## ความสัมพันธ์ระหว่างคุณภาพฟันเทียมทั้งปากถอดได้ ความพึงพอใจของผู้ป่วย และคุณภาพชีวิตในมิติ สุขภาพช่องปาก



## จุหาลงกรณ์มหาวิทยาลัย

## บทคัดย่อและแฟ้มข้อมูลฉบับเต็มของวิทยานิพนธ์ตั้งแต่ปีการศึกษา 2554 ที่ให้บริการในคลังปัญญาจุฬาฯ (CUIR) เป็นแฟ้มข้อมูลของนิสิตเจ้าของวิทยานิพนธ์ ที่ส่งผ่านทางบัณฑิตวิทยาลัย

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## THE QUALITY OF COMPLETE DENTURE, PATIENT'S SATISFACTION, ORAL HEALTH-RELATED QUALITY OF LIFE, AND THEIR ASSOCIATION



A Dissertation Submitted in Partial Fulfillment of the Requirements for the Degree of Doctor of Philosophy Program in Prosthodontics Department of Prosthodontics Faculty of Dentistry Chulalongkorn University Academic Year 2017 Copyright of Chulalongkorn University

Thesis Title	THE QUALITY OF COMPLETE DENTURE, PATIENT'S
	SATISFACTION, ORAL HEALTH-RELATED QUALITY
	OF LIFE, AND THEIR ASSOCIATION
Ву	Miss Nareudee Limpuangthip
Field of Study	Prosthodontics
Thesis Advisor	Associate Professor Mansuang Arksornnukit, D.D.S.,
	M.S., Ph.D.
Thesis Co-Advisor	Assistant Professor Tewarit Somkotra, D.D.S., Ph.D.

Accepted by the Faculty of Dentistry, Chulalongkorn University in Partial Fulfillment of the Requirements for the Doctoral Degree

\_\_\_\_\_Dean of the Faculty of Dentistry

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

THESIS COMMITTEE

\_\_\_\_\_Chairman

(Associate Professor Morakot Piemjai, D.D.S., M.S., Ph.D.)

\_\_\_\_\_Thesis Advisor

(Associate Professor Mansuang Arksornnukit, D.D.S., M.S., Ph.D.)

\_\_\_\_\_Thesis Co-Advisor

(Assistant Professor Tewarit Somkotra, D.D.S., Ph.D.)

\_\_\_\_\_Examiner

(Assistant Professor Wacharasak Tumrasvin, D.D.S., Ph.D.)

Examiner

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

External Examiner

(Assistant Professor Sutee Suksudaj, D.D.S., M.P.H., Ph.D.)

ณฤดี ลิ้มปวงทิพย์ : ความสัมพันธ์ระหว่างคุณภาพฟันเทียมทั้งปากถอดได้ ความพึงพอใจ ของผู้ป่วย และคุณภาพชีวิตในมิติสุขภาพช่องปาก (THE QUALITY OF COMPLETE DENTURE, PATIENT'S SATISFACTION, ORAL HEALTH-RELATED QUALITY OF LIFE, AND THEIR ASSOCIATION) อ.ที่ปรึกษาวิทยานิพนธ์หลัก: รศ. ทพ. ดร. แมนสรวง อักษร นุกิจ, อ.ที่ปรึกษาวิทยานิพนธ์ร่วม: ผศ. ทพ. ดร. เทวฤทธิ์ สมโคตร, 75 หน้า.

การศึกษานี้มีวัตถุประสงค์เพื่อศึกษาความสัมพันธ์ระหว่างคุณภาพฟันเทียมทั้งปากต่อความ พึงพอใจของผู้ป่วย และคุณภาพชีวิตในมิติสุขภาพช่องปาก อาสาสมัครได้แก่ผู้ป่วยที่ใส่ฟันเทียมทั้ง ปากจำนวน 126 คน ผลลัพธ์หลักคือคุณภาพชีวิตในมิติสุขภาพช่องปากซึ่งได้จากการสัมภาษณ์ผู้ป่วย ้ว่าได้รับผลกระทบจากสภาวะช่องปากต่อการดำเนินกิจวัตรประจำวันหรือไม่ ผลลัพธ์รองคือความพึง พอใจต่อฟันเทียม และประสิทธิภาพการบดเคี้ยว นอกจากนี้ยังทำการประเมินการยึดอยู่และความ เสถียรของฟันเทียมตามเกณฑ์ของคาเปอร์แบบดั้งเดิมและซียูโมดิฟายด์คาเปอร์ รวมถึงวิเคราะห์ ภาพถ่ายของผู้ป่วยเพื่อประเมินว่าจุดตำแหน่งบนฟันเทียมและใบหน้ามีความสอดคล้องกับเกณฑ์การ ้ประเมินความสวยงามหรือไม่ ผลการศึกษาพบว่าปัญหาที่เกิดขึ้นบ่อยสุดคือเรื่องกิน/เคี้ยว ซึ่งมีสาเหตุ ้จากฟันเทียมหลวมขยับเป็นหลัก ฟันเทียมที่มีการยึดอยู่และ/หรือความเสถียรในระดับที่ไม่ผ่านเกณฑ์ สัมพันธ์กับการเกิดผลกระทบต่อการดำเนินชีวิตประจำวัน ความไม่พึงพอใจต่อฟันเทียมในด้านการ ้กิน/เคี้ยวและการลดลงของประสิทธิภาพการบดเคี้ยว การประเมินการยึดอยู่และความเสถียรของฟัน ้เทียมด้วยเกณฑ์ซียูโมดิฟายด์คาเปอร์ให้ความไวสูงกว่าแบบดั้งเดิมในการทำนายผลลัพธ์ที่ประเมินได้ จากอาสาสมัคร อายุฟันเทียมและเกณฑ์ความสวยงามไม่สัมพันธ์กับการเกิดผลกระทบต่อการดำเนิน ชีวิตประจำวัน จากผลการศึกษาสรุปได้ว่าเกณฑ์ซียูโมดิฟายด์คาเปอร์ซึ่งใช้ประเมินการยึดอยู่และ ความเสถียรของฟันเทียมทั้งปากสามารถเป็นเครื่องมือหนึ่งที่ใช้ทำนายประสิทธิภาพการบดเคี้ยวและ คุณภาพชีวิตในมิติสุขภาพช่องปาก และสามารถใช้เป็นแนวทางในการตัดสินว่าผู้ป่วยควรได้รับการใส่ ฟันเทียมชุดใหม่หรือไม่ การประเมินร่วมกันของตัวผู้ป่วยเองในแง่ผลกระทบต่อการดำเนิน ชีวิตประจำวันและผู้เชี่ยวชาญในแง่คุณภาพฟันเทียมใช้ในการประเมินความต้องการในการใส่ฟัน เทียมทั้งปากหรือผลลัพธ์จากการรักษา

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สาขาวิชา	ทันตกรรมประดิษฐ์	ลายมือชื่อ อ.ที่ปรึกษาหลัก
ปีการศึกษา	2560	ลายมือชื่อ อ.ที่ปรึกษาร่วม

# # 5576052032 : MAJOR PROSTHODONTICS

KEYWORDS: ORAL IMPACTS ON DAILY PERFORMANCES (OIDP) / ORAL HEALTH-RELATED QUALITY OF LIFE (OHRQOL) / COMPLETE DENTURE / MASTICATORY PERFORMANCE / RETENTION AND STABILITY / PATIENT SATISFACTION

NAREUDEE LIMPUANGTHIP: THE QUALITY OF COMPLETE DENTURE, PATIENT'S SATISFACTION, ORAL HEALTH-RELATED QUALITY OF LIFE, AND THEIR ASSOCIATION. ADVISOR: ASSOC. PROF. MANSUANG ARKSORNNUKIT, D.D.S., M.S., Ph.D., CO-ADVISOR: ASST. PROF. TEWARIT SOMKOTRA, D.D.S., Ph.D., 75 pp.

The objective of this study was to determine the association of complete denture quality, patient's satisfaction, and Oral Health-related Quality of Life (OHRQoL). A total of 126 complete denture wearers was interviewed for the primary outcome, OHRQoL, using Oral Impacts on Daily Performances (OIDP) index. Secondary outcomes were patient's satisfaction and masticatory performance. Denture retention and stability were scored following the conventional and Chulalongkorn University (CU)-modified Kapur criteria. Esthetic-assessment criteria was evaluated from patient's photographs. It was found that limited eating/chewing was the most common problem, and an ill-fitting denture was a primary cause of any reported problems. Unacceptable denture retention and/or stability associated with lower masticatory performance, eating dissatisfaction, and reported oral impact. CU-modified Kapur criteria revealed higher sensitivity in estimating all patient-based outcomes compared to the conventional criteria. Denture age and esthetic-assessment criteria associated with none of patient-based outcomes. In conclusion, the CU-modified Kapur criteria for complete denture retention and stability evaluation is an alternative tool in estimating masticatory ability and OHRQoL with higher sensitivity. The CU-modified Kapur criteria helps clinician in making decision whether a denture needs refabrication. In addition to professional evaluation, OHRQoL assessment should be used in evaluating a treatment need or outcome.

Department:	Prosthodontics	Student's Signature
Field of Study:	Prosthodontics	Advisor's Signature
Academic Year:	2017	Co-Advisor's Signature

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# CHAPTER I

#### Background and Rationale

An elderly population in the world including Thailand is continuously increasing.<sup>1, 2</sup> Although prevalence of tooth loss is gradually declined, complete edentulous condition remains due to increased life expectancy of people.<sup>3</sup> Complete edentulous condition is one of the major public health concerns in several countries because it limits masticatory ability and impairs quality of life. Several dental public health programs targeting edentate elderly were implemented such as the Thai Royal Denture Project and health insurance coverage. However, a number of complete denture wearers reported difficulty in daily activities despite prosthesis obtaining,<sup>4, 5</sup> but the underlying factors remain unexplored.

As stated by FDI endorsement, "oral health" is multifaceted and covers a wide range of physical activities and psychosocial attributes that are essential to the quality of life.<sup>6</sup> Therefore, Oral Health-Related Quality of Life (OHRQoL) is generally considered as a primary treatment outcome.<sup>7-14</sup> Recently, the treatment principle has been changed from biomedical to biopsychosocial concept, therefore, the treatment outcome is not only based on professional, but also patient evaluation.<sup>15, 16</sup>

The rationale for conducting this study were; first, the earlier studies were generally conducted in middle-to-high income or developed countries, the findings of which could not be generalized to and being a representative of Thai complete denture wearers due to differences in lifestyle and socioeconomic conditions. In addition, Thai healthcare system was different from those of other countries particularly, the presence of inequity and inequality in accessing oral health care system.<sup>17</sup> Second, this was a pioneer study in complete denture wearers investigating the impacts of both patient- and denture-related conditions on masticatory ability, patient's satisfaction, and quality of life. This study would be beneficial to healthcare professionals to concern the predisposing and risk factors for impaired quality of life.

#### **Research** questions

#### Primary question

Was there any difference in the proportion of complete denture wearers who report oral impacts on daily performances between those with acceptable and unacceptable denture quality as evaluated by professionist?

#### Secondary question

Was there any difference in the proportion of complete denture wearers who report denture dissatisfaction between those with acceptable and unacceptable denture quality as evaluated by professionist?

#### Research objectives

#### Primary objective

To assess the difference in proportion of complete denture wearers who reported oral impacts on daily performances between those with acceptable and unacceptable denture quality as evaluated by professionist.

#### Secondary objective

To assess the difference in proportion of complete denture wearers who reported denture dissatisfaction between those with acceptable and unacceptable denture quality as evaluated by professionist.

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#### **Research** hypotheses

#### Primary hypothesis

H1<sub>0</sub>: There was no difference in the proportion of complete denture wearers who reported oral impacts on daily performances between those with acceptable and unacceptable denture quality as evaluated by professionist.

H1<sub>a</sub>: There was difference in the proportion of complete denture wearers who reported oral impacts on daily performances between those with acceptable and unacceptable denture quality as evaluated by professionist.

#### Secondary hypothesis

H1<sub>0</sub>: There was no difference in the proportion of complete denture wearers who reported denture dissatisfaction between those with acceptable and unacceptable denture quality as evaluated by professionist.

H1<sub>a</sub>: There was difference in the proportion of complete denture wearers who reported denture dissatisfaction between those with acceptable and unacceptable denture quality as evaluated by professionist.

#### Statistical hypotheses

Primary hypothesis;  $H1_0: p_1 = p_2$ 

 $H1_a: p_1 \neq p_2$ 

 $p_1$  = Proportion of complete denture wearers who reported oral impacts on daily performances but possessed acceptable denture quality as evaluated by professionist.  $p_2$  = Proportion of complete denture wearers who report oral impacts on daily performances and possessed unacceptable denture quality as evaluated by professionist.

Secondary hypothesis; 
$$H2_0: p_3 = p_4$$
  
 $H2_a: p_3 \neq p_4$ 

 $p_3$  = Proportion of complete denture wearers who reported denture dissatisfaction but possessed acceptable denture quality as evaluated by professionist.

 $p_4$  = Proportion of complete denture wearers who reported denture dissatisfaction and possessed unacceptable denture quality as evaluated by professionist.

Theoretical framework<sup>14, 18</sup>



#### Operational definition

- Oral Impacts on Daily Performances: a patient who reported difficulty in any of 8 daily activities was considered as having oral impacts on daily performances (OIDP) or reported "oral impact".
- **Removable complete denture:** removable acrylic resin complete denture prosthesis without implant- or tooth-retained.
- Oral tissue condition: included both soft (denture bearing tissue) and hard tissue (residual ridge)

#### Keywords

- Oral Health-related Quality of Life (OHRQoL)
- Oral Impacts on Daily Performances (OIDP)
- Complete denture
- Patient satisfaction
- Masticatory performance
- Retention and stability

#### Study design

Retrospective cohort study

#### Expected benefits and applications

1. To further knowledge in the association between underlying patient- and denturerelated factors and patient-based treatment outcomes.

2. To identify the important clinical/laboratory procedures to develop a guideline for complete denture treatment.

3. To develop the outcome measurement method for clinical- and community-based study or healthcare program.

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## CHAPTER II LITERATURE REVIEW

Due to changing of biomedical into bio-psychosocial concept, medical treatment outcomes including prosthodontic treatment does not consider only professionally-based, but also place importance on patient-based or patient-centered outcomes. Therefore, the term "Oral Health-Related Quality of Life (OHRQoL)" has been emerged because it indicates physical and psychosocial condition, which reflects the true "oral health" of people.<sup>6</sup> OHRQoL is defined as the impact of oral disorder on activities in daily life or the impact that affect individual's perception of their overall life.<sup>19</sup>

# Assessment of Oral Health-Related Quality of Life (OHRQoL) in complete denture wearers

A number of index have been used to evaluate OHRQoL of complete denture wearers, including the Geriatric Oral Health Assessment Index (GOHAI)<sup>7</sup>, Oral Impacts on Daily Performances (OIDP)<sup>20</sup>, and short-form Oral Health Impact Profile (OHIP)<sup>11, 21</sup> including Oral Health Impact Profile specific for edentulous patients (OHIP-EDENT).<sup>7, 14, 22-24</sup> In Thailand, "Oral Impacts on Daily Performances (OIDP)" is generally used for OHRQoL assessment as it has been validated in adults and elderly Thai including complete denture wearers.<sup>5, 25</sup> The index was also used in the 6<sup>th</sup> and 7<sup>th</sup> Thai National Oral Health survey. The comparisons between OIDP and OHIP-EDENT are shown in Table 1.

	OIDP <sup>26</sup>	OHIP-EDENT <sup>8</sup>
	(Adulyanon S and Sheiham A, 1997)	(Allen F and Locker D, 2002)
Theoretical	Functional level of Locker's interpretation of	Locker's model of oral health
framework	the World Health Organization (WHO)	
Measuring	8 Items in 3 impacts including	19-question survey with 7 domains
questions	1) Physical impact	including
	• Eating and enjoying food	1) Functional limitation
	• Speaking and pronouncing	Difficulty chewing
	Cleaning teeth or denture	Food catching
	2) Psychological impact	• Denture not fitting
	Sleeping and relaxing	2) Physical pain
	Maintaining usual emotion without	<ul> <li>Painful aching</li> </ul>
	being irritable	Uncomfortable to eat
	• Smiling, laughing and showing teeth	<ul> <li>Sore spot</li> </ul>
	without embarrassment	Uncomfortable dentures
	3) Social impact	3) Psychological discomfort
	Enjoying contact with people	Worried
	• Carrying out major work, social role	<ul> <li>Self-conscious</li> </ul>
	or physical activities	4) Physical disability
	Contraction of the second	Avoid eating
		<ul> <li>Interrupt meals</li> </ul>
		Unable to eat
	จุหาลงกรณ์มหาวิทยา	5) Psychological disability
		Upset
	UNDEALONGKONN UNIVER	Been embarrassed
		6) Social disability
		• Less tolerant of others
		• Irritable with others
		• Avoid going out
		7) Handicap
		• Unable to enjoy company
		• Life unsatisfying
Method of	Interviewing	Self-administered questionnaire
measurement		
Recall	Past 6 months	Past 12 months
periods		

## Table 1: Comparisons between ODIP and OHIP-EDENT index.

	OIDP <sup>26</sup>	OHIP-EDENT <sup>8</sup>
Frequency of	Five-point Likert scale	Five-point Likert scale
impacts	1 = never affected/less than once a month	0 = never, not applicable
	2 = once or twice a month	1 = hardly ever
	3 = once or twice a week	2 = occasionally
	4 = 3-4 times a week	3 = fairly often
	5 = every or nearly everyday	4 = very often
Severity of	Five-point Likert scale	No severity scale
impacts	1 = very less severe	
	2 = less severe	
	3 = moderately severe	
	4 = severe	
	5 = very severe	
Score	Overall impact score is determined by total	A total OHIP score is determined by
calculation	frequency and severity of each condition-	total frequency of each impact.
	specific (CS) impact score.	
Measurement	Impacts on daily performances	Based on patient's satisfaction in their
outcome		life and prostheses
Advantages	1. Concise and cover main sequences as it	1. This modified shorten version of
	focuses on mainly ultimate impact	OHIP-49 is suggested for edentulous
	2. Decrease an overscoring occurred from	patient.
	repeated scoring of the same impact of each	2. No observer's judgment because
	level	the questions were derived from
	3. Exclude all feeling-state dimensions such as	patients' response.
	pain and discomfort, thus the index solely	3. No need for well-trained
	focuses on impacts that affect daily activities'	interviewer, thus, reducing interviewing
	performance.	cost.
	4. Able to determine patient need in order to	
	facilitate dental service plan because casual	
	problems can be identified and severity score	
	indicates importance of problems.	
	5. Face-to-face interview allows interviewer to	
	retrieve actual problem from patients	
	6. Relatively high validity and reliability	
	because the index was developed and widely	
	used in both dentate and edentulous Thai	
	people.	

	OIDP <sup>26</sup>	OHIP-EDENT <sup>8</sup>
Disadvantages	1. Need for a well-trained interviewer	1. Each item is related to patient
	(Interviewer's bias)	satisfaction of denture rather the
	2. No construct validity as there were no	impact of denture on OHRQoL.
	rationales for item's selection. <sup>27</sup>	2. Unable to identify patient's need
		because of non-investigating problem.
Cross-culture	Thai, English, French, Japanese, Chinese,	Thai, Brazilian, Portuguese, Romanian,
languages	Korean, Malaysian, Myanmar, Persian, Afrikaans	Japanese, Chinese
	Spanish, Greek	

The conceptual framework of OIDP categorizes oral impairments and their consequences into 3 levels;

Level 1: Oral impairment

Level 2: Intermediate impact (pain, discomfort, functional limitation, appearance dissatisfaction)

Level 3: Ultimate impact or Impacts on daily performances (physical, psychological, and social difficulty)

The main advantage of OIDP index is that it focuses on measuring the serious oral impacts on the ability to perform daily activities (ultimate impacts) rather than patient's perception. Although a number of short-form OHIPs are regularly used to assess OHRQoL of complete denture wearers, they measure the secondary level of oral impairment, or feeling-state dimensions such as pain, discomfort, and functional limitation which might occasionally occur but not impact daily activities.

#### Assessment of patient's satisfaction of complete denture

Apart from OHRQoL, patient's satisfaction is often used to determine complete denture treatment. The two most common scales are Likert<sup>28-30</sup> and Visual Analogue Scale (VAS).<sup>14, 31-33</sup> Likert is an ordinal scale which a person rates his/her level of agreement/satisfaction according to the supporting (anchorage) statements, while VAS is a continuous line, on which the respondents mark their level of

agreement/satisfaction. The strengths and weaknesses between Likert and VAS are shown in table 2.

Likert scale	VAS	
1. Ordinal (Categorical) scale, Qualitative measure.	1. Continuous scale, Quantitative measure.	
Thus, the unequal distance between two	Thus, the equaled distance between categories is	
categories is assumed.	assumed.	
2. The scale comprises the supporting statements	2. No supporting statement. Two anchorage	
or labels on each interval.	statements may, sometimes, be provided at both	
Thus, it is easier for respondent, especially the	ends of the scale.	
elderly, to understand and make an absolute	Thus, patients do not make absolute judgment	
judgment, as well as for researcher to interpret the	but rather relative with their frame of reference	
results clinically.	which is constantly shifting. In addition, it is more	
	difficult for clinical interpretation.	
3. If there are too few categories, the different	3. There is only a single continuous scale. Arbitrary	
responses may be unnoticeable.	cut-off values to distinguish the levels of	
In contrast, if the categories are too many, further	satisfaction are often established	
categorical combination is needed.		
4. There is higher chance of floor and ceiling	4. There is lower chance of floor and ceiling	
effects. In other words, respondents' answer is at	effects.	
the either end of the scale.		

Table 2. Comparisons between Likert scale and VAS<sup>34</sup>

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#### Studies of OHRQoL and satisfaction of complete denture wearers in Thailand

From the 7<sup>th</sup> Thai National Oral Health Survey, there was an increasing number of elderly population who have increased tooth loss compared to an adult age. In addition, complete denture treatment need was upraised especially at the age of 80. Several studies related to success of complete denture treatment were carried out in Thailand (Table 3) **Table 3:** Summary of studies in Thai removable complete denture wearers regardingpatient-based outcome after prosthodontic treatment.

Author(s);	Primary	Sample	Objectives, Summary findings	
year	outcome	(Sample size)		
Songpaisan Y;	OHIP-14,	44-85 y in	After receiving prosthesis in the Royal Denture Program,	
2007. <sup>35</sup>	Satisfaction	Nonthaburi	patients were generally satisfied with denture, and	
		(N = 96)	83.6% had no oral health impact (OHIP-14 score; mean	
			±SD =.40 ±0.54)	
Sirithepmontr	OIDP	60-88 y in	After receiving prosthesis in the Royal Denture Program,	
ee T; 2008. <sup>36</sup>		Bangkok	patients generally had good quality of life. Although,	
		(N = 104)	30.8% of them reported at least one oral impact,	
			mostly on eating and speaking activities, they were not	
			severe.	
		////	Frequency of reported impacts was higher in the older	
			age and poor socio-economic status.	
Teekayupan S	Satisfaction	≥60 y in Roi-et	After receiving prosthesis in the Royal Denture Program,	
and Padee P;		(N = 158)	patients were generally satisfied with their denture.	
2008. <sup>37</sup>			Nearly all of them used denture for chewing and	
			esthetics.	
Chomjai J and	OHIP-14	>60 y in Roi-et	In general, patient had no oral health impact. Higher	
Chapman RS;		(N = 270)	OHIP score (lower satisfaction) were associated with	
2010.21	Ģ		wearing dentures at bedtime.	
Bancherdpong	OIDP	≥60y in Uttaradit	About half of participants had no oral impacts, whereas	
chai, V;2010. <sup>38</sup>		(N = 101)	moderate to severe impacts were reported in the other	
	ຈຸ ນ	าลงกรณ้ม	half, predominantly on eating performance. Ill-fitting or	
	Сни		damaged denture was found in 18.70% of patients.	
Suepathima B;	OIDP,	≥60 y in Nakhon	After receiving prosthesis in the Royal Denture Program,	
2013. <sup>39</sup>	satisfaction	Sawan	90% of patients were satisfied with their denture, and	
		(N = 183)	71% had no oral impacts. Slight oral impact was	
			reported in approximately 13% of them, while 16% had	
			severe impact. The most important issue that increased	
			satisfaction and improved quality of life of elderly was	
			the ability to chew food.	
Intasaro P;	Satisfaction	≥60 y in Ranong	Approximately 70% of patients was satisfied with their	
2014.40		(N = 198)	denture. The most important issue that increased	
			satisfaction and improved their quality of life was the	
			ability to chew food.	

Author(s);	Primary	Sample	Objectives Summany findings	
year	outcome	(Sample size)	Objectives, summary maintes	
Setthaworaph	OHIP-	≥60 y in Trang	Overall denture satisfaction and OHRQoL were related	
an et al;	EDENT	(N = 155)	to denture quality and masticatory efficiency. OHIP-	
2014.24			EDENT was suggested for OHRQoL evaluation in Thai	
			elderly.	
Srisilapanan	OIDP	≥60 y in 4	After receiving prosthesis in the Royal Denture Program,	
et al; 2016.4		provinces	denture wearers had better OHRQoL than edentate	
		(complete	elderly without prosthesis.	
		denture, N = 68)		
Chaichana et	OIDP,	≥50 y in Tak	After receiving prosthesis in the Royal Denture Program,	
al; 2017. <sup>41</sup>	Satisfaction	(N = 111)	patients were generally satisfied with their denture.	
			Approximately 70% of them had no oral impacts, while	
			17% and 13% reported slight and severe impact	
			respectively.	

Note: All were cross-sectional studies. The free-of-charge acrylic-based removable prostheses were provided for Thai elderly (aged  $\geq$  60 years) in the Royal Denture Program to celebrate King Rama the 9<sup>th</sup> for his the 80<sup>th</sup> Birthday.

Most previous Thai studies reported patient-based assessment after denture delivery without investigating the underlying factors that would affect the treatment outcome, such as denture quality and satisfaction with denture service. Thus, neither associations nor risk factors could be identified. In addition, the primary outcome was mostly patient's satisfaction or secondary level of oral impairment of which the questionnaire varied among studies and may not reflect the impact on daily activities.

#### Masticatory ability evaluation

Eating/masticatory ability improvement is one of the primary purposes for complete denture treatment.<sup>31, 42, 43</sup> Previous studies recommended using both subjective and objective measures to evaluate masticatory ability.<sup>44, 45</sup> Subjective measure reflected patient's perception,<sup>45</sup> whereas objective evaluation quantitatively measures patient's masticatory performance.<sup>44</sup> Nevertheless, there is no standard method in assessing the complete denture wearer masticatory ability.

#### I. Subjective evaluation

Subjective evaluation which allows patients to rate their eating/ masticatory ability comprises 2 common methods;<sup>42, 46</sup> food intake questionnaire<sup>47</sup> and self-perceived or satisfaction with eating/masticatory ability.<sup>48, 49</sup> Regarding a food intake questionnaire, the patient rates a level of difficulty in eating the given food choices, categorized based on their hardness/toughness; the more hardness/toughness of food indicates higher masticatory ability. However, there are too varieties of food choices in a food intake questionnaire across social and environmental context, thus, there would be relatively low external validity for clinical application. On the other hand, patient satisfaction can be evaluated by using a continuous visual analogue scale (VAS) or an ordinal Likert scale. The strengths and weaknesses of these two methods were shown in Table 2.

#### II. Objective evaluation

Objective evaluation or laboratory-based method can be divided into swallowing threshold test and masticatory performance.<sup>42, 45, 46</sup> Swallowing threshold test allows a patient to chew tested food, then, the number of chewing stoke is recorded when the patient is ready to swallow the tested food; the lower chewing cycle indicates better masticatory ability. This method, however, whole food portion is not analyzed, then, the patient may be able to swallow a portion of comminuted food particles by leaving remaining large unswallowable parts. As a result, the chewing stroke is underestimated, leading to a false interpretation. Masticatory performance, in contrast, allows the patient to masticate tested food within a specified stroke, and comminuted food particles are then analyzed with various techniques. The common artificial and natural tested food, as well as analyzing techniques are as following examples;

- Silicone cube (particle size, surface area, delta E); the smaller particle size, higher surface area or higher delta E (higher degree of color changing) indicated a better masticatory performance.
- Gummy jelly<sup>50</sup> (glucose concentration); the higher concentration indicated better masticatory performance.

• Peanut, carrot (particle size)<sup>51</sup>; comminuted food particle was analyzed by either single or multiple sieve method.<sup>29</sup>

Artificial silicone mastication may deviate from the patient's habitual pattern because silicone texture and toughness are different from natural food. Glucose from jelly is easily dissolved in oral cavity and swallowed. Therefore, peanut is preferred because it is a natural tested food, and the comminuted particles can be easily dried and sieved without dimensional changes. In addition, a 20-stroke peanut mastication together with a multiple sieve method for particle size analysis is considered as one of the standard protocols for complete denture wearer masticatory ability evaluation.<sup>47, 51, 52</sup>

#### Factors related to OHRQoL or patient evaluation of complete denture

#### 1. Patient-related factors

#### 1.1) Socioeco-demographic characteristics;

Previous studies reported that age, sex, marital status, educational level, and personal income affected patient satisfaction of their denture.<sup>13, 53</sup> Women tended to concern about their esthetics, while men focused on denture function. Patients with higher income were more satisfied with their denture compared with those whose income was lower. The higher-income patient might have a greater awareness in the treatment necessity, also the higher income could fulfill their requirements. Moreover, the patients with higher educational level better realized the importance of denture treatment and understood the instruction of dentist.<sup>53</sup> On the contrary, some studies found that age, marital status, and educational level were not associated with denture satisfaction.<sup>37, 54-56</sup> Study of Thai elderly in Trang province reported no correlation between complete wearer satisfaction and sex, religion, educational level, occupation, general health related factors, and number of previous dentures.<sup>24</sup>

#### 1.2) Psychological status;

There was a variety of psychological assessments; therefore, it would be difficult to compare the psychological conditions among studies. In general, psychological condition of elderly edentulous patients had no effect on prosthodontic treatment outcome<sup>11</sup> except patients with neuroticism who continuously dissatisfied with their dentures.<sup>28, 57</sup>

#### 1.3) Oral conditions;

According to the Structural Equation Model (SEM) analysis, Fenlon MR and Sherriff M (2008)<sup>58</sup> and Yamaga et al (2014)<sup>14</sup> suggested that mandibular ridge form had an influence on patient satisfaction which further affected OHRQoL. However, some studies found no correlation between anatomical condition and denture satisfaction,<sup>29, 55</sup> except a presence of tissue problem such as ulceration.<sup>54</sup> van Waas MA (1990)<sup>29</sup> stated that denture-bearing tissue would have no influence on patient satisfaction after a patient had already adapted to a new denture (usually at least 3 months). Thus, complete denture wearers with good soft tissue and bone quality cannot infer to treatment success.

#### 2. Denture-related factors

Previous studies found the effect of denture-related factors on treatment outcomes; including denture retention and/or stability,<sup>11, 14, 24, 57, 59</sup> accuracy of jaw relation or coincidence between maximum intercuspation and retruded jaw relation,<sup>14, 57, 59</sup> and faulty design such as under-/over-extension.<sup>54</sup> In contrast, some studies found that complete denture quality such as its clinical fitting did not always indicate the more patient satisfaction.<sup>29, 30, 56</sup> This might be due to patient's adaptation to the new dentures after a period of denture use.<sup>30</sup>

Masticatory performance and perceived masticatory ability of the removable complete denture wearers were lower than those of dentate patients.<sup>60</sup> A study in Thai complete denture wearers revealed that the greater masticatory efficiency and number of occlusal contact led to the more patient satisfaction and better OHRQoL.<sup>24</sup> Nevertheless, some studies reported that masticatory performance neither related to patient satisfaction/self-perceived masticatory ability nor professional evaluation of denture qualities.<sup>31, 56</sup>

The artificial posterior occlusal teeth form (anatomic, semi-anatomic, and nonanatomic teeth) and occlusal scheme (bilateral balanced, lingualized, and monoplane occlusion) have been one of the topic of interests whether they affected patient satisfaction of complete denture. Although there was no significant difference in masticatory performance between anatomic and non-anatomic teeth,<sup>52</sup> some patients preferred anatomic teeth (either bilateral balanced or lingualized occlusion) over non-anatomic teeth (monoplane occlusion) because of their superior aesthetics and masticatory ability.<sup>61-63</sup>

Other factor including denture fabrication technique (simple and traditional protocol) had no influence on chewing ability,<sup>60</sup> patient satisfaction, or OHRQoL<sup>33, 64</sup> of complete denture wearers.

#### 3. Dentist-related factors

Clinician with prosthodontic experience would lead to the more patient satisfaction with complete denture, compared to those without experience. This might be a result of superior communication and technical skill of experienced dentist such as impression technique, denture adjustment, and ability to identify chief complaint and patient-reported denture problem.<sup>32</sup>

#### Complete denture retention and stability evaluation

There were several methods to evaluate denture retention and stability; for example, professional assessment based on a specified criteria, cone-beam computed tomography together with finite element analysis<sup>65</sup> and specific devices for retentive force measurement.<sup>66</sup> Despite the accuracy of the technologies and devices, they may be not clinically applicable and too costly. Professional-self assessment, on the other hand, is more practical in clinic and community field as it requires no special instruments and consumes less chair-time.

Since 1965, a number of professional-based assessment criteria for complete denture retention and stability have been proposed; including Woelfel (1965),<sup>67</sup> Kapur (1967),<sup>68</sup> Olshan-modification of Kapur scale (1992),<sup>69</sup> Functional assessment of denture (FAD) (2002),<sup>70</sup> and FAD-modification criteria (2002).<sup>71</sup> Regarding Woelfel,<sup>67</sup> FAD,<sup>70</sup> and FAD-modification criteria, and stability of the maxillary and mandibular denture are separately evaluated. Although there were significant association between

retention and/or stability of denture and patient satisfaction as evaluated by these criteria,<sup>49, 59</sup> no studies reported their validity in predicting masticatory ability or OHRQoL of complete denture wearers.

To determine a clinical quality of complete denture, Kapur method and criteria had been one of the most common use.<sup>14, 52, 68</sup> However, a previous study demonstrated the low sensitivity and specificity of the criteria in predicting masticatory performance and perceived masticatory ability of complete denture wearers.<sup>46</sup> Later, Olshan (1992) modified retention and stability scales of Kapur by extending the upper limit scores and defined a new criteria to classify clinical quality of complete denture.<sup>69</sup> This modified scale was generally used to increase sensitivity in detecting clinical efficacy of denture adhesives.<sup>72, 73</sup> However, the retention/stability level was based on professional judgment which may not accurately reflect clinical performance or patient's perception. In other words, there might detect statistically but not clinically significant changes of denture quality. Also, it is difficult for health care personnel to discriminate the extended scale such as excellent, very good and good retention. For these reasons, the more-complicated extended Kapur scale may reveal similar clinical outcome to the conventional one. Consequently, Kapur criteria was considered to be the most clinically applicable, but may be needed some modifications in order to improve validity and generalizability in clinical application.

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#### Determination of bite force and occlusal equilibration

Several methods have been used to analyze the occlusal equilibration in human, including force transducer<sup>74</sup> and image analysis technology such as T-scan,<sup>75</sup> prescale,<sup>76</sup> and dental prescale system.<sup>77</sup> Force transducer and T-scan require an analyzing machine which would be unavailable in clinical application. In addition, the sensitivity and reliability of force transducer are uncertain because it does not directly measure a produced force but an electrical signal. Therefore, the apparent force value may vary upon a location of transducer attachment. Prescale and dental prescale were in sheet-form with similar compositions and analyzing principle, except their shape and pressure range. The prescale can be divided into two types; mono-sheet and two-

sheet. Mono-sheet type consisted of a polyester base on which color-developing material was coated on top with the micro-encapsulated color-forming material layer. Two-sheet type consisted of two polyester bases; one was coated with a micro-encapsulated color forming material layer, and the other with a color-developing material layer. The working principle was that when pressure was applied, microcapsules were broken and color-forming material reacted with color-developing material giving red patches on the film which were further analyzed for pressure, force and pressed area.<sup>77</sup> In this study, mono-sheet of medium-sheet (MS) type prescale (pressure range = 10-50 MPa) was used to determine maximum bite force and contact area in complete denture wearers as it was within the pressure range of complete denture wearers.<sup>76</sup>

From all the above mentioned, there has been no conclusive evidence which underlying factors play important role in predicting complete denture treatment outcome. Lack of studies have been reported the overall aspects of patient=based treatment outcome; masticatory ability, satisfaction, or OHRQoL. Also, the investigation for the impact of overall patient- and denture-related factors on patient-based outcomes have never been clarified. Therefore, the author carried out this study with the aim to close the gap of these knowledge by providing supportive scientific methodology and evidences.

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#### CHAPTER III

#### METHODOLOGY

#### Population and Sample

#### 1) Population

Removable complete denture wearers

#### 2) Target population

Removable complete denture wearers who wore the prostheses for at least 2 years after last recheck visit.

#### 3) Study population

Removable complete denture wearers who received treatment from undergraduated or postgraduated students of Department of Prosthodontics, Faculty of Dentistry, Chulalongkorn University for at least 2 years.

#### 4) Sample population

Removable complete denture wearers from study population who passed all inclusion criteria

#### Eligible criteria

- 1) Inclusion criteria
- Wearing maxillary and mandibular removable acrylic resin complete dentures
- At least 2 years denture wearing period since the last recheck visit.
- Ability to understand and communicate in Thai language

#### 2) Exclusion criteria

- Temporomandibular disorder
- Debilitating systemic conditions/diseases that affect oral or psychological status including radiation therapy, malignant disease.

#### Sample size calculation

Sample size was calculated according to the primary hypothesis that there is no difference in the proportion of complete denture wearers who reported oral impacts on daily performances between those with acceptable and unacceptable denture quality evaluated by professionist. The sample size determination followed the Equation 1;<sup>78</sup>

$$n_{1} = \left[\frac{z_{1-\frac{\alpha}{2}}\sqrt{\bar{p}\,\bar{q}\left(1+\frac{1}{r}\right)} + z_{1-\beta}\sqrt{p_{1}q_{1}+\frac{p_{2}q_{2}}{r}}}{\Delta}\right]^{2}$$

$$r = \frac{n_{1}}{n_{2}}, \quad q_{1} = 1 - p_{1}, q_{2} = 1 - p_{2},$$

$$\bar{p} = \frac{p_{1}+p_{2}r}{1+r}, \quad \bar{q} = 1 - \bar{p}$$

Equation 1; An equation for sample size determination based on the hypothesis testing of 2 independent proportions.

From the preliminary study, the proportions of complete denture wearer who possessed good ( $p_1$ ) and fair denture quality ( $p_2$ ) following the conventional Kapur criteria were 0.16 and 0.40, respectively. Therefore, a total sample size of 124 ( $n_1 = n_2 = 63$ ) with a continuity correction was required to achieve 80% power with type I error of 5%.

Samples were selected by a stratified random sampling. A study population (N = 498) was stratified using age (<60,  $\geq$ 60 years)-sex (male, female) and denture age (2 to 4, >4 years) as stratum. One quarter of samples was randomly selected from each stratum. After randomization, they were asked to attend the study via the telephone contact. Finally, a total of 126 samples were participated in this study.

However, it was noted that some denture wearers were unable to participate in the study with either of the following reasons; non-available telephone contact, passing away, household responsibility, difficulty in transportation, or no longer use the denture obtained from the faculty. Approximately 18 denture wearers who no longer wore the denture obtained from the faculty was mostly due to an ill-fitting denture, then, they had a new denture fabricated from other dental clinics or hospitals. At the end of the study, the proportion of complete denture wearers with oral impacts who had acceptable ( $n_1 = 7$ ,  $p_1 = 0.07$ ) and unacceptable ( $n_2 = 97$ ,  $p_2 = 0.77$ ) denture quality based on the CU-modified Kapur criteria were 0.07 and 0.77, respectively. According to the different proportions between two groups, 99% power of study with 5% type I error was achieved.

#### Ethical Approval

The preliminary and final protocols of study was approved by the Human Research Ethics Committee of the Faculty of Dentistry, Chulalongkorn University; number HREC-DCU-P 2015-003 and HREC-DCU 2016-071 respectively.

#### Data collection

This study consisted of three patient-based outcomes; OHRQoL, satisfaction, and masticatory performance. Patient's satisfaction regarding eating aspect and masticatory performance of peanut mastication were considered as subjective and objective masticatory ability, respectively. Masticatory performance was objectively used to confirm the two patient-reported outcomes; OHRQoL and satisfaction. Subjective measures reflected patient's perception, while objective measure reflected patient's performance.

#### Primary outcome: Oral Health-related Quality of Life (OHRQoL)

Oral Health-Related Quality of Life (OHRQoL) was assessed by face-to-face interview using the validated Thai version of Oral Impacts on Daily Performances (OIDP). The index determines the impact caused by denture on 8 daily activities within 3 performances; 1) physical (eating, speaking, and cleaning), 2) psychological (emotional stability, smiling/laughing, and sleeping/relaxing), and 3) social (enjoying contact with people and carrying out major work/social role).<sup>26</sup> Frequency and severity of each activity, so called "condition-specific (CS) impacts", were determined by five-point ordinal scale (0-5). The scores of each CS-impact were multiplied, and summation of overall OIDP score was calculated. The score was further categorized into presence (score > 0) or absence (score = 0) of overall and each CS-impact. In addition,

participants gave information regarding the main oral impairments and symptoms caused by their dentures.

#### Secondary (Subjective) outcomes: Patient's satisfaction

Participants rated satisfaction level with their complete denture regarding eating/chewing ability, comfortable, speech/speaking, aesthetics, and overall aspects using a 5-point Likert scale; very satisfied (5), satisfied (4), neither (3), dissatisfied (2) and very dissatisfied (1). The score was further dichotomized into satisfied (0; very satisfied, satisfied) or dissatisfied (1; neither, dissatisfied, very dissatisfied).

#### Secondary (Objective) outcome: Masticatory performance

Masticatory performance was evaluated using a multiple sieve method of peanut mastication.<sup>52</sup> Participants sat in upright position and masticate 3 grams of roasted peanut for 20 strokes. Comminuted food particles were rinsed with distilled water and dried in incubator at 37°C for 24 h. The dried peanut particles were sieved via 12 standard test sieves with a diameter exponentially decreased from 5.6, 4.75, 4, 3.55, 3.35, 3.15, 2.8, 2, 1.4, 1, 0.5 to 0.25 mm. The test sieves were vibrated on a vibratory sieve shaker at a frequency of 70 Hz for 3 min. The peanut particles passing through test sieves were collected and calculated as follows;

Cumulative weight percentage of each sieve = (1 - [cumulative of mass retained on that sieve & previous sieve]/total sample mass) x 100

Cumulative weight of each sieve and diameter of each test sieve were plotted into a simple linear regression to determine median peanut particle size. Median peanut particle size was defined as the sieve diameter through which 50% of comminuted particles could pass which was calculated by simple linear regression from the plot. The smaller median particle size indicated higher masticatory performance.

#### Explanatory (Independent) variables

#### 1) Oral tissue condition:

• Denture-bearing tissue condition: determined by visual examination and scored according to Woelfel (1965);<sup>67</sup>

- 4 (Excellent): Generalized firm and good color of tissue and no sign of abrasion/injury
- 3 (Good): Generalized firm and good color of tissue excepted for some small isolated regions
- 2 (Fair): Movable tissue on crest of ridge or irritated region with poor color covering more than 1/3 of denture-bearing surface
- 1 (Poor): The presence of large amount of movable tissue or large region of redness covering more than half of denture bearing surface

Soft tissue condition was further dichotomized into good (good, excellent) and poor (fair, poor)

- Maxillary and mandibular ridge form; determined by visual examination and palpation, and then classified according to Cawood and Howell.<sup>79</sup>
  - 4 (Class III): Well-round ridge form, adequate height and width
  - 3 (Class IV): Knife-edge ridge form, adequate height but inadequate width
  - 2 (Class V): Flat ridge form, inadequate height and width
  - 1 (Class VI): Depressed ridge form

Residual ridge form further dichotomized into round and others (flat, knifeedge, depressed)

**2)** Clinical complexity of edentulous condition; The complexity or case severity was categorized according to American College of Prosthodontics (ACP) classification into class I (uncomplicated) to class IV (most complex/high-risk clinical situation) by intraoral and panoramic radiographic examination.<sup>80</sup>

#### 3) Retention and stability (Denture quality):

In the present study, denture retention and stability was termed "denture quality". The conventional Kapur method was initially utilized for complete denture quality evaluation as it possesses a criteria to determine retention and stability, and classifies the overall clinical quality of complete denture into good, fair, and poor. However, it was still a major concern that the "professional-based assessment" was not made in an objective manner. Therefore, the CU-modified Kapur method was developed by more specifically define the retention and stability level in order to improve the generalizability of evaluation technique.

According to the CU-modified Kapur method, the applied force was calibrated using a digital luggage scale prior to each evaluation. Denture retention was evaluated by placing the thumb and index fingers on the labial and lingual surface of the central incisor teeth. Then, an approximately 10.0, 5.0, or 2.5 N vertical pulling force was applied along the path of insertion. These values were obtained from the preliminary study that measured the pulling force required for denture dislodgement with predetermined different retention levels. Meanwhile, denture stability was evaluated by placing the thumb and index fingers on the buccal surface of the premolar teeth. Then, the denture was moved horizontally anteroposteriorly and mediolaterally. The criteria for scoring denture retention and stability were demonstrated in Table 4.

The clinical quality of the complete denture was then classified following the conventional and CU-modified Kapur criteria. As opposed to the conventional criteria, the modified criteria determine maxillary and mandibular denture quality separately into acceptable or unacceptable (Table 5). According to the modified criteria, the overall denture quality was considered as unacceptable when either or both dentures were unacceptable. Denture examination was done by the calibrated examiner (NL). One month later, denture quality was re-evaluated in 16 participants, giving a 0.91 to 0.99 Kappa score, indicating an excellent intra-examiner reliability.

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Conventional Kapur			CU-modified Kapur	
		Retention		
3 (Good)	Maximal resistance to vertical pull	3 (Good)	Maximal resistance to vertical pulling	
	and sufficient resistance to lateral force		and lateral force (> 10 N for dislodgement)	
2 (Moderate)	Moderate resistance to vertical pull	2 (Moderate)	Moderate resistance to 5 N vertical pulling and/or	
	but little/no resistance to lateral force		lateral force (5 to 10 N for dislodgement)	
1 (Minimum)	Slight resistance to vertical pull	1 (Minimum)	Slight resistance to 2.5 N vertical pulling and/or	
	and little/no resistance to lateral force		lateral force (2.5 to 5 N for dislodgement)	
0 (No)	Displaced itself when seated	0 (No)	Displaced itself when seated	
		Stability		
2 (Sufficient)	Slightly/No rocking on supporting-	2 (Sufficient)	Slightly/No rocking or horizontal movement	
	structure under pressure		(1 to 2 mm)	
1 (Some)	Moderate rocking on supporting structure	1 (Some)	Moderate rocking or horizontal movement	
	under pressure		(2 to 4 mm)	
0 (No)	Extreme rocking on supporting structure	0 (No)	Extreme visible rocking or horizontal movement	
	under pressure		(> 4 mm)	

 Table 4. Conventional and CU-modified Kapur method and score for evaluating

 complete denture retention and stability

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evaluation.

Retention and Stability criteria (score range)				
Conventional	UCD + LCD Score	CU-modified Kapur	Retention criteria	Stability criteria
Kapur	(0 to 10)		(0 to 3)	(0 to 2)
Good	> 8	Acceptable UCD	≥ 2	2
Fair	6 to 8	Acceptable LCD	≥ 1	2
Poor	< 6	Acceptable CD	Acceptable bot	h UCD and LCD

UCD, upper (maxillary) complete denture; LCD, lower (mandibular) complete denture; CD, both UCD and LCD

#### 4) Maximum occlusal force, number- and area of occlusal contacts

Participants sat in upright position and clenched with maximal pressure on pressure-sensitive film (Monosheet, MS type Prescale; Fujifilm, Tokyo, Japan) at maximum intercuspal position for 5 seconds. The procedures were done in triplicate with 5-minute resting interval. The films were scanned and analyzed using a digital analysis software (FujiFilm Pressure Distrubution Mapping System FPD-8010E, version 1.1; Fuji Photo Film Co, Ltd). Maximum bite force (N), area (mm<sup>2</sup>) and number of occlusal contacts (n) were determined from the sheet with the highest biting force. The occlusal contact cusp was counted only when the occlusal pressure was more than 10 MPa.

#### 5) Anatomical tooth form

The occlusal tooth form of posterior denture teeth was determined by visual examination. It was categorized into anatomical and non-anatomical tooth form based on the presence of occlusal anatomy on either maxillary or mandibular denture teeth. It was noted that a non-anatomical teeth might originally be an anatomical, but had been changed due to tooth wear.

#### 6) Esthetic-assessment criteria

Participants stood in front of a dark background with 100-mm scale at a constant distance to camera mounted on a tripod to avoid facial distortion. Their extraoral photographs were taken with the digital single lens reflex (DLSR) camera (Canon EOS 1100D; Canon Inc.; Japan). Facial and dental anatomical landmarks related to prostheses were measured from extraoral photographs using ImageJ program (National Institute of Health, NIH) (Table 6). Aesthetic-assessment criteria were assessed whether patient's profile was matched to the following criteria (1 = yes, 0 = no);<sup>81</sup>

- Parallelism between interpupillary line and incisal edge of the maxillary central incisors
- Parallelism between facial and dental midline
- A ratio of the maxillary central incisor width to bizygomatic width (Criteria =1:16 (±10%) or 1:17.6 to 1:14.4)

- A ratio of the total maxillary anterior teeth width to bizygomatic width (Criteria =1:3 (±10%) or 1:3.3 to 1:2.7)
- Golden proportion (proportion of the width of left maxillary central incisor to lateral incisor to canine)

(Criteria = 1.618: 1: 0.618 ( $\pm$ 10%) or 1:1.780 to 1:1.456 and 1:0.680 to 1:0.556)

Table 6: Patient's posture and anatomical landmarks

Patients'	Anatomical landmarks for measurement		
posture			
Front view	Facial profile		
Front view (Biting on wooden piece)	Interpupillary line and width: Distance between midpupil of eyes Incisal plane of maxillary central incisors		
Front view (maximal smile)	<ul> <li>Facial midline; connecting line between 2 points of <ul> <li>n (nasion): midpoint between eyebrows</li> <li>sn (subnasale): midpoint where nose meets upper lip</li> </ul> </li> <li>Dental midline; <ul> <li>Vertical line along contact area of maxillary of central incisors</li> </ul> </li> <li>Maxillary central incisor width; <ul> <li>Distance between most distal surface of left maxillary central incisor</li> </ul> </li> <li>Total maxillary anterior teeth width; <ul> <li>Distance between most distal surface of right to left maxillary canine</li> </ul> </li> </ul>		

### จุหาลงกรณ์มหาวิทยาลัย

## Other covariates

The following information was obtained from face-to-face interview and patient's record.

**1)** Socio-demographic characteristics: age, sex, marital status, educational level, occupation, primary source of income

2) Conditions related to the current denture: reasons for treatment need, removable denture experience, type of health insurance supported

3) Facilities obtained: under-graduated or post-graduated dental student

**4) Treatment duration and frequency:** a number of total and recheck duration and visit.

#### Data analysis

All data were analyzed using a statistical software package STATA, Release 13 (StataCorp. LP, College Station, TX, USA) at a significant level of 0.05. Descriptive analyses were carried out to determine the median peanut particle size (mean, S.D.), eating satisfaction score (mean, median), and OIDP prevalence (%), including overall and specific performances. The descriptive data was identified according to the overall, patient-, and denture-related conditions. OIDP score (mean, 95% CI), main symptoms (%), and main oral impairment (%) were calculated among participants with oral impacts. In addition, distribution of satisfaction level (%) and score (mean, median) of complete denture satisfaction were calculated. Spearman correlation coefficient (rho) was calculated to identify the association among overall and specific oral impacts among participants who reported oral impacts.

After mutually adjusting for potential covariates, the association between the unacceptable denture quality, determined by conventional and CU-modified Kapur criteria, and patient-based outcomes were analyzed. The association between unacceptable retention/stability and median peanut particle size was analyzed using linear regression, while their association with eating dissatisfaction and oral impacts were determined using binary logistic regression to calculated into the adjusted beta-coefficient ( $\beta$ , 95% CI) and adjusted odds ratio (OR, 95% CI) respectively.

The sensitivity and specificity of the conventional and CU-modified Kapur criteria was assessed. Initially, a receiver operating characteristic (ROC) curve was plotted to determine a cut-off value of a peanut particle size which best estimates OIDP prevalence. After the binary logistic regression was done to determine the association between patient-based outcomes, the goodness-of-fit postestimation was conducted to evaluate the sensitivity and specificity of each denture quality criteria in estimating all patient-based outcomes.

To determine the assumed relationship among the variables and outcomes, a path analysis was conducted using a structural equation modeling (SEM) and estimation. Participants' characteristics and their oral conditions related to denture were considered as exogenous variables, while the endogenous factors included
denture quality, maximum bite force, and masticatory ability. Overall oral impact was considered as the primary outcome. The direct effect of exogenous variables on denture quality were analyzed using binary logistic regression, which was also employed to identify the direct, indirect, and total effects of exogenous and endogenous variables on overall oral impacts. Meanwhile, the direct, indirect, total effects of variables on eating satisfaction and masticatory performance were determined by using the ordinal logistic and linear regression, respectively. The best fit model with the highest adjusted R<sup>2</sup> values was chosen as the representative to demonstrate the association between the outcome and variables.



**Chulalongkorn University** 

# CHAPTER IV RESULTS

General characteristics of participants were demonstrated in Table 7 and 8. Participants were mostly elderly with an average (mean ±s.d.) 71.4 (±9.3) years of age and 57% of them was female. They were generally literate, self-sufficient, and economically inactive, but with living expenses supported by their children or relatives. Almost all participants could perform daily activities independently without any assistance. Approximately 60% had to wear glasses, however, a hearing aid was used in only 5 persons. The presence of at least one diagnosed chronic diseases, most of which were hypertension, hyperlipidemia, and diabetes was reported by 70% of participants. For the current denture expense, participants generally paid out-of-pocket or utilized health care insurance, predominantly a universal coverage scheme (Table 8). The main reason for complete denture treatment need was due to eating/chewing problem, whereas appearance dissatisfaction was only a minor problem. Most of them previously had removable either partial or complete denture experience.

From a total of 126 participants, 55 (43.7%) persons reported at least one oral impact on daily performance, mostly on physical (42.9%), followed by psychological (27.8%) and social performance (7.1%). A specific-performance score followed the prevalence trend, highest in physical and lowest in social performance (Table 8). Participants who had never worn a removable partial denture or previously wore higher sets of removable complete denture was more likely to have oral impact compared with their counterparts. In general, the OIDP score among whom reported oral impact was relatively approximate within each patient-related conditions.

	Proportionate		Prevale	nce and OID	P score of Ov	erall and Spe	citic pertorm	ances	
Patient-related conditions	distribution:	Over	all	Phy	sical	Psychol	ogical	SQ	cial
(=1 if yes, =0 if otherwise)	u (%)	Prevalence;	Score;	Prevalence	; Score;	Prevalence;	Score;	Prevalence;	Score;
		%	mean (SD)	%	mean (SD)	%	mean (SD)	%	mean (SD)
OIDP prevalence and score	126 (100.0%)	43.7	33.3 (23.5)	42.9	21.7 (11.4)	27.8	16.3 (9.6)	7.1	13.7 (8.3)
Socio-ecodemographic characteristics									
Sex;									
Male	54 (42.9)	46.3	33.4 (20.4)	44.4	20.9 (8.7)	33.3	17.4 (9.0)	5.6	15.0 (12.3)
Female	72 (57.1)	41.7	33.2 (26.1)	41.7	22.4 (13.2)	23.6	15.2 (10.2)	8.3	13.0 (6.9)
Educational level attainment;									
Up to primary	84 (66.7)	42.9	32.8 (20.7)	42.9	21.2 (9.7)	27.4	16.3 (9.5)	3.6	14.0 (13.2)
Above primary	42 (33.3)	45.8	34.2 (28.0)	43.8	22.6 (13.9)	25.0	16.4 (10.1)	12.5	13.5 (6.3)
Literacy;									
Iliterate	23 (18.3)	47.8	34.2 (23.7)	41.8	22.6 (10.9)	26.2	16.7 (9.7)	7.8	14.3 (8.7)
Literate	103 (81.7)	42.7	29.7 (23.3)	47.8	17.9 (12.8)	34.8	15.1 (9.7)	4.4	9.0 ( - )
Marital status;									
Single/Divorced/Widow/Separated	65 (51.6)	43.1	31.3 (22.9)	43.1	20.7 (12.1)	26.2	13.6 (9.1)	4.6	10.7 (4.4)
Married	61 (48.4)	44.3	35.3 (24.3)	42.6	22.7 (10.6)	29.5	18.9 (9.5)	9.8	19.7 (12.1)
Working status as a routine;									
Economically Inactive	95 (75.4)	45.3	28.6 (13.8)	45.3	20.5 (7.9)	28.4	15.6 (6.8)	9.5	13.7 (8.3)
Economically Active	21 (24.6)	37.1	34.8 (25.7)	35.5	21.5 (12.1)	25.8	16.6 (10.3)	0.0	
Performing daily activites without assistance;									
Yes	114 (90.5)	42.9	19.7 (8.3)	42.1	22.2 (11.4)	28.1	17.0 (9.7)	7.9	13.7 (8.3)
No	12 (9.5)	50.0	35.3 (24.8)	50.0	14.8 (8.6)	25.0	9.7 (17.0)	0.0	
Being beneficiaries of government fund;									
No	99 (78.6)	42.4	32.3 (22.6)	41.8	20.4 (10.9)	28.6	15.4 (9.9)	7.1	12.7 (8.4)
Yes (Social security/Government pension/	27 (21.4)	46.3	37.8 (28.5)	46.3	24.3 (12.7)	25.0	20.1 (7.6)	7.1	17.0 (9.9)
Allowance subsidy for senior people)									
Primary source of daily expenditure;									
By work	23 (18.3)	34.8	29.6 (17.2)	30.4	21.4 (8.0)	21.7	17.4 (8.0)	0.0	,
Supported by Children/Spouse/Relatives	84 (66.7)	45.9	32.2 (23.6)	45.9	20.5 (11.4)	28.2	15.9 (10.0)	5.9	14.8 (9.2)
Saving/Donation/Allowance subsidy for senior people	19 (15.0)	44.4	44.5 (30.8)	44.4	25.3 (14.0)	33.3	17.3 (10.6)	22.2	12.3 (8.0)
OIDP prevalence was calculated within a row. OIDP score	was calculated ar	nong participa	ints who report	ted oral impa	act.				

Table 7. OIDP prevalence and score regarding overall and specific-performance according to patient-related conditions

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-	Proportionate		-	evalence and (	DIDP score of Ov	erall and Speci	fic performance:	S	
Patient-related conditions	distribution:	NO NE	rall	Phy	sical	Psychol	logical	Soc	cial
(=1 if yes, =0 if otherwise)	u (%)	Prevalence;	Score;	Prevalence;	Score;	Prevalence;	Score;	Prevalence;	Score;
		%	mean (SD)	%	mean (SD)	%	mean (SD)	%	mean (SD)
OIDP prevalence and score	126 (100.0%)	43.7	33.3 (23.5)	42.9	21.7 (11.4)	27.8	16.3 (9.6)	7.1	13.7 (8.3)
Health-related conditions									
Visual ability;									
Clear	52 (41.3)	38.5	30.4 (14.4)	36.5	21.8 (9.1)	25.0	11.8 (5.2)	7.7	9.8 (4.5)
Unclear, Clear with visual aids	74 (58.7)	47.3	35.5 (28.1)	47.3	21.1 (12.5)	29.7	19.0 (10.6)	6.8	16.8 (9.7)
Hearing ability;									
Clear	121 (96.0)	43.8	34.1 (24.3)	43.0	12.5 (3.5)	28.1	16.4 (9.7)	7.4	13.7 (8.3)
Unclear, Clear with hearing aids	5 (4.0)	40.0	20.0 (7.1)	40.0	21.7 (11.4)	20.0	15.0 ( - )	0.0	
Co-morbidity condition (Number of diagnosed chronic	c diseases);								
None	37 (29.4)	45.9	31.3 (15.2)	43.2	20.4 (9.0)	35.1	14.6 (7.2)	5.4	8.0 (2.8)
1 condition	46 (36.5)	32.6	30.5 (25.3)	32.6	20.9 (13.6)	17.4	14.8 (8.7)	4.4	12.5 (4.9)
<b>2</b> conditions	43 (34.1)	53.5	37.3 (28.5)	53.5	22.3 (11.6)	32.6	18.9 (11.8)	11.6	16.4 (10.2)
Variables related to the current denture									
Thai government insurance for denture fabrication;									
Universal coverage scheme	47 (37.3)	48.9	32.2 (27.3)	46.8	19.2 (11.0)	34.0	15.7 (10.7)	10.6	14.8 (9.3)
Social security scheme	16 (12.7)	43.8	41.0 (21.6)	43.8	25.0 (11.5)	31.3	21.2 (8.9)	6.3	( - ) 0.9
Civil Servant Medical Benefit Scheme	27 (21.4)	29.6	30.5 (35.0)	29.6	20.6 (15.3)	7.4	27.5 (10.6)	3.7	24.0 ( - )
Out-of pocket payment	36 (28.6)	47.2	33.8 (13.2)	47.2	23.3 (8.0)	33.3	13.3 (6.6)	5.6	9.5 (0.7)
Reasons for treatment need;									
Limited eating	103 (81.7)	39.8	33.6 (22.4)	39.8	21.0 (10.5)	27.3	15.9 (9.5)	5.8	14.3 (8.1)
Limited speaking	11 (8.7)	27.3	32.7 (22.0)	27.3	18.0 (13.1)	27.3	14.7 (9.2)	0.0	I
Appearance dissatisfaction	8 (6.3)	50.0	15.0 (7.3)	50.0	11.5 (2.6)	12.5	10.0 ( - )	12.5	4.0(-)
By suggestion	29 (23.0)	37.9	33.3 (31.6)	34.5	21.9 (14.5)	17.2	22.0 (9.8)	10.3	12.3 (10.4)
Others; spare	4 (3.1)	75.0	34.3 (22.9)	75.0	23.0 (16.6)	75.0	11.3 (8,1)	0.0	ı
Removable prostheses experience;									
No	24 (19.0)	54.2	29.8 (16.3)	50.0	21.6 (9.5)	29.2	17.9 (6.4)	4.2	4.0(-)
Yes; Removable partial denture	48 (38.1)	37.5	38.5 (27.8)	37.5	24.3 (12.4)	25.0	16.5 (10.2)	12.5	13.5 (6.3)
Complete denture:	54 (42.9)	44.4	31.3 (23.2)	44.4	19.0 (11.2)	29.6	15.6 (10.6)	3.7	19.0 (14.1)
- Number of previous complete denture: 1	33 (26.2)	36.4	35.4 (29.2)	36.4	23.2 (11.3)	24.2	16.7 (12.4)	6.1	19.0 (14.1)
> 1	21 (16.7)	57.1	26.5 (18.1)	57.1	19.0 (11.2)	38.1	14.4 (9.2)	0.0	I
Oral impact prevalence was calculated within a row. OIDI	P score was calcı	ulated among p	articipants who n	eported oral im	ipact.				

Table 8. OIDP prevalence and score regarding overall and specific-performance according to patient-related conditions (continued)

Participants with oral impacts mostly had difficulty in one or two performances, while only 15% had an impact on all three performances (Table 9). A single affected performance was predominantly on physical activities, whereas psychological performance was generally occurred together with physical performance. Nearly all participants with oral impacts had eating difficulty, approximately twice more prevalent than speaking, followed by psychological performances including maintaining emotional status and smiling/laughing. Meanwhile, social contact was the least frequently affected. The problems with cleaning, sleeping, or working/carrying out physical activities were the least prevalent. CS-specific score of each activity tended to be identical, within a range of 12.0 to 14.0, except cleaning and contacting people of which the scores were less than 10. The most common main symptoms were functional limitation, pain, and discomfort, predominantly caused by an ill-fitting denture regardless of the activities affected. On the other hand, only 5.3% of participants with smilling/laughing difficulty was dissatisfied with denture appearance.

Table 9	: OIDP	prevalence,	OIDP	score,	main	symptoms,	and	oral	impairment	among
participa	nts wh	o reported o	oral in	npact (	N=55)					

			- Colling (				
	Drovaloncov		Main sym	nptoms; %	Main ora	al impairm	ents; %
Reported CS-impact	Prevalence;	OIDP score,	Functional	Pain,	Ill-fitting	Chewing	Bulky
	n (%)	mean (SD)	limitation	Discomfort	denture	pain	denture
Number of affected performance							
1: only Physical	19 (34.5)	17.4 (8.7)					
only Psychological	1 (1.8)	15.0 ( - )					
2: both Physical & Psychological	26 (47.4)	35.5 (16.3)					
both Physical & Social	1 (1.8)	16.0 ( - )					
3: Physical & Psychological & Social	8 (14.5)	70.5 (30.3)					
CS-impact							
Physical; 1) Eat	53 (96.4)	14.2 (5.0)	94.3	79.3	81.1	50.9	22.6
2) Speak	29 (52.7)	13.7 (5.1)	100.0	55.2	79.3	3.4	27.6
3) Clean	3 (5.4)	6.7 (3.1)	66.7	33.3	33.3	66.7	-
Psychological; 4) Smile/Laugh	19 (34.5)	12.3 (5.7)	94.7	31.6	94.7	-	-
5) Maintain emotion	24 (43.6)	12.4 (5.2)	62.5	83.3	75.0	20.8	33.3
6) Sleep/Relax	3 (5.4)	13.7 (7.1)	-	100.0	33.3	33.3	33.3
Social; 7) Contact people	9 (16.3)	9.4 (4.4)	100.0	55.6	88.9	-	11.1
8) Work, Carry out physical activities	3 (5.4)	12.7 (7.0)	100.0	33.3	100.0	-	33.3

OIDP prevalence, score, main symptoms, and oral impairments were calculated among participants who reported the CS-impact.

Only first three main symptoms and oral impairments were shown.

Each participant could report more than one symptoms and impairments.

When oral impact was reported, a total OIDP score was highly correlated with the scores of physical performances including eating and speaking, followed by the psychological aspects of maintaining emotional status and smiling/laughing. Meanwhile, its correlation with social performances was marginal (Table 10). On the other hand, cleaning and sleeping/relaxing were marginally correlated with the overall oral impact. When more than a single performance was affected, eating impact score was moderately correlated with maintaining emotional status, while speaking impact score was significantly correlated with smiling and social performances, but with a marginal association.

 Table 10. Spearman correlation coefficient (rho) among reported overall and condition-specific oral impact

	Total		CS-impact score	9
CS-impact score	OIDP score		Physical <b>††</b>	
	-	Eat	Speak	Clean
Physical: Eat	0.73***	1		
Speak	0.72***	0.41*	1	
Clean	0.09	0.29	0.30	1
Psychological: Smile	0.51***	0.21	0.34*	0.28
Emotion	0.63***	0.42*	0.30	-0.03
Sleep	0.17	0.20	0.32	0.68*
Social: Contact	0.46***	0.23	0.35*	0.38*
Work	0.38**	0.16	0.35*	-0.05

Significant association at \*\*\*p<0.001, \*\*p<0.01, \*p<0.05.

Strength of correlation (Rho): >0.6=high, 0.4 to 0.59=moderate, <0.4=marginal.

Correlation with total OIDP and CS-impact score of physical activities were calculated among

participants who had  $\geq 1$  affected activities(†) and >1 affected performances (††) respectively.

In general, participants were satisfied with their complete denture with a median satisfaction score of 4 in overall and four specific aspects; eating, speaking, comfort, and esthetics (Figure 1). Denture satisfaction was reported in approximately 60% of participants, and up to 80% in esthetic aspect. It was noted that dissatisfaction prevalence was less than that of reported oral impacts. They were less likely to express dissatisfaction, but rather reported "neither" as the worst condition. Among five items, eating aspects showed the highest percentage of (very) dissatisfaction.



Figure 1. Patient's satisfaction level (%) regarding overall and four specific aspects.

The main reason for treatment need was initially due to limited eating/chewing ability. Meanwhile, it was also the main problem among whom currently had oral impacts. Therefore, masticatory ability was considered as the secondary outcome in the present study. Masticatory ability was measured both subjectively and objectively through eating satisfaction and masticatory performance of peanut mastication. Table 11 represented the patient-based outcomes, including subjective and objective masticatory ability, as well as OIDP prevalence (overall and eating) according to the patient characteristics and their oral conditions related to denture. The higher satisfaction score and/or smaller median peanut particle size indicated better masticatory ability. It was found that participants with a flat/knife-edge residual ridge, lower mandibular height, and the most severe edentulous condition (ACP class IV) tended to generate poorer subjective and objective masticatory ability compared with their counterparts. On the contrary, younger participants with less than 70 years of age and those with good soft tissue condition tended to produce smaller peanut particle size. OIDP prevalence was relatively higher in older age ( $\geq$  70 years), poor soft tissue condition, flat residual ridge form, and the more severe edentulous condition.

	Masticato	ory ability	OIDP pre	valence
Patient-related conditions (n)	Median peanut	Eating satisfaction	Overall;	Eat;
	particle size (mm);	score;	%	%
(=1 if yes, =0 if otherwise)	mean (SD)	mean / median		
Overall (N = 126)	3.7 (1.1)	3.7 / 4	43.7	42.1
General characteristics of participants				
<b>Age</b> ; < 70 years (51)	3.5 (1.1)	3.8 / 4	35.3	33.3
≥ <b>7</b> 0 years (75)	3.9 (1.1)	3.6 / 3	49.3	48.0
Sex; Male (54)	3.7 (1.1)	3.7 / 4	46.3	44.4
Female (72)	3.7 (1.2)	3.8 / 4	41.7	40.3
Previous complete denture experience; Yes (54)	3.6 (1.1)	3.8 / 4	43.1	41.7
No (72)	3.8 (1.2)	3.7 / 3.5	44.4	42.6
Oral conditions related to denture				
Soft tissue; Maxillary: Good (110)	3.7 (1.2)	3.7 / 4	41.8	40.0
Poor (16)	4.0 (1.1)	3.9 / 4	56.3	56.3
Mandibular: Good (110)	3.6 (1.2)	3.8 / 4	40.0	38.2
Poor (16)	4.3 (0.7)	3.6 / 3	68.8	68.8
Ridge form; Maxillary: Round (115)	3.6 (1.1)	3.8 / 4	40.9	39.1
Flat/Knife-edge (11)	4.5 (1.2)	3.1 / 3	72.7	72.7
Mandibular: Round (37)	3.1 (1.0)	4.1 / 4	29.7	24.3
Flat/Knife-edge (89)	4.0 (1.1)	3.6 / 3	49.4	49.4
Mandibular height (mm); < 10 (15)	4.1 (1.1)	3.5 / 3	60.0	60.0
10 to 15 (36)	3.9 (1.1)	3.8 / 4	36.1	33.3
16 to 20 (57)	3.6 (1.1)	3.8 / 4	47.4	45.6
> 20 (18)	3.4 (1.3)	3.8 / 4	33.3	33.3
ACP classification;   (16)	3.3 (1.2)	3.8 / 4	31.3	31.3
II (35)	3.2 (1.1)	4.1 / 4	34.3	31.4
III (27)	3.5 (1.0)	3.7 / 4	44.4	40.7
IV (48)	4.3 (1.0)	3.5 / 3	54.2	54.2

 Table 11. Masticatory ability and OIDP prevalence according to patient-related

 conditions

Masticatory ability was highlighted because 96.4% of participants with oral impact reported eating/chewing problem.

The patient-based outcomes, masticatory ability and OIDP prevalence (overall and CS-impacts), according to denture-related conditions were presented in Table 12. Regarding esthetic-assessment criteria, unparallelism and un-coincidence between dental and facial anatomical landmarks were found in approximately 20% of participants. On the average, a degree of midline deviation (mean  $\pm$ s.d) was 1.9 ( $\pm$ 0.8) mm with a maximum degree of 4.5 mm. More than 90% of participants had mismatched proportions between the maxillary anterior teeth and bizygomatic width.

Meanwhile, there were no participants whose maxillary anterior teeth proportion met the golden proportion criteria. With regard to a posterior occlusal tooth form, participants with anatomical tooth were more likely to generate smaller median peanut particle size and lower eating satisfaction score; however, the oral impact prevalence between these two groups were relatively comparable. Masticatory ability and OIDP prevalence between the two denture age ranges (2 to 4 and above 4 years) were indifferent.

Table 13 also represented masticatory ability and OIDP prevalence, but with regard to the clinical quality of complete denture in terms of retention and stability, determined by both conventional and CU-modified Kapur criteria. Based on the CUmodified Kapur criteria, the unacceptable denture quality was found in 14.3% in maxillary but 50.8% in mandibular denture. However, the prevalent impacts among the participants with unacceptable quality were up to 94.4% in maxillary and 78.1% in mandibular denture. An acceptable quality of both dentures was found in about 50% of participants, but OIDP was still reported in 6.7% of them, particularly eating difficulty. The unacceptable maxillary and/or mandibular denture quality were related to higher percentage of the overall and CS-impacts on eating, eating dissatisfaction, and larger median peanut particle size. The conventional Kapur criteria correspondingly revealed a monotonic dose-response relationship with these patient-based outcomes. The associations between denture quality and all outcomes, determined by regression analyses after covariates adjustment, still conformed to these descriptive findings (Table 14). When a fair denture quality was used as the reference group, a poor quality demonstrated more frequent overall and CS-impacts on eating, while the impact was significantly less prevalent in the participants with good denture quality.

Table 12. Masticatory ability and OIDP prevalence according to denture-related conditions

	Nasticato						prevalen	ce; %o			
Denture-related conditions (n)	Median peanut	Eating satisfaction				SF	oecific pe	rformanc	e		
(=1 if yes, =0 if otherwise)	particle size (mm);	score;	Overall		Physcial		Psy	/chologic:	al	Soci	al
	mean (SD)	mean / median		Eat	Speak	Clean	Smile	Emotion	Sleep	Contact	Work
Overall (N = 126)	3.7 (1.1)	3.7 / 4	43.7	42.1	23.0	2.4	15.1	19.0	2.4	7.1	2.4
<b>Denture age</b> (years); 2 - 4 (80)	3.7 (1.1)	3.7 / 4	41.9	40.7	20.9	3.5	15.1	18.6	0.0	4.7	2.3
> 4 (46)	3.8 (1.2)	3.8 / 4	47.5	45.0	27.5	0.0	27.5	7.5	3.5	12.5	2.5
Posterior occlusal tooth form; Non-anatomic (44)	4.2 (1.1)	3.5/3	52.3	50.0	25.0	0.0	14.6	25.0	0.0	4.6	2.3
Anatomic (82)	3.5 (1.1)	3.9 / 4	39.0	37.8	22	3.7	15.9	15.9	3.7	8.5	2.4
Esthetic-assessment criteria;											
- Unparalelled Interpupillary line and			C 71	C 71	15	Ċ	0	7 7	Ċ	7 7	
Incisal edge of maxillary central incisor (26)	I		40.4	40.2	+.CT	0.0	17.2		0.0		0.0
- Un-coincident Facial and Dental midline (26)	I		28.9	26.9	17.3	1.9	9.6	9.6	3.9	1.9	1.9
- Mismatched proportional criteria:											
Maxillary central incisor:Bizygoma (42)	I		47.6	47.6	23.8	0.0	23.8	16.7	0.0	4.8	0.0
Maxillary anterior teeth:Bizygoma (116)	I		44.0	42.2	23.3	1.7	17.2	14.7	1.7	6.9	2.6
Maxillary central incisor:lateral incisor:canine (126)	I		43.7	23.0	23.0	2.4	19.1	15.1	2.4	7.1	2.4
Masticatory ability was highlighted because 96.4% of pa	articipants with oral im	pact reported eating/o	chewing p	roblem.							

The other groups refer to the opposing characteristics including paralleled, coincidence, and those with proportional values within  $\pm 10\%$  of criteria.

Table 13. Masticatory ability and C	<b>DIDP</b> prevalenc	e according to	dentur	e dni	ality (	reten	tion a	nd sta	bility)	criteri	σ
	Masticato	ory ability				OIDP	prevale	nce; %			
Denture quality criteria (n)	Median peanut	Eating satisfaction				SF	becific p	erformar	ces		
(=1 if yes, =0 if otherwise)	particle size (mm);	score;	Overall		hyscial		Psy	vchologia	al	Soci	al
	mean (SD)	mean, median		Eat	Speak	Clean	Smile	Emotion	Sleep	Contact	Work
Overall (N = 126)	3.7 (1.1)	3.7 / 4	43.7	42.1	23.0	2.4	15.1	19.0	2.4	7.1	2.4
1) CU-modified Kapur criteria											
Unacceptable UCD; Retention (6)	4.4 (1.0)	3.2 / 3	83.3	66.7	16.7	0.0	0.0	66.7	16.7	33.3	0.0
Stability (16)	4.8 (0.6)	2.7/3	100.0	100.0	50.0	6.3	31.3	62.5	6.3	25.0	0.0
Overall (18)	4.7 (0.7)	2.8/3	94.4	88.9	44.4	5.6	27.8	55.6	11.1	22.2	0.0
Unacceptable LCD; Retention (25)	4.7 (0.8)	3.0/3	92.0	88.0	52.0	0.0	28.0	44.0	8.0	20.0	12.0
Stability (63)	4.4 (0.9)	3.3 / 3	77.8	74.6	41.3	4.8	27.0	33.3	4.8	11.1	4.8
Overall (64)	4.4 (0.9)	3.2 / 3	78.1	75.0	40.6	4.7	26.6	34.4	4.7	12.5	4.7
<ul> <li>Maxillary and Mandibular dentures;</li> </ul>											
Acceptable both UCD and LCD (60)	3.0 (0.9)	4.3 / 4	6.7	6.7	3.3	0.0	3.3	3.3	0.0	0.0	0.0
Acceptable UCD but Unacceptable LCD (48)	4.3 (1.0)	3.2 / 3	70.8	68.8	39.6	4.2	25.0	25.0	2.1	10.4	6.3
Unacceptable UCD but Acceptable LCD (2)	3.6 (0.6)	3.0 / 3.5	50.0	50.0	50.0	0.0	0.0	0.0	0.0	50.0	0.0
Unacceptable both UCD and LCD (16)	4.8 (0.6)	3.1/3	100.0	93.8	43.8	6.3	31.3	62.5	12.5	18.8	0.0
2) Kapur criteria											
Good (23)	2.9 (0.9)	4.3 / 4	4.3	4.3	4.3	0.0	0.0	0.0	0.0	4.3	0.0
Fair (74)	3.5 (1.1)	3.8/3	35.1	33.8	18.9	4.1	16.2	12.2	1.4	2.7	0.0
Poor (29)	4.8 (0.7)	3.0 / 3	9.96	93.1	48.3	0.0	24.1	51.7	6.9	20.7	10.3
UCD, upper (maxillary) complete denture; LCD, lov	wer (mandibular) com	olete denture.									
Masticatory ability was highlighted because 96.4%	of participants with or	al impact reported eat	ting/chewi	ldord gr	.em.						

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Masticatory ability

Reported oral impacts; Adjusted OR (95%CI)

Denture quality criteria (n);	Median peanut	Eating dissatisfaction:			Sp	ecific performances		
(=1 if yes, =0 if otherwise)	particle size (mm);		Overall	Physi	cal	Psychol	ogical	Social
	Adjusted <b>B</b> (95% CI)	Adjusted OR (95% CI)		Eat	Speak	Emotion	Smile	Contact
Denture quality criteria (n);								
1) CU-modified Kapur criteria								
• Unacceptable UCD <sup>A</sup> ; Retention (6)	0.68 (-0.27, 1.62)	2.43 (0.39, 15.0)	5.6 (0.61, 51.9)	2.29 (0.38, 14.0)	0.68 (0.07, 6.48)	14.1 (1.74, 113.7)*	None reported <sup>§</sup>	7.64 (0.89, 65.2)
Stability (16)	1.10 (0.50, 1.70)*	17.8 (3.07, 102.7)*	All reported <sup>5</sup>	All reported <sup>§</sup>	8.90 (2.12, 37.5)*	31.1 (5.43, 178.2)*	4.11 (1.04, 16.2)*	12.1 (2.18, 66.8)*
Overall (18)	1.05 (0.48, 1.62)*	6.91 (1.85, 25.8)*	29.5 (3.58, 242.4)*	13.8 (2.84, 67.4)*	2.87 (1.17, 4.57)*	15.5 (2.73, 87.8)*	2.46 (0.51, 11.7)	4.88 (0.69, 34.3)
• Unacceptable LCD <sup>A</sup> ; Retention (25)	0.99 (0.53, 1.46)*	5.67 (1.89, 15.01)*	21.5 (4.68, 99.0)*	14.3 (3.84, 53.0)*	12.13 (1.52, 96.59)*	3.06 (0.64, 14.7)	8.25 (0.97, 70.3)	0.85 (0.15, 5.00)
Stability (63)	1.23 (0.89, 1.56)*	9.41 (3.80, 23.3)*	37.2 (11.9, 116.6)*	27.2 (9.27, 80.0)*	30.3 (6.34, 144.6)*	8.49 (2.27, 31.7)*	12.1 (2.48, 59.3)*	3.15 (0.56, 18.0)
Overall (64)	1.22 (0.88, 1.55)*	11.0 (4.30, 28.0)*	47.1 (13.9, 159.5)*	33.9 (10.8, 106.6)*	29.7 (6.64, 133.2)*	6.36 (1.96, 20.7)*	10.2 (2.50, 41.6)*	3.43 (0.61, 19.3)
<ul> <li>Maxillary and Mandibular dentures;</li> </ul>								
Acceptable both UCD and LCD (60)	0 (Reference)	1 (Reference)	1 (Reference)	1 (Reference)	1 (Reference)	1 (Reference)	1 (Reference)	1 (Reference)
Acceptable UCD but Unacceptable LCD (48)	1.08 (0.72, 1.43)*	28.7 (5.46, 150.4)*	42.1 (10.8, 163.7)*	32.2 (8.88, 116.5)*	36.0 (7.88, 164.9)*	11.4 (2.10, 61.4)*	8.79 (2.08, 37.1)*	7.05 (0.73, 68.5)
Unacceptable UCD but Acceptable LCD (2)	0.55 (-0.74, 1.84)	8.88 (0.40, 198.7)	17.2 (0.68, 434.9)	19.7 (0.86, 450.2)	None reported <sup>§</sup>	35.8 (1.80, 711.8)*	None reported <sup>§</sup>	40.8 (1.30, 1282.6)*
Unacceptable both UCD and LCD (16)	1.63 (1.10, 2.17)*	10.7 (3.77, 30.1)*	All reported	204.4 (18.6, 2252.6)*	17.7 (1.84, 171.4)*	162.2 (10.2, 2570.2)*	16.0 (2.03, 125.3)*	26.7 (1.83, 790.4)*
2) Conventional Kapur criteria								
Good (23)	-0.62 (-1.08, -0.16)*	0.26 (0.07, 0.98)*	0.06 (0.01, 0.55)*	0.06 (0.01, 0.50)*	0.15 (0.02, 1.33)	None reported <sup>§</sup>	None reported <sup>§</sup>	1.45 (0.11, 19.2)
Fair (74)	0 (Reference)	1 (Reference)	1 (Reference)	1 (Reference)	1 (Reference)	1 (Reference)	1 (Reference)	1 (Reference)
Poor (29)	0.99 (0.56, 1.43)*	4.36 (1.46, 13.0)*	22.3 (4.59, 108.5)*	48.0 (5.84, 395.0)*	7.65 (2.32, 25.2)*	9.16 (2.63, 31.9)*	1.57 (0.48, 5.10)	13.8 (2.03, 93.8)*
UCD, upper (maxillary) complete denture; LCD, low	er (mandibular) complet	e denture; N/A, not applic	able. Masticatory ability	/ was highlighted becaus	e 96.4% of participants	s with oral impact repoi	rted eating/chewing pi	oblem.

Significant association at \*p < 0.05. <sup>§</sup> No p-value available. Reported oral impacts on cleaning, sleeping, and working were disregarded due to a small sample size in these subgroups.

Multivariable analyses were adjusted for age (years), sex (women), soft tissue condition (good), residual ridge form (round), mandibular height (mm), denture age (years) and previous complete denture experience (yes).

Reference variable correspond to A was acceptable quality group.

Comparing between the conventional and CU-modified Kapur criteria, good denture quality was classified as acceptable by both maxillary and mandibular dentures, while poor denture quality was unacceptable on either or both dentures. However, a fair quality (score = 6 to 8) of conventional Kapur criteria could be either acceptable or unacceptable quality (APPENDIX A). Unacceptable denture quality determined by CU-modified Kapur criteria demonstrated stronger association with both masticatory ability and oral impacts, as shown by the higher adjusted beta-coefficient ( $\beta$ ) and odds ratio (OR) (Table 14). Also, denture stability revealed stronger associations with all patient-based outcomes compared with its retention.

 Table 15. Sensitivity (%) and specificity (%) of denture quality criteria in estimating

 patient-based outcomes

			Masticatory	y ability; %		1	Reported Ora	al Impacts; 9	6
Denture quality cr	iteria	Median particle siz	peanut e (≥3.6mm)	Eat dissatis	ting sfaction	Ove	erall	Eat	ting
(=1 if yes, =0 if oth	erwise)	Sensitivity	Specificity	Sensitivity	Specificity	Sensitivity	Specificity	Sensitivity	Specificity
CU-modified Kapur crite	ria								
• Unacceptable UCD <sup>A</sup> ; F	Retention	67.8	69.3	48.2	77.8	49.1	93.0	47.2	90.4
Sta	oility	68.8	72.6	51.9	81.9	7.7	95.8	8.1	95.9
Ove	erall	67.2	74.2	51.9	80.6	36.4	94.4	37.7	93.2
• Unacceptable LCD <sup>A</sup> ; R	etention	75.0	74.2	61.1	81.9	61.8	77.5	56.6	82.2
Sta	oility	84.4	83.9	75.9	76.4	89.1	80.3	86.8	78.1
Ove	erall	84.4	82.3	77.8	77.8	90.9	80.3	90.6	78.1
Unacceptable overall	CD	84.4*	80.7	77.8*	81.9	84.6*	78.9	88.7*	78.1
Conventional Kapur crit	eria (Poor)	B 76.6	74.2	66.7	79.2	65.5	92.9*	66.0	91 7*

UCD, upper (maxillary) complete denture; LCD, lower (mandibular) complete denture; CD, both UCD and LCD.

Significant difference between conventional and CU-modified Kapur criteria at \*p < 0.05 determined by likelihood ratio test after hierarchical logistic regression. Reference variables correspond to A and B were acceptable quality and good/fair quality groups. Interpretations are, for example, sensitivity for oral impact is 'percentage of participants with oral impact that the criteria can detect', whereas specificity is 'percentage of participants without oral impacts that the criteria can detect'.

Both subjective and objective masticatory ability were significantly associated with reported oral impact; the higher eating satisfaction or masticatory performance, the lower OIDP prevalence. The receiver operating characteristic (ROC) curve suggested that a peanut particle size of 3.6 mm was an optimal a cut-off value to classify masticatory performance into the higher and lower levels as it gave the highest sensitivity and specificity in predicting the OIDP prevalence with a 90.4% under-curved area. The sensitivity of the CU-modified Kapur criteria in estimating all patient-based

outcomes was about 10.0% to 20.0% higher than the conventional one (Table 15). When the CU-modified Kapur criteria was used as a predictor to estimate patient-based outcomes, the lowest sensitivity was shown for estimating the eating satisfaction.

The result of path analysis was exhibited graphically in Figure 2. The unacceptable denture quality, categorized based on the CU-modified Kapur criteria, was significantly associated with a flat/knife-edge residual ridge regardless of mandibular bone height. A flabby maxillary soft tissue was more likely to be associated with an unacceptable quality of maxillary denture, but with statistical insignificance (Table 16). Moreover, the increased number of occlusal contact points and male participants generated a higher maximum bite force. Subjective and objective masticatory ability were both significantly associated with unacceptable denture quality. Masticatory performance, in addition, increased with a higher maximum bite force and mandibular bone height (>15 mm) (Table 17). These results indicated that objective masticatory performance reflected denture retention/stability, bite force, and occlusal contacts; whereas the subjective eating satisfaction was predominantly explained only by denture retention/stability. Overall, the unacceptable denture quality affected the oral impact directly, and indirectly through masticatory ability, both eating satisfaction and masticatory performance (Table 18) It was noted that neither esthetic-assessment criteria nor denture age was associated with OIDP prevalence.

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Figure 2. Path analysis of the direct and indirect effects of variables on OHRQoL

Note: A causal effect between reported oral impact and lower eating satisfaction score might be a two-head arrow as it could possibly be an association. However, a causal-relation was proposed based on the previous theoretical framework.<sup>14,18</sup>

			103			
Variables	Unacceptable denture quality				Maximum bita farca (N)	
Valiables	UCD		LCD			
(=1 if yes, =0 if otherwise)	β	(95% CI)	β	(95% CI)	β	(95% CI)
Patient characteristic and denture-related condition						
• Sex (Female) <sup>A</sup> ;						
Direct, Total effect					-52.0	(-88.2, -15.9)**
• Number of occlusal contact points;						
Direct, Total effect					14.2	(11.3, 17.2)***
Oral conditions related to denture						
• Soft tissue (Fair/Poor) <sup>B</sup> ;				-		
Maxillary; Direct, Total effect	2.95	(-0.88, 9.95) <b>†</b>		-		
• Ridge form (Flat/Knife-edge) <sup>C</sup> ;		-		-		
Maxillary; Direct, Total effect	4.32	(1.09, 17.1)*	-			
Mandibular; Direct, Total effect			1.25	(0.42, 2.07)**		

Table 16. Direct and total effects of variables on denture qu	ality
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UCD, upper (maxillary) complete denture; LCD, lower (mandibular) complete denture;  $\beta$ , beta-coefficient.

Significant association at \*\*\*p<0.001, \*\*p<0.01, \*p<0.05, †p<0.1.

Reference variables correspond to A, B, and C were male, excellent/good condition, and round ridge.

Variables	Masticatory ability			
variables	Median pea	anut particle size (mm)	Eating satisfaction score	
(=1 if yes, =0 if otherwise)	β	(95% CI)	β	(95% CI)
Patient characteristics, performance				
• Sex (Female) <sup>A</sup> ;				
Indirect (Max bite force), Total effect	0.17	(0.05, 0.29)**		-
Maximum bite force;				-
Direct, Total effect	-0.003	(-0.004,-0.002)***		-
Oral tissue conditions related to denture				
• Maxillary ridge form (Flat/Knife-edge) <sup>B</sup> ;				
Indirect (unaccept UCD quality), Total effect	0.72	(-0.19, 1.64)	-1.91	(-4.31, 0.47)
• Mandibular ridge form (Flat/Knife-edge) <sup>B</sup> ;				
Indirect (unaccept LCD quality), Total effect	1.24	(0.35, 2.14)**	-2.24	(-3.98, 0.49)
• Mandibular height (≤15 mm) <sup>C</sup> ;				
Direct, Total effect	0.28	(0.01, 0.56)*		-
Denture characteristics				
• Unacceptable denture quality <sup>D</sup> ;				
- UCD; Direct, Total effect	0.52	(0.11, 0.93)*	-1.37	(-2.42, -0.33)**
- LCD; Direct, Total effect	1.00	(0.70, 1.29)***	-1.80	(-2.54, -1.05)***
• Number of occluding cusp;				
Indirect (Maximum bite force), Total effect	0.17	(0.05, 0.29)**		-

#### Table 17. Direct, indirect, and total effects of variables on masticatory ability

UCD, upper (maxillary) complete denture; LCD, lower (mandibular) complete denture;  $\beta$ , beta-coefficient. Significant association at \*\*\*p<0.001, \*\*p<0.05.

Reference variables correspond to A, B, C, and D were male, round ridge, >15 mm., and acceptable quality.

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Variables	Reported Oral Impacts			
(=1 if yes, =0 if otherwise)	β	(95% CI)		
Patient characteristic				
• Sex (Female);				
Indirect (Max bite force $\rightarrow$ Peanut size), Total effect	0.15	(-0.01, 0.31) <b>†</b>		
Oral tissue conditions related to denture				
• Maxillary soft tissue (Fair/Poor) <sup>°</sup> ;				
Indirect (unaccept UCD quality)	3.15	(-1.40, 7.70)		
Indirect (unaccept UCD quality $ ightarrow$ Peanut size)	0.55	(-0.29, 1.38)		
Indirect (unaccept UCD quality $ ightarrow$ Eating satisfaction score)	2.00	(-0.88, 4.88)		
Total effect	5.69	(-1.31, 12.7)		
• Maxillary ridge form (Flat/Knife-edge) <sup>C</sup> ;				
Indirect (unaccpet UCD quality)	3.65	(-8.83, 1.53)		
Indirect (unaccept UCD quality $ ightarrow$ Peanut size)	2.32	(-0.97, 5.61)		
Indirect (unaccept UCD quality $ ightarrow$ Eating satisfaction score)	0.63	(-0.32, 1.59)		
Total effect	6.61	(-1.32, 14.5)†		
• Mandibular ridge form (Flat/Knife-edge) <sup>C</sup> ;				
Indirect (unaccept LCD quality)	3.45	(-0.59, 6.30) <b>†</b>		
Indirect (unaccept LCD quality $ ightarrow$ Peanut size)	1.09	(-0.10, 2.28) <b>†</b>		
Indirect (unaccept LCD quality $ ightarrow$ Eating satisfaction score)	2.71	(-0.07, 5.49) <b>†</b>		
Total effect	7.25	(-1.68, 12.8)		
• Mandibular height (≤15 mm) <sup>D</sup> ;				
Indirect (Peanut size), Total effect	-0.25	(-0.56, 0.07)		
Denture characteristics and patient performance				
Number of occlusal contact point;				
Indirect (Max bite force $ ightarrow$ Peanut size), Total effect	-0.04	(-0.07,-0.003)*		
Maximum bite force;				
Indirect (Peanut size), Total effect	-0.003	(-0.005,-0.0003)*		
Unacceptable denture quality ;	2 ( )	(0.02 5.00)+		
- UCD: Direct	2.62	(-0.03, 5.28) <b>†</b>		
Indirect (Fealul Size)	1.40	(-0.00, 0.97)†		
Total effect	4 74	(1 56 7 93)**		
- I CD: Direct	2 76	(1.38, 4.15)***		
Indirect (Peanut size)	0.87	(0.11 1.64)*		
Indirect (Fating satisfaction score)	2 17	(0.46, 3.88)*		
Total effect	5.81	(3.52.8.10)***		
Masticatory ability		(,,		
Median peanut particle size: Direct effect	0.88	(0.16, 1.60)*		
Eating satisfaction score: Direct effect	-1.21	(-2.02, -0.40)**		

### Table 18. Direct, indirect, and total effect of variables on reported oral impact

UCD, upper (maxillary) complete denture; LCD, lower (mandibular) complete denture;

 $\beta$  , beta-coefficient. Significant association \*\*\*p<0.001, \*\*p<0.01, \*p<0.05, +p<0.1.

### CHAPTER V DISCUSSION

The proportions of complete denture wearers who reported oral impacts on daily performances or eating dissatisfaction were different between those with acceptable and unacceptable denture quality, evaluated by using the CU-modified Kapur criteria. Therefore, the primary and secondary null hypotheses were rejected.

As with previous studies which determined the oral impacts in Thai edentulisms with and without complete denture wearing,<sup>4, 5</sup> the major oral impact was on a physical performance, while the social impact was not so important. However, oral impact prevalence in those studies was about 60%, while it was only 44% in the present study. The higher prevalence was shown in those without denture wearing. On the other hand, Sirithepmontree D (2008)<sup>36</sup> and Suepattima B (2013)<sup>39</sup> revealed lower oral impact prevalence in complete denture wearers, approximately 30%. Nevertheless, those studies had never been explored the underlying determinants for reported oral impact. Besides, the duration for denture wearing was not clarified.

The most common problem among removable complete denture wearers was limitation in eating/chewing ability in accordance with other complete denture wearer populations.<sup>4, 5, 54, 82</sup> In addition to the OHRQoL, therefore, masticatory ability was expressed as the patient-based outcomes in the present study. Masticatory ability was determined both subjectively and objectively. Subjective eating satisfaction was considered as secondary outcome because it reflected patient's perception, while objective masticatory performance was used to confirm the subjective measures.

All participants with oral impact predominantly reported an ill-fitting denture as the most common cause, regardless of affected activities. An ill-fitting or loose denture was also reported as the major problem in complete denture wearers by several studies.<sup>5, 44, 54, 83</sup> The term "ill-fitting denture" reported by the patients coincided with professional terms of "denture retention and stability". Since now, however, neither a standard method nor criteria for professional evaluation of complete denture retention and stability had been identified. Kapur method was one of professionally based methods that had been used to assess complete denture retention and stability in several studies.<sup>14, 46, 52, 84</sup> This study initially employed Kapur method for denture retention and stability evaluation because it possesses a criteria for classifying the overall clinical quality of complete denture. However, an ordinal scale of Kapur criteria, which classifies clinical quality of complete denture into good/fair/poor, cannot justify whether a denture quality is clinically acceptable or functioning. In addition, Kapur criteria cannot identify whether the problem is on maxillary or mandibular denture because denture quality was determined through a total score of both dentures. As a result, the "CU-modified Kapur criteria" was developed by establishing the cut-off values in order to change the ordinal scale of retention and stability scores in the conventional Kapur criteria into a dichotomous outcome; acceptable or unacceptable. The dichotomous outcomes of CU-modified Kapur criteria offers more benefits in terms of clinical interpretation, and ability to identify unacceptable piece or pair of maxillary and mandibular dentures.

The conventional and modified criteria were both associated with the patientbased outcomes, however, the CU-modified criteria showed higher sensitivity in estimating these outcomes. The result indicated that the CU-modified criteria is able to detect the impaired masticatory ability and OHRQoL more accurately than the conventional one. A lower sensitivity of the conventional Kapur criteria was due to its ambiguous "fair" quality, which can be either acceptable or unacceptable based on the CU-modified Kapur criteria (APPENDIX A). It can be explained that the same total score may be summed up from different scores or qualities of maxillary and mandibular dentures. For example, a total score of 7 may come from 5-score maxillary but 2-score mandibular denture with slight stability, which is unacceptable based on the CU-modified criteria. On the other hand, it can be summed up from 4-score maxillary but 3-score mandibular denture with sufficient stability, which is acceptable. Therefore, the CU-modified Kapur criteria is recommended to identify a clinical quality of complete denture especially when an overall quality is questionable.

Earlier studies found the associations of satisfaction or OHRQoL of the complete denture wearers and the retention and/or stability of only maxillary,<sup>10</sup>

mandibular,<sup>14</sup> or both dentures.<sup>49, 59</sup> Based on the CU-modified Kapur criteria, retention and stability are both significantly important qualities but with uneven impacts between maxillary and mandibular dentures. Both maxillary and mandibular dentures should possess sufficient stability in order to avoid oral impacts (APPENDIX B). Acceptable denture retention, on the contrary, at least a moderate level is needed for maxillary, but only a minimum level for the mandibular denture. Hence, mandibular denture with a slight retention, but sufficient stability should be considered whether a refabrication or implant-retained overdenture is really needed, especially when the patients are satisfied with their denture and have no difficulties in daily activities.

Subjective eating satisfaction and objective masticatory performance can be used to assess complete denture retention/stability. However, in addition to an acceptable denture quality, masticatory performance can be improved by an increased maximum bite force. Although a female was able to generate a relatively lower bite force than male, dentists can help a patient improve masticatory ability by creating an adequate number of occlusal contacts, regardless of the posterior occlusal tooth form. These findings suggested that objective masticatory performance better indicates complete denture qualities including retention/stability and occlusal contact, whereas subjective eating satisfaction predominantly reflects retention/stability. Satisfaction was recommended by previous studies as it reflects patient's perception,<sup>42, 45</sup> and can be performed easier compared with peanut mastication test. However, it can be affected by other unobservable factors, such as past experiences, expectations, and emotion pf patients.<sup>85, 86</sup> Therefore, the decision for choosing subjective or objective measure for masticatory ability evaluation may be based on available human, time, and financial resources.

According to a bio-psychosocial principle,<sup>15</sup> either patient's satisfaction or OHRQoL can be used as a major treatment outcome because they both reflect patient's perception or patient-center outcome. Meanwhile, masticatory performance of peanut masticatory is an objective measure that confirms these subjective evaluations. The present study suggested oral impact as a primary outcome, while patient's satisfaction is a surrogate end point. The reasons are as follows; First, OIDP index measures all aspects of "oral health" which reflects the physiologic, social, and psychological attributes that are essential to a quality of life,<sup>6</sup> while satisfaction is more likely to reflect the second level of oral impairment such as pain and discomfort. Second, unacceptable denture quality has a negative impact on oral health directly, thus, measuring a surrogate outcome of masticatory ability is unnecessary. Lastly, the sensitivity value of denture quality criteria in predicting eating satisfaction was the lowest, compared with masticatory performance and oral impact. In other words, a lower percentage of patients with unacceptable quality can be detected by using a satisfaction compared with an oral impact evaluation. Possibly, patient's satisfaction is often too positive despite impaired objective masticatory ability or OHRQoL. To be summarized, only oral impacts on daily performances is enough for evaluating patientbased outcome, while satisfaction and masticatory performance are surrogate measures. But in case of rapid survey or surveillance, satisfaction might be more applicable, compared with oral impacts.

The findings demonstrated substantial impacts of unacceptable complete denture retention and stability on impaired masticatory ability and OHRQoL. As supported by several studies, retention and/or stability of complete denture were associated with the wearer's satisfaction<sup>31, 46, 48, 49, 59</sup> and quality of life although OHRQoL was generally assessed through the shorted versions of Oral Health Impacts Profiles (OHIP).<sup>10, 14, 87</sup> The CU-modified Kapur criteria is proposed as a reliable tool for assessing patient-based treatment outcomes because unacceptable denture quality, either or both maxillary and mandibular dentures, negatively affect both patient's perception and performance of mastication.

In some cases, their masticatory ability and daily activities were unaffected by wearing unacceptable retention/stability denture. This is possibly due to the influence of their past experiences, expectations, and adaptation. Because professional evaluations remain imperfect surrogates for patient's perception and performance, complete denture treatment outcome should consider both professional and patient evaluation. However, these results need caution interpretations. Reported satisfaction or no oral impact might be due to dietary restriction after patient's adaption to an unacceptable denture. Otherwise, a current denture may be more fitting and better improve their masticatory ability compared with their past dentures. Therefore, health care professional should also concern about a dietary food intake especially in elderly because an impaired masticatory function can be a risk for nutritional deficiency, leading to several health problems.<sup>88</sup>

To optimize denture retention and stability, border molding and impression making are ones of the important procedures in a clinical practice. A preliminary impression was to make a definite individual tray for final impression. Meanwhile, an accurate final impression with proper border molding will enhance a closed adaptation between tissue surface of denture and underneath denture-bearing area, as well as an appropriate denture extension for a border seal. However, the acceptable denture retention/stability should not only be created only during denture fabrication, but also prolong to a maintenance period for denture quality evaluation. This is to monitor any occurrences of pain/comfort or denture quality alteration because of changes in underneath residual ridge and soft tissue after a period of denture wearing.<sup>89</sup>

It should be concerned that the unacceptable retention/stability denture was frequently found in patients with a flat/knife-edge residual ridge, while a shorter mandibular bone height was related only to lower masticatory performance. However, oral impact was not directly related to these two characters or case severity based on ACP classification. While maxillary and mandibular denture quality are classified separately, the ACP classification considered bone and soft tissue conditions of both jaws. Thus, ACP classification may be inappropriate for estimating denture quality and oral impact. The result was in accordance with previous studies which found an association between mandibular bone height and OHRQoL<sup>90</sup> or patient's satisfaction.<sup>91</sup> However, Marcell-Machado et al (2016)<sup>90</sup> concluded that an atrophic mandible, classified based on a mandibular bone height, was related to mandibular denture retention, but not masticatory performance. The opposite findings might because of different methods for measuring mandibular height and masticatory performance. Therefore, it can be implied from the present study that visual inspection and residual ridge palpation are adequate for screening an edentulous condition severity or case

complexity. A patient particularly female with relatively shorter mandibular bone height (≤15 mm) should be concerned for dietary habit as they might have difficulty in masticating hard food or require more chewing strokes, compared with male or those with relative higher mandibular bone (>15 mm). Nevertheless, patients with a compromised residual ridge morphology will be able to have a good quality of life whenever their denture achieves an acceptable quality.

On the other hand, posterior occlusal tooth form played no significant role in denture retention and stability, as well as masticatory ability and OHRQoL. This was in accordance with the earlier studies which revealed no association between posterior occlusal tooth form and masticatory performance.<sup>52</sup> In contrast, some studies demonstrated a more patient's satisfaction with anatomical tooth form including bilaterally balanced or lingualized occlusion, compared with a non-anatomical teeth or monoplane occlusion in terms of better masticatory ability and esthetics.<sup>62, 92</sup> However, those studies did not mention about denture retention/ stability as well as a number of occlusal contact, the true indicators for patient's masticatory ability. As supported by a previous systematic review, no occlusal design is suggested as the most appropriate for successful complete denture treatment.<sup>93</sup>

In this study, denture esthetics was not an issue for the participants. There are several possible explanations for this phenomenon. First, it might be that a primary chief compliant for treatment need was to improve eating/chewing ability, rather than appearance concern. Second, despite a facial and dental midline deviation, no participants could detect. As supported a previous study, lay people and general dentists could not recognize even with a 4-mm midline deviation,<sup>94</sup> and in this study, an average and maximum degree were only 2.0 and 4.5 mm. Third, an esthetic assessment by professionist might be differed from that of patients. While there are professional criteria for denture esthetics, patients can accept esthetic appearance without any standard criteria. As suggested by a modern complete denture esthetic concept of "unity with variety", dental and facial components should be complimented to each other and by itself, which is individually uniqueness.<sup>95</sup> Lastly, all participants received treatment from dental students in a university setting where

denture try-in appointments are available for patients to assess their denture appearance, then, patients have to accept their esthetics prior to denture delivery.

Previous studies revealed a controversial issue whether denture age was one of the underlying determinant for impaired denture quality or patient's dissatisfaction.<sup>37, 49, 96</sup> However, the authors who suggested the association between a longer denture wearing period and more patient's satisfaction did not explain this event.<sup>37, 49</sup> Also, the cut-off point for a longer denture wearing duration was arbitrarily established. From the present finding, it was apparent that denture age was not associated with denture quality, masticatory ability, or oral impacts. Thus, patients should be informed about no definite period for longevity of complete denture prostheses, but rather varies among individuals. In addition, a denture age is an inappropriate criteria for receiving a new set of complete denture.

There are limitations in the present study which need clarification. The CUmodified Kapur criteria cannot be applied to other types of dental prostheses and it is still unable to identify the patients' perception such as esthetic dissatisfaction or pain/discomfort. In addition, professional tool cannot indicate patient's oral health. The oral impact prevalence in this study might be underestimated because denture wearers who no longer wore the denture obtained from the faculty were not be selected through the randomization. Most of them experienced an ill-fitting denture and have the dentures fabricated at other health care providers. Moreover, some information retrieved from the patient's interview including duration of edentulism and denture wearing periods were not included in the analyses because it might introduce recall bias.

This study has a number of strengths. Firstly, both patient- and denture-related potential risk factors for impaired OHRQoL were investigated, thus, the true risk factor was proven while controlling for other possible confounders. Secondly, the sample was considered as a strong representative of Thai complete denture wearer population because samples were randomly selected by a two-stage stratified sampling using patient's age-sex and denture age as stratum, which are general characteristics of complete denture wearers. However, only removable complete denture wearers were included in this study. Thus, future researches on the masticatory ability and OHRQoL in people with other types of prostheses are recommended to identify the risk factors for impaired quality of life. The findings encourage other professionals to find the innovative techniques or methods to improve complete denture retention and stability. In addition, the underlying reasons for continuing to use a denture despite impaired masticatory ability or OHRQoL are need to be investigated in order to increase awareness for the health care providers and caregivers in taking care of patients with edentulism.

The findings lead to several guidelines for clinical practice and national oral health policy planning regarding a removable complete denture rehabilitation. The newly established "CU-modified Kapur criteria" is suggested for oral impact screening and surveillance in both clinical practice and community field because it can be performed by any trained health care personnel within limited time and financial resources. A criteria for completed prosthetic treatment and denture refabrication should be based on professional evaluation of unacceptable denture quality and patient-reported oral impact. The Thai National Oral Health policy regarding a free-of-charge complete denture treatment for elderly should revise a 5-year denture age as a standard criteria for a new denture fabrication because longevity of denture with acceptable quality are varied among individuals. The ultimate goal of complete denture treatment strategy should be changed from an increased 'output', or a greater number of delivered prostheses, to an improved 'outcome' that is good quality of life of complete denture wearers.

## CHAPTER IV CONCLUSIONS

The present study provided a strong evidence that complete denture retention and stability, both maxillary and mandibular dentures, are the important indicators in estimating patient-based treatment outcomes. The outcomes included oral impacts on daily performances, as well as subjective and objective masticatory ability, evaluated by eating satisfaction and masticatory performance. A greater number of occlusal contact points helps improve masticatory performance, regardless of occlusal tooth form. On the other hand, severity of edentulous condition, denture age, or esthetic-assessment criteria has no association with oral impact.

In rendering complete denture treatment, both patient's perception and professional evaluation are suggested to be concertedly considered. Regarding professional evaluation, the CU-modified Kapur criteria for denture retention/stability assessment is proposed as a risk assessment tool of impaired masticatory ability and OHRQoL of the wearers. It also assists clinician in making decision whether a denture needs refabrication. This newly-established criteria can be applied in both clinical practice and community field. To determine patient's need and treatment outcome, oral impacts on daily performances is suggested as a primary outcome, while subjective masticatory ability is considered as a surrogate outcome. Masticatory performance can be objectively used to confirm the OHRQoL and satisfaction.

#### APPENDIX

**Appendix A.** Distribution of participants according to conventional and CU-modified Kapur criteria

Conventional	CU-modified Kapur criteria (%)				
Kapur criteria (n)	Maxillary		Mandibular		
	Accepatable	Unacceptable	Acceptable	Unacceptable	
Good (23)	95.7	4.3	95.7	4.3	
Fair (74);	95.9	4.1	54.1	45.9	
Score; 8 (35)	100.0	0.0	97.1	2.9	
7 (25)	100.0	0.0	20.0	80.0	
6 (14)	78.6	21.4	7.1	92.9	
Poor (29)	51.7	48.3	0.0	100.0	

**Appendix B.** Distribution of participants who reported overall and CS-impact on eating according to retention and stability level of Kapur criteria.

Depture quality (p)	Reported oral impacts (%)		
	Overall	Eating	
Denture Retention			
- Maxillary; Maximum (99)	36.4	35.4	
Moderate (21)	66.7	66.7	
Minimum (5)	80.0	60.0	
Displace (1)	100.0	100.0	
- Mandibular; Maximum (12)	8.3	8.3	
Moderate (17)	14.3	14.3	
Minimum (72)	38.8	37.5	
Displace (25)	92.0	88.0	
Denture Stability			
- Maxillary; Sufficient (110)	35.5	33.6	
Some (15)	100.0	100.0	
No (1)	100.0	100.0	
- Mandibular; Sufficient (63)	9.5	9.5	
Some (38)	65.8	60.5	
No (25)	96.0	96.0	

Masticatory performance and	Quarall	Reported	Eating	Lower Masticatory Performance
related factors; mean (SD)	Overall	Oral Impact	Dissatisfaction	(Peanut size < 3.6 mm )
Median peanut particle size (mm)	3.7 (1.1)	4.5 (0.9)	4.6 (0.8)	4.6 (0.8)
Maximum bite force (N)	182 (136)	142 (104)	139 (90)	138 (93)
Occlusal contact area (mm <sup>2</sup> )	16.2 (11.8)	12.7 (9.2)	12.4 (7.9)	12.3 (8.2)
Number of occlusal contact point	15 (6)	12 (6)	12 (6)	12 (6)

Appendix C. Mean (SD) of masticatory performance and related factors



**Chulalongkorn University** 

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## VITA

Name: Miss Nareudee Limpuangthip

Date of Birth: January 13, 1988

Place of Birth: Bangkok, Thailand

Nationality: Thai

Address: 561/3 Soi Suan Plu 1, Sathorn Tai Rd, Sathorn district, Bangkok

10120, Thailand.

Tel. (Home): 02-2862337

Tel. (Mobile): 089-1426076

E-mail address: pin\_nandee@hotmail.com

Academic Qualification

2012: Doctor of Dental Surgery (DDS), Faculty of Dentistry, Chulalongkorn University, Bangkok, Thailand

> จุฬาลงกรณ์มหาวิทยาลัย Chulalongkorn University



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