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Article

Impact of Surgeons' Experience on Implant Placement Accuracy Using a Dynamic Navigation System: A Cadaver Pilot Study

Francesco Pera [1,*,†], Camillo Vocaturo [1,*,†], Armando Crupi [1], Beatrice Longhi [1], Alessandro Campagna [1], Antonino Fiorino [2], Umberto Gibello [1,3,‡] and Andrea Roccuzzo [4,5,6,‡]

1 C.I.R. Dental School, Department of Surgical Sciences, University of Turin, 10126 Turin, Italy; armando.crupi@unito.it (A.C.); beatrice.longhi@unito.it (B.L.); alessandro.campag181@edu.unito.it (A.C.); umberto.gibello@polito.it (U.G.)
2 Department of Neuroscience, Reproductive and Odontostomatological Sciences, University of Naples Federico II, 80131 Naples, Italy; fiorinodr.antonino@gmail.com
3 DIMEAS, Politecnico di Torino, 10129 Turin, Italy
4 Shanghai Perio-Implant Innovation Center, Institute for Integrated Oral, Craniofacial and Sensory Research & Department of Oral and Maxillofacial Implantology Shanghai Ninth People Hospital, Shanghai Jiao Tong University School of Medicine, Shanghai 200115, China; andrea.roccuzzo@unibe.ch
5 Department of Periodontology, School of Dental Medicine, University of Bern, 3010 Bern, Switzerland
6 Unit for Practice-Based Research, School of Dental Medicine, University of Bern, 3010 Bern, Switzerland
* Correspondence: francesco.pera@unito.it (F.P.); camillovocaturo@gmail.com (C.V.)
† These authors contributed equally to this work.
‡ Co-shared senior author position.

Abstract: Objectives: The study's objective was to evaluate the accuracy of dynamic computer-assisted surgical implant placement systems during practical training on fresh defrozen cephali. **Methods:** Three defrozen cephali with terminal dentition received a total of 26 implants (15 4.3 × 13 mm and 11 4.3 × 13 mm, Nobel Biocare Service AG (Zrich-Flughafen Switzerland)) following a standardized protocol: a digital scanning and planning protocol followed by dynamic navigation surgery (X-Guide, X-Nav Technologies, LLC, Lansdale, PA, USA). All surgical interventions were performed by two surgeons: a senior oral surgeon (OE) with more than 5 years of implant dentistry experience and a non-experienced surgeon (NE). **Results:** Different linear and angular measurements (i.e., deviation shoulder point; deviation tip point; depth deviation shoulder point; depth deviation tip point; B/L and M/D angular deviations) were calculated in duplicate to estimate the discrepancy of the virtual digital planning with respect to the real clinical scenario. The differences between the two operators were also explored. The results of the bivariate analysis detected clinical negligible differences between the operators, without any statistically significant differences for all investigated parameters ($p > 0.05$). **Conclusions:** The preliminary positive findings of this pilot study suggest that the investigated dynamic navigation system could be a viable and safe technique for implant surgery and may offer additional safety benefits to non-experienced operators, despite the required learning.

Keywords: dental implants; dynamic computer-assisted surgery; computer-guided implantology; navigation systems

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1. Introduction

It was widely reported that, despite the decrease over the last two decades of the prevalence of tooth loss, edentulism is still a global prevalent condition with differences among countries, age groups, and socioeconomic status [1]. Consequently, to overcome this problem, during the last three decades, the use of implant-supported oral rehabilitations has become the standard of care dramatically improving individuals' chewing function, esthetics, and patient-reported quality of life (PRQoL) [2,3].

From a diagnostic point of view, the implementation of cone beam computed tomography (CBCT) imaging prior to dental implant has increased significantly in recent years with documented advantages such as a decrease in radiation exposure compared with conventional computed tomography [4,5]. However, implant placement might present some clinical challenges, such as the presence of narrow ridges and slim margins and the need for preserving critical anatomical structures (i.e., mandibular nerve) [6]. In this respect, the use of pre-operative planning including CBCTs do represent a crucial step to minimize complications and maximize proper 3-D implant placement [7]. From a technical aspect, recent developments have allowed the use of voxel sizes down to tenths of a millimeter and the ability to visualize and measure anatomic structures in all spatial dimensions [5,8]. From a descriptive point of view, computer-assisted surgical (CAS) implant placement systems were the first to be introduced. Such systems can be categorized as either static or dynamic [5,9]. In the first clinical scenario, CAS systems use a drill within templates with embedded sleeves, which could be placed on the neighboring side of the surgical site to facilitate the transferring of the position of implant planning [10,11]. These templates could be supported by teeth, mucosa, or bone, helping conduct implants in an optimal position [10,12]. The reliability of this procedure has been clinically proven [10,13–15]. However, several studies have already shown that different factors could influence the accuracy of static CAS, e.g., the fabrication technology of surgical guides, the axial accuracy of the sleeves' housings, the lack of direct visual contact with the surgical site, intraoral positioning, and template fixation [10,16–19].

Static CAS systems use guides fabricated with a computer-aided design (CAD/CAM) based on 3D scans of the patient [5,9,19]. It is essential to highlight the differences in terms of digital impression accuracy on full-arch implant rehabilitations depending on the timing; in fact, immediate post-surgical intraoral digital scans may show a higher risk of imprecision than those obtained after tissue healing [20].

In contrast, dynamic CAS systems track the patient and surgical instruments and present real-time positional and guidance feedback on a computer display [5,16].

To improve these two technologies, the use of dynamic navigation systems was developed based on "motion-tracking technology", which tracks the position of the surgical site and drill real-time behaviors combined to the patient's presurgical CBCT [10,21–23]. In addition, during implant placement, tracking cameras are in use to continuously monitor the attached marker on the patient's jaw and surgical handpiece. This procedure is displayed in real-time on a screen superimposed on implant planning. Therefore, from a clinical perspective, any potential deviation of the implant and drill axis could be controlled and corrected [10,24]. Furthermore, the real-time monitoring of the procedure allows the surgeon to modify virtual planning during surgery [10,15].

Nevertheless, it is clinical experience that dynamic CAS requires higher training and experience than static CAS [25]. In this respect, considering the increasing use of dCAS among oral surgeons, and although previous investigations evaluated several factors in the accuracy of implant placement, there is a lack of evidence on the role of the surgeon's experience in the use of such technology and surgery accuracy [25,26].

To the best of the authors' knowledge, this study is the first cadaver study evaluating the influence of operator's experience on the accuracy of implant placement using dCAS. The primary aim was to investigate differences in terms of implant placement accuracy between expert and non-expert operators by evaluating discrepancies superimposing pre-operative and post-operative CBCT, measuring linear (mm) and angular (degrees) deviations.

2. Materials and Methods

2.1. Study Design

This pilot study evaluated the accuracy of implant placement using dCAS during practical training on fresh defrozen cephali. The samples were donated by individuals for scientific purposes and official laboratory permission to work on the cadavers was obtained from the Italian competent authority. This study was conducted according to the revised guidelines of the Declaration of Helsinki and did not require any ethical approval.

For this study, surgical sessions were performed on adult fresh defrozen cephalus, fixed with 10% formalin. Three partial edentulous cadavers with terminal dentition were selected to be treated with conventional implants.

The operators had different degrees of experience: one (NE) was a senior oral surgery resident at University of Turin, with implant dentistry experience of more than 5 years, while the second (OE) was a non-experienced oral surgeon (less than 5 years of clinical experience in implant dentistry).

2.2. Inclusion Criteria

The following inclusion criteria were used: (1) the absence of macroscopic pathology in the bony regions of the maxilla and mandible; (2) at least 3 residual teeth, required for the positioning and stabilization of thermoplastic devices (clip) with 3 radiopaque fiducials (X-Clip, X-Nav Technologies, Lansdale, PA, USA) during CBCT scan and surgical procedures.

2.3. Scanning and Planning Protocol

In this case, considering that fresh defrozen cephali had terminal dentition with >3 stable adjacent teeth and located in an area of the dental arch that did not violate the implant milling, a fiducial-based registration protocol was performed.

This protocol involves, before the acquisition of the pre-operative CBCT scan, placing a thermoplastic clip with three radiopaque fiducials (X-Clip, X-Nav Technologies) on the remaining teeth of the dental arch involved in the implant surgery (Figure 1).

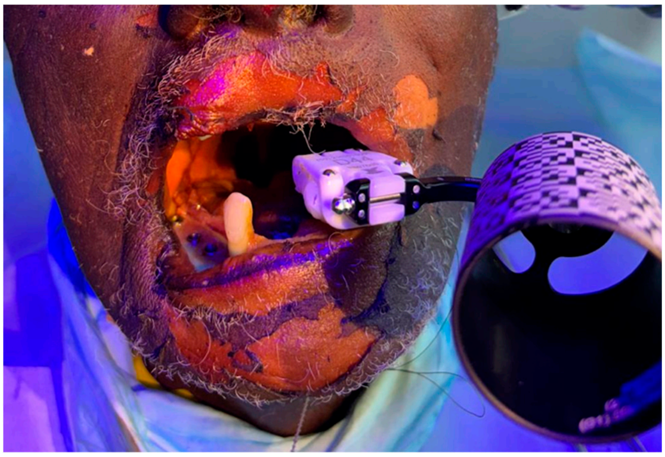

Figure 1. X-Clip placement on the fresh defrozen cephalus.

Then, a CBCT scans (NNT—Medical Suite®; NewTom, Imola, Italy) was performed with the following set up: 110 Kv, 1.94 mA, 3.6 s, 685.41 DAP (mGy$\times$m^2), 100 $\times$ 140 FOV (mm) (Figure 2).

Figure 2. Representation of CBCT scan processing.

The digital information (.dicom data set) was uploaded to the dynamic navigation planning system (DTX StudioTM Implant 3.4.3.3, Nobel Biocare AB, 402 26 Vasta Hamngatan 1, 411 17 Göteborg, Sweden).

This software allowed us to define the arch, nerve mapping, and implant planning through MPR (multiplanar reformation). We used it to plan the ideal implant placement, which was identical to the implant placed in the cadavers (diameter, apical diameter, length, shape), thanks to an implant library contained on DTX.

Files from intraoral scanners were superimposed on a DICOM data set and the combined images allowed us to plan, with the osseous, dental, and soft tissue structures visible along with the patient's occlusion, prosthetic-guided implant placement (Figure 3).

Figure 3. Example of implant placement planning.

When starting the planning, a panoramic curve for the arch is drawn on the axial plane of the patient's scan, and the inferior alveolar nerve also can be identified and referenced on the mandible.

Once the surgical plan was defined, the data set was exported by DTX (DTX StudioTM Implant 3.4.3.3, Nobel Biocare AB, 402 26 Vasta Hamngatan 1, 411 17 Göteborg, Sweden) and imported as an .stl file into the DN software.

A total of 26 implants were successfully placed by the two operators. At the end of the surgical interventions, a post-operative CBCT scan was taken to perform the accuracy evaluation.

2.4. Calibration Sessions and Surgical Procedures

Each surgeon performed a surgical session after five days of training, which included training on manikins, mentoring with over-the-shoulder observation and hands-on mentoring. No surgery was performed prior to the assurance of a high level of agreement between the two operators.

Before the initiation of this study, all practitioners received standard hands-on training for virtual planning with implant treatment planning software (DTX StudioTM Implant 3.4.3.3, Nobel Biocare AB, 402 26 Vasta Hamngatan 1, 411 17 Göteborg, Sweden) and surgical procedure simulation with the navigation system to achieve minimal proficiency.

All implants were positioned using a dynamic navigation surgery system (X-Guide, X-Nav Technologies). Depending on the implant site characteristics, conventional (with flap) or flapless surgical procedure was performed. Standardized implants were placed in all cases (15 NobelReplace Conical Connection 4.3 × 13 mm in mandible and 11 NobelActive TiUltra 4.3 × 13 mm in maxilla, Nobel Biocare, Zürich-Flughafen, Switzerland).

Prior to each surgical procedure, the clip was mounted on the teeth in the same position as CBCT scanning and attached fiducial markers and the cylinder of the attached patient tracking matrix, extraorally oriented. Likewise, the handpiece, patient tracking array, and drills were calibrated. All these instruments must be within the line of sight of the overhead stereo cameras to be tracked on the monitor.

Calibration of the surgical handpiece was performed before the surgical acts. Handpiece calibration relates the geometry of the handpiece tracking array to the drill axis and CBCT fiducials, hence providing a link between the pre-operative planning coordinate system and a trackable coordinate system. After calibration, the operators performed the surgery. Real-time checks were performed through patient's CBCT anatomy, and the implant coordinates were pre-planned to guarantee the accuracy of the tracking, all using the navigation screen on the monitor (Figure 4).

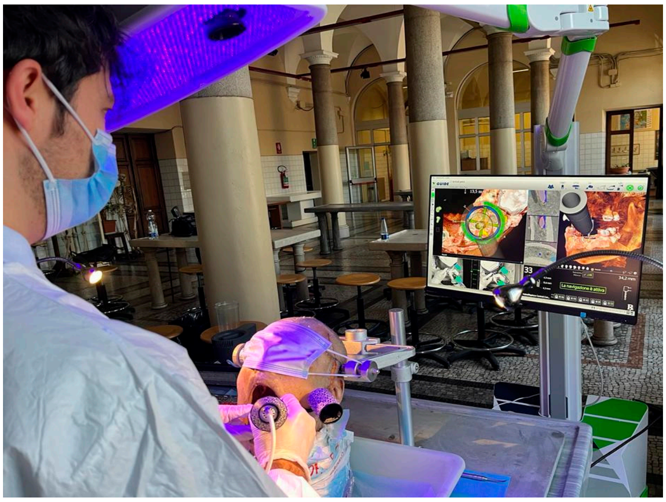

Figure 4. Real-time monitoring of implant placement.

If necessary, changes in the plan were made during surgical acts, including implant size, length, width, shape, and positioning, to achieve an accurate implant position.

Dynamic reference frame calibration relates the geometry of the patient-tracking array to the CT fiducials (i.e., three radiopaque fiducials of thermoplastic clip placed during

CBCT). This provides a link between the pre-operative planning coordinate system and a trackable coordinate system. The stereo-tracking system simultaneously triangulated each tracking array to determine their precise position and orientation in a common coordinate frame. In combination with the calibrations, this real-time link allowed the drill's body and tip to be related.

The patient dynamic reference frames included the clip with the connected patient-tracking cylinder. It was placed onto the teeth in the same location for CBCT acquisition. The tracking software algorithm triangulated the 2 arrays continuously. Two live video windows allowed the surgical team to obtain virtual feedback from the navigation system to visualize site preparation and monitor the quality of tracking in the surgical field volume.

2.5. Accuracy Analysis

The evaluated outcome variables were previously described [5]. After surgery, post-operative CBCT was performed with the same FOV and resolution of the pre-operative CBCT (110 Kv, 1.94 mA, 3.6 s, 685.41 DAP (mGy$\times$m^2), 100 $\times$ 140 FOV (mm)), to compare deviations between the planned and placed implants.

The accuracy of the implant placement of the two operators was assessed by superimposing the pre-operative virtual surgical plan and the post-operative CBCT scan and quantifying deviations of the delivered implant from the planned position and orientation. The same methodology proposed and validated by Block MS. et al. and Jorba-García A. et al. was implemented [25,27].

The DICOM images of the post-operative CT were uploaded in a dedicated software.

To obtain very precise results, the implants were planned and superimposed on placed implants to perfectly replicate the morphology of the implants (centroid apex and shoulder, and their spatial coordinates).

The accuracy was assessed overlapping the post-operative CT scan (with placed implants) with the pre-operative one (with planned implants). The accuracy evaluation involved angular and linear (coronal, apical, and depth) deviations. The DICOM images of the post-operative CT were uploaded in a dedicated software (NobelGuide validation study tool in DTX Studio Implant 3.6). A segmentation based on tissue density was carried out to separate implants from the surrounding bone.

The STL files of the maxillary and mandible bone with the planned implants obtained from the pre-operative CBCT were uploaded into the software. The superimposition of the pre-operative and post-operative CT images was achieved by using the best-fit alignment tool. The planned and inserted implants were considered as cones with a base and a centroid apex and shoulder and their spatial coordinates (the center of the base and the apex) were registered by using DTX and were exported in an Excel sheet to calculate coronal, apical, depth, and angular deviations.

A mathematical algorithm was used on the presurgical case with the plan, the post-surgical case with the virtual implant overlaid on the actual implant, and the meshed CBCT scans to calculate angular and positional deviations between the planned and actual implant positions in 3 dimensions.

The following deviations (mean $\pm$ standard deviation) from the virtual plan were calculated and listed in Figure 5:

- Mesiodistal (M/D) Angular Deviation: The mesiodistal angle between the vertical axes of the planned and placed implants.
- Buccolingual (B/L) Angular Deviation: The buccolingual angle between the vertical axes of the planned and placed implants.
- Deviation Shoulder Point (mm): A 2-dimensional distance between the shoulder centroids of the planned and placed implants.

- Deviation Tip Point (mm): A 2-dimensional distance between the apex centroids of the planned and placed implants.
- Depth Deviation Shoulder Point (mm): Depth distance between the shoulder centroids of the planned and placed implants on the *z*-axis.
- Depth Deviation Tip Point (mm): Depth distance between the apex centroids of the planned and placed implants on the *z*-axis.

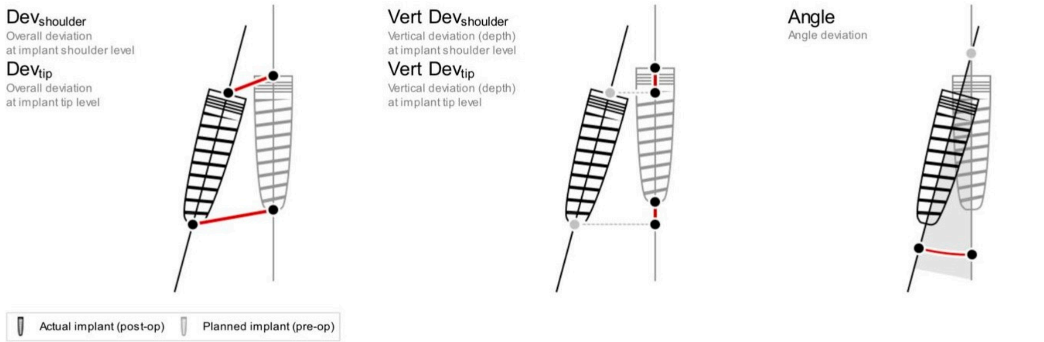

Figure 5. Representation of positional and angular deviations: first two images illustrate positional deviations; third image illustrate exemplification of angular deviations (M/D and B/L).

For each parameter, the mean of the two measurements performed by the two blinded and previously calibrated operators (Cohen's kappa coefficient = 0.72) was calculated and used for statistical analysis.

2.6. Statistical Analysis

To ensure objectivity and avoid bias, the operator variable was anonymized and a blinded external statistician, independent of the research team, conducted the data analysis. A database was created using Microsoft Excel (Microsoft, Redmond, WA, USA) for data recording and management.

Statistical analysis was performed using Stata (StataCorp LLC, College Station, TX, USA). The distribution of all continuous numerical variables was assessed using the Skewness/Kurtosis test for normality (sktest in Stata). Descriptive statistics were reported for each variable as mean, standard deviation (SD), median, and interquantile range as none of the variables satisfied the assumption of normality. Data were stratified according to operator experience level (i.e., experienced or non-experienced) as the primary outcome, and the jaw (maxilla or mandible) position (anterior or posterior). Statistical differences between the groups were evaluated using the Wilcoxon–Mann–Whitney test for non-parametric comparisons. A p-value < 0.05 was considered the threshold for statistical significance.

3. Results

A total of twenty-six implants were placed and analyzed in three fresh defrozen cephali, without deviations from the original digital surgical planning. All specimens were available for analysis since no intra-surgical complications were recorded.

Table 1 shows the deviation from the virtual plan of the main outcomes for each surgeon, in terms of mean, standard deviation (SD), median, and interquantile range of all placed implants and apex linear (shoulder, apex and depth) and angular deviations (M/D, B/L) stratified according to the analyzed variables.

Table 1. Results of main outcome variables for expert surgeon (OE), non-experienced surgeon (NE), and overall.

Group	Stats	N	Deviation Shoulder Point (mm)	Deviation Tip Point (mm)	Depth Deviation Shoulder Point (mm)	Depth Deviation Tip Point (mm)	B/L Angular Deviation (Grades)	M/D Angular Deviation (Grades)
OE	Mean	13	3.08	2.38	1.02	1.03	3.34	3.75
	SD		1.95	1.85	1.05	1.04	2.23	5.97
	p50		2.41	1.61	0.49	0.53	3.6	1.8
	IQR		2.43	1.96	1.22	1.22	3.5	2.8
NE	Mean	13	2.91	2.53	1.02	1.03	3.34	3.75
	SD		3.08	3.36	1.05	1.04	2.23	5.97
	p50		1.48	1.46	0.7	0.68	2.4	2.3
	IQR		1.57	1.38	0.55	0.51	4.2	3.8
p-value			0.23	0.52	0.98	0.88	0.78	0.54
TOTAL	Mean	13	3	2.45	0.88	0.86	3.76	3.38
	SD		2.53	2.66	0.81	0.80	2.97	4.44
	p50		1.94	1.60	0.62	0.66	3	2.15
	IQR		2.82	1.58	0.65	0.63	3.6	3

Data (mean values) with respect to the stratification according to jaw (i.e., maxilla vs. mandible) and position (i.e., anterior vs. posterior) are reported in Tables 2 and 3.

Table 2. Results of secondary outcome variables for site and overall.

Site	Stats	N	Deviation Shoulder Point (mm)	Deviation Tip Point (mm)	Depth Deviation Shoulder Point (mm)	Depth Deviation Tip Point (mm)	B/L Angular Deviation (Grades)	M/D Angular Deviation (Grades)
Mand	Mean	15	2.80	2.53	0.64	0.65	2.79	1.79
	SD		3.05	3.40	0.63	0.63	1.87	1.20
	p50		1.73	1.29	0.42	0.44	2.3	1.8
	IQR		1.25	0.7	0.65	0.59	3.1	1.5
Max	Mean	11	3.27	2.36	1.20	1.15	5.08	5.53
	SD		1.67	1.22	0.94	0.92	3.71	6.29
	p50		3.48	1.85	0.92	0.83	4.1	5.1
	IQR		3.42	1.94	1.37	0.93	6.3	3.9
p-value			0.17	0.15	0.14	0.10	0.12	0.018 *

* Indixates Statistically significant difference.

Analyzing the results regarding the role of the surgeon's experience, expert and non-expert surgeons showed an analogous accuracy during implant placement for each variable studied, so deviations were negligible ($p > 0.05$) in all outcomes. Details of all recorded data are listed in Tables 1–3.

Table 3. Results of secondary outcome variables for position and overall.

Position	Stats	N	Deviation Shoulder Point (mm)	Deviation Tip Point (mm)	Depth Deviation Shoulder Point (mm)	Depth Deviation Tip Point (mm)	B/L Angular Deviation (Grades)	M/D Angular Deviation (Grades)
Ant	Mean	13	2.92	1.83	0.78	0.78	4.59	2.93
	SD		1.51	0.99	0.65	0.59	3.39	1.81
	p50		2.62	1.61	0.49	0.64	4.4	2.6
	IQR		2.26	1.58	0.55	0.59	3.6	2.6
Post	Mean	13	3.07	3.08	0.97	0.94	2.93	3.82
	SD		3.32	3.59	0.96	0.97	2.31	2.31
	p50		1.68	1.6	0.7	0.68	2.4	2
	IQR		1.4	1.21	0.65	0.57	2.3	2.3
p-value			0.23	0.63	0.74	0.94	0.18	0.50

4. Discussion

To the best of the authors' knowledge, this is the first cadaver pilot study investigating the influence of surgeons' experience on the accuracy of implant placement using dCAS. The goal of the present study was to assess the potential differences between the operators' experiences and the definite outcomes: implant placement accuracy.

Since the introduction of three-dimensional imaging and visualization software before implant placement in the 1990s and the further introduction of dynamic navigation in the 2000s, the majority of recent research has been conducted on computer-assisted guidance to create the most accurate device for prosthetic-guided implant placement [28].

In this context, the goal of the present study was to investigate the association between surgeons' experiences and implant placement accuracy. The findings revealed encouraging results concerning the role of surgeons' experiences. Specifically, unexperienced surgeons showed higher performance than those with more experience in terms of linear and angular deviations during navigated implant placement, but no significant differences were found for any variables evaluated between the two operators ($p > 0.05$).

These results may seem counterintuitive, as one would typically expect higher accuracy from experienced surgeons because, with this surgical system, they might further improve their implant placement accuracy [29]. However, a possible reason could be that unexperienced surgeons adhered more strictly to the dynamic navigation system's guidance because of their short surgical experience, resulting in similar precision. In contrast, experienced surgeons may have relied more on their prior experience, which could have led to slight deviations from the system's guidance [30].

In light of the obtained descriptive results of this study, the outcomes aimed to evaluate the depth accuracy, requiring a more detailed analysis, as shown by the overall mean deviation at tip depth (0.86 mm—SD 0.79) and shoulder depth (0.88 mm—SD 0.81). It is a large discrepancy from the planning that is unacceptable in critical anatomical areas where the inferior alveolar nerve is at risk [31].

Consequently, a risk of implant deviation still exists with the navigation system due to the errors that might be generated during the workflow steps of image acquisition, tracking clip stability, registration and calibration, and errors when overlaying the two CBCT scans, as reported by prior studies [9,25,32–34].

Thus, in the authors' opinions, for other surgical approaches, a 2 mm safety margin should be applied to all important anatomical structures in presurgical planning [25]. From a clinical perspective, it should be recalled that the application of such a margin might raise some questions on the overall reliability of navigation systems. In other words, the clinical question, "Does this tool help implant placement in complex cases?", remains open.

When comparing the presented results with those available in the literature, it should be underlined that an in vitro study by Jorba-Garcià et al. revealed negligible differences between two operators ($p > 0.05$) using a dynamic navigation system. Consequently, the outcomes evaluated in the present cadaver study are in accordance with this paper [25]. Similarly, Pellegrino et al. showed an analogous implant placement accuracy between four operators with different grades of implant surgery experience, resulting in not statistically significant differences in the majority of the evaluated outcomes in terms of two/three-dimensional deviations [35].

Furthermore, Wang et al. investigated three different approaches (i.e., free hand, sCAS, and dCAS) and showed that experienced vs. non-experienced operators had an analogous accuracy, and differences between operators were not statistically significant ($p > 0.05$) [34,36].

Finally, Sun et al. and Wu et al. showed that the surgeons' experience levels did not influence implant placement accuracy with dCAS [37,38].

All cited studies revealed partially lower linear and angular deviations than the present study, but such results should be interpreted with more caution because the data concerning the accuracy of dCAS are obtained during in vitro trainings (i.e., using artificial models), which can lead to higher accuracy in comparison to real clinical scenarios, such as fresh defrozen cephalus [9,25,39,40].

In addition, a direct comparison with the pre-clinical scenario with respect to the type of implant placement (i.e., flapless vs. open surgery) might be an important confounding factor requiring further investigation.

Although the dynamic navigation system offers excellent accuracy, its application is limited in clinical practice mainly because of the required learning curve, the risk of inaccurate implant placement, as mentioned above, due to system error, and the high cost of the device. It represents a large economic investment for oral surgeons, which includes the cost per single case of fiducial clips, markers, and plates [25,36,41,42].

Despite the limitations, the present results can be considered promising positive preliminary results acting as a starting point for future clinical research with a larger sample size. Moreover, an important aspect that should be investigated is a bivariate analysis considering the implant planning (i.e., the gold-standard) and each operator's effective implant placement.

5. Conclusions

Within the limitations of this study in terms of sample size and clinical parameters evaluated (such as bone density), the present findings suggest that dynamic computer-assisted surgical implant placement systems could be a viable and safe technique for implant surgery by any operator, independently of surgical experience.

Based on the obtained results, this system might offer additional clinical benefits to an unexperienced operator, despite the required learning curve and the cost originated by the initial investment.

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Informed Consent Statement: Not applicable.

Data Availability Statement: Data are available after the authors' consultations.

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