การศึกษาเปรียบเทียบเสถียรภาพของรากฟันเทียมแบบสั้นในขากรรไกรบนและล่างส่วนหลัง

นายชลธี เวโรจน์

วิทยานิพนธ์นี้เป็นส่วนหนึ่งของการศึกษาตามหลักสูตรปริญญาวิทยาศาสตรมหาบัณฑิต
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A COMPARATIVE STUDY OF STABILITY OF SHORT IMPLANT IN THE POSTERIOR MAXILLA AND MANDIBLE

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A Thesis Submitted in Partial Fulfillment of the Requirements
for the Degree of Master of Science Program in Oral and Maxillofacial Surgery
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Thesis Title	A COMPARATIVE STUDY OF STABILITY OF SHORT IMPLANT IN THE POSTERIOR MAXILLA AND MANDIBLE
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วัตถุประสงค์ของการวิจัย เพื่อเปรียบเทียบความเสถียรของรากเทียมแบบสั้นในขากรรไกรบนและล่างส่วนหลัง ภายในระยะเวลา 4 เดือนหลังฝังรากเทียม

วิธีวิจัย ผู้ป่วยที่มีการสูญเสียฟันหลังบางส่วนจำนวน 24 คน ได้รับการคัดเลือกให้เข้าร่วมในการศึกษานี้ รากเทียมแบบสั้นซึ่งมีพื้นผิวขรุขระ จำนวนทั้งหมด 30 ราก (15 รากในขากรรไกรบน และ 15 รากในขากรรไกรล่าง) ถูกนำมาฝังให้กับผู้ร่วมวิจัย โดยใช้เทคนิคการผ่าตัดแบบ 2 ขั้นตอน และใช้ Resonance frequency analysis (RFA) วัดความเสถียรของรากเทียม ซึ่งมีหน่วยเป็น ISQ ในวันที่ผ่าตัดฝังรากเทียม และ 2, 3, 4 เดือนหลังจากผ่าตัดฝังรากเทียม ค่า ISQ ที่ได้จากการวัดความเสถียรของรากเทียมในขากรรไกรบนและขากรรไกรล่าง ถูกนำมาเปรียบเทียบกัน โดยใช้สถิติแมนน์วิทนีย์ และสถิติวิลคอกสันไซน์แรงก์

ผลการวิจัย ค่า ISQ ของรากเทียมทั้งในขากรรไกรบนและล่างเพิ่มขึ้นอย่างต่อเนื่องในช่วงระยะเวลา 4 เดือนหลังจากฝังรากเทียม ค่า ISQ เฉลี่ยของรากเทียมในขากรรไกรล่างมากกว่าของรากเทียมในขากรรไกรบนอย่างมีนัยสำคัญตลอดทุกช่วงเวลาที่ทำการวัด ความสำเร็จของรากเทียมแบบสั้นในการศึกษานี้ คือ 96.7%

สรุปผลวิจัย รากเทียมแบบสั้นที่มีพื้นผิวขรุขระในขากรรไกรบนมีความเสถียรน้อยกว่าในขากรรไกรล่างตลอดช่วงเวลา 4 เดือนหลังการฝังรากเทียม ข้อมูลที่ได้จากการศึกษาบ่งชี้ว่ารากเทียมแบบสั้นที่มีพื้นผิวขรุขระ สามารถเกิดกระดูกเชื่อมประสานระดับสูงภายใน 2 เดือนในขากรรไกรล่าง และภายใน 3 เดือนในขากรรไกรบนถ้ารากเทียมนั้นมีความเสถียรที่ดีตั้งแต่ตอนผ่าตัดฝัง

ภาควิชา	ศัลยศาสตร์	ลายมือชื่อนิสิต .....
สาขาวิชา	ศัลยศาสตร์ช่องปากและแม็กซิลโลเฟเชียล	ลายมือชื่อ อ.ที่ปรึกษาวิทยานิพนธ์หลัก .....
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5475809632 : MAJOR ORAL AND MAXILLOFACIAL SURGERY
KEYWORDS: SHORT IMPLANT / IMPLANT STABILITY / RESONANCE FREQUENCY ANALYSIS / RFA

CHOLATHEE VEROCHANA: A COMPARATIVE STUDY OF STABILITY OF SHORT IMPLANT IN THE POSTERIOR MAXILLA AND MANDIBLE. ADVISOR: ASSOC. PROF.SOMCHAI SESSIRISOMBAT, CO-ADVISOR: ASST. PROF.NIYOM THAMRONGANANSKUL, Ph.D., ASSOC. PROF.SOONTRA PANMEKIATE, Ph.D., 86 pp.

Objective: To compare the stability of short implants placed in the posterior maxilla and mandible within a 4-month healing period.

Material and methods: A total of 24 patients who were partially edentulous in the posterior were enrolled in the study. Thirty short implants (4.2 mm in diameter and 7.5 mm in length) with rough surface were placed with 2-stage surgical approach (15 implants each in maxilla and mandible). Resonance frequency analysis (RFA) was used to measure implant stability at time of surgical placement, at 2 months, at 3 months, and at 4 months after surgical placement. Implant stability quotient (ISQ) values of maxillary and mandibular implants were compared using Mann Whitney test and Wilcoxon Signed Ranks test.

Results: Within the 4-month healing period, the ISQ values increased gradually in both maxillary and mandibular implants. The mean ISQ values of implants in the mandible were significantly greater than those in the maxilla at every respective length of healing time. The success of short implants in this study was 96.7%.

Conclusions: Short implants with rough surface in the posterior maxilla had less stability than those in the posterior mandible during the 4-month healing period. Our study indicated that short implants with rough surfaces can gain a high degree of osseointegration within 2 months in the mandible and within 3 months in the maxilla if good stability was achieved at implant placement.

Department:	Oral and Maxillofacial Surgery	Student's Signature	.....
Field of Study:	Oral and Maxillofacial Surgery	Advisor's Signature	.....
Academic Year:	2013	Co-Advisor's Signature	.....
		Co-Advisor's Signature	.....

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Last but not least, I want to express my deepest appreciation to my family for their support, love, and encouragement. Thank you with all my heart.

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CHAPTER I
INTRODUCTION

Background and rationale

In Thailand, a large number of patients are suffering from oral health and masticatory problems which can deteriorate their general health and affect their quality of life. Most patients lose their teeth due to dental caries and periodontal disease, and as a result, need treatment to replace their missing teeth. Technological advancements in dental implants have revolutionized the replacement of missing teeth with endosseous implants the standard of care, and implant-supported prostheses have become the treatment of choice. Moreover, dental implants have proven to be a successful long-term solution for oral rehabilitation.[1]

Studies revealed that dental implants are highly predictable with very high rates of success (91% - 100%).[2-6] Osseointegration, a direct contact between bone and implant surface, is the basis of the success of modern dental implants. Implants in the mandible have higher success than those placed in the maxilla.[7] Several studies reported the highest failure rate in the posterior region of the maxilla, which is attributed to the fact that insufficient bone volume and/or poor bone density are often found in this area.[5, 8] Moreover, surgical implant placement in the posterior maxilla is difficult because of various complicating factors.[9] These factors are difficult access, limited visibility, poor bone quality, pneumatization of maxillary sinus and postextraction bone resorption. Surgical placement of standard dental implants in this area is often limited by inadequate vertical bone height due to maxillary sinus pneumatization.[10] Several techniques have been developed to build up sufficient height of bone for implant placement. These techniques include the sinus lift procedure, total or segmental bone onlays, and Le Fort I osteotomy with interpositional bone grafts.[9] However, these procedures are not favourable to most patients due to increased time, cost and risk of morbidity. In the severe resorbed mandible from long-term wearing of removable denture, one of the anatomical limitations is inferior alveolar nerve, which is quite often injured during implant

placement.[11] Various bone grafting techniques and inferior alveolar nerve reposition have been developed to provide sufficient bone height for placement of longer implants. Nevertheless vertical bone augmentation in the resorbed mandible is difficult and the complications or failure of the graft are common.[12] The inferior alveolar nerve reposition may allow the placement of longer implants, though it has a risk of nerve injury or prolonged paresthesia. From these reasons, short dental implants could be an alternative choice in the posterior maxilla and the posterior mandible to avoid morbidity and complications in these patients.

One of the most important criteria of implant success is no clinical mobility. Moreover, implant stability is utmost important to the process of osseointegration.[13] Consequently, failing implants show a continuous decrease in stability.[14] Recently, resonance frequency analysis (RFA) has gained more popularity as a noninvasive method for assessing and monitoring the implant stability at the time of implant placement and in the healing period. Studies have demonstrated clinical benefits of the RFA technique. Identification of short implant stability may be applied clinically to help clinicians decrease early failure and decide the optimal timing to load short implants. Recent studies show high success rates of short implants. However, there have been few studies of short implant stability in the posterior maxilla and mandible, and the optimal timing to load short implants has not been reported.

Hypothesis

The stability of short implant in both the posterior maxilla and the posterior mandible are not different after 4 months of placement.

Objective

To compare the stability of short implants placed in the posterior maxilla and mandible within the first 4 months after placement.

Scope of this study

1. Sample in this study includes patients who need dental implant prostheses in the posterior regions of maxilla and/or mandible.
2. Independent variable is the SICmax® dental implants with 7.5 mm in length and 4.2 mm in diameter.
3. Dependent variable is the stability of implants.

Limitation of this study

Research outcome of this study merely applies to patients who possess the same characteristics as the patients in this study. The follow-up period and amount of patients are limited by the duration of the master degree course.

Conceptual framework

Conceptual framework is shown in Figure 1.

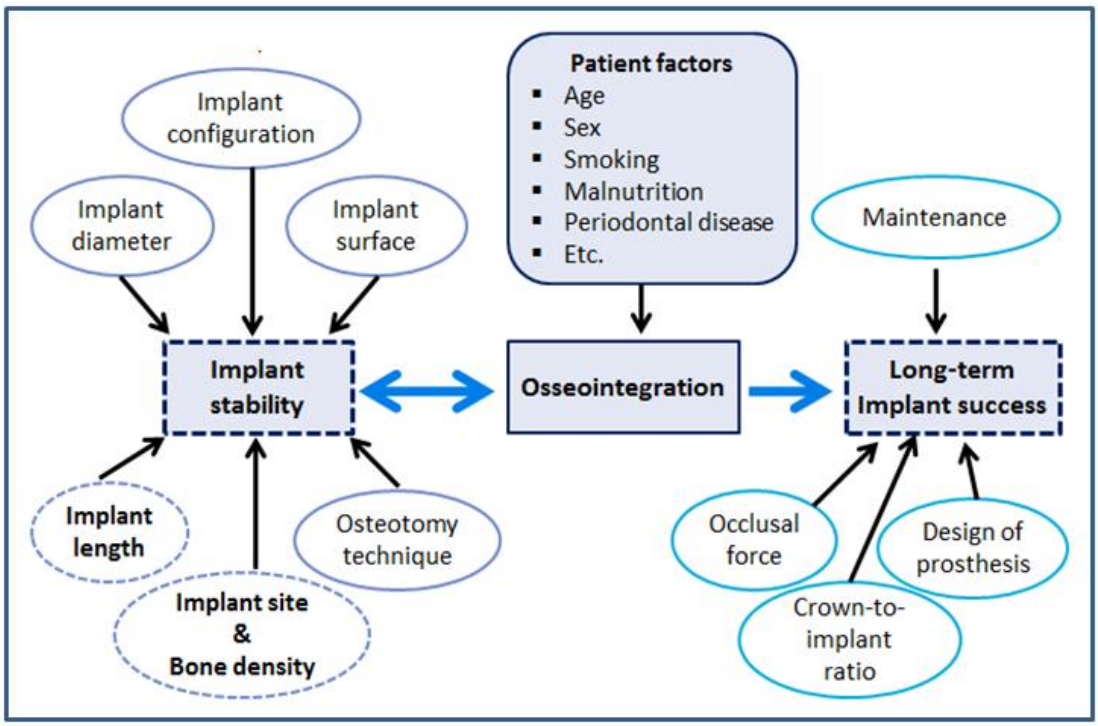

Figure 1 Conceptual framework

CHAPTER II
LITERATURE REVIEWS

In adults, dental caries and periodontal disease were considered major causes of tooth loss.[15] Tooth loss impairs speech, chewing ability, esthetics, and self-esteem. Decades ago, traditional tooth-supported prostheses for replacement of the missing teeth can be divided into removable denture and fixed bridge. However, these conventional prostheses have several disadvantages and can cause lots of consequences. Removable dentures tend to slip while eating or speaking and may lead to bone resorption in the denture bearing area. Fixed bridges are more stable but are relatively more expensive and rely on neighboring teeth for support. Patients who have fixed bridges often have food impaction under the bridges so conscientious oral care is required. Otherwise, dental caries and periodontal disease can cause failure of fixed bridges. Owing to its immense benefits, dental implants are now an option for replacing missing teeth for its natural look and feel.

In the mid-1960s, typical designs of dental implants were subperiosteal frames, blade vents or transmandibular devices and were being used in a narrow range and a very small number of patients.[16] Per-Ingvar Brånemark placed his first titanium dental implant in human and achieved osseointegration successfully in 1965.[16] He defined the term “osseointegration” as the direct structural and functional connection between ordered living bone and the surface of a load-carrying implant.[17] In the last decade, dental implants have been developed rapidly with the same basis of osseointegration. Practically, all dental implants used nowadays are root-form endosseous implants, this means that they imitate natural tooth roots and are placed within the jawbone. The success of implant-supported prostheses is higher than of natural tooth-supported traditional prostheses.[18]

Implant-supported prosthesis can be an effective alternative to replace missing teeth. However, inadequate bone volume and other vital structures can be obstacles for prosthetically-driven implant placement, especially in the posterior regions of the maxilla and the mandible. In the posterior maxilla, inadequate bone

height is usually found when patients lost their teeth for a long time due to periodontal diseases in conjunction with sinus pneumatization after tooth extraction. The sinus lift surgery has become a standard procedure to increase vertical bone volume in the posterior maxilla, allowing for placement of longer dental implants. Nevertheless, the complications commonly found in sinus lift surgery are: sinusitis, cyst formation, loss of bone graft particles, mucosal dehiscence and, finally, perforation of the sinus membrane which is the most common intraoperative complication.[19, 20] The incidence of sinus membrane perforation is varied from 10% to 34%.[19] In the posterior mandible, inferior alveolar nerve may limit the implant placement in the ideal position and angulation. Dental implant placement was reported to be the most common risk of inferior alveolar nerve injury, which accounted for 56.3%.[11] Surgical procedures to increase bone height for implant placement in the posterior mandible, such as autogenous bone augmentation and inferior alveolar nerve repositioning, have shown high morbidity.[21] Therefore, the placement of short dental implants can be considered an alternative treatment for patients with inadequate bone height of the posterior maxilla and mandible.

The term “short implant” is still controversial, with some articles stating that implants shorter than 10 mm are considered “short”.[22] However, 10-mm length implants are more commonly referred to as “standard length implants”.[9] A systematic review showed that the failure rates of implants with the lengths of 6, 7, 7.5, 8, 8.5, 9, and 10 mm were 4.1%, 5.9%, 0%, 2.5%, 3.2%, 0.6%, and 6.5%, respectively. The total failure rate was 4.5%. Furthermore, 57.9% of the failure happened early on, before prosthetic loading.[22] Another study reported that an overall survival rate of short implants in the posterior partially edentulous patients was 98.9%.[18]

Bruggenkate et al[23] reported on a multicenter clinical trial. In a period of 6 years, of all 126 patients, 253 short implants with a length of 6 mm were installed. The follow-up periods were ranging from 1 to 7 years. The 6-mm length implants were retained several types of restorations. Altogether, 7 implants from 253 were failed and removed; 6 of them were located in the maxilla. Five implants were removed because of inflammation. Of these 5 implants, 4 were lost during the early

healing phase. The other was lost two years later. The absolute survival rate was 97%. The remaining implants were 246, 28 of which were lost to follow-up for different reasons. After six years, the cumulative survival rate was 94%.

Misch et al[18] reported on a multicenter retrospective 6-year case series study of 745 implants placed in 273 consecutive posterior partially edentulous patients. The 7 or 9 mm short implants were used to retain 338 restorations over a period of 1 to 5 years in four private offices. There were six implant failures during the time of implant placement to second stage surgery. The survival rate at uncovering accounted for 99.6% of 505 implants that underwent a two-stage surgical approach in the maxillary and mandibular arches. One failure was in the maxilla and the other one was in the mandible. Total amount of one-stage implants were 240, three of them failed in the posterior mandible (from 218 implants) for a 98.3% survival. For short implants in the posterior regions of the mouth, the overall survival rate was 99.2%. All six implants which failed in this study were 9 mm in length and 4 mm in diameter.

Anitua and Orive[24] evaluated 1,287 short implants (shorter than 8.5 mm) in 661 patients between 2001 to 2008 in Spain. The mean follow-up period for the implants was 47.9 ± 24.4 months. The overall survival rates of short implants were 99.3% and 98.8% for the implant-based and patient-based analysis, respectively. During the observation period, only 9 implants were lost. They concluded that if treatment with short implants was used under a strict clinical protocol, it can be considered predictable and safe.

Malo et al[25] reported the outcome of 7-mm short implants with 4-mm diameter in the posterior regions of atrophic jaws 1 year after loading. In this prospective study, 217 implants were placed in 127 patients to support 165 fixed prostheses. The final prosthesis was delivered 6 months afterwards, but 18 implants in 11 patients completed immediate loading on the day of surgical placement with a provisional acrylic resin crown or bridge. During a follow-up period of 7 months, 3 patients with 5 implants were lost. After 1-year follow-up period, the overall survival rate was 95% and the mean marginal bone resorption was 1.27 ± 0.67 mm.

Compared to longer implants, short implants offer some advantages in surgical aspect.[18] The need for bone grafting procedures before or together with implant placement in both jaws is reduced when using short implants in the posterior regions. In addition, surgical risks are reduced. These risks include perforation of maxillary sinus, or paresthesia of the inferior alveolar nerve, and overall surgical complexity is reduced. The surgical site preparation for short implants has lower risk of bone necrosis caused by overheating, and the shorter length of drills and implants make it easier for site preparation and implant insertion in patients with limited mouth opening. When the concern is about apical dilacerations of the adjacent teeth, shorter implants may be coronally inserted to the apical region of the adjacent teeth, and the implant position is not compromised. In a surgeon's perspective, office overhead and inventory are also decreased, while in a patient's viewpoint, short implants offer less treatment time, feeling of discomfort, and total costs associated with bone grafting procedures. With all of the mentioned, short implants have become a highly attractive treatment option to replace the missing teeth.

If we consider the advantages of short implants, one could possibly now place it within mainstream implant dentistry. Nonetheless, their indications are still controversial because of many challenges that have been associated with them[9]:

1. Decreased implant surface; thus resulting in reduced bone-to-implant contact.
2. Decreased surface of force distribution after loading; more pressure at the crestal bone; thus more bone resorption could happen leading to more implant threads exposed and may lead to hygienic and esthetic problems.
3. Compromised crown-to-implant ratio.

I. Reduced implant surface

The surface area of an implant is related to 4 factors: diameter, length, configuration, and surface texture of the implant.[9] If we considered a root form implant as a cylinder, the implant surface area is dependent on the length and the diameter). With the increased diameter, the surface area is increased. After the

evaluation of the influence of diameter, length, and form of implants on strains in the alveolar crest with a three-dimensional finite-element analysis, Petrie and Williams[26] reported that increasing implant diameter resulted in as much as a 3.5-fold reduction in strain at the crestal bone, increasing length caused as much as a 1.65-fold reduction, whereas taper increased crestal strain, especially in narrow and short implants, where it increased 1.65-fold. Due to the interactive effects on crestal bone strain, diameter, length, and shape of an implant must be considered together. They concluded that a wide and relatively long, cylindrical implant seems to be the most favorable choice in order to minimize strain in the crestal bone around the implant. Short, narrow implants with taper configuration should not be used, especially in soft bone.

Renouard and Nisand[27] reviewed the relationship between implant survival rates and their length and diameter in 53 human studies. They reported that a relatively large amount of published studies showed an increased failure rate with short implants which was related to experience of operator, routine surgical site preparation (without considering bone density), the use of smooth-surfaced implants, and the placement in poor bone density sites. They suggested that if bone density was concerned during surgical site preparation, rough-surfaced implants were used, operators developed their skills, and indications for implant treatment were brought to attention, the survival rate of implants, either short or wide diameter, would be comparable with those obtained with longer implants and those of a standard diameter implants.

In addition, the implant surface area can be considerably increased by modifying the texture configurations on roughed-surfaced implants. Le Guéhennec et al[28] reviewed the surface treatment of titanium dental implants for rapid osseointegration in published studies. They found a relationship between osseointegration rate of titanium dental implants and their surface roughness and composition. There are numerous studies revealed that the surface roughness of titanium implants affected the rate of osseointegration and biomechanical fixation. If bone quantity is not sufficient or there are anatomical limitations, short implants with a rough surface have shown better clinical outcomes than implants with smooth

surface. Several studies have indicated that titanium implants with roughened surface had more bone-to-implant contact than implants with smooth surface. The surface chemical composition of implants is another factor influencing the hydrophilicity of the surface and the rate of osseointegration. Highly hydrophilic surfaces seem to be better than hydrophobic ones considering their interactions with biological fluid, cells and tissues. They concluded that it was somewhat too complicated to understand about the exact role of surface chemistry and topography on the previous events in dental implant osseointegration.

Moreover, an implant fixture can be modified by varying the thread geometry parameter such as thread pitch so as to increase functional surface area.[18] Thread pitch is defined as the distance between adjacent threads or the number of threads per unit length in the same axial plane and on the same side of the axis. In other words, reduction of the distance between threads will increase the amount of threads per unit length. If all other factors are not changed, greater amount of threads results in greater surface area. The amount of threads may be more important for the shorter implant in the posterior regions of the jaws with poor bone density. In order to increase the implant surface area, another implant thread geometry parameter that can be modified is thread depth. Abuhussein et al[29] demonstrated how thread geometry affects the distribution of stress forces around the implant. A reduced thread pitch may improve implant stability. Deeper threads may have a crucial effect on primary implant stability in the areas with poor bone quality. The added microthreads at the collar or crestal area of an implant could probably yield positive result on bone-to-implant contact and on the preservation of marginal bone as well.

II. Crown-to-implant ratio and occlusal forces

The crown-to-root ratio is defined as the physical relationship between that portion of the tooth within the alveolar bone and that portion not within the alveolar bone, as determined by a radiograph. When the length of the tooth coronal to the bone is divided by the length of the root that is in the bone, the crown-to-root ratio is determined. The crown-to-root ratio is an important diagnostic indicator

for dentist to evaluate whether a tooth is appropriately chosen to be an abutment for a fixed or removable partial denture. The crown-to-root ratio is also used as a prime indicator of the long-term prognosis of a given tooth. It is known that 1:2 or smaller is an ideal crown-to-root ratio for a potential abutment supporting a removable or fixed partial denture. Nevertheless, there is still no establishment of crown-to-implant ratio guidelines.[30] Available bone height is reduced when osteoplasty is used to increase the width of crestal bone or as the crestal height of the ridge is resorbed. Prosthetic crown height is increased when these conditions occur and short implants are often used. Normally, the biomechanics of crown height are related to lever mechanics and the crown height is a vertical cantilever. There will be an increase of force on the implants by 100% when the crown height is increased from 10 to 20 mm. An angled prosthetic load also acts as a force magnifier to the implant. From these reasons, when short implants are located in the posterior regions, there should not be lateral forces applied to the prosthesis.[18]

Birdi et al[30] evaluated 309 single implant-supported fixed restorations in a retrospective study. The study was composed of 194 patients who possessed at least 1 single 5.7 mm or 6 mm length plateau design implant-supported restoration that had been placed between February 1997 and December 2005. They reported that the mean follow-up time was 20.9 ± 23.2 months. The mean crown-to-implant ratio was 2.0 ± 0.4 and ranged from 0.9 to 3.2. No statistically significant relationship was found between increasing crown-to-implant ratios and decreasing mesial and distal first bone-to-implant contact levels around the implant.

Tawil et al[31] determined the influence of some prosthetic factors on the survival and complication rates of 262 short (10 mm or shorter in length) machined-surface implants placed in 109 patients. No significant difference in peri-implant bone loss was correlated with crown-to-implant ratio or occlusal table width. Cantilever length and bruxism had no significant effect on peri-implant bone loss. The follow-up period in this study was ranging from 12 to 108 months (mean, 53 months). The mean bone loss was 0.74 ± 0.65 mm. The difference in the complication rate between the bruxer and the nonbruxer group accounted for 15% which was not statistically significant. Only one implant was lost in a heavy bruxer after 7 years of

function. They concluded that in cases of favorable load distribution and force orientation, addition of crown-to-implant ratio by 2 to 3 times did not appear to be a mechanical risk factor. Short implants seem to be a long-term feasible treatment option in areas with decreased bone height even when the prosthetic parameters may not be favorable.

Studies showed that forces in the posterior regions of the mouth are often 400% more than those in the anterior regions. Nevertheless, longer implants are usually placed in the anterior regions, where the force is not strong. The higher failure rates of short implants after loading may be caused by the higher bite forces in the posterior regions of the jaws.[18]

III. Bone density and implant stability

Several clinical studies have shown that survival rate of dental implants in the mandible is higher than those in the maxilla. It has been regarded that the variation of the survival rates of the implants placed in the mandible and the maxilla may be resulted from the bone quality at the implant sites. It is apparent that the bone surrounding the implants in the mandible has higher quantity and quality than those in the maxilla.[32] The bone volume or bone quantity simply means width and height of the alveolar bone at the area of implant placement. Implant literature generally considered bone quality to be equivalent to bone density[33] which defined clinically as the amount of mineral per square centimeter of bone. Currently, computed tomography (CT) is a widely used method to measure the bone density in skeletal sites other than the jawbone.[33] By computed tomography, bone density can be measured using Hounsfield units (HU), which are directly related to tissue attenuation coefficients. The Hounsfield units are based on density values for air, water and dense bone, which are designated arbitrarily values of -1,000, 0, and +1,000, respectively. Clinicians have used the Hounsfield scale to evaluate bone density in the areas of implant placement, and the results were considered site specific, objective, and quantitative.[34] Recently, Misch has classified bone density using CT scan by correlating to a range of Hounsfield units.[35] According to the Misch bone density classification, bone density has been classified into five categories, D1-

D5. D1 bone primarily refers to dense cortical bone (>1250 Hounsfield units), while D5 bone is very soft bone with incomplete mineralization and large trabecular spaces (<150 Hounsfield units). Almost half of patients belong to D2 category (850 to 1250 Hounsfield units) in the posterior mandible. D3 category (350 to 850 Hounsfield units) is frequently found in the maxilla. Almost half of the patients have D3 bone in posterior maxilla (more often in premolar area). Almost half of the posterior mandibles have D3 bone. The D4 category (150 to 350 Hounsfield units) is common in the posterior maxilla (about 40%). Several studies demonstrate that bone density of the posterior maxilla is lower than that in the posterior mandible as evaluated by computed tomography.[36, 37]

Bone density plays an important role in implant stability that promotes implant osseointegration.[38] Basic and clinical research confirmed that primary implant stability is very important for implant success.[7, 13] Some evidences indicated that early implant failure before loading may be caused by excessive mechanical stresses and poor primary stability. Adequate primary stability of an implant is essential to prevent micromovement and allow osseointegration to occur and also to transfer optimal stress distribution from occlusal load to the implant-tissue interface. Primary implant stability at placement is a mechanical phenomenon that is related to the bone quality and quantity, the macrostructure of implant, and surgical technique. Secondary implant stability is a biological phenomenon happened later through the process of bone formation and remodeling at the implant/tissue interface and in the surrounding bone.[13] Implant stability has been confirmed to affect the process of osseointegration, the pattern of implant loading, and, finally, the implant success.[39] Therefore, it is important to take quantitative assessment of implant stability at different periods. Previously, microscopic or histologic analysis was the gold standard method used to assess degree of osseointegration in animal experimental studies. However, owing to their destructiveness and related ethical issues, other methods have been suggested.[40] Several invasive methods, for example removal torque and push-out/pull-out test are widely used in animal experiments. Noninvasive methods include cutting torque test during implant placement, the Periotest™ (Siemens AG, Benshein, Germany) and resonance frequency analysis (RFA).[41] RFA has recently

gained popularity. It is a noninvasive diagnostic method used to measure implant stability based on vibration and a principle of structural analysis. After the first in vitro study on RFA by Meredith et al[42] in 1996, the Osstell™ (Osstell AB, Göteborg, Sweden)(Figure 2) was the first commercial device of RFA launched in 2000, followed by the Osstell™ Mentor (Figure 3). Recently in 2009, the Osstell™ ISQ (Figure 4) was introduced. Originally, the Osstell™ used kilohertz, ranging from 3500 to 8500 kHz, as the units of measurement. The Osstell™ Mentor and the Osstell™ ISQ were developed subsequently, converting kHz units to Implant Stability Quotient (ISQ) values. The ISQ values are ranging from 1 to 100. The high ISQ value indicates high stability of an implant. The Osstell™ ISQ releases magnetic pulses to stimulate a SmartPeg™ that is screwed directly into the implant (Figure 5). The magnetic pulses vibrate the SmartPeg™ and the response signal is calculated into the ISQ values.[41] According to the manufacturer's guidelines, a successful implant usually has an ISQ higher than 65. An ISQ less than 50 may indicate higher risk of failure or potential failure.[40]

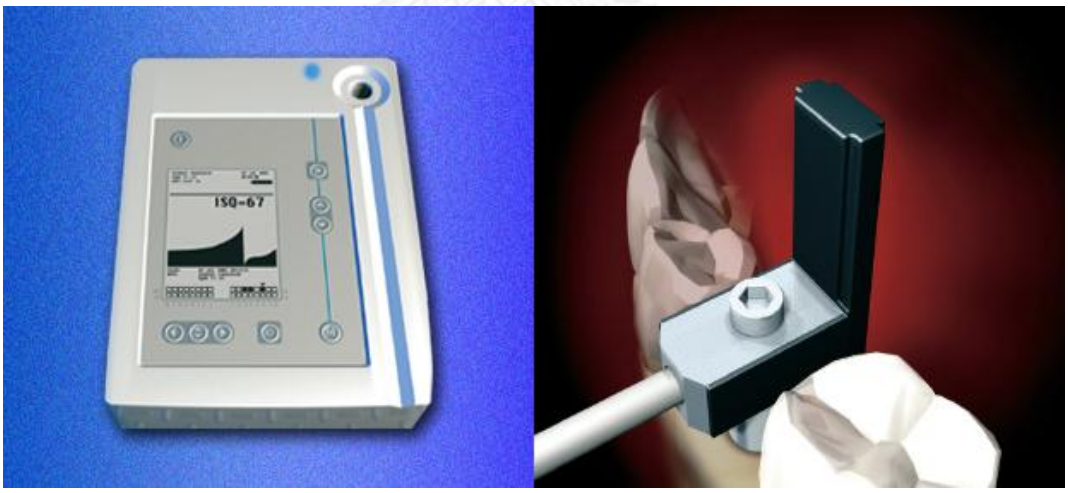

Figure 2 The first generation of Osstell

Figure 3 Osstell Mentor

Figure 4 Osstell ISQ

Figure 5 The Osstell ISQ releases magnetic pulses to stimulate the SmartPeg

Friberg et al[43] evaluated changes of implant stability in a 20-month clinical study. A total of 61 implants were installed in nine patients with edentulous maxilla. The length of implants varied from 6 to 18 mm. Cutting torque measurements and RFA were done at implant placement and corresponding values were analyzed for correlation. In addition, the implant stability was measured with RFA at abutment connection (8^{th} month) and at a follow-up period of 1 year in order to identify possible changes in implant stability. Two implants were lost in this study. The highest correlation was found when comparing the mean torque values with the resonance frequency values at implant placement. Based on the values of the cutting torque, the implant sites were divided into three groups; soft (group 1), medium (group 2), and dense (group 3) bone. The study revealed significant differences in resonance frequency at implant placement between groups 1 and 2 and between groups 1 and 3. At second stage surgery and at one-year follow-up, there was no significant difference between any of the groups. They concluded that stability of implants placed in softer bone seemed to catch up with those in more dense bone as the time rolls on.

Friberg et al[44] evaluated stability changes of 75 implants with three different designs in 15 edentulous mandibles during the healing period by RFA. All implants

had 3.75 mm in diameter and length ranging from 10 to 18 mm. Repeated stability measurements were done from implant placement to prosthetic loading (3 to 4 months afterwards). RFA values of all implant designs are slightly lowered for the most of implants. Consequently, 3-4 months after implant placement, they were as stable as when measured at surgical placement. During healing period, one implant failed with RFA value, at six weeks post-surgery, that was far below the one measured at implant placement. At the six-week visit, the failing implant showed excessive marginal bone loss of 2-3 mm radiographically, though it was still clinically stable and free of symptom at percussion. The lowered RFA value was found several weeks before the clinical mobility of the failing implant. The study revealed that the RFA technique was more sensitive in detecting changes of implant stability than the clinical and radiographic examination in detecting changes of implant stability.

Barewal et al[17] determined the stability changes of 27 implants with 4.1-mm diameter placed in the posterior maxilla or mandible in 20 patients. The lengths of the implants in this study were 10 and 12 mm. Bone type was classified into 1 of 4 groups according to the Lekholm and Zarb index (1985). Implant stability was measured at implant placement and consecutively once per week for 6 weeks and at the 8th and 10th week using RFA. One implant failed during the healing period in a patient with parafunction. Stability measurement showed that the lowest mean was at the third week for all bone types. The decrease of percentage in stability from placement to 3 weeks was greater for the Type 4 bone (8.6%), and the stability of implant increased from the third to the tenth week (26.9%). At the third week, statistical analysis showed highly significant difference between implant stability in Types 1 and 4 bone (P = 0.004), and a moderately significant difference between Type 2, 3, and 4 bone (P = 0.08). By the fifth week, there was no statistical difference in implant stability between any groups (P = 1.0). They concluded that the pattern of stability changes was not significantly different among various bone types after 5 weeks of healing.

Glauser et al[14] analyzed the changes of implant stability by repeated RFA measurements in 23 patients treated under an immediate/early-loading protocol during a period of one year. Eighty-one machined-surface implants were placed in all

jaw regions. The length of implants was ranged from 7 to 18 mm. Of these 81 implants, 30 of them were placed in extraction sockets, 62 implants with exposed thread were treated by guided-bone regeneration procedures, and 37 implants were immediately loaded. The implant stability was determined with RFA at placement, prosthesis loading and 1, 2, 3, 6 and 12 months after prosthesis loading. Nine implants (11.2%) failed during the first year of loading. The implants failure during the course of this study revealed significant decrease of stability after 1 month. They concluded that failing implants showed a continuous decrease of stability until failure. Implants with low RFA values at 1 and 2 months after placement had a high risk for future failure. The result of this study may be applied clinically by unloading implants with decreasing stability with time to avoid future implant failure.

Nedir et al[45] evaluated 63 immediately loaded (IL) implants in 18 patients and 43 delayed loaded (DL) implants in 18 patients. The implants used in this study had two different diameters (4.1 and 4.8 mm), and lengths ranging from 8 to 13 mm. Implant stability was measured using RFA technique at implant placement, after 1, 2, 4, 6, 8, 10, and 12 weeks. All implants were reviewed for one year after prosthetic loading. Two implants with 8 mm in length were failed, one in the IL group and the other in the DL group. The failed implant in the DL group had ISQ value at placement (ISQi) of 48, while the other one in the IL group that failed had ISQi of 53. The ISQ values of these two implants at failure were 43 and 46 respectively, both of them showed clinical mobility. They concluded that there was high possibility of failure if implant stability was less than 47 ISQ at the time of placement. After 1 year of loading, all DL implants with an ISQi ≥ 49 and all IL implants with an ISQi ≥ 54 were stable and successful.

Aparicio et al[46] reviewed implant literature regarding the RFA and Periotest techniques to compare the validity and prognostic value of each technique to detect implants that are at risk for failure. Factors such as bone density, implant site, abutment height and supracrestal implant length seem to influence both RFA and Periotest values. Data suggested that high RFA and low Periotest values indicate successful osseointegration of implants and that low or decreasing RFA and high or increasing Periotest values may be signs of continuous disintegration and/or marginal

bone loss. However, single measurement using any of the two techniques has low clinical merit. In predicting loss of implant stability, further prospective clinical studies should be established to evaluate the prognostic value of both the RFA and Periotest techniques.

Huwiler et al[47] reported the ISQ value in relation to the jawbone characteristics and during the early healing period. Seventeen implants with 4.1 mm in diameter and seven implants with 4.8 mm in diameter were placed in 13 patients. All implants were 10 mm in length. Implant stability was measured using RFA at placement and after 1, 2, 3, 4, 5, 6, 8 and 12 weeks. During implant insertion, bone quality was assessed according to the Lekholm and Zarb classification (1985). No significant correlation was found between bone density or bone trabecular connectivity and ISQ values. One 4.1-mm diameter implant lost stability at 3 weeks after placement. In this case, ISQ value had decreased from 68 to 45. Nevertheless, the latter value was determined after the mobility was detected clinically. They concluded that an ISQ value between 57 and 70 represented homeostasis and stability of an implant during the healing period. However, no predictive value for loosing implant stability can be attributed to RFA.

Sim and Lang[48] compared the development of stability of 8-mm and 10-mm length implants using RFA in 32 patients and determined the influence of instrument positioning, bone structure and implant length on the RFA measurement. During the implant site preparation, bone quality was evaluated according to the Lekholm and Zarb classification (1985). The ISQ value was measured at implant placement and after 1, 2, 3, 4, 5, 6, 8 and 12 weeks. They reported that positioning of the Osstell™ Mentor device did not affect the ISQ values. During healing period, the mean ISQ values increased continuously. Lower bone density (Type III or IV) resulted in significantly lower ISQ values up to 8 weeks. Implant length influenced the increase in ISQ values over time. Although no significant increase was found with 10-mm diameter implants, ISQ values of 8-mm diameter implants increased significantly from placement to 6, 8 and 12 weeks. They concluded that ISQ values were influenced by the bone structure and implant length. Osstell™ Mentor can reproducibly evaluate implant stability and ISQ values are not affected by the positioning of the instrument.

CHAPTER III
MATERIALS AND METHODS

This prospective clinical study was conducted from June 2012 to February 2014 at the Department of Oral and Maxillofacial Surgery, Faculty of Dentistry in Chulalongkorn University.

1. Materials

1.1 Samples are patients who need dental implant prostheses in the posterior regions of the maxilla and/or the mandible which alveolar height is not suitable for placing standard length implants. Twenty four patients (7 males and 17 females) were enrolled in the study by convenience sampling. Patients' ages ranged from 21 to 79 (mean 43). The inclusion and exclusion criteria were as follow:

1.2 Inclusion criteria

1.2.1 Aged at least 20 years old.

1.2.2 The edentulous space was 6-10 mm.

1.2.3 Having adequate bone height suitable for placement of implant 7.5 mm in length and 4.2 mm in diameter.

1.2.4 Missing at least one permanent first premolar, second premolar, first molar, or second molar in mandible and/or maxilla.

1.2.5 Having at least two pairs of natural posterior teeth (premolars and/or molars) occluding together on the same side in which the short implant was placed.

1.3 Exclusion criteria

1.3.1 Inadequate bone height (less than 9.5 mm from the alveolar crest to the upper border of inferior alveolar canal in the mandible or less than 8 mm from the alveolar crest to the sinus floor in the maxilla) as evaluated from cone-beam CT.

1.3.2 Inadequate bone width (less than 6 mm).

1.3.3 Unwilling to participate in short implant placement study but possessing adequate bone height and width.

1.3.4 Heavy smoking (more than 10 cigarettes per day).

1.3.5 Severe bruxing or clenching habits.

1.3.6 Patients who had taken bisphosphonate for more than 3 years.

1.3.7 History of chemotherapy or radiation treatment in the area of head and neck.

1.3.8 Uncontrolled diabetes or other metabolic bone diseases.

1.3.9 Having a need for bone or soft tissue grafting at the time of implant placement.

1.3.10 No canine or natural tooth guidance on lateral movement of the jaw.

1.3.11 Having severe tipping of the tooth adjacent to the edentulous area.

The study protocol and consent form were reviewed and approved by the ethics committee of Faculty of Dentistry, Chulalongkorn University. Informed consent was obtained from all patients enrolled in the study. The mean age was 43 ± 15.9 years. Thirty short implants (7.5 mm in length and 4.2 mm in diameter) were placed in the posterior maxilla and the posterior mandible (15 implants each).

1.4 Implants used in this study

Thirty SICmax® (SIC invent AG, Basel, Switzerland) implants sized 4.2 mm in diameter and 7.5 mm in length were used in this study (Figure 6). The SICmax® threaded cylindrical implant is characterized by a basic cylindrical shape with rounded apical base and parallel thread flanks. The deeper thread notch of the self-cutting thread and the implant core diameter, which is double-butted in the upper part of the implant body, with an overlayed microthread improve the stability in soft bone. The prosthesis is attached via an internal hexagon with platform switching design.

Figure 6 The SICmax implant (4.2 mm in diameter and 7.5 mm in length)

1.5 Osstell™ ISQ

Osstell™ ISQ (Osstell AB, Göteborg, Sweden) is a device working on the basis of RFA for measurement of implant stability (Figure 4).

1.6 SmartPeg™

SmartPeg™ (Osstell AB, Göteborg, Sweden) is used together with the Osstell™ ISQ for measurement of implant stability. The SmartPeg™ is made from a soft metal with a zinc-coated magnet mounted on top of it. In this study, Type 44 SmartPeg™ (Figure 7) is used for measurement of stability of the SICmax® implant.

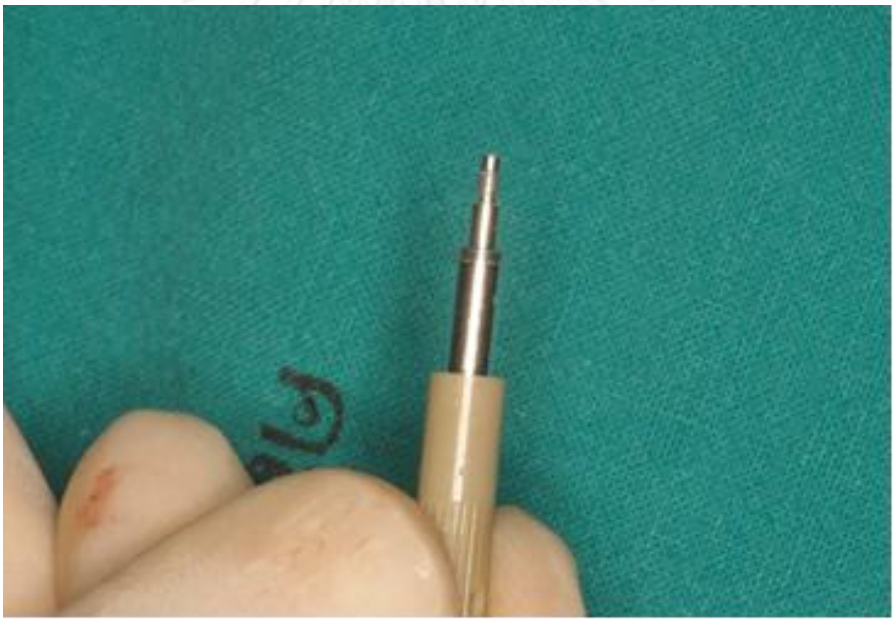

Figure 7 Type 44 SmartPeg

2. Methods

2.1 Surgical and prosthetic procedures

The preoperative planning was based on clinical and radiographic examinations. The orthopantomogram was used for initial assessment of bone height in the planned surgical site (Figure 8), and cone-beam computerized tomography (CBCT) was used for an accurate preoperative surgical planning (Figure 9).

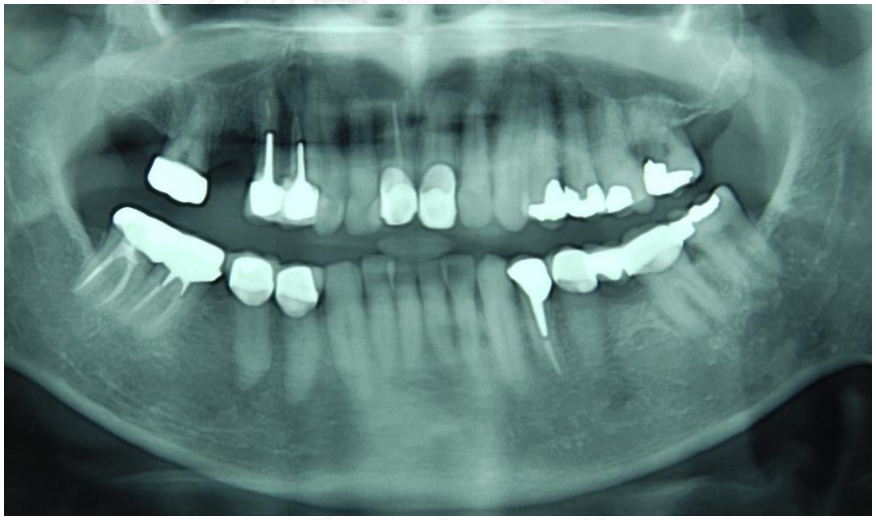

Figure 8 A preoperative panoramic radiograph

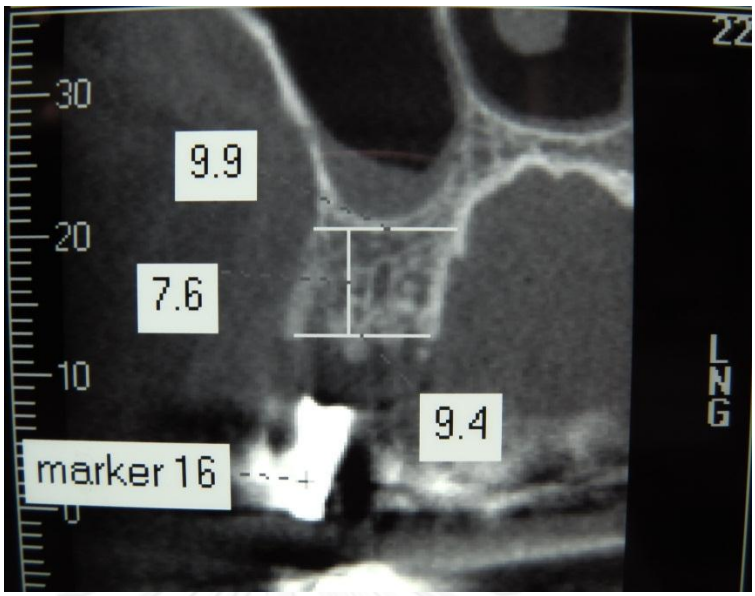

Figure 9 Accurate evaluation of bone volume at the surgical site using CBCT

In this study, a total of 30 SICmax® (SIC invent AG, Basel, Switzerland) implants (7.5 mm in length and 4.2 mm in diameter) was placed (Figure 6). Patients were premedicated with 1,000 mg of amoxycillin 30 minutes before operation, for those who were allergic to penicillin, 600 mg of clindamycin was prescribed. After the local anesthetic (2% mepivacaine with 1:100,000 epineprhine) was administered, a crestal incision was made. A meticulous and atraumatic elevation of full-thickness flap was reflected. The surgical site was exposed and crestal alveoloplasty was done if necessary. The osteotomy for implant placement was performed following the surgical protocol of the manufacturer. The implant was installed into the osteotomy site. The implant stability was then measured using Osstell™ ISQ and Type 44 SmartPeg™ (Osstell AB, Göteborg, Sweden)(Figure 7). To perform the stability measurement, the SmartPeg™ was hand-screwed into the internal thread of an implant (Figure 10). The measurement probe was held still on the buccal side aiming to the top of the SmartPeg™ at a distance of 1-2 mm (Figure 11). The baseline implant stability (ISQ value) was recorded. The cover screw was placed (Figure 12) and primary closure of the flap was done using the absorbable suture, 3-0 Coated Vicryl Rapide® (Ethicon, Johnson & Johnson, Belgium)(Figure 13). Postoperative

medications include ibuprofen 400 mg, three times a day for pain control. Wearing of removable denture was not allowed after the implant placement. Postoperative panoramic radiography was also taken on the day of implant placement (Figure 14). Two months after implant placement, the second stage surgery was performed. The second implant stability was measured before a healing abutment was secured to the implant. Three months after implant placement, before an impression was taken, the third implant stability was measured. Four months after implant placement, the forth implant stability was measured. Then the abutment and crown were fixed to the implant, and a periapical radiography was taken immediately. All of the prostheses in this study were implant-supported single crowns. Three months later (seven months after implant placement), the implant prosthesis was then evaluated for success or failure using the criteria proposed by Buser et al.[49]

The criteria of implant success proposed by Buser et al includes:

1. Absence of persistent subjective complaints, such as pain, foreign body sensation and/or dysesthesia.
2. Absence of a recurrent peri-implant infection with suppuration.
3. Absence of mobility.
4. Absence of a continuous radiolucency around the implant.
5. Possibility for restoration.

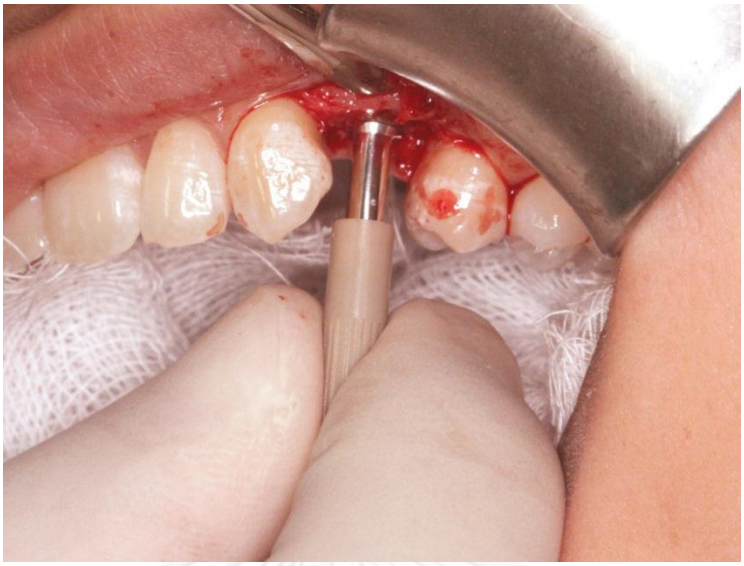

Figure 10 Clinical picture showing a SmartPeg was hand-screwed into an implant

Figure 11 Clinical picture showing measurement of the implant stability from the buccal side

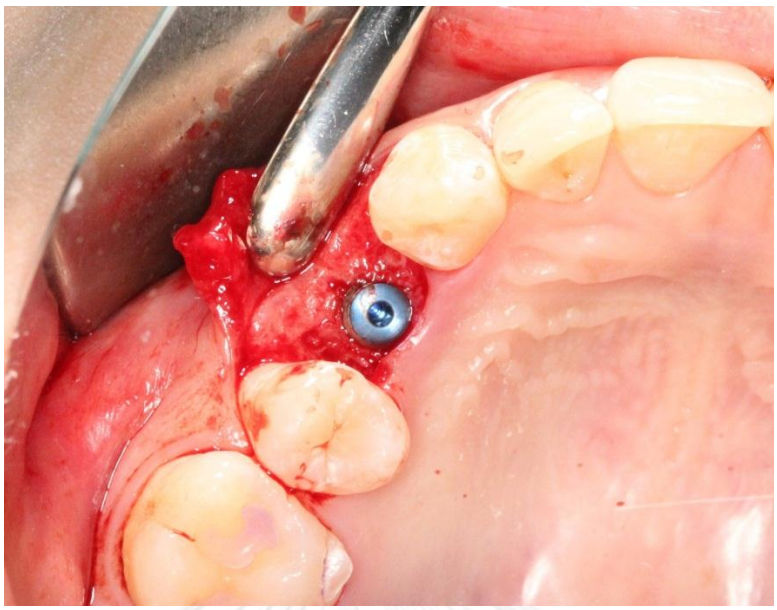

Figure 12 The cover screw was placed into an implant

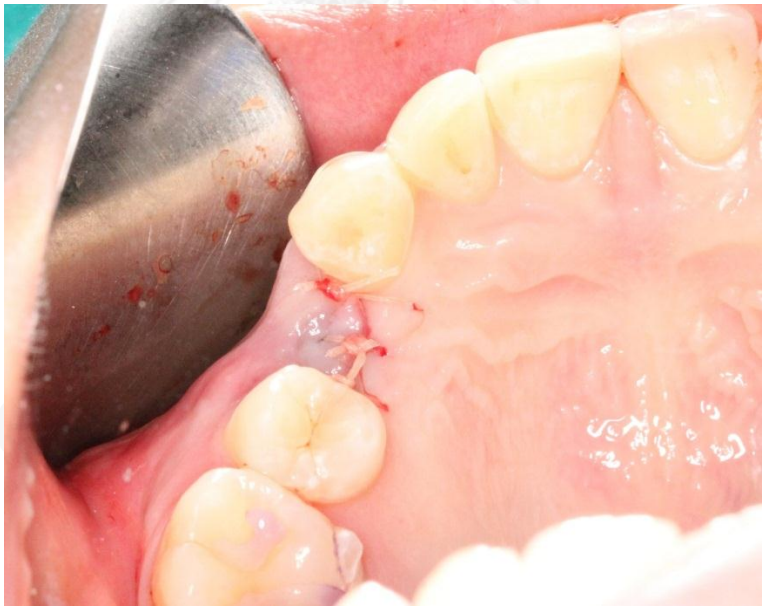

Figure 13 Primary closure of the flap

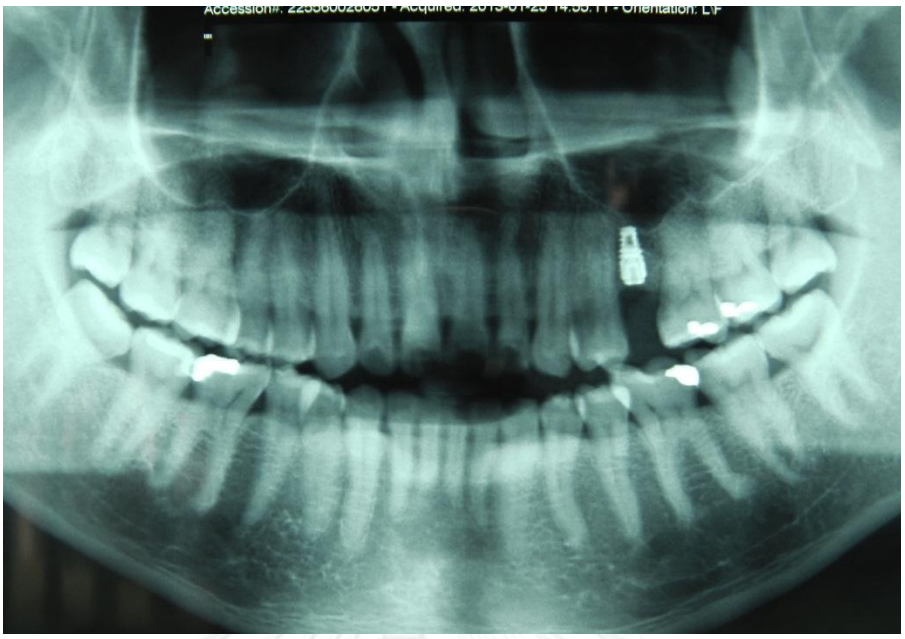

Figure 14 Postoperative panoramic radiography

2.2 Statistical analysis

Statistical analyses were determined using the Statistical Package for the Social Sciences software (SPSS) version 17.0 (SPSS Inc., Chicago, US). Both descriptive and inferential statistics were determined. The level of significance for all statistical test was set at $\alpha = 0.05$. Continuous variables were determined for normality of the distribution using Kolmogorov–Smirnov test and determined for homogeneity of variance using Levene's test.

Demographic data was determined and presented as mean ± SD, median, percentage or frequency where appropriate for qualitative or quantitative variables.

The implant stability was determined and presented as mean ± SD and range. Statistical comparison of the stability between short implants in the maxilla and the mandible was performed using independent t-test or Wilcoxon Signed Ranks test. The success of short implants was reported as percentage.

CHAPTER IV
RESULTS

Part 1. Demographic data

The 24 patients were enrolled in the study. Most of the patients (87.5%) were nonsmoker. The duration of tooth loss before implant placement was in the range of 3 months to 25 years (median 15 months). Thirty short implants (7.5 mm in length and 4.2 mm in diameter) were placed in posterior maxilla and mandible (15 implants each in the posterior maxilla and the posterior mandible). One implant in the posterior maxilla failed to osseointegrate during second stage surgery. All implants were restored with implant-retained single crown. The patients' demographic data is shown in Table 1.

Table 1 Patient demographic data

Descriptive data	N	%
Number of patients	24	100
Age (year),		
Mean ± SD	43 ± 15.9	
Sex		
Male	7	29.2
Female	17	70.8
Smoking		
Yes	3	12.5
No	21	87.5
Number of implants	30	100.0
Success	29	96.7
Failure	1	3.3
Duration of tooth loss (months)		
< 6 months	10	33.3
6-12 months	2	6.7
> 12 months	18	60.0
Implant placement		
Maxilla	15	50.0
Mandible	15	50.0

Abbreviations: SD, standard deviation

Part 2. The stability of implants in the maxilla and the mandible

Twenty-four posterior partially edentulous patients were included in the study; one was excluded due to an implant in the posterior maxilla failed to osseointegrate during the second stage surgery. Therefore, the ISQ values of 29 implants were used in the analysis. Range, mean ± SD and median ISQ values of short implants were presented in Table 2. In the mandible, the mean ISQ values at implant placement, 2, 3, and 4 months after implant placement were higher than the mean ISQ values of short implants in the maxilla (Figure 15).

Table 2 The ISQ values of implants in the maxilla and the mandible

Stability (ISQ values)	Insertion (ISQ 0)	2 months (ISQ 2)	3 months (ISQ 3)	4 months (ISQ 4)
Maxilla				
Mean ± SD	70.1 ± 11.8	74.1 ± 4.1	77.6 ± 3.9	78.7 ± 3.3
Median	73.0	74.5	78.0	79.5
Range	32-79	65-80	68-82	71-84
Mandible				
Mean ± SD	76.9 ± 4.7	78.8 ± 4.9	80.7 ± 5.0	81.3 ± 4.4
Median	79.0	81.0	82.0	83.0
Range	68-83	69-84	65-85	67-85

Abbreviations: ISQ, Implant stability quotient; SD, standard deviation

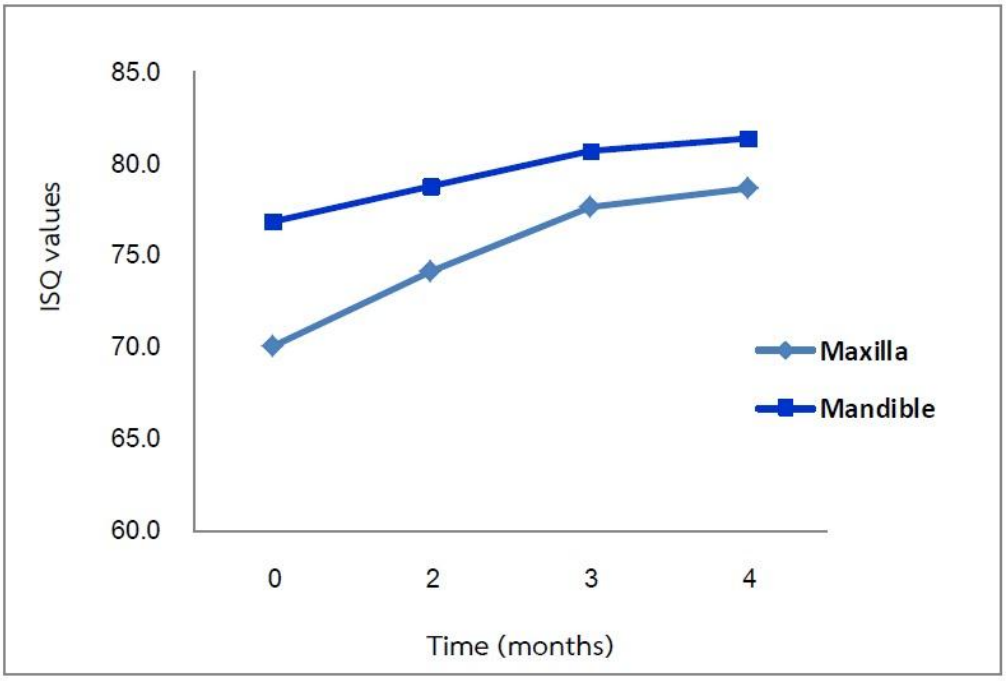

Figure 15 Mean ISQ values of short implants in the maxilla and the mandible

Part 3. Comparison of stability in different implant sites

The different implant sites influenced ISQ values at 2 months after implant placement. The ISQ value in maxilla was lower than those in mandible. The mean ISQ values of different implant sites were shown in Table 3.

Table 3 The average stability of implants in the maxilla and the mandible at different periods

Stability (Mean ± SD)	Maxilla	Mandible	*P-value*[#]
Insertion (ISQ 0)	70.1 ± 11.8	76.9 ± 4.7	0.05
2 months (ISQ 2)	74.1 ± 4.1	78.8 ± 4.9	0.009*
3 months (ISQ 3)	77.6 ± 3.9	80.7 ± 5.0	0.07
4 months (ISQ 4)	78.7 ± 3.3	81.3 ± 4.4	0.82

Notes: [#]*P*-value as Independent T-Test; **P*-value <0.05

Abbreviations: ISQ, Implant stability quotient, SD, standard deviation

The median ISQ values were presented Table 4 because the data was not normally distributed. The normality tests of ISQ values were shown in appendix F.

Table 4 The median stability of implants in the maxilla and the mandible at different periods

Stability (Median)	Maxilla	Mandible	*P-value*[#]
Insertion (ISQ 0)	73.0	79.0	0.022*
2 months (ISQ 2)	74.5	81.0	0.008*
3 months (ISQ 3)	78.0	82.0	0.005*
4 months (ISQ 4)	79.5	83.0	0.012*

Notes: The ISQ values were reported as median due to the non-normal distribution of data; [#]*P*-value as Mann Whitney Test; **P*-value <0.05

Abbreviations: ISQ, Implant stability quotient

Part 4. Comparison of short implant stability in different time periods

The median ISQ values of short implants in both the maxilla and the mandible at 3 and 4 months increased significantly when compared with the median ISQ values at immediately after implant placement (in the maxilla *P*=0.002 and *P*=0.001; in the mandible *P*=0.007, *P*=0.004, respectively), as shown in Table 5.

In the maxilla, the median ISQ value of short implants at 2 months was significantly lower than the median ISQ values at 3 and 4 months respectively (*P*=0.003, *P*=0.002). The median ISQ value of short implants at 3 months was significantly lower than the median ISQ value at 4 months (*P*=0.024).

In the mandible, there was no significant difference among the ISQ values of short implants at 2, 3, and 4 months after implant placement.

Table 5 Comparison of the stability (ISQ values) at different time periods

Stability comparison	Maxilla		Mandible	
	Difference of ISQ values (Median)	*P*-value[#]	Difference of ISQ values (Median)	*P*-value[#]
ISQ 0 *vs.* ISQ 2	1.5	0.185	2.0	0.185
ISQ 0 *vs.* ISQ 3	5.0	0.002*	3.0	0.007*
ISQ 0 *vs.* ISQ 4	6.5	0.001*	4.0	0.004*
ISQ 2 *vs.* ISQ 3	3.5	0.003*	1.0	0.057
ISQ 2 *vs.* ISQ 4	5.0	0.002*	2.0	0.078
ISQ 3 *vs.* ISQ 4	1.5	0.024*	1.0	0.470

Notes: The ISQ values were reported as median due to the non-normal distribution of data; [#]*P*-value as Wilcoxon Signed Ranks Test; **P*-value <0.05

Abbreviations: ISQ, Implant stability quotient

CHAPTER V
DISCUSSION

Several studies have revealed that RFA is a noninvasive and reliable method to indicate implant stability. Regarding RFA concept, Osstell™ ISQ is the latest commercial product of Osstel™ for measuring short implant stability. An in vitro study by Huang et al demonstrated that the 3D bone-implant contact percentage (3D BIC%) has strongly positive correlation to the ISQ values.[50] Park et al presented similar results in their experiment that 16 implants placed in rabbit tibias. This study also demonstrated significant correlation between the BIC% and primary stability of implants.[51] Al-Moaber et al studied stability changes of 2 different implant systems during a healing period of 8 weeks in beagle dogs using RFA and evaluated periimplant bone healing using microcomputed tomography (micro-CT). The study confirmed the efficacy of RFA in determining the implant stability and the healing status of bone around dental implants.[52] Clinical studies also demonstrated that RFA is an accurate and reliable method to determine the stiffness of implant-bone interface or degree of osseointegration clinically.[4, 48]

In the present study, the latest generation of Osstell™ device, Osstell™ ISQ, was used with type 44 SmartPegs™ that connected to the implant screw holes to measure the stability of implants placed in the posterior maxilla and mandible on the day of placement, 2, 3, and 4 months respectively. The manufacturer claimed that the SmartPeg™ can resonate in two perpendicular directions automatically – hence providing two ISQ values, the higher and the lower ones, in non-homogenous bone. In cases of two different ISQ values, the author chose the lower one to represent the stability of short implants. The reason we chose the lower ISQ values was because the dental implants will be loaded with occlusal forces in all different directions when functioning. Therefore it was reasonable to use the lower value as the baseline. In this study, the Osstell™ ISQ was used to measure and compare stability of short implants placed in the posterior maxilla and the posterior mandible within a 4-month healing period. Thirty SICmax® implants were installed (15 implants

each in maxilla and mandible) and restored by only one operator. The major variable in this study was the implant sites (the maxilla or the mandible). One maxillary implant failed to integrate with unknown cause at the second stage surgery, though the failed implant had good primary stability (68 ISQ) and the patient had no apparent symptoms. The ISQ value of this failed implant was excluded from statistical analysis. In this study, the success rate of short implants was 96.7%, comparable to the success rates of longer implants in other previous studies. From initial implant placement to month 4, ISQ values of short implants in the maxilla were different from those in the mandible. Hence the hypothesis of the study was rejected. In the maxilla, ISQ values were lower than in the mandible because of the poorer bone density commonly found in the posterior maxilla. This finding is consistent with a previous retrospective study[4] which found strong positive correlation between bone density as evaluated by CT scan and ISQ values.

The ISQ values progressively increased in both the maxilla and the mandible throughout the 4-month healing period. Moreover, the mean ISQ values of mandibular implants were significantly higher than those of maxillary implants in every time period. In the mandible, ISQ 3 and ISQ 4 were not significantly different from ISQ 2. There were, however, statistical differences among ISQ 2, ISQ 3, and ISQ 4 in the maxilla. This data suggests that osseointegration is a dynamic process that occurs from the first day of surgery to 4 months. Favorable implant stability can be found in the mandible within 2 months after implant placement. In the maxilla, the bone healing process is slower and the implant stability is not as strong as that of the mandible. Nevertheless, there was no statistical difference between ISQ 0 and ISQ 2 in both the maxilla and the mandible. This may be attributed to the taper design of short implants which provided excellent primary stability. A review article[53] stated that factors influencing RFA include the design of transducer, the stiffness of implant fixture and its interface, and the total effective length above the marginal bone level. As all implants used in this study were identical in size and shape, and all of them were placed at alveolar crest level, the variation in measured ISQ values must therefore be related to the bone-implant interface or degree of osseointegration.

In this study, the mean primary stability (ISQ 0) of short implants placed in the maxilla and the mandible were 70.1 ± 11.8 and 76.9 ± 4.7 respectively. According to a review article of Rao and Gill[54] which emphasized the significant roles of primary stability, the major factors influencing primary stability are: 1) bone quality and quantity, 2) implant design and configuration, and 3) surgical techniques. In this study, all short implants placed were taper form with 7.5 mm in length and 4.2 mm in platform. Moreover, the surgical technique used for all patients was similar and the implant placement was done by only one operator. Therefore the primary stability measured of each implant was directly dependent only on the quality and quantity of bone at each implant site. The majority (62.1%) of implants were placed in edentulous areas of more than 1 year after tooth extraction, which were completely healed. Only 31% of the implants were placed in the edentulous areas earlier than 6 months after tooth extraction, and the earliest implant placement was 3 months after tooth extraction, where the bone in the socket may not solid enough. In cases of partial bone healing or very poor bone density, undersized drilling may be performed to acquire better primary stability. However, one maxillary implant had very poor primary stability with the ISQ value of 32. Its ISQ values increased to 65, 68, and 71 at 2, 3, and 4 months respectively. Due to the 2-stage surgical protocol used in this study, the short implant with poor primary stability could have osseointegration under soft tissue protection. In the author's opinion, if the short implants did have good primary stability, it would be possible to perform a 1-stage surgical approach and would have successful osseointegration. Short implants should not be loaded within the first 6 weeks after placement because several studies showed that the weakest stability was found during 3 to 6 weeks after implant placement.[17, 47, 55] This was the reason why the second stage surgery was performed at 2 months after placement. Furthermore, there has not been enough evidence supporting the immediate or early loading of short implant.

The secondary stability is a biological phenomenon caused by bone healing and remodeling around an implant surface. Factors influencing the osseointegration process include implant related factors, the status of bone, primary stability, and adjunctive therapies such as bone grafting.[56] In our study, every patient who enrolled

in the study must have enough bone volume both in width and height suitable for short implant placement with no additional bone grafting. Furthermore, two-stage surgical approach was employed and wearing of removable partial denture was not allowed after implant placement. One of the most important factors influencing osseointegration process is chemical and physical properties of implant surface.[56] Titanium has been the most widely used material for dental implants. Nowadays, most implant systems in the market are rough-surface implants. Numerous studies have demonstrated that rough-surface implants have better stability and higher success than smooth-surface implants.[57] Sandblasted with large grits and acid etched (SLA) surface is the most popular among other implant surfaces. The SLA implants have demonstrated good outcomes both *in vivo*[58, 59] and long-term clinical studies.[60] In the current study, the implants used had SLA surfaces and showed excellent primary and secondary stability, and had good clinical outcomes in short term. However, a long-term follow-up should be done for a study of long-term success of these implants.

Currently, a few evidences of short implant stability are available but the normative range of ISQ values for short implants does not exist in the literature. Therefore the data from the present study cannot be compared with other previous studies. In a pilot study of 45 implants with lengths of 7 to 18 mm[61], the ISQ values of successfully osseointegrated implants ranged from 57 to 82 with a mean ISQ value of 69 after one year of loading. The stability of implants in the mandible was significantly higher than those in the maxilla with the ISQ values of 72.8 ± 5.4 (range 62 to 82) and 64.7 ± 4.8 (range 57 to 72), respectively.

Another previous study on 106 SLA Straumann® implants revealed that implants with the ISQ values of more than 47 can successfully osseointegrate[45]. All implants with the ISQ values of more than 49 at placement can be loaded in 3 months later and can maintain osseointegration after 1 year of loading. In another study on 24 SLA Straumann® implants with 10 mm in length[47], the results showed that the ISQ values between 57 and 70 at the time of implant placement represented homeostasis and implant stability. However, there was no correlation between the ISQ values and the bone density as evaluated by micro-CT.

According to consensus statements and clinical recommendations for implant loading protocols published in 2013[62], a minimal ISQ value in the range of 60 to 65 was recommended for immediate or early loading (during 1 week to 2 months after implant placement) of single implant crowns in partially edentulous patients. However, conventional implant loading (more than 2 months after placement) was recommended for some situations such as low primary stability of implants, substantial bone augmentation, and implants with reduced dimensions (short or small-diameter implants). In the present study, the mean ISQ values of short implants in the posterior maxilla and mandible at 2 months after placement were 74.1 ± 4.1 and 78.8 ± 4.9 respectively. In the mandible, the ISQ values had not increased significantly after 2 months. In contrast, the ISQ values of short implants in the posterior maxilla continued to increase significantly after 2 months. However, the ISQ 4 increased slightly from the ISQ 3. Based on these ISQ values, it can be implied that short implants with rough surface had a high degree of osseointegration within 2 months after placement in the mandible and within 3 months after placement in the maxilla. However, long-term follow-up and a larger sample size are necessary for more predictable treatment outcome. Further studies should also compare the stability of short and longer implants with similar design and surface, and compare the stability of short implants with different surfaces during the healing periods.

CHAPTER VI
CONCLUSION

In conclusion, the results of this study indicate that short implants in the posterior maxilla have lower stability than those in the posterior mandible during the 4-month healing period. Though the ISQ values suggest that short implants with rough surfaces can gain a high degree of osseointegration within 2 months in the mandible and within 3 months in the maxilla if good stability was achieved at implant placement.

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APPENDICES

APPENDIX A

เอกสารข้อมูลคำอธิบายสำหรับอาสาสมัครที่เข้าร่วมในการวิจัย
(Patient/Participant Information Sheet)"

โครงการเรื่อง การศึกษาเปรียบเทียบเสถียรภาพของรากฟันเทียมแบบสั้นในขากรรไกรบนและล่างส่วนหลัง

ชื่อผู้วิจัยหลัก ทันตแพทย์ชลธี เวโรจน์ นิสิตระดับปริญญาโท ภาควิชาศัลยศาสตร์

สถาบันที่สังกัด คณะทันตแพทยศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย

แหล่งทุนวิจัย กองทุนรัชดาภิเษกสมโภช จุฬาลงกรณ์มหาวิทยาลัย

วัตถุประสงค์ของโครงการ เปรียบเทียบเสถียรภาพของรากฟันเทียมแบบสั้นที่ฝังลงในขากรรไกรบนและล่างส่วนหลังในช่วงเวลา 3 เดือน

สถานที่ดำเนินการวิจัย คณะทันตแพทยศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย

วิธีการที่เกี่ยวข้องกับการวิจัย

หากท่านมีความประสงค์เข้าร่วมในโครงการวิจัย ท่านจะต้องมีฟิล์มเอกซเรย์พานอรามิกและได้รับการตรวจช่องปากจากทันตแพทย์ก่อน เพื่อประเมินว่าท่านมีคุณสมบัติตรงตามเกณฑ์ดังกล่าว หลังจากนั้นท่านจะต้องทำการเอกซเรย์คอมพิวเตอร์สามมิติ (CT scan) เพื่อยืนยันว่าท่านมีกระดูกเพียงพอในการฝังรากฟันเทียมแบบสั้นได้ โดยท่านจะได้รับส่วนลดในการเอกซเรย์คอมพิวเตอร์เป็นกรณีพิเศษ และได้รับรากฟันเทียมรวมถึงอุปกรณ์ส่วนต่อของรากฟันเทียมฟรี รากฟันเทียมที่ใช้ในการวิจัยนี้ คือ รากฟันเทียมระบบ SIC® ความยาว 7.5 มิลลิเมตร ขนาดเส้นผ่านศูนย์กลาง 4.2 มิลลิเมตร ซึ่งผลิตจากประเทศเยอรมันนี

ในวันที่ท่านมารับการผ่าตัดฝังรากฟันเทียม ท่านจะได้รับการรักษาตามขั้นตอนปกติเหมือนกับการผ่าตัดฝังรากฟันเทียมโดยทั่วไปโดยฉีดยาชาเฉพาะที่ เพียงแต่มีขั้นตอนในการวัดเสถียรภาพของรากฟันเทียมเพิ่มขึ้นมาจากปกติ ซึ่งใช้เวลาเพิ่มขึ้นไม่เกิน 5 นาที หลังจากวันที่ผ่าตัดฝังรากเทียมประมาณ 1 สัปดาห์จะนัดท่านกลับมาเพื่อตรวจแผลผ่าตัดและทำการตัดไหม

2 เดือนหลังการผ่าตัดฝังรากฟันเทียม ท่านจะได้รับการผ่าตัดครั้งที่สอง โดยเพียงเปิดเหงือกที่คลุมรากฟันเทียมเพื่อต่อส่วนต่อของรากฟันเทียมให้พ้นเหงือก และทำการวัดเสถียรภาพของรากฟันเทียมครั้งที่ 2

3 เดือนหลังการผ่าตัดฝังรากฟันเทียม จะทำการวัดเสถียรภาพของรากฟันเทียมครั้งที่ 3 และพิมพ์ปากเพื่อเตรียมฟันปลอม และดำเนินการตามขั้นตอนของการใส่ฟันจนท่านได้ฟันปลอมยึดติดบนรากฟันเทียมเรียบร้อย

6 เดือนหลังการผ่าตัดฝังรากฟันเทียม จะนัดท่านกลับมาตรวจและติดตามผลการรักษาและประเมินความสำเร็จของรากฟันเทียม จึงเป็นอันเสร็จสิ้นกระบวนการวิจัย

หากท่านยินดีเข้าร่วมในโครงการวิจัย ผู้วิจัยจะปฏิบัติต่อท่านเป็นขั้นตอน**ดังแสดงในตาราง**

ครั้งที่	เวลา	รายละเอียด
1	-	ซักประวัติ, ตรวจภายในช่องปาก, เอกซเรย์ และพิมพ์ปากทำเครื่องมือกำหนดตำแหน่งของรากฟันเทียม
2	-	เอกซเรย์คอมพิวเตอร์สามมิติ
3	วันที่ 1	**ผ่าตัด**ฝังรากฟันเทียมลงในกระดูกขากรรไกร
4	1 สัปดาห์หลังผ่าตัด	ตรวจแผลผ่าตัด และตัดไหม
5	2 เดือนหลังผ่าตัด	ต่อส่วนต่อของรากฟันเทียมให้พ้นเหงือก
6	3 เดือนหลังผ่าตัด	พิมพ์ปากเพื่อทำฟันปลอม และนัดใส่ฟัน (ประมาณ 1 - 2 สัปดาห์)
7	6 เดือนหลังผ่าตัด	ตรวจและติดตามผลการรักษา, ประเมินความสำเร็จของรากฟันเทียม

เหตุผลที่เชิญท่านเข้าร่วมในการวิจัย

ท่านได้รับเชิญให้เข้าร่วมการศึกษาวิจัยนี้ เนื่องจากคาดว่าท่านเป็นอาสาสมัครที่มีสุขภาพดี โดยท่านจะได้อ่านข้อมูลที่เกี่ยวข้องกับโครงการนี้ก่อน ถ้าท่านมีข้อสงสัยใดๆเกี่ยวกับการศึกษาวิจัยนี้ สามารถซักถามผู้วิจัยได้ หากท่านตัดสินใจเข้าร่วมการศึกษาวิจัย ท่านจะได้รับสำเนาใบยินยอมที่ท่านเซ็นชื่อกำกับเก็บไว้ 1 ฉบับ

คุณสมบัติของผู้เข้าร่วมการวิจัยสามารถสรุปได้ดังต่อไปนี้

1. มีอายุตั้งแต่ 20-70 ปี
2. มีสุขภาพร่างกายสมบูรณ์
3. มีความต้องการใส่ฟันปลอมติดแน่น ซึ่งเป็นครอบฟันซี่เดี่ยวบนรากฟันเทียมแบบสั้น

4. เคยถอนฟันกรามหรือฟันกรามน้อยไปอย่างน้อย 1 ซี่ และมีฟันหลังบนล่าง(ด้านที่จะใส่รากฟันเทียม)สบกันอย่างน้อย 2 คู่
5. มีความกว้างและความสูงของกระดูกขากรรไกรเพียงพอที่จะใส่รากฟันเทียมแบบสั้น
6. มีฟิล์มเอกซเรย์พานอรามิก

ความรับผิดชอบของอาสาสมัคร และระยะเวลาที่อาสาสมัครจะอยู่ในโครงการ

ขอให้ท่านปฏิบัติตามที่ผู้วิจัยแนะนำในระหว่างที่ท่านเข้าร่วมโครงการวิจัยนี้ โดยระยะเวลาที่ท่านจะอยู่ในโครงการนี้คือ 6 เดือนนับตั้งแต่วันที่ทำการผ่าตัดฝังรากฟันเทียม

ประโยชน์ของการวิจัยที่อาสาสมัครและ/หรือผู้อื่นอาจได้รับ

1. ท่านจะได้ใส่รากฟันเทียมโดยไม่ต้องผ่าตัดปลูกกระดูก
2. ข้อมูลการวัดเสถียรภาพของรากฟันเทียมแบบสั้นของท่าน จะช่วยให้ผู้วิจัยนำไปเป็นแนวทางในการกำหนดระยะเวลาที่เหมาะสมในการใส่ฟันปลอม และลดอัตราความล้มเหลวของการใส่รากฟันเทียมแบบสั้น

ความเสี่ยงหรือความไม่สะดวกที่อาจจะเกิดขึ้นแก่อาสาสมัคร

ท่านอาจมีความเสี่ยงต่อการเกิดผลแทรกซ้อนจากการผ่าตัด ซึ่งเหมือนกับการผ่าตัดในช่องปากโดยทั่วไป เช่น มีอาการปวด บวม มีเลือดออก หรืออาจมีการติดเชื้อบริเวณแผลภายหลังการผ่าตัด รวมทั้งมีโอกาสที่รากฟัน-เทียมอาจหลุดหรือไม่ยึดติดกับกระดูกขากรรไกร แต่ขอให้ท่านปฏิบัติตามที่ผู้วิจัยแนะนำ ทั้งนี้ผู้วิจัยตระหนักถึงผลแทรกซ้อนต่าง ๆ ที่อาจเกิดขึ้น และมีมาตรการในการลดความเสี่ยงเหล่านี้โดยกระทำการรักษาตามมาตรฐานของวิชาชีพอย่างเคร่งครัด

ค่าใช้จ่ายที่อาสาสมัครจะต้องจ่าย หรืออาจจะต้องจ่าย

อาสาสมัครจะมีค่าใช้จ่ายในการผ่าตัดฝังรากฟันเทียม ค่าเอกซเรย์ ค่าเอกซเรย์คอมพิวเตอร์สามมิติ และค่าทำฟันปลอม ตามอัตราที่กำหนดไว้โดยคณะทันตแพทยศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย ส่วนวัสดุและอุปกรณ์ที่ใช้ในการวัดเสถียรภาพของรากฟันเทียม ผู้วิจัยจะเป็นผู้ออกค่าใช้จ่ายให้แก่ท่าน

การชดเชยใดๆ และการรักษาที่จะจัดให้แก่อาสาสมัครในกรณีที่ได้รับอันตรายซึ่งเกี่ยวข้องกับการวิจัย

หากท่านได้รับอันตรายจากการทำวิจัย ผู้วิจัยจะดำเนินการให้ท่านได้รับการรักษาโดยผู้วิจัยและผู้สนับสนุนการวิจัยจะเป็นผู้รับผิดชอบค่าใช้จ่ายของการรักษา

ในกรณีที่รากฟันเทียมมีการโยกหรือหลุดในช่วงระยะเวลาที่ยังไม่เสร็จสิ้นกระบวนการวิจัย (ช่วงระยะเวลา 6 เดือน นับตั้งแต่วันที่ผ่าตัดฝังรากฟันเทียม) ผู้วิจัยยินดีจะทำการผ่าตัดฝังรากฟันเทียมตัวใหม่ให้แก่ท่านโดยไม่มีค่าใช้จ่ายในส่วนของการผ่าตัดและรากฟันเทียมตัวใหม่ แต่ท่านจะต้อง

ชำระค่าใช้จ่ายในส่วนอื่น ๆ เอง เช่น ค่าฟัน-ปลอมใหม่ ค่าเอ็กซเรย์ เป็นต้น ซึ่งท่านสามารถตรวจสอบอัตราค่าใช้จ่ายต่าง ๆ ได้จากคณะทันตแพทยศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย

เหตุการณ์ที่อาจจะเกิดขึ้น หรือเหตุผลซึ่งผู้วิจัยจะต้องยกเลิกการเข้าร่วมในโครงการวิจัยของอาสาสมัคร

หากผลการเอกซเรย์คอมพิวเตอร์สามมิติ พบว่าท่านมีความกว้างและ/หรือความสูงของกระดูกขากรรไกร ไม่เพียงพอต่อการฝังรากฟันเทียมแบบสั้น ผู้วิจัยจำเป็นต้องขอยกเลิกการเข้าร่วมในโครงการวิจัยของท่าน โดยผู้วิจัยจะดำเนินการให้ท่านได้รับการรักษาที่เหมาะสมต่อไป

การกำกับดูแลและควบคุมการดำเนินโครงการ

ผู้กำกับดูแลการวิจัย ผู้ตรวจสอบ คณะกรรมการพิจารณาจริยธรรม และคณะกรรมการที่เกี่ยวข้อง สามารถเข้าไปตรวจสอบการดำเนินโครงการ รวมทั้ง ตรวจสอบบันทึกข้อมูลของอาสาสมัคร เพื่อเป็นการยืนยันถึงขั้นตอนในการวิจัยทางคลินิกและข้อมูลอื่นๆ โดยไม่ล่วงละเมิดเอกสิทธิ์ในการปิดบังข้อมูลของอาสาสมัคร ตามกรอบที่กฎหมายและกฎระเบียบได้อนุญาตไว้ นอกจากนี้ โดยการลงนามให้ความยินยอม อาสาสมัครหรือผู้แทนตามกฎหมายจะมีสิทธิตรวจสอบและมีสิทธิที่จะได้รับข้อมูลด้วยเช่นกัน

จริยธรรมการวิจัย

การดำเนินการโครงการวิจัยนี้ ผู้วิจัยคำนึงถึงหลักจริยธรรมการวิจัย ดังนี้

1. หลักความเคารพในบุคคล (Respect for person) โดยการให้ข้อมูลจนอาสาสมัครเข้าใจเป็นอย่างดี และตัดสินใจอย่างอิสระในการให้ความยินยอมเข้าร่วมในการวิจัย รวมทั้งการเก็บรักษาความลับของอาสาสมัคร โดยไม่มีการบันทึกข้อมูลใด ๆ ที่จะระบุถึงตัวอาสาสมัครลงในแบบบันทึกข้อมูล

2. หลักการให้ประโยชน์ไม่ก่อให้เกิดอันตราย (Beneficence/Non-Maleficence) การวิจัยนี้มีความเสี่ยงเหมือนกับการผ่าตัดเล็กในช่องปากโดยทั่วไป ผู้วิจัยได้ป้องกันและลดโอกาสการเกิดผลแทรกซ้อนต่าง ๆ โดยการซักประวัติ ตรวจในช่องปาก รวมถึงการเอกซเรย์คอมพิวเตอร์สามมิติ เพื่อวางแผนการรักษาให้มีประสิทธิภาพและปลอดภัย รวมทั้งติดตามผลการรักษาอย่างต่อเนื่องจนสิ้นสุดโครงการวิจัย

3. หลักความยุติธรรม (Justice) คือ มีเกณฑ์คัดเข้าและคัดออกชัดเจนข้อมูลที่อาจนำไปสู่การเปิดเผยตัวของอาสาสมัครจะได้รับการปกปิด ยกเว้นว่าได้รับคำยินยอมไว้โดยกฎระเบียบและกฎหมายที่เกี่ยวข้องเท่านั้นจึงจะเปิดเผยข้อมูลแก่สาธารณชนได้ ในกรณีที่ผลการวิจัยได้รับการตีพิมพ์ชื่อและที่อยู่ของอาสาสมัครจะต้องได้รับการปกปิดอยู่เสมอ และอาสาสมัครหรือผู้แทนตามกฎหมาย

จะได้รับแจ้งโดยทันท่วงที ในกรณีที่มีข้อมูลใหม่ซึ่งอาจใช้ประกอบการตัดสินใจของอาสาสมัครว่าจะยังคงเข้าร่วมในโครงการวิจัยต่อไปได้หรือไม่

หากท่านมีข้อสงสัยต้องการสอบถามเกี่ยวกับสิทธิของท่านหรือผู้วิจัยไม่ปฏิบัติตามที่เขียนไว้ในเอกสารข้อมูลคำอธิบายสำหรับผู้เข้าร่วมในการวิจัย ท่านสามารถติดต่อหรือร้องเรียนได้ที่ ฝ่ายวิจัย คณะทันตแพทยศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย ตึกสมเด็จย่า 93 ชั้น 10 หรือที่หมายเลขโทรศัพท์ 0-2218-8816 ในเวลาราชการ

หากท่านต้องการยกเลิกการเข้าร่วมเป็นอาสาสมัครในโครงการนี้ ให้ท่านกรอกและส่งเอกสารขอยกเลิกมาที่ : ทันตแพทย์ชลธี เวโรจน์

ภาควิชาศัลยศาสตร์ คณะทันตแพทยศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย

34 ถนนอังรีดูนังต์ เขตปทุมวัน กรุงเทพฯ 10330

อาสาสมัครสามารถติดต่อผู้วิจัยได้ตลอด 24 ชั่วโมง ที่:

1. ทันตแพทย์ชลธี เวโรจน์
   ที่อยู่ ภาควิชาศัลยศาสตร์ คณะทันตแพทยศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย

   โทรศัพท์ติดตามตัว 08-6320-5542

2. รองศาสตราจารย์ ทพ.นพ.สมชาย เศรษฐศิริสมบัติ
   ที่อยู่ ภาควิชาศัลยศาสตร์ คณะทันตแพทยศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย

   โทรศัพท์ที่ทำงาน 0-2218-8581

   ขอขอบคุณในความร่วมมือของท่านมา ณ ที่นี้

.....

(ทันตแพทย์ชลธี เวโรจน์)

ผู้วิจัยหลัก

วันที่...../...../.....

APPENDIX B

เอกสารยินยอมเข้าร่วมการวิจัย (Consent Form)

การวิจัยเรื่อง การศึกษาเปรียบเทียบเสถียรภาพของรากฟันเทียมแบบสั้นในขากรรไกรบนและล่างส่วนหลัง

“ข้าพเจ้า (นาย, นาง, นางสาว).....

อยู่บ้านเลขที่.....ถนน.....ตำบล/แขวง.....

อำเภอ/เขต.....จังหวัด.....รหัสไปรษณีย์.....

ก่อนที่จะลงนามในใบยินยอมให้ทำการวิจัยนี้ ข้าพเจ้าได้รับเอกสารข้อมูลคำอธิบายสำหรับอาสาสมัครที่เข้าร่วมในการวิจัยแล้ว 1 ฉบับ รวมทั้งได้รับการอธิบายจากผู้วิจัยถึงวัตถุประสงค์ของการวิจัย วิธีการทำวิจัย อันตรายหรืออาการที่อาจเกิดขึ้นจากการทำวิจัยหรือจากยาที่ใช้ รวมทั้งประโยชน์ที่จะเกิดขึ้นจากการวิจัยอย่างละเอียดและมีความเข้าใจดีแล้ว

ผู้วิจัยรับรองว่าจะตอบคำถามต่างๆที่ข้าพเจ้าสงสัยด้วยความเต็มใจไม่ปิดบังซ่อนเร้นจนข้าพเจ้าพอใจ

ข้าพเจ้าเข้าร่วมโครงการวิจัยนี้โดยสมัครใจ ข้าพเจ้ามีสิทธิที่จะบอกเลิกการเข้าร่วมในโครงการวิจัยนี้เมื่อใดก็ได้และการบอกเลิกการเข้าร่วมการวิจัยนี้จะไม่มีผลต่อการรักษาโรคที่ข้าพเจ้าจะพึงได้รับต่อไป

ผู้วิจัยรับรองว่าจะเก็บข้อมูลเฉพาะเกี่ยวกับตัวข้าพเจ้าเป็นความลับ และจะเปิดเผยได้เฉพาะในรูปที่เป็นสรุปผลการวิจัย การเปิดเผยข้อมูลเกี่ยวกับตัวข้าพเจ้าต่อหน่วยงานต่าง ๆ ที่เกี่ยวข้องกระทำได้เฉพาะกรณีจำเป็น ด้วยเหตุผลทางวิชาการเท่านั้น และผู้วิจัยรับรองว่าหากเกิดอันตรายใด ๆ จากการวิจัยดังกล่าว ข้าพเจ้าจะได้รับการรักษาพยาบาลโดยไม่คิดมูลค่า

ข้าพเจ้าได้อ่านเอกสารและข้อความข้างต้นแล้ว มีความเข้าใจดีทุกประการ และได้ลงนามในใบยินยอมนี้ด้วยความเต็มใจ

ข้าพเจ้าได้รับสำเนาเอกสารใบยินยอมที่ข้าพเจ้าลงนามและลงวันที่ และเอกสารยกเลิกการเข้าร่วมวิจัย อย่างละ 1 ฉบับ เป็นที่เรียบร้อยแล้ว

ลงนาม..... ผู้ยินยอม

(.....)

วันที่.....เดือน.....พ.ศ.....

ลงนาม..... พยาน

(.....)

วันที่.....เดือน.....พ.ศ.....

ลงนาม..... ผู้วิจัยหลัก

(.....)

วันที่.....เดือน.....พ.ศ.....

ข้าพเจ้าไม่สามารถอ่านหนังสือได้ แต่ผู้วิจัยได้อ่านข้อความในใบยินยอมนี้ให้แก่ข้าพเจ้าฟังจนเข้าใจดีแล้ว ข้าพเจ้าจึงลงนาม หรือประทับลายนิ้วหัวแม่มือขวาของข้าพเจ้าในใบยินยอมนี้ด้วยความเต็มใจ

ลงนาม.....ผู้ยินยอม

(.....)

วันที่.....เดือน.....พ.ศ.....

ลงนาม.....พยาน

(.....)

วันที่.....เดือน.....พ.ศ.....

ลงนาม.....ผู้วิจัยหลัก

(.....)

วันที่.....เดือน.....พ.ศ.....

ในกรณีที่ผู้ถูกทดลองยังไม่บรรลุนิติภาวะ จะต้องได้รับการยินยอมจากผู้ปกครองหรือผู้อุปการะโดยชอบด้วยกฎหมาย

ลงนาม..... ผู้ยินยอม

(.....)

วันที่.....เดือน.....พ.ศ.....

ลงนาม..... พยาน

(.....)

วันที่.....เดือน.....พ.ศ.....

ลงนาม..... ผู้วิจัยหลัก

(.....)

วันที่.....เดือน.....พ.ศ.....

APPENDIX C

เอกสารยกเลิกการเข้าร่วมวิจัย (Withdrawal Form)

การวิจัยเรื่อง การศึกษาเปรียบเทียบเสถียรภาพของรากฟันเทียมแบบสั้นในขากรรไกรบนและล่างส่วนหลัง

“ข้าพเจ้า (นาย, นาง, นางสาว).....

อยู่บ้านเลขที่.....ถนน.....ตำบล/แขวง.....

อำเภอ/เขต.....จังหวัด.....รหัสไปรษณีย์.....

ขอยกเลิกการเข้าร่วมโครงการวิจัยนี้ โดยมีเหตุผลในการยกเลิกการเข้าร่วมวิจัยคือ

- ❑ ย้ายภูมิลำเนา
- ❑ ไม่สะดวกในการเดินทาง
- ❑ เหตุผลอื่น.....

ลงนาม.....ผู้ยกเลิก

(.....)

วันที่.....เดือน.....พ.ศ. .....

ลงนาม.....พยาน

(.....)

วันที่.....เดือน.....พ.ศ. .....

ลงนาม.....ผู้วิจัยหลัก

(.....)

วันที่.....เดือน.....พ.ศ. .....

ที่อยู่สำหรับส่งเอกสาร ชื่อ ทพ.ชลธี เวโรจน์
บ้านเลขที่ 9/19 อาคาร CENTRIC SCENE ถนนพหลโยธิน ซอย 9 แขวงสามเสนใน เขตพญาไท จังหวัดกรุงเทพมหานคร รหัสไปรษณีย์ 10400

หมายเหตุ - สำเนาเอกสารยกเลิกการเข้าร่วมวิจัย แล้วมอบให้อาสาสมัครแต่ละคนๆ ละ 1 ชุด

APPENDIX D

แบบบันทึกข้อมูลผู้ป่วย

วันที่.....

ส่วนที่ 1: ข้อมูลทั่วไปของผู้ป่วย

1. Code No. .....

2. วัน เดือน ปี เกิด ...../...../..... อายุ.....ปี

3. ประวัติการแพ้ยา ❒ ไม่มี ❒ มี ระบุ.....

4. ประวัติโรคประจำตัว ❒ ไม่มีโรคประจำตัว ❒ มีโรคประจำตัวระบุ.....

5. ยารักษาโรคประจำตัว มีจำนวน.....ชนิด ได้แก่

.....

.....

6. ประวัติการสูบบุหรี่ ❒ ไม่สูบ ❒ สูบ ระบุจำนวน.....มวน/วัน

ตอนที่ 2: ข้อมูลเกี่ยวกับการรักษา

1. ระยะเวลาที่สูญเสียฟันไป

❒ น้อยกว่า 6 เดือน ❒ 6-12 เดือน ❒ ตั้งแต่ 12 เดือนขึ้นไป

2. ระยะเวลาที่ใส่ฟันปลอมถอดได้

❒ ไม่เคยใส่

❒ เคยใส่.....ปี.....เดือนและปัจจุบันเลิกใส่แล้ว

❒ ใส่อยู่.....ปี.....เดือน

ตอนที่ 3: ข้อมูลการการฝังรากฟันเทียมแบบสั้น

1. ความกว้างของสันกระดูก ..... มิลลิเมตร
2. ความสูงของสันกระดูก ..... มิลลิเมตร
3. Mesio-distal width (ที่ระดับ alveolar crest)..... มิลลิเมตร
4. การนัดและติดตามผู้ป่วย

- ฟันซี่ที่ .....

ครั้งที่	วันที่	หัตถการ	ภาวะแทรกซ้อน	เสถียรภาพ (ISQ)
1		ฝังรากฟันเทียม		
2		2nd stage surgery		
3		พิมพ์ปาก		
4		ใส่ฟัน		
5		ประเมินความสำเร็จ		

5. การประเมินผลหลังการใส่ส่วนต่อของรากฟันเทียม 3 เดือน

Success criteria	Yes	No
Absence of persistent subjective complaints		
Absence of a recurrent peri-implant infection with suppuration		
Absence of mobility		
Absence of a continuous radiolucency around the implant		

Complication (ถ้ามี)

.....

.....

APPENDIX E

Raw Demographic Data and the ISQ values

											ISQ values			
	HN	Sex	Age	Smoking	Duration of tooth loss	Denture	Tooth No.	Width (mm.)	Height (mm.)	MD width at crest (mm.)	0	2	3	4
1	53-15222	F	55	No	>1 year	Never	36	8	16	9	80	81	83	82
2	54-19820	M	66	No	>1 year	Never	26	11.9	11.5	9.5	69	73	75	77
3	55-14666	F	53	No	>1 year	2 years till now	36	6	15	11	75	75	81	80
					>1 year	2 years till now	46	6	16.5	13	81	82	80	80
4	50-5547	F	37	No	>1 year	Never	25	6	15	6	79	78	82	84
					>1 year	Never	36	6	16	12	78	80	80	82
5	55-1590	M	21	Yes	>1 year	only 2 months	35	8	12	9	79	72	83	83
6	55-15183	F	21	No	6-12 months	Never	24	8	19	7	73	71	80	80
7	55-10977	M	40	No	>1 year	Never	36	7	15	15	79	83	83	84
					>1 year	only 1 month	37	6	14	11	71	70	75	83
8	53-11312	F	25	No	4 Mo	Never	47	10.5	11	10	71	69	65	67
9	55-14956	F	27	No	5 Mo	Never	24	8	9.5	6.5	73	75	78	82
					4 Mo	Never	46	8	16	13	68	82	82	79
10	55-8486	F	79	No	<6 Mo	Never	27	13	8.5	9	73	75	81	81
11	55-14889	F	64	No	6-12 Mo	Never	37	6	13	N/A	80	78	81	83
12	51-11748	F	53	No	>1 year	Never	25	6	12	7.5	76	69	78	79
13	46-3355	F	42	No	>1 year	only 3 months	36	7	13	9	81	83	83	84

											ISQ values			
	HN	Sex	Age	Smoking	Duration of tooth loss	Denture	Tooth No.	Width (mm.)	Height (mm.)	MD width at crest (mm.)	0	2	3	4
13	46-3355	F	42	No	>1 year	Only 3 months	36	7	13	9	81	83	83	84
14	55-11050	F	37	No	>1 year	Never	26	7	8	10	70	74	77	77
					>1 year	Never	36	8	14.5	11	81	84	84	84
15	55-21155	M	32	Yes	<6 Mo	Never	25	7	9	9.5	69	80	82	81
16	55-21700	F	48	No	>1 year	6 months til now	16	6	15	N/A	76	78	80	80
					>1 year	6 months til now	17	8	12	N/A	78	79	78	78
17	56-91	F	29	Yes	<6 Mo	Never	16	9	16	10	62	75	75	75
18	53-9837	M	59	No	<6 Mo	Never	37	8	13	N/A	71	80	84	84
19	56-973	F	36	No	>1 year	Never	36	6	15	11	83	81	85	85
20	56-909	F	22	No	>1 year	Never	46	7	13	11	75	82	82	80
21	41-10273	M	38	No	<6 Mo	Never	14	11	16	8.5	76	72	80	81
22	54-10116	M	63	No	>1 year	Never	16	10	8	11	32	65	68	71
23	56-6990	F	51	No	>1 year	2 years till now	16	9	10	11	75	73	73	76
24*	49-10462	F	45	No	4 Mo	Never	17	12	14	N/A	68	-	-	-

*Excluded from the study due to implant failure

APPENDIX F

Statistic Output

Table 1 and 2 Normality test of the overall ISQ values

Tests of Normality

	Implant sites	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
		Statistic	df	Sig.	Statistic	df	Sig.
ISQ	Maxilla	.191	56	.000	.678	56	.000
	Mandible	.246	60	.000	.827	60	.000

a. Lilliefors Significance Correction

Descriptives

			Statistic	Std. Error
ISQ	Mean		77.35	.612
	95% Confidence Interval for Mean	Lower Bound	76.14	
		Upper Bound	78.57	
	5% Trimmed Mean		77.95	
	Median		79.00	
	Variance		43.448	
	Std. Deviation		6.592	
	Minimum		32	
	Maximum		85	
	Range		53	
	Interquartile Range		7	
	Skewness		**-3.150**	**.225**
	Kurtosis		**18.457**	**.446**

Table 3 Normality test of the ISQ values in the maxilla and the mandible

Descriptives

Implant sites			Statistic	Std. Error
	95% Confidence Interval for Mean	Lower Bound	73.14	
		Upper Bound	77.11	
	5% Trimmed Mean		75.98	
	Median		76.00	
	Variance		54.802	
	Std. Deviation		7.403	
	Minimum		32	
	Maximum		84	
	Range		52	
	Interquartile Range		7	
	Skewness		**-3.782**	**.319**
	Kurtosis		**20.660**	**.628**
Mandible	Mean		79.43	.639
	95% Confidence Interval for Mean	Lower Bound	78.16	
		Upper Bound	80.71	
	5% Trimmed Mean		79.85	
	Median		81.00	
	Variance		24.487	
	Std. Deviation		4.948	
	Minimum		65	
	Maximum		85	
	Range		20	
	Interquartile Range		5	
	Skewness		**-1.353**	**.309**
	Kurtosis		**.936**	**.608**

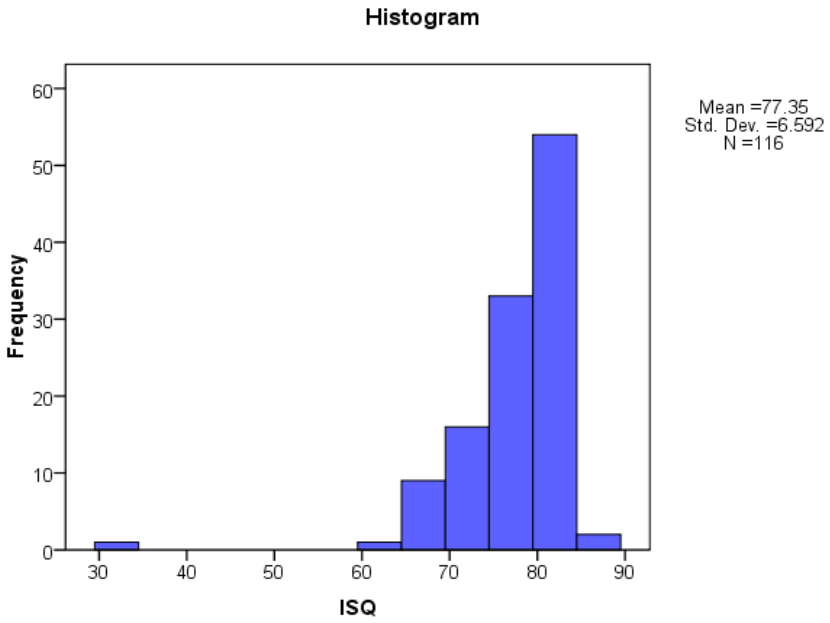

Figure 1. Histogram of overall ISQ values

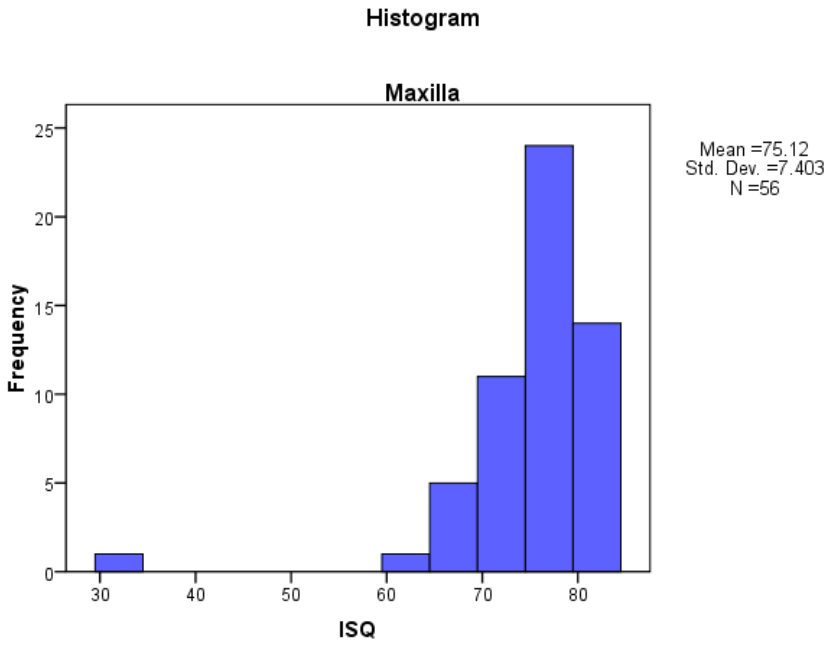

Figure 2. Histogram of ISQ values in maxilla

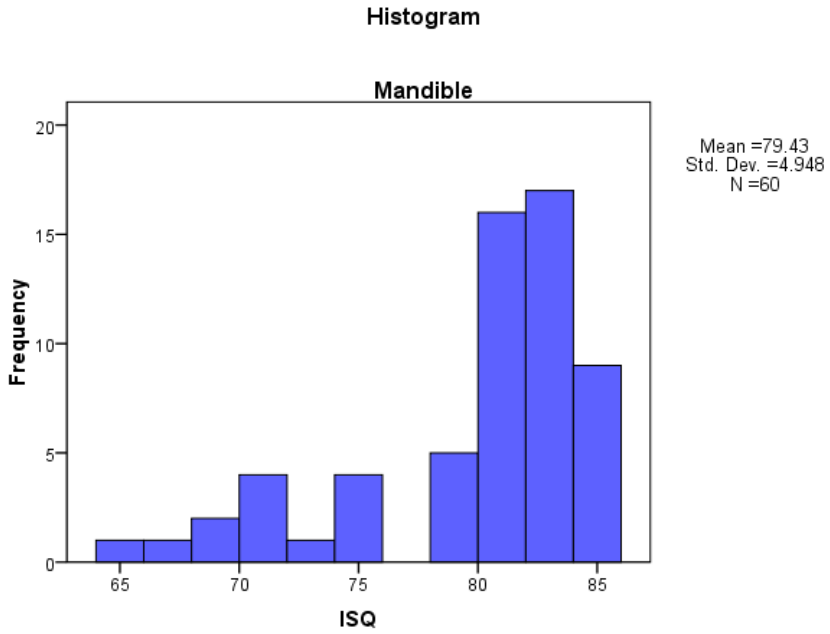

Figure 3. Histogram of ISQ values in mandible

Table 4 and 5 Comparison of the ISQ values among different implant sites at the time of implant placement by Mann-Whitney test

Ranks

	Implant sites	N	Mean Rank	Sum of Ranks
ISQ 0	Maxilla	14	11.25	157.50
	Mandible	15	18.50	277.50
	Total	29		

Test Statistics[b]

	ISQ 0
Mann-Whitney U	52.500
Wilcoxon W	157.500
Z	-2.299
Asymp. Sig. (2-tailed)	.022
Exact Sig. [2*(1-tailed Sig.)]	**.020**[a]

a. Not corrected for ties.

Table 6 and 7 Comparison of the ISQ values among different implant sites at 2 months after implant placement by Mann-Whitney test

Ranks

	Implant sites	N	Mean Rank	Sum of Ranks
ISQ 2	Maxilla	14	10.68	149.50
	Mandible	15	19.03	285.50
	Total	29		

Test Statistics[b]

	ISQ 2
Mann-Whitney U	44.500
Wilcoxon W	149.500
Z	-2.649
Asymp. Sig. (2-tailed)	.008
Exact Sig. [2*(1-tailed Sig.)]	**.007**[a]

a. Not corrected for ties.

b. Grouping Variable: Implant sites

Table 8 and 9 Comparison of the ISQ values among different implant sites at 3 months after implant placement by Mann-Whitney test

Ranks

	Implant sites	N	Mean Rank	Sum of Ranks
ISQ 3	Maxilla	14	10.43	146.00
	Mandible	15	19.27	289.00
	Total	29		

Test Statistics[b]

	ISQ 3
Mann-Whitney U	41.000
Wilcoxon W	146.000
Z	-2.812
Asymp. Sig. (2-tailed)	.005
Exact Sig. [2*(1-tailed Sig.)]	**.004**[a]

a. Not corrected for ties.

Table 10 and 11 Comparison of the ISQ values among different implant sites at 4 months after implant placement by Mann-Whitney test

Ranks

	Implant sites	N	Mean Rank	Sum of Ranks
ISQ 4	Maxilla	14	10.89	152.50
	Mandible	15	18.83	282.50
	Total	29		

Test Statistics[b]

	ISQ 4
Mann-Whitney U	47.500
Wilcoxon W	152.500
Z	-2.526
Asymp. Sig. (2-tailed)	.012
Exact Sig. [2*(1-tailed Sig.)]	**.010**[a]

a. Not corrected for ties.

b. Grouping Variable: Implant sites

Table 12 and 13 Comparison of the ISQ values in the maxilla at different periods by Wilcoxon Signed Ranks test

Ranks

		N	Mean Rank	Sum of Ranks
ISQ2 - ISQ0	Negative Ranks	5[a]	6.30	31.50
	Positive Ranks	9[b]	8.17	73.50
	Ties	0[c]		
	Total	14		
ISQ3 - ISQ0	Negative Ranks	1[d]	1.50	1.50
	Positive Ranks	12[e]	7.46	89.50
	Ties	1[f]		
	Total	14		
ISQ4 - ISQ0	Negative Ranks	0[g]	.00	.00
	Positive Ranks	13[h]	7.00	91.00
	Ties	1[i]		
	Total	14		
ISQ3 - ISQ2	Negative Ranks	1[j]	1.00	1.00
	Positive Ranks	11[k]	7.00	77.00
	Ties	2[l]		
	Total	14		
ISQ4 - ISQ2	Negative Ranks	1[m]	1.50	1.50
	Positive Ranks	12[n]	7.46	89.50
	Ties	1[o]		
	Total	14		
ISQ4 - ISQ3	Negative Ranks	1[p]	2.00	2.00
	Positive Ranks	7[q]	4.86	34.00
	Ties	6[r]		
	Total	14		

a. ISQ2 < ISQ0

b. ISQ2 > ISQ0

c. ISQ2 = ISQ0

d. ISQ3 < ISQ0

e. ISQ3 > ISQ0

j. ISQ3 < ISQ2

k. ISQ3 > ISQ2

l. ISQ3 = ISQ2

m. ISQ4 < ISQ2

n. ISQ4 > ISQ2

o. ISQ4 = ISQ2

Test Statistics[b]

	ISQ2 - ISQ0	ISQ3 - ISQ0	ISQ4 - ISQ0	ISQ3 - ISQ2	ISQ4 - ISQ2	ISQ4 - ISQ3
Z	-1.326[a]	-3.079[a]	-3.183[a]	-2.991[a]	-3.082[a]	-2.257[a]
Asymp. Sig. (2-tailed)	**.185**	**.002**	**.001**	**.003**	**.002**	**.024**

a. Based on negative ranks.

b. Wilcoxon Signed Ranks Test

Table 14 and 15 Comparison of the ISQ values in the mandible at different periods by Wilcoxon Signed Ranks test

Ranks

		N	Mean Rank	Sum of Ranks
ISQ2 - ISQ0	Negative Ranks	5[a]	6.30	31.50
	Positive Ranks	9[b]	8.17	73.50
	Ties	1[c]		
	Total	15		
ISQ3 - ISQ0	Negative Ranks	2[d]	6.50	13.00
	Positive Ranks	13[e]	8.23	107.00
	Ties	0[f]		
	Total	15		
ISQ4 - ISQ0	Negative Ranks	2[g]	4.50	9.00
	Positive Ranks	13[h]	8.54	111.00
	Ties	0[i]		
	Total	15		
ISQ3 - ISQ2	Negative Ranks	2[j]	3.25	6.50
	Positive Ranks	7[k]	5.50	38.50
	Ties	6[l]		
	Total	15		
ISQ4 - ISQ2	Negative Ranks	4[m]	6.13	24.50
	Positive Ranks	10[n]	8.05	80.50
	Ties	1[o]		
	Total	15		
ISQ4 - ISQ3	Negative Ranks	4[p]	5.13	20.50
	Positive Ranks	6[q]	5.75	34.50
	Ties	5[r]		
	Total	15		

a. ISQ2 < ISQ0

b. ISQ2 > ISQ0

c. ISQ2 = ISQ0

d. ISQ3 < ISQ0

e. ISQ3 > ISQ0

f. ISQ3 = ISQ0

j. ISQ3 < ISQ2

k. ISQ3 > ISQ2

l. ISQ3 = ISQ2

m. ISQ4 < ISQ2

n. ISQ4 > ISQ2

Test Statistics[b]

	ISQ2 - ISQ0	ISQ3 - ISQ0	ISQ4 - ISQ0	ISQ3 - ISQ2	ISQ4 - ISQ2	ISQ4 - ISQ3
Z	-1.326[a]	-2.675[a]	-2.904[a]	-1.904[a]	-1.765[a]	-.723[a]
Asymp. Sig. (2-tailed)	**.185**	**.007**	**.004**	**.057**	**.078**	**.470**

a. Based on negative ranks.

b. Wilcoxon Signed Ranks Test

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