Received: 27 November 2022 | Revised: 29 January 2023 | Accepted: 30 January 2023

DOI: 10.1111/clr.14050

ORIGINAL ARTICLE

CLINICAL ORAL IMPLANTS RESEARCH WILEY

Accuracy of dental implant placement with or without the use of a dynamic navigation assisted system: A randomized clinical trial

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Abstract

Objectives: To assess dental implant placement accuracy with a dynamic computer-assisted implant surgery (dCAIS) system and a freehand approach. Secondarily, to compare the patients' perception and quality of life (QoL) with the two approaches.

Methods: A double-arm randomized clinical trial was conducted. Consecutive partially edentulous patients were randomly allocated to the dCAIS or standard freehand approach groups. Implant placement accuracy was evaluated by overlapping the preoperative and postoperative Cone Beam Computer Tomographs (CBCT) and recording linear deviations at the implant apex and platform (in mm) and angular deviations (in degrees). Questionnaires recorded self-reported satisfaction, pain and QoL during surgery and postoperatively.

Results: Thirty patients (22 implants) were enrolled in each group. One patient was lost to follow-up. A significant difference ($p < .001$) in mean angular deviation was found between the dCAIS (4.02°; 95% CI: 2.85 to 5.19) and the FH (7.97°; 95% CI: 5.36 to 10.58) groups. Linear deviations were significantly lower in the dCAIS group, except for the apex vertical deviation, where no differences were found. Although dCAIS took 14 min longer (95% CI: 6.43 to 21.24; $p < .001$), patients in both groups considered the surgical time acceptable. Postoperative pain and analgesic consumption during the first postoperative week were similar between groups and self-reported satisfaction was very high.

Conclusion: dCAIS systems significantly increase the accuracy of implant placement in partially edentulous patients in comparison with the conventional freehand approach. However, they increase the surgical time significantly and do not seem to improve patient satisfaction or reduce postoperative pain.

KEYWORDS
computer-assisted, dental implants, dental prosthesis, implant-supported, surgery, surgical navigation systems

1 | INTRODUCTION

Dental implant placement is one of the most reliable and predictable options for replacing missing teeth (Moraschini et al., 2015). In order to obtain excellent outcomes, implants should be placed in a prosthetic-driven manner (Buser et al., 2004; Sammartino et al., 2007).

The use of Cone-Beam Computer Tomography (CBCT) has improved the diagnosis and treatment planning but most surgeons still use a freehand approach when placing dental implants (Benavides et al., 2012; Bornstein et al., 2014; Jacobs et al., 2018; Wismeijer et al., 2018). To reduce inaccuracies between the planned and final position of the dental implant, several static and dynamic computer-assisted implant surgery (CAIS) systems have been developed. (Block, 2016; Vercruyssen et al., 2014). Static CAIS (sCAIS) systems are considered predictable and accurate, and have been used for some time (Tahmaseb et al., 2014). Nonetheless, in recent years several studies have assessed different dynamic CAIS (dCAIS) systems and the scientific background is increasing fast (Jorba-García et al., 2021). Today, dCAIS systems, also called navigation systems, seem to be a promising option for placing dental implants accurately (Aydemir & Arisan, 2020; Block, Emery, Cullum, Sheikh, 2017; Kaewsiri et al., 2019; Sun et al., 2020; Yimarj et al., 2020). Navigation systems provide real time feedback on the relative position of the bur or dental implant in relation to the CBCT of the jaw.

Jung et al. (2009) pointed out in a systematic review that these dCAIS systems seemed to be highly accurate. Likewise, both preclinical (Block, Emery, Lank, & Ryan, 2017; Jorba-García et al., 2019) and clinical studies (Stefanelli et al., 2019; Stefanelli, Mandelaris, Franchina, et al., 2020), have yielded positive results for these navigation systems. However, well design randomized clinical trials comparing dCAIS with the conventional freehand approach are scarce (Aydemir & Arisan, 2020; Wei et al., 2022). Furthermore, there is a need to evaluate different dCAIS systems and few studies assess the patient's satisfaction and Quality of life (QoL) (Feine et al., 2018).

Hence, the aim of this double-arm, randomized clinical trial was to compare the accuracy of a dCAIS system with the conventional freehand implant placement approach. Secondarily, the patient satisfaction and QoL of the two groups were also compared.

2 | MATERIALS AND METHODS

2.1 | Study design

A double-arm randomized clinical trial was conducted in a private practice setting. The study protocol was approved by the ethical review board for research of the QuirónSalud-Catalunya Hospital Group (protocol code: 2020/11-CMF-HUSC) and was registered in clinicaltrials.gov (reference: NCT04344808). The Consolidated Standards of Reporting Trials (CONSORT) statement was followed (Schulz, Altman, Moher, 2010). The objectives and possible complications of the study were explained to all the patients, who agreed to participate by signing an informed consent form.

2.2 | Study population

All consecutive partially edentulous patients seeking an implant supported restoration at the Bara-Gaseni Dental and Maxillofacial Institute (Barcelona, Spain) were screened for eligibility. Inclusion criteria were: (1) partially edentulous patients who required a partial fixed implant-supported prosthesis and had at least three remaining teeth, (2) healthy patients (patients classed as ASA I and II according to the American Society of Anesthesiologists (Saklad, 1941)) and (3) adequate bone availability to place dental implants without a need for bone-grafting techniques. Fully edentulous patients were excluded from the trial. Participants lost during the follow-up period, with implant losses or who voluntarily decided to withdraw from the study were considered dropouts.

Patients were assigned to one of the two study groups using a computer-generated random sequence. The patients and the surgeon could not be blinded due to the nature of the study and the dCAIS requirements (for example, the placement of an optical maker). In the dCAIS group (15 participants), implant placement was performed with the Navident system (Navident®, ClaroNav Technology Inc.®) whereas no guidance was used in the freehand hand group (FH) (15 participants).

2.3 | Sample size calculation

The sample size was calculated using the G * Power program version 3.1.9.2 (Universität Kiel, Germany). It was estimated that a 5° difference in the angular deviation between the groups would be clinically significant. Considering a common standard deviation (SD) of 4° (Jorba-García et al., 2019), an allocation ratio of 1:1, a risk of 0.05, a power of 80%, and a 20% exclusion rate, 30 patients (15 patients per group) were required.

2.4 | Randomization sequence, allocation concealment and blinding

An independent researcher (OC-F) generated the randomization sequence using STATA 14 software (StataCorp, College Station, TX, USA) and prepared 30 opaque envelopes with the patients' allocation information. The remaining researchers and the surgeon had no access to the randomization sequence during the trial.

To guarantee the allocation concealment, the envelopes were opened after performing the virtual planning, preparing the surgical field and administering the local anesthetic. Thus, the surgeon was only informed of the allocation just before starting the surgical procedure.

To avoid observation bias, a blinded researcher registered all the primary outcome variables (implant placement accuracy variables).

2.5 | Interventions

All patients in both groups underwent a preoperative CBCT and all implants were virtually planned using a specific software (Navident®, ClaroNav Technology Inc.®) by the same surgeon (J.B-C), who was unaware of the patients' allocation information. The type, length, and diameter of the dental implants was decided by the surgeon (JB-C) based on clinical and anatomical considerations.

All patients were prescribed a preoperative antibiotic (2 g of Amoxicillin 1 h before the surgery, or 600 mg of Clindamycin in patients with a history of penicillin allergy) and all surgeries were performed under local anesthesia with lidocaine 2% with 1:80.000 epinephrine (Xilonibsa 2% 1:80,000, Laboratorios Inibsa S.A., Lliça de Vall, Spain). A 2% chlorhexidine solution was used to clean the extraoral area and patients were instructed to rinse their mouth with a 0.12% chlorhexidine solution (PerioAid; Dentaid SL, Cerdanyola del Vallés, Spain) for 1 min.

All surgical procedures were performed by an experienced (over 20 years) oral and maxillofacial surgeon (J.B-C) that has been using dCAIS systems in a regular basis for the last 5 years.

2.5.1 | dCAIS group

In the test group (dCAIS group), an experienced clinician placed the optical markers as recommended by the manufacturer and performed the registration process. When implants were to be placed in the upper arch, an optical marker was attached to a head-mounted device that was placed on the nasion and stabilized in the ears (Figure 1). In the lower arch, the optical marker was placed on the remaining teeth using a light-curing resin.

The Navident 2.0 system uses a tracing technology to register the patients' anatomy through the CBCT data. By selecting at least three anatomical landmarks on the CBCT and touching them on the patient with a pre-calibrated probe, the system correlates the CBCT with the real patient's anatomy. Once the registration process has been completed successfully, its accuracy should be checked by touching different anatomical areas.

After trace registration, implant placement was performed following the manufacturer's recommendations. Whenever possible, the surgical procedure was performed using a flapless approach. Calibration of the axis was performed before using each bur and before implant placement.

2.5.2 | Freehand group

In the control group, the surgical field was prepared and implant placement was performed following the manufacturer's recommendations, using a flapless approach whenever possible.

Patients were instructed to take ibuprofen 600 mg every 8 h for 3 days, paracetamol 1 g as a rescue analgesic and amoxicillin 750 mg every 8 h for 4 days. A chlorhexidine 0.12% solution was also prescribed (mouth rinses with 15 cL every 12 h for 10 days). A follow-up appointment was scheduled for 7 days after the surgical procedure.

2.6 | Outcomes

2.6.1 | Primary outcome—accuracy outcomes

The implant placement accuracy was measured by overlapping the planned position of the implant in the preoperative CBCT and its final position assessed through a postoperative CBCT. Deviations between the preoperative planned position and the final location of the implant were calculated using EvaluNav software (Navident®, ClaroNav Technology Inc.®).

The following deviation variables were employed: angular deviation, platform lateral (2D) and global (3D) deviation, apex global (3D) deviation and apex depth deviation. These variables have been described and used in a recent meta-analysis published by the same authors (Jorba-García et al., 2021).

To test intraexaminer agreement and consistency, an assessment of five randomly selected implants (60 measurements) was repeated after 2 weeks. The intraclass correlation coefficients (ICC) were 0.98 (95% CI: 0.95 to 0.99; $p < .001$) and 0.97 (95% CI: 0.95 to 0.99; $p < .001$), showing excellent reliability and consistency.

2.6.2 | Secondary outcomes

Patient perception, discomfort, and satisfaction after surgery were assessed through questions based in previously published studies (Bacevic et al., 2021; Sancho-Puchades et al., 2019). These were completed by the patient at different timepoints (preoperatively, immediately after surgery, and every 24 h until the 7th postoperative day).

All patients filled in the validated Spanish version of the Oral Health Impact Profile 14 (OHIP-14Sp) (Montero-Martín et al., 2009) to measure the baseline oral health-related quality of life (QoL).

Immediately after surgery, a questionnaire (Likert scale) was employed to assess the patient's perception of the surgical procedure. It comprised eight questions with five possible answers (totally agree, agree, neutral, disagree and totally disagree). The questions focused on the experience and perception of the patient, exploring different aspects such as duration of the surgery, discomfort due to the instruments and devices employed, likelihood of undergoing the same surgery, recommendation to relatives or friends and the patient's perception of CAIS (which had been explained briefly to all the patients preoperatively). Finally, the patients indicated their overall satisfaction on a 100 mm VAS scale.

During the first seven postoperative days, the patients were asked to record their rescue analgesic intake (Ibuprofen 600 mg and

FIGURE 1 Optical markers used in the dynamic computer-assisted surgery group. (a and b) Upper jaw optical marker, which is placed on the nasion, over the head and stabilized in the ears. (c and d) Lower jaw optical marker stabilized with light curing resin to the remaining teeth.

Paracetamol 1gr) and pain intensity using a 100 mm visual analog scale (VAS).

Finally, 7 days after the procedure, a second OHIP-14Sp questionnaire (Montero-Martín et al., 2009) was answered by the patient.

A researcher, who was unaware of the randomization sequence, explained how to fill all the questionnaires preoperatively. Immediately after surgery and at the 7-day postoperative appointment, the participants were asked to fill all the forms in a quiet environment. Data of these questionnaires were analyzed by a blinded researcher.

2.7 | Statistical analysis

Categorical outcomes were presented as absolute and relative frequencies. A bivariate analysis using Pearson's χ^2 test, or Fisher's exact test when application conditions were not achieved, was used to compare the groups. The normality of scale variables was explored using the Shapiro–Wilk test and through visual analysis of the P–P plot and box plot. Where normality was rejected, the interquartile range (IQR) and median were calculated. Where distribution was compatible with normality, the mean and SD were used. Differences between groups of scale variables were explored using parametric (Student's *t* test for independent or paired samples) or nonparametric tests (Mann–Whitney U-test or Wilcoxon signed-rank test).

Multilevel linear regression models were conducted to evaluate accuracy outcomes based on the guidance method using generalized estimating equations (GEE). The GEE method was used to account for the fact that repeated observations (several implants) were available for a single patient. Group (dCAIS or freehand), location (maxilla or mandible), region (premolar or molar) and the interaction between group and region were included as predictor variables. Adjusted beta coefficients for linear regression models including 95% CIs were obtained from the Wald χ^2 statistic.

To analyze the influence of the group variable on the evolution of pain over time, a repeated measures mixed model was performed for each categorical covariate. Fulfillment of the assumptions was

checked by means of the graphical distribution of the residuals. The reliability of each questionnaire was assessed with the Cronbach α.

The statistical analysis was carried out with SPSS software version 27 (SPSS Inc.), and plots were made with another software package (Stata 14, StataCorp, College Station, TX). The level of significance was set at $p < .05$.

3 | RESULTS

Thirty patients were enrolled consecutively in the trial and randomized to the dCAIS group or to the FH group (1:1 ratio). All participants were treated between May 2020 and January 2021 in accordance with the allocated interventions. One patient in the FH group failed to attend the postoperative checkup and was considered to have dropped out. A total of 15 patients in the dCAIS group (22 implants) and 14 patients in the FH group (22 implants) were analyzed. The CONSORT flowchart is shown in Figure 2.

The main patient and implant characteristics, stratified by study group, are shown in Table 1.

Placement of implants took an average of 36.83 min (SD = 10.83) with dCAIS and 23 min (SD = 8.35) with the FH technique, so the surgical time (time elapsed from incision to the last suture or healing abutment placement in case of a flapless approach) was significantly shorter in the FH group (MD = 13.83 min; 95% CI: 6.43 to 21.24; $p < .001$).

All implants were clinically stable, and free of signs of infection.

3.1 | Accuracy outcomes

Accuracy analyses revealed that dCAIS produced significant reductions in angular (B = −3.86°; IC 95%: −7.46 to −0.25; $p = .036$),

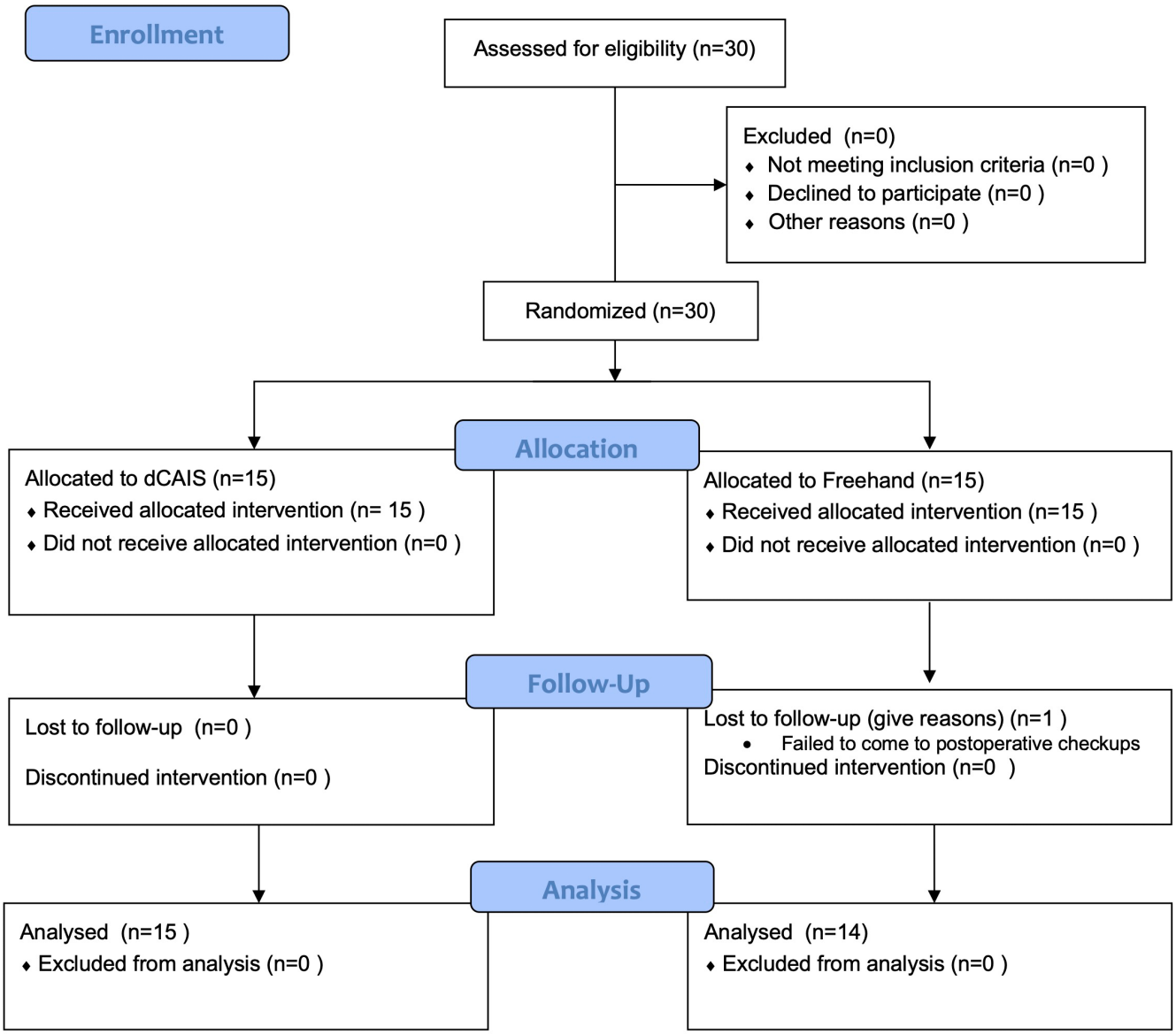

FIGURE 2 Consolidated standards of reporting trials (CONSORT) flow diagram. dCAIS: Dynamic computer-assisted implant surgery.

TABLE 1 Main patient and implant features, stratified by group.

	dCAIS	FH
Patients	**15**	**14**
Gender		
Female	9 (60)	7 (50)
Male	6 (40)	7 (50)
Age (years) (SD)	59.38 (15.85)	61.38 (16.85)
OHIP Pre (SD)	6.53 (4.72)	4.64 (4.47)
ASA		
I	13 (86.67)	9 (64.29)
II	2 (13.33)	5 (35.71)
Smoking		
No smoker	14 (93.33)	14 (100)
0–10 cig/day	1 (6.67)	0 (0)
Surgical technique		
Flapless	14 (93.33)	13 (92.86)
Flap elevation	1 (6.67)	1 (7.14)
Number of implants		
1	8 (53.33)	8 (57.14)
2	7 (46,67)	5 (35.71)
3	0 (0)	0 (0)
4	0 (0)	1 (7.14)
Implants	**22**	**22**
Implant position		
Premolars	12 (54.55)	9 (40.91)
Molars	10 (45.45)	13 (59.09)
Side of arch		
Right	12 (54.55)	10 (45.45)
Left	10 (45.45)	12 (54.55)
Arch		
Maxilla	11 (50.0)	6 (27.27)
Mandible	11 (50.0)	16 (72.73)
Implant manufacturer		
Straumann	17 (77.27)	13 (59.09)
Zimmer	5 (22.73)	9 (40.91)
Implant diameter		
Narrow (≤3.75)	4 (18.18)	0 (0)
Regular (3.8 to 4.6))	12 (54.55)	15 (68.18)
Wide (≥4.7)	6 (27.27)	7 (31.81)
Implant length		
Short (≤8 mm)	2 (9.09)	2 (9.09)
Regular (8.5 to 12 mm)	19 (86.36)	20 (90.91)
Long (≥12 mm)	1 (4.55)	0 (0)

platform global (B = −1.13 mm; IC 95%: −1.83 to −0.42; p = .002), platform lateral (B = −1.12 mm; IC 95%: −1.85 to −0.39; p = .003), and apex global (B = −1.36 mm; IC 95%: −2.49 to −0.23; p = .018) deviations (Table 2 and Figure 3). Additionally, platform global (B = −1.15 mm; IC 95%: −1.93 to −0.37; p = .004), platform lateral (B = −1.31 mm; IC 95%: −2.07 to −0.55; p < .001), and apex global (B = −1.18 mm; IC 95%: −2.14 to −0.21; p = .017) deviations were also influenced by the region (molar or premolar) where the implant was inserted (Table 3).

Interaction between group and region was significant for platform global (B = 1.09 mm; IC 95%: 0.19 to 1.99; p = .018) and platform lateral (B = 1.11 mm; IC 95%: 0.22 to 2.00; p = .014) deviations. Specifically, while precision in the dCAIS group was not influenced by the region where the implant was placed, fixtures inserted in the molar region using the FH technique exhibited greater differences in linear deviation than those in the premolar region (Table 3).

3.2 | Patient satisfaction and QoL outcomes

Postoperative pain varied significantly over time (χ^2 = 41.19; df = 8; p < .001), was similar between groups (χ^2 = 0.01; df = 1, p = .933) and followed the same pattern of evolution over time in both groups (χ^2 = 13.87; df = 8; p = .085) (Figure 4). Likewise, the percentage of patients who took analgesics each day and the mean number of days of analgesic intake were similar in the two groups (p > .05).

The impact of implant placement on OHIP-14Sp is reported in Table S1. The mean overall postoperative OHIP-14Sp score was 2.86 (SD = 3.68; Range = 0 to 14), indicating mild oral health-related impairment. Both groups had similar postoperative OHRQoL scores (U = 497.07; p = .473).

Although most patients considered the surgical time to be acceptable, patients in the dCAIS group complained of a longer surgery time (p = .005). Patients in both groups would strongly recommend the surgery to a friend/familiar or would undergo the surgery again, and were highly satisfied with the surgery (VAS over 85). Table S2 shows the results of the patient satisfaction questionnaire.

A Friedman test showed that the number of implants (1 implant Vs ≥2 implants; Q (1) = 0.37; p = .543) and the surgical technique (flap elevation Vs. flapless; Q (1) = 0.26; p = .612) did not have a significant impact on the postoperative pain pattern.

4 | DISCUSSION

This randomized clinical trial demonstrates that using dCAIS significantly increases the accuracy of implant placement when compared with a freehand approach. However, dCAIS did not seem to improve patients' perception, postoperative pain, and postoperative QoL.

The present study has some limitations that should be addressed. Firstly, the results cannot be applied to fully edentulous patients since this was an exclusion criterion. dCAIS systems might be less reliable in these cases due to the lack of reference points (Jaemsuwan et al., 2022). Secondly, the surgeon and the patients could not be blinded due to the nature of the intervention. To limit this source of bias, surgeons were only informed about the group allocation just before the start of the surgery and after the placement of the local anesthetic (allocation concealment). Furthermore, the patients' eyes

TABLE 2 Summary of accuracy variables.

Accuracy variable	dCAIS Mean (SD)	FH Mean (SD)	MD (95% CI)	*p*-value
Angular (°)	4.02 (2.80)	7.97 (6.25)	−3.86 (−7.46 to −0.25)	.036[a]
Platform lateral (mm)	0.88 (0.33)	1.44 (0.70)	−1.12 (−1.85 to −0.39)	.003[a]
Platform global (mm)	1.12 (0.38)	1.70 (0.69)	−1.12 (−1.83 to −0.42)	.002[a]
Apex global (mm)	1.42 (0.52)	2.49 (1.43)	−1.36 (−2.49 to −0.23)	.018[a]
Apex depth (mm)	0.54 (0.42)	0.65 (0.44)	−0.16 (−0.49 to 0.17)	.348

Abbreviations: dCAIS: Dynamic computer-assisted implant surgery; FH: Freehand surgery; SD: Standard deviation; MD: Mean difference (dCAIS–FH); 95% CI: 95% Confidence interval.

Note: MD adjusted according to the generalized estimating equations (GEE), considering other covariates.

[a]Statistically significant difference.

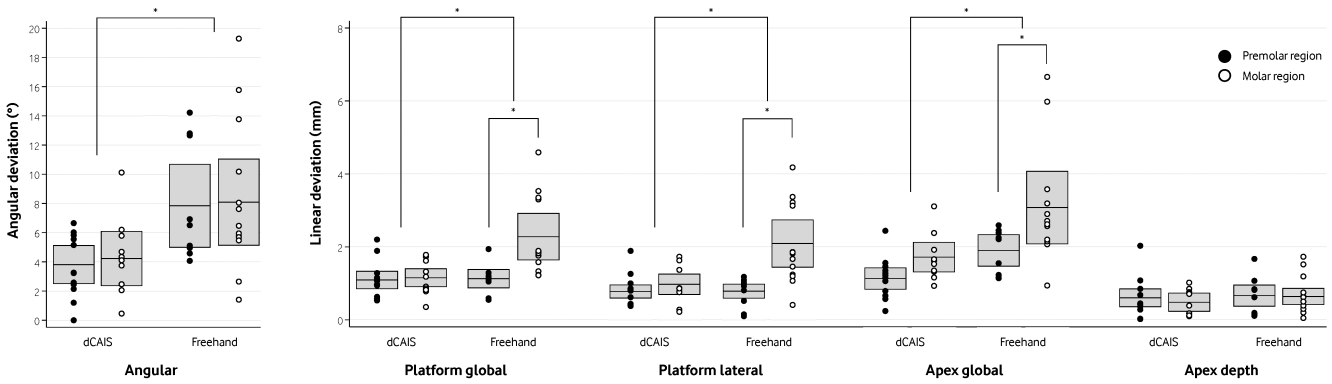

FIGURE 3 Box and scatter plots of angular and linear deviations for dCAIS and Freehand groups in premolar and molar regions. For each box, the interior line in bold shows the mean, and the edges of the box are estimates of the lower and upper 95% CIs. dCAIS: Dynamic computer-assisted implant surgery.

were covered throughout the procedure and the surgeons were instructed not to provide information regarding the employed technique to the patient. However, these drawbacks might still affect the patients' satisfaction and QoL outcomes. Another limitation of the present RCT is related with the number of implants placed per patient, since the groups were slightly unbalanced. Thus, the results concerning the surgical time and postoperative pain should be interpreted with caution. Finally, the study outcomes might have a reduced external validity when novice professionals are involved. Indeed, an "in vitro" study has shown that experience significantly affects the accuracy of implant placement in both free-hand and dCAIS cases (Jorba-García et al., 2019).

Since dCAIS is a relatively new technology and improvements and updates are being introduced at a fast rate, the available clinical literature is still scarce. A recent meta-analysis published on this topic included only three randomized clinical trials, with some risk of bias (Jorba-García et al., 2021). Two of them compared dCAIS and sCAIS (Kaewsiri et al., 2019; Yimarj et al., 2020), and the other compared dCAIS with freehand implant placement (Aydemir & Arisan, 2020). One additional RCT has been published in 2022 with a sample of 24 patients that required immediate implant placement (Wei et al., 2022). These authors (Wei et al., 2022) concluded that machine-vision-based dynamic navigation-assisted immediate implant placement is more accurate than the conventional free-hand technique. Still, it is of the utmost importance to perform well-conducted randomized clinical trials with larger samples and with a low risk of bias following the CONSORT guidelines (Schulz, et al., 2010). This study aimed to increase the evidence on this topic.

Nowadays, markerless tracing registration is gradually replacing radiographic markers (Scheyer et al., 2020; Stefanelli, Mandelaris, DeGroot, et al., 2020). Before the introduction of markerless point-to-point tracing registration, the preoperative CBCT had to be obtained with a custom splint or clip holding a radiographic marker attached to the jaw or teeth (D'haese et al., 2017). The most recent navigation system updates only require a CBCT without radiographic markers and at least three fiducial points selected by the clinician. A specific probe can be used to select these reference points in any of the patient's remaining teeth (usually at the top of the teeth's cusps). It is important to stress that since these new tools might affect the accuracy outcomes, new clinical studies should be conducted. A recent study from (Stefanelli, Mandelaris, DeGroot, et al., 2020) showed accurate results in the placement of 136 dental implants. Interestingly, the authors showed that tracing between 5 to 6 landmarks during the registration process was significantly more precise than tracing only 3–4 teeth. The present randomized clinical trial employed a tracing registration process and confirms

TABLE 3 Comparison between groups (dCAIS vs. FH) considering the implant region.

Accuracy variable	Region	Group	Mean (SD)	MD (95% CI)	*p*-value
Angular (°)	Premolar	dCAIS	3.81 (3.12)	−4.03 (−6.94 to −1.13)	.007[a]
		FH	7.84 (6.80)		
	Molar	dCAIS	4.23 (4.45)	−3.86 (−7.46 to −0.25)	.036[a]
		FH	8.09 (7.07)		
Platform lateral (mm)	Premolar	dCAIS	0.78 (0.43)	−0.01 (−0.28 to 0.26)	.951
		FH	0.79 (0.46)		
	Molar	dCAIS	0.98 (0.67)	−1.12 (−1.85 to −0.39)	.003[a]
		FH	2.09 (1.55)		
Platform global (mm)	Premolar	dCAIS	1.09 (0.57)	−0.04 (−0.38 to −0.30)	.830
		FH	1.13 (0.60)		
	Molar	dCAIS	1.15 (0.59)	−1.12 (−1.83 to −0.42)	.002[a]
		FH	2.28 (1.53)		
Apex global (mm)	Premolar	dCAIS	1.13 (0.70)	−0.77 (−1.27 to −0.27)	.003[a]
		FH	1.90 (1.03)		
	Molar	dCAIS	1.72 (0.97)	−1.36 (−2.49 to −0.23)	.018[a]
		FH	3.08 (2.38)		
Apex depth (mm)	Premolar	dCAIS	0.60 (0.59)	−0.06 (−0.42 to 0.30)	.742
		FH	0.66 (0.70)		
	Molar	dCAIS	0.48 (0.60)	−0.16 (−0.49 to 0.17)	.348
		FH	0.64 (0.53)		

Abbreviations: dCAIS: Dynamic computer-assisted implant surgery; FH: Freehand surgery; SD: Standard deviation; MD: Mean difference (dCAIS–FH); 95% CI: 95% Confidence interval.
[a]Statistically significant difference.

that this system guarantees accurate implant placement. Moreover, the tracing registration is more comfortable for the patient and clinician and does not require splint fabrication or storage.

The main disadvantages of static CAIS are the need to fabricate a specific splint preoperatively, limited visibility, irrigation of the bur during the surgery, and the fact that the surgical guide does not allow modifications (Gargallo-Albiol et al., 2019). Dynamic CAIS overcomes these limitations.

As mentioned at the beginning of this section, CAIS can be less reliable in fully edentulous patients (Bover-Ramos et al., 2018; Joda et al., 2018). In sCAIS, the surgical guide might be difficult to place and stabilize, and in dCAIS, the lack of clearly identifiable reference landmarks hinders both registration and navigation during the surgery. Several strategies have been designed to overcome this limitation: replacing bone-supported surgical guides with mucosal-supported guides in a flapless approach (Bover-Ramos et al., 2018), placing miniscrews along the patient's arch to serve as reference points, or using a head-mounted optical marker (Stefanelli, Mandelaris, Franchina, et al., 2020). Going one step further, (Pomares-Puig et al., 2021) have designed a technique that combines sCAIS and dCAIS in the same approach to treat fully edentulous patients. Despite no evidence being available on this technique, (Sun et al., 2020) showed that using a combination of static and dynamic CAIS provided more accurate outcomes than any individual system.

Our results indicate that accuracy might be affected by the anatomical region. Indeed, implants placed in molars presented larger differences than in premolars when comparing dCAIS and FH. In molars, the gap is wider and sometimes the distal tooth is missing. Thus, the reduced visibility and access and the lack of reference points seem to favor the use of dCAIS.

Currently, the analysis of patient reported outcome measures (PROMs) is considered paramount to assess the validity and success of a technique. In the present sample, patient satisfaction and subjective perception were similar in both groups. Likewise, (Engkawong et al., 2021) reported no differences between static or dynamic CAIS and freehand implant placement in this respect. A recent critical review (Pimkhaokham et al., 2022) also seems to be in line with our results since these authors found no differences in terms of patient report outcomes and experience. Furthermore, this paper showed no direct improvement in implant survival, peri-implant diseases risk and intraoperative and early healing events (Pimkhaokham et al., 2022). However, it is relevant to state that, according to these authors, the use of CAIS may indirectly lead to significant benefits in all the above-mentioned parameters since it may facilitate flapless surgery, immediate loading, and prosthetic-driven implant placement.

According to the present results, the use of navigation surgery increases the surgical time in comparison with the conventional freehand approach, with a mean difference of almost 14 min. This

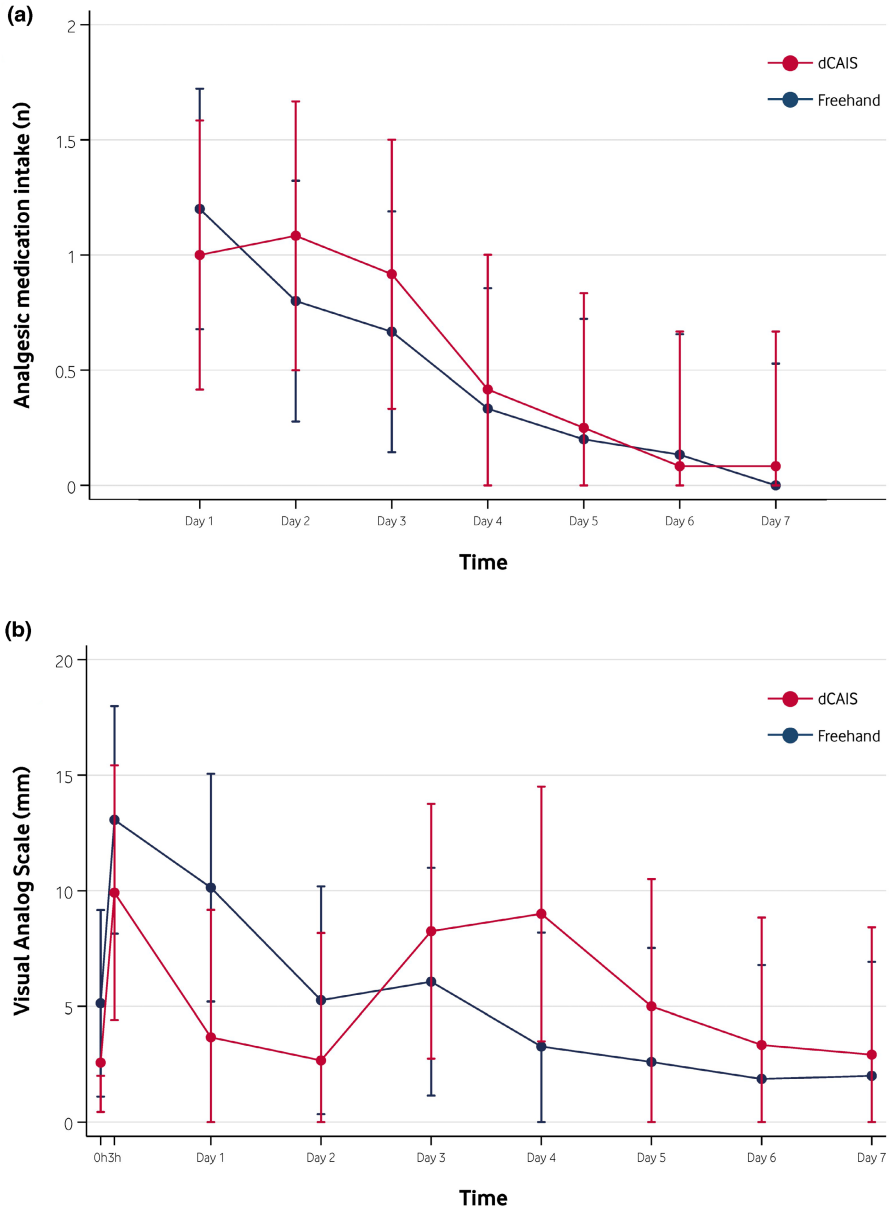

FIGURE 4 Postoperative analgesic medication intake (a) and pain evolution (b) diagram. The mean and IC 95% bars are plotted for each time point for the patients in the dCAIS group and the Freehand group. dCAIS: Dynamic computer-assisted implant surgery; h: hours.

finding has been reported in several studies and, on some occasions, the time required for implant placement doubled (Jorba-García et al., 2019; Sun et al., 2020). Variables like the number of implants and the surgical technique (flapless Vs. flap elevation) should also be taken into consideration since they might affect the surgery time. In the FH group, there were slightly more single-implant patients (57.14% Vs. 53.3%) which might have led to an underestimation of the surgical time in this group. On the other hand, flap elevation could increase the length of the surgical procedure, but this variable was well-balanced in both groups. Thus, in this particular study, the global impact of these variables seems to be scarce.

Further research into dynamic CAIS is needed for several reasons. Firstly, new devices and registration methods are constantly being launched on the market and require validation. Furthermore, most published papers are based on case series or cohort studies, so randomized clinical trials should be encouraged. Additional research is also required to determine the effect of dCAIS in QoL impairment, postoperative pain, and patient perception when fully edentulous patients are involved.

5 | CONCLUSIONS

Dynamic CAIS significantly increases the accuracy of implant placement in partially edentulous patients. However, the use of this technology seems to extend the surgical time and does not seem to improve the patient's perception or QoL in comparison with the conventional freehand approach.

AUTHOR CONTRIBUTIONS

Adrià Jorba-García: Conceptualization, Methodology, Investigation, Data Curation, Writing—Original Draft. Jose Javier Bara-Casaus: Conceptualization, Validation, Resources, Writing—Review & Editing. Octavi Camps-Font: Methodology, Validation, Formal analysis, Data Curation, Writing—Review & Editing. Maria Ángeles Sánchez-Garcés: Writing—Review & Editing, Supervision. Rui Figueiredo: Conceptualization, Methodology, Investigation, Writing—Review & Editing, Supervision. Eduard Valmaseda-Castellón: Conceptualization, Methodology, Writing—Review & Editing, Supervision.

ACKNOWLEDGMENTS

Mary Georgina Hardinge provided English language editing assistance.

FUNDING INFORMATION

This work has not been funded by any grant-giving organization.

CONFLICT OF INTEREST STATEMENT

The authors declare no grants, personal fees, or non-financial support in relation to this study. Dr. Octavi Camps-Font reports grants and non-financial support from Avinent (Santpedor, Spain), Inibsa Dental (Lliçà de Vall, Spain), Dentaid SL (Cerdanyola del Vallés, Spain), non-financial support from Nobel Biocare, personal fees from Avinent SA outside the submitted work. Dr. Rui Figueiredo reports grants, personal fees, and non-financial support from MozoGrau (Valladolid, Spain), Avinent (Santpedor, Spain), Inibsa Dental (Lliçà de Vall, Spain), Dentaid SL (Cerdanyola del Vallés, Spain), non-financial support from Nobel Biocare, personal fees from Geistlich Pharma AG (Wolhusen, Switzerland), BioHorizons Iberica (Madrid, Spain), Araguaney Dental (Barcelona, Spain), Septodont (Saint-Maur-des-fossés, France) and Laboratorios Silanes (Mexico city, Mexico) outside the submitted work. Dr. Figueiredo has also participated as a principal investigator in a randomized clinical trial sponsored by Mundipharma (Cambridge, UK) and in another clinical trial as a sub-investigator for Menarini Richerche (Florence, Italy). Dr. Eduard Valmaseda-Castellón reports grants, personal fees, and non-financial support from MozoGrau (Valladolid, Spain), Avinent (Santpedor, Spain), Inibsa Dental (Lliçà de Vall, Spain) Dentaid SL (Cerdanyola del Vallés, Spain) and personal fees from BioHorizons Iberica (Madrid, Spain), and Laboratorios Silanes (Mexico city, Mexico) outside the submitted work. Dr. Eduard Valmaseda-Castellón has also participated as a principal investigator in a randomized clinical trial sponsored by Geistlich Pharma AG (Wolhusen, Switzerland) and in another clinical trial as a sub-investigator for Mundipharma (Cambridge, UK).

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

ETHICS STATEMENT

The study was approved by the ethical review board for research of the QuirónSalud-Catalunya Hospital Group (protocol code: 2020/11-CMF-HUSC) and was carried out in accordance with the Declaration of Helsinki. Data collection and analysis were conducted in such a manner that the study subjects could not be identified.

PATIENT CONSENT STATEMENT

All patients were previously informed of the study design, objective, and possible benefits and complications, and agreed to participate. Written informed consent was obtained from all patients prior to their inclusion in the study.

CLINICAL TRIAL REGISTRATION

ClinicalTrials.gov Identifier: NCT04344808.

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SUPPORTING INFORMATION

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How to cite this article: Jorba-García, A., Bara-Casaus, J J., Camps-Font, O., Sánchez-Garcés, M Á., Figueiredo, R., & Valmaseda-Castellón, E. (2023). Accuracy of dental implant placement with or without the use of a dynamic navigation assisted system: A randomized clinical trial. *Clinical Oral Implants Research*, *34*, 438–449. https://doi.org/10.1111/clr.14050