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COMPARISON THE ACCURACY OF IMPLANT POSITION AMONG MENTAL, STATIC AND DY NAMIC COMPUTER-ASSISTED IMPLANT SURGERY IN TOTALLY EDENTULOUS PATIENTS

Mr. Svas Jaemsuwan

A Thesis Submitted in Partial Fulfillment of the Requirements
for the Degree of Master of Science in Oral and Maxillofacial Surgery
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การเปรียบเทียบความแม่นยำของตำแหน่งรากฟันเทียมระหว่างการผ่าตัดฝังรากฟันเทียมด้วยวิธีคอมพิวเตอร์ช่วยแบบผ่านจิตใจ สถิต และพลวัต ในผู้ป่วยสันเหงือกไร้ฟันทั้งปาก

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วิทยานิพนธ์นี้เป็นส่วนหนึ่งของการศึกษาตามหลักสูตรปริญญาวิทยาศาสตรมหาบัณฑิต
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Thesis Title	COMPARISON THE ACCURACY OF IMPLANT POSITION AMONG MENTAL, STATIC AND DYNAMIC COMPUTER-ASSISTED IMPLANT SURGERY IN TOTALLY EDENTULOUS PATIENTS
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ศวัส แจ่มสุวรรณ : การเปรียบเทียบความแม่นยำของตำแหน่งรากฟันเทียมระหว่างการผ่าตัดฝังรากฟันเทียมด้วยวิธีคอมพิวเตอร์ช่วยแบบผ่านจิตใจ สถิต และพลวัต ในผู้ป่วยสันเหงือกไร้ฟันทั้งปาก . (COMPARISON THE ACCURACY OF IMPLANT POSITION AMONG MENTAL, STATIC AND DYNAMIC COMPUTER-ASSISTED IMPLANT SURGERY IN TOTALLY EDENTULOUS PATIENTS) อ.ที่ปรึกษาหลัก : รศ. ทพ. ดร. อาทิพันธุ์ พิมพ์ขาวขำ

วัตถุประสงค์: งานวิจัยนี้มีวัตถุประสงค์เพื่อประเมินความแม่นยำของรากฟันเทียมที่ถูกฝัง โดยใช้การผ่าตัดฝังรากเทียมด้วยวิธีคอมพิวเตอร์ช่วยที่แตกต่างกันสามระบบ ในผู้ป่วยสันเหงือกไร้ฟันทั้งปาก

วัสดุและวิธีการ: กลุ่มตัวอย่างของงานวิจัยนี้คือผู้ป่วยสันเหงือกไร้ฟันทั้งปากที่ต้องการรากเทียมสำหรับงานบูรณะทั้งปาก รากเทียมทั้งหมด 60 ตัว ถูกแบ่งเป็น3กลุ่มเท่าๆกัน ตามกลุ่มของระบบคอมพิวเตอร์ช่วยการผ่าตัดฝังรากเทียม ในกลุ่มการผ่าตัดฝังรากเทียมด้วยวิธีคอมพิวเตอร์ช่วยแบบผ่านจิตใจ และ สถิต จะใช้ซอฟท์แวร์ coDiagnostiX™ (Dental Wings Inc, Canada) สำหรับการวางแผนรากฟันเทียม ภาพเสมือนจริงถูกใช้เพื่อช่วยนำทางศัลยแพทย์ในการฝังรากเทียมด้วยวิธีดั้งเดิมสำหรับกลุ่มการผ่าตัดฝังรากเทียมด้วยวิธีคอมพิวเตอร์ช่วยแบบผ่านจิตใจ และ ภาพเสมือนจริงยังถูกนำไปสร้างแผ่นนำทางการผ่าตัดสำหรับกลุ่มการผ่าตัดฝังรากเทียมด้วยวิธีคอมพิวเตอร์ช่วยแบบสถิต ในส่วนของกลุ่มการผ่าตัดฝังรากเทียมด้วยวิธีคอมพิวเตอร์ช่วยแบบพลวัต ซอฟท์แวร์ Iris–100 software (EPED Inc., Taiwan) ถูกใช้สำหรับวางแผนภาพเสมือนจริงของตำแหน่งรากเทียม และนำทางการผ่าตัด ในขั้นตอนการเตรียมฐานรองรับรากเทียม และ การใส่รากเทียมในช่องปาก จากนั้นไฟล์ DICOMหลังการรักษาจะถูกนำเข้าสู่ซอฟท์แวร์การวางแผนในแต่ละซอฟท์แวร์ เพื่อที่จะประเมินความคลาดเคลื่อนเชิงมุม ความคลาดเคลื่อนในสามมิติของตำแหน่งขอบบน และตำแหน่งปลายของรากฟันเทียม ระหว่างตำแหน่งที่ฝัง และตำแหน่งรากเทียมที่วางแผนไว้ โดย One-way ANOVA ถูกใช้เพื่อวิเคราะห์ข้อมูลทางสถิติ

ผลการศึกษา: รากเทียมถูกฝังโดยใช้การผ่าตัดฝังรากเทียมด้วยวิธีคอมพิวเตอร์ช่วยที่แตกต่างกันสามระบบ (ระบบละ 20 ซี่) โดยมีค่าเฉลี่ยความคลาดเคลื่อนเชิงมุมของกลุ่มการผ่าตัดฝังรากเทียมโดยวิธีคอมพิวเตอร์ช่วยแบบผ่านจิตใจ สถิต และ พลวัต คือ 10.09±4.64 องศา 4.98±2.16 องศา และ 5.75±2.09 องศา ตามลำดับ มีค่าเฉลี่ยความคลาดเคลื่อนในสามมิติของตำแหน่งขอบบนรากเทียมคือ 3.48±2.00 มม. 1.40±0.72 มม. และ 1.73±0.43 มม. ตามลำดับ ขณะที่ค่าเฉลี่ยความคลาดเคลื่อนในสามมิติของตำแหน่งปลายรากเทียมมีค่า 3.6±2.11 มม. 1.66±0.61 มม. และ 1.86±0.82 มม. ตามลำดับ โดยกลุ่มการผ่าตัดฝังรากเทียมด้วยวิธีคอมพิวเตอร์ช่วยแบบสถิต และ พลวัต ไม่พบความแตกต่างอย่างมีนัยสำคัญทางสถิติของความแม่นยำของการฝังรากเทียม และ ทั้งสองกลุ่ม ยังแสดงถึงความแม่นยำที่เหนือกว่ากลุ่มการผ่าตัดฝังรากเทียมด้วยวิธีคอมพิวเตอร์ช่วยแบบผ่านจิตใจ ในทุกตัวแปรอย่างมีนัยสำคัญทางสถิติ ในผู้ป่วยสันเหงือกไร้ฟันทั้งปาก

สรุปผลการศึกษา: งานวิจัยทางคลินิกนี้แสดงให้เห็นว่ากลุ่มการผ่าตัดฝังรากเทียมด้วยวิธีคอมพิวเตอร์ช่วยแบบผ่านจิตใจ มีค่าความแม่นยำน้อยที่สุด และ ไม่พบความแตกกต่างระหว่างกลุ่มการผ่าตัดฝังรากเทียมด้วยวิธีคอมพิวเตอร์ช่วยแบบสถิต

สาขาวิชา	ศัลยศาสตร์ช่องปากและแม็กซิลโลเฟเชียล	ลายมือชื่อนิสิต ....
ปีการศึกษา	2562	ลายมือชื่อ อ.ที่ปรึกษาหลัก ....

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COMPARISON THE ACCURACY OF IMPLANT POSITION AMONG MENTAL, STATIC AND DYNAMIC COMPUTER-ASSISTED IMPLANT SURGERY IN TOTALLY EDENTULOUS PATIENTS . Advisor: Assoc. Prof. ATIPHAN PIMKHAOKHAM, Ph.D.

Objective: To evaluate the accuracy of placed implants using three different CAIS systems in totally edentulous patients

Materials and Methods: Totally edentulous patients requiring implants for full-mouth restoration were eligible for this study. All implants (n=60) were classified into three groups of CAIS systems equally. In mental and static CAIS groups, coDiagnostiX™ software (Dental Wings Inc, Canada) was selected for implant planning. All virtual images were used to facilitate the surgeon placing implant by conventional manner in mental CAIS group, and fabricate the surgical template for guided implant surgery in static CAIS group. On the other hand, the Iris–100 software (EPED Inc., Taiwan) was chosen for virtually planning of implant position, and navigating the implant bed preparation and insertion intraoperatively in dynamic CAIS group. Post-operative DICOM files were imported to each planning software in order to evaluate the angular deviations, 3D deviations at implant platform and apex between placed and planned implant positions. Statistical data analysis was tested by One-way ANOVA.

Results: Groups of 20 Implants were installed following three different CAIS protocols. The mean angular deviations among mental, static and dynamic CAIS groups were 10.09°±4.64°, 4.98°±2.16° and 5.75°±2.09° respectively. The mean 3D deviations at implant platform among mental, static and dynamic CAIS groups 3.48±2.00 mm, 1.40±0.72 mm and 1.73±0.43 mm respectively. While, the mean 3D deviations at implant apex were 3.6±2.11 mm, 1.66±0.61 mm and 1.86±0.82 mm. The static and dynamic CAIS groups showed no statistically significant difference in term of implant accuracy and both groups also demonstrated statistically significant superior accuracy in all variables compared to the mental CAIS group in totally edentulous patient.

Conclusion: In this clinical trial, the mental CAIS group reported the least accuracy and there was no difference between static and dynamic CAIS groups in the totally edentulous.

Field of Study:	Oral and Maxillofacial Surgery	Student's Signature ....
Academic Year:	2019	Advisor's Signature ....

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Svas Jaemsuwan

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CHAPTER I

INTRODUCTION

I.1 Background and Rationales

Multiple Implant placement in totally edentulous patient presents a challenge for the oral surgeon because of complex consequences after tooth loss, lack of the patient's anatomical structures and local references. According to the mentioned, there are difficulties in tooth replacement and negative effects on the planning of implant position. To achieve long term success, excellent esthetic and functional outcomes, computer-assisted implant surgery (CAIS) has been using for surgical planning, guiding and performing a surgery.

In implant surgery, computer-assisted implant surgery (CAIS) was developed to plan the implant placement with computerized tomographic (CT) data. Based on the 3D approach, the surgeon is allowed to virtually place and adjust the implants for the ideal position before surgery (1, 2). To transfer the planned position to the operative field, guided surgical template from the pre-operative planning emphasizes accomplishment in the desired implant position for precise placement the implant in the same position as plan.

From the limitations and disadvantages of conventional implant placement technique (1, 2), the modified technique called "mental CAIS" that use CT data with implant planning software will generate the virtual planning of implant, make measurement of the surgical site, and selects suitable size of implant (3). Even though mental CAIS gives the surgeon more information about the planned sites for guiding and allowing the surgeon to compare the result of the treatment, surgeon still prepare the implant site and insert the implant manually without ability of angulation and depth controlled (3-6).

For correcting the angulation and controlling the depth, "static CAIS" is used with the CT data, surface scanning data and implant planning software for designing, fabricating the static surgical guide with metal sleeves and performing a surgery with guided surgical kits. However, this technique is an indirect technique that surgeon inability to see the drilling directly (7).

Recently, dental navigation technology called "dynamic CAIS" is used with the CT data and implant planning software with optical tracking technology for planning the implant position, registration and performing and displaying an implant site preparation and implant insertion during surgery on real-time (8, 9). The technique immediately calculates and displays the actual position of the surgical instruments that working in the surgical field superimpose on the CBCT data on a screen throughout the implant placement (7).

Many reports demonstrated the accuracy of these three systems when comparing to the freehand implant surgery (3, 7, 9-13). Nevertheless, the publications comparing the accuracy of implant position using three types of CAIS system in totally edentulous patients have been rarely reported. For this reason, the aim of this prospective clinical trial is to compare the accuracy of guided and planned positions among static, mental and dynamic CAIS in totally edentulous patients.

I.2 Objective

To compare the accuracy of implant positions among mental CAIS, static CAIS (static surgical guide) and dynamic CAIS (dynamic navigation) in totally edentulous patient.

I.3 Research question

Are there any differences in the accuracy of implant positions among mental CAIS, static CAIS and dynamic CAIS in totally edentulous patient?

I.4 Research hypothesis

H0 = There are no differences in the accuracy of implant positions among mental CAIS, static CAIS and dynamic CAIS groups in totally edentulous patient.

Ha = At least 2 of groups are different.

I.5 Statistic hypothesis

$H0 = \mu 1 = \mu 2 = \mu 3$

Ha = At least 2 of μ I 's are different.

I.6 Conceptual framework

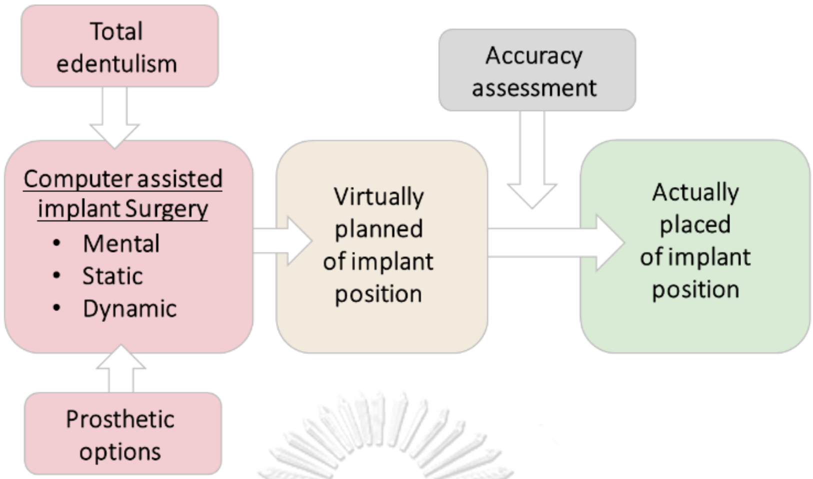

Figure 1 Conceptual framework in this study

CHAPTER II

LITERATURE REVIEW

An understanding of changes of the edentulous ridge and selecting a suitable treatment planning are necessary to achieve the implant placement, osseointegration, prosthetically optimal positions, esthetics and functions. In this chapter, the relevant information to this research is gathered.

II.1 Total edentulism

Total tooth absence is one of the most common oral health problems among the elderly, it is most often the result of dental extractions from dental caries, periodontal disease (14, 15) and other factors that contribute to tooth loss or extractions include unrestorable teeth and periapical lesions (16). In addition, some studies have observed a correlation between tooth loss and illness, in particular, cardiovascular disease and ischemic stroke and mortality (17, 18) and negative impact on quality of life regarding functional, social and esthetic affecting on aspects (19).

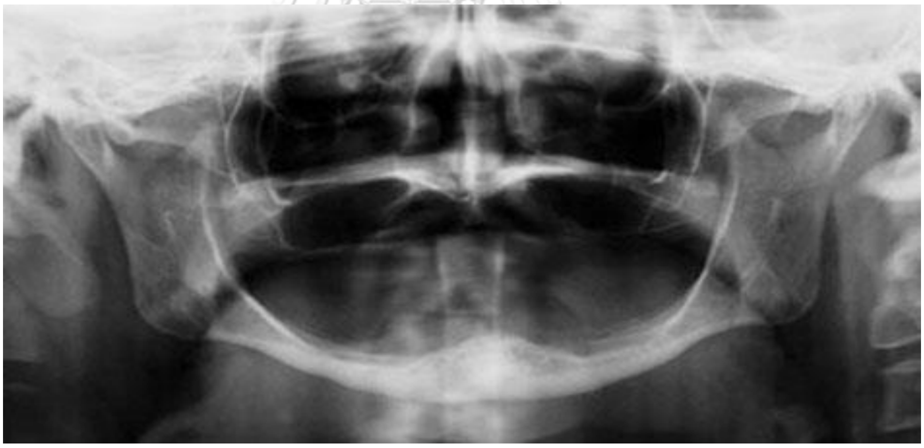

Figure 2 Orthopantomograph (OPG) showing upper and lower edentulous jaws which are severely resorpted for many years.

II.1.1 Consequences of tooth loss in edentulous patient

<u>Hard Tissue Consequences in edentulous patient</u>

After the tooth absence, alveolar bone surrounding and supporting the tooth loss is resorpted because of lacking stimulation (physiologic function) for maintaining its form and density. The bone trabeculae and density are decreased at external side horizontally and then vertically of its volume, especially at the buccal aspect of the ridge than at the lingual aspect. The mandible will result in reduction of the bone volume greater than that of the maxilla (20-24).

In 1998, Cawood and Howell describe the alterations in the dimension in the edentulous jaws according to the most generally observed changes in morphology into six types (25).

Class I - Dentate.

Class II- Immediately post extraction.

Class III- Well-rounded ridge form, adequate in height and width.

Class IV - Knife-edge ridge form, adequate in height and inadequate in width.

Class V - Flat ridge form, in adequate in height and width.

Class VI - Depressed ridge form, with some basalar loss evident.

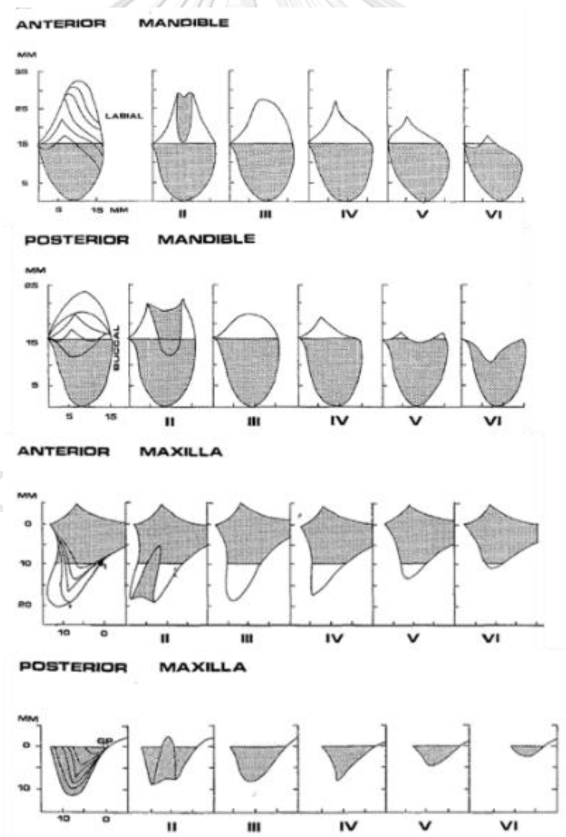

Figure 3 Cawood and Howell jaw classification which is depended on the volume of bone.

<u>Soft Tissue Consequences</u>

Resulting in the changes in bone resorption, soft tissue of gingiva gradually decreases. Attached gingiva that normally lies over the resorbed Jaw is absent and increasing of non-keratinized area is caused by abrasion from the overlaying prosthesis. Moreover, high muscle attachments and hypermobile tissue are even more complicate after the bone resorption (26).

From these reasons, Implant-supported restorations are used for totally edentulous jaws for enhancing retention of prosthesis, improving the masticatory function and decreasing the resorption of the bone by regulating neuromuscular modulation (27).

Consequences of edentulous patient
• Decreased in width & height of supporting bone • Thinning of mucosa, with sensitivity to abrasion • Progressive decrease in keratinized mucosa surface • Affecting of on esthetic appearance of lower third of face • Increased risk of mandibular fracture from excessive bone loss • Unattached mucosa for denture support causes increased soft spots • Increased denture movement and sore spots during function • Decreased neuromuscular control of jaw in the elderly

Table 1 Anatomical changes in edentulous patient according to loss of teeth.

II.2 Prosthetic options for totally edentulous patient in implant dentistry

II.2.1 Treatment planning for totally edentulous patient

The prosthetic design for totally edentulous jaw will be depended on the distribution of the implants in the arch, location and number of implant placement, the natural dentition, the intermaxillary relationship, the occlusal scheme and esthetic considerations. Many treatment options of implant placement offer differences of function and comfort, including implant-retained dentures and implant-supported dentures.

II.2.1.1 Implant-retained dentures

In the past, patients with ill-fitting dentures were treated by pre-prosthetic surgery to correct the bone or soft tissue morphology or treated with soft linings. Lately, dental implants provide predictable results by enhancing retention, stability, and patient satisfaction.

During wearing the overdentures, the dentures are seated on the mucosal tissue in denture bearing areas with an attachment mounting on the implants which can provide support and retention. The attachments are a magnet, ball attachment, or bar attachment (Fig.3) (28).

In the case of severe mandibular atrophy, the mandibular implant-retained overdenture is an option for dental implant treatment. It is not only relatively simple, but also improves masticatory function, retention and stability of prosthesis, patient satisfaction and quality of life than traditional manner (29-31).

According to the McGill Consensus, it recommended a two implant-retained overdenture as the standard treatment for the edentulous mandible (32). The study of McGill University showed that the implant-retained mandibular overdenture is superior to conventional denture not only in overall satisfaction, eating and social activity, but also in a cost-effective and less invasive treatment option for edentulous patients (33, 34).

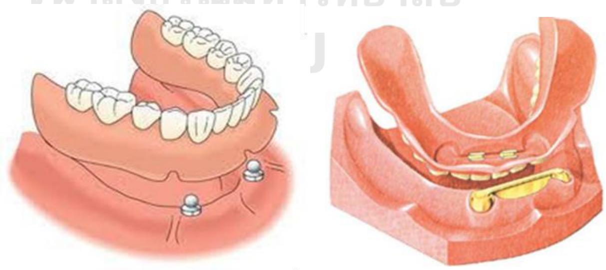

Figure 4 Ball and bar attachment in implant-retained or supported dentures.

II.2.1.2 Implant-supported dentures

To avoid movement and improve stability, implants were used to support the dentures. In this type of prosthesis, the dentures are seated on the superstructures attached to the implants. Therefore, the force is distributed over the implants and barely loads on mucosal bearing areas (35).

For removable implant supported dentures, the study has shown that patients are more satisfied with them than conventional complete dentures and success rate in long term study of implant supported maxillary overdentures is less than that of implant supported mandibular overdentures (28, 36), For fixed implant supported dentures, the meta-analysis mentions an estimated survival rate about 96% after 5 years and 93% after 10 years (37). In addition, comparison among conventional complete denture, removable and fixed implant-supported dentures showed that the patient satisfaction about mastication, social interaction, and overall satisfaction after restorative treatments were higher in the fixed and removable implant supported denture groups than that of the conventional complete denture group. There, however, were no significant differences between removable and fixed.

Figure 5 Removable and fixed implant-supported dentures.

II.3 Implant surgery

From the previous time until now, a conventional implant surgery is the one method that used a titanium root form for replace tooth roots with artificial crown and surgical procedure is done freehand by using intraoral examination, intraoral/extraoral radiographs and a study model.

For planning and analyzing, all the radiographs and models are used to evaluate the soft tissue, bone and vital anatomical structures around the surgical site without using a technology of planning software.

The Standard radiographs such as periapical film, orthopantomography and cone beam computed tomography (CBCT) are used to evaluate the quality and quantity of the bone that available in the planning site and to guide a surgery. Waxing and analyzing a study model will help understanding the available space corresponding to the future prosthesis.

Nonetheless, the conventional technique still has disadvantage due to limitation of planning and guiding, uncontrollable angulation and depth of implant placement during osteotomy, trauma to adjacent tooth and vital structures, unpredictable and achieved less prosthetic outcome (1, 2).

II.3.1 Mental CAIS

As a result of development of planning technology, the conventional technique is modified manner by using the planning software with CBCT data and digital 3D data is created in the software using DICOM files from preoperative CBCT.

In treatment planning, surgeon could simulate the virtual implant placement, plan the implant position, measure the available space and select the suitable implant for the surgical site in all directions before the surgical procedure in the software. During a surgery, surgeon can monitor the visual planned in three-directions and perform an osteotomy and placement procedure by freehand manner without any surgical guide. Moreover, when using mental CAIS technique, surgeon is allowed to compare the deviation of implant position between pre-operative and post-operative position which is different from the conventional technique (3, 4, 6).

However, this technique has a weak point that the surgeon cannot control the implant angulation and depth by freehand operation. Moreover, there is no tools for transferring the relationship from the virtual implant planning to the preparative filed.

II.3.2 Computer Assisted Implant Surgery (CAIS)

According to the disadvantages in the conventional technique, computer assisted implant surgery is developed to improve the implant planning, to approach the surgical site as 3D virtually and to facilitated in guiding and performing surgery by using patient’s CBCT data and implant planning software (38).

The surgeon can virtually plan position and choose the optimal implant size which is suitable for anatomical structures corresponding to the bone availability for proper prosthesis before the surgical procedure (38-40). Moreover, there is possibility for transferring the planned implant positions to the operative filed and laboratory in this system (38).

Bitra et al., in 2015 summarized the advantages and disadvantages of computer assisted implant surgery in many aspects in the following table (41).

Advantages	Disadvantages
1. Real- time 3D imaging and matching 2. Immediate surgical procedures can be performed in most cases 3. Minimal invasion and allowing some cases to be treated flapless 4. Preservation of vital structures from injury by security stops 5. Allowing proper preoperative treatment plan 6. Allowing pre-operative and post-operative comparison 7. Improving surgical skills of unexperienced surgeons 8. Experienced surgeons can treat more challenging cases with more comfort and confidence and less chair-time.	1. Requires highest amount of preparation and patient coordination 2. Expensive 3. High installation time 4. Needs proper training 5. Inaccurate data 6. Minimum three natural markers should be visible

Table 2 Advantages and disadvantages of computer assisted implant surgery.

Computer assisted implant surgery is mainly divided into two groups there are dynamic CAIS and static CAIS. (7, 9, 42).

II.3.2.1 Dynamic CAIS

"Computer-navigated dynamic surgery is using of a surgical navigation system that reproduces virtual implant position directly from computerized tomographic data and allows intraoperative changes in implant".

Dynamic CAIS is surgical navigation and computer-aided navigation technology that guiding surgeon with the real time virtual implant placement during the drilling function without any surgical guide. The surgeon can adjust and modify the plan simultaneously with anatomical data from preoperative CBCT scan (43). This is a one of publications that reported about the accuracy of dynamic CAIS group and other types.

Jung et al., in 2009 reported in their systematic review that the static CAIS group have the tendency to be more accurate than the dynamic CAIS (7). Although, Michael S. Block et al., in 2016, stated that the comparison of the accuracy of the implant placement position in dynamic CAIS system, the results showed that the accomplishment of accuracy position is same as static CAIS group and more precise in placement over the conventional implant placement technique (freehand) (10).

Lately, Michael S. Block et al., in 2017, their comparative study about accuracy and precision for implant placement that compared between the conventional implant placement technique (freehand) and dynamic CAIS group reported that the accomplishment of accuracy position in dynamic CAIS showed a smaller deviations between the planned placement and actual placement when comparing with conventional implant placement technique (9).

Figure 6 Implant surgery by dynamic CAIS technique.

II.3.2.2 Static CAIS

" Computer-guided static surgery is using of a static surgical guide that reproduces virtual implant position directly from computerized tomographic data and does not allow intraoperative modification of implant position (44).

In this system, the CT or CBCT data is used to combine with implant planning software for planning and performing the implant surgery. The software can simulate the virtual planned for implant with the patient's jaw that makes the surgeon can virtually choose and place the implant properly, including the design and fabrication of guided template in the planning software (7). The placed implant position in this system is depended on the surgical guide without the ability to change planned position. The surgical guide with metal sleeves are controlling the planned axis by navigate the drill in the certain planned direction (7).

According to several benefits over the conventional technique, static CAIS is used in many complicated cases. For example, the cases need a precise implant position to prevent injury to vital anatomical structures (e.g. maxillary sinus, mandibular nerve) and need flapless procedure that is used to reduce the error from surgical technique (38) which makes a less invasive surgery and less patient morbidity (45).

Nonetheless, there are small limitations about using the static CAIS in some situation. For instance, there is no real-time visualization of the osteotomies, the surgeon cannot modify or alter the planned position during intraoperation, the static surgical guide cannot use in limit mouth opening especially in posterior teeth, and the cases have no available space for irrigation, placing a surgical guide and drills.

This is a one of publications that reported about the accuracy of static CAIS group with other types.

Nickenig et al. in 2010 published a comparative study about the accuracy of guided implant position between surgical guide group and the conventional freehand technique group, the result showed that the accuracy of the surgical guide group is superior than that of conventional group (11).

Farley et al. in 2013 published a split-mouth comparative study about the accuracy of placed implants with guided template and conventional template using, the result showed that guided template demonstrated the superior accuracy in a lateral direction than that of conventional method and guided template were more consistent in their deviation from the planned locations than conventional technique (12).

Kang et al., in 2014 published the comparative study using a navigation comparing with the printed surgical template, the result showed that printed surgical template group demonstrated fewer errors than the real-time navigation method (13).

Tahmaseb et al., in 2014 published their systematic review about the issues that involved in accuracy of implant position in many aspects such as flapless versus flap approach, conventional method versus implant guided surgery and type of template support.

The result about flapless and flap approach showed that flapless procedures seemed to show a significantly better accuracy than that of flap approach. When comparing the accuracy between freehand and guided implant, the guided implant placement showed a statistically superior accuracy when they are compared with freehand placement after guided osteotomy. In guide-supported cases, the accuracy of mini-implant–supported guides was significantly higher than that of all other types of support, except mucosa. Bone-supported guides showed significantly larger deviations than other types of guide support. Tooth-supported guides tended to be slightly more accurate than mucosa or mucosa and pin-supported guides and bone supported guides were considerably lower in all observed variables and there was no clinical studies available that evaluate accuracy of guided implant placement with mini-implants (46).

And lately, Zhou et al., in 2017 published their systematic review about clinical factors affecting the accuracy of guided implant surgery. The result showed that the position of guide (maxilla or mandible), guide fixation (use of fixation screw or not), type of guide (totally or partially guided), and flap approach (open flap or flapless) influenced the accuracy of computer assisted implant surgery. In totally guided systems using fixed crews with a flapless approach had greater accuracy. To minimize the cumulative errors, clinicians can make a totally guided system with fixed screws as the first choice in daily practice, which can be made better with a flapless approach (47).

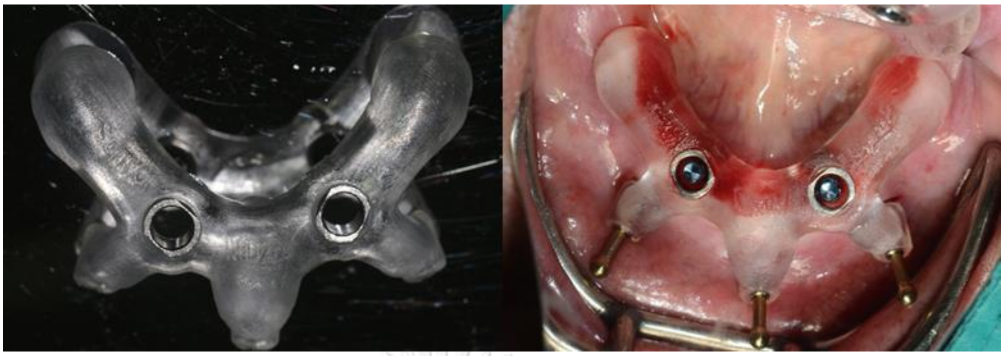

Figure 7 Static surgical guide / the guide placed over the edentulous ridge with screws fixation.

II.4. Planning software for CAIS

In conventional planning for a dental implant treatment, the data from study models and conventional dental radiographs is used for designing a model-based surgical guide.

In the past few years, the implant planning technology and CT scans helped the surgeon to plan and place predictably. The planning software is used to merge the patient's CBCT data with/without surface scanning data and to generate the visualization and manipulation of the images of the surgical site that resulted in improvement of the accuracy of implant position. Nowadays, there are many available implant planning software from many manufacturers, third-party software programs and the proprietary software of the CBCT unit (Table 3) (48, 49).

The software allows the surgeon to see a virtual implant planning, determine the proper space between the implant and relative vital structures. Furthermore, this visualization provides a conveniently analysis, predictable planning in preoperative planning and communicating the prosthodontist.

coDiagnostiX™ is a digital implant planning software that covers the implant surgery from preoperative planning, designs surgical drilling guides, and even evaluates of postoperative results which provides safe and predictable outcomes.

The software can read 3D data from CBCT scanning and integrating the digital impression data form surface scanning (STL file). Furthermore, the software allows the surgeon to compare the treatment outcomes with treatment evaluation function that can determine accuracy of implant positions between the preoperative radiograph and postoperative radiograph automatically with high accuracy.

Kühl et al., in 2015 published their study about the determination of accuracy of a digitally designed and fabricated guided template for implant installation based on a surface scan using the coDiagnostiX™ software. The result showed that generated template for performed implant surgery from coDiagnostiX™ software was achieved a high accuracy of implant position (50)

Implant planning software	Companies
Third-party software programs	
coDiagnostiX	Dental wings inc, Canada
Implant Studio	3shape, Denmark
Invivo5	Anatomage, USA
Simplant	Materialise Dental, USA
NobelClinician	Nobel Biocare, Sweden
OnDemand3D	Cybermed, Korea
Virtual Implant Placement software	BioHorizons, USA
Blue Sky Plan	BlueSkyBio, USA
Proprietary software of the CBCT units	
Galileos system	Sirona Dental Systems, USA
TxSTUDIO software	iCATÒ, Imaging Sciences International LLC, USA
NewTom implant planning software	NewTom, Italy
Products for dynamic CAIS	
Image Guided Implantology	IGI: Image Navigation, USA
Inliant	Inliant Dental Technologies, Canada
IRIS-100 Implant Real-time Imaging System	EPED Incorporated, Taiwan
Mona-Dent	DDI Group, Germany
Navident	ClaroNav, Canada
Robodent/Navipanel/NaviBase	Robodent, Germany
X-Guide Dynamic 3D Navigation	X-Nav Technologies, Israel

Table 3 CAIS Planning software for implant treatment.

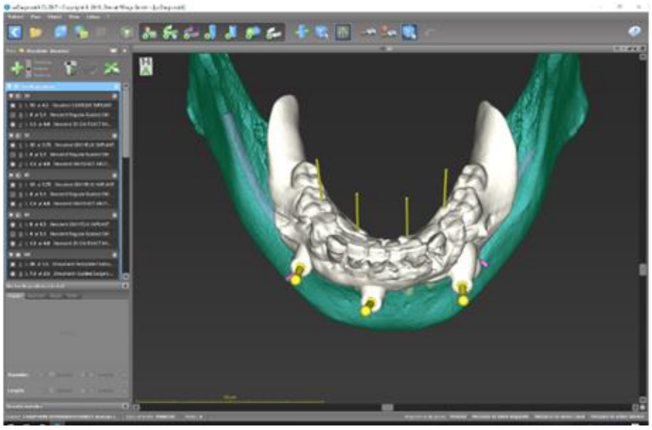

Figure 8 coDiagnostiX™ software program (Dental wings inc, Montreal, CA).

II.5. Accuracy analysis of implant position

Accuracy of implant placement is estimated by the precision of implant positions that is correct as the planned. According to the technology of implant software planning, the treatment outcomes will be compared with implant planning software combined with CBCT data.

For the analyzing accuracy of implant positions, the data from preoperative and postoperative position was used to determine the deviation between actual position and the planned position. The planned position is compared with the actual position after insertion procedure, DICOM file (Digital Imaging and Communication in Medicine) of postoperative position are imported in the implant planning software.

The software automatically/ manually matching the planned and placed position of implant together in virtual planning software and automatically. After that, the volume of planned implant is superimposed with volume of actual implant using automated surface best-fit matching with the iterative closest point algorithm to calculate the deviation of implant placement within the analyzed software.

In general, the accuracy is in three parameters:

· Error at the platform, measured at the center of the implant platform

· Error at the apex, measured at the center of the implant apex

· Angular deviation

Error at the entry and the apex are evaluated in mm or µm, while the angular deviation is evaluated in degrees. The error or deviation of these points is calculated in three dimensions, though several techniques are used to describe the distance between the given points. The most common method is the actual distance measurement between the planned and placed point in 3D directions (46).

By using differences between the deviation measured in the x, y, and z-axis and calculation from Pythagorean Theorem (Equation 1) where

x = horizontal deviations in implant position in the mesio-distal direction,

y = horizontal deviations in implant position in the bucco-lingual direction,

z = axis of the planned implant and describes deviations in the apico-coronal direction.

$$3Ddev = \sqrt{x^2 + y^2 + z^2}$$

Equation 1 3D deviations using Pythagorean Theorem.

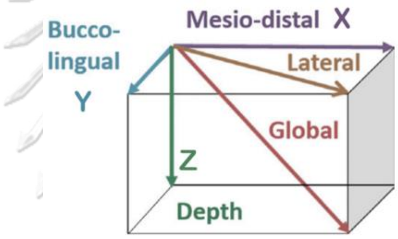

Figure 9 Deviation measured in x, y, z-axis.

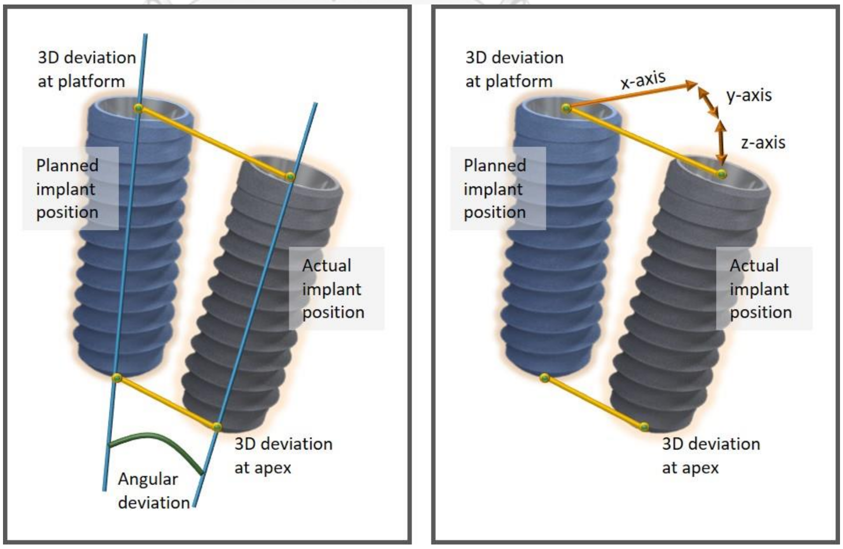

Figure 10 Illustration of different parameters for describing the deviations (Left). Different variables for describing deviations per implant illustrated (Right) Illustration of distinction between deviation measured in x, y, z-axis.

II.5.1 Accuracy of Mental CAIS

Bencharit et al., in 2015 published their study about the accuracy analysis of 18 implant positions in single immediate implant placement using computer-aided implant planning with cone-beam computed tomography (CBCT) [SimPlant Pro 15 (Dentsply, Waltham, Mass)]. The results of accuracy were showed that no statistical difference between the planned and actual implant position in any observed variables. (Table 4) Accordingly, it can be concluded that mental CAIS may improve the accuracy of single immediate implant placement (51).

Study	Implant number	Type of space	MI Distance	DI Distance	LI Distance	Angular deviation (°)
Bencharit et al., 2015	18	Single tooth gap	-0.02 (-0.40, 0.37)	-0.02 (-0.42, 0.39)	-0.11 (-0.73, 0.50)	1.23 (-1.59, 4.05)

Table 4 Accuracy of implant placed with mental navigation.

II.5.2 Accuracy of Static CAIS

Several studies have been performed to determine the accuracy of stereolithographic and laboratory-based surgical guide templates in clinical situation.

Di Giacomo et al., 2005 evaluated the accuracy of 21 implants placed using SLA surgical guides generated from CT with Simplant software program in 4 patients. The result concluded that SLA surgical guides may be useful equipment in implant placement. However, the stability of template was important factor especially in cases of unilateral bone supported and non-tooth supported guides (Table 5) (52).

Ersoy et al., 2008 evaluated the accuracy of 94 implants placed using SLA surgical guides generated from CT with Stent Cad software program (Media Lab Software, La Spezia, Italy). They suggested that SLA surgical guides might be accurate tools for transferring ideal implant positions from computer planning to the actual implant surgical phase of treatment and flapless implant surgery was possible with these guides (Table 3) (38).

Ozan et al., 2009 evaluated the accuracy of 110 placed implants using surgical guides generated from CT with Stent Cad software program (Media Lab Software, La Spezia, Italy). The result showed that significant differences were found between tooth-supported and bone-supported, and between tooth-supported and mucosa-supported surgical template. They concluded that SLA surgical guides using CT data may be reliable in implant placement, and tooth-supported SLA surgical guides were more accurate than bone- or mucosa-supported SLA surgical guides (Table 5) (53).

Valente et al., 2009 reported their retrospective study that evaluated the accuracy of 89 SLA surgical guides generated from CT with Simplant software program (Materialise Dental Inc, Glen Burnie, MD, USA) in 25 patients. The deviation was 1.4 ± 1.3 mm at the implant shoulder, 1.6 ± 1.2 mm at the implant apex, and angular deviation of 7.9° ± 4.7°. The survival rate of 96% with this method (mean follow-up, 36 months) and no complications were found (Table 5) (54).

Van Assche et al. 2010 evaluated the accuracy of implants placed flapless by SLA template with Nobel Guide software program (Nobel Biocare, Yorba Linda, CA, USA) in 8 partially edentulous patients. They concluded that implants in partially edentulous patients can be installed flapless via guide templates with suitable deviations towards their digital planning (Table 5) (55).

Behneke et al., 2012 evaluated the accuracy of 132 implants placed using laboratory-based surgical guides generated from CBCT with Med3D software program (Med3d, Heidelberg, Germany) in 52 partially edentulous patients. The deviation was 0.27 mm (range 0.01–0.97 mm) at the implant shoulder, 0.46 mm (range 0.03–1.38 mm) at the implant apex, and angular deviation of 1.84° (range 0.07°–6.26°). The extension of deviation is depended on tooth gap size and remaining teeth distribution. They concluded that laboratory-based surgical guides were the good transferring accuracy tools for patients with partial dentitions (Table 5) (56).

Pettersson et al., 2012 evaluated the accuracy of 139 SLA surgical guides generated from CBCT with Nobel Guide software program (Nobel Biocare, Yorba Linda, CA, USA) in fully edentulous patients. The deviation was 0.8 mm at the implant shoulder, 1.09 mm at the implant apex, and angular deviation of 2.26° Statistic differences were not observed between upper and lower jaws. The greatest error was found when comparing between patients moving during the computed tomography scans and those who did not move (Table 5) (57).

Schneider et al., in 2009 published their systematic review from analysis of the accuracy of computer-guided template-based implant dentistry. They reported that

SLA surgical guides were the reliable tools in implant placement; nevertheless, there are some disadvantages in this method, for instance, unable to insert surgical drill in the patient with limited interocclusal space, reduction of predictability of implant positioning with sufficient implant stability from under- or overestimation of bone volume during CT-data analysis and virtual implant planning (Table 5) (58).

Van Assche et al., in 2012 publish their meta-analysis from that analyzing accuracy of 1,326 implants with static computer-guided implant placements in 12 vivo studies. This study included 10 different "static" computer-assisted implant systems were used (Ay-Design®, Aytasarim®, EasyTaxis®, SinterStationHiQ®, SurgiGuide®, Safe SurgiGuide®, SICAT®, Med3D®, NobelGuide®, Facilitate®). They reported that, in vivo studies, mean deviation at implant shoulder was 1.0 mm (95% CI: 0.7 to 1.3 mm), mean deviation at the apex was 1.4 mm (95% CI: 1.1 to 1.7 mm), and mean angular deviation 4.2° (95% CI: 3.6° to 5.0°) (59). However, comparisons between 10 implant planning software were impossible because the heterogeneity in study designs. Moreover, they suggested that the stability of guide template was the most crucial factor on the final accuracy of implant placement (Table 5) (59).

Study	Study design	Software program	Implant number	Deviation		
				Shoulder (mm)	Apex (mm)	Angle (°)
Di Giacomoet et al., 2005	Prospective	Simplant*	21	1.45±1.42	2.99±1.77	7.25±2.67
Ersoy et al., 2008	Prospective	Stent Cad**	94	0.74±0.40	1.66±0.28	3.71±0.93
Ozan et al., 2009	Prospective	Stent Cad**	50	1.28±0.9	1.57±0.9	4.63±2.6
			30	0.87±0.4	0.95±0.6	2.91±1.3
			30	1.06±0.6	1.60±1.0	4.51±2.1
Valente et al., 2009	Retrospective	Simplant*	89	1.4±1.3	1.6±1.2	7.9±4.7
Van Assche et al., 2010	Prospective	NobelGuide***	19	0.6±0.3	0.9±0.	2.2±1.1
Behneke et al., 2012	Prospective	med3D****	132	0.27(0.01-0.97)	0.46(0.03-1.38)	1.84 (0.07-6.26)
Pettersson et al., 2012	Prospective	NobelGuide***	139	0.8	1.09	2.26
Schneider et al., 2009	Systematic	3 systems	155	1.16 (0.92-1.39)	1.96 (1.33-2.58)	5.73 (3.96-7.49)
Van Assche et al., 2012	Meta-analysis	10 systems	1,326	1.0 (0.74-1.31)	1.4 (1.06-1.7)	4.2 (3.59-4.96)

* Simplant (Materialise Dental Inc, Glen Burnie, MD, USA) ** Stent Cad (Media Lab Software, La Spezia, Italy)

*** NobelGuide (Nobel Biocare, Yorba Linda, CA, USA) **** med3D (Med3d, Heidelberg, Germany)

Table 5 Accuracy of implant placed with static CAIS.

II.5.3 Accuracy of Dynamic CAIS

Wittwer et al. in 2006 evaluated the accuracy of 78 implants in 20 full edentulous patients using dynamic navigation system (The StealthStation Treon navigation system, Medtronic, Minneapolis, MN) with flapless approach. The result showed the mean deviation of 1.1 ± 0.7 mm at implant shoulder and 0.8 ± 0.6 mm at implant apex. They concluded by using dynamic navigation system that transmucosal implant placement can be done with flapless approach and this is a predictable and accurate procedure with suitable patient selection (60).

Wittwer et al. in 2007 also compared the 2 dynamic navigation systems (The StealthStation Treon navigation system, Medtronic, Minnesota, MN versus VISIT navigation system, University of Vienna, Vienna, Austria) about the accuracy of implant placement in 16 full edentulous patients. They reported that the labio-lingual deviation at the implant entry and the implant 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 entry vs 0.6 ± 0.2 mm in labial, 0.7 ± 0.3 mm in lingual direction at the implant apex versus Treon : 1.0 ± 0.5 mm in labial , 1.2 ± 0.8 mm in lingual direction at the implant entry vs 0.8 ± 0.6 mm in labial, 0.7 ± 0.5 mm in lingual direction at the implant apex) (40).

Block et al. in 2016 published their comparative study about the accuracy of implant position between using dynamic CAS system (X-Guide, X–Nav Technologies) and using freehand approach in 100 patients with single tooth gap. The result showed that the accuracy of navigation system was superior compared to freehand approach. Using navigation system, mean entry error, apex error and angle error were 1.37 ± 0.55 mm, 1.56 ± 0.69 mm and 3.62 ± 2.73 degrees respectively, while in freehand were 2.51 ± 0.86 mm, 1.67 ± 0.43 mm and 7.69 ± 4.92 degrees respectively (61).

Study	Study design	System	Implant (N)	Error entry (mm)	Error apex (mm)	Error angle (degree)
Wittwer et al., 2006	Prospective	Treon	78	1.1 ± 0.7	0.8 ± 0.6	-
Wittwer et al., 2007	Randomized Controlled Trial	Treon	16	La 1.0 ± 0.5 Li 1.2 ± 0.8	La 0.8 ± 0.6 Li 0.7 ± 0.5	-
		VISIT	16	La 1.0 ± 0.5 Li 0.7 ± 0.3	La 0.6 ± 0.2 Li 0.7 ± 0.3	
Block et al., 2016	Clinical Controlled	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

La = deviation in labial / buccal direction; Li = deviation in lingual / palatal direction

Table 6 Accuracy of implant placed with dynamic navigation.

II.5.4 Comparison of the accuracy between Static CAIS and Mental CAIS

There are many clinical studies that measured the accuracy of static guided implant surgery. However most of investigations due to the intrinsic nature of their study design were unable to determine whether the static guided implant surgery was more accurate than the conventional implant surgery (62).

In additions, the split-mouth design used by Farley et al., in 2013 compared the accuracy of static CAIS with mental CAIS within the same patients. All the implants were planned with the iDent Imagine planning software (iDent Imaging) and then allocated toward one of the two groups. After surgery, the postoperative CBCT data was superimposed to preoperative CBCT data, then volumetric or overlap differences were measured to compare the planned and actual implant position. The results showed that implants positions placed with static CAIS were closer to the planned positions in all directions, however statistically significant differences (P = 0.0409) were shown only at the entry point, providing greater accuracy than implants placed with mental CAIS (Table 7) (12).

	Deviation at entry point	Deviation at apex	Angular deviation (°)
Static CAIS	1.45 ± 0.60 mm	1.82 ± 0.60 mm	3.68 ± 2.19
Mental CAIS	1.99 ± 1.00 mm	2.54 ± 1.23 mm	6.13 ± 4.04

Table 7 Comparison of the accuracy of computer-guided implant surgery with freehand conventional implant placement within the same patients.

Besides, Nickenig et al., 2010 published their study that compared the accuracy of implant position between static CAIS and mental CAIS using coDiagnostiX™ implant planning software. In static CAIS group, 23 implants were placed in lower jaws of 10 patients with a Kennedy Class II. In mental CAIS group, manual implantation was performed in radiopaque anatomical casts of the same 10 patients who had undergone real implantation. The results were static CAIS produced significantly smaller deviation than mental CAIS in all positions and accuracy of axis was also significantly improved. They concluded that implant placed with static CAIS method produced more accuracy than in mental CAIS and method of superimposing radiographic images of postoperative casts and preoperative virtual planning images is a useful method, which allows reducing patient radiation exposure (Table 8) (63).

	Tip distance (mm)		Base distance (mm)		Axis deviation (°)
	Mediallateral	Anteriorposterior	Mediallateral	Anteriorposterior	
Static CAIS	0.6 ± 0.57	0.9 ± 0.94	0.9 ± 1.06	0.9 ± 1.22	4.2 ± 3.04
Mental CAIS	2.5 ± 2.48	2.0 ± 2.02	3.5 ± 2.24	2.4 ± 1.91	9.8 ± 4.25

Table 8 Deviation of implant position between static and mental CAIS groups.

II.5.5Comparison of the accuracy among Static CAIS, Mental CAIS and conventional implant surgery

Vercruyssen et al., in 2015 compared accuracy of implant placements in 60 fully edentulous patients (72 jaws). The surgical interventions were divided into 6 groups (12 jaws per group):

- Materialise Universal® Mucosa (Mat Mu)
- Materialise Universal® Bone (Mat Bo)
- Facilitate® Mucosa (Fac Mu)
- Facilitate® Bone (Fac Bo)
- Mental group
- Template group

The results were showed that based on types of guide supported template, no significant difference was found between bone and mucosa-supported templates. Based on the differences in product handling in guided template group (Materialise

Universal® VS Facilitate®), no significant difference was found between no physical stop during drilling and physical stop on the drills, and implant was placed without guidance and implant insertion was guided by the fixture mount.

They concluded that inaccuracy of Materialise Universal®, Facilitate® groups were clearly less than in Mental and Template group in all positions (deviation at coronal, deviation at apex, and angular deviation) (Table 9) (3, 4).

	Mat Mu	Mat Bo	Fac Mu	Fac Bo	Mental	Template
Coronal (mm)	1.23±0.60	1.60±0.92	1.38± 0.64	1.33±0.82	2.77±1.54	2.97±1.41
Apex (mm)	1.57±0.71	1.65±0.82	1.60±0.70	1.50±0.72	2.91±1.52	3.40±1.68
Angular (°)	2.86±1.60	3.79±2.36	2.71±1.36	3.20±2.70	9.92±6.01	8.43±5.10

Table 9 Deviation of different type of implant placement in fully edentulous patients.

From literature reviews, there is less scientific evidence to make a clear conclusion that static CAIS is better than Mental CAIS in term of accuracy implant position in totally edentulous patient. For this reason, the rationale in this study is to evaluate the accuracy of implant position using static surgical guide and mental CAIS in totally edentulous patient.

CHAPTER III
MATERIALS AND METHODS

III.1 Materials

III.1.1 Patient

This a prospective case control study included 60 implants in the totally edentulous upper and/or lower jaws treated with implant-supported dentures in the Department of Oral and Maxillofacial Surgery, Faculty of Dentistry, Chulalongkorn University from September 2018 to April 2020.

III.1.1.1 Sample selection

<u>Inclusion criteria for the patient selection:</u>

• Healthy patient

• Being totally edentulous ridge in upper and/or lower jaws at least 2 months prior to implant placement

• Sinus lifting, guided bone/tissue regenerative procedures must be carried out at least 6 months before implant surgery

• No bony pathological lesion that supported the surgical guide

• Clinical examination and CBCT image display adequate bone quality and quantity for implant placement

• Adequate mouth opening for placing both surgical guide and drills

<u>Exclusion criteria:</u>

• Patients with severe systemic condition such as severe cardiac vascular disorders, uncontrolled endocrine disorders, leukocyte dysfunction or deficiency, bleeding disorders, coagulation disorders, neoplastic disease, renal failure, pregnancy or lactation

• Patients with history of radiation therapy/medication-related osteonecrosis of the jaw

• Having bone augmentation during operative time

• Abrupt alteration in treatment planning the surgical time

III.1.1.2 Sample size estimation

Sample size estimation (implant number) was performed via G*Power version 3.1.9.2. The effect size (f) of 0.639 was calculated from Computer-supported implant planning and guided surgery: a narrative review (4, 9) with significance level (α) of .05, power (1-β) of .95, and allocation ratio of 1. The calculated sample size each group is 14 implants.

However, for losing the data at any period of time, the total sample size will be used in this study is 60 implants and is divided into 3 groups; mental CAIS, static CAIS and dynamic CAIS. Each group comprises of 20 implants.

III.1.2 Cone Beam Computed Tomography (CBCT) scanner

Accuitomo 3D machine (J. Morita Inc., Kyoto, Japan) is used for bone evaluating in pre- and post-implantation. [120 kV, 80 mAs, FOV 100x100 mm, 140x100 mm (depend on patient’s arch size), Voxel size 125 µm]

III.1.3 Surface scanner

D900L scanner (3shape, Copenhagen, Denmark) is used for creating STL file in order to plan and fabricate the static surgical guide

III.1.4 Implant and mini-implant

Implant and mini-implant, bone level or tissue level implant with any connection types (Straumann, institute Straumann AG, Basel, Switzerland)

III.1.5 Mental CAIS system

III.1.5.1 Planning and accuracy analysis software

coDiagnostiX software version 9.7 (Dental Wings inc, Montreal, CA)

III.1.5.2 Surface scanner

Model scanner (3shape, Copenhagen, Denmark)

III.1.6 Static CAIS system

III.1.6.1 Planning and accuracy analysis software

coDiagnostiX software version 9.7 (Dental Wings inc, Montreal, CA)

III.1.6.2 Surface scanner

Model scanner (3shape, Copenhagen, Denmark)

III.1.6.3 Surgical guide stents

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

III.1.7 Dynamic CAIS system

III.1.7.1 Planning and accuracy analysis software

Iris–100 software (EPED Inc., Taiwan)

III.1.7.2 Occlusal stent for registration

Plastic splint sheet (3A MEDES, South Korea) and vacuum former machine (Ultraform, Ultradent Products, Inc., Utah, USA)

III.1.7.3 Occlusal appliance set for registration

Iris–100 (EPED Inc., Taiwan)

III.1.7.4 Navigation machine

Iris–100, (EPED Inc., Taiwan)

III.1.8 Statistic analysis software

IBM SPSS Statistics software version22 (SPSS Inc., Chicago, IL)

III.2 Methods

All implants will be planned and operated by the same oral surgeon, and the data will be collected and analyzed by researcher.

III.2.1 Preoperative phase

III.2.1.1 The study clinical protocol will be approved by ethic committee of faculty of Dentistry, Chulalongkorn University. Written consent will be obtained from all subjects.

III.2.1.2 With consideration of inclusion and exclusion criteria, patient will be assigned into 3 groups; mental CAIS, static CAIS and dynamic CAIS groups.

III.2.1.3 Mini-implant placements: before radiographic taking, patient in static CAIS and dynamic CAIS groups must be received three mini-implant placements (7.5 mm long, 2.5 mm in diameter) with flapless approach under local anesthesia. The mini-implants were inserted into the jaws in the midline and premolar area bilaterally as fixed reference points for registration of the surface scanning data and supported surgical guide & occlusal appliance set for registration in surgical procedure.

III.2.1.4 Arch impression: all of mental CAIS, static CAIS and dynamic CAIS groups will be received full arch impression with alginate for fabricating study model.

III.2.1.4.1 In mental CAIS, static CAIS groups, the model scanning will be done for the standard tessellation language (STL) by D900L scanner (3shape, Copenhagen, Denmark).

III.2.1.4.2 In dynamic group, the model will be used for fabrication occlusal stent with plastic splint sheet (3A MEDES, South Korea) and vacuum former machine (Ultraform, Ultradent Products, Inc., Utah, USA). The occlusal stent will be cut 5 mm. below gingival margin, left some space on edentulous area for placing implant and attached with the occlusal guide appliance that contains 4 radiopaque fiducial markers (Iris – 100, EPED Inc., Taiwan)

III.2.1.5 Radiographic taking

III.2.1.5.1 Mental CAIS and static CAIS groups: after finishing the mini-implant placements, the patient in will be scanned with cone beam computed tomography (CBCT) (3D Accuitomo 170 machine, J. Morita Inc., Kyoto, Japan).

III.2.1.5.2 Dynamic CAIS group: after the occlusal stent with the occlusal guide appliance will be placed on the mini-implants of the arch that is planned, the patient will be scanned with cone beam computed tomography (CBCT) (3D Accuitomo 170 machine, J. Morita Inc., Kyoto, Japan).

III.2.1.6 The Digital Imaging and Communications in Medicine (DICOM) file of CBCT data and STL files of model scanning data will be transferred into the planning software.

- Mental CAIS and static CAIS groups: coDiagnostiXTM software version 9.7 (Dental Wings inc, Montreal, CA) that provides 3-dimensional information for planning implant positions. (in static CAIS, will be registered to the CBCT image for treatment planning by use the mini-implants as references.)

- Dynamic CAIS group: IRIS 100 software EPED, Taiwan.

III.2.1.7 After surgeon and prosthodontist completely plan optimal position of the implants together, the virtual planned of mental and dynamic CAIS will be used in the operative phase and the digital data of static CAIS, surgical guide with sleeves will be sent to dental laboratory to 3D print out the surgical guide for surgical procedure.

III.2.2 Operative phase

III.2.2.1 Mental CAIS procedure

III.2.2.1.1 Before the surgical procedure start, the fit of conventional stent will be checked and confirmed via inspection the guide stability.

III.2.2.1.2 After local anesthetic injection, the implant positions will be reviewed again by visualize pre-op planning in the software.

III.2.2.1.3 Flap operation will be performed, the preparation of the surgical sites and implant insertion will be done following to surgical protocol (Straumann, institute Straumann AG, Basel, Switzerland).

During surgery, the surgeon constantly reminding to place the implants corresponding to the planned in freehand manner.

III.2.2.1.4 Insertion torque and the resonance frequency analysis (RFA) measurement will be recorded.

III.2.2.1.5 Inserting the closure screw or healing abutment will be done.

III.2.2.1.6 Post-operative instruction will be given.

III.2.2.2 Static CAIS procedure

III.2.2.2.1 Before implant surgery, the static surgical guide will be completely seated on the mini-implants to secure a proper position, the optimal fit and appropriate position of the guide will be confirmed via inspection the guide stability.

III.2.2.2.2 After local anesthetic injection and the surgical guide is seated properly, fully guided implant surgery will be used in osteotomy and implant insertion step.

III.2.2.2.3 Flap operation will be performed for avoiding the interference with the surgical guide, the preparation of the surgical sites will be done following guided surgical protocol and implant fixtures will be guided inserted through the sleeves into osteotomized sites.

III.2.2.2.4 Insertion torque and the resonance frequency analysis (RFA) measurement will be recorded

III.2.2.2.5 Inserting the closure screw or healing abutment will be done.

III.2.2.2.6 Post-operative instruction will be given.

III.2.2.3 Dynamic CAIS procedure

III.2.2.3.1 The surgical procedure will be performed using the dynamic navigation system machine and accessories (Iris – 100, EPED Inc., Taiwan). Before the procedure, a handpiece extension collar that contains registration markers will be assembled to the handpiece.

III.2.2.3.2 Registration of the surgical handpiece will be performed by insert the registration bur into a registration plate and aim the tracking camera to the plate and the handpiece extension collar. This process will identify the relationship between the geometry of the handpiece extension collar and the axis of the bur.

III.2.2.3.3 The occlusal guided device will be mounted to an extraoral patient tracking collar that contain registration markers and placed on the mini-implants in the same position as during CBCT scan.

III.2.2.3.4 Registration of the position will be performed to provide a link between the preoperative planning coordinated system and the tracking coordinated system by touch the registration probe to 4 fiducial markers in the occlusal appliance. Then, align the patient tracking collar to face the tracking camera, finally, remove the occlusal guide appliance and the navigation is ready.

III.2.2.3.5 Flap operation under local anesthesia will be performed by one surgeon. The preparation of the surgical sites and implant insertion (Straumann, institute Straumann AG, Basel, Switzerland) will be performed under the guidance by the dynamic navigation system machine (Iris – 100, EPED Inc., Taiwan). The system will continuously track both the handpiece tracking collar and patient tracking collar and display the position of virtual bur superimposed onto the preoperative CBCT image with virtual plan implant position on the monitor as a live video. Surgical team can get interactive feedback from the system to visualize drilling procedure and implant placement and adjust the position to match the treatment plan. In case of changing the planned position operatively, the new plan will save as a new file for evaluating the implant deviation in accuracy analysis

III.2.2.3.6 The closure screw or healing abutment will be inserted

III.2.2.3.7 Post-operative instruction will be given.

II.2.3 Postoperative phase

III.2.3.1 All of mental CAIS, static CAIS and dynamic CAIS groups will be taken post-op CBCT for determine a deviation of the planned and actual position of the implants with 3D Accuitomo 170 machine (J.Morita Inc., Kyoto, Japan).

III.2.3.2 The post-op CBCT will show a 3D data which demonstrated volume that can be superimposed with pre-op CBCT and evaluated implant position.

III.2.3.2.1 In mental CAIS, static CAIS groups will use a treatment evaluation tool in coDiagnostiX^{TM} (Dental wings inc, Montreal, CA) for evaluate the deviation between planned and actual positions.

III.2.3.2.2 In dynamic CAIS group will use IRIS-100 software (EPED Inc., Taiwan) for evaluate the deviation between planned and actual positions.

III.2.4 Evaluation phase

III.2.4.1Accuracy analysis

For evaluating the accuracy of implant position, the planned (virtual) and placed (actual) position will be compared with a treatment evaluation tool function in coDiagnostiX^{TM} (Dental wings inc, Montreal, CA) for mental CAIS and static CAIS groups and IRIS-100 software (EPED Inc., Taiwan) for dynamic CAIS group. This software will automatically match the implants volume and calculating a deviation of the post-op CBCT (placed position) with virtual (planned position) implant planning.

In this study, the deviation will be measured at the platform and the apex point in three parameters (Table 10). This process will be performed two separate times by one examiner and these two datasets will be compared in order to calculate the intraclass correlation coefficient of the postoperative analysis between two planning software. The result was 0.99, that demonstrated very good reliability.

Parameters	Description
3D deviation at platform	Difference in length of actual implant platform from the virtually planned implants in anterior/posterior (sagittal view), medial/lateral (coronal) and apical/coronal (sagittal view) directions.
3D deviation at apex	Difference in length of actual implant apex from the virtually planned implants in anterior/posterior (sagittal view), medial/lateral (coronal) and apical/coronal (sagittal view) directions.
Deviation of implant axis	The angle difference of the actual implant axis from the planned axis line that cross the center of the implant shoulder and the center of the implant apex between the planned and actual implant.

Table 10 Parameters for accuracy analysis.

III.2.4.2 Statistic analysis

All implant position data will be gathered and imported into SPSS Statistics software (version22 software SPSS Inc., Chicago, IL).

All groups will be compared to calculate the intraclass correlation of the postoperative analysis. One-way ANOVA will be used to determine the significant of mean difference between planned and placed implant position in mental CAIS, static CAIS and dynamic groups. The results will be considered statistically significant when P-value < 0.05.

III.3 Period of this study

Plan/Procedure	Feb 2018	Mar 2018	Apr 2018	May 2018	Jun 2018	Jul 2018	Aug 2018	Sep 2018 – Apr 2020	May 2020	Jun 2020	Jul 2020	Aug 2020	Sep 2020
Literature review													
Proposal presentation													
Submitting research proposal for ethics review													
Testing													
Data analysis													
Result and discussion													
Report and presentation													

Table 11 Period of this study

III.4 Expected benefits and application

1. The information about accuracy of implant position among patients who had received mental, static and dynamic CAIS will be compared.
2. Creating the new standard protocol for implant guided surgery in totally edentulous patient.

III.5 Budget

1. Material
   - Mini-Implant (Straumann, Switzerland) 36 implants (36 X 5,000) 180,000 Baht
2. Laboratory services
   - CBCT scanning (12 X 3,000) 36,000 Baht
   - Surgical guided fabrication (6 X2,000) 12,000 Baht

Total 228,000 Baht

CHAPTER IV

Result

A total of 60 implants (13 patients) were randomly assigned to three CAIS systems. The mean ± standard deviation (SD) age of patients was 66±6.73 years (range 51-75). All implant distribution among the groups were showed as in Table 12.

	Mental CAIS Group (n=20)	Static CAIS Group (n=20)	Dynamic CAIS Group (n=20)
Subject	6	4	3
Age (mean ± SD)	64.66±7.39	68±4.54	66±9.53
Gender			
-Male	3 (50%)	3 (75%)	3 (100%)
-Female	3 (50%)	1 (25%)	0 (0%)
Implant diameter			
3.3 mm	1 (5%)	0 (0%)	3 (15%)
4.1 mm	18 (90%)	14 (70%)	11 (55%)
4.8 mm	1 (5%)	6 (30%)	6 (30%)
Implant Length			
≤10 mm	17 (85%)	15 (75%)	14 (70%)
>10 mm	3 (15%)	5 (25%)	6 (30%)
Jaw			
- Maxilla	10 (50%)	8 (40%)	12 (60%)
- Mandible	10 (50%)	12 (60%)	8 (40%)
Position			
- Anterior	12 (60%)	12 (60%)	9 (45%)
- Posterior	8 (40%)	8 (40%)	11 (55%)

Table 12 Patient demographic in this study.

The mean ± SD angular deviations between planned and placed implants among the mental, static and dynamic CAIS groups were 10.09°±4.64°, 4.98°±2.16° and 5.75°±2.09°, respectively. The mean ± SD 3D deviation at implant platform and apex in the mental CAIS group were 3.48±2 mm and 3.60±2.11 mm The mean ± SD 3D deviation at implant platform and apex in the static CAIS group were 1.40±0.72 mm and 1.66±0.61 mm, while in the dynamic CAIS group were 1.73±0.43 mm and 1.86±0.82 mm, respectively (Table 13).

	Group	N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum	Maximum
						Lower Bound	Upper Bound		
Angular deviation	Mental	20	10.09	4.64	1.04	7.92	12.26	3.90	17.90
	Static	20	4.98	2.16	0.48	3.96	5.99	1.60	8.70
	Dynamic	20	5.75	2.09	0.47	4.77	6.73	1.43	10.23
3D deviation at Platform	Mental	20	3.48	2.00	0.45	2.55	4.42	1.19	7.72
	Static	20	1.40	0.72	0.16	1.06	1.73	0.53	3.14
	Dynamic	20	1.73	0.43	0.10	1.53	1.93	1.03	2.76
3D deviation at Apex	Mental	20	3.60	2.11	0.47	2.62	4.59	0.71	8.85
	Static	20	1.66	0.61	0.14	1.38	1.95	0.49	2.65
	Dynamic	20	1.86	0.82	0.18	1.48	2.24	0.69	4.19

Table 13 The mean deviations of guided implant positions among three CAIS groups.

According to Shapiro Wilk's test, all data are in normal distribution. Then, the Levene's test was used for evaluating the homogeneity of variance before using One-way ANOVA test. The results showed that all observed variables were unequal variance assuming. Hence, Welch's ANOVA was chosen for comparing the mean of deviation in the observed variables among all groups.

There were statistically significant differences among three groups in all observed variables. (Angle deviation $p< 0.001$, 3D deviation at implant platform $p=0.001$ and 3D deviation at implant apex $p= 0.002$) (Table 14).

Welch's ANOVA	Statistic	df1	df2	Sig.
Angular deviation	9.820	2	35.705	<0.001
3D deviation at Platform	9.589	2	32.209	0.001
3D deviation at Apex	7.673	2	34.012	0.002

Table 14 Welch's ANOVA was used for comparing the mean of deviation among all groups.

Games-Howell post-hoc analysis was selected for pairwise comparison (Table 15). From multiple comparison, the static and dynamic CAIS groups showed no statistically significant difference between planned and actual positions in term of angular deviation, 3D deviation at platform and apex (p=0.490,0.190 and 0.665, respectively). Both groups also demonstrated statistically significant superior accuracy in all variables compared to the mental CAIS group in the total edentulous (p<0.05)

Multiple Comparisons

Dependent Variable				Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval Lower Bound	95% Confidence Interval Upper Bound
Angular deviation	Games-Howell	Mental	Static	5.115000*	1.144915	.000	2.27563	7.95437
			Dynamic	4.341500*	1.137999	.002	1.51627	7.16673
		Static	Mental	-5.115000*	1.144915	.000	-7.95437	-2.27563
			Dynamic	-.773500	.672770	.490	-2.41435	.86735
		Dynamic	Mental	-4.341500*	1.137999	.002	-7.16673	-1.51627
			Static	.773500	.672770	.490	-.86735	2.41435
3D deviation at Platform	Games-Howell	Mental	Static	2.086000*	.474892	.001	.89969	3.27231
			Dynamic	1.749450*	.456912	.003	.59683	2.90207
		Static	Mental	-2.086000*	.474892	.001	-3.27231	-.89969
			Dynamic	-.336550	.188149	.190	-.79959	.12649
		Dynamic	Mental	-1.749450*	.456912	.003	-2.90207	-.59683
			Static	.336550	.188149	.190	-.12649	.79959
3D deviation at Apex	Games-Howell	Mental	Static	1.940500*	.491293	.002	.70690	3.17410
			Dynamic	1.743200*	.506112	.006	.48116	3.00524
		Static	Mental	-1.940500*	.491293	.002	-3.17410	-.70690
			Dynamic	-.197300	.227784	.665	-.75465	.36005
		Dynamic	Mental	-1.743200*	.506112	.006	-3.00524	-.48116
			Static	.197300	.227784	.665	-.36005	.75465

*. The mean difference is significant at the 0.05 level.

Table 15 The multiple comparison of implant deviation among studied CAIS groups.

Figure 11 Statistically significant differences in term of angular deviation, 3D deviation at platform and apex were observed between the mental and static CAIS groups and between mental and dynamic CAIS groups. No significant differences were found between the static and dynamic CAIS groups in totally edentulous patient.

CHAPTER V

Discussion

This study was designed to determine deviation of guided implant positions among three different CAIS groups in totally edentulous situation. Our result demonstrated the implant deviation was higher than previous clinical studies in single tooth space (64-66) and partially edentulous space (67). The implant deviation in static and dynamic CAIS groups demonstrated the greater accuracy than that of mental CAIS group with no statistically significant differences between static and dynamic CAIS groups (64). Comparing our results with other model and cadaveric studies, it found out that our results showed greater deviation than that of the others (68-72). We can say that the better visualization, convenient access, no patient movement, no saliva, and no bleeding might be the key components achieving the higher accuracy in those studies (38, 73). Our clinic results were however still in range of clinical acceptable deviation (74).

Comparing the accuracy of implant position with the other totally edentulous studies, our results showed the same inclination with others.

For mental CAIS system

The mental CAIS group usually referred to as a control group by performing freehand implant placement technique in order to compare with other CAIS systems (3, 4). According to the review literature, a few clinical studies reported using mental CAIS system. Furthermore, there were some studies in cadaver and were just only few clinical studies that used the mental CAIS system in totally edentulous condition.

Vercruyssen et al., 2015 reported their prospective randomized control trial which compared implant position between static and mental CAIS groups in 60 totally edentulous patients. The results showed that the most inaccuracy was in the vertical direction (depth) in static CAIS group, and, in mental CAIS group, also showed larger deviation in all observed variables. This study, however, analyzed the variables in 2D position, so we cannot compare with our study which is 3D analysis (4).

In 2019, Smitkarn et al. published randomized clinical control trial (60 implants in 52 patients) which compared the guided implant accuracy between static and mental CAIS groups in single tooth space. The result displayed the superior accuracy in static CAIS group compared to the mental CAIS group (65). Besides, Aydemir and Arisan, 2020 published the split-mouth randomized controlled clinical trial that compared implant placement using dynamic CAIS and freehand methods in the patient who need one implant for each side of posterior maxilla. The results showed that dynamic CAIS group achieved less linear deviation than mental CAIS group (75). According to our clinical study, totally edentulous patients, the deviations were higher in all aspects compared to single and partial tooth spaces, and also showed the same trend that static and dynamic CAIS groups had better accuracy compared with mental CAIS group.

Gillot et al., 2014 compared the deviation of virtually planned and placed implant positions in five totally edentulous cadavers. Sixty implants were placed by five surgeons using mental CAIS system. The result showed that the implant position (mental CAIS group) had lesser accuracy compared to other static CAIS system studies (76). Fortunately, our results showed the larger deviation than that of this cadaveric study. This was maybe because the cadaveric study could not imitate the real situation, therefore, the clinical relevance of implant placement deviation might be regardless.

For static CAIS system

Cassetta et al., 2012 mentioned that the accuracy of guided implant positions using fixed surgical guide in totally edentulous maxilla (8 templates with 66 implants) showed the mean angular, 3D platform and 3D apex deviation were 4.1±2.43° (0.28-14.34°), 1.66±0.57mm. (0.13-3.00 mm.) and 2.11±0.75 mm. (0.46-3.67mm.), respectively (77). Vieira et al., 2013 also reported the same trend in the accuracy of placed implants using static CAIS system in 14 totally edentulous patients with 62 implants. The mean angular, 3D platform and 3D apex deviation were 1.89±0.46°, 1.79±0.81mm. and

2.21±1.5 mm., respectively (78). Moreover, Chmielewski et al., 2019 published their retrospective study about image analysis of planned and placed implants in full-arch prosthetic rehabilitation in 9 patients, 12 edentulous jaws, 62 implants, 4 centers. The results were quite the same as our study. The mean angular, 3D platform and 3D apex deviation were 4.89°, 1.60 mm. and 1.86 mm., respectively (79). Comparing with our study, 3D deviations at platform and apex were smaller than that of retrospective clinical studies, however, our angular deviation displayed slightly higher amount than that of them.

Ersoy et al., 2008 showed the results of prospective clinical study that were quite the same as our study by reporting 65 placed implants in totally edentulous group. The mean angular, 3D platform and 3D apex deviation were 5.1±2.59°, 1.28±0.92 mm. and 1.6±1.08 mm (38). On the other hand, Verhamme et al., 2015 reported their prospective clinical study of guided implant position in totally edentulous maxilla using static CAIS system with the results of smaller deviation than that of ours. The mean angular, 3D platform and 3D apex deviation were 2.819°, 1.37 mm. and 1.587 mm., respectively (80). Marliere et al., 2018, however, demonstrated the systematic review of static CAIS system in totally edentulous group and our results were in the range of theirs (mean angular deviation: 1.85-8.4°, 3D platform deviation: 0.17-2.17 mm. and 3D apex deviation: 0.77-2.86 mm.) (74).

Vinci et al., 2020 showed their retrospective multicenter study about the 3D deviation and angle deviation between virtual planned and clinical position using static CAIS in totally edentulous patients (All-on 4/6 protocol). The mean angular, 3D platform and 3D apex deviations were 5°, 1 mm. and 1.6 mm., respectively (81). All observed variables demonstrated the outcomes which correlated to our study.

For dynamic CAIS system

There were some studies about the accuracy of guided implant placement using dynamic CAIS system.

Ruppin et al., 2008 reported cadaveric study about the accuracy of 120 placed implants in 20 human cadaver mandibles using three different CAIS systems (2 dynamic and 1 static systems). Both partially and totally edentulous conditions were chosen to perform in this study. The results were shown in 2D deviation; axis, vertical and horizontal deviations which demonstrated no statistically significant difference among those 3 systems (82). Even in our study, 3D analysis, also showed no statistically significant difference between static and dynamic CAIS groups.

Block et al., 2017 reported the accuracy of 219 fully guided implant placements using dynamic CAIS system in their prospective cohort study with the patients who needed at least 1 implant. The mean angular, 3D platform and 3D apex deviations were 2.97°, 1.16 mm. and 1.29 mm., respectively (9). The space condition in this study was not totally edentulous ridge in all sample, the inaccuracy of implant placement seemed therefore smaller than that of our study.

Jorba-Garcia et al., 2019 reported randomized in vitro study of partially edentulous model about role of surgical experience on the implant accuracy using freehand manner and dynamic CAIS system. In the experienced surgeon group, the dynamic CAIS group showed the mean angular, 3D platform and 3D apex deviations; 2.15°, 1.19 mm. and 1.24 mm., respectively. All observed variables in this study were lesser compared to our results (71). However, our study showed the same trend that dynamic CAIS group demonstrated superior accuracy compared to freehand manner group. In addition, in amateur surgeon group of this study, dynamic CAIS system also improved the implant accuracy in all observed variables.

Pellegrino et al., 2020 published their in vitro study about influence of surgical experience on the implant accuracy using dynamic CAIS system in totally edentulous model. In the experienced surgeon with expertise in dynamic CAIS system group (28 implants) showed the mean angular, 3D platform and 3D apex deviations; 2.93°±1.50, 1.55±1.08 mm. and 1.44±0.95 mm., respectively (72). Since this model study could not simulate the real clinical situation, the smaller deviations were found compared to our clinical study.

Yimarj et al., 2020 reported their randomized controlled clinical trial about the accuracy of implant placement between static and dynamic CAIS systems in partially edentulous patients. The results of static CAIS group showed the mean angular, 3D platform and 3D apex deviations; 4.08°±1.69, 1.04±0.67 mm. and 1.54±0.79 mm., respectively. For dynamic CAIS group, the results displayed the mean angular, 3D platform and 3D apex deviations; 3.78°±1.84, 1.24±0.39 mm. and 1.58±0.56 mm., respectively (67). Although, the differences of mean deviation were found in all variables between two systems, all observed variables showed no statistically significant difference which correlated to our study.

The outcome of our study demonstrated better accuracy compared to some previous CAIS studies. It maybe because of the following factors.

The planning software can accurately generate the digital guide drill that corresponded to the real edentulous ridge with mini implants, and help confirming correctly verified alignment of STL and DICOM files while doing superimposition. Mini implants were used as referent points to perfectly transfer the surgical guide position from digital planning to surgical field as same as tooth-supported surgical guide (69). It might be the consequence of the precise repositioning of the surgical guide position during the implant surgery (83). Thus, the surgical guide can be placed precisely in the patient mouth. Since mini implants were used in our study, the lesser deviations were shown in our static CAIS group. The systematic review of Tahmaseb et al., 2014 also stated that the accuracy of mini-implant-supported guide was higher than the other types of support except mucosa (46). Mucosa supported guide, however, could be displaced by swelling of soft tissue due to anesthesia injection (84), and by resilience of mucosa which might be the reasons of inaccuracy in placed implant position (38, 85).

In addition, our dynamic CAIS group also used mini implant in order to retain the registration stent. The reproducibility of registration stent influenced the accuracy of implant position during CT scanning, registration process and implant navigation especially in totally edentulous ridge. Mini-implant-supported registration stent in our study thus was the key role of achieving good accuracy as in tooth-supported registration stent or bone marker registration (69). Apart from being referent points, mini implants can be used to retain interim prosthesis in order to provide the better retention in case of non-immediate loading while waiting for final restoration.

According to our study, the different CAIS groups demonstrated the various amounts of deviation. The most inaccuracy was still found in the group of mental CAIS system. Static and dynamic CAIS groups, on the other hand, displayed the acceptable amount of deviation from the planned position. Considering mean deviation in both groups, these systems could provide reliable outcome, it however should be performed with careful attention especially in case of risking vital structures. The deviations, however, were still happened when using just only static or dynamic CAIS system. Therefore, static and dynamic CAIS systems would be combined for integrating benefits, compensating pitfalls and improving the accuracy in further study.

From our clinical observation, the mental CAIS took less time consuming during the implant surgery since there was no extra instrument use for guided the drill, while other two CAIS system use either surgical guided template or the tracking devices to control all the drill sequences. These might be one of the time consuming, however the more learning experience and the number of cases the surgeon did, the less duration of operation time might be shorter.

CHAPTER VI

Conclusion

In full edentulous situation, our clinical trial showed that static and dynamic CAIS groups achieved higher accuracy than that of mental CAIS group with no statistically significant difference between static and dynamic CAIS groups. According to the guidance of static and dynamic CAIS, their workflow allowed the surgeon to overcome the limitation in advanced implant surgery with clinically acceptable in term of implant position and accurately predictable outcome.

APPENDICES

Appendix A Thai consent form

เอกสารยินยอมเข้าร่วมการวิจัย
(Consent Form)

การวิจัยเรื่อง การเปรียบเทียบความแม่นยำของตำแหน่งรากฟันเทียมระหว่างการผ่าตัดฝังรากฟันเทียมด้วยวิธีคอมพิวเตอร์ช่วยแบบผ่านจิตใจ สถิต และพลวัต ในผู้ป่วยสันเหงือกไร้ฟันทั้งปาก

ข้าพเจ้า (นาย/ นาง/ นางสาว)..
อยู่บ้านเลขที่...................................ถนน...............................ตำบล/แขวง.....................................
อำเภอ/เขต......................................จังหวัด.................................รหัสไปรษณีย์..............................
ก่อนที่จะลงนามในใบยินยอมให้ทำการวิจัยนี้

1. ข้าพเจ้าได้รับทราบรายละเอียดข้อมูลคำอธิบายสำหรับอาสาสมัครที่เข้าร่วมในการวิจัย รวมทั้งได้รับการอธิบายจากผู้วิจัยถึงวัตถุประสงค์ของการวิจัย วิธีการทำวิจัย อันตรายหรืออาการที่อาจเกิดขึ้นจากการทำวิจัยหรือจากยาที่ใช้รวมทั้งประโยชน์ที่จะเกิดขึ้นจากการวิจัยอย่างละเอียดและมีความเข้าใจดีแล้ว
2. ผู้วิจัยได้ตอบคำถามต่างๆ ที่ข้าพเจ้าสงสัยด้วยความเต็มใจไม่ปิดบังซ่อนเร้นจนข้าพเจ้าพอใจ
3. ผู้วิจัยรับรองว่าจะเก็บข้อมูลเฉพาะเกี่ยวกับตัวข้าพเจ้าเป็นความลับและจะเปิดเผยได้เฉพาะในรูปที่เป็นสรุป ผลการวิจัย การเปิดเผยข้อมูลเกี่ยวกับตัวข้าพเจ้าต่อหน่วยงานต่างๆ ที่เกี่ยวข้องกระทำได้เฉพาะกรณีจำเป็นด้วยเหตุผลทางวิชาการเท่านั้น และผู้วิจัยรับรองว่าหากเกิดอันตรายใดๆ จากการวิจัยดังกล่าว ข้าพเจ้าจะได้รับ
การรักษาพยาบาลโดยไม่คิดมูลค่า
4. ข้าพเจ้ามีสิทธิที่จะบอกเลิกการเข้าร่วมในโครงการวิจัยนี้เมื่อใดก็ได้และการบอกเลิกการเข้าร่วมการวิจัยนี้จะไม่
มีผลต่อการรักษาโรคที่ข้าพเจ้าจะพึงได้รับต่อไป

ข้าพเจ้าจึงสมัครใจเข้าร่วมโครงการวิจัยนี้ตามที่ระบุในเอกสารข้อมูลคำอธิบายสำหรับอาสาสมัครและได้ลง นามในใบยินยอมนี้ด้วยความเต็มใจ และได้รับสำเนาเอกสารใบยินยอมที่ข้าพเจ้าลงนามและลงวันที่ และเอกสารยกเลิกการเข้าร่วมวิจัย อย่างละ 1 ฉบับ เป็นที่เรียบร้อยแล้ว ในกรณีที่อาสาสมัครยังไม่บรรลุนิติภาวะจะต้องได้รับการยินยอมจากผู้ปกครองด้วย

ลงนาม.. (อาสาสมัคร) (..) วันที่....../................/................	ลงนาม.. (ผู้ปกครอง) (..) วันที่....../.............../...............

ลงนาม.. (ผู้วิจัยหลัก) (...) วันที่......./................./.................	ลงนาม... (พยาน) (..) วันที่......./................./.................

ข้าพเจ้าไม่สามารถอ่านหนังสือได้ แต่ผู้วิจัยได้อ่านข้อความในใบยินยอมนี้ให้แก่ข้าพเจ้าฟังจนเข้าใจดีแล้วข้าพเจ้าจึงลงนาม หรือประทับลายนิ้วหัวแม่มือขวาของข้าพเจ้าในใบยินยอมนี้ด้วยความเต็มใจ

ลงนาม.. (อาสาสมัคร) (...) วันที่......./................./.................	ลงนาม... (ผู้ปกครอง) (..) วันที่......./................./.................
ลงนาม... (ผู้วิจัยหลัก) (...) วันที่......./................./.................	ลงนาม.. (พยาน) (...) วันที่......./................./.................

Appendix B Patient demographic and clinical data in Mental CAIS group

ID	Age	Sex	Tooth	Diameter	Type	H	Torque	RFA (B)	RFA (M)
M01	64	F	33	4.1	BL	10	25	75	83
M02	64	F	43	4.1	BL	10	15	58	59
M03	64	F	33	4.1	BL	10	25	71	71
M04	64	F	43	4.1	BL	10	20	68	68
M05	64	F	16	4.1	BL	10	20	70	70
M06	64	F	14	4.1	BL	10	15	53	67
M07	64	F	24	4.1	BL	10	15	41	41
M08	64	F	26	4.1	BL	8	15	57	56
M09	51	M	15	4.1	SP	10	N/A	60	75
M10	51	M	12	3.3	SP	8	N/A	64	75
M11	51	M	22	4.1	SP	8	N/A	66	81
M12	51	M	25	4.1	SP	10	N/A	81	80
M13	51	M	33	4.1	SP	10	N/A	79	79
M14	51	M	43	4.1	SP	10	N/A	75	81
M15	71	M	15	4.1	BL	12	35	71	71
M16	71	M	26	4.8	BL	12	30	68	69
M17	71	F	33	4.1	BL	10	20	61	61
M18	71	F	43	4.1	BL	10	20	57	57
M19	67	M	33	4.1	BLT	12	40	82	80
M20	67	M	43	4.1	BLT	10	35	85	85

Appendix C Patient demographic and clinical data in Static CAIS group

ID	Age	Sex	Tooth	Diameter	Type	H	Torque	RFA (B)	RFA (M)
S01	62	M	33	4.1	BLT	12	25	N/A	N/A
S02	62	M	35	4.8	SP	8	35	N/A	N/A
S03	62	M	37	4.8	SP	6	25	N/A	N/A
S04	62	M	43	4.1	BLT	12	35	N/A	N/A
S05	62	M	45	4.8	SP	8	25	N/A	N/A
S06	62	M	47	4.8	SP	6	25	N/A	N/A
S07	67	F	13	4.1	BLT	12	35	80	70
S08	67	F	23	4.1	BLT	12	35	68	64
S09	71	M	13	4.1	BLT	14	35	70	70
S10	71	M	21	4.1	BLT	10	35	72	72
S11	72	M	14	4.1	BLT	10	25	74	74
S12	72	M	12	4.1	BLT	10	25	71	71
S13	72	M	22	4.1	BLT	10	25	68	70
S14	72	M	24	4.1	BLT	10	25	72	72
S15	72	M	35	4.8	SP	6	25	70	70
S16	72	M	33	4.1	BLT	8	35	73	73
S17	72	M	31	4.1	BLT	10	35	70	71
S18	72	M	41	4.1	BLT	10	35	74	74
S19	72	M	43	4.1	BLT	10	35	72	72
S20	72	M	45	4.8	SP	6	25	73	72

Appendix D Patient demographic and clinical data in Dynamic CAIS group

ID	Age	Sex	Tooth	Diameter	Type	H	Torque	RFA (B)	RFA (M)
D01	56	M	35	4.1	BLT	8	35	81	80
D02	56	M	33	4.1	BLT	12	35	81	81
D03	56	M	43	4.1	BLT	12	35	78	80
D04	56	M	45	4.1	BLT	8	35	83	83
D05	75	M	16	4.8	BLT	8	25	56	67
D06	75	M	14	4.1	BLT	10	25	61	61
D07	75	M	12	4.1	BLT	12	25	61	65
D08	75	M	22	4.1	BLT	10	25	32	53
D09	75	M	24	4.1	BLT	12	25	56	56
D10	75	M	26	4.8	BLT	8	15	32	35
D11	75	M	32	4.1	BLT	12	35	80	45
D12	75	M	37	4.8	BLT	8	35	42	42
D13	75	M	42	4.1	BLT	12	25	72	71
D14	75	M	47	4.8	BLT	8	35	67	66
D15	67	M	16	4.8	BLT	8	35	70	78
D16	67	M	13	3.3	BLT	10	15	N/A	N/A
D17	67	M	11	3.3	BLT	10	25	N/A	N/A
D18	67	M	21	3.3	BLT	10	25	N/A	N/A
D19	67	M	24	4.1	BLT	10	25	61	70
D20	67	M	26	4.8	BLT	8	35	71	70

Appendix E The deviation between planned and placed implants in Mental CAIS group

ID	Angular deviation (degree)	Platform (mm)				Apex (mm)			
		3D offset	distal	vestibular	apical	3D offset	distal	vestibular	apical
M01	7.92	3.66	-3.55	-0.1	-0.37	2.62	-2.6	0.19	-0.27
M02	4.07	1.83	-1.22	0.3	1.33	1.66	-0.92	-0.32	1.35
M03	7.83	1.31	-0.01	1.16	0.59	0.71	-0.01	-0.19	0.68
M04	5.04	1.35	1.33	0.04	-0.22	2.21	2.2	-0.09	-0.19
M05	8.11	5.31	5.29	-0.19	0.36	6.55	6.52	0.5	0.46
M06	15.45	1.19	0.83	-0.52	0.67	2.16	-0.39	1.86	1.03
M07	12.7	4.9	3.77	-2.2	2.21	4.38	3.63	-0.01	2.45
M08	7.08	4.3	3.91	0.55	1.68	3.72	3.1	1.09	1.74
M09	17.89	3.41	-2.14	0.11	-2.65	2.76	0.54	1.62	-2.17
M10	16.62	6.11	-5.94	-1.36	-0.42	6.39	-6.32	0.9	-0.09
M11	17.68	7.72	-7.16	-1.7	2.36	8.85	-8.41	0.39	2.74
M12	14.21	1.76	0.04	-0.7	1.62	3.07	2.38	-0.29	1.92
M13	10.29	1.78	-0.26	-1.09	-1.39	2.84	1.01	-2.35	-1.23
M14	7.51	2.34	2.32	0.16	0.28	2.7	1.76	-1.03	0.37
M15	3.89	5.76	4.28	1.7	-3.47	6.38	5.09	1.7	-3.44
M16	5.69	6.45	-6.23	1.26	-1.07	5.29	-5.04	1.25	-1.01
M17	6.09	3.22	2.54	0.25	1.95	3.01	1.94	1.13	2.01
M18	8.22	3.66	3.61	-0.39	0.48	3.76	3.57	1.04	0.59
M19	15.03	1.24	-0.32	1.18	-0.24	2.14	1.89	-1	0.016
M20	10.65	2.33	-1.95	-1.05	-0.73	0.87	-0.13	-0.65	-0.56

Appendix F The deviation between planned and placed implants in Static CAIS group

ID	Angular deviation (degree)	Platform (mm)				Apex (mm)			
		3D offset	distal	vestibular	apical	3D offset	distal	vestibular	apical
S01	4.78	0.58	0.4	-0.39	-0.13	1.55	1.32	-0.81	-0.09
S02	3.02	2.02	1.61	-0.29	-1.18	2.34	1.96	-0.52	-1.17
S03	4.69	1.36	1.24	-0.25	-0.51	0.97	0.84	0.04	-0.49
S04	1.81	0.54	-0.37	0.25	-0.3	0.49	-0.02	0.39	-0.29
S05	8.57	1.37	0.47	-1.02	-0.79	2.39	1.32	-1.86	-0.7
S06	3.58	0.67	0.13	0.13	-0.64	0.82	0.51	0.14	-0.63
S07	6.61	0.86	-0.08	0.8	-0.3	0.99	0.96	-0.1	-0.22
S08	6.22	1.19	0.46	0.28	1.06	2.14	1.34	1.23	1.13
S09	6.05	2.1	0.8	1.88	-0.46	1.6	1	0.43	-0.38
S10	4.30	3.14	1.15	-1.96	-2.16	2.65	0.99	-1.22	2.13
S11	2.07	1.06	0.52	0.23	0.89	0.96	0.33	-0.06	0.9
S12	5.10	1.47	-0.18	0.54	-1.36	1.91	-0.93	1.02	-1.32
S13	1.58	2.45	1.77	0.38	-1.66	2.58	1.88	0.64	-1.65
S14	2.50	0.93	0.71	0.6	0.08	1.36	1.01	0.91	0.09
S15	8.41	2.15	0.38	1.41	-1.58	1.97	0.99	0.77	-1.52
S16	6.04	2.08	0.18	1.68	-1.22	1.97	0.92	1.29	-1.17
S17	5.00	1.56	0.7	1.22	-0.68	1.68	1.39	0.7	-0.65
S18	4.57	1.03	-0.71	0.66	-0.35	1.55	-1.47	0.4	-0.32
S19	8.68	0.53	0.5	-0.03	-0.2	1.93	1.63	-1.04	-0.08
S20	6.03	0.82	0.8	0.03	0.19	1.41	1.36	-0.25	0.23

Appendix G The deviation between planned and placed implants in Dynamic CAIS group

ID	Angular deviation (degree)	Platform (mm)				Apex (mm)			
		3D offset	distal	vestibular	apical	3D offset	distal	vestibular	apical
D01	5.40	2.035	-0.043	1.123	-1.696	4.193	0.145	-1.702	-3.829
D02	5.00	1.386	0.807	1.127	0.002	2.378	1.185	2.061	0.048
D03	6.92	1.76	-0.353	1.285	1.15	2.55	-1.676	1.472	1.237
D04	9.12	1.031	-0.282	0.973	0.191	1.539	-1.438	0.541	0.089
D05	5.27	1.521	0.263	0.871	1.219	1.277	0.153	0.124	-1.262
D06	4.94	1.513	1.058	-0.961	-0.497	0.951	-0.761	0.055	-0.0567
D07	3.05	1.823	-0.24	-1.535	-0.954	2.377	0.113	2.129	-1.051
D08	5.06	1.755	0.107	-0.038	-1.751	2.037	-0.76	0.83	-1.698
D09	5.26	1.79	-1.113	1.401	0.052	2.041	0.326	-2.014	0.0012
D10	5.33	1.753	0.871	0.513	-1.433	1.618	-0.009	-0.696	-1.461
D11	5.46	2.758	-0.199	1.873	-2.015	2.126	-0.055	-0.979	-1.886
D12	5.88	1.514	-0.303	-1.168	-0.916	2.128	0.066	1.847	-1.055
D13	1.43	2.647	0.841	-0.066	-2.509	2.741	-1.039	0.187	-2.53
D14	7.51	1.416	0.209	-1.298	-0.526	2.033	-1.145	1.545	-0.659
D15	8.07	1.592	1.508	0.429	-0.273	1.98	-1.23	-1.54	-0.187
D16	2.44	1.103	1.003	0.137	-0.439	0.83	-0.665	0.177	-0.465
D17	10.23	2.088	1.218	-1.569	-0.645	1.388	-1.116	-0.304	-0.767
D18	6.47	1.698	0.832	-1.43	-0.383	0.691	-0.255	0.4	-0.503
D19	6.94	2.006	0.456	-1.953	-0.028	0.819	-0.318	0.729	-0.196
D20	5.19	1.452	1.209	0.725	0.349	1.509	-0.759	-1.254	0.359

Appendix H Statistical output

Descriptive statistic of implant angular deviation among three CAIS systems

Descriptives

	Group			Statistic	Std. Error
Angular deviation	Mental	Mean		10.11250	1.233453
		95% Confidence Interval for Mean	Lower Bound	7.48346	
			Upper Bound	12.74154	
		5% Trimmed Mean		10.02500	
		Median		8.00000	
		Variance		24.342	
		Std. Deviation		4.933812	
		Minimum		3.900	
		Maximum		17.900	
		Range		14.000	
		Interquartile Range		9.150	
		Skewness		.417	.564
		Kurtosis		-1.340	1.091
	Static	Mean		4.51667	.600105
		95% Confidence Interval for Mean	Lower Bound	3.19584	
			Upper Bound	5.83749	
		5% Trimmed Mean		4.45185	
		Median		4.50000	
		Variance		4.322	
		Std. Deviation		2.078825	
		Minimum		1.600	
		Maximum		8.600	
		Range		7.000	
		Interquartile Range		3.150	
		Skewness		.395	.637
		Kurtosis		-.255	1.232
	Dynamic	Mean		5.70313	.556138
		95% Confidence Interval for Mean	Lower Bound	4.51774	
			Upper Bound	6.88851	
		5% Trimmed Mean		5.75069	
		Median		5.75500	
		Variance		4.949	
		Std. Deviation		2.224553	
		Minimum		1.430	
		Maximum		9.120	
		Range		7.690	
		Interquartile Range		3.438	
		Skewness		-.557	.564
		Kurtosis		-.395	1.091

Descriptive statistic of 3D guided implant deviation at platform among three CAIS systems

Descriptives

	Group				Statistic	Std. Error
3D deviation at Platform	Mental	Mean			3.69875	.534570
		95% Confidence Interval for Mean		Lower Bound	2.55934	
				Upper Bound	4.83816	
		5% Trimmed Mean			3.61472	
		Median			3.53500	
		Variance			4.572	
		Std. Deviation			2.138279	
		Minimum			1.190	
		Maximum			7.720	
		Range			6.530	
		Interquartile Range			3.883	
		Skewness			.382	.564
		Kurtosis			-1.204	1.091
	Static	Mean			1.47417	.233901
		95% Confidence Interval for Mean		Lower Bound	.95935	
				Upper Bound	1.98898	
		5% Trimmed Mean			1.43352	
		Median			1.36500	
		Variance			.657	
		Std. Deviation			.810258	
		Minimum			.540	
		Maximum			3.140	
		Range			2.600	
		Interquartile Range			1.363	
		Skewness			.749	.637
		Kurtosis			-.078	1.232
	Dynamic	Mean			2.16744	.214852
		95% Confidence Interval for Mean		Lower Bound	1.70949	
				Upper Bound	2.62538	
		5% Trimmed Mean			2.08787	
		Median			2.02400	
		Variance			.739	
		Std. Deviation			.859407	
		Minimum			1.031	
		Maximum			4.736	
		Range			3.705	
		Interquartile Range			1.101	
		Skewness			1.760	.564
		Kurtosis			4.777	1.091

Descriptive statistic of 3D guided implant deviation at apex among three CAIS systems

Descriptives

	Group			Statistic	Std. Error
3D deviation at Apex	Mental	Mean		3.89313	.552787
		95% Confidence Interval for Mean	Lower Bound	2.71489	
			Upper Bound	5.07136	
		5% Trimmed Mean		3.79458	
		Median		2.95500	
		Variance		4.889	
		Std. Deviation		2.211147	
		Minimum		.710	
		Maximum		8.850	
		Range		8.140	
		Interquartile Range		3.795	
		Skewness		.804	.564
		Kurtosis		-.011	1.091
	Static	Mean		1.68583	.214298
		95% Confidence Interval for Mean	Lower Bound	1.21417	
			Upper Bound	2.15750	
		5% Trimmed Mean		1.69870	
		Median		1.65500	
		Variance		.551	
		Std. Deviation		.742348	
		Minimum		.490	
		Maximum		2.650	
		Range		2.160	
		Interquartile Range		1.402	
		Skewness		-.195	.637
		Kurtosis		-1.398	1.232
	Dynamic	Mean		2.56650	.253482
		95% Confidence Interval for Mean	Lower Bound	2.02622	
			Upper Bound	3.10678	
		5% Trimmed Mean		2.52033	
		Median		2.30100	
		Variance		1.028	
		Std. Deviation		1.013928	
		Minimum		1.067	
		Maximum		4.897	
		Range		3.830	
		Interquartile Range		1.180	
		Skewness		.850	.564
		Kurtosis		.651	1.091

Normality test of 3D guided implant deviation in all observed variables among three CAIS systems

Tests of Normality

	Group	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
		Statistic	df	Sig.	Statistic	df	Sig.
Angular deviation	Mental	.221	16	.036	.900	16	.080
	Static	.112	12	.200*	.967	12	.872
	Dynamic	.145	16	.200*	.951	16	.508
3D deviation at Platform	Mental	.184	16	.150	.912	16	.126
	Static	.198	12	.200*	.926	12	.337
	Dynamic	.183	16	.153	.848	16	.013
3D deviation at Apex	Mental	.208	16	.064	.920	16	.171
	Static	.159	12	.200*	.929	12	.370
	Dynamic	.175	16	.200*	.938	16	.331

*. This is a lower bound of the true significance.

a. Lilliefors Significance Correction

Testing homogeneity of variance using Levene's test

Test of Homogeneity of Variances

	Levene Statistic	df1	df2	Sig.
Angular deviation	13.345	2	57	.000
3D deviation at Platform	22.247	2	57	.000
3D deviation at Apex	12.250	2	57	.000

Welch's ANOVA test for comparing the mean of deviation in the observed variables among all groups

Robust Tests of Equality of Means

		Statistic[a]	df1	df2	Sig.
Angular deviation	Welch	9.820	2	35.705	.000
3D deviation at Platform	Welch	9.589	2	32.209	.001
3D deviation at Apex	Welch	7.673	2	34.012	.002

a. Asymptotically F distributed.

Pairwise comparison using Games-Howell post-hoc analysis

Multiple Comparisons

Dependent Variable		(I) Group	(J) Group	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval Lower Bound	95% Confidence Interval Upper Bound
Angular deviation	Games-Howell	Mental	Static	5.115000*	1.144915	.000	2.27563	7.95437
			Dynamic	4.341500*	1.137999	.002	1.51627	7.16673
		Static	Mental	-5.115000*	1.144915	.000	-7.95437	-2.27563
			Dynamic	-.773500	.672770	.490	-2.41435	.86735
		Dynamic	Mental	-4.341500*	1.137999	.002	-7.16673	-1.51627
			Static	.773500	.672770	.490	-.86735	2.41435
3D deviation at Platform	Games-Howell	Mental	Static	2.086000*	.474892	.001	.89969	3.27231
			Dynamic	1.749450*	.456912	.003	.59683	2.90207
		Static	Mental	-2.086000*	.474892	.001	-3.27231	-.89969
			Dynamic	-.336550	.188149	.190	-.79959	.12649
		Dynamic	Mental	-1.749450*	.456912	.003	-2.90207	-.59683
			Static	.336550	.188149	.190	-.12649	.79959
3D deviation at Apex	Games-Howell	Mental	Static	1.940500*	.491293	.002	.70690	3.17410
			Dynamic	1.743200*	.506112	.006	.48116	3.00524
		Static	Mental	-1.940500*	.491293	.002	-3.17410	-.70690
			Dynamic	-.197300	.227784	.665	-.75465	.36005
		Dynamic	Mental	-1.743200*	.506112	.006	-3.00524	-.48116
			Static	.197300	.227784	.665	-.36005	.75465

*. The mean difference is significant at the 0.05 level.

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