APPLICATION FORM FOR THE RESEARCH PROTOCOL

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Línea de investigación: Investigación básica y aplicada en odontología
Título de la investigación: "Clinical and anatomical factors influencing accuracy in fully guided implant placement"

1. Introduction.

Digital technologies have been widely used in current implant dentistry practice improving clinical outcomes. Computer-guided surgery (CGS) has been introduced to transfer the planed implant position from specific planning software to a surgical procedure. Therefore, implant placement using CSG provides better outcomes regarding the 3-Dimensional (3D) implant position than free-hand implant placement, shorter surgical time, less discomfort to the patient, and allows prosthetically driven implant placement. [1]

Nowadays, static system surgery has been more often applied in clinical practice than dynamic systems. The literature has reported that there exist cumulative sums of errors throughout the guided implant surgery sequence, for example improper

guide positioning. Mucosal thickness and mobility can be a variable that might affect the final position of the guide; therefore, the outcome of the implant position can be influenced as well. [2,3]

Studies regarding the accuracy of implant placement with CGS have reported that there can be a deviation between planned and placed implant position. A recent systematic review has demonstrated that the total mean deviation of 1.2 mm (1.04–1.44 mm) at the implant platform level and 1.4 mm (1.28–1.58 mm) at the implant apex level was found in the case of implant placement with CGS.[3]

Several reports revealed that some clinical factors such as the surgical technique, guide type, and implant position can affect the accuracy of the implant placement with CGS.[3,4]

Moreover, the impact of the jawbone condition, such as bone quantity and quality in the implant placement site, affecting the accuracy of implant placement with CGS remains unclear. [4,5]

Putra et al.[6] reports that with low bone density, the drilling trajectory might deviate toward the softer part of the bone after the second drilling procedure. Therefore, highest deviation was found in the cases that the bone density was less than 500 Hounsfield unit (HU).

Multiple bone condition predictors like bone density, bone width, and cortical bone thickness significantly influenced the accuracy in implant placement with CGS.

Some other factors like implant site, type of implant (immediate, early or delay), mucosal thickness, graft in the area, quantity of implants have been reported as a factor influencing the accuracy of the guided surgery.[6,7]

The aim of this cohort prospective study is to assess the influence of clinical and anatomical factors on the accuracy of computer-guided surgery. The following factors will be taken into consideration for the analysis of the data: 1) Implant location (anterior or posterior); 2) Single or multiple implants; 3) Mucosal thickness; 4) Native or regenerated bone, 5) immediate or delay implant.

2. Objectives.

Overall objective.

The aim of this cohort prospective study is to assess the influence of clinical and anatomical factors on the accuracy of computer-guided implant surgery on immediate and delayed implant placement:

Specific objectives:

1) To assess the influence of implant location (anterior or posterior) on the accuracy of CGS

2) To assess the influence of time for implant placement (immediate or delay) on the accuracy of CGS.

3) To assess the influence of type of bone (native or regenerated bone)

4) To assess the influence of bone density on the accuracy of CGS.

Hypothesis.

1: H1implant location (anterior or posterior) has an influence on the accuracy of CGS

2: H1The time for implant placement (immediate or delay) has an influence on the accuracy of CGS.

3: H0 The mucosal thickness does not have an influence on accuracy of CGS.

4: H1The bone density has an influence on the accuracy of CGS.

Material and methods.

The study will be performed at a private practice (Blasi Dental Clinic) which is under the tutelage of the Universitat Internacional de Catalunya (UIC) CEIm. Moreover, the present study will be registered in clinicaltrials.gov.
For the sample size calculation, we use as reference Putra´s[14] article where it is reported correlations between different deflection parameters and bone density. These are weak-moderate magnitude correlations (0.3<r<0.5).

The sample size was calculated calculated for 3 levels of statistical power, a 95% confidence level with Pearson's linear correlation coefficient null test)

Degree of correlation	Power reached		
	70%	80%	90%
r=0.3 (weak)	67	84	112
r=0.5 (moderate)	23	29	37

To detect a weak magnitude correlation as significant, 84 patients will be needed for this study.

Inclusion criteria.

- Patients between 25 to 60 years old.
- Periodontally stable patients. Adequate oral hygiene with less than 15% Full Mouth Plaque Score (FMPS).
- Patients who need dental implant treatment without simultaneous regeneration.
- Ability to follow instructions and availability to attend for regular compliance during the entire study.
- With presence of partial edentulism (at least 6 remaining teeth distributed in the dental arch to support the guide).

Exclusion criteria:

- Active infections

- Untreated periodontal disease
- Heavy smokers (>10 cigarettes per day)
- Drug / Alcohol dependency
- Medical condition contraindicating implants dependency
- Patients under bisphosphonate therapy
- Limited mouth opening

All the information will be given to the patients before sign and obtain the inform consent form.

Clinical procedures.

After assessing the fulfillment of the inclusion criteria, pre-operative cone beam computed tomography (CBCT) (Newtom, Cefla S.C.) and intraoral digital impressions (Trios®, 3Shape Dental Systems, Denmark) will be obtained for each patient to achieve a digital wax-up and a presurgical plan for the exact position of the implants by a single calibrated operator (RP).

Every patient could have a maximum of four implants to be placed (one per quadrant), in those cases, there will be one guide per implant.

The digital imaging and communications in medicine (DICOM) files will be imported to a guided-surgery planning software (Codiagnostix, Dental wings) to perform an implant planning based on the digital wax up; in this step the assessment of the mucosal thickness will be performed using the STL and the DICOM files superimposed. The measurement will be taken from the crestal bone until the soft tissue surface (mm).

Furthermore, a surgical guide will be designed, and 3D printed (SprintRay Pro S; SprintRay Inc) with implant guide resin (SprintRay EU Surgical Guide Clear; SprintRay Inc) by RP for the surgical procedure, supported by the whole dental arch, and reinforced with one bar across the arch.

Through guided surgery, previously planned and designed based on CBCT study and CAD/CAM scanning, placement of Conelog Progressive line implants

(Biohorizons Camlog, Iberia) will be performed in maxilla or mandibula in a one stage surgery by a 8 years' experience operator (GB).

Implant placement will be fully guided and a postoperative CBCT in ECO mode (35µSv) will be taken after the implant placement to assess the final position.

Both CBCT will be aligned (pre-op scan and post-op scan) to make calculations by a single evaluator (AB) included the following (Fig. 1): (1) angle: angle deviation measured in degrees; (2) base: deviation at implant shoulder in millimeters; (3) tip: deviation at implant apex in millimeters; (4) 3D offset: global deviation in 3D directions in millimeters; (5) mesiodistal deviation in millimeters: (+) deviated to the distal direction and (−) deviated to the mesial direction; (6) buccolingual deviation in millimeters: direction: (+) deviated to lingual direction and (−) deviated to buccal direction; and (7) apicocoronally deviation in millimeters: direction: (+) deviated in the apical direction. and (−) deviated in the coronal direction.

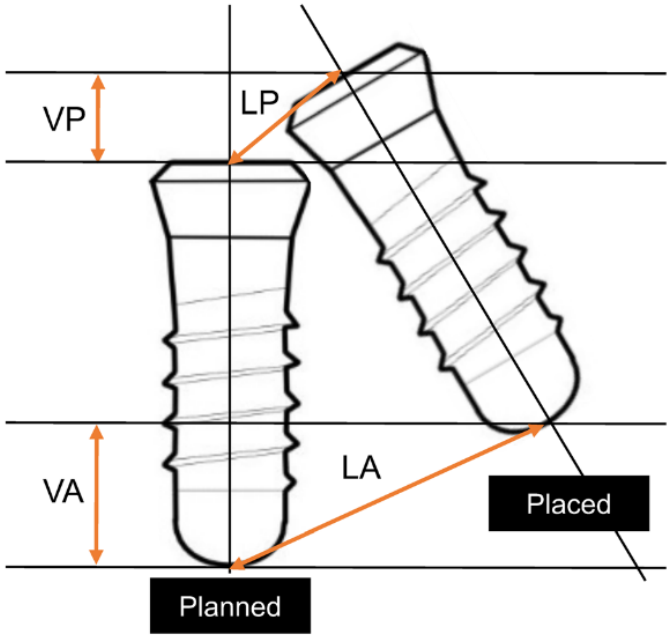


Figure 1. Parameters to evaluate de position of the implant. [14]

Clinical and study schedule

The estimated appointments for all patients:

- Screening visit: Selection, recruitment of patients, and signing of informed consent.
- First visit: Data collection (intraoral scanning and CBCT acquiring).
- Second visit: Implant placement and post-operative CBCT.

Ethics

This protocol follows the ethical principles regarding human experimentation recommended by the World Medical Association in the Declaration of Helsinki.
After fulfilling the inclusion criteria, all patients will receive a full inform consent.
After evaluation and clarification of possible concerns, the patient will return the signed consent as an agreement of participation.

Statistical analysis.

A descriptive analysis will perform by analyzing the mean, standard deviation, minimum, maximum values, and median for each outcome. For a 95% confidence level and an estimated standard deviation, T-test and Pearson's linear correlation coefficient null test will be used to analyze the data.

Study limitations

This clinical study presents some limitations to be taken into considerations. First, if the surgical guide could not fit properly, present movements or brake during the procedures, Second, the need of taking two CBCT in one month can represent a topic to be aware. And finally, the data should permit the correct alignment for further analysis and evaluation and its quality must be enough to facilitate the data analysis.

Contingency plan.

Rewarding the mishap of the fitting of the guide, in those cases we will print two guides per case, to have a backup if the first guide brakes. If the guides are not fitting properly, the patient should be excluded from the study.

For this study we will use the ECO mode which only presents a minimum effective dose of 9 μSv (four times less radiation than a regular CBCT and almost the same radiation as an orthopantomography)

Moreover, if any of the data collected presents any error that could interfere in the data analysis, the patient will be excluded for the study.

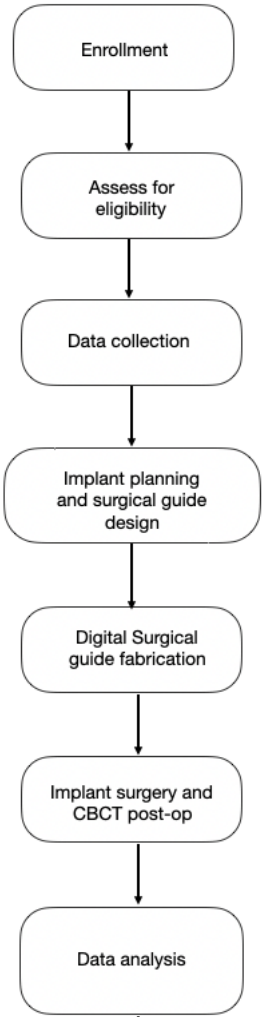
Annexes

a. Flow chard

b. Patient data collection

c. Timeline

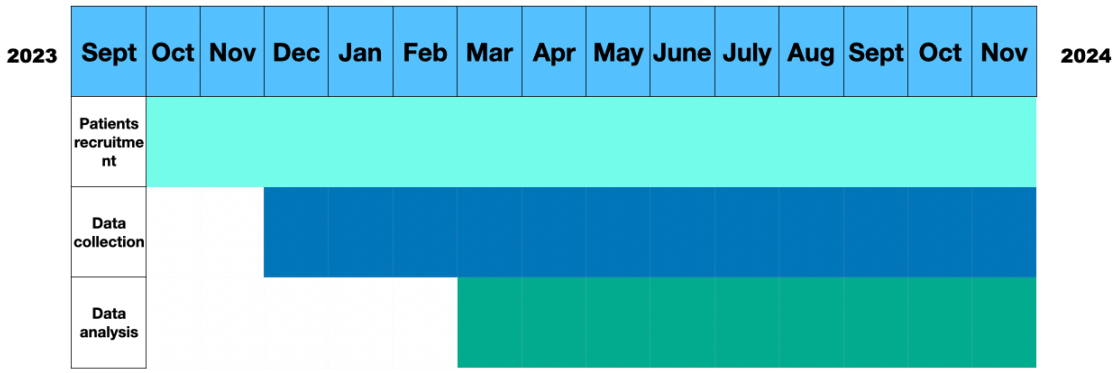
a. Flow chard



b. Data collection

PATIENT DATA COLLECTION
PATIENTS PRE-SURGICAL INFORMATION
Patient number: _____
Age: ____
Sex: ____
Medical conditions_____
Allergies: _____
Smoker: Yes___ No___ How many per day? _____
Site of implant placement: _____
Immediate implant? Yes___ No___
Native bone? Yes___ No___
Single or multiple implants? _____
Mucosal Thickness (millimeters) _____
Bone Density (Hounsfield units) _____
Complications with the surgical guide? Yes___ No___
Other complications _____

c. Timeline of study



Glosario de términos.

1. **Computer-guided surgery (CGS)**
2. **Cone beam computed tomography (CBCT).**
3. **3-Dimensional (3D)**
4. **Hounsfield unit (HU).**
5. **Full Mouth Plaque Score (FMPS).**

Investigador Principal Dra. Marta Valles

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IP or tutor signature	**Supporting researcher:**

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