COMPARISON OF THE ACCURACY OF IMPLANT POSITION USING DIFFERENT DRILLING SYSTEM FOR STATIC COMPUTER-ASSISTED IMPLANT SURGERY: *IN VITRO* STUDY

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A Thesis Submitted in Partial Fulfillment of the Requirements
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การเปรียบเทียบความแม่นยำของตำแหน่งรากฟันเทียม โดยใช้ระบบหัวเจาะต่างๆในการฝังรากฟันเทียมด้วยวิธีคอมพิวเตอร์ช่วยแบบสถิต

น.ส.พักตร์นิสา สิทธิกรไพบูลย์

วิทยานิพนธ์นี้เป็นส่วนหนึ่งของการศึกษาตามหลักสูตรปริญญาวิทยาศาสตรมหาบัณฑิต
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Thesis Title	COMPARISON OF THE ACCURACY OF IMPLANT POSITION USING DIFFERENT DRILLING SYSTEM FOR STATIC COMPUTER-ASSISTED IMPLANT SURGERY: *IN VITRO* STUDY
By	Miss Paknisa Sittikornpaiboon
Field of Study	Oral and Maxillofacial Surgery
Thesis Advisor	Associate Professor ATIPHAN PIMKHAOKHAM, D.D.S. Ph.D.

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

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พักตร์นิสา สิทธิกรไพบูลย์ : การเปรียบเทียบความแม่นยำของตำแหน่งรากฟันเทียม โดยใช้ระบบหัวเจาะต่างๆในการฝังรากฟันเทียมด้วยวิธีคอมพิวเตอร์ช่วยแบบสถิต. (COMPARISON OF THE ACCURACY OF IMPLANT POSITION USING DIFFERENT DRILLING SYSTEM FOR STATIC COMPUTER-ASSISTED IMPLANT SURGERY: *IN VITRO* STUDY) อ.ที่ปรึกษาหลัก : รศ. ทพ. ดร. อาทิพันธุ์ พิมพ์ขาวขำ

วัตถุประสงค์: เพื่อเปรียบเทียบความแม่นยำของการฝังรากฟันเทียมโดยใช้คอมพิวเตอร์ช่วยแบบสถิต โดยใช้ระบบหัวเจาะ 5 แบบ

วัสดุและวิธีการ: แบบจำลองฟันบนที่สูญเสียฟันกรามน้อยซี่แรกทั้งสองด้าน จำนวน 25 ชิ้น ถูกแบ่งเป็น 5 กลุ่มตามชนิดระบบหัวเจาะ ได้แก่ กลุ่มเอ ระบบสลีฟอินสลีฟ กลุ่มบี ระบบสลีฟอินสลีฟแบบเซลฟ์ล็อคกิ้ง กลุ่มซี ระบบเมาท์สลีฟออนดริล กลุ่มดี ระบบอินทีเกรทสลีฟออนดริลแบบมีเมทัลสลีฟ และ กลุ่มอี ระบบอินทีเกรทสลีฟออนดริลแบบไม่มีเมทัลสลีฟ จากนั้นวางแผนตำแหน่งรากฟันเทียมโดยใช้โปรแกรมโคไดแอกโนสติค ทำการฝังรากฟันเทียมผ่านแผ่นจำลองนำทางผ่าตัดโดยแต่ละกลุ่มได้รับการฝังจำนวน 10 ซี่ วิเคราะห์ผลความคลาดเคลื่อนของตำแหน่งรากฟันเทียมหลังฝังเทียบกับตำแหน่งรากฟันเทียมที่วางแผนไว้ โดยวัดจากค่าเฉลี่ยของความคลาดเคลื่อนที่ตำแหน่งของบนของรากเทียม ปลายรากเทียม และความคลาดเคลื่อนเชิงมุม

ผลการศึกษา: ค่าความคลาดเคลื่อนเฉลี่ยที่ตำแหน่งขอบบนของรากเทียมต่ำสุด 0.42±0.12 มม. (กลุ่มบี) และสูงสุด 1.18±0.19 มม. (กลุ่มซี) ที่ปลายรากเทียมต่ำสุด 0.76±0.22 มม. (กลุ่มบี) และสูงสุด 1.95±0.48 มม. (กลุ่มดี) และค่าความคลาดเคลื่อนเชิงมุมต่ำสุด 2.50±0.89 องศา (กลุ่มบี) และสูงสุด 5.30±1.04 องศา (กลุ่มอี) เมื่อทดสอบค่าเฉลี่ยระหว่างกลุ่มของพารามิเตอร์ทั้งสามด้วยสถิติครัสคัล วอลลิส พบว่ามีความแตกต่างอย่างมีนัยยะสำคัญ และเมื่อเปรียบเทียบพหุคูณด้วยวิธีดันน์ เทส พบว่า ทั้งกลุ่มเอและบีมีค่าเฉลี่ยความคลาดเคลื่อนเชิงมุมแตกต่างอย่างมีนัยยะสำคัญทางสถิติเมื่อเทียบกับกลุ่มดีและอี ตามลำดับ ($P < .05$) ส่วนในคู่กลุ่มเอและบี และ คู่กลุ่มดีและอี ไม่แตกต่างกันอย่างมีนัยยะสำคัญทางสถิติ ($P > .05$) ในทุกพารามิเตอร์

สรุปผลการศึกษา: ความแม่นยำของการฝังรากฟันเทียมในระบบหัวเจาะ 5 ระบบมีความแตกต่างกันอย่างมีนัยยะสำคัญ โดยพบว่าอุปกรณ์นำฝังและหลักการออกแบบของแผ่นจำลองนำทางผ่าตัดของแต่ละระบบมีผลต่อความแม่นยำของการฝังรากฟันเทียม

สาขาวิชา	ศัลยศาสตร์ช่องปากและแม็กซิลโลเฟเชียล	ลายมือชื่อนิสิต ....
ปีการศึกษา	2563	ลายมือชื่อ อ.ที่ปรึกษาหลัก ....

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KEYWORD: dental implant, accuracy of implant surgery, static computer-assisted implant surgery

Paknisa Sittikornpaiboon : COMPARISON OF THE ACCURACY OF IMPLANT POSITION USING DIFFERENT DRILLING SYSTEM FOR STATIC COMPUTER-ASSISTED IMPLANT SURGERY: *IN VITRO* STUDY. Advisor: Assoc. Prof. ATIPHAN PIMKHAOKHAM, D.D.S. Ph.D.

Purpose: The aim of this *in vitro* study was to compare the accuracy of implant placement among five drilling systems of sCAIS.

Materials and Methods: Twenty-five 3D printed models with two edentulous bilateral premolar spaces were allocated to five different drilling systems: group A: sleeve-in-sleeve, group B: sleeve-in-sleeve with self-locking, group C: mounted sleeve-on-drill, group D: integrated sleeve-on-drill with metal sleeve in the guide, group E: integrated sleeve-on-drill without metal sleeve. All implants were digitally planned and 10 implants placed with sCAIS in each group. Postoperative 3D deviation of actual vs planned position was measured by means of platform, apex and angular deviation. Data was analyzed using Kruskal-Wallis test ($P \leq .05$). Pairwise comparisons were tested with Dunn's test.

Results: The overall platform deviation ranged from 0.42±0.12 mm (group B) to 1.18±0.19 mm (group C). The overall apex deviation ranged from 0.76±0.22 mm (group B) to 1.95±0.48 mm (group D). The overall angular deviation ranged from 2.50±0.89 degrees (group B) to 5.30±1.04 degrees (group E). Group A and B showed significantly less angular deviation than groups D and E ($P < .05$). There was no statistically significant differences in all parameters between group A and B, as well as between group D and E ($P > .05$).

Conclusions: Significant differences were found with regards to accuracy among the five sCAIS systems tested, suggesting that the drilling protocol, the devices used and the design principles of the guides could influence the accuracy of implant placement.

Field of Study: Oral and Maxillofacial Surgery Student's Signature ....
Academic Year: 2020 Advisor's Signature ....

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Paknisa Sittikornpaiboon

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Chapter I

INTRODUCTION

Background and rationale

Treatment planning for implant placement follows today a prosthetically driven concept in order to achieve long term successful treatment outcomes. As the malposition of dental implants can predispose to esthetic, biological and mechanical failures, prosthetically-driven treatment planning and the accuracy of the implant placement in the ideal planned position are among the major challenges in implant dentistry at present (1).

The recent introduction of computer-assisted implant surgery (CAIS) allows for increased accuracy in achieving the ideal planned implant position through two main approaches; dynamic and static. The sCAIS utilizes a virtual implant planning system and a computer-designed surgical guide (2, 3). Many studies have by now documented the ability of sCAIS to reach significantly higher accuracy of implant position than conventional freehand techniques (4-7).

Nevertheless, sCAIS utilizes a workflow with many steps and the overall accuracy depends on the sum of individual errors from each step of the protocol, starting from the CT radiographic assessment all the way to the surgical implant placement (8, 9). Moreover, the exact configuration of the components and the procedures utilized at the surgical execution, can impact the accuracy of implant placement. For example, the “gap”, or tolerance between the drill and the guiding sleeve can allow a certain extent of lateral and rotational movement of the drill during surgery potentially resulting in deviations (10, 11). Such errors can be categorized as an “intrinsic” (9, 12). Cassetta et al (9) assessed the clinical relevance of the potential error caused by the size of the gap between the sleeve of the surgical guide and the drill, attributing 62.6% of the total deviation to the intrinsic error. Such results suggest the intrinsic error to be a significant influence compared to all of potential factors which could affect the accuracy of computer-aided implant placement.

As each component of the drill guidance system can have an impact on the accuracy of implant placement, different designs of surgical drilling systems have been developed aiming to decrease the potential for errors originating from the fit of the different components (12-14). Consequently, different levels of “tolerance” of movement of the drill within the guiding sleeve have been introduced in different systems (12, 15-17). The sCAIS protocols are still evolving in different directions, utilizing different techniques and modifications. While several different approaches are proposed by manufacturers, very little is known as to the impact of design features to the accuracy and performance.

Hence, the present study aimed to compare the accuracy of implant position using five different sCAIS drilling systems, each with a different drill stabilization configuration. The study was based on an in vitro experimental model, which can eliminate most confounding variables and control each step of the procedures.

Research question

Are there any differences in implant position accuracy in five different drilling systems of static CAIS in an experimental model?

Objective

To compare the accuracy of dental implants placed with a static CAIS system by using different drilling systems.

Hypothesis

The null hypothesis is that the accuracy of implant placement is not different in each group of static CAIS system.

The alternative hypothesis is that the accuracy of implant placement is different in each group of static CAIS system.

Conceptual framework

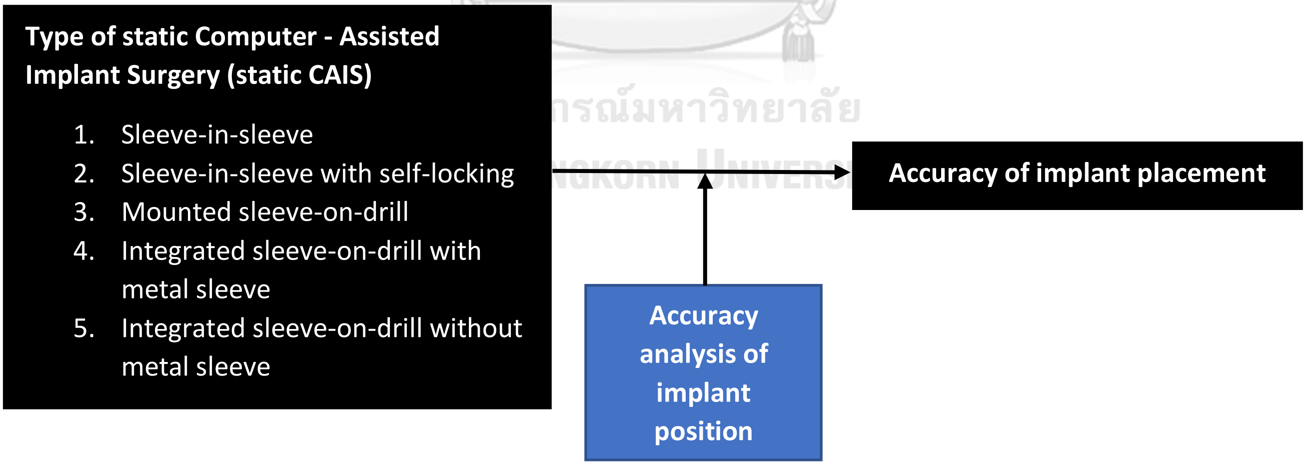


Figure 1 Conceptual framework

Chapter II

REVIEW OF LITERATURES

2.1 Computer-assisted implant surgery (CAIS)

The conventional dental panoramic film with a radiographic template has a limitation, such as distortion, setting error, and position artifacts. This radiograph did not provide 3-dimensional (3D) information of the dental arch. When conventional surgical templates were used, the clinical outcome was often unpredictable (3). They neither reference the underlying anatomical structures nor provide accurate 3D guidance (18). The deviation of the position of the implant may be compromised prosthetic outcome (3).

The introduction of cone-beam computed tomography (CBCT) scanning to implant dentistry as a three dimensional (3D) imaging tool led to a breakthrough in this field, because of these scanning devices result in lower radiation doses than conventional computed tomography (CT) scanners (19). CBCT allows the practitioner to visualize cross-sectional, axial, and panoramic views of the patient’s jaws for more precise planning of the implant therapy (20).

When combining the CBCT and implant planning program, it can create virtual planning to provide the optimal implant position concerning both prosthetic and anatomical parameters (18, 19). The predicted ideal implant position could be achieved that includes the precise dimension of the implant, the ideal depth, and angulation of the implant without damaging the surrounding anatomical structures (19, 20).

Computer-assisted implant surgery(CAIS) was categorized into static and dynamic systems (18). First, the static systems or static computer-assisted implant surgery was any virtual implant planning system using a 3D software application in combination with implant placement by using a CAD/CAM-processed to create a surgical guide. The implant position depended on the stent, which not allow altering position during surgery (2, 21). Second, the dynamic system or dynamic computer-assisted implant surgery use the optical technologies to track the patient and the handpiece and to display images onto a monitor. So the drill was seen in realtime relationship to the three-dimensional image of CBCT, allowed intraoperative changes in implant position (2, 18, 19).

2.2 Static computer-assisted implant surgery

The static computer-assisted implant surgery (sCAIS) used CT-generated computer-aided design and computer-aided manufacturing to created a surgical guide. Traditionally, The surgical guide contained holes for metallic drill-guiding sleeves or metal tube, which use combined with guided surgical kits (2). Recently, sleeve-incorporated stereolithographic guide template design has introduced (12, 16). These type of guide template eliminates the need for additional insertion of metal guide sleeves into the guide template and allow to design the template with a closed or opened hole. Consequently, the workflow was more simple and faster (16). The advantage of sCAIS was the design of guide restricting the drilling process and placement of the implant in three dimensions. The result of implant placement was more predictable and limiting the ability to change the implant position (2, 12).

The workflow of the static computer-assisted implant surgery was summarized (Figure 2). sCAIS requires three-dimensional (3D) imaging of the bone and the planned prosthesis (10). A cone-beam CT scan (CBCT) was used to the visualization of critical anatomic structures and bone configuration for more precise treatment planning and presurgical preparation. The Digital Imaging and Communications in Medicine (DICOM) data was generated from the CBCT scan (22). Conventionally, the CBCT scan was taken with the prosthetic plan in the mouth as an imaging guide. Fabrication of the imaging guide requires laboratory work before scanning, which will necessitate time delays and additional cost to the team and, hence, added cost to the patient (6). At present, a virtual computerized prosthetic wax-up or digital scanning from an analog wax-up can be used as an alternative way to visualize the ideal prosthetic setup.

Because of the poor contrast resolution of the CBCT imaging, the information for soft tissue was inaccurate. Optical scanning technology was used to provide soft tissue profile information as well as accurate information of teeth contours because the optically scanned model was scattered free. Optical scanning was divided into two types; model scan and intraoral scan. This scanning system provides the STL (Standard Tessellation Language) file (23). Both STL file and DICOM file were imported into the implant planning software which matching to create a 3D model for virtual planning of implant surgery. When the planning completed, the plan will be uploaded to fabricate a surgical guide with CAM rapid prototyping or an analog method (3D printing or milling). Once the guide stent has been delivered, the surgery can be performed (10).

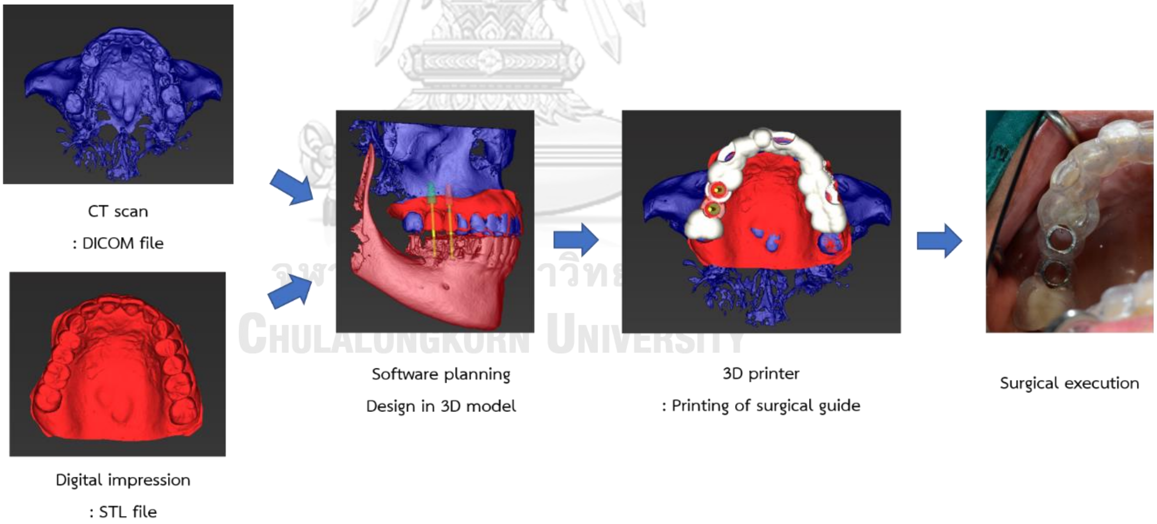


Figure 2 Workflow of the static guided surgery

2.3 Accuracy of static computer-assisted implant surgery (static CAIS)

Several recent systematic reviews of static computer-assisted implant placement summarized the accuracy of implant placement (Table 1). For analyzing the accuracy, the planned position of the implant was compared with the placed position of the implant after insertion (19). Data from the latest systematic by Tahmaseb er al. (2018) (24) review reported that the accuracy (20 clinical) revealed a total mean error of 1.2 mm (1.04 mm to 1.44 mm) at the entry point, 1.4 mm (1.28 mm to 1.58 mm) at the apical point and deviation of 3.5°(3.0° to 3.96°). This review concluded data from a total of 2,238 implants in 471 patients that had been placed using static guides in partial and fully edentulous human subjects. There was a significant difference in accuracy in favor of partial edentulous comparing to fully edentulous cases.

Previously, the systematic review by Tahmaseb et al. (2014) (19) was also analyzed the accuracy of guided implant surgery in various type of study. Data included from the total of 24 articles; 14 clinical studies, 5 model studies, and 5 cadaver studies. Overall mean deviation at the entry point of 0.9 mm (95% CI 0.7–1.1), with a maximum of 4.5 mm. The corresponding data at the apex were 1.3 mm (95% CI 0.05–1.5), with a maximum of 7.1 mm. The overall mean deviation in angulation was 3.5° (95% CI 3.0–4.1), with a maximum of 21.2 mm. Statistically significant differences were observed for all three parameters in the clinical trials versus the model studies. Model studies showed significantly better accuracy.

Recently, the systematic review by Bover-Ramos F et al. (2018) (25) analyzed the accuracy relate with study type (model, clinical and cadaver). Data included from the total of 34 articles; 22 clinical studies, 8 model studies and 4 cadaver studies. The outcome was measured in 2D deviation. Significantly less horizontal apical deviation and angular deviation were observed in model studies compared to clinical and cadaver studies, but there were no statistically significant differences in a vertical deviation between the groups. Only 14 of the 34 articles of the meta-analysis measured vertical deviation. The overall vertical deviation was 0.64±0.09 mm (95% CI 0.47–0.82). Mean value of 0.28±0.05 mm for cadaver studies, 0.74±0.10 mm for clinical studies, and 0.61±0.15 mm for model studies.

No.	Study (year)	Study type	No. article	No. subjects	No. implants	Angle deviation (°)		Platform deviation (mm)		Apex deviation (mm)	
						Mean	CI 95%	Mean	CI 95%	Mean	CI 95%
1	Tahmaseb et al. (2018)	Overall	20	471	2,238	3.5	[3.0 to 3.96]	1.2	[1.04 - 1.44]	1.4	[1.28 - 1.58]
		Partially edentulous cases	-	-	-	3.3	[2.07-4.63]	0.9	[0.79 - 1.00]	1.2	[1.11-1.20]
		Fully edentulous case	-	-	-	3.3	[2.71-3.88]	1.3	[1.09 - 1.56]	1.5	[1.29-1.62]
2	Tahmaseb et al. (2014)	Overall	24	-	2,819	3.53	[2.98 – 4.08]	0.93	[0.74 – 1.13]	1.29	[1.05 – 1.52]
		Cadaver	5	-	390	3.32	[2.28 – 4.36]	1.22	[0.93 – 1.51]	1.28	[0.92 – 1.65]
		Model	5	-	74	1.44	[0.68 – 2.21]	0.36	[0.23 – 0.49]	0.73	[0.27 - 1.19]
		Clinical	14	-	2,355	4.06	[3.50-4.62]	1.04	[0.85-1.24]	1.45	[1.18 – 1.73]
3	Bover-Ramos, F., et al. (2018)	Overall	34	-	3,033	3.48±0.26	[2.96 – 3.99]	1.03±0.08	[0.88 – 1.18]	1.29±0.10	[1.11 – 1.48]
		Cadaver	4	-	246	2.82±0.40	[2.03 – 3.61]	1.18±0.12	[0.95 – 1.43]	1.52±0.18	[1.17 – 1.87]
		Model	8	-	543	2.39±0.35	[1.70 – 3.08]	0.77±0.15	[0.48 – 1.07]	0.85±0.17	[0.54 – 1.18]
		Clinical	22	-	2,244	3.98±0.34	[3.31 – 4.64]	1.10±0.09	[0.91 – 1.28]	1.40±0.12	[1.16 – 1.64]

Table 1 Systematic review on the accuracy of static computer-assisted implant surgery (static CAIS)

2.4 The tolerance within the surgical guide

However, The deviations between the placed and the planned implant are summations of all individual errors. An error can occur at each step of the protocol; starting from imaging to the transformation of data into a guide, to the improper positioning of the guide during surgery (8-11) (Figure 3).

Possible individual errors result from both intrinsic sources and extrinsic source, the intrinsic was include issues with radiography quality, file conversion, CAD software; and extrinsic sources, which relate to the fit of the surgical guide, the mucosal thickness at the surgical site, the position of the edentulous area, and the surgeon’s experience (12).

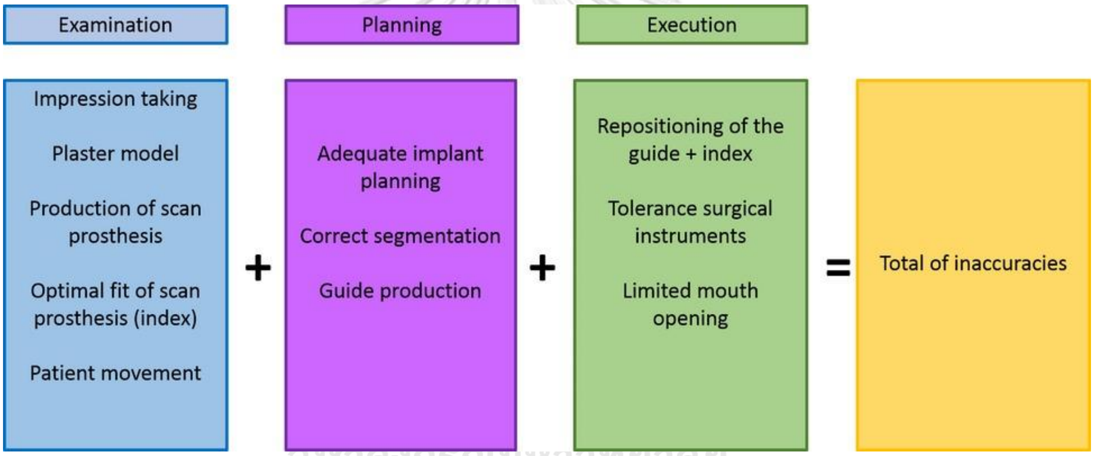


Figure 3 Deviations may reflect the sum of all errors occurring from imaging to the transformation of data into a guide, to the improper positioning of the latter during surgery. From “Computer-supported implant planning and guided surgery: a narrative review” by Vercruyssen M et al., 2015, Clin Oral Implants Res, 26(Suppl11), 69-76

An error can also occur during surgery due to the tolerance of the drill within the metal sleeve (11, 13). The tolerance caused by the gap between the drill and metal sleeve, which allowed lateral movements and rotational movement of the drill during surgery (Figure 4). This error can be defined as an intrinsic error. (9, 12) This error might be critical in a clinical situation where difficult to access of instrument, especially in the posterior region. When using static guide surgery in the posterior region, the eccentric force might accidentally occur during the drilling process, thereby affecting the overall accuracy (8). On the other hand, static CAIS use a tolerance between the drill and sleeve to prevent friction-related heat and cutting of metal sleeve during the surgery (7, 8). During the drilling process, the surgeon should be aware of the direction of the drill within the sleeve. The drill should keep parallel to the guide in a centric position (11).

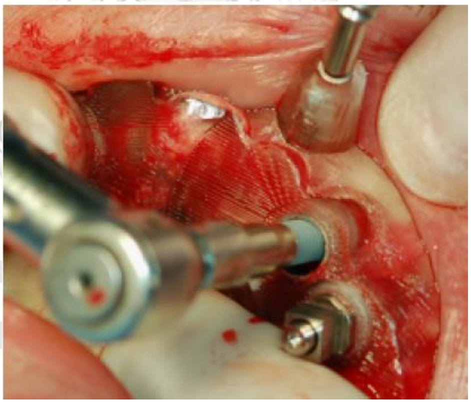


Figure 4 The tolerance of the drill within the guiding sleeve.

The intrinsic error impacted the accuracy of computer-aided implant placement. Cassetta et al. was assessed the clinical relevance of the potential mechanical error (intrinsic error) caused by the cylinder-burr gap in fully edentulous patients. The result of a fixed Safe® guide (External Hex Safe®, Materialise Dental, Leuven, Belgium) gave a mean angular deviation of 4.11 degrees. These compare to a theoretical angular error was 2.57 degrees. The intrinsic error was 62.6% of the total error, indicating that the intrinsic error was a significant factor compared to all of the factors which could affect the accuracy of computer-aided implant placement (9).

Some experimental model study showed to evaluated the degree of deviation that can occur during the drilling procedure due to the tolerance of the drill in the guiding sleeve (Table 2). Van Assche N and Quirynen M (11) estimate the amount of the deviation due to the tolerance of the drill in the drill key in two static guide system. A mean of angular deviation was 4.7 degrees and coronal deviation was 0.8 mm and 1.8 mm at the apex of implant length 13 mm. Koop et al. (13) found that the maximum deviation of angulation was 5.2 degrees and a maximum coronal deviation of 1.3 mm and apical deviation of 2.4 mm for implant length 13 mm.

Laederach et al. (8) compare the deviation of different systems for guided implant surgery related to the tolerance between drills and sleeves. Four different systems were tested: Camlog Guide® (CG), Straumann Guided Surgery® (SG), SIC Guide® (SIG), and NobelGuide® (NG). There were statistically significant differences in angular deviation between centric and eccentric drilling for all four systems. Coronal and apical deviations, showed no statistical significance between centric and eccentric drilling for SIG and NG, in contrast to CG and SG. The angular deviation ranged from 0 (SG) to 5.64 degrees (CG). The apical deviations ranged between 0.01 mm (SIG) and 3.2 mm (NG) and the coronal deviations ranged from 0.01 mm (SIG) to 1.60 mm (NG) (8). A significance analysis between the individual systems were not analyzed because each system has the difference of cavity depth preparation, sleeve length, the distance of sleeve to bone and finally drill diameters. Therefore, the deviation of each system was depended on the design of the surgical guide components. However, the degree of deviation that caused by tolerance of the drill in the guiding sleeve has limited evidence to be evaluated and inconclusive.

Study	Manufacture	Drilling system	Drilling force	Drill ø /length (mm)	Angular deviation (°)			Coronal deviation (mm)			Apical deviation (mm)		
					Mean	SD	Range	Mean	SD	Range	Mean	SD	Range
Van Assche et al. (2010)	Overall	-	EA*	Ø 2, 3.2 / 13	4.7	1	3.5-6	0.8	0.2	0.6-1.1	1.8	0.5	1-2.7
	Nobelguide®	Sleeve-in-sleeve	EA	Ø 2 / 13	5.6	0.5	5-6	1.0	0.3	0.6-1.3	2.0	0.7	1-2.7
	Facilitate®	Sleeve-in-sleeve	EA	Ø 3.2/ 13	3.8	0.3	3.5-4.0	0.7	0.2	0.6-0.9	1.4	0.3	1.1-1.6
Koop et al. (2013)	Overall	-	EA	Ø 2.9 and 3.15 / 13	4.8	0.5	3.9-5.2	1.0	0.2	0.7-1.3	2.1	0.3	1.7-2.4
	Expertease®	Mounted sleeve-on-drill	EA	Ø 2.9/13	5	0.2	4.9-5.2	1.1	0.2	0.9-1.2	2.2	0.2	2-2.4
	SurgiGuide universal®	Sleeve-in-sleeve	EA	Ø 3.15/13	4.7	0.7	3.9-5.2	1.0	0.2	0.7-1.3	2.0	0.3	1.7-2.2
Laederach et al. (2017)	Camlog Guide®	Integrated sleeve-on-drill	EA	Ø 3.8, 4.3 / 11, 13	3.21	1.32	1.73-5.64	0.34	0.12	0.18-0.49	0.68	0.25	0.37-0.98
			C**		1.2	1.36	0.36-4.48	0.12	0.06	0-0.21	0.23	0.12	0- 0.41
	Nobel Guide®	Integrated sleeve-on-drill	EA	Ø 2, 2.8 and 3.6 / 10, 13	3.05	1.66	1.4-5.36	0.84	0.53	0.35-1.6	1.68	1.07	0.69-3.2
			C		1.01	1.46	0.01-3.3	0.38	0.52	0-1.1	0.75	1.04	0-2.19
	SIC Guide®	Sleeve-in-sleeve	EA	Ø 2.8, 3.1 and 3.25 / 11.5, 13	0.36	0.21	0.09-0.7	0.1	0.08	0.01-0.26	0.21	0.15	0.01-0.51
			C		0.02	0.03	0-0.06	0.04	0.06	0-0.19	0.07	0.12	0-0.37
	Straumann Guided Surgery®	Sleeve-in-sleeve	EA	Ø 2.2, 2.8 and 3.5 / 10, 12	0.37	0.34	0-1.02	0.15	0.08	0.02-0.29	0.31	0.15	0.03-0.57
			C		0.04	0.03	0-0.12	0.05	0.03	0.01-0.11	0.1	0.05	0.01-0.21

*EA= Eccentric drilling force, maximum inclination of the drill to the left and to the right.

**C= Centric drilling force, the most centric position of the drill in the sleeve.

Table 2 Model studies on degree of deviation due to tolerance of the drill within guiding sleeve

2.5 Factor influence the accuracy due to the tolerance within the surgical guide

Each component of the drill guidance system has been shown to impact the accuracy of implant placement. Some study showed to investigate the effect of the different guide components on the accuracy of the guide system.

Koop et al. (13) evaluated the degree of deviation that can occur due to the tolerance of the drill in the sleeve insert by using an plexiglass box for representing the bone. The drill was maximum inclination of the to the left and right. The degree of deviation was measured from theoretically ideal osteotomy and concluded in term of coronal, apical and angular deviation (Figure 5c). The study reported in descriptive data. They suggested that different type of sleeve insert affect to degree of deviation. The result showed that the hand hold sleeve inserts was less deviation than the drill hold sleeve insert (Figure 5a). Moreover, the deviation increased by longer distance of the sleeve to the bone (Figure 5b), shorter drill key height (Figure 6), shorter sleeve height (Figure 7) and longer implant length. The result coincided with Van Assche N and Quirynen M (11) who estimated the amount of the deviation due to the tolerance of the drill in the drill key in two static guide system using an experimental model. The study revealed that apical deviation depended on implant length in any distance on the sleeve to the bone. The coronal and apical deviation also increased if the distance from sleeve to bone and implant length increased. The author also suggested that increased drill key height will minimize the inaccuracy. And during the surgery, the drill should be used in a centric position to reduced the deviation (11, 13).

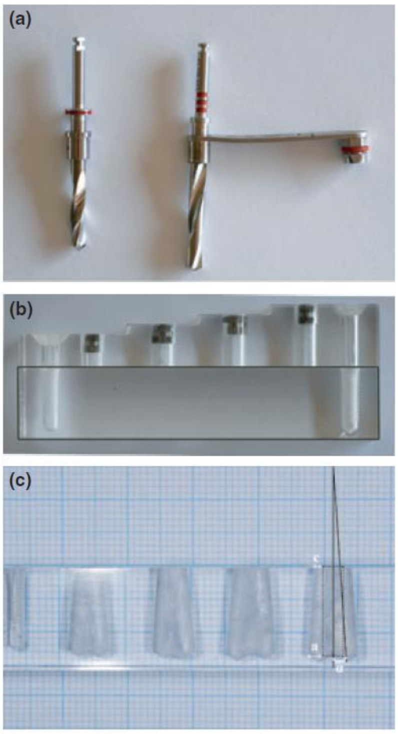


Figure 5 (a) At left the drill hold sleeve insert and at right the hand hold sleeve insert attached to the drill. (b) Box representing surgical guide (from left to right) with sleeves at a distance of 3, 5, 7 and 9 mm from a plexiglass box. (c) Plexiglass box after preparation of osteotomies with maximal inclination of the drill within the sleeve insert to the left and right placed on millimeter paper (dotted line represents the theoretically ideal osteotomy). Measured distances and angle from theoretically ideal osteotomy, mean of mesial and distal measurements; c, coronal deviation; a, apical deviation; α*, deviation in angulation.*

Figure 6 At left 5 mm and at right 8 mm hand hold sleeve insert (drill key).

Figure 7 Surgical guide (from left to right) with different sleeve heights of 3, 5, 7 and 9 mm respectively.

El Kholy et al. (14) evaluated the effect of guided sleeve height (distance from the apical border of the sleeve to the implant shoulder) (Figure 8), free drilling distance (FDD) (Figure 9), and drill key height on the accuracy of sCAIS by using 30 acrylic models simulating human bone with 6 potential sites for implant placement corresponding to FDI positions 12, 15, 21, 23, 25, and 26. And the surgery was performed according to manufacturer's recommendations (Straumann® Guided Surgery, Straumann AG, Basel, Switzerland). Pre-planned and post-surgical implant position were superimposed in the implant planning software (coDiagnostiX software, Dental Wings GmbH, Chemnitz, Germany). The 3D deviation at implant platform and implant apex and angle deviation were measured. Data was analyzed using multivariate analysis ANOVA. The result showed that the accuracy of implant position was not influenced significantly by guided sleeve height and implant length alone. However, the FDD and guided key height or drill key height were markedly affected on the accuracy of the implant position.

The free drilling distance (FDD) defined as the linear measurement from the bottom of the guided sleeve to the tip of the surgical drill (bottom of the osteotomy). The FDD was calculated into three groups; 14 mm, 16 mm and 18 mm. The results of the analysis demonstrated significant effects of the FDD ($P < .01$). FDD 18 mm resulted in a significantly higher deviation, when compared to FDD 14 mm or 16 mm, irrespective of sleeve height or implant length ($P < .01$).

Moreover, the drilling key height had a significant effect on the accuracy of implant position ($P < .01$). Key height 3 mm resulted in significantly less 3D deviation than 1 mm key height ($P < .01$). The result can be concluded that decreasing the FDD (by using shorter sleeve heights or shorter implants) and increasing of the guided key height above the sleeve can significantly improve the accuracy of static CAIS.

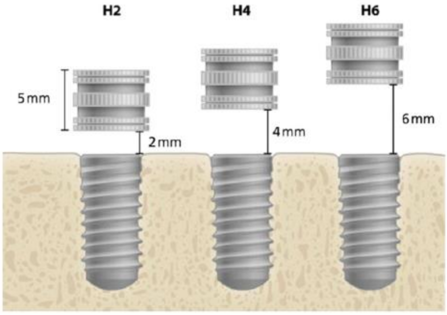


Figure 8 Sleeve height: Distance from the apical border of the sleeve to the implant shoulder

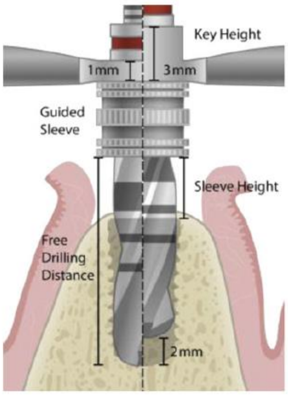


Figure 9 Free drilling distance (FDD) calculation in static CAIS.

Free drilling distance = drill length – (sleeve length + guided key height).

Cassetta M et al. (9) determined the accuracy of a 'single type' stereolithographic surgical guide (External Hex Safe®, Materialise Dental, Leuven, Belgium) in fully edentulous patients. The study showed the tolerance between the master tube and internal tube allows for a theoretical error of 2.86° in a condition which internal tube has a diameter 0.2 mm smaller than master tube and master tube height 4 mm. The tolerance between the internal tube and the drill leads to a theoretical angular error of 2.29° in a condition of internal tube height 5 mm and 0.2 mm is the difference between the diameters of the internal tube and the drills. If the angular deviation between the master tube and the internal tube, and the angular deviation between the internal tube and drills were summed together, it results in a theoretical total angular deviation of 5.15° (2.86° + 2.29°). The authors' calculations showed that the length of sleeve height is one of the variables that affect accuracy. A longer tube, while maintaining the other variables constant, corresponds to less deviation between the pre-planned and post-surgical implant positions. This result was consistent with Choi M et al. (26) They conducted in vitro study and found that the length of the surgical guide channel may be the primary factor in controlling the angular deviation of implant.

Cassetta M et al. (9) also found that in the coronal and apical deviation also influenced by the mucosal thickness and implant length. The conclusion suggested that the mucosa thickness affects coronal and apical deviations, whereas the implant length only affects the apical deviation. These finding was similar to the previous study conducted by Van Assche N and Quirynen M (11) showed that that coronal and apical deviations increased with an increasing distance of the sleeve from the bone and longer implant.

Schneider et al. (13) evaluated the tolerance of the surgical guide components by using 3-D printing with reduced sleeve diameter compared with conventional metal sleeves from two different manufacturers; Astra Facilitate Guided Surgery System (Astra Tech Dental, MÖlndal, Sweden) and Straumann Guided Surgery System (Institute Straumann AG, Basel, Switzerland). The 3-D printing with reduced sleeve diameter and the metal sleeve was inserted in a T-shaped 4-mm-thick device containing two holes simulating a surgical guide.

3-D printing with reduced sleeve diameter was used to decrease amount of the tolerance between the printed sleeves and the drill-guiding keys. The results revealed that the amount of lateral movement of the tip of the drill was statistical significance reduced in both groups. The use of 3-D printing with reduced sleeve diameter can decrease the amount of lateral movement due to tolerance between the sleeve and the drill key was reduced. And the author also concludes that the lateral movement of the drill can be further reduced by using a shorter drill and a higher drill key. For geometric reasons, the amount of lateral movement at the tip of the drill also depended on the length of drills and drill keys. A longer guiding channel was found to be reducing the angular deviations of implants in an in-vitro investigation (26). Based on the lever principle, longer drills exhibit more lateral movement. Longer drill keys lead to longer guidance of the drill within the drill key, and therefore, the lateral movement of the drill is reduced. Also, the movement between the drill key and the sleeve seems to be reduced by increasing the drill key height.

2.6 Various design of the static Computer-Assisted Implant Surgery

Nowadays, sCAIS had developed various designs of surgical guide templates. The drill guidance varies upon the system. Most systems were used the metal sleeve inserted into the surgical guide template to control the drilling. The drilling system component was difference according to manufacturer recommendation (27) (Table3).

Implant company	System	Surgical guide	Guidance by	Guidance for
Astratech, MÖlndal, Sweden	Facilitate	Simplant SICAT	Drill Positioning Handle	All drills and implants
BioHorizons, Birmingham, AL, USA	Pilog Compu-Guide	Pilog Compu-Guide	Multiple sleeves	Pilot drills
Biomet 3i, Palm Beach Gardens, FL, USA	Navigator	Simplant SICAT	Drill Positioning Handle	All drills and implants
Bredent, Senden, Germany	SKYplanX	SKYplanX	Sleeve in sleeve	All drills and implants
Camlog, Wimsheim, Germany	Camlog Guide	coDiagnostiX med3D SICAT Simplant	Integrated sleeve on drill	All drills and implants
Dentsply Friadent, Mannheim, Germany	ExpertEase	coDiagnostiX med3D SICAT Simplant	Mounted sleeve on drill	All drills and implants
Keystone Dental, Drillington, MA, USA	Easy Guide	Easy Guide	Sleeve	Drills
Nobel Biocare, GÖteborg, Sweden	Nobel Guide	Nobel Guide	Drill Positioning Handle	All drills and implants
Straumann, Basel,	Guided	coDiagnostiX	Drill Positioning	All drills and

Implant company	System	Surgical guide	Guidance by	Guidance for
Switzerland	Surgery	med3D Scan2Guide SICAT Simplant	Handle	implants

Table 3 Implant systems with instruments for guided surgery.

The recent study field of the accuracy of sCAIS developed the modified system of the guide surgery component to decrease the error that originated from tolerance of the drill within the guiding sleeve or an intrinsic error (Table 4). Cassetta et al. (15) determined the effect of limiting tolerance among the mechanical components (intrinsic error) on the accuracy of implants placement. They modified mechanical components. Two tubes were used; the guide tubes were connected directly to the head of the surgical handpiece (Figure 10), and a master tube was attached to the surgical guide. Guide tubes were inserted into the master tube and allowed movement only vertical direction (Figure 11). Because the tolerance between the master tube and the guide tube was reduced. The guide tube has a diameter 0.05 smaller than the master tube, and this leads to a maximum theoretical angular deviation of 0.71°. Each system gave a mean of angular deviation of 1.8° for modified components system and 4.3° for the system without the guide tube. As a result, the modified mechanical component system showed statistically significant better accuracy of angular deviation than the system without the guide tube. These results confirm that accuracy is influenced by the surgical guide’s intrinsic error showing that by limiting the error that originates from the mechanical components, the total error could be statistically significantly reduced.

Figure 10 A guide tube directly screwed to the head of the surgical handpiece

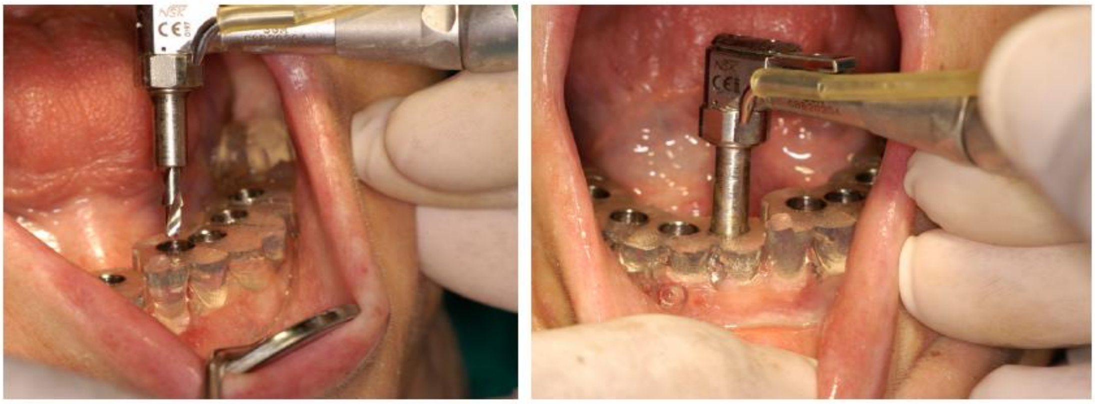


Figure 11handpiece inserted into the master tube.

In the present, 3-D printing has becoming popular in industrial application. Due to its relatively low costs and its high precision, this technology has also been introduced for surgical guide production from biocompatible acrylate materials. These surgical guides can be designed and modified using computer-aided design (CAD) software. This guide allows to eliminate the incorporation of metal guiding sleeves and possibly to decrease the tolerance between drill and sleeve.

Lee DH et al. (12) evaluated the accuracy of a direct drill-guiding system in partially edentulous patients. This system design was modified by using shank-modified drills and a sleeve-incorporated stereolithographic guide template. The structure of shank-modified drills has three parts: The stopper part, the guide part, and the drilling part (Figure 12). The guide part of the drill used as a guiding component to limit drilling motion with little tolerance. And a metal sleeve was not necessary because a guide sleeve integrated with the stereolithographic surgical guide (Figure 13). The study showed the result of a mean horizontal deviation of

0.642 mm and mean vertical deviation of 0.925 mm and a mean angular deviation was 2.207°. The guiding surface makes direct contact with the inner surface of the sleeve, the tolerance of the drill was markedly decreased. And the combination using of shank-modified drill and sleeve integrated stent will restrict the implant instruments and leads to more accurate implant placement.

Figure 12 Surgical instruments used in the direct drill guiding system (R2GATE).

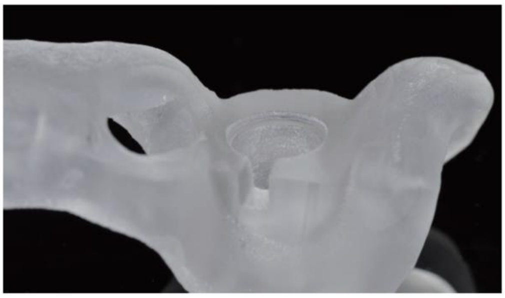


Figure 13 Guide sleeve component of the guide template.

Tallarico M. et al. (16) investigated the accuracy of the sleeve-incorporated stereolithographic guide template design (Osstem Guide Kit[Taper], Osstem) in partially edentulous patients. The study design was a multicenter prospective study. A total of 39 patients with 119 implants were evaluated. Implant placement performed at two centers by two expert clinicians. At center one, the surgical templates were sleeve designed with a closed hole in case of implants to be placed between premolars, while open holes were designed for molars replacement. While, at center two, all the surgical templates were sleeve-designed with closed holes (Figure 14).

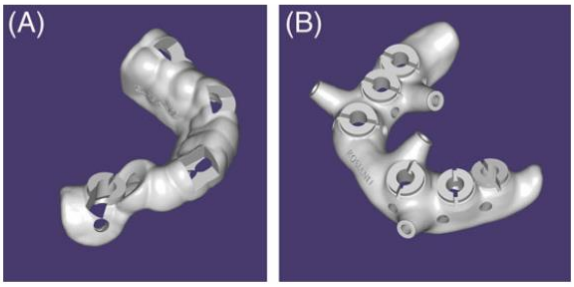


Figure 14 A, Surgical templates designed with open holes used for molars replacement. B, Surgical templates designed with closed hole in case of implants to be placed between premolars

The total mean deviations were 0.53 ± 0.46 mm (range 0.05-3.38 mm; 95% CI 0.32-0.48 mm) in the horizontal plane (mesio-distal); 0.42 ± 0.37 mm (range 0.0-1.53 mm; 95% CI 0.26-0.40 mm) in the vertical plane (apico-coronal); and 1.43 ± 1.98° (range 0.03-11.8°; 95% CI 0.31-1.01°) in angle. Moreover, the result of accuracy when data of accuracy of open hole design template was excluded, the total mean deviation of center one group was improved. The subgroup comparison of implants accuracy between anterior and posterior implants revealed statistically significant differences between groups with more accurate results for anterior implants in both horizontal plane and angle. Viceversa, no statistically significant differences between groups were reported for vertical plan accuracy.

Tallarico M et al. (28) also compared the accuracy of implant placement between surgical template with and without metallic sleeves. They found that the angle deviation were significant difference. And the implant placed with template without metallic sleeve were lower vertical deviation. Hence, these studies suggest that surgical template without metallic sleeve were more accurate in term of the vertical and angle of implant placement when compared to the metallic sleeve template.

The sleeve-in-sleeve concept (Figure 15) was popular system for drill guidance. In briefly, the system uses the drill key as a main component of guidance. The drill key has cylindrical guide sleeves which an external diameter that fits precisely into the sleeve. The surgical drill kit was passed through this guide sleeve to make precise guidance during the drilling procedure. The drill key composes of two different heights as the optional for surgeon to adjust according to clinical situation.

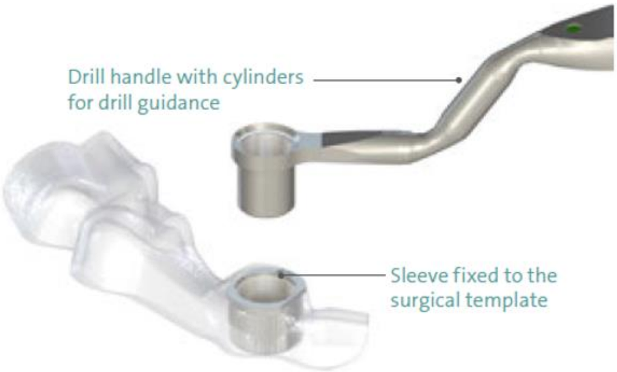


Figure 15 Illustrating device of sleeve-in-sleeve system

Smitkarn P et al. compare the accuracy of implant position between sCAIS and freehand implant surgery in a single tooth space. Fifty-two patients received 60 single implants. The guide implant surgery was done by using Straumann® Guided Surgery (Straumann AG, Basel, Switzerland) which used sleeve-in-sleeve system. The median (IQR) deviations in angles, platform and apex were 2.8 (2.6)°, 0.9 (0.8) mm and 1.2 (0.9) mm, respectively, in the sCAIS group, and 7.0 (7.0)°, 1.3 (0.7) mm and 2.2 (1.2) mm, respectively,

Recently, the sleeve-in-sleeve with self-locking system (Figure 16) was newly developed. This system was used for placement of implant BLX by guided surgery (Straumann® VeloDrill™ Guided Surgery, Straumann AG, Basel, Switzerland). This system was modified drill key that guides sleeves with an exterior surface and a sleeve that an internal surface defining a through bore configured to receive the guide sleeve of the drill key. This modified design supported an anti-rotation function and locked the drill key into the sleeve. The drill key height and sleeve height was like previous system.

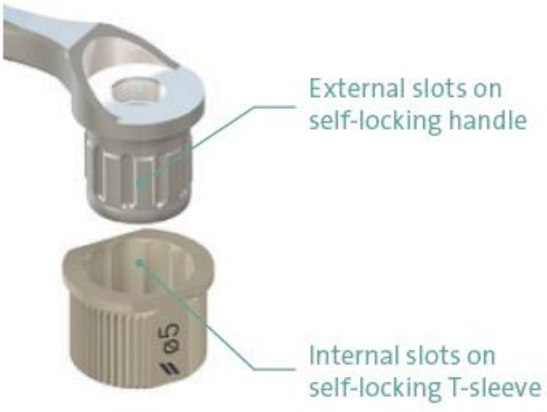


Figure 16 Illustrating the self-locking design component.

No.	Study (year)	Study design	Manufacture	Drilling system	No. implants	Angle deviation (°)			Platform deviation (mm)			Apex deviation (mm)			Vertical deviation (mm)		
						Mean	Range	CI 95%	Mean	Range	CI 95%	Mean	Range	CI 95%	Mean	Range	CI 95%
1.	Cassetta et al (2015)	Retrospective study	External Hex Safe system	-	66	4.3	0.28-14.34	-	-	-	-	-	-	-	-	-	-
			Modified External Hex Safe system	integrated sleeve-on-drill with metal sleeve system	71	1.8	0.30-3.48	-	-	-	-	-	-	-	-	-	-
2	Lee, D. H. et al. (2016)	Prospective clinical study	R2GATE 1.0	integrated sleeve-on-drill without metal sleeve system	21	2.21±1.05	-	-	0.642±0.296	-	-	-	-	-	0.925±0.376	-	-
3	Tallarico, M. et al. (2019)	Multicenter prospective study	OsstemGuide Kit [Taper]	integrated sleeve-on-drill without metal sleeve system	119	1.43±1.98	0.03-11.8	(0.31-1.01)	0.53±0.46	0.05-3.38	(0.32-0.48)	-	-	-	0.42±0.37	0.0-1.53	(0.26-0.40)
4	Tallarico, M. et al. (2019)	RCT	OsstemGuide Kit [Taper]	integrated sleeve-on-drill without metal sleeve	49	1.98±2.38	0.1-11.8	0.13-1.47	0.61±0.49	0.05-2.53	0.36-0.64	-	-	-	0.37±0.28	0-1.3	0.23-0.39

				system													
				integrated sleeve-on-drill with metal sleeve system	41	2.25±1.41	0.3-5.0	0.52-1.65	0.52±0.3	0.1-1.1	0.39-0.61	-	-	-	0.58±0.44	0-1.6	0.44-0.76
5	Smitkarn P et al.	RCT	Straumann® Guided Surgery	Sleeve-in-sleeve	30	3.1±2.3	0.00-8.60	-	1.0±0.6	0.2-2.67	-	1.3±0.6	0.24-2.57	-	-	-	-

Table 4 Studies on accuracy of static computer-assisted implant surgery (static CAIS) according to the design of drilling system

Chapter III

MATERIALS AND METHODS

3.1 Materials

3.1.1 Material for model preparation

- Synthetic polyurethane foam block (Sawbones®, Washington, United States)
- Grey Resin P Pro (Straumann AG, Basel, Switzerland)

3.1.2 Cone Beam Computed Tomography (CBCT) scanner

- X-mind Trium (de Götzen S.r.l.-Acteon Group, Varese, Italy)

3.1.3 Implant guided surgery kit

- Straumann® Guided Surgery (Straumann AG, Basel, Switzerland)
- Straumann® VeloDrill™ Guided Surgery (Straumann AG, Basel, Switzerland)
- Astra Tech Implant System® EV Guided surgery (Dentsply Sirona, Pennsylvania, United States)
- Dentium Guide Kit (Dentium, Seoul, South Korea)

3.1.4 Implant

- Implant Bone level tapered (BLT), RC Ø 4.1 x 12 mm (Straumann AG, Basel, Switzerland)
- Implant BLX Ø 4.0 x 12 mm (Straumann AG, Basel, Switzerland)
- Implant Astra Tech OsseoSpeed EV conical Ø 4.2 x 11 mm Dentsply Sirona, Pennsylvania, United States)
- Implant Superline II Ø 4.0 x 12 mm (Dentium, Seoul, South Korea)

3.1.5 Planning and accuracy analysis software

- coDiagnostiX software (Dental Wings GmbH, Chemnitz, Germany)

3.1.6 Surface scanner

- 3shape intraoral scanner (3shape, Copenhagen, Denmark)
- Cares 7 SERIES (Dental wings, Montreal, Quebec, Canada)

3.1.7 Surgical guide stent

- P Pro Surgical Guide (Straumann AG, Basel, Switzerland)

3.1.8 3D Printer

- Straumann® CARES® P30+ (Straumann AG, Basel, Switzerland)

3.1.9 Statistic analysis software

- IBM SPSS Statistics software version 22 (SPSS Inc., Chicago, Illinois)

3.2 Method

3.2.1 Sample assignment

The models were randomly assigned according to a computer-generated randomization list into five groups (A-E); group A: sleeve-in-sleeve system (Straumann® Guided Surgery, Straumann AG, Basel, Switzerland), group B: sleeve-in-sleeve with self-locking system (Straumann® VeloDrill™ Guided Surgery, Straumann AG, Basel, Switzerland), group C: mounted sleeve-on-drill system (Astra Tech Implant System® EV Guided surgery, Dentsply Sirona, Pennsylvania, United States), group D: integrated sleeve-on-drill with metal sleeve system (Dentium Guide Kit, Dentium, Seoul, South Korea), and group E: integrated sleeve-on-drill without metal sleeve system (Dentium Guide Kit, Dentium, Seoul, South Korea). Each group used five models and ten implants.

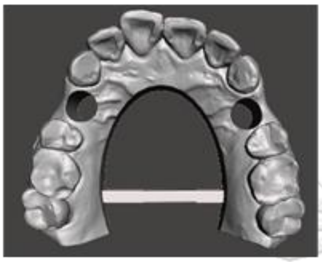
3.2.2 Sample size calculation

The sample size was calculated using mean and standard deviations obtained from a previous study by Laederach V et al (8). The mean of the angle deviation of four groups of static CAIS systems were 1.2, 1.01, 0.02 and 0.04, with SD within each group was 0.7. The calculation was performed using statistical software (G*Power 3.1, Franz Faul, Christian-Albrechts-Universität Kiel, Kiel, Germany) for ANOVA test with 90% of study power and a significant level (α) of 0.05. Based on these settings, we obtained 36 implants and for drop out 10%. We needed ten implants per group. The total samples were 50 implants.

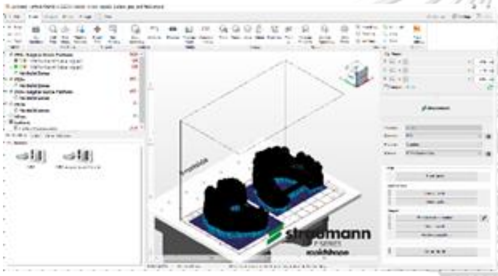
3.2.3 Model preparation

The intraoral scan were obtained from a subject with an edentulous site at both sides of the maxillary first premolar. The subject was scanned using the 3shape intraoral scanner (3shape, Copenhagen, Denmark) to generate the Standard Tessellation Language (STL) file used as a model prototype. The SLT file was imported into Meshmixer version 3.5.474 (Autodesk Inc., California, United States) to create a digital horseshoe-shaped full-arch model with a bar. The hollow was designed into a digital model for inserting a cylinder-shaped bone block size 7 mm in diameter and 15 mm in length at both sides of the edentulous area. The slicing software, like Netfabb Premium 2020 (Autodesk Inc., California, United States) was used to prepared digital model for 3D printing. This file was imported to Netfabb Premium 2020 to generated support and sliced object into layer with specific code file. The digital models were printed with P Pro Master Model Grey (Straumann AG, Basel, Switzerland) at a layer thickness of 0.05 mm using a Straumann® CARES® P30+ (Straumann AG, Basel, Switzerland). The model was rinsed with isopropyl alcohol and cured with UV. The hollow was filled with the polyurethane block density 0.32 g/cc (Sawbones®, Washington, United States) to simulate the cancellous bone of low-to-medium density at edentulous areas (29). Synthetic polyurethane foams are a similar structure and equivalent mechanical characteristics of bone. The American Society for Testing Materials was shown that synthetic polyurethane foam used as a standard material for performing mechanical tests on orthopaedic devices and instruments (30). Twenty-five models were printed. The model preparation was summarized (Figure 17).

Step 1: Intraoral scan as model prototype (3shape intraoral scanner)



Step 2: Created horseshoe-shaped full-arch model with a bar (Meshmixer version 3.5.474)



Step 3: Prepared model for printing (Netfabb Premium 2020)

Step 4: Printing the model (Straumann® CARES® P30+)

Step 5: Finished model

Figure 17 Model preparation

3.2.4 Presurgical preparation

The models assigned randomly to five modalities according to the drilling system; sleeve-in-sleeve system, sleeve-in-sleeve with self-locking system, mounted sleeve-on-drill system, integrated sleeve-on-drill with metal sleeve system, and integrated sleeve-on-drill without metal sleeve system.

Each model scanned by using desktop scanner (Cares 7 SERIES, Dental wings, Montreal, Quebec, Canada) with scanning accuracy 0.015 mm and exported as the Standard Tessellation Language (STL) files. CBCT scans were acquired using the X-mind Trium machine (de Götzen S.r.l.-Acteon Group, Varese, Italy) at the following settings: 7 mA, 70 kV, 63-second exposure time, 0.15x0.15x0.15 mm voxel size, field of view 11x9 cm. The scans exported as the Digital Imaging and Communications in Medicine (DICOM) files.

The DICOM format file of CBCT data and STL files of the models imported to the implant planning software (coDiagnostiX software version 9.7, Dental Wings GmbH, Chemnitz, Germany). The software matched between the DICOM and STL file and created the 3D model for virtual planning of implant surgery. A digital wax up was conducted on the prosthesis design software (CARES Visual software, Straumann AG, Basel, Switzerland) with the proper crown shape and size for bilateral first premolar. One investigator planned all implants in the optimal prosthetic position and designed all 25 surgical guides, aiming for the implant position and angulation to be the same plan in all cases.

Fifty implants were then planned, ten for each of the five drilling protocols. Each protocol utilizes a specific surgical kit, sleeve height, sleeve position, and implant design. Furthermore, due to differences in the available implant dimensions among different systems, implant diameter, and implant length slightly varied in some of the groups. (Table 5). To reduce the discrepancy between the guided sleeve and the surgical drill’s tip, the free-drilling-distance (FDD) was calculated (14). The implant length selection was done in order to set an equal FDD length in all groups. The parameter of guide surgery set as following (Table 5).

- Group A: sleeve-in-sleeve system
  Implant BLT, RC Ø 4.1 x 12 mm (Straumann AG, Basel, Switzerland) was planned. According to the Straumann® Guided Surgery (Straumann AG, Basel, Switzerland) protocol, the distance between the apex of the sleeve and the bone was 6 mm and guided key height 1 mm.
- Group B: sleeve-in-sleeve with self-locking system
  Implant BLX, RB Ø 4.0 x 12 mm (Straumann AG, Basel, Switzerland) was planned. According to the Straumann® VeloDrill™ Guided Surgery (Straumann AG, Basel, Switzerland) protocol, the distance between the apex of the sleeve and the bone was 6 mm and guided key height 1 mm.
- Group C: mounted sleeve-on-drill system
  Implant OsseoSpeed™ EV conical Ø 4.2 x 11 mm (Astra Tech, Dentsply Sirona, Pennsylvania, United States) was planned. According to Astra Tech Implant System® EV Guided surgery (Dentsply Sirona, Pennsylvania, United States) protocol, the distance between the apex of the sleeve and the bone was 6 mm and sleeve on drill ND type was selected.
- Group D: integrated sleeve-on-drill with metal sleeve system
  Implant Superline II Ø 4.0 x 12 mm (Dentium, Seoul, South Korea) was planned. According to Dentium Guide Kit (Dentium, Seoul, South Korea) protocol, the distance between the apex of the sleeve and the bone was 5.3 mm.
- Group E: integrated sleeve-on-drill without metal sleeve system
  Implant Superline II Ø 4.0 x 12 mm (Dentium, Seoul, South Korea) was planned. According to Dentium Guide Kit (Dentium, Seoul, South Korea) protocol, the distance between the apex of the sleeve and the bone was 5.3 mm.

Group	Sleeve height (mm)	Sleeve position* (mm)	Specific instrument	Drill length (mm)	FDD** (mm)
Sleeve-in-sleeve (Group A)	5.0	6.0	Drill key height 1 mm	24	18
Sleeve-in-sleeve with self-locking system (Group B)	5.0	6.0	Drill key height 1 mm	24	18
Mounted sleeve-on-drill (Group C)	4.0	6.0	Drill sleeve height 5 mm	23	18
Integrated sleeve-on-drill with metal sleeve system (Group D)	4.0	5.3	N/A	22	18
Integrated sleeve-on-drill without metal sleeve system (Group E)	4.0	5.3	N/A	22	18

*Sleeve position, Distance between bottom of the sleeve to implant platform.

**Free drilling distance (FDD), the distance from the bottom of the guided sleeve to the surgical drill's tip

Table 5 According to the manufacturer's recommendation, the parameters were set up for the five different sCAIS.

When the planning completed, the surgical guide exported to Netfabb Premium 2020 (Autodesk, United States) to fabricate the surgical guide template by using P Pro Surgical Guide (Straumann AG, Basel, Switzerland) with Straumann® CARES® P30+ (Straumann AG, Basel, Switzerland). All the surgical templates design with a minimum of four inspection windows of 5 mm of diameter. The thickness of the surgical templates was 2.0 mm. The clearance between the surgical guide and tooth was set at 0.05 mm. The printer was set at layer thickness of 0.1 mm.

3.2.5 Surgical stage

- Guides were checked for proper seating on the model.

- The surgery was conducted with the models mounted on a phantom head in the supine position, with the operator sitting at the right rear position (11 o'clock) (Figure 18).

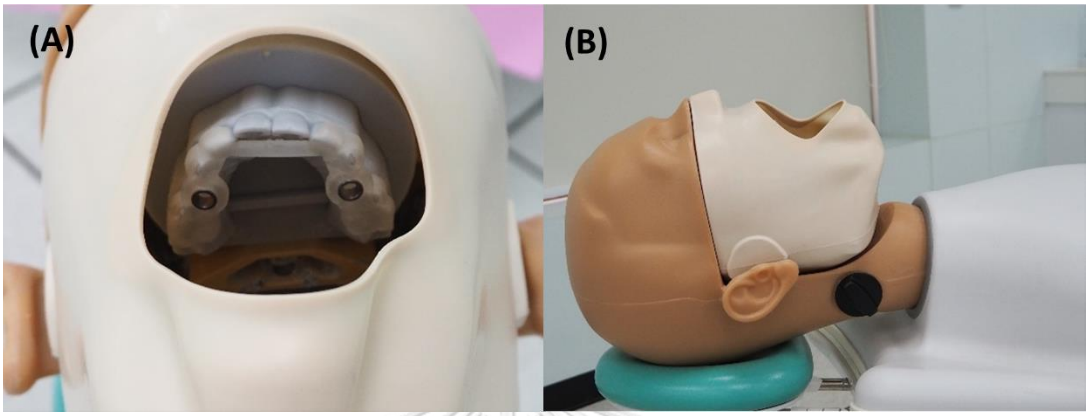


Figure 18 The surgery was simulated in phantom head. (A) A Model mounted into phantom head. (B) The phantom head was set in the supine position.

- One experienced operator performed all guided surgeries for implant placement. The five different drilling systems (group A-E, Figure 19) were described as follows:

Group A: sleeve-in-sleeve system (Straumann® Guided Surgery, Straumann AG, Basel, Switzerland, Figure 19A)

Group B: sleeve-in-sleeve with self-locking system (Straumann® VeloDrill™ Guided Surgery, Straumann AG, Basel, Switzerland, Figure 19B).

Group C: mounted sleeve-on-drill system (Astra Tech Implant System® EV Guided surgery, Dentsply Sirona, Pennsylvania, United States, Figure 19C).

Group D: integrated sleeve-on-drill with metal sleeve in the guide system (Dentium Guide Kit, Dentium, Seoul, South Korea, Figure 19D).

Group E: integrated sleeve-on-drill without metal sleeve in the guide system (Dentium Guide Kit, Dentium, Seoul, South Korea, Figure 19E).

- Sequence of drilling was performed according to the manufacturer's recommendations (Table 6-9). And implant insertion with fully guided by using a guided adapter. Minor adjust of implant position with a torque wrench if necessary.

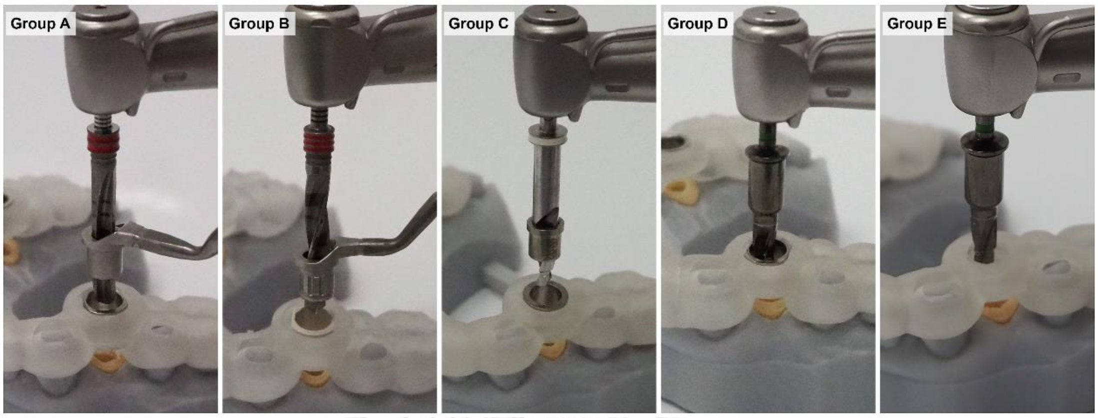


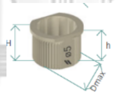
Figure 19 The simulation of the final drill of each drilling system used. (A) Sleeve-in-sleeve system which used the drill key insert into metal sleeve within the surgical guide template. And the drill was guided by the drill key. (B) Sleeve-in-sleeve with self-locking system which modified from group A. The sleeve and drill key component were changed into self-locking design. (C) Mounted sleeve-on-drill system which used drill sleeve insert into metal sleeve within the surgical guide template. The drill sleeve mounted on the drill while drilling. (D) Integrated sleeve-on-drill with metal sleeve system which used modified shape of the drill by using drill sleeve integrated on the drill. The shank part of the drill was modified to fit into the metal sleeve in surgical guide template. (E) Integrated sleeve-on-drill without metal sleeve system which modified from group D by using sleeve designed incorporated into the surgical guide template.

Drilling system	Manufacturer	Implant	Sleeve height	Sleeve position	Basic implant bed preparation					Final implant bed preparation		
					Milling cutter	Step drilling			Guided key height	Profile drill	C-handle	Tap
Sleeve-in-sleeve (Group A)	Straumann® Guided Surgery (Straumann AG, Basel, Switzerland)	BLT, RC Ø 4.1 x 12 mm	5 mm	6 mm	No	**Long drill** Ø2.2	**Long drill** Ø2.8	**Long drill** Ø3.5	• +1 mm	BLT Ø 4.1	H6	Yes

Table 6 Protocol and drilling sequence of sleeve-in-sleeve system

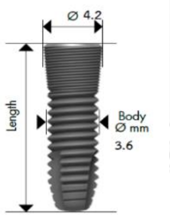
Drilling system	Manufacturer	Implant	Sleeve height	Sleeve position	Basic implant bed preparation						Final implant bed preparation		
					Milling cutter	Step drilling				Guided key height	Profile drill	C-handle	Tap
Sleeve-in-sleeve with self-locking (Group B)	Straumann® VeloDrill^{TM} Guided Surgery (Straumann AG, Basel, Switzerland)	BLX, RB Ø 4.0 x 12 mm	5 mm	6 mm	No	**Long drill** Ø2.2	**Long drill** Ø2.8	**Long drill** Ø3.2	**Long drill** Ø3.5	• +1 mm	N/A	H6	N/A

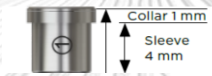
Table 7 Protocol and drilling sequence of sleeve-in-sleeve with self-locking system



Drilling system	Manufacturer	Implant	Sleeve height	Sleeve position	Sleeve-on-drill		Basic implant bed preparation			Final implant bed preparation		
					type	Sleeve height	Initial Drill	Step drilling		Conical Drill	V-Drill	X-Drill
Mounted sleeve-on-drill (Group C)	Astra Tech Implant System® EV Guided surgery (Dentsply Sirona Implants, York, USA)	EV, C Ø 4.2 x 11 mm	4 mm	6 mm	ND sleeve	5 mm	Ø4.2	① Ø1.9	③ Ø2.5/3.1	A/B Ø3.1/4.2	no	no

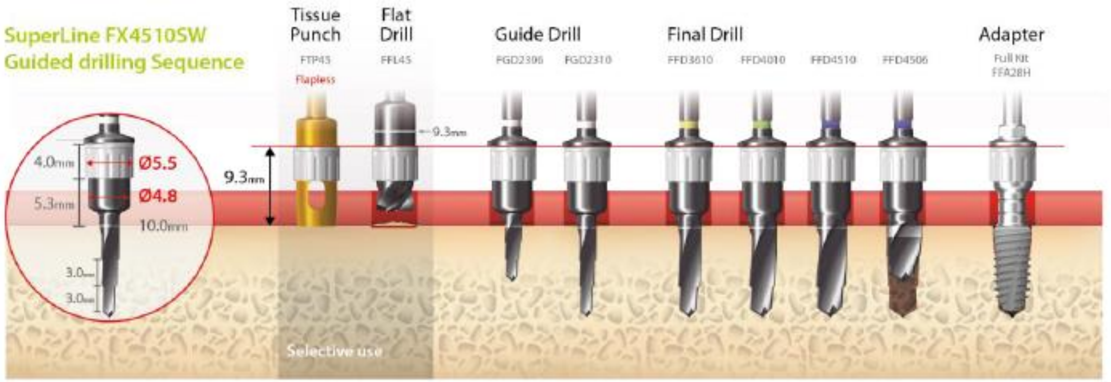
Table 8 Protocol and drilling sequence of mounted sleeve-on-drill system





Drilling system	Manufacturer	Implant	Sleeve height	Sleeve position	Basic implant bed preparation				Final implant bed preparation	
					Step drilling				Cortical Drill	Cortical Tap
Integrated sleeve-on-drill with or without metal sleeve system (Group D and E)	Dentium Guide Kit (Dentium, Seoul, South Korea)	Superlinell Ø 4.0 x 12 mm	4 mm	5.3 mm	Ø2.3 6, 8, 10 ,12 mm Drill	Ø2.3 12 mm Drill	Ø3.6 12 mm Drill	Ø4.0 12 mm Drill	Yes	N/A

Table 9 Protocol and drilling sequence of integrated sleeve-on-drill with metal sleeve and without metal sleeve system



3.2.6 Postsurgical stage

After implants were placed, all models were scanned with the CBCT using the same settings as previously described. The DICOM files were inserted in the coDiagnostiX software and segmented at a threshold of -540 to 3500 H. The postoperative CBCT was superimposed onto the preoperative CBCT, which contained the virtual plan implant via surface-based registration. All procedures and measurements were conducted by one operator. By means of the treatment evaluation module, the software automatically calculated the 3D deviation of the implant platform, apex, and angular deviation between the plan and placed position.

3.2.7 Accuracy analysis

For accuracy analysis, the planned position of the implant was compared with the placed position of the implant after insertion. The measurement of accuracy collected (Figure 20). Two outcomes were measured:

The primary outcomes were:

The discrepancy in mm between the planned and placed implant position (3D deviation) at the implant platform and apex.

- 3D deviation at the platform (mm)
  The displacement between the planned and actual implant at the implant platform in total direction, measured at the center of the implant (mm)
- 3D deviation at the apex (mm)
  The displacement between the planned and actual implant at the implant apex in total direction, measured at the center of the implant (mm)
- Deviation of the angulation (degrees)
  The difference of the long axis of the implant between the planned and actual implant

The secondary outcome was:

- The direction of the implant deviation as mesial, distal, buccal and palatal at the implant platform and apex.

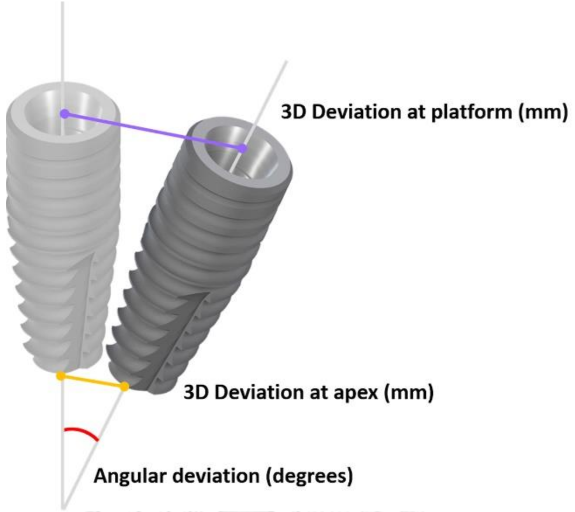


Figure 20 Deviation measurement for planned and placed implant position.

3.2.8 Statistical analysis

The data was analyzed with IBM SPSS Statistics software version 22 (SPSS Inc., Chicago, Illinois). Shapiro-Wilks test confirmed the data distribution to be non-normal. Thus, Kruskal-Wallis test was used to compare the 3D deviation at implant platform, apex and angular deviation. P-value less than 0.05 was set as statistically significant. Pairwise comparisons were conducted with Dunn's test. The implant direction among the five groups was visualized as a scatter plot.

CHAPTER IV

RESULTS

The main results of 3D deviation are presented in Table 10. The means of platform deviation for each of the five (A-E) groups were 0.56±0.19, 0.42±0.12, 1.18±0.19, 1.09±0.12, 0.81±0.15 mm, respectively. The means of apex deviation for the same groups were 0.83±0.32, 0.76±0.22, 1.70±0.41, 1.95±0.48, 1.73±0.23 mm, respectively. While the means of angular deviation were 2.70±1.37, 2.50±0.89, 4.37±1.34, 5.13±1.86, 5.30±1.04 mm in all group, respectively. Kruskal-Wallis test demonstrated that there were significant differences among five group of sCAIS in all parameters (P < .001).

Group	Group A (n = 10)	Group B (n = 10)	Group C (n = 10)	Group D (n = 10)	Group E (n = 10)	Overall (n = 50)
Platform deviation (mm)						
Mean ± SD	0.56 ± 0.19	0.42 ± 0.12	1.18 ± 0.19	1.09 ± 0.12	0.81 ± 0.15	0.81 ± 0.33
Median	0.51	0.41	1.13	1.09	0.83	0.84
Min-Max	0.32-0.96	0.25-0.63	0.86-1.48	0.90-1.25	0.47-1.01	0.25-1.48
Range	0.64	0.38	0.62	0.35	0.54	1.23
95% CI	0.42, 0.69	0.33, 0.50	1.04, 1.31	1.00, 1.17	0.70, 0.92	0.72, 0.90
Apex deviation (mm)						
Mean ± SD	0.83 ± 0.32	0.76 ± 0.22	1.70 ± 0.41	1.95 ± 0.48	1.73 ± 0.23	1.39 ± 0.60
Median	0.75	0.73	1.63	1.98	1.72	1.46
Min-Max	0.49-1.49	0.45-1.14	1.08-2.38	0.94-2.53	1.41-2.07	0.45-2.53
Range	1.00	0.69	1.30	1.59	0.66	2.08
95% CI	0.60, 1.06	0.61, 0.91	1.40, 1.99	1.61, 2.29	1.56, 1.90	1.22, 1.56
Angular deviation (º)						
Mean ± SD	2.70 ± 1.37	2.50 ± 0.89	4.37 ± 1.34	5.13 ± 1.86	5.30 ± 1.04	4.00 ± 1.46
Median	2.95	2.70	4.00	5.45	5.45	3.70

Group	Group A (n = 10)	Group B (n = 10)	Group C (n = 10)	Group D (n = 10)	Group E (n = 10)	Overall (n = 50)
Min-Max	0.90-5.10	0.70-3.60	2.70-6.50	0.70-6.90	3.60-6.50	0.70-6.90
Range	4.20	2.90	3.80	6.20	2.90	6.20
95% CI	1.72, 3.68	1.87, 3.13	3.41, 5.33	3.80, 6.46	4.55, 6.05	3.50, 4.50

Table 10 Summary of 3D deviations at platform, apex and angular deviation.

No statistically significant difference was shown in any measured parameter between group A and B and also between group D and E (Figure 21).

With regards to 3D deviation at the platform, both group A and B demonstrated the second lowest and lowest deviation and were significantly different to group C and D (Figure 21A).

With regards to 3D deviation at the apex, both group A and B showed the second lowest and lowest deviation and were significantly different to group C, D and E (Figure 21B).

With regards to the angular deviation, both group A and B showed the second lowest and lowest deviation and were significantly different to group D and E (Figure 21C).

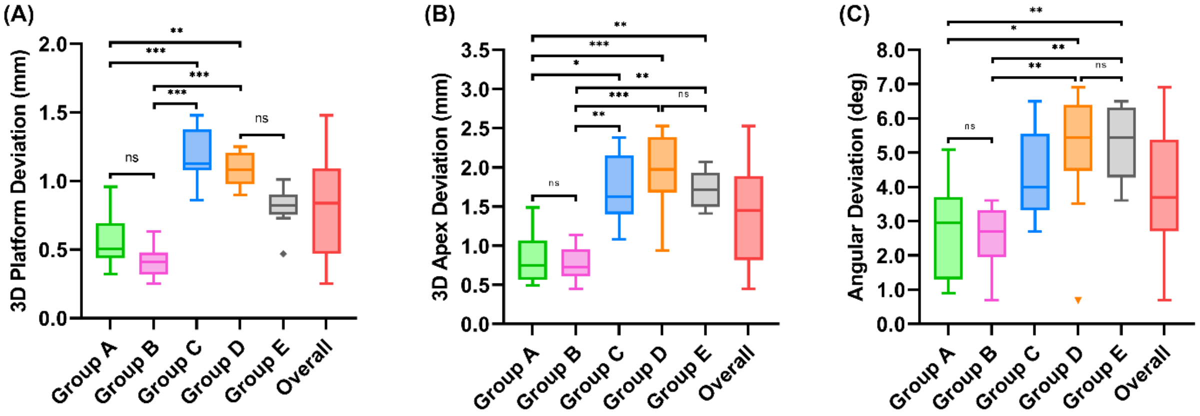


*Figure 21 Box-and-whisker plot diagrams presenting the distribution of 3D deviation in each group. (A) 3D platform deviation. (B) 3D apex deviation. (C) Angular deviation. Median, Q1(25th percentile), Q3 (75th percentile), minimum value, maximum value, and outliers of each group shown in diagrams. The statistically significant differences between groups were determined by Kruskal-Wallis test under Dunn's test with adjusted p values. Denoted as * for P < .05, ** for P < .01, *** for P < .001, ns for not significant, respectively.*

The direction of implant deviation in terms of mesial, distal, buccal, palatal, apical and coronal discrepancy at the implant platform and apex are shown in the scatter plot (Figure 22). The implant platform and apex mostly deviated in the palatal direction in all groups. Interestingly, for group C, D and E, the discrepancy occured in both buccal and palatal directions, however the deviation in the palatal direction was greater than in the buccal direction.

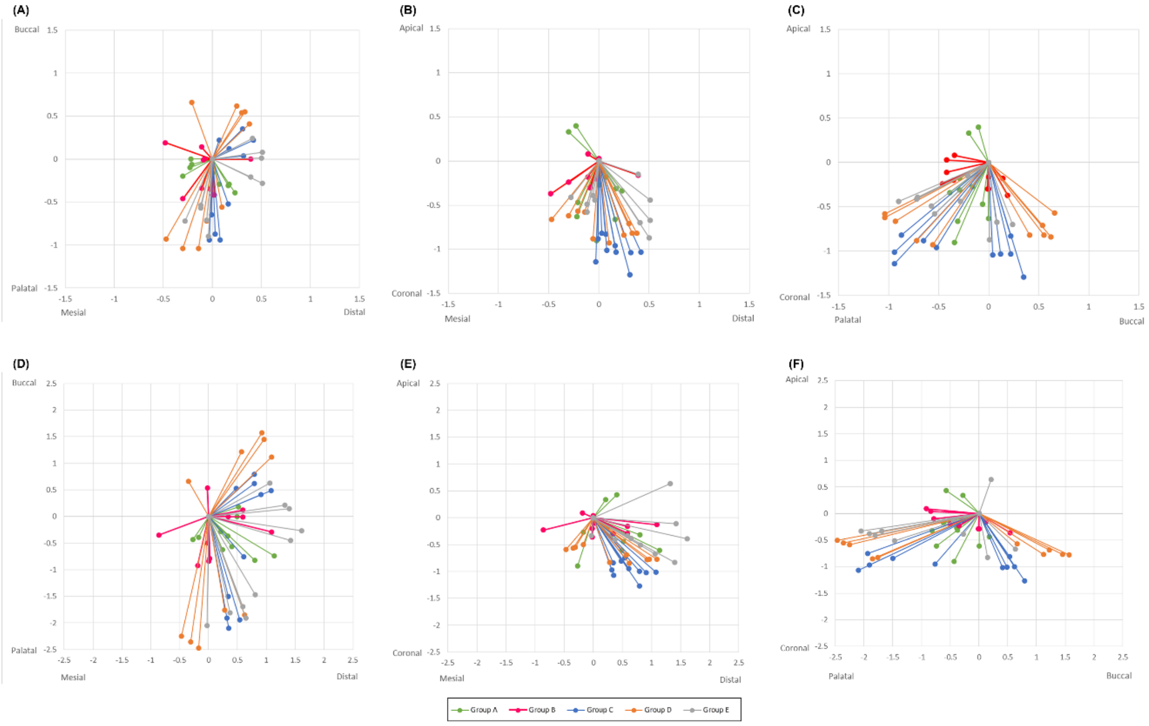


Figure 22 The 2D scatter plot illustrating the deviation of each implant. (A) Mesiodistal and buccopalatal planes at implant platform. (B) Mesiodistal and apicocoronal planes at implant platform. (C) Buccopalatal and apicocoronal planes at implant platform. (D) Mesiodistal and buccopalatal planes at implant apex. (E) Mesiodistal and apicocoronal planes at implant apex. (F) Buccopalatal and apicocoronal planes at implant apex.

CHAPTER V

DISCUSSION

This study, aimed to investigate the potential influence of the design of different guided surgery devices and protocols in the accuracy of implant placement, under a strictly controlled in vitro environment. Collectively, the accuracy of implant placement for all five groups presented with a mean deviation of the platform, apex and angle of 0.81 mm, 1.39 mm and 4.0 degrees respectively. These results present somewhat lower deviation than what is shown in clinical studies, where the mean of platform deviation, apex and angle is reported in a systematic review to be 1.04 mm, 1.45 mm and 4.06 degrees, respectively (19). Nevertheless, significant differences occurred with regards to accuracy among the 5 systems tested, suggesting that the drilling protocol, the devices used and the design principles of the guides could significantly influence the clinical outcomes.

As sCAIS is currently rapidly evolving, many different designs are being proposed and utilised from different implant systems. At present, there is very little data to suggest the impact of the different designs in the clinical outcomes, which would be essential in order to identify best practices, streamline procedures and improve the overall accuracy of sCAIS.

The five groups of this study were selected in order to reflect main directions with regards to the design principles and the drilling protocols, in particular with regards to the device used for controlling and guiding the drill. Group A and B used the combination of drill key and sleeve, while group C used the drill sleeve insert into a sleeve. Finally, group D used the shank modified drill that fits on the metallic sleeve, while group E did not have a metallic sleeve, thus using the printed guide channel for guidance of the drill.

The result of 3D deviation at platform, apex and angulation in sleeve-in-sleeve system (group A) was similar to that previously reported by El Kholy K et al. (14), while there has not been any report so far on the accuracy of implant position when using the sleeve-in-sleeve with self-locking (group B). The mean deviation of all parameters in group B was lower than group A. The smooth-cylindrical design of the drill key in group A with a diameter of 4.85 mm, allows for a 0.15 mm gap with the 5 mm-sleeve widths. This gap could allow the lateral movement of the drill key within the sleeve which could potentially result into deviation of up to 0.56 mm in the horizontal deviation (lateral tolerance) (17). On the other hand, the self-locking design of both drill key and sleeve as in group B, might have contributed to reducing movement tolerance between the sleeve and the drill key and improved accuracy.

This study is the first experiment, to investigate the accuracy of implant placement in terms of 3D deviation with mounted sleeve-on-drill configuration as in group C. The sleeve position of the surgical guide was set with the same value as in group A and B (Table 5). The results showed group C to present with higher deviation in all parameters than group A and B. This difference might be related to the sleeve insert type. Similarly, in a previous in vitro study Koop R et al. (13) showed that the drill-held sleeve insert results in more coronal and apical lateral deviation as well as angular deviation than the hand-held sleeve insert. The platform and apex deviation of group C were significantly different from group A and B, but not the angular deviation. When using a drill key, the operator is stabilizing the drill through holding the drill key as in groups A and B, while in the mounted sleeve-on-drill configuration as in group C the drill is stabilized directly through the surgical guide. Using a drill key might present with certain ergonomic disadvantage, as the operator needs to hold the key manually, but it might have contributed to the higher accuracy observed in this study.

The shank-modified drill which was used in group D and E was aimed at limiting the drilling motion and also reducing the tolerance to lateral movement (12). Both group D and E in this study had the same settings with regards to guide components, implant diameter and length. There was no significant difference between group D and E in all parameters. As from the result, the use of sleeve-incorporated within the surgical guide template, the tolerance between sleeve and guide was limited. So, the platform and apex deviation was decreased. However, the angular deviation had a reverse result. This might be attributed to the fact that group E utilized a sleeve shaped by the guide instead of an incorporated metallic sleeve. The resin material of the surgical guide template might allow for more flexibility. Hence the mean angular deviation of group E was higher than this of group D.

In previous CAIS studies, the direction of the deviation observed in the platform and apex of the implant has been attributed to potential influence of the field of view of the operator, especially when real time navigation systems are used (31). In the case of this experiment however, as the same two contralateral teeth were utilised equally for all groups, any differences in the direction of the deviation shown between the groups are unlikely to be attributed to operator related factors.

The results of this study should be seen in the light of its limitations. The experimental design aimed to minimize all possible variables which could lead to discrepancies between the different systems. Thus, all implant positions were designed with the same software by the same operator, while the same software was used to design the surgical guides, which were also printed with the same printer and settings. Efforts were taken to standardize critical parameters such as the FDD. Nevertheless, all systems had different components, and some differences with regards to sleeve height, sleeve position, implant diameter and length. As a result, each group had specific length of the guide channel: group A and B was 6 mm, group C was 5 mm, group D and E was 4 mm. Whether this could possibly impact the differences observed in the angular deviation and how much remains to be further investigated. Our study showed that the lower angular deviation was observed in group A and B, which had the longest overall guide channel. Therefore, the length of the guide channel might be the critical factor influence angular deviation. An in vitro study has suggested the guide channel length to be a factor in minimizing angular deviation (26), while previous studies have shown the elongated guide channel to lower coronal and apical deviation and the angulation of the drill (11, 13).

The length of the guide channel depends on the sleeve height, which positively affects the accuracy of implant placement. Koop R et al. (13) found that sleeves of 7 and 9 mm gave less deviation than the shorter sleeves. However, longer sleeves could pose ergonomic problems and might not be applicable in actual clinical situations due to limitations in the patient mouth opening. A sleeve height of up to 5 mm might be the best compromise between accuracy and ergonomics in clinical situations. Increasing the length of the guide channel might be achieved indirectly through the use of a drill key or customizing the height of sleeve in cases where the anatomy and mouth opening allows.

CHAPTER VI
CONCLUSION

This study has demonstrated significant differences with regards to accuracy among the 5 sCAIS systems tested, suggesting that the drilling protocol, the devices used and the design principles of the guides could significantly influence the accuracy of implant placement. Groups utilizing a sleeve-in-sleeve with or without self-locking design showed significantly less angular deviation, however other design principles might have also contributed to this finding.

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