

3D Evaluation the Accuracy of Free-Handed- Countersink Guided and Fully-Guided Implant Surgery in Partially Edentulous Patients: A Protocol for Clinical Trial with Quasi-experimental Study

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Conflict of interest:

There are no conflicts of interest. Dental implants, surgical guides were supplied free of charge by Dentsply Implants (M4 Implant MIS MF4-10330).

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ABSTRACT

Aim: to evaluate the accuracy of tooth-supported fully-guided surgery to free-handed, countersink surgery in the posterior maxilla and mandibular of partially edentulous patients by using CBCT image after placing implant and superimposed it with pre-operative CBCT.

Materials and methods:

A total of 30 implants of the same brand and type (M4 MIS Dentsply, Germany) were placed in 15 partially edentulous volunteers in need of implantation in the mandible or maxilla or both. All cases were digitally planned using data from cone beam computed tomography, and the comparison of the planned and actual implant positions was performed using a medical image analysis software (blue sky plan 4). Post-op. CBCT was used for nine measurements representing the deviations in angles, implant shoulders and apices. The outcome parameter was angular deviation (AD, degrees), crestal global deviation (CGD, mm), vertical linear deviation (VLD, mm), lateral linear deviation (LLD, mm), apical global deviation (AGD, mm), apical vertical deviation (AVD, mm), apical lateral deviation (ALD, mm), distance from maxillary sinus and distance from inferior alveolar nerve. Statistical analysis was performed using Fisher's exact test to compare the proportion between groups and Chi square test to test the relationship between two categorical variables.

Keywords: Countersink guided, Quasi experimental study, fully guided, Accuracy, partially edentulous.

Trial registration: Palestinian Health Research Council ethical approval attains from the Helsinki committee trial registration number (PHRC/HC/1242/23) at date of registration in its meeting on 23/02/2023.

INTRODUCTION

The successful establishment of a dental implant not only depends on osseointegration but also on the function and aesthetics of the final prosthesis (Bell et al., 2018; Motta et al., 2016; Smitkarn et al., 2019). Many of the investigations concerning guided implant surgery had different approaches to the factors that could affect how precise the surgery will be. Dental implants have proven to offer high survival and clinical success rates in various indications (De Angelis et al., 2017; Derks et al., 2015). For this reason and under this scenario, present implant dentistry has been concentrating on improving the treatment plan, so that an aesthetic result is a new variable.

Precise three-dimensional (3D) positioning of the implant is needed for the best esthetic results (Ruppin et al. 2008; Tahmaseb et al. 2014). The implant should be placed prosthetically, and taking into consideration the anatomy and bone availability. In addition to esthetics, precision in placement can assist in reducing biologic/technical complications (Canullo et al.; Cassetta et al.).

Among the surgical guide protocols, two common design protocols, fully guided and free hand, countersink guided, are often mentioned in relation to their effects on accuracy. Fully guided surgery entails the surgical guide guiding all actions with guide sleeves, from the first drilling through the implant insertion. On the other hand, countersink guided surgery is used especially in hard bone, to provide passive seating of the implant neck. These special countersink drills are adapted to enlarge the crestal zone into thick cortical bone.

However, until now there is no clinical study specifically addressing the accuracy of countersink guided implant placement, which is supported by the implant industry. One single randomized clinical trial (Younes et al., 2018) investigated the accuracy of FH, PG, and FG implant placement procedures.

In the past, radiographic stents, which were later translated to surgical guides after cone-beam computed tomography (CBCT) scanning, were used to place implants (Misch, 2004). However, this approach is fraught with various technical laboratory procedures and errors in the placement of implants are a common consequence (Nickenig & Eitner, 2007). Digital surgical guides have since solved these problems by combining intraoral scans with CBCT images to plan implant positions according to the bone, soft tissue, and adjacent teeth (Ganz, 2015). These guides, if perfectly designed and fitted from the beginning to the end of the procedure, will allow for more accurate implant installation (Kim, Huh, & Yun, 2016).

Recently, technological progress in the digital era has allowed for the emergence of the static computer-assisted implant surgery (s-CAIS) that provides visualization of 3D bone, soft tissue and teeth morphology in the preoperative planning (Deeb et al., 2017;

Ozan et al., 2009; Whitley & Bencharit 2015). Some studies have compared the accuracy of implant position between preoperative and postoperative CBCT and concluded that s-CAIS has a good precision. Nevertheless, results diverge and cannot yet be universally applied due to the heterogeneity of study designs, most of which were in vitro experiments (Deeb et al., 2017).

Whereas, few clinical studies have reported about the accuracy of implant positioning in partially edentulous ridges. Besides, most of the accuracy studies have been still laboratory-based and have lacked clinical evidence (Ma et al., 2018). The accuracy of implants is generally assessed by comparison between primary and secondary surveyor. The primary outcome is the angular deviation (AD) and the secondary outcomes are the crestal global deviation (CGD), apical global deviation (AGD), vertical linear deviation (VLD), lateral linear deviation (LLD), apical vertical deviation (AVD), and apical lateral deviation (ALD) (Younes, Yildiz, Bouferguene, Ursi, & Brunharo, 2018).

MATERIAL & METHODS

Inclusion criteria were as follows:

- Partially dentate adults with at least 6 remaining teeth
- The anticipated presence of sufficient bone volume allowing for implant placement with no simultaneous bone grafting
- Extractions within 2 months of welding.
- Want the missing tooth to be replaced by an implant
- Adequate related attached mucosa was found
- Mouth opening ≥ 40 mm
- Good oral hygiene
- Good general health

Exclusion criteria were as follows:

- Parafunctional habits
- Heavy smoking
- Physical or psychiatric disorders preventing the implant treatment.
- Previous radiotherapy of the head-neck region
- Younger than 18 years

Study design:

Researcher adopted pre and post Quasi-Experimental study design to fulfill the research objectives quantitatively. The Quasi-Experimental design is a popular design used in research. Pre/post-test design is a type of quasi-experimental study, in which an easily applied intervention can be studied in relationship to the group of subjects in the study. Conclusion Because the research design has problems that the validity of pre-post and type study is not easily satisfied, we cannot expect it, but we can obtain associations in outcome measures in this popular research design by choosing randomization, controlling inner and external bias, and correctly applying simple statistics.

Study setting:

The current study conducted in dental implant clinic at Al-Azhar university. Data gathered from the patient by using CBCT before and after implant placement to compare the result between free hand, countersink guided vs implant placement with fully surgical guide.

Data Collection procedure:**Analysis method:**

Free hand (countersink guided) and surgical guide surgeries were carried out by a parallel surgical kit (Dentsply®, MIS, M4, Germany), following the manufacturer's recommendations. The surgical guide surgeries were carried out using a dedicated (Dentsply®, MIS, M4 Germany) following the above-mentioned surgical plan. Both of the implants were performed for the same patient, on the same day and with the same devices. One implant per side was placed free hand, countersink guided and the other side with a computer-assisted implant guide.

With Blue Sky Plan 4 (Blue Sky Bio, Grayslake, IL, USA) software, the post-operative fixture was extracted as an STL file by segmentation the DICOM file of the CBCT taken after surgery used 3D slicer program as show in Figure 1.

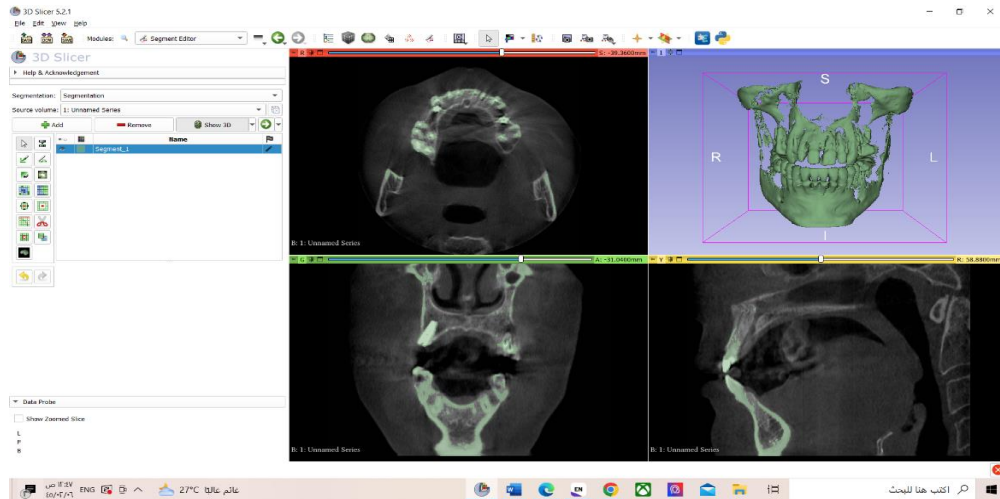


Figure 1: show segmentation the DICOM file of the CBCT taken after surgery used 3D slicer program.

Then, the STL file post-operative fixture imported to Blue Sky Plan 4 program and superimposing with planned fixture on the CBCT on the planned implant location before surgery as presented in Figure 2.

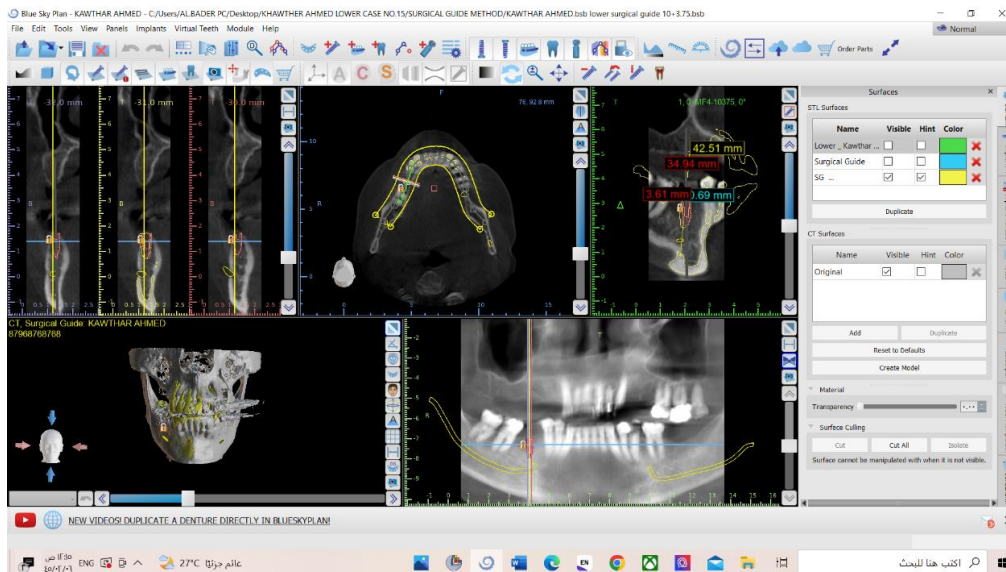


Figure 2: show import the DICOM file post-operative fixture to Blue Sky Plan 4 program and superimposing with the CBCT which have the planned implant location before surgery.

More than twenty points marked on the two images using a point-based automatic image registration algorithm to ensure correspondence as show in Figure 3.

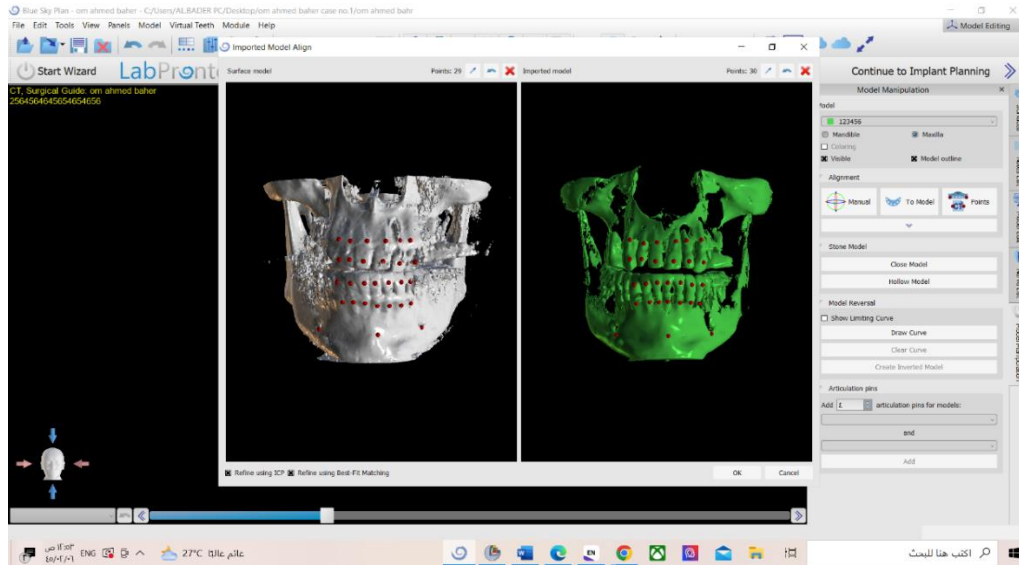


Figure 3 : aligned using a point-based automatic image registration algorithm.

Measure the deviation for each parameter:

The definitions concerning accuracy outcome measures are as follows: The primary outcome was angular deviation defined as the angle closed by the principal axis of the planned implant and the principal axis of the inserted implant in degrees. The secondary outcomes were crestal global deviation; the distance between the center of the coronal end of the planned and the inserted implants in millimeters, apical global deviation ; the distance between the apical endpoints of the planned and the inserted implants in millimeters, and vertical linear deviation ; the distance between perpendicular line on the hexagon of planned implant and another line draw parallel to it on the hexagon of actual implant in millimeters, lateral linear deviation ; the distance between vertical line on the long axis of planned implant and another line draw parallel to it on the long axis of actual implant in millimeters, apical vertical deviation ; the distance between perpendicular line on the apex of planned implant and another line draw parallel to it on the apex of actual implant in millimeters, apical lateral deviation ; the distance between vertical line on the long axis of planned implant and another line draw parallel to it on the long axis of actual implant in millimeters, Two anatomical parameters were added to these ones : the distance from the inferior alveolar nerve (IAN) and the distance from the maxillary sinus (MS).

Primary outcome is Angular deviation of the final position to the planned implant position. Meanwhile, secondary outcomes are described by the following eight measurements.

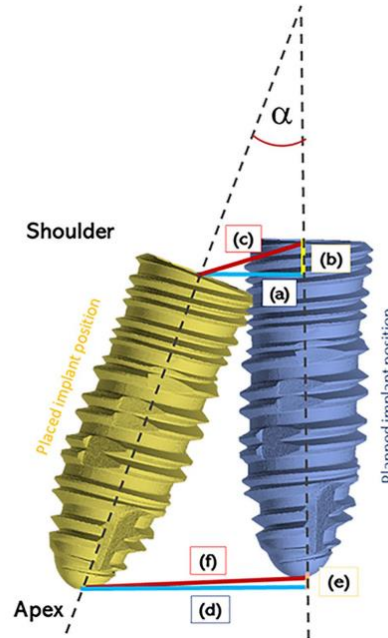
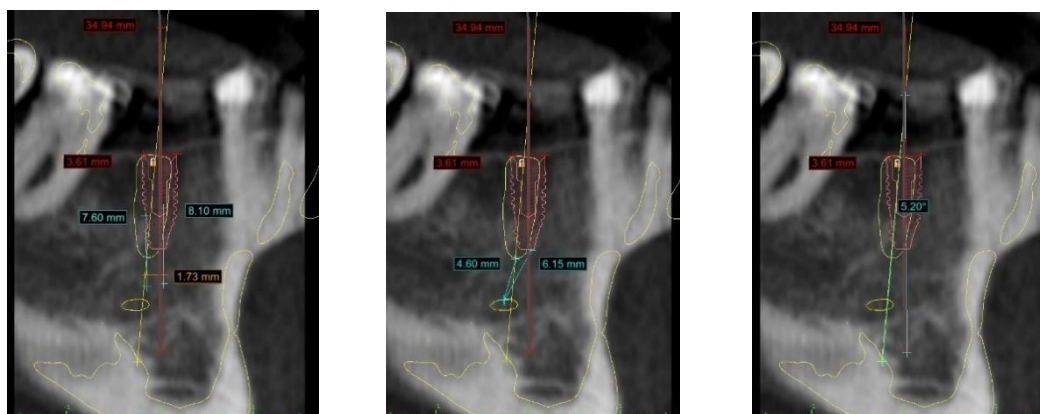


Figure 4: Deviation parameters between the planned implant position (blue) and placed implant position (yellow): (a) Lateral Linear deviation (mm); (b) Vertical Linear deviation (mm); (c) Global Crestal deviation (mm); (d) Apical Lateral deviation (mm); (e) Apical Vertical deviation (mm); (f) Apical Global deviation (mm); α , Angular deviation (degree). (Ngamprasertkit et al., 2022)

The real measurements of the primary and secondary outcomes using Blue Sky Plan 4 Software are presented in Figure 5.



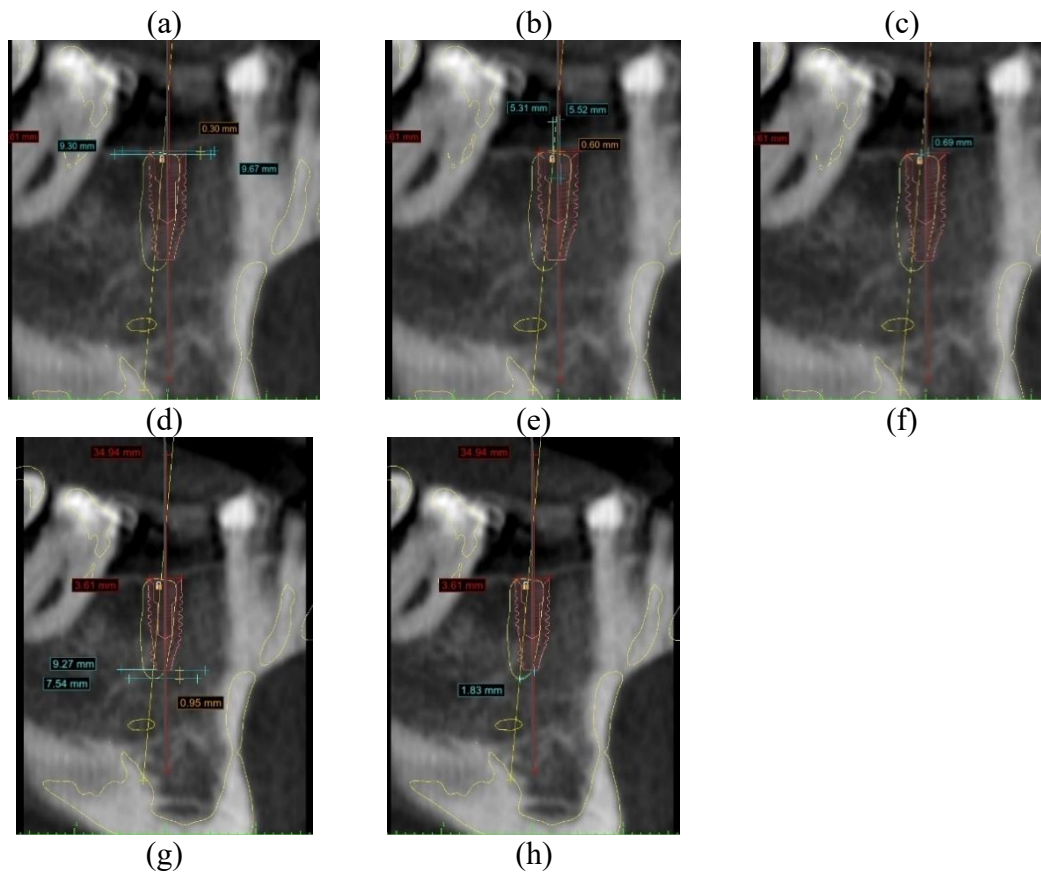


Figure 5: Deviation parameters between the planned implant position (red) and placed implant position (yellow): (a) apical lateral deviation (mm); (b) distance from inferior alveolar nerve (mm); (c) angular deviation (degree); (d) vertical linear deviation (mm); (e) lateral linear deviation (mm); (f) crestal global deviation (mm); (g) apical vertical deviation (mm); (h) apical global deviation.

Data Analysis

The researcher employed the Statistical Package for the Social Sciences (SPSS) version 22 program for both data entry and statistical analysis. The data analysis process comprised two stages: first, descriptive analysis to summarize the data, followed by an inferential analysis that elucidated the relationships between the variables under investigation. Also, the Central tendency measures were performed to describe the collected data from patients. Exact Fisher's Test, Chi-square Test and Independent t-Test were used to examine the possible relationship between variables. The confidence interval was considered at 95% and a margin of error 5%. P-value less than 0.05 was considered to indicate a statistically significant difference.

Categorical outcomes were presented as absolute and relative frequencies. A bivariate analysis using Independent t-Test, or Fisher's exact test when application conditions were not achieved, was used to compare the groups. Differences between groups of scale variables were explored using parametric (Student's t test for independent or paired samples) or nonparametric tests. Chi square test was used to test the relationship between two categorical. In the present study the Independent t-Test, Fisher's exact test and Chi square test as well as median were used where the data was classified nonparametric.

Abbreviations:

Symbol	Description
CBCT	Cone Beam Computed Tomography
CAD	Computer Aided Design
CAM	Computer-aided manufacturing
CAI	Computer Assisted Inspection
DICOM	Digital Imaging and Communications in Medicine
GIS	Guided Implant Surgery
STL	Standard Tessellation Language OR Standard Triangulated
AD	Angular deviation
CGD	crestal global deviation
VLD	Vertical Linear Deviation
LLD	Lateral Linear Deviation
AGD	apical global deviation
ALD	Apical Lateral Deviation
MS	Maxillary Sinus
IAN	Inferior Alveolar Nerve
s-CAIS	Static computer-assisted implant surgery
IOS	Intra oral scan
3D	Three-dimensional
FG	Fully guided
FH	Freehand
CS	Countersink
SD	Standard deviation
AVD	apical vertical deviation
FHM	free hand method
SGM	surgical guide method
FH	free hand

SG	surgical guide
PG	pilot guide
FG	fully guided

Declaration Funding:

I declare that this article has been composed solely by myself and that it has not been submitted, in whole or in part, in any previous application for a degree. Except where states otherwise by reference or acknowledgment, the work presented is entirely my own.

Ethics approval and consent to participate:

The study was designed as a Quasi-Experimental study including consecutive patients referred for implants and seeking treatment in four oral and maxillofacial surgery department (Clinics university). The study was approved by the Helsinki Committee for Ethical Approval, Palestinian Health Research Council (Number: PHRC/HC/1242/23) at its meeting on 23/02/2023 and implemented in strict adherence with ethical principles, that are on par with the World Medical Association's Declaration of Helsinki. Moreover, study goals were explained to patients. Privacy and confidentiality as well as voluntary participation were guaranteed. A consent form was signed by each patient enrolled in the present study.

Consent for publication:

All participants gave written informed consent for their anonymized data to be used in publications.

Availability of data and materials:

The materials described in the study are available from the corresponding author upon.

Competing interests:

The authors declares that they have no competing interests.

Finding:

The authors report no funding.

Author contributions

Conception and design: Th.A , H.M and Y.A, Provision of study materials: Th.A and Y.A, Literature review: Th.A , Data analysis: Th.A , Manuscript writing: Th.A, Final approval of manuscript: Th.A , H.M and Y.A

All authors have critically reviewed and approved the final draft and are responsible for the content and similarity index of the manuscript.

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