



The implant position accuracy between using only surgical drill guide and surgical drill guide with implant guide in fully digital workflow: a randomized clinical trial

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Abstract

Background To evaluate and compare accuracy in position and inclination of a single-tooth implant placement using tooth-supported surgical drill guide (SDG) and surgical drill guide with implant insertion guide (SDIG) in fully digital workflow.

Materials and methods Thirty partially single edentulous patients were recruited. After randomization, participants were divided into 2 groups equally. The first group underwent implant placement through SDG only, while the second group was subjected to SDIG. All procedure proceeded under a fully digital workflow as the combination of digital scanning from an intraoral scanner, 3D radiographic images from cone-beam computed tomography (CBCT), implant planning software, and a 3D manufacturing machine. A post-operative CBCT was performed to compare the deviations (7 parameters) between planned and actual implant positions.

Results The mean global deviations at the shoulder and apex were 0.74 ± 0.36 and 1.29 ± 0.61 mm, respectively in the SDG group and 0.48 ± 0.22 mm and 0.71 ± 0.31 mm, respectively in the SDIG group. Likewise, the other parameters in the SDIG group showed fewer deviations than SDG for all measurements. Statistically significant differences were indicated by all parameters except for the horizontal deviation at the implant shoulder ($p < .05$).

Conclusion In single-tooth implant placement with a tooth-supported guide using a computer-assisted (static) system with the SDIG could reduce deviations of actual implant position when compared with using SDG only. Besides, guided implant surgery by fully digital workflow is a practical procedure and provides precise implant position regarding the prosthetic-driven concept.

Keywords Computer-assisted implant placement · Surgical drill guide · Implant insertion guide · Fully digital implant surgery · Fully digital implant placement · Randomized clinical trial

Introduction

Dental implants are efficient with widespread use these days. They can restore the masticatory function and maintain an aesthetic appearance while also providing predictable outcomes with high long-term success rates [1, 2]. Several factors affect the treatment outcome and two of the most important are implant position and angulation.

Prosthetic planning before implant surgery is now recognized and acknowledged to be a crucial and important aspect of success. Determination of implant location, position, angulation regarding definitive prosthesis provides a better treatment outcome for optimal function, aesthetics, and also implant longevity [3]. Disregarding prosthetic-driven implant concepts often leads to a compromised final prosthesis that can have an adverse effect on long-term implant success with unfavorable biomechanics and poor aesthetics [4–6].

Several methods have been developed for placing dental implants. Initially, free-hand placement was used without any guides until surgical drilling templates were invented. Integration of three-dimensional (3D) radiographic images from CBCT has now improved the accuracy of implant

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surgery compared with traditional techniques [7, 8]. The combination of digital intraoral scanning models, 3D radiographic images from CBCT, implant planning software, and 3D manufacturing machines now offers full digital workflow in computer-assisted implant placement. This technique is increasingly used and will become the norm in the future.

Computer-assisted implant placement can be divided into static and dynamic systems [9]. A static system transfers the planned implant position to the actual sites through intraoral surgical templates, while a dynamic system communicates through optical tracking devices and computer-aided navigation technologies. Operators can alter the drilling angulation and implant position in real time during the surgery. Static template-based guidance is preferred to the dynamic system because of its simplicity, practical usage, friendly cost, and reduced patient's mouth opening clearance [10]. Static computer-guided systems can be categorized in terms of protocol and type of surgical templates. Some systems use only a surgical drill guide (SDG), whereas others also allow the insertion of implants through a guided template, defined as "surgical drill guide with implant insertion guide" (SDIG) [11].

Fabrication of the digital surgical guide requires computer-aided design and computer-aided manufacturing (CAD/CAM) technology [12–14]. Intraoral models and 3D radiographic images are superimposed on each other using 3D implant planning software to simulate the final restoration, to plan the implant position, and to design the surgical template. Then, rapid prototype 3D printing is used to produce the guides and transfer the planned implant position using a prosthetic-driven concept to the actual surgical site through surgical templates.

Digital guided surgery offers several advantages such as optimal and precise implant position harmonizing with definitive restoration [15], a minimally invasive approach, and faster surgery [16, 17]. Digital guided surgery also minimizes operator errors by dentists with limited experience of implant placement [18] and reduces the possibility of damaging the surrounding critical anatomical structures [19]. This technique allows a proper fit with the primary stability of the implant after placement [20].

However, some doubts have been raised concerning the accuracy of computer-guided implant surgery. Accuracy in guided implant surgery is defined as matching the planned implant position in the 3D-planning software with the actual implant position at the surgical site [21]. Comparison between the planned and placed implant positions is often conducted by a pre-operative and post-operative CBCT scan. The accuracy of the implant position is commonly evaluated by three discrepancies in three dimensions as deviation at the entry point, deviation at the apex, and deviation of the implant long axis (angular deviation).

Computer-guided implant surgery has been investigated and improved over the past two decades. A number of studies have assessed the accuracy of computer-guided surgical templates that still show some discrepancies [12, 17, 22–24], while others indicated that the clinician can slightly alter the implant position while inserting the implant into the bone [25–27]. A discrepancy might occur in this step; therefore, using a digital implant insertion guide after the surgical drill guide may reduce this alteration. Studies of the comparison between computer-assisted implant surgery with and without an implant guide have not provided conclusive results. Some measured discrepancies were based on bone-mucosal-supported guides that provide a less precise measurement than tooth-supported surgical guides [28]. The most recent studies have assessed in cadavers or in vitro models [11, 22, 23] and few have evaluated the accuracy of a fully digital system [29].

The purpose of the study was to evaluate and compare accuracy in position and inclination of a single-tooth implant placement using SDG and SDIG with full digital workflow.

Materials and methods

This randomized clinical trial study was approved by the Human Experimentation Committee, Faculty of Dentistry, Chiang Mai University, and registered in the Thai Clinical Trial Registry (No. TCTR 20,200,128,003). The study conformed to the World Medical Association (WMA) Declaration of Helsinki. All patients gave informed consent prior to participation in the study. The consort 2010 checklist for reporting a randomized trial was also used.

Preparation

Sample size calculation and selection of participants

Participants were recruited at the Centre of Excellence for Dental Implantology, Faculty of Dentistry, Chiang Mai University. The sample size was calculated using the mean and standard deviation (SD) of the global deviation at the implant apex based on the results of our pilot study. The significance level (α) was set at 0.05 and the power of the test ($1-\beta$) was set at 80%. Each group was made up of 15 participants with inclusion and exclusion criteria shown in Table 1.

Examination and planning procedure

Firstly, pre-operative cone-beam computed tomography (CBCT) was recorded by DentiiScan© (NECTEC, Bangkok,

Table 1 Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Single-tooth edentulous area	Uncontrolled systemic disease
Anterior and premolar teeth	Contraindication against implant surgery (e.g., history of radiotherapy around head and neck regions, intravenous injection of bisphosphonate, bleeding disorders)
Presence of mesial and distal neighboring teeth	Heavy smoker (≥ 10 cigarettes/day)
Mesio-distal space ≥ 6.5 mm	Pregnancy
Good oral hygiene	Presence of pathology at the surgical site
Adequate bone quantity for implant placement surrounding the bone ≥ 1 mm after surgery (no need for bone augmentation)	
Aged 18–65	

Thailand). After that, an oral optical scanner (Planmeca Emerald™, Planmeca Co., Ltd., Helsinki, Finland) was used to collect intraoral 3D images. The digital imaging and communications in medicine (DICOM) files from CBCT and the intraoral 3D model were merged through Planmeca Romexis™ software (Planmeca Co., Ltd., Helsinki, Finland). Then, a virtual tooth wax-up and implant position were determined in accordance with the prosthetic-driven concept (Fig. 1) as the “planned implant position.”

Randomization

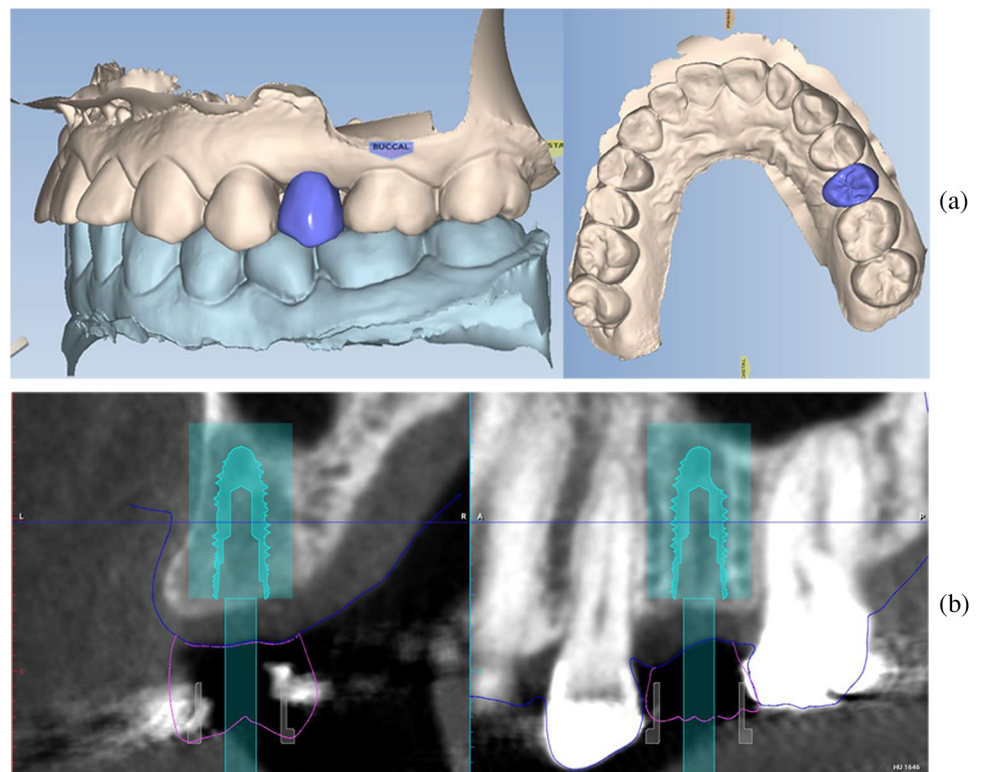
A subject identification number was given to each participant. A blinded investigator (WE) (who was not involved in the screening, treatment, follow-up, data collection, or analysis) used computer software

to randomize the subject identification numbers into two groups equally. The first group underwent implant placement through a surgical drill guide (SDG) only, while the second group was subjected to a surgical drill guide and implant insertion guide (SDIG). This information was placed in sealed envelopes.

Surgical template fabrication

After the implant position was determined, drill guides were designed and fabricated using a 3D printer. All the templates were conducted with tooth-supported guides. The sealed envelopes were opened during this step and if the patient was in the SDIG group, the implant insertion guide was produced additionally.

Fig. 1 Implant position planning in Planmeca Romexis™ Software: **a** virtual wax-up and **b** planned implant position regarding final prosthesis



Surgical procedures and data collection

The static computer-guided surgical system used in this procedure had surgical templates with sleeves of an increasing diameter for both drilling and insertion. In group I, only surgical drill guides were used with insert implant fixture to bone by free-hand technique, whereas in group II both drill guides and implant insertion guide were used for implant loading. The surgical treatments were performed by one of the investigators (PK).

Group I: SDG group (n=15)

All the surgeries were identically operated. The surgery was performed under local anesthesia using 4% articaine with epinephrine 1:100,000. A full-thickness flap was reflected and surgical drill guides were used only for osteotomy preparation. The implant bed was prepared using a round bur, a pilot drill with a diameter of 2.0 mm, and matching twist drills. The implant (NOVEM®, Novem Innovations Co., Ltd., Chiang Mai, Thailand) was inserted into the bone by free-hand manipulation (Fig. 2a). Then, the implant was closed with a cover screw and gingival suturing.

Post-operative CBCT was taken since post-operative DICOM files were used in the analysis procedure.

Group II: SDIG group (n=15)

The protocol was the same as for group I but both the implant osteotomy drilling and implant insertion were performed through the guides (Fig. 2b).

Data analysis and evaluation

Comparison between the planned and placed implant positions was determined in Planmeca Romexis™ software

(Planmeca Co., Ltd., Helsinki, Finland) by means of pre- and post-operative CBCT superimposition (Fig. 3). Measurement was performed by an investigator (CN) using Image J software (National Institute of Health (NIH) and the Laboratory for Optical and Computational Instrumentation (LOCI, Wisconsin, USA). Three measurements were used for the evaluation.

Deviation at implant shoulder and apex

Discrepancies were measured for the six parameters shown in Fig. 4 as:

- Base vertical deviation (mm)
- Base horizontal deviation (mm)
- Base global deviation (mm)
- Apical vertical deviation (mm)
- Apical horizontal deviation (mm)
- Apical global deviation (mm)

Angular deviation

The angle of the long axis between the planned and placed implant positions (degrees) is shown in Fig. 4.

Direction of implant deviation at shoulder and apex

Data and Statistical analysis

After embedding the data with code No.001 to 030, the results were transferred to the investigator for measurement. All data parameters of both groups were evaluated. The Shapiro–Wilk test was used to evaluate normal data distribution. Then, statistical analysis was performed using an independent sample T-test for comparison using SPSS

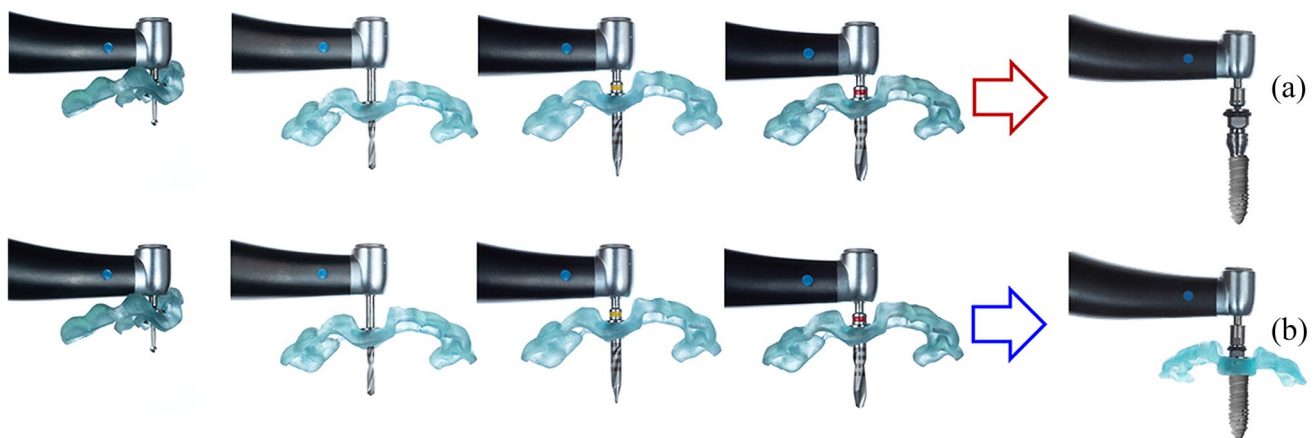


Fig. 2 Two surgical procedures. **a** Surgical drill guide (SDG) and free-hand implant insertion(no implant insertion guide). **b** Surgical drill guide and implant insertion guide (SDIG) at last procedure

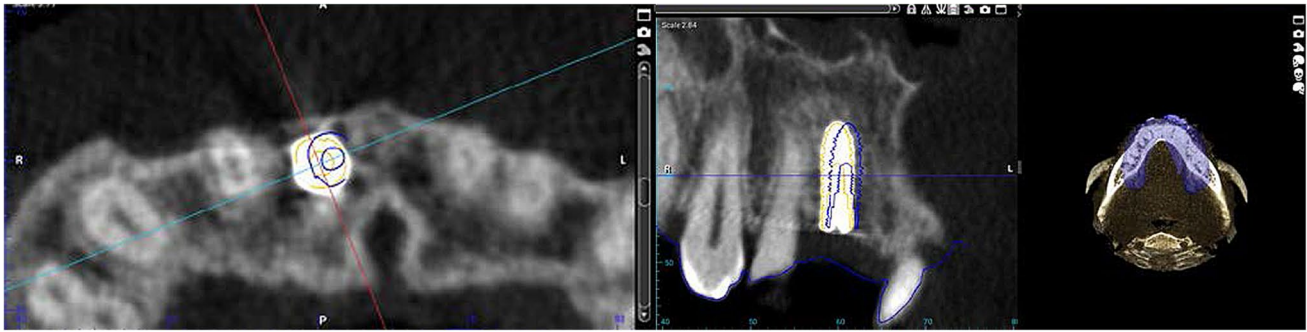


Fig. 3 Comparison between planned implant position (blue) and placed implant position (yellow)

26 (IBM SPSS, Chicago, IL, USA). Differences at $p < 0.05$ were considered statistically significant.

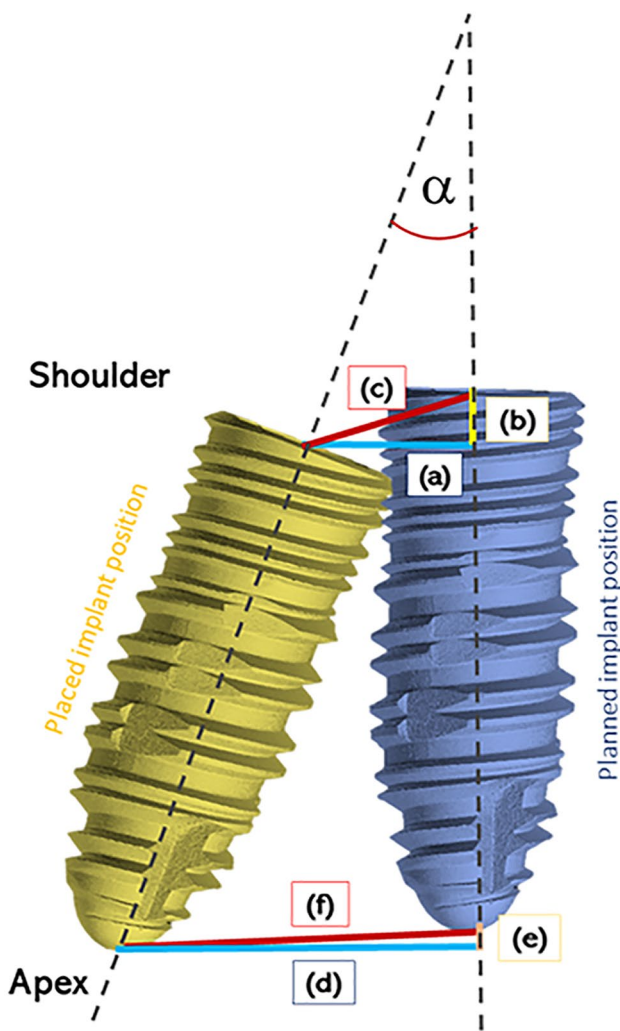


Fig. 4 Deviation parameters between the planned implant position (blue) and placed implant position (yellow): **(a)** base horizontal deviation (mm); **(b)** base vertical deviation (mm); **(c)** base global deviation (mm); **(d)** apical horizontal deviation (mm); **(e)** apical vertical deviation (mm); **(f)** apical global deviation (mm); α , angular deviation (degrees)

Results

Initial enrollment of 47 patients was performed by visual screening. After CBCT scanning, 17 patients were excluded because of insufficient bone width or height. The total number of participants in this study was 30. The patients were recruited after the permission of the ethics committee. After randomization, participants were randomized and divided into the SDG group and SDIG group equally. Each patient received an implant for anterior tooth or premolar replacement between January 31, 2020, and June 30, 2020. The SDG group contained seven males and eight females with a mean age of 43.9 (21–64). Meanwhile, the SDIG group contained eight males and seven females with a mean age of 45.2 (21–65) (Table 2).

Analyses of deviations in each group are presented in Table 3. On average, the SDIG group showed statistically significant less deviations than the SDG for all outcomes. The horizontal deviation on implant shoulder level nevertheless did not reach statistical significance ($p < 0.05$).

Patterns of dispersion in both groups did not clearly delineate the exact directions of deviation but dispersions in the SDG group were wider and more variable than in the SDIG group in many cases, especially at the implant apex. Mean and SD of global deviation at the implant apex were used to calculate the power of the study using G*Power (Version 3.1.9.4). The result was 0.94 at 0.05 α probability level.

Discussion

This randomized clinical trial for a fully digital workflow aimed to measure and compare the accuracy between two surgical guide systems. Evaluations of discrepancy in computer-aided implant surgery have been conducted for decades, initially using in vitro techniques and then cadavers.

Table 2 Demographic and clinical data of patients

Group	SDG	SDIG
Mean age	43.9 (21–64)	45.2 (21–65)
Gender		
Male	7	8
Female	8	7
Position		
Anterior teeth	5	4
Premolar	10	11

Tahmaseb et al. [22] proposed that static measurements should be performed in clinical studies because the lack of cadaver movement and the absence of blood and saliva in models were different from real situations. Therefore, here, a clinical study using a tooth-supported guide surgical template was performed to provide the most precise measurement [23].

The comparison showed that using a drill guide together with an implant insertion guide reduced discrepancies in all measurements. On average, the SDIG group showed less deviations than the SDG for all outcomes. The mean horizontal deviation at implant in the SDIG group (0.64 ± 0.37 mm) was less than in the SDG group (1.17 ± 0.68 mm). On the contrary, the horizontal deviation on implant shoulder level did not reach statistical significance ($p < 0.05$). Patterns of dispersion in both groups did not clearly delineate the exact directions of deviation but dispersions in the SDG group were wider and more variable than in the SDIG group in many cases, especially at the implant apex. All previous studies concerning the accuracy of static surgical guides found higher horizontal deviation at the implant apex than the shoulder because the metal sleeve required a tolerance space for the drilling bur during osteotomy [30, 31]. Higher horizontal deviation occurred with increased distance of the drilling tip from the sleeve. Van Assche and Quirynen [32] and Koop et al. [31] indicated this as one of the several

influencing factors. Another interesting factor was the slope of the alveolar ridge, higher resistance of cortical bone, and bone density at the surgical site [33]. Hence, the implant insertion guide was invented in the hope that it might help to control the implant position and direction during insertion. Results showed that using the implant insertion guide for loading the implant diminished horizontal deviation at the implant apex.

Due to the vertical stop of the implant insertion guide, vertical discrepancies in the SDIG group (0.20 ± 0.13 mm) were less than in the SDG group (0.37 ± 0.27 mm). Statistical analysis showed significant differences in both implant shoulder and apex; however, the mean vertical discrepancy between these two groups was only 0.16 mm. This was explained by the limited drilling length and surrounding reference points as follows. Firstly, even though the drill guide was only used in the SDG group, the depth of implant insertion was limited by the length of drilling burs and their stoppers in osteotomy preparation. Secondly, the cementoenamel junction (CEJ) level of the adjacent teeth or bone level at the surgical site could be used as a reference point for the implant insertion stop [34]. For further evaluation, the box plot in Fig. 5 shows that the apical vertical discrepancy in the SDG group was more variable than in the SDIG group. This implied that the possibility of error could be reduced by using an additional implant insertion guide.

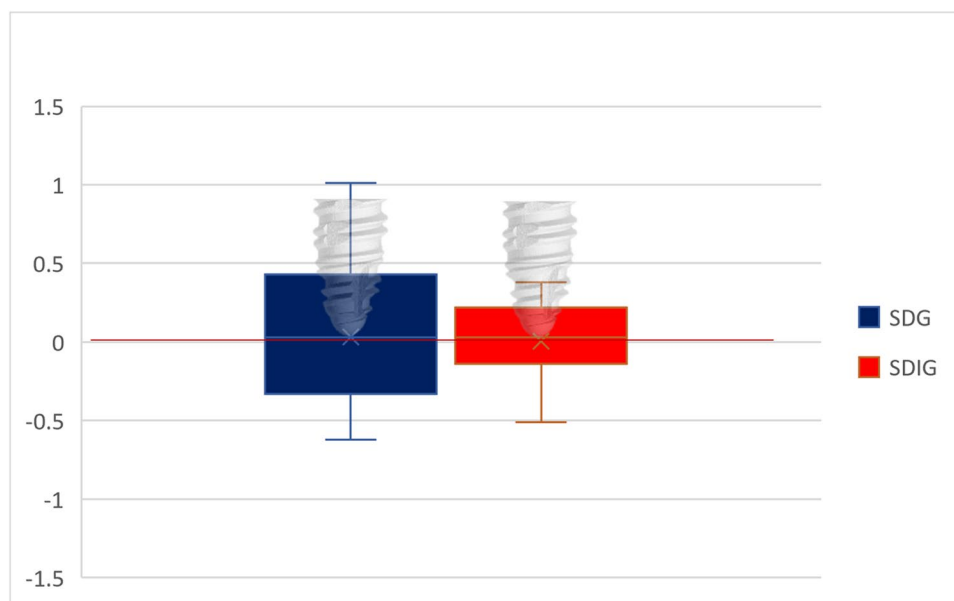
The most discrepancy in all measurements was global deviation. Basically, this value resulted from the combination of vertical and horizontal deviation. Several pieces of literature used global deviation and angular deviation for presenting the accuracy of implant placement. The study of Kuhl et al. [11] analyzed the accuracy of guides, which is similar to our study but performed in cadavers. They also used the angular deviation and global deviation at the implant shoulder and apex to explain their study. They reported mean deviation in each parameter as 4.3 degrees, 1.56 mm and 1.84 mm respectively for the SDG group and

Table 3 Total deviations of actual implant position in the surgical drill guide group (SDG) and surgical drill guide with implant insertion guide group (SDIG)

		Surgical drill guide (SDG)		Surgical drill guide with implant insertion guide (SDIG)		<i>p</i> value
		n = 15		n = 15		
		Mean \pm SD	Min–Max	Mean \pm SD	Min–Max	
Base	Horizontal	0.57 ± 0.39	0.08–1.38	0.39 ± 0.26	0.08–0.87	0.168
	Vertical	0.36 ± 0.27	0.01–0.95	0.19 ± 0.14	0.01–0.51	0.041*
	Global	0.74 ± 0.36	0.09–1.38	0.48 ± 0.22	0.20–0.87	0.024*
Apex	Horizontal	1.17 ± 0.68	0.04–2.31	0.64 ± 0.37	0.03–1.33	0.015*
	Vertical	0.37 ± 0.27	0.03–1.01	0.20 ± 0.13	0.03–0.51	0.047*
	Global	1.29 ± 0.61	0.36–2.32	0.71 ± 0.31	0.18–1.34	0.004*
Angular deviation		3.44 ± 1.61	0.95–6.68	2.03 ± 1.00	0.88–4.03	0.007*

*significant difference $p < 0.05$

Fig. 5 Box plot showing apical vertical discrepancy in each group (blue: SDG, red: SDIG)



3.6 degrees, 1.52 mm and 1.55 mm for the SDIG group, and concluded that there were no statistical differences between both groups. These three parameters showed fewer deviations in our study, with statistically significant differences between the SDG and SDIG groups. Possible reasons are that their study used a tooth-tissue supported guide and placed multiple implants simultaneously in each cadaver, while different template fabrication procedures were also followed.

The accuracy of computer-assisted static implant placement has greatly improved in accordance with two systematic reviews. Schneider et al. [35] analyzed studies between 2002 and 2009 and summarized that the deviation of computer-assisted (static) systems at the entry point or implant shoulder was 1.07 mm with 1.63 mm at the apex. The mean angular deviation was 5.26 degrees. Tahmaseb et al. [36] analyzed studies conducted from 2011 to 2016. They reported increasing accuracy of this static system over time as 0.9 mm, 1.2 and 3.3 degrees, respectively. Similarly, our study demonstrated that using a static surgical guide in a fully digital system for implant placement provided an acceptable result. Increased accuracy might result from applying the knowledge garnered from numerous previous studies and new surgical guide processing technologies to improve and develop the digital-assisted implant surgical system.

As mentioned before, this study proceeded under a fully digital workflow as the combination of digital scanning from an intraoral scanner, 3D radiographic images from CBCT, implant planning software, and a 3D manufacturing machine [37]. All procedures were performed by digital computer technologies at every step. The digital guide from this study can be used for implants without following conventional

procedures of oral impression and model pouring. Digitally guided implant surgery can accumulate errors and deviations from the transformation of data into a guide composed of errors during image acquisition, data processing in software, and surgical template fabrication [21, 38]. Hence, this study also showed the efficiency of a fully digital system that has been continuously replacing the conventional procedure over time.

This study considered only one type of several static guide systems as the tube and drill, while the surgical drill guide and insertion guide were separated. In some systems, these two guides were combined into a single guide and this might provide different results. All implants were placed in the anterior or premolar region due to avoidance of error from limited mouth opening problem. The results of our study indicated the efficiency of a fully digital system for implant placement using a drill guide together with an implant insertion guide. This reduced the possibility of error and provided an acceptable deviation in all directions.

The measurement of the study was a two-dimensional measurement from the computer software which is the limitation of the study. The three-dimensional measurement software is required for future study to verify the accuracy of the SDG and SDIG.

Further studies could investigate the accuracy in more sophisticated procedures such as multiple implant placements, inadequate bone quantity, poor bone quality, immediate implant placement, or flapless surgery. Evaluating the accuracy in these different surgeries as well as using the surgical drill guide with implant insertion guide would be helpful for simple implant placement and also for more varied and complex cases.

Conclusion

Within the limitation of the study, in single-tooth implant placement, it may be concluded that the usage of SDIG reduced deviations of actual implant position when compared with using SDG only. Besides, guided implant surgery by fully digital workflow is a practical procedure and provides precise implant position regarding the prosthetic-driven concept.

Abbreviations *CBCT*: Cone-beam computed tomography; *DICOM*: Digital imaging and communications in medicine; *SDG*: Surgical drill guide; *SDIG*: Surgical drill guide with an implant insertion guide

Supplementary Information The online version contains supplementary material available at <https://doi.org/10.1007/s10006-021-00975-7>.

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Author contributions C.N. performed a clinical study, analyzed, interpreted the data, and wrote the first draft of the manuscript. W.A. read, corrected, and proved the manuscript. P.K. performed the study design, approved the data analyzed, and finalized the manuscript.

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Data availability The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate This randomized clinical trial study was approved by the Human Experimentation Committee, Faculty of Dentistry, Chiang Mai University, and registered in the Thai Clinical Trial Registry (No. TCTR 20200128003).

Consent for publication Not applicable.

Competing interests The authors declare no competing interests.

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