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How much does experience in guided implant surgery play a role in accuracy? A randomized controlled pilot study

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Abstract. The current literature is not consistent on whether experience influences accuracy. The aim of this study was to analyze the accuracy of implant insertion performed by inexperienced versus experienced surgeons. Thirty-three implants were inserted by the inexperienced group and 37 implants by the experienced group. Planning and post-surgical computed tomography images were matched and the accuracy data compared. The positioning error was also evaluated. Quantitative data for the two groups were described and illustrated using box plots. The *t*-test was used to compare accuracy values and positioning error. Significance was set at $P \leq 0.05$. In the inexperienced group, the mean coronal, apical, and angular deviation values were 0.75 mm (range 1.01–0.51, standard deviation (SD) 0.18), 1.02 mm (range 1.99–0.64, SD 0.44), and 3.07° (range 9.22–0.73, SD 2.70). In the experienced group, the mean coronal, apical, and angular deviations were 0.60 mm (range 1.00–0.06, SD 0.25), 0.67 mm (range 1.67–0.24, SD 0.34), and 3.21° (range 8.01–1.41, SD 1.57). The *t*-test did not show any statistically significant difference when coronal ($P = 0.125$), apical ($P = 0.060$), and angular ($P = 0.859$) deviations were considered. A statistically significant difference ($P = 0.000$) was determined when the positioning error was considered. Experience had a limited influence on accuracy, but reduced positioning error to a statistically significant degree.

Key words: dental implants; computer-assisted surgery; clinical research; randomized controlled trial; positioning error.

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Three-dimensional (3D) implant planning software, image-guided template production techniques, and computer-guided implantology have been employed for many years[1,2]. These techniques were primarily aimed at improving diagnostic, surgical, and prosthetic precision, simplifying technique-sensitive and operator-dependent surgical procedures[3,4]. However, commercially driven marketing has led to unrealistic clinical expectations for the clinical efficacy and ease of use of these developing techniques, which have wrongly been described as effective and easy to apply[5]. A risk is the progressive misuse of a technique, which, if properly applied, can improve the final result in implant–prosthetic rehabilitation[6].

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The use of surgical guides for the placement of dental implants is designed to provide greater control and to eliminate the risks involved in standard implant surgery; however, the risk of deviation between the planned and the placed implant position remains substantial (loss of accuracy)[7]. Today computer-guided implantology is applied in the clinical setting using a single surgical guide in order to prepare the site and to insert the implant – multiple guides are no longer used and the single guide is fixed. The single-type guide consists of a 3D-printed surgical template with guide sleeves for fixture installation, additional guide sleeves to insert fixation screws, and depth-calibrated drills to prepare osteotomies. Computer-guided implantology involves a sequence of diagnostic and therapeutic steps, and errors can arise at different stages[6,7]. The accuracy of the entire procedure is defined as the deviation between the position of the implant as expected according to the planning (or planned implant position) and the actual postoperative position of the implant (or inserted implant position); this deviation is the 'total error'[7].

Computer-guided implantology uses a diagnostic template (a radiopaque replica of the patient's temporary prosthesis, or the patient's actual denture) to determine the prosthesis-driven implant position[7]. In the planning phase, the position of the diagnostic template during the computed tomography (CT) scan is taken as a reference and must be reproduced exactly by the surgical guide during surgery[7]. Positioning of the surgical guide on the support surface that is different to that of the diagnostic template generates a 'positioning error'[7].

Computer-guided implantology is not a method that allows the operator to perform surgeries that cannot be performed using standard implantology, but rather it simplifies the treatment phases of complex clinical cases, performing minimally invasive implant surgery more accurately[8]. As such, it is essential to determine whether the level of surgical experience affects the accuracy of the results.

The aim of the present study was to evaluate the accuracy of implants inserted by experienced surgeons (expert in computer-guided implantology) compared to the accuracy of implants inserted by inexperienced surgeons (none the less expert in standard implantology), both employing a computer-guided surgery method. The positioning error was also evaluated. The null hypothesis was that no significant difference would be found between the experienced and inexperienced surgeons in the accuracy and in the positioning error of inserted implants.

Materials and methods

Enrolment

The present pilot study was conducted on totally edentulous patients who needed a complete implant prosthetic rehabilitation and were seeking oral implant therapy. The CONSORT guidelines for clinical trials were followed. The study was approved by the local ethics committee and conducted in accordance with the Declaration of Helsinki of 1975 as revised in 2000. All patients were assessed clinically and radiographically before enrolment (panoramic radiographs and CT were taken).

Inclusion criteria were the following: (1) agreement with informed consent; (2) male/female at an age of at least 18 years; (3) fully edentulous in the maxilla or mandible, with a vertical bone height of at least 10 mm, adequate transverse buccopalatal or buccolingual dimensions at the planned implant site, and a minimum of six implants planned in the upper arch or five implants in the lower arch; (4) a history of edentulism of at least 3 months.

Exclusion criteria were (1) subject unlikely to be able to comply with the study procedures, as judged by the clinician; (2) previous or current bisphosphonate treatment; (3) general health conditions and medical history such as current pregnancy, ongoing alcohol and/or drug abuse, or current smoker (more than 10 cigarettes/day), as well as major systemic diseases that would negatively impact on implant insertion; (4) untreated, uncontrolled caries and/or periodontal disease; (5) history of local irradiation therapy; (6) current need for bone grafting and/or sinus lift at the planned implant site.

Out of 34 patients assessed for eligibility from January 2016 to March 2016, 24 were excluded: 21 did not meet the inclusion criteria and three declined to participate. Ten healthy patients were recruited and treated (mean age 57.5 years, range 39–75 years; seven males, three females). The enrolment was conducted at the Department of Oral and Maxillofacial Sciences, ''Sapienza'' University of Rome, Umberto I General Hospital.

Allocation and blinding

The patients were divided into two groups using randomization tables; the patient was allocated a number with a corresponding envelope. Group 1 comprised experienced surgeons and group 2 comprised inexperienced surgeons. The allocation ratio was 1:1. The patients and the investigators examining the outcomes were not informed of the groupings.

Procedure

The patients were treated by five expert surgeons (at least 500 implants inserted using computer-guided implantology) and five inexperienced surgeons (no experience in computer-guided implantology, but at least 500 implants inserted using conventional implantology).

The same protocol was used by the two groups of surgeons during planning and surgery. The protocol employed in this clinical study comprised an integrated treatment sequence that involved the following steps:

(1) Construction of a radiolucent diagnostic template, which was an exact replica of the temporary removable prosthesis (scanno-guide). This fulfilled all the aesthetic and functional requirements, and was accepted by the patient.
(2) Positioning and fixation of an Evobite (3Diemme, Cantù, Italy) directly in the patient's mouth. Evobite is a radiopaque landmark, fixed using a silicone material between the scanno-guide and the opposing arch. The Evobite was used to obtain perfect matching of stereolithography (STL) files (Fig. 1).
(3) Optical scanning of the edentulous arch model cast, the model cast with the scanno-guide, and the model cast with the scanno-guide and the Evobite fixed.
(4) CT scanning of the patient's arch while employing the scanno-guide and Evobite. The correct positioning of the scanno-guide and Evobite was checked carefully. A spiral CT device was used (Asteion Multi; Toshiba Medical Systems, Rome, Italy), with the following CT parameters: 0° gantry tilt, high resolution bone kernel, 0.5 mm nominal slice thickness, 0.5 mm interval, and 0.5 mm pitch. The scans included the scanno-guide and Evobite to integrate the anatomical data with the functional and aesthetic determinants and to allow the overlap of STL files.
(5) Digital three-dimensional CT-based surgical planning. The planning software (3Diagnosys; 3Diemme) employed in the present study uses

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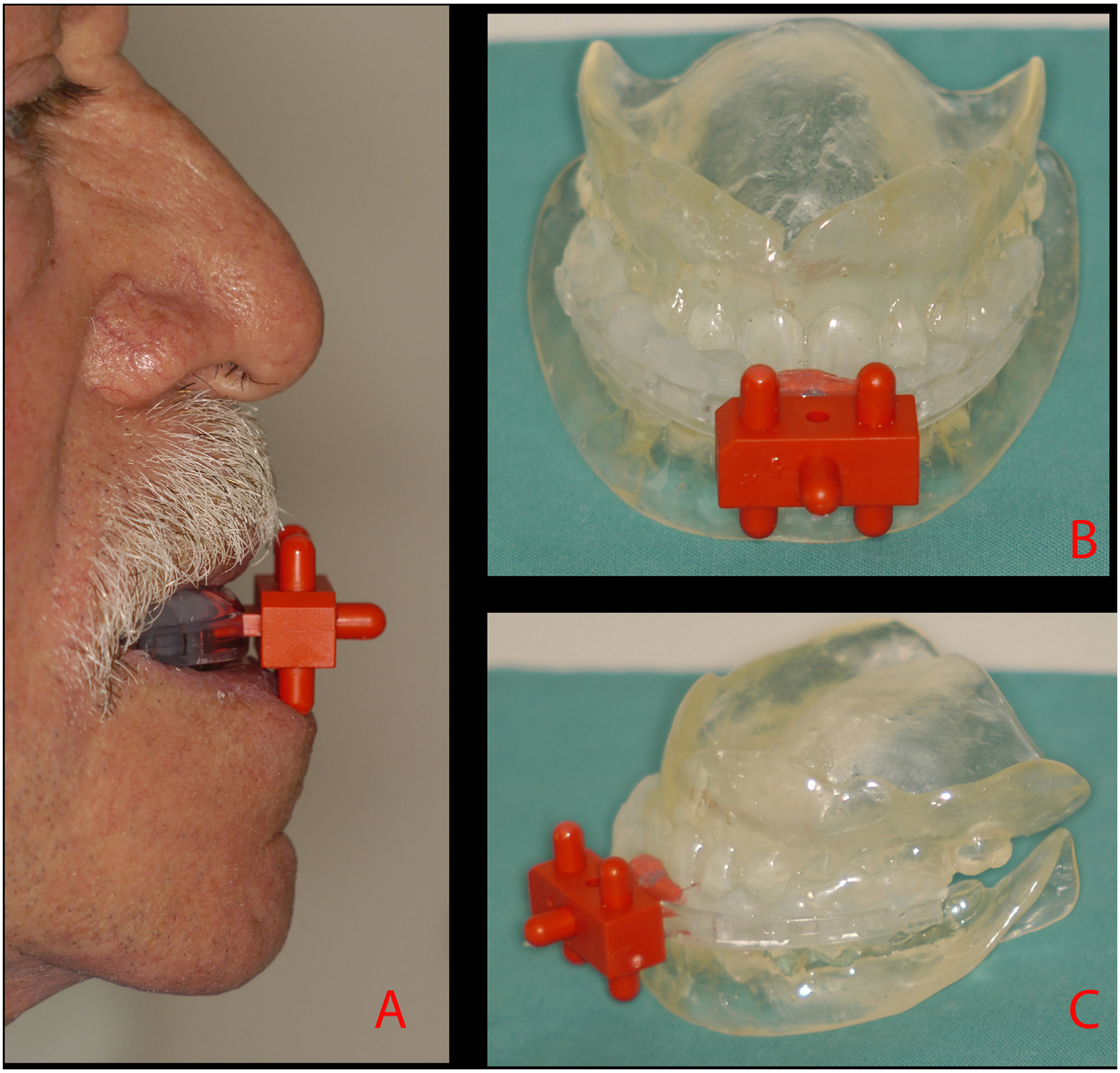

Fig. 1. The scanno-guide (duplicate of denture) and Evobite (3Diemme) positioned and fixed using a silicone material. A) Evobite in the patient's mouth; B),C) Evobite fixed using silicone material between the scanno-guide and the opposing arch.

the original CT data, in DICOM format (Digital Imaging and Communication in Medicine), to produce axial, 3D, panoramic, and cross-sectional images, all of which are visible at the same time in four interactive windows on a computer monitor (Fig. 2). STL files of the model cast, scanno-guide, and Evobite were also imported into the program. This software enables clinicians to virtually place implants according to the bone anatomy and prosthetic design.

(6) Computer-aided design (CAD) of the surgical guide. Using CAD technology, the clinician designed the drilling template according to the patient's prosthetic and anatomical requirements.

(7) Computer-aided manufacturing (CAM) of the surgical guide to transfer the digital planning to the surgical environment. The surgical guides were mucosa-supported, in accordance with the type of supporting structure. The mucosa-supported guides permitted a flapless approach. A single-type 3D-printed surgical guide was manufactured. The fully guided implant system RealGUIDE (3Diemme) allowed for controlled osteotomy site preparation and implant placement in three dimensions. Specific cylinders are embedded within the guide to accommodate drill handles or implant mounting, which intimately engages the cylinders. The first drill used was a mucotome, to punch and remove gingival soft tissue. The guide was properly fixed to the jaw using at least three fixation screws. A silicone occlusal index was used to reduce the positioning error of the surgical guide (Fig. 3). Osteotomy site-specific drills with vertical stops to control apico-coronal site preparation were used. Implant placement was performed using specific delivery mounts to a controlled angulation, apico-coronal depth, and positioning of the internal hex, which was set by the computerized 3D plan.

(8) Computer-aided implantology. Seventy implants (Sharp Implant; Impla-Dent, Formia, LT, Italy), which were tapered and had an internal hex (diameter ranging from 3.80 mm to

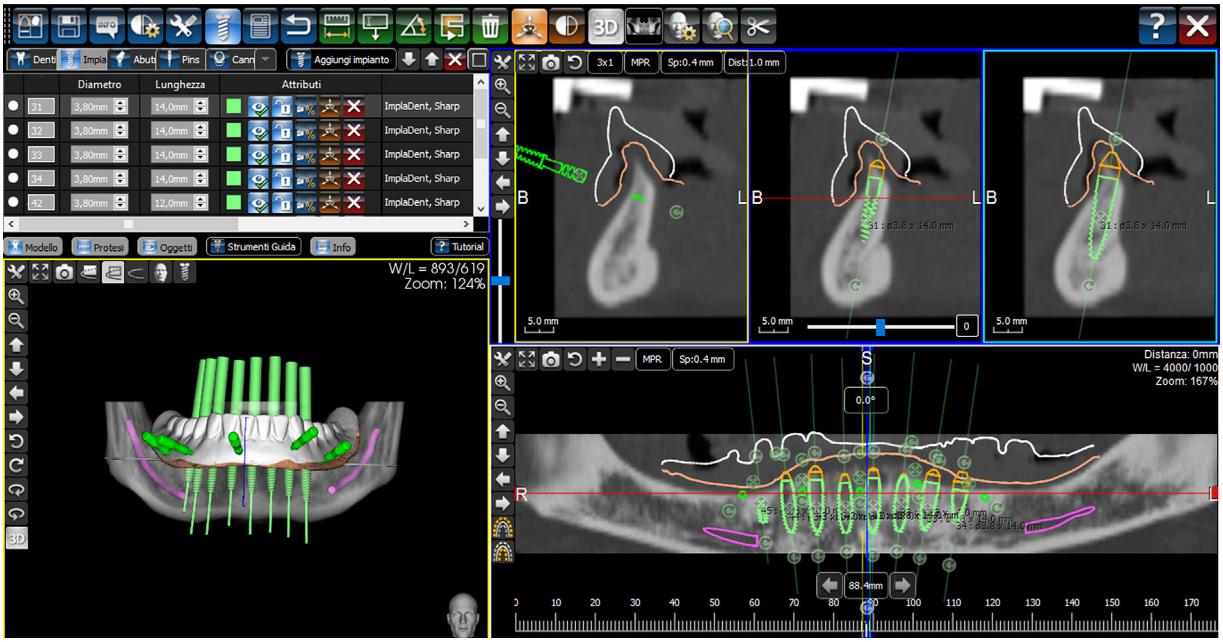

Fig. 2. The planning phase using 3Diagnosys planning software (3Diemme).

4.30 mm and length ranging from 10 mm to 14 mm), were inserted in completely edentulous patients using the 3D-printed surgical guides (Fig. 4).

Outcome variables

The primary outcome was the accuracy of the implant inserted. The secondary outcome was the positioning error. The accuracy is the deviation from the software planning stage to the surgical field. The cumulative loss of accuracy is the total error, the sum of single errors (procedure-related and product-related). The total error (accuracy) and the procedure-related error (positioning error) were determined in the present study.

Evaluation of accuracy

Immediately after surgery, all patients underwent postoperative CT using the same spiral CT device and the same parameters as used for the preoperative scan. The postoperative scan was overlapped onto the virtual plan. The combined scans were analyzed using the method described by Testori et al.[9]. The same grey-level threshold used to define the bone was applied to the preoperative and postoperative images. 3Diagnosys software (3Diemme) was used to convert the preoperative implant planning into a CAD project, which comprised the STL files of 3D models of the planned implants, readable by any surface-analyzing software. The postoperative images of the implants were extracted virtually using a very high threshold, including all metal parts of the dataset. As metal impinges on the geometry of the extracted implant models, those parts were substituted with the corresponding virtual implant models through a best-fit procedure using the reverse-engineering software Geomagic Studio 12 (Geomagic, Rock Hill, SC, USA). In essence, the virtual implant models are positioned as accurately as possible according to the geometry and position of the implants as revealed in the postoperative CT scan, thus permitting the substitution of all metal-corrupted implant files with their corresponding CAD file. The virtual implant models are therefore placed in the positions that best fit the geometry and position of the implant extracted from the postoperative CT scan. This procedure enables the full replacement of the metal-corrupted implant files extracted from the CT with the corresponding CAD files from the implant library[9]. The comparison of the planned implants with the placed ones and the evaluation and calculation of three parameter deviations (i.e., coronal, apical, and angular deviation) using their 3D coordinates at the apical and coronal level is thereby made possible.

The coronal deviation was defined as the 3D distance between the coronal cen-

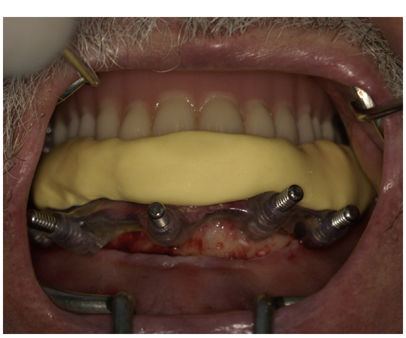

Fig. 3. The use of a silicone occlusal index to properly fix the lower mucosa-supported surgical guide RealGUIDE (3Diemme). Due to reduced keratinized gingiva, a mucoperiosteal flap was raised in the incisive area.

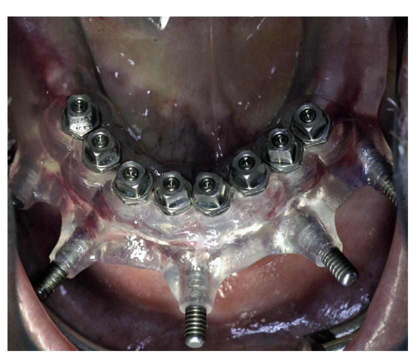

Fig. 4. Implant positioning of eight implants (Sharp Implant, ImplaDent) using specific delivery mounts. The implants were inserted with a controlled angulation, apico-coronal depth, and positioning of the internal hex.

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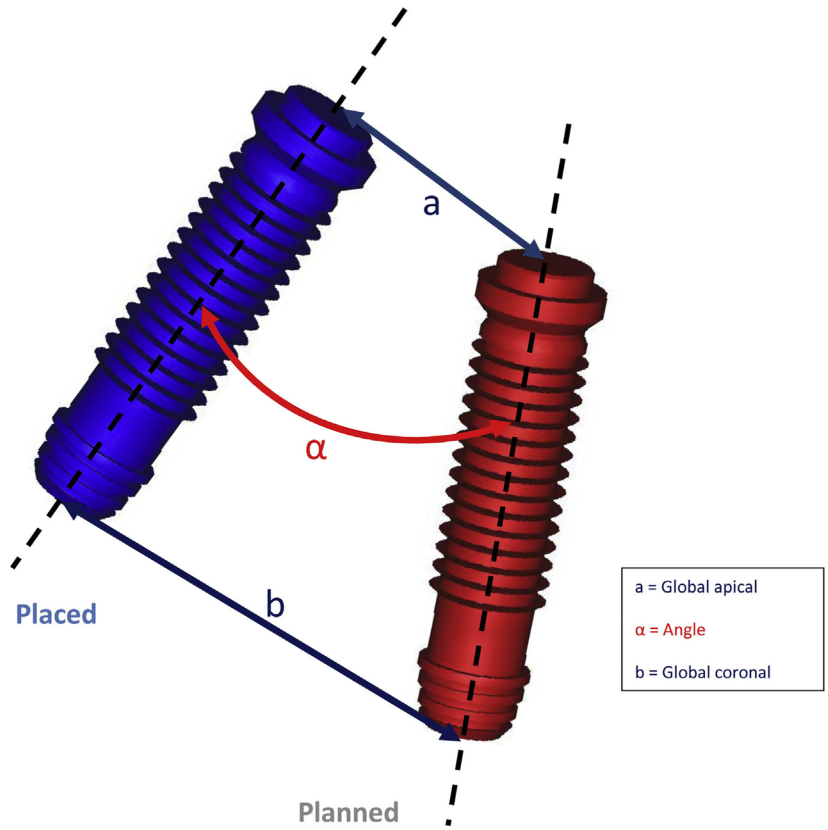

Fig. 5. Definition of deviation parameters: coronal (a), apical (b), and angular deviations (α).

tre of the corresponding planned and placed implants. The apical deviation was defined as the 3D distance between the apical centre of the corresponding planned and placed implants. Finally, the angular deviation was calculated as the 3D angle between the longitudinal axis of the planned and placed implant (Fig. 5).

Evaluation of positioning error

A central parameter was adopted to analyze the study sample and explain the possible deviations between the planned and actual implant positions[9]. In other words, the positioning error, or the error that arises from the inaccurate positioning of the surgical guide, was estimated. The guide sleeves are kept together by the guide resin. The guide sleeves correspond to the planned implant positions. So, the centre of mass of the inserted implants was considered as a global group and compared to the centre of mass of the surgical guide. On comparing the distance of the centre of mass preoperatively and postoperatively, a significant difference would lead to the conclusion that the deviation was due to a positioning error of the surgical guide rather than another source of error (Fig. 6).

Statistical analysis

Data were evaluated using IBM SPSS Statistics version 17.0 software (IBM Corp., Armonk, NY, USA). Quantitative data for the two groups were described using the mean, minimum and maximum values, and standard deviations. Accuracy data were also illustrated using box plots. The *t*-test was used to determine the influence of experience on accuracy and positioning error comparing the two groups. Significance was set at $P \leq 0.05$.

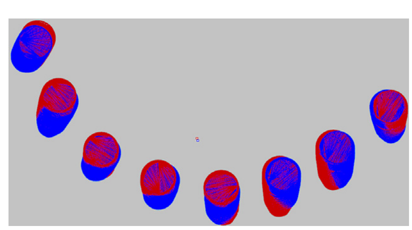

Fig. 6. Overlap of the three-dimensional virtual models of the planned (in blue) and inserted (in red) implants using Geomagic Studio 12 software. The two points at the centre of the image represent the centre of mass of the implants planned (in blue) and inserted (in red). The distance between the two points corresponds to the positioning error. (For interpretation of the references to color in this figure legend, the reader is referred to the web version of this article.)

Results

In the inexperienced surgeon group, 33 implants were inserted in five jaws (five patients) by five surgeons. In the experienced group, 37 implants were inserted in five jaws (five patients) by another five surgeons. No patient was lost to follow-up before the second scan was taken. All implants were immediately loaded after performing the postoperative CT. All 70 implants were analyzed for accuracy.

In the experienced group, the mean coronal deviation was 0.60 mm (range 0.06–1.00, SD 0.25), the mean apical deviation was 0.67 mm (range 0.24–1.67, SD 0.34), and the mean angular deviation was 3.21° (range 1.41–8.01, SD 1.57). In the inexperienced group, the mean coronal deviation was 0.75 mm (range 0.51–1.01, SD 0.18), the mean apical deviation was 1.02 mm (range 0.64–1.99, SD 0.44), and the mean angular deviation was 3.07° (range 0.73–9.22, SD 2.70). The inexperienced group performed better only in terms of the angular deviation results. These data are further visualized in detail in the box plots presented in Figs. 7–9, showing the accuracy data of inexperienced versus experienced surgeons.

Considering the difference in the centre of mass of the preoperative and postoperative analyses, the mean value for the experienced group was 0.23 mm (range 0.17–0.28, SD 0.12) and the mean value for the inexperienced group was 1.00 mm (range 0.80–1.20, SD 0.32).

Application of the *t*-test did not show any statistically significant differences when coronal ($P = 0.125$), apical ($P = 0.060$), and angular ($P = 0.859$) deviations were considered. A statistically significant difference ($P = 0.000$) was determined when the deviation of the centre of mass was considered, indicating a higher positioning error for the inexperienced surgeons group.

Discussion

There appear to be few 'in vivo' studies evaluating the influence of a clinician's experience on the accuracy and positioning error of computer-guided implantology[10]. The initial hypothesis was partially confirmed by the results: experience was not found to improve accuracy, but was found to reduce the positioning error. However, this study has limitations. It was a pilot study performed on a small number of patients and the results need to

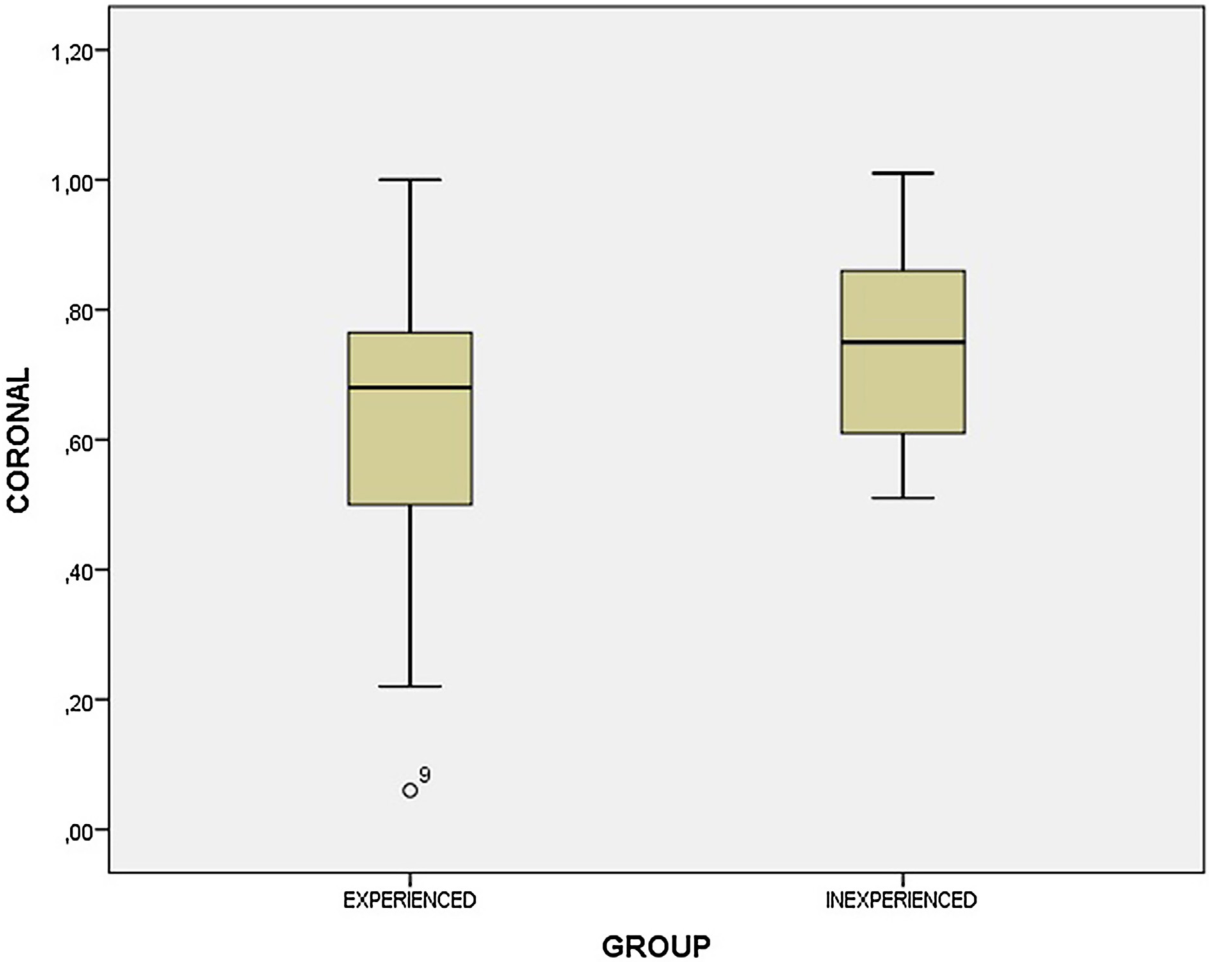

Fig. 7. Box plot of the coronal deviation values for the inexperienced and experienced groups. The median, quartiles, and extreme values of implant deviations are shown: the box contains 50% of all values; the horizontal line inside the box indicates the median; the vertical line extends to 1.5 of the interquartile range. Circles depict outliers.

be confirmed in prospective studies with a larger number of patients. Another limitation of the present study is that the results refer to a specific method of computer-guided implant surgery and cannot be generalized.

In a recent review on computer-guided implantology, the presence of a learning curve was evaluated[11]. The authors of that review stated that the literature is not consistent on whether a learning curve is important in computer-guided surgery: one clinical trial observed a learning curve[12], while two other studies did not[13,14]. In a study aimed at evaluating and comparing the mean accuracy and maximum deviation values of dental implant placement using two stereolithographic (SLA) guide systems, a scatter plot was used to evaluate intra-operator variability of accuracy and to determine whether a learning curve was present[13]. Correlating the angular deviation values with the time variable, indicating the number of computer-guided surgeries performed by the surgeon, the intra-operator variability analysis did not indicate a clear learning curve[13]. Consequently, the time variable was evaluated as having a minor impact. Given the results of this study, the absence of a learning curve could originate from the fact that the coronal and apical deviation values were not considered, values which may be the most affected by the level of experience, as demonstrated in the present study.

In a study aimed at evaluating the in vivo accuracy of SurgiGuide (Materialise Dental) – a multiple stereolithographic drill guide – the intra-operator variability in accuracy was also considered to determine whether a learning curve was present[15]. The deviation values were regressed versus time as above. In this study, the time variable was determined to have only a minor impact on surgical accuracy and a learning curve was not demonstrated[15]. The authors of that study stated that surgical accuracy is dependent on the hardware used (surgical guide) rather than the technical procedure applied. As stated by D'haese et al., errors in positioning of a surgical template are categorized as procedure-related, whereas the accuracy or stiffness of a surgical template is considered product-related (dependent on the hardware)[16]. The absence of a learning curve confirms that accuracy is influenced more by intrinsic error (inherent error that originates from the mechanical component tolerance of the surgical guide) rather than the operator's procedural errors[16].

Valente et al. evaluated intra-operator variability of accuracy using multiple SLA surgical guides and determined whether a learning curve was present[14]. The deviation values were regressed versus time. A clear learning curve was not demonstrated when the accuracy data of the two centres involved in the study were considered[14]. The authors stated that the similarity in accuracy between the two clinicians in-

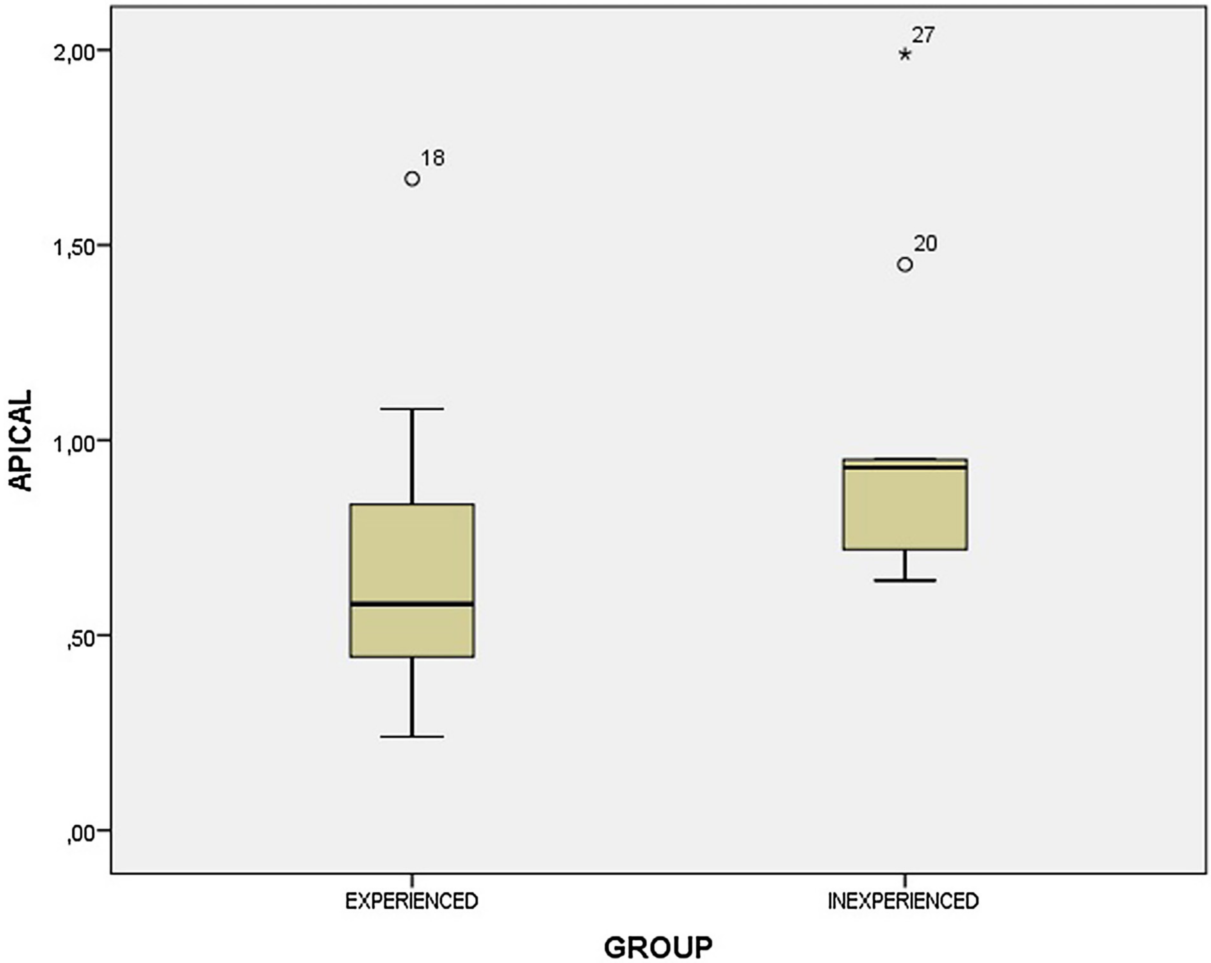

Fig. 8. Box plot of the apical deviation values for the inexperienced and experienced groups.

volved in the study and the absence of a clear learning curve provide preliminary support to the hypothesis that the human factor may play a limited role in computer-guided surgery.

In another study aimed at determining the accuracy of implant insertion depth, scatter plots were used to evaluate intra-operator variability in depth deviation in relation to the number of surgeries performed and to determine whether a learning curve was present[6]. By evaluating the intra-operator variability, the depth deviation values regressed over time (i.e., the number of surgeries performed), which demonstrated a clear learning curve. The influence of time, as the number of surgeries performed, on the occurrence of early surgical complications or unexpected events was also investigated[6]. Correlating the number of complications arising during each surgery with the time variable, the occurrence of early surgical complications or unexpected events decreased as the surgeon became more experienced. The results of this study confirm that the level of experience does not affect accuracy, but that it does reduce the frequency of complications or the occurrence of unexpected events[6].

Vasak et al. evaluated the factor 'surgeon' as a potential reason for deviations[12]. All patients underwent implantation by two experienced surgeons who were inexpert in implantology; the implantation was performed strictly according to the manufacturer's protocol. No statistically significant difference between the two surgeons was identified regarding the deviations measured. However, a learning effect over the time period of performance of the surgical procedures was observed regarding the buccolingual and depth deviations[12]. These observations indicate that computer-guided implantology may allow the implementation of complex implant–prosthetics, but may only offer a simple guide without any gain in procedural reliability and security during the first implant placements for the dentist inexperienced in implantology, on account of the lack of approval process experience and the technological sensitivity of the system. The results of this study probably originate from the lack of experience in implant surgery of the investigators[12], and are not comparable with the results of the present study. The study does, however, confirm the statement that computer-guided implant placement should be the preserve of surgeons experienced in implant surgery[8].

In a recent prospective study, Van de Wiele et al. analyzed the accuracy of implant placement with mucosa-supported stereolithographic guides, executed by inexperienced surgeons under the supervision of an experienced colleague[17]. The accuracy data of 75 OsseoSpeed implants, placed in 17 fully edentulous jaws (16 patients) using a mucosa-supported stereolithographic guide were compared with the data (12 jaws, 52 implants) of an experienced surgeon. All the deviation values were better in the inexperienced group; only the angular deviation value was similar in the two groups. The coronal inter-implant deviation (0.32 mm,

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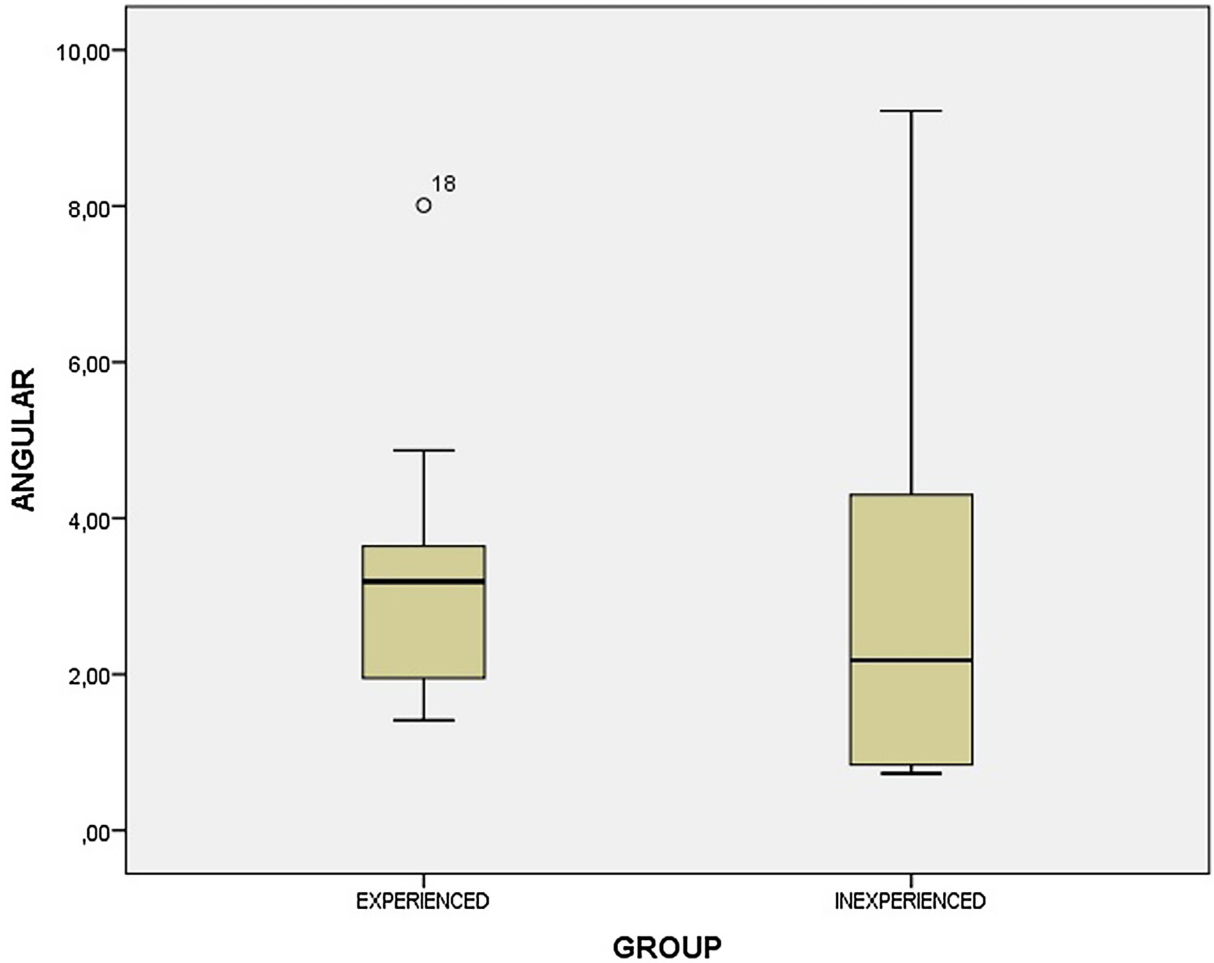

Fig. 9. Box plot of the angular deviation values for the inexperienced and experienced groups.

SD 0.52) was significantly less than the global coronal deviation, which supports the notion that inaccuracy was principally due to the incorrect positioning of the guide. In that study, all the different stages undertaken to plan and carry out the implant placement were supervised by an experienced surgeon. The authors stated that this may be the reason for the comparable outcomes in accuracy in the two groups with differing experience[17].

The results of the study by Van de Wiele et al.[17] and those of the present study are extremely similar. The accuracy data of the two experimental groups were similar in both. This evidence confirms how important intrinsic error is compared to other sources of error[18]. Indeed, intrinsic error is not a procedural error and as such it is not affected by the level of experience, i.e. it occurs more due to the method than to the operator[16]. In the study of Van de Wiele et al.[17], as in the present study, positioning error was found to be an important component of the total error – statistically significant in the present study. The positioning error, being a procedure-related error, is influenced by the level of experience and it is expected to be greater in inexperienced operators[7]. In the present study, the positioning error was significantly higher for the inexperienced surgeons even when a silicone occlusal index was used to reduce the error when the surgical guide was fixed.

To better understand the results of the present study, it is useful to consider the different sources of error in computer-guided implantology and the deviation values that are influenced by the different sources of error. Most sources of error can lead to an error that affects every single implant randomly (random error)[7]. Computer-guided surgery systems use a replica of the patient's temporary prosthesis, or the patient's actual denture (double-scan technique) to determine the prosthesis-driven implant position[7]. The position of the diagnostic template during the CT scan is taken as a reference guide during the planning phase and must be reproduced exactly by the surgical guide during surgery[7]. Positioning of the surgical guide on the supporting surface that is different to that of the diagnostic template may generate an error that reoccurs for each implant inserted with the same surgical guide (systematic error)[7]. This error arises from the positioning of the surgical guide on the support surface different to that of the diagnostic template[7]. Inexact positioning of the surgical guide significantly affects the coronal deviation, whereas angular deviation is not significantly affected. In the present study the angular deviation values were better in the inexperienced group, whereas the coronal and apical deviation values were better in the experienced group. These results are determined by the fact that the inexperience can lead to a greater positioning error, but not to an increased intrinsic error, which is a random error. In fact, the random angular deviation of the inexperienced group

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was actually lower, which means they performed better.

The data obtained in the present study show that, in the case of surgeons who are already expert in implantology, computer-guided implant placement allows them to obtain high levels of accuracy from the beginning. However, the positioning error was significantly higher in the inexperienced group, resulting in higher coronal and apical deviations. The use of a 'single guide', the accurate positioning of the surgical guide, and the use of at least three osteosynthesis screws to fix the surgical template can reduce the positioning error when a mucosa-supported surgical guide is used in completely edentulous patients, but does not eliminate it. The angular deviation value was better in the inexperienced group: this deviation value is not influenced by experience and originates from the intrinsic characteristics of the guide. The knowledge of different types of errors and their effects on the overall accuracy of computer-guided systems should prove helpful to the surgeon who seeks a more accurate result.

The persistent belief that computer-guided implant therapy requires less training is inaccurate. As stated by Sicilia et al., when computer-guided implantology is employed ''surgical skills and experience go above and beyond those necessary for providing regular implant surgery''[19].

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None.

Competing interests

None.

Ethical approval

Ethics Committee of Policlinico Umberto I, Rome, Italy (Prot. 304/07).

Patient consent

Patient consent was obtained.

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