Assessment of the Accuracy of Surgical Guide Designed from Digital Impression, Dental Model Scanning using CBCT and Desktop Scanner in Computer Guided Implantology:Randomized Clinical Trial.

تقييم دقة الدليل الجراحي المصمم من الانطباع الرقمي, مسح نموذج الاسنان عن طريق الاشعة المقطعية بالحاسوب مخروطية الشعاع والماسح المكتبي في زراعة الاسنان الموجهة عن طريق الحاسوب: تجربة سريرية عشوائية

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Oral & Maxillofacial Radiology department

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Evidence based committee (Reviewers)

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Research plan committee

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I. Administrative information:

1. Title:

Assessment of the Accuracy of Surgical Guide Designed from Digital Impression, Dental Model Scanning using CBCT and Desktop Scanner in Computer Guided Implantology: Randomized Clinical Trial.

2. Protocol Registration:

Site and registration number of the protocol should be reported before final approval of the protocol (e.g. Clinicaltrials.gov: NCT01066572).

3. Protocol version:

Date and version identifier. (e.g. 25 Jul 2018 Protocol number: 5)

4. Funding:

Self funding

5. Roles and responsibilities:

1. The researcher (AT) will be responsible of case preparation and coding of cases.
2. Expert implantologist will be responsible for the surgical procedure.
3. The main supervisor (MD) will be responsible of the randomization, allocation concealment and assessing of final CBCT images.
4. The co-supervisor (AMA) will be responsible for data entry and data monitoring.

II. Introduction:

6. Background and rationale:

Implant nowadays is the most important treatment option suggested for patients to restore missing teeth in partially or completely edentulous arches ,and achieves a long term successful results and prognosis (Hultin, Svensson, and Trulsson 2012).

To obtain these successful results, implant planning is mandatory .Proper implant planning is achieved by gathering a clinical and radiographic information and their correlation. Implant planning must be a crown-to-bone approach, starting from crown or suprastrcture design and end with determination a proper position of implant in bone.This planning concept will guarantee a proper biomechanics, esthetics and maintenance. All of these aspects lead to a long term successful tooth restoration using implants(Worthington, Rubenstein, and Hatcher 2010).

CBCT is the best imaging modalities for bone scan. From CBCT bone height and thickness and location of surrounding vital structure can be evaluated (Vercruyssen et al. 2015)(Jamjoom et al. 2018).

Evolution of digital dentistry, 3rd party software and CBCT machine make implant planning more accurate by enabling virtual implant planning on a laptop to rapidly review treatment. options and saves the surgeon's time in planning the surgery while improving accuracy. (Hultin, Svensson, and Trulsson 2012).

Computer guided implantology aims to transfer the virtual implant planning into the clinical situation and helps the clinician to insert the implant in safe and predictable manner and with less time and fast healing for patient. Computer guided implantology can be either dynamic system or static system.Dynamic system depends on surgical navigation and computer-aided navigation technologies, which allows the surgeon to alter the implant position in real time but it is not commonly used due to it's a high cost. Static system (template base system) is commonly used nowadays as templates are easily integrated into the intraoperative workflow by using a surgical template designed and produced using compute aided- design/computer-aided-manufacturing (CAD/CAM) technology (Jamjoom et al. 2018).

Proper surgical guide planning depends on collection of 3D data of both, bone using CBCT and dent-gingival tissue of the patient. Many softwares were introduced in dentistry to utilize both data by superimposition of soft tissue data over the 3D CBCT images, virtual patient can be obtained and virtual implant placement can be performed in situation resembling the clinical situation.The surgical template transfer the virtual implant to the real surgical field (Dolcini, Colombo, and Mangano 2016).

3D dent-gingival data can be obtained by creating of digital model of patient by scanning of conventional cast by desktop scanner,scanning of conventional cast by CBCT machines or by intraoral digital impression (IOS) (Becker et al. 2018).

Research question:

In computer guided Implantology, are surgical stents designed from scan of dental model by CBCT and from digital impression as accurate as surgical stents designed from desktop scanner?

Statement of the problem:

The role digital dentistry is improved in computer guided implantology especially with development of computer guided implant software, desktop scanner and intra oral scanner development and CBCT machines(van der Meer et al. 2012).

Intra-oral scanner, desktop scanner and CBCT scanner can be used in creation of 3D digital model that can be used with computer guided implant in fabrication of the surgical stent(Rossini et al. 2016).

And the question, is the accuracy of surgical guide will be affected when designed by one of these different modalities?

Rationale for conducting the research:

Digital 3D dentoginival details are very important in computer guided implantology and designing of surgical stent.nowadays there are many methods to obtain this soft tissue replica as CBCT,desktop scanner and intra oral scanner.this study is conducted to asses the effect of different method of soft tissue digitization on the accuracy of surgical template used in computer guided implantology.

Review of literature:

Many studies were conducted to evaluate the accuracy of desktop scanne, CBCT and intraoral scanner to obtain 3D dentogingival details that used in many dental application as orthodontic treatment and computer guided implantology.

In Akyalcin et al. 2013 after scanning 60 dry skulls by intraoral scanner and CBCT (CS 9300 unit Carestream Health, Atlanta, Ga) to evaluate the accuracy of 3-dimensional digital models acquired from intraoral scanner compared with both manual and cone-beam computed tomography measurements of the same dental anatomy. Measurements from the intraoral scanner demonstrated near-perfect agreement (ICC, 0.91-0.99) with the caliper measurements. Cone-beam computed tomography measurements had moderate to high levels of agreement (ICC, 0.65-0.99) compared with the caliper measurements.Study conclusion was that intraoral scanner provide almost 1-to-1 diagnostic information of the investigated anatomy and was superior to the cone-beam computed tomography measurements (Akyalcin et al. 2013)

Kim & Lagravére, 2016 revealed that of desktop laser scanned digital models are highly accurate compared to physical models and CBCT scans for assessing the spatial relationships of dental arches for orthodontic diagnosis after scanning 50 plaster models using the Ortho Insight 3D laser scanner and Bolton ratios were calculated with its software. CBCT scans were imported and analyzed using AVIZO software. Plaster models measurements with a digital caliper were considered as a gold standard (Kim and Lagravére 2016) .

Systematic review of Ferreira et al 2017 concluded that digital models obtained from CBCT were not accurate for all measures assessed. The differences were clinically acceptable for all dental linear measurements, except for maxillary arch perimeter. Digital models are reproducible for all measurements when intraexaminer assessment is considered and need improvement in interexaminer evaluation (Ferreira et al. 2017).

In José et al. 2017 one hundred patients were scanned by intraoral scanner and CBCT (Planmeca Promax 3D ,Planmeca, Helsinki, Finland). Patients initial plaster models were scanned by desktop scanner scanner to be used as a control group.measurment that performed on these digital models revealed that intraobserver and interobserver error for the intraoral scanner model was less than 0.44 mm while for segmented CBCT models, the error was less than 0.97 mm. intraoral scanner models provided statistically and clinically acceptable accuracy for all dental measurements, while CBCT models showed a tendency to underestimate measurements in the lower arch, although within the limits of clinical acceptability (José et al. 2017).

In Robben et al. 2017 ,patients cast was scanned by five different CBCT devices to evaluate the accuracy of CBCT cast digitization by different machines. The accuracy measurements showed significant differences among the CBCT devices in comparison to direct measurements in plaster cast but study conclusion was CBCT devices are suitable for the digitization of plaster casts and show very good clinical accuracy. Dental offices equipped with CBCT devices could digitize plaster casts without the need for additional devices (Robben et al. 2017).

Explanation for choice of comparators:

Desktop scanner is selected as a control group depending on the following studies:

Flügge et al. 2013 revealed that of scanning with the intraoral scanner is less accurate than scanning with the extraoral scanner . Intraoral scanning with the iTero (IOS)is less accurate than model scanning

with the iTero(IOS), suggesting that the intraoral conditions (saliva, limited spacing) contribute to the inaccuracy of a scan (Flügge et al. 2013).

Wesemann et al. 2017 revealed that the most accurate results were obtained by the extraoral scanner. The R700 and the TRIOS intraoral scanner showed comparable results. CBCT-3D-rendering with the Promax 3D Mid CBCT unit revealed significantly higher accuracy with regard to dental casts than dental impression after sixty-four scans were taken with each of the desktop scanners R900 and R700 (3Shape), the intraoral scanner TRIOS Color Pod (3Shape), and the Promax 3D Mid cone beam computed tomography (CBCT) unit (Planmeca). All scans were measured with measuring software (Wesemann et al. 2017).

Another study considered desktop scanner as a gold standard to asses the accuracy of 7 intraoral scanner (Patzelt et al. 2014) (Renne et al. 2017).

7. Objectives:

This study is conducted to assess the effect of different method of digitization of dento-gingival details (intraoral scanner,CBCT or desktop scanner) on the accuracy of surgical guide used for computer guided implantolgy.

Hypothesis:

Null

Primary objective:

P: Partially edentulous patient seeking implant restoration using computer guided implantology

I1: Surgical guided manufactured using intra oral digital impression

I2: Surgical guide manufactured using model cast scanning by CBCT

C: Surgical guide manufactured using model cast scanning by extra-oral laser scanner

O: Assessment of accuracy of surgical guided manufactured using digital impression, model cast scanning by CBCT and Desktop scanner by Evaluation of angular deviation of virtual implants and actual implant position by 3rd party software in degrees.

Secondary objectives

Evaluation of linear deviation of virtual implants and actual implant position by 3rd party software in mm.

8. Trial design:

Randomized clinical trial will be conducted on nine patients in outpatient clinic of oral and maxillofacial radiology department in Faculty of Dentistry, Cairo university.

Patients will be divided into 3 group :

Intervention Group one : Surgical guide manufactured using intra oral digital impression

Intervention Group two: Surgical guide manufactured using model cast scanning by CBCT

Control group: Surgical guide manufactured using model cast scanning by desktop scanner

III. Methods

A) Participants, interventions & outcomes

9. Study settings:

Randomized clinical trial will be conducted in outpatient clinic of oral and maxillofacial radiology department in Faculty of Dentistry, Cairo university.

10. Eligibility criteria:

Inclusion criteria

- partially edentulous patient.
- Patients with bucco-lingual bone thickness more than 6 mm allowing flapless implant placement.

Exclusion criteria:

- Completely edentulous patient or free end saddle edentulous area.
- Patients needing graft or sinus lifting with implant placement.
- Patients with thin ridges.
- Patients with systemic disease that may affect bone quality.
- Patients with poor oral hygiene and active periodontal diseases.
- Patient with limited mouth opening

11. Interventions

Patients fulfilling inclusion criteria will be divided randomly into 3 groups,

- Group 1: Full arch digital impression will be taken by IOS carestream CS3600 to produce the digital cast for patient in form of STL file.
- Group 2: Conventional impression will be taken for patient then poured to obtain a plaster cast. This plaster cast will be scanned by CBCT to produce a digital cast in form of STL file.
- Group 3: Conventional impression will be taken then poured to obtain a plaster cast that will be digitized by desktop scanner to obtain a digital cast in form of STL file.

All Patients will be scanned by CBCT machine (Planmeca Promax 3D Mid - Asentajankatu, Helsinki, Finland)) to obtain the bony data in the edentulous area in which implant will be placed.

Digital model from each group & CBCT scanning will be imported by 3rd party software (blue sky), and digital cast will be superimposed over CBCT images for each patient. Then virtual implant planning will be performed.

Surgical guide will be designed and exported as STL file to be 3D printed.

Implant placement will be performed by 10 years' experience implantologist using the surgical guide.

After implant placement, post-operative CBCT scan for each patient will be performed by the same parameters of pre operative CBCT scans.

Postoperative CBCT scanning will be imported by 3rd party software and superimposes over the preoperative CBCT images that used in implant planning and surgical guide designing to assess the accuracy of implant placement by surgical guide in comparison to the virtual implant planning to determine the effect of method of digitization of dento-gingival data of patient on the accuracy of surgical guide

12. Outcomes:

Outcome	Measuring device	Measuring unit
Evaluation of angular deviation of virtual implants and actual implant position	Special computer software (Blue sky bio)	(Degrees)
Evaluation of linear deviation of virtual implants and actual implant position	Special computer software (Blue sky bio)	(mm)

13. Participant timeline

Group one	Group two	Group three
Pre operative CBCT scan	Pre operative CBCT scan	Pre operative CBCT scan
Digital impression by IOS.	Patient cast will be scanned by CBCT.	Patient cast will be scanned by desktop scanner
Digital model & CBCT scanning will be imported by 3rd party software (blue sky), and digital cast will be superimposed over CBCT images for each patient. Then	Digital model & CBCT scanning will be imported by 3rd party software (blue sky), and digital cast will be superimposed over CBCT images for each patient. Then	Digital model & CBCT scanning will be imported by 3rd party software (blue sky), and digital cast will be superimposed over CBCT images for each patient. Then

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14. Sample size:

Sample size calculation was done using R statistical package, version 3.3.1 (21-06-2016). Copyright (C) 2016. The R Foundation for Statistical Computing. (1)

One-way analysis of variance power calculation for more than two groups was used to detect the proper sample size. Means and standard deviations were determined according to Arisan et al. (2010) based on the degree of angular deviation.

The results showed that, at a power of 80% and a two-sided significance level of 5%; a total sample size of 9 implants will be adequate to reject the null hypothesis that the group means are equal. This means with equal allocation to three arms, there will be 3 implants in each group.

15. Recruitment:

Patients will be selected from the outpatient clinic of the Oral and Maxillofacial Surgery Department – Cairo University.

Screening of patients will continue until the target population is achieved.

Identifying and recruiting potential subjects is achieved through patient database.

B) Assignment of interventions

16. Allocation:

16a. Randomization:

- Patients will be randomly divided to three groups according to three different method of digitization of dento-gingival details(IOS,CBCT and desktop scanner)

The patients will be randomly divided into 3 groups using www.random.org

The whole sample size will be divided into equal 3 groups

16b. Allocation concealment mechanism:

- All patients who give consent for participation and who fulfill the inclusion criteria will be randomized.
- Funded patient files in a dark sealed envelope will be the method for allocation concealment.

• The supervisors (M.D. and A.M.) are responsible of division the sealed envelopes into three groups and implementation for patients allocation.

16c. Implementation

- Main supervisor (MD) will generate the allocation sequence.
- (AM) and implantologist will enroll participants.
- Co-supervisor will assign participants to interventions.

17. Masking/blinding:

- Each patient will be given a code by the researcher (AT) and the observers will be blind to which group this case belong.
- Evaluators and statistician will be blinded

C) Data collection, management, and analysis:

18. Data collection methods

Accuracy of surgical guide

a- The angular and linear deviation between the virtual planning and the post-operative result using CBCT.

b- Plans to promote participant retention

Telephone numbers of all patients included the study will be recorded as a part of the written consent.

-All patients will be given a phone call at the time of the pre-determined follow up dates -

19. Data management:

• All data will be entered electronically.

• Patient files funded in a dark sealed envelope, stored in numerical order and stored with the co-supervisor.

• All data will be maintained in storage for 1 year after completion of the study.

20. Statistical methods:

Statistical analyses will be carried out using SAS Version 9.1.3. USA). A power

analysis with n = 10 and a standard deviation of 1 revealed a power of 90% (power analysis of a noninferiority test of one mean).

D) Data monitoring:

21. Monitoring

The trial and its data will be monitored by MD and A.A to ensure that there are no problems with trial's procedure and ways of collecting data.

22. Harms

- The possible adverse effect of the intervention is inaccuracy of the process of surgical guide fabrication and this require remake of surgical guide.

23. Audit

- Auditing of the study design will be done by the evidence based committee-oral and maxillofacial radiology department - Faculty of Dentistry, Cairo University, at the end of the trial.

IV. Ethics and dissemination

24. Research ethics approval

- This protocol and the template informed consent form will be reviewed by the ethics committee of scientific research, Faculty of Dentistry, Cairo University.

25. Protocol amendments

- Any modification to the protocol which may impact on the conduct of the study, potential benefit of the patient or may affect patient safety, including changes of study objectives, study design, sample sizes, study procedures, or significant administrative aspects will require a formal amendment to the protocol.

- Such amendment will be agreed upon by the council of oral radiology department.

26. Informed consent

- The researcher will introduce the trial to patients and will discuss the trial with patients. The purpose, the nature of this study and detailed surgical procedure with possible complications will be also discussed.

- Patients will then be able to have an informed discussion with the participating consultant. The researcher will obtain written consent from patients willing to participate in the trial. All consent forms will be translated into Arabic.

27. Confidentiality

All study related information will be stored securely at the study site. All participant information will be stored in locked file cabinets in areas with limited access. All CT images, reports, data collection, process and administrative forms will be identified by a coded ID (identification number) only to maintain participant confidentiality. All records that contain names or other personal identifiers, such as informed consent forms, will be stored separately from study records identified by code number.

28. Declaration of interest

The study is self-funded and there is no conflict of interest to declare.

29. Access to data

- The co-supervisor will be given access to the data.
- To ensure confidentiality, data dispersed to project team members will be blinded of any identifying participant information

30. Post-trial care

All patients will be followed up until complete healing and satisfactory reconstruction results occur.

31. Dissemination policy

- Study will be registered online on the clinical trial.gov.
- Study results will be published in a thesis as partial fulfillment of the requirements for PHD degree of oral and maxillofacial radiolgy.
- Paper will be extracted from the study for publication..

V. Appendices

32. Informed consent

- The researcher will introduce the trial to patients and will discuss the trial with patients. The purpose, the nature of this study and detailed surgical procedure with possible complications will be also discussed.
- Patients will then be able to have an informed discussion with the participating consultant. The researcher will obtain written consent from patients willing to participate in the trial. All consent forms will be translated into Arabic.

33. Biological specimens

Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable.

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