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Accuracy of dynamic computer-assisted implant surgery in fully edentulous patients: An in vitro study

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ABSTRACT

Objectives: To compare miniscrew versus bone tracing registration methods on dental implant placement accuracy and time efficiency in edentulous jaws using a dynamic computer-assisted implant surgery (d-CAIS) system.

Methods: Twelve fully edentulous maxillary models were allocated into two groups: miniscrew tracing (MST) group, where registration was performed by tracing four miniscrews; and bone tracing (BT) group, where registration was conducted by tracing maxillary bone fiducial landmarks. Six implants were placed on each model using the X-Guide® d-CAIS system. Pre- and postoperative cone-beam computed tomography (CBCT) scans were superimposed to evaluate implant placement accuracy. The time required for registration and the overall surgery time were also recorded.

Results: Thirty-six implants were placed in each group. The MST group showed significantly lower mean angulation deviations (mean difference (MD): -3.33°; 95 % confidence interval (CI): -6.56 to -0.09); $p = 0.044$), 3D platform deviations (MD: -1.01 mm; 95 % CI: -1.74 to -0.29; $p = 0.006$), 2D platform deviations (MD: -0.97 mm; 95 % CI: -1.71 to -0.23; $p = 0.010$), and 3D apex deviations (MD: -1.18 mm; 95 % CI: -1.92 to -0.44; $p = 0.002$) versus the BT group. The overall surgery time was similar for both groups (MD: 6.10 min.; 95 % CI: -0.31 to 12.51; $p = 0.06$), though bone tracing required significantly more time compared with miniscrew registration (MD: 4.79 min.; 95 % CI: 2.96 to 6.62; $p < 0.05$).

Conclusions: Registration with MST increases the accuracy of implant placement with a d-CAIS system in edentulous jaws compared with the BT method, and slightly reduces the overall surgery time.

Clinical significance: Miniscrew tracing registration improves implant placement accuracy in comparison with bone tracing registration.

1. Introduction

The rehabilitation of fully edentulous maxillas by means of an implant-supported fixed prosthesis is a common procedure in dental practices [1]. In order to achieve an optimal outcome, clinicians should perform a thorough prosthodontic evaluation and adequate preoperative implant planning [2,3]. In this regard, professionals should seek a correct 3D positioning of the implants. The conventional free-hand placement of dental implants might prove complex in a fully edentulous maxilla, due to the absence of anatomical landmarks to determine correct angulation and positioning of the implants. The development of static computer-assisted surgery (s-CAIS) systems has resulted in significant improvement of the accuracy of dental implant placement [4–6].

More recently, dynamic computer-assisted surgery (d-CAIS) has been introduced with excellent results, improving the accuracy of implant placement over the freehand and even over the s-CAIS approaches [7,8]. Dynamic computer-assisted surgery systems use a specific technology

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and software that allow real-time tracking of the drilling sequence and implant placement on a screen, where the planed position of the implant can be seen in the cone-beam computed tomography (CBCT) images of the patient [9].

The registration process is considered a crucial step in d-CAIS. It involves virtual merging of the CBCT image with the real anatomy of the patient ("image-to-patient registration") [10]. In partially edentulous patients, a markerless pair-point registration can be employed. Accordingly, several fiducial points on the remaining teeth can be selected from the CBCT scan and then matched with the corresponding anatomical landmarks in the patient's mouth. This process allows the navigation system software to recognize the exact patient position [11]. However, this method might be less accurate in fully edentulous patients, since anatomical landmarks (remaining teeth) are lacking. Thus, other fiducial markers, such as miniscrews placed prior to the CBCT scan, have been suggested for these cases [12]. Some d-CAIS systems propose the possibility of tracing fiducial points directly on the patient's maxillary bone using a specific probe. This alternative offers several important advantages as it eliminates the need for an additional procedure (i.e. miniscrew placement), is more comfortable for the patient and reduces the treatment costs but has not been adequately tested in fully edentulous patients [13]. Moreover, the data available comparing different registration methods are still limited [14,15]. For this reason, the authors decided to conduct a study aimed at comparing the impact of a miniscrew versus a bone tracing registration method on the accuracy and time efficiency of dental implant placement in completely edentulous maxillas when using a d-CAIS system.

2. Methods

An in vitro study was conducted with the X-Guide® d-CAIS system (X-Guide®, X-Nav Technologies®, LLC, Lansdale, PA, USA) to compare two patient registration methods: miniscrew tracing (MST; control group) and bone tracing (BT; test group). The CRIS guidelines for reporting in-vitro studies were followed [16]. Fig. 1 shows the main steps performed in each group. Since this study used artificial models, Ethics Committee approval was not necessary.

2.1. Sample size

The sample size was calculated with the G*Power v3.1.3 software (Heinrich - Heine Universität, Düsseldorf, Germany) with an alpha value of 0.05 and a statistical power of 80 %. Based on the results reported by Jaemsuwan et al. [17] (mean angular deviation of 5.75° and standard deviation of 2.09°) and considering that a 1.5° difference is clinically significant, a total of 64 implants would be required. To compensate possible protocol deviations, a total number of 72 implants and 12 models were employed (36 implants per group; 6 implants per model).

2.2. Study design

Twelve fully edentulous upper maxillary resin models (BoneModels®, Castellón de la Plana, Spain) were randomly assigned to each study group (6 models per group). The models were placed in preclinical learning phantom heads mimicking real patient conditions (presence of soft tissue and limited oral opening) (Frasaco GmbH, Tettnang, Germany) (Fig. 2).

2.3. Presurgical procedures

2.3.1. Bone tracing (BT) group

A preoperative CBCT scan (94 kV, 9 mA, 0.2 × 0.2 × 0.2 mm voxel size, 110 × 80 mm FOV) (Vistavox S, Dürr Dental, Germany) was obtained of all the models, which were fixed on a platform to prevent movement during image capture.

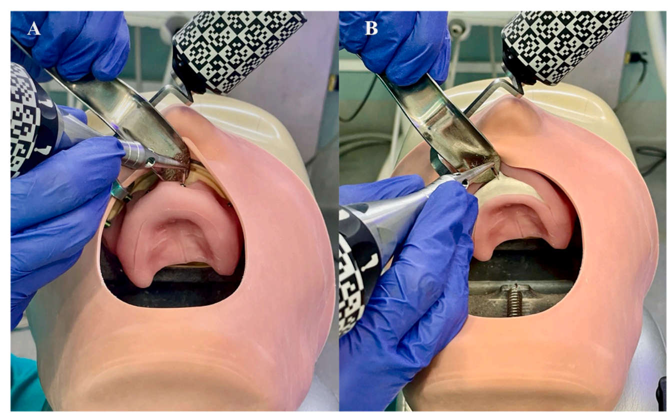

Fig. 2. A) Registration process in the miniscrew tracing group (MST). Probe tip touching the head of the miniscrews. B) Registration process in the bone tracing group (BT). Probe tip touching the maxillary cortical bone.

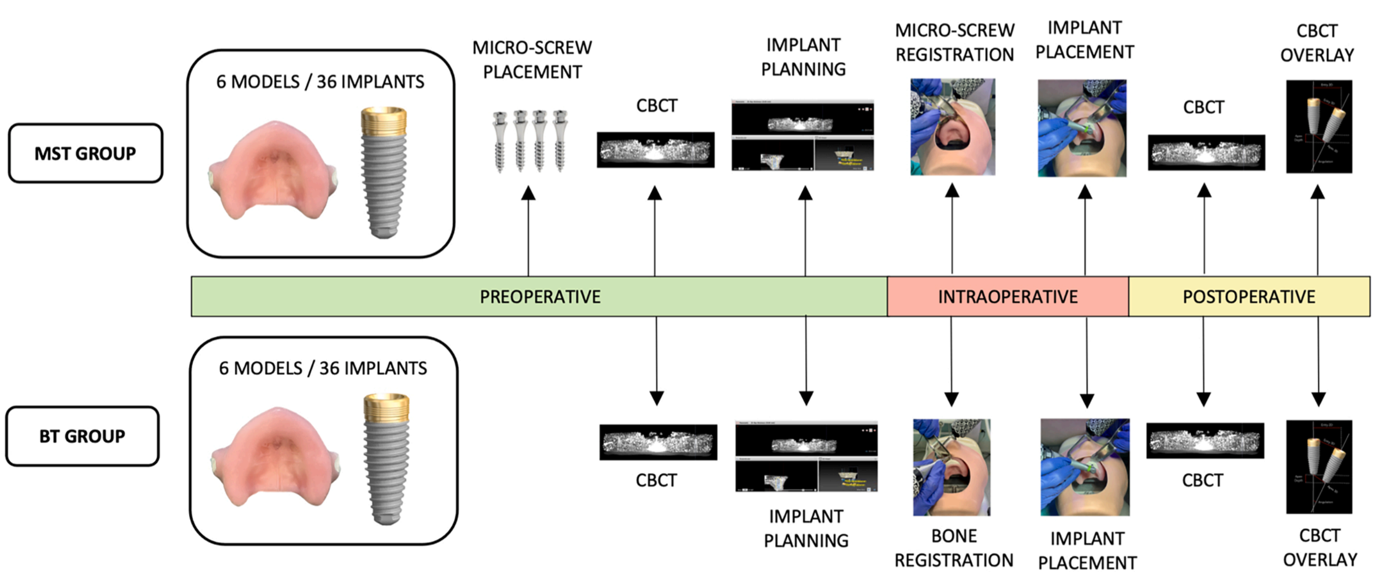

Fig. 1. Main steps in each study group. STL: Standard Tessellation Language (intraoral scan files); CBCT: cone-beam computed tomography.

Virtual implant planning in the lateral incisors, first premolars and first molars positions was performed with DTX Studio Implant (Nobel Biocare AB, Gothenburg, Sweden).

2.3.2. Miniscrew tracing (MST) group

Prior to the CBCT scan and virtual implant planning, four miniscrews (9 mm x 1.5 mm; ACE truSCREW®) were placed symmetrically (2 on each side: in the maxillary tuberosity area and in the incisor area near the midline) using a flapless technique on the buccal aspect of the maxilla as radiological markers (Fig. 2A).

2.4. Calibration and registration

All optical markers were placed according to the instructions of the manufacturer. The optical marker in the upper jaw was attached using the two X-Guide fixation screws for completely edentulous jaws. The cylindrical optical markers were firmly attached to the handpiece and the X-Guide tracer probe. Then, instrument calibration was performed following the steps established by the X-Guide software.

The registration process was carried out by selecting fiducial points on the Digital Imaging and Communication in Medicine (DICOM) file displayed on the monitor, followed by tracing with the X-Guide tracer probe. The accuracy of the registration process was verified by touching different points of the model with the tracer probe and checking whether these matched those seen on the screen of the navigation system.

2.4.1. MST group

The four miniscrews were selected as fiducial points. Each miniscrew was traced with the tracer probe (Fig. 2A).

2.4.2. BT group

The fiducial points were distributed separately in the upper jaw as symmetrically as possible in well-defined bony areas of the maxillary model. Three fiducial points were selected on each side of the model (incisor area (midline zone), premolar area and molar area (maxillary tuberosity zone) (Fig. 2B).

2.5. Surgical procedures

A single surgeon (V.R-R) raised a full-thickness flap and followed the surgical drilling sequence recommended by the manufacturer using the navigation system. Each drill was calibrated by placing its tip on a specific metal plate with an optical marker (Go Plate; X-Guide®, X-Nav Technologies®, LLC, Lansdale, PA, USA). Then, the drill tip was placed on different anatomical areas or radiological markers to check the accuracy of the registration. In case of inaccuracy, a re-registration process was carried out, and new fiducial points were traced. Finally, 6 Nobel Replace TiUltra® 4.3 mm x 10 mm implants (Nobel Biocare AB, Göteborg, Sweden) were placed per maxilla (72 implants in total) (Figs. 3A and 3B) with the X-Guide system. The implants were calibrated using the same procedure.

2.6. Postoperative procedures

Postoperative CBCT scans of the models were obtained to assess the accuracy of implant placement in relation to the preoperative planning. A second researcher (A.J-G) superimposed the pre- and postoperative CBCT scans using EvaluNav software (Navident®, ClaroNav Technology Inc.®, Toronto, Canada), which automatically detects the implant position and calculates the deviations in relation with the preoperative planning.

2.7. Outcome variables

The following accuracy variables were evaluated for each implant (Fig. 4):

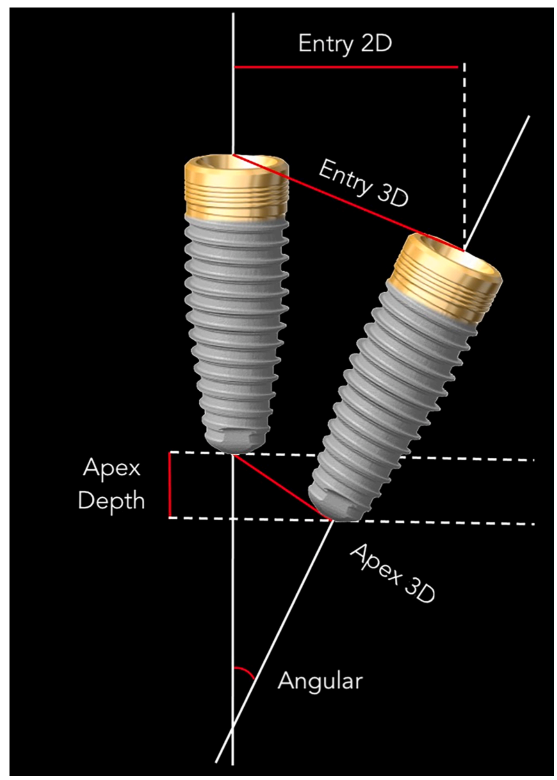

Fig. 4. Implant accuracy variables.

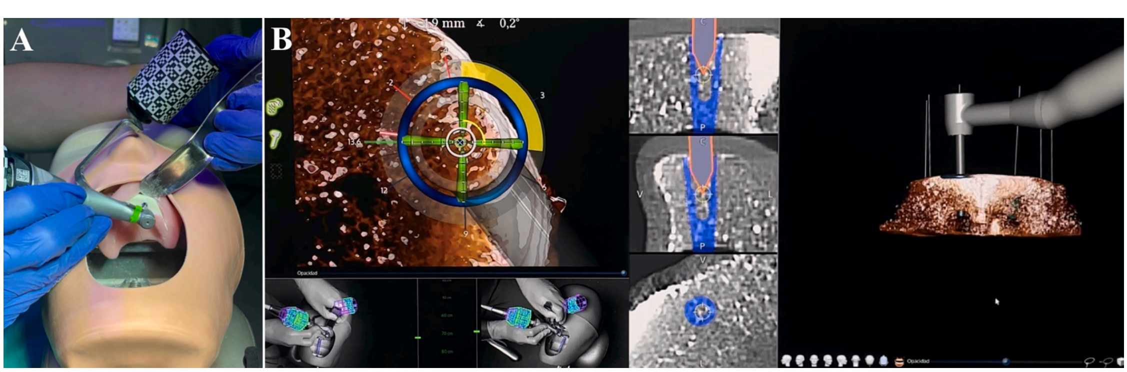

Fig. 3. Implant placement using the X-Guide navigation system. A) Real scenario placing an implant in the resin model. B) Virtual vision on the screen of the navigation system during implant placement.

- Angular deviation (in degrees): deviation between the central axes of the planned implant and the final implant position.
- Platform three-dimensional (3D) deviation (in mm): global deviation of the implant platform in the three axes of space (X, Y and Z).
- Platform two-dimensional (2D) deviation (in mm): lateral or horizontal deviation of the implant platform in the X and Y axes of space from an occlusal view, without considering the deviation in depth (Z axis).
- Apex 3D deviation (in mm): global deviation of the implant apex in the three axes of space (X, Y and Z).
- Apex depth deviation (in mm): depth or vertical deviation (Z axis) of the implant apex.

Additionally, in each group, the total duration of the surgery was documented. This included the insertion of the miniscrews (only in the MST group), the calibration and registration processes, and the surgical procedure itself (from the elevation of the flap to the placement of the implant). The need for re-registration (number of registrations and required time) was also recorded in each group.

2.8. Blinding and randomization

Blinding of the surgeon and the researcher who overlaid the CBCT scans was not feasible due to the presence of the miniscrews.

The treatment sequence of the models was randomized via the website www.randomization.com by a researcher who was not involved in the surgical procedures. The treatment order for each model was deemed significant due to a potential learning curve effect.

2.9. Statistical analysis

Statistical analysis was conducted using Stata 14 software (StataCorp, College Station, TX, USA) and SPSS software version 27 (IBM Corp, Armonk, NY, USA). The normal distribution of scale variables was assessed through the Shapiro-Wilk test and visual examination of P-P plots and box plots. In instances where normality was rejected, calculations were made for the interquartile range (IQR) and median. For variables exhibiting a normal distribution, the mean and standard deviation (SD) were used.

Differences between groups of scale variables were investigated employing parametric methods (Student *t*-test for independent or paired samples) or nonparametric tests (Mann-Whitney *U test* or Wilcoxon signed-rank test).

Multilevel linear regression models were generated to assess accuracy outcomes based on the guidance method using generalized estimating equations (GEEs). The GEE method was employed to accommodate repeated observations (several implants) within the same model. Adjusted beta coefficients for linear regression models, including 95 % confidence intervals (CIs), were derived from the Wald $\chi 2$ statistic. The significance level was set at $p < 0.05$.

3. Results

A total of 72 implants were analyzed. The MST group showed significantly superior accuracy in terms of mean angulation deviation (MD: −3.33°; 95 % CI: −6.56 to −0.09; $p = 0.044$), 3D platform (MD: −1.01 mm; 95 % CI: −1.74 to −0.29; $p = 0.006$), 2D platform (MD: −0.97 mm; 95 % CI: −1.71 to −0.23; $p = 0.010$) and 3D apex (MD: −1.18 mm; 95 % CI: −1.92 to −0.44; $p = 0.002$) versus the BT group. There were no statistically significant differences in terms of apex depth deviation between the two groups (MD: −0.34 mm; 95 % CI: −0.70 to 0.03; $p = 0.068$). The outcomes of the accuracy variables are summarized in Table 1 and Fig. 5.

The registration time was significantly longer in the BT group (MD: 4.79 min; 95 % CI: 2.96 to 6.62; $p < 0.05$; Table 2). However, the overall surgery time, which comprised calibration, registration, flap elevation, drilling sequence, implant placement, recalibration, as well as placement and removal of miniscrews in the control group, was similar for both groups ($p = 0.06$), with a mean of 48.39 min (SD: 5.39) and a mean of 54.49 min (SD: 4.53) for the MST and BT groups, respectively (Table 2).

Table 1
Outcomes of the implant accuracy variables.

	MST (SD)	BT (SD)	MD (95 % CI)	P-value
Angular deviation (°)	3.34 (1.01)	6.67 (1.41)	−3.33 (−6.56 to −0.09)	0.044*
Entry 3D (mm)	0.90 (0.14)	1.91 (0.35)	−1.012 (−1.74 to −0.29)	0.006*
Entry 2D (mm)	0.63 (0.13)	1.61 (0.36)	−0.97 (−1.71 to −0.23)	0.010*
Apex 3D (mm)	0.99 (0.18)	2.17 (0.32)	−1.18 (−1.92 to −0.44)	0.002*
Apex depth (mm)	0.55 (0.11)	0.90 (0.14)	−0.34 (−0.70 to 0.03)	0.068

Abbreviations: BT: bone tracing; CI: confidence interval; MD: mean difference; mm: millimeters; MST: miniscrew tracing; SD: standard deviation; °: degrees.

A single re-registration was required in the MST group, and three re-registrations were needed in the BT group ($p = 0.221$).

4. Discussion

The present in vitro study compared the effect of two registration methods (BT and MST) upon the accuracy of implant placement using d-CAIS in fully edentulous resin models. When miniscrews are employed as fiducial points, implant placement is significantly more accurate. Furthermore, the use of miniscrews enables the placement of dental implants without the need to elevate a flap, unlike the BT technique, which requires bone tracing. However, the use of such devices has some drawbacks [18]. Primarily, they are invasive for the patient, as the miniscrews must be inserted during a prior surgical procedure conducted before the CBCT scan. Secondly, these devices must stay in place until implant placement surgery and may interfere with the use of removable prostheses. Moreover, the miniscrews might generate radiographic artifacts and increase the treatment costs.

The results referred to accuracy in the MST group are in agreement with the data reported in two meta-analyses [19,20] that included clinical and in vitro studies in partially and fully edentulous patients using miniscrews and other radiographic markers.

When partially edentulous patients are involved, the remaining teeth are usually used as fiducial points for d-CAIS registration. These are excellent landmarks that allow simple, comfortable, and minimally invasive registration. However, some authors [21] have reported that miniscrews can afford a more reliable registration in comparison with teeth. Emery et al. [22] used self-tapping screws as a registration method in fully edentulous maxillary models. These authors recorded similar 3D platform (0.58 mm; SD 0.18) and 3D apex deviations (0.63 mm; SD 0.17). However, they obtained a substantially lower angulation deviation (1.26°; SD: 0.67), probably because 5 fiducial points were used instead of only four. The number of required fiducial markers is still a matter of debate and requires additional research. Stefanelli et al. [23,24] showed that tracing 3 fiducial markers seems to be sufficient, but the accuracy increases when 5–6 fiducial points are employed. The same research group also published a study on fully edentulous patients using 4 miniscrews placed prior to the CBCT scan with satisfactory results [25]. Other recent studies have also demonstrated precise implant placement with d-CAIS using the MST registration method in fully edentulous patients. A retrospective cohort study [26] evaluating 22 patients and using 4–6 fiducials obtained mean linear deviations at the 3D platform entry and at the 3D apex of 1.08 mm (SD 0.52) and 1.15 mm (SD 0.60), respectively. The mean angular deviation was 2.85 ± 1.20°. Similarly, Fu et al. [27] employed 4–5 miniscrews and recorded a

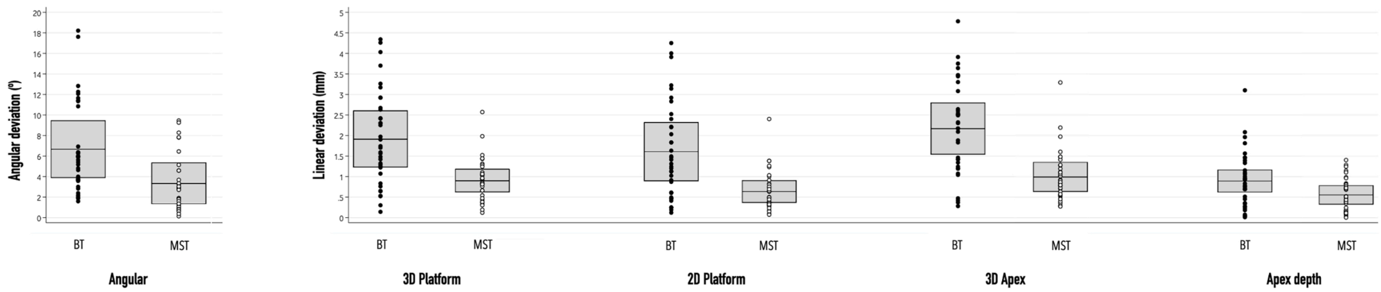

Fig. 5. Box and scatter plots of angular and linear deviations in both study groups. BT: bone tracing; MST: miniscrew tracing.

Table 2
Registration time outcomes.

	MST (SD)	BT (SD)	MD (95 % CI)	P-value
Registration (minutes)	5.01 (1.29)	9.79 (1.54)	4.79 (2.96 to 6.62)	<0.05*
Surgery (minutes)	48.39 (5.39)	54.49 (4.53)	6.10 (−0.31 to 12.51)	0.06

Abbreviations: BT: bone tracing; CI: confidence interval; MD: mean difference; MST: miniscrew tracing; SD: standard deviation.

statistically significantly reduction in 3D platform and apex deviation using d-CAIS compared to s-CAIS. However, implants placed in the s-CAIS group seemed to yield better results in terms of angulation in comparison with d-CAIS. In the present study, 4 fiducials were used in the MST group while 6 points were traced in the BT group. Despite this discrepancy, the use of miniscrews improved the accuracy results.

The position of the fiducial markers might also play an important role in the implant accuracy results. In general, the fiducials should be placed as far away as possible on both sides of the jaw, aiming to form a large polygonal shape. Several studies have used fiducials in the molar (near the maxillary tuberosity), canine, premolar and palate areas [22, 25–27].

The required number and location of miniscrews when zygomatic implants are involved has also been studied [15]. Recently, an in vitro study [14] showed a higher registration accuracy with the MST approach using 4 fiducials in comparison with the BT method. These authors also noted that tracing 6 fiducial markers in bilateral cases appears to enhance the results.

The use of adhesive markers on the palate seems to be an interesting noninvasive alternative, since this method has been shown to be as accurate as MST registration [28]. However, these types of markers also have some disadvantages, such as the risk of detachment and the need to use a large number of devices.

Intraoral radiographic splints with markers might also be an interesting method for performing registration in fully edentulous patients [18]. Radiological fiducial points are marked on the radiographic splint, and a CBCT scan is obtained with the splint positioned in the patient's mouth. During surgery, the guide must be securely placed to warrant an accurate registration, enabling the navigation system software to reliably detect the patient position. However, this method also has some drawbacks, such as the risk of splint movement during the CBCT scan or surgery, splint fracture, radiological artifacts arising from the presence of radiopaque markers, and the associated costs [29]. Indeed, Zhu et al. [30] reported higher angular deviations and lesser patient satisfaction using these devices in comparison with a markerless registration process.

The recently described combination of d-CAIS and s-CAIS has been associated with high patient-reported satisfaction and improvement of quality of life after surgery [31]. However, the accuracy outcomes obtained are similar to those reported in the literature for implant placement with d-CAIS [7,15,20,21]. Furthermore, unlike d-CAIS, this combined technique does not allow intraoperative changes and requires adequate mouth opening for implant placement in the posterior areas.

Recent reports have demonstrated encouraging results with robotic-assisted implant systems (r-CAIS) [32]. A recent meta-analysis showed overall mean implant deviations of 0.81 mm, 0.77 mm and 1.71° for 3D platform, 3D apex and angulation, respectively [33]. However, the scientific data on these devices remain limited, and the high costs of the equipment should be considered.

This study provides clinically useful information regarding the use of bone fiducial points in the registration process of a d-CAIS system. However, some limitations should be mentioned. Firstly, only one d-CAIS system was tested. Secondly, the in vitro nature of the study did not allow full simulation of a clinical scenario. Even though the models were specifically fabricated for this purpose, had soft tissues, and were placed in simulation phantom heads, some clinical variables could not be considered. Thus, there is a need for randomized clinical trials to compare the different available registration techniques (such as miniscrews, bone tracing, adhesive markers, radiographic splints, etc.) to determine the most suitable registration method for d-CAIS. In addition, future research should also measure target registration error and include Patient-Reported Outcome Measures (PROMs) and Patient Reported Experiences (PREMs).

5. Conclusions

The MST registration method increases the accuracy of implant placement with d-CAIS in edentulous maxillas in comparison with the BT method. Although registration is faster when miniscrews are used as fiducial points, the overall surgery time is similar, since some time is required to place and remove these devices.

CRediT authorship contribution statement

Víctor Ruiz-Romero: Writing – original draft, Visualization, Methodology, Investigation, Formal analysis, Conceptualization. **Adrià Jorba-Garcia:** Writing – review & editing, Methodology, Investigation, Formal analysis, Conceptualization. **Octavi Camps-Font:** Writing – review & editing, Visualization, Methodology, Investigation, Formal analysis, Conceptualization. **Rui Figueiredo:** Writing – review & editing, Supervision, Resources, Methodology, Funding acquisition, Conceptualization. **Eduard Valmaseda-Castellón:** Writing – review & editing, Validation, Supervision, Resources, Methodology, Funding acquisition, Conceptualization.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:

The authors declare that they have no known competing financial interests or personal relationships directly related with this study. However, they would like to declare the following interests outside the submitted work:

Dr. Octavi Camps-Font reports grants and non-financial support from Avinent (Santpedor, Spain), and non-financial support from Nobel Biocare (Zürich, Switzerland) outside the submitted work.

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