# Accuracy comparison between the three-dimensional position of planned and placed implants with flapless fully-guided surgery: 1-year follow-up from a single-cohort retrospective study

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# ABSTRACT

**Aim** This research was performed to evaluate the *in vivo* accuracy of flapless, computer-guided implant placement by comparing the three-dimensional position of planned and placed implants.

**Materials and methods** In this retrospective study the results from a 1-year follow-up of a single-cohort of 15 patients (30 implants) are reported. A 3D planning software was used to determine the correct placement, considering the bone volume, the functional and the aesthetic prosthetic result. CAD/CAM technology was used to turn the virtual plan into the surgical quide.

**Results** The statistical analysis showed a mean radial deviation of the implant head of 0.3 mm (SD 0.21), a mean radial deviation of the implant apex of 0.58 mm (SD 0.33), a mean depth deviation of the implant head of 0.37 mm (SD 0.29), a mean depth deviation of the implant apex of 0.43 mm (SD 0.25) and a mean angular deviation of the long axis of 2.87° (SD 1.99); the mean actual translation between the planned and the placed implant was 0.66 mm (SD 0.35) at implant platform and 1.04 mm (SD 0.47) at apex. **Conclusion** Flapless and computer-guided implant placement proved to be a reliable clinical option for an accurate implant insertion.

KEYWORDS Dental implants, Computer-guided implant dentistry, Guided surgery, Flapless surgery.

# INTRODUCTION

In the early age of dental implantology, clinicians used to place implants depending on the availability and morphology of the patient's bone (1). The results in terms of prosthetic success could not clearly be considered satisfactory. The direction of masticatory forces was not often in accordance with the long axis of the implant leading to unfavourable biomechanics (2). It was possible to obtain a positive occlusal scheme and aesthetics only when the bone itself permitted it.

During the last few decades, diagnostic casts and wax-ups started to be used as pre-operatory devices in order to choose the proper position of the implant, considering the subsequent prosthetic restoration (3). Clinicians started to use guided bone regeneration, sinus augmentation, ridge splitting and other techniques in order to obtain the amount of bone volume needed, leading to a "prosthesis driven" implant placement (4, 5).

The recent improvement of 3D technology, such as the introduction of cone beam computed tomography (CBCT), has given the possibility to have a loyal virtual copy of the patient bone together with a lower radiation exposure. Thanks to the representation of three-dimensional images through interactive software equipment, the clinician has the ability to view, in advance, anatomical structures as they would be seen in reality (6). The communication between surgeon and prosthodontist has become even more important during the planning of the surgical procedure (7,8).

The protocol is made up of various steps including a radiographic template, impressions, planning and surgery. The precision of the outcomes is determined by the overall deviation from the beginning of the planning until the surgical placement of the implants. It is clear how each step is essential for obtaining a good result as mistakes tend to accumulate during the phases. Furthermore, it is important not only to avoid damaging vital structures, but also to guarantee the implant placement inside the bone confines. The use of customised radiographic and surgical templates is essential for transferring the implant position that was digitally planned to the surgical site. This is done in two different ways: a computer-navigated (dynamic) system or a static surgical splint that reveals the virtual implant position chosen on the basis of the CBCT data. These guides can be produced by CAD-CAM technology, stereolithography or a laboratory made template fabricated on a dental stone model (9). The accuracy of dynamic navigation and stereolithographic guide systems have been demonstrated to be superior to the conventional implant placement (10-12).

The aim of this research is to evaluate the accuracy of implant placement with fully guided flapless implant surgery after computer-aided planning using a stereolithographic surgical guide with dental support considering parameters such as radial deviation, depth deviation and angulation. This study has been reviewed by an independent statistician.

# **MATERIALS AND METHODS**

In this retrospective study we reported the results from a 1-year follow-up of a single-cohort of 15 patients, treated during 2017, with a total of 30 implants (3i T3 implant, Biomax Spa, Vicenza, Italy) placed using a fully guided flapless implant surgery. Demographic features of the study population are reported in table 1. A total of 18 (60%) implants were positioned in the mandible while the remaining 12 (40%) in the maxilla. The mean age of the patients was 55 years. The sample consisted of partially edentulous patients needing implant rehabilitation in the posterior area, in a good general health and without any local or systemic contraindications to implant surgery. Peri-implant keratinised gingival tissue of at least 2 mm was needed. The inclusion criteria also included the presence of adequate quantity of bone at implant receptor site, a class III Cawood-Howell classification of the maxillary or mandibular bone in which the implant was placed and no need for bone regeneration.

Patients with poor oral hygiene (Plaque Index, PI > 1), active periodontitis, uncontrolled systemic diseases, smokers (> 10 cigarettes/day) and limited accessibility to the oral cavity (less than physiological 40 mm) were excluded from the study.

Systemic diseases (13), such as metabolic syndrome (14) or other syndromic diseases (15), that can cause dental anomalies were evaluated to achieve a better management of the surgical procedures. Immune dysfunctions (16) were also checked to avoid severe

Demographic features of the study population			
Number of patients	15		
Mean age (years)	55		
Gender (Male)	20%		
Smoker	0		
Number of implants placed	30		
Implants in molar area	14		
Implants in premolar area	16		
Implants in the mandible	60%		
Implants in the maxilla	40%		

TABLE 1 Demographic characteristics of the study population.



FIG. 1 The radiological bite (Navibite) before the occlusal fitting made with silicone.

complications. Moreover, the risk of bleeding has been assessed because several coaugulation disorders may require hematologic indices before the surgery (17,18). The patients were well informed about the computeraided implant planning approach and the template-guided surgery; they all gave their written consent.

Before the acquisition of the CBCT scan, a radiological bite (Navibite, Biomax Spa, Vicenza, Italy) was tried intraorally and the occlusal fit was set using silicone in order to reach a reproducible and standardised fitting position. With the radiological bite in place, the CBCT scan was performed with Rayscan Alpha-3D (Ray Co., Samsung 1-ro, Hwaseong-si, Gyeonggi-do, Korea) (Fig. 1).

The scanning parameters were as follows: voxel size 0.140 mm, acquisition time 14s, FOV (Field Of View) 9 cm X 9 cm and a slice thickness of 0.25 mm.

Data obtained were transferred into DICOM (Digital Imaging and Communications in Medicine) format and it was then examined with 3D software Navimax (Biomax Spa, Vicenza, VI, Italy) to check if the implant insertion would have been possible without any grafting procedure.

Chalk models were built from alginate impressions and a preliminary prosthetic wax-up was created, this corresponded to the projected definitive prosthesis accepted by the patient as being functionally and



FIG. 2 Visualization of the 3D software: soft tissues are delimited by a pink line, prostethic wax-up is delimited by a white line.

aesthetically optimised. An optical scan of the models (STL data) was performed, then importation and accurate matching with the CBCT scan (DICOM data) was made using the landmark on the Navibite to overlap the different data. After this procedure it was possible to visualize with Navimax 3D software the matched images of hard and soft tissue of the patient together with the prosthetic wax-up. Planning and simulation of the implant placement was completed considering bone volume and optimal future prosthetic position. Transferral from the virtual project to reality was accomplished with the fabrication of a stereolithographic surgical template provided with internal irrigation to prevent overheating during the surgical procedure and peek sleeves to reduce the friction of the drills (Fig. 2). Because of the retrospective nature of the present study, it was granted an exemption in writing by the institutional review board of the Catholic University of Sacred Heart of Rome. An informed consent form was obtained from all patients. The study was conducted according to the criteria set by the Declaration of Helsinki.

# **Surgical procedure**

The surgical template was previously prepared with chemical sterilisation using chlorhexidine 0.2%. An antibiotic prophylaxis consisting of 2g of amoxicillin clavulanate (Augmentin, GlaxoSmithKline, Brentford, London, United Kingdom) was given 1 hour before surgery and continued for the following 5 days. After rinsing with a 0.2% chlorhexidine mouthwash (Dentosan, Recordati SpA, Milan, Italy) the fitting of the surgical guide was tested intraorally and gaps on the occlusal area were necessary to make sure that the guide was perfectly inserted. Local anaesthesia (mepivacaine with epinephrine, 1:100.000) was made and a surgical mucotome was used to perform an operculectomy in

order to remove soft tissue on the implant site (flapless surgery). Osteotomies were made with a set of specific drills dedicated to guided surgery 3i Tapered Navigator System (Biomax Spa, Vicenza, Italy). Several tools were used to perform the osteotomy: cortical perforator at first, twist drills used with a specific adapter, shaping drills (800-1200 rpm) in ascending order until planned depth and diameter was reached. Finally, implants were template-guided inserted (20 rpm; Torque value – 35 Ncm) through the sleeves. Countersink drills were used at the discretion of the clinician. No suture was required (Fig. 3).

Immediately after the surgical procedure, 100 mg of oral nimesulide (Aulin, Helsinn Birex Pharmaceuticals Ltd., Dublin, Leinster, Ireland) was administered to the patient in order to avoid postoperative pain.

#### Superimposition and accuracy evaluation

The comparison between surgical results and virtual planned implant positions was performed by means of STAP protocol (Superimposition Touch Absolute Precision):

- Phase 1: A perforated custom-made impression tray was used to take a silicone impression so that the exact position of the implant could be reproduced on a chalk model.
- Phase 2: A chalk jig, with an implant transfer included in it, was then fabricated to check directly if the implant position obtained on the model was exactly the same in the clinical situation; an endobuccal x-ray was made to make sure the transfer was well tightened to the implant and the surface of chalk should not reveal any cracks; If this did not happen phase 1 and 2 had to be repeated again (Fig. 4).
- Phase 3: A plaster model was analysed with the tactile scanner Renishaw Scanner DS 10 (Renishaw, Wottonunder-Edge, Gloucestershire, United Kingdom) to

FIG. 3 Surgical protocol. A: surgical guide with the drilling

sleeves corresponding to the location and the inclination of the planned implants in place tested intraorally. B: osteotomy preparation using 3i

Tapered Navigator System. C: implant insertion. D: post-operative clinical situation.





FIG.4 The chalk jig is tried intraorally to ensure that there is no discrepancy between the clinical position of the implant and the position on the model.

accurately register implant position and then rescanned with Renishaw DS30 (Renishaw, Wottonunder-Edge, Gloucestershire, United Kingdom).

 Phase 4: Scanned presurgical and postsurgical plaster models were superimposed using software Geomagic studio (Geomagic, Morrisville, NC, USA) and precision analysis was performed with software Rhinoceros (McNeel Europe SL, Barcelona, Spain).



FIG.5 The virtual plan built on the 3 points is used as a reference point during the entire analysis.

- Phase 5: Taking as a reference point, a virtual plan built on 3 points: central pit of right first molar; central pit of left first molar; interincisive area of central incisors; linear and angular deviations between planned and surgically positioned implants were finally measured on the superimposed images:
- Radial deviation (mm): horizontal distance between the middle axis of the planned and inserted implant

measured at the implant shoulder and apex.

- Depth deviation (mm): vertical distance between the middle axis of the planned and inserted implant measured at the implant shoulder and apex.
- Angulation: angular deviation between the long axis of the planned and inserted implant.
- \_ Actual translation: distance between the centre of the platforms of the planned and placed implants with a direct measurement between the two points (Fig. 5).

# **Statistical analysis**

Statistical analysis was made by an independent statistician with IBM SPSS Statistics software v.25 (IBM; Chicago, IL, U.S.A). Measured data were used to work out mean values, standard deviations, median values, minima, maxima and interquartile range. Wilcoxon's signed rank test was used to assess the presence of statistically significant differences between deviations at the implant shoulder and apex.

# RESULTS

A total of 30 dental implants (3i T3 implant, Biomax Spa, Vicenza, Italy) were placed in 15 partially edentulous adult subjects. Demographic characteristics of the study population are reported in table 1. In total, 18 (60%) implants were positioned in the mandible and 12 (40%) in the maxilla. The mean age of the patients was 55 years. At the 1 year follow up all 30 implants were osseointegrated with a survival rate of 100%. The rationale of the 1-year follow-up was to demonstrate that osseointegration was not affected by the use of the surgical guide during surgery. Post-operative healing was uneventful, and no nerve injuries were reported, nor sinus pathologies or infections occurred due to inaccurate implant placement. Implants were placed with their length and diameter as virtually planned, none of the surgical guides created problems in terms of fitting and stability (Table 1).

# **Accuracy analysis**

Radial deviations revealed a mean difference of 0.3 mm (max 0.77; min 0.01; SD 0.21) at the crestal level while at the apex the mean radial deviation detected was 0.58 mm (max 1.42; min 0.15; SD 0.33).

Mean vertical deviation at the implant platform was 0.37 mm (max 0.75; min 0.002; SD 0.29); the measurement at the implant apex showed a mean value of 0.43 mm (max 0.7; min 0.1; SD 0.25).

Analysis of angular deviation revealed a mean difference of 2.87° (max 7.85; min 1.1; SD 1.99).

Mean actual translation (i.e. the distance between the centre of the platforms of planned and placed implants with a direct measurement between the two points) was 0.66 mm at the implant platform (max 1.125; min

	Radial dev. (mm) (plat./ apex)	Vertical dev. (mm) (plat./ apex)	Angular dev. (°)	Actual translation (mm) (plat./ apex)
Mean	0,30/0,58	0,37/0,43	2,87	0,66/1,04
SD	0,21/0,33	0,29/0,25	1,99	0,35/0,47
Мах	0,77/1,47	0,75/0,7	7,85	1,12/2,04
Min	0,01/0,15	0,002/0,1	1,1	0,05/0,25

TABLE 2 Superimposition and accuracy evaluation.

0.052; SD 0.35) and 1.04 mm at the implant apex (max 2.042; min 0.25; SD 0.47) (Table 2).

Focusing on radial deviation at the implant platform, 50% of the results included were between 0.17 mm (1° quartile) and 0.41 mm (3° quartile) with a median value of 0.285 mm, the maximum value observed was 0.77 mm. The 50% values regarding the radial deviation at the implant apex were between 0.37 mm (1° quartile) and 0.63 mm (3° quartile) with a median and maximum value of 0.58 mm and 1.42 mm respectively. Wilcoxon's signed rank turned out to be significant demonstrating less radial deviation at the implant platform than at apex level.

Vertical deviation at crestal level showed a median value of 0.38 mm and an interquartile range between 0.07 mm and 0.67 mm, this appeared to be similar to vertical deviation at the apex (median 0.47 mm, interquartile range between 0.12 mm and 0.69 mm). The same Wilcoxon's test resulted as not significative considering vertical deviation at implant platform and apex.

Finally, angular deviation revealed a median value of 2.01°, 25° and 75°. This was included between 1.69° and 3.93° (Fig. 6).

The methodology of this study was reviewed by an independent statistician.

# DISCUSSION

Traditional implantology contemplates an openflap approach performed with the elevation of a full thickness flap for the purpose of exposing the bone surface to place dental implants, postsurgical sutures are required to guarantee the healing of the surgical wound. This conventional procedure has demonstrated to be reliable and with good clinical outcomes. According to Moraschini et al. in a systematic review they carried out with a mean follow-up of 13.4 years, implant survival is 94.6% with the open flap technique (19). However, elevation of a flap could also produce unwanted results in terms of bone volume resorption, gingival recession and discomfort for the patient.

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FIG.6 Implant translation analysis

performed on the 3 axis.



Therefore, a flapless approach has been developed and clinical trials have showed its effectiveness and validity compared to the traditional technique (20-22). This approach has shown various advantages: reduced intraoperative bleeding, reduced surgical time, no suturing is needed, preservation of soft tissue integrity, preservation of hard tissue volume at the implant site, faster healing allowing normal oral hygiene procedures just a few days after surgical procedure, less pain and less discomfort for the patient (23).

Nowadays, computer-guided implant virtual planning and surgical procedure is a technology that mirrors the clinician's effort to have a more predictable, accurate and less invasive procedure for implant placement (24). The aim of computer-guided implantology is to give the clinician the tools to perform implant surgery with the maximum surgical safety using 3D diagnosis, virtual planning and a precise surgical guide. The accuracy of this procedure is measured as the deviation between planned and actually placed implants, the data which has emerged from this study appears to be encouraging as it has shown a high accuracy when compared to virtual planning. According to Behneke et al. (23) linear deviations measured at implant platform and apex were 0.27 mm (range 0.01-0.97 mm) and 0.46 mm (range 0.03–1.38 mm) respectively, angular deviation was 1.84° with a range of 0.07-6.26. These data appear to be similar to results achieved in our study.

Komiyama et al. (25) used a similar way to investigate virtual planning and post-operative implant position by means of a comparison of pre-op and post-op model scans. The exact implant position was determined in this study with a tactile scanner. Mean linear deviation at the apex was 0.59 mm when the implants were placed in the maxilla and 0.4 mm when placed in the mandible. Linear deviation at the implant platform was 0.59 mm and 0.39 mm in the maxilla and the mandible respectively (25).

Deviations are determined by errors that occur in each

step of the entire procedure and the final difference can be interpreted as the cumulative error made in every step. At the planning stage, errors can be generated during the acquisition of the CBCT data set on the basis of the image quality, presence of a metal artefact or motion. CBCT data which is transferred to the planning software could create errors in terms of volume rendering, conversion of the images and accuracy of the details. Additionally, deviations could result from an intrinsic error of the stereolitographic guide and a wrong placement of the surgical guide during surgery (26,27).

Raico-Gallardo et al. (28) carried out a metanalysis which compared the different surgical guides based on the type of support used. Tooth-supported guides guarantee the highest grade of accuracy. Mucosalsupported guides, even if less accurate, did not show statistically significant differences while bonesupported guides showed the least positive results.

Many authors have examined the effectiveness of computer guided surgery compared to the free hand technique. Vercruyssen et al. (29) established a statistically significant inferior mean linear deviation at entry point (1.4 mm, range: 0.3-3.7), at apex (1.6 mm, range: 0.2-3.7) and angular deviation (3.0°, range: 0.2-16°) in a guided surgery treated group compared to a free-hand treated group (2.7 mm, range: 0.3- 8.3; 2.9 mm, range: 0.5-7.4 and 9.9°, range: 1.5-27.8).

Considering the lack of bone exposure because of flapless surgery, it could be interesting, in future studies, to investigate the bone temperature reached during drilling. According to Gehrke et al. (30) the temperature values reached during open flap implant surgery can vary from  $20.4 \pm 1.17$ °C and  $22.2 \pm 1.38$ °C depending on the sequence of drills used where 44° is considered the maximum value to avoid bone damage. All the implants placed in this study are osseointegrated, a follow-up is necessary to evaluate their long-term success rates. The

sample size should also be larger to increase statistical reliability.

#### CONCLUSION

The results of this study demonstrated that computerguided implant surgery can be considered as a highly reliable technique for accurate implant placement. Virtual planning based on CBCT guarantees the preservation of anatomical structures such as blood vessels and nerves by knowing their exact position. Moreover, flapless surgery reduces post-operative discomfort for the patient in terms of pain and swelling.

#### **Conflict of interest**

The authors declare that they have no conflict of interests.

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