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A COMPARISON OF MASTICATORY EFFICIENCY
BEFORE AND AFTER MINI DENTAL IMPLANT
RETAINED LOWER COMPLETE DENTURE DELIVERY
BY SUBJECTIVE METHOD AND OBJECTIVE METHOD

Miss Onnicha Teampun

A Thesis Submitted in Partial Fulfillment of the Requirements
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Department of Prosthodontics
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METHOD

By   Miss Onnicha Teampun

Field of Study   Prosthodontics

Thesis Advisor   Assistant Professor Orapin Kaewplug, D.D.S., Ph.D.

Thesis Co-Advisor   Vannaporn Chuenchompoonut, D.D.S., Ph.D.

Accepted by the Faculty of Dentistry, Chulalongkorn University in Partial Fulfillment of the Requirements for the Master's Degree

....Dean of the Faculty of Dentistry

(Assistant Professor Suchit Poolthong, D.D.S., Ph.D.)

THESIS COMMITTEE

....Chairman

(Assistant Professor Prarom Salimee, D.D.S., Ph.D.)

....Thesis Advisor

(Assistant Professor Orapin Kaewplug, D.D.S., Ph.D.)

....Thesis Co-Advisor

(Vannaporn Chuenchompoonut, D.D.S., Ph.D.)

....Examiner

(Assistant Professor Atiphan Pimkhaokham, D.D.S., Ph.D.)

....External Examiner

(Matana Kettratad, D.D.S., Ph.D.)

อรณิชา เทียมพันธ์ : การเปรียบเทียบประสิทธิภาพการบดเคี้ยวก่อนและหลังใส่ฟันเทียมทั้ง
ปากล่างคร่อมรากเทียมขนาดเล็กด้วยวิธีการตรวจพินิจแบบจิตวิสัยร่วมกับวิธีการตรวจพินิจ
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ชมพูนุท, 107 หน้า.

การศึกษานี้มีวัตถุประสงค์เพื่อประเมินประสิทธิภาพการบดเคี้ยวของผู้ป่วยฟันเทียมทั้งปาก
ล่างคร่อมรากเทียมขนาดเล็กโดยวิธีการตรวจพินิจแบบจิตวิสัยร่วมกับวิธีการตรวจพินิจแบบวัตถุวิสัย
ผู้ป่วยที่มีปัญหาเรื่องการยึดอยู่ของฟันเทียมทั้งปากล่างได้รับการคัดเลือกตามเกณฑ์ของการศึกษาให้เข้า
ร่วมวิจัยจำนวน 33 คน (ชาย 10 คน หญิง 23 คน อายุเฉลี่ย 67.50 ± 7.66 ปี) ผู้เข้าร่วมวิจัยรับการฝัง
รากฟันเทียมขนาดเล็กจำนวน 4 ตัวในขากรรไกรล่างเพื่อยึดฟันเทียมทั้งปากล่าง ทำการประเมิน
ประสิทธิภาพการบดเคี้ยวโดยวิธีการตรวจพินิจแบบจิตวิสัยร่วมกับวิธีการตรวจพินิจแบบวัตถุวิสัย
จำนวน 3 ครั้ง ได้แก่ การทดสอบครั้งที่ 1 หลังจากการใช้ฟันเทียมทั้งปากล่างเป็นเวลาอย่างน้อย 3 เดือน
ก่อนการฝังรากเทียมขนาดเล็ก การทดสอบครั้งที่ 2 หลังใส่ฟันเทียมคร่อมรากเทียมขนาดเล็กเป็นเวลา
1 เดือน และ การทดสอบครั้งที่ 3 หลังใส่ฟันเทียมคร่อมรากเทียมขนาดเล็กเป็นเวลา 3 เดือน การตรวจ
พินิจแบบจิตวิสัยใช้แบบสอบถามแบบ 4 ช่วงคะแนน โดยประเมินประสิทธิภาพการบดเคี้ยวของผู้ป่วย
ในอาหารจำนวน 14 ชนิด คำนวณออกมาเป็นค่าคะแนนความสามารถในการบดเคี้ยว ส่วนการตรวจ
พินิจแบบวัตถุวิสัยใช้วิธีการวิเคราะห์ชิ้นขี้ผึ้ง 2 สี (ขาวและแดง) คำนวณออกมาเป็นค่าร้อยละของ
ความสามารถในการบดเคี้ยว ในระยะเวลาการติดตามผล 3 เดือนหลังจากใส่ฟันเทียมทั้งปากล่างคร่อม
รากเทียมขนาดเล็กพบว่า อัตราการอยู่รอดของรากเทียมขนาดเล็กภายใน 3 เดือนหลังการใส่ฟันเทียม
ทั้งปากมีค่าอยู่ที่ร้อยละ 96.97 จากการตรวจพินิจแบบจิตวิสัยพบว่าค่ามัธยฐานของคะแนน
ความสามารถในการบดเคี้ยวของผู้ป่วยในการทดสอบครั้งที่ 1 มีค่า 20±5.93 และเพิ่มขึ้นเป็น 40±2.03
และ 41±1.82 ในการทดสอบครั้งที่ 2 และ 3 ตามลำดับ จากการตรวจพินิจแบบวัตถุวิสัยพบว่าค่าเฉลี่ย
ของร้อยละของความสามารถในการบดเคี้ยวของผู้ป่วยในการทดสอบครั้งที่ 1 มีค่า 19.22±3.75 และ
เพิ่มขึ้นเป็น 29.61±4.27 และ 31.02±3.70 ในการทดสอบครั้งที่ 2 และ 3 ตามลำดับ โดยอายุ เพศ
สภาวะสุขภาพของผู้ป่วย ชนิดของฟันเทียมบน ความสูงและความกว้างของกระดูกขากรรไกรล่าง ไม่มี
อิทธิพลต่อผลการศึกษา ผลการศึกษาชี้ให้เห็นว่าค่าเฉลี่ยของคะแนนทั้งสองการวินิจฉัยมีความแตกต่าง
กันอย่างมีนัยสำคัญทางสถิติ (P≤.001) ในก่อนและหลังการรักษาด้วยฟันเทียมทั้งปากล่างคร่อมราก
เทียมขนาดเล็ก โดยผู้ป่วยฟันเทียมทั้งปากล่างมีประสิทธิภาพการบดเคี้ยวจากทั้งสองการวินิจฉัยสูงขึ้น
หลังจากการฝังรากเทียมขนาดเล็กเพื่อยึดฟันเทียม รากเทียมขนาดเล็กจึงเป็นอีกหนึ่งทางเลือกในการ
รักษาที่เหมาะกับผู้ป่วยสูงอายุ เพื่อแก้ปัญหาการขาดเสถียรภาพของฟันเทียมถอดได้ นำไปสู่การเพิ่ม
ประสิทธิภาพการบดเคี้ยวและคุณภาพชีวิตของผู้ป่วย

ภาควิชา   ทันตกรรมประดิษฐ์   ลายมือชื่อนิสิต ....

สาขาวิชา   ทันตกรรมประดิษฐ์   ลายมือชื่อ อ.ที่ปรึกษาวิทยานิพนธ์หลัก ....

ปีการศึกษา 2556   ลายมือชื่อ อ.ที่ปรึกษาวิทยานิพนธ์ร่วม ....

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KEYWORDS: MINI DENTAL IMPLANT RETAIN LOWER COMPLETE DENTURE / MASTICATORY EFFICIENCY / SUBJECTIVE EVALUATION / OBJECTIVE EVALUATION / ELDERLY PATIENT

ONNICHA TEAMPUN: A COMPARISON OF MASTICATORY EFFICIENCY BEFORE AND AFTER MINI DENTAL IMPLANT RETAINED LOWER COMPLETE DENTURE DELIVERY BY SUBJECTIVE METHOD AND OBJECTIVE METHOD. ADVISOR: ASST. PROF. ORAPIN KAEWPLUG, D.D.S., Ph.D., CO-ADVISOR: VANNAPORN CHUENCHOMPOONUT, D.D.S., Ph.D., 107 pp.

The purpose of this study was to evaluate the masticatory efficiency of mini dental implants (MDIs) retained lower complete denture patients by subjective and objective method. Thirty-three patients (10 males and 23 females, mean age 67.50 ± 7.66 years) who had functional problems of their lower complete dentures (L-CD) were selected according to the criteria of the study. All patients received 4 MDIs in the mandible to retain their L-CD. The masticatory efficiency were evaluated by subjective and objective method 3 times; Test 1: after using lower complete denture at least 3 months before MDIs placement; Test 2: after loading lower complete denture 1 month and Test 3: after loading lower complete denture 3 months. The subjective evaluation using the four-point rating scale questionnaire about food chewing performance on 14 common food types, determined as the "perceived chewing ability score" (PCAS). The objective evaluation using two-colored (red/white) wax cube analysis, calculated as the "percentage of chewing ability" (PCA). The MDIs survival rate within 3 months follow up after loading L-CD was 96.97%. By subjective evaluation, the median of the PCAS was 20±5.93 in Test 1 and increased to 40±2.03 and 41±1.82 in Test 2 and 3, respectively. By objective evaluation, the mean of the PCA was 19.22±3.75 in Test 1 and increased to 29.61±4.27 and 31.02±3.70 in Test 2 and 3, respectively. The influence of age, gender, general health status, type of upper prosthesis, the mandibular bone height and width had no effect on the outcomes of this study. The results demonstrated a statistically significant difference ($P \leq .001$) in the mean scores of both evaluations between before and after MDIs retained L-CD treatment. It was found that all lower complete denture wearers improve their masticatory efficiency after treatment with the MDIs by both subjective and objective evaluations. This could be suggested that minimally invasive treatment of mini dental implants can be optimal treatment option for elderly to solve the problems of denture instability, lead to improve masticatory efficiency and quality of life.

Department:	Prosthodontics	Student's Signature	....
Field of Study:	Prosthodontics	Advisor's Signature	....
Academic Year:	2013	Co-Advisor's Signature	....

ACKNOWLEDGEMENTS

CONTENTS

LIST OF TABLES

LIST OF FIGURES

Page

LIST OF ABBREVIATIONS

MDIs   Mini Dental Implants

CD   complete denture

L-CD   lower complete denture

RPD   removable partial denture

FPD   fix partial denture

Fig   Figure

mm   millimeter

ANOVA   Analysis of Variance

SD   standard deviation

yrs.   years

F/U   follow-up

PCAS   Percieved Chewing Ability Score

PCA   Percentage of Chewing Ability

CHAPTER I

INTRODUCTION

Background and rationale

Most of the elderly in Thailand (94.04%) had tooth loss in average 13.38 teeth/person and 10.47% of Thai elderly were complete edentulism (Dental Health Division Department of Health, The 7th National Oral Health Survey in Thailand, 2013). Tooth loss can cause chewing problems, malnutrition and decreasing quality of life. The ability to chew, speak and smile in the patients with complete edentulous arches are depended on well-retained and accurately fitting denture. The first therapeutic option in the complete edentulism is conventional complete denture. However, severe bone resorption in mandible can cause lack of retention and reduce function of lower complete denture (L-CD) (Tallgren, 1972). The use of two conventional dental implant retained L-CD presents an opportunity to improve denture retention, stability and comfort (Feine et al., 2002). As there are some limitations of the standard size implant treatment such as cost, time-consuming, anatomical limitation and patient health. Then, the use of Mini Dental Implants (MDIs) can be an optional attractive treatment (Shatkin, Shatkin and Oppenheimer, 2003).

The Mini Dental Implants (MDIs) are one piece titanium alloy implants which have smaller diameters compare to the conventional one ranging from 1.8 to 2.9 mm lead to enable placement in areas which insufficient bone present for conventional implants, without bone grafting or other complicated procedures (Preoteasa et al., 2010). The MDIs are minimally invasive compared to the wider-diameter implants and typically shorter healing period. The surgical procedure is simpler and quicker (Bulard, 2001). They can be immediately loaded, shortening treatment time and cost-effective (Ahn et al., 2004). Placement of the MDIs can be performed with or without a surgical flap (Christensen, 2006). Minimally invasive MDIs can enable the treatment of patients with relative contraindications to the standard size implant treatment including limitation of the ridge width, systemic problems and geriatric patients (Flanagan and Mascolo, 2011). The MDIs were initially used for transitional prosthetic stabilization and were approved for long-term used by the United States Food and Drug Administration (FDA) in 2003 (United States Food and Drug Administration, 2003; Christensen, 2006;

Bidra and Almas, 2013). Survival rate analysis demonstrated more than 90% for the long term high performance of the MDIs used for denture stabilization, anyway it depends on the methodology and survival criteria of each study (Griffitts et al., 2005; Bulard and Vance, 2005; Shatkin et al., 2007; Morneburg and Proschel, 2008). The MDIs are now used for short- and long-term prosthodontics treatment, for complete and partial removable denture stabilization and for fixed prostheses. The minimum numbers of the MDIs required for appropriate retention of complete denture are six in the maxilla and four in the mandible (Shatkin et al., 2003).

In edentulous patients, the prosthesis treatment can improve chewing ability that lead to improve general health and quality of life (Miura, et al., 2000; Takata et al., 2006), therefore the masticatory efficiency could be an important indicator in the success of dental treatment and the improvement of quality of life. The measurement of masticatory efficiency can be divided into two broad categories, the terms "subjective evaluation" referring to data obtained from patients' self reports and the terms "objective evaluation" referring to data obtained from object analysis. Using subjective assessment, chewing ability can be measured through self-assessment of chewing complaints by interview and/or questionnaire. Kunon and Kaewplung (2014) developed questionnaire about food chewing performance of 14 common food types in Thailand, using four-point rating scale to evaluate the chewing ability of the conventional dental implant-retained L-CD wearers. According to the objective assessment, various objective methods have been used to analyze the chewing ability of subjects (Hayakawa et al., 1998; Sato et al., 2003; Ishikawa et al., 2007). Prapatrungsri, Petsom and Kaewplung (2010) developed two-colored wax cube analysis method for use in Thailand. This analysis can be another method for the evaluation of chewing ability in denture wearers (Liangbunyaphan, Chaiteerapapkul and Kaewplung, 2012; Chokpreecha and Kaewplung, 2013; Kunon and Kaewplung, 2014). Although the objective evaluations are reliable and can be perform quantitative data, they are unable to assess the psychosocial aspect of patient's oral function. Then the subjective evaluation which depends on the patients' expectations and opinions is better to achieve the psychological assessment of patients which is more important as it can indicate the treatment success (Giddon and Hittelman, 1980).

To evaluate the masticatory efficiency before and after the MDIs retained L-CD treatment, this study carried on the subjective method by using the questionnaire and the objective method by using the two-colored wax cube analysis.

Objective

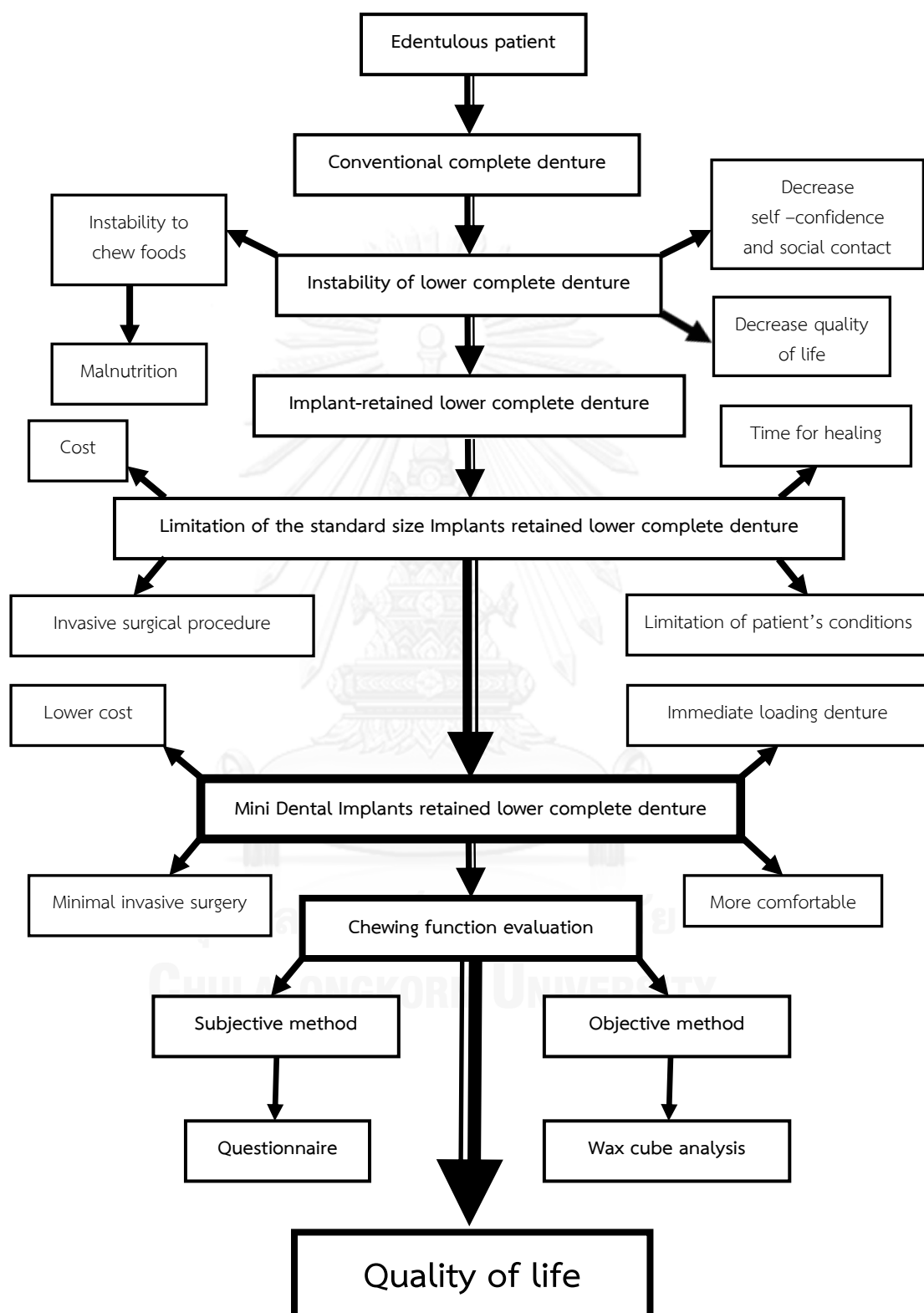The objective of this study was to compare the masticatory efficiency before and after the MDIs retained L-CD delivery by the subjective method using the questionnaire and the objective method using the two-colored wax cube analysis.

Hypothesis

Null hypothesis: There is no difference of masticatory efficiency between before and after the MDIs retained L-CD treatment.

Alternative hypothesis: There is difference of masticatory efficiency between before and after the MDIs retained L-CD treatment.

Expected Outcomes

1. The results can be demonstrated the difference of masticatory efficiency between before and after the MDIs retained L-CD treatment in the elderly patients.

2. The results may be the basis for development of clinical guideline treatment with the MDIs in lower complete edentulous of the elderly patients.

3. The results may be the basis for further longitudinal study of the MDIs retained overdenture treatment.

Conceptual framework

Edentulous patient

Conventional complete denture

Instability to chew foods

Instability of lower complete denture

Decrease self –confidence and social contact

Malnutrition

Decrease quality of life

Implant-retained lower complete denture

Cost

Time for healing

Limitation of the standard size Implants retained lower complete denture

Invasive surgical procedure

Limitation of patient's conditions

Lower cost

Immediate loading denture

Mini Dental Implants retained lower complete denture

Minimal invasive surgery

More comfortable

Chewing function evaluation

Subjective method

Objective method

Questionnaire

Wax cube analysis

Quality of life

Scope and limitations of the Study

      1 This study was conducted to evaluate the masticatory efficiency in L-CD wearer patients who used their L-CD at least 3 months prior the MDIs placement. The process of MDIs started from May 2012 to October 2013 and the completed follow-up time at 3 months after loading L-CD on the MDIs were done within February 2014 due to the limitation of the schedule time of the study.

      2. The number of the patients in this study were limited by the financial support from the Geriatric Unit, Dental hospital, Faculty of Dentistry, Chulalongkorn university and the 90th Year Chulalongkorn Scholarship, Chulalongkorn University.

CHAPTER II

LITERATURE REVIEW

1. <u>**The edentulous elderly and problems of conventional complete denture**</u>

Thailand became an ageing society as well as many countries over the world. The expectation of Thailand elderly population (aged 60 and older) in 2014 is about 15.30% of total Thai citizens (Institute for Population and Social Research, Mahidol University, 2014). The Number of the elderly population will be expanded from 5 million in the last 10 years to more than 10 million in the next 10 years from now. This is the result of decreasing of productivity and expansion of life span (Bureau of Policy and Strategy, Ministry of public health, 2000). In this situation, well prepare supporting to achieve high quality of life in the elderly population is very important. Also appropriate dental cares for the elderly are necessary to improve oral health related quality of life.

Tooth loss is one of the principle problems of oral health in the senior citizen leading to chewing problems, malnutrition and decreasing of quality of life (Brennan et al., 2008). The prevalence of tooth loss increases in advance aging and progressive tooth loss generally happen in the elderly (Locker, 2002). The 7th National Oral Health Survey in Thailand reported that 94.04% of the elderly in Thailand had tooth loss at least one tooth which average tooth loss 13.38 teeth/person and 10.47% of Thai elderly were complete edentulism (Dental Health Division Department of Health, 2013).

The numbers of the functional teeth are directly related to chewing ability and masticatory system (Brennan et al., 2008). The principle functions of masticatory system are to grind and diminish food size then prepare it to swallow. Loss of many natural teeth is considered to affect the chewing ability and quality of life. The individuals with at least 20 natural teeth and at least 4 posterior occluding pairs had better oral health-related quality of life (OHRQoL) than those with less than 20 natural teeth and less than 4 posterior occluding pairs (Somsak and Kaewplung, 2014). The

edentulous patients tended to rate their perceive chewing ability lower than the dentate subjects (Agerberg and Carlsson, 1981). The removable partial or full denture wearer shown chewing difficulties 1.62-fold more frequently than those with natural teeth or fixed prosthesis patients (Choi, Park and Kim, 2013). Some of them avoid hard foods that are difficult to chew lead to increase risk of malnutrition (Gunne, 1985). The edentulous patients often have a diet that is deficient in fiber and vitamins (Morais et al., 2003). The previous study reported that daily nutritional intakes of energy, protein, fat and minerals were decreased significantly in elderly with removable partial or complete dentures compared with those who have no prosthesis or have fixed prosthesis (Choi et al., 2013).

There are several factors considered to decrease chewing ability of removable denture wearers such as limitation in ability to effort bite forces, lack of retention and stability in denture, discomfort and pain of underlining tissue (Wilding, 1993). Those problems were commonly experience in conventional complete denture wearers. The retention of denture significantly influence on oral health impact profile (Hassel et al., 2006). Sufficient retention of complete dentures may lead to improve oral health related quality of life in edentulous patients (Komagamine, 2012). While the quality of life score and chewing function in edentulous patients with a complete denture were significantly lower than that of other denture patients (Koshino et al., 2006). As support, retention and stability of complete dentures are limited by continuous alveolar bone resorption after tooth loss consecutively followed by the impairment of denture bearing area (Allen and McMillan, 2003). The majority of the denture complaints concerns in lower than upper complete denture because there is more severe alveolar bone resorption in mandible than maxilla. The rate of bone resorption in mandible during long term follow-up periods was approximately 4 times greater than maxilla (Tallgren, 1972). The severe continuous resorption of alveolar bone in total edentulous mandible had significantly effect in functional deficiency of conventional L-CD by decreasing stability and retention and also increasing discomfort of patient from improper denture adaptation. Moreover, instability and discomfort of L-CD were related to socioeconomic and psychological problems (McCord and Grant, 2000).

2.   <u>**The Standard size implant retained lower complete denture**</u>

The limitation of retention and stability in conventional lower complete denture can be considerably improved by dental implants (Naert et al., 1988). The root-form dental implants have become a mainstream in contemporary dental treatment for implant-retained fixed prostheses and removable denture with high success rates. Several studies reported more than 90% success rate with long term follow-up of two implants retained L-CD treatment (Van Steenberghe et al., 1987; Mericske-Stern et al., 1994; Jemt et al., 1996). Moreover, dental implants have been considered as capable in alveolar bone preservation due to the load-related bone formation can minimize the physiologic age-related mandibular bone loss (Von Wowern and Gotfredsen, 2001).

The use of two-implants retained overdenture is recommended as the standard treatment for improving function of complete denture especially in severe resorption mandible. In 2002, The McGill consensus statement suggested that two-implant retained overdenture should become the first choice of treatment for the edentulous mandible (Feine et al., 2002). Furthermore, the York Consensus Statement in 2009 supported the McGill consensus statement in recommendation of two-implant retained L-CD treatment (Thomason et al, 2009).

The conventional complete denture wearers gave negative impacts on oral health related quality of life. The use of dental implants to retain L-CD reported significantly increase patient satisfaction and oral health related quality of life (Strassburger, Kerschbaum and Heydecke, 2006; Turkyilmaz, Company and McGlumphy, 2010). The implant-retained overdenture patients shown significantly higher rating outcomes in comfort, stability, and chewing performance of their dentures (Turkyilmaz, Company and McGlumphy, 2010). The edentulous elderly patients who received two-implant retained L-CDs combined with upper conventional complete dentures provided better function and oral health related quality of life than conventional complete dentures group (Awad et al., 2003). Edentulous elderly patients who received mandibular implant retained overdentures rated their general

satisfaction approximately 36% higher than conventional complete dentures elderly patients (Thomason et al., 2003).

The chewing efficiency of dentures retained on implants are considerably higher than conventional dentures (Morais et al., 2003; Fueki et al., 2007; Thomason et al., 2003). Bite forces achieved with overdentures retained by implants were greater than conventional full dentures, thus the implant retained patients could increase the ability to chew hard and tough food (Fontijn-Tekamp et al., 2000). Mandibular implant-retained overdenture wearers had significantly higher unilateral and bilateral maximum bite forces than complete denture wearers possibly because pain or sensitivity of tissue covering mandibular edentulous ridge could limit bite forces in complete denture wearers while the implant treated patients experienced improvement in function of dentures and decreasing of chewing pain. (Fontijn-Tekamp et al., 1998). Moreover, the duration of the chewing cycle in implant retained overdenture patient was reduced (Bakke, Holm and Gotfredsen, 2002). Significantly better chewing ability and reduction of chewing cycles after implant treatment consequently related to decrease food particle size before swallow (Van Kampen et al., 2004). A randomized controlled trial study demonstrated increasing of maximum voluntary bite force, denture satisfaction and oral health-related quality of life in implant-supported mandibular overdentures patients (Müller et al., 2013).

There are several treatment options in implant-retained overdenture for an edentulous mandible such as bar-clip or ball attachments. Previous study found that stresses on the peri-implant bone with bar-clip attachments are greater than ball attachments for overdentures (Menicucci et al, 1998). While, other study found the contributed load sharing onto implants in rigid bars attachment (Mericske-Stern, Piotti and Sirtes, 1996). However, several studies in two implants retained overdenture found no significantly differences in implant survival rate, health of peri-implant tissue, or marginal bone loss in the 2 different anchorage systems (Gotfredsen and Holm, 2000; Naert et al, 1998; Bergendal and Engquist, 1998). Furthermore, there are no significantly differences in stress concentration between implants retained with or without bar and the direction of occlusal forces has more influence than the connection of implants

(Chao et al, 1995). The solitary ball attachments may be suitable for oral hygiene maintenance of patients because they are easier to clean than bar type attachments (Batenburg et al., 1998).

Although the use of standard size implant retained L-CD tend to be effective treatment in edentulous mandible, the techniques are considerably confined with complicated intervention, time consuming, expensive cost and limitation with anatomical and health of patients (Flanagan and Mascolo, 2011). The continuing of alveolar bone resorption often increase in the advance aging patients (Tallgren, 1972). The morphology study in early elderly patients (52–72 years) which average age of 61 years reported average ridge width in frontal area of mandible as 4.95 mm and found 59% of all subjects had ridge width lower than 5 mm which inadequate for the standard size implant application (Preoteasa et al., 2010). In case with deficient bone area of implant placement site, additional surgical procedure to gain bone can be done. Several augmentation techniques have been reported to facilitate placement of the standard size implants in an atrophy ridge such as block grafts, particulated grafts, or ridge expansion (Spray et al., 2000; Misch and Misch, 1995). These additional surgeries are more complicated and require several stages, prolonged treatment times, and incurring additional costs. These can cause post-operative pain and discomfort for the patients (Choi, 2007). These additional surgical interventions might be harder to accept by elderly and medically compromised patients (Preoteasa, 2010).

The edentulous elderly patients often present with systemic disease that may be the problem in advanced surgical procedure of the standard size implant intervention. One of the reasons to deny implant treatment is an anxiety of pain and complications of the surgery even when offered without any expense (Ellis et al., 2011; Walton and MacEntee, 2005). Therefore, the minimal invasive treatment of the Mini Dental Implants might be offered as the compromised treatment option for implant retained complete denture.

3. <u>**The Mini dental implants retained lower complete denture**</u>

The Mini Dental Implants or "MDIs" have diameter less than 3 mm, typically ranges from 1.8 mm to 2.9 mm They are one-piece implants that integrate endosteal portions and abutments into a single unit. This lead to simplify the treatment procedure and reduce cost (Ahn, 2004). Initially, the MDIs were designed for temporary stabilize the removable denture during the healing period of conventional permanent implants (Sendax, 1996). In 2001, the first histological study in human of the 1.8 mm transitional MDIs for immediately stabilized L-CDs found that the MDIs had the potential to become osseointegrated after immediate loading (Balkin et al., 2001). Another study found that immediately transitional 26 of 27 MDIs remained stable until their removal at 21 weeks to stabilized L-CDs in the healing phase of conventional implants and bone graft areas (Ahn et al, 2004). In 2003, the MDIs were accepted by the United States Food and Drug Administration for long-term use. (United States Food and Drug Administration, 2003; Christensen, 2006; Bidra and Almas, 2013).

The first implant diameters to be introduced were the standard diameter implants followed by the narrow implants, the wide implants and the mini dental implants. The diameters of the narrow, standard and wide implants typically range in combination from 3 mm to as much as 6 mm The standard size implants have typically around 3.75 mm in diameter. The diameter of the mini dental implants typically range from 1.8 mm to 2.9 mm. The 2.9 mm mini dental implants are also known as hybrid implants because their diameter approximate that of narrow diameter root-form implants (Jeffrey C., 2011). The standard size implant placement requires adequate bone width at least 5 mm (Preoteasa et al., 2010). In the condition of inadequate bone morphology, the augmentation procedures such as bone grafting can be used to solve the problems but these techniques are complex with more time-consuming and more expensive. The MDIs can be an alternative treatment to solve these kinds of limitations in many such cases (Choi, 2007). The use of the MDIs enables insertion of implants in areas where there is inadequate bone present for wider diameter implants without bone grafting or other complicated procedures especially in conditions with atrophic bucco-lingual bone contour (Shatkin et al., 2003), insufficient interdental space, convergent of adjacent roots or close in adjacent roots proximity (Flanagan D, 2008). It

is claimed that the 1.8 mm MDIs are possible to place in bone that is as narrow as 3 mm in bucco-lingual dimension (Chopra and Grover, 2011).

The MDIs are considered to be the minimally invasive dentistry beneficial achieve in some compromise patients. The Narrow diameter of the MDIs may not only solve the problem in the patients where there is severe bone atrophy but also affordable in the patients with systemic conditions that may contraindicate for the standard size implant treatment including elderly patients, medically compromised patients and psychological disorders patients such as anxiety (Flanagan and Mascolo, 2011). The narrow diameter of the MDIs can provide simplified treatment technique including placement without extensive flap resulting in less bleeding and postoperative discomfort (Shatkin et al., 2003; Shatkin et al., 2007; Flanagan, 2008). Without flap surgery, healing process of periosteum is undisturb (Gibney, 2001; Campelo and Camara, 2002) lead to shorten the healing period (Shatkin et al., 2007). The gingival healing phase could be completed in 2 to 5 days with flapless procedure (English and Bohle, 2003). The design and insertion techniques of the MDIs can minimize soft tissue and bone displacement with also preserved the periosteal and endosteal blood supply (Shatkin et al, 2007). The minimally invasive surgical approach of the MDIs can bring greater postoperative comfort and decreased morbidity for the patients, allowing patients with health problems that preclude extensive surgical procedures for implant treatment to retained ill-fitting denture (Choi, 2007). The feeble patients may tolerate the placement of the 4 MDIs with flapless and immediate loading to improve the retention of lower complete denture but could not able to tolerate the extensive treatment time required for the standard size implants (Flanagan and Mascolo, 2011). However, as with conventional implant treatment, there are relatively few systemic contraindications for implant treatment including radiation therapy over 50 Gy, severe osteoporosis, and excessive long-term cigarette smoking (Flanagan and Mascolo, 2011).

Based on a consensus from the International Congress of Oral Implantologists in 2006, immediate loading was described as a technique in which the implant supported restoration is placed into functional occlusal loading within 48 hours of implant insertion (Wang et al., 2006). The MDIs can also provide immediate functional loading denture after implants placement in appropriate primary stability. When the placement of MDIs had an insertion torque at least 35 Ncm, they can be immediately

loaded to retain an overdenture lead to stabilize denture and achieve immediately function for the patient (Bulard and Vance, 2005). To provide the high primary stability of the implants, the depth of osteotomy should not be drilled to the full length of the implants because the MDIs are self-tapped for the final position with primary mechanical retention (Ahn et al., 2004). However, the insertion torque of 50 Ncm may be as maximum torque for the MDIs placement because of the potential of implant's fracture (Bulard and Vance, 2005; Flanagan and Mascolo, 2011).

The surface area of the five 1.8 mm MDIs are considered to be equivalent to the two conventional 3.75 mm implants in the equal length (English and Bohle, 2003). The histological study of the 1.8 mm diameter MDIs placed as transitional implants for immediately stabilized L-CDs found that the bone around the MDIs appeared to be healing with vascular elements and well integrate to the MDIs surface after four to five month post-insertion period (Balkin et al., 2001). The percentage bone to implant contact for the MDIs is comparable to the standard size implants (Simon and Caputo, 2002). Previous study found that the pull-out strength of an implant based on its length rather than its diameter (Block, Delgado and Fontenot, 1990).

The MDIs can improve retention and stability of removable dentures by eliminating rocking effect and tend to be effectively optional treatment for implant retained lower complete denture (Christensen, 2006). The appropriate minimum number of the MDIs required to retain complete dentures are six in the maxilla and four in the mandible. (Shatkin, 2003; Bulard and Vance, 2005; Morneburg and Proschel, 2008). The MDIs retained overdentures could be placed as parallel as possible to obtain effective retention in the denture and to prevent wear of the O-ring overtime. The parallelism of the implants generally should not exceed 20 degrees to avoid non-seating of the denture so the surgical guide may be needed to ensure close parallelism for the MDIs placement. (Shatkin, 2003; Flanagan, 2008; Bulard and Vance, 2005). In the edentulous arch, the multiple MDIs are considered to be more stable than the two standard implants. The arch distribution of the multiple MDIs will better reduce any fulcrum or tipping problems of the denture that can occur in the two standard implants positioned at the canine area (English and Bohle, 2003). Moreover, the MDIs have also been found to be cost-effective (Ahn et al., 2004). The cost of 4 MDIs was

equivalent to 1 conventional implant and achieves high level of patients' satisfaction (Griffitts, Collins and Collins, 2005)

The MDIs are manufactured in 1.8 mm, 2.1 mm, 2.4 mm and 2.9 mm in diameter and are available in 10mm, 13mm, 15mm and 18mm in length. They are recommended as longest MDIs as possible for the available bone to maximize stability of the implants (Block et al., 1990). Several designs of attachments are available for use with the MDIs to retain prostheses such as square head for fixed prostheses or O-ball head for removable or fixed prostheses, which act as a shock absorber (Bulard and Vance, 2005). For complete denture, retention can be obtained using a metal housing with O-ring that are fits over the head of the implant (Christensen, 2009). The denture was relieved to provide sufficient space for the metal housings and acrylic then the acrylic was placed in the denture over the metal housings and seated. After the acrylic set, the denture was removed with the metal housings. The existing denture was retrofitted with MDIs and attachments as MDIs retained overdenture (Jeffrey, 2011).

According to Misch's bone classification, D1 and D2 bone type with thick cortical bone and dense underlying trabeculae bone are recommended for MDIs placement. D3 bone type with fine trabeculae bone underneath the cortical bone is adequate. But D4 bone type with thin cortical bone and loose underlying trabeculae bone is not recommended (Misch CE, 1990).

Several studies demonstrated the long term high performance of the MDIs retained overdenture with more than 90% implant survival rate depending on methodology and survival criteria of the studies. Previous study reported 97.4% success rate after 13 months in the 116 MDIs retained overdenture treatment with the improvement of retention, comfort, chewing and speaking ability using individual questionnaire (Griffitts et al., 2005). The retrospective study of the 1,029 MDIs treatment in five clinics with a follow-up period from 5 months to 8 years reported more than 91% success rate and considered that the MDIs are effective for long term denture stabilization (Bulard and Vance, 2005). Another retrospective study evaluated the 2,514 MDIs in 531 patients over 5.5 years with a mean follow-up of 2.9 years found that the overall implant survival rate was 94% and the implant survival rates for lower complete denture was 95%. (Shatkin et al., 2007). The prospective study of 2.5 mm implants retained lower complete denture reported the survival rate of implants as

95.5% which average observation time of 6 years (Morneburg and Proschel, 2008). Another prospective study of the 112 immediately loaded MDIs retained lower complete dentures in 28 patients reported the cumulative survival rate as 96.4% and the success rates of the MDIs as 92.9% with favorable clinical and radiographic outcomes after 3 years follow-up (Elsyad et al., 2011).

Implant failure are multifactorial also associated with implant failure including the poor bone quality, advanced age, systemic diseases, chronic periodontitis, heavy smoking, short implants, acentric loading, inadequate number of implants, parafunctional habits and inappropriate prosthesis design (Porter and Von Fraunhofer, 2005). Tomasi et al. (2013) claimed that early implant failures may related to inadequate prepared of denture space for implant attachment, resulting in excessive load to implants during the healing phase (Tomasi et al., 2013). Shatkin et al (2007) found the major factors for MDIs failure including the loose posterior maxillary bone, the atrophic bone and the heavy smokers. The thin cortical bone and loose underlining trabecular bone provide a decreased matrix for osseointegration (Jaffin and Berman, 1991). Furthermore, the implant failure may be related to over preparation of the implant site lead to loss of primary stability and early mobilization (Tiziano et al, 2011).

4. <u>The masticatory efficiency evaluation</u>

Tooth loss and edentulous condition can cause deterioration in chewing ability lead to reduce food and dietary consumption. The lower of nutritional intake directly effect general health and quality of life (Miura et al., 2005). The impairment of chewing ability may increase the risk of decline in dietary variety (Kwon et al., 2006). The study of nutritional status of the community elderly in Japan found that the bad chewing ability group (able to chew only soft foods) had lower protein, Ca, Fe, dark green and yellow vegetables, rice, fat and total energy intake compared with the good chewing ability group (able to chew hard foods) (Nagai et al., 1991). In the elderly, better chewing ability leads to better nutritional status and quality of life (Takata et al., 2006).

The goal of dental treatment is to rehabilitate the natural teeth or replace the missing teeth to recover the masticatory function related to maintain the dietary intake and healthiness of patients. The maintenance or the improvement in the masticatory

function is extremely important to maintain healthy life in advance ageing (Lee et al., 2014). Several studies shown that loss of masticatory function can affected the quality of life (Miura et al., 2005; Brennan et al., 2008). Kim et al. (2009) found highly significant relation between masticatory efficiency and oral health-related quality of life (OHRQoL) measured by the Oral Health Impact Profile-14 (OHIP-14) score. Choi et al. (2013) demonstrated that oral health status and perceived masticatory disability could lead to dietary imbalances in the elderly.

All together, masticatory efficiency was considerably related to general health and oral health related quality of life, possibly reflecting the impact of food consumption and nutritional status. Thus, the masticatory efficiency evaluation is a significant indicator to assess the success of dental treatment related the quality of life.

There are 2 broad categories in measurement of masticatory efficiency. The term "subjective evaluation" refer to data gathered from patients' assessment of their chewing function and the term "objective evaluation" refer to data gathered from laboratory tests.

The Subjective evaluation of the masticatory efficiency

This evaluation of chewing function determined by patients themselves is essential because the aim of prosthetic treatment is to rehabilitate patients' oral function of chewing food. The treatment success depends on the patients' expectations and opinions so the psychological assessment of a patient is important (Giddon and Hittelman, 1980). Previous study shown a close relation between subjective chewing ability and quality of life (Miura et al., 2000). Patient based measurements include satisfaction in chewing function and chewing difficulty (Feine and Lund, 2006). Self-assessed masticatory ability is significantly important in evaluation of how dental treatment improved masticatory ability (Hsu et al., 2012). This suggests that the evaluation of treatment success should be found on the patients' themselve of treatment outcome. Feine and Lund (2006) recommended patient-based outcomes as the most appropriate variables of the masticatory efficiency.

The subjective evaluation of masticatory efficiency is easy to perform with cost effective and time saving. Additional information from qualitative interview can achieve better understanding in chewing experience of the individuals (Demers et al., 1996). Moreover, this method is appropriate in an epidemiological study with a large sample size (Hirai et al., 1994). However, this subjective assessment has some limitation of evaluation such as the results are based on subject's perceptions and interpretation (Slagter et al., 1992).

The personal interviews and questionnaires are largely used to get information of person's subjective responses in chewing ability related to psychosocial aspect and self-satisfaction of chewing function from individual's patients (Boretti, Bicke and Geering, 1995). The variety of questionnaires have been developed to be an indicator of individual's perception in their chewing ability. In 1990, Leake developed an index of chewing ability suitable for epidemiologic surveys by scalogram analysis using 0-5 scale that ranged from the most difficult to chew to the least difficult to chew in five food type various in textures and hardness. The author suggested that using a questionnaire on food intake is simple and accurate in the evaluation of chewing ability (Leake, 1990). Several studies used visual analogue scales (VAS) for measurement of five determinents including comfort, stability, ability to chew, ability to speak, and esthetics which directly related to treatment outcome and patients' satisfaction (Awad and Feine, 1998; Feine and Lund, 2006).

Some studies recommend the food intake questionnaire to be useful for evaluating masticatory function (Hirai et al, 1994; Miura et al, 2000). There are several food types questionnaires have been developed for use depened on the differences of foods preference in each country and ethnic backgrounds. In Thailand, Kunon and Kaewplung (2014) developed food intake questionnaire using four-point rating scale of 14 common food types in Thailand to evaluate the chewing ability of conventional dental implant-retained L-CD patients.

The Objective evaluation of the masticatory efficiency

This evaluation is the quantitative methods allowing assessment of masticatory function by objective indicators. Many different objects and medthods have been used such as the measurement of particularly mastication time and number of chewing

strokes (Jemt and Stalblad, 1986), the measurement of muscle activity by electromyographic (EMG) bursts (Heqberg, 1987), the measurement of maximum biting force (Haraldson, Karlsson and Carlsson, 1979) and the measurement of particle size of artificial or natural food (Kapur, Soman and Yurkstars, 1964).

The masticatory efficiency can be represented as the ability to grind food. The degree of broken down chewed food or test material was measured by fractionating the particles in a sieve system, so this evaluation is called as sieve method (Kapur et al., 1964). After a specified number of chewing strokes, the particles are collected and measured the size (Lucas and Luke, 1986). One of the purposes of chewing food is to enlarge the surface area to be exposed to the digestive juices, so the summarized area of the masticated test material can be applied to evaluate the masticatory evaluation (Gunne, 1985). There are several natural foods such as nuts, carrots (Lucas and Luke, 1986) and artificial food such as formalin hardened gelatin (Gunne, 1985) have been used as test foods. The artificial food can reproducibility of the shape dimensions and physical properties which have no taste or odor that might affect chewing process, so the use of artificial food is preferred to natural food for the measurement of the masticatory efficency (Sato et al., 2003b). While, there are some limitatios of those seive method including complicated data analysis, time-consuming and applicable only brittle substances (Feine and Lund, 2006).

The additional method is the evaluation of the ability to mix and knead food bolus. Various artificial test food such as chewing gum and paraffin wax cubes have been developed which various shapes and colors to assess masticatory efficiency based on mixing ability test (Ishikawa et al., 2007; Sato et al., 2003b). The degree of color mixing and shape of the test objects can be quantified using a computer-assisted method (Van der Bilt et al., 2010). Hayakawa et al. (1998) determined the color changes of the gum after chewing with L*a*b* color space using spectrophotometer. Sato et al. (2003) developed paraffin wax cubes as a test food, which had six red and green coloured layers and the images of the chewed samples were captured and analysed using a digital image analyzer. Compared to the sieving method, the mixing ability method of bolus objects is not complicate in manipulation and image analysis of these artificial substances is more simple, quick, accurate, reproducible, and clean (Sato et al., 2003).

In Thailand, Prapatrungsri et al. (2010) developed a two-colored wax cube to evaluate the masticatory efficiency based on mixing ability method. This wax cubes were developed using an uncomplicated manufacturing process and the evaluation system spends only a few minutes to perform the test and to analyze the sample. The subjects could not feel uncomfortable and also be easy to understand the result of the test visually (Liangbunyaphan, Chaiteerapapkul and Kaewplung, 2011). Following study modified this two-colored wax cube system into 3 levels of hardness and found that the original soft wax cubes were suitable for use to assess the masticatory efficiency of complete edentulous patients because the hardness score of the soft wax cubes were in the range of common diets in the population of this study. (Liangbunyaphan et al., 2012). This system can be applied clinically in both normal dentition and patients with fix or removable denture to evaluate masticatory ability after dental treatment (Liangbunyaphan et al., 2011). The previous studies utilized this wax cube system to compared the masticatory efficiency before and after the standard size implant retained L-CD delivery and found significantly improvement of chewing ability after implant treatment (Chokpreecha and Kaewplung, 2013; Kunon and Kaewplung, 2014).

The objective masticatory evaluation was considered to have many advantages such as reliable results, comparable with the quantitative data and no emotional effect from the individual (Slagter et al., 1992). However, these objective evaluation are time consuming and require the subjects' willingness and co-operation as well as special equipment which causes more expensive and more complicated to investigate in large population.

CHAPTER III

METHODOLOGY

1. Subject population

The Ethical Committee of Chulalongkorn University, Bangkok, Thailand approved the protocol of this study on 14th March 2012. Thirty-three patients (10 males and 23 females, mean age 67.50 ± 7.66 years) were selected. All patients in this study were the elderly patients of Prosthodontic Department, Faculty of Dentistry, Chulalongkorn University. Written informed consent was obtained from each subjects after a full explanation of the clinical trial.

All subjects were recruited into this study using the following inclusion criteria:

- Had functional problems of retention and stability in their L-CD.
- The upper dentition had good posterior support and could be any conditions such as full natural teeth or partial edentulous or complete edentulous which any kind of prosthesis such as conventional complete denture (CD), acrylic removable partial denture or metal removable partial denture (RPD) or fix partial denture (FPD).
- The conventional upper and lower dentures were accepted in quality and function; they had worn their dentures for 3 months or above prior to participating in this project.
- The subjects might not accept the surgical procedure of the standard size implant retained lower complete denture because of their severe resorption of mandible (insufficient bone width, less than 5 mm) or weakness from their general health or have limitation in cost and time-consuming.
- The bone in the implant placement area had at least 3 mm in width, 12 mm in height and had bone density classified in D1–D3 according to Misch's bone classification (Misch, 1990).
- Had ability to understand written and spoken Thai language and respond to the questionnaire.

- No medical condition that contraindicate for implant surgery.
- No psychological or psychiatric conditions that could influence treatment or the study.
- No previous or current radiotherapy or chemotherapy in the head and neck region.
- No smoking or smoking less than 20 rolls of cigarettes per day.
- No treatment with any of the bisphosphonate drugs.

2. Radiographic examination

All subjects had evaluated quality and quantity of bone site for implant placement by panoramic radiograph and cone beam computed tomography with surgical stent (Figure 1a, 1b).
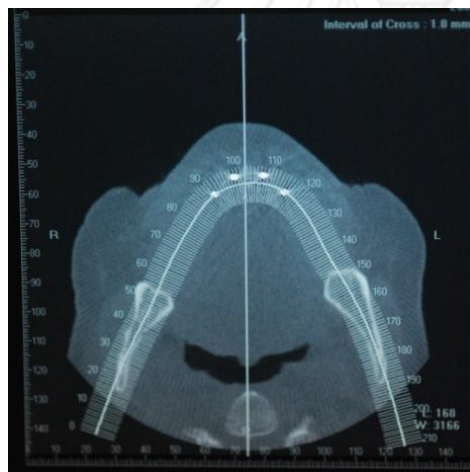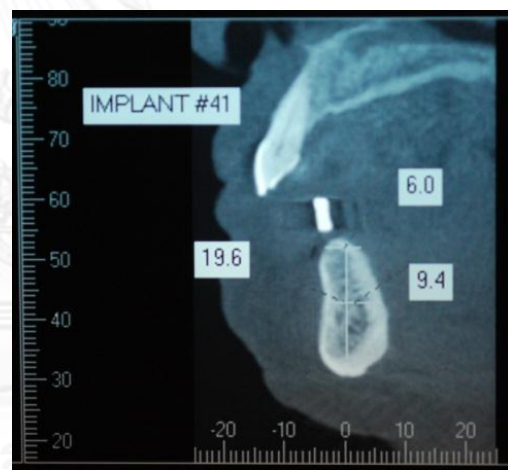

Figure 1a   Figure 1b

Figure 1 Cone beam computed tomography shown implants' position and angulation guided by surgical stent.
1a: axial view, 1b: cross-sectional view

To classify about the bone height from the cone beam computed tomography, the least vertical bone height of the residual mandible were classified by The American College of Prosthodontists (ACP) in four types (McGarry et al., 1999): type I ($\geq$21mm), type II (16-20mm), type III (11-15mm), type IV ($\leq$10mm). According to the modification of ACP classification, all subjects in this study were classified into 2 groups: **High bone**

group (ACP type I and II: the least vertical bone height >15 mm) and **Low bone group** (ACP type III and IV: the least vertical bone height ≤ 15 mm).

To classify about the bone width from cross-sectional view of cone beam computed tomography, the least bone width of the residual mandible were classified into two group depended on the minimum bone width required for the standard size implant placement (5 mm) as **Wide bone group** (bone width ≥5 mm, can receive the standard size implant or MDI) and **Narrow bone group** (bone width <5 mm, can receive the MDI but unable to receive the standard size implant without bone graft) (Preoteasa et al., 2010).

3. Surgical and prosthetic procedures

The MDIs were selected for individual subject by diameter, length, and type of fixture according to the manufacturer's instructions (3M ESPE, USA) (Table 1). The MDIs used in this study had diameter 1.8, 2.1 or 2.4 mm and length 10, 13 or 15 mm. O-ball implants with collar were used in thick attached gingiva (≥2mm) (Figure 2a) and O-ball implants without collar were used in thin attached gingiva (<2mm) (Figure 2b).

Table 1 Guideline of the MDIs selection (3M ESPE, USA)

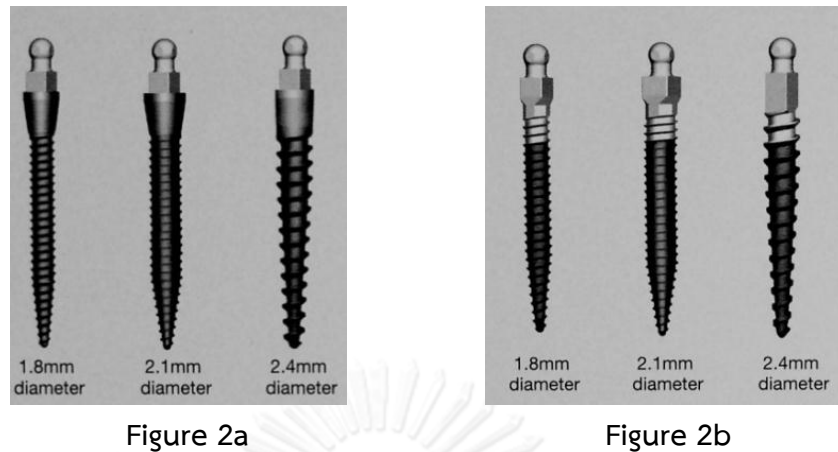| Implant type	Bone density				Soft tissue depth		Buccolingual width		
	D1	D2	D3	D4	≤2mm	>2mm	≤4mm	>4mm	≥5.5mm
Ø1.8mm with collar	/	/	NR	NR	NR	/	/	/	/
Ø1.8mm without collar	/	/	NR	NR	/	NR	/	/	/
Ø2.1mm with collar	/	/	NR	NR	NR	/	NR	/	/
Ø2.1mm without collar	/	/	NR	NR	/	NR	NR	/	/
Ø2.4mm with collar	NR	/	/	NR	NR	/	NR	NR	/
Ø2.4mm without collar	NR	/	/	NR	/	NR	NR	NR	/

NR=Not Recommend

Figure 2a   Figure 2b

Figure 2 The MDIs (3M ESPE, USA)

2a: O-ball implants with collar, 2b: O-ball implants without collar

Prior to surgery, all subjects were evaluated for the mandibular bone height and width at the implant placement sites using panoramic and cone beam CT imaging. The surgical procedure was performed by the specialists and the postgraduate students from Oral and Maxillofacial department, Faculty of Dentistry, Chulalongkorn University. The surgical stent was used in order to guide position and direction of implants placement. All subjects were received 4 MDIs at least7 mm anterior from the mental foramen, at least 5 mm from each other and at least 2 mm above the inferior border of the mandible (Figure 3).
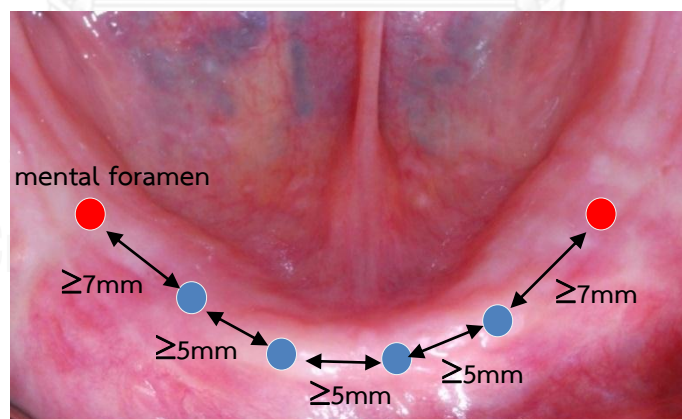

Figure 3 The MDIs placement position in mandible,

Blue dot = 4 MDIs placement position, Red dot = mental foramen position

Flapless surgical procedure can be used in general case except knife-edge ridge was recommended in flap procedure to remove knife-edge bone before implant placement. Immediate load of prosthesis could be done if the implant had good initial

stability which torque to minimum of 35 Ncm. If torque lower than 35 Ncm, delay loading prosthesis within 4-6 months was recommended, soft liner (SECURE Soft Reline Kit, 3M ESPE, USA) was relined for denture function during this time. The L-CD was fitted to ball attachments with metal housing and O-ring by the intra-oral technique using hard acrylic pick-up method (SECURE Hard Pick-Up Kit, 3M ESPE, USA). The treatment was completed as the MDIs retained L-CD (Figure 4a, 4b).

Figure 4a   Figure 4b

Figure 4 The 4 MDIs retained lower complete denture

4a: The 4 MDIs placement in the oral cavity,

4b: Tissue surface of the L-CD after picked up O-ring with self-cured acrylic

The metal housing used in this study were standard metal housing (MH-1) and micro metal housing (MH-2). The MH-1 provided firm retention and could apply for more implants divergence (up to 30°). The MH-2 was 30% smaller than the MH-1 and provided extra-firm retention and could apply for less implants divergence (up to 15°) (Figure 5a, 5b).
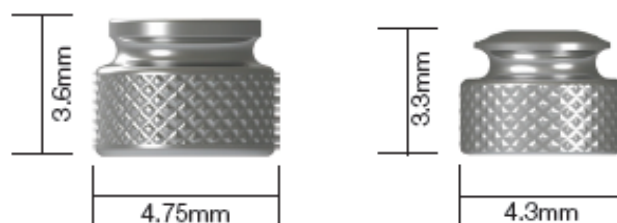

Figure 5a   Figure 5b

Figure 5 The metal Housing

5a: Standard metal housing (MH-1), 5b: Micro metal housing (MH-2)

Careful instructions were given to all subjects, including daily cleaning of the denture and the implants. Recall appointment to examine the MDIs, the denture, the soft tissue and the subject's oral hygiene were perform within 1 week after loading denture, then in 1 month and 3 months. The marginal bone loss around each MDI in the individuals also be measured by analyzing the panoramic radiography with INFINITT program (Infinitt Healthcare. CO., Ltd, UK).

4. The masticatory efficiency evaluation

Each subject's chewing function were performed both subjective and objective at each test. There were 3 tests :

Test 1 after using L-CD for more than 3 months before the MDIs placement.
Test 2 after loading L-CD 1 month.
Test 3 after loading L-CD 3 month.

4.1 Subjective assessment using the a self-reported questionnaire

The subjects were interviewed to evaluate their subjective chewing ability using a self-reported questionnaire as developed in the previous study (Kunon and Keawplung, 2014). The self-reported questionnaire consisted of food chewing performance of 14 common food types: Porridge, Chinese Vegetable Stew, Chinese Cabbage Soup, Steamed Rice, Noodle Soup, Omelet, Steamed Fish, Sour Curry, Banana, Fried fish, Orange, Fresh Guava, Fried pork and Stir-fried Vegetables. The subjects were asked to rate their chewing ability for each food type. Each food was rated using a four-point rating scale ranging from 0 points (could not chew at all) to 3 points (could chew well), shown in Figure 6. One examiner performed all the interviews in all subjects.

could not chew at all   could chew well

0   1   2   3
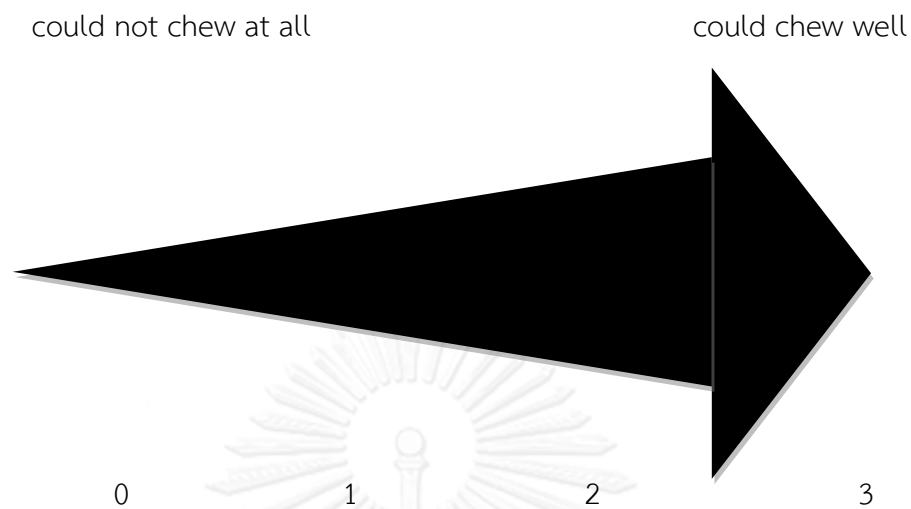
Figure 6 The four-point rating scale for each food choice

The total score of these 14 foods (ranging from 0–42) was calculated as the "Perceived Chewing Ability Score" (PCAS) of each subject. Higher scores indicated better chewing ability. The improvement of chewing ability by subjective evaluation were calculated using the following formula:

$$\text{Percentage change of the PCAS} = \frac{(\textbf{Test 3} \text{ score} - \textbf{Test 1} \text{ score})}{42} \times 100$$

4.2 <u>Objective assessment using the two-colored (red and white) wax cubes</u>

At the same time, right after the subjective chewing test, the subjects were measured the masticatory efficiency by objective method using the wax cube analysis as developed and used in the previous study (Prapatrungsri et al., 2010; Liangbunyaphan et al, 2011; Liangbunyaphan et al., 2012; Chokpreecha and Kaewplung, 2013; Kunon and Kaewplung, 2014). The 10x10x10 mm two-colored (red and white) wax cubes (Figure 7) were kept in an incubator at 37°C for 24 hours and soaked in a water bath at 37°C more than 10 minutes before the test. Each subject was requested to sit on the dental chair in the upright position. Lubricant was applied on the occlusal surfaces of the upper and lower posterior teeth. All subjects were instructed to chew a one piece of wax cube in 10 habitual strokes on the right side

then remove and repeat the process again on the same side with another wax cube. After finished two cycles of chewing on the right side, the subjects were requested to repeat all of the above chewing process on the left side. Thus each subject had 4 pieces of chewed wax per test.
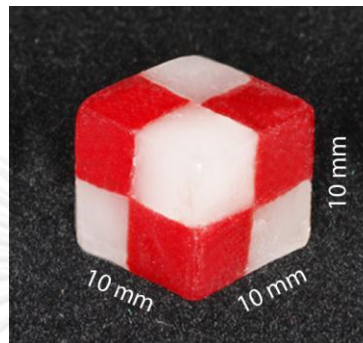

Figure 7 The two-colored wax cube

The images of the chewed wax performed on both side were captured using a digital camera (Nikon D80, Nikon Coporation., Tokyo, Japan) with a macro lens (Sigma macro 105 mm) under standardized distances and light conditions (a photo stand kit; Copy stand CS920 and Copy light CL-150 with 2 light bulbs; Phillips$^®$ Cool Daylight 125 Watts, Color temperature 6,500 K and a luxmeter; DigiconLX-70, Protonics Inter-trade Co,Ltd., Thailand). Eight digital images per subject (from both upper and lower sides of all 4 pieces of chewed wax) were obtained from each test. All images of chewed wax were transferred and analyzed using the Image J program (Version 1.42Q, NIH, MD, USA) which seen in Figure 8.
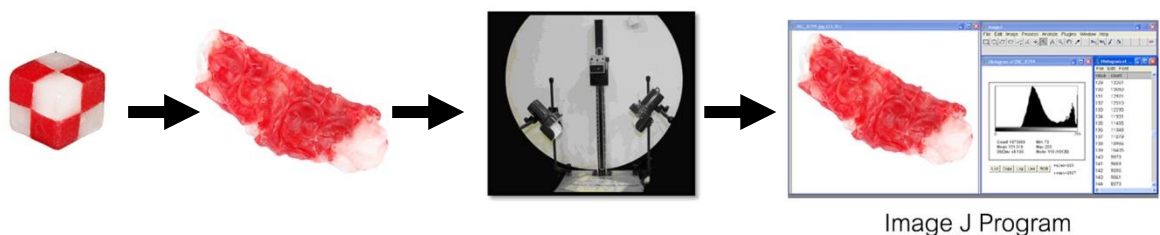

Image J Program

Figure 8 Chewed wax cube analysis method

The standard color value represented well mixed red and white color of wax cube and obtained by mixing, then equal amount of red and white wax by weight in homogeneous orange color. Then the image of the mixture were also captured and analyzed by the Image J Program.

After each test, the average value of the degree of mixing of the white and red wax was calculated to the average "Percentage of Chewing Ability" (PCA) by the following formula:

$$\text{The PCA} = \frac{\text{Total number of pixels of standard color value} \times 100}{\text{Total Number of pixels of the chewed wax}}$$

Repeating analysis one time in all chewed wax image with the Image J Program for all subjects in Test 1 assessed the test-retest reliability of this objective evaluation.

The improvement of chewing ability by objective evaluation were calculated using the following formula:

$$\text{Percentage change of the PCA} = \frac{(\textbf{Test 3}\text{ score} - \textbf{Test 1}\text{ score})}{100} \times 100$$

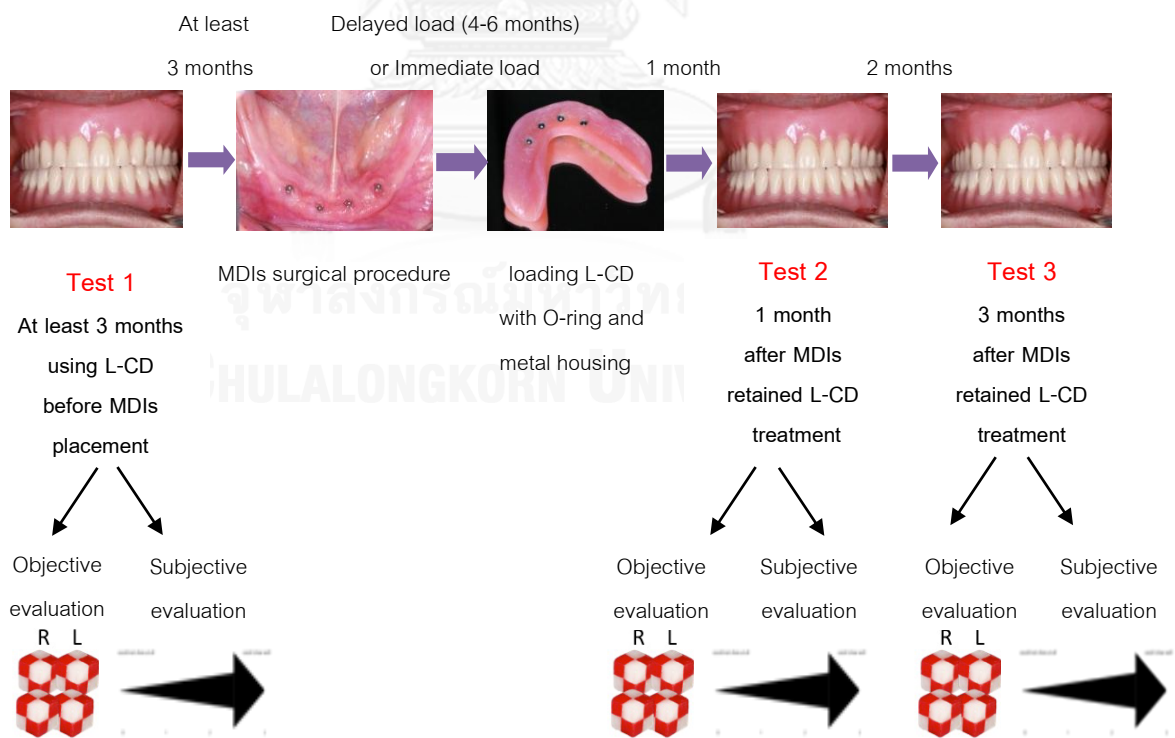The schematic of the methodology of this study can be seen in Figure 9

Figure 9 The Schematic of the methodology

5. Statistical analysis

The statistical analyses were tested using the Statistics Package for the Social Sciences (SPSS) version 17.0 (SPSS [Thailand] Co., Ltd., Bangkok, Thailand). A P-value less than .05 was considered significant in all statistical analysis. Friedman test and Wilcoxon Signed Ranks Test was assessed to compare the values of the PCAS among 3 tests. One way repeated measures analysis of variance (ANOVA) was carried out to compare the values of the PCA among 3 tests. The normality of the data distribution was tested using one sample Kolmogorov-Smirnov test. The influence of sex, the ASA physical status classification of the patients, the mandibular bone height and width on the PCAS and the PCA were tested using an independent t-test or Mann-Whitney U test depending on data distribution. The effect of age, the systemic disease, and type of upper dentition were tested using One-way analysis of variance (ANOVA) or Kruskal-Wallis test depending on data distribution and homogeneity of variance. The test-retest reliability of the two-colored wax cube analysis method by the image J program was investigated by the Reliability analysis. The relationship between subjective and objective chewing ability was demonstrated using Pearson's correlation analysis.

CHAPTER IV

RESULTS

1. Subjects characteristics

At the beginning, 39 patients were participated in this study. Six patients were excluded along the study time line as the limitation of paticipants individual's schedule. Thus, 33 patients remained throughout the masticatory efficiency evaluation of the study. Among 33 patients, 4 of the MDIs (3.03%) from 4 patients failed to integrate with the alveolar bone, three cases lost the implants during 4 month healing phase before loading denture and the other lost the implant one month later after loading denture. However, all these cases were replaced with the new MDIs, 2 MDIs were placed at the same position and the others were placed at the area distally to the previous position. All the new 4 MDIs were replaced with successful osseointegration within the follow-up period of this study. Therefore, these 4 cases still included in the 33 subjects.

The total 33 subjects consisted of 10 males and 23 females aged from 55-83 years old with mean age of 67.50 ± 7.66 years. Most of the subjects in this study (32 subjects, 96.97%) were the elderly aged over 60 years old, the only one subjects (3.03%) aged lower than 60 years old (55 years old). According to the ASA physical status classification (Daabiss, 2011), 12 subjects (36.36%) were healthy without any systemic disease and were classified as ASA classification I. While 21 subjects (63.64%) reported at least one systemic disease from often found; hypertension (13 subjects, 39.39%), hyperlipidemia (6 subjects, 18.18%), diabetes mellitus (5 subjects, 15.15%), heart disease (2 subjects, 6.06%), osteoarthritis (1 subject, 3.03%), liver disease (1 subject, 3.03%), anemia (1 subject, 3.03%) and Systemic Lupus Erythematosus (SLE) (1 subject, 3.03%), respectively. All these 21 subjects had mild to moderate systemic disease, which were well-controlled condition and were classified as ASA classification II. All subjects had worn their dentures for 3–48 months prior participated in this study. Twenty-five subjects (75.76%) had total upper and lower edentulous arch and wear upper and lower complete denture (CD). Seven subjects (21.21%) remained some natural teeth in their upper arch, both anterior and posterior teeth and wear upper

removable partial denture (RPD). Only one subject (3.03%) had upper natural teeth with fix partial denture (FPD).

From the cone beam computed tomography, the least vertical bone height of the residual mandible were vary from 12.13-27.31 mm (mean 19.59±5.84 mm). The bone height of the mandible was classified by The American College of Prosthodontists (ACP) in four types (McGarry et al., 1999). The number and the percentage of the subjects in each bone height classification were shown in Table 2. All subjects were classified into 2 modified groups as **High bone group** (ACP type I and II: the least vertical bone height > 15 mm) and **Low bone group** (ACP type III and IV: the least vertical bone height ≤ 15 mm) (Table 2).

Table 2 The number and the percentage of the subjects in each bone height classification according to the ACP

The least bone height of mandible (mm)	Bone height classification	Number of subjects (%)	Modified group	Number of subjects (%)
≥21	Type I	8 (24.24%)	High bone group >15 mm	20 (60.60%)
16-20	Type II	12 (36.36%)		
11-15	Type III	13 (39.40%)	Low bone group ≤15 mm	13 (39.40%)
≤10	Type IV	0 (0%)		

From cross-sectional view of cone beam computed tomography, the least bone width of the residual mandible were vary from 3.37-9.50 mm (mean 4.80±0.66 mm). The bone width of mandible were classified into two groups according to the minimum bone width as 5 mm required for the standard size implant placement (Preoteasa et al., 2010) as **Wide bone group** (bone width ≥ 5 mm) and **Narrow bone group** (bone width < 5 mm). The number and the percentage of the subjects in each bone width classification were shown in Table 3.

Table 3 The number and the percentage of the subjects in each bone width classification

The least bone width of mandible (mm)	Modified group	Number of subjects (%)
≥ 5	Wide bone group	19 (57.58%)
< 5	Narrow bone group	14 (42.42%)

2. The Perceived Chewing Ability Score (PCAS) and the Percentage of Chewing Ability (PCA)

The masticatory efficiency in Test 1 (before the MDIs placement), Test 2 (1 month after loading L-CD on the MDIs) and Test 3 (3 month after loading L-CD on the MDIs) was compared by the subjective and the objective evaluation. In the subjective evaluation, the subjects rated their PCAS at 20±5.93 in Test 1 and increased to 40±2.03 in Test 2 then 41±1.82 in Test 3. By the objective evaluation, the mean of the PCA was 19.22±3.75 in Test 1 and increased to 29.7±4.79 in Test 2 and 31.02±3.70 in Test 3. The means and standard deviations of the PCAS and the PCA of all 3 Tests are presented in Table 4.

Due to the differences in the measurement scales between the results of the PCAS and the PCA, these two outcomes were converted into the same measurement type as the "percentage change of the PCAS" and the "percentage change of the PCA" which refer to the improvement of these outcomes and derive from

$$\text{Percentage change of the PCAS} = \frac{(\textbf{Test 3} \text{ score} - \textbf{Test 1} \text{ score}) \times 100}{42}$$

$$\text{Percentage change of the PCA} = \frac{(\textbf{Test 3} \text{ score} - \textbf{Test 1} \text{ score}) \times 100}{100}$$

The outcome of these two were shown in Table 4.

A repeated measures ANOVA found statistically significant differences in the means of the PCAS and the mean of the PCA between the 3 tests ($p<.001$). Post hoc tests (Bonferroni test) demonstrated statistically significant differences ($p<.001$) between the means of the PCAS and the PCA in each test except the means of the

PCAS and the PCA between Test 2 and Test 3 as shown in Table 4. The result showed that all of the subjects significantly improved their masticatory efficiency after treatment with the MDIs retained L-CD (Test 2 and Test 3) by both subjective and objective evaluation.

Table 4 The perceived chewing ability scores (PCAS) and the percentage of chewing ability (PCA) obtained from the 3 tests and the percentage change of PCAS and the percentage change of PCA from test 1 to test 3 (n=33)

	Test 1	Test 2	Test 3	Percentage change from test 1 to test 3 (mean ± sd)
The PCAS (median ± sd)	20±5.93	40±2.03	41±1.82	45.60±13.50
The PCA (mean ± sd)	19.22±3.75	29.61±4.27	31.02±3.70	11.80±2.90

"a" denotes statistical difference with *p*<.001, "b" denotes statistical difference with *p*>.001

3. The Effect of variables on the subjective and the objective masticatory evaluation

The descriptive data of the masticatory efficiency as the PCAS, the PCA, the percentage change of the PCAS and the percentage change of the PCA were evaluated by age, gender, type of the upper prosthesis, general health status by ASA Classification, the least vertical bone height and the least bone width of mandible were shown in Table 5.

Statistical analysis revealed that there were no significant differences in all measurement outcomes between male and female, the four age groups, the two ASA classification and any systemic disease and the three type of upper dentition. Moreover, there were no significant differences in all measurement outcomes between the High bone group and the Low bone group as well as between the Wide bone group and the Narrow bone group.

Table 5 The median and standard deviation of the PCAS. The mean and standard deviation of the PCA, the percentage change of the PCAS and the percentage change of the PCA shown by age, gender, ASA Classification, type of upper prosthesis, modified bone height and modified bone width

Characteristics	N (%)	The Perceived Chewing Ability Scores (PCAS)				The Percentage of Chewing Ability (PCA)			
		Test 1	Test 2	Test 3	percentage change	Test 1	Test 2	Test 3	percentage change
Age (years)									
<60	1 (3.03)	24±0.00	39±0.00	41±0.00	40.48±0.00	19.58±0.00	25.16±0.00	31.69±0.00	12.11±0.00
60-69	16 (48.48)	20±5.22	41±1.86	41±1.82	40.36±11.97	18.33±3.61	29.80±4.29	30.77±3.47	12.44±3.35
70-79	15 (45.45)	22±6.90	40±2.23	40±1.78	43.97±15.92	20.04±4.04	29.90±4.45	31.60±3.80	11.56±2.22
>80	1 (3.03)	26±0.00	40±0.00	41±0.00	35.71±0.00	20.89±0.00	26.71±0.00	29.63±0.00	8.74±0.00
Gender									
Male	10 (30.30)	20.5±6.28	39.5±1.70	41±1.51	45.71±15.01	18.60±3.42	28.11±2.60	29.99±1.89	11.39±3.23
Female	23 (69.70)	21±5.70	40.5±2.07	41±1.87	44.91±13.09	19.69±3.89	30.54±4.65	31.84±3.90	12.15±2.72
ASA Classification									
ASA I	12 (36.36)	20±5.78	40±2.22	41±2.02	47.82±13.18	19.22±2.65	30.20±3.95	31.40±4.03	12.18±3.23
ASA II	21 (63.64)	22±6.10	40±1.97	41±1.74	44.33±13.83	19.22±4.31	29.28±4.50	30.80±8.58	11.58±2.75
Type of Upper Prosthesis									
CD	25 (75.76)	20±5.63	40±1.59	41±1.58	46.00±13.22	19.30±3.53	29.70±4.09	31.15±3.28	11.85±3.05
RPD	7 (21.21)	24±6.23	39±2.64	40±2.14	42.18±13.92	19.54±4.34	30.05±4.68	31.69±4.03	12.16±2.06
FPD	1 (3.03)	12±0.00	36±0.00	37±0.00	59.52±0.00	15.12±0.00	24.39±0.00	23.15±0.00	8.03±0.00
Modified bone height									
High bone group (> 15 mm)	20 (60.60)	20±6.23	40±2.16	41±1.73	47.02±14.63	19.74±3.60	29.66±4.43	31.18±3.79	11.44±2.34
Low bone group (≤15 mm)	13 (39.40)	21±5.61	40±1.88	40±1.98	43.41±11.75	18.42±3.97	29.49±4.19	30.77±3.70	12.35±3.63
Modified bone width									
Wide bone group (≥ 5 mm)	19 (57.58)	20±6.58	40±2.12	41±2.06	45.24±14.57	18.59±4.10	29.97±4.06	30.73±4.12	12.14±3.23
Narrow bone group (< 5 mm)	14 (42.42)	20.5±5.14	40.5±1.94	40.5±1.50	45.92±12.23	20.09±3.15	29.13±4.65	31.42±3.16	11.33±2.40

4. The correlation between the subjective and the objective evaluation of the masticatory efficiency

Pearson's correlation coefficient demonstrated that there were significant positively correlation between the PCAS and the PCA in Test 3 ($p<.05$, $r=.382$), while there were no significant positively correlation between the PCAS and the PCA in Test 1 and 2 and between the percentage change of the PCAS and the percentage change of the PCA ($p>.05$).

CHAPTER V

DISCUSSION

There were 39 patients of the Prosthodontic Department, Faculty of Dentistry, Chulalongkorn University which functional problems of retention and stability in their L-CD have been treated with the MDIs retained L-CD in this study. According to the scheduled time of this study, 4 patients delayed to participate in the surgical and prosthodontic procedure and 2 patients lost their denture after surgical procedure, so these 6 patients were excluded from the study. However, they were completely received the treatment of the MDIs retained lower complete denture finally. At the end of the study, 33 patients were recruited as the subject of the study throughout the masticatory efficiency evaluation.

The elderly patients often present compromised medical condition and usually anxious of perceived risks and complications of the surgical intervention in the conventional implant, some elderly patients might reject the standard size implant retained overdenture treatment (Ellis et al., 2011). Therefore, the minimal invasive MDIs should be the alternative treatment for this situation. All subjects in this study were in old age (average age 67.50 ± 7.66 years) which 12 healthy subjects (36.36%) classified as ASA classification I, while 21 subjects (63.64%) classified as ASA classification II and had at least one or more than two systemic disease (as described in previous chapter). The results shown that all of the elderly and medically compromised subjects in ASA classification I and II can receive the treatment of the MDIs retained L-CD with 100% clinical success in 3 months follow-up period after functional loading denture with reported only 0.63±0.46 mm average bone loss. It might be suggested that advancing age and some kind of well-controlled systemic disease from this study including hypertension, hyperlipidemia, diabetes mellitus, heart disease, osteoarthritis, liver disease, anemia and SLE might not limit the MDIs treatment. Moreover, there were no statistically significant difference in the mean value of all measurement between the patients in ASA classification I and II, and between the reported systemic diseases. Therefore, from this study it is suggested that in any geriatric patient, whose systemic health does not contraindicate for minor oral surgery can be treated with the MDIs to

improve their L-CD function with favorable outcome of osseointegration. However, the long-term follow-up is recommended.

One subject of Systemic Lupus Erythematosus (SLE) with Sjogren's syndrome in this study had primary complaints before implant treatment with tissue discomfort, denture sores, dry mouth, difficulty in chewing, and L-CD instability. The significant effect to the oral treatment of Sjogren's syndrome were xerostomia due to the reduced salivary flow rate and irritated oral mucosa, this cause to reduce the success of conventional complete denture (Binon, 2005). After treatment with the MDIs retained L-CD in this project, the subject was satisfied with treatment outcome which reduced in denture stomatitis and tissue irritation as well as improvement of L-CD stability. We suggested that implant treatment to retained complete denture offer a practicable treatment alternative for patients with Sjogren's syndrome which related to the suggestion of the previous study (Isidor et al., 1999).

This study aimed to evaluate the masticatory efficiency before and after the MDIs retained L-CD treatment by both subjective and objective method. The subjective method is easy to carry out with low cost and less time consuming. Moreover, the patient-based measurement of satisfaction in chewing function of denture is important to assess the treatment success (Hsu et al., 2012). The food intake questionnaire is recommended to be used due to its simple and accurate in the chewing ability evaluation (Leake, 1990). Many studies used a food intake questionnaire in variety of the number and types of foods according to the different culture and ethnic of the subjects. In Thailand, the self-reported questionnaire for subjective evaluation with 4 point rating scale has been developed in the previous study to evaluate the chewing ability of implant L-CD in the elderly population (Kunon and Kaewplung, 2014). The 14 food types in this questionnaire were selected from the common native Thai foods which commonly consumed by the elderly populations who live in central region of Thailand as well as the elderly populations of this study. So, this developed food intake questionnaire was appropriate in assessment of the subjective evaluation of the masticatory efficiency in this study.

The objective masticatory evaluation method in this study used the two-colored wax cube analysis as developed and utilized in the previous studies (Prapatrungsri et al., 2010; Liangbunyaphan et al, 2011; Liangbunyaphan et al., 2012;

Chokpreecha and Kaewplung, 2013; Kunon and Kaewplung, 2014). The objective method provided reliable result with quantitative data and no emotional effect from the subjects (Slagter et al., 1992). This wax cube analysis method had uncomplicated manufacturing and also spends a few minutes to perform the test without uncomfortable to any subjects. Moreover, the analysis of the chewed wax is uncomplicated and the subjects could understand the result of the assessment visually. The reliability test for the Image J Program was done for all chewed wax in Test 1 to confirm that the outcomes for the same chewed wax analyzed under the Image J Program was not significant different at a Alpha value of .999.

The result of the masticatory efficiency in this study revealed 100% of subjects improved their chewing ability after the placement of the MDIs retained L-CD by both subjective and objective evaluations. These might be because the MDIs retained overdenture can increase retention and stability of the dentures result in improving the subjects' chewing function. The improvement of masticatory efficiency could lead the patient to chew more variety of food and increased their food consumption of hard and coarse foods such as fruits, vegetables and meats followed by increased their nutritional status and quality of life. The dietary counsel from the dentist was important to advise the elderly in choosing high beneficial food intake containing vitamins, minerals, proteins and fiber.

We observed the improvement of the masticatory efficiency by analyzing the percentage change of the PCAS and PCA in the individual subject. Therefore, the different type of the upper prosthesis among the individual and different dentists prepared the dentures of each individual subjects are not effect. The results indicated that after the placement of the MDIs, it helps in improving the chewing ability significantly both subjectively (PCAS) and objectively (PCA) no matter the types of the upper prosthesis are.

There are two previous studies evaluated the masticatory efficiency of the two standard size implants retained L-CD patients under the same objective measurement by using two-color wax cube analysis (Chokpreecha and Kaewplung, 2013; Kunon and Kaewplung, 2014). Chokpreecha and Kaewplumg (2013) reported the PCA of 33 patients in 1 month follow-up after treatment with the two conventional implant

(Tapered Screw-Vent® Implant system, Zimmer dental, Carlsbad, CA) retained L-CD as 28.17±6.16 and the percentage change of the PCA as 12.73±6.34 (Table 6). Kunon and Kaewplung (2014) reported the PCA in 3 month follow-up after treatment with the two domestically Thai implant ("Fun-Yim", Advanced Dental Technology Center, Thailand) in 38 patients as 33.75±4.57 and the percentage change of the PCA as 9.33±7.67 (Table 6). While in this study, the PCA at 3 months follow-up after treatment of the MDIs retained L-CD in 33 patients was 31.02±3.70 and the percentage change of the PCA was 11.80±2.90. By this objective assessment, we found that the improvement of the PCA in the MDIs retained L-CD patients in this study were compatible to the improvement of the PCA with the standard size implants retained L-CD patients in the previous studies.

Table 6 The Mean and standard deviation of the PCA and the percentage change of the PCA of 3 implant retained L-CD systems

System	PCA		Percentage change of the PCA
	Before implant treatment	After implant treatment (F/U time)	
The two conventional implant (Tapered Screw-Vent® Implant system, Zimmer dental, Carlsbad, CA) (n=33) (Chokpreecha and Kaewplumg, 2013)	15.43±4.36	28.17±6.16 (1 month)	12.73±6.34
The two domestically Thai implant "Fun-Yim" (Advanced Dental Technology Center, Thailand) (n=38) (Kunon and Kaewplung, 2014)	24.42±7.61	33.75±4.57 (3 month)	9.33±7.67
The mini dental implant system (n=33) (MDIs, 3M ESPE, USA)	19.22±3.75	31.02±3.70 (3 month)	11.80±2.90

This study also revealed the subjective assessment of the masticatory efficiency using the developed questionnaire according to our previous study (Kunon and Kaewplung, 2014) reported the average of the PCAS after 3 months treatment with the standard size implants retained L-CD as 39.45±4.44 and the percentage change of the PCAS as 23.50±17.86 (Table 7). This study demonstrated that the average of the PCAS in 3 months follow-up after treatment with the MDIs retained L-CD was 40±1.82 which

was consistent to our previous study while the percentage change of the PCAS was 45.60±13.50 which seem to be higher than the previous report. This could be because of the PCAS before implant treatment of the MDIs patients which mainly have the lower ridge resorption problem were lower than those in the standard implants patients. It can be noticed that after treatment with the MDIs, the patients can improve their subjective chewing ability in the same agreement with those of the standard size implants patients.

Table 7 The Mean, median and standard deviation of the PCAS and the percentage change of the PCAS in 2 implant retained L-CD systems

System	PCAS		The percentage change of the PCAS (mean ± sd)
	Before implant treatment	3 months After implant treatment	
The two domestically Thai implant "Fun-Yim" (Advanced Dental Technology Center, Thailand) (Kunon and Kaewplung, 2014) (n=38) **(mean ± sd)**	29.58±5.87	39.45±4.44	23.50±17.86
The mini dental implant system (MDIs, 3M ESPE, USA) (n=33) **(median ± sd)**	20±5.93	40±1.82	45.60±13.50

According to these three studies, the implant retained L-CD can improve the chewing ability no matter the type or size of the implant is. The results from three studies are in closed agreement, so we suggest this values of the PCAS and the PCA as the standard satisfied outcome for evaluate the other dental treatment outcome whenever treated with the implant retained complete denture in the lower arch.

This study also determined the variables affecting the masticatory efficiency before and after treatment with the MDIs retained L-CD. It was found that age and gender of the subjects did not affect the masticatory efficiency. These findings support the results of Millwood and Health's study (2000) and Kunon and Kaewplung's study (2014). Moreover, the results of the subjective and the objective chewing ability showed that it was not influenced by type of upper prosthesis. All subjects had opposing pairs of posterior teeth. Although the dentures of each subjects had different

in cusp angulation, the previous study found that there was no statistically significant difference in masticatory efficiency between 30, 20, and 0 degree artificial teeth as well as between porcelain and acrylic resin teeth (Nasr et al., 1967). This might be concluded that the treatment of MDIs can improve the masticatory efficiency in L-CD patients no matter what type of upper prosthesis they wear.

This study also focused on bone height and width of the mandible, we found that all classified bone groups showed the results in the same direction among 3 tests. There was no statistically significant difference in the mean value between high and low bone group as well as between wide and narrow bone group. This could be noticed that the bone height and width of residual mandible did not have an impact on the result of this study. All patients with high or low bone as well as with wide or narrow bone had improved the masticatory efficiency in their L-CD after MDIs treatment.

The MDIs used in this study had small diameter only 1.8-2.4 mm. These enable 14 severe bone resorption subjects in this study (42.42%) who had ridge width less than 5 mm and classified in the Narrow bone group to afford the treatment of MDIs retained their L-CD without any additional surgical procedure such as bone graft or ridge augmentation. While the conventional implant placement require adequate bone width, despite augmentation procedures should be used to solve these problems but these techniques are complex and can cause post-operative pain and discomfort for the patient as well as incurring additional costs and time consuming. The MDIs can be used in many cases to break of these limitations in severe resorption mandible and this study also reported 100% clinical success in 3 months follow-up after functional loading L-CD in all severe mandibular resorption patients.

The home care after treatment with any kind of dental implants was very necessary. The dentists should motivate the patients and their care giver about how to clean implants and denture daily by themselves. Routine recall and follow up to monitor the MDIs, the fit of the dentures and the health of soft tissue are important. The O-rings will also get loose or tear because of frequency removal of denture and will need to be replaced due to wear out. Therefore it is very important to inform the elderly patient for the long term care and expense before the placement of the implant.

The treatment of the MDIs retained L-CD in this study have been found not only improve denture stability and masticatory efficiency but also improve in patient satisfaction and overall outcomes. Their minimal invasive intervention appropriate in patients who may not be candidates for conventional surgical procedures of the standard size implant placement or ridge augmentation procedures. They possibly get some advantages from the flapless insertion technique and immediate loading denture on the MDIs. From this study, all of the subjects were in old age which the maximum age was 83 years old and most of them have at least one systemic disease. The least bone width of all subjects reported only 3.37 mm. All those cases in this study can achieve the MDIs treatment with favourable clinical outcome. Suggested indication for the MDIs treatment included the elderly or medically compromised patients with some systemic disease as previously described or the patients in ASA classification I and II, the patients with inadequate bone width (less than 5 mm but at least 3 mm) who avoid extensive bone augmentation procedures for the standard size implant placement. Moreover, the relatively inexpensive of the MDIs enables the dentists to offer this treatment option to more patients. The cost of the 4 MDIs treatment in this study was about 10,000 baht while those of the 2 standard size implant treatment was about 20,000 baht. However, the analysis of the available clinical data on the survival rate of the MDIs for definitive prosthodontic treatment in long-term study should be done to confirm the treatment success of the MDIs retained overdenture.

CHAPTER VI

CONCLUSIONS

From the results of this study, it can be concluded that

1. All elderly patients with conventional L-CD showed statically significance in the improvement of their masticatory efficiency after treatment with the MDIs retained L-CD by both subjective and objective evaluations.
2. The age, gender, general health status, type of upper prosthesis, mandibular bone height and width had no influence on the improvement of the masticatory efficiency after the MDIs placement in this study.
3. The treatment of the MDIs retained L-CD can be an alternative compromised treatment in the elderly to improve their denture stability and masticatory efficiency with favourable outcomes.

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APPENDIX

CONTENTS

LIST OF TABLES

LIST OF FIGURES

Page

The clinical consideration and case report of

the MDIs retained L-CD treatment

1. **The surgical and prosthetic procedures**

The surgical procedure were performed with both flapless and flap procedure (Table A). Eight subjects (24.24%) were performed with flapless procedure and the clinical examination shown complete healing within 2 weeks follow up without gingival inflammation in those subjects. Other 25 subjects (75.76%) remained in flap procedure because of the limitation in bone and soft tissue conditions. Sixteen subjects (48.48%) had knife-edge ridge and were considered to remove knife-edge bone before implant placement.

The prosthetic procedure with immediate loading L-CD was achieved in 5 subjects (15.15%) which had adequate primary stability of 35 Ncm for minimum toque of all 4 MDIs and reported average toque of 39.75 (rage from 35-50 Ncm) for 20 MDIs placement. The others 28 subjects (84.85%) were obtained delay loading L-CD within 4-6 months because the toque of at least 1 implant in each subject was lower than 35 Ncm (Table A)**.** However, all 28 delay loading cases remained using their lower denture during this bone healing period with transitional soft liner reline until be replaced with metal housing and o-ring pick-up with hard acrylic resin for permanent restoration.

Table A The surgical and prosthetic procedures

Procedures	Number of patients (%)
The surgical procedure	
Flapless	8 (24.24)
Flap opening	25 (75.76)
The prosthetic procedure	
Immediate loading L-CD	5 (15.15)
Delay loading L-CD	28 (84.85)

The treatment with narrow diameter of the MDIs is considered as the minimal invasive dentistry. The simplified placement technique involving insertion without flap procedure can be performed. From the report in Table A, eight subjects were received flapless surgical procedure, which resulted in decreased operation time, decrease traumatic and postoperative discomfort for the subjects and shortening the recovering period. While other 25 subjects remained in flap procedure because of the limitation

in bone due to severe mandibular resorption and soft tissue conditions. About 50% of all subject in this study had knife-edge ridge which was recommended in flap procedure to remove knife-edge bone before implant placement. The other cases had atrophy bone contour and uncertain position of bone ridge, flap elevation should be used to directly determine the amount of bone and proposed site for placement of implants may be beneficial to ensure accurate placement and angulation of implants.

The MDIs also enable immediate loading in adequate primary stability which minimum toque of 35 Ncm. In this study, 5 subjects were achieved immediate loading their L-CD lead to valuably increase patient's satisfaction by immediately improve their function of dentures. We noticed that the bone density of those immediate loading case had dense bone in D1 (1 case) and D2 (4 cases). Thus, the density of bone might be related to the toque of implant insertion, dense bone in D1 and D2 have potential to achieve high toque level with adequate primary stability of implant for immediate loading denture. However, the others 28 subjects were obtained delay loading L-CD whether in D1 or D2 bone density because the toque of at least 1 implant in each subject was lower than 35 Ncm. This might because the loose bone density in those site of the implant placement. Furthermore, over bone preparation can reduce primary stability of the implants. The self-tapping MDIs could be placed in under preparation site to achieve adequate torque for good primary stability. The drilling depth for the MDIs placement is based on the length of thread portion of implant, the thickness of soft tissue and the density of bone (Tiziano et al, 2011).

2. The survival and failure of the MDIs

Each subjects were received 4 MDIs in the mandible to retained their ill-fitting lower complete denture, so 132 MDIs were placed in all 33 subjects. In 3 months follow-up period after loading denture (about 7-9 months after MDIs placement in 28 delay loading cases and 3 months after MDIs placement in 5 immediate loading cases), there were 128 MDIs still stable with absence of pain, infection and mobility of the implants. This constitute an overall MDIs survival rate of 96.97%. The 4 MDIs in 4 cases (3.07%) failed to integrate with the alveolar bone, 3 cases lost the implants during 4 month healing phase before loading denture and 1 case lost the implant in 1 month after loading denture. However, all these 4 cases were replaced the new MDIs with fully osseointegrated in 3 months follow-up after loading denture and still participated in the study. The overall MDIs failure rate shown in this study was 3.03%. Several factors were thought to be influence in implant failure. In this study, the first failed MDI case obviously presented moderate plaque and calculus accommodation around the o-ball and neck of all MDIs with slightly peri-implantitis at 1 month follow-up visit, then 1 MDI was lost in 3 month follow-up. It was noted that in area of the lost MDI in this case had thin band of attached gingiva about 1.5 mm in width and no attached gingiva in labial side of the implant (Figure A), this might be the cause of MDI failure in this case. Previous study revealed that oral hygiene maintenance; peri-implantitis and implant location may contribute to implant failure (Porter and Von Fraunhofer, 2005). We suggested from the finding of this study that frequently motivation of daily cleansing of the denture and implants by the patients' themselves and routine follow-up by the dentist was very important for long-term implant success.

Figure A The position of the failed MDIs area #41 presented plaque accommodation at 1 month after implantation

The second failed MDI case reported lingual plate perforation in the surgical procedure and the position of this failed MDI was too lingually. The thin remaining ligual bone adjacent to the MDI might be associated with MDI failure in this case. Flanagan and Mascolo (2011) suggested that 1 mm of cortical thickness was required for appropriate osseous support in the MDIs for long-term success. The third MDI failed came from the case with the traumatic occlusion of upper and lower complete denture in eccentric movement along healing phase of the MDIs. Occlusal overloading denture was considered to be the primary risk factor in biomechanical complications of implant treatment, which commonly included marginal bone loss and implant failure. So, the prevention of denture overloading by carefully check the occlusion also helps to ensure the long-term stability of Implant retained prostheses (Hsu et al., 2012). The fourth case of the failure in this study came from the technical problem of the elderly patient in seating the denture in the place, we suggest to train for the skill in put in and take off the denture from the MDIs as the overforce may dislodge the implant easily especially in the elderly.

The minimum attached gingiva width of at least 2 mm was required to prevent peri-implant mucositis and marginal bone resorption (Berglundh and Lindhe, 1996). In this study, there was one case lacking of attached gingiva and were performed mucosal graft procedure in area of the MDIs placement, then adequate 2 mm of attached gingiva had been achieved with satisfied outcome and healthy gingiva without inflammation around the MDIs after 10 month follow-up of the MDIs placement.

3. **The marginal bone loss around the MDIs**

The marginal bone loss around each MDI in the individuals also be investigated by panoramic radiography analyzing with the INFINITT program. The marginal bone loss at 3 months after loading L-CD compared with the initial bone within 2 weeks after MDIs placement were analyzed. The measured distance of the true bone level from the reference point were calculated to correct for image distortion of panoramic radiography using the following formular:

$$\text{True bone level} = \frac{\text{True implant length} \times \text{Measured bone level}}{\text{Measured implant length}}$$

.   The marginal bone loss in the 132 MDIs of all 33 subjects after 3 months loading L-CD were ranged from 0.02-2.11 mm with average 0.63±0.46 mm. Independent t-test demonstrated that there were no significant differences in marginal bone loss between High and Low bone group, Wide and Narrow bone group, immediate loading and delay loading L-CD and between ASA classification I and II patients (P>.05). One-way analysis of variance (ANOVA) also found that there were no significant differences in marginal bone loss between any type of upper prosthesis, any kind of systemic disease and between D1, D2 and D3 bone density (P>.05) as shown in Table B.

However, the gold standard providing the best resolution for radiographic evaluation of the marginal bone loss around implants were intraoral periapical radiographs with standard mounted film holders (Ma, 2010). While some study suggested panoramic radiographs as a reliable radiographic assessment because the standardized projection in the vertical plane was suitable for vertical measurements of marginal bone loss (Geckili, Mumcu and Bilhan, 2012). Moreover, the previous study found that the panoramic radiographs were comparable with intraoral periapical radiographs and can be the alternative evaluation for analyzing peri-implant marginal bone loss (Zechner et al., 2003). Nevertheless, the distortion of the image by superimposition of the vertebral column over the anterior maxilla and mandible were regularly occurred (Ma, 2010). Therefore, we recommended intraoral periapical radiograph for assessment the marginal bone loss around the implants in the further studies.

Table B The mean and standard deviation of the marginal bone loss around the MDIs in 33 subjects

Characteristics	N (%)	Marginal bone loss (mm)
Total subjects	33 (100)	0.63±0.46
Type of loading L-CD		
Delay loading L-CD	28 (84.85)	0.68±0.48
Immediate loading L-CD	5 (15.15)	0.36±0.29
Type of upper prosthesis		
Complete denture	25 (75.76)	0.56±0.47
Removable partial denture	7 (21.21)	0.79±0.33
Fix prosthesis	1 (3.03)	1.36±0.00
Modified bone height		
High bone group	20 (60.60)	0.73±0.49
Low bone group	13 (39.40)	0.48±0.40
Modified bone width		
Wide bone group	19 (57.58)	0.58±0.43
Narrow bone group	14 (42.42)	0.72±0.51
Bone density		
D1	3 (9.09)	0.90±0.14
D2	14 (42.42)	0.45±0.43
D3	16 (48.49)	0.75±0.47
D4	0	-
ASA Classification		
ASA I	12 (36.36)	1.38±0.95
ASA II	21 (63.64)	0.55±0.46
Systemic disease		
hypertension	13 (39.40)	0.50±0.37
hyperlipidemia	6 (18.18)	0.71±0.45
diabetes mellitus	5 (15.15)	0.28±0.22
heart disease	2 (6.06)	0.34±0.35
osteoarthritis	1 (3.03)	1.46±0.00
liver disease	1 (3.03)	1.21±0.00
anemia	1 (3.03)	0.09±0.00
SLE	1 (3.03)	0.09±0.00

All of the 4 MDIs failure in this study were in delay loading cases and statistical analysis showed no significant difference in the marginal bone loss between immediate loading and delay loading group. The results from this study indicated that the immediate loading denture was not be the risk factor of the MDIs failure or the marginal bone loss when appropriate primary stability with minimal toque of 35 NCm of the MDIs has been performed. The average marginal bone loss in D2 bone density (0.45±0.43 mm) was lower than in D3 (0.75±0.47 mm) and D1 (0.90±0.14 mm) bone density, respectively. Therefore D2 bone density could be appropriated for the MDIs placement with present the least marginal bone loss compared with D1 and D3 bone density. However, statistical analysis also showed no significant difference of the marginal bone loss between all bone density (P>.05). The radiographic results also showed that there was no significant difference in the marginal bone loss within 3 months after loading L-CD in any factors difference. Anyway, the long term observation is strongly recommended.

In 1 month follow-up after loading L-CD, we found progressive marginal bone loss of the MDIs in two cases. The first case has average 2.91 mm of marginal bone loss in the MDIs area #31 and #41 (Figure B and C), while the second case has average 2.06 mm of marginal bone loss in the MDI area #33. We noticed that these two cases remained upper natural anterior teeth which can bring traumatic occlusion to the opposite implants when they remove their upper and lower denture at night. Thus, we instructed the patients to wear their upper removable denture and lower complete denture at night to prevent the mechanical overload on the MDIs. Then, in 2 months later (at 3 months after loading L-CD), the marginal bone in those area gained for average 2.78 mm in the first case (Figure D) and 1.94 mm the second case. This could be suggested that the marginal bone loss is reversible process if the offending force were eliminated and this finding was agreed with those clinical finding of Tawil (2008). Therefore, in partial edentulous upper arch remaining some natural teeth which occlude to the MDIs, we recommended to suggest the patients wear their upper and lower denture at night to prevent traumatic occlusion to implants.

Figure B The Radiographic examination in 3 days after MDIs placement
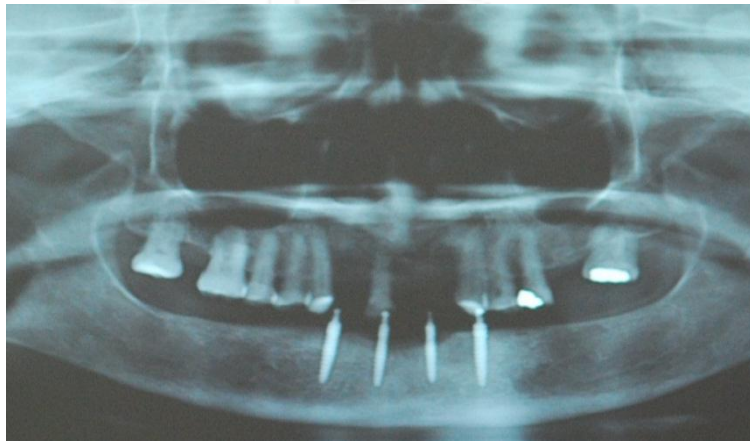
Figure C The Radiographic examination in 1 month after loading L-CD,
noticed the progressive marginal bone loss on the MDIs area #31 and #41

Figure D The Radiographic examination in 2 months later,
after the patients wear their upper removable denture and
lower complete denture at night

4. The surgical and prosthesis complications

One MDI in area #43 fractured at ball attachment during the placement process at toque nearly 60 Ncm. The new MDIs were placed 5 mm mesially to the fractured one. The fractured implant with residual neck portion was left in alveolar bone by relieve denture base to prevent any forces directly applied in the residual fixgure. After 7 months post-insertion follow-up period, the fractured one was remained stable with only 0.65 mm average bone loss (Figure E1, E2). The only 1 fractured MDI from all 137 MDIs placement in this study (including the 4 lost MDIs as previously described) presented 0.73% failure rate of fracture. We also noted that the bone in area of the MDI fracture were classified in D1 bone density, therefore, careful preparation of the MDs receptor site in dense bone could be considered by increasing lenght of drill appoximate to implant length combined with using wider-diameter of surgical drill and/or using round bur to enlarge dense cortical bone in coronal part. Incidence of the MDIs fracture has been reported by Bulard and Vance (2005). The author reported failure rate of 0.4% in 556 fixtures due to fracture during MDIs tightening. Previous evidence suggested that insertion torque of 50 Ncm may be as maximum torque for the MDIs placement to avoid risk of MDIs fracture (Bulard and Vance, 2005; Flanagan and Mascolo, 2011).
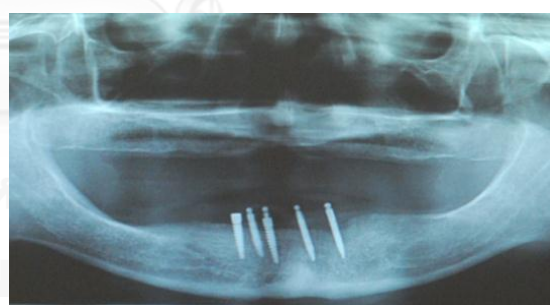
Figure E1   Figure E2

Figure E The clinical and radiographic examination of the MDI fracture case after
7 months post-insertion follow-up period.
E1: clinical aspect, E2: radiographic aspect

Another case was reported surgical drill fracture in alveolar bone during the drilling process. The residual surgical drill with 3 mm in length and 1.1 mm in diameter was left. The MDIs placed about 1 mm mesially from the residual drill reported only

0.16 mm bone loss in 7 months post-insertion follow-up visit (Figure F). We noted that this case also had D1 bone density, so we suggested that in area of dense bone could be performed with cautiously surgical preparation.
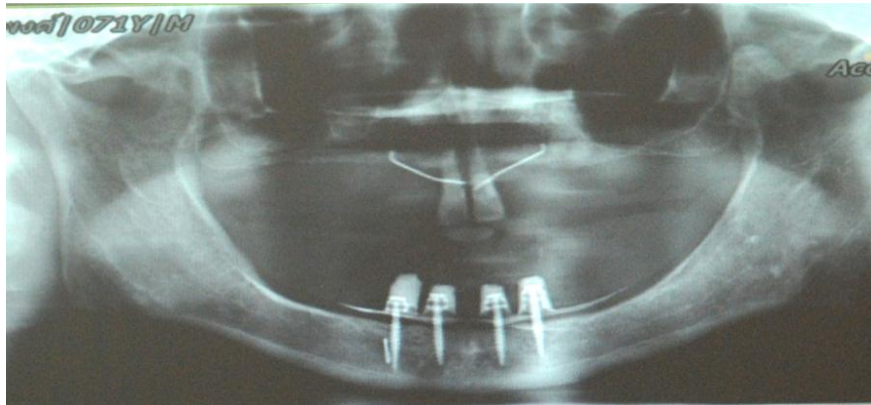
. Figure F The radiographic examination of the surgical drill fracture case
in 7 months post-insertion follow-up visit

Fracture of the acrylic resin denture base is one of the most common complications in overdentures (Gonda et al, 2010). In this study, the incidence of fractures in lower denture base recorded in 4 cases (12.12%) after functional loading of overdenture on the MDIs. Fracture area in all those cases were adjacent to the metal housing, It might be because the denture base around metal housing area were too thin according to space limitation of the denture base on ball attachment of the implants. Therefore, awareness of implant position and adequate remaining space for denture base were important. According to the manufacturer's instructions (3M ESPE, USA), the MDIs should be at least 5 mm from each other for sufficient bone. Previous study suggested the thickness between 1.5 to 3 mm for acrylic resin base of complete denture (Reeson and Jepson, 1999). As the metal housings used in the MDIs system are 4.3-4.75 mm in diameter, thus we suggested at least 6 mm spacing from the center of the one O-ball to the center of the next O-ball to gain adequate space for minimum thickness of acrylic resin base (1.5mm) between two metal housings. Moreover, the interarch clearance as a minimum of 8 mm from the mucosal surface to the opposing occlusal plane is necessary to provide sufficient space to accommodate the O-ball head, metal housing, acrylic denture and prosthetic tooth (English and Bohle, 2003)

5. Effect on the upper prosthesis

Twelve of all 33 subjects (36.36%) complained a decreasing of upper denture stability within 3 months after treatment with the MDIs retained L-CDs, then their upper denture base had been relined. Nine of them (75%) wear upper complete dentuers and the other three of them (25%) wear upper partial dentures. Some studies found that the use of implant retained lower denture combined with conventional upper denture can lead to increase anterior occlusal force and perceive loosening of the upper denture as similar to the effects of combination syndrome (Lechner and Mammen, 1996; Thiel, Evans and Burnett, 1996). However, the 10 years follow up studies reported that subjects treated with implant-retained L-CDs didn't have more residual ridge resorption in the anterior maxilla compared with conventional complete denture subjects (Tymstra et al, 2011). The more stable occlusion of denture provides a better distribution of occlusal forces and prevent the maxillary anterior ridge resorption (Thiel, et al., 1996). We suggested that the long term routine recall should be considered to monitor the dentures and the tissues. The Occlusal evaluation and adjustment with relines or rebases of denture base are needed to maintain proper occlusal stabilization of the dentures.

6. The clinical consideration for the MDIs retained L-CD treatment

As the incidence of surgical and prosthesis complications reported in this study, proper diagnosis and treatment planning are major factors to achieve the predictable outcomes. Careful selection of the patients treat with the MDIs follow with the guideline of the subject selection of this study also be very essential. This study suggested that the Implant placement sites must be considerably selected which offer adequate in quantity and quality of bone to ensure the properly placed and well osseointegrate of the implants. By the result of the marginal bone loss, D2 bone density was appropriate for the MDIs placement with presented less bone loss than D1 and D3. Radiographic examination is important whether or not a flap is raised. Cone beam computed tomography could help to achieve the important data for MDIs treatment plan including the amount of bone height (at least 12 mm) and bone width (at least 3 mm) adequate in the implant site, the position of mental foramen to be avoid at least 7 mm from the most distal implant position, the density of bone which D4 bone type was contraindicated for MDIs placement, the appearance of knife-edge bone which

should be remove before MDIs placement. Carefully preparation to avoid implant and surgical drill fracture could be concerned especially in D1 bone density. Moreover, surgical stent is necessary to identify the implants' position and angulation. At least 6 mm between the center of the O-ball head and minimum thickness of 1.5 mm of acrylic resin could be gained to prevent fracture of the denture base. The MDIs position should not be either too labial or lingual in order to prevent bone perforation and preserve sufficient bone at least 1 mm around the implants. The MDIs placement procedure required professional surgical skill due to the limitation of the implant's insertion area. Adequate attached gingiva at least 2 mm were required to prevent peri-implantitis and peri-implant mucositis. After implantation, the occlusal evaluation of upper and lower denture is very important to prevent occlusal overload on the implants for long term stabilization.

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The self-reported questionnaire

แบบบันทึกข้อมูลสัมภาษณ์ผู้ป่วย

No.

....

<u>ส่วนที่ 1</u> ข้อมูลพื้นฐาน

1. เพศ

☐ ชาย ☐ หญิง

2. อายุ

อายุ .... ปี .... เดือน

3. ประเภทของฟันคู่สบด้านบน

☐ ฟันเทียมบางส่วนติดแน่น

☐ ฟันเทียมบางส่วนถอดได้

☐ ฟันเทียมถอดได้ทั้งปาก

☐ ฟันธรรมชาติ

4. ระยะเวลาในการใช้งานฟันเทียมทั้งปากล่างถึงปัจจุบัน

ระยะเวลา................ ปี .... เดือน

5. ระยะเวลาในการใส่ฟันเทียมทั้งปากล่างใน 1 วัน

ระยะเวลา................ ชั่วโมง

ส่วนที่ 2 ข้อมูลส่วนอาหาร

    1. อาหารที่สามารถรับประทานได้ เคี้ยวได้ละเอียดโดยไม่มีอาการใดๆ

....

    2. อาหารที่ไม่สามารถรับประทานได้หรือรับประทานแล้วมีอาการเจ็บปวด

....

<u>ส่วนที่ 3</u> ข้อมูลความสามารถในการบดเคี้ยวอาหาร

<u>คำชี้แจง</u> กรุณาตอบแบบสอบถามโดยทำเครื่องหมายกรุณาทำเครื่องหมาย◯ ที่ระดับตัวเลขที่
ตรงกับสภาพความเป็นจริงของท่านหรือความน่าจะเป็นตามความคิดเห็นของท่านเมื่อรับประทาน
อาหารดังต่อไปนี้

0   หมายถึง **ไม่สามารถเคี้ยวอาหารได้เลย** และ/หรือมีอาการ**เจ็บปวด**บริเวณเนื้อเยื่อที่
         รองรับฟันเทียม**มาก**

1   หมายถึง สามารถเคี้ยวอาหารได้**ละเอียดเล็กน้อย** และ/หรือมีอาการ**เจ็บปวด**บริเวณ
         เนื้อเยื่อที่รองรับฟันเทียม**ปานกลาง**

2   หมายถึง สามารถเคี้ยวได้อาหารได้**ละเอียดปานกลาง** และ/หรือมีอาการ**เจ็บปวด**
         บริเวณเนื้อเยื่อที่รองรับฟันเทียม**น้อย**

3   หมายถึง สามารถเคี้ยวได้อาหารได้**ละเอียดมาก** โดยไม่มีอาการใดๆ

1. ข้าวต้ม

ไม่ได้	เล็กน้อย	ปานกลาง	มาก
0	1	2	3

2. ต้มจับฉ่าย

ไม่ได้ **เล็กน้อย** **ปานกลาง** **มาก**
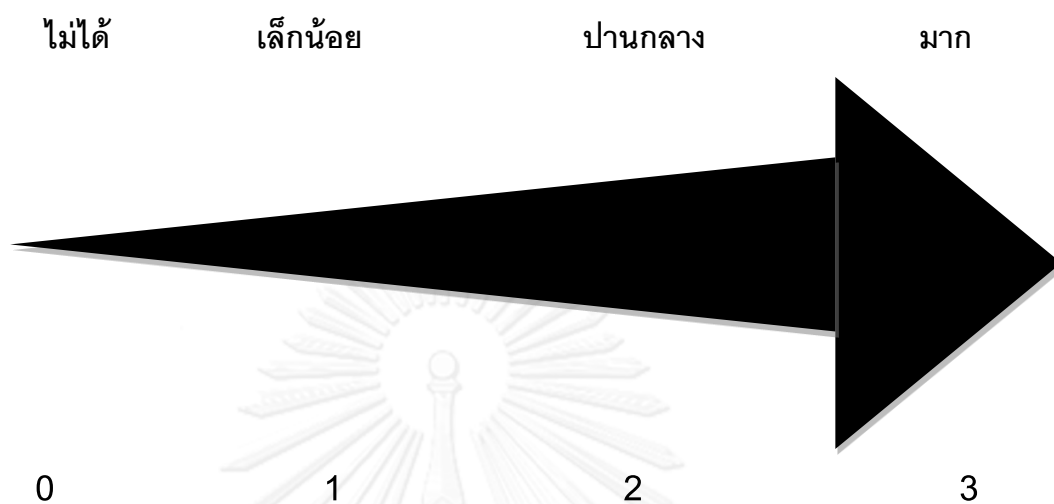
0   1   2   3

3. แกงจืดผักกาดขาว

ไม่ได้	เล็กน้อย	ปานกลาง	มาก

0	1	2	3

4. ข้าวสวย(หอมมะลิ)

| ไม่ได้ | เล็กน้อย | ปานกลาง | มาก |

| 0 | 1 | 2 | 3 |

5. ก๋วยเตี๋ยวเส้นเล็ก
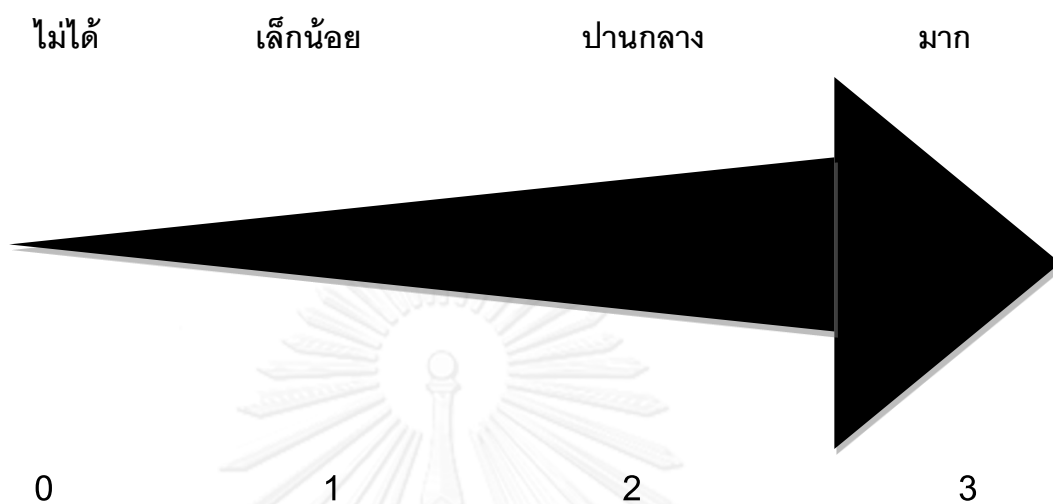
ไม่ได้	เล็กน้อย	ปานกลาง	มาก
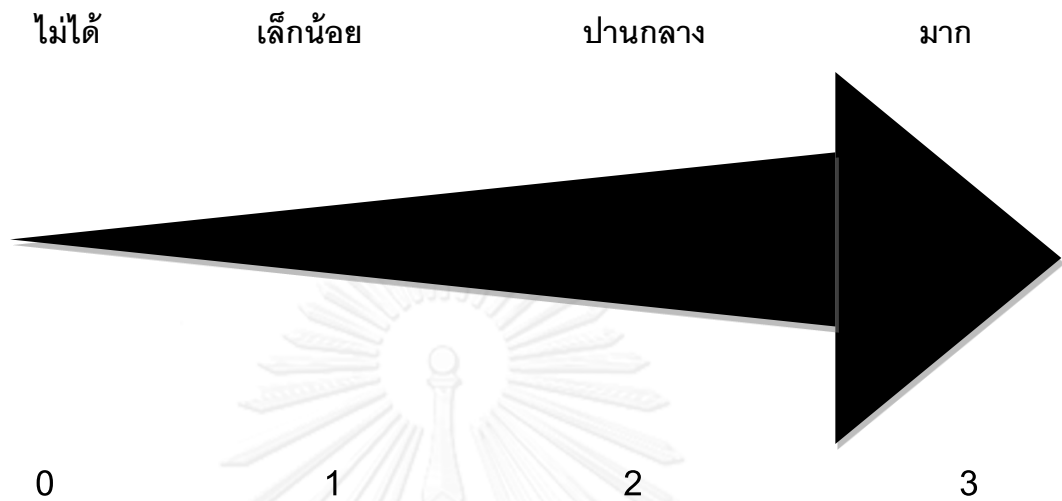
0	1	2	3

6. ไข่เจียว

| ไม่ได้ | เล็กน้อย | ปานกลาง | มาก |

| 0 | 1 | 2 | 3 |

7. ปลานึ่ง

ไม่ได้　　　**เล็กน้อย**　　　**ปานกลาง**　　　**มาก**
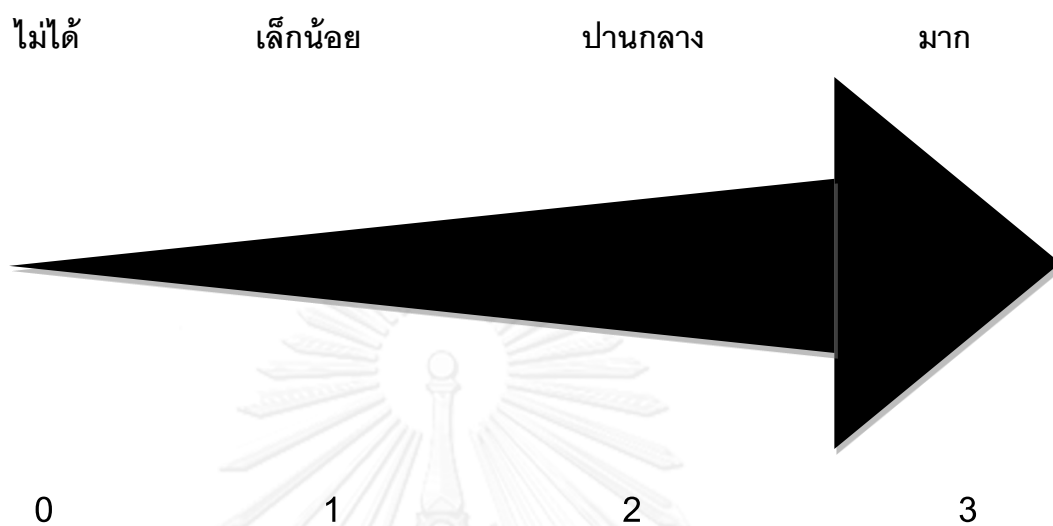
0　　　　　1　　　　　2　　　　　3

8. แกงส้มผักรวม

ไม่ได้   เล็กน้อย   ปานกลาง   มาก

0   1   2   3

9. กล้วย

ไม่ได้   **เล็กน้อย**   **ปานกลาง**   **มาก**

0   1   2   3

10. ปลาทอด

ไม่ได้	เล็กน้อย	ปานกลาง	มาก
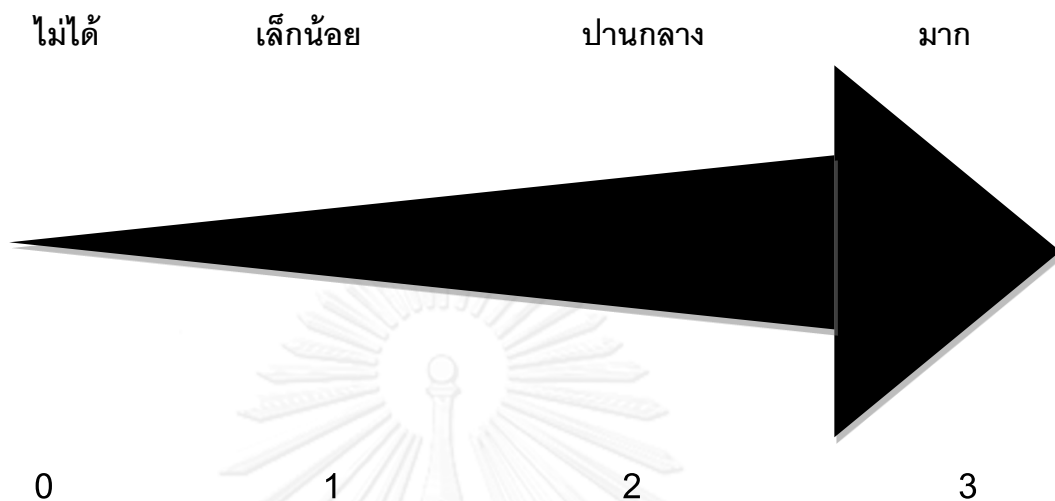
0	1	2	3

11. ส้ม

ไม่ได้   **เล็กน้อย**   **ปานกลาง**   **มาก**

0   1   2   3

12. ฝรั่งดิบ
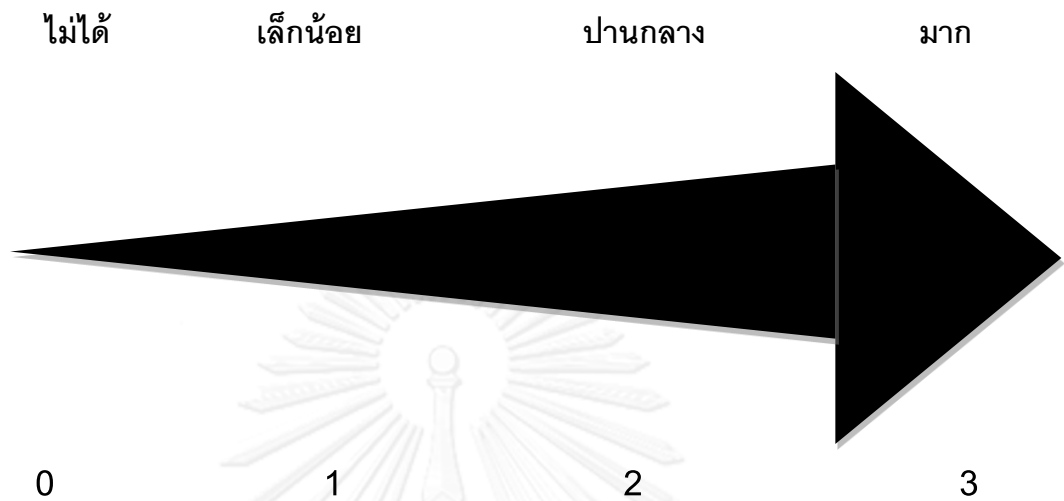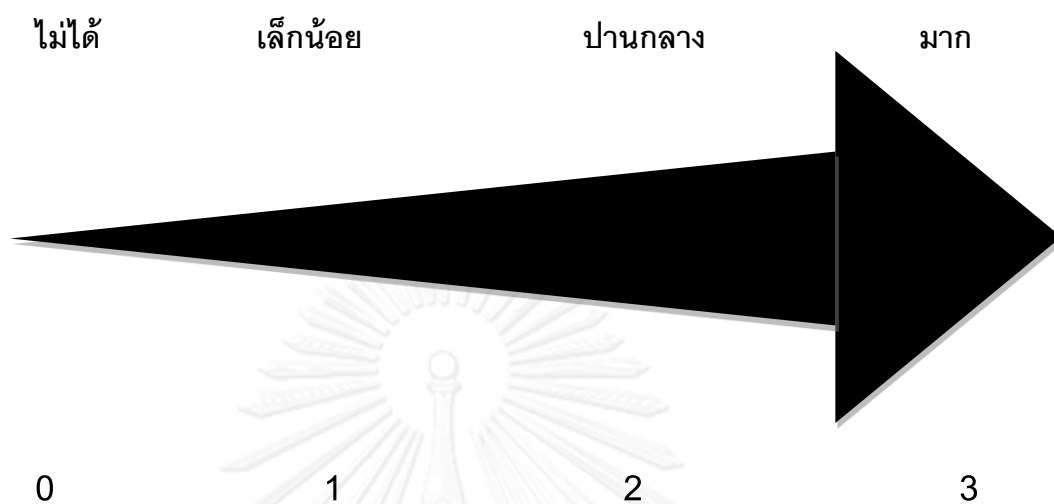
ไม่ได้   **เล็กน้อย**   **ปานกลาง**   **มาก**

0   1   2   3

13. หมูทอด(เป็นชิ้น)

| ไม่ได้ | เล็กน้อย | ปานกลาง | มาก |

0   1   2   3

14. ผัดผักคะน้า

ไม่ได้	เล็กน้อย	ปานกลาง	มาก

| 0 | 1 | 2 | 3 |

The statistical analysis

Descriptive statistical analysis in the PCAS, the PCA and the percentage change of PCAS
and the percentage change of PCA of all subjects

Descriptive Statistics

	N	Minimum	Maximum	Mean	Std. Deviation
PCAS@T1	33	12.00	31.00	21.2424	5.92679
PCAS@T2	33	36.00	42.00	39.8788	2.02728
PCAS@T3	33	36.00	42.00	40.3939	1.81899
ChangePCAS	33	21.43	71.43	45.5988	13.49619
PCA@T1	33	11.70	25.16	19.2230	3.74788
PCA@T2	33	21.69	39.14	29.6136	4.26900
PCA@T3	33	23.15	40.15	31.0197	3.70080
ChangePCA	33	7.54	19.74	11.7967	2.89681
Valid N (listwise)	33				

Normality Test in the PCAS, the PCA, the percentage change of PCAS and the
percentage change of PCA of all subjects

One-Sample Kolmogorov-Smirnov Test

		PCAS@T1	PCAS@T2	PCAS@T3	ChangePCAS	PCA@T1	PCA@T2	PCA@T3	ChangePCA
N		33	33	33	33	33	33	33	33
Normal Parameters[a,b]	Mean	21.2424	39.8788	40.3939	45.5988	19.2230	29.6136	31.0197	11.7967
	Std. Deviation	5.92679	2.02728	1.81899	13.49619	3.74788	4.26900	3.70080	2.89681
Most Extreme Differences	Absolute	.115	.191	.237	.096	.165	.141	.116	.102
	Positive	.115	.148	.189	.096	.088	.094	.116	.102
	Negative	-.103	-.191	-.237	-.086	-.165	-.141	-.111	-.078
Kolmogorov-Smirnov Z		.660	1.094	1.359	.549	.949	.811	.665	.585
Asymp. Sig. (2-tailed)		.777	.182	.050	.924	.328	.527	.769	.883

a. Test distribution is Normal.

b. Calculated from data.

Statistical analysis of the PCAS of all subjects

Friedman test

Test Statistics[a]

N	33
Chi-Square	61.357
df	2
Asymp. Sig.	.000

a. Friedman Test

Wilcoxon Signed Ranks Test

Ranks

		N	Mean Rank	Sum of Ranks
PCAS@T2 - PCAS@T1	Negative Ranks	0[a]	.00	.00
	Positive Ranks	33[b]	17.00	561.00
	Ties	0[c]		
	Total	33		
PCAS@T3 - PCAS@T1	Negative Ranks	0[d]	.00	.00
	Positive Ranks	33[e]	17.00	561.00
	Ties	0[f]		
	Total	33		
PCAS@T3 - PCAS@T2	Negative Ranks	0[g]	.00	.00
	Positive Ranks	13[h]	7.00	91.00
	Ties	20[i]		
	Total	33		

a. PCAS@T2 < PCAS@T1
b. PCAS@T2 > PCAS@T1
c. PCAS@T2 = PCAS@T1
d. PCAS@T3 < PCAS@T1
e. PCAS@T3 > PCAS@T1
f. PCAS@T3 = PCAS@T1
g. PCAS@T3 < PCAS@T2
h. PCAS@T3 > PCAS@T2
i. PCAS@T3 = PCAS@T2

Test Statistics[b]

	PCAS@T2 - PCAS@T1	PCAS@T3 - PCAS@T1	PCAS@T3 - PCAS@T2
Z	-5.013[a]	-5.014[a]	-3.418[a]
Asymp. Sig. (2-tailed)	.000	.000	.001

a. Based on negative ranks.
b. Wilcoxon Signed Ranks Test

Statistical analysis of the PCA of all subjects
One Way Repeated Measures Analysis of Variance

Multivariate Tests[b]

Effect		Value	F	Hypothesis df	Error df	Sig.
test	Pillai's Trace	.946	272.114[a]	2.000	31.000	.000
	Wilks' Lambda	.054	272.114[a]	2.000	31.000	.000
	Hotelling's Trace	17.556	272.114[a]	2.000	31.000	.000
	Roy's Largest Root	17.556	272.114[a]	2.000	31.000	.000

a. Exact statistic

b. Design: Intercept
 Within Subjects Design: test

Mauchly's Test of Sphericity[b]

Measure:MEASURE_1

Within Subjects Effect	Mauchly's W	Approx. Chi-Square	df	Sig.	Epsilon[a]		
					Greenhouse-Geisser	Huynh-Feldt	Lower-bound
test	.933	2.156	2	.340	.937	.993	.500

Tests the null hypothesis that the error covariance matrix of the orthonormalized transformed dependent variables is proportional to an identity matrix.

a. May be used to adjust the degrees of freedom for the averaged tests of significance. Corrected tests are displayed in the Tests of Within-Subjects Effects table.

b. Design: Intercept
 Within Subjects Design: test

Tests of Within-Subjects Effects

Measure:MEASURE_1

Source		Type III Sum of Squares	df	Mean Square	F	Sig.
test	Sphericity Assumed	2740.133	2	1370.067	286.890	.000
	Greenhouse-Geisser	2740.133	1.874	1462.101	286.890	.000
	Huynh-Feldt	2740.133	1.987	1379.367	286.890	.000
	Lower-bound	2740.133	1.000	2740.133	286.890	.000
Error(test)	Sphericity Assumed	305.638	64	4.776		
	Greenhouse-Geisser	305.638	59.971	5.096		
	Huynh-Feldt	305.638	63.568	4.808		
	Lower-bound	305.638	32.000	9.551		

Tests of Within-Subjects Contrasts

Measure:MEASURE_1

Source	test	Type III Sum of Squares	df	Mean Square	F	Sig.
test	Linear	2296.162	1	2296.162	547.259	.000
	Quadratic	443.971	1	443.971	82.901	.000
Error(test)	Linear	134.264	32	4.196		
	Quadratic	171.374	32	5.355		

Tests of Between-Subjects Effects

Measure:MEASURE_1

Transformed Variable:Average

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Intercept	70147.427	1	70147.427	1926.297	.000
Error	1165.302	32	36.416		

Estimated Marginal Means
test

Estimates

Measure:MEASURE_1

test	Mean	Std. Error	95% Confidence Interval	
			Lower Bound	Upper Bound
1	19.223	.652	17.894	20.552
2	29.614	.743	28.100	31.127
3	31.020	.644	29.707	32.332

Pairwise Comparisons

Measure:MEASURE_1

(I) test	(J) test	Mean Difference (I-J)	Std. Error	Sig.[a]	95% Confidence Interval for Difference[a]	
					Lower Bound	Upper Bound
1	2	-10.391[*]	.604	.000	-11.916	-8.866
	3	-11.797[*]	.504	.000	-13.071	-10.523
2	1	10.391[*]	.604	.000	8.866	11.916
	3	-1.406[*]	.500	.025	-2.668	-.144
3	1	11.797[*]	.504	.000	10.523	13.071
	2	1.406[*]	.500	.025	.144	2.668

Based on estimated marginal means

*. The mean difference is significant at the .05 level.

a. Adjustment for multiple comparisons: Bonferroni.

Multivariate Tests

	Value	F	Hypothesis df	Error df	Sig.
Pillai's trace	.946	272.114[a]	2.000	31.000	.000
Wilks' lambda	.054	272.114[a]	2.000	31.000	.000
Hotelling's trace	17.556	272.114[a]	2.000	31.000	.000
Roy's largest root	17.556	272.114[a]	2.000	31.000	.000

Each F tests the multivariate effect of test. These tests are based on the linearly independent
pairwise comparisons among the estimated marginal means.

a. Exact statistic

Statistical analysis of the PCAS (effected by age)

Kruskal-Wallis Test

Ranks

	age	N	Mean Rank
PCAS@T1	50-59	1	21.00
	60-69	16	15.72
	70-79	15	17.57
	80-89	1	25.00
	Total	33	
PCAS@T2	50-59	1	10.00
	60-69	16	18.09
	70-79	15	16.43
	80-89	1	15.00
	Total	33	
PCAS@T3	50-59	1	18.00
	60-69	16	18.66
	70-79	15	15.10
	80-89	1	18.00
	Total	33	

Test Statistics[a,b]

	PCAS@T1	PCAS@T2	PCAS@T3
Chi-Square	1.192	.854	1.146
df	3	3	3
Asymp. Sig.	.755	.837	.766

a. Kruskal Wallis Test

b. Grouping Variable: age

Statistical analysis of the PCA, the percentage change of the PCA
and the percentage change of the PCAS (effected by age)

ANOVA

		Sum of Squares	df	Mean Square	F	Sig.
PCA@T1	Between Groups	25.489	3	8.496	.581	.632
	Within Groups	424.003	29	14.621		
	Total	449.492	32			
PCA@T2	Between Groups	27.061	3	9.020	.370	.775
	Within Groups	706.216	29	24.352		
	Total	733.278	32			
PCA@T3	Between Groups	7.956	3	2.652	.201	.895
	Within Groups	382.870	29	13.202		
	Total	390.826	32			
ChangePCA	Between Groups	16.314	3	5.438	.664	.581
	Within Groups	237.596	29	8.193		
	Total	253.910	32			
ChangePCAS	Between Groups	285.425	3	95.142	.484	.696
	Within Groups	5698.152	29	196.488		
	Total	5983.577	32			

Statistical analysis of the PCAS (effected by gender)

Mann-Whitney Test

Ranks

	gender	N	Mean Rank	Sum of Ranks
PCAS@T1	male	10	17.05	170.50
	female	23	16.98	390.50
	Total	33		
PCAS@T2	male	10	16.05	160.50
	female	23	17.41	400.50
	Total	33		
PCAS@T3	male	10	16.35	163.50
	female	23	17.28	397.50
	Total	33		

Test Statistics[b]

	PCAS@T1	PCAS@T2	PCAS@T3
Mann-Whitney U	114.500	105.500	108.500
Wilcoxon W	390.500	160.500	163.500
Z	-.020	-.380	-.265
Asymp. Sig. (2-tailed)	.984	.704	.791
Exact Sig. [2*(1-tailed Sig.)]	.985[a]	.714[a]	.802[a]

a. Not corrected for ties.

b. Grouping Variable: gender

Statistical analysis of the PCA, the percentage change of the PCA and the percentage change of the PCAS (effected by gender)

Independent Samples Test

		Levene's Test for Equality of Variances		t-test for Equality of Means					95% Confidence Interval of the Difference	
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
ChangePCAS	Equal variances assumed	.117	.735	.052	31	.959	.26878	5.16658	-10.26853	10.80610
	Equal variances not assumed			.049	15.207	.961	.26878	5.46951	-11.37543	11.91299
PCA@T1	Equal variances assumed	.154	.698	-.798	31	.431	-1.11817	1.40169	-3.97695	1.74060
	Equal variances not assumed			-.833	19.026	.415	-1.11817	1.34280	-3.92842	1.69207
PCA@T2	Equal variances assumed	2.029	.164	-1.733	31	.093	-2.85283	1.64614	-6.21014	.50449
	Equal variances not assumed			-2.181	29.460	.037	-2.85283	1.30829	-5.52677	-.17888
PCA@T3	Equal variances assumed	4.279	.047	-1.593	31	.121	-2.21222	1.38897	-5.04504	.62061
	Equal variances not assumed			-2.094	30.878	.045	-2.21222	1.05663	-4.36757	-.05687
ChangePCA	Equal variances assumed	.054	.817	-.921	31	.364	-1.09404	1.18801	-3.51700	1.32891
	Equal variances not assumed			-.905	16.531	.379	-1.09404	1.20916	-3.65067	1.46258

Statistical analysis of the PCAS (effected by ASA Classification)

Mann-Whitney Test

Ranks

	ASA	N	Mean Rank	Sum of Ranks
PCAS@T1	ASA I	12	15.75	189.00
	ASA II	21	17.71	372.00
	Total	33		
PCAS@T2	ASA I	12	17.83	214.00
	ASA II	21	16.52	347.00
	Total	33		
PCAS@T3	ASA I	12	18.25	219.00
	ASA II	21	16.29	342.00
	Total	33		

Test Statistics[b]

	PCAS@T1	PCAS@T2	PCAS@T3
Mann-Whitney U	111.000	116.000	111.000
Wilcoxon W	189.000	347.000	342.000
Z	-.562	-.382	-.581
Asymp. Sig. (2-tailed)	.574	.703	.561
Exact Sig. [2*(1-tailed Sig.)]	.593[a]	.726[a]	.593[a]

a. Not corrected for ties.

b. Grouping Variable: ASA

Statistical analysis of the PCA, the percentage change of the PCA
and the percentage change of the PCAS (effected by ASA Classification)

Independent Samples Test

		Levene's Test for Equality of Variances		t-test for Equality of Means							
										95% Confidence Interval of the Difference	
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
ChangePCAS	Equal variances assumed	.012	.912	.708	31	.484	3.48524	4.92242	-6.55410	13.52457
	Equal variances not assumed			.718	23.983	.480	3.48524	4.85576	-6.53693	13.50741
PCA@T1	Equal variances assumed	3.293	.079	.000	31	1.000	-.00083	1.37796	-2.81120	2.80954
	Equal variances not assumed			.000	30.746	.999	-.00083	1.21340	-2.47641	2.47474
PCA@T2	Equal variances assumed	.317	.577	.593	31	.558	.92536	1.56073	-2.25778	4.10849
	Equal variances not assumed			.615	25.615	.544	.92536	1.50487	-2.17021	4.02092
PCA@T3	Equal variances assumed	.012	.915	.440	31	.663	.59631	1.35643	-2.17014	3.36276
	Equal variances not assumed			.425	20.841	.675	.59631	1.40197	-2.32061	3.51323
ChangePCA	Equal variances assumed	.034	.856	.564	31	.577	.59714	1.05964	-1.56400	2.75829
	Equal variances not assumed			.539	20.128	.596	.59714	1.10794	-1.71305	2.90733

Statistical analysis of the PCAS (effected by systemic disease)

Kruskal-Wallis Test

Ranks

	Disease	N	Mean Rank
PCAS@T1	Hypertension	13	15.73
	Hyperlipidemia	6	18.00
	DM	5	13.50
	HeartDisease	2	26.75
	Osteoarthritis	1	2.00
	LiverDisease	1	13.50
	Anemia	1	8.00
	SLE	1	8.00
	Total	30	
PCAS@T2	Hypertension	13	17.73
	Hyperlipidemia	6	14.92
	DM	5	15.60
	HeartDisease	2	16.25
	Osteoarthritis	1	15.00
	LiverDisease	1	4.50
	Anemia	1	7.50
	SLE	1	7.50
	Total	30	
PCAS@T3	Hypertension	13	18.23
	Hyperlipidemia	6	14.25
	DM	5	15.70
	HeartDisease	2	15.50
	Osteoarthritis	1	19.50
	LiverDisease	1	2.50
	Anemia	1	5.50
	SLE	1	5.50
	Total	30	

Test Statistics[a,b]

	PCAS@T1	PCAS@T2	PCAS@T3
Chi-Square	8.005	4.255	6.692
df	7	7	7
Asymp. Sig.	.332	.750	.462

a. Kruskal Wallis Test

b. Grouping Variable: Disease

Statistical analysis of the PCA, the percentage change of the PCA
and the percentage change of the PCAS (effected by systemic disease)

ANOVA

		Sum of Squares	df	Mean Square	F	Sig.
ChangePCAS	Between Groups	1471.953	7	210.279	1.066	.417
	Within Groups	4340.183	22	197.281		
	Total	5812.135	29			
PCA@T1	Between Groups	115.644	7	16.521	.841	.566
	Within Groups	432.422	22	19.656		
	Total	548.066	29			
PCA@T2	Between Groups	139.929	7	19.990	.874	.542
	Within Groups	503.250	22	22.875		
	Total	643.179	29			
PCA@T3	Between Groups	100.518	7	14.360	1.286	.303
	Within Groups	245.673	22	11.167		
	Total	346.191	29			
ChangePCA	Between Groups	41.966	7	5.995	.707	.666
	Within Groups	186.564	22	8.480		
	Total	228.530	29			

Statistical analysis of the PCAS (effected by upper prosthesis)

Kruskal-Wallis Test

Ranks

	UpperPr osthesis	N	Mean Rank
PCAS@T1	1	25	17.24
	2	7	18.36
	3	1	1.50
	Total	33	
PCAS@T2	1	25	18.06
	2	7	15.29
	3	1	2.50
	Total	33	
PAS@T3	1	25	17.86
	2	7	15.86
	3	1	3.50
	Total	33	

Test Statistics[a,b]

	PCAS@T1	PCAS@T2	PAS@T3
Chi-Square	2.733	2.881	2.405
df	2	2	2
Asymp. Sig.	.255	.237	.300

a. Kruskal Wallis Test

b. Grouping Variable: UpperProsthesis

Statistical analysis of the PCA, the percentage change of the PCA
and the percentage change of the PCAS (effected by upper prosthesis)

ANOVA

		Sum of Squares	df	Mean Square	F	Sig.
ChangePCAS	Between Groups	279.702	2	139.851	.756	.478
	Within Groups	5549.003	30	184.967		
	Total	5828.705	32			
PCA@T1	Between Groups	17.675	2	8.838	.614	.548
	Within Groups	431.817	30	14.394		
	Total	449.492	32			
PCA@T2	Between Groups	28.893	2	14.446	.782	.467
	Within Groups	554.286	30	18.476		
	Total	583.179	32			
PCA@T3	Between Groups	65.514	2	32.757	2.636	.088
	Within Groups	372.755	30	12.425		
	Total	438.269	32			
ChangePCA	Between Groups	15.153	2	7.577	.897	.418
	Within Groups	253.375	30	8.446		
	Total	268.528	32			

VITA

Miss Onnicha Teampun was born on January 17, 1985 in Samutsongkram, Thailand. She received degree of Doctor of Dental Surgery (D.D.S) from Chulalongkorn University, in 2008. After graduation, she worked as general dentist at Sikhoraphum Hospital, Surin, Thailand during 2009 until now.