Int. J. Oral Maxillofac. Surg. 2017; 46: 922–930
http://dx.doi.org/10.1016/j.ijom.2017.03.010, available online at http://www.sciencedirect.com

International Journal of Oral & Maxillofacial Surgery

Clinical Paper
Dental Implants

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

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M. Cassetta, M. Bellardini: How much does experience in guided implant surgery play a role in accuracy? A randomized controlled pilot study. Int. J. Oral Maxillofac. Surg. 2017; 46: 922–930.

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.

Accepted for publication 10 March 2017
Available online 31 March 2017

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].

0901-5027/070922 + 09

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