การเปรียบเทียบความแม่นยำของแผ่นจำลองนำทางผ่าตัดระหว่างชิ้นงานที่ได้จากวิธีสแกนในช่องปาก
กับวิธีสแกนแบบจำลองฟันสำหรับการฝังรากฟันเทียมด้วยการผ่าตัดโดยใช้คอมพิวเตอร์ช่วยเหลือ

นางสาวพฤษพร เกียรติ์เกริกไกร

วิทยานิพนธ์นี้เป็นส่วนหนึ่งของการศึกษาตามหลักสูตรปริญญาวิทยาศาสตรมหาบัณฑิต
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COMPARISON OF THE ACCURACY OF SURGICAL GUIDED TEMPLATE PRODUCED FROM INTRAORAL SCAN TECHNIQUE AND MODEL SCAN TECHNIQUE FOR IMPLANTATION USING COMPUTER ASSISTED IMPLANT SURGERY

Miss Prudsaporn Kiatkroekkrai

A Thesis Submitted in Partial Fulfillment of the Requirements
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พฤษพร เกียรติ์เกริกไกร : การเปรียบเทียบความแม่นยำของแผ่นจำลองนำทางผ่าตัดระหว่างชิ้นงานที่ได้จากวิธีสแกนในช่องปากกับวิธีสแกนแบบจำลองฟันสำหรับการฝังรากฟันเทียมด้วยการผ่าตัดโดยใช้คอมพิวเตอร์ช่วยเหลือ (COMPARISON OF THE ACCURACY OF SURGICAL GUIDED TEMPLATE PRODUCED FROM INTRAORAL SCAN TECHNIQUE AND MODEL SCAN TECHNIQUE FOR IMPLANTATION USING COMPUTER ASSISTED IMPLANT SURGERY) อ.ที่ปรึกษาวิทยานิพนธ์หลัก: รศ. ทพ. ดร. อาทิพันธุ์ พิมพ์ขาวขำ, หน้า.

วัตถุประสงค์: เพื่อเปรียบเทียบความแม่นยำของแผ่นจำลองนำทางผ่าตัดระหว่างชิ้นงานที่ได้จากวิธีสแกนในช่องปากกับวิธีสแกนแบบจำลองฟันสำหรับการฝังรากฟันเทียมโดยใช้คอมพิวเตอร์ช่วยเหลือ

วิธีการศึกษา: ผู้ป่วยที่ต้องการรากฟันเทียมแบบซี่เดี่ยวทดแทนฟันธรรมชาติถูกสุ่มเพื่อรับการผ่าตัดโดยใช้แบบจำลองนำทางผ่าตัดระหว่างชิ้นงานที่ได้จากกลุ่มวิธีสแกนในช่องปากกับ กลุ่มวิธีสแกนแบบจำลองฟันกลุ่มละ 30 ซี่ ผู้ป่วยจะได้รับการผ่าตัดฝังรากฟันเทียมโดยใช้คอมพิวเตอร์ช่วยเหลือทั้งในขั้นตอนการวางแผนการรักษา ออกแบบ และพิมพ์แผ่นจำลองนำทางผ่าตัด ความแม่นยำของตำแหน่งรากฟันเทียมในแนว 3 มิติ จะถูกประเมินโดยใช้ภาพรังสีส่วนตัดอาศัยคอมพิวเตอร์ชนิดโคนบีมร่วมกับคอมพิวเตอร์ซอฟต์แวร์

ผลการศึกษา: ค่าเฉลี่ยการเบี่ยงเบนทั้งเชิงมุมและระยะขจัดเบี่ยงเบนของตำแหน่งรากฟันเทียมทั้งบริเวณฐานและปลายรากฟันเทียมในกลุ่มที่ผ่าตัดโดยใช้แผ่นจำลองนำทางที่ได้จากวิธีสแกนในช่องปากมีค่าน้อยกว่าในกลุ่มที่ได้จากสแกนแบบจำลองฟัน อย่างไรก็ตาม ความแตกต่างนี้ไม่ถึงระดับนัยสำคัญทางสถิติ ($P > .05$).

บทสรุป: แผ่นจำลองนำทางผ่าตัดที่ได้จากวิธีสแกนในช่องปากสามารถทำให้เกิดความแม่นยำของตำแหน่งรากฟันเทียมได้ดีเช่นเดียวกับวิธีสแกนแบบจำลองฟันสำหรับการฝังรากฟันเทียมโดยใช้คอมพิวเตอร์ช่วยเหลือ

ภาควิชา ศัลยศาสตร์ ลายมือชื่อนิสิต .....

สาขาวิชา ศัลยศาสตร์ช่องปากและแม็กซิลโลเฟเชียล ลายมือชื่อ อ.ที่ปรึกษาหลัก .....

ปีการศึกษา 2560

5875824332 : MAJOR ORAL AND MAXILLOFACIAL SURGERY
KEYWORDS: ACCURACY OF SURGICAL GUIDED TEMPLATE / INTRAORAL SCAN / MODEL SCAN / STATIC COMPUTER ASSISTED IMPLANT SURGERY

PRUDSAPORN KIATKROEKKRAI: COMPARISON OF THE ACCURACY OF SURGICAL GUIDED TEMPLATE PRODUCED FROM INTRAORAL SCAN TECHNIQUE AND MODEL SCAN TECHNIQUE FOR IMPLANTATION USING COMPUTER ASSISTED IMPLANT SURGERY. ADVISOR: ASSOC. PROF. ATIPHAN PIMKHAOKHAM, D.D.S.,Ph.D., pp.

Objectives: To compare the accuracy of implant position placed by CAIS technique using surgical guided template produced by intraoral scan and model scan.

Materials and methods: Patients who needed single tooth implant restoration were enrolled in this study and devided into two groups randomly according to the surface scan technique (n=30 each group). Intraoral scans were done using the Trios Scanner (3shape). While, diagnostic casts were scanned by D900L lab scanner (3shape). The templates were design by the clinician using coDiagnostiX software (Dental Wings Inc.). Implant surgery were performed according to fully CAIS protocol. CoDiagnostiX software was used to compare the deviations between planned and placed implant.

Results: Total of 60 implants were treated. The average angular deviation was 2.41°±1.48° and 3.23°±2.09°, the average 3D deviation at platform was 0.87±0.49 mm and 1.01±0.53 mm, while, the average 3D deviation at apex was 1.10±0.53 mm and 1.38±0.68 mm for intraoral scan group and model scan group respectively. Nevertheless, there was no statistically significant difference between groups (P > .05).

Conclusion: The results of this study demonstrated that the accuracy of intra-oral scan technique was similar to model scan technique in all implant dimensions and axis for computer assisted implant surgery.

Department:	Oral and Maxillofacial Surgery	Student's Signature	.....
		Advisor's Signature	.....
Field of Study:	Oral and Maxillofacial Surgery		
Academic Year:	2017		

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CHAPTER 1

INTRODUCTION

1.1 Background and rationales

The most important factor for long term success in single tooth implant restoration is appropriate 3-dimensional implant position related to restoration (1). From previous study, suitable implant positioning has several advantages such as a favorable esthetic and prosthetic outcome and the potential to ensure optimal occlusion and implant loading (2). Moreover, the consideration of correct implant positioning may enable design optimization of the final prostheses, allowing for adequate dental hygiene. Consequently, all of these factors may contribute to the long-term success of dental implants (3).

There are many techniques for evaluation 3D implant position at the time of surgery, for example the estimation by mental navigation or the use of a pilot-drill template (4-6), surgical template technique (7-10) or computer assisted dental implant surgery (CAIS). Nowadays, the most popular traditional method is surgical template technique. This template is produced from diagnostic restoration on stone model. Patient wear this template with some type of marker during the cone beam computerized tomography (CBCT) scan. The quantity of bone can be measured by CBCT data. After that, the template will be transferred to use for surgery. Nevertheless,

the main problem of this technique is low accuracy due to lack of a physical depth and axis control. Consequently, surgeon maybe stagger the drill handpiece during the implant site preparation.

Computer-assisted surgery (CAS) method is regarded as a surgical concept and series of methods, that use computer technology for surgical planning, guiding or performing surgical interventions (14). It is also used in implantology. Computer assisted implant surgery (CAIS) has been recommended to override limitations of the conventional technique (11-13). Angulation and depth of the implants can be simulated before the surgery. CAIS can be classified into static and dynamic (navigation) systems (12, 15, 16). A major limitation of navigation is high cost (17). Whereas static system is more feasible by surgical computer guide template fabrication. Deviations of implant position may be the result from guide template production (18).

Surgical guided template manufacturing for static CAIS can be generated from several methods (18). At present, the process is fabrication from surface scan data (digital impression), includes intraoral scan and model scan together with the CBCT data. However, lack of published article comparing the accuracy of implant position using two types of surface scan data have been reported. Thus, the aims of this randomized controlled clinical trial are to compare accuracy of guided implant position placed CAIS technique using data between intraoral and model scanner.

1.2 Objective

To compare the accuracy of the implant position between using CAIS technique with surgical guide template produced by oral scan and model scan.

1.3 Research question

Are there any differences in accuracy of implant position using CAIS technique between intraoral scan versus model scan production of guide template?

1.4 Statement of hypothesis

H_0 = There is no differences in accuracy of implant position using CAIS technique between intraoral scan versus model scan production of guide template.

H_a = There is a difference in accuracy of implant position using CAIS technique between intraoral scan versus model scan production of guide template

1.5 Research design

Prospective randomized clinical trial

1.6 Keywords

accuracy of surgical guided template, intraoral scan, model scan, static computer assisted implant surgery

1.7 Expected benefits and application

1. The information about accuracy of implant position between patients who had received intraoral scan and model scan could be compared.

2. This study is expected to compare the accuracy between two types of surface scan, intraoral scan and model scan. This could be a suggestion for dentists to choose the proper surface scan technique. If the intraoral scan group shows more accurate results, impression for models will not be necessary. This would lead to minimization of the conventional impression procedure. In contrast, if there is no difference in accuracy between the two groups, conventional impression procedure will be enough for guided surgery.

1.8 Conceptual framework

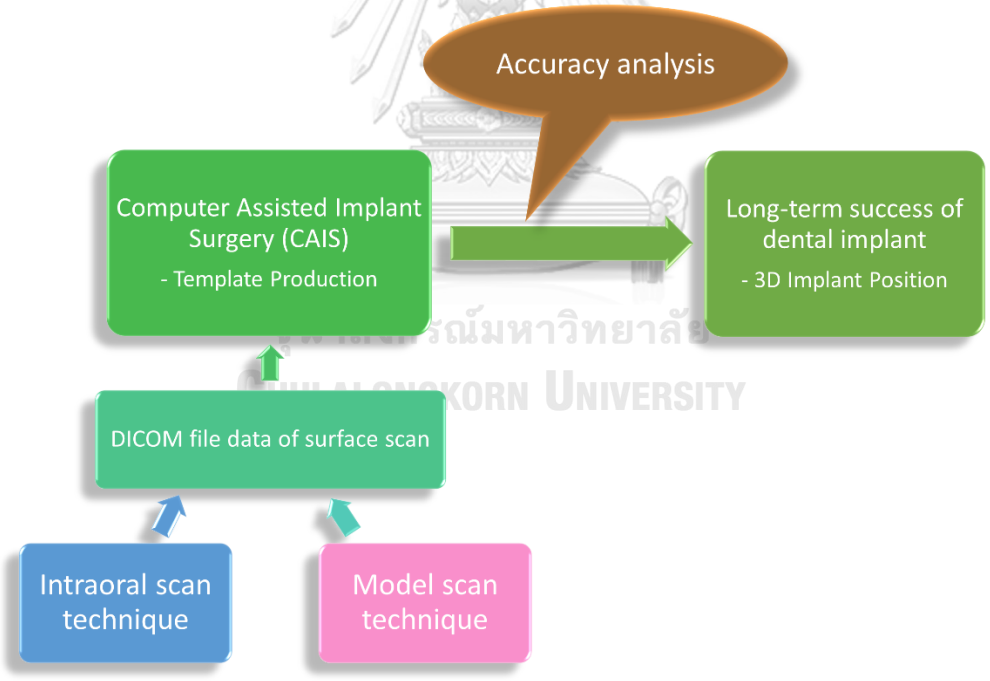


Figure 1 Conceptual framework

CHAPTER 2

LITERATURE REVIEW

2.1 Dental implants

A dental implant (also known as an endosseous implant or fixture) is a surgical component that interfaces with the bone of the jaw or skull to support a dental prosthesis such as a crown, bridge, denture, facial prosthesis or to act as an orthodontic anchor. The basis for modern dental implants is a biologic process called osseointegration where materials, such as titanium, form an intimate bond to bone. The implant fixture is first placed, so that it is likely to osseointegrate, then a dental prosthesis is added. A variable amount of healing time is required for osseointegration before either the dental prosthesis (a tooth, bridge or denture) is attached to the implant or an abutment is placed which will hold a dental prosthesis.

Success or failure of implants depends on the health of the person receiving it, drugs which may result in compromised osseointegration (19) and the health of oral tissues. The amount of stress that will be put on the implant during normal function is also evaluated. Planning the position and number of implants is key to the long-term health of the prosthesis since biomechanical forces created during chewing can be significant (20). The prerequisites to long-term success of osseointegrated dental implants are healthy bone and gingiva. Since both can atrophy after tooth extraction,

pre-prosthetic procedures such as sinus lifts or gingival grafts are sometimes required to recreate ideal bone and gingiva.

The final prosthesis can be either fixed or removable. In each case an abutment is attached to the implant fixture. Where the prosthesis is fixed, the crown, bridge or denture is fixed to the abutment with either lag screws or dental cement. Where the prosthesis is removable, a corresponding adapter is placed in the prosthesis so that the two pieces can be secured together.

The risks and complications related to implant therapy are divided into those that occur during surgery (such as excessive bleeding or nerve injury), those that occur in the first six months (such as infection and failure to osseointegrate) and those that occur long-term (such as peri-implantitis and mechanical failures). In the presence of healthy tissues, a well integrate implant with appropriate biomechanical loads can have 5-year plus survival rates from 93 to 98 % (21-23). Moraschini *et al*. 2014 conclude that success rate of dental implant over 10 years was 96.5% and over 20 years was 91.2% (24). Moreover, there are several factors that are quoted as resulting in implant success, such as clinician, medical or local factors.

2.2. Local factors relate to implant success

2.2.1 Implant position and spacing

Preserving an adequate blood supply to the bone is critical to dental implant success; therefore, it is essential to maintain adequate separation between implants

and natural teeth (25). Proper evaluation of 3D tooth position, angulation, and restorative space is essential during treatment evaluation for preoperative assessment of implant sites. Positioning of single implants within the dental arch is challenging considering the proximity to adjacent tooth roots, vital structures, occlusal plane, and relative position within the arch. In general, there should be a minimum separation of 3.0 mm between a natural tooth and an implant to preserve the blood supply to the natural tooth's periodontal ligament (25). The clinical evidence suggest that implants should be spaced 4.0–7.0 mm apart to avoid bone necrosis (25, 26). Falling within certain defined guidelines, recommendations are based on generally accepted criteria (Table 1, Figures 2 and 3) (27-30).

Table 1 Recommendation minimum distance for single implant (27-30)

Position	Distance (mm)
Implant to tooth	1.5
Implant to vital structure	2.0
Implant to implant (fixed restoration)	3.0
Implant to facial/lingual bone	1.5

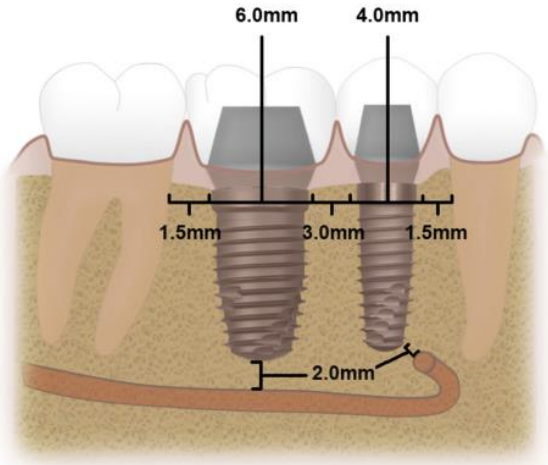


Figure 2 Tangential view presents recommendation of the distance between two implants and implant to adjacent structure (27-30)

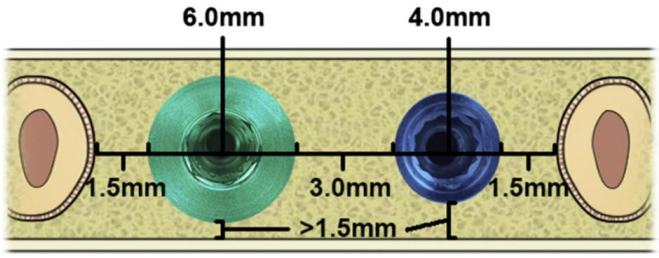


Figure 3 Axial view presents recommendation of the distance between two implants and implant to adjacent structure (27-30)

2.2.1.1 Implant complication relate to malposition

Appropriate implant position is an crucial factor for the long-term success of implant (1). Inadequate attention to analyzing the restorative space can lead to problems such as an over-contoured restoration, artificially opened occlusal vertical dimension, and the need to perform additional surgical and restorative procedures (31-34). These complications can be prevented by

planning the appropriate treatment, proper implant site preparation according to final restoration (35).

2.2.1.1.1 Mis-axis problem

Implants that are inclined too far facially are often associated with recession of the facial mucosa. Complications from mesio-distal mis-axis are including, restriction of implant or abutment impression by obstruction of impression copings and damage to adjacent tooth (Figure 4), insufficient implant-adjacent tooth root distance followed by interproximal marginal bone loss, interdental papilla loss and food impaction.

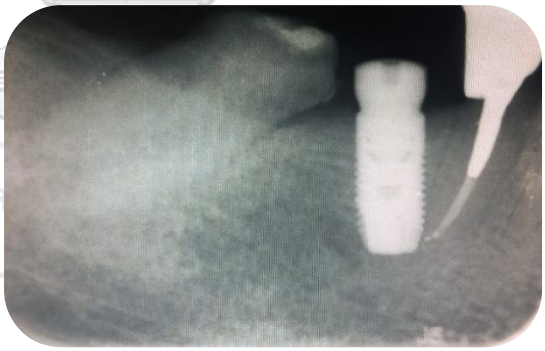


Figure 4 Mis-axis implant leads to damaging of adjacent tooth root

If the axis problem is minor, the axis problem can usually be corrected by prosthetic means using angled abutments which are available for most implant systems. If the axis problem is severe and if it is combined with a facial malposition of the implant shoulder the

esthetic complication is usually very difficult or impossible to resolve. However, in the majority of cases, the most effective treatment is to remove the implant, augment the site, and place a new implant in the correct position (36).

Distribution of forces on implants is must be adhered remarkably along the implant (26, 37, 38). Off-axis inclination be capable of the factor that contribute to overloading prosthesis (20). Implant failure is a consideration if the axis change exceeds 25 degrees, because offset loading of this type may lead to shearing forces that the bone cannot tolerate (25).

2.2.1.1.2 Mesio-distal malposition

Implant, which is placed too close to an adjacent tooth, can cause a reduced papilla at the adjacent tooth, and was first described by Esposito *et al*. 1993 (39). This complication is mainly caused by the development of a crestal bone modeling process during healing and after implant restoration. This biologic phenomenon is routinely observed around commonly used implants such as the Brånemark system or the Straumann implant system, and results in what is often termed a “bone saucer”. This saucer has a horizontal component of 1.0–1.5 mm, whereas the vertical component measures around 2–3 mm. Thus, the clinician has to keep a distance of at least 1.0 mm or

preferably 1.5 mm to the root surface to avoid such a complication. If an implant is placed too close to a root surface, a reduced papilla height will result, since there is not enough space for the soft tissues to develop. Such situations cause a disturbed emergence profile of the implant restoration, although the correct mesiodistal position is only altered by approximately 1 mm. When the mesiodistal malposition of the implant is extreme and differs by 2–3 mm from the ideal prosthetic position, this can lead to significant and permanent loss of hard- and soft-tissue support with extremely adverse esthetic outcomes. Moreover, William *et al* (40) performed a review of the literature to determine local risk factors for implant therapy. They concluded that when an implant is placed within 3 mm of the adjacent tooth, proximal bone is at risk. Two clinical studies (both prospective clinical trials) found statistically significant increase proximal bone loss at neighboring teeth following implant placement close to adjacent tooth (< 3 mm) (41, 42).

2.2.1.1.3 Bucco-lingual malposition

For buccolingual implant position, buccal and lingual bone thickness around implant should be at least 2 mm (43). Buccolingual malposition of an implant can also cause two different complications. The first complication occurs if the implant is positioned too far

palatally. This will often lead to a ridge-lap design of the implant crown. While this does not always lead to an esthetic complication, it may make it difficult for the patient to maintain optimum plaque control, with subsequent long-term implications for the health of the peri-implant tissues. If the palatal malposition is combined with deep placement, it can sometimes be difficult to seat the abutment because of the thick facial and palatal mucosa. Patients may also complain that the palatal surface of the implant crown feels bulky.

The second complication is a recession of the facial mucosa if the implant is clearly positioned too far facially. This can cause severe esthetic complications, since the harmonious gingival course is significantly disturbed. These complications have frequently been observed in patients with immediately placed implant (44-49). Some of these studies clearly showed that the facial malposition is a risk factor for the development of a mucosal recession (46, 49).

2.2.1.1.4 Corono-apical malposition

For occlusogingival implant position, the implant shoulder should be placed approximately 3 mm toward apical to the gingival margin at midfacial of the virtual restoration (50). Corono-apical malposition can cause two different esthetic complications. If the

implant is not inserted deep enough into the tissues, the metal implant shoulder can be visible, causing an unpleasant esthetic outcome, although no recession of the mucosa is present.

The more common complication is an implant that is placed too deep into the tissues. This apical malposition can cause recession of the facial mucosa (Figure 5), if the implant only has a thin facial bone wall at implant placement. Following restoration, this thin bone wall is resorbed during the bone modeling process, since the already discussed bone saucer is a circumferential phenomenon. This leads to bone resorption not only at the mesial and distal aspect of the implants, as seen on the radiograph (Figure 6), but also on the facial and palatal aspect. Bone resorption on the facial aspect can lead within a few weeks to a recession of the facial mucosa. Small and Tarnow 2000 (51) reported the development of a mucosal recession in about 80% of the patients, on average of about 1 mm. The recession can be more pronounced if an apical malposition is combined with a facial malposition.

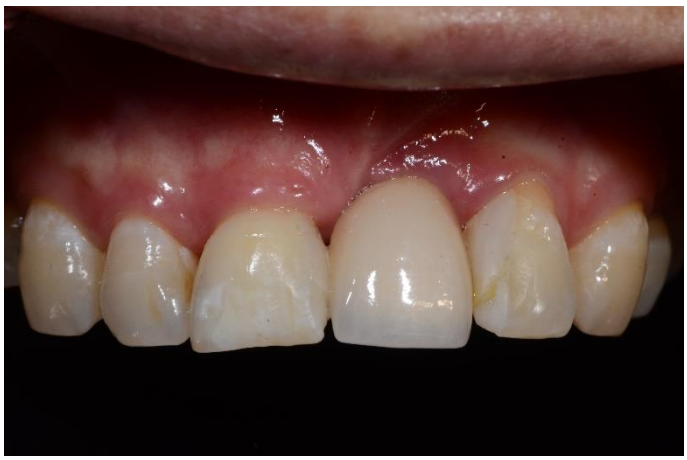


Figure 5 Gingival recession of tooth No.21 due to too deep implant position

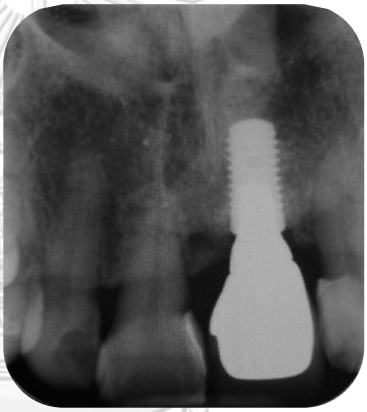


Figure 6 Bone resorption at the mesial and distal aspect of the implants due to too deep implant position

Furthermore, too deep implant position can cause violation of apical anatomical structures. Dental implants within the maxilla have unique and specific boundary conditions to be cautious. For anterior implants, the location and size of the nasopalatine canal and foramen should be identified at the midline. The nasal floor is most commonly seen in the anterior regions. For implants distal to the midline, the

location, boundary, and morphology of the maxillary sinus floor should be assessed.

Excessive apically position of mandibular implant can lead to serious and permanent complications. For the mandible, the boundary conditions are the proximity and locations of nerve and/or vascular canals. The most common is the pathway of the inferior alveolar nerve (IAN) canal, which limits the height of the available bone in most posterior mandibular implant cases. Injuries of the IAN canal can lead to permanent paresthesia of that side of the patient's jaw, teeth, and lips. IAN canal anomalies are also possible, such as bifid canals that can further limit implant placement potential. The location of the mental foramen exit point of the inferior alveolar canal should be identified, and a careful evaluation should be done to determine the presence and extent of the anterior loop. In fact, the IAN canal may extend significantly beyond the mental foramen as an intra-osseous anterior loop. The presence of symmetric anterior loops can be as frequent as 76% to 88% (52). Placing implants anterior to the mental foramen does not protect from violation of prominent anterior loops; the functional consequences could include paresthesia of the anterior mandibular teeth if present. Anterior projections or incisive branches of the inferior

alveolar canal can also be present and may or may not pose problems with implants placed anterior to the mental foramen.

Another canal to consider is the median lingual vascular canal located at the lingual midline of the mandible. Hemorrhages can also occur that lead to serious complications after the invasion of this important anatomic structure, in some cases reported to be fatal (53). Jeopardizing of this canal can lead to serious hemorrhagic situation (54).

2.2.2 Periodontal health might predispose peri-implantitis

Oral bacteria, along with inadequate dental care and oral hygiene, it promotes the risk for bacterial contamination of the implant site (26, 55). Poor oral hygiene induces plaque formation and, in severe cases, the establishment of calculus and sub and supragingival calculus deposits. The orientation of suprabony connective tissue fibers surrounding dental implants makes them particularly susceptible to plaque accumulation and bacterial attack. If the disease processes and their causes are not eliminated, the initiation of inflammatory processes due to bacterial ingress, plaque accumulation, and/or calculus formation ultimately leads to implant failure (20).

Keratinized soft tissues is factor that might predispose peri-implantitis. Inflammation and plaque accumulation to be statistically higher in keratinized and attached mucosa widths < 2 mm, whereas the absence of adequate keratinized mucosa had little or no impact on alveolar bone level (56). Implants in area < 2 of

keratinized tissue also showed significantly higher mean alveolar bone loss than Implants in area ≥ 2 mm (57).

2.2.3 Patient 's occlusal pattern

Para-functional habits (i.e. bruxism, clenching and grinding) are potential risk factors for peri-implantitis and dental implant failure (58). Bruxism causes occlusal overload and consequently alveolar bone loss around dental implant. Detection and elimination of the main bruxism reason is necessary before implant treatment (59).

2.2.4 Primary implant stability

Esposito *et al*. (60) performed systematic review of the literature, which included randomized controlled trials looking at implant success rates in immediate, early, and conventionally loaded root-form implants. They concluded that a high degree of primary implant stability seems to be one of the prerequisites for successful immediate/early loading.

Orenstein *et al*. 2000 (61) conducted a prospective multicenter clinical study of 3,111 implants in 800 patients in which they evaluated the 3-year postplacement survival of 89 implants (HA-coated) that exhibited clinical mobility at the time of placement. Mobility was assessed during the surgical procedure by gently applying pressure to the implant to see if it could be depressed or rotated. Survival was defined as clinically stable and free of associated pain and/or infection. Survival rates were

reported for two periods: from placement to 36 months and from prosthetic loading to 36 months. The latter eliminated early failures and resulted in higher survival rates. Implant survival was 78.8% from placement to loading and 95.9% from prosthetic loading to 36 months. Implant mobility at placement was significantly related to 3-year survival ($P < .001$).

Long term success of dental implant depends on multiple factors. The one important factor is proper 3-dimensional implant position. Because of malposition of implant, prosthodontic or surgical complication can occur. Consequently, computer assisted surgery for dental implant may be the technique to improve the accuracy of implant position.

2.3 Computer assisted implant surgery (CAIS)

Traditional surgical technique of dental implant placements involves careful preoperative planning (62), open flap access, osteotomy of the site adhering to well-established surgical protocol, followed by proper wound closure. One of the major disadvantages of this method is that the systems always required a scanning template, with a radiopaque prosthetic design, to be made before the CBCT. On the other hand, computer assist surgery (CAS) for dental implant placement, clinician can decide implant position after a diagnostic CBCT to apply guided surgery. This term is also represented computer-aided dental implantology, computer-assisted dental implant intervention, image-guided surgery or guided implant surgery.

Computer assisted implant surgery (CAIS) includes static and dynamic system (12, 15). Static system uses computerized tomography (CT) generated 3D printed (stereolithography) templates, with sleeves (metal cylinders) and a surgical system that uses coordinated instrumentation to place implants with the help of the guided template. Treatment planning is used in conjunction of CT images with surface scanning data. Special computer software which allows visualization and manipulation of the images of the patient's jaw bone and surrounding tissue makes possible the most accurate approach to implant surgery. Digital software will allow the user to place a virtual analog of the proposed implant at the best position and angulation follow prosthetic driven concept. The software provide measurement tool for ascertain the distance between implant and previously mentioned structures. This visualization allows for rapid site analysis with predictable treatment planning whereby the surgeon can order specific implant diameters and sizes, healing abutments, and provisional crowns. Implant position is dependent on the template without the ability to change implant position while performing surgery. Static in this case is synonymous with a predetermined implant position without real-time visualization of the implant preparation site as the site is being developed. This technique offers several benefits over the conventional approach. Computer-guided surgical templates allow surgeon to perform osteotomy site preparation in more accurately and efficiently (63-65). In addition, it is also reported that less patient discomfort than freehand method (66).

Dynamic (navigation) surgery is the use of a system that allows the surgeon to visualize implant site development while the drills are in function. Deviations from the predetermined plan can be seen in “real time” and changes to the plan can be made at the time of surgery (67). Surgeons are not forced to abandon a plan should they desire to make a change. Full guidance is possible, as real-time visualization and adjustment of position can be made at any time (68).

Systematic review by Jung *et al*. 2009 (12) stated that the static systems have the tendency to be more accurate than the dynamic approaches. In the dynamic approach, the osteotomy and implant insertion can be changed during the surgery. Thus, the osteotomy has then no other guidance than the surgeon’s vision. Therefore, no true comparison is possible between the planned and placed implant position.

2.3.1 Static CAIS

Aforementioned above, static CAIS for dental implant is the technique which use computer software for surgical planning and performing the surgery. The position is dependent on the template. No intraoperative implant position changes can be done. Thus, templates play important role for static CAIS. According to this technique, templates are computer-designed and stereolithography-generated surgical guided stent. Sleeves, metal cylindrical tubes within the drill guides template assist in transferring the axis by orienting the drill in the exact planned direction (69).

2.3.1.1 Factors influence the accuracy of static CAIS

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

A guide template can be tooth, bone, or mucosa supported (Figure 7). The choice is primarily made on the number of remaining teeth for support of the template and on the need/wish for a flapless approach. Whenever template is planned to be supported by the oral mucosa, surgical technique must be performed with a flapless surgical approach (mucosal-supported). Template can be supported by the bone of the patient (bone-supported), which requires the use of an open flap technique to expose the underlying bone. On the condition that there are remaining natural teeth, the template can be supported by teeth (tooth-supported).

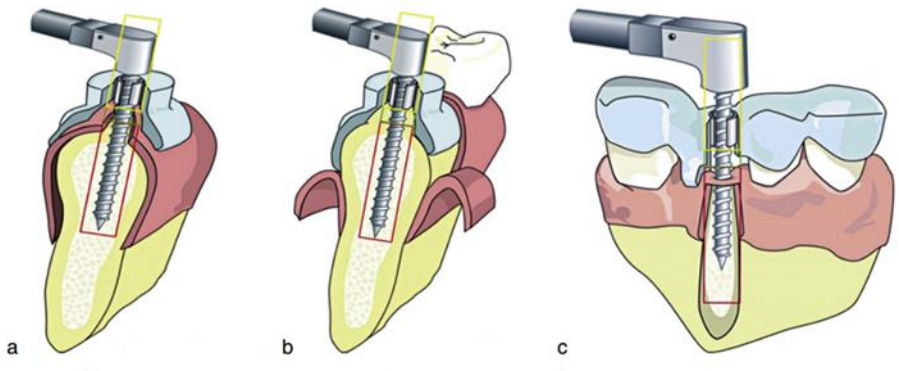


Figure 7 Type of guide supported template

a = mucosal-supported; b = bone-supported; c = tooth-supported (70)

The tooth supported surgical guide are perfect for minimal invasive surgery. Since all the planning has been finished and the bone has been evaluated extensively, it is not necessary to create flap operation for insert the drill and the implants. A small punched hole through the mucosa is enough to position the implants accurately. The template should be stable and rigid when in the correct position. If the arch treated has remaining teeth, the template should fit over and/or around enough teeth to stabilize it in position. Tooth-supported guides tend to be slightly more accurate than mucosa-supported and bone-support-guides, but the differences are small (71-74).

2.3.1.1.2 Type of arch (maxilla / mandible)

Behneke *et al*. (2012) (75) studied 132 implants placed in 52 partially edentulous patients using virtual planning software and laboratory-fabricated templates. They reported borderline significant difference was found between maxillae and mandibles for the linear deviation at the tip of the implants, which was larger in the maxillae (0.50 vs 0.40 mm, P = 0.033) but no significant difference at entry point and axis. Though the apical deviation was larger in the upper jaw, the numerical difference amounted to only 0.1 mm in median, that is clinically not meaningful. Ozan *et al* 2009 (76) studied 110 implants

placed in 30 subjects using stereolithographic surgical guides and reported significant difference between maxilla and mandible for the angular deviation (maxilla: 4.58 ± 2.4°, mandible: 3.32 ± 1.9° , p=0.001) and deviation at entry (maxilla: 0.95 ± 0.5 mm, mandible: 1.28 ± 0.9 mm, p=0.028) but not for the deviation at apex.

A larger amount of maxillary deviations of implant position may be explained that upper jaw has lower bone density that is easier to transfer inaccuracies than the compact mandibular bone. The findings should be interpreted with caution because the differences between upper and lower were low magnitude and therefore not clinically meaningful (75).

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

Fully digitally planned guided surgery and prosthetics can result in performed in two visits without the need for conventional impressions, laboratory procedures and advanced clinical skills (77). Behneke *et al*. 2012 (75) studied the accuracy of CT-generated guide surgery for different sections of the implant surgery. The fully guided placement meant that the implants were inserted through the sleeves

into the guided osteotomy using a special implant carrier which fit the internal diameter of the guide sleeves. Freehand placement meant that the templates were used for controlling all of the osteotomy procedure and the implants were inserted manually without a surgical guide. Freehand final drill meant that templates were used for supported osteotomy up to the standard diameter (4–4.1 mm). The site development for implants with a wider diameter was performed manually. The implants were set without a surgical guidance. He reported that significant differences were found at all aspects of measurement (implant platform level, apex level, and angle). The highest deviations were found in the freehand final drilling group. Moreover, surgical templates may interfere with effective use of the drills in the posterior jaws segments especially in the patient with limited mouth opening till the placing of both surgical templates and drills are not possible. Therefore, the templates may be used as partial guides (only for the initial steps of osteotomy) but this 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 (at shoulder: 0.52 (0.97), 0.30 (0.78), and 0.21 (0.60) mm respectively, at apex: 0.81 (1.38), 0.47 (1.30), and 0.28 (0.77) mm respectively). The result shows that an increased

in the number of sleeve-guided site preparation steps compensate for freehand preparation steps result in higher accuracy of implant placement.

2.3.1.1.4 Accuracy of the CT image

Multi-slice Computed Tomography (MSCT) is widely used for accurate preoperative implant position planning and navigation in maxillofacial surgery (11, 78). However, the development of Three-Dimensional (3D) imaging led to the introduction of Cone-Beam Computed Tomography (CBCT), also known as Digital Volume Tomography (DVT) (79). The benefits of CBCT scanning include the reduction the field of view (FoV) of the exposed area, which reduces the amount of radiation dose to the patient, available to high resolution of images, faster scanning time, reduced image artifacts. Furthermore image in dicom file type from CBCT can be converted and imported into several programs for further interpretation or analysis (80).

Kobayashi *et al.* (2004) (81) studied error from measurement of distance on 5 cadaver mandibles using Spiral Computed Tomography (SCT) and Cone-Beam Computed tomography (CBCT) and reported significant difference between the 2 methods. The average measurement error was 0.36 ± 0.24 mm (2.2%) with SCT and 0.22 ± 0.15

mm (1.4%) with CBCT (P<0001). CBCT was shown to be a useful tool in preoperative evaluation for dental implants because of its high resolution and the relatively small field size of its images.

Moreover, clinical accuracy of surgical guide template can result from 2 major parts, CBCT data and surface scanning data. Inexact positioning of the template affects accuracy, which is more affected by a translational movement than a rotational one (82).

2.3.1.2 Procedure for fabricating the template

There are two techniques for fabrication the template. The first method is precision milling of radiographic template by CAD/CAM software, and a model-based technique using a special laboratory device (parallelometer) (83). starts by study prosthesis is fabricated and duplicated in radiopaque acrylic resin to serve as a scanning template. Axial images were obtained by cone-beam CT and transferred to planning software that provides real three-dimensional (3D) information for planning implant positions. Once the final position of the implant was defined, preoperative data such as implant size or the distance from anatomical structures were recorded. The position of the scanning template could be detected by an automatic search of three integrated titanium markers, allowing calculation for the virtual planning of the implant position. The technician remounts this template into a special

laboratory appliance, according to coordinates of each virtual implant position. The scanning template is then drilled step-by-step for each implant position, as defined by the different coordinates. The drilled template is then prepared with sleeve with varied channel diameters (2 mm, 2.5 mm, or 3mm) because of different drill sizes. During surgery, this template is used as a drill guide.

Another method is stereolithography (rapid prototyping or 3D printing) which was firstly introduced by Charles W Hull, 1986 (84). Once the implant is virtually planned, surface scanning data is imported to incorporated to implant planning. After that, surgical guides template is designed and fabricated with polymerization of a photosensitive liquid acrylic through a series of layers (stereolithography or 3D printing). Hence, surface scanning data is significant for accuracy of the template. Although several studies have been reported using the stereolithography method, there are no evidences to support the superiority of any of these two techniques (63, 85).

Some factors should be considered before producing the template. The planned implant length can be limited, due to insufficient interarch space during surgery (patient limitation). The planning might lead to a template involving the use of drill lengths that are not directly available. Furthermore, sufficient interimplant or tooth-implant distance should be foreseen to be able to place the sleeves in the guide with sufficient material to prevent fracture of the guide (hardware limitation).

2.3.1.3 Digital impression / Surface scanning

CBCT imaging information of hard tissues is highly accurate, but the information for soft tissue is inaccurate. Moreover, CBCT data sometimes contain artifacts of metal material, especially at the tooth level. A tooth supported surgical guide template is based on the adjacent teeth. For this reason, surface scanning technology incorporated to implant planning software packages is increasing in popularity. With surface scanning, stone models or intraoral scans provide soft tissue profile information as well as accurate information of tooth contours because surface scanned models are scatter free. When using surface scan technology, 2 scans are required, one of the patient using the radiographic guide and a second one of a scanning scanned plaster cast or intraoral scan. The scanning system provides STL (Standard Tessellation Language) files. These STL files are imported into the planning software where the geometries of the structures are semi-automatically recognized. The files can be used not only to define soft tissue and teeth contours but also to fabricate stereolithographic models and surgical guides. Nonetheless, implants and abutments can be virtually planned based on the information acquired of both soft and hard tissues, which greatly facilitates the immediate loading and restoration of implants in selected cases (86).

Recently, intraoral scan technology play an important role for restorative and prosthodontic digital workflow that seems to gain popularity (87). Nevertheless, a few published articles reported the usage of intra-oral scan data for fully digitally planned guided surgery and prosthetics that can thus be performed for implant surgery. Only one preliminary clinical study reperted by Derksen, *et al.* (2014) (88) showed accuracy of CAIS with surgical guided template based on intra-oral scanner. The study compared the 3D positions of 12 planned and placed implants in the posterior area. coDiagnostiX 9 software (Dental Wings GmbH, Ghemnitz, Germany), in which evaluations were done with a second intra-oral scan of the placed implants using scan bodies. The preliminary results of this study indicated that applying CAIS with the use of intra-oral scanner might be a feasible option if placing dental implants.

2.3.1.4 Accuracy of static CAIS

Accuracy is defined as the deviation between the position of the ‘planned’ and the ‘inserted’ implant in patient ‘s oral cavity (18). The accuracy is most often verified via postoperative CBCT, through dedicated software that allow the matching of preoperative and postoperative implant positioning. Alternatively, preoperative and postoperative master casts can be compared (‘model matching’) (89). The accuracy is commonly investigated at three or four parameters: deviation at the entry point, deviation at the apex, deviation

of the long axis (angulation) and deviation in depth. More recently, additional attention has been given to deviations in mesio-distal and bucco-lingual direction (18, 90).

For static computer assisted implant surgery, one can distinguish different modalities regarding the procedure for fabricating the drill guides such as stereolithography (rapid prototyping) or the use of mechanical positioning devices that convert the radiographic template to a surgical one by executing computer transformation algorithms (12). The different computer guided systems can also be differentiated in terms of their respective design for the drill guidance through the template. Some systems allow a guided implant placement (91-93) whereas in other systems the implants are installed without using a guided device (94-96) or after removal of the template. Some systems use pre-installed reference points such as mini-implants (93, 97) while others use different reference markers (e.g., gutta percha markers on the CT imaging) or no references for performing the procedures. These variations make it extremely difficult to draw a clear line in comparing the different systems. For this reason, a clear description on every system and their variation in use and precision can be beneficial to clinicians who are interested in these techniques.

In addition, different accuracy measurement techniques and terms have been introduced in the literature in the comparison of planned implant

positions to actual inserted implants. Some use baseline criteria such as entry or apical point while others use 3D coordinates (e.g., x-, y-, and z-axes), making it more challenging to conduct a unified comparison.

Up to now, it remains unclear how much inaccuracy can be accepted. The literature seems to indicate that one has to accept an inaccuracy of 1.5 mm which is clearly less than for non-guided surgery (Vercruyssen *et al*. 2014) (4). The improved accuracy obtained with guided implant surgery may provide a better platform for the final prosthetic restoration. Guided implant surgery might also provide a more predictable esthetic outcome, if the preplanned implant positions are transferred precisely into the surgical environment. Furhauser *et al.* (2015) (98) conducted a clinical study using static guided surgery to insert single-tooth implants for the replacement of upper incisors. The inaccuracy was assessed and an evaluation of implant esthetics (Pink Esthetic Score) was performed after a mean follow-up of 2.3 years. Even though guided, a mean deviation at the implant shoulder of 0.84 mm was recorded. The authors also observed that deviations ≥0.8 mm resulted in significantly worse implant esthetics (median PES: 9.5) compared with more accurate implant positions (median PES: 13, P = 0.039).

Several clinical studies using static CAIS system have shown deviation of placed implant position from virtual planned position. Recently, systematic

review by Tahmaseb *et al*. (2014) (3) had been reported the result that total mean deviation of 2,355 dental implants from 14 human clinical studies in 2005 - 2012 was 1.04 mm (95% CI = 0.85-1.24) at platform, 1.45 mm (95% CI = 1.18-1.73) at apex and 4.06 degrees (95% CI = 3.50-4.62) for angle deviation (Table 2). Statistically significant differences were observed when compared between several types of template support (tooth-supported, bone-supported, mucosa-supported). Tooth-supported and mucosa-supported templates seem to have a better accuracy compared to the bone-supported templates. There are 14 studies (total of 1,941 implants) that reported survival and complication rate. After an observation period of at least 12 months, mean failure rate was 2.7% (0% to 10%). Intraoperative or prosthetic complications were reported in 36.4 %, which included: prosthetic misfit (18.0 %), prosthesis fracture (10.2 %), prosthetic screw loosening (2.9 %), template fractures during the surgery (3.6 %), and change of surgical plan (2.0 %).

Most of reviews of scientific literature that using static CAIS system for implant placement in human had shown that the deviation occurred less than 2 mm for linear deviation at platform and apex and less than 6 degrees of angle deviation (Table 2). However, the studies were different in design.

Table 2 Clinical studies of implant accuracy placed by static computer-assisted implant system

Author	Research design	Software -Type of support	Implant number	Deviation at platform (mm)	Deviation at apex (mm)	Angle deviation (°)
Tahmaseb *et al*. 2014 (3)	Systematic review	-	2,355	1.04 (0.85; 1.24)	1.45 (1.18; 1.73)	4.06 (3.50; 4.62)
Di Giacomo *et al*. 2005 (96)	PS	SimPlant	21	1.45 ± 1.42	2.99 ± 1.77	7.25 ± 2.67
Ersoy *et al*. 2008 (94)	PS	StentCad	94	1.22 ± 0.85	1.51 ± 1	4.9 ± 2.36
Ozan *et al*. 2009 (76)	CCT	StentCad	110	1.11 ± 0.7	1.41 ± 0.9	4.1 ± 2.3
Arisan *et al*. 2010 (99)	PS	Atasarim -Bone -Mucosa -Tooth SimPlant -Bone -Mucosa -Tooth	279 	 1.70 ± 0.52 1.24 ± 0.51 1.31 ± 0.59 1.56 ± 0.25 0.7 ± 0.13 0.81 ± 0.33	 1.99 ± 0.64 1.4 ± 0.47 1.62 ± 0.54 1.86 ± 0.4 0.76 ± 0.15 1.01 ± 0.40	 5.0 ± 1.66 4.23 ± 0.72 3.39 ± 0.84 4.73 ± 1.28 2.9 ± 0.39 3.39 ± 0.84
Nickenig *et al*. 2010 (63)	CCT	coDiagnostiX	23	BL 0.9 ± 1.06 MD 0.9 ± 1.22	BL 0.6 ± 0.57 MD 0.9 ± 0.94	4.2 ± 3.04
Ozan *et al*. 2011 (100)	CCT	StentCad Classic StentCad Beyond	94 122	-	-	3.73 ± 1.14 5.32 ± 1.96
Platzer *et al*. 2013 (101)	PS	Simplant	15	BL 0.27 ± 0.19 MD 0.15 ± 0.13	-	-
Vasak *et al*. 2011 (102)	PS	NobelGuide	86	BL 0.46 ± 0.35 MD 0.43 ± 0.32	BL 0.7 ± 0.49 MD 0.59 ± 0.44	3.53 ± 1.77
Arisan *et al*. 2013 (103)	CCT	Simplant	CBCT=52 CT=50	0.81 ± 0.32 0.75 ± 0.32	0.81 ± 0.32 0.8 ± 0.35	3.4 ± 1.14 3.3 ± 1.08
Pettersson *et al*. 2012 (104)	PS	NobelGuide	191	0.80 (0.10-2.68)	1.09 (0.24-3.62)	0.26 (0.24-11.74)
Behneke *et al*. 2012 (75)	PS	Implant 3D	Max=87 Man=45	0.27 (0.03-0.92) 0.28 (0.01-0.97)	0.5 (0.03-1.58) 0.4 (0.03-1.15)	1.82 (0.14-6.26) 1.86 (0.07-5.82)
Cassetta *et al*. 2012 (105)	PS	SimPlant	116	1.47 ± 0.68	1.83 ± 1.03	5.09 ± 3.7
Di Giacomo *et al*. 2012 (95)	PS	Sinterstation	60	1.35 ± 0.65	1.35 ± 0.65	6.53 ± 4.31
D'Haese *et al*. 2012 (106)	PS	Facilitate	72	0.91 ± 0.44	1.13 ± 0.52	2.6 ± 1.61
Farley *et al*. 2013 (65)	RCT	iDent Conventional	10 10	1.45 ± 0.06 1.99 ± 1.00	1.82 ± 0.60 2.54 ± 1.23	3.68 ± 2.19 6.13 ± 4.04

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

To complete planning and producing template for CAIS, this system must consist of the imaging data set (which may originate from computed tomography (CT or CBCT)), surface scanning data, specific implant planning software which allows clinician to merge imaging data set with surface scanning data and also 3D printer.

2.4. Planning software for CAIS

At present, third-party software programs are now available from many manufacturer, for example coDiagnostiX (Dental wings inc, Montreal, CA), Implant Studio (3shape, Copenhagen, Denmark), Invivo5 (Anatomage, San Jose, CA, USA), Simplant (Materialise Dental Inc, Glen Burnie, MD, USA) and NobelClinician (Nobel Biocare, Göteborg, Sweden). There are also some companies that provide treatment planning in the proprietary software of the CBCT units such as Galileos system (Sirona Dental Systems, Inc, Charlotte, NC, USA), TxSTUDIO software (i-CATÒ, Imaging Sciences International LLC, Hatfield, PA) and NewTom implant planning software (NewTom, Verona, Italy). coDiagnostiX is intended to be used for pre-operative planning for dental implant installation and restoration. The performance of this software depends on the quality and accuracy of the (CB)CT radiograph as well as the surface scan imported from digital impression. Moreover, post-operative radiograph can be superimposed onto pre-operative plan by treatment evaluation function in this program.

Certain of the computer guided software can also compare of the planned implant positions to the inserted implants position. This is called “accuracy analysis”. Data from this analysis maybe lead to predict the long-term success of the implant.

2.5. Accuracy analysis

For analyzing the accuracy, the planned position of the implant is compared with the actual position of the implant after insertion. Postoperative CBCT scans are imported as DICOM (Digital Imaging and COmmunications in Medicine) file in the coDiagnostix software for analysis. The software automatically identifies the implants in the postoperative scan and places a virtual implant at the exact position (107). The preoperative CBCT data are then superimposed (aligned) with the postoperative scans using automated surface best-fit matching with the iterative closest point algorithm. After matching the preoperative and postoperative scans, alignment of each implant position using the software is performed. Linear and angular differences in implants positions between planning and postoperative results are automatically calculated using this program at the implant’s apex, neck, and angular deviation. Several measuring points are used in the previous systematic reviews (3, 12, 71, 108) for the comparison of these positions: (Figure 8,9)

Angle deviation

1) Angle deviation is deviation between the axis of the implant

Linear deviation

2) 3D deviation at the platform point is closets distance at the platform of the implant, measured at the center of the implant.
3) Platform deviation at mesio-distal axis: distance between the implant platform of actual implant and the virtual planned implant at mesio-distal dimension.
4) Platform deviation at bucco-lingual axis: distance between the implant platform of actual implant and the virtual planned implant at bucco-lingual dimension.
5) Platform deviation at apico-coronal (vertical) axis: distance between the implant platform of actual implant and the virtual planned implant at apico-coronal dimension.
6) 3D deviation at the apex point is closets distance at the apex of the implant, measured at the center of the implant.
7) Apex deviation at mesio-distal axis: distance between the implant apex of actual implant and the virtual planned implant at mesio-distal dimension.
8) Apex deviation at bucco-lingual axis: distance between the implant apex of actual implant and the virtual planned implant at bucco-lingual dimension.
9) Apex deviation at apico-coronal (vertical) axis: distance between the implant apex of actual implant and the virtual planned implant at apico-coronal dimension

Linear deviation at the platform and the apex and the error in the height are measured in mm or μm. The angle deviation is measured in degrees. The deviation of the other points is 3D, though several methods were used to describe the distance between the given points. The most common method is to measure the actual direct distance between the planned and actual point in 3D (closets distance). Other authors made a distinction between the deviation measured in the x, y, and z-axis, where x = buccolingual, y = mesiodistal, and z = apicocoronal deviation. The apicocoronal deviation was frequently expressed as a negative number if the implant was not inserted as deeply as planned (too coronal). Furthermore, in some studies the deviation in a horizontal plane was measured and referred to as the x-, y-error. Furthermore, it was attempted to convert the data as uniformly as possible. Therefore, in cases where axiomatic (x, y, z) measurements were used, the values were converted to 3D deviations using the Pythagorean Theorem (3). Figure 9 illustrates these parameters before conversion.

$$\text{3D dev} = \sqrt{x^2 + y^2 + z^2}$$

Formula 1 3D deviations using the Pythagorean Theorem

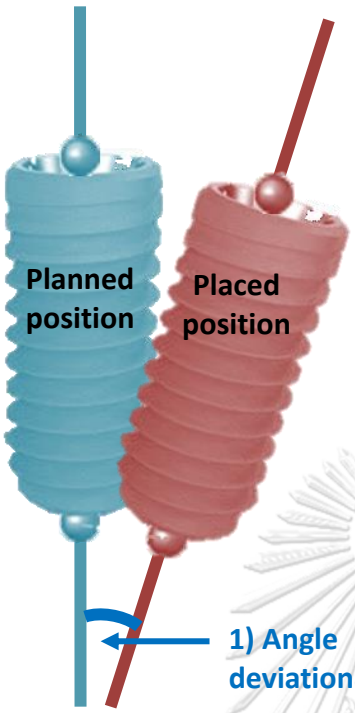


Figure 8 Angle deviation is axis between virtual plan (blue) and placed (red) implant position

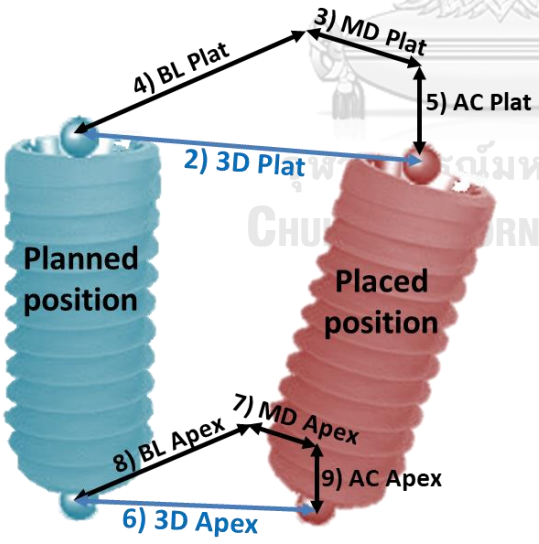


Figure 9 Linear deviation is distance between virtual plan (blue) and placed (red) implant position

2) 3D Plat=3D deviation at the platform point

3) MD Plat=Platform deviation at mesio-distal axis

4) BL Plat=Platform deviation at bucco-lingual axis

5) AC Plat=Platform deviation at apico-coronal (vertical) axis

6) 3D Apex=3D deviation at the apex point

7) MD Apex=Apex deviation at mesio-distal axis

8) BL Apex=Apex deviation at bucco-lingual axis

9) AC Apex= Apex deviation at apico-coronal (vertical) axis

CHAPTER 3

MATERIALS AND METHODS

3.1 Materials

3.1.1 Patients

The samples enrolled in the study were patients who required dental prosthetic substitution with implant placement. This prospective, randomized controlled clinical trial was conducted from June 2017 to February 2018 at the Department of Oral and Maxillofacial Surgery and the Esthetic and Implant Clinic of Faculty of Dentistry, Chulalongkorn University.

3.1.1.1 Inclusion criteria

- Single tooth space in upper and/or lower jaws. The site was chosen for tooth-supported surgical guides, which provided more stable and better fit than tissue-supported guides.
- Extractions completed at least 2 months prior to implant placement
- No pathological mobility of adjacent teeth that supported surgical guide
- CBCT radiograph and clinical examination revealed sufficient bone volume to support the implants.
- No limit mouth opening for placing both surgical templates and drills
- Aged 20 years and over.
- Good general (physical and mental) health at the time of selection.

3.1.1.2 Exclusion criteria

According to completely tooth-supported surgical guided template which provide more stable and better fit than tissue-supported, patients were excluded if there are no teeth distal to the edentulous space bilaterally where present to cross-arch stabilization and mesial and distal tooth support the template. Others exclusion criteria were as follow:

- Patients with interfering systemic diseases such as coagulation disorders, serious cardiac vascular disorders or pregnancy or lactation at the time of enrollment or other significant diseases as judged by the investigator.
- Clinical or radiographic examination presented any pathology in jaw bone.
- Patients on orthodontic appliance
- Pathological mobility of teeth that supported surgical guide
- Patients sustained perioperative complications that make guided implant surgery less precise, such as template fractures, template tilting that can cause mis-alignment of implant position, clinical mobility of implant.

3.1.1.3 Sample grouping

Patient were random into 2 groups, intraoral scan or model scan group, using block randomize technique.

3.1.1.4 Sample size determination

In order to justify the sample sizes for analysis, G*Power version 3.1.9.2 software (Faul, Erdfelder, Buchner & Lang, Germany, 2014) estimates sufficient sample sizes necessary in the comparison of means between two groups. Generally, the level of significance for all statistical tests were set an alpha at 0.05 and power at 0.95. Moreover, effect size d = 1.20 was calculated from mean and SD of angle deviation from this research pilot study (6 implants per groups). According to aforementioned assumptions, the desired sample size is 20 per groups (Figure 10). However, the sample size was adjusted to 30 to compensate for lost subjects during the study. Moreover, the central limit theorem (CLT) (109, 110) established that 30 samples of each groups could be considered sufficiently large samples for normal distribution which is efficacious to parametric statistical analysis.

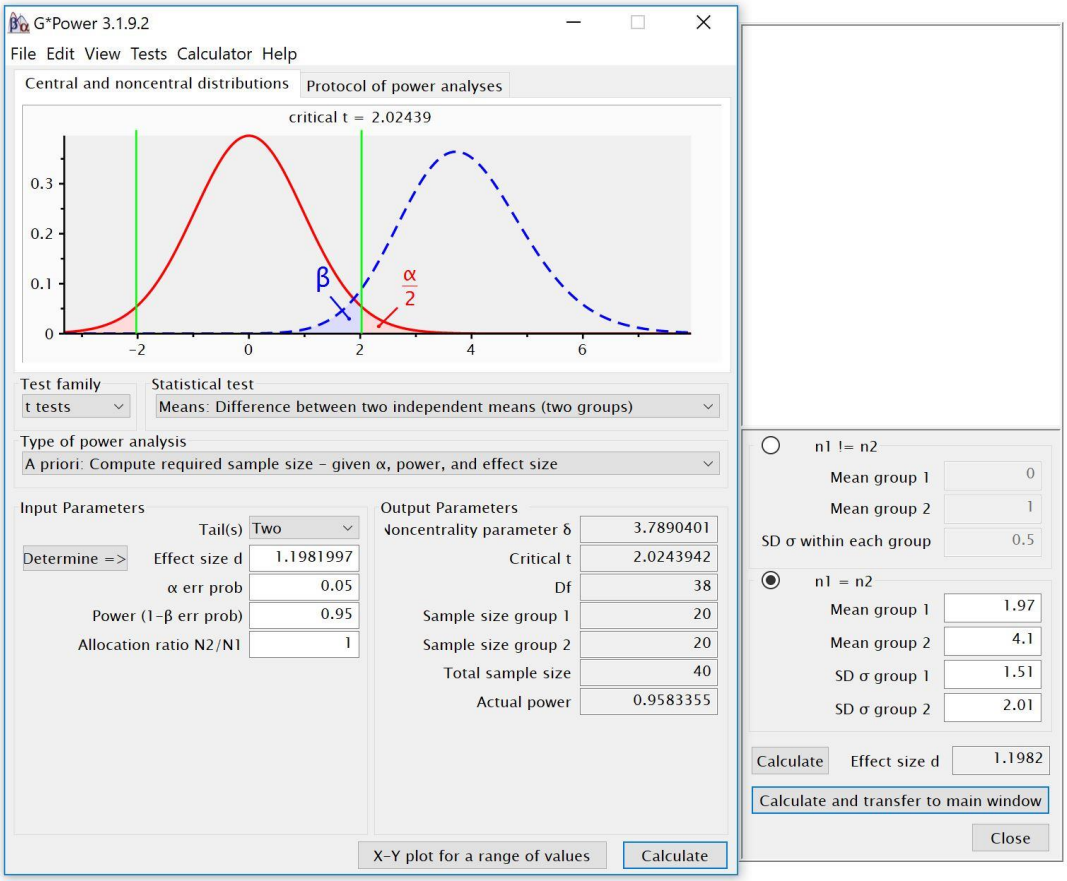


Figure 10 Sample size determination was conducted in G*Power software

(G*Power version 3.1.9.2 software, Faul, Erdfelder, Buchner & Lang, Germany 2014)

3.1.2 Cone Beam Computed Tomography (CBCT) scanner

Accuitomo 170® 3D machine (J. Morita Inc., Kyoto, Japan) for planning and post-implantation.

3.1.3 Surface scanner

Trios® intraoral scanner (3shape, Copenhagen, Denmark) and D900L scanner (3shape, Copenhagen, Denmark)

3.1.4 Impression material

Jeltrate® Alginate Regular Set (DENTSPLY, Pennsylvania, US)

3.1.5 Model fabricated material

Universal G10® Type III model stone (USG Boral Specialty Products, Chicago, US)

3.1.6 Three-dimensional printer and material for digital surgical guided template fabrication

DPPro professional 3D printer and VisiJet MP200 preparation with VisiJet M3 StonePlast organic mixture material (T Dental Lab, Bangkok, Thailand)

3.1.7 Implant

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

3.1.8 Planning and accuracy analysis software

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

3.2 Methods

3.2.1 Ethical consideration

The study clinical protocol was approved by ethical committee of faculty of dentistry Chulalongkorn University (HREC-DCU 2017-022). Written consent were obtained from all patients. The research process and study protocol which are multiple steps of treatment were done as follow (Figure 11).

3.2.2 Guided template production

3.2.2.1 All patients were scanned with cone beam computed tomography (CBCT) (3D Accuitomo 170 machine, J. Morita Inc., Kyoto, Japan). After that, CBCT data were transferred to DICOM format file.

3.2.2.2 To record the configuration of the patients' dentition, edentulous area and mucosa, the surface scan data were derived from two randomized techniques.

For intraoral scan group, full arch intraoral surface scan and subsequent bite-registration scans were done by Trios introral scanner. (3shape, Copenhagen, Denmark).

For model scan group, intraoral conventional impressions were performed with irreversible hydrocolloid (Jeltrate® Alginate Regular Set - DENTSPLY, Pennsylvania, US) and stock tray. ADA Type III model stone (Universal G-10, USG Boral Specialty Products, Chicago, US) was mixed with water, and poured to create the diagnostic models. The casts were scanned by D900L lab scanner (3shape, Copenhagen, Denmark).

3.2.2.3 The Digital Imaging and Communications in Medicine (DICOM) format file of CBCT data were transferred in to the planning software, coDiagnostiX version 9.7 (Dental Wings inc, Montreal, CA) that provides 3-dimensional information for planning implant positions.

3.2.2.4 The Standard Tessellation Language (STL) files of intraoral or model scanning data were import into the program and were registered to the CT image to create alignment between treatment plan and tooth borne surgical guided template.

3.2.2.5 Prosthodontist and surgeon plan appropriate position of the implants. After complete planning, the digital drill guide with sleeves were design. The anchorage teeth location were start from the next more posterior tooth on the ipsilateral side of implant placement to the same tooth position on the contralateral side.

3.2.2.6 All digital surgical guided templates were designed by the same dentist and consequently sent to the dental laboratory for 3D printing the surgical guide (T Dental Lab, Bangkok, Thailand).

3.2.3 Static computer assisted implant surgical procedure and follow-up examination

Only one team of the same another dentist/dental assistance performed all surgeries for both groups. They had prior experience with Straumann® guided implant surgery system. Dentist who performed the surgery was blinded to the surface scan group. Before the surgical procedure start, the fit and stability of surgical guide were verified via inspection windows.

3.2.3.1 Patients were anesthetized by local anesthetic technique with 4% articaine with 1:100,000 epinephrine (Ubistesin Forte 3M ESPE, Seefeld, Germany).

3.2.3.2 Exposure of the alveolar bone by mucosa punch was done. In case of inadequate keratinized mucosa, incision extending to the adjacent teeth then mucoperiosteal flap reflection was performed.

3.2.3.3 Surgical guide template was seated. Prior the start of osteotomy, the retention, stability and adaptation of the template to dentition were verified via inspection window and pressure.

3.2.3.4 Fully guided implant surgery system were accomplished. Implant site preparation were done by sequentially drilling follow guided surgical protocol of the manufacturer. Thoroughly in-depth tapping and profiling osteotomy were also performed in all cases. The implant fixtures were placed through the metal sleeves of surgical guided template into the prepared site. Then insertion torque were recorded.

3.2.3.5 Implant stability (ISQ value) was examined using RFA measurement method to confirm implant stability with Osstell™ ISQ device and type 53 (for implant with NC type connection) and type 54 (for implant with RC type connection) SmartPeg™ (Osstell AB, Göteborg, Sweden). The SmartPeg™ was hand-screwed into the internal thread of an implant. The measurement probe was held still on the buccal side aiming to the top of the

SmartPeg™ at a distance of 1-2 mm. Immediate implant stability quotient (ISQ value) were recorded.

3.2.3.6 Inserting the closure screw or healing abutment.

3.2.3.7 In case of flap operation, flap approximation and suturing were done using the absorbable suture, 4-0 Coated Vicryl® (Ethicon, Johnson & Johnson, Belgium).

3.2.3.8 Routine post-operative protocols for implant surgery included mefenamic 500 mg, three times daily for pain control and amoxicillin 1000 mg twice daily for 5 days, for those who were allergic to penicillin, clindamycin 300 mg three times daily were prescribed to patients. Instruction about wound care, surgical site hygiene, avoidance of crushing force on installed implant. by consideration of each attending surgeon

3.2.3.9 Postoperative CBCT were taken for comparing the planned and achieved positions of the implants. These postoperative 3D data of the implant position can be superimposed onto the preoperative data of the guided planned implants, also using treatment evaluation tool in the same software. The treatment evaluation tool in this software was used to match the virtual planned and the installed (actual) implant position.

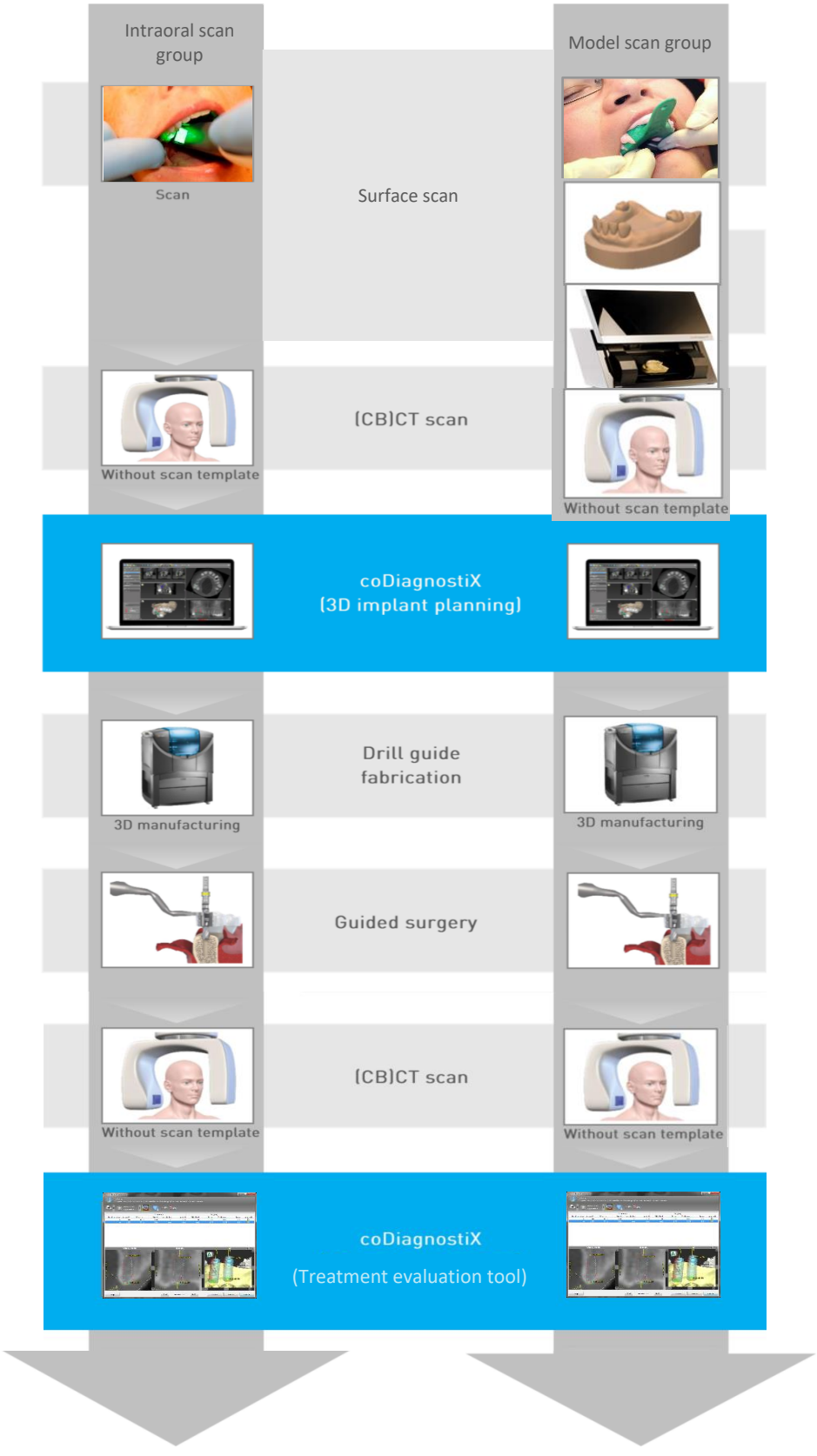


Figure 11 Workflow for research protocol

3.2.4 Data collection and accuracy analysis

Same observer performed deviation analysis for all patients. Postoperative dicom file of CBCT was imported to the planning software. The virtual planned position of the implant was compared with the actual position of the implant after insertion by treatment evaluation tool function (coDiagnostiX™, Dental wings inc, Montreal, CA). The super-imposition of the post-op CBCT with pre-op CBCT data set was performed using the landmark method. Software allows for verification of the result of the fusion using different colourings. In our study, we were able to verify a match for at least three pairs of teeth as landmarks (Figure 12). Two measuring points were used in the studies for the comparison of nine parameters as follow (see Figure 8,9,13):

1) Angle deviation: angle between the axis of actual implant and the virtual planned implant.

2) 3D deviation at platform: direct distance between the implant platform of actual implant and the virtual planned implant.

3) Platform deviation at mesio-distal axis: distance between the implant platform of actual implant and the virtual planned implant at mesio-distal dimension.

4) Platform deviation at bucco-lingual axis: distance between the implant platform of actual implant and the virtual planned implant at bucco-lingual dimension.

5) Platform deviation at apico-coronal (vertical) axis: distance between the implant platform of actual implant and the virtual planned implant at apico-coronal dimension.

6) 3D deviation at apex: direct distance between the implant apex of actual implant and the virtual planned implant.

7) Apex deviation at mesio-distal axis: distance between the implant apex of actual implant and the virtual planned implant at mesio-distal dimension.

8) Apex deviation at bucco-lingual axis: distance between the implant apex of actual implant and the virtual planned implant at bucco-lingual dimension.

9) Apex deviation at apico-coronal (vertical) axis: distance between the implant apex of actual implant and the virtual planned implant at apico-coronal dimension.

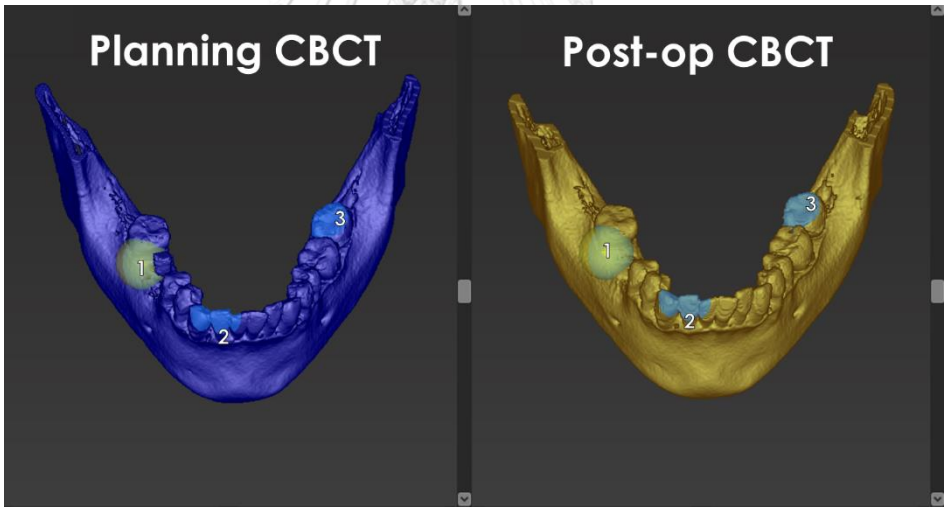
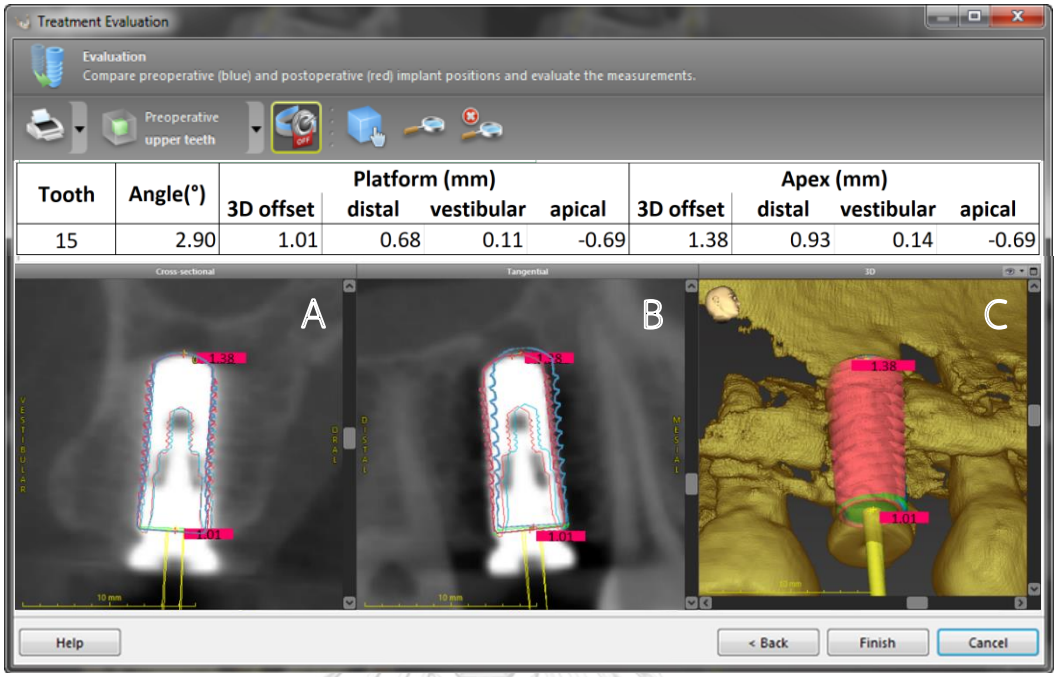


Figure 12 Matching for at least three pairs between virtual planning CBCT and corresponding to post-operative CBCT as landmarks in treatment evaluation tool function in coDiagnostix software



Tooth	Angle(°)	Platform (mm)				Apex (mm)			
		3D offset	distal	vestibular	apical	3D offset	distal	vestibular	apical
15	2.90	1.01	0.68	0.11	-0.69	1.38	0.93	0.14	-0.69

Figure 13 Interface of treatment evaluation tool function in coDiagnostix software

Presentation of three-dimensional implant position accuracy was measured in. Blue = Pre-operative (virtually planned) implant position, Red = Actual (placed) implant position. (A) Cross-sectional view showing bucco-lingual dimension. (B) Tangential view showing mesio-distal dimension. (C) 3D view of planned and actual implant position. 3D deviations at platform and apex are 1.01 and 1.38 mm respectively.

3.3 Reliability tests

To assure that the examiner reported the reliable results, intra-examiner calibration and training by the expert were performed by measuring all the parameters of randomly selected subjects until the results of the expertise and the examiner showed no significant differences. After that, intra-examiner calibration, ensuring the reliability, was achieved by measuring all the parameters of ten randomly selected subjects for two separate times. Two datasets of ten implants were compared to calculate the intraclass correlation coefficients of the postoperative analysis.

3.4 Data entry / analyses

Measurement data were gathered and entered IBM SPSS Statistics software version22 (International Business Machines Corp., New York, US). Association of demographic variables between intraoral scan and model scan groups is shown by Chi-Square test. Normality test, via Shapiro-Wilk test, and the test of equal variance, via Levene's test are done before hypothesis statistical test in order to apply the parametric statistic firstly due to the superior power of test than non-parametric statistic. Therefore, mean difference between planned and actual position were compared between intraoral scan vs model scan group using t-test. P-value < 0.05 were considered statistically significant.

3.5 The conflict of interest

The author declares no support from manufacturers of any materials used and no potential conflicts of interest with respect to the process of this thesis.

CHAPTER 4

RESULTS

4.1 Patient information and demographic data

Patient demographic information appear in table 3. Forty-six patients who received total 60 implants, including implants from pilot study, according to the inclusion and exclusion criteria were recruited. Thirty implants were allocated to intraoral scan group while 30 implants were allocated to model scan group by block randomization. Nineteen patients were male and twenty-seven female with similar in gender distribution both groups. The Patients ranged in age of 28 to 75 years old with a mean age of 56.53 ± 10.55 years. Twenty implants were placed in posterior mandible while 40 implants were place in maxilla (13 at anterior teeth area and 27 at posterior teeth area). The diameter and length of implants used in this study were 3.3NC10, 3.3NC12, 4.1RC8, 4.1RC10, 4.1RC12, 4.8RC8, 4.8RC10 and 4.8RC12. Implants were placed in 3 incisors, 2 canines, 6 premolars and 9 molars. According to Chi-square test, No statistical significant difference of association of demographic variables is found between two groups.

Table 3 Description of patient demographic data according to intraoral and model scan group

Variables	Intraoral (n = 30)	Model (n = 30)	Total (n = 60)	*p-valuea*
Gender				
Male	12	12	24	1.000
Female	18	18	36	
Age mean=56.53 SD=10.55 max=75 min=28				
Under 45 years	3	5	8	0.174
46–64 years	17	21	38	
More than 65 years	10	4	14	
Implant location				0.855
Anterior maxilla	6	7	13	
Posterior maxilla	13	14	27	
Anterior mandible	0	0	0	
Posterior mandible	11	9	20	
Implant dimension ***(mm)***				0.244
3.3x10	2	5	7	
3.3x12	1	3	4	
4.1x8	2	2	4	
4.1x10	17	8	25	
4.1x12	1	0	1	
4.8x8	4	4	8	
4.8x10	3	7	10	
4.8x12	0	1	1	

a: The overall association of patient demographic according to the study and comparison group by Chi-square test statistical significance at 95% confident interval

4.2 Accuracy analysis

Intraclass correlations ranged between 0.76-0.99 for nine measured parameters. Therefore, the results were not affected by human error in performing deviation analysis. Normality test revealed the data were not normally distributed. Consequently, all parameters were tested for difference of means by Mann–Whitney U-test.

4.2.1 Difference in the deviation between intraoral scan group and model scan group

The mean deviation and deviation intensity were compared in order to reveal the association of these between intraoral and model scan of patient's groups. In intraoral scan group, the average angle deviation and SD were 2.41°±1.47°. The average platform 3D deviation and SD were 0.87±0.49 mm. While, the average apical 3D deviation was 1.10±0.53 mm. On the other hand, in model scan group, the average angular deviation was 3.23° (SD: 2.09°). The average platform 3D deviation was 1.01 mm (SD: 0.56 mm). While, the average apical 3D deviation was 1.38 mm (SD: 0.68 mm) (Table 4 Figure 14). Moreover, when compare all parameters between intraoral scan group and model scan group, the results demonstrate quite the same amount of deviations MD, BL and AC (vertical) axis not only platform level but also at apex level in both groups (Table 4). According to Mann–Whitney U-test, no statistically significant difference (P>0.05) was found in all 9 parameters between intraoral scan group and model scan group.

For all axes of deviation, the intraoral scan group reported less deviation than model scan group but unable to show statistical significant difference. MD axis and BL axis presented more deviation at apex than platform. While, AC (vertical) axis at platform in both group showed similar deviation as apex so there was no statistical significant (Table 4 Figure 15).

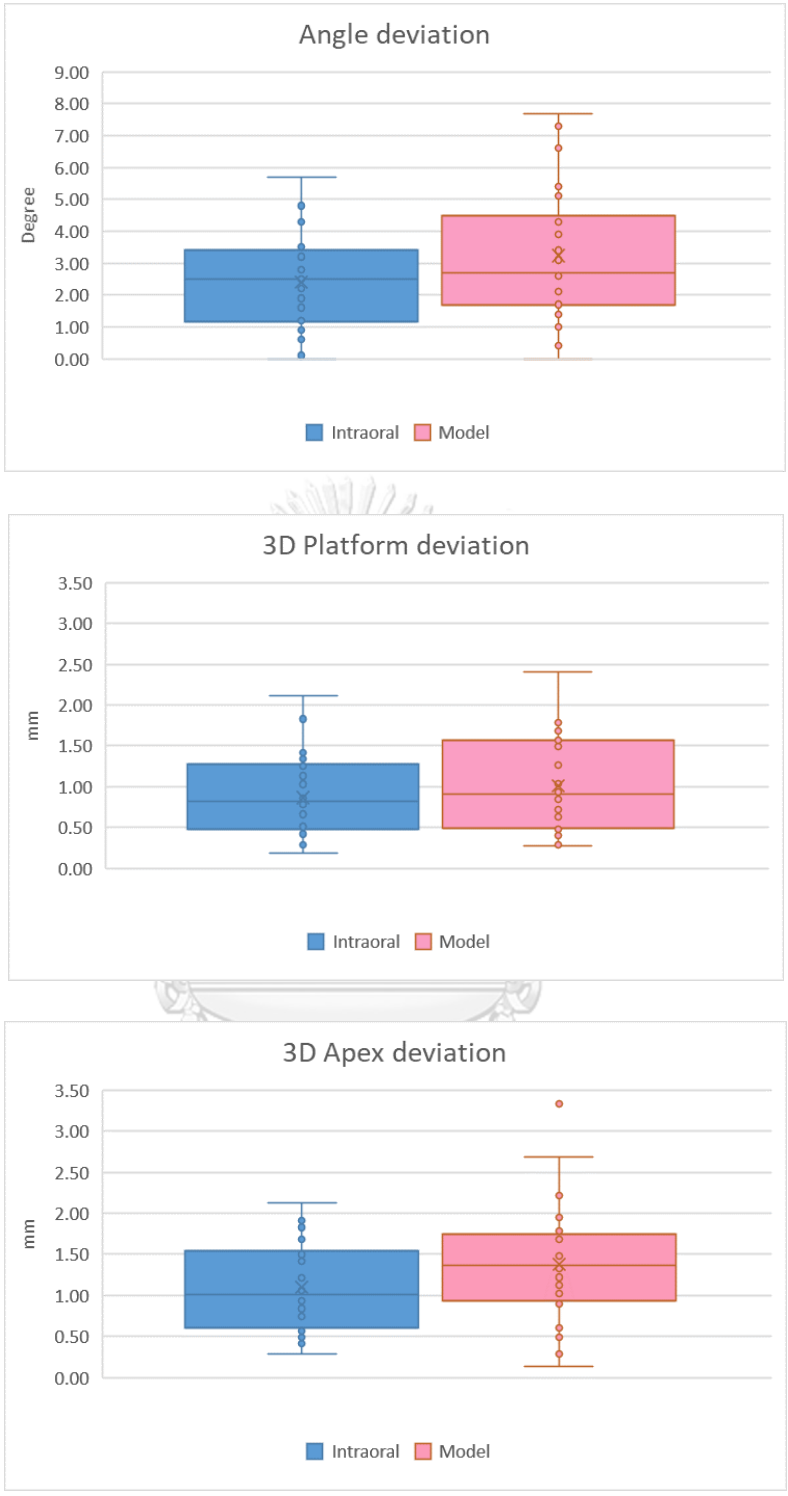


Figure 14 Box plots and whisker demonstrated the mean angle deviation and mean 3D deviation at platform and apex comparison between intraoral and model scan group

No Statistical significant different by Mann-Whitney (p-value > 0.05)

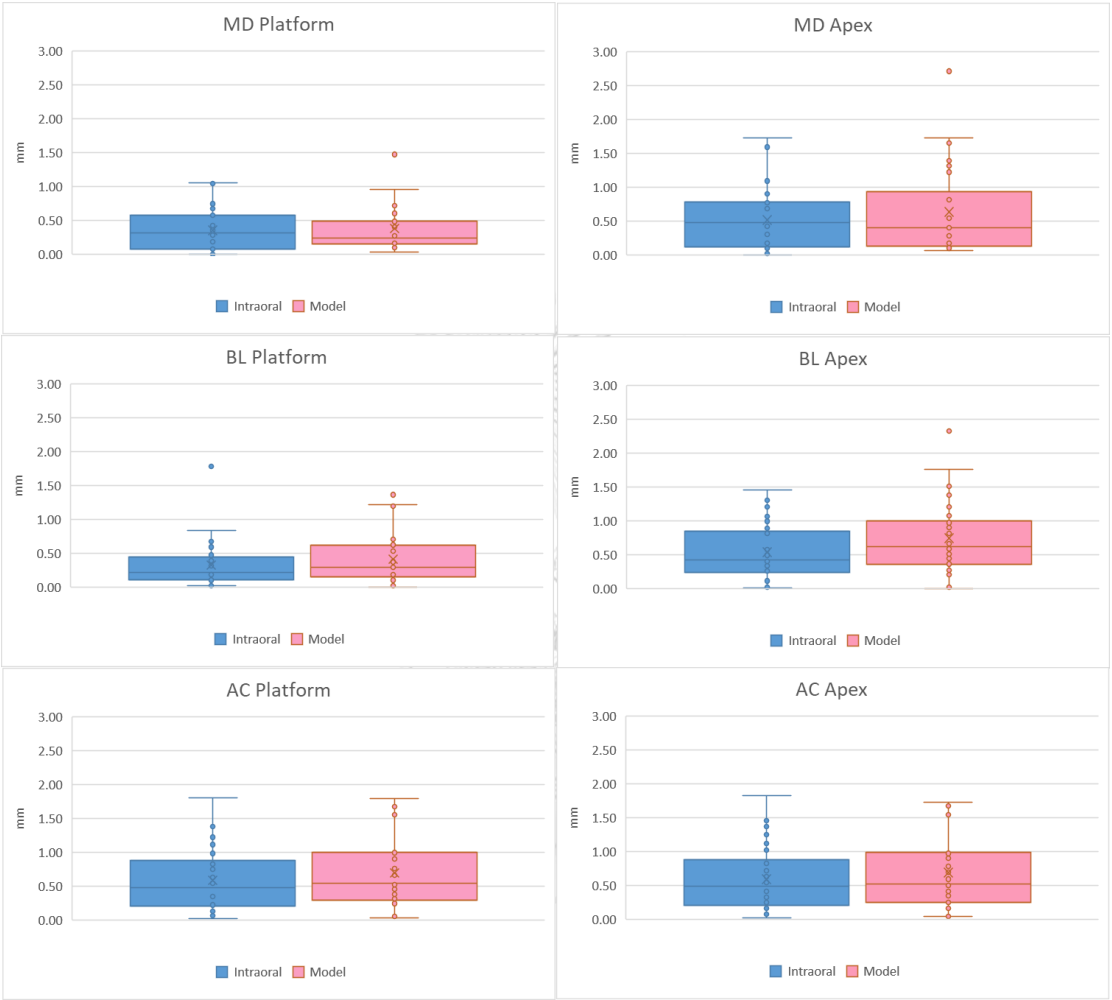


Figure 15 Box plots and whisker demonstrated mean of deviation in each axis at platform and apex comparison between intraoral and model scan group

No Statistical significant different by Mann-Whitney (p-value > 0.05) MD=mesio-distal, BL=bucco-lingual, AC=apico-coronal (vertical)

Table 4 Detailed data and statistical results (mean±SD)

	Angle(°)	Platform (mm)				Apex (mm)			
		3D	M-D axis	B-L axis	Vertical axis	3D	M-D axis	B-L axis	Vertical axis
Intraoral scan	2.41±1.48	0.87±0.49	0.35±0.30	0.32±0.35	0.58±0.47	1.10±0.53	0.52±0.45	0.54±0.41	0.59±0.48
Model scan	3.23±2.09	1.01±0.53	0.38±0.37	0.41±0.36	0.69±0.54	1.38±0.68	0.63±0.64	0.74±0.52	0.69±0.54
Statistics	*P=0.228*	*P=0.325*	*P=0.853*	*P=0.287*	*P=0.515*	*P=0.099*	*P=0.605*	*P=0.117*	*P=0.579*

No significant differences according to Mann–Whitney U-test of all parameters two groups (p-value>0.05).

4.3 Post-operative complications and clinical prosthesis condition

All static CAIS procedure, for this study, were accomplished without any significant complication, such as fracture of the template, incorrect implant positioning or failure of prostheses. Although post-operative mild redness or slightly wound swelling were occurred at the surgical site, they could be completed recovery. The stability of implants were adequate for prosthetic loading after 4-6 months of healing period.

CHAPTER 5

DISCUSSION

Comparison between intraoral scan group and model scan group, for the overview, implants placed in intraoral scan group are closer to the planned in angle and in all axis. In details, at platform, implants deviated more from the planned positions in a vertical direction than in the horizontal direction. In contrast, at apex of implant, vertical displacements were similar to horizontal errors. These results were shown in Table 5.

Advantages of the present study, one clinician created the virtual planning and guided template design. Another dentist performed guided implant surgery. This protocol leads to single blind design which is the reliable study to compare a treatment between two groups because the bias of researchers were minimized. In addition, the clinician strict to patient dentition, template design also statistically analysis that describe in the methodologies, to minimized bias and variability.

The results of this study are similar to those of previous studies assessing the accuracy of CAIS surgical guides in single tooth space based on model scan data and intra-oral scan data. A summary of these results appears in Table 5. In general, the accuracy of CAIS surgical guides used for the current study were well within the range of results reported by previous authors. Angular differences using model scan were

similar to those reported by both Ersoy *et al* (94) and Farley *et al* (65). Ersoy *et al* (94) studied the accuracy of 94 implant placements in 21 patients (9 single tooth loss, 20 partial edentulous and 65 total edentulous) using stereolithographic templates (Stent Cad, Media Lab Software, La Spezia, Italy) created from combining with digital radiographic data and scanning template data for CAIS. For single tooth loss, they found that mean deviation at the platform was 0.74 ± 0.4 mm, at the apex was 0.66 ± 0.28 mm and angle deviation was 3.71 ± 0.93 degrees. They reported significant differences in the deviation at the implant apex between single-tooth loss and partial edentulous groups and between single tooth loss and total edentulous groups while significant difference were not found between open flap and flapless group. They concluded that using stereolithographic guides may be reliable for implant placement and make flapless surgery possible. For intraoral and model scan group, platform deviations were comparable to those of Behneke *et al* (75). With regard to platform position in intraoral scan group, the results were similar to those of Ersoy *et al.* The present apex differences in both group were comparable to those of Farley *et al*. In summary, the deviation in this study for model scan group resemble previous study, whereas the deviation for intraoral scan group was lesser. However, there are no statistical significance differences were shown.

Table 5 Comparison of results with resemble research on the accuracy of static CAIS (mean±SD)

Studies	Angle deviation (°)	3D Deviation at platform (mm)	3D Deviation at apex (mm)
Derksen *et al.* 2015 (88) (n=12) (intraoral)	1.91 ± 1.37	0.56 ± 0.22	0.75 ± 0.33
Ersoy *et al.* 2008 (94) (n=9) (model)	3.71 ± 0.93	0.74 ± 0.4	0.66 ± 0.28
Farley *et al.* 2013 (65) (n=10) (model)	3.68 ± 2.19	1.45 ± 0.06	1.82 ± 0.60
Present study: Intraoral (n=30)	2.42 ± 1.47	0.87 ± 0.49	1.10 ± 0.53
Present study: Model (n=30)	3.23 ± 2.09	1.01 ± 0.56	1.38 ± 0.68

Implants placed by CAIS through guided template fabricated from intraoral scan data were more consistent in the level of accuracy compared to implants placed through template created from model scan data. The deviation from the model scan group may result of conventional impression technique. Distortion of impression can cause incorrect proportionated model. Malformed model probably results in inaccurate STL file data of model scan. Finally, this data can further reduce the accuracy of this dental restoration fabrication process (87, 111).

In vitro studies displayed that the accuracy of conventional impressions are as well as different intraoral scanning systems for dentate full arches (112, 113) and edentulous patients (114). Nevertheless, there are still disadvantage in intraoral scanning system. Some systems need a layer of powder spray on the tooth surface, and the inhomogeneous powder thickness may cause slightly adjust the tooth outline. Recent clinical study concluded that intraoral scanner is less accurate than model

scanner. Authors discussed that inaccuracy of intraoral scan maybe result of intraoral condition such as saliva and limited maximum mouth opening (115).

Operator's learning curve (experienced / inexperienced) may have an effect on the accuracy of CAIS has been studied, but the results are still a matter of controversy. Several clinical studies pointed out the emphasis of the learning curve (102, 116, 117) while other studies did not (4, 118-120). Rungcharassaeng *et al.* (2015) (118) studied the effect of operator experience on the accuracy of implant placement in mandibular model. Each operator (10 experienced and 10 inexperienced) placed 1 dental implant on the model that had been planned with software by following a computer-guided surgery (NobelGuide) protocol. They reported no significant differences were found in the angular and linear deviations at coronal and apical level between the experienced and in experienced operators (P>0.1). Though not statistically significant, the amount of vertical deviation in the coronal direction of the implants placed by the inexperienced operators was about twice that placed by the experienced operators. Thus, the inexperienced operators might be more careful about the implant depth than the experienced group. In our study, a singer dental surgeon with same dental assistant team who performed all operation are experienced practitioners. Especially, the surgeon has expert knowledge and clinical skill in implantology. They have been trained in CAIS, all aspects of dental surgery and handle intraoperative surgical complications.

The present study has several limitations. First, more distortion of alginate impression material than polyether or silicone material. This material was chosen for the study due to simulation dental daily practice. The other limitation is the learning curve experience needed to perform intraoral scan. Inexperienced clinician takes a longer time to scan than experienced clinician. Another problem is scanner displacement during the scanning process, especially when full arch intraoral scan was done, which may affect accuracy of scanning data.

Limitations of this study include instance in which tooth-support guided template for single tooth edentulous. These guided templates should provide more accuracy than for totally edentulous. Therefore, more of differences in regard to accuracy when multiple consecutive implants are placed. Moreover, the inclusion criteria that cross-arch stabilization and present of mesial and distal tooth support template, may become the limitation for patient with reduced residual dentition.

There are several topics that could be suggested for further study. Research in same intraoral scan device to perform scanning both direct intraoral and cast model in term of reduce deviation of implant position when combining with digital radiographic data for static CAIS could be required. Further study in larger patient population and with partially or fully edentulous, also compare with shorten guided template are recommended. Lack of another evidence based in detail of factor questionable to accuracy static CAIS technique such as difference drill length and drill

handle protocol, connection platform type of dental implant as well as dental implant system. Additional bone augmentation technique simultaneous with static CAIS such GBR, ridge splitting and onlay block graft should be studied to confirm the association with the accuracy. In addition, difference in the accuracy between static and dynamic CAIS technique are still waiting for study. For inform patients, Information of the reduction of operation time, cost-effectiveness and OHRQoL as well as, the potentially increased accuracy need to be studied. Success rate on clinical and radiographic aspect of implant placed by CAIS technique are interesting to study.

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APPENDICES

Appendix A Patient information sheet, Consent form, Withdrawal form in case drop-out is demanded (In Thai)

เอกสารข้อมูลคำอธิบายสำหรับอาสาสมัครที่เข้าร่วมในการวิจัย
(Patient/Participant Information Sheet)

1. ชื่อโครงการ (ไทย) การเปรียบเทียบความแม่นยำของแผ่นจำลองนำทางผ่าตัดระหว่างชิ้นงานที่ได้จากวิธีสแกนในช่องปากกับวิธีสแกนแบบจำลองฟันสำหรับการฝังรากฟันเทียมด้วยการผ่าตัดโดยใช้คอมพิวเตอร์ช่วยเหลือ

   ชื่อโครงการ (อังกฤษ) Comparison of The Accuracy of Surgical Guided Template Produced from Intraoral Scan Technique and Model Scan Technique for Implantation Using Computer Assisted Implant Surgery

2. ชื่อผู้วิจัยหลัก ทพญ.พฤษพร เกียรติ์เกริกไกร
   สถาบันที่สังกัด ภาควิชาศัลยศาสตร์ คณะทันตแพทยศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย
   อาจารย์ที่ปรึกษา รศ.ทพ.ดร.อาทิพันธุ์ พิมพ์ขาวขำ
   แหล่งทุนวิจัย ทุน 90 ปีจุฬาลงกรณ์มหาวิทยาลัย

3. วัตถุประสงค์ของโครงการ เพื่อเปรียบเทียบความแม่นยำของแผ่นจำลองนำทางผ่าตัดระหว่างชิ้นงานที่ได้จากวิธีสแกนในช่องปากกับวิธีสแกนแบบจำลองฟันสำหรับการฝังรากฟันเทียมด้วยการผ่าตัดโดยใช้คอมพิวเตอร์ช่วยเหลือ

4. สถานที่ดำเนินการวิจัย ภาควิชาศัลยศาสตร์ คณะทันตแพทยศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย

5. วิธีการที่เกี่ยวข้องกับการวิจัย

หากท่านมีความประสงค์เข้าร่วมในโครงการวิจัย ท่านจะต้องได้รับการตรวจช่องปากจากทันตแพทย์และถ่ายภาพรังสีส่วนตัดอาศัยคอมพิวเตอร์ชนิดโคนบีม เพื่อประเมินว่าท่านมีคุณสมบัติตรงตามเกณฑ์ที่กำหนด และมีกระดูกเพียงพอในการฝังรากเทียมได้ จากนั้น ผู้วิจัยจะวางแผนการรักษาสำหรับการใส่ฟันปลอมและการผ่าตัดฝังรากฟันเทียม รวมทั้งออกแบบแผ่นจำลองนำทางผ่าตัด

ในวันที่ท่านมารับการผ่าตัดฝังรากฟันเทียม ท่านจะได้รับการรักษาด้วยวิธีมาตรฐานสำหรับการผ่าตัดฝังรากฟันเทียมโดยทั่วไป โดยจะมีการฉีดยาชาเฉพาะที่ เปิดเหงือก กรอกระดูกเพื่อเป็นที่อยู่ของรากฟันเทียม ฝังรากฟันเทียมลงในเบ้ากระดูก วัดเสถียรภาพของรากฟันเทียม และเย็บปิดปากแผล

หลังจากผ่าตัดฝังรากฟันเทียมประมาณ 2 สัปดาห์ จะนัดท่านกลับมาเพื่อตรวจแผลผ่าตัดและทำการตัดไหม

1 เดือนหลังการผ่าตัดฝังรากฟันเทียม จะตรวจแผลผ่าตัด ถ่ายภาพรังสีส่วนตัดอาศัยคอมพิวเตอร์ชนิดโคนบีม และวัดเสถียรภาพของรากฟันเทียม

3 เดือนหลังการผ่าตัดฝังรากฟันเทียม จะทำการประเมินอัตราสำเร็จของรากฟันเทียมจากทางคลินิกและภาพรังสี และวัดเสถียรภาพของรากฟันเทียม หากผลการตรวจและการวัดเสถียรภาพเป็นที่น่าพอใจ (ค่าเสถียรภาพมากกว่า 60) ทันตแพทย์จะพิมพ์ปากเพื่อเตรียมทำฟันปลอม และดำเนินการตามขั้นตอนของการใส่ฟันจนท่านได้ฟันปลอมยึดติดบนรากฟันเทียมเรียบร้อยโดยใช้เวลาประมาณ 1-1.5 เดือน หลังจากนี้ ในเดือนที่ 5 หลังการผ่าตัดฝังรากฟันเทียมท่านจะได้รับการนัดกลับมาเพื่อทำการประเมินอัตราสำเร็จของรากฟันเทียมจากทางคลินิกและภาพรังสีอีกครั้งก่อนสิ้นสุดโครงการ

ในรายที่ค่าเสถียรภาพของรากฟันเทียมน้อยกว่า 60 หรือมีความผิดปกติใดๆเกิดขึ้นกับบริเวณที่ทำการฝังรากฟันเทียม ผู้วิจัยจะทำการแก้ไขความผิดปกตินั้น และรอให้มีการหายของแผลต่ออีก 2 เดือน และจะทำการประเมินอัตราสำเร็จของรากฟันเทียมจากทางคลินิกและภาพรังสี และวัดเสถียรภาพของรากฟันเทียมอีกครั้ง โดยในครั้งนี้ หากผลการตรวจและการวัดเสถียรภาพเป็นที่น่าพอใจ (ค่าเสถียรภาพมากกว่า 60) ทันตแพทย์จะพิมพ์ปากเพื่อเตรียมทำฟันปลอม และดำเนินการตามขั้นตอนของการใส่ฟันจนท่านได้ฟันปลอมเช่นกัน แต่หากผลตรวจยังไม่เป็นที่น่าพอใจ (ค่าเสถียรภาพยังคงน้อยกว่า 60) ทันตแพทย์จะดำเนินการถอนรากฟันเทียมออกและเป็นอันสิ้นสุดโครงการวิจัย

หากท่านยังมีความประสงค์จะผ่าตัดฝังรากฟันเทียมใหม่หลังจากที่แผลถอนรากฟันเทียมหายดีแล้ว (ในรายที่รากฟันเทียมมีการโยก หลุด หรือต้องถอนออกภายใน 5 เดือน นับตั้งแต่วันที่ผ่าตัดฝังรากฟันเทียม) โดยที่ลักษณะกระดูกของท่านยังเหมาะสมสำหรับการฝังรากฟันเทียม ทันตแพทย์จะดำเนินการอย่างเหมาะสมเพื่อให้ท่านได้รับการฝังรากฟันเทียมใหม่โดยไม่เสียค่าใช้จ่ายในค่าผ่าตัดฝังรากฟันเทียม ค่ารากฟันเทียมและอุปกรณ์ส่วนต่อ รวมถึงถ้าจำเป็นต้องมีการใส่กระดูกเทียมผู้วิจัยจะเป็นผู้รับผิดชอบค่าใช้จ่าย แต่ท่านจะมีค่าใช้จ่ายในการทำฟันปลอม ค่าถ่ายภาพรังสี

หากท่านไม่ประสงค์จะผ่าตัดฝังรากเทียมใหม่หรือลักษณะกระดูกของท่านไม่เหมาะสมที่จะฝังรากฟันเทียม ทันตแพทย์จะให้คำแนะนำเพื่อให้ท่านได้รับการใส่ฟันที่เหมาะสม โดยท่านจะมีค่าใช้จ่ายในการทำฟันปลอม

หลังจากสิ้นสุดโครงการวิจัยแล้ว ทันตแพทย์ผู้ทำการวิจัยจะนัดท่านกลับมาตรวจและติดตามผลการรักษาอย่างต่อเนื่อง

หากท่านยินดีเข้าร่วมในโครงการวิจัย ผู้วิจัยจะปฏิบัติต่อท่านเป็นขั้นตอนดังแสดงในตาราง

ครั้งที่	**เวลา**	**รายละอียด**
1	-	ซักประวัติ ตรวจในช่องปาก พิมพ์ปากหรือสแกนในช่องปาก เตรียมสภาพช่องปาก ถ่ายภาพรังสีส่วนตัดอาศัยคอมพิวเตอร์ชนิดโคนบีม
2	วันที่ 1	ผ่าตัดฝังรากฟันเทียมลงกระดูกขากรรไกร วัดเสถียรภาพของรากฟันเทียม

3	2 สัปดาห์หลังผ่าตัด	ตรวจแผลผ่าตัด ตัดไหม
4	1 เดือนหลังผ่าตัด	ตรวจแผลผ่าตัด ถ่ายภาพรังสีส่วนตัดอาศัยคอมพิวเตอร์ชนิดโคนบีม วัดเสถียรภาพของรากฟันเทียม
5	3 เดือนหลังผ่าตัด	- ประเมินอัตราสำเร็จของรากฟันเทียม ถ่ายภาพรังสี วัดเสถียรภาพของรากฟันเทียม - พิมพ์ปากเพื่อทำฟันปลอมและดำเนินการจนท่านได้รับฟันปลอมโดยใช้เวลาประมาณ 1-1.5 เดือน (เฉพาะในรายที่ค่าเสถียรภาพของรากฟันเทียมมากกว่า 60 และไม่มีความผิดปกติหรือภาวะแทรกซ้อนเกิดขึ้นกับบริเวณที่ทำการฝังรากฟันเทียม) - แต่หากค่าเสถียรภาพของรากฟันเทียมน้อยกว่า 60 หรือมีความผิดปกติใดๆเกิดขึ้นกับบริเวณที่ทำการฝังรากฟันเทียม ผู้วิจัยจะทำการแก้ไขความผิดปกตินั้น และรอให้มีการหายของแผลต่ออีก 2 เดือน
6	5 เดือนหลังผ่าตัด	ในรายที่ได้รับการทำฟันปลอมที่ 3 เดือน - ประเมินอัตราสำเร็จของรากฟันเทียม ถ่ายภาพรังสี ในรายที่ยังไม่ได้รับการทำฟันปลอมที่ 3 เดือน - วัดเสถียรภาพของรากฟันเทียม ถ่ายภาพรังสี - พิมพ์ปากเพื่อทำฟันปลอมและดำเนินการจนท่านได้รับฟันปลอมโดยใช้เวลาประมาณ 1-1.5 เดือน (เฉพาะในรายค่าเสถียรภาพของรากฟันเทียมมากกว่า 60 และไม่มีความผิดปกติหรือภาวะแทรกซ้อนเกิดขึ้นกับบริเวณที่ทำการฝังรากฟันเทียม) - แต่หากค่าเสถียรภาพของรากฟันเทียมน้อยกว่า 60 หรือมีความผิดปกติใดๆเกิดขึ้นกับบริเวณที่ทำการฝังรากฟันเทียม ผู้วิจัยจะทำการถอนรากฟันเทียมออก

6. เหตุผลที่เชิญเข้าร่วมเป็นอาสาสมัครในโครงการ

ท่านได้รับเชิญเข้าร่วมการศึกษาวิจัย เนื่องจากท่านเป็นอาสาสมัครที่มีสุขภาพดี โดยท่านจะได้อ่านข้อมูลที่เกี่ยวข้องกับโครงการนี้ก่อน ถ้าท่านมีข้อสงสัยใดๆเกี่ยวกับการศึกษาวิจัยนี้ สามารถซักถามผู้วิจัยได้ หากท่านตัดสินใจเข้าร่วมการศึกษาวิจัย ท่านจะได้รับสำเนาใบยินยอมที่ท่านเซ็นชื่อกำกับเก็บไว้ 1 ฉบับ

คุณสมบัติของผู้เข้าร่วมการวิจัยสามารถสรุปได้ดังต่อไปนี้

1. สูญเสียฟันกลายเป็นสันเหงือกว่างขนาดเทียบเท่ากับฟัน 1 ซี่ อย่างน้อย 1 ช่องว่าง ที่ไม่ใช่ซี่หลังสุดของขากรรไกร และต้องการทำรากฟันเทียมเพื่อบูรณะฟันที่สูญเสียไป
2. อายุมากกว่า 20 ปี
3. ถอนฟันไปอย่างน้อย 2 เดือน ก่อนผ่าตัดฝังรากฟันเทียม
4. มีสภาพปริทันต์ที่ดี ให้ความร่วมมือในการดูแลรักษาสุขอนามัยของช่องปาก
5. ไม่มีฟันโยก
6. ไม่มีพยาธิสภาพปลายรากบริเวณที่จะฝังรากฟันเทียม
7. สามารถอ้าปากได้กว้างปกติ เพียงพอต่อการวางแผ่นจำลองนำทางผ่าตัดโดยไม่น้อยกว่า 3 เซนติเมตร
8. มีสุขภาพดี(ทั้งทางร่างกายและจิตใจ)
9. สามารถเข้าร่วมการวิจัยได้ตลอดโครงการ

7. ความรับผิดชอบของอาสาสมัครและระยะเวลาที่อาสาสมัครจะอยู่ในโครงการ

ขอให้ท่านปฏิบัติตามที่ผู้วิจัยแนะนำในระหว่างที่ท่านเข้าร่วมโครงการวิจัยนี้ โดยระยะเวลาที่ท่านจะอยู่ในโครงการนี้คือ 5 เดือนนับตั้งแต่วันที่ทำการผ่าตัดฝังรากฟันเทียม

8. ประโยชน์ของการวิจัยที่อาสาสมัครและ/หรือผู้อื่นที่อาจได้รับ

1. ท่านจะได้ใส่ฟันเทียมชนิดติดแน่นและรากฟันเทียมที่มีตำแหน่งแม่นยำใกล้เคียงกับแผนการรักษา เพื่อทดแทนฟันที่สูญเสียไป เสริมให้ท่านมีคุณภาพชีวิตที่ดีขึ้น

2. ผลการวิจัยของท่านจะได้ข้อมูลความแม่นยำของแผ่นจำลองนำทางผ่าตัดระหว่างชิ้นงานที่ได้จากวิธีสแกนในช่องปากกับวิธีสแกนแบบจำลองฟัน จะช่วยในการตัดสินใจเลือกวิธีการรักษาของทันตแพทย์ที่มีต่อการผ่าตัดฝังรากฟันเทียมโดยใช้คอมพิวเตอร์ช่วยเหลือ

9. ความเสี่ยงหรือความไม่สะดวกที่อาจจะเกิดขึ้นแก่อาสาสมัคร และในบางกรณีแก่ทารกในครรภ์หรือทารกที่ดื่ม นมมารดา

การฝังรากฟันเทียมของท่านมีโอกาสประสบความล้มเหลวอันเป็นภาวะแทรกซ้อนของการรักษาที่เกิดขึ้นได้ และอาจเสี่ยงต่อการเกิดผลแทรกซ้อนจากการผ่าตัด ซึ่งเหมือนกับการผ่าตัดในช่องปากโดยทั่วไป เช่น อาการปวด บวม หรืออาจติดเชื้อบริเวณแผลภายหลังการผ่าตัด แต่ขอให้ท่านปฏิบัติตามที่ผู้วิจัยแนะนำ ทั้งนี้ผู้วิจัยตระหนักถึงผลแทรกซ้อนต่างๆ ที่อาจเกิดขึ้น และมีมาตรการในการลดความเสี่ยงเหล่านี้ โดยกระทำการรักษาตามมาตรฐานของวิชาชีพอย่างเคร่งครัด

10. ค่าใช้จ่ายที่อาสาสมัครจะต้องจ่าย หรืออาจจะต้องจ่าย

ท่านจะมีค่าใช้จ่ายในการผ่าตัดฝังรากฟันเทียมและค่าฟันเทียมตามปกติ โดยราคาขึ้นอยู่กับจำนวนซี่ฟันตามอัตราที่กำหนดไว้โดยคณะทันตแพทยศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย ค่าภาพรังสี

ส่วนตัดอาศัยคอมพิวเตอร์ชนิดโคนบีมเพื่อวางแผนการรักษา (3,000 บาท) ค่าพิมพ์ฟันและแบบจำลองฟันเพื่อวางแผนการรักษา (ประมาณ 1,000 บาท)

ค่าแผ่นจำลองนำทางผ่าตัด ค่าสแกนในช่องปาก ค่าสแกนแบบจำลองฟัน ค่าโปรแกรมคอมพิวเตอร์ช่วยเหลือ ค่าอุปกรณ์การผ่าตัดฝังรากฟันเทียมด้วยคอมพิวเตอร์ช่วยเหลือ ค่าถ่ายภาพรังสีส่วนตัดอาศัยคอมพิวเตอร์ชนิดโคนบีมหลังการรักษา ท่านจะได้รับการสนับสนุนโดยไม่เสียค่าใช้จ่าย

หากท่านเป็นผู้มีสิทธิ์เบิกจ่ายตรง ประกันสังคมหรือบัตรทอง ท่านสามารถเบิกค่ารักษาในส่วนของค่าทำฟันปลอมและค่าถ่ายภาพรังสี โดยอัตราที่สามารถเบิกได้ สามารถตรวจสอบจากผู้วิจัยหรือประชาสัมพันธ์ ตึกสมเด็จย่า 93 คณะทันตแพทยศาสตร์ จุฬาลงกรณ์มหาวิทยาลัยได้

11. การชดเชยใดๆ และการรักษาที่จะจัดให้แก่อาสาสมัครในกรณีที่ได้รับอันตรายซึ่งเกี่ยวข้องกับการวิจัย

หากท่านได้รับอันตรายจากการทำวิจัย ท่านจะได้รับการดูแลจนหายโดยผู้วิจัยเป็นผู้รับผิดชอบค่าใช้จ่าย

ในกรณีที่รากฟันเทียมมีตำแหน่งผิดปกติจนไม่สามารถทำฟันใส่ได้ หรือรากฟันเทียมไม่ยึดติดกับกระดูก จะถือว่าท่านไม่ใช่กลุ่มตัวอย่างของการวิจัย แต่ท่านยังคงได้รับการดูแลรักษาตามมาตรฐานการรักษา โดยผู้วิจัยจะถอนรากฟันเทียมออก และดูแลจนกว่าแผลจะหายเป็นปกติ หรือหากท่านต้องการฝังรากฟันเทียมอีกครั้ง ผู้วิจัยจะทำการผ่าตัดฝังรากฟันเทียมอีกครั้งให้แก่ท่าน โดยไม่มีค่าใช้จ่ายในส่วนการผ่าตัด ค่ารากฟันเทียม ค่าปลูกกระดูก แต่ท่านจะต้องจ่ายในส่วนอื่นๆเอง เช่น ค่าถ่ายภาพรังสี ค่าใช้จ่ายในการทำฟันเทียม เป็นต้น ซึ่งท่านสามารถตรวจสอบอัตราค่าใช้จ่ายต่างๆ ได้จากคณะทันตแพทยศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย

12. การจ่ายค่าเดินทาง ค่าเสียเวลา (ถ้ามี ซึ่งต้องกำหนดไว้เป็นรายครั้ง) แก่อาสาสมัครที่เข้าร่วมในการวิจัย

อาสาสมัครจะไม่ได้รับค่าใช้จ่ายสำหรับการเดินทาง

13. เหตุการณ์ที่อาจเกิดขึ้น หรือเหตุผลซึ่งจะต้องยกเลิกการเข้าร่วมโครงการวิจัยของอาสาสมัคร

หากท่านไม่สามารถปฏิบัติตามข้อตกลงในกระบวนการวิจัย เช่น ไม่สามารถมาตามนัดได้ ส่งผลให้ผลที่วัดได้คลาดเคลื่อนนำไปสู่ผลของการวิจัยที่ไม่น่าเชื่อถือ ผู้วิจัยจำเป็นต้องขอยกเลิกการเข้าร่วมในโครงการของท่าน โดยหากท่านยังมีความประสงค์จะรับการรักษาต่อ ผู้วิจัยจะดำเนินการให้ท่านได้รับการรักษาต่อไป

14. มีการเก็บชิ้นตัวอย่างที่ได้มาจากอาสาสมัครเอาไว้ใช้ในโครงการวิจัยในอนาคตหรือไม่ เก็บจำนวนเท่าไหร่ อย่างไร และที่ไหน

หลังจากจบโครงการจะไม่มีการเก็บตัวอย่างหรือภาพรังสีของอาสาสมัครไว้เป็นการส่วนตัว แต่ภาพรังสีของคนไข้จะยังถูกเก็บอยู่ในระบบภาพรังสีออนไลน์ของโรงพยาบาลเช่นเดียวกับผู้ป่วยของโรงพยาบาลรายอื่น

15. การกำกับดูแลและควบคุมการดำเนินโครงการ

ผู้กำกับดูแลการวิจัย ผู้ตรวจสอบ คณะกรรมการพิจารณาจริยธรรม และคณะกรรมการที่เกี่ยวข้อง สามารถเข้าไปตรวจสอบการดำเนินโครงการ รวมทั้ง ตรวจสอบบันทึกข้อมูลของอาสาสมัคร เพื่อเป็นการยืนยันถึงขั้นตอนในการวิจัยทางคลินิกและข้อมูลอื่นๆ โดยไม่ล่วงละเมิดเอกสิทธิ์ในการปิดบังข้อมูลของอาสาสมัคร ตามกรอบที่กฎหมายและกฎระเบียบได้อนุญาตไว้ นอกจากนี้ โดยการลงนามให้ความยินยอม อาสาสมัครหรือผู้แทนตามกฎหมายมีสิทธิตรวจสอบและมได้รับข้อมูลด้วยเช่นกัน

16. จริยธรรมการวิจัย

การดำเนินการโครงการวิจัยนี้ ผู้วิจัยคำนึงถึงหลักจริยธรรมการวิจัย ดังนี้

1. หลักความเคารพในบุคคล (Respect for person) โดยการให้ข้อมูลจนอาสาสมัครเข้าใจเป็นอย่างดีและตัดสินใจอย่างอิสระในการให้ความยินยอมเข้าร่วมในการวิจัย รวมทั้งการเก็บรักษาความลับของอาสาสมัคร

2. หลักการให้ประโยชน์ไม่ก่อให้เกิดอันตราย (Beneficence/Non-Maleficence) ซึ่งได้ระบุในข้อ 8 และ 9ว่าจะมีประโยชน์หรือความเสี่ยงกับอาสาสมัครหรือไม่

3. หลักความยุติธรรม (Justice) คือมีเกณฑ์คัดเข้าและคัดออกชัดเจน มีการกระจายความเสี่ยงและผลประโยชน์อย่างเท่าเทียมกัน โดยวิธีสุ่มเข้ากลุ่มศึกษา

17. ข้อมูลที่อาจนำไปสู่การเปิดเผยตัวของอาสาสมัครจะได้รับการปกปิด ยกเว้นว่าได้รับคำยินยอมไว้โดยกฎระเบียบและกฎหมายที่เกี่ยวข้องเท่านั้น จึงจะเปิดเผยข้อมูลแก่สาธารณชนได้ ในกรณีที่ผลการวิจัยได้รับการตีพิมพ์ ชื่อและที่อยู่ของอาสาสมัครจะต้องได้รับการปกปิดอยู่เสมอ และอาสาสมัครหรือผู้แทนตามกฎหมายจะได้รับแจ้งโดยทันท่วงที ในกรณีที่มีข้อมูลใหม่ซึ่งอาจใช้ประกอบการตัดสินใจของอาสาสมัครว่าจะยังคงเข้าร่วมในโครงการวิจัยต่อไปได้หรือไม่

18. หากท่านมีข้อสงสัยต้องการสอบถามเกี่ยวกับสิทธิของท่านหรือผู้วิจัยไม่ปฏิบัติตามที่เขียนไว้ในเอกสารข้อมูล คำอธิบายสำหรับผู้เข้าร่วมในการวิจัย ท่านสามารถติดต่อหรือร้องเรียนได้ที่ ฝ่ายวิจัย คณะทันตแพทยศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย ตึกสมเด็จย่า 93 ชั้น 10 หรือที่หมายเลขโทรศัพท์ 02-218-8866 ในเวลาทำการ

19. หากท่านต้องการยกเลิกการเข้าร่วมเป็นอาสาสมัคร ให้ท่านกรอกและส่งเอกสารขอยกเลิกมาที่

ทพญ.พฤษพร เกียรติ์เกริกไกร

ภาควิชาศัลยศาสตร์ คณะทันตแพทยศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย

34 ถนนอังรีดูนังต์ แขวงวังใหม่ เขตปทุมวัน กรุงเทพฯ 10330

20. อาสาสมัครสามารถติดต่อผู้วิจัยได้**ตลอด 24 ชั่วโมง** ที่:

1. ทพญ.พฤษพร เกียรติ์เกริกไกร

   ที่อยู่ 144/1 อาคารพญาไทเพลส แขวงทุ่งพญาไท เขตราชเทวี กรุงเทพมหานคร

   โทรศัพท์ติดตามตัว 095-9520674

2. รศ.ทพ.ดร.อาทิพันธุ์ พิมพ์ขาวขำ

   ที่อยู่ 21 เพชรเกษม28 ถนนเพชรเกษม แขวงบางจาก เขตภาษีเจริญ กรุงเทพมหานคร

   โทรศัพท์ติดตามตัว 089-1308046

.....

(ทพญ.พฤษพร เกียรติ์เกริกไกร)

ผู้วิจัยหลัก

วันที่...../...../.....

หมายเหตุ - ให้พิมพ์ข้อความโดยละเอียดลงในช่องว่าง โดยใช้ตัวอักษร TH SarabunPKS ขนาด 16

- หลังจากกรอกข้อความครบถ้วน พิมพ์เอกสารทั้งหมด แล้วให้ผู้วิจัยหลักลงนาม
- ทำสำเนาเอกสารข้อมูลคำอธิบายสำหรับอาสาสมัครที่เข้าร่วมในการวิจัย (Patient/Participant Information Sheet) มอบให้อาสาสมัครแต่ละคนๆ ละ 1 ชุด

เอกสารยินยอมเข้าร่วมการวิจัย (Consent Form)

การวิจัยเรื่อง การเปรียบเทียบความแม่นยำของแผ่นจำลองนำทางผ่าตัดระหว่างชิ้นงานที่ได้จากวิธีสแกนในช่องปากกับวิธีสแกนแบบจำลองฟันสำหรับการฝังรากฟันเทียมด้วยการผ่าตัดโดยใช้คอมพิวเตอร์ช่วยเหลือ

ข้าพเจ้า (นาย/ นาง/ นางสาว/ เด็กชาย/เด็กหญิง).....

อยู่บ้านเลขที่.....ถนน.....ตำบล/แขวง.....

อำเภอ/เขต.....จังหวัด.....รหัสไปรษณีย์.....

ก่อนที่จะลงนามในใบยินยอมให้ทำการวิจัยนี้

1. ข้าพเจ้าได้รับทราบรายละเอียดข้อมูลคำอธิบายสำหรับอาสาสมัครที่เข้าร่วมในการวิจัย รวมทั้งได้รับการอธิบายจากผู้วิจัยถึงวัตถุประสงค์ของการวิจัย วิธีการทำวิจัย อันตรายหรืออาการที่อาจเกิดขึ้นจากการทำวิจัยหรือจากยาที่ใช้รวมทั้งประโยชน์ที่จะเกิดขึ้นจากการวิจัยอย่างละเอียดและมีความเข้าใจดีแล้ว
2. ผู้วิจัยรับรองว่าจะตอบคำถามต่างๆ ที่ข้าพเจ้าสงสัยด้วยความเต็มใจไม่ปิดบังซ่อนเร้นจนข้าพเจ้าพอใจ
3. ผู้วิจัยรับรองว่าจะเก็บข้อมูลเฉพาะเกี่ยวกับตัวข้าพเจ้าเป็นความลับและจะเปิดเผยได้เฉพาะในรูปที่เป็นสรุปผลการวิจัย การเปิดเผยข้อมูลเกี่ยวกับตัวข้าพเจ้าต่อหน่วยงานต่างๆ ที่เกี่ยวข้องกระทำได้เฉพาะกรณีจำเป็นด้วยเหตุผลทางวิชาการเท่านั้น และผู้วิจัยรับรองว่าหากเกิดอันตรายใดๆ จากการวิจัยดังกล่าว ข้าพเจ้าจะได้รับการรักษาพยาบาลโดยไม่คิดมูลค่า
4. ข้าพเจ้ามีสิทธิที่จะบอกเลิกการเข้าร่วมในโครงการวิจัยนี้เมื่อใดก็ได้และการบอกเลิกการเข้าร่วมการวิจัยนี้จะไม่มีผลต่อการรักษาโรคที่ข้าพเจ้าจะพึงได้รับต่อไป

ข้าพเจ้าจึงสมัครใจเข้าร่วมโครงการวิจัยนี้ตามที่ระบุในเอกสารข้อมูลคำอธิบายสำหรับอาสาสมัครและได้ลงนามในใบยินยอมนี้ด้วยความเต็มใจ และได้รับสำเนาเอกสารใบยินยอมที่ข้าพเจ้าลงนามและลงวันที่ และเอกสารยกเลิกการเข้าร่วมวิจัย อย่างละ 1 ฉบับ เป็นที่เรียบร้อยแล้ว ในกรณีที่อาสาสมัครยังไม่บรรลุนิติภาวะจะต้องได้รับการยินยอมจากผู้ปกครองด้วย

ลงนาม..... อาสาสมัคร

(.....)

วันที่.....เดือน.....พ.ศ.....

ลงนาม..... ผู้ปกครอง

(.....)

วันที่.....เดือน.....พ.ศ.....

ลงนาม..... ผู้วิจัยหลัก

(นางสาวพฤษพร เกียรติ์เกริกไกร)

วันที่.....เดือน.....พ.ศ.....

ลงนาม..... พยาน

(.....)

วันที่.....เดือน.....พ.ศ.....

ข้าพเจ้าไม่สามารถอ่านหนังสือได้ แต่ผู้วิจัยได้อ่านข้อความในใบยินยอมนี้ให้แก่ข้าพเจ้าฟังจนเข้าใจดีแล้วข้าพเจ้าจึงลงนามหรือประทับลายนิ้วหัวแม่มือขวาของข้าพเจ้าในใบยินยอมนี้ด้วยความเต็มใจ

ลงนาม..... อาสาสมัคร

(.....)

วันที่.....เดือน.....พ.ศ.....

ลงนาม..... ผู้ปกครอง

(.....)

วันที่.....เดือน.....พ.ศ.....

ลงนาม..... ผู้วิจัยหลัก

(นางสาวพฤษพร เกียรติ์เกริกไกร)

วันที่.....เดือน.....พ.ศ.....

ลงนาม..... พยาน

(.....)

วันที่.....เดือน.....พ.ศ.....

เอกสารยกเลิกการเข้าร่วมวิจัย (Withdrawal Form)

การวิจัยเรื่อง การเปรียบเทียบความแม่นยำของแผ่นจำลองนำทางผ่าตัดระหว่างชิ้นงานที่ได้จากวิธีสแกนในช่องปากกับวิธีสแกนแบบจำลองฟันสำหรับการฝังรากฟันเทียมด้วยการผ่าตัดโดยใช้คอมพิวเตอร์ช่วยเหลือ

ข้าพเจ้า (นาย/ นาง/ นางสาว/ เด็กชาย/ เด็กหญิง).....

อยู่บ้านเลขที่.....ถนน.....ตำบล/แขวง.....

อำเภอ/เขต.....จังหวัด.....รหัสไปรษณีย์.....

ขอยกเลิกการเข้าร่วมโครงการวิจัยนี้ โดยมีเหตุผลในการยกเลิกการเข้าร่วมวิจัยคือ

- ❑ ย้ายภูมิลำเนา
- ❑ ไม่สะดวกในการเดินทาง
- ❑ เหตุผลอื่น

.....

ลงนาม.....ผู้ยกเลิก

(.....)

วันที่.....เดือน.....พ.ศ. .....

ลงนาม.....พยาน

(.....)

วันที่.....เดือน.....พ.ศ. .....

ลงนาม.....ผู้วิจัยหลัก

(.....)

วันที่.....เดือน.....พ.ศ. .....

ที่อยู่สำหรับส่งเอกสาร

ทพญ.พฤษพร เกียรติ์เกริกไกร
ภาควิชาศัลยศาสตร์ คณะทันตแพทยศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย
34 ถนนอังรีดูนังต์ เขตปทุมวัน กรุงเทพฯ 10330

หมายเหตุ - สำเนาเอกสารยกเลิกการเข้าร่วมวิจัย แล้วมอบให้อาสาสมัครแต่ละคนๆ ละ 1 ชุด

Appendix B Data collected form

Group No. □□□

Surgical date ...../...../.....

Name..... **HN.** .....

Gender ○ **Male** ○ **Female** **Age**.....

Tel.....

Straumann Implant Fixture

Tooth No.	○ Bone level ○ Tissue level Connection type_____ Diameter_____ mm. Length_____ mm.

Guided surgical protocol .....

Flap reflection ○ Yes ○ No

Ridge augmentation

○ No ○ GBR ○ Ridge expansion

○ Others .....

Insertion torque ..... Ncm **RFA** Buccal..... Mesial..... ISQ

Complications:

.....

.....

.....

.....

Appendix C Accuracy analysis result (mean and standard deviation) from this research pilot study (6 implants per groups) with implant angle deviation, 3D deviation and deviations in each axis (MD=mesio-distal, BL=bucco-lingual, AC=apico-coronal (vertical)) in intraoral scan group.

Intraoral No.	Angle (°)	Platform (mm)				Apex (mm)			
		3D	MD	BL	AC	3D	MD	BL	AC
O01	1.40	0.90	0.68	0.59	0.09	1.07	0.68	0.83	0.09
O02	4.80	1.34	1.04	0.39	0.75	2.13	1.59	1.23	0.71
O03	1.10	0.57	0.35	0.45	0.02	0.49	0.42	0.26	0.02
O04	2.50	0.32	0.30	0.04	0.11	0.75	0.73	0.04	0.12
O05	0.80	0.89	0.06	0.33	0.82	0.89	0.09	0.33	0.82
O06	1.20	0.66	0.00	0.31	0.59	0.78	0.00	0.51	0.59
Mean	1.97	0.78	0.41	0.35	0.40	1.02	0.59	0.53	0.39
SD	1.51	0.35	0.39	0.18	0.36	0.58	0.58	0.43	0.35

Appendix D Accuracy analysis result (mean and standard deviation) from this research pilot study (6 implants per groups) with implant angle deviation, 3D deviation and deviations in each axis (MD=mesio-distal, BL=bucco-lingual, AC=apico-coronal (vertical)) in model scan group.

Intraoral No.	Angle (°)	Platform (mm)				Apex (mm)			
		3D	MD	BL	AC	3D	MD	BL	AC
M01	5.30	1.04	0.11	0.70	0.76	1.95	0.44	1.76	0.71
M02	1.20	1.75	0.19	0.21	1.72	1.78	0.40	0.27	1.72
M03	3.30	1.49	0.95	0.53	1.02	2.00	1.65	0.53	1.00
M04	2.80	0.48	0.29	0.30	0.24	0.94	0.54	0.72	0.25
M05	5.40	0.63	0.44	0.32	0.31	1.52	1.31	0.69	0.36
M06	6.60	0.47	0.27	0.37	0.09	1.52	0.10	1.51	0.16
Mean	4.10	0.98	0.38	0.41	0.69	1.62	0.74	0.91	0.70
SD	2.01	0.55	0.30	0.18	0.61	0.39	0.60	0.59	0.59

Appendix E Accuracy analysis with implant angle deviation, 3D deviation and deviations in each axis (distal, buccal, apical) in intraoral scan group

Intraoral No.	Angle (°)	Platform (mm)				Apex (mm)			
		3D	distal	buccal	apical	3D	distal	buccal	apical
O01	1.40	0.90	0.68	-0.59	0.09	1.07	0.68	-0.83	0.09
O02	4.80	1.34	1.04	0.39	-0.75	2.13	1.59	1.23	-0.71
O03	1.10	0.57	0.35	0.45	-0.02	0.49	0.42	0.26	-0.02
O04	2.50	0.32	0.30	-0.04	0.11	0.75	0.73	-0.04	0.12
O05	0.80	0.89	-0.06	-0.33	-0.82	0.89	0.09	-0.33	-0.82
O06	1.20	0.66	0.00	0.31	0.59	0.78	0.00	0.51	0.59
O07	3.20	0.49	0.35	0.06	-0.34	0.97	0.91	0.15	-0.32
O08	2.80	0.67	0.59	0.19	0.25	1.13	1.09	0.14	0.26
O09	3.20	0.90	-0.02	-0.33	-0.84	1.22	-0.02	-0.89	-0.83
O10	1.90	0.51	-0.43	-0.03	-0.27	0.74	-0.69	0.08	-0.26
O11	0.60	0.42	-0.11	-0.40	-0.10	0.53	-0.15	-0.50	-0.10
O12	2.70	0.86	0.57	0.15	0.63	1.21	0.90	0.49	0.64
O13	1.20	0.35	0.00	0.31	-0.16	0.41	-0.21	0.31	-0.16
O14	4.30	1.42	0.02	0.12	1.42	1.68	-0.30	0.81	1.45
O15	4.30	1.13	-1.05	-0.10	0.40	1.83	-1.73	-0.40	0.43
O16	2.40	0.52	-0.43	0.19	-0.22	0.84	-0.82	0.01	-0.21
O17	3.50	2.11	0.28	1.78	1.11	1.84	-0.09	1.45	1.12
O18	3.50	1.49	-0.42	0.83	-1.16	1.83	-0.74	1.20	-1.18
O19	4.30	1.45	-0.39	0.67	-1.22	1.97	-0.79	1.30	-1.25
O20	2.20	1.39	0.18	0.02	-1.38	1.42	-0.04	-0.38	-1.37
O21	2.50	0.18	-0.07	-0.16	0.06	0.58	-0.46	-0.34	0.07
O22	0.20	1.03	-0.67	0.47	0.63	1.06	-0.69	0.50	0.63
O23	3.40	0.78	0.13	-0.53	0.55	1.21	-0.13	-1.06	0.57
O24	2.80	0.29	-0.19	0.18	-0.13	0.61	-0.19	0.57	-0.12
O25	0.10	0.54	0.00	0.02	-0.54	0.54	-0.03	0.02	-0.54
O26	5.70	1.25	0.74	-0.24	0.98	1.50	0.48	-0.99	1.02
O27	3.20	1.83	0.33	0.06	1.80	1.91	0.48	-0.36	1.82
O28	1.60	0.42	0.02	0.13	0.40	0.57	0.17	0.36	0.41
O29	0.30	0.93	0.73	0.49	-0.29	0.97	0.78	0.49	-0.29
O30	0.90	0.36	0.22	-0.11	0.26	0.29	0.06	-0.11	0.27

Appendix F Accuracy analysis with implant angle deviation, 3D deviation and deviations in each axis (distal, buccal, apical) in model scan group

Model No.	Angle (°)	Platform (mm)				Apex (mm)			
		3D	distal	buccal	apical	3D	distal	buccal	apical
M01	5.30	1.04	0.11	0.70	-0.76	1.95	0.44	1.76	-0.71
M02	1.20	1.75	-0.19	-0.21	-1.72	1.78	-0.40	-0.27	-1.72
M03	3.30	1.49	0.95	-0.53	-1.02	2.00	1.65	-0.53	-1.00
M04	2.80	0.48	-0.29	-0.30	0.24	0.94	-0.54	-0.72	0.25
M05	5.40	0.63	-0.44	0.32	0.31	1.52	-1.31	0.69	0.36
M06	6.60	0.47	0.27	0.37	0.09	1.52	0.10	1.51	0.16
M07	0.00	0.49	0.12	0.29	0.38	0.49	0.12	0.29	0.38
M08	3.40	1.72	-0.29	0.14	-1.69	1.74	-0.19	-0.44	-1.67
M09	0.40	0.91	-0.17	-0.02	-0.90	0.90	-0.10	-0.02	-0.90
M10	3.90	0.70	-0.09	-0.18	0.67	1.02	0.46	-0.58	0.69
M11	2.10	1.58	0.12	-0.29	-1.55	1.68	0.12	-0.66	-1.54
M12	3.10	0.40	0.40	-0.02	-0.05	0.29	-0.06	0.28	-0.04
M13	2.20	1.28	-0.17	1.21	0.40	1.29	0.22	1.20	0.41
M14	7.40	0.35	0.15	-0.12	-0.30	1.48	0.83	-1.21	-0.22
M15	5.10	1.78	-0.60	0.10	1.67	2.22	-1.37	-0.36	1.71
M16	1.60	1.60	-1.48	0.33	-0.52	1.82	-1.73	0.20	-0.52
M17	3.10	1.08	0.48	0.15	0.96	1.33	0.81	0.44	0.97
M18	7.30	2.40	1.47	-0.62	-1.79	3.33	2.71	-0.94	-1.70
M19	2.20	0.63	-0.11	0.62	0.03	0.93	-0.12	0.92	0.04
M20	1.90	0.93	0.48	0.76	-0.26	1.25	0.59	1.07	-0.25
M21	1.00	0.29	-0.28	0.00	0.08	0.13	-0.11	0.00	0.08
M22	1.70	0.72	-0.15	-0.54	0.45	0.97	-0.28	-0.81	0.46
M23	4.30	0.90	0.71	0.15	-0.53	1.55	1.39	0.47	-0.50
M24	2.10	0.28	0.17	0.21	-0.05	0.54	0.17	0.51	-0.04
M25	7.70	1.68	-0.74	1.36	-0.66	2.68	-1.22	2.32	-0.59
M26	1.40	1.57	0.13	1.19	1.02	1.72	0.13	1.38	1.02
M27	2.30	0.40	-0.03	0.22	0.34	0.60	0.34	0.36	0.34
M28	1.50	1.26	-0.16	0.76	-0.99	1.4	-0.21	0.97	-0.98
M29	2.60	0.69	0.21	0.38	-0.54	1.12	0.40	0.90	-0.52
M30	3.90	0.85	0.33	0.22	0.76	1.22	0.82	-0.45	0.78

Appendix G Intraclass correlations for each parameter

Intraoral scan group: Angle deviation

Intraclass Correlation Coefficient

	Intraclass Correlation[b]	95% Confidence Interval		F Test with True Value 0			
		Lower Bound	Upper Bound	Value	df1	df2	Sig
Single Measures	.960[a]	.849	.990	49.408	9	9	.000
Average Measures	.980	.919	.995	49.408	9	9	.000

Two-way random effects model where both people effects and measures effects are random.

a. The estimator is the same, whether the interaction effect is present or not.

b. Type C intraclass correlation coefficients using a consistency definition. The between-measure variance is excluded from the denominator variance.

Intraoral scan group: 3D deviation at platform

Intraclass Correlation Coefficient

	Intraclass Correlation[b]	95% Confidence Interval		F Test with True Value 0			
		Lower Bound	Upper Bound	Value	df1	df2	Sig
Single Measures	.927[a]	.734	.981	26.279	9	9	.000
Average Measures	.962	.847	.991	26.279	9	9	.000

Two-way random effects model where both people effects and measures effects are random.

a.The estimator is the same, whether the interaction effect is present or not.

b.Type C intraclass correlation coefficients using a consistency definition. The between-measure variance is excluded from the denominator variance.

Intraoral scan group: Platform deviation in mesio-distal axis

Intraclass Correlation Coefficient

	Intraclass Correlation[b]	95% Confidence Interval		F Test with True Value 0			
		Lower Bound	Upper Bound	Value	df1	df2	Sig
Single Measures	.913[a]	.690	.978	21.931	9	9	.000
Average Measures	.954	.816	.989	21.931	9	9	.000

Two-way random effects model where both people effects and measures effects are random.

a.The estimator is the same, whether the interaction effect is present or not.

b.Type C intraclass correlation coefficients using a consistency definition. The between-measure variance is excluded from the denominator variance.

Intraoral scan group: Platform deviation in bucco-lingual axis

Intraclass Correlation Coefficient

	Intraclass Correlation[b]	95% Confidence Interval		F Test with True Value 0			
		Lower Bound	Upper Bound	Value	df1	df2	Sig
Single Measures	.925[a]	.729	.981	25.658	9	9	.000
Average Measures	.961	.843	.990	25.658	9	9	.000

Two-way random effects model where both people effects and measures effects are random.
a.The estimator is the same, whether the interaction effect is present or not.
b.Type C intraclass correlation coefficients using a consistency definition. The between-measure variance is excluded from the denominator variance.

Intraoral scan group: Platform deviation in apico-coronal (vertical) axis

Intraclass Correlation Coefficient

	Intraclass Correlation[b]	95% Confidence Interval		F Test with True Value 0			
		Lower Bound	Upper Bound	Value	df1	df2	Sig
Single Measures	.900[a]	.649	.974	18.913	9	9	.000
Average Measures	.947	.787	.987	18.913	9	9	.000

Two-way random effects model where both people effects and measures effects are random.
a.The estimator is the same, whether the interaction effect is present or not.
b.Type C intraclass correlation coefficients using a consistency definition. The between-measure variance is excluded from the denominator variance.

Intraoral scan group: 3D deviation at apex

Intraclass Correlation Coefficient

	Intraclass Correlation[b]	95% Confidence Interval		F Test with True Value 0			
		Lower Bound	Upper Bound	Value	df1	df2	Sig
Single Measures	.964[a]	.864	.991	55.102	9	9	.000
Average Measures	.982	.927	.995	55.102	9	9	.000

Two-way random effects model where both people effects and measures effects are random.
a.The estimator is the same, whether the interaction effect is present or not.
b.Type C intraclass correlation coefficients using a consistency definition. The between-measure variance is excluded from the denominator variance.

Intraoral scan group: Apex deviation in mesio-distal direction

Intraclass Correlation Coefficient

	Intraclass Correlation[b]	95% Confidence Interval		F Test with True Value 0			
		Lower Bound	Upper Bound	Value	df1	df2	Sig
Single Measures	.907[a]	.670	.976	20.398	9	9	.000
Average Measures	.951	.803	.988	20.398	9	9	.000

Two-way random effects model where both people effects and measures effects are random.
a.The estimator is the same, whether the interaction effect is present or not.
b.Type C intraclass correlation coefficients using a consistency definition. The between-measure variance is excluded from the denominator variance.

Intraoral scan group: Apex deviation in bucco-lingual axis

Intraclass Correlation Coefficient

	Intraclass Correlation[b]	95% Confidence Interval		F Test with True Value 0			
		Lower Bound	Upper Bound	Value	df1	df2	Sig
Single Measures	.947[a]	.803	.987	36.809	9	9	.000
Average Measures	.973	.891	.993	36.809	9	9	.000

Two-way random effects model where both people effects and measures effects are random.
a.The estimator is the same, whether the interaction effect is present or not.
b.Type C intraclass correlation coefficients using a consistency definition. The between-measure variance is excluded from the denominator variance.

Intraoral scan group: Apex deviation in apico-coronal (vertical) axis

Intraclass Correlation Coefficient

	Intraclass Correlation[b]	95% Confidence Interval		F Test with True Value 0			
		Lower Bound	Upper Bound	Value	df1	df2	Sig
Single Measures	.910[a]	.682	.977	21.287	9	9	.000
Average Measures	.953	.811	.988	21.287	9	9	.000

Two-way random effects model where both people effects and measures effects are random.
a.The estimator is the same, whether the interaction effect is present or not.
b.Type C intraclass correlation coefficients using a consistency definition. The between-measure variance is excluded from the denominator variance.

Model scan group: Angle deviation

Intraclass Correlation Coefficient

	Intraclass Correlation[b]	95% Confidence Interval		F Test with True Value 0			
		Lower Bound	Upper Bound	Value	df1	df2	Sig
Single Measures	.947[a]	.801	.986	36.398	9	9	.000
Average Measures	.973	.889	.993	36.398	9	9	.000

Two-way random effects model where both people effects and measures effects are random.
a.The estimator is the same, whether the interaction effect is present or not.
b.Type C intraclass correlation coefficients using a consistency definition. The between-measure variance is excluded from the denominator variance.

Model scan group: 3D deviation at platform

Intraclass Correlation Coefficient

	Intraclass Correlation[b]	95% Confidence Interval		F Test with True Value 0			
		Lower Bound	Upper Bound	Value	df1	df2	Sig
Single Measures	.932[a]	.751	.983	28.327	9	9	.000
Average Measures	.965	.858	.991	28.327	9	9	.000

Two-way random effects model where both people effects and measures effects are random.
a.The estimator is the same, whether the interaction effect is present or not.
b.Type C intraclass correlation coefficients using a consistency definition. The between-measure variance is excluded from the denominator variance.

Model scan group: Platform deviation in mesio-distal axis

Intraclass Correlation Coefficient

	Intraclass Correlation[b]	95% Confidence Interval		F Test with True Value 0			
		Lower Bound	Upper Bound	Value	df1	df2	Sig
Single Measures	.903[a]	.658	.975	19.549	9	9	.000
Average Measures	.949	.794	.987	19.549	9	9	.000

Two-way random effects model where both people effects and measures effects are random.
a.The estimator is the same, whether the interaction effect is present or not.
b.Type C intraclass correlation coefficients using a consistency definition. The between-measure variance is excluded from the denominator variance.

Model scan group: Platform deviation in bucco-lingual axis

Intraclass Correlation Coefficient

	Intraclass Correlation[b]	95% Confidence Interval		F Test with True Value 0			
		Lower Bound	Upper Bound	Value	df1	df2	Sig
Single Measures	.607[a]	.008	.885	4.087	9	9	.024
Average Measures	.755	.015	.939	4.087	9	9	.024

Two-way random effects model where both people effects and measures effects are random.
a.The estimator is the same, whether the interaction effect is present or not.
b.Type C intraclass correlation coefficients using a consistency definition. The between-measure variance is excluded from the denominator variance.

Model scan group: Platform deviation in apico-coronal (vertical) axis

Intraclass Correlation Coefficient

	Intraclass Correlation[b]	95% Confidence Interval		F Test with True Value 0			
		Lower Bound	Upper Bound	Value	df1	df2	Sig
Single Measures	.939[a]	.775	.984	31.707	9	9	.000
Average Measures	.968	.873	.992	31.707	9	9	.000

Two-way random effects model where both people effects and measures effects are random.
a.The estimator is the same, whether the interaction effect is present or not.
b.Type C intraclass correlation coefficients using a consistency definition. The between-measure variance is excluded from the denominator variance.

Model scan group: 3D deviation at apex

Intraclass Correlation Coefficient

	Intraclass Correlation[b]	95% Confidence Interval		F Test with True Value 0			
		Lower Bound	Upper Bound	Value	df1	df2	Sig
Single Measures	.966[a]	.869	.991	57.570	9	9	.000
Average Measures	.983	.930	.996	57.570	9	9	.000

Two-way random effects model where both people effects and measures effects are random.
a.The estimator is the same, whether the interaction effect is present or not.
b.Type C intraclass correlation coefficients using a consistency definition. The between-measure variance is excluded from the denominator variance.

Model scan group: Apex deviation in mesio-distal axis

Intraclass Correlation Coefficient

	Intraclass Correlation[b]	95% Confidence Interval		F Test with True Value 0			
		Lower Bound	Upper Bound	Value	df1	df2	Sig
Single Measures	.984[a]	.936	.996	121.947	9	9	.000
Average Measures	.992	.967	.998	121.947	9	9	.000

Two-way random effects model where both people effects and measures effects are random.
a.The estimator is the same, whether the interaction effect is present or not.
b.Type C intraclass correlation coefficients using a consistency definition. The between-measure variance is excluded from the denominator variance.

Model scan group: Apex deviation in bucco-lingual axis

Intraclass Correlation Coefficient

	Intraclass Correlation[b]	95% Confidence Interval		F Test with True Value 0			
		Lower Bound	Upper Bound	Value	df1	df2	Sig
Single Measures	.966[a]	.871	.992	58.287	9	9	.000
Average Measures	.983	.931	.996	58.287	9	9	.000

Two-way random effects model where both people effects and measures effects are random.
a.The estimator is the same, whether the interaction effect is present or not.
b.Type C intraclass correlation coefficients using a consistency definition. The between-measure variance is excluded from the denominator variance.

Model scan group: Apex deviation in apico-coronal (vertical) axis

Intraclass Correlation Coefficient

	Intraclass Correlation[b]	95% Confidence Interval		F Test with True Value 0			
		Lower Bound	Upper Bound	Value	df1	df2	Sig
Single Measures	.934[a]	.759	.983	29.322	9	9	.000
Average Measures	.966	.863	.992	29.322	9	9	.000

Two-way random effects model where both people effects and measures effects are random.
a.The estimator is the same, whether the interaction effect is present or not.
b.Type C intraclass correlation coefficients using a consistency definition. The between-measure variance is excluded from the denominator variance.

Appendix H Normality test of all deviation parameter for both groups

Tests of Normality

Group		Kolmogorov-Smirnov[a]			Shapiro-Wilk		
		Statistic	df	Sig.	Statistic	df	Sig.
Angle	Intraoral scan	.097	30	.200*	.970	30	.541
	Model scan	.138	30	.150	.926	30	.038
3DPlatform	Intraoral scan	.128	30	.200*	.936	30	.071
	Model scan	.132	30	.191	.930	30	.048
PlatformMDaxis	Intraoral scan	.126	30	.200*	.912	30	.016
	Model scan	.226	30	.000	.746	30	.000
PlatformBLaxis	Intraoral scan	.191	30	.007	.730	30	.000
	Model scan	.200	30	.003	.859	30	.001
PlatformAC (vertical)axis	Intraoral scan	.151	30	.077	.910	30	.015
	Model scan	.143	30	.120	.896	30	.007
3DApex	Intraoral scan	.116	30	.200*	.937	30	.077
	Model scan	.094	30	.200*	.967	30	.468
ApexMDaxis	Intraoral scan	.151	30	.079	.892	30	.005
	Model scan	.205	30	.002	.809	30	.000
ApexBLaxis	Intraoral scan	.193	30	.006	.915	30	.020
	Model scan	.124	30	.200*	.923	30	.033
ApexAC (vertical)axis	Intraoral scan	.146	30	.100	.907	30	.013
	Model scan	.154	30	.066	.889	30	.005

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

a. Lilliefors Significance Correction

Appendix I Levene's test to assesss the equality of variences for a parameter calculated for two or more groups

		Levene's Test for Equality of Variances	
		F	Sig.
Angle	Equal variances assumed	2.906	.094
	Equal variances not assumed		
3DPlatform	Equal variances assumed	1.097	.299
	Equal variances not assumed		
PlatformMDaxis	Equal variances assumed	.208	.650
	Equal variances not assumed		
PlatformBLaxis	Equal variances assumed	.741	.393
	Equal variances not assumed		
PlatformACaxis (vertical)	Equal variances assumed	.504	.480
	Equal variances not assumed		
3DApex	Equal variances assumed	.571	.453
	Equal variances not assumed		
ApexMDaxis	Equal variances assumed	2.656	.109
	Equal variances not assumed		
ApexBLaxis	Equal variances assumed	1.047	.310
	Equal variances not assumed		
ApexACaxis (vertical)	Equal variances assumed	.400	.530
	Equal variances not assumed		

Appendix J Descriptive statistics details of deviation in intra-oral and model scan group

Descriptives

Deviation	Groups		Intraoral scan		Model scan	
			Statistic	Std. Error	Statistic	Std. Error
Angle	Mean		2.4200	.26766	3.2267	.38156
	95% Confidence Interval for Mean	Lower Bound	1.8726		2.4463	
		Upper Bound	2.9674		4.0070	
	5% Trimmed Mean		2.3815		3.1556	
	Median		2.5000		2.7000	
	Variance		2.149		4.368	
	Std. Deviation		1.46603		2.08987	
	Minimum		.10		.00	
	Maximum		5.70		7.70	
	Range		5.60		7.70	
	Interquartile Range		2.25		2.83	
	Skewness		.226	.427	.780	.427
	Kurtosis		-.621	.833	-.182	.833
3DPlatform	Mean		.8667	.08941	1.0117	.10218
	95% Confidence Interval for Mean	Lower Bound	.6838		.8027	
		Upper Bound	1.0495		1.2206	
	5% Trimmed Mean		.8389		.9865	
	Median		.8200		.9050	
	Variance		.240		.313	
	Std. Deviation		.48972		.55966	
	Minimum		.18		.28	
	Maximum		2.11		2.40	
	Range		1.93		2.12	
	Interquartile Range		.80		1.09	
	Skewness		.758	.427	.573	.427
	Kurtosis		-.036	.833	-.512	.833

Deviation	Groups		Intraoral scan		Model scan	
			Statistic	Std. Error	Statistic	Std. Error
PlatformMDaxis	Mean		.3457	.05509	.3763	.06760
	95% Confidence Interval for Mean	Lower Bound	.2330		.2381	
		Upper Bound	.4583		.5146	
	5% Trimmed Mean		.3259		.3333	
	Median		.3150		.2400	
	Variance		.091		.137	
	Std. Deviation		.30175		.37027	
	Minimum		.00		.03	
	Maximum		1.05		1.48	
	Range		1.05		1.45	
	Interquartile Range		.51		.33	
	Skewness		.801	.427	1.976	.427
	Kurtosis		-.011	.833	3.690	.833
PlatformBL	Mean		.3227	.06317	.4103	.06542
	95% Confidence Interval for Mean	Lower Bound	.1935		.2765	
		Upper Bound	.4519		.5441	
	5% Trimmed Mean		.2761		.3828	
	Median		.2150		.2950	
	Variance		.120		.128	
	Std. Deviation		.34599		.35831	
	Minimum		.02		.00	
	Maximum		1.78		1.36	
	Range		1.76		1.36	
	Interquartile Range		.35		.47	
	Skewness		2.777	.427	1.308	.427
	Kurtosis		10.428	.833	1.162	.833

Deviation	Groups		Intraoral scan		Model scan	
			Statistic	Std. Error	Statistic	Std. Error
PlatformACaxis	Mean		.5840	.08630	.6910	.09893
	95% Confidence Interval for Mean	Lower Bound	.4075		.4887	
		Upper Bound	.7605		.8933	
	5% Trimmed Mean		.5541		.6676	
	Median		.4700		.5350	
	Variance		.223		.294	
	Std. Deviation		.47270		.54186	
	Minimum		.02		.03	
	Maximum		1.80		1.79	
	Range		1.78		1.76	
	Interquartile Range		.67		.71	
	Skewness		.889	.427	.799	.427
	Kurtosis		.010	.833	-.369	.833
3DApex	Mean		1.0990	.09686	1.3803	.12492
	95% Confidence Interval for Mean	Lower Bound	.9009		1.1248	
		Upper Bound	1.2971		1.6358	
	5% Trimmed Mean		1.0874		1.3506	
	Median		1.0150		1.3650	
	Variance		.281		.468	
	Std. Deviation		.53053		.68421	
	Minimum		.29		.13	
	Maximum		2.13		3.33	
	Range		1.84		3.20	
	Interquartile Range		.94		.81	
	Skewness		.440	.427	.628	.427
	Kurtosis		-.975	.833	1.248	.833

Deviation	Groups		Intraoral scan		Model scan	
			Statistic	Std. Error	Statistic	Std. Error
ApexMDaxis	Mean		.5153	.08228	.6313	.11718
	95% Confidence Interval for Mean	Lower Bound	.3470		.3917	
		Upper Bound	.6836		.8710	
	5% Trimmed Mean		.4787		.5650	
	Median		.4700		.4000	
	Variance		.203		.412	
	Std. Deviation		.45068		.64180	
	Minimum		.00		.06	
	Maximum		1.73		2.71	
	Range		1.73		2.65	
	Interquartile Range		.66		.80	
	Skewness		1.007	.427	1.559	.427
	Kurtosis		.893	.833	2.401	.833
ApexBLaxis	Mean		.5370	.07516	.7420	.09581
	95% Confidence Interval for Mean	Lower Bound	.3833		.5460	
		Upper Bound	.6907		.9380	
	5% Trimmed Mean		.5181		.7056	
	Median		.4450		.6200	
	Variance		.169		.275	
	Std. Deviation		.41168		.52479	
	Minimum		.01		.00	
	Maximum		1.45		2.32	
	Range		1.44		2.32	
	Interquartile Range		.61		.64	
	Skewness		.734	.427	1.146	.427
	Kurtosis		-.455	.833	1.569	.833

Deviation	Groups		Intraoral scan		Model scan	
			Statistic	Std. Error	Statistic	Std. Error
ApexACaxis	Mean		.5890	.08736	.6850	.09776
	95% Confidence Interval for Mean	Lower Bound	.4103		.4851	
		Upper Bound	.7677		.8849	
	5% Trimmed Mean		.5581		.6635	
	Median		.4850		.5200	
	Variance		.229		.287	
	Std. Deviation		.47850		.53546	
	Minimum		.02		.04	
	Maximum		1.82		1.72	
	Range		1.80		1.68	
	Interquartile Range		.68		.74	
	Skewness		.900	.427	.807	.427
	Kurtosis		.019	.833	-.386	.833

Appendix K Statistical analysis for comparison between groups of angle deviation, 3D deviation at platform, platform deviation at each axis (mesio-distal axis, bucco-lingual axis, apico-coronal axis(vertical)) 3D deviation at apex, apex deviation at each axis (mesio-distal axis, bucco-lingual axis, apico-coronal axis (vertical))

Ranks

	Group	N	Mean Rank	Sum of Ranks
Angle	Oral scan	30	27.78	833.50
	Model scan	30	33.22	996.50
	Total	60		
Platform3D	Oral scan	30	28.28	848.50
	Model scan	30	32.72	981.50
	Total	60		
PlatformMD	Oral scan	30	30.08	902.50
	Model scan	30	30.92	927.50
	Total	60		
PlatformBL	Oral scan	30	28.10	843.00
	Model scan	30	32.90	987.00
	Total	60		
PlatformAC (vertical)	Oral scan	30	29.03	871.00
	Model scan	30	31.97	959.00
	Total	60		
Apex3D	Oral scan	30	26.78	803.50
	Model scan	30	34.22	1026.50
	Total	60		
ApexMD	Oral scan	30	29.33	880.00
	Model scan	30	31.67	950.00
	Total	60		
ApexBL	Oral scan	30	26.97	809.00
	Model scan	30	34.03	1021.00
	Total	60		
ApexAC (vertical)	Oral scan	30	29.25	877.50
	Model scan	30	31.75	952.50
	Total	60		

Test Statistics[a]

	Angle	Platform3D	PlatformMD	PlatformBL	PlatformAC(vertical)
Mann-Whitney U	368.500	383.500	437.500	378.000	406.000
Wilcoxon W	833.500	848.500	902.500	843.000	871.000
Z	-1.206	-.983	-.185	-1.065	-.651
Asymp. Sig. (2-tailed)	.228	.325	.853	.287	.515

a. Grouping Variable: Group

Test Statistics[a]

	Apex3D	ApexMD	ApexBL	Apex AC(vertical)
Mann-Whitney U	338.500	415.000	344.000	412.500
Wilcoxon W	803.500	880.000	809.000	877.500
Z	-1.649	-.518	-1.568	-.555
Asymp. Sig. (2-tailed)	.099	.605	.117	.579

a. Grouping Variable: Group

*: Statistical significant at 95% confident interval by Mann-Whitney U test

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