverse torque are different among patients which depend on bone quality and quantity of individuals. For example, reverse torque testing in implant placed in poor bone quality may has a higher risk of implant failure.[43]

2.3.6 Resonance frequency analysis

RFA is a test that can assess implant stability in an objective way which is non-destructive method that does not destroy implant –bone interface. It has been widely used in research for the last 10 years. The bending force which is stimulated by magnetic or electric from transducer that connected to implant is applied to the implant and elastic bone deformation can cause displacement of the implant. Measurement unit of implant displacement is resonance frequency value which are ranging from 3500-8500 hertz and are converted into ISQ 1-100. The frequency value expressed is affected by the stiffness of bone-implant attachment. The higher of ISQ value means the higher of implant stability while the lower values indicated lower stability. There are several generations of resonance frequency analysis .The first and the second generation need computer, oscilloscope and frequency analyzer to visualize the resonance frequency. Moreover, the transducer need to be calibrated before using, so it is considered not user-friendly. From the development of third generation instruments (Osstell®; ISQ, Gothenburg, Sweden), computer is not necessary to analyze the information due to a combination of computer and analyzer in one machine and it can be used without calibration of transducer prior measurement therefore, it is light and simple to use in everyday clinic practice. The machine is wireless and transducer called “smartpeg” is connected to implant via screw and the top of smartpeg contained a magnet which can be stimulated by electromagnetic wave from computer instrument and expressed in ISQ unit. [21,42]

2.3.7 Periotest

Periotest is used to measure the stability of dental implant in an objective and non- invasive way. It is adapted from measuring the clinical mobility of the tooth. The principle of this technique is to use the electrically controlled rod taps the implant 4 times in 1 second at a constant speed. The scale of the stability scale is ranging from -8 to +50. The lower the value means the higher implant stability. [44]

2.4 Factors that affect primary stability of implant

2.4.1 Surgical technique

In poor bone quality, such as the area of posterior maxilla that has thin cortical bone and low density trabecular bone, the clinician can modified a surgical technique to obtain a higher primary stability of implant . There are various surgical techniques for improving the primary stability of implants, such as using osteotome technique, self-tapping implantation, and under preparation of osteotomy. [45]

2.4.2 Implant used

Nowadays, there are various implant shape available in the market. The different shape or macrodesign of implant influences directly on the primary stability. In poor bone quality or in extraction socket, tapered – screw type implants have been used to achieved good primary stability. The level of stability increases because of the compression force that occur between the thread of implant and osteotomy site. [45]

2.4.3 Bone quantity and bone quality

The success of implant treatment depend on the volume and also the quality of the bone at the implant recipient site which is the local factor of the patient that cannot be modified in implant treatment. In implant dentistry, bone quality often refer to bone density however, the meaning of bone quality include other factors than bone density such as bone metabolism, cell turnover, vascularization which may affect on implant treatment outcome. It is difficult to achieve a high primary stability when

placing the implant in poor bone quality and quantity therefore it is challenge in surgery stage of treatment to achieve good stability in this bone type. [25]

2.5 Factors that affect secondary stability of implant

Secondary stability is based on the osseointegration of the implant. Osseointegration is defined as a direct bone contact on an implant surfaces under the light microscope[1].

It consists of two stages:

(1) Formation of woven bone

(2) Formation of lamellar bone

During the third stage, when functional loading has been initiated, the bony structures adapt to the load by improving the quality of the bone; replacing pre-existing, necrotic and/or initially formed more primitive woven bone with mature, viable lamellar bone. This leads to functional adaptation of the bony structures to the load. The dimensions and orientation of the supporting elements change. In vitro studies have shown the importance of loading forces between an implant and the surrounding tissues interface. Even if implants were initially integrated, the overloading that was applied can create microfractures and mobility which may promote bone resorption around the implant and may promote repair by the undesirable growth of fibrous tissue. [46]

Several factors can affect the secondary stability of an implant, among these.

2.5.1 Bone modeling and remodeling

2.5.2 Primary stability

2.5.3 Implant surface conditions

Several studies have shown that surface condition of dental implants strongly influenced the secondary stability.[40,47] A number of implant surfaces have been developed to achieve a good secondary stability. Implant with roughened surface show higher bone to implant contact or removal torque than the smooth one. Nowadays, implant surfaces modification by acid etching and sandblasted is being

developed to create a microroughness on implant surfaces in order to accelerate the process of osseointegration. Moreover, surface chemistry of implant may affect the secondary stability of implant therefore, various attempts have been made to add more bioactive molecule including titanium oxide, hydroxyapatide on implant surface to improve osseointegration.[48]

2.6 Relationship between bone quality and primary implant stability

Recently, with implant surfaces and clinical techniques development, the initial healing time decrease to the concept of an early or even immediate loading which has been widely accepted. The successful outcome of immediate or early loading concept is dependent on level of primary stability of implant which could be advantageous when the clinician can evaluate the level of primary implant stability before implant placement. [21]

Several studies have shown that the bone quality at the implant recipient site, measured as bone density and cortical bone thickness from CBCT, can affect primary stability at the time of implant placement. [19,24]

Isoda et al [19] evaluated relationship between bone density at the implant sites preoperatively, derived from CBCT and insertion torque values and implant stability qoutient values. The study showed a significant correlation between bone density and primary stability of implants. However, some studies reported that bone density measurement derived from CBCT was not the absolute density value, similar to Hounsfield unit in CT.[36,49]

The cortical thickness at the implant sites was found as a factor that affect primary stability of miniscrews.[50]

Miyamoto,[24] evaluated the cortical bone thickness of 225 the implant sites in 50 subjects by using CBCT scan prior implant surgery and RFA measurement was performed to measure primary implant stability. A strong correlation was found between cortical bone thickness and primary stability ($r = 0.84$, $P < 0.0001$) outcome.

CHAPTER III
MATERIALS AND METHODS

3.1 Research design

Clinical study.

3.2 Patients

3.2.1 Population and samples

3.2.1.1 Population is patients who had partial edentulous area at the posterior area of mandible and need dental implant prostheses.

3.2.1.2 The research sample includes patients who had the same characteristics as the defined population.

3.2.1.3 The sample size in this study contains 12 implants.

3.2.2 Inclusion criteria

3.2.2.1 At least 18 years old.

3.2.2.2 Have partially edentulous at posterior mandible area and need implant placement

3.2.2.3 Have adequate bone volume suitable for placing implant 4 mm. in diameter and 10 mm. in length.

3.2.2.4 Healthy patients with no uncontrolled systemic diseases.

3.2.2.5 Adequate oral hygiene.

3.2.3 Exclusion criteria

3.2.3.1 Have inadequate bone height (less than 12 mm. from the alveolar crest to the inferior alveolar nerve which evaluated from CBCT preoperatively)

3.2.3.2 Patients with uncontrolled systemic diseases

3.2.3.3 Patients who had previous chemotherapy or radiotherapy

3.2.3.4 Patients who have taken bisphosphanate for more than 3 years

3.2.3.5 Patients who were heavy smoker (more than 10 cigarettes per day)

3.2.3.6 Patients who had tooth extraction in the implant recipient site < 3 months ago

3.2.3.7 Patients who had bone grafting procedures prior or during implant surgery

3.3 Study site

Department of Oral and Maxillofacial surgery, Faculty of Dentistry, Mahidol University, Bangkok, Thailand.

3.4 Study period

January 2014 to December 2014.

3.5 Study protocol

The study protocol and consent form were reviewed and approved by the faculty of Dentistry and Pharmacy board ethics committee, Mahidol university. All the participants signed an informed consent form before enrollment. Patients were reviewed and selected according to the inclusion and exclusion criteria.

3.5.1 Preoperative preparation

At the first visit, patients' medical and dental histories were reviewed and inclusion and exclusion criteria were confirmed.

3.5.2 Radiologic evaluation

Panoramic scanning was performed for initial evaluation and the cortical bone thickness of the implant recipient sites was preoperatively estimated using CBCT. (3D Accuitomo, J. Morita) In cross sectional image of CBCT under radiographic indicator, cortical bone thickness at the implant at the crestal area was measured. Buccal, lingual cortical thickness and trabecular thickness were measured at the level of 5 mm. below the alveolar crest and each bone area were classified in 4 different bone types (modifided from Leckholm & Zarb bone classification):

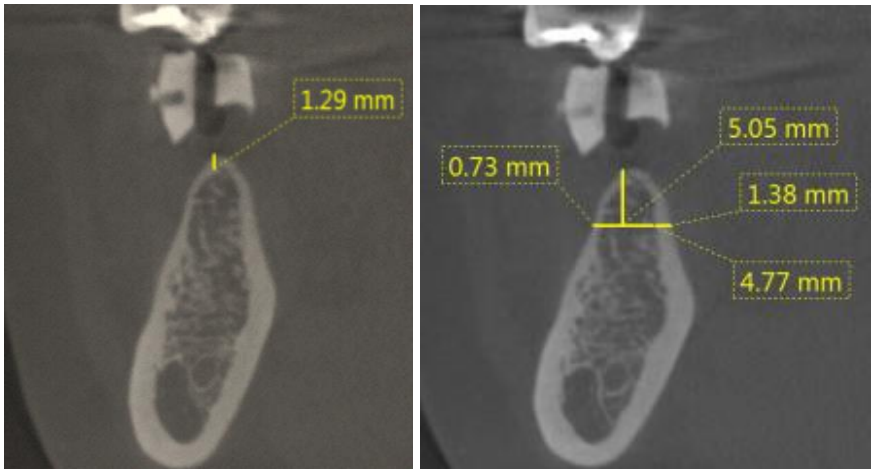

Figure 3.1 Crestal cortical thickness and buccolingual bone thickness measurement from CBCT

Bone quality type 1: buccal and lingual cortical thickness is more than 75% of whole bone thickness.

Bone quality type 2: buccal and lingual cortical thickness is 50-75% of whole bone thickness.

Bone quality type 3: buccal and lingual cortical thickness is 25-50% of whole bone thickness.

Bone quality type 4: buccal and lingual cortical thickness is less than 25% of whole bone thickness.

3.6 Implant surgery

Patients were premedicated with amoxicillin 1000 mg and ibuprofen 400 mg 30 minutes before implant surgery. For patients who were allergic to penicillin, clindamycin 600 mg was prescribed. A total of 12 Intra-lock implants (Boca Raton, FL, USA, Blossom design) size 4.0 * 10 mm. were inserted. All implants were inserted at the reciepient site by one oral surgeon, according to a standard surgical guideline following the manufacturer's instructions by using a nonsubmerged technique.

After the implant placement, the Osstell ISQ was used to assess primary stability of the implant by one observer.

Smartpeg was tightened on the implant according to the manufacturer's guidelines:

- Interposition of no soft tissue
- Using a specific plastic screwdriver to tighten smartpeg at 5-8 Ncm manually.
- No contact between any part of smartpeg and neighboring teeth
- One new Smartpeg were used in each implant at the time of implant placement
- After the completion of each measurement, the smartpeg was removed from the implant after finish of each measurement.

The RF values were measured four times in buccal, lingual, mesial, distal direction for each implant. The results were expressed in ISQ values and averaged for each implant.

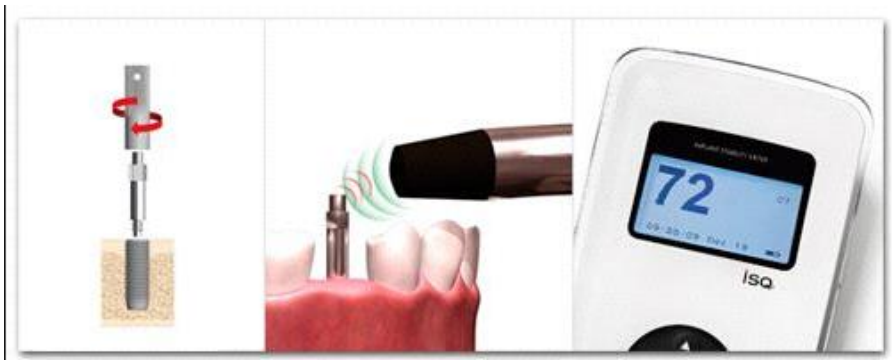

Figure 3.2 Ostell ISQ

After measuring, healing abutments were applied to implants and sutures were placed. Antibiotic therapy was given to the patients: amoxicillin 500 mg 3 times/day during following 5 days. Clindamycin 300 mg 3 times/day during following 5 days was given to the patients who were allergic to amoxicillin. An analgesic, Ibuprofen 400 mg 3 times/day was prescribed for following 1 week.

3.7 Post-operative follow up

The sutures were removed 7 days following the surgery.

3.8 Prostheses

2 months after implant placement, implant supported crown were constructed.

3.9 Implant used in this study

The intralock implants diameter 4.0 * 10 mm. were used in this study. The surface of the implant was a OSSEAN surface which is hydrophilic surface impregnated with calcium phosphate which can increase the bone healing by minimizing the catabolic phase of surrounding bone and increasing directly to anabolic phase. The macrodesign of the implant was BLOSSOM design which is a

fully integrated tapping configuration located along the entire body of the implant. It is designed to eliminate the high compressive force, this thread design continually cuts through the bone with increased efficiency and minimal insertion torque. The connection between implant and abutment is an internal connection with Morse taper design which provide a friction fit, the IN-DEX retentive system which can eliminate micromovement and prevent screw loosening.

Figure 3.3 Intralock implant

3.10 Statistical analysis

Demographic data, the implant stability at the time of implant placement, crestal cortical bone thickness, buccolingual bone thickness at 5 mm. below the alveolar crest and bone quality were determined and presented as a mean ± SD, median, percentage or frequency where appropriate for qualitative and quantitative variables.

Kolmogorov-Smirnov test was used to test for normal distribution. The correlation between buccolingual bone thickness and primary implant stability and correlation between crestal cortical bone thickness and primary stability were tested with Pearson's correlation at P value less than 0.05 was considered statistically significant.

CHAPTER IV
RESULTS

4.1 Demographic data

A total of eight patients were enrolled in this study. The mean age was 52 years. The duration of tooth loss before implant placement was controlled to be more than 3 months, in the range 1-10 years. Twelve implants (Intralock, diameter 4 mm. and length 10 mm.) were inserted in the posterior mandible area. All restorations were implant supported crown.

The demographic data of all patients were shown in the table 4.1.

Table 4.1 Patient demographic data

Descriptive data	N	%
1. Patients	8	100
- Age (mean)		53
- Sex		
Male	1	12.5
Female	7	87.5
2. Implants		
- Number of implants	12	100
- Position of implants		
Premolar	4	33.33
Molar	8	66.67
- Duration of tooth loss (months)		
< 6 months		
6-12 months		
> 12 months	12	100

4.2 The stability of implants at the time of implant placement

Eight patients with twelve implants placed at partial edentulous area of posterior mandible were included in statistical analysis of this study.ISQ values of each implant at the time of placement were presented in table 4.2. Range, mean ± SD and median ISQ values at the time of implant placement were presented in table 4.3.

Table 4.2 ISQ values of each implant at the time of placement

Implant No.	ISQ values at the time of implant placement
1	66.25
2	76.75
3	59
4	76.5
5	74.75
6	78
7	78.75
8	80
9	72.5
10	76.5
11	68
12	73

Table 4.3 Mean±SD, range and median of ISQ values at the time of implant placement

	ISQ values at the time of implant placement
Mean ± SD	73.33 ± 6.14
Median	75.63
Range	59-80

4.3 Bone quality, Crestal cortical bone thickness and Buccolingual bone thickness

Preoperatively, in cross sectional image of CBCT under radiographic indicator, crestal cortical bone thickness at the implant sites were measured. Buccal, lingual cortical thickness and trabecular thickness were measured at the level of 5 mm. below the alveolar crest and each bone area were classified in 4 different bone types:

Bone quality type 1: buccal and lingual cortical thickness is more than 75% of whole bone thickness.

Bone quality type 2: buccal and lingual cortical thickness is 50-75% of whole bone thickness.

Bone quality type 3: buccal and lingual cortical thickness is 25-50 % of whole bone thickness.

Bone quality type 4: buccal and lingual cortical thickness is less than 25% of whole bone thickness.

Table 4.4 Percentage of each bone quality

Bone quality type	Percentage
I	0
II	25
III	75
IV	0

Table 4.5 The thickness of cortical bone, trabecular bone and type of bone at the implant sites

Implant No.	Crestal cortical bone thickness	Buccolingual cortical bone thickness At 5 mm. below the crest	Buccolingual Trabecular bone Thickness At 5 mm. below the crest	Bone type	Buccolingual bone thickness
1.	1.01	2.50	3.67	III	6.17
2.	1.10	2.72	2.57	II	5.29
3.	1.36	2.32	2.81	III	5.13
4.	1.10	2.77	4.01	III	6.78
5.	2.10	3.21	4.31	III	7.52
6.	1.19	3.31	5.32	III	8.63
7.	1.22	3.79	2.32	II	6.11
8.	2.11	4.68	4.23	II	8.91
9.	2.94	2.94	6.36	III	9.30
10.	1.10	2.94	3.65	III	6.59
11.	0.55	1.92	4.22	III	6.14
12.	1.29	2.11	4.77	III	6.88

Table 4.6 Mean±SD, range and median of crestal cortical bone thickness and buccolingual bone thickness

	Crestal cortical bone thickness	Buccolingual bone thickness
Mean ± SD	1.42 ± 0.65	6.95 ± 1.37
Median	1.21	6.69
Range	0.55 - 0.94	5.13 - 9.30

4.4 The relationship between crestal cortical bone thickness, buccolingual bone thickness and primary implant stability

No significant correlation was found between crestal cortical bone thickness or buccolingual bone thickness and ISQ value at p value 0.05

Table 4.7 Correlation between, crestal cortical bone thickness, buccolingual bone thickness and ISQ value

	Crestal cortical bone thickness	**Buccolingual bone thickness**
ISQ value correlation coefficient	0.171	0.473
ISQ value P-value	P > 0.05	P > 0.05

Note: Kolmorgorov-Smirnov was used to test normality of all variables. Crestal cortical bone thickness, buccolingual bone thickness and ISQ values were normally distributed. The correlation between buccolingual bone thickness and primary implant stability and correlation between crestal cortical bone thickness and primary stability were tested with Pearson's correlation.

CHAPTER V
DISCUSSION

Implant stability can be described as the lack of clinical mobility. It has been clinically demonstrated that implant stability plays a significant role in determining the treatment outcome. Therefore, being able to objectively measure the level of implant stability at various stages of treatment will increase the satisfactory treatment oucome.[21] Histomorphometric analysis was a gold standard method that used to quantify degree of osseointegration under light microscope. However, because of the invasiveness and cannot use in clinical practice, other various methods have been introduced to objectively determine the level of implant stability such as cutting torque resistance during osteotomy preparation or resonance frequency analysis after implant placement. Implant stability measured by resonance frequency analysis seems to be an objective and non-destructive method. Several studies showed that resonance frequency analysis was a reliable tool to assess the stability of implant. A study in cadaver by T. Gedrange et al showed that the resonance frequency value is related to the stiffness of the implant in the surrounding tissues corresponding to histological results[51] Clinical studies also demonstrated that RFA is a highly reliable implant stability measurement tool regarding repeatability.[52] The RFA method can provide clinically relevant information about the state of the implant–bone interface at any stage of the treatment.However, the obvious benefits obtained from this information has been question in clinical situations.Until now, No studies reported clear benefits for therapeutic decision from RFA measurement.Studies reported that high RFA values are indicative of successful implant treatment. Conversely, low RFA values may increase the risk of implant failure.However, the exact minimum of RFA value have yet to be identified.

The resonance frequency analysis technique may be useful for assessing immediate loading implants during the various stages of treatment.According to the consensus statements and clinical recommendations for implant loading protocol [53]

For immediate or early loading in implant supported single crowns in partially edentulous area, a minimum of ISQ value in the range of 60-65 was recommended.However, in some situations such as using short or small diameter implants, large amount of bone augmentation, conventional loading was recommended. A certain ISQ value can be used as an inclusion criterion for immediate loading of implants. Lower failure rates of implant treatment was found when using ISQ 60 as an inclusion criterion for immediate loading in totally edentulous maxillae and in posterior mandibles.[54]Moreover, the author found that RFA was a useful method for deciding when to replace an immediately loaded temporary prosthesis with a permanent prosthesis after implant placement.In this study, resonance frequency analysis was used to assess implant stability. The latest generation of Osstell device, Osstell ISQ was used to measure the primary stability of 12 implants by connected the specific smartpeg to the implant screw hole and the RF values were measured four times in buccal, lingual, mesial, distal direction for each implant. The results were expressed in ISQ values and averaged for each implant by one observer. The factors affect RF values include the implant length above marginal bone level, transducer orientation and stiffness of implant and its interface. [21] All implants used in this study were identical (Intralock implant diameter 4.0 length 10 mm.) and were placed in the alveolar crest level. Therefore, the different in ISQ values must be related to the stiffness of implant and its interface. The mean primary stability of implants in this present study were 73.33 ± 6.14. Based on these ISQ values, it can be implied that immediate or early loading may be possible. According to the review article, primary stability of implant was influenced by bone quality and quantity, implant macrodesign and surgical technique. In this study, the implant used and surgical techniques were controlled, using the identical implant size and performed surgery by only one surgeon according to a standard surgical guideline following the manufacturer's instructions. Therefore, the primary stability of implant in this study was directly depend on only bone quality and quantity at the implant sites.

The definition "bone quality" is not clearly defined. It is not only bone density but includes bone architecture, skeleton size and also bone mineralization.[28] In implant dentistry, the most widely used bone quality classification is introduced by Leckholm and Zarb in the year 1985.[12] They classified bone in 4 different types based

on the amount of cortical and trabecular bone pattern in preoperative radiograph and surgeon's tactile sensation during drilling at implant sites. However, it is subjective method, therefore an objective and precise assessment of bone quality was developed by Misch[13], using CT for classified bone density at the implant sites into D1, D2, D3, D4 according to Hounsfield unit values, which correlated with the bone quality classification by Leckholm and Zarb. The anterior of mandible presented a highest bone density due to a thick layer of cortical bone and also dense trabecular bone while, posterior maxilla area shown the lowest bone density because normally, this area comprised of thin layer of cortical bone and loose trabeculae bone, so the higher failure rate of implant treatment in posterior of maxilla may be the influence of this factor. However, because of high radiation exposure from CT, in the field of implant dentistry, CBCT was introduced to assess bone density instead. However, in one study[36], found controversial association between bone density values obtained from CBCT and CT. Therefore, this values derived from CBCT to determine bone density may not indicate the actual bone quality. Therefore, in this study, bone at the implant sites were classified into 4 different types modified from the bone quality classification by Leckholm and Zarb by using preoperative cross-sectional CBCT image , measured cortical bone thickness and trabecular thickness at 5 mm. below the alveolar crest and classified by using the ratio of percentage of cortical bone to whole bone thickness in attempt to present bone quality at implant sites which was more objective than Leckholm and Zarb classification.Bone at the implant sites were classified as type II and III. Because all the implant sites that were included in this study were posterior mandible area, therefore the bone quality at all implant sites were identical, presented in bone quality type II and III which correlate with the Leckholm and Zarb bone quality classification. Morever, several studies used cortical bone thickness at implant sites represented a bone quality and also found a significant correlation between cortical bone thickness and implant stability.[22,50] Therefore, cortical bone thickness at alveolar crest of the implant sites were also measured from preoperative CBCT. Regarding bone quantity measurement, buccolingual bone thickness at 5 mm. below the alveolar crest was considered to represent the quantity of the bone at the implant sites.

Primary stability is important for successful outcome of implant treatment. Therefore, implant stability measurement may reduce the risk of implant failure. The high implant stability is an indicative for successful treatment outcome. On the other hand, low implant stability may increase the risk of failure.[21] Moreover, to reduce overall treatment time, the concept of immediate loading has been widely accepted. Primary stability measurement at the time of implant placement may be used as an indicator for immediate loading therefore it is advantageous, if the clinician can predict implant stability before implant placement.[22] The significant correlation between bone quality and implant stability parameters indicate that the clinician may predict primary stability of implant before implant surgery (from CBCT) and may modify the treatment to achieve a good primary stability of implant such as under preparation, using osteotome and also change the macrodesign of the implant to wider, longer or taper implant. However, This study demonstrated that the implant stability at the time of placement was weakly influenced by cortical bone thickness and buccolingual bone thickness. (Correlation coefficient = 0.171 and 0.473, respectively) In contrast with various studies that found a positive a correlation between cortical bone thickness and primary stability.[22,24] In a previous study[22], that assessed primary implant stability from RFA in 61 implants from 20 patients and found a positive correlation between primary stability and cortical bone thickness obtained from preoperative CBCT, patients were sent to take more CBCT image after implant placement to measure cortical bone thickness at the implant sites which seems to be an accurate position of cortical bone that affect the primary stability of implant but in this study the cortical bone thickness was measured preoperatively from CBCT which may not be the accurate position of cortical bone that engaged by the implant. However, in the clinical situation, CBCT doesn't have to be taken after the surgery. Moreover, in both review articles, the size of all implants used were not controlled to be an identical size. Therefore, this macrodesign factor which was considered as a factor that influenced the primary stability of implant may affect the outcome of the studies. Other limitation of this study was the number of the sample size, to achieve a significant correlation, increasing number of sample size may be required. Regarding bone quantity, there is lack of studies reported the correlation between buccolingual bone thickness and primary implant stability. However, it is hypothesized that

buccolingual bone thickness may affect the primary stability of implant because it may affect the compressive force around implant during implant insertion. In this study, weak correlation was found between buccolingual bone thickness and primary implant stability. The explanation for not finding the correlation may be from all implant recipient sites had adequate bone quantity for implant placement without any need of grafting procedures. Further research is required to confirm the outcome and should compare the primary stability of implant by using RFA with other methods such as cutting torque resistance to ensure the primary stability values and regarding bone quality, bone density measurement with calibrated CBCT should be assessed in the other various implant sites that had a different bone quality.

CHAPTER VI
CONCLUSION

With the limitations of this study, crestal cortical bone thickness and buccolingual bone thickness seem not to influence the primary implant stability. Further research is required to confirm the outcome.

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APPENDICES

APPENDIX A

CASE RECORD FORM

Serial number.....

MAHIDOL UNIVERSITY
Wisdom of the Land

Correlation between cortical bone thickness and implant stability.

Socio-Demographic

Age.....years Sex..... How long loss teeth.....years

Systemic disease Yes.....No .....

.....1.DM 2.HT

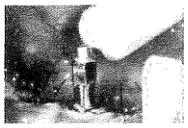
Medication.....

.....

PSI (SCORE).....0.....1

Serial number.....

MAHIDOL UNIVERSITY
Wisdom of the Land



Radiographic Record (X-ray and CBCT)

.....
.....
.....
.....
.....
.....

Bone Type.....

Cortical bone thickness .....mm

CT number.....

Operative record

Operator.....

Date...../...../.....

Bucco lingual Width.....

Height.....

Size implant.....

Position of implant.....

Crestal.....mm Sub crestal.....mm

Mpi (SCORE).....0.....1.....2

Medication.....
.....

Duration of operation.....

MAHIDOL
UNIVERSITY
Wisdom of the Land

ISQ (1-100 unit) at implant placement

Mesial .....

Distal .....

Buccal .....

Lingual.....

APPENDIX B
PARTICIPANT INFORMATION SHEET

เอกสารชี้แจงผู้เข้าร่วมการวิจัย

(Participant Information Sheet)

ในเอกสารนี้อาจมีข้อความที่ท่านอ่านแล้วยังไม่เข้าใจ โปรดสอบถามหัวหน้าโครงการวิจัย หรือผู้แทนให้ช่วยอธิบายจนกว่าจะเข้าใจดี ท่านจะได้รับเอกสารนี้ ๑ ฉบับ นำกลับไปอ่านที่บ้านเพื่อปรึกษาหารือกับญาติที่น้อง เพื่อนสนิท แพทย์ประจำตัว ของท่าน หรือผู้อื่นที่ท่านต้องการปรึกษา เพื่อช่วยในการตัดสินใจเข้าร่วมการวิจัย

ชื่อโครงการ ความสัมพันธ์ระหว่างความหนาของกระดูกทึบกับเสถียรภาพของรากเทียม

ชื่อผู้วิจัย ทญ. พบพลอย เพ็ชรเม็ดใหญ่

สถานที่วิจัย คลินิกศัลยศาสตร์ช่องปากและแม็กซิลโลเฟเชียล คณะทันตแพทยศาสตร์มหาวิทยาลัยมหิดล ถนนโยธี แขวงราชเทวี เขตพญาไท กรุงเทพฯ ๑๐๔๐๐

สถานที่ทำงาน ภาควิชาศัลยศาสตร์ช่องปากและแม็กซิลโลเฟเชียล คณะทันตแพทยศาสตร์มหาวิทยาลัยมหิดล ถนนโยธี แขวงราชเทวี เขตพญาไท กรุงเทพฯ ๑๐๔๐๐

หมายเลขโทรศัพท์ ๐๒-๖๔๔-๘๖๔๔, ๐๘๑-๘๓๐-๕๓๔๐

ผู้ให้ทุน ภายในมหาวิทยาลัย ทุนหลักสูตรวทม. ทันตกรรมรากเทียม

ภายนอกมหาวิทยาลัย อยู่ระหว่างดำเนินการขอทุนจากสำนักงานคณะกรรมการวิจัยแห่งชาติ

อัตราการประสบความสำเร็จของการทดแทนช่องว่างของฟันด้วยการใส่รากฟันเทียมขึ้นอยู่ปริมาณและคุณภาพของกระดูกขากรรไกรบริเวณที่จะฝังรากเทียมโดยคุณภาพของกระดูกเป็นปัจจัยสำคัญในการทำนายเสถียรภาพของรากฟันเทียม ซึ่งเสถียรภาพที่ดีจะเอื้อต่อการยึดติดระหว่างรากฟันเทียมกับกระดูก โครงการวิจัยนี้จึงทำขึ้นเพื่อ

ศึกษาความสัมพันธ์ระหว่างคุณภาพของกระดูกขากรรไกรโดยการวัดความหนาของกระดูกทึบกับเสถียรภาพของรากฟันเทียมซึ่งจะนำผลที่ได้จากงานวิจัยมาประกอบการพิจารณาวางแผนการรักษาในผู้ป่วยได้อย่างเหมาะสม

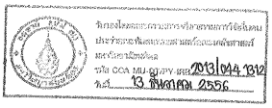
ท่านได้รับเชิญให้เข้าร่วมการวิจัยนี้เพราะ

- อายุมากกว่า ๑๘ ปีไม่มีโรคประจำตัวหรือมีโรคเบาหวานและความดันโลหิตที่ควบคุมได้
-มีปริมาณกระดูกเพียงพอในการฝังรากฟันเทียมจากการประเมินทางคลินิกและถ่ายภาพรังสีคอมพิวเตอร์สามมิติทางทันตกรรม
-มีสุขภาพช่องปากดีโดยพิจารณาจาก คะแนนดัชนีความรุนแรงของสภาวะโรคปริทันต์
-ยินยอมเข้าร่วมในงานวิจัย

โดยจะมีผู้เข้าร่วมการวิจัยนี้ทั้งสิ้นอย่างน้อย ๗ คน ซึ่งงานวิจัยนี้ท่านจะต้องมาพบทันตแพทย์ เพื่อฝังรากฟันเทียมและใส่ครอบฟัน๖ ครั้ง เท่ากับการรักษาโดยทั่วไป โดยจะมีขั้นตอนเพิ่มจากการรักษาปกติ ใช้เวลาประมาณ ๕ นาทีเพื่อประเมินเสถียรภาพของรากฟันเทียมหลังการฝังรากเทียม การรักษาจะใช้ระยะเวลาทั้งหมดประมาณ ๒-๔ เดือน ผู้วิจัยจะขอเก็บข้อมูลเพิ่มเติมจากท่านในวันที่ท่านมีนัดมาพบทันตแพทย์โดยท่านจะเสียเวลาเพิ่มขึ้นประมาณ ๕-๓๐ นาทีในแต่ละครั้ง โดยในงานวิจัยนี้จะทำการศึกษาในระยะการฝังรากฟันเทียมทันที

หากท่านตัดสินใจเข้าร่วมการวิจัยแล้ว จะมีขั้นตอนการวิจัยดังต่อไปนี้คือ

ครั้งที่ ๑. ทันตแพทย์ของท่านจะนัดท่านมาตรวจสุขภาพช่องปากซึ่งเป็นการรักษาตามขั้นตอนปกติ และภาพถ่ายรังสีสามมิติทางทันตกรรมเพิ่มเติมเพื่อประเมินปริมาณและคุณภาพของกระดูกขากรรไกรบริเวณที่จะฝังรากเทียม รวมถึงตำแหน่งของอวัยวะสำคัญบริเวณใกล้เคียง เช่น เส้นประสาท โพรงอากาศ หลังจากนั้นจะนัดท่านมาเพื่อทำการฝังรากฟันเทียม



ครั้งที่ ๒. หลังทันตแพทย์ของท่านทำการผ่าตัดเพื่อฝังรากฟันเทียม ผู้วิจัยจะขอประเมินเสถียรภาพของรากฟันเทียมโดยใช้เครื่องวิเคราะห์คลื่นความถี่เรโซแนนซ์โดยจะต่อเครื่องมือกับรากฟันเทียมที่ฝังเรียบร้อยแล้ว และปล่อยคลื่นแม่เหล็กไฟฟ้าความถี่ต่ำเพื่อกระตุ้นให้เกิดการสั่นสะเทือนของเครื่องมือและวัดออกมาเป็นค่าที่แสดงถึงเสถียรภาพของรากฟันเทียม ซึ่งแรงที่จะกระทำต่อรากฟันเทียมและกระดูกโดยรอบจะมีปริมาณน้อยมาก เมื่อเทียบกับแรงบดเคี้ยว วิธีการวัดเสถียรภาพของรากฟันเทียมวิธีนี้จึงมีความปลอดภัยสูง ใช้เวลา ๕ นาที

หากท่านไม่เข้าร่วมในโครงการวิจัยนี้ ท่านก็จะได้รับการตรวจเพื่อการวินิจฉัยและรักษาโรคของท่านตามวิธีการที่เป็นมาตรฐาน

หากท่านมีอาการผิดปกติ รู้สึกไม่สบายกาย หรือมีผลกระทบต่อจิตใจของท่านเกิดขึ้นระหว่างการวิจัย ท่านจะแจ้งผู้วิจัยโดยเร็วที่สุด

หากเกิดผลข้างเคียงที่ไม่พึงประสงค์จากการวิจัย ท่านจะได้รับการช่วยเหลือตามหลักมาตรฐานวิชาชีพและหากมีการติดเชื้อหรือมีการสูญเสียรากเทียม ท่านจะได้รับการใส่รากฟันเทียมทดแทนใหม่โดยไม่มีค่าใช้จ่ายใดๆ

หากท่านมีข้อข้องใจที่จะสอบถามเกี่ยวข้องกับการวิจัยหรือบาดเจ็บ/เจ็บป่วยจากการวิจัยหรือในกรณีเกิดผลข้างเคียงที่ไม่พึงประสงค์จากการวิจัย ท่านสามารถติดต่อกับ ทญ. พบพลอย เพ็ชรเม็ดใหญ่

การวิจัยนี้มีค่าใช้จ่ายที่ท่านต้องรับผิดชอบดังนี้

๑. ค่าตรวจวินิจฉัยทางเอกซเรย์คอมพิวเตอร์ ๒,๐๐๐ บาทเพิ่ม ๑,๐๐๐ บาทต่อ ๑ ตำแหน่ง จากราคาปกติ ๔,๐๐๐ บาท

๒. ค่าผ่าตัด ๒,๐๐๐ บาท จากราคาปกติ ๑ ๔,๐๐๐ บาท

๓. ค่ารากฟันเทียม ๘,๕๐๐ บาท จากราคาปกติ ๑๓,๐๐๐ บาท

หากมีข้อมูลเพิ่มเติมทั้งด้านประโยชน์และโทษที่เกี่ยวข้องกับการวิจัยนี้ ผู้วิจัยจะแจ้งให้ทราบโดยรวดเร็วไม่ปิดบัง

ข้อมูลส่วนตัวของท่านจะถูกเก็บรักษาไว้ ไม่เปิดเผยต่อสาธารณะเป็นรายบุคคล แต่จะรายงานผลการวิจัยเป็นข้อมูลส่วนรวม ข้อมูลของท่านเป็นรายบุคคลอาจมีคณะบุคคลบางกลุ่มเข้ามาตรวจสอบได้ เช่น ผู้ให้ทุนวิจัย สถาบัน หรือองค์กรของรัฐที่มีหน้าที่ตรวจสอบ คณะกรรมการจริยธรรมฯ เป็นต้น

ท่านมีสิทธิ์ถอนตัวออกจากโครงการวิจัยเมื่อใดก็ได้ โดยไม่ต้องแจ้งให้ทราบล่วงหน้า และการไม่เข้าร่วมการวิจัยหรือถอนตัวออกจากโครงการวิจัยนี้ จะไม่มีผลกระทบต่อการบริการและการรักษาที่สมควรจะได้รับแต่ประการใด

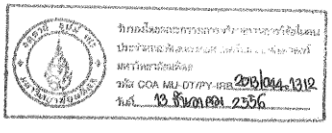
โครงการวิจัยนี้ได้รับการพิจารณารับรองจาก คณะกรรมการจริยธรรมการวิจัยในคนประจำคณะทันตแพทยศาสตร์และคณะเภสัชศาสตร์ มหาวิทยาลัยมหิดล ซึ่งมีสำนักงานอยู่ที่ คณะทันตแพทยศาสตร์ มหาวิทยาลัยมหิดล อาคารเฉลิมพระเกียรติฯ ชั้น ๑๑ เลขที่ ๖ ถนนโยธี แขวงทุ่งพญาไท เขตราชเทวี กรุงเทพฯ ๑๐๔๐๐ หมายเลขโทรศัพท์ ๐๒-๒๐๐๗๖๒๒ โทรสาร ๐๒-๒๐๐๗๖๒๒ หากท่านได้รับการปฏิบัติไม่ตรงตามที่ระบุไว้ ท่านสามารถติดต่อกับประธานคณะกรรมการฯ หรือผู้แทนได้ตามสถานที่และหมายเลขโทรศัพท์ข้างต้น

ข้าพเจ้าได้อ่านรายละเอียดในเอกสารนี้ครบถ้วนแล้ว

ลงชื่อ.....ผู้เข้าร่วมวิจัย

(.....)

วันที่.....



APPENDIX C
INFORMED CONSENT FORM

หนังสือแสดงเจตนายินยอมเข้าร่วมการวิจัยโดยได้รับการบอกกล่าวและเต็มใจ

วันที่..... เดือน..... พ.ศ.....

ข้าพเจ้า.....อายุ.....ปี อาศัยอยู่บ้านเลขที่.....

ถนน.....ตำบล.....อำเภอ.....

จังหวัด.....รหัสไปรษณีย์.....โทรศัพท์ .....

ขอแสดงเจตนายินยอมเข้าร่วมโครงการวิจัย เรื่อง ความสัมพันธ์ระหว่างความหนาของกระดูกทึบและเสถียรภาพของรากเทียม

โดยข้าพเจ้าได้รับทราบรายละเอียดเกี่ยวกับที่มาและจุดมุ่งหมายในการทำวิจัยรายละเอียดขั้นตอนต่างๆ ที่จะต้องปฏิบัติหรือได้รับการปฏิบัติ ประโยชน์ที่คาดว่าจะได้รับของการวิจัยและความเสี่ยงที่อาจจะเกิดขึ้นจากการเข้าร่วมการวิจัย รวมทั้งแนวทางป้องกันและแก้ไขหากเกิดอันตรายขึ้น ค่าตอบแทนที่จะได้รับ ค่าใช้จ่ายที่ข้าพเจ้าจะต้องรับผิดชอบจ่ายเอง โดยได้อ่านข้อความที่มีรายละเอียดอยู่ในเอกสารชี้แจงผู้เข้าร่วมการวิจัยโดยตลอด อีกทั้งยังได้รับคำอธิบายและตอบข้อสงสัยจากหัวหน้าโครงการวิจัยเป็นที่เรียบร้อยแล้ว โดยไม่มีสิ่งใดปิดบังซ่อนเร้น

ข้าพเจ้าจึงสมัครใจเข้าร่วมในโครงการวิจัยนี้

ข้าพเจ้าได้ทราบถึงสิทธิ์ที่ข้าพเจ้าจะได้รับข้อมูลเพิ่มเติมทั้งทางด้านประโยชน์และโทษจากการเข้าร่วมการวิจัย และสามารถถอนตัวหรือถอดถอนตัวเข้าร่วมการวิจัยได้ทุกเมื่อ โดยจะไม่มีผลกระทบต่อการบริการและการรักษาพยาบาลที่ข้าพเจ้าจะได้รับต่อไปในอนาคต และยินยอมให้ผู้วิจัยใช้ข้อมูลส่วนตัวของข้าพเจ้าที่ได้รับจากการวิจัย แต่จะไม่เผยแพร่ต่อสาธารณะเป็นรายบุคคล โดยจะนำเสนอเป็นข้อมูลโดยรวมจากการวิจัยเท่านั้น

หากมีอาการผิดปกติ รู้สึกไม่สบายกาย หรือมีผลกระทบต่อจิตใจของข้าพเจ้าเกิดขึ้นระหว่างการวิจัย ข้าพเจ้าจะแจ้งผู้วิจัยโดยเร็วที่สุด

หากข้าพเจ้ามีข้อข้องใจเกี่ยวกับขั้นตอนของการวิจัย หรือหากเกิดผลข้างเคียงที่ไม่พึงประสงค์จากการวิจัยขึ้นกับข้าพเจ้า ข้าพเจ้า จะสามารถติดต่อกับทญ. พบพลอย เพ็ชรเม็ดใหญ่ หมายเลขโทรศัพท์ 089-1170606

หากข้าพเจ้าได้รับการปฏิบัติไม่ตรงตามที่ได้ระบุไว้ในเอกสารชี้แจงผู้เข้าร่วมการวิจัย ข้าพเจ้าจะสามารถติดต่อกับประธานคณะกรรมการจริยธรรมการวิจัยในคนหรือผู้แทน ได้ที่สำนักงานคณะกรรมการจริยธรรมการวิจัยในคนประจำคณะทันตแพทยศาสตร์และคณะเภสัชศาสตร์ มหาวิทยาลัยมหิดล คณะทันตแพทยศาสตร์ อาคาร 4 ชั้น 5 เลขที่ 6 ถนนโยธี แขวงทุ่งพญาไท เขตราชเทวี จังหวัดกรุงเทพฯ 10400 หมายเลขโทรศัพท์ 02-200-7622 โทรสาร 02-200-76223

ข้าพเจ้าเข้าใจข้อความในเอกสารชี้แจงผู้เข้าร่วมการวิจัย และหนังสือแสดงเจตนายินยอมนี้โดยตลอดแล้ว จึงลงลายมือชื่อไว้

ลงชื่อ.....ผู้เข้าร่วมการวิจัย/ผู้แทนโดยชอบธรรม/ วันที่.....

(.....)

ลงชื่อ.....ผู้ให้ข้อมูลและขอความยินยอม/หัวหน้าโครงการวิจัย/ วันที่.....

(.....)

ในกรณีผู้เข้าร่วมการวิจัยไม่สามารถอ่านหนังสือได้ผู้ที่อ่านข้อความทั้งหมดแทนผู้เข้าร่วมการวิจัยคือ.....

จึงได้ลงลายมือชื่อไว้เป็นพยาน

ลงชื่อ..... พยาน/ วันที่.....

(.....)

APPENDIX D

ETHICAL APPROVAL CERTIFICATE

Documentary Proof of Faculty of Dentistry/Faculty of Pharmacy, Mahidol University, Institutional Review Board

Title of Project: Correlation between Cortical Bone Thickness and Implant Stability

Project Number: MU-DT/PY-IRB 2013/071.0811

Type of approval / acceptance: Project Amendment

1. MU-DT/PY-IRB Submission form version 3, June 23, 2014
2. Add Title of Investigator Dr. Pobploy Petchmedyai
3. Participant information sheet version 3, June 23, 2014
4. Consent form version 3, June 23, 2014
5. Advertisement for recruitment version 2, June 23, 2014
6. Case record form version 2, June 23, 2014

Principle Investigator: Dr. Pobploy Petchmedyai

Date of Approval: July 8, 2014

Faculty of Dentistry/Faculty of Pharmacy, Mahidol University, Institutional Review Board is in full compliance with International Guidelines for Human Research Protection such as Declaration of Helsinki, the Belmont Report, CIOMS Guidelines and the International Conference on Harmonization in Good Clinical Practice (ICH-GCP)

Signature of Chair:

(Associate Professor Dr.Choltacha Harnirattisai)

Chair

Office of Faculty of Dentistry/Faculty of Pharmacy, Mahidol University, Institutional Review, Board
The 50th Anniversary of HRH Princess Mahachakri Sirindhorn Building, 11st Floor, Faculty of Dentistry,
Mahidol University, 6 Yothi Street, Rajthevi, Bangkok 10400, THAILAND Tel: (662)-200-7622

BIOGRAPHY

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