คุณภาพชีวิตในมิติสุขภาพช่องปากของผู้ป่วยที่เข้ารับการผ่าตัดฝังรากฟันเทียมร่วมกับการปลูกกระดูก

นายสุชาติ เขม้นเขตรการ

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ปีการศึกษา 2557

ORAL HEALTH-RELATED QUALITY OF LIFE IN PATIENTS UNDERGOING SURGICAL IMPLANT PLACEMENT SIMULTANEOUSLY WITH GUIDED BONE REGENERATION

Mr. Suchat Kamankatgan

A Thesis Submitted in Partial Fulfillment of the Requirements
for the Degree of Master of Science Program in Oral and Maxillofacial Surgery
Department of Oral and Maxillofacial Surgery
Faculty of Dentistry
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Thesis Title	ORAL HEALTH-RELATED QUALITY OF LIFE IN PATIENTS UNDERGOING SURGICAL IMPLANT PLACEMENT SIMULTANEOUSLY WITH GUIDED BONE REGENERATION
By	Mr. Suchat Kamankatgan
Field of Study	Oral and Maxillofacial Surgery
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สุชาติ เขม้นเขตรการ : คุณภาพชีวิตในมิติสุขภาพช่องปากของผู้ป่วยที่เข้ารับการผ่าตัดฝังรากฟันเทียมร่วมกับการปลูกกระดูก (ORAL HEALTH-RELATED QUALITY OF LIFE IN PATIENTS UNDERGOING SURGICAL IMPLANT PLACEMENT SIMULTANEOUSLY WITH GUIDED BONE REGENERATION) อ.ที่ปรึกษาวิทยานิพนธ์หลัก: ผศ. ทพ. ดร.อาทิ พันธุ์ พิมพ์ขาวขำ, อ.ที่ปรึกษาวิทยานิพนธ์ร่วม: รศ. ทญ. ดร.สุดาดวง กฤษฎาพงษ์, 152 หน้า.

วัตถุประสงค์: เพื่อประเมินการเปลี่ยนแปลงคุณภาพชีวิตในมิติสุขภาพช่องปากของผู้ป่วยที่เข้ารับการผ่าตัดฝังรากฟันเทียมร่วมกับการปลูกกระดูก และศึกษาถึงความสัมพันธ์ระหว่างปัจจัยทางสังคมประชากรและคลินิกต่อการเปลี่ยนแปลงคุณภาพชีวิตในมิติสุขภาพช่องปาก

วิธีการศึกษา: ผู้ป่วย 52 ราย (14 รายได้รับการปลูกกระดูก) ที่เข้ารับการรักษาด้วยรากฟันเทียมเพื่อบูรณะสันเหงือกว่างบางส่วน ได้รับการสัมภาษณ์ด้วยดัชนีชี้วัดคุณภาพชีวิตในมิติสุขภาพช่องปาก ก่อนการรักษา, 2 สัปดาห์, 1 และ 3 เดือนภายหลังผ่าตัด และภายหลังใช้งานฟันเทียม วิเคราะห์เปรียบเทียบระดับคุณภาพชีวิตในมิติสุขภาพช่องปาก รวมทั้งหาความสัมพันธ์ระหว่างปัจจัยที่เกี่ยวข้องกับการเปลี่ยนแปลงที่เกิดขึ้น

ผลการศึกษา: ระดับดัชนีชี้วัดมีค่าสูงขึ้นที่ 2 สัปดาห์ (p=0.002) จากนั้นมีค่าลดลงเทียบเท่าก่อนการรักษาที่ 1 และ 3 เดือนภายหลังการผ่าตัด และต่ำกว่าก่อนการรักษาภายหลังการใช้งานฟันเทียม คุณภาพชีวิตในมิติสุขภาพช่องปากของผู้ป่วยที่ได้รับการปลูกกระดูกลดลงภายหลังการผ่าตัดมากกว่า (p=0.01) แต่มีการเพิ่มขึ้นภายหลังใช้ฟันเทียมน้อยกว่า (p=0.029) กลุ่มเปรียบเทียบ จำนวนรากฟันเทียมมีความสัมพันธ์ต่อการเปลี่ยนแปลงภายหลังการผ่าตัด (p=0.031) ในขณะที่เพศ (p=0.02) และประวัติการใส่ฟันเทียมถอดได้ (p=0.012) มีความสัมพันธ์ต่อการเปลี่ยนแปลงภายหลังการใช้งานฟันเทียม

บทสรุป: การผ่าตัดฝังรากฟันเทียมโดยเฉพาะอย่างยิ่งในการปลูกกระดูกร่วมด้วยนั้นส่งผลให้เกิดการลดลงของคุณภาพชีวิตในมิติสุขภาพช่องปากในช่วงแรกภายหลังการผ่าตัด อย่างไรก็ตามพบการคืนกลับสู่สภาวะเริ่มต้นภายใน 1 เดือนภายหลังการผ่าตัด ฟันเทียมที่รองรับด้วยรากเทียมทำให้ผู้ป่วยมีคุณภาพชีวิตในมิติสุขภาพช่องปากที่ดีขึ้น การปลูกกระดูกไม่มีอิทธิพลต่อการเปลี่ยนแปลงคุณภาพชีวิตในมิติสุขภาพช่องปาก

ภาควิชา ศัลยศาสตร์ ลายมือชื่อนิสิต .....

สาขาวิชา ศัลยศาสตร์ช่องปากและแม็กซิลโลเฟเชียล ลายมือชื่อ อ.ที่ปรึกษาหลัก .....

ลายมือชื่อ อ.ที่ปรึกษาร่วม .....

ปีการศึกษา 2557

5575826332 : MAJOR ORAL AND MAXILLOFACIAL SURGERY
KEYWORDS: ORAL HEALTH-RELATED QUALITY OF LIFE (OHRQOL) / GUIDED BONE REGENERATION / ORAL IMPACTS ON DAILY PERFORMANCES (OIDP) / IMPLANT SURGERY

SUCHAT KAMANKATGAN: ORAL HEALTH-RELATED QUALITY OF LIFE IN PATIENTS UNDERGOING SURGICAL IMPLANT PLACEMENT SIMULTANEOUSLY WITH GUIDED BONE REGENERATION. ADVISOR: ASST. PROF. ATIPHAN PIMKHAOKHAM, D.D.S., B.P.A., Ph.D., CO-ADVISOR: ASSOC. PROF. SUDADUANG KRISDAPONG, D.D.S., Ph.D., 152 pp.

Objective: To assess the Oral Health-Related Quality of life (OHRQoL) alteration in implant patients with guided bone regeneration (GBRs) and investigate the association of socio-demographic and clinical factors to those alteration.

Methods: The 52 implant-treated patients (14 with GBRs) were individually interviewed Oral Impact on Daily Performance (OIDP) before, 2 weeks, 1 and 3 months after surgery and after prosthesis used. Differences in OIDP scores were compared. Association of the factors to changed score were analyzed.

Results: OIDP score increased at 2 weeks (p=0.002) and recovered at 1 and 3 months after surgery then decreased after prosthesis used. Patients with GBRs showed more post-surgical impacts (p=0.01) but less post-prosthesis improvement (p=0.029) than the other. GBRs had no association while amount of implant placed (p=0.031) as well as gender (p=0.02) and denture experience (p=0.012) associated to post-surgical and -prosthesis OHRQoL changes, respectively.

Conclusion: Implant surgery with GBRs procedure shortly deteriorated OHRQoL however recovery within 1 months after surgery. Implant prosthesis improved OHRQoL. GBRs did not associate to these OHRQoL alterations.

Department:	Oral and Maxillofacial Surgery	Student's Signature	.....
		Advisor's Signature	.....
Field of Study:	Oral and Maxillofacial Surgery	Co-Advisor's Signature	.....
Academic Year:	2014		

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Introduction

Background and rationale

Since osseointegrated dental implants become the standard of care for missing teeth reconstruction of both total and partial edentulism, a large number of patients are now ongoing with this treatment which demonstrate high survival rate, long-term clinical success and also achieve high patient satisfaction. (1-5) The applications of dental implant are including single tooth replacement, fixed partial denture anchorage or implant-retained overdenture in order to promote oral rehabilitation not only physical functions, esthetic appearance but also psychosocial perspective.

Adequate quality and quantity of implant-supported alveolar tissue is considered as one of the important factors which influence the success of dental implant treatment. (6) However, the loss of alveolar tissue, both hard and soft tissues, usually occurs at the implant planning sites due to pre-existing tissue defects or the physiologic gradual loss following tooth extraction as the result of disuse atrophy. Several augmentation methods were introduced by aiming to restore lost tissue for proper placement of predictable success dental implants. Soft tissue augmentation is indicated in the case of the deficiency on peri-implant soft tissue quantity and/or quality. While alveolar bone augmentation is commonly performed for implant site development which composed of various surgical techniques depending on the existing bone volume.

In current clinical practice, augmentation procedure can be done at different time point related to implant placement. Most of alveolar bone augmentation was performed before implantation in order to allow grafting biomaterials completely heal in the form of integration with host bone. These procedures, such as onlay block graft, lateral approach maxillary sinus floor elevation, usually indicate for large bone volume loss or severe atrophic alveolar ridge in order to restore the bony foundation for the stable initial engagement of dental implant fixtures. While in some situations that acceptable initial implant stability was gained by the existing alveolar bone, but partial implant surface was still left exposed to surrounding bone, known as fenestration and dehiscence defects. In addition, augmentation for the appropriate alveolar bone thickness and contour needed to stabilize the overlying soft tissue particularly in the anterior esthetic region, known as contouring augmentation. These augmentation procedures could be done simultaneously with surgical implant placement. Various surgical techniques were proposed to deal with these mentioned clinical scenarios such osteotome-mediated sinus floor elevation in atrophic posterior maxilla, alveolar bone splitting technique for parallel horizontal expansion in narrow alveolar ridge and, recently, regenerative therapy for bone augmentation via bone grafting materials and covered membranes, called Guided bone regenerations (GBRs).

GBRs is now well-accepted and commonly performed simultaneously with implant placement in high clinical success. (7) As mentioned above, correction of peri-implant defect and building up the alveolar bone contour are two main indications for GBRs performed immediately with implant placement. Dental implant with regenerative bone by GBRs showed comparable survival rate to implant placed in naturally host bone. (8, 9) In addition, systematic review study reports that 60-100

% of defect was filled regardless of the material used or the early membrane exposure which clearly state the successful of GBRs for dehiscence and fenestration defect correction. (10) By the way, recently confidential clinical evidence proves that GBRs as contour augmentation for maxillary anterior implant prosthesis has beneficial on maintaining peri-implant soft tissue stability as well as preserving the facial bone wall. (11) Among current bone augmentation techniques, GBRs demonstrate many advantages over the other procedures such as only single surgery required, less postoperative morbidity and shorter treatment time, however, case selection should be considered properly.

Outcome evaluation on dental implant treatment should involve comprehensively in longevity or survival outcome, physiologic outcome and psychological outcome. (12) Survival outcome represents the number of dental implants that still maintain their function during an interested period of time. Many studies clearly showed that dental implant-supported prosthesis demonstrate high long-term survival rate. (13, 14) Whereas the physiological outcome mainly focuses on the physio-biological responses to the placed implant such efficacy on mastication, bite force, surrounding soft tissue reactions and enveloped alveolar bone status. Implant prosthesis improves masticatory function (15) with the respectively low incidence of crestal bone loss or peri-implantitis condition (16) demonstrate the well patient response to the treatment. Beside the previous mentioned outcomes, psychological outcome considered as the one of subjectively patient-based assessment in order to reflect the behavioral, emotional and social response, otherwise, the perception on health interventions by measuring through sense of personal appearance, ability on daily and social activities, perceived

satisfaction and, entirely, perceived quality of life. The psychological outcome studies were performed through treatment satisfaction assessment, specified oral function questionnaire and standardized oral health-related quality of life questionnaire.

Oral health-related quality of life (OHRQoL) is defined as an individual perception on several dimensions of life related to oral conditions, including physical function, pain, psychological discomfort, and social difficulties. Alteration of oral status whatever from oral diseases, dental treatment or the psychosocial environment may affect to oral health-related quality of life. Many previous studies used different approaches such as measuring the satisfaction level or self-administered questionnaires which usually constructed for the study's purpose with questionable in reliability, validity and psychometric properties. Oral impact on daily performance (OIDP) is one of the widely-accepted standard OHRQoL measurement aiming to define the effect of the impairment, disability and handicap from oral conditions to common daily activities including eating, talking, oral hygiene care, sleeping, smiling and social contact. Focusing on the endpoint consequence of oral impacts, evaluating both frequency and severity of impacts and the ability for condition-specific impact assessment are the major advantages of OIDP over the other tools. OIDP had been translated into many languages and standardize tested for reliability, validity and psychometric properties, especially in Thai adults and young population. Recently, the additional scoring formats such as prevalence, extent and intensity bring this OIDP interpretation more descriptive, which could better demonstrate the exact individual perception on the specified oral condition, in order to overcome the concern about the meaningless of the summative scoring.

(17) Moreover, concerning to identify important changed scores from the individual perspective, minimally important different has been introduced, by various approaches to estimate the smallest of changed score that individual actually perceived the improvement or deterioration. (18) Besides the epidemiological population survey studies, OIDP has actually become the effective tool for determination of treatment outcome, in term of oral health-related quality of life, in various dental patient groups such as cleft lip and cleft palate patients (19), orthognathic surgical patients (20), malocclusion adolescents (21), patients with xerostomia (22) and patients with implant-retained overdenture. (23, 24)

Oral rehabilitation with dental implant seems to improve patient's oral health-related quality of life. Most of the studies interested in oral health-related quality of life in patients receive implant-supported complete mandibular denture because it dramatically changes denture retention and/or stability, which clearly significantly showed the improvement in oral health-related quality of life. (24-27) Limited studies on oral health-related quality of life associated with implant reconstruction for partial edentulous patients showed the positive change of measuring score that implies the improvement of oral health-related quality of life (28-30) although some negative change score during post-operative period was found. (31) Post-operative pain and swelling considered as the individual physiologic response to oral surgical procedures and also represent only as a part of intermediate level of impacts according to oral consequence from impairments. A patient whom reported some degree of pain and swelling following surgical implant placement could not imply to the overall of the patient's oral health-related quality of life. (32, 33) Eventhough, dental implants supported fixed prosthesis such

as single crown or partial denture are now becoming the standard of care for partial edentulous reconstruction, publication of the well-designed studies that demonstrate patient's perceptions in form of patient-based outcome aspect to this treatment modality is not only less in number but also present some limitations in conclusion. (28, 30) Furthermore, the result of previous studies cannot be inferred to the general population due to the homogeneity or specificity of the study samples. (29, 34) Moreover, studies were designed without a comparison group leading to the uncertainly conclusion that oral health-related quality of life really improves from interested treatment variable. (34) By the way, the data interpretation of oral health-related quality of life from available studies were problematic due to the lack of proper analytical approach.

In addition to current clinical practice, guided bone regeneration procedures have been popularly used for improving the installed-implant site, the clinical outcome studies are increasing, whereas the patient-based outcome studies on this type of intervention are still limited in number. (31, 34) To comprehensively evaluate this treatment modality, clinical success assessment alone is insufficient to confirm the usefulness and value of the treatment, well-designed study with standard measuring tools for patient aspect appraisal is still required. (35)

Research Question

Does guided bone regeneration procedure simultaneously with surgical implant placement for partial edentulous reconstruction affect the patient's oral health-related quality of life?

Research Objectives

To assess the overtime change in OHRQoL in patients undergoing surgical implant placement simultaneously with guided bone regeneration and compare with those who were placed implant without guided bone regeneration

Research Hypothesis

Hypothesis :

1. OHRQoL in patients undergoing surgical implant placement simultaneously with guided bone regeneration *changes* overtime through treatment processes
2. OHRQoL in patients undergoing surgical implant placement simultaneously with guided bone regeneration is *different from* those who were placed implant without guided bone regeneration

Alternative hypothesis :

1. OHRQoL in patients undergoing surgical implant placement simultaneously with guided bone regeneration *does not change* overtime through treatment processes
2. OHRQoL in patients undergoing surgical implant placement simultaneously with guided bone regeneration is *similar to* those who were placed implant without guided bone regeneration

Expected Benefits

While the guided bone regeneration procedure, nowadays, intends to improve clinical outcomes of dental implant reconstruction for dimensional insufficient edentulous alveolar ridge, this study is expected to demonstrate how this type of procedure affects to the patient's oral health-related quality of life which considered as one of the valuable patient-based outcome. This could be assured to the implant prosthesis associated-dental health care providers in understanding about what the patient will be encountered postoperatively and also the patient's perception to entire of the treatment. Moreover, theses could be used wisely to inform patient who requires this procedure and also beneficial for patient management at pre-, intra- and postoperatively in order to avoid or eliminate, as much as possible, correlated factors that would negatively affect to patient's oral health-related quality of life for the complete success both clinical outcomes and patient perspective.

Conceptual Framework

Chapter 2
Literatures Review

Health, oral health and quality of life

Changing the definition of health by the World Health Organization in 1946 from the absence of disease to the state of complete physical, mental, and social well-being obviously change the medical, also dental, treatment outcomes. (36) Thus, all of medical health services are ongoing to get the optimal goal of patient well-being. As in the present day of Dentistry, oral health care providers are not only treating patients for oral disease but also willing patients to improve their quality of life due to the impacts on daily activities from pathologic and/or psychosocial-related oral conditions.

Quality of life is defined as the individuals' perceptions of the position of life in the context according to the culture and value systems in which they live and in relation to their goals, expectations, standards and controls. (37) While oral health is defined as the comfortable and functional dentition that allows individual to perform their social function and daily activities without physical, psychological or social difficulties. (38) That is, the effect in any dimension to quality of life predisposed by oral health impairments infer to oral health-related quality of life. (39) Several oral health dimensions, including physical oral function, pain, psychological discomfort, and social impacts are used to access the oral health-related quality of life. However, many factors including socio-demographic, medical, dental or environmental through attitude, believe are also influenceed directly or indirectly to the difference of an individual's oral health-related quality of life for

example age, ethnicity, educational level, tooth loss experience, oral pain or related symptoms, frequency of dental visits, prosthesis wearing as well as cultural, psychological, dietary, and financial factors. (40, 41) The original application of quality of life assessment is the epidemiological purpose which aim to demonstrate the impact of oral conditions to the quality of life within the interested population to state the needs for dental care as health policy planning. However, this assessment is currently used for intervention effectiveness evaluation and, sometimes, represent patient satisfaction to oral health care services.

Assessment of oral health-related quality of life

There are various well-documented tools in measuring the OHRQoL such as the Social Impacts of Dental Disease (SIDD), Oral Health and the Sickness Impact Profile, Dental Health Questions from the Rand Health Insurance Study, the General Oral Health Assessment Index (GOHAI), the Dental Impact Profile, Subjective Oral Health Status Indicators, the Oral Health-related Quality of Life Measure, the Dental Impact on Daily Living (DIDL), Oral Health Quality of Life Inventory, the Oral Health Impact Profile (OHIP) and Oral Impacts on Daily Performances (OIDP), etc. (42) In contrast to the bio-physiological or clinical indicators which intend to measure the disease progression in various clinical aspects, most of OHRQoL measurements intend to demonstrate individual perception from oral conditions or disease to their life in various dimensions which mostly involve in physical function, cognitive function, self-care, pain, usual activities, energy/fatigue, social function, self-esteem and perceived health.

The two commonly used indicators for measuring oral health-related quality of life in the current literatures is OHIP (43) and OIDP (44) due to its simplicity, reliability, validity, statistical analysis capability and wide acceptability. Both of indicators are theoretical-based and designed according to Locker's model of oral health (45) which proposed about the consequence of oral impacts from the taking place on disease to the impairment, functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability to the handicap condition (Figure 1) by based on the international classification of Impairments, Disabilities and Handicaps.

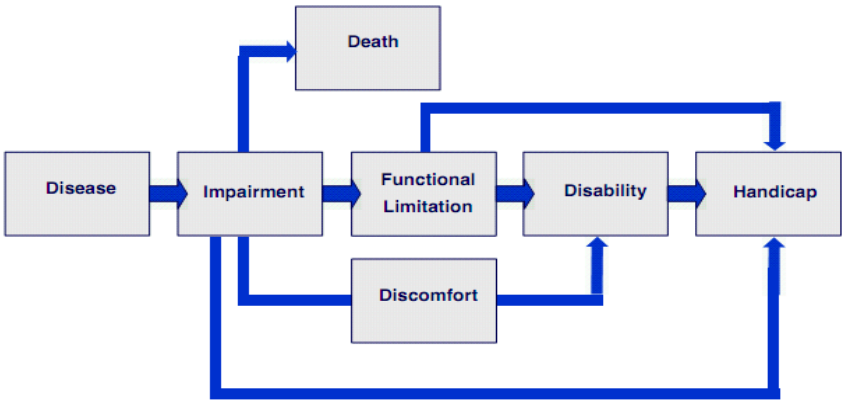


Figure 1 Locker's model of oral health

OHIP were originally constructed as 49 items-questionnaire, then latterly be modified in the shorter form that compose only 14 items comprehensively on seven dimensions such functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability and handicap. This indicator was designed as self-questionnaire that request the respondents in order to rate the frequency of assessed questions during the period of interest. The assessment in several oral health dimensions and long-term various clinical studies

used are considered as the strengths of OHIP. However, similar dimension assessed for example functional limitation and physical disability or psychological discomfort and psychological disability were seemed to be repeatable measured, which leads to the occurrence of over scoring.

In 1996, the Thai dentist, Adulyanon S., introduced OIDP. The conceptual framework of this index is mainly focused on the assessment only the finally difficulties that result from the consequence of the take place according to all abnormalities. This conceptual model also originates from the World Health Organization's statement of the international classification of Impairments, Disabilities and Handicaps, however, been modified in order to categorize the occurrence impacts into 3 levels (Figure 2). (44) Level 1 is called "impairment" that represents the disease or condition in clinical aspect, such as loss of tooth, dental caries, tooth mobility, etc. The level 2 is called "intermediate impacts" that represents the early impacts on individual resulting from the impairments including the pain perception, psychological discomfort, functional limitation and appearance dissatisfaction. The endpoint impacts (Level 3) called ultimate impacts represent the impacts that affected to daily performed activities which comprehensively on physical, psychological and social difficulty. In order to achieve the truly difficulties that affected to the individual daily life, OIDP is designed to measure the ultimate impacts which would exclude any impairments or impacts that do not influence enough. The three difficulty dimensions are transformed into 8 main routine daily activities that involving oral health. Physical performances were evaluated through the difficulty in eating or enjoying food, speaking or pronouncing words clearly and cleaning teeth. While sleeping or relaxing, smiling, laughing or showing teeth without embarrassment

and maintaining the usual emotional state without being irritable are the representation of the psychological difficulties. Lastly, carrying out major work/social role and ability to contact with people are also being measured as social performance difficulties.

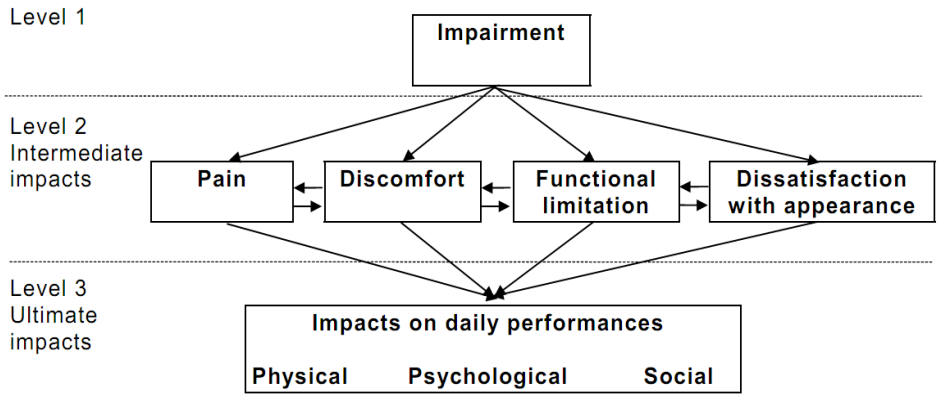


Figure 2 Theoretical framework of the consequences of oral impacts proposed by Adulyanon S. and Sheiham A. 1997

OIDP demonstrates some advantages for measuring the oral health-related quality of life over other measuring tools. The OIDP encompasses only all of the ultimate impacts which consider as the overall major consequences for oral health. Therefore, over scoring from repeating or similar measure from another level of impacts may not be happening. Unlike most of the indicators which generally assess only how often of the impacts affected to individual, OIDP assess both the frequency and the severity of that impact which additionally reveal about how important of the reported difficulties related to oral condition in the individual's perception on quality of life. In addition, OIDP can be assessed as condition-specific impacts in order to show specific oral problems that affected to individual's life. Since OIDP evaluate the difficulties from individual daily living activities which considered as behavioral-based

information more than feeling-based information, respondents feel more comfortable and easy to answer assessed questions.

The OIDP has been tested for the reliability and validity in various groups of age, populations and countries including Thailand. The OIDP was used in the epidemiological study for determination of the impact from oral health in different adult and elderly populations which shown that pain and functional limitation were the main causes of impacts for almost every daily performance. (46, 47) Because dental health care in children and adolescent groups are challenging and currently be interested, child-OIDP were developed and used to assess the oral impacts that will imply the treatment needed for this population. In contrast to the study of adult and elderly group, the main causal symptoms of impacts are toothache and oral ulcers which effect on eating performance. (48, 49) Moreover, the 6th Thailand National Oral Health Survey had been incorporated the assessment on oral health-related quality of life in 12-year children and 15-year adolescence population by the application of child-OIDP and OIDP, respectively. This national survey revealed that more than 80 percent of samples shown at least one difficulty in daily activities that related to their oral condition, in addition, trouble on eating or chewing food, oral hygiene cleaning and maintaining emotional status are respectively the three most common activities that impacted to their life. (50) Besides the population community-based study, OIDP is actually become the effective tool for determination of oral health-related quality of life in various specifically patient groups such as cleft lip and cleft palate patients (19), orthognathic surgical patients (20), malocclusion adolescents (21), xerostomic patients (22) and also implant-retained overdenture patients. (23, 24)

Scoring interpretation according to oral health-related quality of life measurement

As subjective assessment is now interested, attempt to transform this information to the computable form is also developed. All of the OHRQoL indexes request the responders to evaluate the assessed questions in the form of numerical data and summarized as a rating score in various formats, which then be defined for the meaning. The OHRQoL in the form of theses score sometimes considered as the worthless data because of the lack of clear internal explanation, for example, we cannot define the patient's problem with OHRQoL score equal to 12 or we cannot exactly conclude that the patient with a 9 OHRQoL score has inferior oral health well-being to the one with 11 OHRQoL score. According to the absent of the intrinsic meaning of these scores which is considered as the meaningless nature, thus, overall score could not address the exactness of the individual perception on their life. In the earlier oral health-related quality of life studies, the mean of the overall score was used as the representation of the quality of life degree in each study group and actually also used to calculate statistical difference between groups at the specified significance level. This is now considered as the inadequate or, sometimes, inappropriate method for this type of data interpretation.

The alternative way, reporting the data related to the quality of life measurement, was introduced in order to overcome the meaningless scoring. Others formats of the quality of life data scoring such prevalence, extent and intensity of the impacts have been recommended to be reported in conjunction with the conventional aggregated scores while performing the oral health-related quality of life studies. (17) The differences in the OHRQoL indexes result in the diversity of the

prevalence, extent and intensity determination. For the OIDP, the prevalence refers to the proportion of respondents who report at least one or more performances impact, in contrast, the extent refers to the amount of performance that respondent report impact which also called Performance With Impact (PWI), thereby, range from one to eight. The Intensity of OIDP is determined by the highest of the performance score among the eight performances assessed in each individual. In addition, the intensity is classified into six ordinal levels, according to the achieved scores (Table 1). Krisdapong S, et al. (17) analyzed the OHRQoL data in a form of child-OIDP and OIDP from the Sixth Thailand National Oral health survey in order to determine the correlation between the various score formats and the global subjective rating, which is considered as the overall individual perception on the specified condition. Statistical correlation among these was found, however, the intensity not only obviously presented the strong correlation, but also demonstrated the increase in agreement to the global subjective rating.

Intensity	Frequency/ severity score		Frequency/ severity score	Performance score
No impacts	0	x	Any score	0
Very little	1	x	1	1
	2	x	1	2
Little	3	x	1	3
	4	x	1	4
	2	x	2	4
	5	x	1	5
Moderate	3	x	2	6
	4	x	2	8
	3	x	3	9
	5	x	2	10
	4	x	3	12
Severe	5	x	3	15
	4	x	4	16
Very severe	5	x	4	20
	5	x	5	25

Table 1 Classification of oral impact intensity accroding to OIDP score

Generally, the change or difference in the quality of life score are clinically considered as the alteration of the quality of life level in the sense of the attending physician. Although, that change could not be correctly inferred to the quality of life alteration in the patient point of view or how that changed score useful for the clinical judgment and patient management. Therefore, to determine that clinically useful or individually meaningful change, Minimally Important Different (MID) was introduced. MID is defined as "the smallest difference in OHRQoL index score in the domain of interest which patients perceive as beneficial and which would mandate, in the absence of troublesome side-effects and excessive cost, a change in the patient's management". (51) Two methods are conducted to calculate the MID. Distribution-based method uses the distribution pattern of the existing data, such standard deviation or standard error for calculation thus also calls internally referenced method. Anchor-based method calculates from the other quality of life data reference value such known clinical group, population norms, subjective global transition scale thus also calls externally referenced method. Effect Size (ES), Standardized Response Mean (SRM), Standard Error of Measurement (SEM) and Norman's rule of thumb are the current methods to generate distribution-based MID (Table 2). ES and SRM are derived from the similar manner. ES derives by the ratio of the mean changed score and the standard deviation of the baseline score, whereas SRM is the ratio of the mean changed score and the standard deviation of changed score. While SEM is derived from the multiplication between the standard deviation

of the baseline score and the square root of the 1 minus with the alpha value, that represent the reliability of the specified measurement. Norman's rule of thumb suggests that MID could be approximated from the half of the baseline score's standard deviation. (52) Due to absent of the actual consensus about the most suitable method for identifying MID in the quality of life study, giving a wide range of MID by multiple approaches conjunction with the triangulation method converging to the narrow range or single value, are still recommended. (53) Tsakos G, et al. published the study about the determination of MID for the OHRQoL in the patients with periodontitis according to the different therapeutic means by the assessment of OHRQoL through the OIDP index. MID was calculated by various methods including the anchor-based method, which reference to subjective global transition scale, and distribution-base method consist of ES, SRM and SEM. MID was found around five points OIDP score, imply the meaning that the change in OIDP score at least five points are considered for individual perception significant. (54) Recently, these additional methods in order to address the MID, which transform the meaningless score to the meaningful interpretation, were recommended for the minimum requirement needed to be reported in conjunction with the mean score, alternative scoring format; prevalence, extent and intensity and the oral health global ratings while study on the OHRQoL. (18)

Distribution-based method of MID	Formula
Effect Size (ES)	$\frac{Mean\ changed\ score}{\text{St. deviation of the baseline score}}$
Standardized Response Mean (SRM)	$\frac{Mean\ changed\ score}{\text{St. deviation of the changed score}}$
Standard Error of Measurement (SEM)	$\text{St. deviation of the baseline score} \times \sqrt{1-\alpha}$

Table 2 Formulas of distribution-based method for MID calculation

Alteration of alveolar tissue following tooth loss

Alveolar tissues including bone and soft tissue originate at the same time of tooth eruption which commonly determines the alveolar volume and shape. As the consequence after tooth loss, surrounding alveolar tissue has been changed which mostly resulting in the reduction in all dimensions. Alveolar bone tends to decrease in width and height over time following tooth loss, these pronounced dimensional reductions occur in the first two to three months. (55) Moreover, Horizontal dimension reduction seems to occur more than the vertical dimension leading to the narrow and also short edentulous ridge clinically. (55, 56) As soft tissue is supported by the underlying alveolar bone, alteration also occurs which usually relate to the coronal migration of the facial keratinized mucosa resulting in the reduction of the keratinized tissue width. (55, 57) In addition, alteration of alveolar tissues may occur according to pre-existing alveolar defect moreover from the physiological change following tooth loss, such as periodontal disease, peri-radicular pathology, trauma, pre-existing tissue defect or destructive pathology and surgical trauma during tooth extraction. These conditions compromise the quantity as well as the quality of dental implant supporting structure which affected to biological, functional and esthetic success of implant-supported prosthesis.

Timing for implant placement post-extraction

Implant placement could be performed at different time period following tooth extraction, this placement time also influence on the clinical outcomes of the treatment. (58) The widely accepted classification of timing for implant placement post-extraction is based on the degree of individual socket healing rather than the

fixed time frame. Immediate implant placement is classified as type 1 that implant is placed in the extraction socket immediately following tooth extraction, by means of the absence of any soft or hard tissue healing. Early implant placement which allowed extraction socket to heal, however, incompletely is classified as type 2 and type 3. The condition in which soft tissue properly healed without any clinical signs of alveolar bone fill, typically 4-8 weeks post-extraction, represents as type 2 early implant placement while type 3 early implant placement refer to the placement of dental implant in the completely healed soft tissue with a partially bone healed socket that normally occurs during 12-16 weeks post-extraction. Late or delayed implant placement means the placement of dental implant in the completely healed socket that commonly take place 6 month post-extraction. (59) In current recommendation for immediate implant placement, the fresh extraction socket need to reveal the completeness of facial bone wall by the minimum thickness about 1 mm without the acute infectious condition. In addition, the thick soft tissue biotype and the adequate quantity of peri-radicular bone for gaining the optimal implant primary stability are also required in order to achieve treatment success especially for an esthetically implant prosthesis. (60) However, the main concerned problem for the implant placed immediately post-extraction is the apical migration of the facial gingiva according to the unpredictable resorptive modeling of the alveolar bone which could compromise the aesthetical perspective of the prosthesis. In case of the inability to fulfill the minimum requirements for immediate implant placement or the avoidance of esthetic troubles, the early implant placement is latterly recommended. The substantial healing at the socket site provides the adequate soft tissue to achieve the desired esthetic outcomes and also facilitate the flap

manipulation in the surgical implant placement. In addition, primary implant stability and the good implant position are more easily attainable than immediate approach when partial bone formation occurs. Lastly, delayed implant placement recently do not recommend due to the excessive loss of alveolar tissue from a physiologic modeling process that could compromise both quantity and quality of the implant supporting tissue. Patients in the continuing growth period or whom unable to receive implant placement at that suitable period are suggested to perform the socket preservation procedure prior delayed implant placement to overcome the undesirable dimensional socket change.

Implant site development

The primary goal of surgical implant placement is to properly place the dental implant into the alveolar bone in order to gain maximum implant stability and obtain the appropriate implant position for a planned-prosthesis. However, the proper clinical condition in which the adequate quantity and quality of the implant planning sites is sometimes not primarily obtained. An additional procedure involving the improvement of bone and soft tissue which objectively to built-up the appropriate supporting structures surrounding dental implants call implant site development procedures. These surgical procedures often associate with the augmentation procedures. The procedures for bone augmentation including the use of growth factors to induce new bone formation, overlay bone graft, distraction osteogenesis and bone splitting for ridge expansion while mucogingival surgery, including free gingival graft and connective tissue graft usually be considered for peri-implant soft tissue augmentation. Clinical application of these procedures could be

different according to the various clinical situations and could be performed at the different implant treatment time.

Surgical augmentation procedure for implant site development could be done pre-, peri- and post-implant placement. Augmentation procedures that perform before implant placement usually involve in the large tissue volume deficiency that could clinically compromise the initial stability of the installed implant. These procedures usually associate with multiple surgeries, long treatment time and post-operative morbidities especially for the graft harvesting procedure from the local or distant autogenous donor sites. In contrast, augmentation procedures that perform post-implant placement often indicate in the regenerative surgery for correction of the peri-implant disease or complication such as peri-implantitis that produce peri-implant bone destruction. (61, 62) Simultaneous augmentation procedures performed during implant placement demonstrate some benefits such time saving, avoid multiple surgeries, less post-operative morbidities and shorten overall treatment time. (63)

Overlay bone graft

Autogenous onlay block grafts harvested from both extra-oral, such as iliac crest, rib, fibula bone or calvarium, and intra-oral, such as symphysis, maxillary tuberosity or mandibular ramus, are commonly used for vertical and/or horizontal bone deficiency corrections both before and during implant placement. The main benefits of block graft augmentation performed prior implant placement are the ability of the integrated graft to engage the installed implant resulting in the clinically accepted initial implant stability (64), improve ridge dimensions (65, 66) and

demonstrate the high survival rate of dental implant placed in this type of graft. (67) Though, onlay bone grafting procedure routinely performs prior implant placement, the concern of the graft resorption, which mostly occur early after graft transplantation (68, 69) and the attempt to shorten the treatment time resulting in the recommendation of the onlay block graft simultaneous with implant placement. Implant success and implant survival was still comparable whether immediately or delayed placement of dental implant on this onlay block graft. (70) However, simultaneous implant placement with onlay block graft is not nowadays popular due to the unpredictable resorption pattern of the augmented graft and the introduction of the alternative bone grafting during implantation that also present the comparable or higher success with the lower morbidities and easier to perform. Autogenous bone graft, in the form of block or particulate, commonly be harvested from both extra-oral sites and intra-oral sites. Due to the donor site surgery, some adverse event may be present as post-operative morbidities. Sensory alteration, especially at the lip and mental area is the most common post-operative complication from mandibular symphysis and ramus bone harvesting procedure (71) with the prevalence range from 10-50% and 0-5%, respectively. (70, 72) Extra-oral bone harvesting, commonly from iliac crest, is required in order to gain much more bone quantity and also the high quality of grafted bone. However, this procedure also causes several morbidities such as prolong post-operative pain, gait problem, sensory alteration and scar formation. (73) Thus, mandibular ramus still becomes the donor site of choice for alveolar bone augmentation because of its low morbidities, predictable outcome and uncomplicated surgical procedure.

Sinus floor elevation

Dental implant reconstruction in the posterior maxillary region often encounter with the unfavorable residual alveolar ridge mostly in the form of the deficiency in vertical alveolar height as the result from alveolar ridge resorption, physiologic sinus pneumatization or in combination of both. The sinus floor elevation procedure was introduced to overcome the vertical alveolar bone deficiency due to the sinus pneumatization (74), however, unable to correct the problems related to alveolar ridge resorption which resulting in the inappropriate horizontal and/or vertical alveolar ridge dimension. Lateral osteotomy approach maxillary sinus floor elevation with the grafting procedure demonstrates the predictable clinical outcomes and high success of implant prosthesis irrespectively to timing of implant placement whether simultaneous or delay placement. (75-77) However, the most important factor for implant to integrate well with surrounding bone is the implant initial stability. So the recommendation for simultaneous implant placement with lateral osteotomy approach maxillary sinus floor elevation with grafting is stated only in case of the residual alveolar ridge height at least 4-5 mm. (70) Latterly, the less invasive and more simpler surgical procedure alternative to the lateral osteotomy approach was introduced. By mean of localized sinus floor elevation by the crestal osteotomy approach is called Osteotome-Mediated Sinus Floor Elevation (OMSFE). OMSFE is performed through the sequential sized osteotomes in which to relocate crestal bone apically with or without bone grafting toward the sinus floor then place dental implant simultaneously. (78) This surgical technique requires at least 5-6 mm. of the residual bone height to obtain sufficient initial implant stability. (78) Although, this technique limits the alveolar height gain about only 2-4 mm. (79) In addition,

the placed implant demonstrated the high success and survival rate even if no additional bone grafting performed (79-83). Whereas the implant survival rate substantially decreased if the residual alveolar height less than 4 mm. (84-86) The most common intra-operative complication of these kind of procedures is the sinus membrane perforation, however, this is not significantly affected to the clinical implant survival (87, 88) while post-operative maxillary sinusitis is uncommon but considered to be the potentially important complication. (89, 90) Pre-existing ostium stenosis, previous maxillary sinusitis, mucosal pathology, free floating graft due to the large membrane perforation, post-operative swelling of the sinus mucosa, disturbance of sinus physiology from anatomy alteration are considered as the predisposing factors for sinus to be infected following surgery. (91)

Alveolar bone splitting

There are the alternative interventions for narrow atrophic alveolar ridge beside the onlay bone graft, guided bone regeneration or distraction osteogenesis which often concern about the resorption or infection of the graft, time consuming for graft healing and post-operative morbidity of the donor site. Alveolar bone splitting technique simultaneous with implant placement was proposed in order to expand an alveolar ridge in the horizontal dimension by splitting the parallel cortical bone plate of the alveolar ridge and immediately places the implant then allows the gap to heal naturally similar to the fracture healing pattern or fill it with the bone-substitute grafting materials. (92) Due to the need for bone plate separation, the clinical application of this technique is limited especially for the broad-based alveolar ridge and highly flexible bone quality because of the avoidance of split

plate fracture. Thus, this technique is preferred to perform in the upper jaw more than the lower due to the looser bone density with more spongy bone separate the thin bone plate. Dental implants placed in this expanded ridge demonstrate the good initial stability (93) and also show the high rate of success and long-term survival. (94-97)

Guided bone regeneration technique

Guided bone regeneration (GBRs) is considered to be one of the reliable surgical techniques for alveolar ridge augmentation including for the correction of local defects or increase the vertical and horizontal deficiency. (98) Theoretically, GBR was introduced according to the principle of the alveolar bone formation stimulation by the blood clot filled space created under the barrier membrane in order to prevent the nonosteogenic cells ingrowth that might impede new bone formation in conjunction with tension-free primary wound closure. (99) Later, various grafting biomaterials show the significant role for new bone formation in the GBR procedure through their osteogenesis, osteoinduction and osteoconduction characteristics corresponds to their types, compositions and properties. Various clinical applications of GBR are widely accepted and had been studied in order to state the success of the GBR and the survival of dental implant placed in the GBR augmented bone. For alveolar bone augmentation before implant placement, GBR demonstrates evidently increase the vertical bone height and horizontal bone width that facilitate the proper implant placement. (100-102) In addition, GBR demonstrate high success for the correction of vertical deficiency (103, 104) or dehiscence/fenestration defects simultaneously with implant placement. (8, 105,

106) However, the indication or clinical requirement for the ideal GBR technique simultaneous with implant placement is also limited to the implant with acceptable primary stability, implant in proper position and the defect that enclosed by the surrounding bone. (107) The most common complication of GBR is the early exposure of the overlying barrier membrane consequence with the infectious events or disturbance of new bone formation. (108-110) Intensive oral hygiene care with regular anti-septic mouthwash are suggested to reduce that deteriorate effects from early membrane exposure. (111, 112)

Soft tissue augmentation

Healthy peri-implant soft tissue is important for biological and esthetical dental implant success. Keratinized or attached mucosa acts as a physical barrier from pathogenic invasion to the underlying peri-implant tissue especially the surrounding integrated bone. Thus, the high quality, stability and healthy of the soft tissue surrounding the implant, the long-term survival of dental implants predicted. (113, 114) Moreover, peri-implant soft tissue is considered as one of the most important esthetical determinant especially in the anterior teeth. Various surgical techniques could be done to manage peri-implant soft tissue at different treatment time related to implant placement. Soft tissue augmentation procedure which perform before implant placement commonly aim to facilitate the ongoing bone augmentation procedure in order to provide adequate soft tissue for complete coverage of the underlying augmented graft or to create the favorable soft tissue type. As well as at the time of implant placement, soft tissue augmentation also plays a pivotal role not only for primary wound closure particularly when perform in

combination with bone augmentation such guided bone regeneration which concern about the disturbance of graft healing from the environmental contamination but also for contour maintaining of the facial soft tissue. While post-implant placement soft tissue augmentation mainly intends to improve aesthetic perspective of peri-implant soft tissue such papilla formation, improper facial soft tissue contour correction. In order to preserve as well as reconstruct peri-implant soft tissue, mucogingival surgery procedure is needed, generally associate to the autogenous gingival and connective tissue graft in form of both pedicle and free graft. (115) Clinical application in order to choose the appropriate surgery depends on the deficiency or trouble of the peri-implant soft tissue for each clinical scenario. The free gingival graft is primarily intended to increase the width of keratinized mucosa. In contrast, the connective tissue graft is usually applied to increase the thickness or fullness of the surrounding soft tissue. (116, 117) However, the main drawbacks of the free gingival graft especially at the esthetic site are the unpredictable result, color mismatch and the risk for keloid formation. (115) In addition, free gingival graft showed more post-operative pain and bleeding due to the palatal donor site denuded area from the harvesting procedure while connective tissue graft present less morbidity due to subepithelial approach which primary closure can be achieved. (118, 119)

Implant site development according to existing defect

In order to decide which type of site development procedure is appropriate to restore alveolar tissue supported dental implant, surgeons need to assess the existing defects that can compromise the treatment result physically, functionally as well as esthetically. Both bone and/or gingival tissue might bring a various type of

defect in a different volume affected. Small volume soft tissue defect could be corrected with the subepithelial connective tissue graft which generally performs during implant placement in conjunction with the application of suitable graft-supported healing abutment. This procedure provides predictable vertical soft tissue augmentation. In contrast, the large volume soft tissue defect usually requires more soft tissue augmentation procedures before implant placement. Subepithelial connective tissue graft or vascularized interpositional periosteal connective tissue flap is suggested to improve soft tissue volume in this condition. Small volume hard tissue defect such fenestration and dehiscence defect could be corrected by guided bone regeneration procedure. The fenestration defect, a partial implant surface exposure defect due to insufficient horizontal bone thickness with intact alveolar crestal bone, and dehiscence defect, a partial implant surface exposure defect that exposes apically from crestal alveolar bone, were successfully reported the acceptable clinical outcomes following defect correction simultaneously with implant placement. (8, 105, 106) In addition, combination defect of hard and soft tissue in the small volume could also be corrected together during implant placement with the same manner. While a large volume of hard tissue defect unsurprisingly needs to be corrected with a large volume grafting procedure such onlay block graft, sometimes in conjunction with soft tissue augmentation to compensate relatively soft tissue insufficiency following bulky bone augmentation, before implant placement. (120)

Anterior maxillary region is one of the most common sites for implant prosthesis, uncomfortable to removable prosthesis as well as highly esthetic demand considered as the main reasons for the reconstruction with dental implant at this

region. Thin facial bone wall results in rapid and severe horizontal ridge resorption that compromised implant placement. Ridge width is suggested as empirical guideline for the selection of suitable augmentation procedure. Guided bone regeneration procedure and ostetomes-mediated ridge splitting which could be done simultaneously with implant placement are recommended when ridge thickness about 7-10 mm. and 6-7 mm. respectively. While ridge width less than five mm. requires more invasive procedure such as onlay block graft or distraction osteogenesis. (121)

In some clinical scenarios, simultaneous bone augmentation according to the guided bone regeneration procedure is performed even there is no existing defects. For instance, the immediate and early dental implant placement which extraction socket is not completely healed the discrepancy between socket space and implant size can lead to unavoidable peri-implant gap. If surrounding bone walls are intact with the marginal peri-implant gap lesser than 3 mm. in width, spontaneous bone filled is expected to correct this defect naturally without the need for the additional bone augmentation. However, unpredictable physiologic horizontal resorption exactly occurs at the following time, this could be serious in the esthetically needed area due to soft tissue contour reduction as the supporting bone loss. Simultaneous bone augmentation could be used to compensate this undesirable resorption, known as contouring augmentation, which is also beneficial in maintaining the esthetic soft tissue contours. (11, 59)

Barrier membrane and bone-substitute biomaterials in the guided bone regeneration

Rapidly growing up of the biomaterial technology in conjunction with numerous publications on various aspects in dental implant is the result from the advance development in biomaterial related to osseointegrated implant. Concentration was not only on implant components but also interested in grafting materials for hard and soft tissue augmentation. Guided bone regeneration was applied in clinical practice for bone augmentation in different indications such horizontal or vertical ridge augmentation prior to implant placement, regenerative treatment for peri-implantitis and the correction of local defect or contour augmentation during implant placement. This technique involves the main two biomaterials such the barrier membrane and bone substitute material.

The barrier membrane was popularly classified according to the pattern of degradation including non-resorbable and resorbable membrane. Recently, the most widely used and accepted non-resorbable membrane is the expanded polytetrafluoroethylene (e-PTFE). This type of membrane presents the superior in conformational stability which is the critical function of the barrier membrane to create the space for new bone formation. Well- integrated of installed implants to the regenerated site (122), successful in the vertical bone augmentation (104) and predictable result on the correction of peri-implant defect (105) were reported in the use of e-PTFE membrane for GBR procedure during implant placement regardless of the different bone-substitute materials applied. However, the requirement of re-entry surgery to remove the membrane and the risk of early membrane exposure that could negatively affect to the bone formation, are the main disadvantages of this

membrane. (123) In contrast, the resorbable membrane, commercially available in various forms with different in origin and characteristics, does not require the second surgery, and has lower risk for membrane exposure. (124) Collagen membrane originally derives from both allogenic and xenogeneic biomaterial is generally applied in the current clinical practice. The common properties of collagen membranes that are considered for the important characteristic of the barrier membrane are the blood clot forming stimulation, chemotaxis, highly biocompatibility, naturally biodegradable without the toxic by-product (125) as well as promoting bone regeneration. (126) The installed implants with GBRs procedure via collagen membrane showed the long-term survival and high success rate (127) and the satisfied peri-implant defect correction. (128) However, the installed implants with GBRs procedure either with resorbable collagen membrane or non-resorbable e-PTFE membrane demonstrated the similar accepted clinical and radiographic results as well as the high survival rate to the non-grafted implants in the long-term, more than 10 years, study. (129) Another alternative group of resorbable membrane is the alloplastic or bio-chemical synthetic membrane such polyglactin, polyglycoside synthetic copolymers: polylactic acid, polyglactide, polyethylene glycol membrane. This type of membrane was developed based on the avoidance of animal products but still need to combine the conformational stability and the self-biodegradation properties. The polyethylene glycol membrane was comparable in the gaining of bone height and bone width to collagen membrane following the correction of peri-implant defect by assessing cone beam computed tomography at 5-year after implant placement. (130) In addition, the modified polylactide/polyglycolide acid

membrane was also found the comparable clinical result to the e-PTFE membrane for the peri-implant defect correction. (131)

Although the principle of the GBRs technique for the new bone formation primarily mentioned to the barrier membrane in order to exclude the unwanted cell, the bone-substitute materials were also interested as the important component of the current GBRs. The bone-substitute particles act as not only the scaffold for new bone apposition but also maintain the created space by prevention the membrane collapsed. (123) Autogenous bone is still considered as the gold standard for grafting materials that initiate and facilitate new bone formation from its superior biological properties especially the outstanding osteogenesis potential. (121, 132) Preferable of the peri-implant soft and hard tissue health was found when autogenous bone was used to augment around dental implant in immediate implant placement compare to synthetic bone grafting. (133) As well as in the correction of exposed implant surface during implant placement, autogenous bone by the technique of GBRs present the clinical accepted bone gain over the implant surface. (134, 135) However, the donor site morbidities following harvesting procedure and the limited amount of bone harvested causes this type of graft restrictedly used only in the specific indication which truly needs its obvious osteogenic characteristic such the onlay block graft, craniofacial reconstruction or in the need for a small amount of graft material that could be simply collected at the osteomy site or the adjacent area. The other bone-substitute materials including allogenic, alloplastic and xenograft bone were developed and improved to become the grafting material alternative or in combination to the autogenous bone for this regenerative therapy. In GBRs procedure, most of these bone-substitute materials act as osteoconductive

scaffold allowing the new bone formation replacement the partially or totally resorbed grafting materials and protective function on the collapse of the overlying membrane. The freeze-dried form of allogenic bone in conjunction with the application of membrane as GBRs technique demonstrated the more than 70% reduction of the peri-implant dehiscence. (136) In addition, new developed technique by sandwich augmentation of both autogenous and aloogenic bone revealed the significant bone gain. (137) Various applications of anorganic bovine xenograft is now widely accepted, one of those was for GBRs technique during implant placement. Well-designed long-term studies reported the high survival rate (127), furthermore, the survival rate was comparable in either pristine bone or regenerated with GBRs procedure using anorganic bovine bone, Bio-oss®. (8) Clinical sustainability of peri-implant tissue health including soft and hard tissue was satisfy reported in anterior implant concurrently with contour augmentation via the GBRs technique of the layered autogenous bone and anorganic bovine bone used. (11) The application of synthetic or alloplastic bone is currently increasing. These bone-substitute materials mainly composed of the two kinds of inorganic mineral such hydroxyapatite and tricalcium phosphate in the different proportion for each market brands. Osteoconductive property in the animal study was proved by the evaluation of the peri-implant defect resolution. (138) Comparable ability of the hydroxyapatite and tricalcium phosphate mixture and anorganic bovine bone for correction of the dehiscence defect around the installed implant was also reported. (139)

Pain, anxiety and discomfort following implant placement

When undergoing oral surgical procedures, patients are unavoidable to encounter with undesirable events such sharp needle injection, incision with knife, bleeding per mouth, peri- , post-operative pain and discomfort. Most of oral surgical patients still present the high degree of anxiety when compare to others dental procedures. (140) Pain is considered as the closely associated causative factor for the anxiety in oral surgical operations. (141) By the way, implant placement to the jaw bone necessarily needs the surgical procedure which related to inflammatory process such pain and swelling following surgical tissue trauma. Patients report moderate level of pain at 1 days then decreases to the mild level nearly the absent of pain at 7 days post-surgical implant placement, respectively. Gender, number of implant placed, skills of surgeon and surgical difficulty were demonstrated the association to that reported pain. (33, 142) For post-operative swelling, a previous study addressed that most of surgical implant placement patients report about the extra-oral swelling correspond to the surgical area. In addition, much more swelling was observed in patients with increasing age, posterior surgical location, multiple implants placed and site development simultaneously with implant placement. (32) As known, the pain and swelling is a part of the main clinical signs for the infection. However whether prescribe the different regimens or discard the use of peri- and post-operative antibiotic medication, patients were reported the similar degree of pain and swelling following surgical implant placement. (143)

Oral health-related quality of life in patients with dental implant rehabilitation

Tooth loss is consider as one of the major oral impairment because of the limitation on physical oral function especially chewing food and the difficulty in social function such as talking, smiling. (144) As in the current dental care, dental implants become the standard of treatment for reconstruction of both total and partial tooth loss. Especially in patient with complete edentulous mouth, implant-supported prosthesis significantly demonstrated the better patient satisfaction as well as the improvement in the oral, and also, general health-related quality of life due to the increase in physical function and psychosocial ability over the conventional denture. (24-26, 145, 146) As in the partial edentulous patients, preferable OHRQoL and high long-term satisfaction was found in patients who receive implant-supported single crown or fixed partial prosthesis. (4, 5, 147-149)

Measurement of treatment outcome particularly dental implant rehabilitation should consist of multi-dimensional assessments including longevity/survival outcome, functional outcome, psychological and economic outcomes. (12) Most of the well-established studies concentrated on the assessment of treatment success which mostly referred to longevity/survival and functional outcomes while psychological and economic outcomes were paid less attention. Moreover, study related to psychological impacts as well as patient-based outcomes measurement is unreliable due to poorly design study or unaccepted measuring tools. (150) Therefore, doing the studies that aiming to evaluate patient response to dental implant treatment was latterly recommended. (35)

After the introduction of dental implant for edentulous reconstruction which formerly use as an anchorage for conventional prosthesis, later known as implant

retained/supported prosthesis, in order to solve the problem of conventional denture especially to improve the retention and stability which were the most common patient's reported trouble from denture wearing. Patient reaction to this new modality of treatment had begun to study (151) by using the uniquely study-purposive questionnaire aiming to show the patient's point of view on this intervention. The result of these early studies demonstrated that patients were satisfied for implant-anchored prosthesis since the comfortability, masticatory function and esthetical appearance considerably improved. (151, 152) However, due to the poor study designed as well as non-standardized questionnaire without the reliability and validity of the measuring technique, theses earlier study's results are scientifically unreliable. Visual analog scale was applied for patients to rating their opinion on implant-supported prosthesis which shown superiorly in overall satisfaction, comfort, stability, and chewing ability when compare to conventional denture. (153, 154) Later, study of the OHRQoL has been introduced to evaluate patient's perspective treatment outcomes and satisfaction especially in patients who receive implant-supported prosthesis. These studies still present the similar result as previous that implant-supported prosthesis has a positive effect to OHRQoL in both esthetic and functional ways. (26, 155) OHIP was commonly chosen for measuring OHRQoL because of its psychometric properties verification and being used in the numerous patient-based outcome studies which beneficial for study's results comparison. The results of these studies clearly shown that patients with implant-retained/supported overdenture demonstrate a less OHIP score than conventional denture patients that imply the better in OHRQoL following implant treatment. (25,

156-158) OIDP is considered as one of the subjective assessment to evaluate OHRQoL in this group of patients, however, only limited study was used. (24)

Pre-prosthetic surgery which performs in order to improve alveolar tissue prior for implant placement is also interested in the patient-based outcomes study due to the post-operative morbidities potential to affect patient comfortability as well as physical function, sometimes, esthetic aspect. Subjective evaluation in the form of self-assessment questionnaires and visual analog scale to rate the patient's perception of post-operative pain/discomfort, patient's opinion on operation, satisfaction were studied. These study's results clearly shown that patients tolerated to the mandibular bone harvesting procedure and that morbidities did not present the negative affect to patient. (71, 72, 159, 160) However, the quality of life related to these kinds of surgery has been rarely studied. Reissmann DR, et al. (161) studied the effect of different donor sites, including intra-oral and extra-oral sites, for alveolar bone grafting prior implant placement to the quality of life by Short Form-36 which represent the general health-related quality of life and OHIP-G which represent the OHRQoL. OHIP score appeared to increase over the baseline at 3 days post-operation then decreased below baseline at 4 weeks post-operation, however, no statistical significance detected. Therefore, the worsening of the OHRQoL by intra-oral bone harvesting appears to occur in a small degree post-operatively and then recovery to normal in a short period of time. Nevertheless, the authors suggested that the interpretation of OHIP should be precaution due to the patient's inability to distinguish between donor site and recipient site which located in the adjacent area.

Patient's satisfaction in one of the various methods used to represent patient's response after therapeutic means as well as implant treatment. Gibbard LL,

et al. (147) conducted the 5-year survey after implant-supported single tooth replacement in 42 samples. Patient satisfaction was gathered from the satisfaction questionnaires which consist of the satisfaction on different aspect such functioning, cleaning, willingness for another implant and recommendation this treatment to others. Most of patients reported a high level of satisfaction for implant prosthesis in all dimensions assessed. Pjetursson BE, et al. (5) performed the similar study after 10 years post-implant placement for partial edentulous prosthesis by assessed the visual analog scale in various satisfactory dimensions such comfortability on chewing, phonetics, esthetics, cleaning ability and the fulfillment on patient's expectation in 104 patients. The result showed the high satisfaction level in all dimensions evaluated. The 97% of patients satisfied on chewing ability and the esthetic appearance to the implant prosthesis while 96% and 93% also satisfied on the phonetic and hygiene cleansing, respectively. The satisfaction on implant treatment was correlated to the patient's expectation, eventually. Vermylen K, et al. (4) also demonstrated the similar result which esthetic, phonetic, cleaning and valuable of the treatment were satisfied, however, 22.5% of patients unwanted to undergoing this kind of surgery again. Furthermore, patient responded the expectation over the baseline following implant treatment. (162)

Subsequently, the OHRQoL index was also become the interesting and trustful tool to address patient's opinions. Furuyama C, et al. (149) compared the OHRQoL by OHIP-J49 in 79 implant prosthesis and 109 removable prosthesis patients. Better OHRQoL was found on implant prosthesis over the conventional one. However, more than 55% and 77% of patients with respective type of prosthesis reported the trouble about food impaction. Nickenig H-J, et al.(163) reported the

decrease in OHIP-G21 score (median score were 17.1 and 5.4 at preoperative and post-treatment, respectively) at 1-2 months following treatment completion in partial edentulous patients whom received implant placement for fixed prosthesis. Preoperatively, most patients were frequently addressed the problems on appearance dissatisfaction (24.2%) and chewing difficulty (23.7%), but after treatment, the appearance dissatisfaction was reported only 4.1% of patients. Eitner S, et al. (31) evaluated the change of OHRQoL before implant placement, during the healing period and post-prosthesis construction by measurement the OHIP in 16 patients whom received implant placement for partial edentulous reconstruction. OHIP score tended to increase, which imply to the deterioration of OHRQoL, during the healing period simultaneously with the patient's reported of the pain in the same period. Finally, the score decreased below the pre-operation level after delivery the prosthesis that represents the improvement in OHRQoL. However, caution needed to be considered for the interpretation due to timing at the healing period measurement that performed after the complete clinical healing, therefore, this could be unable to represent the OHRQoL in the early post-surgical phase which might potentially affected to patient's lives. Fillion, et al. (164) published the study about the OHRQoL in 176 patients whom receive implant treatment whether for implant- supported fixed prosthesis or implant-retained overdenture. General Oral Health Assessment Index (GOHAI) was used to evaluate the OHRQoL at before treatment and after prosthesis construction. Most of patients reported the better OHRQoL following the treatment regardless of the type of prosthesis received. Kriz Pavel MS, et al. (165) also captured the improvement in GOHAI score on 97 patients at 1 month after prosthesis delivery.

In addition, many of the individual or clinical factors were interested to be studied in order to find out the potentially effect on the OHRQoL by the intervention of dental implant especially for partial edentulous reconstruction. Ponsi J. et al. (28) considered the effect of different anatomical position of the dental implant prosthesis to the OHRQoL. The measurement of OHIP score at before and after prosthesis construction in 80 single space partial edentulous patients demonstrated that implant prosthesis at the anterior and premolar region significantly changed the OHRQoL level in the positive way but implant prosthesis in the molar region that unable to address the improvement in OHRQoL statistical significantly. Reisine S, et al (34) studied the effect of different surgical augmentation procedures that perform during implant placement to the OHRQoL in 48 post-menopausal women. Three augmentation procedures according to the type of defect such dehiscence repair, expansion procedure and in combination of both were studied. OHIP was used to access the OHRQoL at pre-operation, 1 week and 8 weeks for early and late post-operative healing period respectively and 9 months post-prosthesis construction. In contrast to the author's hypothesis which expected the declination of the OHRQoL corresponding to the invasiveness of the augmentation procedures, the result conversely showed the gradual improvement of OHRQoL regardless of timing of measurement or invasiveness of the procedures. However, this study presented the limitations such as the absence of a control group for comparison, the generalizability of the finding due to the specific sampling group. Additional not only OHRQoL but also patients satisfaction studies are summarized in Table 3.

Authors	Objective	Measuring tool	Assessed timing	N	Result
Eitner S, et al. 2012 (31)	Assessment the OHRQoL before, during, and after completion of implant therapy	OHIP-G55	Pre-op 4-5 mo PO Post-prosthesis	16	- Median score at Pre-op, 4-5mth PO and post-prosthesis were 75.8, 84.3 and 29.5 - Reported problems at 4-5mth PO 93.8% Worried 37.5% Uncomfortable about appearance 50% Painful aching in the mouth
Nickenig H-J, et al. 2008 (29)	Assessment the OHRQoL before and after implant therapy	OHIP-G21	Pre-op 1-2 mo post-prosthesis	219	-Median score at pre-op and post-prosthesis was 17.1, 5.4
Reisine S, et al. 2012 (34)	Assessment the change on the OHRQoL with different bone augmentation technique during implant placement	OHIP-14	Pre-op 1 wk PO 8 wk PO 9 mo Post-prosthesis	48 - 12 Dehiscence - 13 Expansion - 24 Expansion with dehiscence	-Mean score at Pre-op, 1 wk, 8 wk PO and 9 mo Post-prosthesis were 15.4, 13.7, 10.6, 7.5 -Younger was significantly poorer the OHRQoL from older at 1 wk PO.
Yu S-J, et al. 2012 (30)	Investigation the relationship between anterior implant prosthesis and the **OHRQoL**	OHIP-14	Pre-op 6 mo PO (delivered prosthesis)	238	-Mean score at Pre-op and 6 mo PO were 23.1, 4.9 -Median score at Pre-op and 6 mo PO were 21.5, 4.0 -Gender and educational level significantly affected to the OHRQoL alteration
Ponsi J, et al. 2011 (28)	Evaluation the change on subjective oral health in single dental implants with different anatomic locations	OHIP-14	2nd stage surgery 3 mo Post-prosthesis	80 - 22 Incisor - 38 Premolar - 26 Molar	-Significant OHIP-14 score difference was found for incisor and premolar implant prosthesis. - Better, the same and worse in OHRQoL was reported in 30%, 65% and 5% of patients post-treatment - 89%of patients satisfied with the treatment but 3% were not.
Goiato MC, et al. 2014 (166)	Evaluation the OHRQoL and satisfaction in implant-supported fixed partial prosthesis patients	OHIP-14 Satisfaction questionnaire	At least 6 mo Post-prosthesis	106 - 26 splinted prosthesis - 48 single prosthesis - 32 combination of both	- Mean score ranged from 1.0-1.8 - No significant different among type of prosthesis - Patients with single implant prosthesis presented more unsatisfied than splinted implant prosthesis for the discomfort during surgery
Furuyama C, et al. 2012 (149)	Investigation the association between implant-supported fixed prosthesis and removable partial dentures (RPDs) to OHRQoL	OHIP-J49	At least 1 mo Post-prosthesis	188 - 79 implant prosthesis - 109 RPDs	-Mean score for implant-supported fixed prosthesis and RPDs were 21, 38 -Age and duration of prosthesis used were associated to the mean score -55.7 and 71.1% of patients in the implant-supported fixed prosthesis and RPDs complaint about the food impaction

Authors	Objective	Measuring tool	Assessed timing	N	Result
Dolz J, et al. 2014 (167)	comparison the effect of conventional or immediate loaded implant on OHRQoL	OHIP-49	Pre-op 3 mo post-surgery 3-5 mo post-prosthesis	104 -75 conventional loaded -29 immediate loaded	-Mean OHIP score for conventional loaded implant patients at pre-op, intermediate and final f/u was 13.7, 10.3, 6.8 -Mean OHIP score for immediate loaded implant patients at pre-op, intermediate and final f/u was 18.6, 9.0, 2.5 -Immediate group was greater improvement in OHRQoL than conventional group
Bramanti E, et al. 2013 (168)	Assessment the OHRQoL before and after implant therapy	OHIP-14	Pre-op 2 yrs post-prosthesis	50	-Mean score at pre-op and post-prosthesis was 2.15, 0.65 -All domains score significantly decrease from pre-op -No association was found between the score and age, gender, occluding dentition
Raes F, et al. 2012 (169)	Assessment the OHRQoL in a single implant patients in the anterior maxilla	OHIP-14	Pre-op 1 mo PO 6 mo PO 12 mo PO	96 -46 Immediate placement -50 Conventional placement	-OHRQoL improves over time in all domain of OHIP-14 -Conventional group shows significant greater in physical disability at 1 month post-operation -Conventional group shows significant greater in physical pain but immediate placement shows more psychological discomfort at 6 month post-operation
Raes F, et al. 2013 (170)	Assessment the patient's opinion as treatment outcome of immediately loaded implants in the anterior maxillary tooth	OHIP-14	Pre-op 1 mo PO 6 mo PO 12 mo PO	48 - 16 Immediate placement - 23 Conventional placement - 9 Placement on healed grafted site	-Overall OHRQoL improvement from baseline to 1 year post-prosthesis -Improvement on chewing ability, taste sensation, relaxation, self-confident, doing the job effectively -No inter-group comparison
Kriz Pavel MS, et al. 2012 (165)	Assessment the OHRQoL in dental implant patients	Modified questions from GOHAI	Pre-op At least 1mo post-prosthesis	97	-Median of overall score at pre-op and post-prosthesis was 4 and 5 that imply for the improvement -Marital status, personal concern and number of anterior teeth placed were found for the association to the score changed.
Fillion M, et al. 2013 (164)	Assessment the different in OHRQoL improvement between implants-supported fixed or retained prostheses	GOHAI	Pre-op At least 6 mo post-prosthesis	176 - 77 single tooth - 75 fixed-partial denture - 24 full	- Overall mean score at pre-op and post-prosthesis was 48.3, 54.7 that imply for the improvement - All types of prosthesis significantly demonstrated the improvement in OHRQoL,

Authors	Objective	Measuring tool	Assessed timing	N	Result
				prosthesis	however, the greatest improvement was found in full prosthesis group - Gender and age found no association to OHRQoL change
Al-Omiri MK, et al. 2011 (171)	Assessment the relationship between OHRQoL and different psychological patients group	DIDL	Pre-op At 3 mo post-prosthesis	80	-Increasing on the satisfaction in appearance, pain, oral discomfort, general performance and eating following prosthesis used -Neuroticisms presented less satisfaction on all dimension of DIDL after treatment
Hof M, et al. 2014 (172)	Comparison patient-based outcome at different implant placement timing in the aesthetic zone	Patient's satisfaction by Visual Analog Scale	At least 1 yr Post-prosthesis	153 - 26 Immediate - 35 Early - 13 Delay - 15 Implant with GBR - 64 Implant after block graft	-Satisfaction level was 95% for immediate, 84% for early, 80% for delay implant placement for implant prosthesis -Satisfaction level was 75% for implant prosthesis underwent guided bone regeneration simultaneously with implant placement, 79% for implant prosthesis underwent autogenous bone graft as staged approach
Schropp L, et al. 2008 (148)	Assessment the outcome of early and delayed placement of single-tooth implants **in the anterior and premolar region**	Patient's satisfaction by Visual Analog Scale	2 yrs Post-prosthesis 5 yrs Post-prosthesis	34 - 18 Early - 16 Delay	-Median satisfaction level to overall treatment at 2 yrs. for early and delay implant placement were 96.5, 92.0 -Median satisfaction level to overall treatment at 5 yrs. for early and delay implant placement were 95.5, 95.0 - Older patients were familiar to the implant prosthesis sooner and reported the easier cleaning than younger patients
Vermylen K, et al. 2003 (4)	Evaluation patient satisfaction following implant treatment	Patient satisfaction questionnaire	33 months in average post-prosthesis (3-89 months)	40	- Positive satisfaction was demonstrated on aesthetic, phonetics, cleaning and cost-effectiveness - 22.5% unwanted to receive the future implant surgery
Pjetursson BE, et al. 2005 (5)	Investigation the patient satisfaction after implant therapy	Patient satisfaction questionnaire	5-15 years post-prosthesis	104	- 97% satisfied in chewing comfort, phonetic and esthetics - 93% reported the ability to clean the prosthesis without difficulty - 94% would like to receive the implant treatment again
Baracat LF, et al. 2011 (162)	Comparison patients' expectations before and outcome perception after dental implant	Visual Analog Scale	Pre-op 1 week post-prosthesis	50	- Pre-treatment expectation score was 5 ients perceived the treatment over their baseline expectation. (Post-treatment score was 9 especially

Authors	Objective	Measuring tool	Assessed timing	N	Result
	therapy				for function and esthetic)
Gibbard LL, et al. 2002 (147)	Assessment the patient's perspective following implant-supported prosthesis	Patient satisfaction questionnaire	5 yrs post-prosthesis	30	- 100% satisfied the appearance and the function of the prosthesis - 90% satisfied the hygiene cleaning of the prosthesis

Table 3 Summarized on current patient-based outcome studies in partial edentulous patients reconstructed by implant prostheses

Pre-op : pre-operation/ PO : post-operation/ mo : month(s)/ yrs : years/ GOHAI : General Oral Health Assessment Index/ DIDL : Dental impact on Daily Living

Chapter 3
Materials and Methods

Research design: Prospective observational clinical study

Population and samples

Target population

- Patients who receive surgical implant placement simultaneously with guided bone regeneration procedure for partial edentulous reconstruction

Sample population

- Patients who receive surgical implant placement simultaneously with guided bone regeneration procedure and patients who receive only surgical implant placement for partial edentulous reconstruction at Faculty of Dentistry, Chulalongkorn University from July 2013 – June 2014

Sample grouping

- Study Group: Patients who receive surgical implant placement simultaneously with guided bone regeneration procedure for partial edentulous reconstruction
- Comparison Group: Patient who receive surgical implant placement without other surgical intervention for site development.

Sample inclusion criteria

- Patients with age over 18 years who sign consent form to participate this study by themselves or the permission of their parents.
- Partial edentulous patients, who plan for implant placement in conjunction with guided bone regeneration for the dimensional deficiency correction of residual alveolar ridge, are enrolled for the study group samples and partial edentulous

patients, who plan for implant placement in the adequate native alveolar ridge are enrolled for the comparison group samples.

Sample exclusion criteria

- Partial edentulous patient who plan for implant placement for fixed-removable (hybrid) prosthesis or implant-retained,-support removable prosthesis
- Patient with history of jaws reconstruction from resected oral and maxillofacial pathology
- Patients with physical and/or psychological disability that demonstrate the communication problems for example deafness, dumbness, blindness, mental retardation, autism etc.
- Patients who unable to continue for all follow-up periods.

Sample size calculation

In order to find out the suitable samples that could present statistical significant difference of this research question, the amount of samples for each group in this study is calculated by the formula, presented below, and replaced the variables derived from related previous studies.

To test the difference of OIDP score for each sample group in order to show the significant change in the oral health-related quality of life pre- and post-treatment period, the formula in which to test the sample size calculation for paired-mean comparison is chosen.

$$n = \frac{\sigma^2 (Z_{1-\alpha/2} + Z_{1-\beta})^2}{(\mu_1 - \mu_2)^2}$$

n = the required amount of samples in the group

μ_1, μ_2 = the mean of the OHRQoL score from previous study pre- and post-treatment, respectively

σ^2 = the calculated variance from the formula as shown;

$$\sigma_1^2 + \sigma_2^2 - 2r\sigma_1\sigma_2$$

σ_1 Represent the standard deviation of μ_1

σ_2 Represent the standard deviation of μ_2

α =Probability of type I error

β = Probability of type II error

Z= Z-score derived from Z-score table

Due to the lack of previous related study that use the OIDP for assessing the OHRQoL in regenerative bone-augmented dental implant patients, only the study of Reisine S, et al. (34) which measure the score by OHIP-14 at different time point in patients who received bone augmentation procedure simultaneously with implant placement was chosen for sample size calculation. By the way, 15.4 ± 8.9 and 7.5 ± 7.6 represented the mean (μ_1, μ_2) and standard deviation (σ_1, σ_2) in this equation derived from the OHIP-14 score in the pre-operative and 9 month post-operative, respectively. The α was set at 0.05 for significance level and the β was set at 0.2 (4 times of α level). Z-score was found from Z-score table, $Z_{1-\alpha/2}$ equal to 1.96 and $Z_{1-\beta}$ equal to 0.842, respectively. The number of 17.23 was calculated according to these values, thus, this study requires at least 18 patients in each group.

However, the other related study performs by Eitner S, et al. (31) which demonstrated the change of OHIP-G score at different period of implant placement without the augmentation procedure. The OHIP score was 75.8 ± 10.3 and 84.3 ±

13.2 for pre-operative and during healing period 3-5 months post-implant placement, respectively. Given the same α and β value, the sample size needed for this study was calculated in the same manner. At least 31 patients in each group are required.

In conclusion, this study decided to collect at least 31 samples for each group because it represents for appropriate amount of samples that could demonstrate statistical difference of the oral health impact profile score in patients who received surgical implant placement from mentioned formula. In addition, the data more than 30 samples could be assumed for normal distribution which beneficial in parametric statistical testing.

Materials

Socio-demographic and clinical data

Patient's medical records of Chulalongkorn University Dental Hospital are planned for collecting the required data which composed of;

Socio-demographic information, medical and dental history

- Socio-demographic data such gender (male/female), age (less than or equal to 45 years/during 46 to 59 years/ equal to or more than or 60 years), educational level (under university/university or above)
- Medical history such current systemic disease (present/absent)
- Dental prosthesis history such experienced on removable denture (ever/never), experienced on implant placement (ever/never)

Clinical and surgical-related information

- Detail on implant surgical procedure such amount of placed implant (single/multiple), implant position (anterior/posterior), implant location

(maxilla/mandible), timing of implant placement post-extraction (early/delay), attending surgeon and prosthodontist (experienced dental staff/post-graduated student)

Oral health-related quality of life assessment

The assessment of oral health-related quality of life will be performed according to OIDP, Thai version. This is the constructed interview questionnaire consist of 8 daily activities in 3 dimensions;

- Physical dimension: eating and enjoying food, speaking and pronouncing clearly and cleaning teeth
- Psychological dimension: sleeping and relaxing, smiling or laughing and showing teeth without embarrassment and maintain usual emotional state without being irritable
- Social dimension: carrying out major work or social role and enjoying contact with people

Each daily activity, patient is requested to rate the score of impact frequency and severity. The 5-point score is used for both frequency and severity which defined as;

For frequency rating score, 2 categories, regular or spell, of frequency is defined according to the pattern of occurrence. Regular pattern frequency rating score is used if the impact occurs more than once a month. On the other hand, spell pattern frequency rating score is used when the occurrence of impact is less than once a month, respondents are asked to count the total days that the impact occurs (Table 4).

Rating Score	Frequency of impact occurrence	
	Regular pattern	Spell pattern
0	Never affected	0 days
1	Less than once a month	Up to 5 days in total
2	Once or twice a month	Up to 15 days in total
3	Once or twice a week	Up to 30 days in total
4	3-4 times a week	Up to 3 months in total
5	Every or nearly every day	Over 3 months in total

Table 4 The OIDP frequency rating score criteria

For severity rating score, patients are asked for the severity level of the occurrence impact to their life. The 5-Likert ordinal scale is used for individual severity evaluation ranging from 0 represent no severity to 5 represent “very severe”.

Not only the frequency and severity are assessed but also perceive cause needs to be recorded. Perceive cause is the causative problem or trouble of the impact to the specified oral-related daily activity.

Global rating of change scale is also designed to collect the patient’s rating about the perceived change that really occurs from their own perception following all of intervention received. Visual Analog Scale (VAS) of 11-point scale is recommended for this type of rating.(173) (Figure 3)

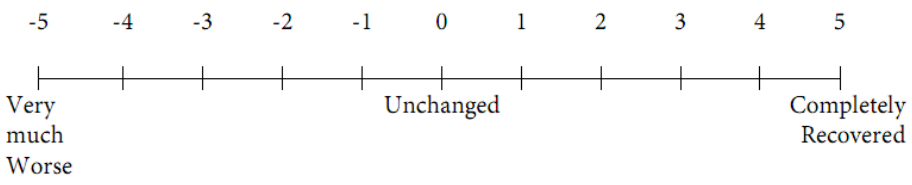


Figure 3 global rating of change using VAS

Scoring methods

The overall OIDP score

Total impact score of each daily performance is calculated by the multiplication of frequency score and the severity score that ranging from score at 0 to the maximum of 25. The overall OIDP score is accumulated from all of 8 total impact scores thereby the possible maximum score is 200. Then, the overall OIDP score is conversed into the percent by multiply it with 100 and divide it by 200.

$$Overall\ OIDP\ score\ = \frac{\sum total\ impact\ score\ of\ 8\ performances \times 100}{200}$$

The prevalence, extent and intensity of OIDP scores

Prevalence, extent and intensity of OIDP score are also planned to present as the other formats of scoring method moreover than mentioned overall score.

- Prevalence represents the proportion of patients whom report impact at least one or more performances.
- Extent represents the number of performance(s) with impact in each patient which range from 0 to 8 then be categorized into 4 group as extent=0, extent 1-2, extent 3-5 and extent more than 6.
- Intensity represents the highest of performance score among eight performances, which range from 0 to 25, then classified this score to 4 categories which compose of no impacts (performance score at 0), little (performance score at 1-5), moderate (performance score at 6-12) and severe (performance score at 15-25).

Methods

Ethical considerations

After approval this research proposal in the human-related research ethical point of view by the ethical committee from Faculty of Dentistry, Chulalongkorn University. Patients who fulfill the study's sample criteria are invited to participate in this study. The research process, study protocol, compliance needed, risk and benefit are clearly explained both written and verbal by the researcher and give chance for patients to interrogate about the distrustful topics related to their rights to know. All patients who obviously understand and pleased to participate the study, consent forms are signed before the beginning of the study. However, patients could quit the study at any study period if they want.

Patient recruitment

All patients who planned to rehabilitate partial edentulous with dental implant(s) at Oral and Maxillofacial Clinic, Special Clinic, Esthetic and Implant Clinic, Maxillofacial Prosthetic Clinic and Post-graduated Prosthetic Clinic at Chulalongkorn University are invited to participate in this study. In addition, public announcement also be done for additional interested patients to enroll in the study.

Treatment process for dental implant prosthesis

Briefly, 5 steps of treatment were divided as follow;

1. Treatment planning

Following patients decide to replace the missing tooth/teeth with dental implant prosthesis, all related histories, clinical examination, radiograph of the

current dentition, study model and the dental computer tomogram at the surgical planed site (optional) are investigated for pre-operative evaluation. Dental implant may be performed at different time period following tooth extraction which classified as immediate, early and delay implant placement. The requirement of guided bone regeneration for alveolar augmentation in conjunction with surgical implant placement is also planned before performing surgery, however, actually re-evaluation could be done during surgical alveolar tissue exposure or following implant installation that clearly shown the defect in which surgeon could make the precise decision for implant site development simultaneously with implant placement, or not. Patients were then informed about the all details of treatment processes, time required and all expenditures.

2. Surgical procedure

Before the surgical placement of dental implant fixture, all patients were thoroughly evaluated about the surgical-related physical health and determine the necessary vital signs. Pre-medication with antibiotics and/or analgesic are optional and prescribed however in the different by the surgeon's prefer and patient's condition. Local anesthetic solution with vasoconstrictor was introduced to all patients for pain control during surgical procedure. Exposure of the underlying alveolar bone by mucoperiosteal flap was adequately done. Prepared surgical stent was used for localization the implant position. Osteotomy for the actually implant size was performed according to manufacturing recommendation for specified implant used. All installed implants showed acceptable clinical primary stability. In case of the need for additional bone augmentation in order to correct peri-implant defect or to reconstruct appropriate alveolar contour, particulate bone whether

autogenous from the adjacent or from the osteotomy site or commercially available allogenic, alloplastic bone was placed at the augment-needed site. Barrier membrane as guided tissue regenerative purposed was placed over the grafted materials. Horizontal periosteum releasing incision was performed in order to coronally- repositioned the surgical flap for tension-free closure. The gingival forming abutment was screwed for one stage approach whereas placing the cover cap then waiting a period of time for healing before screwing the gingival forming abutment as two stage approach. Resorbable suture was used to stitch the flap. Periodontal dressing, COE-PAK™, was sometimes used for wound protection purposed especially when dehiscence area was unavoidable left expose. Routine post-operative instructions were given to all patients that mostly instructed about wound care, surgical site hygiene, avoidance of crushing force on installed implant. Necessary medications such antibiotic, analgesic, anti-inflammatory or antiseptic were prescribed by consideration of each attending surgeon.

3. Post-operative follow-up schedule

Commonly schedule for post-operative follow-up occurs firstly within 2 weeks later for stitches off and wound irrigation then continue for routine check-up at 1 and 3 month post-operatively or until clinical complete healing. In these follow-up visit, patients were examined intra-orally especially at the surgical site. Implant should be stable in placed position. Peri-implant mucosa was inspected for clinical significant abnormalities such excessive tissue overgrowth, inflammation/infection signs, graft rejection or failure. Peri-apical radiograph was taken to assess the integration level of dental implant to surrounding alveolar bone. However, implants which demonstrate the critical events such severe site infection, poorly integrated of

augmented graft, unrestorable implant position etc. were fixed properly following standard practice guidelines in order to re-establish the appropriate implant placement.

4. Prosthetic restoration

Patients were referred for prosthesis construction by the prosthodontist after 4-6 months of healing period. Installed posterior implants mostly do not require temporary restoration while anterior-esthetically related prosthesis sometimes needs the temporary restoration for additional pre-prosthetic gingival manipulation. Screw-retain or cement-retain prosthesis was chosen appropriately by case.

Timing for oral health-related quality of life data collection

To gather data correctly, all data was collected by one researcher whom receives the demonstration how to interview patients for obtaining the actually answer and how to rate the OIDP score from the experienced professor that expertise in the OHRQoL researches. The interview is done in the private and quiet room. Data collection were performed in 5 different time points as pre-operation for baseline information, 2 weeks post-operation to evaluate the effect of surgical procedure, 1 month post-operation for early wound healing, 3 months post-operation for clinically complete healing and 3 months post-prosthesis delivery as treatment completion. OIDP was assessed in all time points determined whereas global transition rating was rated only at 3 months post-prosthesis.

Interview method

Following the researcher introduced himself, describe clearly about the ethical considerations of this study and the consent form was signed, all interviewed and clinical-related data was recorded in the data record form (Appendix 1).

First open-end question was requested to the patient to describe about his/her oral health trouble or problem(s). ..."Could you please describe about your current oral health? Are there any troubles or problems from your mouth to your daily life?" (สุขภาพช่องปากของคุณในปัจจุบันเป็นอย่างไร มีปัญหาอะไรหรือไม่ ถ้ามี ปัญหาสุขภาพช่องปากนั้น ส่งผลอย่างไรกับการใช้ชีวิตประจำวัน) ... After that, the question was focus to the effect of tooth loss or edentulous area to the patient's life. ..."Following you've lost or extracted the tooth/teeth, what happen to your life especially the oral function to your daily life?" (ภายหลังจากที่คุณเสียฟันไป หรือได้รับการถอนฟันออกไป มีการเปลี่ยนแปลงการใช้งานปากและฟันของคุณในชีวิตประจำวันอย่างไรบ้าง) ... Then, each daily performance from all of 8 performances according to OIDP index was interviewed to obtain the difficulty of oral functions in both frequency and severity of that trouble. ..."Following you've lost your tooth/teeth, did you encounter with the difficulty on (8 daily performances such 1. chewing, biting or eating the food 2. speaking, singing or pronouncing the words 3. dentition cleaning or denture (if present) hygiene 4. sleeping or relaxing 5. maintain normal without irritable or moody 6. smiling, laughing or showing your teeth with confidence 7. social contacting with other people 8. working or studying) (ภายหลังจากการสูญเสียฟัน เกิดช่องว่างขึ้นนั้น ท่านมีความลำบากในการ 1 กิน บดเคี้ยว หรือ กัดฉีก 2 พูด ออกเสียง 3 ทำความสะอาดช่องปากและฟัน รวมถึงฟันปลอม 4 พักผ่อน นอนหลับ 5 คงสภาพอารมณ์ไม่ให้หงุดหงิด รำคาญ 6 ยิ้ม โชว์ฟันได้อย่างมั่นใจ 7 พบปะผู้คน 8 ทำงาน หรือเรียนหนังสือหรือไม่ อย่างไร) ... If the patient reported the difficulty in

any of the performance, the question requested to verify the type and rating of the frequency. “Did the difficulty routinely occur or only occur in a period of time? How often of it routinely happened? Or how long that the difficulty occurs?” (ความลำบากดังกล่าวเกิดขึ้นเป็นประจำหรือเกิดขึ้นแค่ช่วงเวลาใดช่วงหนึ่งเท่านั้น ถ้าเกิดขึ้นเป็นประจำ จะเกิดขึ้นบ่อยเพียงใด ถ้าเกิดขึ้นแค่ช่วงเวลาหนึ่ง ช่วงระยะเวลาดังกล่าวนานเท่าใด) The severity of the reported difficulty to their daily life was requested for the score, respectively. “How much of that difficulty impacted to your daily life, please rate 1 to 5 ordinal if the difficulty shown the little to most severely impact to daily life, respectively. However, rate 0 if that difficulty has no impact to your daily life. (ความลำบากที่เกิดขึ้นนั้นกระทบต่อการใช้ชีวิตมากน้อยเพียงใด ถ้าเปรียบเทียบเป็นคะแนนจากหนึ่งถึงห้า โดยที่หนึ่งคะแนนหมายถึงความลำบากนั้นกระทบกับการใช้ชีวิตน้อยมาก ห้าคะแนนหมายถึงกระทบกับการใช้ชีวิตมากที่สุดตามลำดับ ทั้งนี้คะแนนศูนย์จะหมายถึงความลำบากดังกล่าวไม่กระทบกับการใช้ชีวิตประจำวัน)

Finally at post-prosthesis delivery period, the global transition rating of change was interviewed besides above OIDP assessment. … In comparison between before treatment and after using the implant prosthesis for a while, do the problems on your mouth or daily life get better, same or worse? If the problems get better/worse, could you please rating that change from 1 that infer less better/worse change to 5 that infer the highest better/worse change. (ถ้าให้เปรียบเทียบถึงปัญหาในช่องปากที่กระทบต่อการใช้ชีวิต ระหว่างก่อนเข้ารับการรักษากับภายหลังการใส่ฟันบนรากฟันเทียมเสร็จเรียบร้อย ท่านรู้สึกว่าปัญหาดังกล่าวได้เปลี่ยนแปลงไปในทิศทางที่ดีขึ้น เหมือนเดิม หรือ แย่ลง ถ้าปัญหาดังกล่าวเปลี่ยนแปลงไปในทิศทางที่ดีขึ้น/แย่ลง กรุณาบอกระดับของการเปลี่ยนแปลงดังกล่าวจากหนึ่งถึงห้าโดยที่หนึ่งหมายถึงการเปลี่ยนแปลงนั้นอยู่ในระดับที่น้อยมาก และห้าหมายถึงการเปลี่ยนแปลงนั้นอยู่ในระดับที่มาก)

Data analysis

Both descriptive and inferential statistic is used to analyze all data collected from this study. Data presented in nominal or ordinal scale is described by the descriptive statistic in the form of countable number and percent while continuous data, also be described in the form of mean with standard deviation. Association of socio-demographic and clinical-related variables between study's groups is shown by Chi-Square test. OIDP score is presented in mean with standard deviation, median value and minimum-maximum. Impact prevalence presents in form of percent of patients while impact extent and intensity illustrate in form of median, mode and percent of patients. The Box plot represents the OIDP score distribution at different time-point assessed. The Cumulative bar chart shows the percentage of patients categorized by impact extent and intensity level at all time-point assessed.

Normality test, via Kolmogorov–Smirnov test, and the test of equal variance, via Levene's test are done before hypothesis statistical test in order to apply the parametric statistic firstly due to the superior power of test than non-parametric statistic. However, because of the nature of index score that actually characterized as ordinal scale more than interval or ratio therefore non-parametric analysis is applied for all of this data analysis.

For intra-group comparison, OIDP score at various time points is tested for the difference of median by Friedman's test which then tested as match-paired comparison by Related-samples Wilcoxon signed rank test. In order to compare impact intensity at each time-point assessed, Mcnemar test is used for the association analysis between match-paired, 2x2, categorized intensity. For inter-group comparison OIDP score of study and comparison group at each time point is tested

for the difference of median by Mann–Whitney *U* test. Association of impact extent and intensity between study's groups was analyzed by Spearman's correlation.

The smallest of changed score that considered as meaning value in the individual perspective in term of minimal important different (MID) is calculated with various approaches. The anchor-based method is achieved by the use of subjective global transition rating as external reference correlate it with the changed score. The effect size, standardized response mean and standard error of measurement are calculated for the distribution-based method. Effect size derives by the ratio of the mean change score with the standard deviation of the baseline score. Standardized response mean is the ratio of the mean change score with the standard deviation of change score. Standard error of measurement derives from the multiplication the standard deviation of the baseline score with the square root of the 1 minus with the alpha value.

Before analyzing the contributing factors on OHRQoL alteration, patients will be re-classified according to the MID value changed score. The association of categorized changed score to the related variables including socio-demographic variables and clinical-related variables is found by Fisher's exact test for 2 categorized variables and Chi-Square test for more than 2 categorized variables.

Responsiveness of this OIDP measurement is assessed by Pearson's correlation for the associations of OIDP scores and global transition rating. Changed score and intensity change at the different degree of global change are compared by Kruskall-Wallis test and Spearman's correlation, respectively. Wilcoxon Signed rank test is applied to compare the median of pre-operational baseline score and post-prosthesis score at different degree of global change while Mann–Whitney *U* test is

used to compare the changed score at small and large global change to changed score with unchanged global group.

Inferential statistics used in this study to infer the sample's result to the targeted population was operated by the Statistical Package for Social Science version 17.0 (SPSS Inc., Chicago, US). Statistical significance is considered when calculated *p*-value less than 0.05 that represent the confidence interval of 95%.

Chapter 4
Results

Patient recruitment, inclusion and exclusion

The ninety partial edentulous patients whom schedule for surgical implant placement and fulfil the inclusion criteria were invited to participate in this prospective patient-based outcome study. None of them rejected to give the information about daily performances related to their mouth and teeth. In which the study's protocol that needed patient to complete the data from pre-operatively before implant placement until the completely inserted of definitive prosthesis and had been used for a period of time, only fifty-two patients accomplished the data collection corresponding to the study's protocol under the limitation of study period. Others, thirty-eight patients, were unable to complete the planned assessments. Most of them are now waiting for construction of the definitive prosthesis while the installed implants were successfully clinical heal. However, provisional prosthesis had been delivered by some patients in this group in order to manipulate the appropriate architecture of the peri-implant gingiva especially for the anterior esthetic teeth prosthesis that patients were mostly allocated to the study group. Six patients lost their follow up to their attending clinic and unable to contact them via the updated information given on their medical records.

Three implants in two study group patients were failed to integrate with the surrounding peri-implant tissue. One lower posterior implant with bone augmentation by the xenogenic grafting bone and barrier membrane was considerably lost its stability at 1 month post-operation then it was consequently removed. The other

patient with two installed implants simultaneously with bone augmentation by the same type of previous material in the upper anterior region were failed to integrate with the inter-implant gingiva, implants were adjacently placed as the canine and first premolar position. The attending prosthodontist concerned about the movable inter-implant gingival papilla not only for the esthetic appearance of the prosthesis but also for the health of peri-implant tissue. Finally, the explantation procedure of these implants was considered and surgically performed. According to the operative note, the totally labial and inter-proximal bone loss was found in addition with the ingrowth of granulation tissue instead. The implants were removed by the reverse torque technique, inflamed tissue was cleared, allogenic bone-substitute material was then grafted to that defects. This explantation was performed at 8 months post-operation. Overall number of patient recruitment, inclusion and exclusion is shown in (Figure 4).

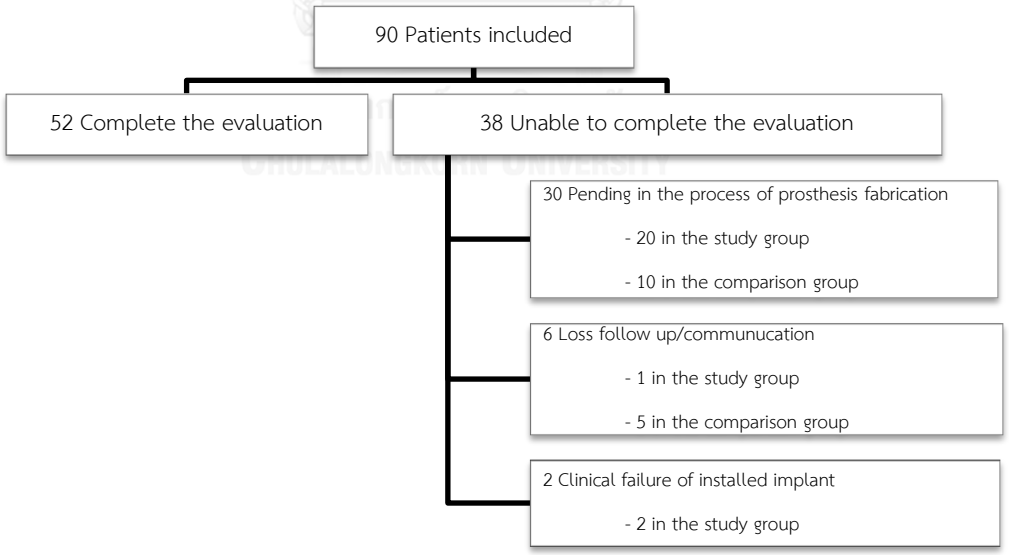


Figure 4 The flow chart represent the number of patients included ,excluded and the reason for exclusion.

Patient characteristics

Socio-demographic and dental history

From fifty-two patients whom complete the evaluation, they were classified into two main groups following this study's objectives. Fourteen patients were received surgical implant placement simultaneously with guided bone regeneration which was considered as "study group" while the others were only received surgical implant placement without the additional bone augmentation called "comparison group". (Table 5) Almost 80% of patients are older than 45 years with mean (SD) of age 54.3 (11.7) years. The patients in the two study's group have the similar mean (SD) of age which are 54.8 (13.2) years for study group and 54.1 (11.2) years for the other one. Although half of patients in the comparison group were classified in the 45-59 years group and 42.8% of study group were in more than 60 years group, the proportion of patients classified by groups of age between study's groups was the same. Proportion of female patients (57.7%) was slightly higher than male. The gender distribution among study group was not different. More than 80% of well-educated patients in the level of university or above participated this study, most of them (57.7%) graduated in the bachelor degree. About the general health of patients, half of them (51.7%) reported at least a kind of systemic disease. In the study group, 64.3% of patients present with systemic disease but 52.6% in the comparison group were healthy. No significant different is found between study's group and the systemic disease reported.

Patients were also interviewed on the past dental history especially the previous denture experience. Removable prostheses which are popularly prosthesis of choice in Thailand due to its conservative, non-invasive, simple and inexpensive

were experienced only 28.8% of patients. The proportion of patients with history of removable prosthesis was higher in the study group while most of patients (81.6%) in the comparison groups had no experience as denture wearer. Statistical significant is found between study's groups according to this experience. (*p*-value=0.006) Uninterestingly, dental implant prosthesis is still the new treatment modality for edentulous reconstruction in Thai population, approximately 80% of all patients and the similar proportion 71.4% and 84.2% in study and comparison group never been treated with this kind of prosthesis.

Clinical and surgical-related variables

The total of 65 implants was placed in these 52 patients. Most of them were installed as single one (80.8%) and mainly located at the posterior dental region (94.2%). The dissimilarity of the amount and location of placed implants was found between study's groups (*p*-value< 0.05). Most of patients (89.5%) in the comparison group required only single implants for single unit prosthesis but patients in the study group required prosthesis-supported by single (57.1%) or multiple implants (42.9%) in the close proportion. All implants in the comparison group were at posterior edentulous (100%) while implants in the study group were even placed at anterior (21.4%) and posterior (78.6%) region. Edentulous mandible was encountered for implant placement more than the maxilla which also distributed in the same proportion among study's group. All patients experienced tooth loss status for a period. Patients (59.6%) were placed following tooth loss more than 6 months as "delay" or "conventional" placement while the others were placed as "early" approach. No proportional difference was found between study's groups in this variable. Attending surgeons and prosthodontists were considered as variable on the

surgical procedure and prosthodontic process, respectively. Patients were treated by experienced dental staffs in the larger proportion than the post-graduate students, however, proportion of dental staffs and students was indifferent distributed between study's groups.

Variables		Total (%) n=52	Study (%) n=14	Comparison (%) n=38	*p*-value[a]
Socio-demographic variables					
Age	≤ 45 years	21.2	28.6	18.4	0.303
	46-59 years	46.2	28.6	52.6	
	≥ 60 years	32.6	42.8	29.0	
Gender	Male	42.3	42.9	42.1	0.961
	Female	57.7	57.1	57.9	
Education level	Under university	15.4	7.1	18.4	0.317
	University or above	84.6	92.9	81.6	
Systemic Disease	Absent	51.9	64.3	47.4	0.279
	Present	48.1	35.7	52.6	
Removable denture experience	Ever	28.8	57.1	18.4	0.006*
	Never	71.2	42.9	81.6	
Implant experience	Ever	19.2	28.6	15.8	0.300
	Never	80.7	71.4	84.2	
Clinical variables					
Amount of implant	Single	80.8	57.1	89.5	0.009*
	Multiple	19.2	42.9	10.5	
Implant position	Anterior	5.8	21.4	0.0	0.003*
	Posterior	94.2	78.6	100.0	
Implant location	Maxilla	28.8	35.7	26.3	0.507
	Mandible	71.2	64.3	73.7	
Timing of placement	Early	40.4	28.6	44.7	0.292
	Delay	59.6	71.4	55.3	
Surgeon	Student	44.2	42.9	44.7	0.904
	Staff	55.8	57.1	55.3	
Prosthodontist	Student	34.6	42.9	31.6	0.448
	Staff	65.4	57.1	68.4	

Table 5 Patient's characteristics according to the study's group and the variable interested.

a: The global association of the socio-demographic and clinical variables according to the study and comparison group by Chi-Square test / *: Statistical significant at 95% confident interval

The overtime change on OIDP assessment

Change in OHRQoL was assessed at before implant placement as pre-operation, 2 weeks-, 1 month-, 3 months post-operation and post-prosthesis. (Table 6) In all patients, median of overall OIDP score was 3.75 at pre-operation increased significantly (*p*-value<0.001) to 8.50 at 2 weeks post-operation then ordinal decreased to 5.0 and 4.0 at 1 month and 3 months post-operation which statistically comparable with pre-operational stage, however, the median of overall OIDP post-prosthesis was 0. The statistical significant difference was found between median score of pre-operation and post-prosthesis (*p*-value<0.001). (Figure 5) The pattern of overall OIDP score change in study and comparison group was similar to the trend of change in all patients. (Figure 6 and Figure 7) The median of overall OIDP score increased from baseline pre-operation at 2 weeks post-operation statistical significantly and then got back in comparable to pre-operation at 1 and 3 months post-operation.

Although patients in the comparison group reported the post-prosthesis median score as 0 that remarkably lower than pre-operation score (*p*-value<0.001), the study group was not. Patients in the study group also reported the reduction in overall OIDP median score from 6.75, pre-operation, to 2.5, post-prosthesis, which unable to show the statistical difference.

Overall OIDP score	Time point assessed				
	Pre-operation	2 wks post-operation	1 mo post-operation	3 mo post-operation	post-prosthesis
Median					
All	3.75	8.50	5.00	4.00	0.00
Study	6.75	13.75	7.25	7.25	2.50
Comparison	2.50	7.00	2.50	2.50	0.00
Mean (SD)					
All	6.35 (6.70)	11.05 (8.09)	6.32 (6.38)	6.17 (6.47)	2.90 (5.83)
Study	9.04 (9.84)	16.71 (10.44)	8.96 (9.47)	8.96 (9.47)	6.11 (9.40)
Comparison	5.36 (4.91)	8.96 (5.94)	5.34 (4.58)	5.14 (4.70)	1.72 (3.23)
Minimum - Maximum					
All	0-38	2.5-38	0-38	0-38	0-31
Study	0-38	3-38	0-38	0-38	0-31
Comparison	0-17.5	2.5-25	0-15	0-15	0-12.5

Table 6 Median, mean and minimum-maximum of overall (aggregate) OIDP score at different time point assessed according to the study's group.

wks: weeks / mo: month(s) / SD.: standard deviation

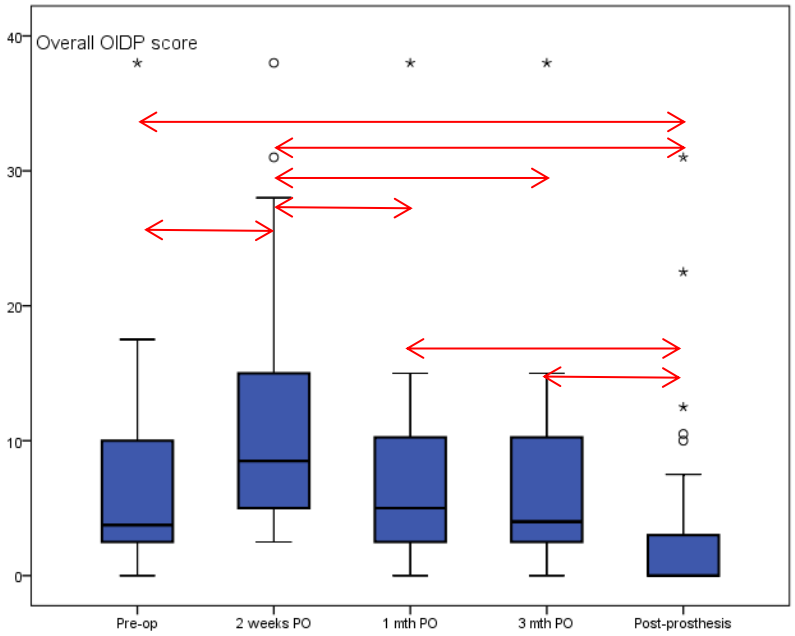


Figure 5 Box plot demonstrates the overall OIDP score in 52 patients at different time assessed

↔ Statistical significant different by Related-samples Wilcoxon signed rank test at *p*-value < 0.001

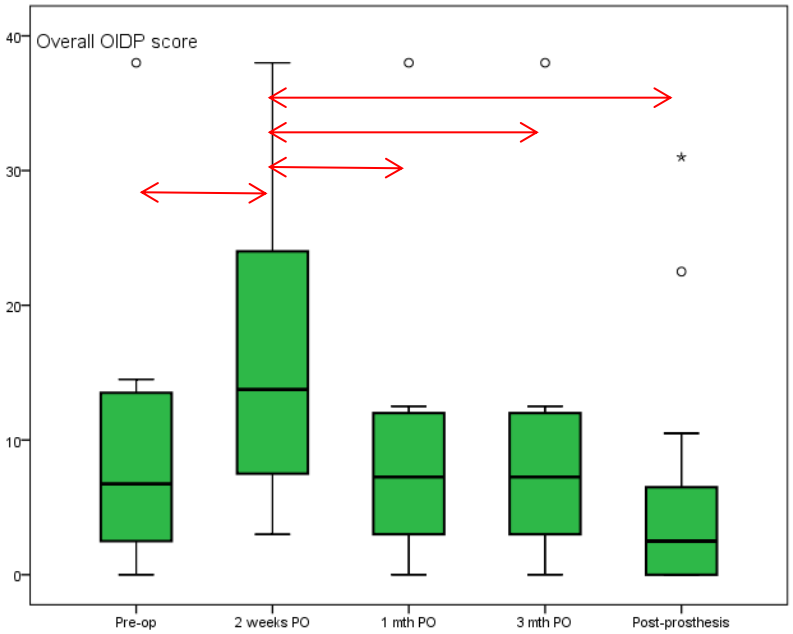


Figure 6 Box plot demonstrates the overall OIDP score in the study group at different time assessed

↔ Statistical significant different by Related-samples Wilcoxon signed rank test at *p*-value < 0.05

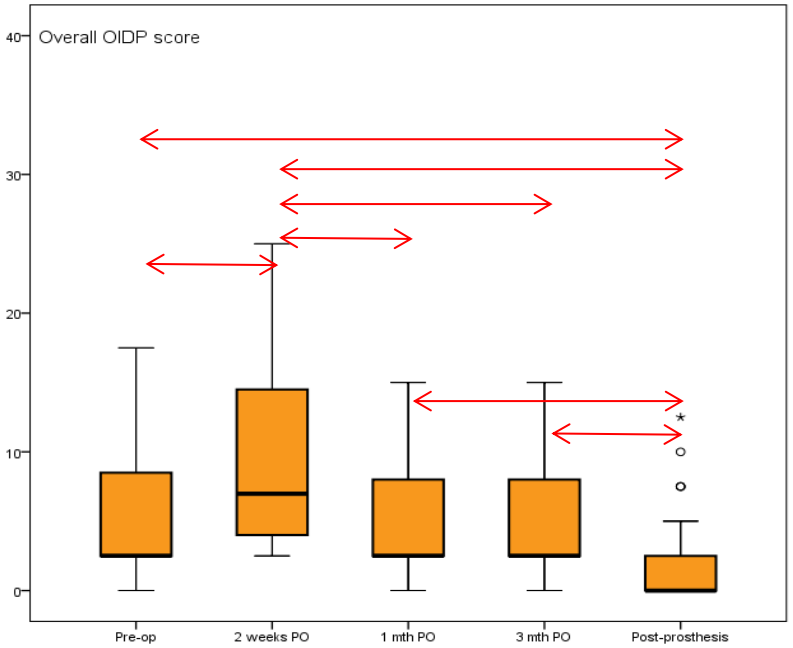


Figure 7 Box plot demonstrates the overall OIDP score in the comparison group at different time assessed.

↔ Statistical significant different by Related-samples Wilcoxon signed rank test at *p*-value < 0.001

The impact prevalence, which infer to how many patients reported the impact, shown that edentulous condition caused daily performances impact in about 84% of patients then, latterly at 2 weeks post-operation, all patients noticeably demonstrated at least one performance impact from surgery. However, the impact prevalence changed in comparable to the pre-operational stage at 1 and 3 months post-operation. Following the prosthesis usage, the reduction in patient proportion with oral impacts was found. Only 31% of patients in the comparison group whereas about 64% in the study group still reported the oral impacts post-prosthesis. (Table 7)

Impact extent counting the number of affected daily performance according to the 8 OIDP activities assessed was grouped into 4 levels, 0, 1-2, 3-5 and 6-8. (Table 7) At pre-operation, most of patients reported only 1 to 2 performances impacts. Increasing number of patients in the study group (42.9%) encountered oral impacts in 3-5 performances during 2 weeks after surgery while only 18.4% in contralateral group shown the same as that impacts magnitude, nevertheless, less than 2 performances were mostly reported again at 1 and 3 months post-operation. Implant prosthesis decreased previous oral impacts till no performance difficulty was reported especially in comparison group but unable to demonstrate that effect to the study group. There was 1-2 performances largely reported after prosthesis delivery in study group. (Figure 8-10)

Other formats of OIDP score	Time point assessed				
	Pre-operation	2 wks post-operation	1 mo post-operation	3 mo post-operation	post-prosthesis
Impacts prevalence (%)					
All	84.6	100.0	88.5	86.5	40.4
Study	85.7	100.0	85.7	85.7	64.3
Comparison	84.2	100.0	89.5	86.8	31.6
Median of impact extent					
All	1-2	1-2	1-2	1-2	0
Study	1-2	3-5	1-2	1-2	1-2
Comparison	1-2	1-2	1-2	1-2	0
Median of impact intensity					
All	Little to Moderate	Severe	Little	Little	No impacts
Study	Moderate to Severe	Severe	Moderate to Severe	Moderate to Severe	Little
Comparison	Little	Moderate	Little	Little	No impacts

Table 7 The impacts prevalence, extent and intensity of OIDP at different time point assessed according to the study's group.

Impact prevalence: the percentage of patients that reported impacts at any degree / Impact extent: the number of daily performance impacts from 8 daily activities assessed (Maximum extent is 8) / Impact intensity: The magnitude of impacts classified ordinally from no impact to very severe / wks: weeks / mo: month(s)

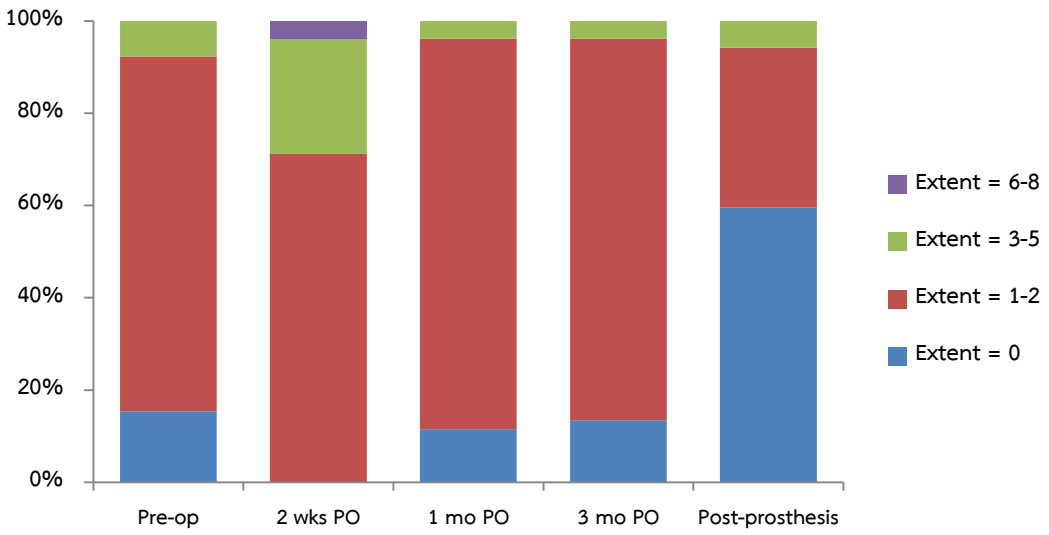


Figure 8 The cumulative bar chart demonstrated the distribution of OIDP extent in 52 patients at different time assessed.

Pre-op: Pre-operation / PO: Post-operation / wks: weeks / mo: month(s)

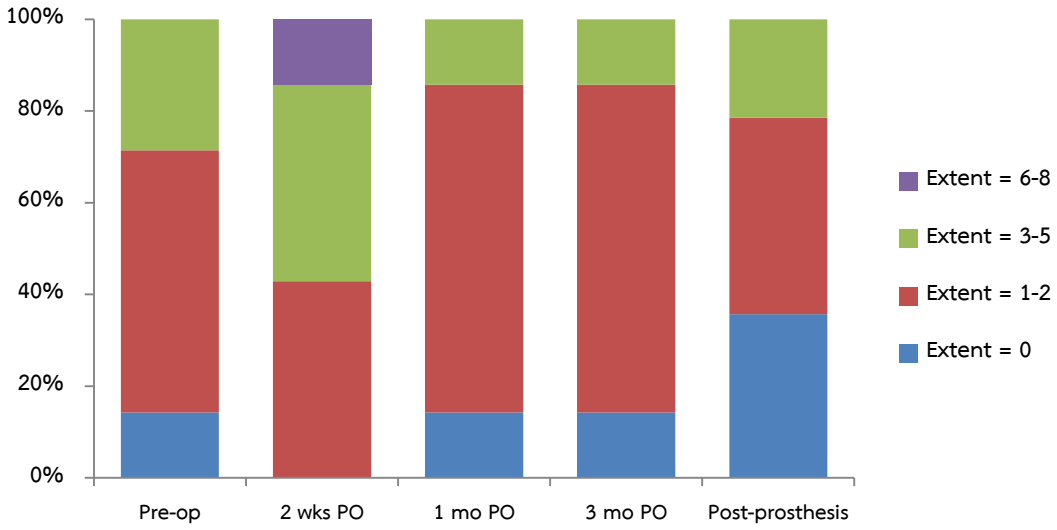


Figure 9 The cumulative bar chart demonstrated the distribution of OIDP extent in study group, 14 patients, at different time assessed.

Pre-op: Pre-operation / PO: Post-operation / wks: weeks / mo: month(s)

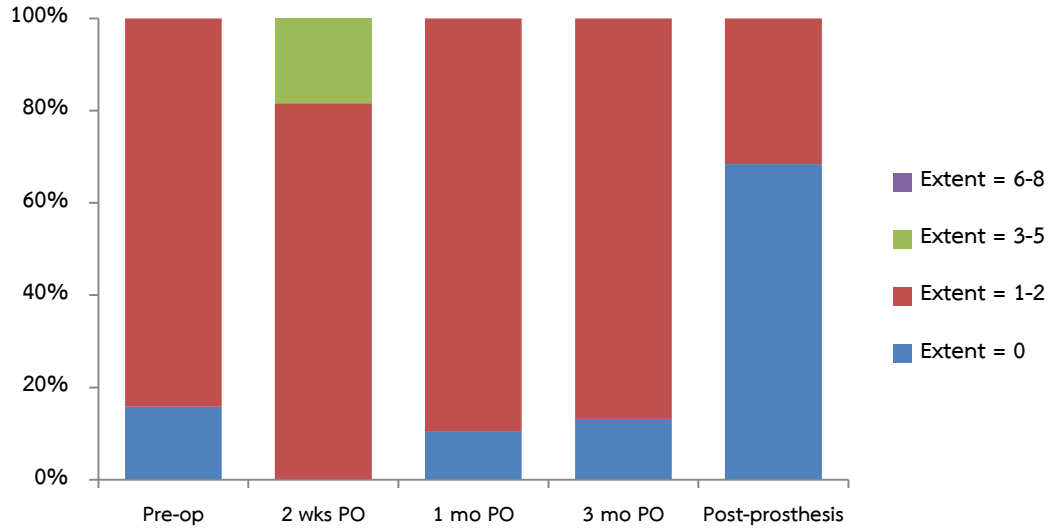


Figure 10 The cumulative bar chart demonstrated the distribution of OIDP extent in comparison group, 38 patients, at different time assessed.

Pre-op: Pre-operation / PO: Post-operation / wks: weeks / mo: month(s)

Intensity of occurred impacts ranging from no impacts to severe impacts was also considered. (Table 7) Tooth loss condition in the study group caused impacts in the moderate to severe intensity which differed from comparison group that caused little intensity of impacts. Alteration of these was found at 2 weeks post-surgery, impact intensity changed to severe and moderate in study and comparison group respectively. At 1 and 3 months post-operation, impact intensity returned to the baseline level and then decreased to little and no impacts in study and comparison group respectively post-prosthesis. (Figure 11-13)

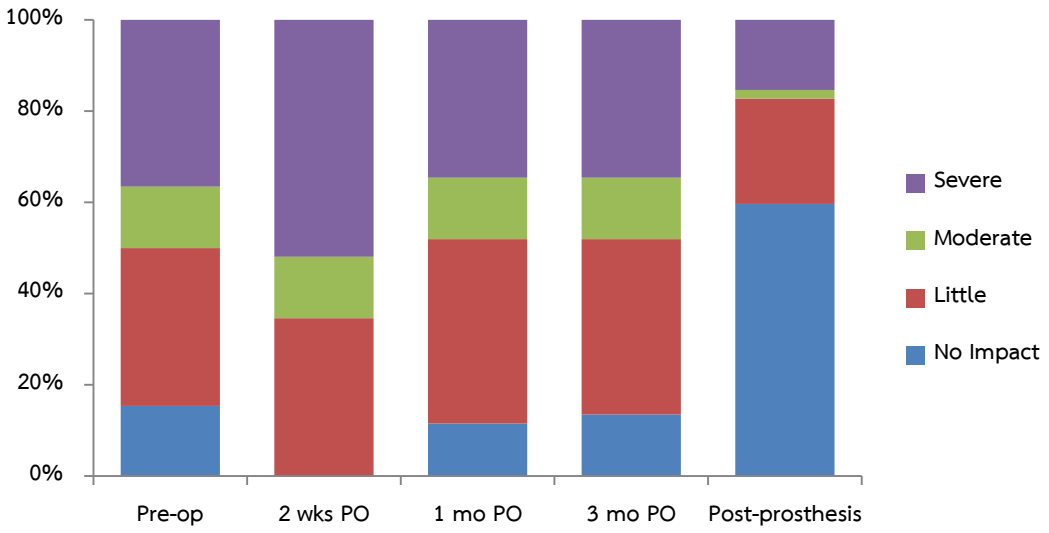


Figure 11 The cumulative bar chart demonstrated the distribution of OIDP intensity in 52 patients at different time assessed.

Pre-op: Pre-operation / PO: Post-operation / wks: weeks / mo: month(s)

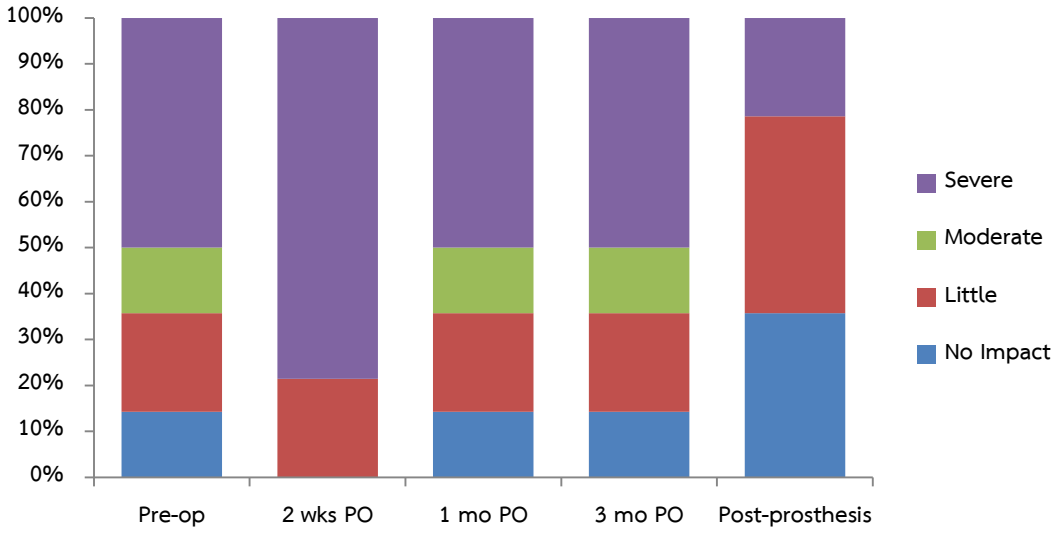


Figure 12 The cumulative bar chart demonstrated the distribution of OIDP intensity in study group, 14 patients, at different time assessed.

Pre-op: Pre-operation / PO: Post-operation / wks: weeks / mo: month(s)

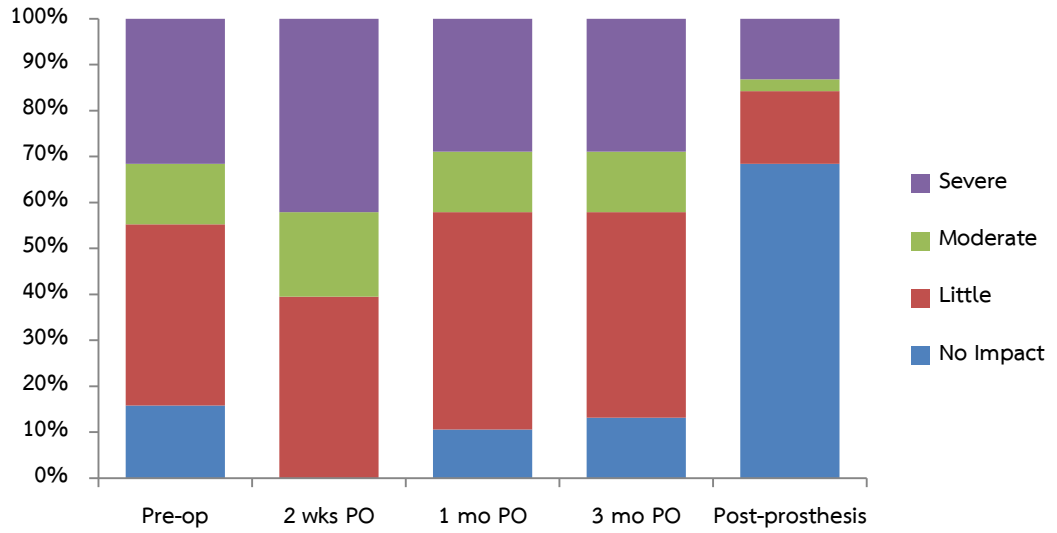


Figure 13 The cumulative bar chart demonstrated the distribution of OIDP intensity in comparison group, 38 patients, at different time assessed.

Pre-op: Pre-operation / PO: Post-operation / wks: weeks / mo: month(s)

Pre-op / 2 wks PO	Less than severe (n)	Severe (n)	*p*-value[a]
Less than severe (n)	25	0	0.008*
Severe (n)	8	19	
Pre-op / 1 mo PO	**Less than severe (n)**	**Severe (n)**	***p*-value[a]**
Less than severe (n)	33	1	1.000
Severe (n)	0	18	
Pre-op / 3 mo PO	**Less than severe (n)**	**Severe (n)**	***p*-value[a]**
Less than severe (n)	33	1	1.000
Severe (n)	0	18	
Pre-op / Post-prosthesis	**Less than severe (n)**	**Severe (n)**	***p*-value[a]**
Less than severe (n)	31	13	0.007*
Severe (n)	2	6	
2 wks PO / 1 mo PO	**Less than severe (n)**	**Severe (n)**	***p*-value[a]**
Less than severe (n)	25	9	0.004*
Severe (n)	0	18	
2 wks PO / 3 mo PO	**Less than severe (n)**	**Severe (n)**	***p*-value[a]**
Less than severe (n)	25	9	0.004*
Severe (n)	0	18	
2 wks PO / Post-prosthesis	**Less than severe (n)**	**Severe (n)**	***p*-value[a]**

Less than severe (n)	24	20	<0.001*
Severe (n)	1	7	
1 mo PO / 3mo PO	**Less than severe (n)**	**Severe (n)**	***p*-value[a]**
Less than severe (n)	34	0	1.000
Severe (n)	0	18	
1 mo PO / Post-prosthesis	**Less than severe (n)**	**Severe (n)**	***p*-value[a]**
Less than severe (n)	31	13	0.021*
Severe (n)	3	5	
3 mo PO / Post-prosthesis	**Less than severe (n)**	**Severe (n)**	***p*-value[a]**
Less than severe (n)	31	13	0.021*
Severe (n)	3	5	

Table 8 Number of patients according to less than severe or severe impact intensity at each match-paired time point comparison (all 52 patients)

Pre-op: Pre-operation / PO: Post-operation / wks: weeks / mo: month(s)

a: The association of the paired patient proportion by McNemar test / *: Statistical significant

Pre-op / 2 wks PO	**Less than severe (n)**	**Severe (n)**	***p*-value[a]**
Less than severe (n)	3	0	0.125
Severe (n)	4	7	
Pre-op / 1 mo PO	**Less than severe (n)**	**Severe (n)**	***p*-value[a]**
Less than severe (n)	7	0	1.000
Severe (n)	0	7	

Pre-op / 3 mo PO	Less than severe (n)	Severe (n)	*p*-value[a]
Less than severe (n)	7	0	1.000
Severe (n)	0	7	
Pre-op / Post-prosthesis	**Less than severe (n)**	**Severe (n)**	***p*-value[a]**
Less than severe (n)	6	5	0.219
Severe (n)	1	2	
2 wks PO / 1 mo PO	**Less than severe (n)**	**Severe (n)**	***p*-value[a]**
Less than severe (n)	3	4	0.125
Severe (n)	0	7	
2 wks PO / 3 mo PO	**Less than severe (n)**	**Severe (n)**	***p*-value[a]**
Less than severe (n)	3	4	0.125
Severe (n)	0	7	
2 wks PO / Post-prosthesis	**Less than severe (n)**	**Severe (n)**	***p*-value[a]**
Less than severe (n)	3	8	0.008*
Severe (n)	0	3	
1 mo PO / 3mo PO	**Less than severe (n)**	**Severe (n)**	***p*-value[a]**
Less than severe (n)	7	0	1.000
Severe (n)	0	7	
1 mo PO / Post-prosthesis	**Less than severe (n)**	**Severe (n)**	***p*-value[a]**
Less than severe (n)	6	5	0.219

Severe (n)	1	2	
3 mo PO / Post-prosthesis	Less than severe (n)	Severe (n)	*p*-value[a]
Less than severe (n)	6	5	0.219
Severe (n)	1	2	

Table 9 Number of patients according to less than severe or severe impact intensity at each match-paried time point comparison (14 patients in study group)

Pre-op: Pre-operation / PO: Post-operation / wks: weeks / mo: month(s)

a: The association of the paired patient proportion by McNemar test / *: Statistical significant

Pre-op / 2 wks PO	Less than severe (n)	Severe (n)	*p*-value[a]
Less than severe (n)	22	0	0.125
Severe (n)	4	12	
Pre-op / 1 mo PO	Less than severe (n)	Severe (n)	*p*-value[a]
Less than severe (n)	26	1	1.000
Severe (n)	0	11	
Pre-op / 3 mo PO	Less than severe (n)	Severe (n)	*p*-value[a]
Less than severe (n)	26	1	1.000
Severe (n)	0	11	
Pre-op / Post-prosthesis	Less than severe (n)	Severe (n)	*p*-value[a]
Less than severe (n)	25	8	0.039*
Severe (n)	1	4	
2 wks PO / 1 mo PO	Less than severe (n)	Severe (n)	*p*-value[a]

Less than severe (n)	22	5	0.063
Severe (n)	0	11	
2 wks PO / 3 mo PO	**Less than severe (n)**	**Severe (n)**	***p*-value[a]**
Less than severe (n)	22	5	0.063
Severe (n)	0	11	
2 wks PO / Post-prosthesis	**Less than severe (n)**	**Severe (n)**	***p*-value[a]**
Less than severe (n)	21	12	0.003*
Severe (n)	1	4	
1 mo PO / 3mo PO	**Less than severe (n)**	**Severe (n)**	***p*-value[a]**
Less than severe (n)	27	0	1.000
Severe (n)	0	11	
1 mo PO / Post-prosthesis	**Less than severe (n)**	**Severe (n)**	***p*-value[a]**
Less than severe (n)	25	8	0.109
Severe (n)	2	3	
3 mo PO / Post-prosthesis	**Less than severe (n)**	**Severe (n)**	***p*-value[a]**
Less than severe (n)	25	8	0.109
Severe (n)	2	3	

Table 10 Number of patients according to less than severe or severe impact intensity at each match-paried time point comparison (38 patients in comparison group)

Pre-op: Pre-operation / PO: Post-operation / wks: weeks / mo: month(s)

a: The association of the paired patient proportion by McNemar test / *: Statistical significant

Among the available scoring formats, impact intensity was the most appropriate format that correlates to individual overall perception. (17) According to the alteration of impact intensity as showed previously, severe intensity seemed to change obviously. The proportions of patients with either severe intensity or others degree of intensity were compared at each match-paired time point. (Table 8-10) The significant difference between 2 weeks post-operation and pre-operation was found when considering in all study's patients (*p*-value=0.008) while this was not found in neither study nor comparison groups. Moreover, the difference of this proportion was demonstrated between post-prosthesis and pre-operation in comparison group (*p*-value=0.039) but did not in study group. The similar severe intensity distribution was found when comparing between 1 or 3 months post-operation and pre-operation in both study's groups.

The change of assessed daily performances

From 8 daily performances assessed, the performance score, impact prevalence and intensity in all patients were illustrated. (Table 11, Figure 14) Before implant placement, the most common complaint of patients with partial edentulous was the difficulty on eating or chewing food that affected almost 80% of patients. The intensity of this impact presented in the moderate to severe and little in study and comparison group respectively. Others performances occurred in small proportion, less than 10% except smiling which affected 15.4% of patients with no impact intensity. After implant surgery, nearly all patients (98.1%) reported the

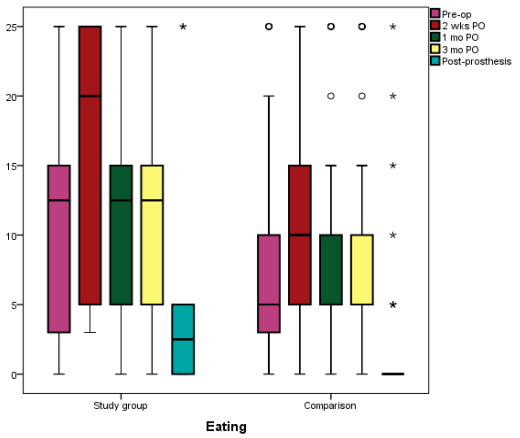
impact on eating performance with moderate intensity while oral hygiene cleaning, that less than 10% of patients previously complaint, distinctly increased in impact prevalence to 73.1% with little intensity. Moreover, the proportion of patients with other performances impact including speaking, sleeping, maintaining emotion, smiling, contacting with people and working also increased in different degree ranging from 3.8-19.2%. In addition, eating (*p*-value=0.003) and cleaning (*p*-value<0.001) performances score in all patients increased significantly from pre-operation. Although the going up of impact prevalence occurred in all performances short period after surgery, this phenomenon was not found at 1 and 3 months post-operation. All performances prevalence and intensity at these time point assessed tended to approximate or less than pre-operational baseline unless cleaning ability that still affected to patient's daily life, nevertheless, in the reduced prevalence and intensity. Dramatically lessening of the eating difficulty prevalence and intensity was evidently revealed following prosthesis delivery but remaining 30.8% of patients shown oral impact on this activity. Oral hygiene cleaning and maintaining emotion demonstrated the higher impact prevalence whereas sleeping, contacting with people and working presented equal or less than pre-operational baseline. Smiling and speaking impact prevalence were reduced till no patients reported these impact after prosthesis used. In all patients, median of performances score was only significant different from pre-operation on eating (*p*-value<0.001) and smiling (*p*-value=0.011). This was inconsistent when considering on study's group. No difference on eating performance score in study group but statistical significant in comparison group (*p*-value<0.001). Conversely, smiling performance score in study group was statistical different (*p*-value=0.039) but not in the comparison group. In addition,

difficulty in oral hygiene cleaning was significantly found in study group (*p*-value=0.024) in comparing to baseline pre-operation.

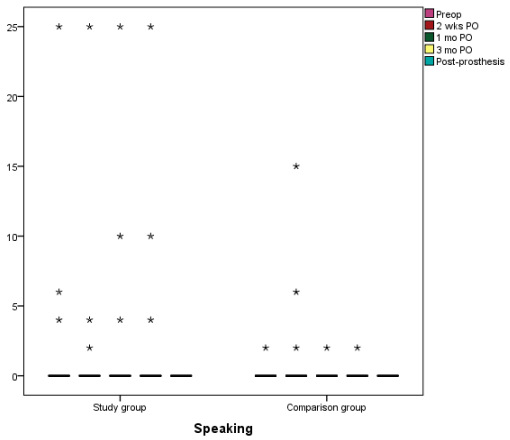
Daily Performances	Pre-operation			2 wks post-operation			1 mo post-operation			3 mo post-operation			post-prosthesis		
	A	S	C	A	S	C	A	S	C	A	S	C	A	S	C
Eating															
Median scores	5	12.5	5	10	20	10	5	12.5	5	5	12.5	5	0	2.5	0
Prevalence (%)	80.8	78.6	81.6	98.1	100	97.4	84.6	78.6	86.8	82.7	78.6	84.2	30.8	57.1	21.1
Median intensity	1	2.5	1	2	3	2	1	2.5	1	1	2.5	1	0	1	0
Speaking															
Median scores	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Prevalence (%)	7.7	21.4	2.6	11.5	21.4	7.9	7.7	21.4	2.6	7.7	21.4	2.6	0	0	0
Median intensity	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Cleaning															
Median scores	0	0	0	4	5	3.5	0	0	0	0	0	0	0	0	0
Prevalence (%)	9.6	7.1	10.5	73.1	85.7	68.4	13.5	21.4	10.5	9.6	21.4	5.2	21.2	42.9	13.2
Median intensity	0	0	0	1	1	1	0	0	0	0	0	0	0	0	0
Sleeping															
Median scores	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Prevalence (%)	1.9	0	2.6	11.5	14.2	10.5	1.9	0	2.6	1.9	0	2.6	1.9	7.1	0
Median intensity	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Maintaining emotional state															
Median scores	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Prevalence (%)	3.8	14.2	0	7.7	14.2	5.3	1.9	7.1	0	1.9	7.1	0	5.8	21.4	0
Median intensity	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Smiling															
Median scores	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Prevalence (%)	15.4	35.7	7.9	19.2	42.9	10.5	11.5	28.6	5.3	11.5	28.6	5.3	0	0	0
Median intensity	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Contacting with people															
Median scores	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Prevalence (%)	3.8	14.2	0	9.6	35.7	0	3.8	14.2	0	3.8	14.3	0	1.9	7.1	0
Median intensity	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Working or studying															
Median scores	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Prevalence (%)	0	0	0	3.8	7.1	2.6	0	0	0	0	0	0	0	0	0
Median intensity	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Table 11 The median of OIDP performance scores and impact prevalence of each daily activity according to study's group and time assessed.

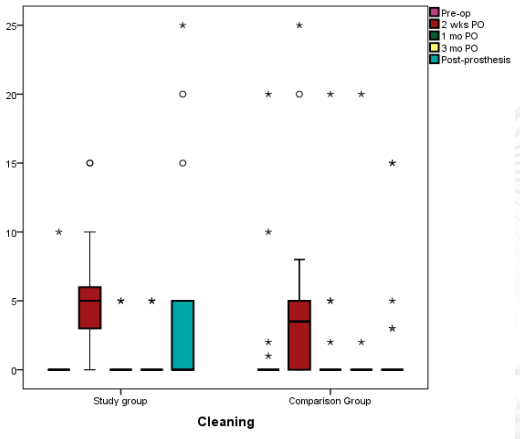
Prevalence: percentage of patient whom reported the impacts / Intensity: magnitude of impacts classified as no impacts (0), little (1), moderate (2) and severe (3) / wks: weeks / mo: month(s) / A: all 52 patients / S: study group / C: comparison group



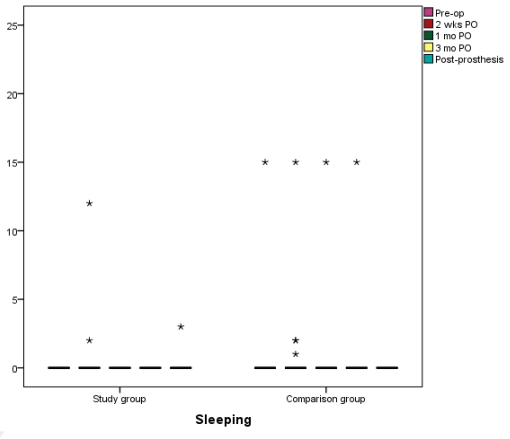
Eating



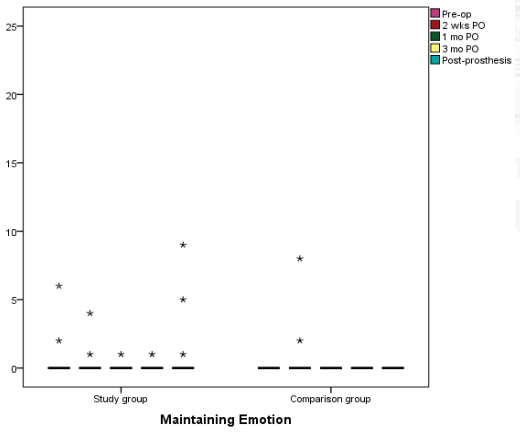
Speaking



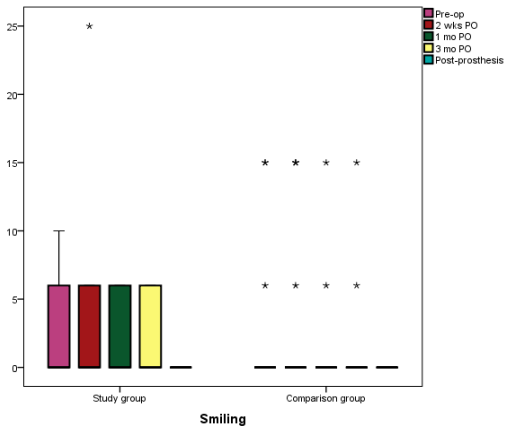
Cleaning



Sleeping



Maintaining Emotion



Smiling

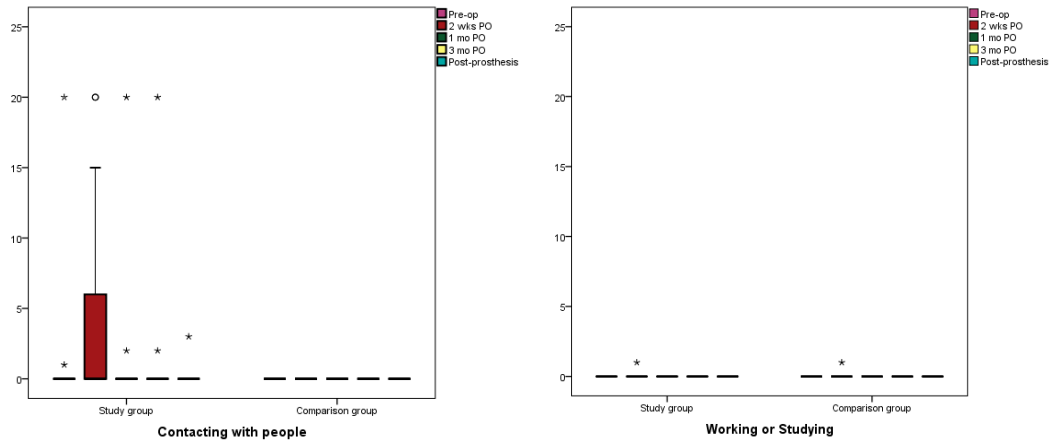


Figure 14 The Box plots of all 8 daily performances scores at different time point assessed in study's groups.

Pre-op: Pre-operation / PO: Post-operation / wks: weeks / mo: month(s)

Difference in the OHRQoL between study and comparison group

The overall OIDP score, impact extent and intensity were compared in order to reveal the association of these between study and comparison patient's groups. Pre-operatively, the study group reported more oral impacts than comparison group with median of overall score at 6.75 and 2.5 respectively but unable to show statistical significant difference. Two weeks after surgery, overall score of patients in both group significantly increased whereas higher score at 13.75 versus 7.00 of study and comparison group demonstrated the statistic difference (*p*-value=0.01). As the score tended to decrease after surgery, patients in study and comparison group showed similar overall score as pre-operation so there was no statistical significant between groups at 1 and 3 months post-operation. At the post-prosthesis assessment, patients in the comparison group presented the median score as 0 while study group still reported median score as 2.5 which was significant difference (*p*-value=0.029). (Figure 15)

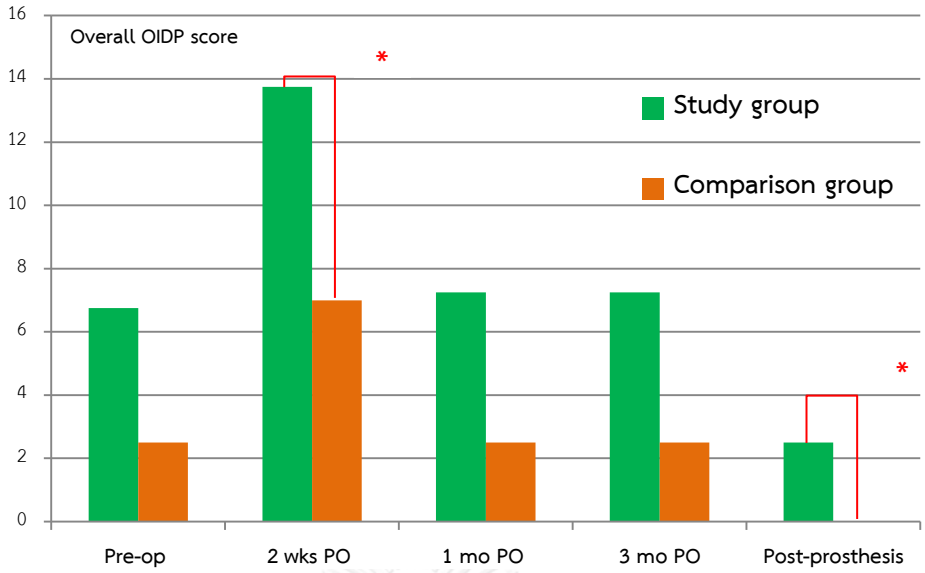


Figure 15 Bar chart demonstrated the overall OIDP median score comparison between the study's group according time assessed

* Statistical significant different by Independent-samples Mann-Whitney U test at *p*-value < 0.05 Pre-op: pre-operation / PO: post-operation / wks: weeks / mo: month(s)

The association among impact extent with study's groups was shown in Table 12. For impact extent, the distribution of patient's proportion in both groups at pre-operation was comparable which mostly demonstrated oral impacts in 1-2 performances without the extremely 6-8 performances oral impact reported. The 2 weeks post-operation, about 85% study group patients showed 1-2 and 3-5 performances impact while 81.6% in comparison expressed only 1-2 performances impact. These proportional discrepancy were statistical significant difference (*p*-value=0.003). At 1 and 3 months post-operation, the proportion of patients according to impact extent presented the same distribution pattern in study and comparison group. Following the prosthesis delivery, 42.9% and 21.4% of study's group patients showed 1-2 and 3-5 performances oral impact while 68.4% and 31.6% of the opposite group showed no and 1-2 performance impact. This inconsistent was significantly in statistic tested (*p*-value=0.011).

Time assessed / Study's group	Impact extent				*p*-value[a]
	0	1-2	3-5	6-8	
Pre-operation					
Study (%)	14.3	57.1	28.6	0	0.056
Comparison (%)	15.8	84.2	0	0	
2 weeks post-operation					
Study (%)	0	42.9	42.9	14.3	0.003*
Comparison (%)	0	81.6	18.4	0	
1 month post-operation					
Study (%)	14.3	71.4	14.3	0	0.435
Comparison (%)	10.5	89.5	0	0	
3 months post-operation					
Study (%)	14.3	71.4	14.3	0	0.352
Comparison (%)	13.2	86.8	0	0	
Post-prosthesis					
Study (%)	35.7	42.9	21.4	0	0.011*
Comparison (%)	68.4	31.6	0	0	

Table 12 The percentage of patients in the study and comparison group according to OIDP extent at different time assessed.

a: The association of the patient's proportion according to the study's group and OIDP extent by Spearman correlation analysis/ *: Statistical significant at 95% confident interval

Although, impact intensity of study group patients at pre-operation was mainly (50%) in severe level while comparison group reported the little and severe in close proportion (39.5% and 31.6%), there was no statistical association between study's group. In contrast to the post-surgery period, about 78.6% of study group patients reported impact intensity as severe but only 42.1% in comparison group reported that intensity. Others in the comparison group demonstrated little (39.5%) and moderate (18.4%) whereas the rest of patient in study group had little intensity. The statistical difference of this was shown (*p*-value=0.047). At 1 and 3 months post-operation, constant patient distribution according to impact intensity was similar to pre-operational baseline that was statistically indifferent between study's groups.

Subsequently post-prosthesis, 42.9% and 21.4% of patients in the study group still reported impact intensity as little and severe while majority (68.4%) in comparison group had no impact intensity. However this was unable to demonstrate any association of this between study's groups. (Table 13)

Time assessed Study's group	Impact intensity				*p*-value [a]
	No impact	Little	Moderate	Severe	
Pre-operation					
Study (%)	14.3	21.4	14.3	50.0	0.268
Comparison (%)	15.8	39.5	13.2	31.6	
2 weeks post-operation					
Study (%)	0	21.4	0	78.6	0.047*
Comparison (%)	0	39.5	18.4	42.1	
1 month post-operation					
Study (%)	14.3	21.4	14.3	50.0	0.246
Comparison (%)	10.5	47.4	13.2	28.9	
3 months post-operation					
Study (%)	14.3	21.4	14.3	50.0	0.226
Comparison (%)	13.2	44.7	13.2	28.9	
Post-prosthesis					
Study (%)	35.7	42.9	0	21.4	0.061
Comparison (%)	68.4	15.8	2.6	13.2	

Table 13 The percentage of patients in the study and comparison group according to OIDP intensity at different time assessed.

a: The association of the patient's proportion according to the study's group and OIDP intensity by Spearman correlation analysis/ *: Statistical significant at 95% confident interval

The change according to the minimal important different concept

According to the previous results shown about the overtime changed in OIDP, irrespective to scoring formats, and the difference among them. There was evidently clear that afterwards 2 weeks post-operation as post-surgical change and post-prosthesis demonstrated significant difference from the others. Changes among post-

surgical and post-prosthesis with pre-operational baseline were used for analyzing the important change in the conceptual theory of minimal important different (MID).

In post-surgical change, median of individual changed score in all patients was 2.5 which equal to comparison group while study group demonstrated the median changed as 4.75 without statistical significant different. The changed score presented in positive way infer to the deterioration in OHRQoL. Conversely at post-prosthesis change, improvement in OHRQoL was found as the median of individual changed score was -3.0 and -2.5. These changes were also similar following statistic tested. (Table 14)

OIDP Individual changed score		All	Study	Comparison	*p*-value[a]
Post-surgical change	Mean (std. deviation)	4.7 (5.5)	7.7 (7.6)	3.6 (4.2)	N/A
	Median	2.5	4.75	2.5	0.066
Post-prosthesis change	Mean (std. deviation)	-3.4 (8.5)	-2.9 (14. 7)	-3.6 (4.9)	N/A
	Median	-2.5	-3.0	-2.5	0.950

Table 14 The mean and median of OIDP individual changed score at two different observed period.

a: The median difference of individual changed score between study's group by Mann-Whitney U test N/A: Not applicable

MID was calculated in 2 different ways; distribution-based and anchor-based method. For the distribution-based MID, the effect size, standardized response mean, standard error of measurement and Norman's rule of thumb were demonstrated. (Table 15) The ES and SRM infer the magnitude of changed effect whether small, moderate or large effect according to Cohen's benchmark. (174) The moderate to large effect was shown in post-surgical change (ES = 0.7, SRM = 0.8) in contrast to post-prosthesis change, the effect was small to moderate level (ES = 0.5 SRM = 0.4). Unlike the SEM and Norman's rule of thumb, they provide MID value in form of the unit of changed score which considered as clinical important or meaningful. These

could be derived in a single value regardless of the different changed period. MID value was 2.3 and 3.4 from SEM and Norman's rule of thumb, respectively. For anchor-based MID, patients were rearranged into new groups according to categorization on change magnitude under the global rating of change. (Table 16) This categorization based on how much of the change happened whether unchanged, small change and large change irrespective to the change direction. The difference value of mean changed score between small change group and unchanged group was 2.9 (2.0-(-0.9)). This was considered as MID.

Observed period	Distribution-based minimal important different			
	Effect size	Standardized Response Mean	Standard Error of Measurement [a]	Norman's rule of thumb
Post-surgical change	0.7	0.8	2.3	3.4
Post-prosthesis change	0.5	0.4		

Table 15 The minimal important different value by the distribution-based method.

a: The internal reliability of this OIDP measure, derived from Cronbach's Alpha, was 0.879

	Categorized of Global Transition rating		
	Unchanged (Rating -1,0,1)	Small change (Rating -3,-2,2,3)	Large change (Rating -5,-4,4,5)
Number of patients (n=52)	7	7	38
Mean changed score (SD) at Post-prosthesis	-0.9 (3.4)	2.0 (6.3)	-4.9 (9.1)

Table 16 The mean of individual changed score categorized by the level of change according to global transition rating in all patients.

SD: standard deviation

In order to obtain the single value MID, the MID value from distribution-based and anchor-based method were pooled and criticized together. The distribution-based MID was 2.3 and 3.4 while anchor-based MID was 2.9. These MID ranged from 2.3 to 3.4 with average at 2.9, however, the assessed score was an integer so this unit of change required to be an integer. Finally, the three units of changed score, approximate from 2.9, was considered as MID value in this study.

Following the obtaining of MID value, 3 units of score change was used to classified patients as had or had not an important change along with considering on the direction of change. (Figure 16) In post-surgical change, the OIDP score at 2 weeks post-operation was greater than pre-operation causing positive changed score that infer deterioration in OHRQoL. The 46.2% of all patients, 64.3% of study group and 39.5% of comparison group, reported at least 3 units of positive score change. In contrast to post-prosthesis change, the score tended to decrease lower than baseline leading to the negative changed score that infer improvement in OHRQoL. Implant prosthesis caused 38.5% of all patients demonstrated the improvement change, 50% and 34.2% of patients in the study and comparison group shown this change.

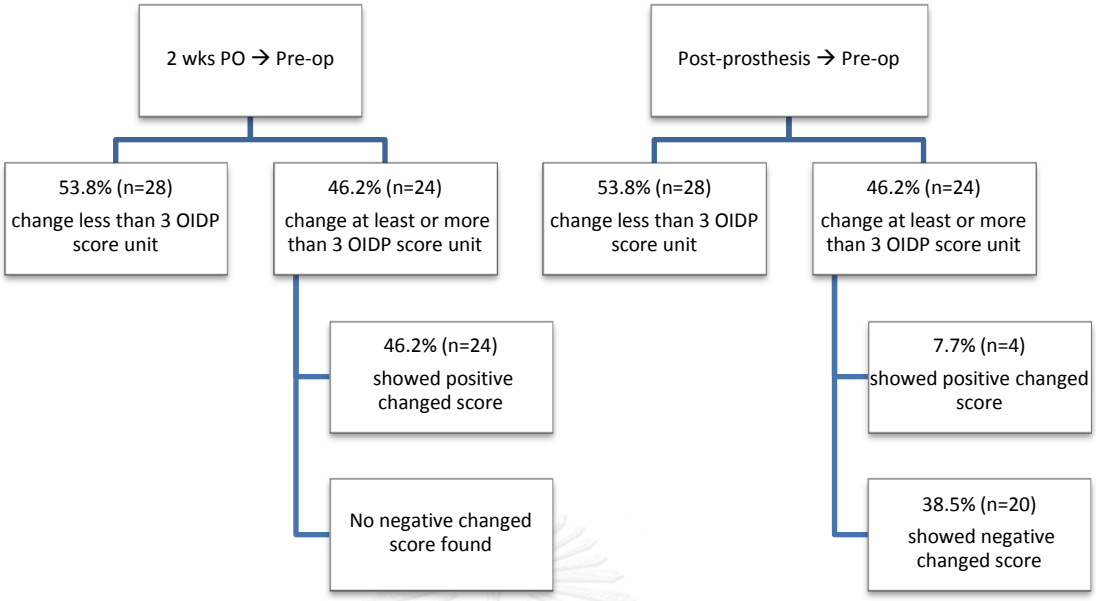


Figure 16 The flow diagram displayed the proportion of patients in the study's groups according to the minimal important different change, 3 unit of changed score.

wks: weeks / Pre-op: pre-operation

Related factors on the change in OHRQoL

Patients were classified according to all interested variables including socio-demographic and clinical variables based on whether meaningful or meaningless change in post-surgical change and post-prosthesis change. (Table 17) For post-surgical change, association between this change and study's variable was illustrated only for amount of placed implant (*p*-value=0.031). The post-surgical change was clinical meaningful in 38.1% in patients whom received single implant placement but almost 80% of patients with multiple implants placement demonstrate this meaningful change. Others variables along with study's group were incapable to show the association. For post-prosthesis change, gender (*p*-value=0.02) and experienced on removable denture (*p*-value=0.012) were the only two variables that associated to the change. The 81.8% of males claimed on the minimal change which

considered as meaningless whereas more than half (53.6%) of females expressed that change meaningfully. The post-prosthesis change of 66.7% on patients with removable denture history was clinical meaningful while only 27% of the other patients group reported that change. Two of these study's groups could not present the association to the meaning of the change.

At post-surgical change, 64.3% of patients in study group but only 39.5% in comparison group reported the clinical significant change. For the post-prosthesis change, half of patients in study group and 34.2% in comparison group showed the meaningful change. Although this was the quietly different proportional ratio between meaningful and meaningless change, there was no association detected statistically.

Variables	Post-surgical change		*p*-value[a]	Post-prosthesis change		*p*-value[a]
	Meaningful (%)	Meaningless (%)		Meaningful (%)	Meaningless (%)	
Socio-demographic variables						
Age						
Under 45 yrs.	54.5	46.5	0.065	46.5	54.5	0.631
46-59 yrs.	29.2	70.8		41.7	58.3	
More than 60 yrs.	64.7	35.3		29.4	70.6	
Gender						
Male	40.9	59.1	0.581	18.2	81.8	0.020*
Female	50.0	50.0		53.3	46.7	
Education level						
Under university	50.0	50.0	1.000	37.5	62.5	1.000
University or above	45.5	54.5		38.7	61.3	
Systemic disease						
Absent	44.4	55.6	1.000	33.3	66.7	0.570
Present	48.0	52.0		44.0	56.0	
Removable denture experience						
Ever	53.3	46.7	0.553	66.7	33.3	0.012*
Never	43.2	56.8		27.0	73.0	
Implant experience						
Ever	60.0	40.0	0.483	40.0	60.0	1.000
Never	42.9	57.1		38.1	61.9	

Variables	Post-surgical change		*p*-value[a]	Post-prosthesis change		*p*-value[a]
	Meaningful (%)	Meaningless (%)		Meaningful (%)	Meaningless (%)	
Clinical variables						
Study's group						
Study	64.3	35.7	0.130	50.0	50.0	0.347
Comparison	39.5	60.5		34.2	65.8	
Amount of placed implant						
Single	38.1	61.9	0.031*	38.1	61.9	1.000
Multiple	80.0	20.0		40.0	60.0	
Implant position						
Anterior	33.3	66.7	1.000	100.0	0.0	0.052
Posterior	46.9	53.1		34.7	65.3	
Implant location						
Maxilla	46.7	53.3	1.000	60.0	40.0	0.061
Mandible	45.9	54.1		29.7	70.3	
Timing of implant placement post-extraction						
Early	38.1	61.9	0.403	38.1	61.9	1.000
Delay	51.6	48.4		38.7	61.3	
Surgeon						
Student	47.8	52.2	1.000	N/A	N/A	N/A
Staff	44.8	55.2		N/A	N/A	
Prosthodontist						
Student	N/A	N/A	N/A	38.9	61.1	1.000
Staff	N/A	N/A		38.2	61.8	

Table 17 The percentage of patients in each interested variables according to the meaningful/meaningless change at two different observed periods.

Meaningful change at 2 weeks Post-operation and Post-prosthesis from Pre-operation: The percentage of patients that reported at least 3 positive changed scores and negative changed scores, respectively. a : The association of the patient's proportion according to the variables and change by Fisher's exact test for 2 categorized variables and Chi-Square test for more than 2 categorized variables/ * : Statistical significant at 95% confident interval

Responsiveness of the OIDP assessment

Responsiveness was defined in order to test the ability of this study's measurement by OIDP index on how sensitive of this instrument to detect occurrence change. Change between post-prosthesis and pre-operation period was used to demonstrate this instrument's property. The correlation of post-prosthesis individual changed score and global transition rating was tested by Pearson's correlation analysis. Our study's result showed the correlation coefficient at -0.614 with *p*-value less than 0.001, implying the conversely significant linear correlation. This means the more negative changed score, the greater positive global transition change. In addition, Kruskal-Wallis test was clarified that individual changed score classifying by global transition rating had dissimilar distribution (*p*-value=0.023). Furthermore, there was the association between individual changed intensity level and global transition rating which tested by Spearman's correlation analysis (*p*-value < 0.001).

The other statistical method to detect instrument's responsiveness was proposed by Juniper E, et al. (175), this method was also used in the OHRQoL study. (176) Comparison of median overall score between pre- and post-operation in patients with various degrees of change according to global transition rating demonstrated significant different only at patients whom report positive large change, global transition rating as +4 and +5 (*p*-value<0.001). While the small change even if in positive or negative direction was unable to show statistical significant difference. (Table 18) The median of post-prosthesis changed score in patients whom were classified as small and large change according to degree of global transition change was compared with the median post-prosthesis changed score of unchanged-

categorized patients. Statistical significant different was found only in positive large change group. (Table 19)

Level of global Perceived change	n	Overall OIDP score (Median)		*p*-value[a]
		Pre-operation	Post-prosthesis	
Positive large change (Global +4,+5)	37	5.0	0.0	<0.001*
Positive small change (Global +2,+3)	5	2.5	1.5	0.109
Unchanged (Global -1,0,+1)	7	2.5	3.5	0.414
Negative small change (Global -2,-3)	2	6.25	16.25	0.180
Negative large change (Global -4,-5)	1	N/A	N/A	N/A

Table 18 The median of overall OIDP score according to the level of global perceived change.

a: The difference of median score between pre-operation and post-prosthesis by Wilcoxon Signed rank test/ *: Statistical significant at 95% confident interval

Level of global perceived change / Changed Score[a]	Negative large change (Global -4,-5)	Negative small change (Global -2,-3)	Unchanged (Global -1,0,+1)	Positive small change (Global +2,+3)	Positive large change (Global +4,+5)
Median	N/A	10.0	0.0	-1.0	-2.5
p-value[b]	N/A	0.176	As anchor	0.981	0.049*

Table 19 The median of individual changed score according to the level of global perceived change.

a: Individual changed score between post-prosthesis and pre-operation. b: The difference of median changed score between unchanged and the others group by Mann-Whitney U test. As anchor: The median changed score in unchanged global perceived changed group was used for match-pair comparison with the others group/ *: Statistical significant at 95% confident interval

Chapter 5
Discussion

Reconstructing the edentulous status with the implant prosthesis aims not only to fulfil the lost teeth, but also intends to restore patient's daily life. Our study purposes to evaluate the outcome of implant prosthesis, especially patients who received bone augmentation by GBRs technique, from patient's perspective through the OHRQoL assessment. The OHRQoL changed overtime throughout the treatment process, deterioration after surgery and improvement following prosthesis usage. Surgical implant placement causes poorer OHRQoL short period afterward surgery, however, recovery was shown later. Eating and oral hygiene were significantly affected. Although patients with simultaneous bone augmentation reported more worsening OHRQoL than who do not require that procedure, this additional bone augmentation had no association to surgical-related OHRQoL deterioration but the association was seen only in multiple-placed implant patients. Advantage of implant prosthesis was remarkably proved by females and patients with removable denture experience while the bone augmentation during implant placement did not relate to the improvement on OHRQoL after treatment completion. Regaining on eating ability and smiling or showing teeth with confidence was illustrated from implant prosthesis construction.

Changing of OHRQoL in implant prosthesis-reconstructed partial edentulous patients was studied in the previous literature. Most of them concentrated on the change from prior to after prosthesis delivery but only few studies monitored the OHRQoL throughout the treatment process especially after implantation prior to

prosthesis construction. Eitner S, et al. (31) showed the significant increase in OHIP-G55 score from 75.8 at pre-operation to 85.3 at 4-5 months post-operation then the score decreased to 29.5 after prosthesis delivery. This pattern of change is identical to our study that OHRQoL was deteriorated following surgery then the improvement would be gained after prosthesis used. The main distinct result was that deterioration still reported at 4-5 months post-operation especially in the psychological dimension and some physical pain while our study clearly showed the restriction of that effect in a short period after surgery and latterly recovered soon at 1 month post-operation. Conversely to the study by Reisine S, et al. (34), they solely found better in OHRQoL after 9 months of implant prosthesis delivery but unable to show any statistical OHRQoL alteration during post-surgical period. In that mentioned study, implants were placed simultaneously with different bone augmentation techniques without the simple implant placement as negative comparison group. The OHIP-14 score at prior treatment, 15.4, and 1 week after surgery, 13.7, was comparable that inconsistent with our study which found the significant worsening scores alteration following surgery in patients receiving GBRs bone augmentation. This different may from the strictly confined patient samples in which only post-menopausal women were included in that study while our study included a diversity of samples that could express their impacts in various dimensions. However, there were very few studies that illustrated this pattern of OHRQoL alteration in surgical implant placement patients which make these findings inability to conclude.

Deterioration in OHRQoL following surgical procedure was found due to the occurrence of post-operative adverse events as well as in surgical implant placement. Pain is commonly complaint in which the 60-80% of patients reported

pain at mild to moderate level especially on the first day following conventional implant placement which then gradually declined to its prevalence and intensity. (33, 142) Post-operative swelling was also addressed in which high degree of swelling was evidenced during 1st and 2nd day post-surgery, moreover, nearly 30% of patients still reported swelling at a week after the operation. (32) Implant treatment rejection was influenced by these general post-operative events. (177) All patients in our study showed the score increasing, more amount of performances with impact and higher degree of impact intensity regardless of study groups. Patients receiving implant placement with bone augmentation addressed the significant OHRQoL impairment than conventional implant placement. The possible explanation of this was the more surgical invasiveness and complexity as well as time consuming are expected. GBRs technique usually requires additional surgical steps such releasing incision in order to coronally-positioned the gingival flap for tension free closure at the augmented sites and/or in some cases that needing localized corticotomy which aim to increase graft's blood supply. Although patients with bone augmentation obviously declined their OHRQoL after surgery comparing to opposite patient group, the augmentation procedure had no association with the meaningful clinical change but only multiple implants placement demonstrated that association. Installation more than single implant evidently reported as a main contributing factor on post-operative pain and also swelling (32, 142) because of its more complicated procedure, extended surgical area required as well as longer operation time than placing a single one. The more surgical invasiveness performed in minor oral surgery, the poorer in OHRQoL post-operatively. (178) Furthermore, the declination of OHRQoL was also influenced by post-operative swelling. (179) Even though patient's age and gender, surgeon

expertise, area of placed implant were formerly stated as contributing factors to post-operative discomforts after implant surgery (32, 33, 142), our study is unable to show any association of these factors with the OHRQoL change. However, worsening or steadiness on OHRQoL in the period after surgery that was found in this study could not totally infer from these post-operative discomforts because OHRQoL assessment particularly via OIDP index that objectively measures ultimate impacts consequently from not only mentioned pain and discomfort but also involving in functional limitation and unsatisfied appearance. Moreover. the pain, discomfort, limitation in function or unsatisfied looks must intense enough that could negatively affect to daily activities.

In current dental practice, the best treatment of choice if patients lost their teeth is going toward implant prosthesis. Clinicians believe on its superiority characteristics over other type of prostheses in various reasons such as its comfortability as fixed prosthesis, ultimately mimic natural tooth, strong enough for physical function, conservation adjacent tooth structure, long-life usage, biological- and hygiene-friendly which eventually hope to bring patient's life better. Moreover, patients perceived this treatment modality in a highly positive way as shown by the notable satisfaction level. (4, 5, 147) Numerous studies were apparently published on the OHRQoL improvement following implant prosthesis construction whether in short term or long term assessment (31, 163, 165, 168, 170, 171) which were in agreement with our study. The majority of patients in this study expressed the extremely low (median score nearly close to 0) OIDP score at post-prosthesis and had no remaining performances with impacts that means they importantly realized the better well-being. However, patients receiving bone augmentation during implant

placement interestingly showed the comparable OHRQoL level to pre-operational baseline along with 1-2 performances difficulty in little intensity. As reported by Hof M, et al. (172) in which implant with GBRs satisfied patients in the lowermost (75%) when comparing to other approaches on implant placement. These findings were inconsistent with the study of Reisine S, et al. (34) that found the better OHRQoL after prosthesis completion whether installed implant receiving site development in any techniques. Although, the overall score of this study group patients unable to reach statistically significant different, some of the raw parameters assessed tends to show the better OHRQoL such reduction of the median overall score, impact prevalence and intensity from 6.75 to 2.5, 85% to 64% and moderate-severe to little, respectively.

The factors influencing the OHRQoL alteration following implant prosthesis rehabilitation were widely considered in the publish literatures. Our study found the association between significant OHRQoL change only with gender and removable denture experience while other socio-demographic and clinical factors, including the bone augmentation by means of GBRs technique lacked of that association. Half of females, while less than 20% of males, in this study meaningfully perceived better shifting on OHRQoL. Similar to patients with removable denture experience, nearly 67% of them expressed meaningful change while only 27% of the opposite group showed the same change. Controversy on gender and OHRQoL alteration was stated, Yu S-J, et al. (30) reported contrast findings to our study in which greater improvement on OHRQoL was found in male over female patients following anterior implant construction whereas the other studies found no association of gender and OHRQoL alteration. (164, 165, 168) Although no previous studies mentioned on the

effect of removable denture experienced in OHRQoL change after implant prosthesis treatment, there was other aspect of studies that compared OHRQoL between removable denture and implant prosthesis patients. Furuyama C, et al. (149) revealed the better OHRQoL in implant prosthesis patients comparing to removable denture wearers. A similar conclusion was reported by Peršić S, et al. (180) which showed greater improvement in OHRQoL on implant-supported fixed prosthesis over removable denture. Improvement on this perceived OHRQoL in whom previously experienced by denture wearer was expected because of the dramatically change from removable uncomfortable denture to the fixed tooth-mimic prosthesis. Besides, there were many factors that had been studied and found to associate with OHRQoL increasing in partial edentulous patients with implant prosthesis. Ponsi J, et al.(28) demonstrated the better OHRQoL of implant prosthesis at incisor and premolar region whereas OHRQoL for molar prosthesis was still unchanged. Timing of implant placement post-extraction was also considered, Raes F et al. (169) performed domain analysis of OHIP-14 between immediate and delayed implant placement. Although gaining on OHRQoL was shown in both groups, physical pain and psychological discomfort was predominant in delayed and immediate implant placement, respectively. In addition to loading protocol of implant prosthesis, Dolz J, et al. (167) demonstrated higher degree of OHRQoL increasing in immediate loaded prosthesis than delayed. However, our study found no association of those mentioned factors, such implant position, placement timing, and others factors including age, educational level, pre-existing systemic disease, implant prosthesis experience, simultaneous bone augmentation, implant location and expertise level of surgeon or prosthodontist. The difference in OHRQoL measuring index, main

factors of interest and also study's population, moreover, the distinction in analysis method of these related factors caused the variety of these results. The majority of studies correlated index changed score between couple period evaluated or solely index score at a single time point with the factors of interest, some applied a type of regression analysis among index score or changed score with related factors but our study achieves the difference. This study classified the change into meaningful and meaningless change according to MID value which then analyzed associated factors through proportional analysis. Further about MID will be discussed later.

Since the outstanding characteristic of OIDP index that capture an ultimate impact from all influential impairment, discomfort, limitation or dissatisfaction on oral-related daily activities, this is the outstanding feature of this index in order to clearly clarify those oral impacts in the form of behavioral-based more than feeling/opinion-based outcomes. Details from all of 8 performances in daily living were analyzed to illustrate the change throughout the implant treatment process in our study. Prior to receiving treatment, impact on eating is expected to be found because almost patients in this study lost the posterior teeth which, commonly known as a key point of the mastication power zone. While an embarrassment on smiling or showing their dentition demonstrated as the second most common difficulty after tooth loss implying the greater concern on personal good looking of current people about existing edentulous space. This finding agrees with Al-Omiri MK, et al. (171) that reported the high prevalence of eating or chewing and appearance dissatisfaction in partial edentulous patients going to receive implant placement. At an early period after surgery, all performances got worse however only eating and oral hygiene cleaning was essentially affected. In routine post-surgical instruction

given to, especially, implant patients is generally advice about the more careful on biting or chewing as well as brushing or rubbing at the surgical area in order to leave the installed implant stable in place as much as possible for the success in osseointegration. Resemble findings was reported by Raes F, et al. (169) which showed more physical disability, composing by two questions about eating difficulty regarding to OHIP index, in patients whom were placed implant in healed ridge over the immediate placement at 1 month after surgery. No more study additionally revealed activities with impacts following surgical implant placement. After treatment completion, significant in eating and smiling difficulty reduction was demonstrated in our study in which improving on eating or chewing was predominantly found in the comparison group whereas smiling or showing teeth without embarrassment was better demonstrated in study group. This was expected because of the difference on region of placed implant between these study's groups. All implants in the comparison group were only placed in the posterior region while about 20% of implants in the study group were placed in the anterior esthetic region. Furthermore, a report on Al-Omiri MK, et al. (171) showed nearly 90% of patients satisfied on chewing and appearance. Moreover Raes F, et al. 2013 (170) found the better chewing comfortability, relaxation, confident smiling, less emotion irritable as well as doing their jobs after 1 year of implant prosthesis used.

Although the majority of patients in this study improved their OHRQoL after receiving implant prosthesis, few of them suffered from this kind of prosthesis. Interesting OHRQoL (data not showed) was the report of oral impacts in severe intensity following implant prosthesis used. Three (3/14) and five (5/38) patients in the study and comparison groups respectively demonstrated that severe impacts.

The majority of them suffered with the interproximal food retention or food impaction that not only disturbed meals enjoying but also annoyed patients when cleaning in that area. Furuyama C, et al. 2012 (149) also stated the same finding on food retention/impaction in more than half of implant prosthesis patients, however, no reported on consequently adverse events from this problem as showed in the current study. The main anatomical consideration of implant prosthesis causing impaction of food suspects from the narrow cervical portion of prosthesis according to the limitation of placed implant diameter although large gingival forming abutment in order to create a suitable emergence profile was applied. However, the interdental papilla formation was quiet more difficult particularly in multiple implants posterior prosthesis. So lacking the gingival papilla might lead to the more susceptible for food retention in that area. Moreover, an alteration on remaining dentition following tooth lost such as tilted angulation of adjacent teeth originate an improper contact embrasure between prosthesis and natural teeth, vertical positioning change toward edentulous space of occluding dentition causing prominent plunger cusp pushing the food into interproximal contact. Beside the interproximal food impaction, some of these patients still avoided to chew the solid food because of worrying about the possibility of prosthesis failure as well as unnatural feeling.

As the measuring indexes require the score value to represent a degree of OHRQoL, increasing or decreasing of index score was interpreted as OHRQoL either improvement or deterioration. Recently, concerning on the meaning of score including changed score was questioned and had been emphasized, minimal important different was proposed to convince these OHRQoL index score more

meaningful interpretability. Both of distribution-based and anchor-based method to find out MID value was applied in this study. The effect size conjunction with standardized response mean demonstrated the moderate to large change effect following implant surgery. No previous study had demonstrated the effect size for this post-surgical change. Only small to moderate change effect was demonstrated in this study when comparing before treatment and after prosthesis used whereas Yu S-J, et al. (30) and Dolz J, et al. (167) reported large change effect (ES > 0.8) on OHIP assessment in almost index after treatment of implant prosthesis. Distinction of current study and the mentioned study on the magnitude of effect following this intervention is suspected to be from the different on the degree of changed score and standard deviation value at pre-operation baseline reported. Lower individual changed score, about 3 unit score, was reported in our study but those cited studies demonstrated the range of changed score during 7 to 18 unit score. Moreover the highly distribution of pre-operational score that might from the small numbers of patients in this study leading to greater value of standard deviation while the mentioned studies included hundreds of patients leading the score less distributed consequently with small values of standard deviation. Unlike the effect size and standardized response mean, standard error of measurement and Norman's rule of thumb provided the approximate score that inferred to MID value. Furthermore, anchoring the changed score with global transition rating in this study conjunction with estimate MID value by distribution-based method revealed the MID value of 3 units of changed score eventually. However, this is the first study that explored MID value according to OIDP index in partial edentulous patients undergoing implant prosthesis reconstruction. A previous study on OHRQoL in periodontitis-treated

patients were the earliest published which assessed the MID value by two similar approached methods as this study and demonstrated MID about 5 units of OIDP changed score.(54) Our study proposed the novel different analytical method in order to explore the influencing factors on the OHRQoL alteration. The calculated MID value, which conceptually considered as the clinically meaningful OHRQoL alteration (51), was applied in order to categorize patients into meaningful or meaningless change and then analyzing for that association with interested factors. This technique might provide the true potential factors causing clinical meaningful change than analyzing them with any degree of changed score.

Responsiveness of OHRQoL measuring index, as OIDP used in this study, for assessing the overtime change is needed to evaluate how sensitive of the index used for capturing that occurrence of change. However, many approaches with different analytical techniques and interpretations were proposed. (181) This study found the significant correlation between changed score and global transition rating in which the better in OHRQoL the more positive global transition rated, implying the correct direction of changed detected by this instrument. Individual change in index score and impact intensity were also importantly different at the classified level of global change, this demonstrate an ability of index to actually discriminate the change. Finally, testing the index sensitivity was performed through the previous proposed method (175) and had been used in OHRQoL study. (176) The significant post-prosthesis change was found only in patients reported large global change while small global change as well as the unchanged group was not found. The index with good sensitivity usually requires to show significant differences at all levels of change especially at the smallest change level categorized. These findings are unsurprising

since MID value also considered as one of the responsiveness approaches in which small global changed group in this study reported the changed score less than 3 units of score therefore that difference was actually not found. Taken together, OIDP measuring in this study characterized as “Fair” according to this responsiveness discussion.

Performing the patient-based outcome studies especially in implant patients as this study is still required in order to show or confirm the ultimate clinical advantages of this treatment modality by the patients themselves. This assessment on OHRQoL through OIDP index not only provides the information on level of patient’s OHRQoL according to its constructed theory but also clarified deeply into details of oral-related daily performances affected. Interpretation these impacts through the predominant scoring method which evaluate impact frequency and severity conjunction with various score formats including overall score, performance score, impact prevalence and impact intensity. This information was useful for attending dentist to inform the patient on which impacts might be happen during treatment process. Moreover this study paid more attention to the meaning of that changed score by assessing the MID value which never been prior studied in this field of literature and also proposed the optional method in order to find out the factors or variables association to OHRQoL alteration through the benefit of MID value. However, this study shows various limitations that could be considered in term of clinical or further literature application. A small number of patients whom completing this evaluation particularly patients with bone augmentation during implant placement was unavoidable due to the limitation of the author’s study period. Each patient in this study received implant prosthesis treatment by the

various specialty dentists in different department therefore longer treatment time from some problems in inter-department communication, high workload of attending dentist or end of semester holidays could be expected. The less patients samples the more distribution of gathering response with low power of statistical analysis was encountered. Measuring OHRQoL in partial edentulous patients that still present remaining dentition in their mouth could be done with caution because assessment was performed in the form of overall perceived impacts on each oral-related activities so confounding effect from others remaining tooth problem could be regarded.

There are several topics that could be suggested for further study. In addition to the bone augmentation by GBR technique, various surgical procedures proposing for implant site development to reconstruct the atrophic edentulous including hard and soft tissue surgery such onlay bone graft, ridge splitting, distraction osteogenesis as well as free gingival- and sub-epithelial connective tissue graft are still waiting for illustration the treatment effectiveness in term of patient's outcome. OHRQoL alteration throughout treatment process corresponding to these kinds of surgery will be useful for not only outcome evaluation but also promoting better patient's care management. Development of the self-reported OIDP questionnaire could gather more OHRQoL data in larger group of patients with less time and human resource consuming. In addition, the modification of performance score weighting in term of the coefficient needs to be considered in order to giving impact priority corresponding to interested oral conditions. For example, if the study focuses on the OHRQoL in anterior implant prosthesis, the performance score on smiling or contacting with people should get more attention than eating by assigning the higher

coefficient such as 1.5 for smiling and 0.5 for eating. Others related factors that suspect to associate on OHRQoL in implant prosthesis patients such as patient's psychological trait, socio-economic level, oral and health concerns, overall treatment duration, type of retained prosthesis, etc. need to be studied. The patient-based outcome study in partial edentulous with implant prosthesis besides OHRQoL such as cost-effectiveness, patient's expectation to the treatment, patient's satisfaction and also post-surgical patient's response including pain, swelling, decrease mouth opening or others possible events was still paid less attention in current literatures. In addition, the association of those mentioned aspects with OHRQoL assessment would make the study more attractive. Patient's psychological trait, prior implant site development, timing approach on implant prosthesis treatment including timing of implant treatment post-extraction, timing of implant restoration or loading would be considered as the factors in patient-based outcomes alteration. The main problem following implant prosthesis such interproximal food impaction needs to be intensively studied in term of etiology and contributing factors such as design of prosthesis, type of prosthesis contact, degree of proximal contact tightness, diameter of installed implant, pre-operative alveolar ridge dimension, angulation of adjacent teeth, pre-existing plunger cusp, occluding dentition and patient's preferable chewing habits. This could provide the more satisfied prosthesis to make a patient's life better.

Chapter 6
Conclusion

The OHRQoL on patients undergoing surgical implant placement changed overtime throughout treatment process. Implant surgery caused oral impacts in a brief period particularly on eating and oral hygiene cleaning performances. Patients with bone augmentation by GBRs technique were affected by surgery more than patients receiving only implant placement. Multiple implants placement was a predominant factor associated to OHRQoL deterioration after surgery. At 1 and 3 months later, the OHRQoL recovered to pre-operational baseline. Following prosthesis used, the better in OHRQoL was found especially in females and patients with removable denture experience. Eating and smiling performances were improved. GBRs technique for simultaneous bone augmentation during implant placement had no association to OHRQoL change neither in post-surgical period nor post-prosthesis used.

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APPENDICES

Appendix A Data recorded form

Research ID☐☐☐

Data Recorded Form

The oral health-related quality of life in patients undergoing surgical implant placement simultaneously with guided bone regeneration

Part I Socio-demographic Data

Gender OMale OFemale

Age _____ years (Birth Date _____/_____/_____)

Education Level

Oประถมศึกษา O ปวช./ปวส. O ปริญญาตรี

O ปริญญาโท O ปริญญาเอก Oอื่นๆ _____

Occupation

O นักเรียน/นักศึกษา O ข้าราชการ/พนักงานรัฐวิสาหกิจ O พนักงาน/ลูกจ้างเอกชน

O ค้าขาย/ธุรกิจส่วนตัว O แม่บ้าน/ไม่ได้ประกอบอาชีพ O อื่น ๆ .....

Medical History

1. Systemic Disease	2. Current Medication	3. Drug Allergy
1.	1.	1.
2.	2.	2.
3.	3.	3.
4.	4.	4.
5.	5.	5.

Research ID☐☐☐

Data related to surgical implant placement

8 7 6 5 4 3 2 1	1 2 3 4 5 6 7 8
8 7 6 5 4 3 2 1	1 2 3 4 5 6 7 8

Implant Fixture

Tooth No.

Manufacturer _____ Diameter_____ mm. Length_____ mm.

☐ Bone level ☐ Tissue level

Operator

OExperienced Oral and Maxillofacial surgeon

O Post-graduatedstudent

Residual ridge size

O Residual ridge height

- O More than 8 mm.
- ODuring 5-8 mm.
- OLess than 5 mm.

OResidual ridge width

- O More than 4 mm.
- ODuring 2-4 mm.
- OLess than 2 mm.

O Defect

- O Dehiscence size .....
- OFenestration size .....

O Inappropriate alveolar bone contour

Ridge augmentation

O No need for ridge augmentation

OGuided bone Regeneration

Graft Material ☐Autogenous bone ☐Allogenic bone

☐ Alloplastic graft ☐Xenograft

☐ None

Graft material trade name ..... particle/block size .....

Membrane Type ☐Resorbable .....

☐ Non- Resorbable .....

Overall operation time ..... minutes

Staged Approach

O One-stage approach O Two-stage approach

Post-operative medication(s)

OAntibiotics

☐ Medication .....

☐ Medication .....

OAnalgesics

☐ Medication .....

☐ Medication .....

OOthers

☐ Medication .....

☐ Medication .....

Research ID☐☐☐

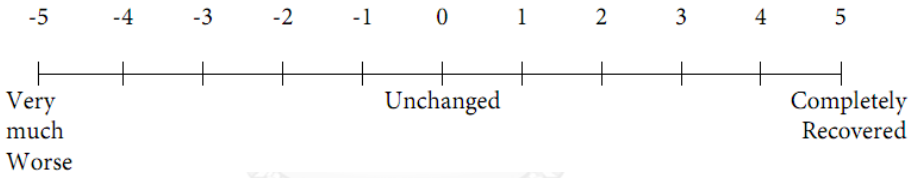
TimingO Pre-op O 2 wk POD O 1 mo POD O 3 mo POD O 3 mo post-prosthesis

Part II Oral Impact on Daily Performance (OIDP)

How about your general oral health?.....

Daily Performance	Frequency	Severity	Perceived cause	Score
Eating				
Speaking				
Cleaning teeth and denture				
Sleeping				
Maintain emotional state				
Smiling				
Contact with people				
Working or studying				

Global transition rating



Note; Frequency and severity criteria

Score	Frequency		Severity
	Regular pattern	Spell pattern	
0	Never affected	0 days	No severe
1	Less than once a month	Up to 5 days in total	
2	Once or twice a month	Up to 15 days in total	
3	Once or twice a week	Up to 30 days in total	
4	3-4 times a week	Up to 3 months in total	
5	Every or nearly every day	Over 3 months in total	Very severe

Appendix B OIDP performance score and global transition rating of patients in study group

No.	Pre-operative performance score								2 weeks post-surgical performance score							
	Eating	Speaking	Cleaning	Sleeping	Emotion	Smiling	Contact	Working	Eating	Speaking	Cleaning	Sleeping	Emotion	Smiling	Contact	Working
1	5	0	0	0	0	0	0	0	5	0	5	0	0	0	15	0
2	15	0	0	0	0	0	0	0	20	0	5	0	0	25	6	0
3	15	0	10	0	2	0	1	0	20	0	15	0	1	6	20	0
4	15	4	0	0	0	10	0	0	20	4	6	12	4	2	0	0
5	10	0	0	0	0	0	0	0	25	0	10	0	0	0	0	0
6	0	0	0	0	0	0	0	0	25	2	15	0	0	0	0	0
7	15	6	0	0	0	6	0	0	15	0	2	0	0	6	0	0
8	15	0	0	0	0	3	0	0	20	0	5	0	0	0	0	0
9	0	0	0	0	6	6	0	0	4	0	5	2	0	2	1	1
10	3	0	0	0	0	0	0	0	15	0	0	0	0	0	0	0
11	5	0	0	0	0	0	0	0	5	0	5	0	0	0	0	0
12	0	0	0	0	0	0	0	0	3	0	3	0	0	0	0	0
13	25	25	0	0	0	6	20	0	25	25	0	0	0	6	20	0
14	25	0	0	0	0	0	0	0	25	0	5	0	0	0	0	0

No.	1 month post-surgical performance score								3 months post-surgical performance score							
	Eating	Speaking	Cleaning	Sleeping	Emotion	Smiling	Contact	Working	Eating	Speaking	Cleaning	Sleeping	Emotion	Smiling	Contact	Working
1	5	0	5	0	0	0	0	0	5	0	5	0	0	0	0	0
2	15	10	0	0	0	0	0	0	15	10	0	0	0	0	0	0
3	15	0	0	0	1	6	2	0	15	0	0	0	1	6	2	0
4	15	4	0	0	0	0	0	0	15	4	0	0	0	0	0	0
5	10	0	0	0	0	0	0	0	10	0	0	0	0	0	0	0
6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7	15	0	0	0	0	6	0	0	15	0	0	0	0	6	0	0
8	15	0	5	0	0	0	0	0	15	0	5	0	0	0	0	0
9	0	0	0	0	0	6	0	0	0	0	0	0	0	6	0	0
10	5	0	0	0	0	0	0	0	5	0	0	0	0	0	0	0
11	5	0	5	0	0	0	0	0	5	0	5	0	0	0	0	0
12	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
13	25	25	0	0	0	6	20	0	25	25	0	0	0	6	20	0
14	25	0	0	0	0	0	0	0	25	0	0	0	0	0	0	0

No.	Post-prosthesis performance score								Global Transition Rating
	Eating	Speaking	Cleaning	Sleeping	Emotion	Smiling	Contact	Working	
1	25	0	25	0	9	0	3	0	-5
2	25	0	20	0	0	0	0	0	-3
3	5	0	15	0	1	0	0	0	3
4	5	0	5	3	0	0	0	0	4
5	0	0	5	0	5	0	0	0	4
6	2	0	5	0	0	0	0	0	-1
7	5	0	0	0	0	0	0	0	4
8	5	0	0	0	0	0	0	0	4
9	3	0	0	0	0	0	0	0	5
10	0	0	0	0	0	0	0	0	5
11	0	0	0	0	0	0	0	0	5
12	0	0	0	0	0	0	0	0	5
13	0	0	0	0	0	0	0	0	5
14	0	0	0	0	0	0	0	0	5

Appendix C OIDP performance score and global transition rating of patients in comparison group

No.	Pre-operative performance score								2 weeks post-surgical performance score							
	Eating	Speaking	Cleaning	Sleeping	Emotion	Smiling	Contact	Working	Eating	Speaking	Cleaning	Sleeping	Emotion	Smiling	Contact	Working
1	25	0	0	0	0	0	0	0	25	0	0	0	0	0	0	0
2	10	0	0	0	0	0	0	0	10	0	2	0	0	0	0	0
3	2	0	0	0	0	15	0	0	9	6	5	0	0	15	0	0
4	25	0	0	0	0	0	0	0	25	0	4	0	0	0	0	0
5	25	0	0	0	0	0	0	0	25	0	0	0	0	0	0	0
6	5	0	0	0	0	0	0	0	5	0	5	0	0	0	0	0
7	10	0	0	0	0	0	0	0	25	0	8	0	0	0	0	0
8	15	0	0	0	0	0	0	0	15	0	4	0	0	0	0	0
9	20	0	0	0	0	0	0	0	20	0	5	2	2	0	0	0
10	5	0	0	0	0	0	0	0	5	0	0	0	0	0	0	0
11	5	0	0	0	0	0	0	0	10	0	3	0	0	0	0	0
12	5	0	0	0	0	0	0	0	10	0	8	0	8	6	0	0
13	5	0	0	0	0	0	0	0	5	0	0	0	0	0	0	0
14	25	0	2	0	0	0	0	0	25	0	2	0	0	0	0	0
15	3	0	0	0	0	0	0	0	3	0	4	0	0	0	0	0
16	5	0	0	0	0	0	0	0	5	0	0	0	0	0	0	0
17	1	0	1	0	0	0	0	0	5	0	0	0	0	0	0	0
18	5	0	20	0	0	0	0	0	5	0	25	0	0	0	0	0
19	0	0	0	0	0	0	0	0	2	0	3	2	0	0	0	0
20	5	0	0	0	0	0	0	0	5	0	0	0	0	0	0	0
21	0	0	0	0	0	0	0	0	15	0	4	0	0	0	0	0
22	5	0	0	0	0	0	0	0	10	0	5	0	0	0	0	0
23	10	0	0	0	0	0	0	0	10	0	0	0	0	0	0	0
24	5	0	0	0	0	0	0	0	5	0	5	0	0	0	0	0
25	10	2	0	0	0	0	0	0	10	2	0	0	0	0	0	0
26	10	0	0	0	0	6	0	0	15	0	20	0	0	15	0	0
27	15	0	0	0	0	0	0	0	15	0	0	0	0	0	0	0
28	0	0	0	0	0	0	0	0	5	0	5	0	0	0	0	0
29	0	0	0	0	0	0	0	0	2	0	5	0	0	0	0	0
30	5	0	0	0	0	0	0	0	5	0	3	1	0	0	0	1
31	5	0	0	0	0	0	0	0	5	0	3	0	0	0	0	0
32	5	0	0	0	0	0	0	0	10	0	5	0	0	0	0	0
33	20	0	0	0	0	0	0	0	25	0	5	0	0	0	0	0
34	25	0	10	0	0	0	0	0	25	15	0	0	0	0	0	0
35	0	0	0	0	0	0	0	0	5	0	5	0	0	0	0	0
36	0	0	0	15	0	15	0	0	0	0	5	15	0	15	0	0
37	0	0	0	0	0	0	0	0	20	0	2	0	0	0	0	0
38	5	0	0	0	0	0	0	0	5	0	0	0	0	0	0	0

No.	1 month post-surgical performance score								3 months post-surgical performance score							
	Eating	Speaking	Cleaning	Sleeping	Emotion	Smiling	Contact	Working	Eating	Speaking	Cleaning	Sleeping	Emotion	Smiling	Contact	Working
1	25	0	0	0	0	0	0	0	25	0	0	0	0	0	0	0
2	10	0	0	0	0	0	0	0	10	0	0	0	0	0	0	0
3	2	0	5	0	0	0	0	0	2	0	0	0	0	0	0	0
4	25	0	0	0	0	0	0	0	25	0	0	0	0	0	0	0
5	25	0	0	0	0	0	0	0	25	0	0	0	0	0	0	0
6	5	0	0	0	0	0	0	0	5	0	0	0	0	0	0	0
7	10	0	0	0	0	0	0	0	10	0	0	0	0	0	0	0
8	15	0	0	0	0	0	0	0	15	0	0	0	0	0	0	0
9	20	0	0	0	0	0	0	0	20	0	0	0	0	0	0	0
10	5	0	0	0	0	0	0	0	5	0	0	0	0	0	0	0
11	5	0	0	0	0	0	0	0	5	0	0	0	0	0	0	0
12	5	0	0	0	0	0	0	0	5	0	0	0	0	0	0	0
13	5	0	0	0	0	0	0	0	5	0	0	0	0	0	0	0
14	25	0	2	0	0	0	0	0	25	0	2	0	0	0	0	0
15	3	0	0	0	0	0	0	0	3	0	0	0	0	0	0	0
16	5	0	0	0	0	0	0	0	5	0	0	0	0	0	0	0
17	1	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
18	5	0	20	0	0	0	0	0	5	0	20	0	0	0	0	0
19	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
20	5	0	0	0	0	0	0	0	5	0	0	0	0	0	0	0
21	5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
22	5	0	0	0	0	0	0	0	5	0	0	0	0	0	0	0
23	10	0	0	0	0	0	0	0	10	0	0	0	0	0	0	0
24	5	0	0	0	0	0	0	0	5	0	0	0	0	0	0	0
25	10	2	0	0	0	0	0	0	10	2	0	0	0	0	0	0
26	10	0	0	0	0	6	0	0	10	0	0	0	0	6	0	0
27	15	0	0	0	0	0	0	0	15	0	0	0	0	0	0	0
28	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
29	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
30	5	0	0	0	0	0	0	0	5	0	0	0	0	0	0	0
31	5	0	5	0	0	0	0	0	5	0	0	0	0	0	0	0
32	5	0	0	0	0	0	0	0	5	0	0	0	0	0	0	0
33	25	0	0	0	0	0	0	0	25	0	0	0	0	0	0	0
34	25	0	0	0	0	0	0	0	25	0	0	0	0	0	0	0
35	5	0	0	0	0	0	0	0	5	0	0	0	0	0	0	0
36	0	0	0	15	0	15	0	0	0	0	0	15	0	15	0	0
37	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
38	5	0	0	0	0	0	0	0	5	0	0	0	0	0	0	0

No.	Post-prosthesis performance score								Global Transition Rating
	Eating	Speaking	Cleaning	Sleeping	Emotion	Smiling	Contact	Working	
1	25	0	0	0	0	0	0	0	0
2	20	0	0	0	0	0	0	0	-2
3	0	0	15	0	0	0	0	0	4
4	15	0	0	0	0	0	0	0	0
5	0	0	15	0	0	0	0	0	5
6	5	0	5	0	0	0	0	0	-1
7	10	0	0	0	0	0	0	0	2
8	5	0	0	0	0	0	0	0	5
9	5	0	0	0	0	0	0	0	4
10	5	0	0	0	0	0	0	0	1
11	0	0	3	0	0	0	0	0	3
12	0	0	3	0	0	0	0	0	4
13	0	0	0	0	0	0	0	0	5
14	0	0	0	0	0	0	0	0	5
15	0	0	0	0	0	0	0	0	3
16	0	0	0	0	0	0	0	0	4
17	0	0	0	0	0	0	0	0	5
18	0	0	0	0	0	0	0	0	4
19	0	0	0	0	0	0	0	0	5
20	0	0	0	0	0	0	0	0	5
21	0	0	0	0	0	0	0	0	4
22	0	0	0	0	0	0	0	0	5
23	0	0	0	0	0	0	0	0	0
24	0	0	0	0	0	0	0	0	4
25	0	0	0	0	0	0	0	0	4
26	0	0	0	0	0	0	0	0	4
27	0	0	0	0	0	0	0	0	5
28	0	0	0	0	0	0	0	0	4
29	0	0	0	0	0	0	0	0	4
30	0	0	0	0	0	0	0	0	4
31	0	0	0	0	0	0	0	0	5
32	0	0	0	0	0	0	0	0	0
33	0	0	0	0	0	0	0	0	5
34	0	0	0	0	0	0	0	0	5
35	0	0	0	0	0	0	0	0	5
36	0	0	0	0	0	0	0	0	5
37	0	0	0	0	0	0	0	0	2
38	0	0	0	0	0	0	0	0	5

Appendix D Descriptive statistics details of OIDP overall score in study group patients

			Statistic	Std. Error
Pre-op	Mean		9.0357	2.62985
	95% Confidence Interval for Mean	Lower Bound	3.3543	
		Upper Bound	14.7172	
	5% Trimmed Mean		7.9286	
	Median		6.7500	
	Variance		96.826	
	Std. Deviation		9.84000	
	Minimum		.00	
	Maximum		38.00	
	Range		38.00	
	Interquartile Range		11.38	
	Skewness		2.087	.597
	Kurtosis		5.641	1.154
2 wks PO	Mean		16.7143	2.79064
	95% Confidence Interval for Mean	Lower Bound	10.6855	
		Upper Bound	22.7431	
	5% Trimmed Mean		16.2937	
	Median		13.7500	
	Variance		109.027	
	Std. Deviation		10.44162	
	Minimum		3.00	
	Maximum		38.00	
	Range		35.00	
	Interquartile Range		17.50	
	Skewness		.663	.597
	Kurtosis		-.379	1.154
1 mo PO	Mean		8.9643	2.53138
	95% Confidence Interval for Mean	Lower Bound	3.4956	
		Upper Bound	14.4330	
	5% Trimmed Mean		7.8492	
	Median		7.2500	
	Variance		89.710	
	Std. Deviation		9.47155	
	Minimum		.00	

			Statistic	Std. Error
	Maximum		38.00	
	Range		38.00	
	Interquartile Range		9.25	
	Skewness		2.375	.597
	Kurtosis		7.227	1.154
3 mo PO	Mean		8.9643	2.53138
	95% Confidence Interval for Mean	Lower Bound	3.4956	
		Upper Bound	14.4330	
	5% Trimmed Mean		7.8492	
	Median		7.2500	
	Variance		89.710	
	Std. Deviation		9.47155	
	Minimum		.00	
	Maximum		38.00	
	Range		38.00	
	Interquartile Range		9.25	
	Skewness		2.375	.597
	Kurtosis		7.227	1.154
Post-prosthesis	Mean		6.1071	2.51325
	95% Confidence Interval for Mean	Lower Bound	.6776	
		Upper Bound	11.5367	
	5% Trimmed Mean		5.0635	
	Median		2.5000	
	Variance		88.430	
	Std. Deviation		9.40372	
	Minimum		.00	
	Maximum		31.00	
	Range		31.00	
	Interquartile Range		7.50	
	Skewness		2.004	.597
	Kurtosis		3.426	1.154

Appendix E Descriptive statistics details of OIDP overall score in comparison group patients

			Statistic	Std. Error
Pre-op	Mean		5.3553	.79693
	95% Confidence Interval for Mean	Lower Bound	3.7405	
		Upper Bound	6.9700	
	5% Trimmed Mean		5.0439	
	Median		2.5000	
	Variance		24.134	
	Std. Deviation		4.91263	
	Minimum		.00	
	Maximum		17.50	
	Range		17.50	
	Interquartile Range		6.38	
	Skewness		.865	.383
	Kurtosis		-.382	.750
2 wks PO	Mean		8.9605	.96330
	95% Confidence Interval for Mean	Lower Bound	7.0087	
		Upper Bound	10.9124	
	5% Trimmed Mean		8.5599	
	Median		7.0000	
	Variance		35.262	
	Std. Deviation		5.93817	
	Minimum		2.50	
	Maximum		25.00	
	Range		22.50	
	Interquartile Range		10.63	
	Skewness		.789	.383
	Kurtosis		-.241	.750
1 mo PO	Mean		5.3421	.74246
	95% Confidence Interval for Mean	Lower Bound	3.8377	
		Upper Bound	6.8465	
	5% Trimmed Mean		5.1418	
	Median		2.5000	
	Variance		20.947	
	Std. Deviation		4.57683	

			Statistic	Std. Error
	Minimum		.00	
	Maximum		15.00	
	Range		15.00	
	Interquartile Range		6.00	
	Skewness		.796	.383
	Kurtosis		-.768	.750
3 mo PO	Mean		5.1447	.76250
	95% Confidence Interval for Mean	Lower Bound	3.5998	
		Upper Bound	6.6897	
	5% Trimmed Mean		4.9225	
	Median		2.5000	
	Variance		22.093	
	Std. Deviation		4.70036	
	Minimum		.00	
	Maximum		15.00	
	Range		15.00	
	Interquartile Range		6.00	
	Skewness		.806	.383
	Kurtosis		-.806	.750
Post-prosthesis	Mean		1.7237	.52352
	95% Confidence Interval for Mean	Lower Bound	.6629	
		Upper Bound	2.7844	
	5% Trimmed Mean		1.2865	
	Median		.0000	
	Variance		10.415	
	Std. Deviation		3.22720	
	Minimum		.00	
	Maximum		12.50	
	Range		12.50	
	Interquartile Range		2.50	
	Skewness		1.982	.383
	Kurtosis		3.182	.750

Appendix F Frequency distribution of OIDP extent and intensity

Study group (n=14)

Extent	Pre-op (n)	2 wks PO (n)	1 mo PO (n)	3 mo PO (n)	Post-prosthesis (n)
0	2.0	0.0	2.0	2.0	5.0
1-2	8.0	6.0	10.0	10.0	6.0
3-5	4.0	6.0	2.0	2.0	3.0
6-8	0.0	2.0	0.0	0.0	0.0

Intensity	Pre-op (n)	2 wks PO (n)	1 mo PO (n)	3 mo PO (n)	Post-prosthesis (n)
No	2.0	0.0	2.0	2.0	5.0
Little	3.0	3.0	3.0	3.0	6.0
Moderate	2.0	0.0	2.0	2.0	0.0
Severe	7.0	11.0	7.0	7.0	3.0

Comparison group (n=38)

Extent	Pre-op (n)	2 wks PO (n)	1 mo PO (n)	3 mo PO (n)	Post-prosthesis (n)
0	6.0	0.0	4.0	5.0	26.0
1-2	32.0	31.0	34.0	33.0	12.0
3-5	0.0	7.0	0.0	0.0	0.0
6-8	0.0	0.0	0.0	0.0	0.0

Intensity	Pre-op (n)	2 wks PO (n)	1 mo PO (n)	3 mo PO (n)	Post-prosthesis (n)
No	6.0	0	4.0	5.0	26.0
Little	15.0	15	18.0	17.0	6.0
Moderate	5.0	7.0	5.0	5.0	1.0
Severe	12.0	16.0	11.0	11.0	5.0

Appendix G The *p*-value of within-group comparison for overall score

Group	Time point assessed					*p*-value
	Pre-op	2 wks PO	1 mo PO	3 mo PO	post-prosthesis	
All	■	■	■	■	■	<0.001**
	■	■				<0.001*
	■		■			0.855
	■			■		0.549
	■				■	<0.001*
		■	■			<0.001*
		■		■		<0.001*
		■			■	<0.001*
			■	■		0.083
			■		■	<0.001*
				■	■	<0.001*
Study	■	■	■	■	■	<0.001**
	■	■				0.002
	■		■			0.812
	■			■		0.812
	■				■	0.255
		■	■			0.002*
		■		■		0.002*
		■			■	0.011*
			■	■		1.000
			■		■	0.272
				■	■	0.272
Comparison	■	■	■	■	■	<0.001**
	■	■				<0.001*
	■		■			1.000
	■			■		0.498
	■				■	<0.001*
		■	■			<0.001*
		■		■		<0.001*
		■			■	<0.001*
			■	■		0.083
			■		■	<0.001*
				■	■	<0.001*

** : Statistical significant at 95% confident interval by Friedman Test

* : Statistical significant at 95% confident interval by Wilcoxon Signed Ranks Test

Appendix H The statistical analysis for across-group on OIDP overall score comparison

Ranks

	Group	N	Mean Rank	Sum of Ranks
Pre-op	GBR	14	30.57	428.00
	Non-GBR	38	25.00	950.00
	Total	52		
2 wks PO	GBR	14	35.43	496.00
	Non-GBR	38	23.21	882.00
	Total	52		
1 mo PO	GBR	14	30.96	433.50
	Non-GBR	38	24.86	944.50
	Total	52		
3 mo PO	GBR	14	31.43	440.00
	Non-GBR	38	24.68	938.00
	Total	52		
Post-prosthesis	GBR	14	33.21	465.00
	Non-GBR	38	24.03	913.00
	Total	52		

Test Statistics

	Pre-op	2 wks PO	1 mo PO	3 mo PO	Post-prosthesis
Mann-Whitney U	209.000	141.000	203.500	197.000	172.000
Wilcoxon W	950.000	882.000	944.500	938.000	913.000
Z	-1.193	-2.586	-1.310	-1.446	-2.186
Asymp. Sig. (2-tailed)	**.233**	**.010**	**.190**	**.148**	**.029**

Appendix I The *p*-value of within-group comparison for OIDP performance score

Performances	All		study		comparison	
	Post-surgical change	Post-prosthesis change	Post-surgical change	Post-prosthesis change	Post-surgical change	Post-prosthesis change
Eating						
p-value	0.003*	<0.001*	0.007*	0.097	0.001*	<0.001*
Speaking						
p-value	0.769	0.556	0.655	0.109	0.180	0.317
Cleaning						
p-value	<0.001*	0.303	0.002*	0.024*	<0.001*	0.593
Sleeping						
p-value	0.433	0.961	0.180	0.317	0.102	0.317
Maintaining emotion						
p-value	0.500	0.715	0.593	0.715	0.180	1.000
Smiling						
p-value	0.310	0.011*	0.893	0.039*	0.180	0.102
Contacting						
p-value	0.068	0.593	0.068	0.593	1.000	1.000
Working						
p-value	0.157	1.000	0.371	1.000	0.317	1.000

* : Statistical significant at 95% confident interval

Statistical analysis by Wilcoxon Signed Ranks Test

Appendix J Calculation methods for distribution-based MID

Prerequisite information

Mean post-surgical change score (Std. deviation) = 4.7 (5.5)

Mean post-prosthesis change score (Std. deviation) = -3.4 (8.5)

Standard deviation of baseline score = 6.7

The internal reliability as Cronbach's Alpha (analyzed through SPSS.) = 0.879

Method	Formula	Calculation
Effect Size (ES)	$\frac{Mean\ changed\ score}{\text{SD of the baseline score}}$	For post-surgical change $ES = \frac{4.7}{6.7} = 0.7$
		For post-prosthesis change $ES = \frac{3.4}{6.7} = 0.5$
Standardized Response Mean (SRM)	$\frac{Mean\ changed\ score}{\text{SD of the changed score}}$	For post-surgical change $SRM = \frac{4.7}{5.5} = 0.8$
		For post-prosthesis change $SRM = \frac{3.4}{8.5} = 0.4$
Standard Error of Measurement (SEM)	$\text{SD of the baseline score} \times \sqrt{1-\alpha}$	$SEM = 6.7 \times \sqrt{1-0.879} = 2.3$
Norman's rule of thumb	$\frac{\text{SD of the baseline score}}{2}$	$Norman's\ value = \frac{6.7}{2} = 3.4$

Appendix K Frequency distribution on meaningful/meaningless change for each interested variables

Variables		Post-surgical change		Post-prosthesis change	
		Meaningless (n)	Meaningful (n)	Meaningless (n)	Meaningful (n)
Age	Under 45 yrs.	5	6	6	5
	46-59 yrs.	17	7	14	10
	More than 60 yrs.	6	11	12	5
Gender	Male	13	9	18	4
	Female	15	15	14	16
Education level	Under university	4	4	5	3
	University or above	24	20	27	17
Systemic disease	Absent	15	12	18	9
	Present	13	12	14	11
Denture experience	Ever	7	8	5	10
	Never	21	16	27	10
Implant experience	Ever	4	6	6	4
	Never	24	18	26	16
Study's group	Study	5	9	7	7
	Comparison	23	15	25	13
Amount of placed implant	Single	26	16	26	16
	Multiple	2	8	6	4
Implant position	Anterior	2	1	0	3
	Posterior	26	23	32	17
Implant location	Maxilla	8	7	6	9
	Mandible	20	17	26	11
Placement timing	Early	13	8	13	8
	Delay	15	16	19	12
Surgeon	Student	12	11	N/A	N/A
	Staff	16	13	N/A	N/A
Prosthodontist	Student	N/A	N/A	11	7
	Staff	N/A	N/A	21	13

Appendix L Statistical analysis related to OIDP responsiveness assessment

Pearson's correlation between post-surgical change score and global transition rating

		Post-prosthesis change	Global Transition Rating
Post-prosthesis change	Pearson Correlation	1	-.614**
	Sig. (2-tailed)		.000
	N	52	52
Global Transition Rating	Pearson Correlation	-.614**	1
	Sig. (2-tailed)	.000	
	N	52	52
** Correlation is significant at the 0.01 level (2-tailed).			

Post-prosthesis OIDP changed score comparison according to global transition rating

	Global rating	N	Mean Rank
Post-prosthesis OIDP score change	-5	1	52.00
	-3	1	51.00
	-2	1	50.00
	-1	2	48.50
	0	4	25.13
	1	1	42.00
	2	2	42.00
	3	3	28.67
	4	16	23.97
	5	21	20.57
	Total	52	

Test Statistics[a,b]	
	Post-prosthesis change
Chi-Square	19.294
df	9
Asymp. Sig.	.023
a. Kruskal Wallis Test	
b. Grouping Variable: T4Global	

Frequency distribution of the OIDP intensity change level according to global transition rating

		Level of intensity change									Total
		-5.00	-4.00	-3.00	-2.00	-1.00	.00	1.00	2.00	3.00	
Global Transition Rating	-5	0	0	0	0	0	0	0	0	1	1
	-3	0	0	0	0	0	0	1	0	0	1
	-2	0	0	0	0	0	0	0	1	0	1
	-1	0	0	0	0	0	1	0	1	0	2
	0	0	0	1	1	1	1	0	0	0	4
	1	0	0	0	0	0	1	0	0	0	1
	2	0	0	0	0	0	2	0	0	0	2
	3	0	0	0	1	0	2	0	0	0	3
	4	1	0	3	6	1	5	0	0	0	16
	5	5	2	0	8	3	3	0	0	0	21
Total		6	2	4	16	5	15	1	2	1	52

Symmetric Measures

		Value	Asymp. Std. Error	Approx. T	Approx. Sig.
Interval by Interval	Pearson's R	-.592	.094	-5.194	.000[c]
Ordinal by Ordinal	Spearman Correlation	-.523	.114	-4.337	.000[c]
N of Valid Cases		52			

Appendix M Consent form (Thai language)

เอกสารยินยอมเข้าร่วมการวิจัย (Consent Form)

การวิจัยเรื่อง คุณภาพชีวิตในมิติสุขภาพช่องปากของผู้ป่วยที่เข้ารับการผ่าตัดฝังรากฟันเทียมร่วมกับการปลูกกระดูก

“ข้าพเจ้า (นาย, นาง, นางสาว).....

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

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

ก่อนที่จะลงนามในใบยินยอมให้ทำการวิจัยนี้ ข้าพเจ้าได้รับเอกสารข้อมูลคำอธิบายสำหรับอาสาสมัครที่เข้าร่วมในการวิจัยแล้ว 1 ฉบับ รวมทั้งได้รับการอธิบายจากผู้วิจัยถึงวัตถุประสงค์ของการวิจัย วิธีการทำวิจัย อันตรายหรืออาการที่อาจเกิดขึ้นจากการทำวิจัยหรือจากยาที่ใช้ รวมทั้งประโยชน์ที่จะเกิดขึ้นจากการวิจัยอย่างละเอียด และมีความเข้าใจดีแล้ว

ผู้วิจัยรับรองว่าจะตอบคำถามต่าง ๆ ที่ข้าพเจ้าสงสัยด้วยความเต็มใจไม่ปิดบังซ่อนเร้นจนข้าพเจ้าพอใจ

ข้าพเจ้าเข้าร่วมโครงการวิจัยนี้โดยสมัครใจ ข้าพเจ้ามีสิทธิที่จะบอกเลิกการเข้าร่วมในโครงการวิจัยนี้เมื่อใดก็ได้และการบอกเลิกการเข้าร่วมการวิจัยนี้จะไม่มีผลต่อการรักษาโรคที่ข้าพเจ้าจะพึงได้รับต่อไป

ผู้วิจัยรับรองว่าจะเก็บข้อมูลเฉพาะเกี่ยวกับตัวข้าพเจ้าเป็นความลับ และจะเปิดเผยได้เฉพาะในรูปที่เป็นสรุปผลการวิจัย การเปิดเผยข้อมูลเกี่ยวกับตัวข้าพเจ้าต่อหน่วยงานต่าง ๆ ที่เกี่ยวข้องกระทำได้เฉพาะกรณีจำเป็น ด้วยเหตุผลทางวิชาการเท่านั้น และผู้วิจัยรับรองว่าหากเกิดอันตรายใด ๆ จากการวิจัยดังกล่าว ข้าพเจ้าจะได้รับการรักษาพยาบาลโดยไม่คิดมูลค่า

ข้าพเจ้าได้อ่านเอกสารและข้อความข้างต้นแล้ว มีความเข้าใจดีทุกประการ และได้ลงนามในใบยินยอมนี้ด้วยความเต็มใจ

ข้าพเจ้าได้รับสำเนาเอกสารใบยินยอมที่ข้าพเจ้าลงนามและลงวันที่ และเอกสารยกเลิกการเข้าร่วมวิจัย อย่างละ 1 ฉบับ เป็นที่เรียบร้อยแล้ว

ลงนาม..... ผู้ยินยอม

(.....)

วันที่.....เดือน.....พ.ศ.....

ลงนาม..... พยาน

(.....)

วันที่.....เดือน.....พ.ศ.....

ลงนาม..... ผู้วิจัยหลัก

(นายสุชาติ เขม้นเขตรการ)

วันที่.....เดือน.....พ.ศ.....

ข้าพเจ้าไม่สามารถอ่านหนังสือได้ แต่ผู้วิจัยได้อ่านข้อความในใบยินยอมนี้ให้แก่ข้าพเจ้าฟังจนเข้าใจดีแล้ว ข้าพเจ้าจึงลงนาม หรือประทับลายนิ้วหัวแม่มือขวาของข้าพเจ้าในใบยินยอมนี้ด้วยความเต็มใจ

ลงนาม.....ผู้ยินยอม

(.....)

วันที่.....เดือน.....พ.ศ.....

ลงนาม.....พยาน

(.....)

วันที่.....เดือน.....พ.ศ.....

ลงนาม.....ผู้วิจัยหลัก

(นายสุชาติ เขม้นเขตรการ)

วันที่.....เดือน.....พ.ศ.....

ในกรณีที่ผู้ถูกทดลองยังไม่บรรลุนิติภาวะ จะต้องได้รับการยินยอมจากผู้ปกครองหรือผู้อุปการะ

โดยชอบด้วยกฎหมาย

ลงนาม..... ผู้ปกครอง

(.....)

วันที่.....เดือน.....พ.ศ.....

ลงนาม..... พยาน

(.....)

วันที่.....เดือน.....พ.ศ.....

ลงนาม..... ผู้วิจัยหลัก

(นายสุชาติ เขม้นเขตรการ)

วันที่.....เดือน.....พ.ศ.....

VITA

Name: Mr. Suchat Kamankatgan

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