**KEY WORDS**
Computer-guided implant placement, Freehand implant placement, Immediately loading

Randomized controlled trial

# COMPUTER-GUIDED *VS.* FREEHAND PLACEMENT OF IMMEDIATELY LOADED DENTAL IMPLANTS: 10-YEAR REPORT FROM A RANDOMIZED CONTROLLED TRIAL

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**PURPOSE.** To compare planning and patient rehabilitation using 3D implant planning software and dedicated surgical templates *versus* conventional freehand implant placement for the rehabilitation of partially or fully edentulous patients using flapless or mini-flap procedures and immediate loading.

**MATERIALS AND METHODS.** Patients requiring at least two implants to be restored with a single prosthesis, having at least 7 mm of bone height and 4 mm in bone width were consecutively enrolled. Patients were randomized according to a parallel-group design into two groups: computer-guided group or conventional freehand group. Implants were loaded immediately with a provisional prosthesis, replaced by a definitive prosthesis 4 months later. Outcome measures were implant and prosthesis failures, any complications, marginal bone levels, number of treatment sessions, duration of treatment, post-surgical pain and swelling, intake of painkillers, surgical and prosthetics times, time required to solve complications, and patient satisfaction. Patients were followed up to 10 years after loading.

**RESULTS.** Ten patients (32 implants) were randomized to the computer-guided group and 10 patients (30 implants) to the freehand group. At the 10-year follow-up, three patients (five implants) in the computer-guided group and three patients (seven implants) in the freehand group dropped out. One prosthesis in the freehand group was remade *versus* none in the computer-guided group (P = 1). Two implants failed in two patients from the freehand group *versus* no implant failure in the computer-guided group (P = 0.4615). Four patients had four complications in the freehand group *versus* five patients with six complications in the computer-guided group. All complications were successfully resolved. The difference between groups was not statistically significant (P = 1). Ten years after loading, the mean marginal bone loss was 1.01±0.51 mm in the computer-guided group and 1.54±0.36 mm in the freehand group. The difference was statistically significant (difference 0.53 mm; 95% CI: 0.16 to 0.89 mm; P = 0.044). Patients' self-reported post-surgical pain (P = 0.037) and swelling (P = 0.007) were statistically higher in the freehand group. There were no statistically significant differences between groups in either the number of sessions from patient recruitment to delivery of the final prosthesis, the number of days from the initial CBCT scan to implant placement, the pain medication intake, or the time taken for surgery/prosthetics. At the 10-year follow-up, all patients declared that they were fully satisfied with the function and aesthetics of their final prostheses.

**CONCLUSIONS.** The results at 10-year follow-up confirm that both approaches achieved positive results, although post-operative pain and swelling were statistically higher at the freehand-treated sites, and less marginal bone loss (0.5 mm) was observed in the computer-guided group at 10-year follow-up.

**CONFLICT OF INTEREST STATEMENT**
This study was not supported by any company, and there are no conflicts of interest to declare.

## INTRODUCTION

The rehabilitation of totally or partially edentulous patients can be a major challenge, particularly in the maxilla[1]. The goal is to obtain a good aesthetics, but also long-term masticatory function and speech[2]. Various techniques have been used to rehabilitate these patients and to achieve satisfactory results in the medium and long term[3]. However, in recent years, preoperative planning for an implant-supported rehabilitation has been made simpler thanks to the use of digital technologies like computed tomography, cone-beam computed tomography, and computer-aided design/computer-aided manufacturing (CAD/CAM)[4]. These technologies allow for virtual planning of implant position, fabrication of interim restorations in cases of immediately loaded implants, and clear communication with the patient, clinicians, and laboratory[5,6].

According to systematic reviews[7,8], the main benefits of fully guided surgery include the placement of interim prostheses with an immediate loading protocol and small adjustments, as well as the possibility of using a flapless procedure, shorter chairside time, and less postoperative discomfort, pain and swelling. Despite the technological advancements, however, the traditional non-guided approach, also known as freehand surgery, is still extensively used since it is more affordable and allows for better depth control when inserting the implant by hand[9].

Although guided surgery is considered the gold standard in several procedures, it is not free of complications. These include three-dimensional deviations between virtual implant position and final position in the oral cavity. In addition, the irrigation fluid at the drill tip is less effective than in the freehand technique because it is blocked by the surgical guide. This may cause tissue overheating and ultimately result in bone resorption and implant non-osseointegration[8,10].

The aim of this 10-year report is to update the previously published 1- and 5-year data from the randomized controlled trial on partially or fully edentulous patients whose planning and rehabilitation was either guided by 3D implant planning software and customized surgical templates or by means of freehand implant placement, using flapless or mini-flap procedures and immediate loading[4,6]. This study tested the null hypothesis that there would be no differences between the two procedures against the alternative hypothesis of a difference. This article is was written in conformity to the CONSORT statement for improving the quality of reports of parallel-group randomized trials (http://www.consort-statement.org/).

## MATERIALS AND METHODS

This study was originally designed as a multicentre randomized controlled trial of parallel-group design with two arms and blind or independent outcome assessment, whenever possible. At the beginning, five centres agreed to participate, each centre to recruit 20 patients, but two centres never recruited any patients, so only three centres provided data for the report published one year after loading. After that, only one centre provided data for the 5- and 10-year follow-ups. Patients were recruited and treated from February 2011 until May 2012 at a private practice in Rome. All treatment was delivered by a single operator (Dr Marco Tallarico).

Any fully or partially edentulous patient aged 18 years or older needing at least two implants under the same prosthesis, having at least 7 mm of bone height and 4 mm in bone width, as measured on computed tomography (CT) or CBCT scans, and able to sign informed consent was considered eligible for this study. In the case of patients requiring multiple prostheses, only the most complex prosthesis was included in this study. The definitive prostheses had to be screw-retained in order to allow assessment of individual implant stability. Implants could be placed immediately after extraction if the residual socket presented a coronal diameter

not wider than 8 mm, and if there was at least 3 mm of bone below the tooth apex, a planned bone-to-implant gap of up to 2 mm, and the presence of a buccal wall up to 2 mm lower than the most coronal bony peak. Otherwise – if the operator decided to wait for the post-extraction socket to heal – the implant sites had to heal for at least 3 months. Adjacent implants had to be placed with an implant-to-implant distance of at least 3 mm, and a distance from implant to tooth of at least 1.5 mm.

Patients were divided into two groups depending on the amount of bone available:

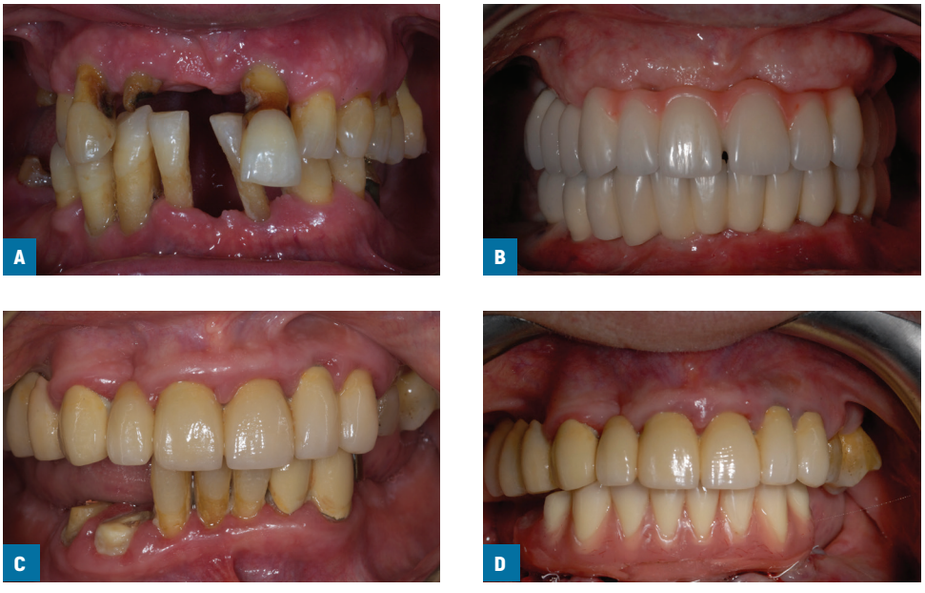
- simple case, if all implant sites had bone height >9 mm and bone width >5 mm;
- complex case, if at least one implant site had bone height between 7 mm and 9 mm and/or bone width between 4 mm and 5 mm.

Patients were not enrolled in the study if any of the following exclusion criteria applied:

- general contraindications to implant surgery;
- irradiation to the head and neck area in the year preceding implantation;
- untreated periodontitis;
- poor oral hygiene and motivation;
- uncontrolled diabetes;
- pregnancy or nursing;
- substance abuse;
- psychiatric problems or unrealistic expectations;
- severe bruxism or clenching;
- immunosuppression or immunocompromise;
- prior or ongoing treatment with intravenous aminobisphosphonates;
- lack of opposing occluding dentition/prosthesis in the area intended for implant placement;
- active infection or severe inflammation in the area intended for implant placement;
- need for bone augmentation procedures at implant placement;
- inability to open mouth sufficiently to accommodate the surgical tools;
- any "complex case" if implants had to be placed in the aesthetic zone (second to second maxillary premolars);
- participation in other studies precluding proper adherence to the present protocol;
- referral only for implant placement or unable to attend a 10-year follow-up;
- only single implant-supported crowns.

Patients were categorized into three groups according to their declarations: non-smoker, moderate smoker (up to 10 cigarettes per day), or heavy smoker (more than 10 cigarettes per day). Prior to being enrolled, all patients received detailed explanation and signed an informed consent form. Two separate CBCT or CT scans were taken in conformity to the double-scan protocol[11].

The Digital Imaging and Communication in Medicine (DICOM) data from the two sets of scans were imported into 3D implant-planning software (NobelGuide, Nobel Biocare, Kloten, Switzerland) and matched to each other. After prosthetics-driven virtual planning was approved, patients were randomly allocated either to the computer-guided group (**FIGS. 1A, B; 2A, B; 3A, B**) or to the freehand group (**FIGS. 1C, D; 2C, D; 3C, D**), according to a parallel-group design, following the indications contained in a sequentially numbered envelope. Planning data from the patients allocated to the computer-guided group were sent to a milling centre located in Sweden (NobelProcera, Nobel Biocare), where stereolithographic surgical templates were fabricated. For all patients, a metal-reinforced, screw-retained provisional acrylic resin restoration, without any cantilever, was prefabricated for immediate implant

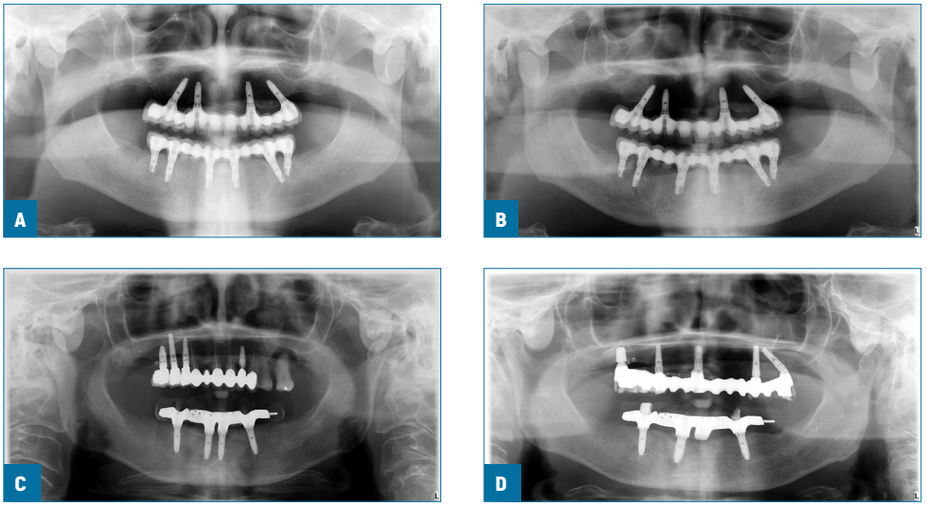



**FIGS. 1A-D:** *Pictures at baseline (A, C) and immediate loading (B, D) in computer-guided (A, B) and freehand groups (C, D)*


**FIGS. 2A-D:** *Pictures at 1- (A, C) and 10-year of follow-up (B, D) examination, in computer-guided (A, B) and freehand groups (C, D). The prosthesis in the free-hand group was remade after 5 years of function (D)*

loading. In the computer-guided group, the stereolithographic surgical template was used to pour the preoperative master casts with the implant replicas in place, while in the freehand group, the master cast used to produce the radiographic template was used. No stents were made for patients allocated to the freehand group.

All patients received 2 g of amoxicillin (or 600 mg clindamycin, if allergic to penicillin) 1 h before implant placement, and rinsed with chlorhexidine mouthwash 0.2% for 1 min prior to the




**FIGS. 3A-D:** *Radiographs at 1- (A, C) and 10-year follow-ups (B, D) examination, in computer-guided (A, B) and freehand groups (C, D). In the freehand group one implant was lost and the prosthesis was adapted to fit over the remaining implants (D)*

intervention. All patients were treated under local anaesthesia using articaine with adrenaline 1:100,000. In the computer-guided group, the fit of the surgical templates was checked before surgery. Then, the surgical templates were stabilized using the silicone surgical index derived from the mounted casts, and fixed with two to three pre-planned anchor pins.

In both groups, parallel-walled implants with external connection and an oxidized surface (Nobel Speedy Groovy, Nobel Biocare) were placed flapless or via a minimally invasive flap. Implant sites were prepared according to the manufacturer's guidelines using the Brånemark System surgery kit (Nobel Biocare, freehand group), or the Brånemark System Guided Surgery Kit, in combination with a customized surgical template (Nobel Biocare, computer-guided group). Implants were to be inserted with an insertion torque of more than 35 Ncm (torque wrench, Nobel Biocare). In the computer-guided-group, the insertion torque was measured after the surgical template was removed. After implant placement, non-engaging titanium temporary abutments (Nobel Biocare) were screwed directly to the implants or to the intermediate straight or angled multi-unit abutments (MUA, Nobel Biocare). If needed, flaps were sutured around the abutments using expanded polytetrafluoroethylene dental sutures (American Dental System, Vaterstetten, Germany). The prefabricated provisional restorations were relined on to the temporary abutments using an auto-polymerising polyurethane resin (Voco, Cuxhaven, Germany), then refined and polished. Occlusion was carefully assessed, avoiding any lateral contact. Patients were instructed to use 0.2% chlorhexidine mouthwash for 1 min twice a day for 2 weeks, to follow a soft diet for 1 month, and to avoid brushing and trauma to the surgical sites. Patients were also provided with twelve 600 mg ibuprofen tablets, or 12 tablets of 1 g paracetamol patients if allergic to NSAIDs, to be taken two to four times a day in the event of pain. Patients were recalled after 3 days to check occlusion and to assess their reported pain, swelling and intake of analgesics. They were recalled again 7 days after implant placement to recheck the occlusion, remove sutures (if required), and deliver oral hygiene instructions.

Four months after initial loading, definitive impressions were taken using a customized open impression tray (Elite LC tray, Zhermack SpA, Badia Polesine, Rovigo, Italy). Definitive ceramic (partial restorations) or composite (full-arch restorations) titanium prostheses were

screw-retained at implant or abutment level. One month after fitting of definitive prostheses, patients were recalled, occlusion and oral hygiene was checked, and the blind outcome assessor evaluated patient satisfaction. Patients were then enrolled on an oral hygiene programme, and occlusion checks were carried out at recall visits every 6 months. Blinded outcome assessors conducted follow-ups up to 10 years after initial loading.

## Outcome measures

Primary outcome measures were the following.

- Prosthesis failure: planned prosthesis which could not be placed due to implant failure(s), loss of the prosthesis secondary to implant failure(s), and any prosthesis which had to be replaced throughout the follow-up period.
- Implant failure: implants which had to be removed at implant insertion due to lack of stability, implant mobility, removal of stable implants dictated by progressive marginal bone loss or infection, and any mechanical complication (e.g., implant fracture) rendering the implant unusable. The stability of individual implants was assessed, without the prosthesis in situ, at delivery of the definitive prostheses (4 months post-loading), and at 1, 5 and 10 years after initial loading, by tightening the abutment screw with a torque of 20 Ncm.
- Any biological or prosthetic complications experienced throughout the follow-up period.

Secondary outcome measures were the following.

- Marginal bone levels: evaluated on peri-apical digital radiographs taken with the paralleling technique using a film-holder (Rinn XCP, Dentsply, Elgin, IL, USA) at implant placement and at 1, 5 and 10 years after initial loading. In cases in which the marginal bone levels around the study implants were obscured or difficult to read, a second radiograph was taken. At baseline and at the 1-year follow-up, marginal bone levels were measured using the Kodak Digital Imaging Software 6.11.7.0 (Kodak, Eastman Kodak Company, Rochester, NY, USA); at the 5- and 10-year follow-ups, DfW 2.8 image analysis software (Soredex, Tuusula, Finland) was used. The software was calibrated for every single image using the known implant diameter. Measurements of the mesial and distal bone crest level adjacent to each implant were made to the nearest 0.01 mm and averaged at patient level and group level. Reference points for the linear measurements were the most coronal margin of the implant collar and the most coronal bone-to-implant contact. The marginal bone loss was calculated as the difference between marginal bone levels.
- Number of sessions with the patient from recruitment to fitting of the definitive prosthesis.
- Days from the initial CBCT scan to implant placement.
- Patient self-reported post-surgical pain: on an ordinal scale: 0 = no pain; 1 = mild pain; 2 = moderate pain; 3 = severe pain, assessed 3 days after surgery at the postoperative check-up visit by a blinded assessor.
- Post-surgical swelling: self-reported by the patients on an ordinal scale: 0 = no swelling; 1 = mild swelling; 2 = moderate swelling; 3 = severe swelling, at the post-operative check-up 3 days after surgery by the blinded assessor.
- Intake of painkillers: how many tablets out of the 12 provided (400 mg ibuprofen, or 1 g paracetamol for those allergic to NSAIDs) had been taken, recorded 3 days after surgery at the postoperative check-up visit by the blinded assessor.
- Treatment time (in minutes), divided into:

a) surgery time: from the delivery of local anaesthesia to placement of the last abutment or suture,
b) prosthetics time: total time employed to fit and adapt the provisional fixed prosthesis, including occlusal, phonetic and aesthetic adjustments.

- Complication time: total time required to solve any complications at the clinic and in laboratory after delivery of the provisional prosthesis.
- Patient satisfaction: evaluated 1 month after delivery of the definitive prosthesis and 5 and 10 years after loading on a questionnaire provided by an independent blinded outcome assessor. The assessor asked the following questions:
  - Are you satisfied with the function of your implant-supported prosthesis? Possible answers: "yes, completely"; "yes, partially"; "not sure"; "not really"; "not at all",
  - Are you satisfied with the aesthetic outcome of your implant supported prosthesis? Possible answers: "yes, completely"; "yes, partially"; "not sure"; "not really"; "not at all",
  - Would you undergo the same treatment again? Possible answers: "yes" or "no".

Patients' comments were also recorded.

One outcome assessor (Dr Anna Vaccarella) handled all the 1-year questionnaires and the radiographic assessment. Another outcome assessor (Dr Erta Xhanari) evaluated the marginal bone levels at 5 years. At the 10-year follow-up examination, two outcome assessors evaluated patient satisfaction (FCM) and marginal bone levels (DM)

None of the outcome assessors had been previously involved in the treatment of patients in the present study, and they performed all measurements without knowing group allocation; therefore, they performed the assessment blind. Failures and complications were evaluated by the treating dentist (MT), who was therefore not blinded.

## Sample size, randomization and allocation concealment

No sample size was calculated. Five computer-generated restricted randomization lists were created. Only one of the investigators (Marco Esposito), not involved in the selection and treatment of the patients, was aware of the random sequence and could have access to the randomization lists, which were stored on a password-protected laptop computer. The random codes were enclosed in sequentially numbered, identical, opaque, sealed envelopes. Envelopes were opened sequentially after eligible patients signed the informed consent; therefore, treatment allocation was concealed to the investigators in charge of enrolling and treating the patients.

## Statistical analysis

All data analyses were carried out according to a pre-established analysis plan. A dentist with expertise in statistics (DM) analysed the data using SPSS for Windows 18.0 (SPSS, Chicago, IL, USA), without knowing the group codes. The patient was the statistical unit of the analyses. Differences in the proportion of patients with prosthesis failures, implant failures and complications (dichotomous outcomes) were compared between the groups using Fisher's exact probability test and relative risk (RR). Differences in means for continuous outcomes (bone levels, number of treatment sessions and time needed to complete the procedures) between groups were compared at patient level by independent sample t-test. Comparison of marginal bone levels between each time point and the baseline measurements were made by paired t-test. The Mann-Whitney U test was used to compare the medians of the two groups for the variables postoperative pain, swelling and patient satisfaction. All statistical comparisons were conducted at a 0.05 level of significance.

## RESULTS

Originally, 20 patients were to be recruited by each of the five different Italian private practices. However, only three centres initiated the study, and only one (Dr Marco Tallarico) followed the patients up to 10 years after loading. A total of 22 patients were originally screened at that centre, with 20 being enrolled for the trial (two patients were not included because they refused to have CBCT scans taken).

Three patients with five implants in the computer-guided group and three patients with seven implants in the freehand group dropped out of the study before the 10-year follow-up examination. Of these six patients, two (one in each group) moved to another country before the 5-year follow-up, while the other four patients were last seen at the 5-year follow-up. Three of these (two in the computer-guided group and one in the freehand group) refused to attend follow-up visits, and the remaining patient died about 6 years after definitive prosthesis delivery. After the 5-year follow-up, Dr Marco Tallarico moved his clinic to another building, which may have contributed to some drop-outs.

Hence, 14 patients with 50 implants (seven patients with 27 implants in the computer-guided group and seven patients with 23 implants in the freehand group) attended the recall 10 years after loading.

Four deviations from the original research protocol occurred, two in the freehand group and two in the computer-guided group. Specifically, one patient from the freehand group who lost one implant did not want to have it replaced and had to be rehabilitated with a prosthesis connecting the residual implant with a natural tooth. Another patient from the freehand group, who received six maxillary implants, had three of them inserted with torque lower than 35 Ncm, and they were therefore conventionally loaded after 6 months. One patient from the computer-guided group had one of the two implants placed with less than 35 Ncm insertion torque; however, it was immediately loaded anyway, with no complications. Another patient from the computer-guided group, who received three implants and a four-unit fixed prosthesis from the right upper first premolar to right upper second molar lost the right upper canine nine years after implant treatment. The definitive screw-retained implant-supported restoration was temporarily removed and replaced with a five-unit temporary fixed prosthesis with a mesial cantilever (canine). Three months later, the patient received an implant in the canine position, which was immediately loaded with the original prosthesis.

Patient and intervention characteristics at baseline are summarized in **TABLE 1**. Groups appeared balanced, with the exception of implant length, since implants in the computer-guided group appeared on average to be longer than those in the freehand group.

- Prosthesis failures. One prosthesis in the freehand group was replaced due to chipping of the veneering material. The new prosthesis was remade in zirconia bonded on a titanium bar. The difference was not statistically significant (P = 1.0).
- Implant failures. At 10-year follow-up examination, two implants had failed in two patients from the freehand group *vs.* none in the computer-guided group. The difference was not statistically significant (P = 0.4612). One maxillary implant failed in a female heavy smoker 11 days after implantation, due to an infection with suppuration. The implant was removed and the infection treated. The temporary prosthesis was modified chairside, connecting the residual implant in position 17 and tooth 15. The patient refused to have it replaced in favour of a hybrid implant-tooth supported restoration. Another implant (mandibular anterior implant) supporting a screw-retained fixed dental prosthesis fitted on four implants in a female patient failed before the 5-year follow-up examination; the prosthesis was modified to be supported by the remaining three implants. No implant failed between 5 and 10 years after loading.

**TABLE 1** BASELINE CHARACTERISTICS OF THE STUDY GROUPS

| | Computer guided group (10) | Freehand group (10) |
|---|---|---|
| Number of female patients | 4 (40%) | 6 (60%) |
| Age at insertion (range) (years) | 60.9 (28-84) | 67.2 (51-78) |
| Number of smokers | 0 | 1 heavy smoker (10%) |
| Complex cases | 4 (40%) | 4 (40%) |
| Number of fully edentulous patients | 4 (40%) | 3 (30%) |
| Number of patients treated in the mandible | 2 (20%) | 6 (60%) |
| Number of patients who had flaps raised | 3 (30%) | 6 (60%) |
| Total number of implants placed | 32 | 30 |
| Total number of post-extractive implants | 6 (18.8%) | 6 (20%) |
| Patients who received two implants | 4 (40%) | 6 (60%) |
| Patients who received three implants | 2 (20%) | 0 |
| Patients who received four implants | 3 (30%) | 3 (30%) |
| Patients who received six implants | 1 (10%) | 1 (10%) |
| Total number of mandibular implants | 6 (18.8%) | 18 (60%) |
| Implant inserted with a torque less or equal to 35 Ncm | 1 (3.1%) | 3 (10%) |
| 7 mm-long implants | 1 (3.1%) | 2 (6.7%) |
| 8.5 mm-long implants | 0 | 5 (16.7%) |
| 10 mm-long implants | 4 (12.5%) | 8 (26.7%) |
| 11.5 mm-long implants | 17 (53.1%) | 6 (20%) |
| 13 mm-long implants | 10 (31.3%) | 9 (30%) |
| 3.3 mm diameter implants | 3 (9.4%) | 3 (10%) |
| 4 mm diameter implants | 25 (78.1%) | 24 (80%) |
| 5 mm diameter implants | 4 (12.5%) | 3 (10%) |
| Implants in incisor position | 6 (18.8%) | 6 (20%) |
| Implants in canine position | 3 (9.4%) | 1 (3.3%) |
| Implants in premolar position | 14 (43.8%) | 11 (36.7%) |
| Implants in molar position | 9 (28.1%) | 12 (40%) |

- Complications. Nine patients (four in the freehand group and five in the computer-guided group) experienced ten minor complications (four in the freehand group and six in the computer-guided group). Eight complications occurred within the first year after loading. After that, only two complications were reported (one at the 5-year follow-up and one at the 10-year follow-up). All complications were successfully resolved. The difference between the groups was not statistically significant (P = 1.0; RR = 0.8; 95% CI: 0.36 to 1.77). A list of complications is reported in **TABLE 2**.
- Marginal bone levels (**TABLE 3**). All the implants were placed with the most coronal margin of the implant collar at bone level or slightly below. One year after loading, the mean marginal bone level/loss was 0.63 mm ± 0.35 (95% CI: 0.37 to 0.83 mm) in the computer-guided group and 0.85 mm ± 0.42 (95% CI: 0.68 to 1.22 mm) in the freehand group

**TABLE 2** LIST OF COMPLICATIONS

| | | |
|---|---|---|
| **Freehand group** | | |
| Patient 10 | Pain, swelling and suppuration 11 days after placement of implant 16 | Implant removal, new implant–tooth prosthesis |
| Patient 5 | Screw-loosening 25 days after implant placement | Tightened chairside |
| Patient 6 | Screw-loosening 30 days after implant placement | Tightened chairside |
| Patient 13 | Chipping of resin composite on titanium 5 years after loading | Repaired chairside |
| **Computer guided group** | | |
| Patient 11 | Pain at implant 45 seven days after placement<br>Chipping of ceramic on titanium 2 months after prosthesis delivery | Painkillers and antibiotics<br>Polished chairside |
| Patient 1 | Fracture of temporary restoration 2 months after implant placement | Repaired chairside |
| Patient 2 | Pain at implant 34 at definitive impression | 2 months of unloaded healing |
| Patient 20 | Chipping of resin composite on titanium 8 months after delivery | Polished chairside |
| Patient 17 | Chipping of resin composite on upper central incisor 9 years after loading | Repaired chairside |

**TABLE 3** MEAN PERI-IMPLANT MARGINAL BONE LEVELS/LOSS (MM) AT DIFFERENT TIME PERIODS AND BETWEEN GROUPS

| | Implant placement (n = 10) | 1 year post-loading (n = 10) | 5 years post-loading (n = 9) | 10 years post-loading (n = 7) | P-value |
|---|---|---|---|---|---|
| | Mean ± SD (95% CI) | Mean ± SD (95% CI) | | | |
| Computer-guided | 0 | 0.63±0.35 (0.37 to 0.83) | 0.87±0.40 (0.54 to 1.06) | 1.01±0.51 (0.64 to 1.39) | 0.000* |
| Freehand | 0 | 0.85±0.42 (0.68 to 1.22) | 1.29±0.31 (1.09 to 1.51) | 1.54±0.36 (1.28 to 1.81) | 0.000* |
| Difference | 0 | 0.22 (-0.13 to 0.57) | 0.42 (0.05 to 0.75) | 0.53 (0.16 to 0.89) | |
| P-value | | 0.219 | 0.024* | 0.044* | |

**Statistically significant difference*

(difference 0.22 mm; 95% CI: -0.13 to 0.57; P = 0.219). At 5 years after loading, the mean marginal bone level/loss was 0.87 ± 0.40 (95% CI: 0.54 to 1.06 mm) in the computer-guided group and 1.29 mm ± 0.31 mm (95% CI: 1.09 to 1.51 mm) in the freehand group. At 10 years, the mean marginal bone level/loss was 1.01 mm ± 0.51 (95% CI: from 0.64 to 1.39 mm) in the computer-guided group and 1.54 mm ± 0.36 (95% CI: from 1.28 to 1.81 mm) in the freehand group. The difference in bone loss between implant placement and 10-year follow-up was statistically significant (difference 0.53 mm; 95% CI: from 0.16 to 0.89; P = 0.044), with less bone loss being observed in the computer-guided group.

- Patient satisfaction. At the 10-year follow-up examination, all patients were still fully satisfied with the function and aesthetics of their definitive prostheses and would repeat the treatment again.
- All remaining outcome measures (**TABLE 4**) were presented in detail in the 1-year follow-up report[6].

**TABLE 4** OUTCOMES

| | Computer guided group | Freehand group | P-value |
|---|---|---|---|
| Patients with prosthesis failures (n = 7) | 0 | 1 | 1.0 |
| Patients with implant failures (n = 7) | 0 | 2 | 0.4615 |
| Patients with complications (n = 7) | 5 | 4 | 1.0 |
| Marginal bone loss (mm) (n = 7) | 1.01 ± 0.51 | 1.54 ± 0.36 | 0.044 |
| Sessions to definitive prostheses (n = 10) | 9.2 ± 2.9 mm | 8.1 ± 1.2 | 0.360 |
| Days from CBCT to implant placement (n = 10) | 30.3 ± 9.2 | 20.8 ± 11.7 | 0.076 |
| Postoperative pain (Median; IRQ°) (n = 10) | 0.00; 0.00 - 1.00 | 1.00; 1.00 - 1.00 | 0.037* |
| Postoperative swelling (Median; IRQ°) (n = 10) | 0.00; 0.00 - 1.00 | 1.00; 1.00 - 2.00 | 0.007* |
| Painkiller intake (n = 10) | 2.3 ± 1.16 | 3.1 ± 1.52 | 0.309 |
| Average surgical time (min) (n = 10) | 43.2 ± 29 | 41.5 ± 32.3 | 0.903 |
| Average prosthetics time (min) (n = 10) | 47.5 ± 31.6 | 46.6 ± 15 | 0.944 |
| Average complication time (min) (n = 7) | 36.7 ± 29.8 | 38 ± 31.5 | 0.412 |
| Patients fully satisfied with function (n = 7) | 7 | 7 | 1.0 |
| Patients fully satisfied with aesthetics (n = 7) | 7 | 7 | 1.0 |
| Patients who would do same treatment (n =7) | 7 | 7 | 1.0 |

*The number in parenthesis refers to the number of patients remaining in each group*
**Statistically significant*
*IRQ°: interquartile range*

## DISCUSSION

This randomized controlled trial was conducted with the aim of understanding whether there were any differences in outcome between computer-guided surgery using a surgical template and freehand implant placement, after having planned the intervention with a dedicated software on a 3D CBCT scan. The null hypothesis that there would be no differences between the two procedures was partially rejected.

Specifically, although both procedures were successful, patients receiving computer-guided surgery reported less postoperative pain and swelling. To our knowledge, this is the only randomized controlled trial comparing guided surgery *versus* freehand surgery with 10-year follow-up. However, the outcomes of both groups are in line with the results of previously published medium-long-term studies, from the same research group[12,13]. The data does, however, contrast with that from another randomized controlled trial comparing patient-reported outcomes and experiences using conventional freehand *versus* dynamic computer-assisted implant surgery and static computer-assisted implant surgery[14]. In that study, similar post-operative levels of patient satisfaction, analgesic intake, swelling and pain were reported for each procedure. However, patient selection also included patients with simultaneous guided bone regeneration[14].

Although the difference found between groups regarding implant failure was not statistically significant, it was interesting to observe that implant failure occurred only in the freehand group with none in the computer-guided group. A possible explanation could be that, although implant placement was previously planned using dedicated software in both groups, insertion was performed either freehand or using a surgical template. Using a surgical guide may have reduced the risk of implant failure due to more accurate three-dimensional and prosthetically driven implant placement[15,16].

In addition, 0.5 mm less marginal bone loss was observed in the computer-guided group. The same consideration could be made regarding the expected amount of bone resorption. In the present study, during the 5- and 10-year follow-ups, the patients in the computer-guided group experienced significantly less marginal bone loss than patients in the freehand group[4]. However, a possible explanation for the difference in peri-implant bone loss could be that four out of seven patients in the computer-guided group were treated with a flapless approach *versus* none in the conventional group.

The main limitation of the present study is the limited number of participants. Unfortunately, only one of the centres initially involved followed the patients for ten years. Nevertheless, it is likely that the results of this trial can be generalised to other patients with similar characteristics.

## CONCLUSIONS

Within the limitations of this study, mainly the very low sample size, both approaches yielded positive outcomes over the 10-year follow-up period. However, post-operative pain and swelling were statistically higher in the freehand-treated sites, and less marginal bone loss (0.5 mm) was observed in the computer-guided group at 10-year follow-up.

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