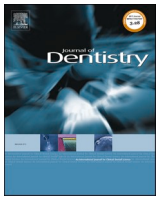
Journal of Dentistry 130 (2023) 104443

Contents lists available at ScienceDirect

Journal of Dentistry

journal homepage: www.elsevier.com/locate/jdent



Dynamic and static computer-assisted implant surgery for completely edentulous patients. A proof of a concept

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ARTICLE INFO

Keywords:
Dental implants
Surgical navigation systems
Computer-assisted surgery
Implant-supported dental posthesis
Jaw Edentulous
Fully edentulous

ABSTRACT

Objectives: To assess the accuracy and patient reported outcome measures (PROMs) of the computer-guided "double factor" technique for treating fully edentulous patients.
Methods: A proof of concept prospective study was designed. Ten consecutive patients requiring full arch dental implant supported rehabilitation in a private practice were enrolled between October 2021 and March 2022. All patients were treated by means of an All-on-four®, and implants were planned and placed according to the "double factor" technique. This technique merges the static and dynamic computer-guided surgical approach in the same surgery. The primary outcome was the accuracy of implant placement, measured by overlapping post- and pre-operative cone-beam computerized tomography with the implant planning. Additionally, PROMs and patient quality of life after surgery were evaluated using different questionnaires. Descriptive and bivariate data analyses were performed. Statistical significance was considered for $p < 0.05$.
Results: A total of 48 implants were placed using the "double factor" technique, and 12 full-arch immediate loading prostheses were delivered. The mean angular deviation was 3.74° (standard deviation [SD]: 2). The total linear deviation at the apex and platform of the implant was 1.25 mm (SD: 0.55) and 1.42 mm (SD: 0.64), respectively. No statistically significant differences were found between tilted and axial implants, the upper and lower jaw, or the right and left side. High self-reported satisfaction was registered, and the Oral Health Impact Profile-14 (OHIP-14) score improved postoperatively ($p = 0.002$).
Conclusions: The "double factor" technique is a valid and accurate treatment approach for fully edentulous patients.
Clinical significance: The double factor technique merges the advantages of both the dynamic and static computer assisted surgery approaches, affording accurate and predictable results when treating fully edentulous patients in a minimally invasive manner.

1. Introduction

Research in dental implants has grown significantly, and clinicians tend to focus their attention on implant success, aesthetics and biological and mechanical complications, since high implant survival rates have been achieved [1]. The final position of the dental implant is of utmost importance for treatment success, and clinicians should seek a prosthetically driven position of the implant [2,3]. Additionally, an adequate implant position may reduce the number of biological and mechanical complications, such as peri-implant diseases, screw loosening or esthetic issues [4].

On the other hand, the concept of minimally invasive surgery has gained hold in implantology, seeking to reduce morbidity and improve the patient-reported outcome measures (PROMs) and patient quality of life (QoL) after surgery. In this respect, techniques such as flapless approaches or immediate loading protocols are now popular [5,6]. Such interest led to the development of computer-assisted surgery (CAS) to facilitate implant placement and posterior adaptation of the provisional or definitive prosthesis [7].

Computer-assisted surgery allows us to perform an accurate preoperative analysis of the patient using planning software. Hard and soft tissues scans are entered in the software application, and implant

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https://doi.org/10.1016/j.jdent.2023.104443
Received 28 November 2022; Received in revised form 24 January 2023; Accepted 26 January 2023
Available online 28 January 2023

planning can be done following the patient anatomy and the position of the virtual wax-up [8].

Two CAS approaches have been established: "static CAS", based on surgical stents that reproduce the virtual implant position; and "dynamic CAS", also known as navigation systems, consisting of a tracking system that guides the clinician in real time to the predefined implant position, giving the relative position of the drill and patient during surgery, and providing immediate feedback when inaccuracies are detected [8,9].

When dealing with fully edentulous patients, several aspects and limitations must be considered. On one hand, the lack of teeth and reference points hinders overlapping of the hard and soft tissue scans, and also hinders fixation and stabilization of the stent [8,10]. On the other hand, in the dynamic CAS approach, the lack of reference points hinders registration of the patient, and the protocols proposed by the manufacturers are invasive and time-consuming [11,12].

In view of the above, and to overcome the limitations of the current dynamic CAS protocols in fully edentulous patients while combining the advantages of dynamic and static CAS, a new approach has been developed, referred to as the "double factor" technique [13]. The aim of the present study was to assess the accuracy and demonstrate the benefits of the "double factor" technique in treating fully edentulous patients.

2. Materials and methods

The present study was designed as a single-arm prospective clinical trial. The article abides with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement [14]. In addition, the study protocol was approved by the Institutional Review Board of Alicante University General Hospital (Alicante, Spain) (Ref.: ISABIAL: 2021–0369) and has been registered in ClinicalTrials.gov with the identifier NCT05512845. All patients were previously informed of the study design, objective, possible benefits and complications, and written informed consent was obtained from all subjects prior to their inclusion in the study. The study was conducted at a private clinic (Clinica Perio&Implant, Alicante, Spain) between October 2021 and March 2022.

2.1. Participants

All consecutive patients treated with full arch implant-supported prostheses based on the All-on-four® concept were included in the trial. All implants were placed using the "double factor" CAS technique, which involves combining the static and dynamic CAS protocols in the same surgery [13].

The inclusion criteria was patients with edentulous lower or upper jaws, or with hopeless teeth, in need for fixed implant-supported rehabilitation. Additionally, the patients were required to be 18 years old or older, classified as ASA I and II according to the American Society of Anesthesiologists [15], and with an interarch space of at least 10 mm, measured as the vertical distance between the edentulous ridge and the occlusal or incisal aspect of the opposing arch. Patients requesting an implant-supported removable prosthesis or a full-arch metal-ceramic prosthesis were excluded.

Sample size calculation was done from the website https://sample-size.net. The results of a previous study using dynamic navigation systems in fully edentulous patients were used as reference [16]. Using angular deviation as a primary outcome, a desired 95% confidence interval (95%CI) width of 0.6°, and assuming a standard deviation (SD) of 0.983° [16], the calculation showed that 41 implants were needed [17]. Since all patients were treated with four implants, a minimum of 44 implants were considered, with the addition of one more patient to compensate for possible dropouts during the study.

2.2. Description of the "double factor" technique

An accurate preoperative study of the patient should be performed, with a wax-up of the final full arch prostheses. Then, a radiographic stent is designed following the wax-up, with the introduction of special fiducial markers to be recognized by the dynamic and static CAS software. Digital Imaging and Communications in Medicine (DICOM) data are imported to the planning software, and the dental implants are located in a prosthetically driven manner. Then, a surgical stent is designed and printed following implant planning, and adding the fiducial markers needed to be detected by the dynamic CAS system. In case the fiducial markers hinder positioning of the guiding sleeve, a removable piece with the fiducial markers should be designed and printed. Finally, after calibrating the dynamic CAS system, the surgical procedure is carried out following a fully guided approach though the surgical guided stent and with real-time feedback from the dynamic CAS system. The "double factor" technique workflow is summarized in Fig. 1. A detailed description of the technique and surgical protocol is available in a previous report published by Pomares-Puig et al. [13].

2.3. Intervention

All surgical treatments were performed by the same surgeon (C.P-P) under local anesthesia. Preoperatively, all patients received oral hygiene instructions, with nonsurgical prophylaxis if needed, and smokers were advised to reduce or stop smoking entirely.

During the preoperative planning phase, a cone-beam computed tomography (CBCT) scan with a radiological stent using specific radiographic markers was performed following the double-scan protocol. Then, implant positioning was established using DTX Studio Implant planning software (Nobel Biocare AB, Gothenburg, Sweden), and a surgical stent was printed with the radiological markers needed by the dynamic computer-guided software to recognize the patient position.

Before surgery, local anesthesia was administrated in the form of 4% articaine with epinephrine 1:100,000 (Artinibsa 4%, 1:100,000, Laboratorios Inibsa S.A., Lliça de Vall, Spain) using a supraperiosteal infiltration technique. In the case of any remaining teeth or implants, these were extracted prior to guided surgery. Optical markers for dynamic computer-guided surgery were firmly attached to the surgical stent and handpiece. Then registration was done, and the X-guide software automatically detected the optical marker attached to the stent and the three radiopaque radiographic markers on the surgical stent. Finally once registration was made, the surgical stent was positioned on the patient's jaw using a maxillomandibular relationship record, and fixed with pins. During surgery, the drill axis was calibrated with a special bur, and when using each drill, the length of the drill was previously calibrated.

All implants placed were Nobel Parallel or Nobel Active TiUnit implants (Nobel Biocare AB, Gothenburg, Sweden), depending on the bone density. Implants were placed using a flapless approach following the static CAS surgical guide and the real time dynamic CAS feedback from the X-Guide® navigation system (X-Nav Technologies, LLC, Lansdale, PA, USA). All implants were required to achieve a minimum insertion torque of 35 Ncm to be eligible for an immediate loading protocol. Multi-unit abutments were placed on the implants, and height and angulation were preoperatively planned according to the mucosal thickness and implant angulation. If regeneration was needed, a small flap was raised to restore the bone architecture with autologous bone, Creos™ Xenogain xenograft and a Creos™ Xenoprotect collagen membrane (Nobel Biocare AB, Gothenburg, Sweden).

Lastly, impression copings were attached to the multi-unit abutments and an open tray implant impression with poly-vinyl siloxane silicone was done to prepare the immediate loaded prosthesis. Then, a prefabricated acrylic provisional prosthesis without distal cantilever was adapted to the implant position, and provisional abutments were cemented. Additionally, the prosthesis design was established considering the maintenance of ideal oral hygiene, and avoiding concave

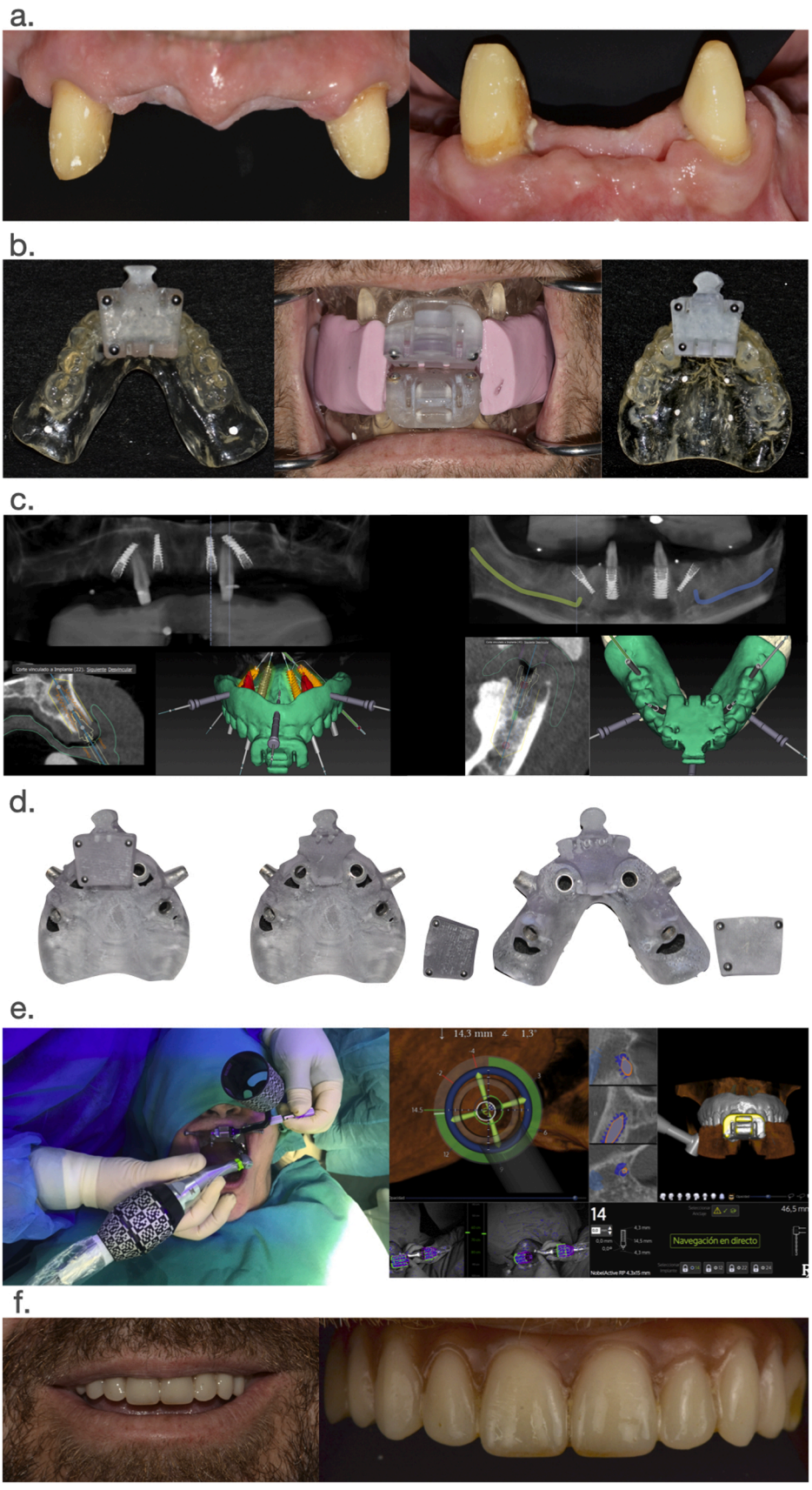

Fig. 1. The "double factor" technique workflow. (a) Preoperative study with intraoral photographs and diagnostic casts for diagnostic waxing. (b) Radiographic stents designed from the diagnostic waxing with the desired tooth positions and fiducial radiopaque spheres and markers. Stents were positioned for a cone-beam computed tomography scan using a maxillomandibular relationship record. (c) Virtual planning software program showing bone anatomy with required tooth positions and virtually planned dental implants in an ideal prosthetically-driven position. Based on this virtual implant position plan, a surgical stent is designed with the software. (d) 3D printed surgical stent with the radiopaque fiducial markers for the dynamic navigation system. (e) Implant placement surgical procedure using the double-factor technique following a fully guided approach though the surgical stent and the dynamic CAS system. (f) Postoperative records with functional immediate loaded prosthesis.

retentive spaces or vestibular acrylic flaps. Approximately two hours later, the screw retained immediate-loaded prosthesis was delivered to the patient. A passive fit was one of the main requirements, and was carefully assessed. Finally, occlusion was adjusted to avoid premature contacts or interferences that could overload the implants.

The patients were instructed to take dexketoprofen 25 mg every 8 h for three days, paracetamol 1 g every 8 h as rescue analgesia, and amoxicillin + clavulanic acid 500/125 mg or 875/125 mg (depending on patient body weight) every 8 h for 7 days. A 0.12% chlorhexidine mouthrinse was also prescribed (15 ml every 12 h for 10 days).

The patients were evaluated 7 days postoperatively. A panoramic X-ray study and clinical evaluation of soft tissue healing were made. Additionally, occlusal stability was reassessed and readjusted if necessary. Where needed, the prosthesis was removed to clean or check the peri-implant soft tissues. Any placed sutures were removed.

2.4. Variables and outcome assessments

Data collection was divided into three categories: patient descriptive variables, accuracy variables and PROMs. Patient data included: age, gender, smoking habit, medical background, mouth opening and implant data (implant location, size, tilted or straight, and need for regeneration or not).

Accuracy variables were obtained by overlapping the preoperative CBCT scan with the virtual implant planning using a postoperative CBCT scan with the implants placed. The postoperative CBCT scan was done after dental implant placement, before placing the multi-unit abutments.

Overlapping was performed by a third independent clinician (A.J-G) using EvaluNav software (ClaroNav, Toronto, Ontario, Canada). This software automatically detects the actual implant position on the postoperative CBCT and automatically calculates the deviations, thereby reducing any possible source of bias during the outcomes assessment.

The assessed variables were:

- Platform 3 dimensions (3D) deviation (in mm): global deviation at the entry point of the dental implant measured in the three spatial dimensions.
- Platform 2 dimensions (2D) deviation (in mm): horizontal deviation of the dental implant at the entry point from an occlusal view without considering depth deviation.
- Apex 3D deviation (in mm): global deviation at the apex of the dental implant measured in the three spatial dimensions.
- Apex depth deviation (in mm): depth or vertical deviation of the apex of the dental implant
- Angular deviation (in degrees): angular deviation between the two axes of the implants.

Lastly, PROMs were evaluated using different questionnaires. Patient wellbeing during the surgical procedure was evaluated by means of a questionnaire answered immediately after surgery. This questionnaire was specially designed for this trial (Table 5). Questions could be answered with 5 possible answers: absolutely disagree, disagree, neutral, agree, absolutely agree (Likert scale). Answers were rated with a score between −2 and 2, according to whether positive or negative. Furthermore, the OHIP-14sp [18] was answered by the patient preoperatively and 7 days postoperatively with the functional immediate loaded prosthesis placed. Lastly, during the first 7 postoperative days, the patients were asked to register the intake of all analgesic and anti-inflammatory medication, and to record postoperative pain using a 100-mm visual analog scale (VAS) every day.

2.5. Statistical analysis

The statistical analyses were made using the STATA 14 package (StataCorp, College Station, TX, USA). Normal data distribution was assessed with the Shapiro-Wilks test and P-P graph. For accuracy data, normality was accepted, but normality could not be assumed in the case of the PROMs.

Accuracy data were displayed using the mean and standard deviation

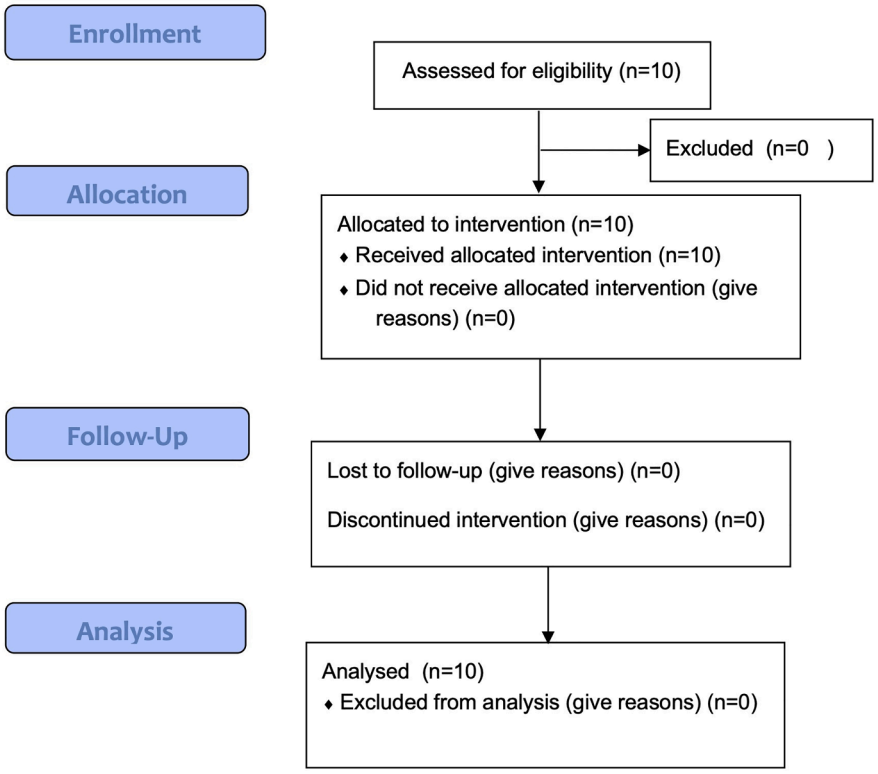

Fig. 2. Patient flowchart.

Table 1
Summary of patient descriptive data.

ID	Age (years)	Gender	Smoking habit	ASA score	Mouth opening	Preoperative status	Arch	Implants	Insertion torque (Ncm)	Surgical technique
1	64	F	No	I	40mm	Edentulous (implants with peri-implantitis)	Maxilla	1.4: Nobel active 4.3 × 15 mm 1.2: Nobel active 4.3 × 15 mm 2.2: Nobel active 4.3 × 15 mm 1.4: Nobel active 4.3 × 15mm	35 Ncm 35 Ncm 35 Ncm 35 Ncm	Flapless
2	75	F	No (ex-smoker)	II	50mm	Pre-edentulous (only canines)	Maxilla	1.4: Nobel Parallel 4.3 × 15 mm 1.2: Nobel Parallel 3.75 × 13 mm 2.2: Nobel Parallel 3.75 × 13 mm 2.4: Nobel Parallel 4.3 × 13mm	50Ncm 30Ncm 50Ncm 50Ncm	Flapless
3	66	M	5 cig/day	I	38mm	Pre-edentulous (only canines)	Mandible	3.4: Nobel active 4.3 × 15 mm 3.2: Nobel active 4.3 × 15 mm 4.2: Nobel active 4.3 × 15 mm 4.4: Nobel active 4.3 × 15mm	50Ncm 50Ncm 50Ncm 50Ncm	Flapless
4	59	M	No (ex-smoker)	I	42mm	Pre-edentulous (only canines)	Maxilla and mandible	1.4: Nobel active 4.3 × 15 mm 1.2: Nobel active 4.3 × 15 mm 2.2: Nobel active 4.3 × 15 mm 1.4: Nobel active 4.3 × 15 mm 3.4: Nobel active 4.3 × 15 mm 3.2: Nobel active 4.3 × 15 mm 4.2: Nobel active 4.3 × 15 mm 4.4: Nobel active 4.3 × 15mm	50Ncm 50Ncm 50Ncm 50Ncm 50Ncm 50Ncm 50Ncm 50Ncm	Flapless
5	63	M	No	I	40mm	Pre-edentulous (only canines)	Maxilla	1.4: Nobel active 4.3 × 15 mm 1.2: Nobel active 4.3 × 15 mm 2.2: Nobel active 4.3 × 15 mm 1.4: Nobel active 4.3 × 15mm	50Ncm 50Ncm 50Ncm 50Ncm	Flapless
6	53	M	No (ex-smoker)	I	40mm	Edentulous (implants with periimplantitis)	Mandible	3.4: Nobel Parallel 4.3 × 10 mm 3.2: Nobel Parallel 4.3 × 15 mm 4.2: Nobel Parallel 3.75 × 13 mm 4.4: Nobel Parallel 4.3 × 10mm	50Ncm 50Ncm 50Ncm 50Ncm	Flapless
7	40	M	20 cig /day	I	42mm	Pre-edentulous (only canines)	Maxilla	1.4: Nobel active 4.3 × 15 mm 1.2: Nobel active 4.3 × 15 mm 2.2: Nobel active 4.3 × 15 mm 1.4: Nobel active 4.3 × 15mm	50Ncm 50Ncm 50Ncm 50Ncm	Flapless
8	47	F	20 cig /day	I	40mm	Pre-edentulous (only canines)	Maxilla	1.4: Nobel active 4.3 × 15 mm 1.2: Nobel active 4.3 × 15 mm 2.2: Nobel active 4.3 × 15 mm 1.4: Nobel active 4.3 × 15mm	50Ncm 50Ncm 50Ncm 50Ncm	Flapless
9	56	M	No	I	40 mm	Pre-edentulous (only canines)	Maxilla and mandible	1.4: Nobel active 4.3 × 15 mm 1.2: Nobel active 4.3 × 15 mm 2.2: Nobel active 4.3 × 15 mm 1.4: Nobel active 4.3 × 15 mm 3.4: Nobel active 4.3 × 15 mm 3.2: Nobel active 4.3 × 15 mm 4.2: Nobel active 4.3 × 15 mm 4.4: Nobel active 4.3 × 15mm	50Ncm 50Ncm 50Ncm 50Ncm 50Ncm 50Ncm 50Ncm 50Ncm	Flapless
10	43	M	No	I	42 mm	Pre-edentulous (only canines)	Maxilla	1.4: Nobel active 4.3 × 15 mm 1.2: Nobel active 4.3 × 13 mm 2.2: Nobel active 4.3 × 13 mm 1.4: Nobel active 4.3 × 15mm	50Ncm 50Ncm 50Ncm 50Ncm	Flapless

F: Female; M: Male; ASA: American Society of Anesthesiologists physical status classification system; mm: millimeters; Ncm (Newton-centimeter).

Table 2
Summary of accuracy outcomes.

	Mean (N = 48)	Standard deviation	95% confidence interval
Angulation (in °)	3.74	2	[3.15 - 4.32]
Platform 3D (in mm)	1.25	0.55	[1.09 - 1.41]
Platform 2D (in mm)	0.97	0.53	[0.82 - 1.13]
Apex 3D (in mm)	1.42	0.64	[1.23 - 1.61]
Apex depth (in mm)	0.61	0.46	[0.47 - 0.74]

2D: 2 dimensions; 3D: 3 dimensions.

(SD), and the Student *t*-test was used to assess possible relationships between accuracy and other variables (i.e., straight and tilted implants, right or left side, upper or lower jaw). Box plots for each variable were generated to illustrate the results. The data referred to PROMs were displayed using the median and interquartile range (IQR), with frequency tables and plots. Possible relationships between the pre- and postoperative OHIP-14 results were explored using the Mann-Whitney *U* test. Statistical significance was considered for $p<0.05$ in all tests.

3. Results

A total of 10 patients were enrolled in the study (7 males and 3 females), with a mean age of 56.6 (11.02) years (Fig. 2). Twelve arches were treated, since two patients received bimaxillary treatment. All patients had a history of periodontal disease, and 8 of the 10 subjects had remaining hopeless teeth in the arch. Descriptive data of the included patients are summarized in Table 1.

All patients received full arch implant supported prostheses by means of the All-on-four® concept. A total of 48 implants were thus placed (38 Nobel Active and 8 Nobel Parallel; Nobel Biocare AB, Gothenburg, Sweden), with a diameter of 3.75 mm or 4.3 mm and a length of between 10 mm and 15 mm. All implants reached the required primary stability and received immediate loading prostheses. The mean surgical time was 43.6 (14.2) minutes.

3.1. Accuracy results

A total of 10 postoperative CBCT scans were overlapped with the preoperative planning, and accuracy of the 48 implants was calculated.

Table 3
Summary of accuracy outcomes comparing the upper and lower jaw.

	Upper jaw (n = 32) Mean (SD)	Lower jaw (n = 16) Mean (SD)	P-value
Angulation (in °)	3.78 (2.15)	3.64 (1.73)	0.822
Platform 3D (in mm)	1.18 (0.46)	1.39 (0.69)	0.212
Platform 2D (in mm)	0.89 (0.44)	1.14 (0.66)	0.129
Apex 3D (in mm)	1.29 (0.59)	1.67 (0.68)	0.054
Apex depth (in mm)	0.59 (0.42)	0.64 (0.54)	0.640

2D: 2 dimensions; 3D: 3 dimensions; SD: standard deviation.

The results yielded a mean angular deviation of 3.74° (SD: 2) and a linear 3D deviation of the platform and apex of the implant of 1.25 mm (SD: 0.55) and 1.42 mm (SD: 0.64), respectively (Table 2 and Fig. 3). Although the implants placed in the upper jaw were slightly more accurate, especially at the apex of the implant, no statistically differences were detected between implants placed in the upper and lower jaw (Table 3). Likewise, regarding implant position, no differences were detected between axial (mesial) and tilted (distal) implants (Supplementary Tables 1 and 2).

3.2. PROMs results

Patient satisfaction after the surgical procedure was evaluated by means of the VAS, and a high degree of satisfaction with the treatment was observed, with a score of 92.08 (4.44). Additionally, the self-reported satisfaction responses showed all patients to be very satisfied with the treatment. However, during 5 surgeries (44.67%), patients found it difficult to keep the mouth open during the entire surgical procedure. Interestingly, all patients considered that CAS significantly improved the outcomes and accuracy of the surgical procedure (Table 4). In addition, the OHIP-14 scores improved significantly between the two timepoints (mean difference [MD] = 13.83; 95%CI: 6.82 to 20.83; p = 0.002). The median overall postoperative OHIP-14 score was 4 (5.5).

With regard to postoperative pain, the peak in pain intensity was reached at three hours postoperatively, and then decreased to postoperative day four, when the VAS pain score was seen to be almost negligible. Median analgesic medication use was between 2 and 3 doses during the first 5 days (Table 5 and Figs. 4 and 5).

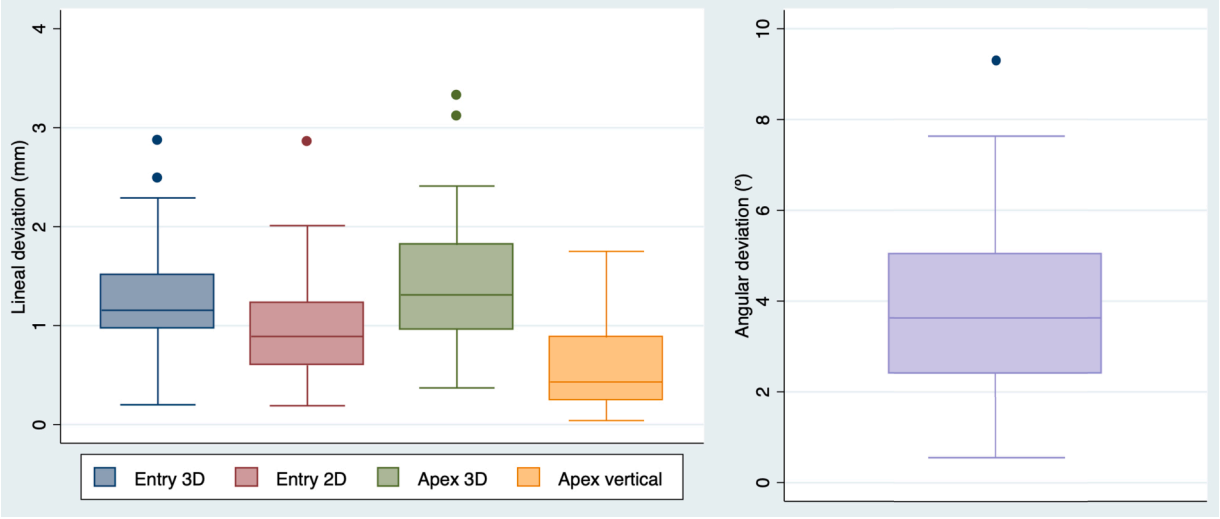

Fig. 3. Box plots for accuracy variables.
2D: 2 dimensions; 3D: 3 dimensions; mm: millimeters; °: degrees.

Table 4
Summary of patient perception and experience during surgery.

	Positive rating (%)	Neutral (%)	Negative rating (%)
1. The duration of surgery was acceptable	12 (100%)	0 (0%)	0 (0%)
2. The presence of liquid in the mouth was uncomfortable	10 (83.3%)	2 (16.6%)	0 (0%)
3. The presence of instruments and devices was uncomfortable	9 (75%)	2 (16.6%)	1 (8.33%)
4. It was easy to keep the mouth open during surgery	5 (41.67%)	2 (16.6%)	5 (41.67%)
5. The vibration produced during surgery was uncomfortable	9 (75%)	2 (16.6%)	1(8.33%)
6. If you need to choose, would you repeat the procedure?	12 (100%)	0 (0%)	0 (0%)
7. Would you recommend this procedure to your family/friends?	12 (100%)	0 (0%)	0 (0%)
8. You consider that placing a dental implant using computer-guided surgery enhances the accuracy and results of the procedure	12 (100%)	0 (0%)	0 (0%)
Intraoperative pain (VAS scale)	11.91 (9.63)		
Satisfaction (VAS scale)	92.08 (4.44)		

VAS: visual analog scale.

Table 5
Summary of postoperative pain (visual analog scale) and analgesic medication use.

	Day 0 (3 h)	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Postoperative pain (VAS) Median (IQR)	35.5 (25.5)	26.5 (23)	20 (22.5)	10 (31.5)	1.5 (9)	0 (4)	0 (1.5)	0 (0)
Use of analgesic medication Median (IQR)	2 (2)	3 (1)	3 (0.5)	3 (1)	2 (2)	0 0.5 (1.5)	0 (1.5)	–

VAS: visual analog scale; IQR: interquartile range.

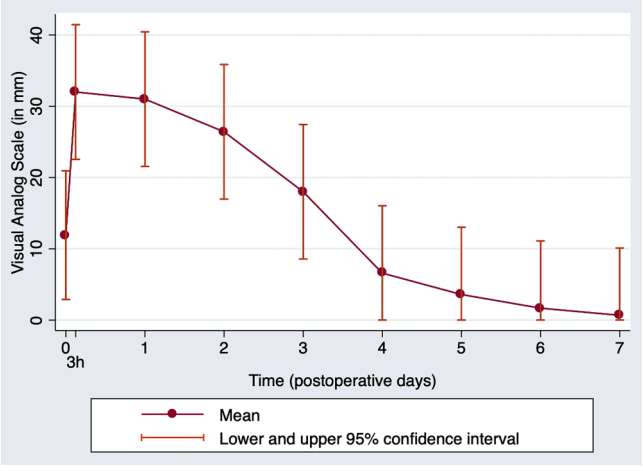

Fig. 4. Evolution of postoperative pain.

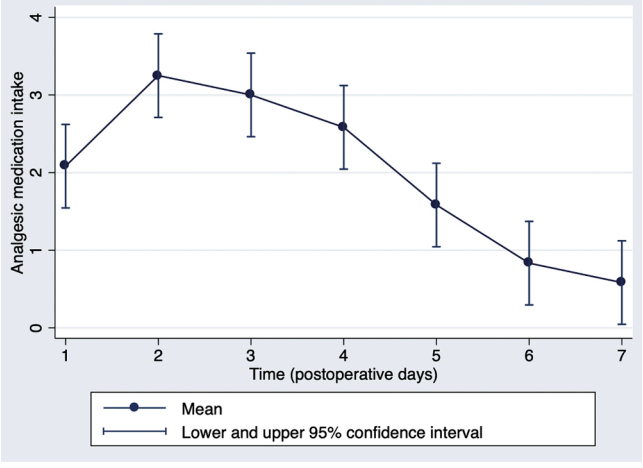

Fig. 5. Postoperative analgesic medication use.

4. Discussion

The present study aimed to validate and support a novel computer-guided technique for the treatment of fully edentulous patients. The results obtained constitute the first reported data validating the "double factor" technique, and this computer-guided procedure appears to be predictable and accurate in treating fully edentulous patients using both the static and dynamic CAS approaches. The main advantages of the technique lie in the double guidance protocol through the stent and navigation system, and the possibility of detecting any inaccuracy during surgery in real time, and of solving it thanks to the dynamic CAS system.

The present study has limitations, such as the fact that it is a single arm study without a control group; hence, no comparisons could be made with other CAS techniques or the freehand approach. Moreover, only 10 patients involving 48 dental implants placed with this technique were included in the study. No accuracy data on this technique were available before the present study, and considering the results obtained, further research is needed to validate the reliability and accuracy of the procedure and to compare it in randomized clinical trials versus the conventional static and dynamic CAS protocols, with a view to establishing recommendations for clinical practice.

We included both edentulous and pre-edentulous patients with only two remaining hopeless teeth. The "double factor" technique is suitable for both clinical situations, and in patients with hopeless remaining teeth, clinicians should perform teeth segmentation with the planning software before designing the surgical stent, with extraction of the teeth before placing the stent. Additionally, the protocol could be adapted to other clinical situations such as full arch ceramic or zirconia rehabilitations on more than four implants, where implant position and emergence are critical for achieving optimal esthetic outcomes.

Historically, CAS implant treatments have been evaluated in terms of accuracy of implant placement and radiological and clinical parameters. Nevertheless, nowadays there is a tendency to evaluate treatments based on patient perception and self-reported satisfaction and wellbeing [19–22]. Different psychometric tests can be used to evaluate self-reported functional limitation, discomfort and disability attributed to oral conditions, such as the Oral Health Impact Profile (OHIP) [18] used in our study. All these questionnaires are subjective, but are useful for assessing treatment outcomes and patient perception of the treatment received [23]. Unfortunately, no evaluation of these subjective

parameters has been made in most of the recently published CAS studies in implantology. In this regard, Joda et al. [24], in a recent systematic review, failed to draw any conclusions on this topic, due to the small number of identified studies that investigated CAS in terms of PROMs, while a recent randomized trial and a review suggest that CAS alone does not appear to improve PROMs, quality of life or patient experience during and after surgery [25,26].

The literature on CAS has grown in recent years, and it is a well-established approach for securing highly accurate implant placement in a minimally invasive manner. Static CAS has been widely tested in different clinical scenarios, even in fully edentulous patients [27]. In contrast, the available literature on dynamic CAS is limited and, although several publications have demonstrated its great accuracy, the validity of these systems in treating fully edentulous patients has not been clearly established. The results obtained in our study are consistent with the findings of different systematic reviews on static CAS [27–28], and evidence an increased deviation of only 1° and of less than 0.5 mm with respect to a meta-analysis on dynamic CAS in which most of the studies involved partially edentulous patients [29].

A recent controlled clinical trial compared the accuracy of implants placed in fully edentulous patients using dynamic CAS, static CAS and a freehand approach [30]. Interestingly, although all the deviations reported using CAS were greater than in studies treating partially edentulous patients, both CAS approaches significantly increased accuracy when compared with freehand implant placement - the most accurate method being the static CAS approach. In fact, the deviations reported in the mentioned trial were greater than those obtained in our study using the "double factor" technique. An angular deviation of 4.98° (2.16°) was reported in the static CAS group, versus 5.75° (2.09°) in the dynamic CAS group.

Two case series [11,16] treated fully edentulous patients using Navident® (ClaroNav, Toronto, Ontario, Canada), a dynamic CAS system, reporting highly accurate results comparable to those obtained with single-site implant placement. Nevertheless, the authors failed to evaluate surgical time, PROMs and quality of life during and after the surgical and prosthetic procedures. In our experience, surgical time is greatly increased when using navigation systems, as reported by different authors [31,32]. This extended time could be irrelevant in single edentulism cases. However, when dealing with fully edentulous patients, it could have a significant impact upon patient perception and wellbeing during surgery. In fact, a recent review pointed out that the use of CAS in itself does not seem to affect PROMs or patient experience during surgery, but it facilitates the use of flapless approaches or immediacy protocols, which indirectly improves the abovementioned parameters [25]. With the "double factor" technique, we could reduce surgery time to about 30 min, with high patient self-reported wellbeing and satisfaction during the surgical procedure. Indeed, postoperatively, all the patients considered that the duration of surgery was acceptable.

Pozzi et al. [33] recently published a prospective case series involving the treatment of fully edentulous patients using a dynamic CAS approach. They designed a fully digital protocol that combines DICOM images, intraoral and extraoral optical surface scans, a smiling scan, and a designed virtual complete-arch wax-up. All these data allowed prosthetic-driven implant placement and immediate delivery of the immediate loading prostheses. During registration of the dynamic CAS system, they placed microscrews as fiducials. In our opinion, this approach is more invasive than the technique described in the present study, since no microscrews (between 4 and 6 mm in length) were needed, and only 2–3 pins had to be placed during the surgical procedure to stabilize the surgical stent. Although both techniques need additional bone perforations, with the dynamic CAS protocol the screws have to be placed before the CBCT scan, adding an additional surgery, while in the "double factor" technique the perforations for the anchor pins are performed during dental implant surgery.

The main source of inaccuracies with this technique is mispositioning of the stents during any step of the presurgical and surgical procedure. It is essential to place all the stents in the same exact position at each step; hence, an accurate maxillomandibular relationship record must be obtained during the presurgical phase and used to correctly stabilize the surgical stent during surgery. To ensure correct positioning of the stent during surgery, periodic checks using the dynamic CAS system should be made, moving one step back in the event an inaccuracy is detected. In bimaxillary cases, it should be taken into account that prosthetic components or swelling and edema of the first treated jaw could hinder correct positioning of the stents with the maxillomandibular relationship record for the other jaw. Special attention is required in this respect, since it is the most sensitive step of the technique.

Interestingly, the only complaint in some patients was difficulty in keeping the mouth opened during the surgical procedure. Mouth opening is an important factor when planning static CAS, because there must be enough opening range to be able to introduce the surgical stent and the guided drill, which is usually longer than a conventional implant bur. Additionally, the All-on-four® concept places two posterior distally tilted implants, to take advantage of the available bone and avoid complex bone reconstructions [34]; hence when using surgical stents, mouth opening should be sufficient to introduce these tilted implants though the sleeves. Malo et al. [35] considered a minimum of 50 mm of mouth opening in order to regard the patient as amenable to treatment using guided surgery, while Pomares [36] reduced the minimum to 40 mm. In the present study, we included patients with a mouth opening of under 40 mm, and only one patient had an opening of 50 mm. In this regard, the reported discomfort due to mouth opening could be reduced by preoperatively evaluating and selecting the patients. Nevertheless, the authors consider that a minimum of 40 mm is enough to treat edentulous patients with static CAS.

In this study we used a partially digital workflow, and a preliminary analogical impression with polyvinyl siloxane silicone was made to obtain the study model casts, while an analogical mock-up was made by the laboratory to check all the occlusal and esthetic parameters. A recent study compared a partially and fully digital workflow in implantology, and the results showed the patients to be more comfortable in a fully digital workflow, with a considerably shorter time required (17–21 min versus 148–151 min) [37]. The authors consider that these poorer results regarding PROMs are probably due to the conventional impression technique, causing gag reflex, discomfort and even pain in some patients. The PROMs findings of the present clinical trial could be improved by adapting the actual workflow to a fully digital protocol, but there are some limitations when treating fully edentulous patients in the context of a fully digital workflow [33,38,39] On the other hand, a fully digital workflow could slightly increase implant placement accuracy when compared to a partially digital workflow [38,40].

In our opinion, this technique could be especially indicated in medically compromised patients, such as osteoporotic individuals or patients with type 1 diabetes, since we can perform a minimally invasive technique without raising a flap, reduce the surgery time and take advantage of the remaining bone to avoid complex bone regenerations by accurately planning the ideal implant position [34,41,42]. Furthermore, from an ergonomic point of view, the surgeon watches the dynamic CAS monitor during surgery, keeping his or her head away from the patient's mouth and thus reducing the risk of blood or saliva contamination. This aspect is of special interest in the context of the COVID-19 pandemic in order to reduce the risk of infection, since imperceptible blood or saliva spattering easily occurs during surgical procedures [43,44].

Conclusions

Within the limitations of the present study, it can be concluded that the "double factor" technique, which combines the static and dynamic CAS approaches, could be a valid and accurate approach for the treatment of fully edentulous patients. In addition, the "double factor"

technique is associated with high patient-reported satisfaction, and increases patient quality of life after surgery.

Funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

CRediT authorship contribution statement

Carmen Pomares-Puig: Conceptualization, Software, Validation, Investigation, Resources, Visualization, Writing – review & editing. **M. Angeles Sánchez-Garcés:** Methodology, Writing – review & editing, Visualization, Supervision. **Adrià Jorba-García:** Methodology, Investigation, Data curation, Writing – original draft, Visualization.

Declaration of Competing Interest

The authors declare no grants, personal fees or non-financial support in relation to this study. Dr. Carmen Pomares-Puig holds the intellectual property rights to the double factor technique.

Acknowledgments

The authors wish to thank Joe Perkins for English-language editing assistance.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.jdent.2023.104443.

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