ผลประเมินด้านอัตวิสัยและวัตถุวิสัยต่อการใช้กาวติดฟันเทียมในผู้ป่วยฟันเทียมทั้งปาก

นางสาวบุษรา ทองย้อย

วิทยานิพนธ์นี้เป็นส่วนหนึ่งของการศึกษาตามหลักสูตรปริญญาวิทยาศาสตรมหาบัณฑิต
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SUBJECTIVE AND OBJECTIVE OUTCOMES ON DENTURE ADHESIVE USAGE AMONG
COMPLETE DENTURE WEARERS

Miss Budsara Thongyoi

จุฬาลงกรณ์มหาวิทยาลัย
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A Thesis Submitted in Partial Fulfillment of the Requirements
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บุษรา ทองย้อย : ผลประเมินด้านอัตตวิสัยและวัตถุวิสัยต่อการใช้กาวติดฟันเทียมในผู้ป่วย ฟันเทียมทั้งปาก (SUBJECTIVE AND OBJECTIVE OUTCOMES ON DENTURE ADHESIVE USAGE AMONG COMPLETE DENTURE WEARERS) อ.ที่ปรึกษาวิทยานิพนธ์ หลัก: ผศ. ทพ. ดร.วัชรศักดิ์ ตุมราศวิน, 45 หน้า.

วัตถุประสงค์ของการศึกษานี้เพื่อประเมินผลของปัจจัยการประเมินด้านอัตตวิสัยและวัตถุ วิสัยที่ส่งผลต่อการตัดสินใจใช้กาวติดฟันเทียมในผู้ป่วยฟันเทียมทั้งปาก ผู้ป่วยฟันเทียมทั้งปากที่เข้า ร่วมการศึกษาจำนวน 66 คน มีอายุระหว่าง 53 ถึง 83 ปี ผู้ป่วยทุกคนจะได้รับการตรวจช่องปากและ เก็บข้อมูลครั้งแรก (T0) ดังนี้ (1) ลักษณะของเนื้อเยื่อรองรับฟันเทียมโดยใช้ตัวชี้วัดตามแบบของ สมาคมทันตกรรมประดิษฐ์อเมริกา (ACP classification) (2) คุณภาพของฟันเทียมใช้ตัวชี้วัดซียู โมดิฟายด์คาเปอร์ (CU-modified kapur criteria) (3) ความพึงพอใจต่อฟันเทียมและ (4) คุณภาพ ชีวิตในมิติสุขภาพช่องปากโดยใช้ดัชนีผลกระทบทางช่องปากต่อกิจกรรมในชีวิตประจำวัน (Oral impact on daily performances: OIDP) หลังจากนั้นผู้ป่วยทุกคนจะได้รับการแนะนำให้ใช้กาวติด ฟันเทียม (ยี่ห้อโพลิเด้นท์, ประเทศไอร์แลนด์) ทุกวันเป็นเวลา 1 เดือน แล้วตัดสินใจด้วยตนเองว่าจะ เลือกใช้กาวติดฟันเทียมต่อ (กลุ่ม U) หรือหยุดใช้กาวติดฟันเทียม (กลุ่ม NU) ความพึงพอใจต่อฟัน เทียมและดัชนีผลกระทบทางช่องปากต่อกิจกรรมในชีวิตประจำวันจะถูกสอบถามครั้งที่สอง (T1) หลังจากการเก็บข้อมูลครั้งแรกไป 1 เดือน (T0 + 1 เดือน) และถูกสอบถามซ้ำอีกครั้ง (T2) หลังจาก การเก็บข้อมูลครั้งที่สองไปแล้วอีก 1 เดือน (T1 + 1 เดือน) ผลการศึกษาพบว่า กลุ่ม U มีสัดส่วนของ คุณภาพฟันเทียมล่างที่ไม่ผ่านเกณฑ์ ความไม่พึงพอใจต่อฟันเทียม และผลกระทบทางช่องปากต่อ กิจกรรมในชีวิตประจำวันสูงมากกว่ากลุ่ม NU อย่างมีนัยสำคัญทางสถิติ ($p<0.05$) การใช้กาวติดฟัน เทียมสามารถช่วยให้กลุ่ม U มีความพึงพอใจต่อฟันเทียมที่ดีขึ้นและมีผลกระทบทางช่องปากต่อ กิจกรรมในชีวิตประจำวันที่น้อยลงตลอดระยะการศึกษา ในขณะที่กลุ่ม NU ได้รับผลกระทบดังกล่าว ที่แย่ลงจากการใช้กาวติดฟันเทียม และเมื่อกลุ่ม NU หยุดใช้กาวติดฟันเทียม ความพึงพอใจต่อฟัน เทียมและผลกระทบทางช่องปากต่อกิจกรรมในชีวิตประจำวันก็กลับมาอยู่ในระดับดีเหมือนเดิม ผล ดังกล่าวแสดงให้เห็นว่าผู้ป่วยฟันเทียมทั้งปากทุกคนไม่จำเป็นต้องใช้กาวติดฟันเทียม กล่าวโดยสรุป ผลกระทบทางช่องปากต่อกิจกรรมในชีวิตประจำวันและคุณภาพของฟันเทียมชิ้นล่างเป็นผลประเมิน ด้านอัตตวิสัยและวัตถุวิสัยที่ส่งผลต่อการตัดสินใจใช้กาวติดฟันเทียมในผู้ป่วยฟันเทียมทั้งปาก ตามลำดับ ผู้ป่วยฟันเทียมทั้งปากที่มีปัญหาเรื่องการกิน หรือปัญหาเรื่องอื่นๆและมีคุณภาพของฟัน เทียมล่างที่ไม่ผ่านเกณฑ์จะมีคุณภาพชีวิตในมิติสุขภาพช่องปากที่ดีขึ้นหลังจากใช้กาวติดฟันเทียม

5875818632 : MAJOR PROSTHODONTICS

KEYWORDS: COMPLETE DENTURE, DENTURE ADHESIVE, ORAL IMPACTS ON DAILY PERFORMANCES. PATIENT SATISFACTION, DENTURE QUALITY, DENTURE-SUPPORTING TISSUE

BUDSARA THONGYOI: SUBJECTIVE AND OBJECTIVE OUTCOMES ON DENTURE ADHESIVE USAGE AMONG COMPLETE DENTURE WEARERS. ADVISOR: ASST. PROF. WACHARASAK TUMRASVIN, D.D.S., Ph.D., 45 pp.

The propose of this clinical study was to evaluate the subjective and objective assessment factors affecting decision of complete denture wearers to use or not use denture adhesive. Sixty-six fully edentulous using upper and lower conventional complete dentures (aged 53 to 83 years) were recruited in this study. (1) Condition of denture-supporting tissue (ACP classification), (2) denture quality (CU-modified kapur criteria), (3) patients' satisfaction in prostheses and (4) oral impact on daily performances (OIDP) were evaluated as baseline (T0). All participants were assigned to use denture adhesive (Polident®, Ireland) for 1 month period and made decision by themselves to continue (Group U) or stop (Group NU) using denture adhesive. Patients' satisfaction in prostheses and OIDP were evaluated again at T1 (T0 + 1 month), and T2 (T1 + 1 month). The results showed that Group U had more significant proportion of unacceptable mandibular denture quality, dissatisfied with their prostheses and oral impact, compared with Group NU ($p<0.05$). The use of denture adhesive in Group U improved satisfaction in prostheses and oral impact along the study period, while Group NU had worsened on these parameters. Group NU had improved satisfaction in prostheses and oral impact again after they stop using denture adhesive. The results showed that denture adhesive did not necessary for all complete denture wearers. In conclusion, oral impact and mandibular denture quality were the best subjective and objective assessments affected the decision of complete denture wearers to use or not use denture adhesive, respectively. Complete denture wearers who had eating impact or had any activities impact and had unacceptable mandibular denture quality could be improved their OHRQoL after using denture adhesive.

Department: Prosthodontics   Student's Signature ....

Field of Study: Prosthodontics   Advisor's Signature ....

Academic Year: 2017

ACKNOWLEDGEMENTS

CONTENTS

CHAPTER I

INTRODUCTION

BACKGROUND AND RATIONALE

Conventional complete denture is one of the treatment of choices for complete edentulism patients. A successful of treatment can be determined by objective functional assessments, patients' acceptance, and satisfaction with their prostheses (1). However, even all treatment procedures has been done completely, in some clinical situations, patients might not satisfy with their dentures. Edentulism patients with conventional complete denture commonly show dissatisfaction with prostheses and report impaired oral health-related quality of life (OHRQoL) (2, 3). Therefore, implant-retained overdenture is promoted to be a treatment of choice for treatment of lower complete edentulism (4). Edentulism with implant-retained overdenture report better function and OHRQoL than conventional dentures (5, 6), nevertheless most of edentulous patients cannot receive implant-retained overdenture due to physical conditions and financial status (7).

Denture adhesive may be an alternative option to improve oral function and patient confidence in wearing prosthesis when properly used (8-10). The mode of action is activated by combine of adhesive and saliva to create retentive force between denture base and denture- supporting tissues (8). Clinical studies show denture adhesive enhance retention, stability (11-16), and objective masticatory efficacy (14, 17-20) in complete denture patients. The results of patient-based outcome studies showed patients' satisfaction and OHRQoL can be improved after using denture adhesive (13, 21-24). In Thailand, complete denture wearers can purchase denture adhesive by themselves without dentist prescription. However, there are no study reports the factors that affect the decision of complete denture wearers to use or not use denture adhesive. Denture adhesive is not always necessary for every complete denture wearers, unreasonably using it without discussion with dentist may waste money unnecessarily.

In view of the background, the aims of the study are to evaluate the subjective and objective assessment factors affecting decision of complete denture wearers to use or not use denture adhesive, in terms of oral impacts on daily performance, patients' satisfaction, denture quality, and condition of denture supporting tissues.

RESEARCH QUESTIONS

1. Which subjective assessment factors affect the decision of complete denture wearers to use or not use denture adhesive?
2. Which objective assessment factors affect the decision of complete denture wearers to use or not use denture adhesive?

RESEARCH OBJECTIVES

1. To assess and compare the oral impacts on daily performance and patients' satisfaction of complete denture wearers who decide to use and not use denture adhesive.
2. To assess and compare denture quality and denture-supporting tissue of complete denture wearers who decide to use and not use denture adhesive.
3. To assess and compare the oral impacts on daily performance and patient satisfaction among time interval within complete denture wearers who decide to use denture adhesive and complete denture wearers who decide to not use denture adhesive.
4. Investigate subjective assessment and objective assessment which most simple and best to predict whether complete denture wearers decide to use or not use denture adhesive.

RESEARCH HYPOTHESES

1. Ho_1 : There is no difference of oral impacts on daily performance scores between complete denture wearers who decide to use and not use denture adhesive at baseline (T0).

    Ha_1 : There is difference of oral impacts on daily performance scores between complete denture wearers who decide to use and not use denture adhesive at baseline (T0).

2. Ho_2 : There is no difference of overall patients' satisfaction scores between complete denture wearers who decide to use and not use denture adhesive at baseline (T0).

    Ha_2 : There is difference of overall patients' satisfaction scores between complete denture wearers who decide to use and not use denture adhesive at baseline (T0).

3. Ho_3 : There is no difference of proportion of denture quality between complete denture wearers who decide to use and not use denture adhesive at baseline (T0).

    Ha_3 : There is difference of proportion of denture quality between complete denture wearers who decide to use and not use denture adhesive at baseline (T0).

4. Ho_4 : There is no difference of proportion of denture-supporting tissue between complete denture wearers who decide to use and not use denture adhesive at baseline (T0).

    Ha_4 : There is difference of proportion of denture-supporting tissue between complete denture wearers who decide to use and not use denture adhesive at baseline (T0).

5. Ho_5 : There is no difference of oral impacts on daily performance scores along the study period (T0, T1, T2) within complete denture wearers who decide to use denture adhesive.

Ha$_5$: There is difference of oral impacts on daily performance scores along the study period (T0, T1, T2) within complete denture wearers who decide to use denture adhesive.

6. Ho$_6$: There is no difference of oral impacts on daily performance scores along the study period (T0, T1, T2) within complete denture wearers who decide to not use denture adhesive.

Ha$_6$: There is difference of oral impacts on daily performance scores along the study period (T0, T1, T2) within complete denture wearers who decide to not use denture adhesive.

7. Ho$_7$: There is no difference of patients' satisfaction scores along the study period (T0, T1, T2) within complete denture wearers who decide to use denture adhesive.

Ha$_7$: There is difference of patients' satisfaction scores along the study period (T0, T1, T2) within complete denture wearers who decide to use denture adhesive.

8. Ho$_8$: There is no difference of patients' satisfaction score along the study period (T0, T1, T2) within complete denture wearers who decide to not use denture adhesive.

Ha$_8$: There is difference of patients' satisfaction scores along the study period (T0, T1, T2) within complete denture wearers who decide to not use denture adhesive.

CONCEPTUAL FRAMEWORK
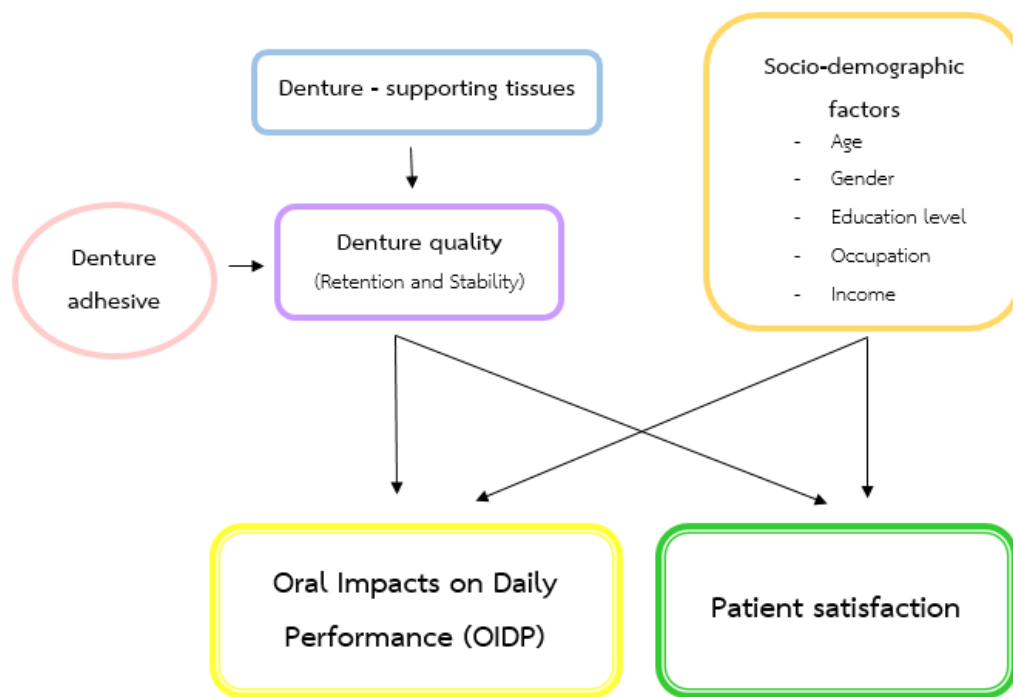
KEY WORDS :   complete denture, denture adhesive, oral impacts on daily performances,

   patient satisfaction, denture quality, denture-supporting tissue

RESEARCH DESIGN

   A clinical study

EXPECTED BENEFITS

1. The result obtained from this study will reveal the influence of subjective and objective assessment factors on decision of complete denture wearers to use or not use denture adhesive.

2. The results will inform which measurement, in any significant level, is best for dentist to prescribe denture adhesive to their complete denture patients.

3. The results will reveal which subjective assessments and objective assessments most simple and best to predict whether complete denture wearers decide to use or not use denture adhesive.

CHAPTER II

REVIEW OF RELATED LITERATURES

Denture adhesive is defined as a material used to adhere a denture to the oral mucosa (25). American Dental Association, Council on Dental Materials, Instruments and Equipment characterized denture adhesives as nonmedical products in 1935 (26). There are many available commercial denture adhesives in formulations of creams, powder, pads/wafers and strips. The mode of action is provided an interface and form a retentive force between the denture base and the denture-supporting tissue, when combine of the adhesive, saliva, and oral fluids (8). According to Grasso (9), denture adhesives can be divided into insoluble and soluble groups. The insoluble group includes wafers and pads. The main ingredients are a fabric carrier and a component that becomes sticky when hydrated. The soluble group consists of creams, powders and pastes. The active ingredients are a blend of polymer salts with differing degree of water solubility. A blend of polymer salts affect the activation process of adhesive and produce a product with short- and long-term action, Carboxymethylcellulose (CMC) and Polyvinylether methyl cellulose (PVM-MA), respectively. Denture adhesive with short-term acting salts have its high solubility level, so it dissolves quickly and loses of its effectiveness within a short period of time. While an adhesive with long-term acting salts has a low solubility level, it become last longer (9). The duration of action range between 3 - 12 hours, based on formulations of denture adhesive and results from patient subjective assessment (21, 27). The common components and its respective functions of denture adhesives are listed in **Table 1** (28).

Table 1 Denture adhesive component

Materials	Purpose
Methyl vinyl ether-maleic anhydride copolymer	High molecular weight copolymers with adhesive and coadhesive properties
Karaya gum	Thickener
Tragacanth	Water-soluble mixture of polysaccharides that absorbs water to become a gel
Acacia	Preservative
Pectin	Gelling agent
Gelatin	Gelling agent
Carboxy methyl cellulose	Viscosity modifier/thickener
Mineral oil	Suspending and levigating agent
Antimicrobial agents	Antimicrobial
Non-toxic additives	Wetting agents and plasticizers
Flavoring agents	Improve taste

The incidence of denture adhesive usage was reported in 26% and 20% of Greek and Dutch complete denture patients, respectively (29). The other study (10) shown 32.9% of patients had experienced to use denture adhesive, but only 6.9% continued to use it daily. A Delphi technique survey in an expert panelist of American dental schools concluded that denture adhesives are a useful adjunct in prosthesis services (30). Denture adhesive can be used in fabrication phase of conventional complete denture to stabilize trial bases for accurate jaw relation record and denture try-in stage (8, 26). There are no any publish state that denture adhesive can cause mucosal irritation of denture-supporting tissues (31), or increase in micro-organisms of the oral flora (32, 33), when properly used.

The effectiveness of denture adhesives has been investigated in the view of objective and subjective assessment (11-24, 34, 35). Clinical studies have demonstrated that denture adhesive enhance retention and stability of dentures (11-15), especially in ill-fitting dentures (16). Some studies show that maximum occlusal force (17, 18)

and masticatory efficacy (14, 18-20) can be increased, while the others (11, 34) reports no effect of denture adhesive on them. Denture adhesive can reduce movement of both upper and lower dentures during chewing and biting (35).

Apart from the objective outcomes, patient-based outcome in denture adhesive has investigated (13, 21-24). Many authors (13, 21, 22) report that denture adhesive improve patients' satisfaction in complete denture wearers. Nicolas *et al* (23) assessed OHRQoL in new conventional complete dentures wearers by using General Oral Health Assessment Index (GOHAI). They found that denture adhesive enhance OHRQoL and improve subject's ability to manage prostheses (23). Polyzois *et al* (24) had also studied OHRQoL on patients who had a new set of conventional complete dentures, using the Oral Health Impact Profile-14 index (OHIP-14). They concluded that after using denture adhesive for at least 15 days, the OHIP-14 score decreased. The results indicated that denture adhesive can improve patient's OHRQoL in short period.

Patient-based outcome is one of an indicator to evaluate the success of prosthodontics treatment. Patients' satisfaction and OHRQoL always use as an outcome measure. The common response scales of patients' satisfaction are Likert-scale (36) and visual analogue scales (37). There are several factors that influence patients' satisfaction with complete dentures. Those factors are patient-related factors and oral conditions (36, 38, 39), dentists' technical (38), patient-dentist relationship (38), and quality of the prostheses (36, 40). van Wass MA (40) studied quality of complete dentures in terms of occlusion, arrangement of the teeth, and border of denture extension. This study found the positive correlation between quality of dentures and patients' satisfaction. Other study (36) also reported the strongest correlation of denture quality and patients' satisfaction. The physical conditions of denture-supporting tissues have no effect on patients' satisfaction (40), but influence the objective masticatory efficiency in edentulous patients (41).

Assessment of patients' satisfaction might not capture the multidimensional of quality of life, so OHRQoL always use to evaluate the effectiveness of dental treatment. OHRQoL have been developed to evaluate the impact of oral health and functional status on quality of life (42). This concept is not only focused on a clinical condition, but also involves the psychosocial condition of patients (43). Many studies

(2, 3, 44) have assessed OHRQoL among complete denture wearers by using several instruments. Oral Impacts on Daily Performances (OIDP) index is one of an OHRQoL instrument, developed by Adulyanon and Sheiham (45). The OIDP index aims to focuses on measuring the oral impact on patients' daily activities (45). The theoretical framework of OIDP index is presented in **Figure 1**.
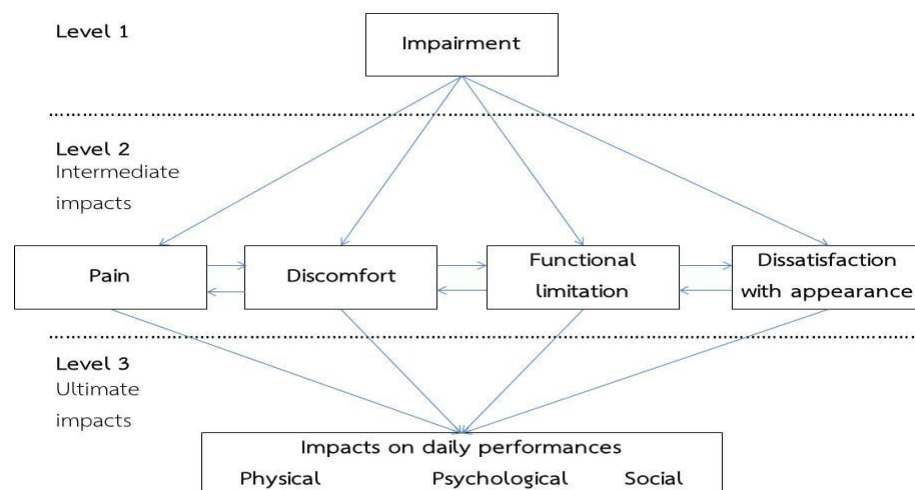
Figure 1 Theoretical framework of OIDP index.

The OIDP index measures in three levels (45). The first level is oral impairment. The second level, the intermediate impact, includes the possible earliest negative impact caused by oral impairment: pain, discomfort, functional limitation and dissatisfaction with appearance. The third level, the ultimate impacts, represents the oral impact on the ability to perform daily activities which consists of physical, psychological and social performances. The eight daily activities of OIDP index is shown in **Table 2**.

Table 2 Performances assessed in the Oral Impacts on Daily Performances

a. Eating and enjoying food

b. Speaking and pronouncing clearly

c. Cleaning teeth / denture

d. Sleeping and relaxing

e. Smiling, laughing and showing teeth without embarrassment

f. Maintain usual emotional state without being irritable

g. Carrying out major work or social role

h. Enjoying contact with people

In Thailand, the OIDP index has been use as instrument in OHRQoL measure (44, 46). The validation test of contents of OIDP index had been studied in Thai elderly (44) and teenagers (47). OIDP is used to assess the impact of oral condition on daily life of patients (44), and evaluate the effectiveness of dental treatment (48, 49). Sirithepmontree (50) assessed OHRQoL in Thai elderly patients after attending the Royal Prosthesis Denture Program, using OIDP index. The result shown the majority of patients have high to very high level of OHRQoL. Suepatthima (51) had also studies OHRQoL in Thai complete dentures wearers. This study reported 71% of complete dentures wearers have no oral impacts on daily life, and most common difficulties were eating and speaking, respectively. There are no any publish in the study of OIDP index in complete denture wearers who decide to use and not use denture adhesive. One of the aims of this study is to evaluate the OIDP of Thai complete denture wearers who decide to use and not use denture adhesive.

CHAPTER III

RESEARCH AND METHODOLOGY

POPULATION AND SAMPLE

1. **Population**

   Thai people who used a conventional complete dentures.

2. **Study population**

   Thai edentulous patients who used a conventional complete dentures treated by undergraduated or postgraduated students in Prosthodontics Department, Faculty of Dentistry, Chulalongkorn University.

3. **Study sample**

   Thai edentulous patients from the above mentioned study population who used a conventional complete dentures and passed all inclusion criteria.

CRITERIA

Inclusion criteria

1. Participants who used an upper and lower conventional complete dentures and treated by undergraduated students or postgraduated students in Prosthodontics Department at Faculty of Dentistry, Chulalongkorn University, Bangkok, Thailand.

2. Participants have been used upper and lower conventional complete dentures at least 6 months after denture delivery.

3. Participants were able to understand and communicate in Thai language.

4. Participants who signed an informed consent to attend.

Exclusion criteria

1. Participants who used only a single denture.

2. Participants who had implant-retained overdenture.

3. Inability to use hands in a proper way.

4. Inability to communicate in a proper way.

5. Participants who used denture adhesive daily.

6. Participants who had history of denture adhesive allergy.

7. Participants who could not attend the whole study.

This study protocol was approved by NO. 036/2016 The Human Research Ethics Committee of the Faculty of Dentistry, Chulalongkorn University, Bangkok, Thailand. All patients signed a written consent form prior to the onset of the study.

DATA COLLECTION

1. **Socio-demographic data**
   i.   Age
   ii. Gender
   iii. Education level
   iv. Occupation
   v.   Income
2. **Clinical data regarding the prosthesis**
   i.   **Condition of denture-supporting tissue** by using The American College of Prosthodontists (ACP) classification system for complete edentulism (52). The checklist was shown in **Table 3**.

Table 3 Checklist for Classification of Complete Edentulism

	Class I	Class II	Class III	Class IV
Bone height-mandibular	21 mm or greater	16–20 mm	11-15 mm	10 mm or less
Residual ridge Morphology-Maxilla	Type A – resist vertical & horizontal, hamular notch, no tori	Type B – no buccal vestibule, poor hamular notch, no tori	Type C – no anterior vestibule minimum support, mobile anterior ridge	Type D – no anterior/posterior vestibule, tori, redundant tissue
Muscle attachments-Mandibular	Type A – adequate attach mucosa	Type B – no buccal attach mucosa	Type C – no anterior, buccal and lingual vestibule	Type D – attach mucosa only in posterior
Maxillo-mandibular relationships	Class I	Class I	Class I Class II Class III	Class I Class II Class III
Conditions requiring preprosthetic surgery	No	No	Minor soft/hard tissue procedures	Hard tissue augmentation
Limited interarch space	No	No	18-20 mm	Surgical correction needed
Tongue anatomy	No	No	Large	Hyperactive – with retracted position
Oral manifestations of systemic disease	No	Mild	Moderate	Severe

Note : When a patient's diagnostic criteria are mixed between two or more classes, any single criterion of a more complex class places the patient into the more complex class.

In this study, we classified ACP classification I and II as uncomplicated denture-supporting tissue, and classified ACP classification III and IV as complicated denture-supporting tissue.

ii. **Denture quality**

Each maxillary and mandibular dentures was evaluated by CU-modified kapur criteria (53). The retention and stability criteria was shown in **Table 4**, and clinical quality interpretation was shown in **Table5**.

Table 4 CU-modified Kapur criteria used for evaluating denture quality

Score	Retention criteria	Stability criteria
0	(No): displaced itself when seated	(No): extreme visible rocking or horizontal movement (> 4mm)
1	(Minimum): slight resistance to 2.5 N verticall pulling and/or lateral force (2.5 to 5 N for dislodgement)	(Some): moderate rocking or horizontal movement (2 - 4mm)
2	(Moderate): moderate resistance to 5 N verticall pulling and/or lateral force (5 to 10 N for dislodgement)	(Sufficient): slightly/no rocking or horizontal movement (1 - 2mm)
3	(Good): maximum resistance to verticall pulling and/or lateral force (> 10 N for dislodgement)	

Table 5 Clinical denture quality interpretation of CU-modified Kapur criteria

CU-modified kapur	Retention score	Stability score
Acceptable maxillary denture	≥ 2	2
Acceptable mandibular denture	≥ 1	2
Acceptable CD	Acceptable both maxillary and mandibular dentures	

One examiner evaluated condition of denture-supporting tissues and denture quality. Intra-individual reliability of one examiner in assessment of denture-supporting tissues and denture quality was performed to make sure that the examiners' measurement was reliable, by repeating the assessment two times in different visits. The agreement in intra-individual reliability was tested using cronbach's alpha coefficients (α). From pilot study, there was a very good in intra-individual reliability for assessment of denture-supporting tissues (α= 1.00) and denture quality (α = 0.88).

3. **Assessment of overall patients' satisfaction in their prostheses**

The participants were asked to rate their overall satisfaction in prostheses by using a five-point Likert scales (36) [1 = not at all satisfied, 2 = slightly satisfied, 3 = moderately satisfied, 4 = very satisfied and 5 = extremely satisfied]. Participants who rated score 4 and 5 were categorized as satisfied in prostheses, while those who rated score 1, 2, and 3 were categorized as dissatisfied in prostheses.

4. **Assessment of Oral Health-Related Quality of Life (OHRQoL)**

In this study, OHRQoL was assessed by using a Thai version of the Oral Impacts on Daily Performances (OIDP) index (45). One interviewer for all patients. For the OIDP index, possible difficulties with eight daily activities was investigated. These activities were eating, speaking, cleaning oral cavity and dentures, relaxing including sleeping, smiling, maintaining emotional state, contact with others and working. If the patients had any experienced of oral impacts on daily performances, the frequency and severity of the impact was scored using five-point Likert scales. The criteria of frequency and severity scores was shown in **Table 6**. If no any impact had experienced, a zero score was assigned.

Table 6 Criteria of frequency and severity scores of OIDP index

Frequency	Severity	Score
Less than once a month	Very little	1
Once or twice a month	Little	2
Once or twice a week	Moderate	3
3-4 times a week	Severe	4
Every or nearly every day	Very severe	5

Analysis of OIDP index

Overall impact scores

Overall impact scores was the sum of the eight performances scores, which each performance score was calculated by multiplying frequency and severity scores. The sum was divided by the maximum possible score (200) and multiplying by 100 to give a percentage score as shown in **Equation 1**.

$$\textbf{Overall impact scores} = \sum_{i=1}^{8} \frac{(frequency\ score_i\ \times\ severity\ score_i)}{maximum\ possible\ score} \times 100$$

If : i = Each daily performances 1 to 8

Equation 1 An equation of the overall impact scores.

STUDY PROTOCOL

Preoperatively, history taking, comprehensive oral and denture-supporting tissues examination, and evaluation of denture quality was carried out. The data of overall patients' satisfaction in prostheses and OIDP at the beginning of the study was used as baseline (T0). Participants were instructed to apply a denture adhesive (Polident®, GlaxoSmithKline, Ireland) according to spot method described by Grasso (26), onto the denture's tissue surfaces of maxillary and mandibular dentures, daily, for a 1-month period. At the second visit after 1 month (T1), participants were interviewed overall satisfaction and OIDP again, and were asked to choose whether they want to continue using or stop using the denture adhesive. At the end of the evaluation period (T2), one month after the second visit (T1), the participants were asked again for overall satisfaction and OIDP. Finally, participants were divided into two groups, which was continue using denture adhesive group (Group U) and stop using denture adhesive group (Group NU). The diagram of study protocol was presented in **Figure 2**.
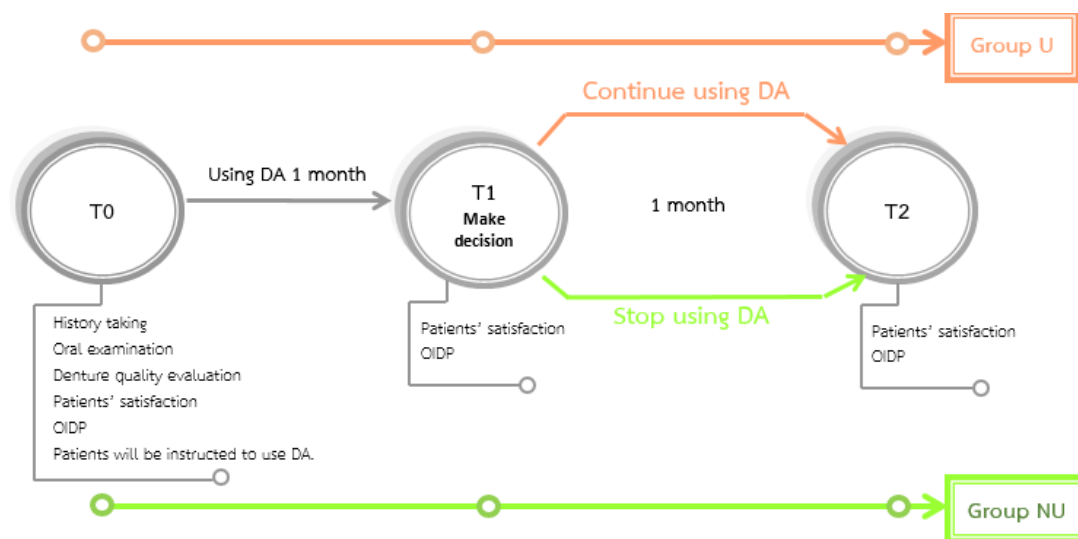
Figure 2 The diagram of study protocol
(DA = denture adhesive, Group U = continue using denture adhesive group,
Group NU = stop using denture adhesive group)

STATISTICAL ANALYSIS

The data was analyzed by the statistic package for the social science version 22 (SPSS, Chicago, IL). From pilot study, test of normality showed the data was not normal distribution, so nonparametric test will be used to analyze. For all statistical analyze, a P-value below 0.05 was considered statistically significant.

Socio-demographic data, condition of denture-supporting tissues, denture quality, patients' satisfaction in prostheses and oral impact between Group U and Group NU were determined by Chi-square test. The evaluation of patients' satisfaction scores and overall impact scores between two groups were analyzed by Mann-Whitney U test. To determine patients' satisfaction scores and overall impact scores within Group U and Group NU along the study period (T0, T1, and T2) were evaluated by using Wilcoxon signed-rank test.

Diagnostic test was used to assess which cut-off point of subjective and objective assessment best to predict participants improved OHRQoL after using denture adhesive.

CHAPTER IV

RESULTS

PART I

Sociodemographic data

A total number of participants was 66 (72.9% response rate), 39 males and 27 females. The age of participants ranged from 53 to 83 years, average 68.9 ± 7.1 years. At the end of the study, participants were divided into two groups according to whether they want to use denture adhesive (Group U) or not use denture adhesive (Group NU). Group U consists of 34 participants and Group NU consists of 32 participants. Sixty-seven-point six percentage of Group U and 50.0% of Group NU were male. Most of participants in Group U and Group NU had primary education level, unoccupied status, and had monthly income lower than 1,000 baht. There was no significantly different of sociodemographic data between Group U and Group NU (**Table 7**).

Oral characteristics and denture characteristic

The oral characteristics and denture characteristics between Group U and Group NU are shown in **Table 7**. Sixty-four-point seven percentage of Group U and 84.4% of Group NU had uncomplicated denture-supporting tissue (ACP classification I & II), while 35.3% of Group U and 15.6% of Group NU had complicated denture-supporting tissue (ACP classification III & IV). The results showed that participants in Group U had more two times of complicated denture-supporting tissue over than those in Group NU. Unfortunately, there was no significantly different of denture-supporting tissue between Group U and Group NU. An average (mean ± SD) age of dentures in Group U and Group NU were 1.9 ± 0.9 and 2.4 ± 1.7 years, respectively. There was no significant difference of denture age between Group U and Group NU. The evaluation of denture quality showed 97.1% of Group U and 96.9% of Group NU had acceptable maxillary denture quality. For mandibular denture quality, 38.2% of Group U had acceptable mandibular denture, while 71.9% of Group NU had acceptable

mandibular denture. There was significantly different of mandibular denture quality between Group U and Group NU (p = 0.006).

Table 7 Sociodemographic data, oral characteristic and denture characteristics according to denture adhesive usage (N = 66)

Characteristics	n (%) Distribution of denture adhesive usage		
	Group U (n = 34)	Group NU (n = 32)	p-value
1) Sociodemographic data			
Gender			
Male	23 (67.6)	16 (50.0)	0.145
Female	11 (32.4)	16 (50.0)	
Age			
Mean (SD)	68.4 (6.7)	69.4 (7.5)	0.621
Range	53 - 81	55 - 83	
Education level			
Primary level	18 (52.9)	21 (65.6)	0.295
> Primary level	16 (47.1)	11 (34.4)	
Occupation			
Occupied status	9 (26.5)	8 (25.0)	0.891
Unoccupied status	25 (73.5)	24 (75.0)	
Income			
≤ 1,000 Baht	19 (55.9)	19 (59.4)	0.215
> 1,000 Baht	15 (44.1)	13 (40.6)	
2) Oral characteristic			
Denture-supporting tissue			
Uncomplicated; ACP Classification I & II	22 (64.7)	27 (84.4)	0.068
Complicated; ACP Classification III & IV	12 (35.3)	5 (15.6)	
3) Denture characteristics			
Denture age, years			
Mean (SD)	1.9 (0.9)	2.4 (1.7)	0.290
Range	0.5 – 4.1	0.9 – 10.0	
Denture quality (CU-modified Kapur criteria)			
Maxillary denture quality			
Acceptable	33 (97.1)	31 (96.9)	1.000
Unacceptable	1 (2.9)	1 (3.1)	
Mandibular denture quality			
Acceptable	13 (38.2)	23 (71.9)	0.006*
Unacceptable	21 (61.8)	9 (28.1)	

Note: The association between outcome and categorical variables were determined by Chi-square or Fisher's Exact test, while that with continuous variables were determined by Mann-Whitney U test.

   * Indicates significant difference at p < 0.05.

Patient satisfaction and OHRQoL

The results of overall patients' satisfaction in their prostheses are shown in **Table 8** and **Figure 3**. At baseline (T0), 61.8% of Group U and 90.6% of Group NU were satisfied with their prostheses. The average satisfaction scores (mean ± SD) in prostheses scores of Group U and Group NU were 3.7 ± 0.9 and 4.6 ± 0.7, respectively. There was significantly different of proportion (p = 0.006) and scores (p = 0.000) of satisfaction in prostheses between Group U and Group NU. One month after using denture adhesive (T1), 91.2% of Group U were satisfied with their prostheses (mean ± SD; 4.3 ± 0.7), while 68.8% of Group NU were satisfied with their prostheses (mean ± SD; 4.1 ± 0.9). There was only significant difference of proportion (p = 0.022) of satisfaction in prostheses between Group U and Group NU, while satisfaction scores of two groups were in the same levels. At the end of the study (T2), 94.1% of Group U and 90.6% of Group NU were satisfied in their prostheses. The average (mean ± SD) satisfaction scores of Group U and Group NU were 4.6 ± 0.6 and 4.5 ± 0.7, respectively. There was no significantly different of proportion (p = 0.668) and scores (p = 0.619) of satisfaction in prostheses between Group U and Group NU. For Group U, they had significantly improved satisfaction in prostheses scores along the study period. For Group NU, they had significantly worsened satisfaction in prostheses scores when they were using denture adhesive at T1, and increased satisfaction scores again after they stop using denture adhesive at T2, as shown in **Figure 3**.

Table 8 Patients' satisfaction in their prostheses according to denture adhesive usage along the study periods at T0, T1, and T2 (N = 66)

| Patient's satisfaction | n (%) Distribution of denture adhesive usage | | | | | | | | |
| | T0 | | | T1 | | | T2 | | |
	Group U	Group NU	p-value	Group U	Group NU	p-value	Group U	Group NU	p-value
Satisfied	21 (61.8)	29 (90.6)	0.006*	31 (91.2)	22 (68.8)	0.022*	32 (94.1)	29 (90.6)	0.668
Dissatisfied	13 (38.2)	3 (9.4)		3 (8.8)	10 (31.2)		2 (5.9)	3 (9.4)	

Note: The association of patient's satisfaction and denture adhesive usage were determined by Chi-square or Fisher's Exact test. * Indicates significant difference at p < 0.05.

Figure 3 Patients' satisfaction in their prostheses scores according to denture adhesive usage along the study periods at T0, T1, and T2 (N = 66)
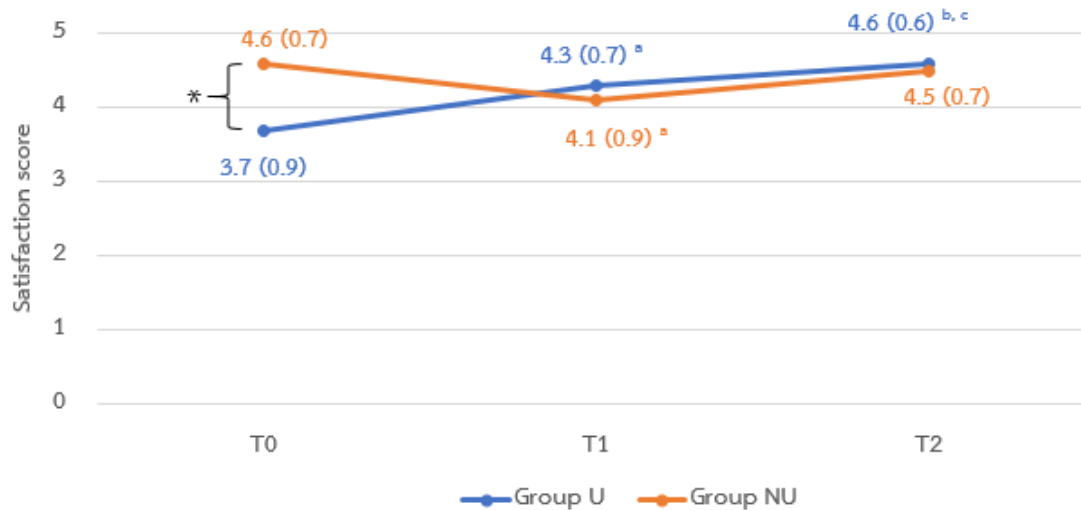
Note: * Indicates significant difference at $p < 0.05$ determined by Mann – Whitney U test.

[a] Significant difference within group between T0 and T1,

[b] Significant difference within group between T1 and T2,

[c] Significantly difference within group between T0 and T2 determined by Wilcoxon signed-rank test.

For OHRQoL, the results of oral impact between Group U and Group NU are shown in **Table 9** and **Figure 4**. At baseline (T0), the prevalence of oral impact on daily activities was 82.4% in Group U and 25.0% in Group NU. The overall impact scores of Group U ranged from 0 to 42.5 (maximum possible scores was 100), with an average (mean ± SD) score of 10.9 ± 11.3 and a median score of 7.5. The overall impact scores of Group NU ranged from 0 to 22.5 (maximum possible scores was 100), with an average (mean ± SD) score of 1.3 ± 4.1 and a median score of 0. There was a statistically significant difference of proportion ($p = 0.000$) and scores ($p = 0.000$) of oral impact between Group U and Group NU at baseline (T0). The characteristics of difficult daily activities of Group U and Group NU are shown in **Figure 5**. Difficult activities of Group U were found on eating, speaking, sleeping and relaxing, emotional stage, smiling, working and social contact activity. Difficult activities of Group NU were found on

eating, speaking and emotional stage. Difficulty of eating and speaking activities were significantly different between Group U and Group NU.

Table 9 Oral impact according to denture adhesive usage along the study periods at T0, T1, and T2 (N = 66)

Oral impact	n (%) Distribution of denture adhesive usage								
	T0			T1			T2		
	Group U	Group NU	p-value	Group U	Group NU	p-value	Group U	Group NU	p-value
Yes	28 (82.4)	8 (25.0)	0.000*	11 (32.4)	19 (59.4)	0.028*	7 (20.6)	1 (3.1)	0.055
No	6 (17.6)	24 (75.0)		23 (67.6)	13 (40.6)		27 (79.4)	31 (96.9)	

Note: The association of oral impact and denture adhesive usage were determined by Chi-square or Fisher's Exact test. * Indicates significant difference at $p < 0.05$.

Figure 4 Overall impact scores according to denture adhesive usage along the study periods at T0, T1, and T2 (N = 66)
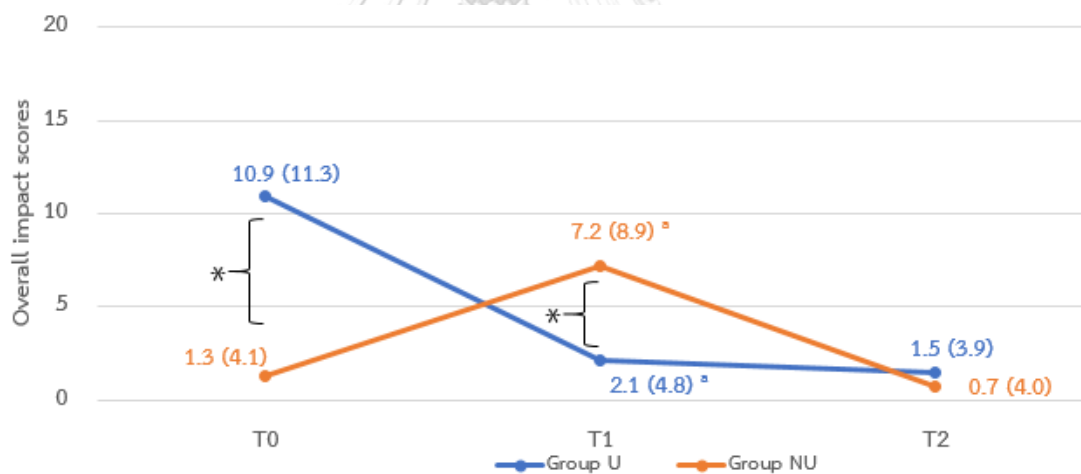
Note: * Indicates significant difference at $p < 0.05$ determined by Mann – Whitney U test.
  [a] Significant difference within group between T0 and T1determined by Wilcoxon signed-rank test.

Figure 5 Prevalence (%) of participants per difficult daily activities according to denture adhesive usage at baseline (T0)
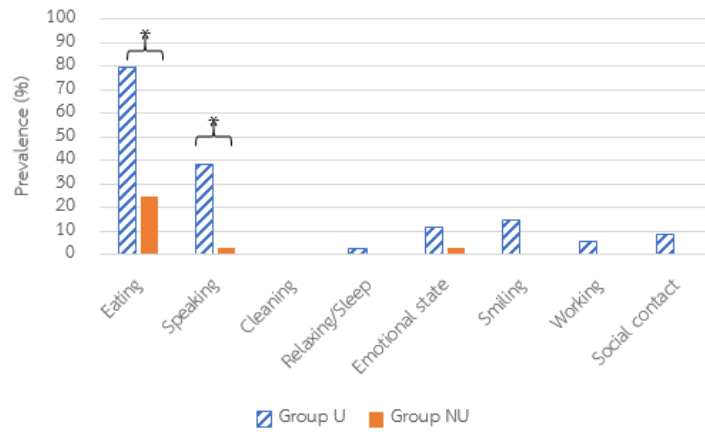
Note: * Indicates significant difference at $p < 0.05$

Figure 6 Prevalence (%) of participants per difficult daily activities according to denture adhesive usage at one month after using denture adhesive (T1)
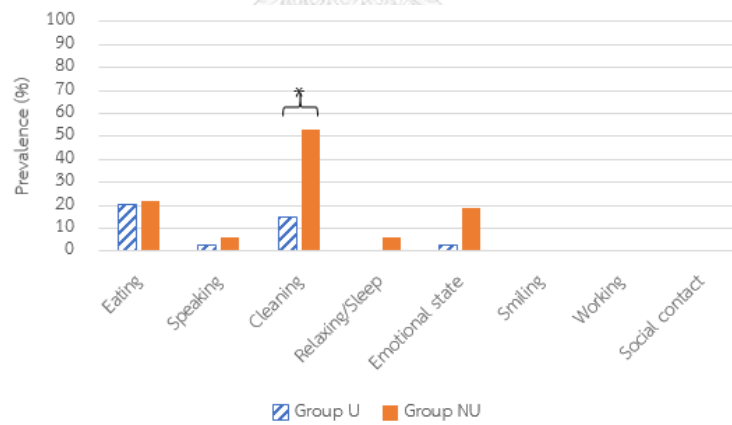
Note: * Indicates significant difference at $p < 0.05$

Figure 7 Prevalence (%) of participants per difficult daily activities according to denture adhesive usage at the end of the study (T2)
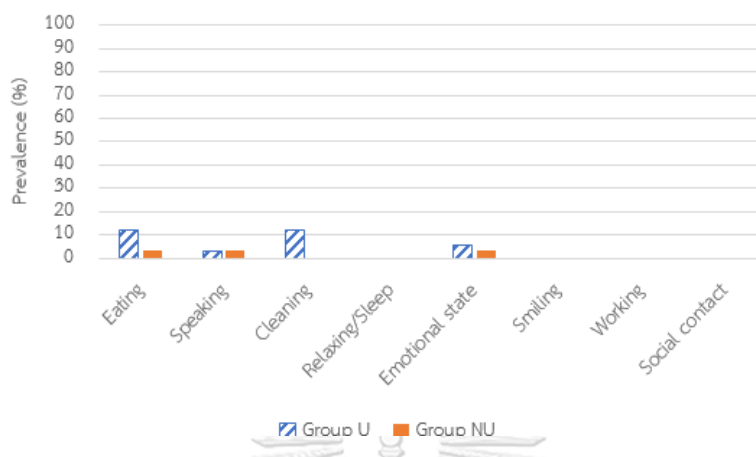
Note: * Indicates significant difference at $p < 0.05$

One month after using denture adhesive (T1), the prevalence of oral impact was 32.4% in Group U and 59.4% in Group NU (**Table 9**). The overall impact scores of Group U ranged from 0 to 24.5 (maximum possible scores was 100), with an average (mean ± SD) score of 2.1 ± 4.8 and a median score of 0. The overall impact scores of Group NU ranged from 0 to 37.5 (maximum possible scores was 100), with an average (mean ± SD) score of 7.2 ± 8.9 and a median score of 5. There was a statistically significant difference of proportion ($p = 0.028$) and scores ($p = 0.005$) of oral impact between Group U and Group NU at T1 (**Table 9** and **Figure 4**). The characteristics of difficult daily activities of Group U and Group NU is shown in **Figure 6**. Difficult activities of Group U were found on eating, speaking, cleaning mouth and dentures, and emotional stage. Difficult activities of Group NU were found on eating, speaking, cleaning mouth and dentures, sleeping and relaxing and emotional stage. Difficulty of cleaning mouth and dentures was significantly different between Group U and Group NU.

At the end of the study (T2), the prevalence of oral impact on daily activities was 20.6% in Group U and 3.1% in Group NU (**Table 9**). The overall impact scores of Group U ranged from 0 to 20.0 (maximum possible scores was 100), with an average

(mean ± SD) score of 1.5 ± 3.9 and a median score of 0. The overall impact scores of Group NU ranged from 0 to 22.5 (maximum possible scores was 100), with an average (mean ± SD) of 0.7 ± 4.0 and a median score of 0. There was no statistically significant difference of proportion (p = 0.055) and scores (p = 0.052) of oral impact between Group U and Group NU at T2 (**Table 9** and **Figure 4**). The characteristics of difficult daily activities of Group U and Group NU is shown in **Figure 7**. Difficult activities of Group U were found on eating, speaking, cleaning mouth and dentures, and emotional stage. Difficult activities of Group NU were found on eating, speaking, and emotional stage.

The use of denture adhesive in Group U improved overall impact scores along the study period. For Group NU, the use of denture adhesive worsen overall impact scores and improved overall impact scores again after they stop using denture adhesive, as shown in **Figure 4**.

Figure 8 Relationship between patients' satisfaction in prostheses scores and overall impact scores at baseline (T0), (r = -0.6, p < 0.01)
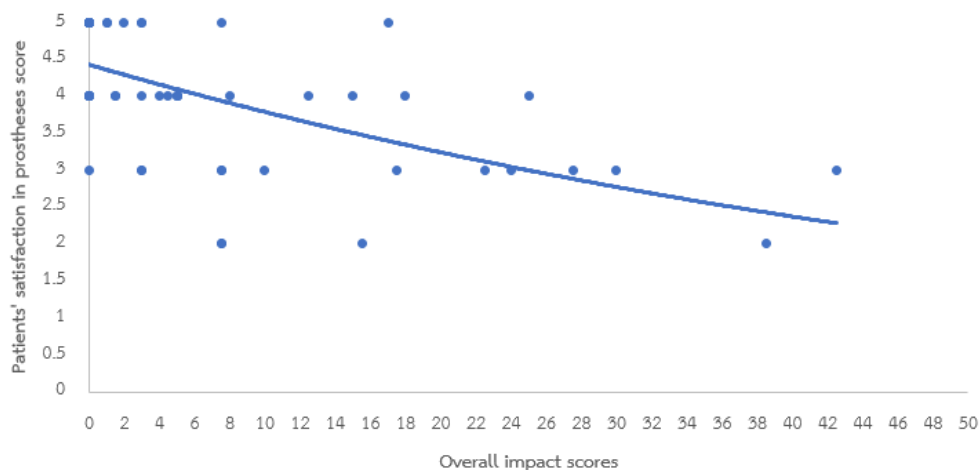
The relationship between patients' satisfaction in prostheses scores and overall impact scores at baseline (T0) was described in **Figure 8**. There was a significant negative relationship (r = -0.6, p < 0.01) between satisfaction scores and overall impact scores in complete denture wearers.

PART II

Investigate subjective assessment and objective assessment which most simple and best to predict whether complete denture wearers decide to use or not use denture adhesive

From the results of this study, an assessment of mandibular denture quality, patients' satisfaction in their prostheses and oral impact were significantly different between Group U and Group NU. The prevalence and scores of satisfaction in prostheses and oral impact at baseline (T0) according to the quality of mandibular denture are shown in **Table 10**. The results showed that overall impact scores was obviously describe the difference of mandibular denture quality. Although, there was no significant difference of overall impact scores according to mandibular denture quality, this can be explained by small sample size. Thus, the appropriate subjective and objective measurement for predicting whether complete denture wearers decide to use or not use denture adhesive were oral impact and mandibular denture quality, respectively.

Table 10 Prevalence and scores of patients' satisfaction in their prostheses and oral impact according to mandibular denture quality at baseline (T0)

| | | n (%) distribution of mandibular denture quality | | p-value |
		Acceptable	Unacceptable	
Patients' satisfaction	Satisfied	30 (83.3)	20 (66.7)	
	Dissatisfied	6 (16.7)	10 (33.3)	0.116
	scores; range	2 – 5	2 - 5	
	mean (SD)	4.3 (0.9)	4.0 (1.0)	0.296
	P (25, 50, 75)	4, 4, 5	3, 4, 5	
Oral imapct	Yes	18 (50.0)	18 (60.0)	
	No	18 (50.0)	12 (40.0)	0.417
	scores; range	0 – 42.5	0 – 30.0	
	mean (SD)	4.3 (9.4)	8.5 (9.9)	0.087
	P (25, 50, 75)	0, 0.5, 5.0	0, 3.5, 17	

Both oral impact and mandibular denture quality were significantly associated with denture adhesive usage. Analysis of the condition of participants and OHRQoL after using denture adhesive is showed in **Figure 9**. Diagnostic test was used to find out a cut-off point of oral imapct and mandibular denture quality which best to predict participants who had improved OHRQoL after using denture adhesive. The analysis showed that **"Participants who had eating impact or had any activities impact and had unacceptable mandibular denture quality improved OHRQoL after using denture adhesive"**. The sensitivity of diagnostic test was 100%, specificity = 84%, positive predictive value (PPV) = 83% and negative predictive value (NPV) = 100% (**Table 11**).

Figure 9 Analysis of participants conditions and OHRQoL after using denture adhesive (N = 66)
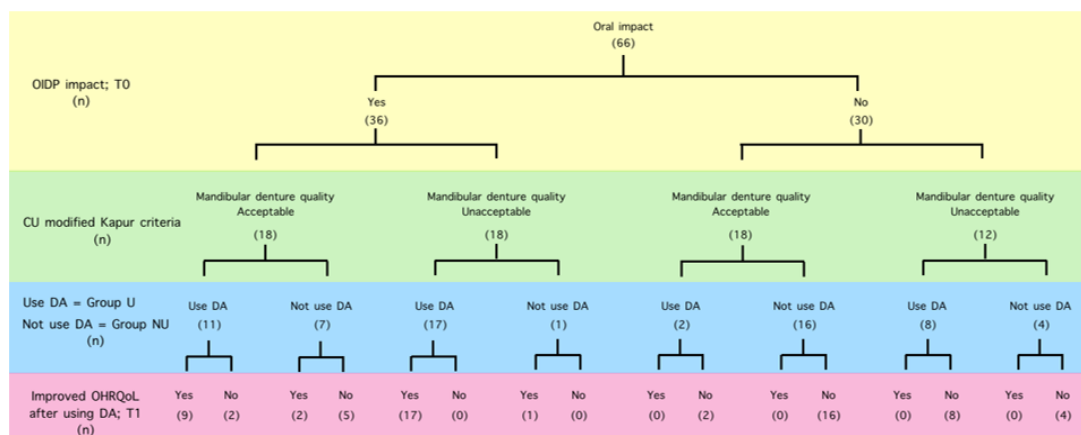
Table 11 Diagnostic table of participants conditions in predicting OHRQoL after using denture adhesive

Predictor of improved OHRQoL	Diagnostic test			
	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
Have oral impact	100	81	80	100
Have acceptable mandibular denture quality	38	32	31	40
Have eating impact or any activities impact and unacceptable mandibular denture quality	100	84	83	100

CHAPTER V

DISCUSSION AND CONCLUSION

DISCUSSION

This clinical study evaluated which subjective assessment and objective assessment affected the decision of complete denture wearers to use or not use denture adhesive. The design of this study was instructed all participants use denture adhesive for 1 month period, and made decision by themselves to use or not use denture adhesive. The study accepted the hypotheses of no difference proportion of condition of denture-supporting tissue between Group U and Group NU, but rejected the hypotheses of no difference proportion of mandibular denture quality between two groups. Results showed a significant improvement in patients' satisfaction in prostheses and OHRQoL when using denture adhesive only in Group U, compared with Group NU.

In this study, we found that there was no significantly different proportion of condition of denture-supporting tissue between Group U and Group NU by using an assessment of ACP classification. This guideline has been developed to classify the denture-supporting tissue for complete edentulism according to diagnostic findings, and ranked from classification I to IV based on degree of difficulty of treatment (52). It did not represent characteristic of each maxillary or mandibular conditions, but reported overall clinical quality of both maxillary and mandibular denture-supporting tissue. Therefore, ACP classification did not thoroughly describe the association of condition of denture-supporting tissue and denture adhesive usage.

According to the previous studies (36, 54), mandibular denture quality was importance in overall denture acceptance. Kulak (21) concluded that patients with ill-fitting mandibular denture reported poor satisfaction in prostheses and improved satisfaction again after using denture adhesive. This was consistent with the result from our study that there was a significant relationship between denture adhesive usage and the quality of mandibular denture. Group U had more proportion of unacceptable

mandibular denture quality than Group NU, and they had improved satisfaction in prostheses when they were using denture adhesive. Other studies have shown that denture adhesive improved retention and stability of dentures (11-15), especially in ill-fitting dentures (16). It improved denture stability and leaded patients being more comfortable with their dentures (23).

Prior to using denture adhesive, Group U presented high overall impact scores compared with Group NU. The most significant impact activities between two groups were eating and speaking which was a similar result to the previous study (51). After using denture adhesive, overall impact scores at T1 and T2 decreased significantly only in Group U, while Group NU increased overall impact scores significantly at T1 and decreased overall impact scores again at T2 after they chose to stop using denture adhesive. The value showed that denture adhesive improved OHRQoL, especially in those Group U participants who had reported high oral impact. This result confirmed previous reports that denture adhesive improved patients' ability to manage their dentures and enhance their OHRQoL (23, 34). Difficulty of eating and speaking activities were improved in Group U when using denture adhesive. The explanation of this improvement can be that denture adhesive limited the movement of dentures during function (35), and also had a cushioning effect which reduced the number of food particles trapped under denture flanges (8). Another explanation might be that denture adhesive increased masticatory efficiency (14, 18-20) and occlusal force (17, 18), while others studies (11, 34) reports no effect of denture adhesive on them. On the other hands, the use of denture adhesive can cause problems or worsen OHRQoL, especially those in Group NU participants who had low oral impact at the beginning of the study. In this study, we found that Group NU had more significant of oral impact than Group U after using denture adhesive. Difficult in cleaning their mouth and dentures was the most impact activity. Participants in Group NU reported that denture adhesive was sticky, messy, and difficulty to remove from oral tissues and denture surface. An Australian study (10) surveyed the incidence of denture adhesive usage found that complete denture wearers ceased using denture adhesive because they did not feel denture adhesive perform to their satisfaction. This demonstrated that denture adhesive did not necessary for all complete denture wearers.

Patients' satisfaction in prostheses and oral impact was used as subjective measurement in this study. The negative relationship between satisfaction scores and overall impact scores showed that if participants had high patients' satisfaction in prostheses scores, they also had low overall impact scores, and vice versa. This showed that participants who had a greater OHRQoL were satisfied with their prostheses. This result confirmed previous reports that there was association between patient satisfaction and OHRQoL (55, 56). In our study, we found that OIDP can be obviously describe participants with different condition of mandibular denture quality, compared to patients' satisfaction. The reason is OIDP index focuses on measuring the oral impact on patients' daily activities (45).

An important finding of this study was that participants who had eating impact or any activities impact and had unacceptable mandibular denture quality improved OHRQoL after using denture adhesive. Diagnostic test was used to verify probability of this situation. Sensitivity and specificity value from diagnostic test were in high level. Positive predictive value of this situation was 83%. If 100 participants had eating impact or any activities impact and had unacceptable mandibular denture quality, 83 participants were improved OHRQoL after using denture adhesive. Analysis of result showed six participants who had eating impact and had acceptable mandibular denture quality reported that OHRQoL was not improved after using denture adhesive. This indicated 16% of false positive of the test. In this study, we accepted the probability of false positive, because if participants with those condition tried to use denture adhesive and they do not perceive improvement of OHRQoL, they usually cease using denture adhesive by themselves. In this study, participants who had deteriorated dentures were informed about their denture quality condition. If they needed to receive a new set of dentures, they were placed on a waiting list.

Although results were being obvious, the problem of small sample size remains a concern. A long-term assessment with higher number of participants need to be implemented to further evaluate the results. It was noted that both patients based outcome and clinician evaluation were important in evaluating the decision of complete denture wearers to use or not use denture adhesive. It is important to note that the design of study led participants use a denture adhesive at no cost, which may

be a limitation of the study. Although a denture adhesive improved OHRQoL and patients' acceptance of prostheses, periodic recall for possible adjustment remains essential for complete denture wearers (1).

CONCLUSIONS

Within the limitations of this study, it can be summarized as follow:

1. Group U had more significant proportion of unacceptable mandibular denture quality, oral impact and dissatisfied with their prostheses, compared with Group NU.

2. Oral impact and mandibular denture quality can be used as a predictor for evaluating OHRQoL after using denture adhesive in complete denture wearers who decide to use or not use denture adhesive.

3. Complete denture wearers who had eating impact or had any activities impact and had unacceptable mandibular denture quality can be improved their OHRQoL after using denture adhesive.

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APPENDIX

Appendix A. n (%) Distribution of difficult activities according to denture adhesive usage at T0, T1, and T2 (N = 66)

Difficult activities		n (%) Distribution of denture adhesive usage								
		T0			T1			T2		
		Group U	Group NU	p-value	Group U	Group NU	p-value	Group U	Group NU	p-value
Eating	No	7 (20.6)	24 (75.0)	0.000	27 (79.4)	25 (78.1)	0.898	30 (88.2)	31 (96.9)	0.357
	Yes	27 (79.4)	8 (25.0)		7 (20.6)	7 (21.9)		4 (11.8)	1 (3.1)	
	range	0 - 25	0 - 15		0 - 15	0 - 25		0 - 10	0 - 15	
	mean (SD)	10.5 (7.8)	1.6 (3.6)	0.000	1.8 (4.1)	3.3 (6.8)	0.673	1.0 (2.9)	0.5 (2.7)	0.208
	P(25, 50, 75)	(6, 9.5, 15)	(0, 0, 1)		(0, 0, 0)	(0, 0, 0)		(0, 0, 0)	(0, 0, 0)	
Speaking	No	21 (61.8)	31 (96.9)	0.001	33 (97.1)	30 (93.8)	0.608	33 (97.1)	31 (96.9)	1.000
	Yes	13 (38.2)	1 (3.1)		1 (2.9)	2 (6.3)		1 (2.9)	1 (3.1)	
	range	0 - 25	0 - 15		0 - 20	0 - 15		0 - 20	0 - 15	
	mean (SD)	6.0 (8.8)	0.5 (2.7)	0.001	0.6 (3.4)	0.6 (2.7)	0.546	0.6 (3.4)	0.5 (2.7)	0.988
	P(25, 50, 75)	(0, 0, 12)	(0, 0, 0)		(0, 0, 0)	(0, 0, 0)		(0, 0, 0)	(0, 0, 0)	
Cleaning	No	34 (100.0)	32 (100.0)	None report	29 (85.3)	15 (46.9)	0.001	30 (88.2)	32 (100.0)	0.114
	Yes	0	0		5 (14.7)	17 (53.1)		4 (11.8)	0	
	range	0	0		0 - 20	0 - 25		0 - 15	0	
	mean (SD)	0	0	1.000	1.8 (4.8)	7.1 (7.8)	0.001	1.1 (3.2)	0	0.047
	P(25, 50, 75)	(0, 0, 0)	(0, 0, 0)		(0, 0, 0)	(0, 6, 15)		(0, 0, 0)	(0, 0, 0)	
Relax/Sleep	No	33 (97.1)	32 (100.0)	1.000	34 (100.0)	30 (93.8)	0.231	34 (100.0)	32 (100.0)	None report
	Yes	1 (2.9)	0		0	2 (6.3)		0	0	
	range	0 - 10	0		0	0 - 15		0	0	
	mean (SD)	0.3 (1.7)	0	0.932	0	0.8 (3.0)	0.142	0	0	1.000
	P(25, 50, 75)	(0, 0, 0)	(0, 0, 0)		(0, 0, 0)	(0, 0, 0)		(0, 0, 0)	(0, 0, 0)	

Difficult activities		o (%) Distribution of denture adhesive usage								
		T0			T1			T2		
		Group U	Group NU	p-value	Group U	Group NU	p-value	Group U	Group NU	p-value
Emotion	No	30 (88.2)	31 (96.9)	0.357	33 (97.1)	26 (81.3)	0.051	32 (94.1)	31 (96.9)	1.000
	Yes	4 (11.8)	1 (3.1)		1 (2.9)	6 (18.8)		2 (5.9)	1 (3.1)	
	range	0 - 12	0 - 15		0 - 5	0 - 25		0 - 5	0 - 15	
	mean (SD)	1.2 (3.4)	0.5 (2.7)	0.208	0.1 (0.9)	2.7 (6.4)	0.033	0.3 (1.1)	0.5 (2.7)	0.619
	P(25, 50, 75)	(0, 0, 0)	(0, 0, 0)		(0, 0, 0)	(0, 0, 0)		(0, 0, 0)	(0, 0, 0)	
Smiling	No	29 (85.3)	32 (100.0)	0.054	34 (100.0)	32 (100.0)	None report	34 (100.0)	32 (100.0)	None report
	Yes	5 (14.7)	0		0	0		0	0	
	range	0 - 25	0		0	0		0	0	
	mean (SD)	1.9 (5.5)	0	0.025	0	0	1.000	0	0	1.000
	P(25, 50, 75)	(0, 0, 0)	(0, 0, 0)		(0, 0, 0)	(0, 0, 0)		(0, 0, 0)	(0, 0, 0)	
Working	No	32 (94.1)	32 (100.0)	0.493	34 (100.0)	32 (100.0)	None report	34 (100.0)	32 (100.0)	None report
	Yes	2 (5.9)	0		0	0		0	0	
	range	0 - 12	0		0	0		0	0	
	mean (SD)	0.5 (2.3)	0	0.167	0	0	1.000	0	0	1.000
	P(25, 50, 75)	(0, 0, 0)	(0, 0, 0)		(0, 0, 0)	(0, 0, 0)		(0, 0, 0)	(0, 0, 0)	
Social contact	No	31 (91.2)	32 (100.0)	0.239	34 (100.0)	32 (100.0)	None report	34 (100.0)	32 (100.0)	None report
	Yes	3 (8.8)	0		0	0		0	0	
	range	0 - 25	0		0	0		0	0	
	mean (SD)	1.4 (5.0)	0	0.088	0	0	1.000	0	0	1.000
	P(25, 50, 75)	(0, 0, 0)	(0, 0, 0)		(0, 0, 0)	(0, 0, 0)		(0, 0, 0)	(0, 0, 0)	

Appendix B. n (%) Distribution of difficult activities according to mandibular denture quality at baseline, T0 (N = 66)

Mandibular denture quality		n (%) Distribution of denture adhesive usage		
		Accept	Unaccept	p-value
Eating	No	19 (52.8)	12 (40.0)	0.300
	Yes	17 (47.2)	18 (60.0)	
	range	0 - 25	0 - 25	
	mean (SD)	4.3 (6.1)	8.5 (8.6)	0.060
	P(25, 50, 75)	(0, 0, 7.5)	(0, 7, 15)	
Speaking	No	33 (91.7)	19 (63.3)	0.005
	Yes	3 (8.3)	11 (36.7)	
	range	0 - 25	0 - 25	
	mean (SD)	1.7 (6.0)	5.3 (7.9)	0.009
	P(25, 50, 75)	(0, 0, 0)	(0, 0, 12)	
Cleaning	No	36 (100.0)	30 (100.0)	None report
	Yes	0	0	
	range	0	0	
	mean (SD)	0	0	1.000
	P(25, 50, 75)	(0, 0, 0)	(0, 0, 0)	
Relax/Sleep	No	35 (97.2)	30 (100.0)	1.000
	Yes	1 (2.8)	0	
	range	0 - 10	0	
	mean (SD)	0.3 (1.7)	0	0.361
	P(25, 50, 75)	(0, 0, 0)	(0, 0, 0)	

Mandibular denture		n (%) Distribution of denture adhesive usage		
		Accept	Unaccept	p-value
Emotion	No	35 (97.2)	26 (86.7)	0.169
	Yes	1 (2.8)	4 (13.3)	
	range	0 - 10	0 - 15	
	mean (SD)	0.3 (1.7)	1.5 (4.1)	0.107
	P(25, 50, 75)	(0, 0, 0)	(0, 0, 0)	
Smiling	No	35 (97.2)	26 (86.7)	0.169
	Yes	1 (2.8)	4 (13.3)	
	range	0 - 25	0 - 15	
	mean (SD)	0.7 (4.2)	1.3 (3.9)	0.123
	P(25, 50, 75)	(0, 0, 0)	(0, 0, 0)	
Working	No	35 (97.2)	29 (96.7)	1.000
	Yes	1 (2.8)	1 (3.3)	
	range	0 - 12	0 - 6	
	mean (SD)	0.3 (2.0)	0.2 (1.1)	0.914
	P(25, 50, 75)	(0, 0, 0)	(0, 0, 0)	
Social contact	No	34 (94.4)	29 (96.7)	1.000
	Yes	2 (5.6)	1 (3.3)	
	range	0 - 25	0 - 6	
	mean (SD)	1.1 (4.8)	0.2 (1.1)	0.643
	P(25, 50, 75)	(0, 0, 0)	(0, 0, 0)	

Appendix C. Table 2x2 of participants conditions in predicting OHRQoL after using denture adhesive (n), Total = 66

		Improve OHRQOL after using denture adhesive		
		Yes	No	Total
Oral impact	Yes	29	7	36
	No	0	30	30
	Total	29	37	66

		Improve OHRQOL after using denture adhesive		
		Yes	No	Total
Acceptable mandibular denture quality	Yes	11	25	36
	No	18	12	30
	Total	29	37	66

		Improve OHRQOL after using denture adhesive		
		Yes	No	Total
Have eating impact or any activities impact and unacceptable mandibular denture quality	Yes	29	6	35
	No			31
		0	31	
	Total	29	37	66

Appendix D. Statistical analysis of relationship between patients' satisfaction in prostheses scores and overall impact scores at baseline (T0)

Correlations

		OIDP1_Percent	Satisfaction1_score
OIDP1_Percent	Pearson Correlation	1	-.600[**]
	Sig. (2-tailed)		.000
	N	66	66
Satisfaction1_score	Pearson Correlation	-.600[**]	1
	Sig. (2-tailed)	.000	
	N	66	66

**. Correlation is significant at the 0.01 level (2-tailed).

Note: OIDP1_Percent = Overall impact scores at baseline (T0)

Satisfaction1_score = Patients' satisfaction in prostheses scores at baseline (T0)
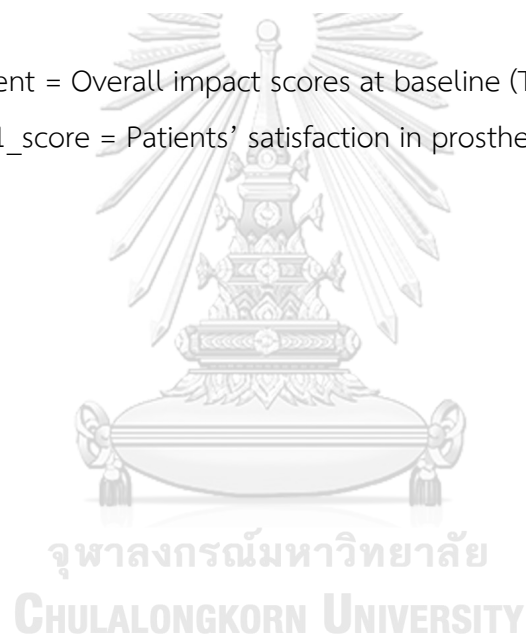
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