Comparison the accuracy of implant position between static and dynamic computer-assisted implant surgery with two-implant support fixed partial prosthesis

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การเปรียบเทียบความแม่นยำของตำแหน่งรากฟันเทียมระหว่างการฝังรากฟันเทียมด้วยวิธีคอมพิวเตอร์ช่วยแบบสถิตและแบบพลวัตโดยใช้รากฟันเทียมสองรากเพื่อรองรับฟันปลอมบางส่วนชนิดติดแน่น

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ปวีณา ยิ้มอาจ : การเปรียบเทียบความแม่นยำของตำแหน่งรากฟันเทียมระหว่างการฝังรากฟันเทียมด้วยวิธีคอมพิวเตอร์ช่วยแบบสถิตและแบบพลวัตโดยใช้รากฟันเทียมสองรากเพื่อรองรับฟันปลอมบางส่วนชนิดติดแน่น. (Comparison the accuracy of implant position between static and dynamic computer-assisted implant surgery with two-implant support fixed partial prosthesis) อ.ที่ปรึกษาหลัก : รศ. ทพ.ดร.อาทิพันธุ์ พิมพ์ขาวขำ

วัตถุประสงค์: เพื่อเปรียบเทียบความแม่นยำของตำแหน่งรากฟันเทียมระหว่างการใช้วิธีคอมพิวเตอร์ช่วยแบบสถิตและแบบพลวัต ในผู้ป่วยที่ต้องการรากฟันเทียมสองรากเพื่อรองรับฟันปลอมบางส่วนชนิดติดแน่น

วัสดุและวิธีการ: รากฟันเทียมจำนวน 60 ซี่ ในผู้ป่วย 30 คนที่ต้องการรากฟันเทียมสองรากเพื่อรองรับฟันปลอมบางส่วนชนิดติดแน่น ด้วยวิธีคอมพิวเตอร์ช่วย 2 ระบบคือวิธีคอมพิวเตอร์ช่วยแบบสถิต (n = 30) โดยการใช้แผ่นนำการผ่าตัดในการฝังรากฟันเทียมและระบบที่ 2 ด้วยวิธีคอมพิวเตอร์ช่วยแบบพลวัต (n = 30) ที่เป็นระบบนำทางผ่าตัด หลังจากฝังรากฟันเทียมจะทำการถ่ายภาพรังสีส่วนตัดอาศัยคอมพิวเตอร์แบบโคนบีมและนำมาเข้าซอฟต์แวร์เพื่อวัดความคลาดเคลื่อนของตำแหน่งรากฟันเทียมที่ฝังได้กับตำแหน่งที่วางแผนไว้ ผลลัพธ์หลักคือค่าความคลาดเคลื่อนที่ตำแหน่งขอบบนของรากฟันเทียม, ปลายรากฟันเทียม และความคลาดเคลื่อนเชิงมุม และผลลัพธ์รองคือความขนานกันของรากฟันเทียมสองรากในรูปของความคลาดเคลื่อนเชิงมุม

ผลการศึกษา: ความคลาดเคลื่อนเฉลี่ยที่ตำแหน่งขอบบนของรากฟันเทียมและปลายรากฟันเทียมในกลุ่มที่ใช้คอมพิวเตอร์ช่วยแบบสถิตคือ 1.04±0.71 มม. และ 1.51±0.86 มม. ตามลำดับ ความคลาดเคลื่อนเฉลี่ยที่ตำแหน่งขอบบนของรากฟันเทียมและปลายรากฟันเทียมในกลุ่มที่ใช้คอมพิวเตอร์ช่วยแบบพลวัตคือ 1.24±0.62 มม. และ 1.58 ± 0.77 มม. ตามลำดับ ความคลาดเคลื่อนเชิงมุมและความขนานกันของรากฟันเทียมสองรากในกลุ่มที่ใช้คอมพิวเตอร์ช่วยแบบสถิตคือ 4.05±2.06 องศา และ 4.32±2.44 องศา ในกลุ่มที่ใช้คอมพิวเตอร์ช่วยแบบพลวัตคือ 3.78±2.38 องศาและ 3.55±2.29 องศา ไม่พบความแตกต่างกันอย่างมีนัยสำคัญทางสถิติของทั้งสองกลุ่ม

สรุปผลการศึกษา: การฝังรากฟันเทียมโดยใช้คอมพิวเตอร์ช่วยแบบสถิตและแบบพลวัตให้ความแม่นยำเทียบเท่ากัน ในผู้ป่วยที่มีช่องว่างไร้ฟันบางส่วนที่ต้องการรากฟันเทียมสองรากเพื่อรองรับฟันปลอมบางส่วนชนิดติดแน่น

สาขาวิชา	ศัลยศาสตร์ช่องปากและแม็กซิลโลเฟเชียล	ลายมือชื่อนิสิต ....
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KEYWORD: dental implant, accuracy of implant surgery, computer-assisted implant surgery, guided surgery, navigation

Paweena Yimarj : Comparison the accuracy of implant position between static and dynamic computer-assisted implant surgery with two-implant support fixed partial prosthesis. Advisor: Assoc. Prof. ATIPHAN PIMKHAOKHAM, D.D.S., Ph.D.

Objectives: To compare the accuracy of position and parallelity of two implants, using static and dynamic CAIS systems.

Materials & Methods: 30 patients received two implants randomly allocated to 2 different CAIS systems. Optimal implant position and absolute parallelity was planned based on preoperative CBCT. Implants were placed using surgical guide (static CAIS, n = 15) and real time navigation (dynamic CAIS, n = 15). Implant 3-dimentional deviation and parallelity was calculated after surgery.

Results: The mean deviation at implant platform, apex and angulation in the static and dynamic CAIS group was 1.04 ± 0.67 mm, 1.54 ± 0.79 mm, 4.08 ± 1.69 degree and 1.24 ± 0.39 mm, 1.58 ± 0.56 mm, 3.78 ± 1.84 degree respectively. The parallelity achieved between two placed implants in static and dynamic CAIS groups were 4.32 ± 2.44 degrees and 3.55 ± 2.29 degrees respectively. There were no significant differences in all parameters between two groups.

Conclusions: Static and dynamic CAIS provides similar accuracy of the 3d implant position and parallelity between two implants.

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

Page

.... iii

ABSTRACT (THAI) iii

.... iv

ABSTRACT (ENGLISH) iv

ACKNOWLEDGEMENTS v

TABLE OF CONTENTS vi

LIST OF TABLES ix

LIST OF FIGURES x

CHAPTER I INTRODUCTION 1

1.1 Background and rationale 1

CHAPTER II REVIEW OF LITERATURE 4

2.1 Dental implant 4

2.2 Complications related to implant malposition 4

2.3 Conventional or freehand implant placement 5

2.4 Computer-Assisted Implant Surgery (CAIS) 6

2.4.1 Static Computer-Assisted Implant Surgery (Static CAIS) 6

2.4.2 Dynamic Computer-Assisted Implant Surgery (Dynamic CAIS) 11

2.5 Important of parallelism? 16

2.6 Accuracy analysis 16

2.7 Research question 18

2.8 Objective 18

2.9 Hypothesis 18

2.10 Conceptual framework 19

CHAPTER III MATERIAL AND METHODS 20

3.1 Material 20

3.1.1 Sample 20

3.1.2 Sample size calculation 20

3.1.3 Cone Beam Computed Tomography (CBCT) 20

3.1.4 Implant 20

3.1.5 Static CAIS system 20

3.1.6 Dynamic CAIS system 21

3.1.7 Statistic analysis software 21

3.2 Methods 21

3.2.1 Sample size calculation 21

3.2.2 CBCT scanning protocal 22

3.2.3 Preoperative implant planning 22

3.2.4 Surgical procedures 22

3.2.4.1 Implant placement with static CAIS 22

3.2.4.2 Implant placement with dynamic CAIS 23

3.2.5 Accuracy measurement 23

3.2.6 Statistical analysis 25

3.2.7 The study workflow 26

CHAPTER IV RESULTS 27

CHAPTER V DISCUSSION 32

CHAPTER VI CONCLUSION 35

REFERENCES 36

VITA... 43

LIST OF TABLES

Page

Table 1 The study on accuracy of the implant position by using static computer-assisted implant surgery. 10

Table 2 The study on accuracy of the implant position by using dynamic computer-assisted implant surgery. 14

Table 3 The deviation of implant position. 27

Table 4 The angular deviations between two placed dental implants (parallelism) in each patient. 28

LIST OF FIGURES

Page

Figure 1 Surgical template with metal sleeves for static CAIS system. 2

Figure 2 Dynamic CAIS system (Navigation system)... 2

Figure 3 The three parameters for analyzing the implant deviations. 17

Figure 4 The deviation of the planned and placed implant position in three............. 24

Figure 5 The angle deviation between two placed implants in each patient.............. 24

Figure 6 The deviation at implant platform in mesio-distal and bucco-lingual direction... 29

Figure 7 The deviation at implant platform in mesio-distal and apico-coronal direction... 29

Figure 8 The deviation at implant platform in bucco-lingual and apico-coronal direction... 30

Figure 9 The deviation at implant apex in mesio-distal and bucco-lingual direction.. 30

Figure 10 The deviation at implant apex in mesio-distal and apico-coronal direction. 31

Figure 11 The deviation at implant apex in bucco-lingual and apico-coronal direction. 31

CHAPTER I

INTRODUCTION

1.1 Background and rationale

Proper prosthetic driven 3-dimentional implant position is considered today a fundamental element for sustainable function and aesthetic outcome in implant prosthodontics (1-4).

Good preoperative and intraoperative planning for dental implant placement are an important to obtain the accurate implant position. Conventional implant placement using free-hand surgery based on 2D radiographic assessment might lead to decreasing accuracy or unfavorable implant positioning especially in complex cases or multiple implants, thus increasing the risk for short or longer term complications (5, 6).

In order to get rid of these limitations, Computer-Assisted Implant Surgery (CAIS) have been introduced in response to the need for increased precision and accuracy, mainly including two approaches: the static and the dynamic. Both systems are based on all three dimensions and simulation of virtually implant in the optimal position (10). Then the virtual implant planning is transferred to surgical sites by means of a custom-made guided surgery template in the case of static CAIS or through a real-time tracking and guidance of the surgical drill in dynamic CAIS systems (11, 12).

The static CAIS system is composed of CT scan, surface scan (model or oral scan) and implant planning software to design surgical guide stents that create CT-generated CAD/CAM guide stents (7). The position of implants in surgical site are controlled by metal sleeve of guide template. However, the static CAIS systems would not allow the surgeon direct visual contact with the working surgical site and intra-operative change from the planned position are different. The patients mouth opening, availability of teeth, teeth position or mobility might be important practical parametres that can influence the ability to place and stabilize a surgical guide, in particular concerning posterior surgical sites (8).

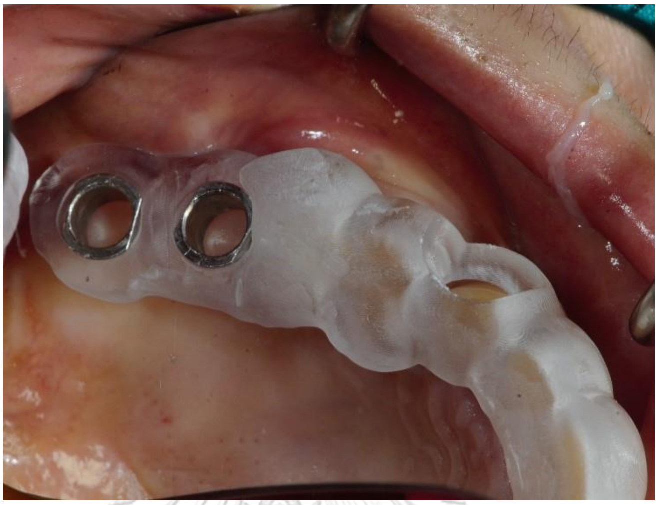


Figure 1 Surgical template with metal sleeves for static CAIS system.

The dynamic CAIS system (navigation system) is the system that directly transfer the virtually implant position through the bone via real time direct visual and require sensitive registration procedures, any mistake during which lead to Tracking Registration Error (TRE) from CBCT image and the actual position of the patient's jaw depicted during the surgery. To such limitations one could add, the necessary learning curve of the surgeon and the high cost of the machine (9-11).

Figure 2 Dynamic CAIS system (Navigation system).

Several studies have documented improved accuracy static or dynamic CAIS as compared to free hand surgery, the majority of clinical studies have only evaluated single implant placement (6, 8, 9, 12). Although studying single-implant clinical scenaria would be an essential proof of principle, the truth is that the cases where increased accuracy is required are mainly concerning complex reconstructions with multiple implants, especially where implant parallelity is required. A fixed dental prosthesis supported by two or more implants would add the complexity element of the implant paralellity or relative angulation, something especially important in the light of sustainable prosthesis design and modern immediate loading protocals.

At present however, there are no clinical studies investigating the accuracy of static or dynamic CAIS on the parallelity of multiple implants. Thus, the aim of this study was to compare the accuracy of implant position, as well as the paralellity between two implants placed with either static or dynamic CAIS to support a fixed dental prosthesis in partially edentulous patients.

CHAPTER II

REVIEW OF LITERATURE

2.1 Dental implant

Dental implants are efficient and predictable so it is widely accepted for the teeth replacement. Success or failure treatment depends on many factors such as medical conditions, drugs intake, smoking and the oral health status (13, 14). It is defined by adjacent teeth in conventional method or using computer technology to design position and insert implants.

2.2 Complications related to implant malposition

In term of “prosthetic-driven implant planning” is considerable and affecting to successful of dental implant. In general, the etiology may be result from improper treatment plan (15). Therefore, the proper evaluation of tooth position, angulation and prosthetic restoration is essential for preoperative assessment of implant sites.

2.2.1 Mesiodistal dimension

The space between implants and adjacent teeth is 1.5 mm, implant and implant abutment level is 3.0 mm should be maintained (16, 17).

2.2.2 Buccolingual dimension

The buccal wall thickness of 1mm should be maintained to prevent gingival recession and improve esthetics. In contrast, placed too lingually often lead to crown on implant with a ridge-lap design (16).

2.2.3 Coronoapical dimension

The implant platform should be placed about 3-4 mm apically of the planned final restoration or the CEJ of an adjacent tooth (16). The implant is placed coronally may lead to a visible metal margin that affect to esthetic outcome (2).

2.2.4 Mis-axis problem

If the axis is insignificant error, using angled abutments can be corrected. If it is severe, very hard to correct. So, the treatment is to explant, bone augmentation and place a new implant fixture in the optimal position (16). The angular deviation over 25 degrees may lead to effect to the crestal bone (18).

The dental implant malposition can prevented by implant planning procedures that determine the proper implant positions such as Computer-Assisted Implant Surgery (CAIS) system (19).

2.3 Conventional or freehand implant placement

This method is implant placement by freehand approach. It can be more challenging to properly place implants because it will guide only the bone entry of the drill but does not virtually plan in three dimensional directions. The conventional implant surgery has limitations such as surgical guide is fabricated from diagnostic model and wax-up or radiographic interpretation without reference from underlying anatomical structure, the surgeon unable to control the depth and angulation of implant during surgery and the implant does not virtually plan in three dimensional directions (5).

The conventional implant placement allows for positioning errors due to deviations during osteotomy or drilling sequences and implant insertion (20). So, the use of this method can be a significant disadvantage as proper position of dental implants are critical factors related to the esthetic and functional outcome of prosthetic restoration (21). Thus, this technique may affect to long-term success of dental implant.

2.4 Computer-Assisted Implant Surgery (CAIS)

CAIS is a digital technology to design three-dimensional image reconstruction and simulation of virtual implant placement that provides many advantages (22). For example, it allows efficient preoperative planning of implant placement leading to improved esthetic, function and prosthetic outcome (23-25). The technology is based on the transformation of the virtually planned implants to the real surgical sites. CAIS divided into static and dynamic CAIS (26, 27).

2.4.1 Static Computer-Assisted Implant Surgery (Static CAIS)

This system can be performed by using Computer-Aided Design/Computer-Assisted Manufacturing (CAD/CAM) technology assist the progress of treatment planning and fabricating guide template. The Digital Imaging and Communications in Medicine (DICOM) file from CBCT is imported to software program. The virtual implant is planned by planning software. Then, the data is transformed into a guide template (24). The position of implants in surgical site are controlled by sleeve (metal cylinders) of guide template that used as drill-guiding to transfer the implant position (28). This surgical template is to direct drill-guiding and allows the surgeon to place the implant according to planning implant position (8, 29).

The advantages of this method include more accurately implant position than using freehand approach and conventional guide templates, the possibility of operating with flapless approach. Reduction of the error from the technique sensitivity and surgeon experience, which may improve current implant surgical practices (5).

The disadvantages of this method are implant position depend on the guided stent that does not change intraoperative implant position. These include require wide mouth opening for surgical drill especially in posterior teeth, limitation of *irrigation* to prevent bone overheating in surgical site (7, 27).

There are many methods for fabricating surgical guide template: manually fabricated templates or milling technique, stereolithographic (rapid prototyping).

There are more studies about the stereolithographic method but there are no evidences to support that this method is better than other methods (8, 12).

2.4.1.1 Accuracy of the static CAIS

Di Giacomo et al. (30) studied in 4 partially and totally edentulous about the deviation of 21 implants placed by using stereolithographic templates (Simplant, CSI Materialise). They reported the deviation at the platform was 1.45±1.42 mm, at the apex was 2.99±1.77 mm and the angular deviation was 7.25±2.67 degrees.

Ersoy et al. (22) reported the deviation of 94 implants placed using stereolithographic templates (Stent Cad, Media Lab Software, La Spezia, Italy) in 21 patients (7 single tooth loss, 7 partial edentulous and 7 total edentulous), the deviation at implant platform and apex were 1.22±0.85 mm and 1.51±1mm and axis deviation was 4.9±2.36 degrees.

Ozan et al. (31) reported the deviation of implant position of 110 implants by using static CAIS (Stent Cad, Media Lab Software, La Spezia, Italy). The mean deviation at the platform and apex were 1.11±0.7 mm and 1.41±0.9 mm. The angular deviation was 4.1±2.3 degrees and concluded the tooth-supported templates were the most accurate.

Valente et al. (32) studied in 25 patients about the accuracy of 89 stereolithographic templates by using Simplant program (Materialise Dental Inc, Glen Burnie, MD, USA). The deviation at the platform was 1.4±1.3 mm, 1.6±1.2 mm at the apex and the axis deviation was 7.9±4.7 degrees.

Nickenig et al. (33) studied the deviation of 23 implant placed between using software planning (coDiagnostiX, IVS-solutions, Chemnitz, Germany) and surgical templates fabricated by model-based technique in 10 mandible (Kenedy class II). They reported the deviation in bucco-lingual and mesio-distal were 0.9±1.06 mm and 0.9±1.22 mm at the implant platform. At the apex in bucco-lingual and mesio-distal were 0.6±0.57 mm and 0.9±0.94 mm. The axis deviation was 4.2±3.04 degrees and they concluded that the implant placement using guided templates is more precise than freehand implant placement.

Vasak et al. (23) studied the deviation of 56 implants placed using static CAIS system (NobelGuidet, Nobel Biocare, Gothenburg, Sweden) in 18 partially edentulous patients. The deviation at implant platform in bucco-lingual, mesio-distal and depth were 0.43 mm, 0.46 mm and 0.53 mm, respectively. The deviation at the apex in bucco-lingual, mesio-distal and depth were 0.7 mm, 0.63 mm and 0.52 mm, respectively.

Pettersson et al. (34) reported the deviation of 139 implants placed in 25 fully edentulous by using static CAIS with Nobel Guide software program (Nobel Biocare, Yorba Linda, CA, USA). The mean deviation at the implant platform was 0.8 mm, at the apex was 1.09 mm and axis deviation was 2.26 degrees.

Behneke et al. (35) reported the deviation of 132 implants placed using planning software (Med3D, Heidelberg, Germany) with tooth-supported templates in 52 partial edentulous patients. The deviation in maxilla at entry point was 0.27mm, 0.28 in mandible, at apex was 0.5 in maxilla, 0.4 in mandible, angular deviation was 1.82 in maxilla and 1.86 in mandible. They concluded that the implant placement using the guided template more accurate than freehand implant placement or partially guided protocal.

Platzer et al. (36) studied the deviation of 15 implants placed using Simplant software program (Materialise Dental Inc, Leuven, Belgium) and tooth-supported templates in 5 partially edentulous patients. They reported that the mean deviation in bucco-lingual, mesio-distal and apico-coronal were 0.27±0.19 mm, 0.15±0.13 mm and 0.28±0.19 mm, respectively and angular deviation was 14.04±11.6 degrees.

Farley et al. (6) studied the deviation of 20 implants placed in 10 patients who have single tooth loss. This study is a split mouth that each patient received two implants and 2 difference templates: CAD/CAM generated guide and conventional template. They concluded that the deviation of implants placement with CAD/CAM templates less than conventional guide but significant differences were found only distances of coronal horizontal direction.

Systematic review from Tahmaseb et al. (25) studied from 14 clinical studies about the accuracy of 2,355 implants. The mean deviation at the implant platform and apex were1.04 mm and 1.45 mm and the axis deviation was 4.06 degrees. Significant differences were found in accuracy of tooth and mucosa-supported more accurate than bone-supported templates.

Table 1 The study on accuracy of the implant position by using static computer-assisted implant surgery.

Study	Study design	Study group	System	Implant (N)	Deaviation		
					Entry point (mm)	Apex (mm)	Angle (degree)
Di Giacomo et al. 2005	PS	4 partial and total edentulous	SimPlant	21	1.45±1.42	2.99±1.77	7.25±2.6
Ersoy et al. 2008	PS	7 single tooth space, 7 partial edentulous, 7 total edentulous	StentCad	94	1.22±0.85	1.51±1	4.9±2.3
Ozan et al. 2009	CCT	30 single tooth space, partial edentulous and total edentulous	StentCad	110	1.11 ± 0.7	1.41 ± 0.9	4.1 ± 2.3
Valente et al. 2009	RS	17 partial edentulous, 10 full edentulous	SimPlant	89	1.4±1.3	1.6±1.2	7.9±4.7
Nickenig et al. 2010	CCT	10 partial edentulous	coDiagnostiX	23	0.9±1.06 B-L 0.9±1.22 M-D	0.6±0.57 B-L 0.9±0.94 M-D	4.2±3.04
Vasak et al. 2011	PS	18 partial edentulous	NobelGuide	86	0.4±0.35 B-L 0.4±0.32 M-D	0.7±0.49 B-L 0.5±0.44 M-D	3.5±1.77
Pettersson et al. 2012	PS	25 full edentulous	NobelGuide	191	0.80	1.09	0.26
Behneke et al. 2012	PS	52 partial edentulous	Implant 3D	Max 87 Man 45	0.27 0.28	0.5 0.4	1.82 1.86
Platzer et al. 2011	PS	5 partial edentulous	Simplant	15	0.2±0.19 B-L 0.1±0.13 M-D	-	-
Farley et al. 2013	RCT	10 single tooth space	iDent Conventional	10 10	1.45±0.06 1.99±1.00	1.82±0.60 2.54±1.23	3.6±2.19 6.1±4.04
Tahmaseb et al. 2014	Systematic review	14 human clinical studies	-	2,355	1.04	1.45	4.06

(PS = Prospective Study; CCT = Controlled Clinical Study; RS = Retrospective Study;
RCT = Randomized Controlled Trial)

2.4.1.2 Factors affecting accuracy in the static CAIS

- Type of arch

Behneke et al. (35) reported significant difference was found for the mean deviation at the apex of implant which larger in the maxilla but the deviation only 0.1 mm, that no effect in clinical.

Ozan et al. (31) studied 110 implants placed in 30 subjects. Significant difference were found for the axis deviation and deviation at entry point.

- Type of template (tooth-supported / bone-supported / mucosa-supported)

Ersoy et al. (22) studied the deviation of 29 implants placed in Kennedy Class I or II). They concluded that single tooth supported templates had better accuracy than free-ending tooth supported templates.

Ozan et al. (31) studied the deviation of 110 implants placed by 3 types of templates. They concluded that tooth-supported template were more precise than bone and mucosa-supported templates.

- Type of guided surgery

Behneke et al. (35) concluded that increase in the number of sleeve-guided site preparation steps made a higher accuracy, so the implant placement with the guide allowed more accurate than freehand approach or freehand final drilling.

- Operator's skill

Rungcharassaeng et al. (29) studied about the effect on the accuracy of implant position of operator experience in partially edentulous mandibular model with a computer-guided surgery. They reported no significant differences were found.

2.4.2 Dynamic Computer-Assisted Implant Surgery (Dynamic CAIS)

This technique is a real time visualization of the drill movements, based on data from CBCT images (37). An intraoperative navigation system consist of optical tracking which registers the position of the handpiece and the patient by tracking camera and show them on a computer monitor as long as the sensors on the handpiece and patient stay within the line of sight of the camera (11, 38)..

The operation of this system begins with a custom made vacuum stent attach with occlusal device composed of 4 radiopaque fiducial markers that uses as reference point to the patient arch is placed in the patient mouth during CBCT scan. The DICOM file from CBCT is imported to the system in order to create optimal implant position. During the surgery, tracking collar with the occlusal appliance and the handpiece will be registered to navigation machine. Then, the surgeon prepares the position of patient and tracking collar. Then, the surgeon performed the osteotomy and implant placement under the dynamic navigation system (39).

The advantages of this method include accuracy over the freehand approach (9) and using conventional guide stent (40), the ability to change the preoperative plan during the surgery. Dynamic navigation system is suitable for implant placement in patients who have limited mouth opening and implant placement at the posterior edentulous area (9).

The disadvantages of dynamic navigation system include requires many steps of registration (5). Using optical tracking need a free line-of sight between the patient, handpiece sensor and tracking camera to prevent the loss of tracking. Moreover dynamic CAIS has high cost and need special training (9).

2.4.2.1 Accuracy of dynamic CAIS system

Wittwer et al. (41) reported the deviation of 78 implants placed in 20 fully edentulous using navigation system (The StealthStation Treon, Medtronic, Minneapolis, MN). The mean deviation at platform and apex were 1.1 ± 0.7 mm and 0.8 ± 0.6 mm.

Wittwer et al. (42) studied about the deviation of implant positon in 16 fully edentulous patient between 2 dynamic systems (The StealthStation Treon, Medtronic, Minnesota, MN versus VISIT navigation system, University of Vienna, Vienna, Austria). The deviation in the bucco-lingual at the platform and apex in both system were similar (VISIT : 1.0 ± 0.5 mm in labial , 0.7 ± 0.3 mm in lingual direction at the implant platform vs 0.6 ± 0.2 mm in labial, 0.7 ± 0.3 mm in lingual direction at the apex versus Treon : 1.0 ± 0.5 mm in labial , 1.2 ± 0.8 mm in lingual direction at the implant platform vs 0.8 ± 0.6 mm in labial, 0.7 ± 0.5 mm in lingual direction at the apex)

Elian et al. (43) reported the deviation of 14 implants placed in 3 single tooth space patients and 3 partially edentulous patients using dynamic system (IGI, DenX Advanced Dental Systems, Moshav Ora, Israel). The mean deviations at implant platform and apex were 0.89 ± 0.53 mm, 0.96 ± 0.50 mm and 3.78 ± 2.76 degrees of angulation.

Block et al. (39) studied compared the deviation of 100 implants placed in single tooth gap patients between using dynamic system (X-Guide, X–Nav Technologies) and conventional implant placement. They concluded that navigation system provides more accurate than freehand approach. The deviations were found 1.37 ± 0.55 mm at implant platform, 1.56 ± 0.69 mm at apex and angle deviation 3.62 ± 2.73 degrees in dynamic group while in conventional placement were 2.51 ± 0.86 mm, 1.67 ± 0.43 mm and 7.69 ± 4.92 degrees respectively.

Table 2 The study on accuracy of the implant position by using dynamic computer-assisted implant surgery.

Study	Study design	Study group	System	Implant (N)	Deviation		
					Entry point (mm)	Apex (mm)	Angle (degree)
Wittwer et al. 2005	PS	20 full edentulous	Treon	78	1.1±0.7	0.8±0.6	-
Wittwer et al. 2007	RCT	16 full edentulous	Treon	16	1.0±0.5La 1.2±0.8Li	0.8±0.6La 0.7±0.5Li	-
			VISIT	16	1.0±0.5La 0.7±0.3 Li	0.6±0.2La 0.7±0.3 Li	
Elian et al. 2008	Case series	3 single tooth space, 3 partial edentulous	IGI	6	0.89±0.53	0.9 ±0.50	3.7±2.76
Block et al. 2016	PS	100 single tooth space	X-Guide	80	1.37±0.55	1.56±0.69	3.62±2.73
			Freehand	20	1.67±0.43	2.51±0.86	7.69±4.92

(PS = Prospective Study; CCT = Controlled Clinical Study; RS = Retrospective Study;
RCT = Randomized Controlled Trial)

Somogyi – Gnass et al. (40) reported the deviation of implant position between dynamic CAIS system (Claron Technology Inc., Toronto, ON, Canada), three static CAIS systems : Simplant (Materialise Dental, Leuven, Belgium), Straumann Guided Surgery (Institut Straumann AG, Basel, Switzerland), NobelClinician, (Nobel Biocare AG, Zurich, Switzerland) and conventional surgical guide stent. They concluded dynamic and static CAIS provide the better accuracy than conventional method.

Ruppin et al. (44) reported about the deviation of implant placement between two dynamic CAIS system and one static CAIS system (Artma virtual patient, RoboDent LapAccedos and Materialise SurgiGuide). No significant differences were found between three CAIS system.

2.4.2.2 Factors affecting accuracy in the dynamic CAIS

There are many factors may affecting in the accuracy of implant position using navigation system: registration error, type of fiducial markers and reference sensor frame support and operator's skill.

-The registration error

The registration procedure is the matching of the points between patient and CBCT image. Including, Fiducial Focalization Error (FLE), the error at the fiducial is measured by locating two fiducial markers on patient's arch by the measure probe. Fiducial Registration Error (FRE), the root-mean square distance between corresponding fiducial points after registration, is computed by the registration algorithm. Target Registration Error (TRE), the distance between corresponding points other than the fiducial points after registration. TRE is measured after registration by convert the position of points on the jaw to CT-space and comparing these positions to the corresponding points on the original image (5, 45, 46).

- Type of markers and reference sensor support

Casap et al. (11) studied registration error (TRE) between two dynamic CAIS: IGI system (DenX Advanced Dental Systems, Moshav Ora, Israel) and LanmarX system

(Medtronic Xomed, Inc., Jacksonville, FL) . They reported that the registration error (TRE) from the IGI system is less than the LanmarX system.

- Operator's skill

Block et al. (39) concluded that implant placed by experienced surgeon had more precise and flat learning curve. And the other two showed more deviation for the first 10 and second 10 cases, and then their learning curve flattened.

2.5 Important of parallelism?

When two or more implants restored or support bridge is need, one of the important factors is implant parallelism (47). The problem when implant placed without parallelism may occurs the modification of abutment such as angle abutment or UCLA abutment. Moreover, the force transfer from occlusal table will not go direct to the long axis of the implant which might occur the crestal bone loss (18). Consequently, the longevity of the implant will be effect. Thus, whenever the implants need to be parallel, implantologist might take an eye on the planning carefully. The limitation of the conventional implant placement using stent produce from wax loss technique might give improper information to the implantologist since it is manual system relied on technician. The advance digital technology such as CAIS, provide the parallelism mode in the virtual implant planning software. The implantologist can check whether two implants on 3D parallel or not. Then the surgery can be performed with the passive technique using guided template provided by 3D printing technology (static CAIS) or direct visual from the navigation plan real time during the surgery by tracking system (dynamic CAIS). However, up until now there are no report the accuracy of the parallelism of two implants placed by static or dynamic CAIS (5).

2.6 Accuracy analysis

For analyzing the accuracy of implant position between using computer-assisted implant surgery is performed by measure the deviation of the placed implant position from the planed position. The postoperative CBCT data are superimposed with preoperative CBCT data automatically by implant planning software and calculate the deviation between both by a mathematical algorithm. Several measuring points were used in the previous systematic reviews for the comparison of these positions (7, 25) :

Linear deviation

- deviation at the implant platform (mm)
- deviation at the implant apex (mm)

Angle deviation

- deviation of the axis of the implant (degree)

The deviation at the implant platform and apex, the most common method is the actual distance measurement between the planned and placed point in three dimensional directions (9, 33). For the deviation of the axis every study reported by degrees of deviation of the imaginary line that cross center of the implant shoulder and the implant tip (22, 25). By using a distinction between the deviation measured in the x, y, and z-axis and calculation from Pythagorean Theorem.

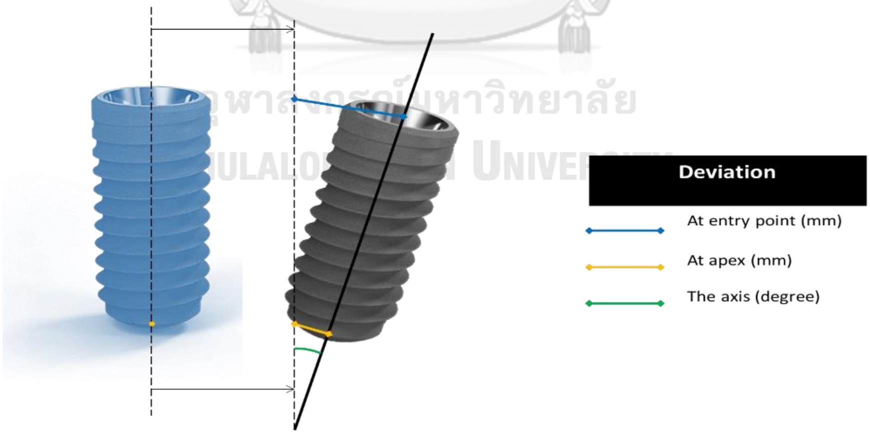


Figure 3 The three parameters for analyzing the implant deviations.

2.7 Research question

1. Are there any differences in accuracy of implant position between using static and dynamic CAIS in partially edentulous patients needing two implants support fixed partial prosthesis?

2. Are there any difference in the parallelism between two placed dental implants in each patient between using static and dynamic CAIS in partially edentulous patients needing two implants support fixed partial denture?

2.8 Objective

1. To compare the implant deviation between planned and placed position using static and dynamic CAIS in partially edentulous patients needing two implants support fixed partial denture.

2. To compare the parallelism between two placed dental implants in each patient using static and dynamic CAIS in partially edentulous patients needing two implants support fixed partial denture.

2.9 Hypothesis

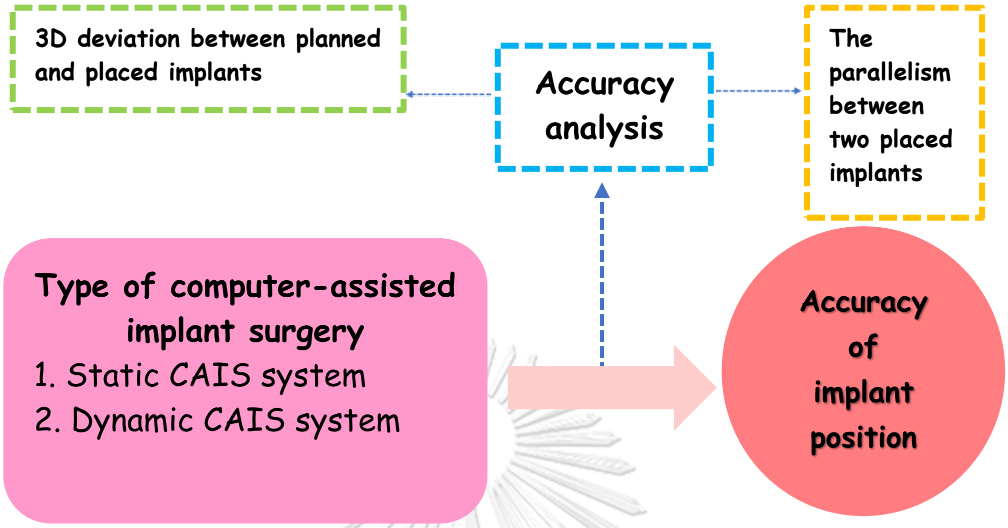
H_0: Linear deviation at implant platform and apex, and angle deviation between using static and dynamic CAIS groups are not different.

H_1: Linear deviation at implant platform and apex, and angle deviation between using static and dynamic CAIS groups are different.

H0: Linear deviation at implant angle deviation between two placed dental implants in each patient using static and dynamic CAIS groups are not different.

H1: Linear deviation at implant angle deviation between two placed dental implants in each patient using static and dynamic CAIS groups are different.

2.10 Conceptual framework



CHAPTER III
MATERIAL AND METHODS

3.1 Material

3.1.1 Sample

Patients who require dental fixtures support fixed partial denture at the Department of Oral and Maxillofacial Surgery, Chulalongkorn University were enrolled for the study. This study is prospective, randomized controlled clinical trial study.

Inclusion criteria

1. Patients with an edentulous space requiring a Fixed Dental Prosthesis supported by two implant fixtures.
2. Extractions completed since at least 3 months
3. No limited mouth opening for placing surgical guide and drill.
4. Age 20 years and over.

Exclusion criteria

1. Patients uncontrolled systemic diseases, conditions or medication which could affect to dental implant treatment.
2. Clinical or radiographic signs of any pathology in the jaw bone.
3. Patients with current use of orthodontic appliances.
4. Patients with pathological mobility of adjacent teeth that supported surgical guide.

3.1.2 Sample size calculation

G*Power version 3.1 software (Faul, Erdfelder, Buchner&Lang, 2009)

3.1.3 Cone Beam Computed Tomography (CBCT)

Accuitomo 3D machine (J. Morita Inc., Kyoto, Japan)

3.1.4 Implant

Bone level implant (Straumann, institute Straumann AG, Basel, Switzerland)

3.1.5 Static CAIS system

3.1.5.1 Implant planning software

coDiagnostiX software (Dental Wings inc, Montreal, Canada)

3.1.5.2 Surface scanner

D900L model scanner (3shape, Copenhagen, Denmark)

3.1.5.3 Surgical guide stents

Stereolithographic (SLA) surgical template (VisiJet MP200, VisiJet M3 Stone Plast, 3D Systems, Inc., South Carolina, USA)

3.1.6 Dynamic CAIS system

3.1.6.1 Implant planning software

Iris–100 software (EPED Inc., Taiwan)

3.1.6.2 Stent for registration

Plastic splint sheet (3A MEDES, South Korea)

3.1.6.3 Navigation machine

Iris–100, (EPED Inc., Taiwan)

3.1.7 Statistic analysis software

IBM SPSS Statistics software version24 (SPSS Inc., Chicago, IL)

3.2 Methods

This study was a randomized controlled clinical trial, approved by the Human Research Ethics Committee of the Faculty of Dentistry, Chulalongkorn University (HREC-DCU 2018-082) and registered at the Thai Clinical Trials Registry (TCTR20181224002).

3.2.1 Sample size calculation

Sample size calculation was conducted by means of statistical software (G*Power software version 3.1) using Mann–Whitney U test with 95% of study power and significance level (α) set at 0.05. Based on the outcomes of a previous study implant deviation of the angle from study of Beneke et al. (2012) (35) that evaluate the positions of the virtually planned and the placed implants using static CAIS in partially edentulous patient and Block et al. (2016) (48) that determine the accuracy for dental implants using navigation which were 7.9 ± 4.7 degree and 3.6 ± 2.7 degree, the minimum sample size requirement was 44 implants. Patients were then randomly allocated into 2 groups: static CAIS (n = 30) and dynamic CAIS (n = 30) by block randomization (6 per block).

3.2.2 CBCT scanning protocal

All patients were received a CBCT examination with a 3D Accuitomo 170 machine (J.Morita Inc., Kyoto, Japan). For the patients in the dynamic CAIS group a vacuum stent with an occlusal device containings 4 radiopaque fiducial markers (IRIS – 100, EPED Inc., Taiwan) was manufactured and used during the CBCT scan. The vacuum stent was kept for later use at the time of the surgery.

3.2.3 Preoperative implant planning

The DICOM (Digital Imaging and Communications in Medicine) file from CBCT were imported into the coDiagnostiX software version 9.7 (Dental Wings Inc, GmbH, Germany) for static CAIS and in the Iris – 100 software (EPED Inc., Taiwan) for dynamic CAIS. Both software allow the virtual placement of the implant in the proper 3D restorative driven position. The ideal prosthesis was designed in the Codiagnostix for the static group (digital wax-up), while a conventional wax up was conducted on a stone model for the dynamic group, which was then incorporated in the radiographic stent. The two implants were planned in perfect parallelity and 0 angle was confirmed by the respective planning software. Patients were parallelity of the implants was not possible or desired due to local anatomic conditions (e.g. angle or dimensions of neighbouring roots) were excluded from the study

3.2.4 Surgical procedures

All surgeries were performed by one surgeon, specialist in OMFS and experienced with the use of both static and dynamic CAIS

3.2.4.1 Implant placement with static CAIS

Before surgery was performed, the fit and stability of the surgical guide verified in the patient’s arch. Fully guided surgery protocol was utilized. Implant bed preparation was conducted according to protocol of the manufacturer. The implant fixtures were placed inserted through the sleeves of the surgical template.

3.2.4.2 Implant placement with dynamic CAIS

Prior to surgery, the registration procedure was performed to determine the location and orientation of the handpiece in relation to the patient's anatomic landmarks. Two tracking sensors were connected with the vacuum stent in the patient's mouth. A registration probe was placed on the handpiece which then was tracked by the infrared for 4 predetermined markers positions on the vacuum stent. The implant placement was conducted then free-hand, with real time guidance through the navigation machine. The position of the drill and the planned implant position were projected on the data from the CBCT displayed on the monitor screen in real time during the surgery.

3.2.5 Accuracy measurement

After implant placement, all patients received a second CBCT scan with the same settings as previously. For the static CAIS group, superimposition of pre- and postoperative CBCT images was conducted, in order to evaluate the deviation between planned and actual implant position via the respective function of the co-DiagnostiXTM software (Dental wings inc, Montreal, CA). For the dynamic CAIS group, the same registration stent that contain 4 fiducials marker was inserted in patient's mouth during the second CBCT scan and was then transfered to the IRIS-100 software (EPED Inc., Taiwan) for superimposision with the preoperative virtual planning. Two outcomes were then measured.

1. The deviation of the actual implant position as compared to the planned one. Three measurements were conducted to express this outcome: 3D deviation at implant shoulder, 3D deviation at implant apex, and angle deviation of implant axis. Each of the three measurements was averaged for each patient (two implants) and the respective results represented the patient level.

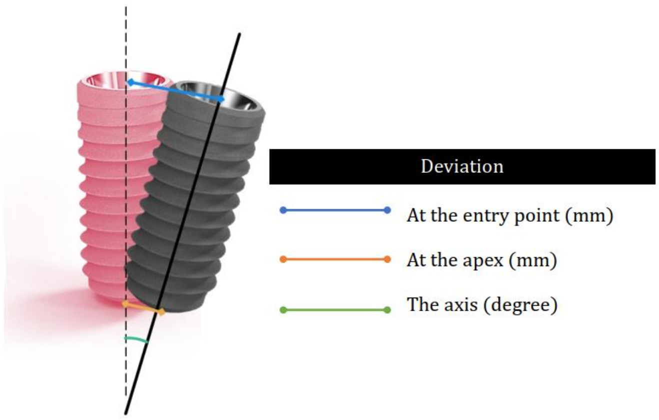


Figure 4 The deviation of the planned and placed implant position in three parameters.

2. The parallelity between the two placed dental implants in each patient. The angle of the two implants that cross the center of the implant shoulder and the center of the implant apex are compared to measure the parallelism. One of the implants was defined as reference and then the deviation of the angle of the second implant as compared to the angle of the reference implant was calculated.

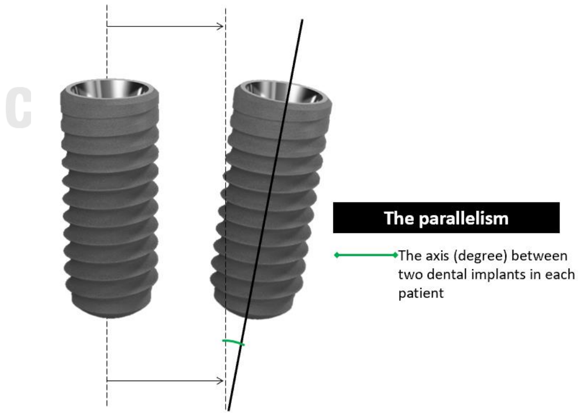
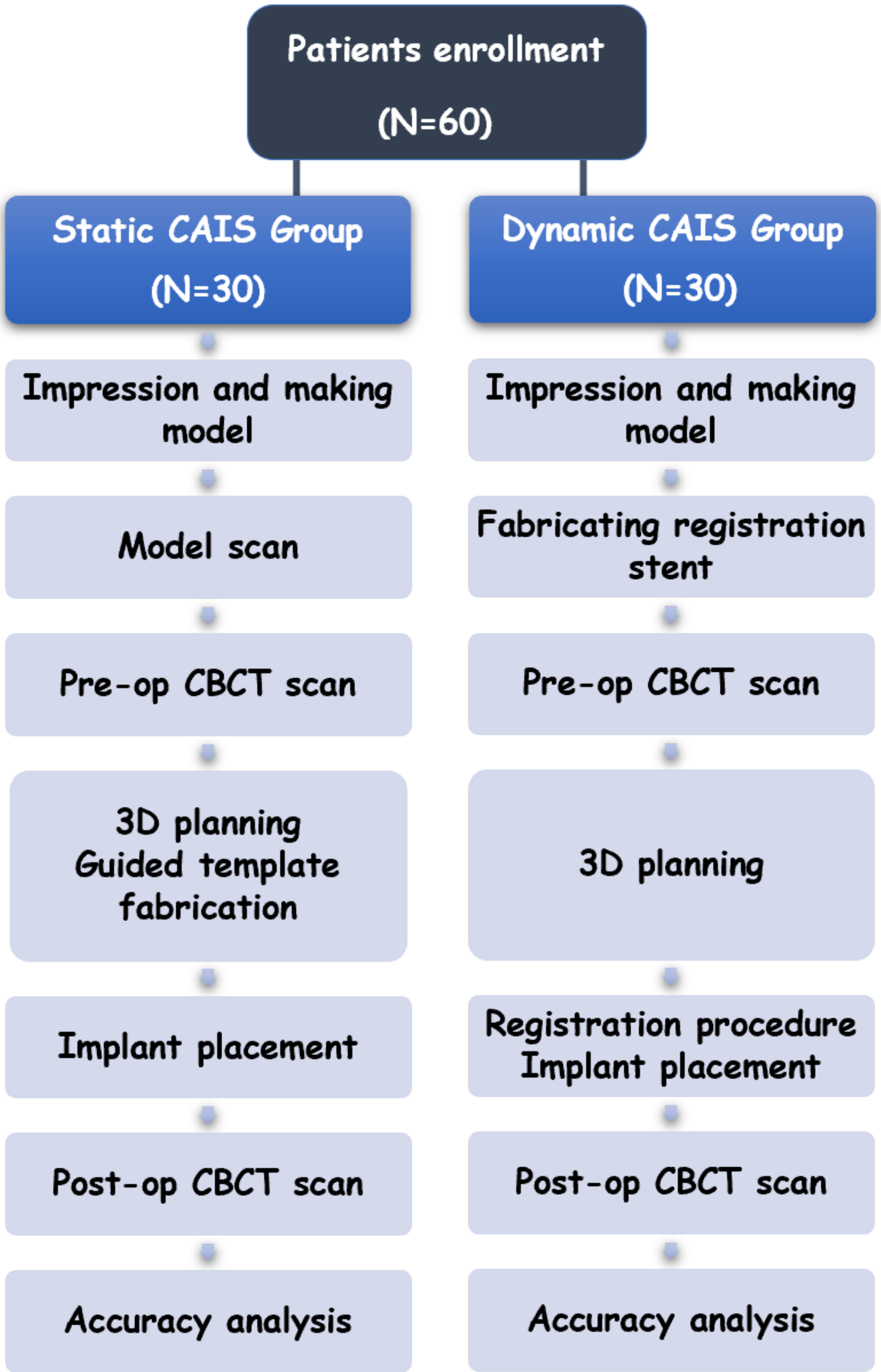


Figure 5 The angle deviation between two placed implants in each patient.

3.2.6 Statistical analysis

All data were calculated under IBM SPSS Statistics software (version24 software SPSS Inc., Chicago, IL). Mean 3D deviation at implant platform, apex and angle deviation at axis between the actual and the planned position were found to be non-normal distribution, therefore Mann-Whitney U test was used for the analysis. Mean 3D deviations of axis between two implants in each patient were compared using independent t-test. P-value < 0.05 was considered as statistically significant.

3.2.7 The study workflow



CHAPTER IV

RESULTS

15 patients (mean age 60; 2 males; 13 females) received 30 implants with static CAIS, while another 15 patients (mean age 60; 5 males; 10 females) received the same amount of implants with dynamic CAIS. All implants were posterior implants and 56 were prosthesis supported by two neighbouring implants (static 30 – dynamic 28), while 4 were 3 unit bridges (static 2 – dynamic 2).

The mean of implant deviations at platform and apex in static CAIS group were 1.04 ± 0.67 mm and 1.54 ± 0.79 mm respectively, while in the dynamic CAIS group were 1.24 ± 0.39 mm and 1.58 ± 0.56 mm respectively. The angular deviations in static and dynamic CAIS groups were 4.08 ± 1.69 degrees and 3.78 ± 1.84 degrees respectively (Table 3). The mean angular deviations between two placed dental implants (parallelity) in static and dynamic CAIS groups were 4.32 ± 2.44 degrees and 3.55 ± 2.29 degrees respectively. There were no statistically significant differences in all parameters between groups (Table 4).

Table 3 The deviation of implant position.

Group	Static CAIS (n=30)	Dynamic CAIS (n=30)	p-Value (Mann-Whitney U Test)
Deviation at platform (mm) Mean ± SD	1.04 ± 0.71	1.24 ± 0.62	0.11
Deviation at apex (mm) Mean ± SD	1.51 ± 0.86	1.58 ± 0.77	0.57
Angular deviation (degrees) Mean ± SD	4.05 ± 2.06	3.78 ± 2.38	0.64

Table 4 The angular deviations between two placed dental implants (parallelism) in each patient.

Group	Static CAIS (n=30)	Dynamic CAIS (n=30)	p-Value (Independent-t test)
Angular deviations between two placed dental implants (degree) Mean ± SD	4.32 ± 2.44	3.55 ± 2.29	0.39

Moreover, when comparing the implant deviation at mesio-distal, bucco-lingual, and apico-coronal directions, significant differences were found. Deviation at platform was significantly more towards the lingual direction while at the apex significantly more towards the distal direction in dynamic CAIS more than static CAIS. No significant difference in the other directions. The deviation to each direction of all implants is presented in Figure 6-11.

Figure 6 The deviation at implant platform in mesio-distal and bucco-lingual direction.

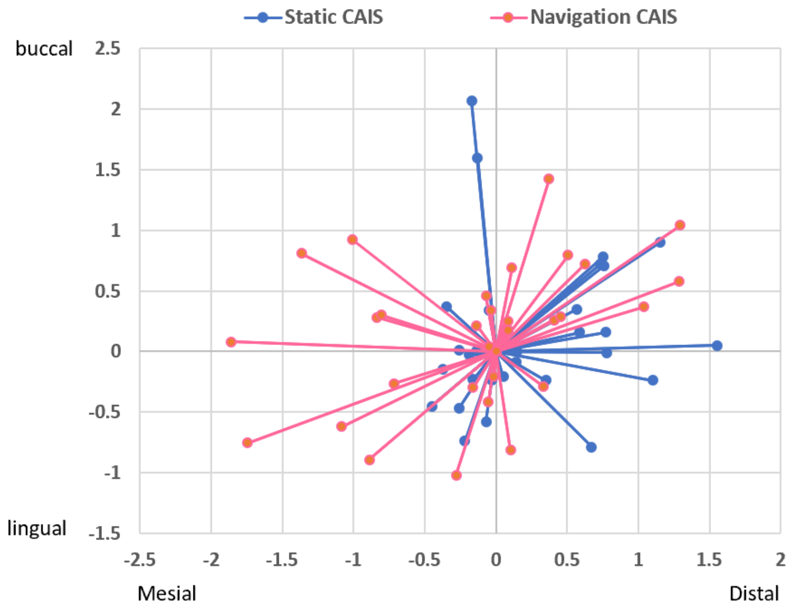


Figure 7 The deviation at implant platform in mesio-distal and apico-coronal direction.

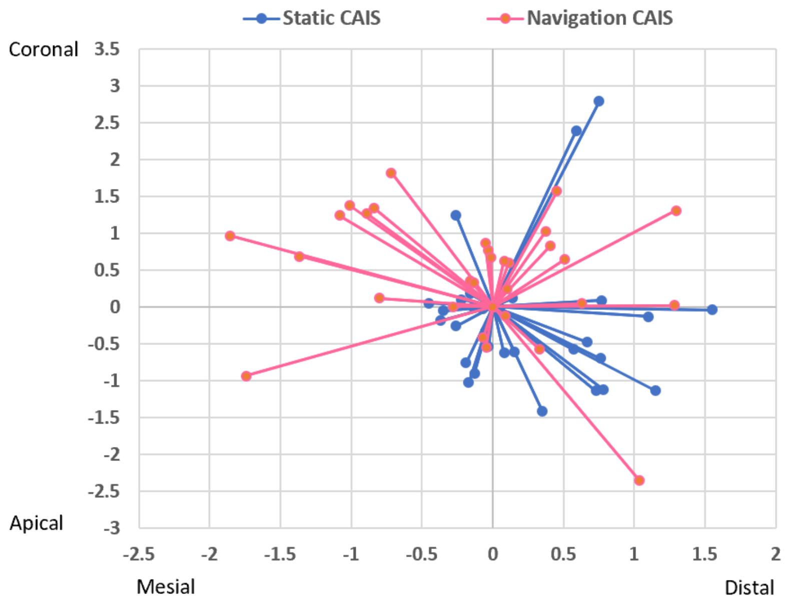


Figure 8 The deviation at implant platform in bucco-lingual and apico-coronal direction.

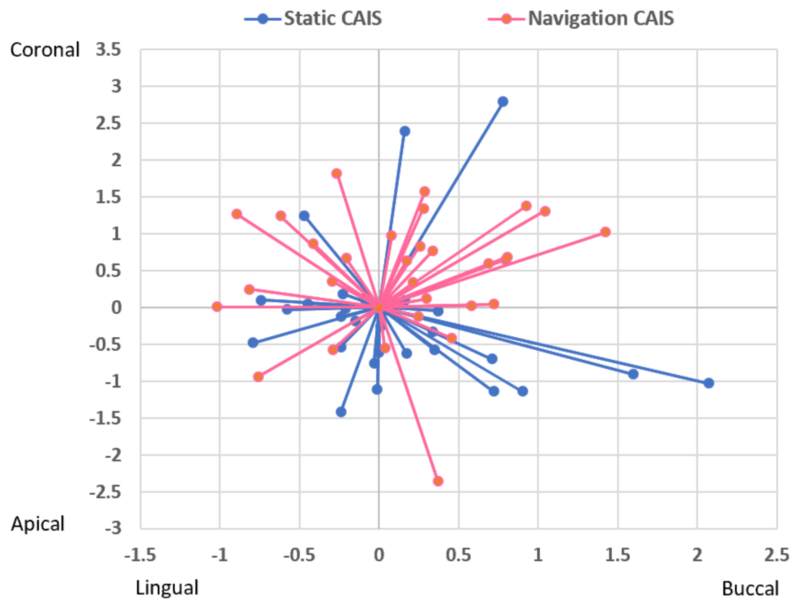


Figure 9 The deviation at implant apex in mesio-distal and bucco-lingual direction.

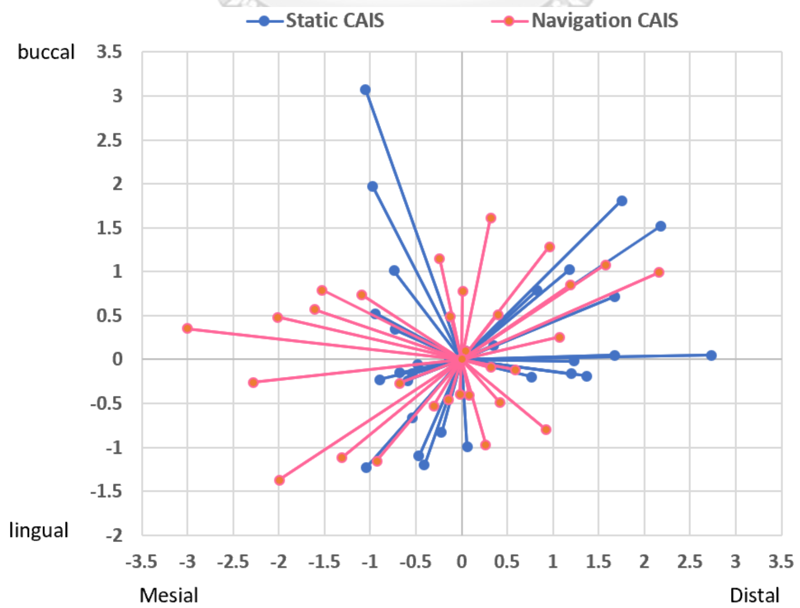


Figure 10 The deviation at implant apex in mesio-distal and apico-coronal direction.

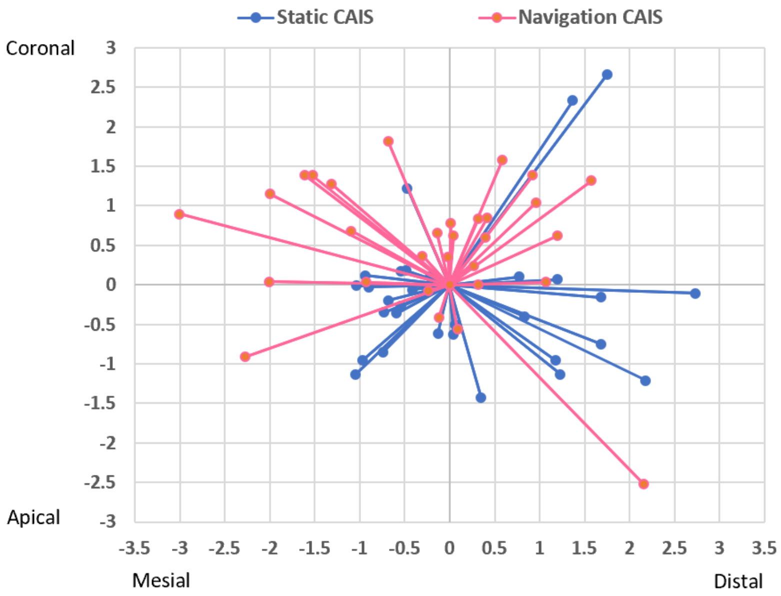
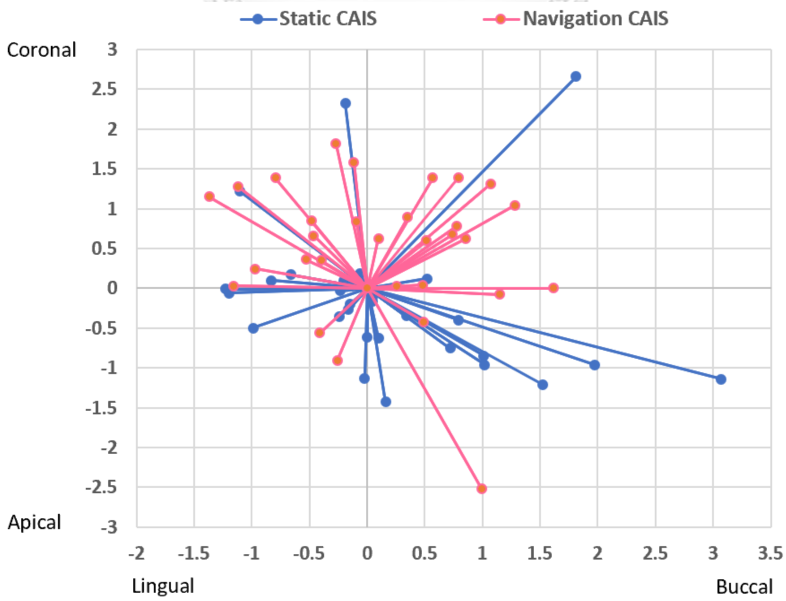


Figure 11 The deviation at implant apex in bucco-lingual and apico-coronal direction.



CHAPTER V

DISCUSSION

Both static and dynamic CAIS have been documented to help clinicians in achieving a favorable and accurate implant positioning, which is a prerequisite for successful implant therapy and can facilitate a sustainable prosthetic restoration.

Although optimal parallelity of multiple implants has been reportedly a critical factor to strive for when supporting the same prosthesis, such an outcome has been frequently compromised by operator, technique or anatomic difficulties. Static CAIS, utilizing a surgical guide might in this aspect differ to dynamic CAIS, which in essense remains a “freehand” surgical placement. Nevertheless, this randomized controlled trial did not find any significant differences in terms of parallelity outcomes between the two techniques. All parameters from both groups were in a range of likely values when compared to the previous studies (9, 25, 43, 49-51). Moreover, the deviations observed in this study were smaller than those reported in in-vitro studies, such as the study by Ruppin et al. (44) on three different CAIS systems, who reported mean platform deviation of less than 1.5 mm and mean angular deviation of less than were 8.1 degrees in partially and fully edentulous human cadaver mandibles. Similarly, Somogyi - Gnass et al. (40), reported mean deviations static and dynamic CAIS at platform and apex less than 1.91mm and 1.14 mm, respectively and mean angular deviation less than 4.2 degrees, with no significant differences to be found. Kaewsiri et al. (49) reported mean implant deviations at platform and apex in static CAIS group of 0.97 mm and 1.28 mm respectively, while in dynamic CAIS group were 1.05 mm and 1.29 mm respectively, with no statistically significant difference. Similarly, angular deviation in static and dynamic CAIS groups were 2.84 degrees and 3.06 degrees respectively (7). In systematic reviews and meta-analyses that reported the accuracy of CAIS systems in clinical studies, the deviation was less than 1.22 mm and 1.45 mm at platform and apex respectively and angular deviation less than 4.06 degrees (25, 27, 51-53).

However, these systematic reviews included various study designs, with different objectives and the collective results are not easy to extrapolate in clinical situations. The present study utilised a homogeneous patient with edentulous space suitable for two dental fixtures to support a fixed dental prosthesis. Albeit still under a strict randomized controlled trial setup, this study presented a more complex scenario than the great majority of similar clinical studies, which report outcomes of CAIS in single tooth space.

When analyze the deviation at platform and apex in mesio-distal, bucco-lingual, and apico-coronal directions, the results showed some significant differences. At the platform level placement with dynamic CAIS deviated more towards lingual direction in the bucco-lingual axis. At the apex dynamic CAIS deviated more to distal direction in the mesio-distal axis. No significant was found difference in any other direction. This observation might be a result of some influence of the field of vision or the surgeon, as placement under dynamic CAIS being still conducted under direct vision and manual control. Nevertheless, there was no evidence that such an effect had any impact in the overall clinical outcomes in terms of accuracy.

The need for parallelity of two implants which support a fixed dental prosthesis is well established. Parallelity will allow a similar path of insertion for both impants, thus allowing screw retention with a more simple design, better contour and a prosthesis that directs the forces along the long axis of the implant fixtures (18). In the absence of such parallelity, the clinician needs to utilize more complex prosthetic manipulation such as multiple, customised or angled abutments, cement retention, angled screw channels and more. Such restorations might increase complexity but also risks for technical and biological complications. The often compromised emergence profile of angled abutments and the risks of cement rests have been reported to increase the prevalence of peri-implant tissue inflammation (54, 55). Furthermore compromise of the biomechanics of the prosthesis -implant complex due to occlusal forces no longer being directed down the long axis of the implant, could increase stresses on the prosthesis components, the implants and the bone (56) predisposing among others to risk of prosthesis or abutment screw loosening (57). Kao et al. (58) that reported cortical bone stress elicited by implant placement and stress loading also increased as the abutment angle increased.

The present study, being the first to compare the ability of static and Dynamic CAIS to support parallelity of the implants placed, showed no significant difference between the two techniques. Implant fixtures require an angled abutment when inserted at an angle greater than 12 degrees (59). Both CAIS systems provide an accurate implant placement and could assist efficiently the surgeon to achieve adequate parallelity of the implants, with less than 4.35 degrees deviation.

Several factors have been reported influencing the deviation of implant position achieved from static and dynamic CAIS (7, 22, 31, 35, 60). In static CAIS, most common limitations or potential sources of error include fracture or misfit of the surgical guide and patients with limited mouth opening. In dynamic CAIS, common limitations and errors include Tracking Registration Error (TRE), or limitations related to the learning curve of using the navigation system.The surgical guides utilized in this study were tooth-support under fully guided protocol. Dynamic CAIS protocol utilized a registration method by means of 4 radiopaque fiducial markers attached to an occlusal stent. All surgeries were performed by one experienced specialist surgeon. In the future, upcoming advanced digital technologies such as Augmented Reality (AR) may be used in conjunction with the CAIS and navigation systems, which may further increase accuracy and effectiveness /efficiency.

CHAPTER VI

CONCLUSION

Static and dynamic CAIS systems appear to achieve similar clinical outcomes when placing in-vivo two implants not only with regards to deviation from the optimal implant position, but also implant parallelity. Both Static and dynamic CAIS can be indicated for placing multiple implants supporting the same prosthesis, with the choice being rather directed by the surgeon's preferences, patients anatomic conditions and inherent indications and limitations of each system.

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