

Comparing patient-reported outcome measures among 3 methods of dental implant  
placement



A Thesis Submitted in Partial Fulfillment of the Requirements  
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การเปรียบเทียบผลที่ผู้ป่วยเป็นผู้รายงานระหว่างการฝังรากฟันเทียม 3 วิธี



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งานวิจัยนี้มีจุดประสงค์เพื่อเปรียบเทียบผลที่ผู้ป่วยเป็นผู้รายงาน ระหว่างผู้ป่วยที่ได้รับการผ่าตัดฝังรากฟันเทียม 3 วิธี ได้แก่ ก.วิธีการใช้มืออย่างอิสระ ข.วิธีการใช้คอมพิวเตอร์ช่วยนำทางอย่างพลวัต ค.วิธีการใช้คอมพิวเตอร์ช่วยนำทางอย่างสถิต ผู้ป่วยจำนวน 90 คน ได้รับการแบ่งเป็น 3 กลุ่ม กลุ่มละ 30 คนโดยการสุ่มเพื่อเข้ารับการฝังรากฟันเทียมด้วยวิธีใดวิธีหนึ่งใน 3 วิธีดังกล่าว เก็บข้อมูลโดยให้ผู้ป่วยตอบแบบสอบถาม 3 ชุด ได้แก่ ชุดที่หนึ่งสอบถามความคาดหวังก่อนการผ่าตัด ชุดที่สองสอบถามอาการที่เกิดขึ้นหลังการผ่าตัด และชุดที่สามสอบถามความพึงพอใจหลังการผ่าตัด ผลการศึกษาพบว่าผู้ป่วยทำแบบสอบถามครบทั้งสามชุด 88 คน โดยผู้ป่วย 2 คนที่ได้รับการฝังรากฟันเทียมด้วยการใช้คอมพิวเตอร์ช่วยนำทางอย่างพลวัตไม่สามารถเข้าร่วมโครงการได้ตามข้อกำหนด จึงถูกนำออกจากงานวิจัย ผู้ป่วยทั้งสามกลุ่มมีความคาดหวังต่อช่วงเวลาที่เกี่ยวข้องอาหารลำบากแตกต่างกันอย่างมีนัยสำคัญ ( $p=0.04$ ) ประสบการณ์ของอาการหลังผ่าตัดของผู้ป่วยทั้งสามกลุ่มในช่วงเวลาที่มีอาการปวด พุดลำบาก และผลกระทบต่อการใช้ชีวิตประจำวันแตกต่างกันอย่างมีนัยสำคัญ ( $p=0.01, 0.038, \text{ และ } 0.046$  ตามลำดับ) เมื่อพิจารณาโดยภาพรวมพบว่าผู้ป่วยคาดหวังช่วงเวลาที่มีอาการปวดและบวมหลังผ่าตัดน้อยกว่าช่วงเวลาของอาการที่เกิดขึ้นจริงอย่างมีนัยสำคัญ ( $p=0.035$  และ  $0.001$ ) แต่ไม่พบความแตกต่างอย่างมีนัยสำคัญของอาการปวด อาการบวม และจำนวนยาแก้ปวดที่ผู้ป่วยรับประทานหลังการผ่าตัดฝังรากฟันเทียมในผู้ป่วยทั้งสามกลุ่ม ผู้ป่วยส่วนใหญ่สามารถยอมรับภาวะรบกวนการใช้ชีวิตประจำวันหลังการผ่าตัดในระยะสั้นได้ และร้อยละ 89 แสดงความพึงพอใจต่อผลการผ่าตัดโดยรวม โดยสรุปการผ่าตัดฝังรากฟันเทียมทั้ง 3 วิธีไม่ทำให้ อาการปวด บวม และความพึงพอใจของผู้ป่วยแตกต่างกันอย่างมีนัยสำคัญ แต่ผู้ป่วยแต่ละกลุ่มมีความคาดหวังต่อภาวะเคี้ยวลำบาก ประสบการณ์ช่วงเวลาที่มีอาการปวด ภาวะพุดลำบาก และภาวะการรบกวนชีวิตประจำวันต่างกันอย่างมีนัยสำคัญ ผู้ป่วยประเมินระยะเวลาที่มีอาการบวมและปวดหลังผ่าตัดน้อยกว่าที่ระยะเวลาที่เกิดอาการจริง

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สาขาวิชา	ศัลยศาสตร์ช่องปากและแม้มัก	ลายมือชื่อนิสิต .....
	ซิลโลเฟเซียล	
ปีการศึกษา	2563	ลายมือชื่อ อ.ที่ปรึกษาหลัก .....
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# # 6175850232 : MAJOR ORAL AND MAXILLOFACIAL SURGERY

KEYWORD: dental implant computer assisted implant surgery guided surgery navigation,  
Satisfaction, expectation, Patient Reported Outcome Measures

Sunida Engkawong : Comparing patient-reported outcome measures among 3 methods of dental implant placement. Advisor: Assoc. Prof. Keskanya Subbalekha, DDS.,Ph.D. Co-advisor: Assoc. Prof. Pagaporn Pantuwadee Pisarntrakit, DDS., M.Sc., Dr.P.H.

The purpose of this study was to compare patient-reported outcome measures including post-operative pain, swelling, patient's expectation and satisfaction among 3 techniques of dental implant placement including a) conventional freehand, b) dynamic, and c) static Computer-Aided Implant Surgery. Ninety patients were randomly assigned to receive dental implant placement with one of the 3 protocols. Participants were asked to fill in a series of self-administered questionnaires assessing 1) pre-operative expectations, 2) post-operative healing events during the first week after surgery, and 3) overall satisfaction with the procedures at two weeks. Eighty-eight patients completed the study, 2 patients in dynamic CAIS group who failed to follow-up were excluded. Comparing among 3 groups, patients' expectation on the duration of post-operative chewing difficulty was significantly different ( $p=0.04$ ). Their experiences of the duration of post-operative pain, speaking limitations, and impact on routine activities were significantly different among 3 groups ( $p=0.01$ ,  $0.038$ , and  $0.046$ , respectively, Kruskal Wallis test). Overall, the duration of post-operative pain and swelling was longer than they expected ( $p=0.035$  and  $0.001$ , respectively, Wilcoxon signed rank test). Nevertheless, no significant difference in magnitude of post-operative pain, swelling, and painkiller consumption was found among the groups. The short-term functional limitations after surgery were deemed acceptable by most participants and 89% were satisfied by the overall procedure. In conclusion, surgical placements of dental implant with conventional freehand, static, and dynamic computer-aided techniques did not result in any difference in the level of post-operative pain and swelling. All techniques appeared to lead to equal levels of satisfaction as expressed by the patients post-operatively. However, the expectation of the duration of chewing difficulty, as well as the experience of pain duration, speaking difficulty and inability to conduct daily routine activities after surgery were significantly different among groups. Patients appeared to significantly underestimate the duration of post-operative pain and swelling.

Field of Study: Oral and Maxillofacial Surgery Student's Signature .....

Academic Year: 2020 Advisor's Signature .....

Co-advisor's Signature .....

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Sunida Engkawong

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## Chapter 1

### Introduction

#### Background and Rationale

Dental implants have been widely used for replacing the lost natural teeth, with evidence of long-term success and improvement of patients' quality of life (1). However, not only the surgical procedure but also the post-operative complications could have negative effect on patient's quality of life. The most unfavorable period for patients occur during the healing period after implant placement due to psychological discomfort and functional limitation (2). Thus, many advance methods were developed for more predictably placement outcome and minimizing operative time and post-operative unfavorable events (3).

Accommodated with three-dimension imaging, implant software planning and computer-aided-design/computer-aided-manufacturing (CAD/CAM) technology, **Computer-Aided Implant Surgery (CAIS)** were introduced to implant dentistry (3) and become favorably. This approach was utilized to overcome the main drawback in conventional freehand technique which is a real time visualization of the critical anatomical structures. It also simplified implant placement by transferring virtual plan of final implant position from planning software and radiographic imaging to operative situation via prefabricated guided stent called **the static CAIS systems** or real time tracking devices called **the dynamic CAIS systems**.

The static CAIS (s-CAIS) indirectly reproduces the virtual-planned implant position from patient's 3D imaging into a surgical guide which is an acrylic resin-based template with metal tubes. This surgical guide template is placed in the patient's mouth and used as a drilling guide for osteotomy preparation. Therefore, intra-operative modification of the implant position is limited (4).

The dynamic CAIS (d-CAIS) or so-called implant navigation system integrates patients' computer tomographic (CT) image into virtual placement planning. The signal from optical tracking devices is detected; thus, the real-time drilling direction and position can be overlapped in the planned position in CT image and is illustrated on the chair side display. Moreover, this technique does not need the surgical guide template (5).

These tools were primarily designed to improve diagnostic planning, surgical and restorative precision along with swiftly simplified usage. Different evidences were available for concluding that the accuracy of s-CAIS is within clinically acceptable range (6). While the d-CAIS has also been achieved in accuracy similar to static guided system and recognized statistically significant superior to conventional freehand technique (7). Using s-CAIS allows surgeons to implement with flapless surgical technique, which results in being safe and predictable outcome and also minimizes discomfort during period of healing in combination with a reduced “ chair time” of operation (8). This was accounted for decreasing post-operative pain and swelling at sites due to the unnecessary to elevate a surgical flap and reaching a functional and aesthetic immediate loading (9).

However, the additional costs of the surgical drill kit, guiding template fabrication along with intra-operative unexpected events such as inadequate range of patient’s mouth opening for guiding instrument insertion, surgical stent misfit or instability on distal extension ridge, and stent fracture were count for disadvantages when using s-CAIS (10-12). In addition, some studies stated that implant survival rate was not significantly different when comparing between the CAIS and non-CAIS (12, 13).

To achieve high quality of care, outcomes in patient’s perspective are one of the most important factors measuring the success apart from clinical effectiveness and safety. A consensus in 1998 dental implant Symposium held in Toronto mentioned that patient’s satisfaction of treatment had to be included in scales to measure the success of the implant treatment (14). While CAIS have been increasingly employed, the benefits of this tool in dental implant therapy in patient's perspectives are not reported yet.

Quality of health care treatment outcomes in patient’s perspective have gained considerable attention in term of **PROMs** or **Patient-Reported Outcome Measures**. It was defined as “measurement tool of report of the status of a patient’s health condition that comes directly from the patient, without interpretation of the patient’s response by a clinician or anyone else” (U S. Food and Drug Administration, 2009) (15). The importance of PROMs was proved by the report of improvement in patient–clinician communication, better clinical outcomes and patient satisfaction (16). Therefore, PROMs represent an important tool to develop actively patient-engaged treatment guidelines (17).

There have been plenty of studies focused on clinical outcomes including accuracy of different kinds of CAIS technique while only few of PROMs were mentioned. Since CAIS is useful when appropriated case was selected, surgeon should carefully decide the proper approach for each patient individually to achieve successful results both in clinician's and patient's perspective.

Only a few of previous studies focused on PROMs in guided dental implant placement. Therefore, this randomized clinical trial was performed and aimed to compare patients' expectations, satisfaction, and post-operative pain and swelling of these three implant placement protocols.

### **1. Research Questions**

1. Do patients receiving dental implant placement with s-CAIS, d-CAIS, or conventional techniques have a different level of expectation?
2. Do the dental implant placements using s-CAIS, d-CAIS, or conventional technique result in different level of post-operative pain and swelling?
3. Do patients receiving dental implant placement with s-CAIS, d-CAIS, or conventional techniques have a different level of satisfaction?

### **2. Research Hypothesis**

- Patients receiving dental implant placement by using s-CAIS, d-CAIS or conventional techniques the have a different level of expectation.
- Post-operative pain intensity and swelling grade in patients receiving dental implant placement by using s-CAIS, d-CAIS or conventional techniques are different.
- Patients receiving dental implant placement by using s-CAIS, d-CAIS or conventional techniques have a different level of satisfaction.

### **3. Research Objectives**

- To compare post-operative pain and swelling between 3 methods of dental implant placement including s-CAIS, d-CAIS, and conventional techniques
- To compare patient expectation and satisfaction between 3 methods of dental implant placement including s-CAIS, d-CAIS, and conventional techniques

### **4. Research Design**

Randomized clinical trial, questionnaire survey

## 5. Expected Benefit

The results from this study may provide the important information to register the patients' expectations before the surgery and to choose an appropriate dental implant placement technique for each patient and encourage clinical service provider to reach better quality of care.

## 6. Operative definition

1) **Patient-reported outcome measures (PROMs)** are self-administrated questionnaires measuring the patient's perception of their health status before, during, and after undergoing medical or dental therapy.

2) **Conventional freehand technique** is the process that dental implant is placed in the correct position after reflected flap. The surgeons have to design their orientation of drilling throughout the surgery. They freely operated with mental navigation. To assess remaining the bone and surrounding anatomy, available diagnostic information from periapical, panoramic radiographs or CBCT are used as the reference.

3) **The static Computer-Aided Implant Surgery (s-CAIS) system** is the use of a tissue or bone-supported surgical guided template to reproduce the virtual implant position directly from computerized tomographic data with or without raising a mucoperiosteal flap before dental implant placement.

4) **The dynamic Computer-Aided Implant Surgery (d-CAIS) system** is the process that directly visualized the virtual implant position from computerized tomographic data by using motion-tracking technology to guide the implant osteotomy preparation and placement.

## 7. Delimitation and limitation of the study

- All surgeries were offered at the same cost to the patients, as additional charges related to equipment for s-CAIS and d-CAIS were covered by the research protocol.
- Due to conducted in circumstance of dental hospital of dental school, dental implant placements were operated by 2 experts staffs in department of maxillofacial surgery, faculty of dentistry, Chulalongkorn University

## 8. Basic assumption

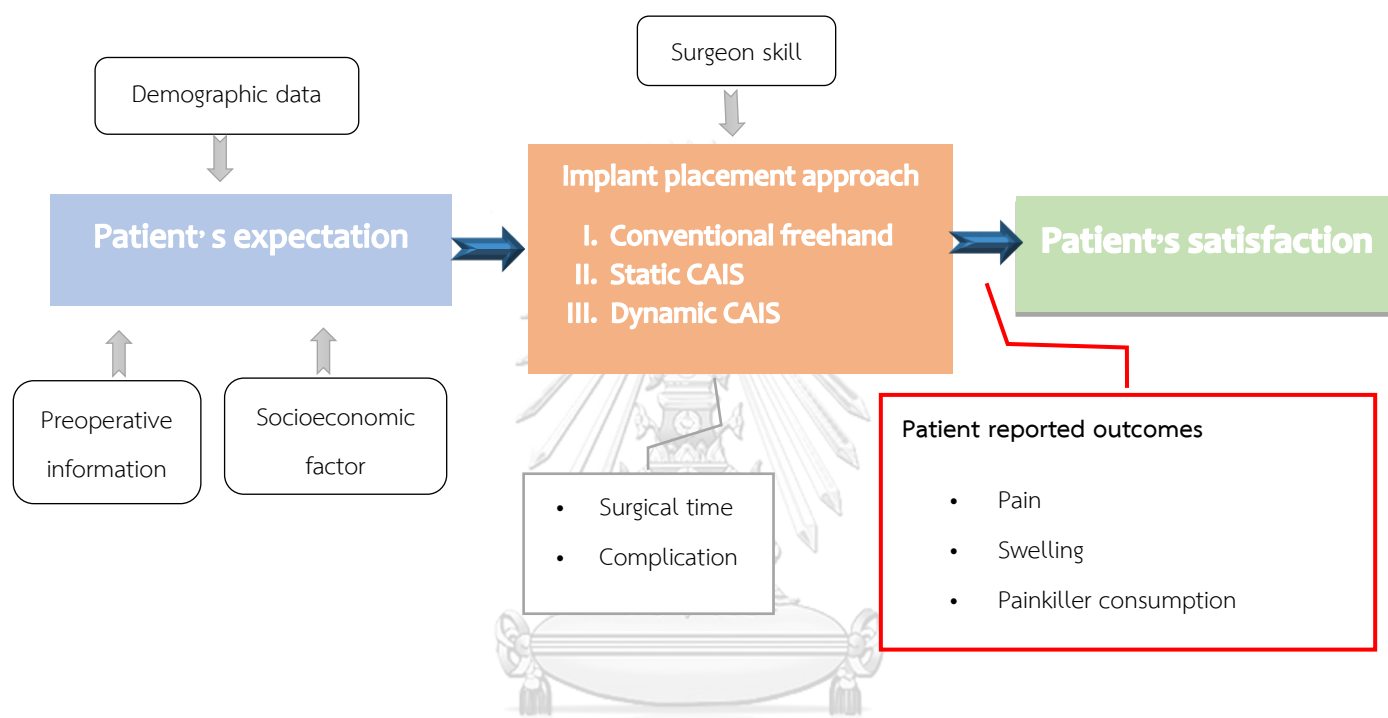
- The participants in this study were the patients who had been referred to Oral and Maxillofacial department, Faculty of Dentistry, Chulalongkorn University for receiving dental implant treatment from July, 2019 – Dec, 2020

- The series of questionnaire used in this study were completed by patients themselves at OPD of dental hospital of faculty of dentistry of Chulalongkorn university. If the patient feels unclear or need more clarification, the patient could ask the researcher.

### 9. Conflict of interest

We are aware of no conflict of interest related to the present study.

### 10. Conceptual framework



### 11. Picture of Protocol





## Chapter 2

### Review Literature

#### 2.1 Quality of health care

The Institute of Medicine in U.S. has defined *quality of health care* as “the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge” (18). Quality of health care can be evaluated across three key dimension: clinical effectiveness, patient safety and patient experiences (19). Clinical outcomes are normally reported as treatment effectiveness measurement, for example periodontal indices, dental implant mobility or radiographic bone loss as the success criteria of dental implant (20). However, good quality of care should not be directly interpreted from the report of clinical outcomes without conclusion from services. Patient experiences including services that provided to patients with a technically competent manner, with good communication, shared decision making, and cultural sensitivity are necessary (21). To execute the higher quality of care, patient feedback is one of the major factors in measuring the level of quality of delivered treatment.

#### 2.2 Patient-reported outcome measures

Patient-reported outcome measures (PROMs) are standardized and validated questionnaires which are constructed to capture patients' perceptions of their health status, perceived level of impairment, disability, and health-related quality of life during or after undergo medical treatment (22). Patients rate their health status after being asked by a series of items, which are also combined to represent treatment result such as pain, symptom severity. Since 2009, National Health Service (NHS) has introduced this term throughout England for initially focusing on hip and knee replacement, hernia, and varicose vein surgery. However, it became one of the most important measurement in every kind of treatment. According to PROMs allow the efficacy of a clinical intervention in the patients' perspective became realistic. The advantages from using PROMs are the ability to follow clinical symptoms over treatment period, improved quality of care, and better disease control among patients and physician (23).

PROMs were also embraced by dentistry. In the 8th European Workshop on Periodontology, Colman McGrath, Otto Lam & Niklaus P. Lang.2012 (24), described the term PROMs as “essentially ‘subjective’ reports of patients' perceptions of their oral health status and

its impact on their daily life or quality of life (termed Oral Health-related Quality of Life [OHRQOL]), reports of satisfaction with oral health status and/or oral health care, and other non-clinical assessments". PROMs play a key role in revealing patients' perceptions on the treatment they received and analyze whether that treatment has achieved their needs or expectation, thus imply the quality of treatment. Moreover, expressing outcomes in common terminology can promote patient's engagement in the treatment decision-making process (25, 26). This adjunct assessment of the quality of care also facilitates to better clinical practice.

### 2.2.1 Types of PROMs

Four types of PROMs can be broadly classified as (27)

I. **Symptoms and symptom burden** such as pain intensity and swelling are key domains for PROMs. Directly reported by patients, these symptoms are normally negative, remaining in short period and vary intensity. the severity of the symptoms should also mark in scales. While, symptom burden is concept that encompasses both the severity of the symptoms and the patient's perception of the impact of the symptoms (28).

II. **Functional status** is patient's ability to perform both basic and more advanced (instrumental) activities of daily life. This can be used in addition to performance-based measures of function.

III. **Health-related quality of life** is a multidimensional concept which represents the patient's general perception of the effect of illness and treatment on various aspects of life such as physical, psychological, and social perception (29).

IV. **Patient ratings of health care** are an integral component of patient-centered care including shared decision making among clinicians, patients, and families; self-efficacy and self-management skills for patients; and the patient's experience of care. Measurement of patient ratings is a complex concept that is related to perceived needs, expectations of care, and experience of care (30). To tailor appropriate decision making for individual, health care professionals need to know patients' preference which based on informed decisions from themselves.

#### *Patient satisfaction*

Patient satisfaction is one type of patient health care ratings that focalized to evaluate medical treatments, services, and interventions from their perspective. It has important implications for designing service plan, improving the delivery of health care services and the indicator of future adherence to treatment (30). Although the concept of patient satisfaction is

unclear and unofficially defined, it can be assumed as a multidimensional construct that includes patient concerns about the disease and its treatment, accessibility and continuity of the service, financial burden, communication characteristics of the service providers, cost-time efficiency, physical environment, and confidence in the physician (30, 31).

Several factors influence on patient satisfaction such as quality of clinical services delivered, accessibility of medicine, health care staff's behavior, service cost, hospital infrastructure, physical and emotional support, and doctor attitude (32, 33). Some studies claimed that patient satisfaction has been achieved when a patient's treatment expectations are met or exceeded (32). Therefore, patient expectation has been recognized as a considerable factor for patient satisfaction with reported of their relationship.

### *Patient expectation*

The fundamental goal of medical treatment is to understand and fulfill the patients' needs and preferences. Expectations are beliefs that a given response will be followed by some event; an event has either a positive or a negative valence or affect (34). Furthermore, Expectations are potentially related to satisfaction as when patients compared what people expect to receive from and their observations of what they received in their healthcare ('experiences') to evaluations of their care ('satisfaction') (33).

The expectations of health care services occurred when patients enter the health care system with a variety of characteristics, attitudes, and prior experiences (35). The knowledge that they were informed enabled them to define their situation and imagined what they should be perceived needs for care. Thus, they formed a set of expectations about treatment outcomes, caregiver behaviors, and the health care system performance. These expectations were changeable along the course of illness and treatment and judged to be satisfactory or not satisfactory after compared against which care actually received (35).

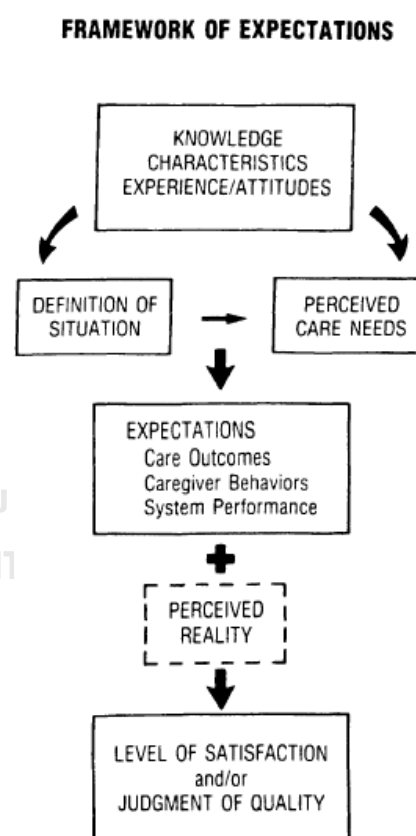


Figure 1. Framework of expectation  
(39)

### *The Relationship of patient satisfaction and patient expectation*

Many studies suggested that satisfaction could be related to perception of the outcome of care and the extent to which it meets patient's expectations. Ross et al. (36) described five suggested theories to conceptualize the interaction between expectations and experience which result in a satisfaction of consumer. Psychological discomfort can occur if expectations are not met. Patients, whose the greater numbers of their expectations were met, reported significantly higher satisfaction than those with lower numbers met (32, 37). Satisfaction was considerably higher with increasing communication between doctor and patients (32). However, there was an evidence on the extent to which unmet expectations is not a necessarily direct relationship with overall satisfaction (38). Since they might not only hold expectations to what will happen but also how it will happen in treatment situation. For instance, Koos (39) found that disappointment of patient expectations focusing on the manner of provided caregiver rather than the nature of the services themselves.

#### **2.2.2 Development of PROMs**

the development of PROMs is based on the psychometric properties of the instrument. Reliability and validity are the key of the tests. Reliability is the ability to reproduce a consistent result in time and space, or from different observers, presenting in stability, equivalence and internal consistency (40). Validity describes the extent to which a measure accurately represents the concept it claims to measure (41). Three approaches to assessing internal validity are content validity, criterion-related validity, and construct validity (41). With concern of these, the research finding will be useful and trustworthy.

Types of reliability	Definition	Example	Statistical tests
Stability	Consistency of repetitions, that is, how stable the measure is throughout time. <sup>15,17</sup>	If an individual concluded a research and repeats it in a few days, similar results are expected.	Test-retest (Intraclass correlation coefficient [ICC])
Internal consistency	It evaluates if the domains of an instrument measure the same characteristic, that is, the average correlation between all the construct items. <sup>21</sup>	In an instrument that assesses satisfaction at work, all the items of a certain domain must measure such construct, not a different one.	Cronbach's alpha (continuous variables) Kuder-Richardson (dichotomous variables)
Equivalence	It is the concordance degree between two or more raters concerning the scores of an instrument.	Two qualified raters fill in the same instrument are supposed to obtain the same score.	Inter-observer reliability (Kappa)

Figure 2. Reliability measurement of instruments (41)

Types of validity	Definition	Example	Statistical tests
Content validity	It is the degree in which a test includes all the necessary items to represent the concept to be measured. <sup>17</sup>	An instrument that assesses the satisfaction at work must include not only work satisfaction, but other variables related to it, such as, salary, promotions, relationship with co-workers, among others.	- Qualitative approach (experts committee) - Quantitative approach (content validity index [IVC])
Criterion validity	It is assessed when a result can be compared to a 'gold standard'.		
Concurrent validity	It can be evaluated using both the target-test and the 'gold standard', at the same time,	In an investigation on depression, a new tool is used, and with it, a supposedly 'gold standard' question: Do you frequently feel sad or depressed? <sup>38</sup>	Correlation tests
Predictive validity	First the target-test is applied, and then, the 'gold standard'. <sup>38</sup>	Results on blood pressure and cholesterol levels are based on its predictive validity to project the risk of cardiovascular diseases. <sup>38</sup>	Correlation tests
Construct validity	Is the extent in which a set of variables represent the construct that was projected to be measured. <sup>44</sup>		
Known-groups technique	Different groups of individuals fill in the research instrument and then the groups' results are compared. <sup>38</sup>	A test that assesses quality of life can be applied to a group of patients with chronic diseases and to a group of healthy youngsters. Differences in the scores on quality of life between these groups are expected. <sup>38</sup>	Hypothesis testing
Convergent validity	It is obtained through the correlation between the instrument and another instrument that assesses a similar construct, expecting high correlation results between them. <sup>39</sup>	When administering two instruments that assess satisfaction at work, researchers expect to obtain strong correlation between them.	Correlation tests
Discriminant validity	It tests the hypothesis that the target-measurement is not improperly related to different constructs, that is, with variables from which it should differ. <sup>39</sup>	An instrument that assesses the motivation to work should present low correlation with an instrument that measures self-efficiency. <sup>32</sup>	Correlation tests
Structural or factorial validity	It assesses if one measure captures the hypothetical dimension of a construct. <sup>39</sup>	Researchers intend to assess if some characteristics of the work environment – such as autonomy and feedback – are predictors of professional satisfaction.	Factorial analysis and structural equation modeling
Cross-cultural validity	Measures in which the evidences support the inference that the original instrument and another one, culturally adapted are equivalent. <sup>39</sup>	A tool that assesses the satisfaction at work and that has been translated and adapted into another cultural context, must have a similar performance to the one of the original version. <sup>51</sup>	- Independent translators and back-translators - Experts committee - Pre-test <sup>51</sup>

Figure 3. Validity measurement of instruments (41)

However, to measure patient's changed outcomes, pre- and post- treatment assessment should be conducted then compared. Overinflated outcomes or 'euphoric effect' can be found when the assessment is too early applied with respect to long-term outcomes. An extended period for tracking of the outcome series provides inform options of which time points for assessment are appropriate for the particular research (24).

### 2.2.3 PROMs in dental implant

Although many articles reported that dental implant therapy improves oral health-related quality of life and achieves patient's overall satisfaction, most of conducted questionnaires are non-standardized, custom-made, weaken evidence. The most frequently asked questions concern of chewing function, esthetics, speech, comfort, stability, ability to conduct oral hygiene and general satisfaction (42, 43).

There are two items commonly assessed as PROMs in implant therapy which is oral health related quality of Life (OHRQOL) and patients' satisfaction. Oral Health Impact Profile (OHIP) including its short versions are globally admitted as qualified instrument for measuring impact in OHRQOL, while a definition of "satisfaction" was not clearly described. Therefore, most utilized questionnaires were conducted with vaguely unspecific question such as "overall satisfaction", or specific questions regarding satisfaction with chewing, or speaking. Consequently, the different outcomes were observed (44).

McGrath (45) reviewed several reports of PROMs among dentate subjects which sample sizes had ranged from 15 to 208. Most of the reports were randomized controlled trials. Even though the length of assessment period varied from within a few days to 5 years, most of them were conducted at a single time point. Some topic issues were assessed including pain intensity, discomfort, physical, social assessments, psychological effects of oral health, and OHRQOL. Visual analogue scale (VAS) was the most common conducted test. This review concluded that a major limitation in both satisfaction and oral health impact assessments was the use of non-standardized data collection instruments. Reliability and validity of the instruments were unclear, whether they were in fact assessing the underlying construct (satisfaction and subjective oral health status). Some studies reported the outcomes from customized scales to which were

created varies in between studies and prohibited meaningful comparison, because of the linguistic and cultural issues measurement that need to be adapted for use in the local setting.

According to the previous study of symptoms (46), the peak intensity of pain was reported at 6 hours after the dental implant surgery and related to the number of implant placed. While facial swelling was recorded a peak intensity at 48 hours postoperatively. There was a significant association between postoperative swelling and older patients, the placement of more than 4 dental implants and intensive operations in which sinus lift or bone regeneration. Swelling became serious in patients with implants that positioned in the posterior and located at distal end or totally edentulous patients (46).

The interference with daily activities after undergoing implant placement was reported in mild to moderate degree. The worst pain and limitation of daily activities were also highest on the first postoperative day, then decreased to about half the maximum level within 3 days (47).

However, there was a study reported most of the patients felt that they had overestimated the unpleasantness of implant surgery while underestimated the discomfort and difficulties of the healing phase (e.g., pain intensity and degree of swelling). Patients perceived that they were well informed about the procedures and trust in the implant clinicians. Thus, their experiences were favorable compared to their earlier expectations (48).

The number of studies interested in patient's expectations as well as patient's satisfaction of dental implant were growing up. Expectations with respect to esthetics, function and psychosocial aspect are key attributes considered. Patients may expect implant treatment regarded their new prostheses as 'just like natural teeth' or a process of 'normalization' (49, 50). The number of implants needed, placement area, gender, age and pre-treatment information may have had an impact on the expectations (49, 51). The focus of expectations In patients with full-arch rehabilitation were primarily on regaining the chewing function while the single anterior tooth implants were more concerned with the esthetic outcome (51).

The systematic review on patients' expectations of dental implants by Yao et al. (52) interestingly revealed that there were not always positive in following satisfaction. Specific items like mastication, phonetic, comfort use and retention issues post-treatment could express in lower satisfaction than pre-treatment expectations. Patients were also reported to often

complain about the high cost of treatment which was one of reasons contributing to unrealistic expectations. The treatment cost related to income could deter subjects from making treatment decisions because it was believed that too expensive. In term of longevity of dental implants, 24%-59% of the subjects believed implants could last for a lifetime. Less than 7% participants thought dental implant need less oral hygiene care than natural teeth. Women who judged aesthetical change as vital were significant higher compared with men. The results also showed patients preferred the minimal invasive treatment alternatives ( not to perform bone graft procedure).

In the other hand, patient satisfaction may have an association with the levels of expectations ( 53). For implant treatment, many important factors are also impacted on satisfaction of implant surgery including demographic data, expectations of end results, pain experienced during and after surgery, the degree of preoperative information, satisfaction with comfort, interpersonal communication between patient and healthcare provider, postoperative appearance, adequacy of the treatment period and reasonability of treatment cost (53-55). There was a reported of more than 90% of the patients receiving dental implant therapy for more than 10 years were completely satisfied with implant therapy (56).

Mccrea (53) reported a significant relationship existence between the overall satisfaction of appearance and satisfaction with comfort. Perceived comfort levels are influenced by patient's gender. It implied that low levels of pain and higher levels of surgical comfort (intra- and postoperatively) could produce positive patient's attitude towards of their treatment. Moreover, there was a significantly positive relationship between the comfort rating and " how well informed" the patient was. Most of the participants felt more positive in comfort when they were very well pre-operatively informed of the level of discomfort and pain. The relationship between overall satisfaction of appearance, comfort, and overall satisfaction with experience were also reported.

Patient satisfaction of implant therapy was also subjectively influenced by other aspects likes pain, service, and especially complication-related factors. Kim (55) studied in 93 patients with a total of 325 implants placed and reported more than 60% of patients grading 'mild' to 'moderate' pain level during and after implant surgery. There was no impact of either



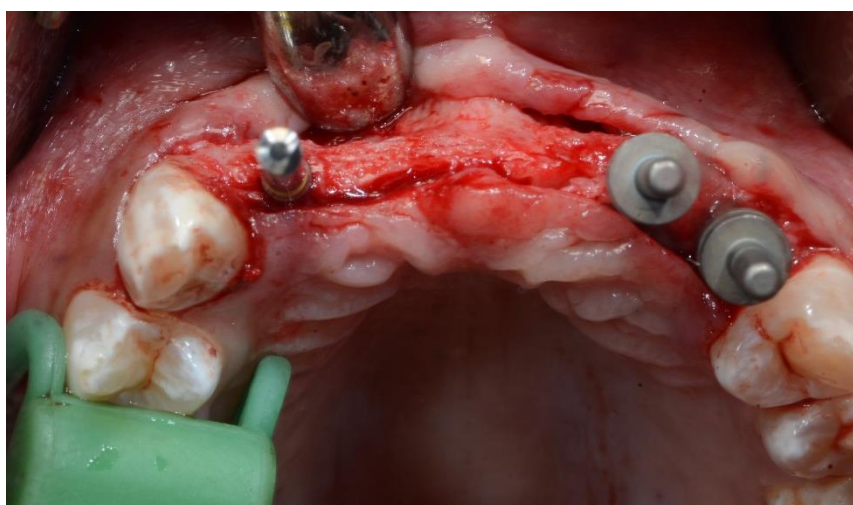
intra-operative or postoperative pain on patient satisfaction ( $P>0.05$ ). As service-related factors, it was remarkable that 70 patients (75.3%) responded 'negative' to the reasonability of treatment cost. 47 patients reported a 'negative' opinion on the adequacy of the treatment period. Approximately 50% of the patients believed that the treatment period was too long. While the experience of complications had a negative impact on patient satisfaction level. The study suggested that the prevention of surgical complications is important to satisfy patients undergoing implant therapy. Development of surgical technique and instruments was necessary for safer implant procedures. Gender differences in the treatment planning stage also could be considered.

## 2.3 Dental implant placement

### 2.3.1 Conventional dental implant placement

Treatment planning in the conventional placement requires 2- or 3-dimensional radiograph for surveying the underlying anatomical structures. After infiltrated with local anesthesia, the incision was made to expose surgical field. Conventional implant preparation was sequentially performed following manufacturers' protocol. The angulation of dental implant drilling was mentally navigated by the surgeon. Dental implant was freely installed in the final position. However, without the precise reference of the surrounding vital structures it is not considered to be a safety guidance. Therefore, the clinical outcomes from conventional approach are occasionally unpredictable and inaccuracy along with some unwanted complications (57, 58).

จุฬาลงกรณ์มหาวิทยาลัย



Picture 1. Conventional freehand dental implant placement

### 2.3.2 Computer-Aided Implant Surgery (CAIS)

Computer-Aided Implant Surgery (CAIS) allows to overcome the limitations by joining the surgical and prosthetic treatment planning. The development of Cone-Beam Computed Tomography (CBCT) enables simulation of virtual implant placement in 3-dimensional level and relates to vital structures (59). Integration of using the computed tomography images, including CBCT, with computer-aided design and manufacturing (CAD/CAM) technology provides virtually surgical planning and surrounding 3D environments, for instance the realistic view of the patient's underlying anatomical structure. Then, the virtual execution of the surgery navigates to an ideal and precise prosthetically driven restoration (60, 61).

Computerized tomography was developed by Sir Godfrey Newbold Hounsfield to acquire different directions and/or angles radiographs and claimed approximately 100 times more sensitive than conventional radiography due to the detection of soft tissues (62). This could be digitally processed to a three-dimensional depiction. In the late 1980s, several software packages were invented to visualize the human head using computerized tomography images (63). Many Advantages of CBCT scan were reported such as lowering the size of the irradiated area, minimizing the radiation dose exposure, high resolution of image, faster scanner time, reducing image artifact, and the image data could be converted and imported into proprietary programs (64). CBCT was shown to be a useful device for preoperative assessment in many specialties of dental treatment.

Virtual implant planning system has been developed to obtain optimal treatment outcome via the planning software. It overcomes limitations in traditional implant placement method. The software reformats 3D image surface and virtually renders position planning of implant placement with exact dimensions on cross-sectional, axial and panoramic views of computerized tomography images. Within this, available products of the implant manufacturer including Implant diameter, length and shape can be modified. It visualized every direction which implant is moved and tilted for real-time. Thus, surgeon can simultaneously correct the implant drilling from different viewpoints (4).

In the clinical application of CAIS systems, two types of guided implant surgery protocols are mentioned – the static and dynamic guided surgery systems.

### 2.3.2.1 Static Computer-Aided Implant Surgery system (s-CAIS)

Static CAIS system or computer-guided surgery refers to the use of a static surgical template. The computer software systematizes the original CT scan data, in Digital Imaging and Communication in Medicine (DICOM) format, to create axial, three-dimensional, panoramic, and cross-sectional radiograph. Then, implants are virtually designed with respect to surrounding anatomy and prosthetic outcome. Surgical template is model-based and made dental laboratory or processed milling or printing through computer-aided design/computer-aided manufacturing (CAD/CAM) technology. After verification of all locating parameters from software, sleeve bed preparation and surgical sleeve placement are carried out using the drilling arm by dental technician (4, 59).

Stereolithographic rapid prototyping technique is the other way to create surgical guide. Starting with taking CBCT from patient and scanning intraoral impression/model, the operator has to upload treatment planning to the stent manufacturer. The template is fabricated by using computer-guided laser beam to photopolymerize liquid acrylic through a series of layers called stereolithography. Then, the metal cylinders used as drill-guiding tubes are then forced into the spaces representing diameter of the drills and/or implants, and the template are ready for clinical usage (65).



Picture2. Surgical guided stent for s-CAIS

The advantages when using s-CAIS are counted for higher accuracy over conventional freehand approach, the possibility to perform less-invasive or less patient discomfort surgery such

as flapless technique, the ability to fabricate pre-operative prosthesis, reduction of technique-sensitive error and operator-dependent surgical procedures (66, 67). Nonetheless, this protocol requires additional time and cost for several preoperative steps. Intraoperative limitation of guided template is inability to change implant position or surgical plan. Moreover, the heat production during the osteotomy may rise as a result of limitation of irrigation through the template (68, 69). In addition, placement of guided template is difficult to apply in posterior area likes second molar regions especially in patient with limited mouth opening (70).

### ***PROMs in s-CAIS system***

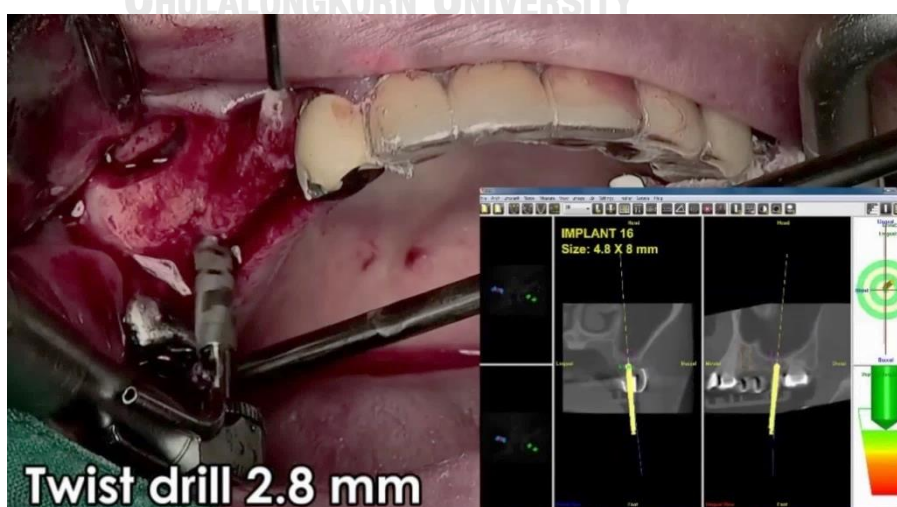
Joda et al. (71) reviewed literature for comparing PROMs , time efficiency, and intra-operative complications of s-CAIS with conventional implant placement. Pain and discomfort were reported significantly lower in s-CAIS with flapless surgery compared to conventional implant placement with an open-flap procedure according to painkiller consumption rate (72). Moreover, mucosa-supported guide in a flapless surgery demonstrated a significantly reduced intake of painkillers (73). The degree of post-operative swelling was stated from none to mild swelling after 3 days of using s-CAIS with a flapless procedure (74). It can be assumed that patients' post-operative discomforts such as swelling and/or pain after guided surgery was almost negligible (75).

It is quite ambiguous to evaluate time efficiency. Some study showed that s-CAIS using mucosa-supported guides in a flapless approach was significantly faster than bone-supported guide using a conventionally raised full-thickness flap and conventional approach (73, 76). In contrary, other were observed no significant differences between these techniques. The lack of primary implant stability and fractures of the implant guide were reported as common surgical complications using s-CAIS (77, 78). Youk et al. (79) also reported that patient who have had implant surgery with the computer-guided template statistically significant felt less pain and higher level of satisfaction. Service-related factors were evaluated for factors influencing patient satisfaction. Although considering dental staff and hospital workers were kind, it was remarkable that 75% patients responded 'negative' to the reasonability of treatment cost and approximately 50% of the patients believed that the treatment period was too long. Therefore, it is important that patients fully understand the healing process, time and cost expense for dental implant therapy at the time of informed consent.

### 2.3.2.2 Dynamic Computer-Aided Implant Surgery system (d-CAIS)

Dynamic CAIS system or implant navigation is an augmented reality technology that allows real-time osteotome position visualizing on a software monitor. Empowered by optical tracking technology digitizers, navigation system continuously registers the position of surgical instrument via tracking sensors on handpiece and tracking cameras. Then, the software monitor which previously imported radiographic patient's jaw anatomy from preoperative CT image can display relationship between implant drill position and surrounding structures when patient stay within the line of sight of the tracking cameras (80, 81).

According to the Image Guided Implantology system (IGI) treatment protocol, dental implant navigation system requires a fixed interfacing template which mounted to the patient's jaw for CBCT scan and the duration of surgery (82). This template is a prefabricated occlusal appliance, which contains radiopaque metallic markers. the object uses as reference point to the patient's jaw position (83). After CBCT was taken and transferred into the navigation software as a DICOM file, A virtual implant position planning is visibly simulated by using commercial implants database including the implant type, platform diameter, apical diameter, and length. At time of surgery, two tracking sensors are attached to the occlusal appliance which accurately repositioned on the patient arch and the handpiece. Then, registration plate is applied to reassure precision of tracking sensors. Surgeon can arrange the position of drills in agreement with the 3D images on the screen to performs the osteotomy and implant placement. The implant can be oriented as needed (4, 83).



Picture3. Dental implant preparation with d-CAIS

The d-CAIS is also claimed with better accuracy than conventional technique. The ability to intraoperative change of the implant size, system, location, and surgical plan and lower rate of trauma to vital surrounding structures are the advantages of the d-CAIS. Furthermore, it allows surgeon to perform less-invasive flap reflection surgical procedure compared with conventional freehand approach and improves surgeon ergonomics during surgery. Dynamic implant navigation can be done in patient who has limited mouth opening or requires an implant at a difficult access like second molar site (83) (84).

However, many potential sources of error, for example loss of tracking sensors and camera, can be found in application of d-CAIS. Some mechanical problems may reduce the precision of the procedure such as loosening of registration template or loose fit of the implant drill (85). Moreover, d-CAIS demands a learning curve of the clinician to gain proficiency, this can waste additional time, cost and effort for training and practice on models (84). This system also requires a team approach. Both surgeon and assistant must learn to work together for efficient use of a dynamic navigation system.

#### ***PROMs in d-CAIS system***

Most of previously published d-CAIS system studies were mainly proved to be higher accuracy than conventional freehand approach. Learning curve of surgeon was the other popular topic. However, PROMs in d-CAIS were scarcely found and mentioned as the interesting drawback from those studies.

## Chapter 3

### Materials and methods

This prospective study was registered with Thai Clinical Trial Registry (TCTR20190918001) and approved by the Human Research Ethics Committee of the Faculty of Dentistry, Chulalongkorn university (HREC-DCU 2019-045, approval no.066/2019).

#### 3.1 Questionnaire construction:

The primary outcome studied was healing events during the first post-operative week. Secondary outcomes included PROMs and overall patient satisfaction at the end of the second week after surgery. A set of custom-made questionnaires was utilized for the purpose of this study. This included 3 series of questionnaire which are

- a) Pre-operative questionnaire for patients' expectations
- b) Post-operative pain, swelling intensity, and painkiller consumption during the first week (6h, 1<sup>st</sup>, 2<sup>nd</sup>, 3<sup>rd</sup>, 5<sup>th</sup>, and 7<sup>th</sup> day after surgery)
- c) Duration of pain, swelling, other functional limitations and overall satisfaction at the two weeks post-operative follow-up visit

The pre-operative questionnaire consisted of 3 parts including 7 items for demographic data, 5 items assessing patient's perceptions to dental implant treatment on a 5-step Likert scale adapted from Yao et al. (86), and 6 items assessing patient's expectations with regards to the upcoming dental implant surgery.

Post-operative pain intensity was recorded by patients' self-assessment on a continuous VAS 0-10 adapted from Tan et al. (87) and Payer et al. (88) and also the painkiller consumption. Swelling score was self-assessed on 4 grades adapted from Santana et al. (46) ranging from no swelling (grade 1), intraoral swelling in the surgical zone (grade 2), extraoral swelling within surgical zone (grade 3), and extraoral swelling extending beyond the surgical zone (grade 4).

The final questionnaire consisted of 6 items assessing experiences of post-operative symptoms similar to the expected questions in the pre-operative questionnaire and 8 items assessing patient overall satisfaction by means of a 5-point Likert scale, adapted from Pjetursson, et al. (56) The internal consistency (Cronbach's alpha) for the perception items was 0.53, for expectation items was 0.76 and for the satisfaction items was 0.85.

Questionnaire examples

ID \_\_ - \_\_ - \_\_ Date \_\_ / \_\_ / \_\_

## ■ 1) Pre-operative questionnaire

---

### Part I. Demographic data

Gender  male  female age \_\_\_\_\_ years old

#### Educational level

- high school or lower
- bachelor's degree
- Master's degree or Doctor's degree

#### Monthly income

- lower than 40,000 baths
- 40,000 - 60,000 baths
- more than 60,000 baths

#### Underlying disease

- ❖ Medical problem \_\_\_\_\_
- ❖ Current medication \_\_\_\_\_

#### Smoking status

- non/former smoker  current smoker




#### Implant placement experience

- had implant surgery  never had implants before








## Part II. Patient's perceptions of dental implant treatment

Please mark (✓) in the table below.

<i>Questions</i>	Agree 	Uncertain 	Disagree 
1. Dental implants would look as nice as natural Teeth			
2. Dental Implants' phonetics are similar to natural teeth			
3. Dental implants would function as well as natural teeth			
4. Dental Implants require less care than natural teeth			
5. Dental Implants last longer than natural teeth.			



Question	Strongly agree 	Agree 	Uncertain 	Disagree 	Strongly disagree 
1. Post-operative pain was acceptable					
2. Post-operative swelling was acceptable					
3. Chewing difficulty after surgery was acceptable					
4. Limitations of phonetics after surgery was acceptable					
5. Inability to perform routine oral hygiene after the surgery was acceptable					
6. Inability to perform daily activities surgery was acceptable					
7. Are you satisfied with the surgical time duration					
8. I am satisfied with the clinical service					
9. I am satisfied with the overall outcome					

### Part III. Pre-treatment patient's expectations from dental implant surgery

Please mark (✓) in the checkbox below.

1. How long do you expect that post-operative pain will last?

no symptom    1-2 days    3-4 days    5-7 days    more than 7 days

2. How long do you expect that post-operative swelling will last?

no symptom    1-2 days    3-4 days    5-7 days    more than 7 days

3. How long do you expect to have chewing difficulty after the surgery?

no symptom    1-2 days    3-4 days    5-7 days    more than 7 days

4. How long do you expect to have speaking difficulty after the surgery?

no symptom    1-2 days    3-4 days    5-7 days    more than 7 days

5. How long do you expect you will be unable to perform routine oral hygiene care after the surgery?

no symptom    1-2 days    3-4 days    5-7 days    more than 7 days

6. How long do you expect to be unable to continue with usual daily activities after the surgery?

no symptom    1-2 days    3-4 days    5-7 days    more than 7 days

## ■ 2) Post-operative healing questionnaire

ID \_ \_ \_ Date \_ / \_ / \_

### \*\*\*\* Self-record post-operative pain \*\*\*\*

✓ Please rate the pain score after surgery from 0-10 in the box below

Pain score/ Time after surgery	6h	1 <sup>st</sup> day	2 <sup>nd</sup> day	3 <sup>rd</sup> day	5 <sup>th</sup> day	7 <sup>th</sup> day
Pain Score (0-10)						
No. painkiller/day						

✓ Name of painkiller 1)..... total amount..... tablets  
2)..... total amount..... tablets

### \*\*\*\* Self-record post-operative swelling \*\*\*\*

- a) no swelling
- b) intraoral swelling in the surgical zone
- c) extraoral swelling within surgical zone
- d) extraoral swelling extending beyond the surgical zone

✓ Please rate the swelling grade after surgery from a-d in the box below

Swelling grade/ Time after surgery	6h	1 <sup>st</sup> day	2 <sup>nd</sup> day	3 <sup>rd</sup> day	5 <sup>th</sup> day	7 <sup>th</sup> day
Swelling grade(a-d)						

✓ Other symptom (i.e. fever, hemorrhage)

1 .....start from Day..... to .....

2 .....start from Day..... to .....

### ■ 3) Patient experience questionnaire

ID -            Date / /

#### Part I. post-operative patient's experience with dental implant surgery

Please mark (✓) in the checkbox below.

1. How long did the post-operative pain last?

no symptom    1-2 days    3-4 days    5-7 days    more than 7 days

2. How long did the post-operative swelling last?

no symptom    1-2 days    3-4 days    5-7 days    more than 7 days

3. How long did you have chewing difficulty after the surgery?

no symptom    1-2 days    3-4 days    5-7 days    more than 7 days

4. How long did you have speaking difficulty after the surgery?

no symptom    1-2 days    3-4 days    5-7 days    more than 7 days

5. How long were you unable to perform routine oral hygiene care after the surgery?






no symptom    1-2 days    3-4 days    5-7 days    more than 7 days

6. How long were you unable to continue with usual daily activities after the surgery?

no symptom    1-2 days    3-4 days    5-7 days    more than 7 days

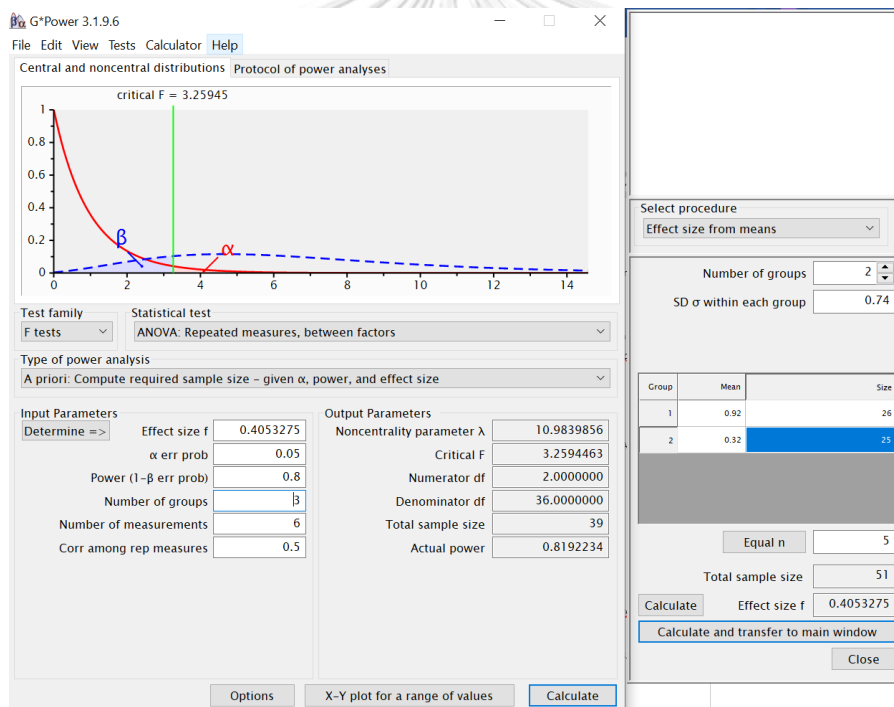
Part II. patient's acceptance of post-operative healing events and overall expression of satisfaction with dental implant surgery

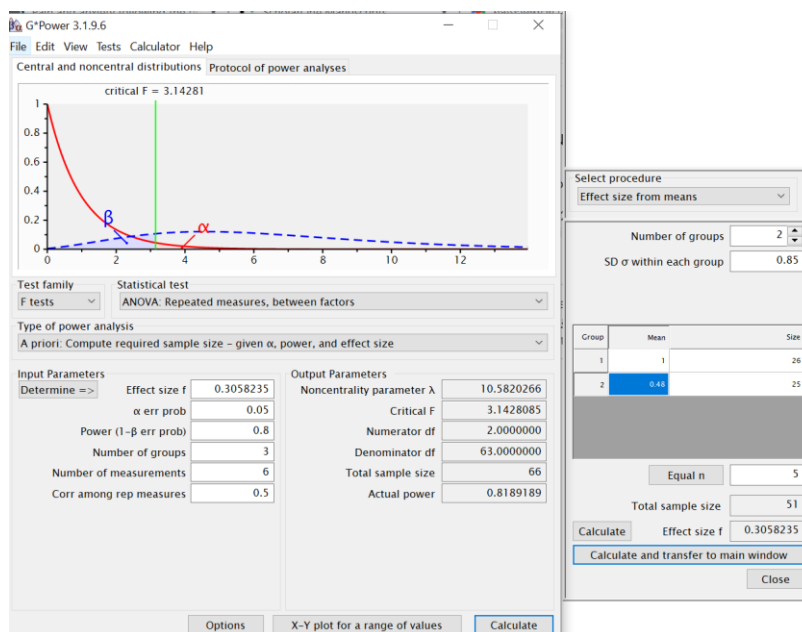
Please mark (✓) in the table below.

Question	Strongly agree 	Agree 	Uncertain 	Disagree 	Strongly disagree 
2. Post-operative pain was acceptable					
2. Post-operative swelling was acceptable					
3. Chewing difficulty after surgery was acceptable					
4. Limitations of phonetics after surgery was acceptable					
5. Inability to perform routine oral hygiene after the surgery was acceptable					
6. Inability to perform daily activities surgery was acceptable					
7. Are you satisfied with the surgical time duration					
8. I am satisfied with the clinical service					
9. I am satisfied with the overall outcome					

### 3.2 Sample size calculation:

Sample size calculation was conducted via statistical software (G\*Power software, version 3.1) using repeated measures ANOVA test with 80% of study power, 6 times of measurement and significance level ( $\alpha$ ) set at 0.05. The effect size was calculated based on a previous study comparing patient rehabilitation using surgical guides and conventional rehabilitation of partially or fully edentulous by Pozzi et al. (76) According to the study, pain scores on the third day after surgery were  $0.92 \pm 0.74$  and  $0.32 \pm 0.56$ , swelling scores were  $1.00 \pm 0.85$  and  $0.48 \pm 0.65$  in conventional group and computer guided group, respectively. The minimum total sample size requirement based on the pain score was 39 patients and 66 patients when based on the swelling score.





Picture4. Sample size calculation

### 3.3 Sample selection:

Patients who were referred to the Oral and Maxillofacial department, Faculty of Dentistry, Chulalongkorn University for receiving dental implant treatment from Aug, 2019 - Oct, 2020 were invited to participate in this study and randomly allocated to 3 groups by observer using block randomization (6 per block): conventional freehand placement, s-CAIS, and d-CAIS (n= 30 per group). Included cases gave written consent and completed all series of questionnaires. All samples were fulfilled with the following criteria

#### Inclusion criteria:

1. Patients underwent dental implant placement under local anesthesia
2. Patients who were healthy or controlled underlying systemic disease
3. Patients who received ITI implant placement (Straumann, institute Straumann AG, Basel, Switzerland)
4. Age 20 years and over that able to sign consent form
5. Well understand in Thai language verbally and written
6. Well co-operate and commit to be able to follow up 2 weeks after implant placement



**Exclusion criteria:**

1. Patients who refused to participate in this study
2. Patients who presented contradiction to implant placement including previous history of radiation therapy or ongoing antiresorptive drug
3. Patients who lost to follow up 2 weeks after implant placement
4. Patients whose dental implant placement operated by Post-graduate student
5. Patients who developed infection at the surgical site

Upon final confirmation of the treatment plan, the patients were then informed about the technique to be utilized for their treatment and the respective pre-operative procedures. The pre-surgery questionnaire was then filled, with the patients knowing which group they were randomized into.

**3.4 Surgical approach:**

For conventional implant placement, local anesthesia was infiltrated. Then, crestal incision was established to expose adequate surgical field. The incision was lingually or palatally shift to increase keratinized tissue in case of slightly inadequate of soft tissue. All osteotomies were completed according to ITI protocol ( Straumann, institute Straumann AG, Basel, Switzerland). The surgeon had to manually execute the virtual positions of the implants from previous radiograph. Dental implant was freely installed and covered with screw or healing abutment. Suture was done for gingival closure.

Surgeries in the CAIS groups were conducted as per previously published protocol (89). All implant treatments were digitally planned, and optimal positions identified with the help of planning software (coDiagnostiX software, Dental Wings Inc, Canada). Implant placement in the s-CAIS group utilized 3D printed stereolithographic surgical guide ( GmbH, Germany; Straumann® Guided Surgery Straumann, institute Straumann AG, Basel, Switzerland), while a real-time navigation system (Iris-100, EPED Inc., Taiwan) was utilized in the d-CAIS group. The additional charge related to equipment for s-CAIS and d-CAIS was covered by the research protocol.

All surgeries were performed by 2 expert surgeons from the department of OMFS, both specialists in OMFS and experienced with all surgical methods. Duration of surgery was measured by the same observer from the first incision until completion of the last suture. After the surgery,



## Chapter 4

### Results

#### 4.1 General characteristics of participants and dental implant surgical procedures

Two patients from d-CAIS group were excluded as they failed to show up for the follow up examination within two weeks; therefore, 88 patients with 179 dental implants were analyzed (figure 4). Mean of the participants' age was 57.66 (SD 10.91, range 24-79) years. Most of them were female (61%), normal healthy patients (ASA class I according to American Society of Anesthesiologists Physical Status Classification System) (55%), non- or former smoker (93%), with monthly income lower than 40,000 Thai Baht (43%), and had no prior treatment with dental implants (64%). The graduation was quite equally distributed between high school (34%) and bachelor's degree (38%). (table1)

Half of the patients received 2 dental implants (45%), 80% were at posterior sites, without simultaneous bone augmentation (56%). Full thickness flap was elevated in most of the cases (89%). (table 2) However, there were no statistically significant differences among the groups except the participant's gender distribution ( $p=0.035$ , table 1). Average total operative time was  $75.80\pm 45.58$  minutes. Operation with conventional freehand technique recorded the shortest surgical time ( $70.30\pm 47.08$ ), followed by d-CAIS ( $70.95\pm 42.48$ ), and then s-CAIS ( $89.70\pm 45.75$ ).

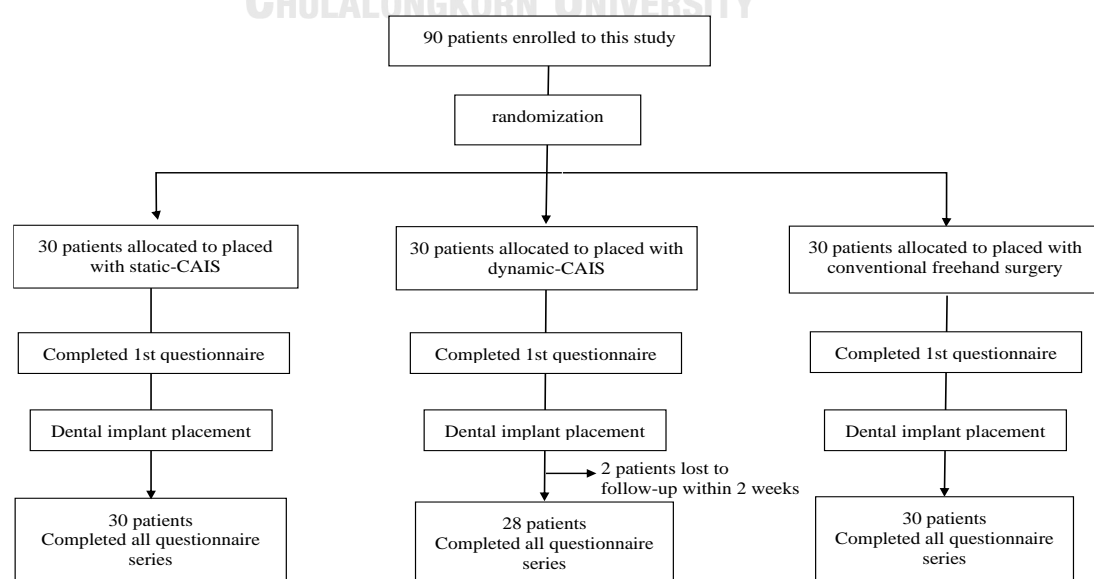


Figure 4. Flow chart of sample allocation and data collection

Table 1. Characteristics of participants

Characteristics	Static CAIS N (total 30)	Dynamic CAIS N (total 28)	Conventional N (total 30)	All groups N (total 88)	p-value
<b>Gender</b>					
Male	9	8	18	35	0.020 <sup>†</sup>
Female	21	20	12	53	
<b>Age</b>					
Years	Years	Years	Years	Years	
Min-max	32-74	51-74	24-79	24-79	0.681 <sup>‡</sup>
Mean (SD)	59.07 (8.86)	56.71 (10.87)	57.13 (12.43)	57.66 (10.91)	
<b>Health status</b>					
ASA I	18	15	15	48	0.733 <sup>†</sup>
ASA II	12	13	15	40	
<b>Educational level</b>					
High school or lower	13	9	8	30	0.461 <sup>†</sup>
Bachelor's degree	8	13	12	33	
Master's or Doctor's degree	9	6	10	25	
<b>Monthly income (Thai Baht)</b>					
< 40,000	12	13	13	38	0.706 <sup>‡</sup>
40,000 - 60,000	8	9	6	23	
> 60,000	10	6	11	27	
<b>Have ever had dental implant treatment</b>					
Yes	12	9	11	32	0.994 <sup>†</sup>
No	18	19	19	56	
<b>Smoking status</b>					
Non- / Former smoker	28	26	29	83	N/A
Current smoker	2	2	1	5	

\* statistically significant at  $p < 0.05$

† comparing among groups using Chi-square test

‡ comparing among groups using Kruskal-Wallis test

Table 2. Characteristics of dental implant procedure

Characteristics	Static CAIS N (total 30)	Dynamic CAIS N (total 28)	Conventional N (total 30)	All groups N (total 88)	p-value
<b>Number of Implants placed</b>					
1 implant	9	11	13	33	0.614 <sup>†</sup>
2 implants	15	13	12	40	
3 or more implants	6	4	5	15	
Amount of implants per patient (Mean ± SD)	2.03±1.07	2.29±2.05	1.80±0.92	2.10±1.45	
<b>Implant placed position</b>					
Anterior	3	2	5	10	N/A
Posterior	25	23	22	70	
Both	2	3	3	8	
<b>Alveolar bone augmentation including sinus augmentation</b>					
Yes	18	14	18	49	0.997 <sup>†</sup>
No	12	14	12	33	
<b>Flap operation</b>					
Flapless	2	2	0	4	N/A
Full-thickness flap	28	26	30	78	
<b>Surgical time</b>					
	Minutes	Minutes	Minutes	Minutes	
1 implant	56.56±37.64 (15-101)	46.64±15.44 (18-90)	45.46±34.24 (15-133)	50.32±32.26 (15-133)	0.076 <sup>‡</sup>
2 implants	97.53±41.48 (34-155)	65.85±30.79 (32-150)	83.08±48.15 (14-122)	82±42.69 (14-155)	
3 or more implants	103.50±37.03 (61-143)	129±27.09 (85-159)	104.20±33.12 (73-164)	110.80±35.13 (61-164)	
Overall	89.70±45.75 (15-155)	70.95±42.48 (18-159)	70.3±47.08 (14-164)	75.80±45.58 (14-164)	

† comparing among groups using Chi-square test

‡ comparing among groups using Kruskal-Wallis test

#### 4.2 Pre-operative patient's perceptions to dental implant therapy

Most participants assumed that dental implants would allow for function (93% ), phonetics (88%), and esthetics (91%) similar to natural teeth. None of them disagreed with the sentence “Dental implants phonetics would be similar to natural teeth” and “Dental implants would look as nice as natural teeth” . Astonishingly, 32% of participants perceived “ dental implants require less care than natural teeth” . Furthermore, 73% believed that dental implants will last for life. (figure 5)

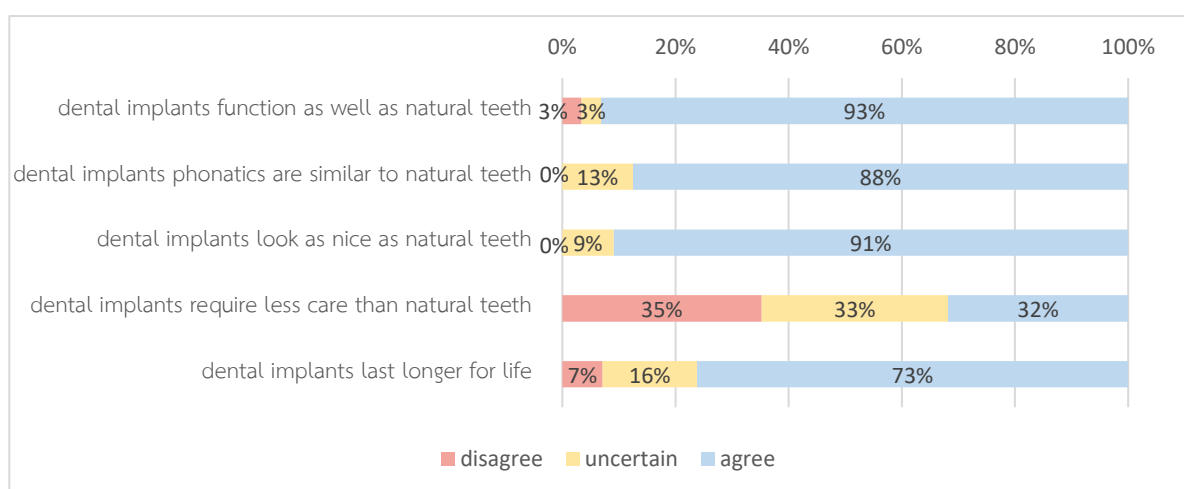


Figure 5. Frequency analysis of patient's perceptions to dental implant therapy

#### 4.3 Patient expectations and actual experience with regards to the duration of post-operative healing events.

Half of patients supposed the post-operative pain and swelling would be last for 1-2 days (51% and 50% respectively), while 41% and 30% respectively of them encountered that complications. 35% of patients expected period of chewing difficulty within 1-2 days but 30% experienced as their expectation. 45% of patients did not concern of speaking difficulty and 58% confirmed no period of the complication after the surgery. 36% of patients anticipated 1-2 days of cleaning problems following surgery, yet 41% reported they had no trouble cleaning afterward. 57% of patients did not have limitation of doing routine activities same as they expected. (figure 6)

Table 3 illustrates the duration of post-operative healing events as expected by the patients and their actual experiences. The expectations of post-operative pain, swelling, speaking difficulty, cleaning difficulty, and inability to perform routine activities were not different among

groups after analyzed with Kruskal-Wallis test. However, there was a significant difference of the expectation on chewing difficulty ( $p= 0.04$ ). Moreover, the experienced post-operative pain, speaking difficulty, and inability to perform routine activities were statistically different among groups ( $p=0.01, 0.038, 0.046$  respectively).

The differences of the expected and the actual reported experiences were analyzed within the same group with Wilcoxon signed-rank test. The conventional freehand group significantly underestimated the duration of post-operative pain ( $p= 0.006$ ) while s-CAIS group significantly underestimated the duration of facial swelling compared to their expectation ( $p=0.004$ ). However, the duration of speaking difficulty was significantly overestimated by patients in d-CAIS group compared to the actual consequence( $p=0.030$ ).

Overall, the expected durations of post-operative pain and swelling were significantly different from the experienced post-operative pain and swelling ( $p=0.035$  and  $0.001$ , respectively)

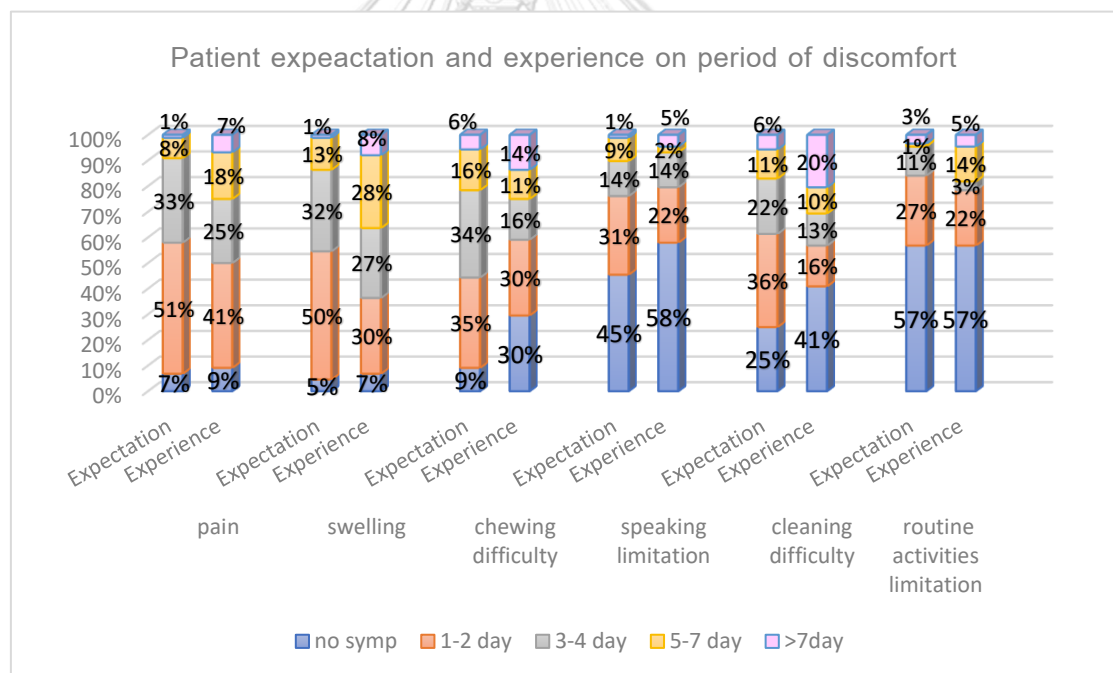


Figure 6. Frequency analysis of patient expected and actual experienced duration of post-operative events

Table 3. Comparison of expected and actual experienced duration of post-operative events

Post-operative event	Pain			Swelling			Chewing difficulty		
	Median	Expectation	p-value†	Median	Expectation	p-value†	Median	Expectation	p-value†
Static CAIS	2.0	2.0	0.714	2.0	2.0	<b>0.004*</b>	3.0	2.0	0.366
Dynamic CAIS	2.5	2.5	0.412	2.0	2.0	0.164	2.0	2.0	0.337
Conventional	2.0	3.0	<b>0.006*</b>	2.0	3.0	0.110	2.0	3.0	0.468
All groups	2.0	2.5	<b>0.035*</b>	2.0	3.0	<b>0.001*</b>	3.0	2.0	0.205
P-value‡	0.884	<b>0.070*</b>		0.889	0.525		<b>0.040*</b>	0.367	
Post-operative event	Speaking difficulty			Cleaning difficulty			Inability to perform routine activities		
Surgical method	Median	Expectation	p-value†	Median	Expectation	p-value†	Median	Expectation	p-value†
Static CAIS	2.0	1.5	0.576	3.0	3.0	0.583	1.0	1.0	0.769
Dynamic CAIS	2.0	1.0	<b>0.030*</b>	2.0	2.0	0.589	1.0	1.0	0.373
Conventional	2.0	2.0	0.610	2.0	3.0	0.775	2.0	2.0	0.249
All groups	2.0	1.0	0.146	2.0	1.5	0.308	1.0	1.0	0.269
P-value‡	0.800	<b>0.038*</b>		0.081	0.267		0.114	<b>0.046*</b>	

\* statistically significant at p&lt;0.05

† Comparing within group using Wilcoxon signed-rank test, ‡ Comparing among groups using Kruskal-Wallis test

Level of scale: 1= no symptom; 2 = 1-2 days; 3 = 3-4 days; 4 = 5-7 days; 5 = more than 7 days



#### 4.4 Patient self-reported post-operative pain intensity

The means of self-reported pain scores reached the highest at 6 hours after surgery in all groups (figure 7). The patients in the conventional freehand group had the highest pain score ( $5.47 \pm 2.29$ ) while those in d-CAIS and s-CAIS group had almost equal ( $4.21 \pm 2.76$  and  $4.13 \pm 2.83$ , respectively, table 4). One patient of each group (3-4%) expressed severe pain at VAS 10 at that time (figure 8). However, 10% of s-CAIS and 3% of Conventional group did not experience any pain (VAS=0) Afterwards, the mean scores gradually dropped in every group day by day (table 4). On the 7<sup>th</sup> day, the conventional freehand group still showed the highest score ( $1.40 \pm 2.43$ ), followed by d-CAIS, and s-CAIS group ( $0.96 \pm 1.62$  and  $0.77 \pm 1.85$ , respectively). Moreover, 73% of s-CAIS group fully recovered from pain more than d-CAIS (64%) and conventional freehand group (63%). Conventional group (10%) had the patients who still suffered from severe pain (VAS $\geq$  7) followed by 3% in s-CAIS but none of d-CAIS group experienced such pain. Nevertheless, Kruskal-Wallis analysis showed no statistically significant difference among 3 groups in every point of time of measurements.

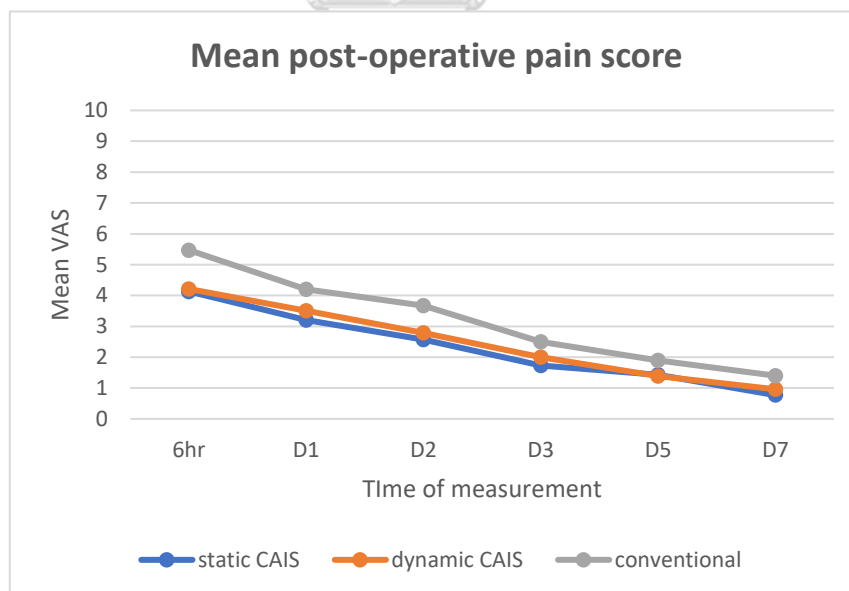


Figure 7. Comparing post-operative mean pain score of 3 groups

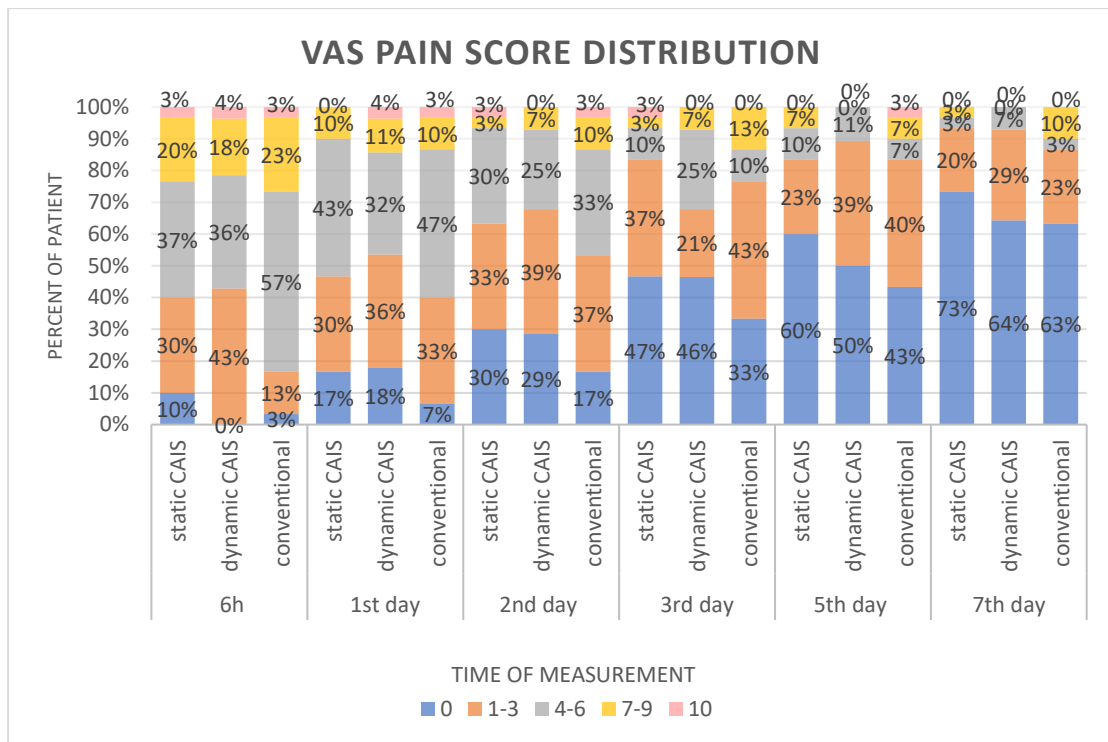


Figure 8. Frequency analysis of VAS pain score of 3 groups

#### 4.5 Painkiller consumption

The change of number of painkillers consumed per day was displayed in figure 10. Similarly, patients in the conventional freehand group showed the highest mean amount of painkiller consumption at 6 hours and the first day after surgery ( $1.33 \pm 0.71$  and  $1.67 \pm 1.47$ , respectively, table 4). At the 1<sup>st</sup> day post-operatively, 4 tablets per day appeared to be the maximum amount of s-CAIS and d-CAIS group while conventional freehand group consumed up to 6 tablets (figure 9). The average painkiller consumption in s-CAIS was closed to d-CAIS group at 6 hours ( $1.20 \pm 0.85$  and  $1.11 \pm 0.96$ , respectively) and rose to  $1.37 \pm 1.30$  and  $1.43 \pm 1.40$  at the 1<sup>st</sup> day even though d-CAIS were the group with the highest patients who did not take any analgesic at that time (32% and 37%). The mean painkiller consumption of all groups decreased on the 2<sup>nd</sup> day and dropped below 1 tablet per day on the 3<sup>rd</sup> day after surgery. After 1 week, 10% of conventional groups still consumed more than 3 tablets of painkiller whereas only 3% of the s-CAIS and none of d-CAIS did. There was no statistical difference among groups at every point of time of measurement after analyzed with Kruskal-Wallis test as shown in table 4.

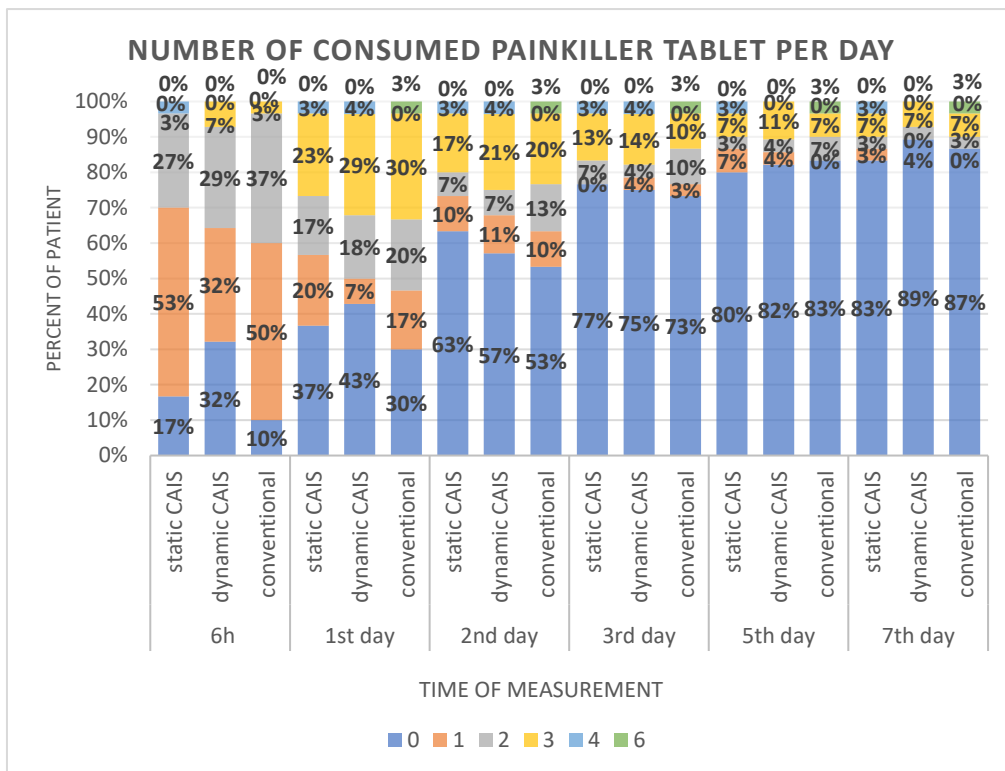


Figure 9. Frequency analysis of painkiller consumption per day of 3 groups

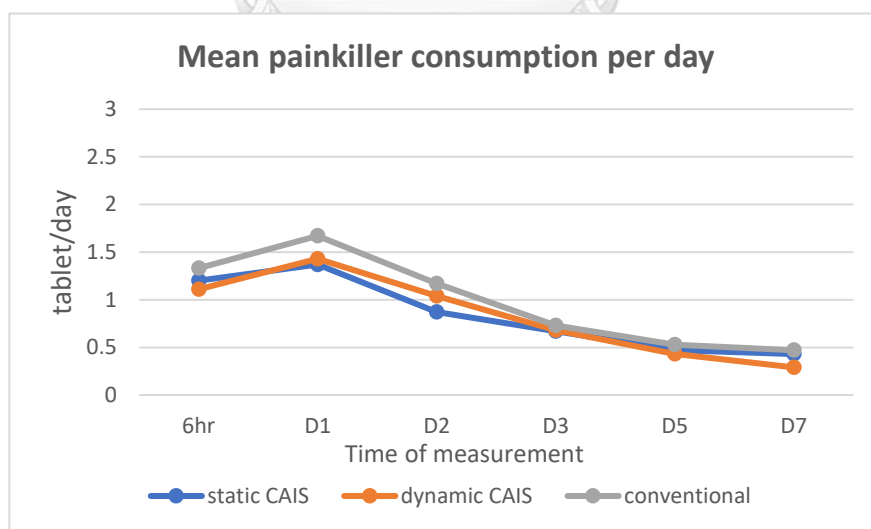


Figure 10. Comparing painkiller consumption per day of 3 groups

### 4.6 Patient self-reported post-operative swelling grading

As seen in figure 12, all groups reported that the peak of swelling was on the 2<sup>nd</sup> day after which it gradually decreased on the following days. The conventional freehand group had the lowest swelling grade at 6 hours and the 1<sup>st</sup> day, followed by d-CAIS then s-CAIS. No patients mentioned grade 4 of swelling at 6 hours post-operatively (figure 11). At the 2<sup>nd</sup> day after the surgery, 54% of the d-CAIS group noticed with grade 3 of swelling followed by s-CAIS(53% ) conventional group(50% ). One patient from s-CAIS (3% ) and 2 patients from conventional freehand group (7%) still ranked the maximum swelling until the 7<sup>th</sup> day. However, no statistical difference among groups was found by Kruskal-Wallis test at every point of time of measurement. (table 4)

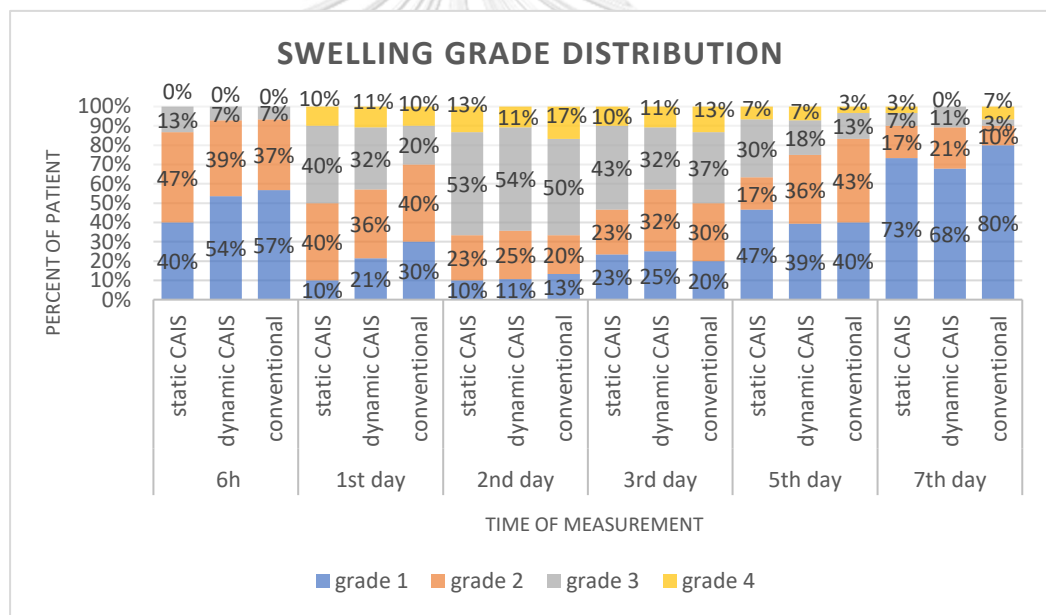


Figure 11. Frequency analysis of swelling grade of 3 groups

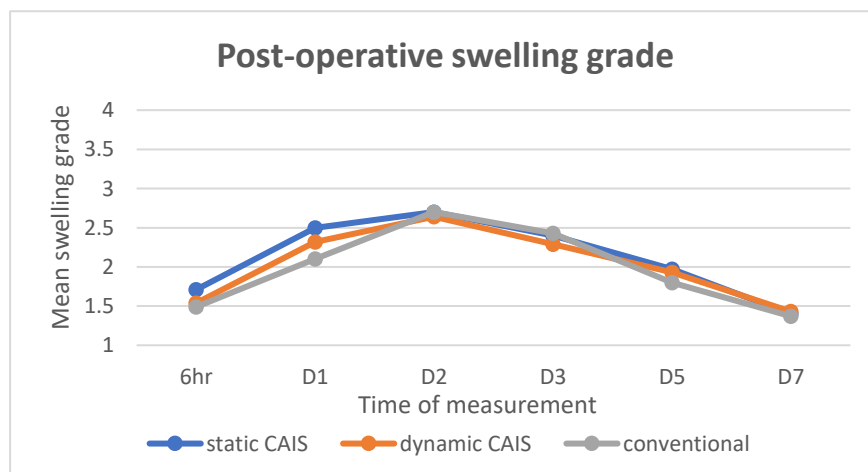


Figure 12. Comparing swelling grade of 3 groups

*Table 4. Comparison of post-operative pain score, painkiller consumption, and swelling grade*

Surgical method	Post-operative pain score [mean $\pm$ SD (range)]					
	6 h	1 <sup>st</sup> Day	2 <sup>nd</sup> Day	3 <sup>rd</sup> Day	5 <sup>th</sup> Day	7 <sup>th</sup> Day
Static CAIS	4.13 $\pm$ 2.83 (0-10)	3.2 $\pm$ 2.46 (0-10)	2.57 $\pm$ 2.54 (0-10)	1.73 $\pm$ 2.41 (0-10)	1.43 $\pm$ 2.37 (0-9)	0.77 $\pm$ 1.85 (0-8)
Dynamic CAIS	4.21 $\pm$ 2.76 (0-10)	3.50 $\pm$ 2.65 (0-9)	2.79 $\pm$ 2.54 (0-8)	2.00 $\pm$ 2.42 (0-8)	1.39 $\pm$ 1.83 (0-6)	0.96 $\pm$ 1.62 (0-6)
Conventional	5.47 $\pm$ 2.29 (0-10)	4.20 $\pm$ 2.50 (0-10)	3.67 $\pm$ 2.84 (0-10)	2.5 $\pm$ 2.89 (0-10)	1.90 $\pm$ 2.83 (0-9)	1.40 $\pm$ 2.43 (0-8)
P-value	0.090	0.291	0.412	0.534	0.636	0.547
Surgical method	Painkiller consumption per day [mean $\pm$ SD (range)]					
	6 h	1 <sup>st</sup> Day	2 <sup>nd</sup> Day	3 <sup>rd</sup> Day	5 <sup>th</sup> Day	7 <sup>th</sup> Day
Static CAIS	1.20 $\pm$ 0.85 (0-4)	1.37 $\pm$ 1.30 (0-4)	0.87 $\pm$ 1.31 (0-4)	0.67 $\pm$ 1.27 (0-4)	0.47 $\pm$ 1.07 (0-4)	0.43 $\pm$ 1.07 (0-4)
Dynamic CAIS	1.11 $\pm$ 0.96 (0-3)	1.43 $\pm$ 1.40 (0-4)	1.04 $\pm$ 1.37 (0-4)	0.68 $\pm$ 1.28 (0-4)	0.43 $\pm$ 1.00 (0-3)	0.29 $\pm$ 0.85 (0-3)
Conventional	1.33 $\pm$ 0.71 (0-3)	1.67 $\pm$ 1.47 (0-6)	1.17 $\pm$ 1.53 (0-6)	0.73 $\pm$ 1.44 (0-6)	0.53 $\pm$ 1.36 (0-6)	0.47 $\pm$ 1.33 (0-6)
P-value	0.493	0.765	0.755	0.983	0.967	0.811
Surgical method	Post-operative swelling grade [mean $\pm$ SD (range)]					
	6 h	1 <sup>st</sup> Day	2 <sup>nd</sup> Day	3 <sup>rd</sup> Day	5 <sup>th</sup> Day	7 <sup>th</sup> Day
Static CAIS	1.71 $\pm$ 0.68 (1-3)	2.50 $\pm$ 0.82 (1-4)	2.70 $\pm$ 0.84 (1-4)	2.4 $\pm$ 0.97 (1-4)	1.97 $\pm$ 1.03 (1-4)	1.40 $\pm$ 0.77 (1-4)
Dynamic CAIS	1.54 $\pm$ 0.63 (1-3)	2.32 $\pm$ 0.94 (1-4)	2.64 $\pm$ 0.83 (1-4)	2.29 $\pm$ 0.98 (1-4)	1.93 $\pm$ 0.94 (1-4)	1.43 $\pm$ 0.69 (1-3)
Conventional	1.49 $\pm$ 0.62 (1-3)	2.10 $\pm$ 0.96 (1-4)	2.70 $\pm$ 0.92 (1-4)	2.43 $\pm$ 0.97 (1-4)	1.80 $\pm$ 0.81 (1-4)	1.37 $\pm$ 0.85 (1-4)
P-value	0.340	0.196	0.937	0.818	0.882	0.675

Comparing among groups using Kruskal-Wallis test

#### **4.7 Patient acceptance of post-operative healing events and functional limitations**

Considering the relatively small number of participants ratings in the levels of strongly disagree and disagree in 5-Likert scale, the scores of patient's acceptances of post-operative healing events were converted into 3 groups for the purpose of analysis: Acceptable/ Uncertain/ Unacceptable. Most participants deemed the post-operative healing events as acceptable including pain (70%), swelling (59%), and limitation of routine activities after the placement of dental implants (figure 13). The least acceptable events were post-operative swelling, with 20% of the patients judging it unacceptable followed by chewing difficulty (15%).

Patients' acceptance as reported for post-operative symptoms and function limitations including pain, swelling, chewing difficulty, and inability to perform usual activities was not significantly different among groups according to Kruskal-Wallis, with the only exception being the s-CAIS patients reporting less acceptable post-operative speaking difficulty ( $p=0.015$ , table 5).

#### **4.8 Overall patient satisfaction**

Ninety-two percent of participants reported satisfaction with the clinical service while 2% of them reported dissatisfaction. Although 89% of participants were satisfied with overall outcome from the surgery, 1% reported dissatisfaction. (figure 13)

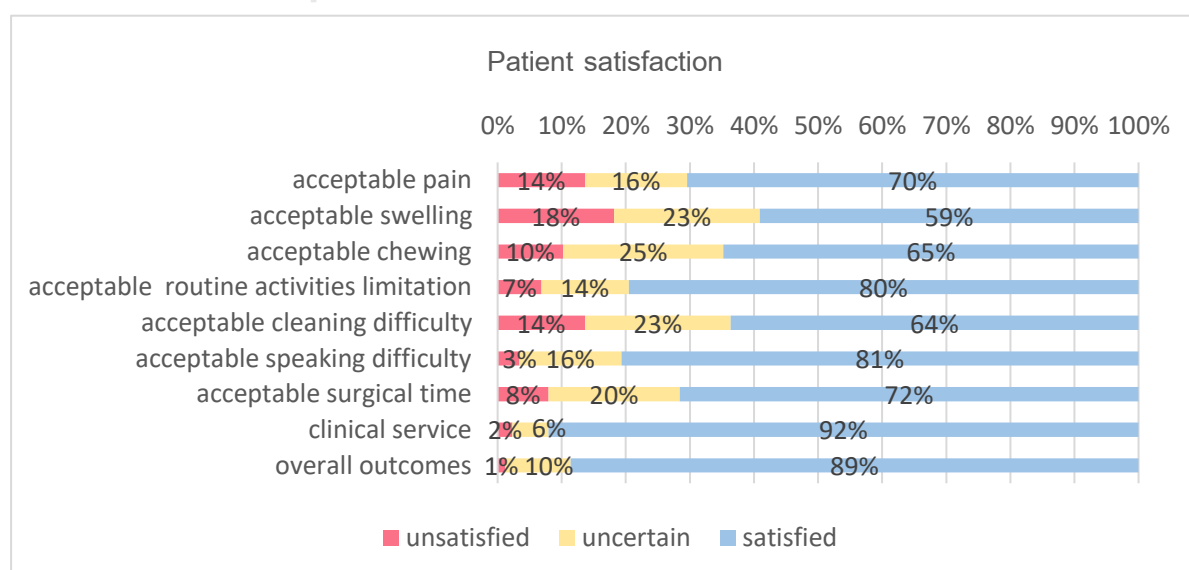
*Table 5. Patient acceptance of functional limitations and overall satisfaction after dental implant surgery*

	Degree of acceptance/satisfaction (median)				p-value
	Static CAIS	Dynamic CAIS	Conventional	All groups	
Acceptable pain	4.0	4.0	4.0	4.0	0.599
Acceptable Swelling	4.0	4.0	4.0	4.0	0.775
Acceptable chewing difficulty	3.0	4.0	4.0	4.0	0.189
Acceptable cleaning difficulty	4.0	4.0	4.0	4.0	0.376
Acceptable inability to perform usual activities	5.0	5.0	4.5	5.0	0.642
Acceptable Speaking difficulty	4.0	5.0	5.0	4.0	<b>0.015*</b>
Acceptable surgical time	4.0	4.0	4.5	4.0	0.432
Clinical service was satisfied	5.0	5.0	5.0	5.0	0.541
Overall outcome was satisfied	4.0	4.5	4.5	4.0	0.511

\* statistically significant at  $p < 0.05$

comparing among groups using Kruskal – Wallis test

Degree of acceptance/satisfaction: 1=strongly disagree, 2=disagree, 3=uncertain, 4=agree, 5=strongly agree



*Figure 13. Acceptance of post-operative complications*

#### 4.9. The relationship of patients' and procedures' characteristics with post-operative pain, swelling and painkiller consumption

The relationship of the 6 hours post-operative maximum mean pain score, painkiller consumption at the first day and swelling grade at the second day with patients' or implant procedures' characteristic were analyzed with Spearman's correlation test. We found only the relationship of flap operation and the maximum swelling ( $p=0.03$ , table 6). No relation between maximum pain or painkiller consumption with other characteristics was detected.

*Table 6. The correlation of patients' and procedures' characteristics with post-operative pain, swelling and painkiller consumption*

Characteristics / P-value	Sex	Age	Education level	Implant experience	Health status
Pain score (at 6h)	0.187	0.561	0.664	0.551	0.473
Swelling grade (2 <sup>nd</sup> Day)	0.211	0.305	0.287	0.387	0.758
Painkiller consumption (1 <sup>st</sup> day)	0.052	0.163	0.074	0.902	0.873
Characteristics / P-value	Numbers of implant	Implant position	Flap operation	Bone augmentation	Operation time
Pain score (at 6h)	0.405	0.806	0.771	0.417	0.610
Swelling grade (2 <sup>nd</sup> Day)	0.760	0.983	<b>0.030*</b>	0.213	0.293
Painkiller consumption (1 <sup>st</sup> day)	0.487	0.602	0.838	0.894	0.447

\* statistically significant at  $p<0.05$

analyzing correlation using Spearman test



## Chapter 5

### Discussion

Post-operative pain and swelling are the most common discomfort the patients reported after implant placement. CAIS has been developed aiming to increase precision and accuracy of the implant placement, and reduce invasiveness of surgical procedures; thus it potentially minimize the discomfort and unpleasant healing events. This study reports the expectation and experience of patients on complications after implant surgery and comparing them among 3 implant placement techniques including s-CAIS, d-CAIS, and conventional freehand. Moreover, the patients' reported post-operative experience was compared with their expectations.

Based on the results, there was no major difference in patients' experience of post-operative complications among 3 implant placement techniques. Although the difference did not reach statistical significance at any timepoint, the higher post-operative pain score as well as the painkiller consumption reported by patients from conventional freehand surgery. On the other hand, experience of post-operative swelling seems less with the conventional technique. The extent and severity of swelling might be very much influenced by individual patient factors, but might be also associated with the duration of the surgery and also the manipulation of the neighboring tissues, retraction techniques and more. The presence of intraoral devices such as surgical guides and the retraction required for CAIS might have constituted a disadvantage with regards to this outcome when compared with freehand. Furthermore, the self-reporting of swelling by the patients might be influenced by location of the surgical site, with patients more likely to report swelling after surgeries in the anterior maxilla or aesthetic zone (90).

The findings of this study were consistent to the previous published study. Joda et al. (71) when reviewed the literature concluded that there is inadequate data to support the impact of s-CAIS in reducing pain and discomfort after surgery. They suggested that a flapless procedure may be more important with regards to reducing the level of pain and swelling than the application of s-CAIS. Fortin et al. (72) reported significantly less analgesics taken by patients

when computer-guided surgery was used for flapless placement of immediately loaded dental implants. The present experiment however did not show any statistical difference in painkiller consumption when full thickness flap was reflected for dental implant preparation whether with or without CAIS. Unfortunately, we could not find the relation of pain relief with type of analgesic because most of patients (60%) did not completely label type of analgesics they took.

Most patients generally reported mild to moderate level of post-operative pain intensity (4.7) and the peak of pain occurred within 24 hours after surgery and registered significant differences in patients' responses over time (91). However, González-Santana and colleagues' study conducted in 41 patients with 131 implants reported the peak of pain after 6 hours (46), thus we included the record at 6 hours post-operation and confirmed their finding with the same peak of pain intensity (average VAS = 4.61). Moreover, they noticed that moderate swelling was also reported in most patients and reached its peak intensity after 48 hours in 48.8%. In accordance to their study, more than 50% of patients in our study had moderate extraoral swelling which was peak at the second day after surgery.

Data expressing patient satisfaction is usually difficult to interpret and generalize, as they tend to strongly relate to individual characteristics of the sample and also the pre-therapeutical expectations of the patients (86). In particular, when new technologies are utilized, there is a risk of a "novelty effect", with the patients developing expectations due to the actual or perceived novelty of the procedure they will be subjected to. It was therefore important to register the patients' expectations before the surgery and investigate possible systemic differences in their expectations. However, the patients in the different groups appeared to harbor few different expectations, pointing towards a limited "novelty effect". Interestingly, patients from conventional freehand group expected significantly shorter duration of pain than they reported in the recovery period, while the expected swelling was significantly underestimated in s-CAIS group. However, the large majority of the patients in all groups deemed as acceptable the pain and swelling. The data showed that even the immediate post-operative complication did not meet their expectations, the patients still satisfied with the treatment and accepted the

consequence they received. Furthermore, the overall satisfaction expressed in all groups was very high (89%). Facial swelling is the least acceptable healing event. However, the group with the highest swelling score (s-CAIS group) - also the group significantly less pleased with the impact of speaking limitations - expressed similar levels of overall satisfaction with all others. In the same way, previous studies also indicated that patients overestimated the discomfort during the actual implant surgery, but underestimated the morbidity of post-surgical healing period, including the severity of the pain, swelling and the discomfort related to the wound (48). Some studies reported that persistent post-operative pain and swelling compromised patient experience and resulted in the reduction of patient satisfaction (92).

Many instruments have been developed for assessing PROMs related to post-operative healing events, without any clear consensus or golden standard emerging. VAS and the consumption of painkillers appear increasingly as the method of choice when measuring pain, while assessing other events such as swelling can be easier through more descriptive scales such as Likert scales ranging from no swelling to severe swelling. For the purpose of simplicity and conformity, this study adopted a swelling rating scale from Santana's study (46). Although more complex instruments have been developed and validated (90) for specific usage in implant therapy, the requirement for closer supervision and more elaborate explanations to the patient might present with practical limitations.

The results of the study should be seen under the limitation of the methodology. In order to conduct a randomized trial with adequate numbers in each group, the authors chose to sequentially enroll patient cases with a wider spectrum of treatment types. The great majority of patients received 2 posterior implants under flap surgery, but some few cases included anterior implants, 3 implants or more and 2 cases were done flapless. Although in ideal conditions the authors would have preferred to have a narrower array of implant treatments, the randomization and the fact that the procedures are not skewed to any specific of the 3 types tested procedures, minimized any risk for systemic bias. The different types of procedures are presented in detail in table 2 and no significant difference in the sample was found with regards to the type

of treatment. The only significant discrepancy among the groups was this of gender distribution but remains unlikely that it could influence the results in any direction. Some studies have reported interaction between gender and pain evaluation, with higher levels of pain being reported by females compared to males (91), while other studies indicated no significant difference between genders (47). In this study, the conventional freehand group showed the highest post-operative pain score, while it was the group with the highest representation of male participants.

Many studies pointed out the cost of implant treatment was believed to be high and became one of the barriers for receiving implant therapy(52). High cost may also relate to unrealistic expectations. In this study, cost of treatment did not involve in correlation analysis for patient satisfaction because the additional charges for s-CAIS and d-CAIS were covered by the research protocol. This effect may disguise the possibly unrealistic expectation. However, the additional cost of CAIS should be studied in the future to prove whether it was a worthwhile treatment.

The mean time spent for the surgical guided stent try-in was 8.69 minutes and for the registration of d-CAIS was 5.13 minutes. As surgical time was counted from the first incision was made until the last suturing in open-flap procedure, this additional time spent was not included in this study. Using guided stent for s-CAIS turn out the most time-consumed technique. The fitting and thickness of surgical stent became a hinder of implant bed preparation especially in space limiting area like posterior molar. Nevertheless, the flapless surgery via surgical guided stent from s-CAIS was proved with significantly faster than conventional surgery in Joda's study(71). Practically, using d-CAIS does not need pre-processing steps that take long time like creating surgical guide stent for s-CAIS. However, surgeons have to weigh the cost-effectiveness from using these.

CAIS provides significant benefits in term of precision and accuracy over conventional surgery. It allows for restorative treatment planning and decreases the risks of misplacement, unfavorable prosthetic position and consequent compromised prostheses. Furthermore, where

indicated, CAIS can empower the predictable fabrication of temporary prosthesis for cases of immediate provisionalisation or loading. Nevertheless, whether CAIS protocols can also result in significant improvements in the PROMs and the patients' overall healing experience was not shown in this study. Further studies with more targeted and specific interventions might be required to investigate the impact of such protocols in short and long term PROMs.

It remains important to explicitly explain CAIS overall advantages to patients, as patient long term overall satisfaction is not only influenced by the experience during or after shortly after the surgery but mainly shaped by mastication function, aesthetics, and perceptions after loading with the prosthesis.



## Chapter 6

### Conclusion

Placing dental implants with static, dynamic computer- aided surgery, or conventional freehand surgery resulted in the same level of post-operative pain intensity, swelling degree, painkiller consumption. Self-reported pain intensity peaked at 6 hours after the operation, while swelling at 2 days in every surgical technique. All techniques got equal levels of patient satisfaction. Moreover, most of patients significantly underestimated the duration of pain and swelling after dental implant placement. The expectation of chewing difficulty, as well as the experience of pain duration, speaking difficulty, and inability to conduct daily routine activities after surgery were significantly different among groups even though they deemed their post-operative symptoms as acceptable.

#### Conflict of interest

The authors declare no conflict of interests.

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