Clinical accuracy between planned and placed posterior implant position of two static implant planning software programs in inexperienced operators

Miss Wanwanat Singthong

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ความแม่นยำทางคลินิกระหว่างตำแหน่งของรากเทียมที่วางแผน และตำแหน่งของรากเทียมที่ฝังในฟันหลัง ด้วยโปรแกรมคอมพิวเตอร์แบบสถิตสองระบบ โดยทันตแพทย์ผู้ไม่มีประสบการณ์

น.ส.วรรณวนัช สิงห์ทอง

วิทยานิพนธ์นี้เป็นส่วนหนึ่งของการศึกษาตามหลักสูตรปริญญาวิทยาศาสตรมหาบัณฑิต
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Thesis Title	Clinical accuracy between planned and placed posterior implant position of two static implant planning software programs in inexperienced operators
By	Miss Wanwanat Singthong
Field of Study	Esthetic Restorative and Implant Dentistry
Thesis Advisor	Associate Professor PRAVEJ SERICHETAPHONGSE, D.D.S., M.S.
Thesis Co Advisor	WAREERATN CHENGPRAPAKORN, D.D.S., Ph.D.

Accepted by the FACULTY OF DENTISTRY, Chulalongkorn University in Partial Fulfillment of the Requirement for the Master of Science

..... Dean of the FACULTY OF DENTISTRY

(Professor Pornchai Jansisyanont, D.D.S., M.S., Ph.D.)

THESIS COMMITTEE

..... Chairman

(Professor MANSUANG ARKSORNNUKIT, D.D.S., M.S., Ph.D.)

..... Thesis Advisor

(Associate Professor PRAVEJ SERICHETAPHONGSE, D.D.S., M.S.)

..... Thesis Co-Advisor

(WAREERATN CHENGPRAPAKORN, D.D.S., Ph.D.)

..... Examiner

(Associate Professor ATIPHAN PIMKHAOKHAM, D.D.S., M.P.A., Ph.D)

..... External Examiner

(Associate Professor Pattapon Asvanund, D.D.S., M.S., Ph.D.)

วรรณวนัช สิงห์ทอง : ความแม่นยำทางคลินิกระหว่างตำแหน่งของรากเทียมที่วางแผน และตำแหน่งของรากเทียมที่ฝังในฟันหลัง ด้วยโปรแกรมคอมพิวเตอร์แบบสถิตสองระบบ โดยทันตแพทย์ผู้ไม่มีประสบการณ์. (Clinical accuracy between planned and placed posterior implant position of two static implant planning software programs in inexperienced operators) อ.ที่ปรึกษาหลัก : รศ. ทพ. ประเวศ เสรีเชษฐพงษ์, อ.ที่ปรึกษาร่วม : อ.ทพญ. ดร.วรีย์รัตน์ เจิ่งประภากร

วัตถุประสงค์: เพื่อตรวจสอบและประเมินความแม่นยำทางคลินิก ระหว่างตำแหน่งของรากเทียมที่วางแผนและตำแหน่งของรากเที่ยมที่ฝังในฟันหลัง โดยการขึ้นรูปแผ่นจำลองทางการผ่าตัด ด้วยโปรแกรมคอมพิวเตอร์ช่วยเหลือแบบสถิตสองระบบ

วิธีการศึกษา: อาสาสมัครจำนวน 24 คนจะได้รับการสุ่มอย่างเป็นระบบ และถูกแบ่งเป็น 2 กลุ่ม จากนั้นจะได้รับการวางแผนการวางตำแหน่งรากเทียม ด้วยโปรแกรมคอมพิวเตอร์ช่วยเหลือการฝังรากเทียม จากนั้นอาสาสมัครจะได้รับการผ่าตัดฝังรากเทียม โดยใช้แผ่นจำลองทางการผ่าตัดที่ได้จากโปรแกรมคอมพิวเตอร์ระบบใดระบบหนึ่ง ซึ่งได้แก่ โปรแกรมโคไดแอกโนสติค (coDiagnostiX) และ โปรแกรมอิมพล้านสตูดิโอ (Implant Studio) จากนั้น ตำแหน่งรากเทียมที่ได้จากการฝังผ่านแผ่นจำลองนำทางผ่าตัดที่ได้จาก 2 โปรแกรม จะถูกนำมาเปรียบเทียบกับตำแหน่งรากเทียมที่ได้วางแผนไว้ จากแต่ละโปรแกรมคอมพิวเตอร์ช่วยเหลือ ข้อมูลความเบี่ยงเบนของตำแหน่งรากเทียมที่ได้ จะถูกนำไปวิเคราะห์ทางสถิติด้วยการทดสอบที (t- test) ที่ระดับนัยสำคัญ .05

ผลการศึกษา: การวิเคราะห์ทางสถิติพบว่าค่าเฉลี่ยของระยะเบี่ยงเบนของตำแหน่งรากเทียมที่ได้จากการใช้แผ่นจำลองนำทางผ่าตัดผ่านโปรแกรมโคไดแอกโนสติค (coDiagnostiX) มีค่าตามแนวต่างๆดังนี้ ระยะเบี่ยงเบนที่ บริเวณบ่าของรากเทียมมีค่าเฉลี่ย 1.07 ± 0.36 มิลลิเมตร มุมที่เบี่ยงเบนมีค่าเฉลี่ย 3.52 ± 1.64 องศา และระยะเบี่ยงเบนในแนวความลึกมีค่าเฉลี่ย -0.71 ± 0.29 มิลลิเมตร ในขณะที่ ค่าเฉลี่ยของระยะเบี่ยงเบนของตำแหน่งรากเทียมที่ได้จากการใช้แผ่นจำลองนำทางผ่าตัดผ่านโปรแกรมอิมพล้านสตูดิโอ (Implant Studio) มี ค่าตามแนวต่างๆดังนี้ ระยะเบี่ยงเบนที่บริเวณบ่าของรากเทียมมีค่าเฉลี่ย 0.97 ± 0.33 มิลลิเมตร มุมที่เบี่ยงเบนมีค่าเฉลี่ย 3.77 ± 2.16 องศา และระยะเบี่ยงเบนในแนวความลึกมีค่าเฉลี่ย -0.84 ± 0.30 มิลลิเมตร อย่างไรก็ตามเมื่อวิเคราะห์ทางสถิติด้วยการทดสอบทีพบว่าค่าเฉลี่ยของทั้งสองกลุ่มในทุกๆแนว ไม่มีความแตกต่างอย่างมีนัยสำคัญทางสถิติ

สรุป: ความเบี่ยงเบนของตำแหน่งรากเทียมทางคลินิกที่ฝังในฟันหลังโดยทันตแพทย์ผู้ไม่มีประสบการณ์ ที่ได้จากแผ่นจำลองนำทางผ่าตัดจากโปรแกรมคอมพิวเตอร์ช่วยเหลือทั้งสองระบบ ได้แก่ โปรแกรมโคไดแอกโนสติค (coDiagnostiX) และ โปรแกรมอิมพล้านสตูดิโอ (Implant Studio) ไม่มีความแตกต่างกันอย่างมีนัยสำคัญทางสถิติ

สาขาวิชา	ทันตกรรมบูรณะเพื่อความสวยงามและทันตกรรมรากเทียม	ลายมือชื่อนิสิต .....
ปีการศึกษา	2564	ลายมือชื่อ อ.ที่ปรึกษาหลัก .....
		ลายมือชื่อ อ.ที่ปรึกษาร่วม .....

6278021432 : MAJOR ESTHETIC RESTORATIVE AND IMPLANT DENTISTRY
KEYWORD: computer-assisted implant surgery, dental implant, posterior implant placement

Wanwanat Singthong : Clinical accuracy between planned and placed posterior implant position of two static implant planning software programs in inexperienced operators . Advisor: Assoc. Prof. PRAVEJ SERICHETAPHONGSE, D.D.S., M.S. Co-advisor: WAREERATN CHENGPRAPAKORN, D.D.S., Ph.D.

Objective: This study aimed to evaluate and examine the difference in posterior implant positioning between the planned and placed positions when inexperienced operators used two static implant planning software packages following a fully guided implant surgery protocol in the clinical field.

Materials and methods: Twenty-four patients who needed single posterior implant placement were randomly divided into two groups based on the used implant planning software (group 1, coDiagnostiX, n=12; group 2, Implant Studio, n=12). The dataset of the placed implant position, generated from digitizing the implant impression, was superimposed on the planned implant position. The number of horizontal, angular, and vertical deviations of the placed implants were measured for each software package and statistically analyzed.

Results: Group 1 (coDiagnostiX) presented with a mean horizontal deviation at the entry point (DE) of 1.07 ± 0.36 mm, mean angular deviation (DA) of 3.52 ± 1.64, and mean depth deviation (DD) of −0.71 ± 0.29 mm, while the mean DE, mean DA, and mean DD in group 2 (Implant Studio) were 0.97 ± 0.33 mm, 3.77 ± 2.16, and −0.84 ± 0.30 mm respectively. Statistically, no significant differences were found between groups 1 and 2 for all results reported above (P>0.05).

Conclusions: No significant differences were found in the accuracy of implant position between coDiagnostiX and Implant Studio programs following posterior implant placement performed by inexperienced operators.

Field of Study:	Esthetic Restorative and Implant Dentistry	Student's Signature .....
Academic Year:	2021	Advisor's Signature .....
		Co-advisor's Signature .....

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Wanwanat Singthong

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CHAPTER I
INTRODUCTION

Background and rationale

An Ideal implant position and angulation are an essential determinant of esthetic and function success in the field of implant dentistry. Empirically, there are many interesting factors indicate that they can be perfectly accomplished, for example, a proper case selection, the use of surgical guides, an adequate site preparation, the use of prosthetic-driven implant placement concept and a qualified surgical experience of operator. [1] [2]

Since implants can be closely placed into vital structures such as vessels and nerves, it is crucial for the surgery techniques to be accurate and unblemished. In fact, serious and fetal complications have been attributed to inaccurate or malposition implant placements. [3] To be more specific, for posterior maxilla area, there are many anatomical structures that we should be aware especially the maxillary sinus. This seems to illustrate that when implant is placed close to the maxillary sinus or during sinus lift procedures, a complication such as the rupture of the Schneider membrane may be occurred. Moreover, for the posterior mandible area, it is widely known that there appear to be many vital structures including mental nerve and inferior alveolar nerve. Therefore, an invasion or a perforation of the inferior alveolar or mental canal during osteotomy can initiate transection, tearing, or laceration of nerves. As it is stated above, a caution needs should be considered when placing implants in the presence of a submandibular or sublingual concavity in the mandible because a large undercut of the lingual plate can be

perforated resulting in hemorrhaging. [4] [5]

Another important aspect is that the angulation of the implant should depend on the long axis of the opposing maxillary tooth and should be precise as much as possible in order to achieve an optimal loading condition. [6] As angulation is mentioned, there is another related concern which is misalign implants as it might affect high stresses on the implant-abutment interface. This, of course, can lead to abutment screw loosening, screw fracture, or fracture of the coronal aspect of an implant. [7] In some cases, minor mesiodistal angulation issues are sometimes considered. For example, there is a need to avoid the root of an adjacent tooth or a vital structure such as the mental foramen, or the desire to avoid the penetration of the maxillary sinus. However, a severe mesiodistal deviation can cause injury to the adjacent teeth, especially in partially edentulous jaw areas and narrow single-tooth gaps. Generally, the mandibular posterior region is more prone to axial deviation. The reason of this occurrence is because the area is very difficult to treat and be handled from a limited access of buccal soft tissues and restricted the field of vision. It is important that clinicians should pay a close attention and gently remedy while placing implant in posterior area. [8]

One essential point that we should consider is that a correct three-dimensional implant position may effectively reduce biological and technical complications which contribute to the long-term success of dental implants. Therefore, it can be seen that there has been a great deal of interests in a computer technology in planning and carrying out implant surgery recently. The interesting idea behind this is computed tomography (CT), three-dimensional implant planning software and CAD-CAM (computer-aided design/ computer-assisted manufacturing)

technology have absolutely been important achievements in this field. As it allows the clinicians to transfer the planned implant position to the surgical field and precisely placed the implant, according to a correct three-dimensional implant position. [9] [10] [11] [12]Furthermore, the combination between computed tomography (CT), implant planning software and CAD/CAM technology can simultaneously display both patient's hard and soft tissues together with all anatomical structures.

In fact, not only the clinicians can be able to plan the proper and impeccable implant position, but they can avoid an invasion of anatomical structures by adjusting a size or an angulation of implant fixture. In addition to this, with these data sets of perfect implant position will be provided to a laboratory to fabricate a guided surgical template. As we can see, the guided surgical template is the key assistance to help the clinicians to place an implant accurately as it was planned. However, many published studies show that there are some errors often occurred during the process of guided plate fabrication.

It appears generally that computer-guided implants were seen to be closer to the planned positions and show more consistency in accuracy from all measurements, while the conventional guides resulted in greater variability of accuracy. The clinical significance of this result may be relevant when multiple parallel distant implants are placed and where the degree of accuracy is critical to reach a single prosthetic path of insertion. [13] [14] Moreover, computer-guided implant was also reported less patient discomfort than free hand method. [13] On the other hand, there is no exact three-dimensional example of implant in the conventional surgical templates in order to serve and provide a visual implant

position for the clinicians. Likewise, it does not show a guided drill penetrate into precisely from the first to final drill.

There are various factors that may have an influence on the accuracy of implant placement using CT-generated guide including: type of arch, kind of template, surgical technique, number of sleeve-guided site preparation steps, operator's skill and the steps for the digital workflow. Those steps include an image acquisition, surface scanning procedures, a use of computer planning software and a surgical guided fabrication via 3-D printing. Therefore, clinicians have to understand limitations within each step for the digital sequence and recognize that an error can happen at every step and cause in an inaccuracy. [9] [11]

We should consider that there are several implant planning software programs which allow clinician to virtually plan treatment for the placement of implants according to an individual patient's anatomy and restoration aspect. [15] Furthermore, it is known that coDiagnostiX (Dental Wings Inc, Montreal, CA, USA) and 3shape Implant studio (3Shape, Copenhagen, Denmark) are widely used third-party implant planning software which claimed to provided predictable implant placement outcome.

To the best of our knowledge, there seems to be no clinical studies have been published so far on the accuracy between planned and placed posterior implant position of two different static implant software programs in inexperienced operators and there are only few clinical studies investigating the clinical outcome of the computer-guided surgery for missing single teeth have been published to date. [16] In addition to this, it might not be easy to construct a comparison study between in vitro studies and the present human subject, as in vitro studies provide

improved control of all contributing parameters and reach lower values of deviation. [3]

Therefore, the objective of this clinical study is to analyze evaluate and examine the accuracy of posterior implant between planned and placed position of two implant software programs including coDiagnostiX and Implant studio in clinical field. Although some studies have shown both good sides of planned and placed position in many programs, yet there is no precise juxtapose between these two in patients by inexperience operators. Furthermore, the result of this study may have an extra benefit that within the inclusion of appropriate implant knowledge in the curriculum and under close supervision. Inexperienced operators may perform implant placement and achieve a correct three-dimensional implant position with computer fully-guided protocols.

Research question

Is there any difference in the accuracy of implant position in posterior region of coDiagnostiX and Implant Studio implant planning software in clinical study using the same implant system?

Research objective

This study aims to examine and evaluate the accuracy of posterior implant position (planned and placed position) of coDiagnostiX and Implant studio software programs in clinical study.

Hypotheses

H0 = There is no differences in the accuracy of implant position of two implant planning software in a clinical study.

Ha = There are differences in the accuracy of implant position of two implant planning software in clinical study.

Keywords:

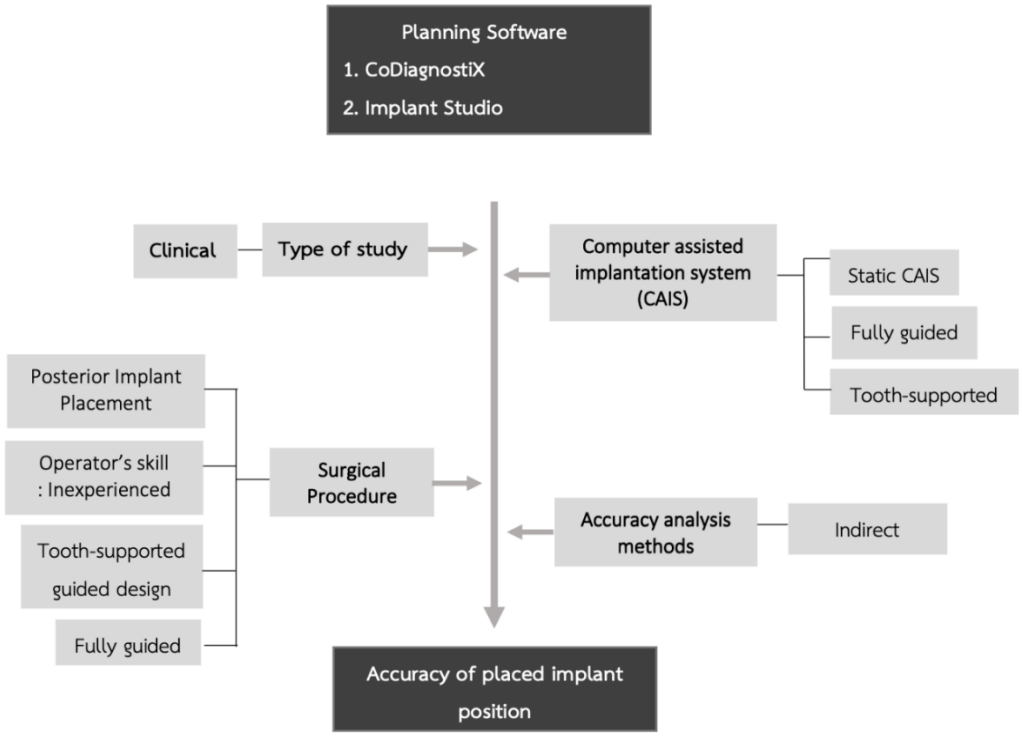
P - Posterior implant

I - Guided surgery

C - Implant planning software

O - Accuracy

Figure 1 Conceptual Framework



Expected Benefit of the research

1. The information regarding the accuracy of implant position between patients who have planned and placed implant position between two software will be examined and compared.
2. If there are differences of accuracy between two software for placing the implants in posterior region, the received measurements and limitation of each software would provide benefits information to software users.

CHAPTER II
REVIEW LITERATURE

1. Implant placement in Posterior maxilla and mandible

A success implant placement, in both maxilla and mandible, requires accurate angulation and position in order to achieve a satisfied function and proper esthetic results.

1.1 Potential causes of implant failure

1.1.1 Anatomic Factors

There are many vital and vulnerable structures in posterior maxilla area that should be careful and gentle, like, maxillary sinus and nasal fossa. In fact, this should be concerned when implanting close to the maxillary sinus or during sinus lift procedures, a complication such as the rupture of the Schneider membrane may be occurred. In addition, it is recommended that an implant placement surgery should be postponed when there is a tear of the membrane become quite extensive. Another important issue that we should be aware is when the hemorrhages happen, there is likely to have a damage to the descending palatine artery or the posterior palatine artery. It usually occurs during implant placement in the retromolar trigone of the maxilla. Furthermore, an inserting of a long implant which is length between 15-20 mm might cause the pterygoid apophyses.

For posterior mandible area, there appears to be many vital structures, for instance, mental nerve and inferior alveolar nerve. When implants are pressed against the inferior alveolar nerve, or there is an invasion or perforation of the inferior alveolar or mental canal during osteotomy, there might be a transection, tearing, or

laceration of the nerves. As we can notice that the majority of cases manifest a paresthesia condition that could be painful or painless. Additionally, a caution should be considered when placing implants in the presence of a submandibular or sublingual concavity in the mandible jaw because a large undercut of the lingual plate can be perforated and resulting in hemorrhaging. [4] [5]

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1.1.2 Iatrogenic Factors

Failures of an implant placement can be caused by an inappropriate implant positioning and improper implant selection. As we know that placing implants in a correct 3-dimensional position is the crucial key to achieve a perfect outcome regardless of the implant system used. This position is dependent on the planned or final restoration which implant fixture will support. The relationship of the position between the implant and the proposed restoration should be based on the position of the implant shoulder because this can influence the final hard and soft tissue response. [17]

Another undesirable effect is prosthetic complications which is resulted in restoration-implant axis problems, making the implant difficult to restore. [6]

1.2 Implant selection

The implant selection depends on the type of tooth which being replaced (molar or premolar) and the number of teeth being replaced. Based on the anatomic site analysis, the natural maxillary first and second premolar, and first molar has an average mesiodistal size around 7.1, 6.6 and 10.4 mm respectively. Therefore, a wider diameter implant should be selected for the molar teeth. For posterior mandible areas, similar guidelines should be followed as mentioned above.

The implant should be placed far enough to the adjacent tooth to allow appropriate contours. In addition, molar teeth which have wider mesiodistally size need to be placed around 2.5 mm away from the adjacent tooth to allow a development of appropriate restorative contours. [17] [18]

1.3 Complication relate to implant malposition

1.3.1 Mis-axis problem

According to implant angulation, it is appropriate to establish a balance between prosthetic and anatomic concerns. For instance, implant may have to be angled to avoid surgical fenestration of the lingual bone when there is a concavity in the lingual cortical plate in the mandible. [6] [7] The angulation of the implant should depend on the curvature of the mandibular occlusal plane and the long axis of the opposing maxillary tooth. Additionally, the functional cusps of the opposing teeth should be positioned at the center of the implant. [18]

Regarding buccolingual angulation issues, an implant may be placed in the correct position, however it may be misaligned. In fact, misalign implants might cause

high stresses which placed on the implant-abutment interface. Moreover, it might lead to abutment screw loosening, screw fracture, or fracture of the coronal aspect of an implant. In addition, the greater masticatory forces which occur in the posterior areas can exacerbate these complications. If the implant axis is inclined too far buccally, it is usually associated with recession of the buccal mucosa. Moreover, if the problem is severe, the esthetic complication is regularly very difficult to resolve. [7] [17]

The mesiodistal axis of posterior implants should be as precise as possible in order to achieve an optimal loading condition. In some cases, minor mesiodistal angulation issues are sometimes considered. For example, there is a need to avoid the root of an adjacent tooth or a vital structure such as the mental foramen, or the desire to avoid a penetration of the maxillary sinus. However, a severe mesiodistal deviation can cause injury to the adjacent teeth, especially in partially edentulous jaw areas and narrow single-tooth gaps. Moreover, those prostheses fabricated in mis-angulated implants lead to additional forces which may contribute to premature mechanical failures. [1] [7]

The mandibular posterior region is more prone to axial deviation. This happen because this area is more difficult to handle from a limit access of buccal soft tissues and restrict the field of vision. Therefore, clinicians must pay a proper attention when placing implant in posterior region. [8]

1.3.2 Mesiodistal malposition

When an implant is placed too close to an adjacent natural tooth, there is a risk of a reduced papilla height at the adjacent tooth due to crestal bone resorption

and modeling during the healing phase. In addition, there might not be enough space for the soft tissues to develop at all so that resulting in complete absence of a papilla. When mesiodistal malposition is extremely differ 2-3 mm from the ideal prosthetic position, this might lead to significant loss of hard and soft tissue support which harmfully affect esthetic results. [17]

However, esthetic is secondary in restoring the posterior areas of oral cavity. A consideration should be based on the position which allows restorations that will functional and allow proper development of occlusion and embrasure forms for patient comfort. Consequently, the following guidelines should be used in selecting implant size and evaluating mesiodistal space for implant placement. Firstly, the implant should be at least 1.5 away from the adjacent teeth. Secondly, the implant should be at least 3 mm. away from adjacent implant. Lastly, a wider diameter implant should be selected for molar teeth. [18]

1.3.3 Buccoligual malposition

A study by Rangert et al. found that a deviation of 15 degrees in a buccolingual direction contributed to occlusal overloading. [19] Moreover, a recent study by Wang T. et al. demonstrated that an angular deviation of implant insertion could statistically increase the risk of buccal and lingual bone plate perforation in posterior mandibular area. Therefore, the incident of bone plate perforation can be reduced through a careful pre-surgical analysis and well controlled the angulation of implant during surgery. [8] A perforation of lingual bone plate may lead to critical complication, such as sublingual bleeding, hematoma, or infection. [4] [5]

A buccolingually bone at least 6 mm is required for placement implant of a 4 mm diameter implant and 7 mm for a wider diameter 5 mm implant. It is essential that posterior mandibular implant should be placed in the position which the exit angle of the screw excess point towards the inner incline of the palatal cusp. For posterior maxillary implants, they should be placed so that the exit angle of the screw access points towards the inner incline of the buccal cusp. [6]

1.3.4 Corono-apical malposition

There are several factors that should be considered in planning the corono-apical position of an implant. This includes interocclusal clearance, bone level, tissue thickness and implant malposition or mis-angulation. [7] An implant placement depth should follow the concept as shallow as possible, as deep as necessary.

If the implant is not inserted deep enough into the soft tissue, the color of metal implant shoulder can be visible and cause an unpleasant esthetic result, despite there is no recession of a mucosa. The more common complication, in contrast, is placing implant too deep into the tissues. This apical malposition can cause a recession of the buccal mucosa particularly when there is a thin buccal bone wall. After a placement of restoration, this thin bone wall is resorbed during the bone modeling process. This will lead to bone resorption at the mesial and distal aspect of the implant together with the buccal and lingual aspect. Furthermore, the deep placement of an implant can also lead to a persistent inflammation of the peri-implant mucosa, an adequate plaque control and a poor soft tissue esthetic result. [17] Generally, it is recommended to place implant 3-4 mm below the cementoenamel junction of adjacent teeth or the cervical margin of final restoration.

2. Computer assisted implantation system (CAIS)

As it is widely known that an implant installation should be based on prosthodontic driven, together with a concern of an anatomical limitations and bone availability. Apart from an esthetically results, a correct three-dimensional implant position may reduce biological and technical complications which contribute to the long-term success of dental implants. Therefore, an introduction of computed tomography (CT), 3D implant planning software and CAD-CAM (computer-aided design/computer-assisted manufacturing) technology have certainly been important achievements in this field. [9] [10] [11] [12]

In addition, computer-guided implants are generally placed closer to the planned positions and show more consistency in accuracy, while the conventional guides resulted in greater variability of accuracy. [14] Another benefit of computer-guided implant that also reported is less patient discomfort than free hand method. [13]

There are different guidance systems, designs and protocols are available recently in clinical practice. Several authors have categorized many of these into static and dynamic systems.

Static guided surgery systems used computerized tomography (CT)-generated CAD/CAM stents, with sleeves (metal cylinders) and surgical systems that use correlate instrumentation to place implants with the assist of guide stent. Thus, an implant position is dependent on the stent without an ability to change the position. [16] Computer software allows visualization and manipulation of the images of the patient's jaw bone and surrounding tissue make possible the most accurate approach to implant surgery. Digital software will allow the user to place a virtual analog of the proposed implant and measure the optimum distance between

adjacent teeth or anatomical structures. This visualization allows for rapid site analysis and predictable treatment planning whereby the surgeon can order specific implant diameters and sizes, healing abutments, and provisional crowns before surgery procedures. [9] [11] [20]

Dynamic guided surgery or dynamic navigation is a surgery guide that the operators receives real-time information on the position of the drill in the operative field through using visual image tools on a monitor. Consequently, any changes to the plan can be made by operator at the time of surgery. It has been reported that the accuracy of the evaluated dynamic navigation system was similar to the accuracy that reported for static CT-generated guides and was significantly improved when compared to freehand implant placement. [20]

Nevertheless, static guided surgery systems have shown to be more practical in present dental offices because they are less expensive and involve less space in surgery field. [21]

2.1 Implant planning software

The planning software programs allow the user to view all of the characteristics of a future implant site by allowing for the precise assessment of bone volume, bone density, and restorative space together with the ability to identify and mark vital anatomic landmarks. Apart from a site assessment, the most useful tool is the ability to virtually place an implant into the proposed site. This can allow accurate implant width, depth, and size determinations prior to surgery in order to assist in the pre-surgical planning stages. [15]

Currently, there are various third-party implant planning software programs. For example, Simplant (Materialise Dental Inc, Glen Burnie, MD, USA), Invivo5 (Anatomage, San Jose, CA, USA), NobelClinician (Nobel Biocare, Goteborg, Sweden), OnDemand3D (Cybermed Inc, Seoul, Korea), Virtual Implant Placement software (BioHorizons, Inc, Birmingham, AL, USA), coDiagnostiX^{TM} (Dental Wings Inc, Montreal, CA, USA), and Blue Sky Plan (BlueSkyBio, LLC, Grayslake, IL, USA). [16]

After the CBCT are taken, the images are exported into DICOM (Digital Imaging and Communications in Medicine) files which are the standard for the distribution and viewing of medical images regardless of their origin. This format is compatible with all third- party software packages mentioned above; however, an additional file conversion steps may be required in some software packages.

coDiagnostiX is the third-party implant planning software claimed to provide predictable implant placement outcome. This software intended to be used for pre-operative planning for dental implant installation and restoration. Moreover, post-operative radiograph can be directly superimposed onto pre-operative plan by a treatment evaluation function in this program.

3 shape Implant Studio is an open implant planning software solution that enables users to develop an implant surgical plan as well as digitally plan the pre-surgical implant placement. The innovative solution also allows users to design customized surgical guides for printing in-house or send those designs to preferred manufacturing partner.

2.2 Factors influence the accuracy of static CAIS system

There are various factors that may have an influence on the accuracy of implant placement using CT-generated guide including: type of arch, kind of template, surgical technique, number of sleeve-guided site preparation steps, operator's skill and image acquisition. In addition, various studies show that the accuracy of implant position was better in studies with models (in vitro) and cadavers than in studies with humans. This can be explained by better access, better visual control of the axis of the osteotomy and there is no movement of the patient and no saliva or blood in the preclinical models. [9]

- *Type of arch (maxilla / mandible)*

A study by Behneke et al. in 2012 reported significant difference between maxilla and mandible for the linear deviation between planned and placed implant position at apex which larger in maxilla (0.50 vs. 0.40 mm, P = 0.033) but not for the linear deviation at neck and angular deviation. Even though the apical deviation was larger in the maxilla, the numerical difference is only 0.1 mm in median which is not clinically meaningful. [22]

This result is partially in agreement of data reported by Ozan et al. in 2009. They demonstrated significant difference between maxilla and mandible for the angular deviation (maxilla: 4.58±2.4 mm, mandible: 3.32±1.9mm, p=0.001) and linear deviation at neck (maxilla: 0.95 ± 0.5 mm, mandible: 1.28 ± 0.9 mm, p=0.028) but not for the linear deviation at apex. [23]

More deviations of implant position in maxilla may be explained that upper jaw has lower bone density that is easier to transfer inaccuracies than the compact mandibular bone. However, the findings should be interpreted with cautions because

the differences between maxilla and mandible were at low magnitude and therefore have no clinically meaningful. [24]

• *Type of guide support template (tooth-supported / bone-supported / mucosa-supported)*

In 2009, Ozan et al. determine deviations in position and inclination of the planned and placed implants using stereolithographic (SLA) surgical guides between three different types of SLA surgical guides including tooth-supported (for single crown restoration), bone-supported (for partial or full edentulous) and mucosa supported (for full edentulous). The results showed that tooth-supported SLA surgical guides were more precise than bone-supported and mucosa-supported SLA surgical guides. After matching procedure, the angular deviation for tooth-supported, bone-supported and mucosa-supported were 2.91° ± 1.3°, 4.63° ± 2.6° and 4.51° ± 2.1° respectively. The linear deviation at implant neck was 0.87 ± 0.4 mm, 1.28 ± 0.9 mm and 1.06 ± 0.6 mm respectively and the linear deviation at implant apex was 0.95 ± 0.6 mm, 1.57 ± 0.9 mm and 1.6 ± 1 mm respectively. [23]

A study by Behneke et al. in 2012 also reported a correlation between the amount of deviation and the type of surgical guided template. They observe less scattering of values and maximum deviations when treating single tooth gaps with mesial and distal tooth-supported templates. In contrast, there was a larger distribution of values for sites with a reduced residual dentition because there were only few teeth could secure the support. [24]

According to Van Assche et al. in 2010, there were no significant differences could be found between the shortened dental arch with free-ending templates and the interrupted dental arch with bilateral anchored templates. This is noticeable

because larger deviations for guides with unilateral anchorage could be found due to tilting or bending of the templates. Therefore, it might be concluded that using rigid template material in this study can prevent the tilting and bending of the templates. This is clinically meaningful in mandible with shortened dental arches in response to the potential risk of an injury of the mandibular nerve. [25]

• *Number of sleeve-guided site preparation steps (fully guided placement / freehand placement / freehand final drilling)*

According to a study by Behneke et al. in2012, they studied the accuracy of CT-generated guide surgery for different sections of the implant surgery. The fully guided placement is happened when implants were inserted through the sleeves into the guided osteotomy using a particular implant carrier which fit into the internal diameter of the guide sleeves. Freehand implant placement mean that the templates were used for controlling all of the osteotomy procedure but the implants were inserted manually without a surgical guide using a regular implant carrier. Regarding to freehand final drill, it usually occurred when we use a wide diameter of implants. This method mean that the template was used for supported osteotomy up to the standard diameter, about 4 mm. and then the site development for wide diameter of implants was performed manually. In this situation, the implants were also placed without a surgical guidance.

For the results of this study, significant differences were found at all aspects of measurement (implant coronal level, apex level, and angle). The highest deviations were found in the freehand final drilling group, followed by freehand placement method. [24]

The use of surgical guides may be limited to the pilot drilling or partial

section of the osteotomy in the posterior jaw segments especially in the patient with limited mouth opening. Therefore, the templates may be used only for the initial steps of osteotomy and this partial guided procedure can affect the accuracy of implant placement as seen in this study. Freehand final drilling, results in significantly higher deviation of implants than freehand placement and fully guided placement. Meanwhile, the fully guided technique could achieve a reduction maximum deviation of 0.3 and 0.6 mm for the implant shoulder and the apex reference points, respectively.

In conclusion, an improvement of the transfer accuracy can be achieved by increasing the number of template-controlled site preparation steps even in cases when the gap is surrounded by adjacent natural teeth, for example; single-tooth gap and interrupted dental arch that can serve as alignment guide for implant positioning. [11] [24]

• *Operator's skill (experienced / inexperienced)*

An in vitro study by Rungcharassaeng et al. in 2015 about the effect of operator experience on the accuracy of implant placement in mandibular model found that there were no significant differences in the angular and linear deviation between two groups of ($P>0.1$). [26] Despite there were no statistically significant, the amount of vertical deviation in the coronal direction of the implants placed by inexperienced operators was about twice that placed by the experienced operators. It is a fact that almost implants were placed more coronally than the planned position because the depth position of the implant is restricted by the contact between the flange of the drill or implant mount and the guiding sleeve of the surgical template. Therefore, the results can imply that the inexperienced operators

might be less confident about the implant depth than the experienced group.

Although this study showed that the differences between two groups were not significant, this must be interpreted with cautions because limitations such as the limit of the maximum mouth opening and the presence of the tongue, cheek, saliva and access during implant surgery did not take into account. It has been suggested that further in vivo studies at multiple implant sites should be investigated.

• *Surgical technique (flapless / open flap)*

An accordance to Behneke et al., they reported a borderline significance difference between the open flap and flapless approach for the shoulder linear deviation, resulting in slightly higher values for the flapless approach (0.36 vs 0.28 mm, P = 0.027) compared with the flap group. Moreover, no significant differences were found for the linear deviation at the implant apex and the angular deviation. Therefore, it can be concluded that the flap elevation did not negatively influence the positioning of the tooth-supported CT-generated guides which the natural dentition allowed a sufficient anchorage. The outcome between flap and flapless protocols noticed in this study is in agreement with the results reported by Ersoy et al. (2008) which could not find a difference in accuracy for the flap and flapless procedure in a human study in totally and partially edentulous patients. [24] [27]

In conclusion, guided flapless implant placement does not cause suboptimal results and the minimally invasive flapless approaches can be considered in concern with sufficient bone volume and an adequate zone of attached mucosa. Moreover, flapless implant surgery may have the advantage in reducing the postoperative discomfort and can further offer implant treatment to general medically

compromised patients who would be excluded for conventional implant procedures. [10] [24]

• *Accuracy of the image acquisition*

Besides the surgical errors during the implant placement, an inaccuracy can be combined by the errors collected during computed tomographic image acquisition and data processing.

CBCT or cone-beam computed tomography is an indication for dental implant procedures including 3D imaging of the facial bony structures. It provides many advantages such as small size, low radiation dose, short scanning times and low acquisition costs. Generally, the quality of CT data depends on the slice thickness and the influence of possible artifacts. To be specific, the thinner the slice thickness and the smaller the voxel size, the higher the resolution and accuracy of measurements of underlying structures are. Therefore, a movement and metallic artifacts of dental restorations may lead to geometric distortions and invalid data acquisition. Furthermore, a 3-D model of patient's oral condition should be precise as much as possible. This can acquire from a careful and correct intra-oral scanning processes. [28] [29]

2.3 Accuracy of computer assisted implantation system

As mentioned above, several authors have documented that implant placement using surgical guides was more accurate than freehand placement after osteotomy. The accuracy of a computer-guided procedure is explained as the deviation in location or angle between the treatment plan and the placement. The

steps for the digital workflow sequences for guided surgery including 1. An image acquisition 2. Surface scanning procedures which can be done by an intra-oral scanning or an extra-oral model scanning 3. A use of computer planning software 4. A surgical guided fabrication via 3-D printing. Therefore, clinicians have to understand limitations within each step for the digital sequence and recognize that an error can happen at every steps and cause in an inaccuracy. [30]

An implant planning software is used to combine all digital data series from the radiographic and surface scanning processes by aligning shared regions on both data sets. An inaccuracy may exist when there is a lack of clearly identifiable shared features. For instance, there is a number of metal restorations which can create an artifact. Moreover, the segmentation of the imported data and operator experiences are in clinically correlate with deviations encoded in drilling guides when using a commercially available planning software. [31]

Another important factor which can cause additionally inaccuracies is a fit of sleeves needed to be inserted into the surgical guides. A suitable fit of these sleeves with a drilling handle ensure that those in sequence drills, with increasing diameter, can be used to prepare the surgical osteotomy. [35] A study by Schnerider et al. in 2015 performed an in vitro study and reported that the use of 3-D printing with reducing sleeve diameter in combination of a tolerance surgical instruments can significantly decrease the lateral movements of the surgical drills. [32]

According to a recent systemic review and meta-analysis which focused on only clinical studies. Mean error for entry point position was 1.2 mm, CI: 95% [1.04-1.44], the average error at the apex position was 1.4 mm, CI: 95% [1.28-1.58], A mean angular deviation was 3.5 degree CI: 95% [3.00-3.96], and a mean error in implant

height at the entry point and at the apex was 0.2 mm, CI: 95% [-0.25 to 0.57] and 0.5 mm, CI: 95% [-.0.08 to 1.13] respectively. For the study design topic, PS refers prospective study, RS refers to retrospective study and RCT refers to randomized clinical trial. **(table.1)** [30]

Table 1 The accuracy of the implant placed by static computer-assisted system.

Authors (year)	Study design	Software / guide system	No. of implants (N)	Error at entry (mm.)	Error at apex (mm.)	Error at angle (degree)	Error in height(mm.) at	
							entry	apex
Arisan et al. (2013)	PS	Simplant	102	1.6 [1.37; 1.75]	0.8 [0.63; 1.04]	3.4 [2.73; 4.04]		
Cassetta et al. (2012)	RS	Simplant ,External hex safe	95	1.6 [1.17; 2.13]	2.1 [-0.35; 4.65]	4.6 [3.00; 6.24]		
Caseetta et al. (2013)	RS	Simplant/ SurgiGuide, External hex safe	227	1.5 [1.22; 1.78]	1.9 [1.53; 2.33]	4.8 [3.43; 6.23]		
Caseetta et al. (2014)	RS	Simplant ,External hex safe	225	1.7 [1.46; 1.90]	2.2 [1.88; 2.50]	4.7 [3.68; 5.66]		
D'haese et al. (2012)	PS	Facilitate	78	0.9 [0.67; 1.15]	1.1 [0.85; 1.41]	2.6 [1.72; 3.48]		
Ersoy et al. (2008)	PS	Stent Cad / swiss plus	94	1.2 [0.86; 1.58]	1.5 [1.08; 1.94]	4.9 [3.89; 5.91]		
Furhauser et al. (2015)	RS	NobelGuide	27	0.8 [0.67; 1.01]	1.2 [0.90; 1.42]	2.7 [1.08; 1.94]		
Geng et al. (2015)	PS	Simplant	111	0.5 [0.28; 0.68]	0.8 [0.70; 0.99]	2.2 [1.35; 3.08]	0.4 [0.25; 0.58]	
Lee et al. (2013)	RS	OnDemand 3D	102	1.1 [0.78; 1.40]	1.6 [1.14; 1.98]	3.8 [2.88; 4.72]	0.7 [0.39; 0.93]	0.7 [0.40; 0.98]

Ozan et al. (2009)	RS	Stent CAD	110	1.1 [0.86; 1.36]	1.4 [1.09; 1.73]	4.1 [3.28; 4.92]		
Pettersson et al. (2012)	PS	Nobel Guide	27	0.8 [0.69; 0.91]	1.1 [0.95; 1.23]	2.3 [1.84; 2.68]		-0.2 [-0.30; 0.00]
Schnutenhaus et al. (2016)	RS	Swiss media Online Planning/Camlog Guide system	24	1.0 [0.75; 1.15]	1.1 [0.68; 1.62]	4.0 [2.80; 5.21]	0.5 [0.24; 0.76]	
Stubinger et al. (2014)	PS	Facilitate	44		0.8 [0.53; 1.01]	2.4 [1.79; 2.99]	0.5 [0.20; 0.74]	0.5 [0.21; 0.73]
Van de Wiele et al. (2015)	PS	Simplant	75	0.9 [0.62; 1.12]	1.1 [0.84; 1.36]	2.8 [2.06; 3.53]	0.5 [0.26; 0.74]	1.1 [0.86; 1.35]
Vasak et al. (2011)	PS	Procera/ Nobel Guide	86	0.8 [0.59; 1.05]	1.1 [0.68; 1.42]	3.5 [2.71; 4.35]		
Vercruyssen et al. (2014, 2015)	RCT	Simplant/ Materialise Universal, Facilitate	209	1.4 [1.19; 1.58]	1.6 [1.37; 1.79]	3.1 [2.55; 3.73]	0.9 [0.71; 1.12]	
Verhamme et al. (2015-1)	PS	Procera/ Nobel Guide	150	2.0 [1.87; 2.05]	2.3 [2.18; 2.39]	3.9 [3.76; 4.09]	-0.6 [-0.64; -0.52]	
Verhamme et al. (2015-2)	PS	Procera/ Nobel Guide	104	1.4 [1.34; 1.40]	1.6 [1.56; 1.62]	2.8 [2.75; 2.88]	-0.8 [-0.88; -0.80]	
Verhamme et al. (2017)	PS	Maxilim/ Nobel Guide	72	2.1 [2.01; 2.09]	1.6 [1.55; 1.64]	5.0 [4.91; 5.13]	-0.6 [-0.70; -0.48]	
Vieira et al. (2013)	RS	Nobel Guide	62	1.8 [1.37; 2.22]	2.2 [1.35; 3.08]	1.9 [1.61; 2.17]		

They also found that there was a significant difference between edentulous and fully edentulous cases at an error at entry point and apex point groups. They indicated a smaller error and less deviation in partially edentulous patients treated with guided surgery. Even though the mean deviation seems to be in a clinically acceptable range, there were a large error in some studies when treating fully edentulous upper jaws. They reported an error up to 7.8 mm at the entry point and 8.7 mm at the apical point and indicated that a major cause of an error is being placed an implant too superficially. [33] [34]

Moreover, an implant placed using free-hand technique is not allow the clinician to make a comparison between placed and placed implant position because there is no preplanned implant position useable.

In conclusion, it can be summarized that the accuracy of static computer-aided implant surgery is excellent and acceptable in the majority of clinical situations especially in partially edentulous patients. [30]

3. Accuracy analysis

The corresponding between planned and placed implant position can be evaluated by two main methods; direct and indirect methods.

The direct method (Postop CBCT) is a method of taking a second cone beam computed tomography (CBCT), which allows a superimpose between the preoperative planning and postoperative planning implant positions by implant planning software. According to a systemic review of an accuracy analysis, most previous studies were evaluated by using radiographic image. [31] Furthermore, there

is the calculation of mathematical algorithm implementing on both image of positional and angular deviation between the planned and the actual implant position. [11]

Secondly, the indirect method (Pick-up Impression) is method of taking an intra-oral scan with an intra-oral scanner through the impression coping or scan body after the implant was placed. Scan-bodies are usually made out of plastic and have unique geometry. They include flat surfaces, lobes, ridges, and other unique contours that help the CAD software accurately identify position of the implant fixture precisely. Followed by, the three-dimensional cast with an actual implant position superimposing onto the preoperative treatment plan model in software program with the same three-point reference positions as in the planned model. In fact, the long axis of the planned implant was used as the baseline reference to compare with the long axis of the placed implant. Therefore, with all mentioned the procedures above, it is the finish of the measurement method. [35] [36]

The obvious advantage of the A coDiagnostiX software program is that there is both direct and indirect evaluation method available, while Implant studio software program has only indirect method available. Empirically, the advantage of an indirect method over a direct method is that the patients do not have to expose the radiation with CBCT after implant surgery. Nevertheless, an error can occurred from an inaccuracy of intraoral scanner or a malposition of the connection between a scan body to the implant fixture. [31] The contraindications to this technique include implants with poor initial stability. [37]

There are several measuring parameters were commonly used in the previous systematic reviews for the comparison of these positions: [9] [11] [32]

- Error at the entry point of the implant (mm), measured at the center of the implant
- Error at the apex of the implant (mm), measured at the center of the implant
- Deviation of the axis of the implant (degree)
- Error in height/depth of the implant (mm)

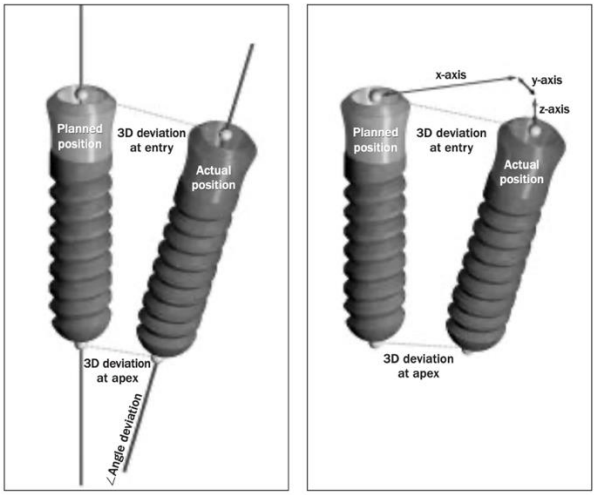


Figure 2 the different variables for describing the deviations
(left) shows the different variables for describing the deviations. (right) demonstrates variables when axiomatic (x,y,z) measurements were used. [11]

For the first two parameters, the most common method is measuring a deviation between the planned and actual point by one distance in 3D.
In the 3D measurement method, two points are located on each planned and real implant long axis. For example, the entry point (center of the most coronal portion

of the implants) and the apex point (center of the implant apex). Then, the distances between the centers of the planned and final implants were calculated mathematically. *(Fig.2)* [38]

On the other hand, there are some studies reported that the distinction between the deviation by individual vectors with a buccolingual or sagittal view (x-axis), mesiodistal or cross section (y-axis) direction and apicocoronal deviation (z axis). *(Fig.2)* [36] [38] [39]

Another parameter, a deviation of the axis, the comparison is less complicated since every study report by degrees of deviation. In addition to this, the deviation in height/ depth, the error in implant height is often reported as a negative value when the implant is not inserted as deeply as planned and a positive value for implants are inserted below the reference line. [11]

CHAPTER III

MATERIAL AND METHOD

Materials

Cone Beam Computed Tomography (CBCT) scanner

iCAT™ (Imaging Science International, Hatfield, PA, USA) with a 170x130 mm. field of view

Surface scanner

D900L scanner TRIOS (3shape, Copenhagen, Denmark)

Implant planning and accuracy analysis software

coDiagnostiX™ software version 9.7 (Dental Wings inc, Montreal, CA) and 3shape

Implant Studio™ version 2019.1.5 (3Shape, Copenhagen, Denmark)

Implant

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

Scan bodies

Straumann® Scanbodies (Straumann, institute Straumann AG, Basel, Switzerland)

Surgical kit

Digital Guided Surgical kit (Straumann, institute Straumann AG, Basel, Switzerland)

Methods

Patient

Patients who required dental implants at the Department of Esthetic Restorative and Implant Dentistry, Chulalongkorn University were enrolled in this study. The block randomization method was used to random subjects into 2 groups.

Sample size

Sample size was calculated by using means and standard deviations obtained from a previous study. [18] The calculation was performed using G*Power program. Based on 5% Type I Error, 80% study power. The sample size from calculations with 20% compensation for attrition was 12 subjects per group. Therefore, total of 24 subjects were needed.

Subject inclusion criteria

- Patients with missing teeth in posterior mandible and/or maxilla, with remaining adjacent teeth. This condition allows the surgical guides to be tooth-supported design.
- There is no pathological mobility of adjacent teeth that supported surgical guide.
- Implants are placed using fully-guided placement systems.

- CBCT radiograph and clinical examination display sufficient bone volume to support the implants.
- There is no limited mouth opening so that the placing of both surgical templates and drills are not restricted.
- Patient with age 20 years and over who able to sign a consent form.
- Patient is in good general health at the time of selection (ASA class I or II).
- The adjacent teeth which is mesial and distal to edentulous area have no metal crown restorations to reduce the error from scattering image.

Subject exclusion criteria

- Patients with severe systemic diseases which implant placement is the contraindication of the disease such as coagulation disorders, serious cardiac vascular disorders or pregnancy or lactation at the time of enrollment or other significant diseases as evaluated by the investigator.
- There are clinical or radiographic signs present any pathology in the jaw bone.
- Patients are on orthodontic appliance which interfere a placement of surgical guide.
- Patients who maintained perioperative complications that may make guided implant surgery less precise, such as unstable or fracture guided surgery that can cause mis-alignment of implant position and clinical mobility of implant.

Study Procedure

Ethical approval

The study of clinical protocol was approved by ethic committee of faculty

of dentistry Chulalongkorn University. HREC-DCU 2020-073.

Patient selection

24 patients who meet the inclusion criteria were randomed into 2 groups using randomization method.

The Digital Imaging and Communications in Medicine (DICOM) file preparation

A diagnostic wax up was performed on the edentulous area and then fabricated a radiographic stent. Standard cone beam computed tomography (CBCT) scan procedures were followed for each patient with a 170x130 mm field of view machine (iCAT^{TM} , Imaging Science International, Hatfield, PA, USA)

The Standard Tessellation Language (STL) file preparation

- An antagonist arch impression was taken with alginate and pour with dental stone.
- Patient's intraoral field of interest were scanned by D900L scanner (3shape, Copenhagen, Denmark) in order to record the configuration of the patients' dentition, edentulous area and adjacent mucosa.

Implant Position Planning process and randomization

- The Digital Imaging and Communications in Medicine (DICOM) format file of CBCT image were imported to the planning software (coDiagnostiX software version 9.7 (Dental Wings Inc, GmbH, Germany) and Implant studio software, (3Shape, Copenhagen, Denmark)

- The Standard Tessellation Language (STL) files of the patient's mouth was imported and superimposed onto the CBCT image of each software by using 3-points registration.
- Patient were randomly classified into two groups of software mentioned. In each software, three-dimensional implants position was planned by one experienced operator according to individual patient's vital anatomical structure, adjacent teeth and the relationship to the implant prostheses aspect which served as the "ideal position" for every implant. (figure3,4) In the accuracy analysis, the position of every implants as surgically realized was compared to its "ideal position".
- Then, the tooth-support surgical drilling guides with sleeves and inspecting window were designed. The extension of tooth-support surgical drilling guides were designed to cover 4 to 6 teeth (about 2 to 3 teeth on each side of the implant placement site) for the guide stability. (figure5) Another important thing is that all of implants were designed for using fully-guided placement systems.

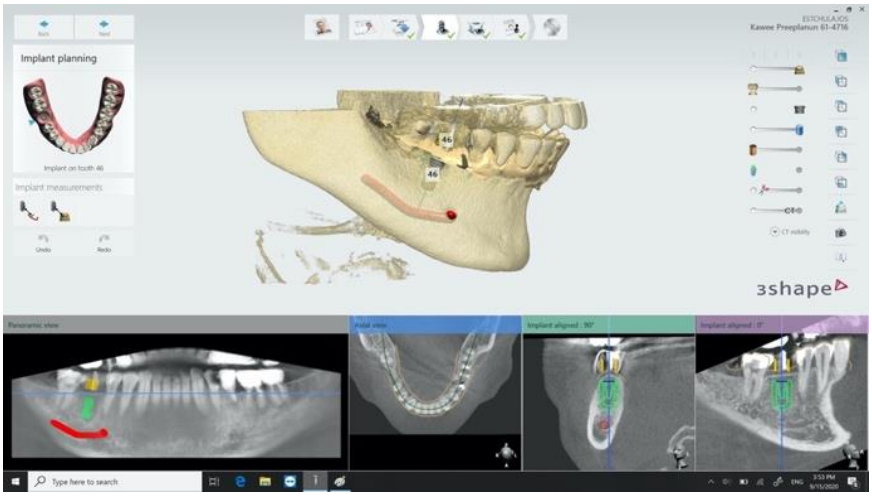


Figure 3 The planning process of Implant Studio software
An ideal implant position was set to be a baseline for accuracy analysis.

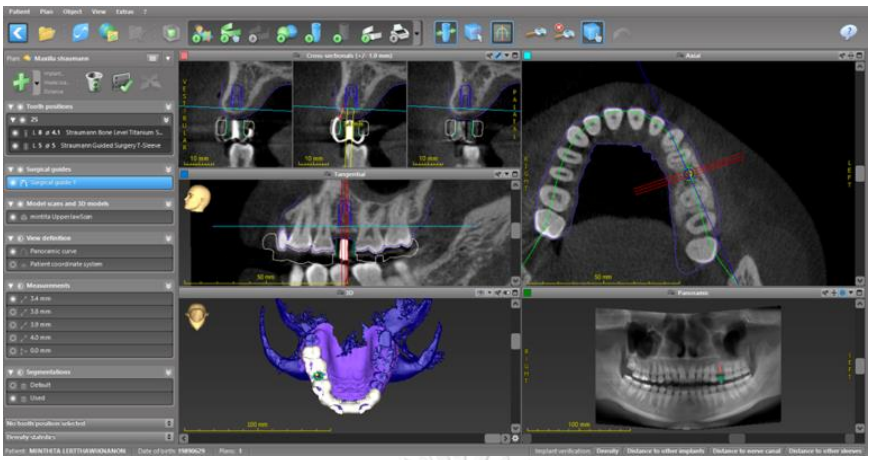


Figure 4 The planning process of coDiagnostiX software

An ideal implant position was set to be a baseline for accuracy analysis.

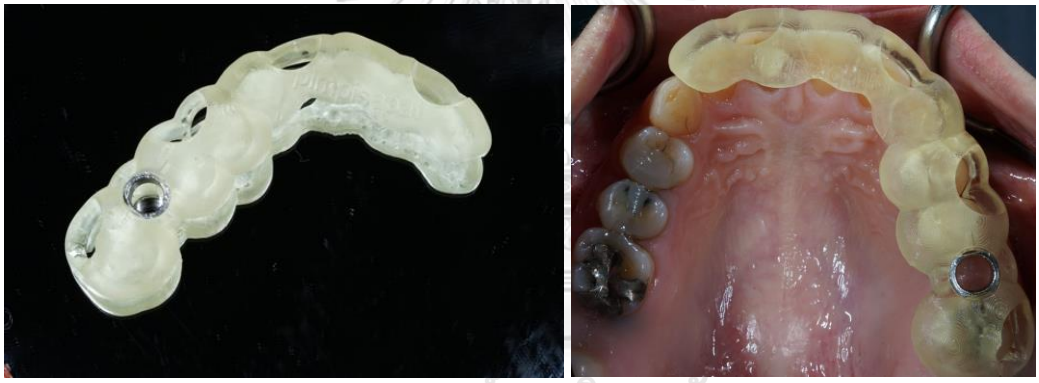


Figure 5 The example of surgical guide template

(Left); The example of surgical guide template which was designed to cover 4 to 6 teeth for the guide stability. **(Right);** The adaptability of surgical drilling guide was verified via inspecting window.

Surgical Guided fabrication

Surgical drilling guides were fabricated at dental lab with same 3D printer.

Surgical protocol

In the implant placement visit, the adaptability of surgical drilling guide was verified

via inspecting window and adjusted manually. After administration of local anesthetics, patients were informed to rinse with 0.12% chlorhexidine solution for 30s. Surgery was performed according to the treatment patients had been assigned to by inexperienced operators under a supervision of experienced operator using fully guided placement systems. All implants were Straumann bone level implant of various dimensions (Straumann, institute Straumann AG, Basel, Switzerland). Fully guided surgery was performed with flap elevation and all the osteotomies and implant installed were completed with the surgical guide in place following the planned implant position.

Data collection

After the complete osseointegration of the implants at around 12 weeks, all patients were scanned intra-orally using the Trios 3Shape scanner through the Straumann Scanbody for both the coDiagnostiX and 3shape Implant studio software. The scan body were connected to an implant fixture with only 15 Ncm^2 of torque. (figure6) After that, the three-dimensional cast with an actual implant position were superimposed onto preoperative treatment plan model in the software programs using the same three-point reference positions as in the planned model.

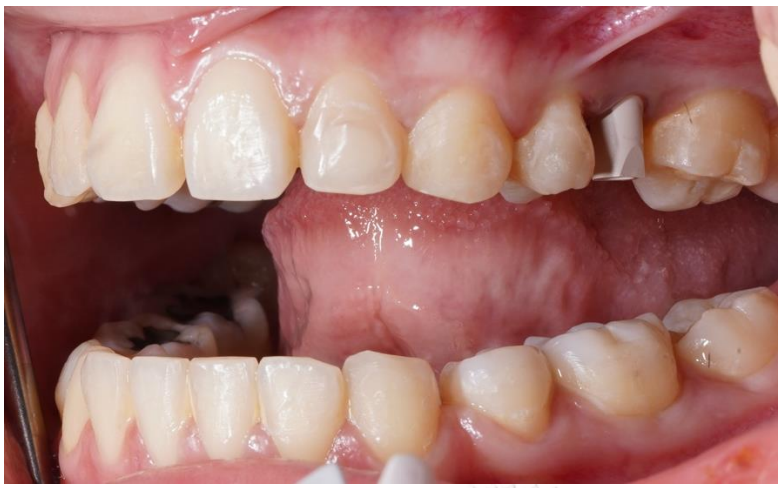


Figure 6 The scan body which was intra-orally connected to an implant fixture.

Accuracy analysis

The accuracy analysis was performed by one experienced clinician. It was based on pre-operative CBCT with the virtually planned implants and postoperative STL image file of the actually placed implant. Deviations which calculate from the surface scan were digitally analyzed and read out in each program. For coDiagnostiX, a treatment evaluation tool in the program was used meanwhile an implant comparer tool was used in implant studio. (figure8,9) Common three parameters between two software which are an error of entry point, angular deviation, and variance of the error depth were calculated and chosen for comparison. (figure7)

1. A deviation at the entry point of the implant (mm), which is the distance between the entry point of the two implants measured at the center of the implant. *(a point)*

2. A deviation of the axis of the implant (degree) ***(A angle),*** which calculated by finding the smallest angle between the two implants axis.

3. A deviation in height / depth of the implant (mm) (*c point),* If the

placed implant is deeper than the planned implant, it will be reported as positive value. In contrast, when the implant is not inserted as deeply as planned it will be reported as a negative value.

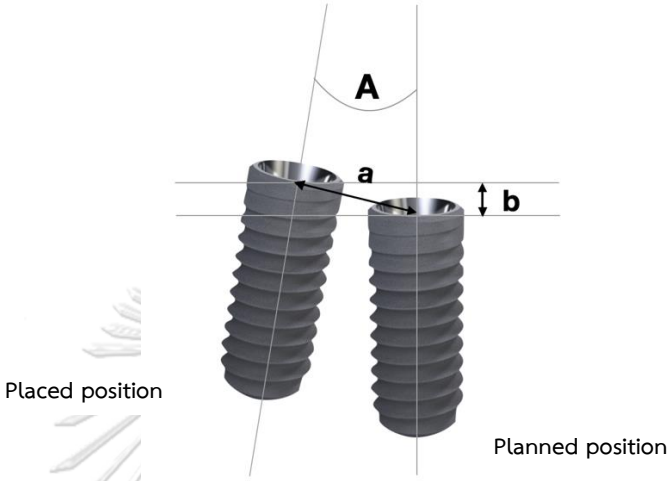
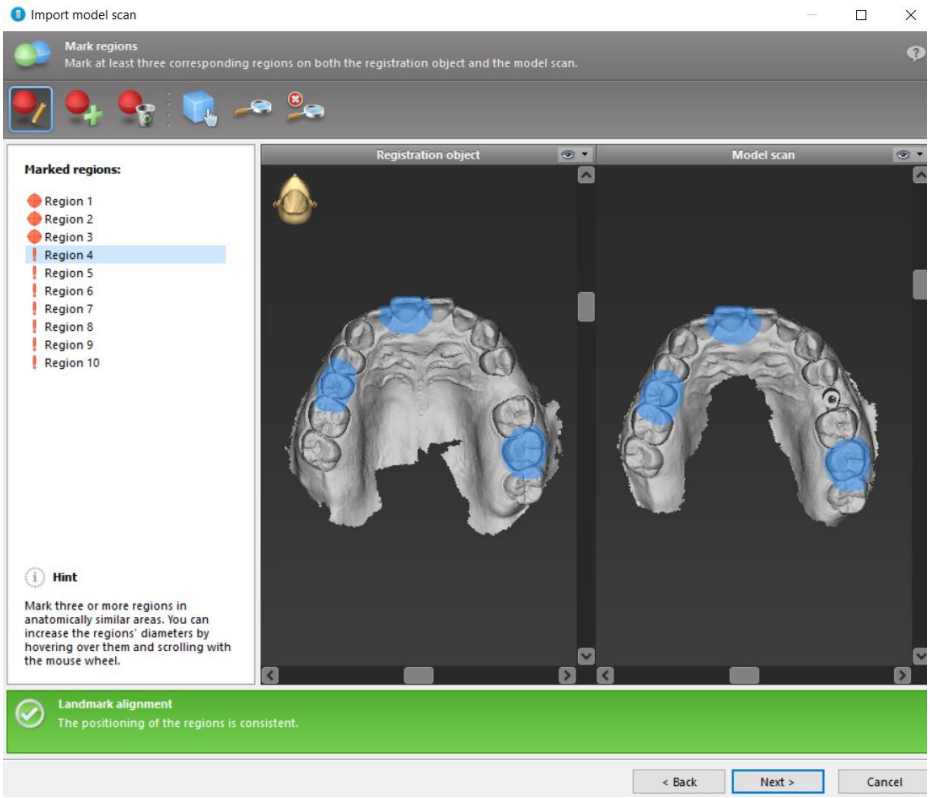


Figure 7 Illustration of the parameters for describing the deviations.



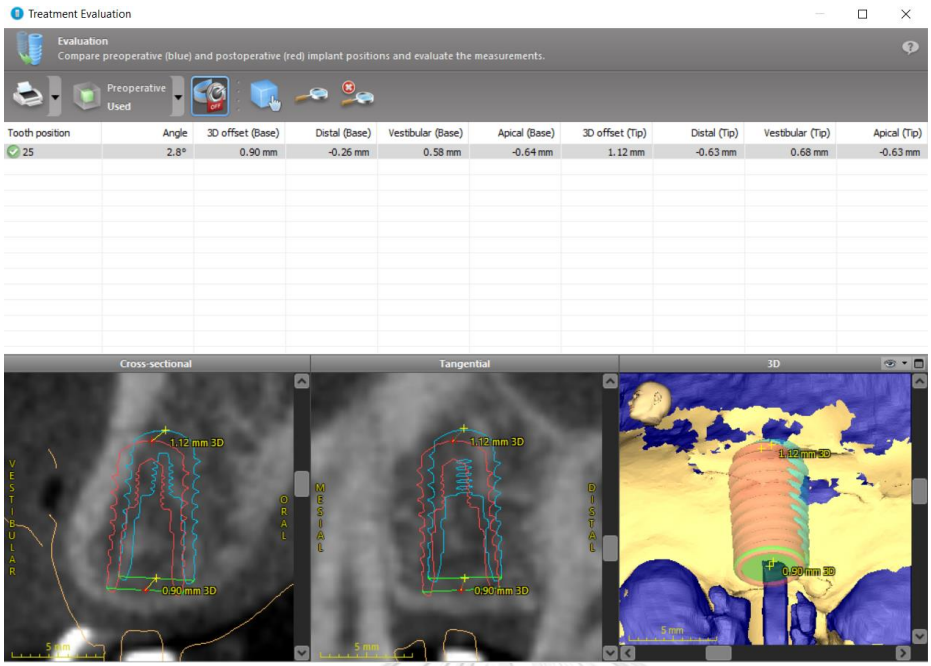


Figure 8 The process of accuracy analysis of coDiagnostiX software

(Upper) The three-point reference positions between the planned and placed model; (Lower) Red line represents the placed implant position while green line is a virtual implant position planning.

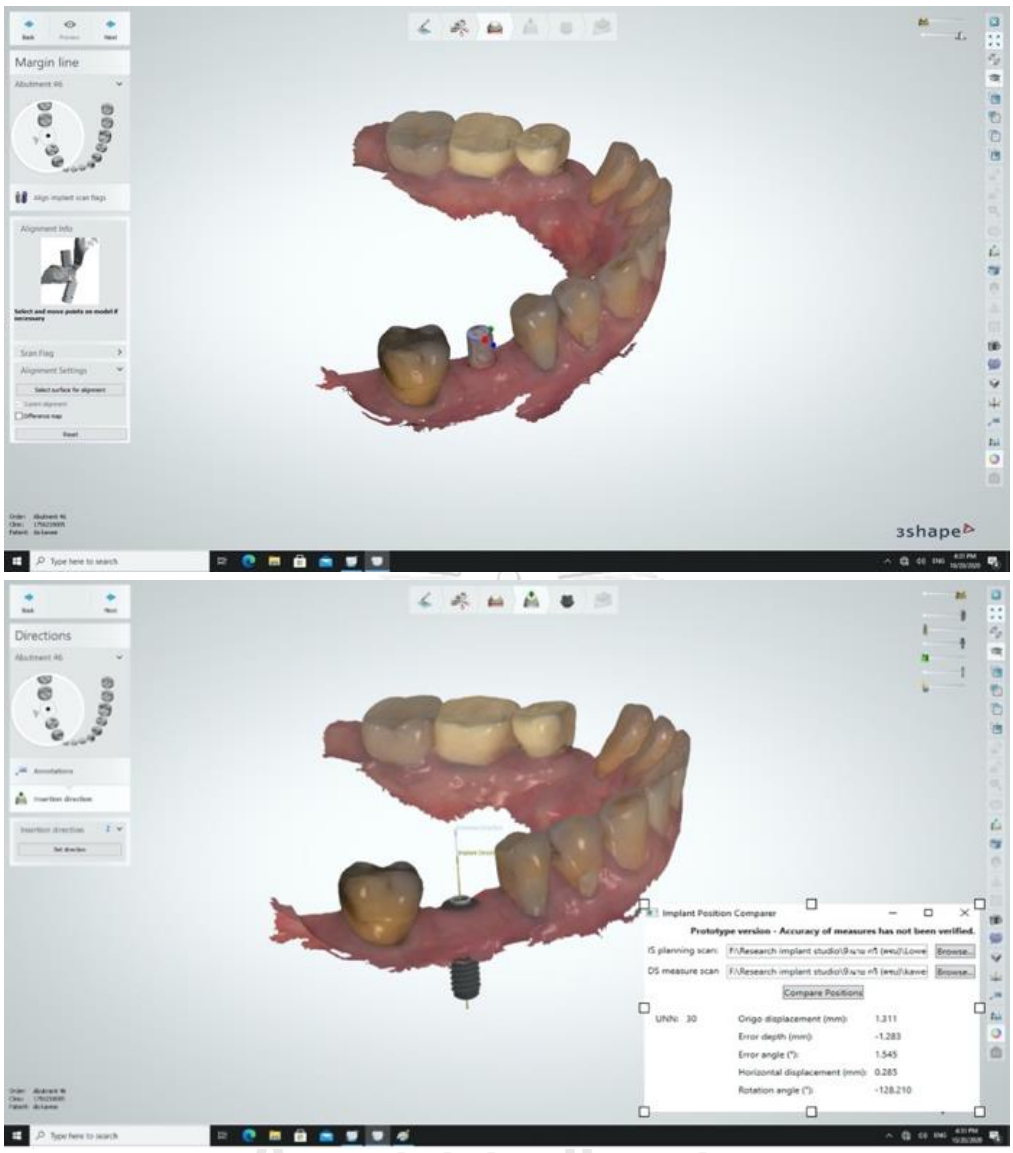


Figure 9 The process of accuracy analysis of Implant studio software
(Upper) The three-point reference positions between the planned and placed model; (Lower) An implant position deviation analysis using implant comparer tool.

Statistical analysis

The measurement data were gathered and analyzed statistically using IBM SPSS Statistics software (version22 software SPSS Inc., Chicago, IL). All variables were analyzed from a descriptive point of view and categorized per software group, bring

about frequency distribution for categorical variables and means and standard deviations for continuous variables. The distribution of continuous variables was assessed using the Shapiro-Wilk test and found the normality. Therefore, the mean value of differences between planned and placed position were compared between two software groups using t-test. P-value less than 0.05 was considered statistically significant.

CHAPTER IV
RESULTS

Results

Patient selection

The sample size calculation showed a total of 12 implants to be placed in the coDiagnostiX and Implant Studio software groups. A total of 24 patients (mean age 49.53 ± 16.83 years; 10 men, 14 women) were included in this study. Table 2 shows the implant characteristics (implant diameter platform, implant body type, and implant length) of the placed implant and patient's arch type. There were no statistically significant differences in these variables between the two software groups ($P>0.05$).

Table 2 Implant characteristics of the placed implant and patient's arch type.

	CodiagX	Implant studio	Total
Implant diameter platform			
Narrow (3.3 mm)	1 (8.3%)	0 (0%)	1 (4.2%)
Regular (4.1 mm)	5 (41.7%)	3 (25%)	8 (33.3%)
Regular (4.8 mm)	6 (50.0%)	9 (75%)	15 (62.5%)
Implant body type			
BL (Bone level)	5 (41.7%)	9 (75%)	14 (58.3%)
BLT (Bone level tapered)	7 (58.3%)	3 (25%)	10 (41.7%)
Implant length			
8 mm	2 (16.7%)	1 (8.3%)	3 (12.5%)
10 mm	120 (83.3%)	11 (91.75%)	21 (87.5%)
Arch type			
Maxilla	5 (41.7%)	8 (66.7%)	13 (45.8%)
Mandible	7 (58.3%)	8 (66.7%)	13 (45.8%)

Accuracy analysis

An analysis of the parameters of each software program is shown in Table 3. The means deviation from the coDiagnostiX software is slightly higher than the deviation from Implant Studio software in all parameters. However, there are no significant differences were found in angular deviations, a deviation at the entry point and a deviation in depth between the 2 groups. ($p>0.05$; Table4)

Table 3 Descriptive statistics for the coDiagnostiX and Implant Studio software study groups.

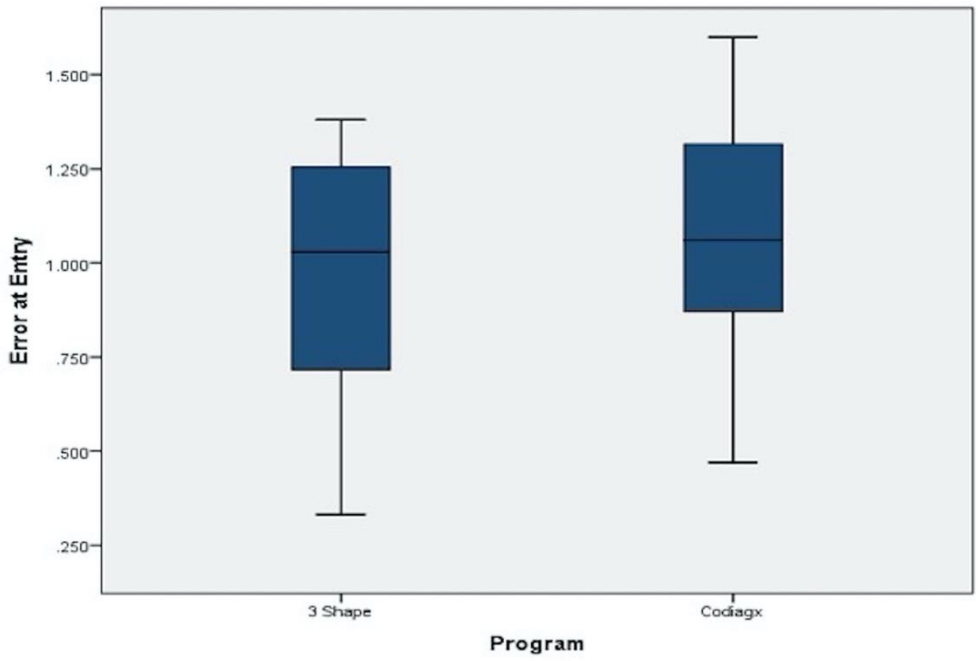
	coDiagnostiX			Implant Studio		
	Maximum	**Minimum**	**Mean ± SD**	**Maximum**	**Minimum**	**Mean ± SD**
DE	1.60	0.47	**1.07 ± 0.36**	1.38	0.33	**0.97 ± 0.33**
DA	6.10	0.60	**3.52 ± 1.64**	7.20	1.05	**3.77 ± 2.16**
DD	-1.15	-0.40	**-0.71 ± 0.29**	-1.28	-0.26	**-0.84 ± 0.30**

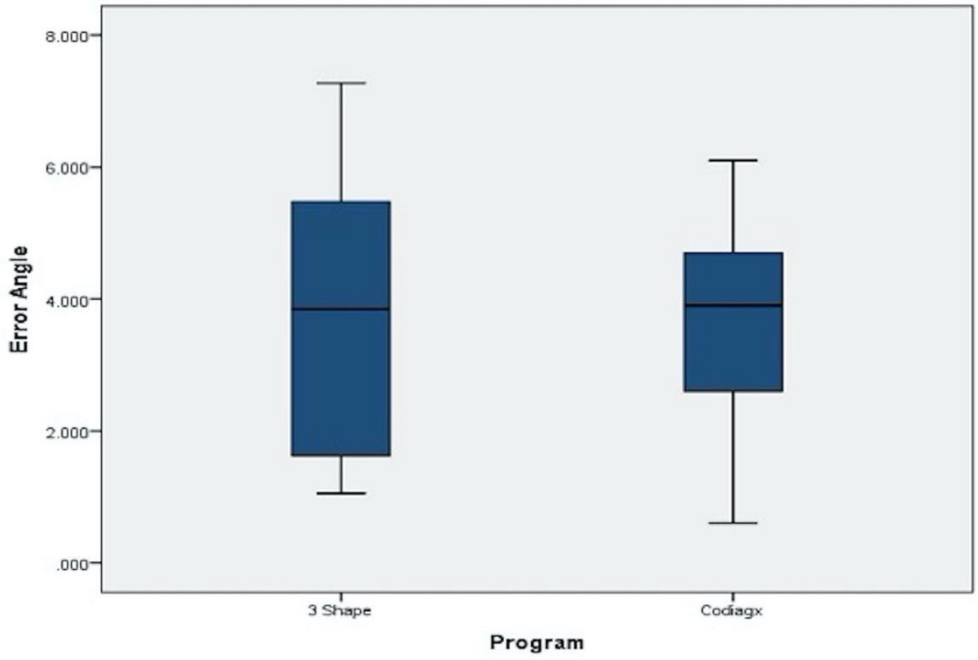
DE, deviation at the entry point in mm); DA, deviation of the axis in degree; DD, deviation in de pth in mm; SD, standard error.

Table 4 An analysis and t-test comparisons for the coDiagnostiX and Implant Studio software study groups.

coDiagnostiX versus Implant Studio			
	Mean difference	**95% confidence interval**	**p-Value**
DE	-0.102	-0.391 to 0.187	0.471
DA	0.248	-0.378 to 0.124	0.305
DD	-0.127	-1.374 to 1.872	0.753

DE, deviation at the entry point in mm); DA, deviation of the axis in degree; DD, deviation in de pth in mm; SD, standard error.


1.500
1.250
1.000
.750
.500
.250
Error at Entry
3 Shape
Codiagx
Program


8.000
6.000
4.000
2.000
.000
Error Angle
3 Shape
Codiagx
Program

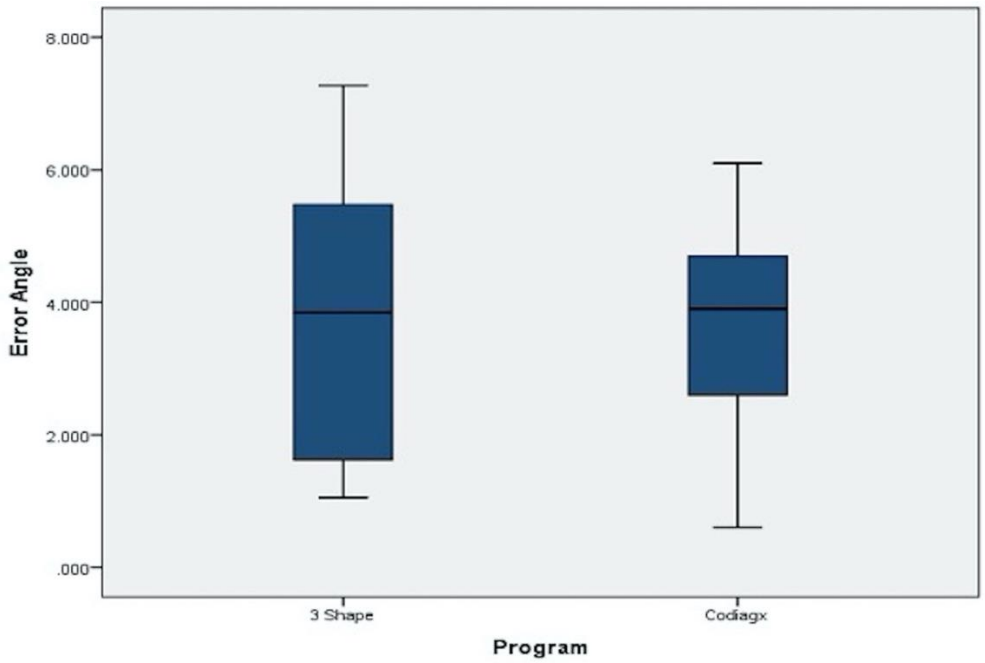


Figure 10 Box plots presenting deviation at the entry point, angular deviation and deviation in depth per software group.

CHAPTER V

DISCUSSION AND CONCLUSION

Discussion

The result of this clinical study indicates that the mean implant position error when using coDiagnostiX software was 1.1 mm, CI: 95% [0.91-1.28] at the entry point, -0.7 mm, CI: 95% [-0.85 to -0.56] in implant height at the entry point, and 4.2degree, CI: 95% [3.07-5.41] of angulation error. In the same way, the deviation of implant position from Implant Studio planning software was 0.98 mm, CI: 95% [0.77-1.17] at the entry point, -0.6 mm, CI: 95% [-0.91 to -0.29] at implant height, and a mean angular deviation was 3.5degree, CI: 95% [2.30-4.61]. The null hypothesis was accepted, there is no significant differences in clinical accuracy of placed implant position between coDiagnostiX and Implant Studio implant planning software for cases performed by inexperienced operators. All inexperienced operators can superbly accomplish the implant surgery with the surgical guide and satisfied with their implant positions without damage to adjacent structures.

According to a recent systemic review and meta-analysis which focused on only clinical studies, mean error for entry point position was 1.2 mm, CI: 95% [1.04-1.44], a mean error in implant height at the entry point was 0.2 mm, CI: 95% [-0.25 to 0.57] and a mean angular deviation was 3.5 degree, CI: 95% [3.00-3.96]. [30]

When compared results received from this experiment to the results from Tamaseb et al., the deviation at the entry point, mean errors in implant height at the entry point and mean mean angular deviation of both software are in line. However, an angular error of the coDiagnostiX was slightly higher than the systemic review. Regarding an error of the implant height, most of placed implant positions achieved

from this study were shallower than planned. The systemic review from Tamaseb et al. included result from multiple software but there are scant of evidence of the error in height of coDiagnostiX and Implant Studio software. The error in implant height was considered to be a positive valued error for implants that were not deep enough and a negative value for implants inserted below the reference line. [30] In this clinical study, contrastingly, placed implants that deeper than planned implants were reported as positive value and the implant which not inserted as deeply as planned were reported as a negative value. However, the interpretation is alike which is the majority of the errors occurred with the implants being placed too superficially. The depth of the implant platform is important. If the implant is not inserted deep enough into the soft tissue, the color of metal implant shoulder can be visible and then cause an unpleasant esthetic result, despite there is no recession of a mucosa. Conversely, implants which were placed too deep can cause a recession of the buccal mucosa particularly when there is a thin buccal bone wall. Moreover, the deep placement of an implant can also lead to a persistent inflammation of the peri-implant mucosa, an adequate plaque control and a poor soft tissue esthetic result. [17]

This clinical investigation shows that the implant accuracy was lower than laboratory studies. These results can be explained by patient-related factors including patient movement, limited mouth opening, limited visibility due to the presence of blood and saliva, and restricted inter-arch clearance. [3] These clinical limitations may interfere with the seating of the surgical guide stent and direction of the drills especially for posterior implants where the access is restricted. Moreover, there are more errors in clinical situations which can be anticipated by CBCT and 3D

segmentation of the hard tissues prior to virtual implant planning. [28] While there might be some deviation, the result of this clinical trial has proven that the advantages of using surgical guide template are minimal implants position deviation and also reducing the risk of damage to adjacent structures.

Although observations confirm the advantage of using the surgical guide template created by implant planning software in controlling all the steps of osteotomy and implant placement, the major errors seem to occur during the surgical procedure. [3] [16] For example, an improper seating of the guide with the adjacent teeth and then distortion the guide inside the mouth

In this study, a full-guided protocol was conducted to minimize errors as a result of several studies confirmed superior accuracy of full-guided protocol than the partial-guided or free-hand protocols. [9] [11] Therefore, inexperienced operators may benefit from full-guided implant placement protocol which was confirmed from earlier studies. For example, the study by Rungcharassaeng et al. which evaluates the effect of operator experience on the accuracy of posterior implant placement found that full-guided protocol decreased differences between experienced and inexperienced operators. [26] Similarly, Park et al. found that the use of surgical guide with a full-guided protocol can reduce discrepancies among operators performing implant surgery regardless of their level of experience. [40] In addition, a mesial and distal tooth -supported template which were used in this study for the treatment of single missing teeth was proven in greater accuracy of implant position than with mucosa-supported or bone-supported templates. [16] Thus, where high accuracy is required, the operator should expect to complete all the drilling procedures and implant placement through the surgical guide.

However, several authors mentioned that the computer assisted implantation system does not eliminate the essential of surgical experience and skills. Also, it is not free from complications. A recent published review indicated common complications from using computer-guided implant surgery including template fracture (3.6%), change in surgical plan (2%) and lack of primary stability (1.3%). Hence, if there are any clinical complication, the operators should be convenient shifting to conventional implant surgery. [16] [30] When the accuracy is concerned, it was recommended to choose a surgical protocol that involves a shorter drill, lower sleeve height, and longer drill key, which may improve the accuracy of sCAIS procedures. [32] Nevertheless, the choice is limited in clinical practice because the sleeve height is normally dictated by soft tissue and hard tissue interferences. Some authors noted that guided surgery performed on the mandible has more angular accuracy than on the maxilla. [41] This might occur due to the bone anatomy and bone density; the structure of the mandible is straight with an arcuate shape while the maxilla is in a circular curve shape, which may affect the angulation control. Additionally, some authors mentioned that the more posterior implant, the more chance of deviation. This can occur due to the limited access, inferior visualization, additional step for wider implants. [42] Contrastingly, a study by Machtei et al. mentioned that the mandibular posterior region is more prone to axial deviation. This happen because this area is more difficult to handle from a limit access of buccal soft tissues and restrict the field of vision. [8]

Despite the fact that several studies reported maxilla is susceptible to a deviation than the compact mandible bone. [12] [23] [38] There were no significant

differences found for the linear deviation at the neck or the angular and these were not relevant in clinical practice. [16]

At present, there are multiple available softwares in the field of computer-guided implantation system. The most investigated software was the NobelClinician software and the pristine version NobelGuide (Nobel Biocare, Kloten, Switzerland). Other evaluated 3D implant softwares include SimPlant (Dentsply, Massachusetts, USA), Implant 3D (med3D, Heidelberg, Germany), iDent software (iDent Imaging, Florida, USA), Stent Cad (Media Lab Software, La Spezia, Italy), Codiagnostix (Dental Wings Inc, Montreal, Canada), Facilitate (Astra Tech, Dentsply Implants, Mölndal, Sweden), Dental Slice Program version 2.7.2 (BioParts Prototi- pagem Biomedica, Brasilia, Brazil), Micerium Implant Planning software (Micerium, Avegno, Italy), Ray Set implant software (Biaggini Medical Devices, La Spezia, Italy) and ImplantMaster (I-Dent, Hod Hasharon, Israel [21] However, most studies evaluated the clinical performance in completely edentulous patients and there were scant evaluations conducted in the partially edentulous patients. Moreover, the evaluation of the accuracy of the Implant Studio software (3shape, Copenhagen, Denmark) is deficient. Only one recently published review by Pyo et al. described various assessment methods using the Implant Studio software in order to compare the accuracy between the virtually planned and clinically placed implant position. [43] The reason very limited evidence may be found is because the evaluation needs a special tool which is 'Implant Position Comparer' that is not equipped within the commence software.

As stated in recent study, there were two main techniques to assess the accuracy of dental implant position in Computer assisted implant placement; direct

and indirect method. [43] The first one can be evaluated by superimposing pre-operative CBCT images and postoperative CBCT images with a planned and placed implant in position respectively. The second method is to use an impression technique, which could be reached via impression coping or scan body in order to obtain implant position. After an implant was placed in the oral cavity, the clinician can connect the scan body to the implant with 15 Ncm^2 of torque. Subsequently, scan the scan body includes adjacent teeth by using an intraoral scanner and export the scanned into an STL format file. Afterward, superimpose the scanned placed implant position STL file with the planned implant position and evaluate the implant accuracy by using Computer-guide implant software. [36] [43]

In this research, the author selected the indirect method for two purposes. First, it was used to control factor between coDiagnostiX and Implant studio sample group when comparing the planned and placed implant position because the implant studio software only has indirect method available at the moment while coDiagnostiX has both direct and indirect methods available. The second reason is that this method has the advantage of being able to verify the placed implant position easily and quickly without radiograph. As this study was conducted in patients, an avoidance of exposing extra radiation is favorable. However, the indirect method could be conducted only on just the same day of surgery or after healing period due to the impression coping or scan body has to connect with the implant fixture. The principle is that the osseointegration should be completed prior to the connection in order to prevent the loss of osseointegration. In case the clinicians have to scan the placed implant immediately after the surgery, it was recommended not to connect the scan body with 30 Ncm^2 of torque as it may affect the implant

position after surgery. [36] From author opinion, the stability should be carefully checked before connecting the scan body to the implant fixture either in the day after surgery or the day after healing period. In this study, the scan was done after the complete of osseointegration at around 12 weeks after implant placement confirming by ISQ or *Implant* Stability Quotient more than 70 and periapical radiographic to ensure the adaptability of the scan body and implant platform, avoiding the effect of implant position from excessive torque and blood that could impair the quality of intraoral scan STL file.

From the view point of the author, there are essential key steps to minimize the deviation of the implant position and achieve accurate outcomes with guided surgery template in clinical practice regardless of implant planning software. First, the clinician should validate an adaptability between CBCT image and surface scan image aiming to ensure the adaptability of DICOM file with STL file when superimposed these files in the implant planning program. The next crucial step is to verify the adaptability of the guided template with patient arch because most of deviation were found when stability of template could not be achieved. [37] Lastly, the clinician should be obligated to make each instrument and drill parallel to the guided cylindrical sleeve on the template during the operation.

Limitations

Limitation of the present study included that the accuracy evaluation for coDiagnostiX and Implant studio programs was performed separately. In future studies, the accuracy of both planning software packages should be performed by third party software program. Moreover, the Implant Studio program did not provide

deviation data for the apex of the placed implants, so the accuracy at the apex location was undetermined. However, the three most widely used variables available in both software packages were evaluated, and the deviation at the entry point, deviation in depth, and angular deviation were compared.

Suggested further studies

In consideration of clinical trial, other variables that might affect the deviation of implant should also be considered apart from the influence of coDiagnostiX and Implant Studio software. Therefore, further studies should evaluate other factors that might influence deviation in the clinical situation, such as the surgical instruments, sleeve height, and surgical template design. Moreover, this in vivo study designed the surgical guide template in tooth-borne design, for multiple implants and long-span edentulous ridges should be further investigated for the accuracy. Furthermore, other variables that involve with the surgical guide template may also be further investigated such as material thickness for strength, guide teeth offset for fit, and the quality of the guide milling or guide-printing procedures.

Conclusion

Under the conditions of this clinical study, the following conclusions were drawn. There were no significant differences in the accuracy of implant position between coDiagnostiX and Implant Studio following posterior implant placement performed by inexperienced operators. However, both software program showed similar results with respect to shallower implant depth than planned (0.71 mm and 0.84 mm, respectively).

Declaration of Conflicting Interest

The authors declare that there is no conflict of interest.

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APPENDICES

Appendix A. The data of coDiagnostiX program.

Participants	Error of entry point	Error depth	Error angle	Arch type	Type of implant	Implant diameter	Gender	Age
1	1.16	-0.64	4.6	Max.	BLT	4.1x10	Female	71
2	0.84	-0.73	1.1	Max.	BL	4.8x10	Male	36
3	0.9	-0.64	2.8	Max.	BL	4.8x10	Female	33
4	0.96	-0.8	2.4	Mand.	BL	4.8x10	Female	22
5	0.97	-0.43	4	Max.	BLT	4.1x10	Male	73
6	1.45	-0.9	3.8	Max.	BLT	3.3x10	Female	39
7	1.6	-0.94	6.1	Max.	BL	4.8x10	Female	58
8	1.18	-0.95	4.8	Max.	BL	4.1x10	Female	34
9	1.57	-0.8	5.2	Max.	BLT	4.8x8	Female	23
10	1.15	-1.15	0.6	Mand.	BLT	4.8x10	Male	63
11	0.47	-0.04	2.8	Mand.	BLT	4.1x10	Male	68
12	0.6	-0.5	4	Mand.	BLT	4.1x10	Male	58

Appendix B. The data of Implant studio program.

Participants	Error of entry point	Error depth	Error angle	Arch type	Type of implant	Implant diameter	Gender	Age
1	0.746	-0.71	1.053	Mand.	BLT	4.1x10	Female	61
2	0.592	-0.515	1.7	Mand.	BL	4.8x10	Female	27
3	0.959	-0.927	1.484	Mand.	BL	4.8x10	Female	46
4	1.279	-1.257	4.106	Mand.	BL	4.8x8	Female	47
5	1.097	-0.808	6.512	Max.	BL	4.8x10	Female	35
6	0.881	-0.827	6.503	Mand.	BL	4.8x10	Female	69
7	0.685	-0.659	3.576	Mand.	BL	4.8x10	Female	35
8	0.331	-0.259	7.27	Max.	BLT	4.1x10	Male	47
9	1.23	-0.811	4.446	Max.	BLT	4.1x10	Male	66

10	1.311	-1.283	1.545	Mand.	BL	4.8x10	Male	60
11	1.381	-1.198	4.373	Max.	BL	4.8x10	Male	62
12	1.13	-0.794	2.619	Max.	BL	4.8x10	Male	66

VITA

NAME	Wanwanat Singthong
DATE OF BIRTH	27 May 1993
PLACE OF BIRTH	Chiangmai
INSTITUTIONS ATTENDED	Chulalongkorn University
HOME ADDRESS	The room Phayathai 567/48 Sri-Ayudhaya Rd., Thanon-Phayathai, Rachadhevi Bangkok, 10400
PUBLICATION	A randomized clinical trial on the accuracy of guided implant surgery between two implant-planning programs used by inexperienced operators, THE JOURNAL OF PROSTHETIC DENTISTRY