UNIVERSITAT DE BARCELONA

Dynamic computer-assisted surgery for the placement of dental implants

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Doctoral thesis

Dynamic computer-assisted surgery for the placement of dental implants

Doctoral thesis dissertation presented by Adrià Jorba García to apply for the degree of doctor at the University of Barcelona

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Another turning point,

a fork stuck in the road

Time grabs you by the wrist,

directs you where to go

So make the best of this test,

and don't ask why

It's not a question,

but a lesson learned in time

Green Day

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ABBREVIATIONS, ACRONYMS AND SYMBOLS

- °: Sexagesimal degree
- <: More than
- >: Less than
- =: equal
- %: Percentage
- Ø: Diameter
- ®: Registered trademark
- 2D: Two-dimensional
- 3D: Three-dimensional
- 95% CI: 95% Confidence Interval
- A.G-B.: Albert González-Barnadas
- A.J-G.: Adrià Jorba-García
- AR: Augmented Reality
- ASA: American Society of Anesthesiologists
- B: Coefficient
- CAD-CAM: Computer-Assisted Design - Computer-Assisted Manufacture
- CAIS: Computer-Assisted Implant Surgery
- CBCT: Cone-Beam Computed Tomography
- CONSORT: Consolidated Standards of Reporting Trials
- CT: Computed Tomography
- dCAIS: Dynamic Computer-Assisted Implant Surgery
- df: Degrees of freedom
- DICOM: Digital Imaging and Communication in Medicine

- EAO: European Association for Osseointegration
- FDI: World Dental Federation
- FH: Non-guided Freehand
- FoV: Field of View
- g: Grams
- GEE: Generalized Estimating Equation
- h: hours
- ICC: Intraclass Correlation Coefficient
- i.e.: id est
- IOS: Intraoral Scan
- IQR: Interquartile Range
- ITI: International Team for Implantology
- J.B-C.: Javier Bara-Casaus
- kV: Kilovolt
- LED: Light-Emitting Diode
- mA: Milliampere
- MD: Mean Diference
- mg: miligrams
- Min: minutes
- mm: Milimeters
- MTR: Markerless Pair-point Tracing Registration
- n: number
- O.C.-F.: Octavi Camps-Font
- OHIP: Oral Health Impact Profile

- P: P-value
- PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
- PRE: Patient-Reported Experience
- PROMs: Patient-Reported Outcome Measures
- QoL: Quality of Life
- RMR: Radiographic Marker Registration
- RoB: Risk of Bias
- rCAIS: Robotic Computer-Assisted Implant Surgery
- RCT: Randomized Controlled Clinical Trial
- sCAIS: Static Computer-Assisted Implant Surgery
- SD: Standard deviation
- STL: Standard Tessellation Language
- UFR: Unitat de Formació i Recerca
- VAS: Visual Analog Scale
- V.R-R.: Victor Ruiz-Romero
- Vs.: Versus
- $\chi 2$: Pearson $\chi 2$ test

1. List of papers included in the PhD thesis

Thesis in compendium of publications format.

The thesis consists of four objectives and four papers (one systematic review and meta-analysis, one randomized controlled clinical trial and two experimental *in vitro* studies):

1. **Jorba-García A**, Bara-Casaus JJ, Camps-Font O, Sánchez-Garcés MÁ, Figueiredo R, Valmaseda-Castellón E. Accuracy of dental implant placement with or without the use of a dynamic navigation assisted system: A randomized clinical trial. Clin Oral Implants Res. 2023;34:438-49.
    - Impact Factor (2023): 4.8
    - JCR position (Dentistry, Oral Surgery and Medicine): 7/157 (1st quartile)
2. **Jorba-García A**, González-Barnadas A, Camps-Font O, Figueiredo R, Valmaseda-Castellón E. Accuracy assessment of dynamic computer-aided implant placement: a systematic review and meta-analysis. Clin Oral Investig. 2021;25:2479-94.
    - Impact Factor (2021): 3.607
    - JCR position (Dentistry, Oral Surgery and Medicine): 26/92 (2nd quartile)
3. **Jorba-García A**, Ruiz-Romero V, Bara-Casaus JJ, Camps-Font O, Sánchez-Garcés MÁ, Figueiredo R, Valmaseda-Castellón E. The effect on the performance of a dynamic navigation system of superimposing a standard tessellation language (STL) file obtained with an intraoral scan on a cone beam computer tomograph (CBCT). An experimental in vitro study. J Dent. 2024;148:105150 (in press).
    - Impact Factor (2023): 4.8
    - JCR position (Dentistry, Oral Surgery and Medicine): 7/157 (1st quartile)

4. **Jorba-García A**, Bara-Casaus JJ, Camps-Font O, Figueiredo R, Valmaseda-Castellón E. The influence of radiographic marker registration versus a markerless trace registration method on the implant placement accuracy achieved by dynamic computer-assisted implant surgery. An in-vitro study. J Dent. 2024;146:105072 (in press).
    - Impact Factor (2023): 4.8
    - JCR position (Dentistry, Oral Surgery and Medicine): 7/157 (1st quartile)

2. THESIS SUMMARY

(Spanish)

Cirugía asistida por ordenador dinámica en implantologia

Introducción:

La Cirugía Asistida por Ordenador (CAIS) en Odontología ha sido diseñada con el propósito de minimizar las discrepancias entre la planificación preoperatoria y la posición final del implante. La CAIS dinámica (dCAIS), también conocida como sistemas de navegación, permite determinar la posición de la fresa quirúrgica y/o del implante con respecto al paciente, mostrándolo en tiempo real sobre las imágenes de la CBCT. Estos sistemas guían al cirujano en tiempo real durante la intervención quirúrgica, asegurando que la colocación tridimensional del implante se ajuste con precisión a la planificación preoperatoria.

Se ha llevado a cabo una revisión sistemática y un metaanálisis para evaluar la precisión de los distintos sistemas dCAIS en implantología y en los estudios clínicos incluidos en el meta-análisis, se observaron desviaciones angulares y de plataforma utilizando dCAIS de 3.68° (IC 95%: 3.61 a 3.74; I^2 = 99.4%) y 1.03 mm (IC 95%: 1.01 a 1.04; I^2 = 82.4%), respectivamente. Las desviaciones fueron menores en los estudios *in vitro* con una desviación angular media de 2.01° (IC 95%: 1.95 a 2.07; I^2 = 99.1%) y una desviación media de plataforma de 0.46 mm (IC 95%: 0.44 a 0.48; I^2 = 98.5%). Los sistemas dCAIS demostraron ser significativamente más precisos que los sistemas de sCAIS (MD: -0.86°; IC 95%: -1.35 a -0.36) y que la colocación de implantes a mano alzada (MD: -4.33°; IC 95%: -5.40 a -3.25).

Hipótesis:

La dCAIS es significativamente más precisa y segura que la cirugía convencional a mano alzada (FH). Por otro lado, el registro del paciente mediante el protocolo sin marcadores radiográficos (MTR) es más preciso que el protocolo tradicional con marcadores radiográficos (RMR). Finalmente, la superposición de un escaneado intraoral (STL) sobre el CBCT no aporta mayor precisión a la dCAIS.

Objetivos:

Evaluar la precisión de la dCAIS en diversos escenarios *in vitro* y clínicos y compararla con la colocación de implantes a mano alzada. Por un lado, se pretendió evaluar y comparar la precisión y seguridad de la dCAIS frente a la cirugía convencional a mano alzada. Adicionalmente, se trató de analizar la precisión del registro del paciente mediante los protocolos MTR vs. RMR y mediante el uso de un escaneado intraoral vs. el CBCT.

Métodos:

Se han realizado dos estudios *in vitro* y un ensayo clínico aleatorizado para evaluar la precisión en la colocación de implantes dentales con un sistema de dCAIS. En el ensayo clínico aleatorio con 2 brazos paralelos se incluyeron pacientes parcialmente edéntulos que fueron asignados aleatoriamente a los grupos dCAIS o FH.

Respecto a los estudios *in vitro*, se emplearon modelos de resina para comprobar si la introducción del STL aportaba una mejora en la precisión del sistema de navegación; y

por otro lado, se compararon dos protocolos de registro, con y sin marcadores radiográficos (RMR vs. MTR), en distintas situaciones clínicas.

La precisión de la colocación de los implantes en los distintos estudios se evaluó superponiendo los CBCTs pre y postoperatorios y comparando la posición real del implante con la planificada. En todos los estudios incluidos en la presente tesis doctoral se calcularon las desviaciones lineales en mm (2D y 3D) a nivel de la plataforma y de la zona apical del implante y se midieron las desviaciones angulares (en grados). En el ensayo clínico, también se registró la satisfacción del paciente, el dolor y la calidad de vida durante la cirugía y en el periodo postoperatorio. En los tres estudios se efectuó un análisis descriptivo, bivariable y multivariante de los datos.

Resultados principales:

En el ensayo clínico se incluyeron 30 pacientes y se encontró una desviación angular media significativamente menor en el grupo de dCAIS (4.02°; intervalo de confianza del 95% (IC 95%): 2.85 a 5.19) frente al grupo FH (7.97°; IC95%: 5.36 a 10.58). Las desviaciones lineales también fueron significativamente menores en el grupo dCAIS, excepto a nivel de profundidad, donde no se encontraron diferencias. La colocación con implantes fue, de media, 14 minutos más lenta en el grupo dCAIS (IC 95%: 6.43 a 21.24; $p < 0.001$), si bien los pacientes de ambos grupos consideraron aceptable el tiempo quirúrgico. No se observaron diferencias en cuanto al dolor postoperatorio y el consumo de analgésicos, y la satisfacción del paciente fue muy alta en ambos grupos.

En el primer estudio *in vitro* se colocaron 136 implantes en 28 modelos de resina para comparar los sistemas de registro con (RMR) y sin marcadores (MTR) radiográficos. Los implantes colocados sin marcadores (grupo MTR) tuvieron desviaciones significativamente menores ($p < 0.001$) a nivel de la plataforma (diferencia de medias (MD) de 0.69 mm; IC 95%: 0.41 a 0.98) y del ápice (MD: 0.55 mm; IC 95%: 0.23 a 0.88). Las desviaciones angulares fueron similares en ambos grupos (MD: 0.41; IC 95%: -0.90 a 1.73); $p>0.05$). El protocolo MTR aumentó la precisión en la colocación de implantes en la zona anterior de la mandíbula ($p<0.05$) y no aumentó significativamente el tiempo quirúrgico ($p=0.489$).

En el segundo estudio *in vitro*, se analizaron 60 implantes y se observó que la introducción del archivo STL (grupo CBCT+STL) permitió una desviación significativamente menor en la zona de la plataforma (MD: 0.17 mm; IC 95% : 0.01 a 0.23; $p = 0.039$) en comparación con el grupo CBCT. No se registraron diferencias en las demás variables de precisión y el tiempo de cirugía.

Conclusiones:

Los sistemas de dCAIS permiten una colocación de implantes altamente precisa con un promedio de desviación angular de menos de 4°. Asimismo, aumentan la precisión en la colocación de implantes en comparación con la colocación de implantes a mano alzada. Sin embargo, aumentan significativamente el tiempo quirúrgico y no parecen mejorar la satisfacción del paciente ni reducir el dolor postoperatorio en comparación con la colocación a mano alzada. Se puede también concluir que los sistemas de dCAIS son más precisos cuando se emplean registros sin marcadores (MTR). Por otro lado, la

introducción de un escaneo intraoral (STL) superpuesto en la imagen de CBCT no parece aumentar la precisión de los sistemas de dCAIS.

3. INTRODUCTION

Since Brånemark defined the concept of osseointegration in the mid-60s (1), oral rehabilitations have significantly changed due to the introduction of dental implants. Nowadays, these medical devices are considered to be a reliable and predictable treatment option to rehabilitate both partially and totally edentulous patients (2,3).

The reported survival rate of dental implants is notably high, estimated to be around 95% (2). However, in contemporary Dentistry, the focus should not rely exclusively on osseointegration or implant survival but rather on the absence of complications related with the implant treatment (4,5). With current implant surfaces, osseointegration is no longer considered the only objective, and other parameters such as aesthetics, function, or the reduction of mechanical (prosthetic component fractures) or biological complications (peri-implant diseases) should be considered paramount (6,7). Several authors have defined success criteria in dental implant treatments, but Albrektsson and colleagues (8) guidelines published in 1986 are still the most commonly-used. However, several papers have added additional parameters related with the prosthetic restoration, aesthetic outcomes, and the presence of peri-implant diseases (9–11).

Dental implants should be planned and placed in an ideal prosthetically driven position to achieve optimal functional, mechanical, and esthetic outcomes (5,12,13). An ideal prosthetically driven implant position refers to the strategic placement of a dental implant considering the design of the final restoration, which is the ultimate goal of implant placement.

Indeed, one study estimates that around 7% of complications might be related to implant malposition (14). Moreover, other authors have reported that the distance to the neighboring teeth/implant was incorrect in almost 1/5 of the analyzed implants (15).

Hence, an adequate pre-surgical planning is of utmost importance to prevent intraoperative complications (e.g. anatomic structure lesion) or postoperative long-term complications such as: mechanical (e.g. screw loosening, prosthetic components or implant fractures), biological (e.g. peri-implant diseases or buccal bone dehiscence), and esthetic complications (e.g. soft tissue deficiencies or interproximal papilla height loss) after loading of the prosthesis (16–18). All these postoperative complications might not affect implant survival but could require additional appointments and lower patient's satisfaction.

Traditionally, dental implants were planned by means of two-dimensional (2D) images such as intraoral or panoramic radiographies. However, these exams have significant drawbacks such as the superimposing of anatomical structures, the distortion of the images, and the absence of three-dimensional (3D) information. These limitations have posed challenges for clinicians in the diagnosis and planning of oral and maxillofacial pathologies for many years. The development of new three-dimensional (3D) imaging technologies has solved many of these limitations.

In 1972 Hounsfield introduced the computerized transverse axial scanning which led to the development of Computed Tomography (CT) (19). Then in late 1990's, Cone-Beam Computed Tomography (CBCT) was developed and introduced in Dentistry, and oral and

maxillofacial surgery. Mozzo et al. (20) in Italy (NewTom-9000; Quantitative Radiology, Verona, Italy) and Arai et al. (21) in Japan, who worked separately at the same time in the same idea, were the first to describe and introduce the CBCTs. CBCT scanners allowed a huge step forward in the diagnosis, assessment of disease severity, planning, delivery of treatment, and follow-up evaluation, allowing a cost-effective and accurate 3D evaluation of the patient's anatomy and pre-surgical planning (22–24).

Nowadays, CBCT have widely replaced the traditional CT scan for dental presurgical assessment, because of its lower radiation dose, reduced cost, short scanning time, better resolution, and ease of interpretation. CBCT scanners can be collimated to reduce the Field of View (FOV) and reduce scanning time and effective radiation dose. Moreover, CBCT can offer high-definition images with low voxel sizes allowing a sub-millimeter resolution ranging from 0.4 mm to as low as 0.09 mm which is precise enough for measurements in oral and maxillofacial applications, such as oral implantology (25). Finally, the data sets obtained from CBCT can be processed and segmented in a non-orthogonal manner, allowing for the creation of oblique or curved planar reconstructions. These reconstructions are highly advantageous as they generate distortion-free simulated panoramic images, which provide a more accurate and comprehensive visualization of the anatomical structures. Additionally, this method enables the production of serial cross-sectional planes, offering detailed views of the region of interest from multiple angles. These capabilities enhance diagnostic precision, especially in implantology, enabling clinicians to better evaluate surgical site in ways that conventional imaging techniques might not allow. (Figure 1).

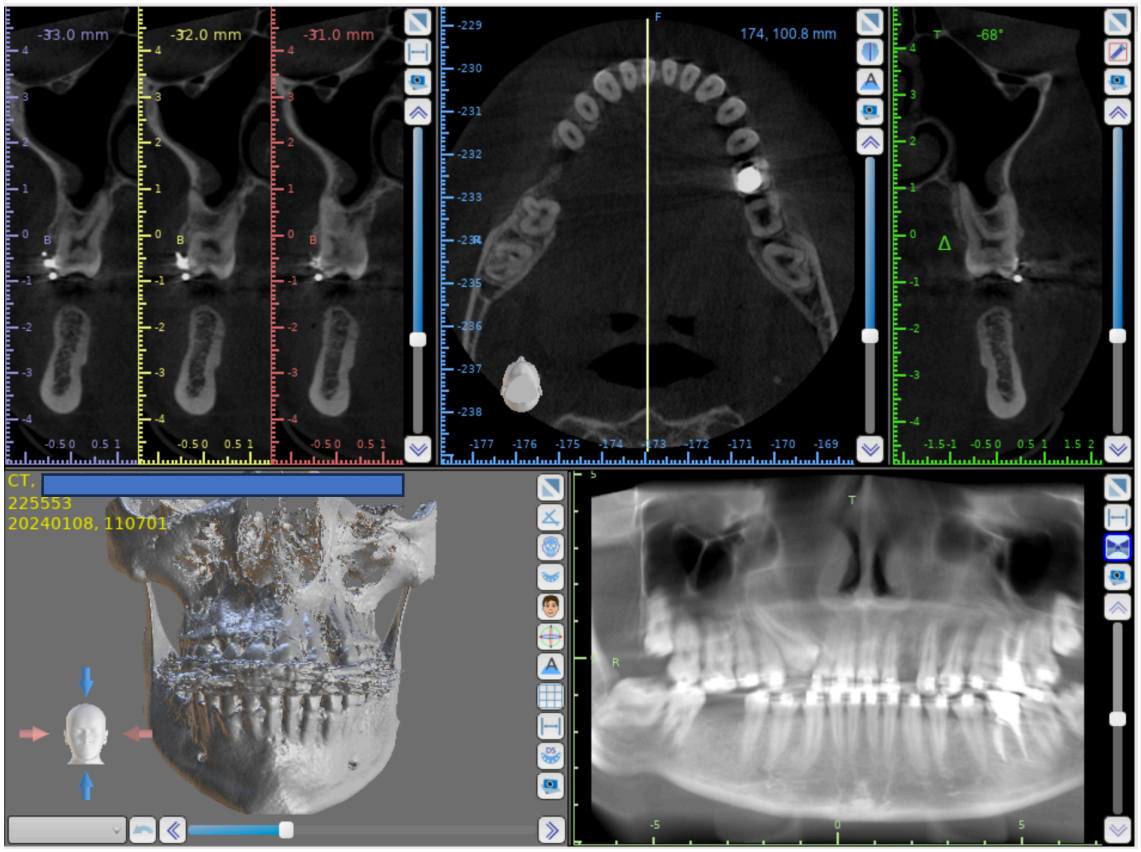

Figure 1: CBCT scan visualization with 3D reconstruction, panoramic reconstruction, cross-sectional planes, and orthogonal planes.

On the other hand, CBCTs have some limitations like the poor soft tissue definition and the presence of artifacts or image noise, which are usually associated with metal devices or patient movements during the scanning (26,27).

Several software programs have been developed to facilitate the diagnostic and preoperative planning phases of implant surgery. One of the first commercially available planning software program was SIM/PLANT® (Columbia, MD, USA), which was launched in 1993 (28). Nowadays, a wide range of planning software options are available to clinicians (29,30). These tools allow dental professionals to visually and interactively analyze CBCT scan data. It is possible to strategically place a virtual implant in the CBCT

images and relate it with the planned prosthesis. Furthermore, these software platforms provide several functions, like the delineation of the mandibular canal, distance measurement, implant parallelization, selection of implants, virtual placement of abutments of different angulation and height, etc. Modern implant planning software programs allow integration of the bone, dental and soft tissue anatomy using a CBCT and an intraoral scan (IOS). With all this information, clinicians can plan the ideal prosthetically-driven implant position before surgery, and virtually simulate the prosthetic rehabilitation (31) (Figures 2 and 3).

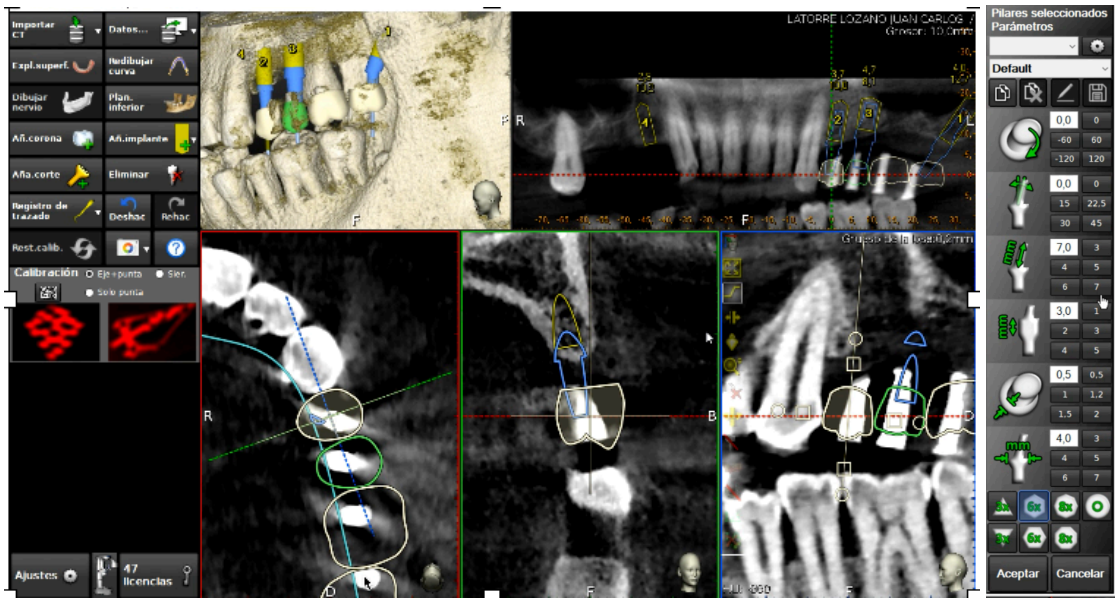

Figure 2: Prosthetic and implant planning using Navident® Software (ClaroNav, Toronto, Canada). Implants were planned in the position of 2.4, 2.5, and pterigoid area. Transepitelial abutments and prosthetic crowns were also planned. The software allows to plan the angulation and height of the abutment according to the implant and crown position.

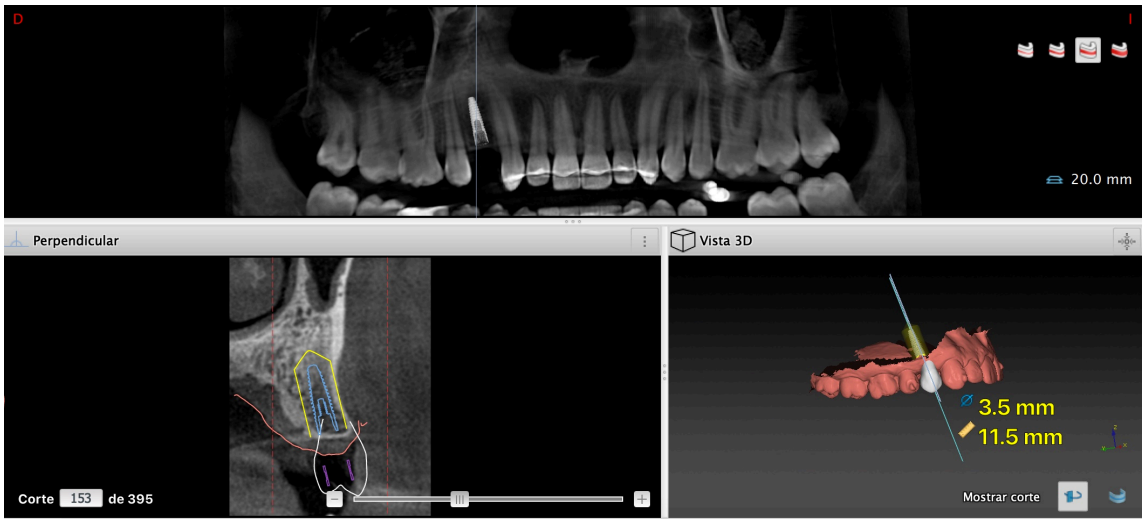

Figure 3: Prosthetic and implant planning using DTX Studio™ Software (Nobel Biocare AG, Zürich, Switzerland). A virtual mock-up of the missing teeth 1.4 was used to determine position of the implant.

During surgery, the reproduction of the planned position of the implant on the CBCT is a sensitive process by which the planned implant position has to be transferred to the patient jaw. Thus, accurate control of the position and angulation of the bur and the implant in the three dimensions of the space (mesio-distal; bucco-lingual and depth) is paramount. Despite the common use of 3D images and planning softwares to virtually simulate surgeries, most dentists still use a freehand non-guided approach when placing dental implants in their clinical practice, which can result in significant deviations between the preoperatively planned positions and the actual position of the implant in the patient's jaw (32).

To reduce inaccuracies between the planned and final position of the dental implant, computer-assisted implant surgery (CAIS) has been developed and introduced into implant dentistry (33). Quoting Nikos Mattheos, "CAIS technology is mainly defined by

the use of digital aids or products during the surgical implant placement" (34). These digital aids can be static, when the surgeon places the implant in a pre-determined position by means of a surgical guide or template; or dynamic, when the implant is placed by following its real time progression on a screen, in relation to a pre-identified position (34).

3.1. Background

Computer-assisted surgery was initially used in the neurosurgery field (35,36). During procedures such as biopsies, electrodes or catheter placement or resection of small intracranial tumors, when accuracy in finding the exact localization and targeting of intracranial structures is of utmost importance. Thus, at the end of 19th century several approaches began to offer some kind of guidance to surgeons to precisely locate intracranial structures (35).

The first attempt to do guided neurosurgeries was using frame-based stereotactic systems, which are the precursors of the current static CAIS approach. Frame-based stereotactic procedures were developed in an attempt to accurately locate intracranial structures. This technique employs a frame, which is firmly attached to the patient's head. The 3D location of the target point in the brain is defined and the corresponding coordinates are defined by the frame's orientation and position (35,36). The foundations of stereotactic surgery were laid down at the beginning of the 20th century (1906) with experiments from Robert Henry Clarke and Sir Victor Horsley, who developed the first stereotactic devices for animal research (37).

Initially, frame-based stereotactic procedures were based on anatomical drawings to give the coordinates of the target anatomical structure. However, since “standard” anatomical landmarks may not be suitable for every patient due to variations or pathological alterations, several inaccuracies were detected (35,36). The first human surgery using frame-based stereotactic procedure was performed by Kirschner in 1933 (38) to treat a idiopathic trigeminal neuralgia by puncturing the skull base’s ovale foramen. Nevertheless, the absence of imaging techniques to visualize intracranial structures and individual variations limited the stereotactic calculations of deep brain targets.

In 1947, Spiegel and Wycis (39) introduced the first framed stereotactic tool with 3D targeting using internal brain anatomy, but it wasn’t until 1979 when the first CT data-based frame-based stereotactic system was developed: the Brown-Roberts-Wells stereotactic system (40–43). This was the first system able to transfer the CT data into an operation setting.

More recently in 2001, a 3D personalized prototyped stent was fabricated to transfer the ideal position of a spinal drilling from a CT into the patient (28,44). Hence, these frame-based stereotactic systems and drilling guides were the percursors of the current static CAIS systems used in implantology.

On the other hand, the advances in 3D imaging technologies, computers and the higher experience in frame-based stereotactic systems led to Roberts and colleagues to develop in 1986 the first device using a frameless stereotactic procedure: the neuronavigation

(35,45,46). These frameless stereotactic systems allow the surgeon to visualize the predefined target point on CT or magnetic resonance images during surgery and use it for intraoperative navigation. Since then, several modifications and improvements of neuronavigation systems have been introduced (i.e. systems based on magnetic sources (47), on pointer emitting ultrasounds signals (48), or on optoelectronic infrared light-emitting diode (LED) (49)).

The introduction of these frameless systems has allowed a significant advance in neurosurgery, eliminating the need for attaching a frame to the patient's head and enabling a broader range of procedures with reduced risks and a shorter surgical time. A recent systematic review and meta-analysis, showed no statistically significant differences when comparing frame-based versus frameless intracranial stereotactic biopsy in terms of diagnostic, morbidity, mortality, post-biopsy hemorrhages or neurological deficit (50).

These motion tracking systems have rapidly evolved, extending their applications to various medical fields, including surgical oncology, orthopedics, and laparoscopic surgery over the past 40 years (51,52). These systems were the predecessors of dynamic CAIS in implant dentistry (53).

3.2. Computer-assisted implant surgery

In the field of computer-assisted implant surgery we can mainly differentiate between two main approaches to place dental implants: the static CAIS (sCAIS), which uses surgical stents to guide the burs and implant placement according to a pre-planned

position; and the dynamic CAIS (dCAIS), which provides an intraoperative real-time tracking of the drills and implants. These dCAIS systems, also called navigation systems, offer an immediate feed-back of the position of the drills and implants in relation to the preoperative planning in the CBCT images that can be seen on the screen.

3.2.1. Static computer-assisted implant surgery

Although sCAIS falls outside of the scope of the present thesis, a brief overview of its principles and workflow will be addressed. Static CAIS is based upon the CAD-CAM (computer-assisted design - computer-assisted manufacture) principle. Hence, once a dental implant is planned in the CBCT using a planning software, a surgical guide with specific holes to place the sleeves is designed. This surgical stents will guide the drilling sequence and implant placement. Figure 4 provides a detailed summary of a clinical case involving a patient treated using a sCAIS approach.

The workflow of sCAIS for partially edentulous patients consists of:

1. Data acquisition: DICOM (Digital Imaging and Communication In Medicine) data of the patient should be obtained through a CBCT scan and the intraoral dental anatomy should also be recorded. There are two different approaches to obtain the information related with the intraoral anatomy: intraoral optical scanners (IOS) or cast models obtained with a conventional impression technique. In the latter, casts must be digitalized, usually by means of a desktop 3D scanner. Regardless of the process, the anatomy of the dental arches will be converted into a STL (Standard Tessellation Language) file.

2. Patient registration: using a planning software, clinicians should import both DICOM and STL files, and accurately overlay both images marking at least 3 common reference points in both 3D images (54).
3. Planning phase: Once all data is imported to the planning software, the clinician can virtually place the implant. As mentioned previously, several software functions are available, such as drawing of the mandibular canal or the virtual design of the prosthesis. This tool enables a prosthetically driven planning of the implant position.
4. Surgical stent design: Once implant position is defined in the software, a surgical stent must be designed to transfer this virtual information to the patient usually with the same planning software. Other parameters could be planned, such as the extension of the surgical stent, the use of additional bone support (i.e. anchor pins), or the opening of windows along the stent to verify the correct fit of the stent during the surgery. Once the stent design is validated, the file is exported to an STL file and the stent is manufactured by the dental technician or using an in-house printer.
5. Surgical stent manufacture: The conversion of the STL file into a stent might be made with and additive (printed) or subtractive (milled) procedure. Printing can usually be performed in-house (in the dental office) or by a dental technician. Once the surgical stent is manufactured, specific metallic sleeves adapted to the drill diameter are usually placed in holes.
6. Surgical phase: During the procedure, the surgical stent must be adapted to the patient arch and the drilling sequence and implant placement should be done through the sleeve of the stent.

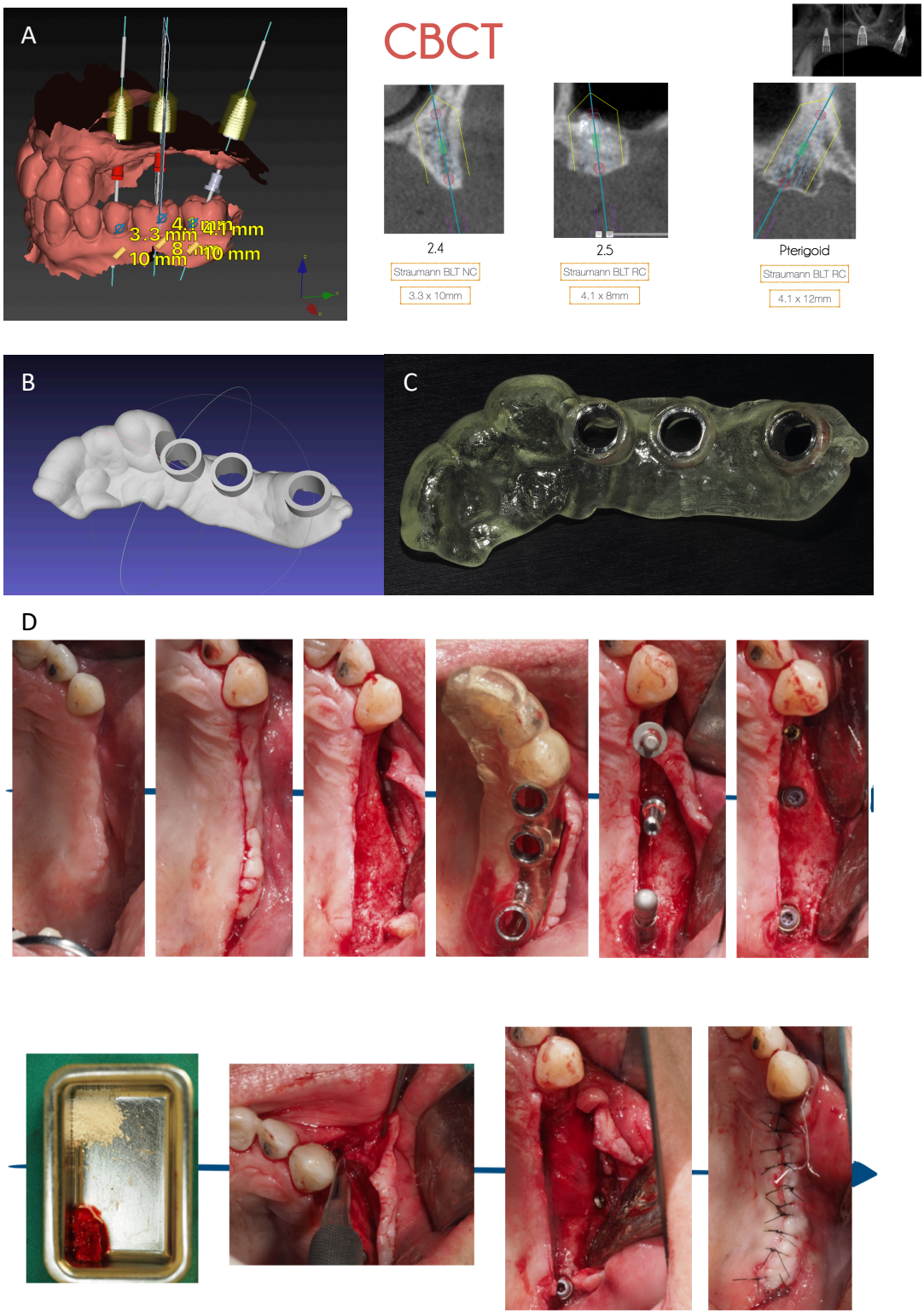

Figure 4: Clinical case showing implant placement using sCAIS. A. implant planning using the software DTX Studio™ Software (Nobel Biocare AG, Zürich, Switzerland). B. 3D designed sugical stent. C. 3D printed sugical stent. D. Detailed surgical procedure: initial situation, incision, flap elevation, surgical guide placement and drilling sequence, pin position check to ensure apropiate

implant position, implant placement, guided bone regeneration using autologous and xenogeneic particulated bone graft covered with a collagen membrane, suture (using PTFE 5/0 suture and Supramid 4/0).

Surgical stents can be classified according to the supporting tissues. In partially edentulous patients, most of the guides are tooth-supported. Nevertheless, in fully edentulous patients or when the remaining teeth do not offer a proper stability, stents can be adapted to the mucosa or bone.

When facing totally edentulous patients, special considerations should be taken into account. Firstly, the oral mucosa does not offer good reference points, so the overlaying of the STL and DICOM files might be challenging. Moreover, intraoral scanning of the patient mucosal anatomy is often inaccurate, since the intraoral scanner lacks reference points. Although several solutions have been developed, probably the most used technique is the double-scan, which consists of firstly do a CBCT of the patient wearing a radiographic stent, and then a CBCT of the radiographic stent itself. These two CBCT scans are overlayed, which gives the clinician information of the desired prosthesis (outer stent surface) and the mucosal surface (inner stent surface) (55). Stabilization of the stent during the surgical procedure is also a matter of concern since this is critical factor to avoid innacuracies. Hence, these stents sometimes need to be supported by anchor pins.

3.2.2. Dynamic computer-assisted implant surgery

The dynamic CAIS systems are also known as navigation systems. As highlighted before, these systems provide a real-time feedback of the relative position of the drill or dental implant and the patient jaw. This relative position is shown by the navigation system software on the preoperative CBCT scan with the implant planning. Hence, clinicians are able to visualize on a screen the position of the surgical drill within the reconstructed images of the CBCT, and guide the drilling and implant insertion during the surgery without any surgical stent. Figure 5.

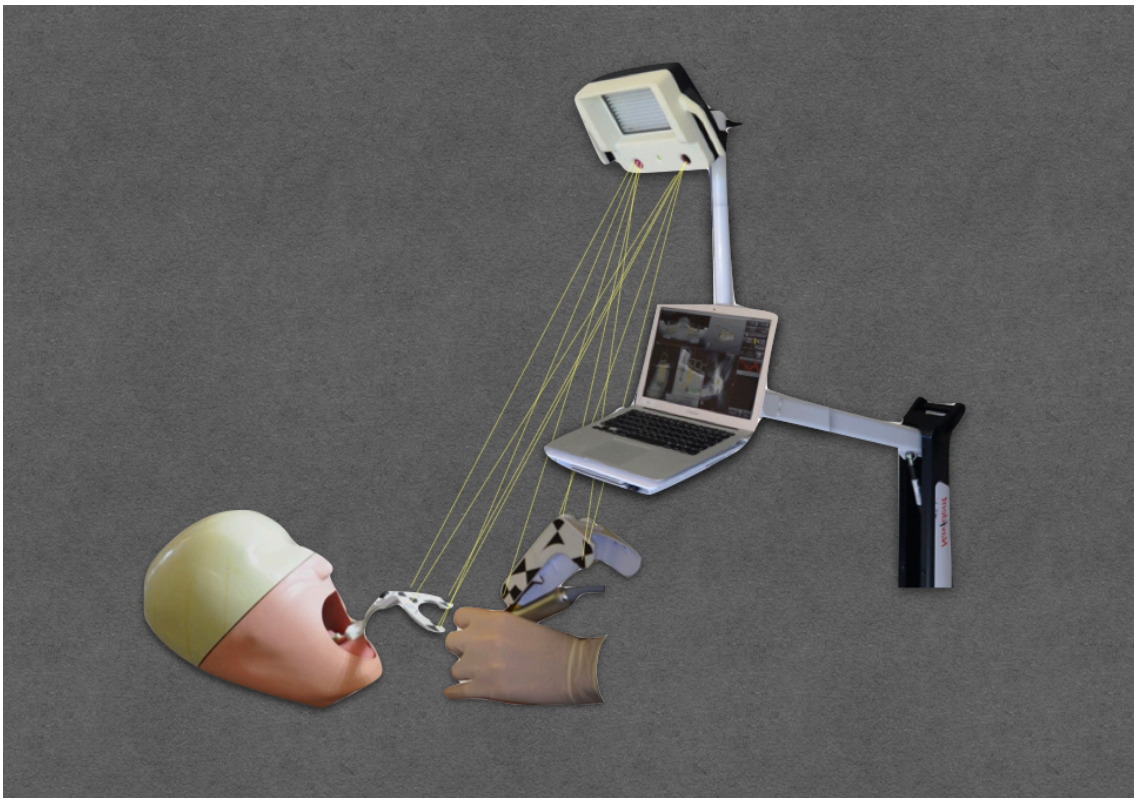

Figure 5: Diagram showing show a dCAIS system works. Reproduced with permission from Jorba-García A, et al. (56).

Nowadays, there are different available dCAIS systems in the market (57). A recent systematic review showed that not all the commercially available navigation systems have the same amount of scientific studies (58). Until 2020, only 9 navigations systems had studies published in indexed journals. In this regard, Navident (Navident®, ClaroNav Technology Inc.®, Toronto, Canada), seems to be the most used device and has been assessed in 10 studies (5 of which were clinical studies), followed by AqNavi (AQNavi, TITC Ltd, Kaohsiung, Taiwan) with 4 studies. The ImplaNav (ImplaNav; BresMedical, Sydney, Australia), AqNavi (AQNavi, TITC Ltd, Kaohsiung, Taiwan), and X-Guide (X-Guide, X-Nav Technologies, LLC, Lansdale, Pa) system were only assessed in 1 clinical study, whereas the remaining systems were tested in *in vitro* settings.

Despite small differences, dCAIS systems usually have the following key components:

- A **compact mobile cart** with a foldable arm that supports the stereoscopic camera and a computer with the dCAIS software. When extended, this arm enables positioning the computer and the optical position sensor above the patient's chest while the cart base is placed next to the patient.
- An **optical position sensor** or a **stereoscopic camera,** which detect the optical markers attached to the patient and the handpiece. It constantly reports their relative positions to the dCAIS software with a precision of a fraction of a millimeter.

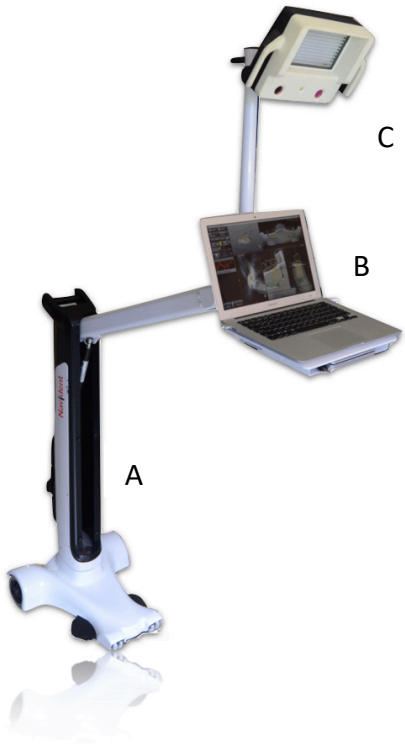

Figure 6: Navident® dCAIS system. A. Mobile cart; B. Laptop with dCAIS system software; C. stereoscopic camera

- A **calibrator** with a specific design to calibrate the axis and the length of the drill or implant.

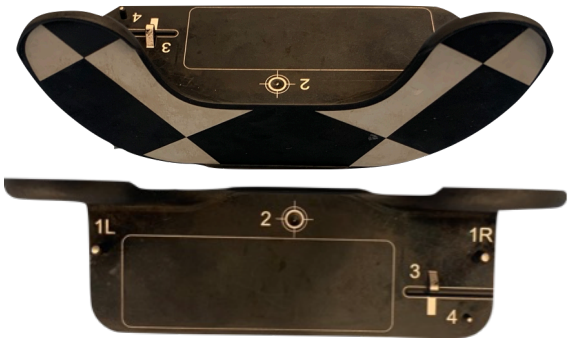

Figure 7: Navident® dCAIS system calibrator. Pins 1R and 1L are designed to calibrate drill axis. The circle 2 is designed to calibrate drill length. The number 3 is designed to calibrate a piezosurgery tip.

- A **handpiece optical marker** with specific patterns that can be recognized by the stereoscopic camera. This optical marker must be firmly attached to the handpiece.

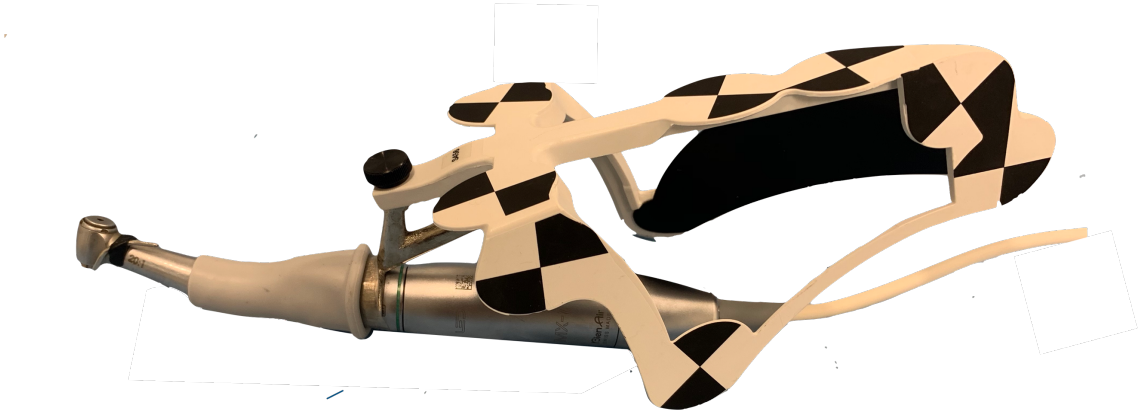

Figure 8: Navident ® dCAIS system handpiece optical marker.

- A **patient optical marker**. This optical marker is recognized by the camera and reports the information on the relative position of the patient. In general, most systems use 2 types of patient optical markers:
    - Extraoral optical markers: they are attached to a head-mounted device placed on the nasion and stabilized in the ears. This type of optical marker can only be used in the maxilla, since it does not detect mandibular movements.
    - Intraoral optical markers: these can be tooth-supported (most common) or bone-supported. These markers can be placed using thermoplastic resins, polyvinylsiloxane additive silicones or light curing resins. In edentulous patients or patients with insufficient tooth support, bone-supported optical markers fixed with microscrews are a valid option.

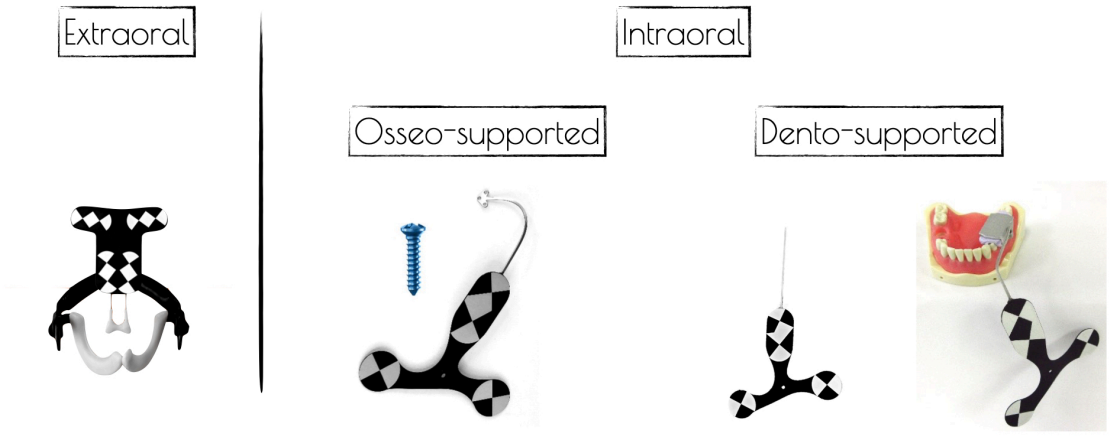

Figure 9: Patient optical markers. The figure shows different support methods for intra and extraoral optical markers.

- Patient registration might require additional devices. This process will be addressed with more detail in this thesis. However, we can define that, depending on the registration process used, the system will require:
    - Radiographic marker registration (RMR): **a radiographic marker** that can be attached to the patient teeth using a thermoplastic intraoral splint or clip.

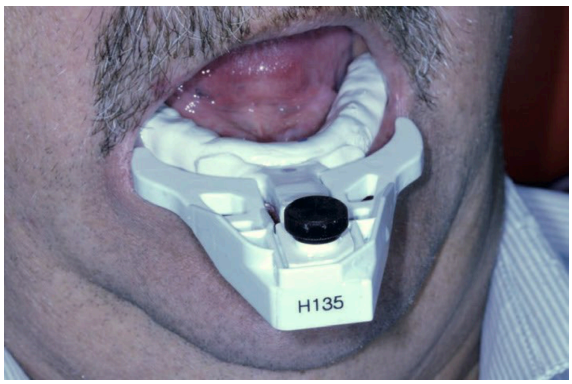

Figure 10: Navident ® radiographic marker attached to a thermoplastic splint.

- Markerless pair-point registration (MTR): **a tracer device**, which consists of a specific probe with optical markers.

Figure 11: Navident ® tracer device.

The navigation software can vary slightly between systems. Software interface providing intraoperative guidance varies according to the system, but usually shows the relative real-time position of the drill or the implant on a panoramic reconstruction, and cross-sectional, coronal, and sagittal slices of the implant position (Figure 12). Moreover, most of the softwares show a dartboard with the real-time deviations of the implant (linear and angular), which facilitates guidance to the preoperative planned position (Figure 13). Finally, some systems use acoustic signs and different colors on the screen to provide information to clinicians regarding the amount of deviations or if the planned depth has been reached.

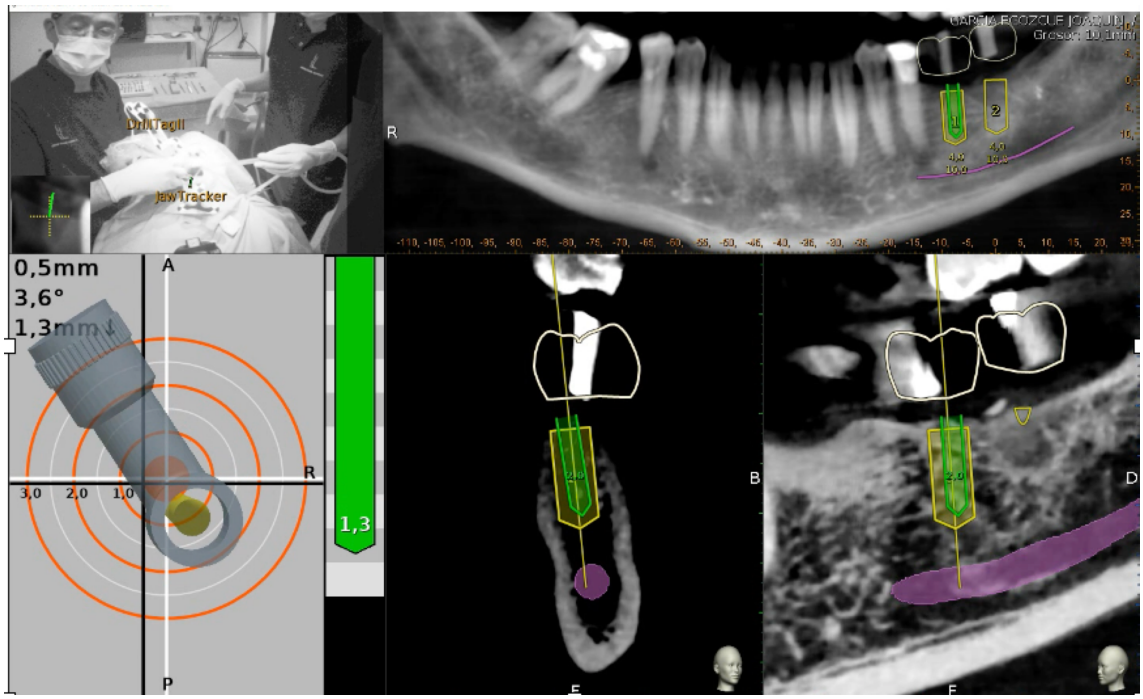

Figure 12: Navident ® dCAIS software guidance interface during a surgical procedure.

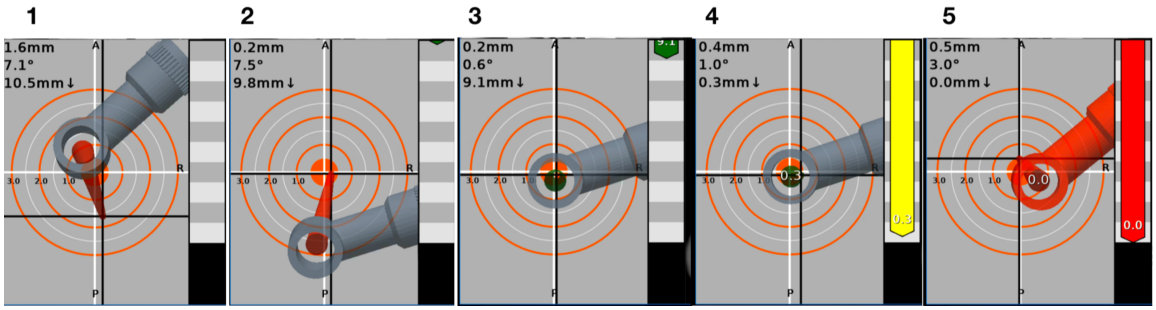

Figure 13: Interpretation of deviations according to the dartboard: (1) Incorrect 2D positioning and angulation. (2) Adequate positioning and incorrect angulation. (3) Adequate positioning and angulation (note the green color on the center of the handpiece). (4) Depth ruler (in yellow) shows that 0.3mm are necessary to reach the desired length. (5) The final position has been reached (note that the depth ruler turns to red).

3.2.2.1. Types of dCAIS systems

dCAIS systems are classified according to the camera and tracking technologies. On one hand, cameras can use visible or infrared lights. For example, the Navident system (ClaroNav Technology Inc.®, Toronto, Canada) works using visible light (32), while Dcarer (Dcarer Medical Technology, Suzhou, China) uses infrared light (59). On the other hand, dCAIS systems use an active or passive tracking (60). Active systems have an optical camera to detect the emission of infrared lights from devices attached to the surgical instruments and patient. Conversly, in passive systems the infrared light source is located next to the camera, and the signal is reflected on specific points of the surgical instruments. Visible light systems are also considered to be passive navigation devices, since the optical camera detects feature codes or patters on surgical instruments, thus enabling the real-time tracking (53,60).

3.2.2.2. Registration process

The registration process of the patient is one of the most critical steps to avoid undesirable deviations. dCAIS systems work with an “image-to-patient registration” which consists of virtually overlaying the 3D images of the CBCT with the planned implant position on the real patient’s anatomy. In other words, is it necessary to merge the CBCT data with the patient’s real anatomy, so the software can calculate the exact location of the patient’s jaw during the surgical procedure.

Today, 2 registration methods are available for dCAIS systems: radiographic marker-registration (RMR) and markerless pair-point registration (MTR) (61).

3.2.2.2.1. Radiographic marker registration (RMR)

The RMR consists of attaching a radiographic marker to the patient, usually by means of an intraoral splint or clip, which will be used during the CBCT. This clip or splint will be placed in the same position during the surgical procedure and, together with the patient's optical marker, will be automatically detected by the dCAIS software. This allows to register the patient's anatomy on the CBCT images (62). Figure 14.

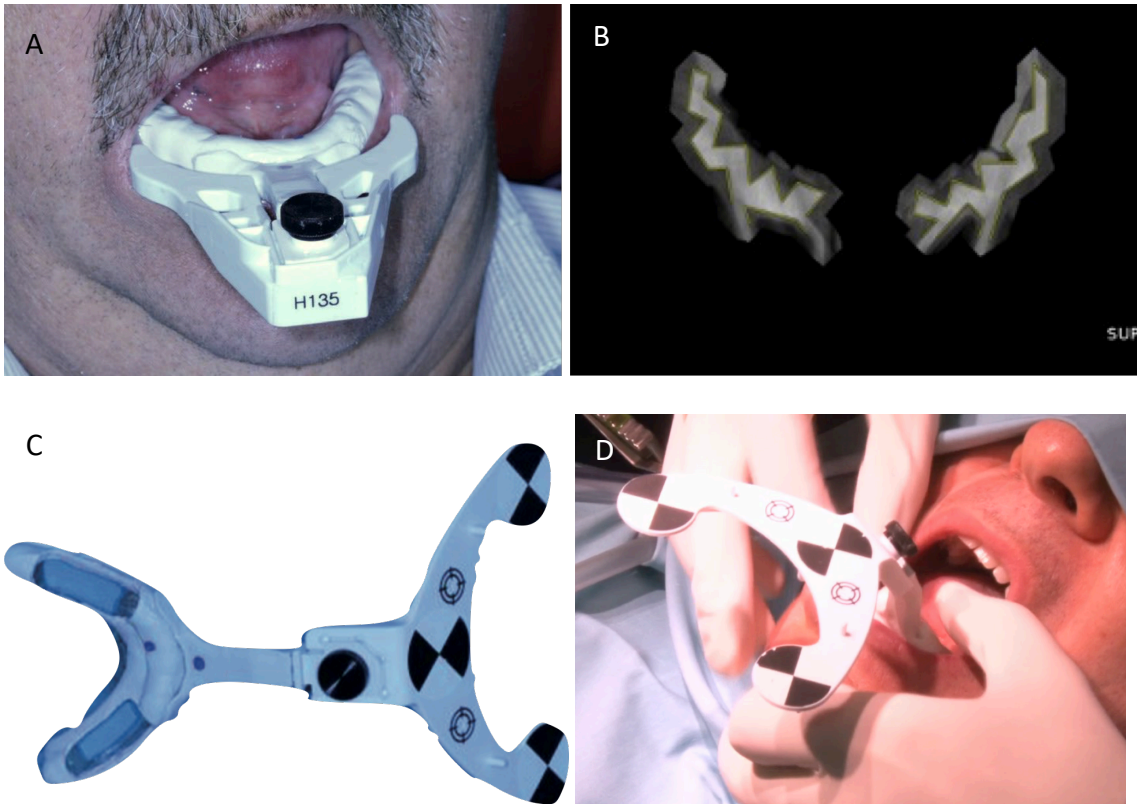

Figure 14: A: Patient wearing an acrylic thermoplastic splint with a radiographic fiducial marker; B: Radiographic marker pattern that allows an automatic recognition by the dCAIS system software; C: Optical marker attached to the splint in the same position where the radiographic marker was previously placed; D: Placement of the splint with the optical marker on the patient's jaw during the surgical procedure.

The workflow for this registration method would be:

1. A thermoplastic stent or device (i.e. clip or stent) is adapted to the remaining teeth. This splint or device must have a perfect fit to avoid any movement.
2. CBCT scan of the patient with the radiographic marker attached to thwe stent.
3. Import DICOM data from the CBCT to the planning software.
4. Implant planning using the navigation software provided by the manufacturer or by a third party (for example, DTX Studio Implant software (Nobel Biocare AB, Gothenburg, Sweden) or Blue Sky Plan (Blue Sky Bio, Grayslake, IL)).
5. Registration of the patient. The navigation system software automatically detects the radiopaque marker pattern (i.e. special pattern or distribution of spheres). Then, this radiographic marker is replaced by an optical marker that will allow to establish a relation between the CBCT images and the patient's dental arch.
6. Calibration of the surgical handpiece, burs and implant. A calibration of the drill axis and tip is required before starting the drilling sequence. This step must be repeated for each new drill.
7. Surgical procedure and implant placement using dCAIS. A registration accuracy check is required before starting the drilling sequence, usually by touching a previously defined anatomic point with the bur tip and checking in the screen if the precision is correct.

3.2.2.2.2. Markerless pair-point registration (MTR)

On the other hand, the MTR, works by selecting different fiducial points or landmarks on the CBCT images (usually on the cusps and edges of the remaining teeth) and then tracing them on the patient's anatomy using a specific probe with optical markers. This

method allows the navigation system to recognize the patient's position in relation to the CBCT images (63). With this approach, a minimum of 3 fiducial points are needed for a correct registration. Figure 15.

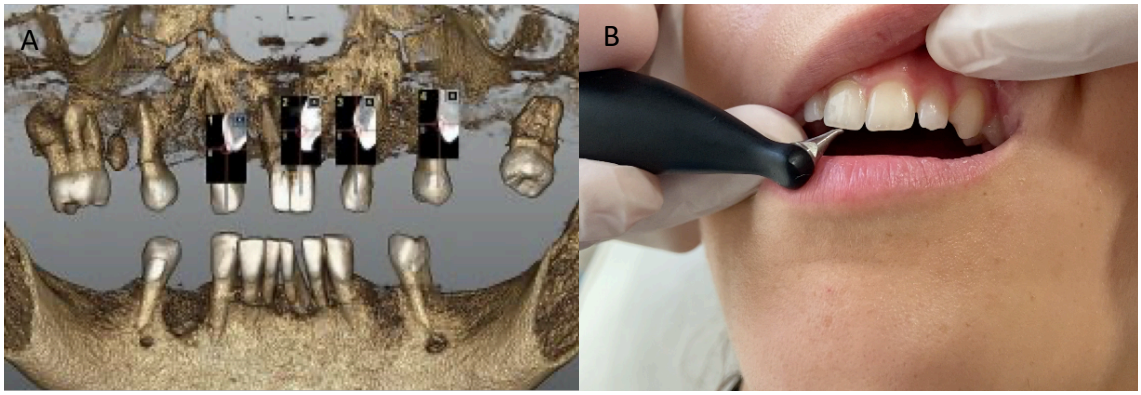

Figure 15: A: Selection of anatomical landmarks in the CBCT reconstruction. B. Tracing of the selected fiducial points with a specific probe.

The workflow for this registration process would be the following:

1. CBCT scan of the patient without the need to use any additional devices. A recently performed CBCT scan can be used if the dental anatomy has not been changed (i.e. restorations, extractions or tooth movements).
2. Import DICOM data from the CBCT to the planning software.
3. Implant planning using the navigation software provided by the manufacturer or by a third party.
4. Registration of the patient. Placement of the optical markers on the patient. Then, select a minimum of 3 fiducial points in the CBCT scan images (usually teeth cusps and/or edges) and then trace them on the patient's dental arch using a specific probe with optical markers. Once registration is completed, a registration accuracy check is done by touching any anatomic point with the probe and ensuring it corresponds with the image on the dCAIS screen.

5. Calibration of the surgical handpiece, burs and implant following the same steps as in the RMR.
6. Surgical procedure and implant placement using dCAIS.

Figure 16 depicts the workflow of both registration approaches.

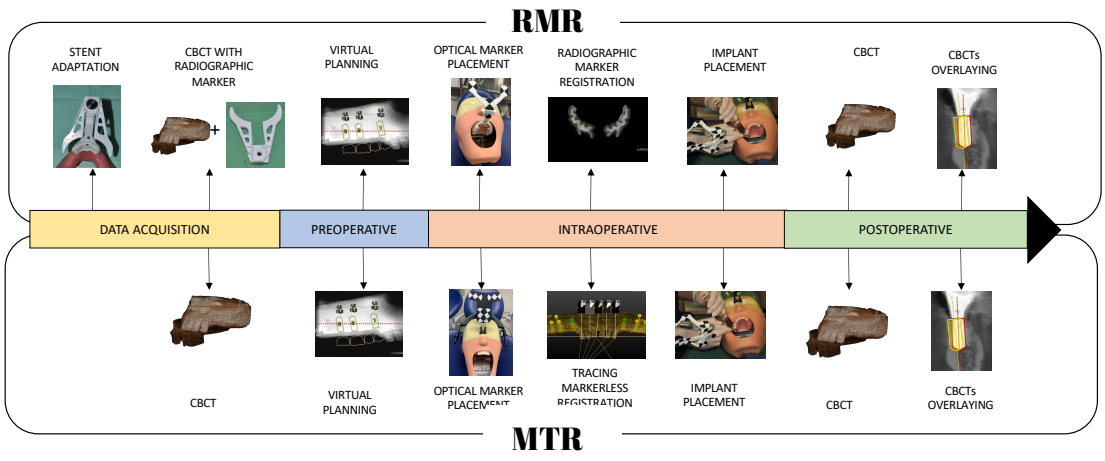

Figure 16: Comparison of the workflow using a radiographic marker registration (RMR) or a markerless pair-point registration (MTR). Figure reproduced with permission from an article which is part of the present thesis (64).

3.2.2.3. Workflow in fully edentulous patients

The management of fully edentulous patients in guided surgery is always challenging due to the absence of teeth as reference landmarks. In dCAIS, the lack of clear fiducial points might compromise the registration accuracy. If a RMR approach is used, the marker needs to be attached with a specific osseo-supported device prior to the CBCT and the surgical procedure. This device cannot be removed until the end of the surgery.

On the other hand, the MTR avoids the placement of an intraoral device with markers but reliable anatomical landmarks are usually absent due to the lack of teeth. In this

case, radiopaque markers (for example, miniscrews) are usually added to serve as fiducials (65). Another option is to fabricate a radiographic splint with at least 3 radiographic marker areas that will be traced before the start of drilling sequence. Other devices like the use of adhesive radiopaque markers or the selection of bone anatomic landmarks have also been suggested, but the scientific evidence of these methods is still scarce (65).

3.2.2.4. Scientific evidence

The first reports on the use of dCAIS systems appeared in the early 2000s (66–68), and the first systematic review was published in 2009 by Jung et al. in the fourth ITI (International Team for Implantology) consensus conference (69). These authors included a total of fifteen papers from 2001 to 2007 reporting the accuracy of dCAIS. Since it was an emerging technology at that time, most of the included studies were performed in models or in human cadaver specimens. The observed accuracy was high with an overall mean deviation at the platform of the implant of 0.74mm (95% Confidence Interval (CI): 0.58 to 0.90 mm), and a mean apical deviation of 0.85mm (95% CI: 0.72 to 0.99 mm)(69). These encouraging results of studies published almost 20 years ago have been followed by a rapid evolution and improvement of these systems.

In the last years, many clinical and preclinical studies have been published on the use of dCAIS systems. Figure 17 shows the growing number of publications per year in this field. This growth has not reached its peak yet. When the present PhD project was presented in 2019, only 18 studies where published that year, one of them by our research team. That year could be considered a turning point in the evidence production. Nowadays,

the number of studies published on the topic has doubled, reflecting the fast evolution of the technology and the increasing interest among clinicians and researchers.

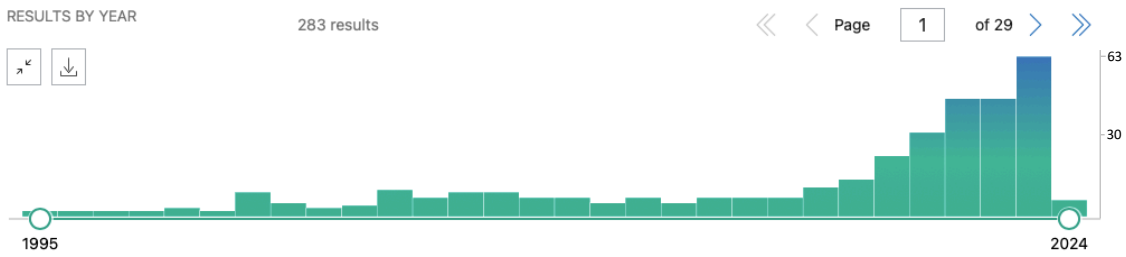

Figure 17: Diagram showing the number of published papers on dCAIS during the last years. This graphic is generated by PubMed by using the following search strategy: (navigation system OR dynamic computer-assisted surgery) AND (dental implants) on 4th of February of 2024.

Today, sCAIS systems are still considered the first-line option for guided implant surgery due to the available scientific data and the reduced cost of the equipment. Nonetheless, dCAIS systems have some advantages that need to be taken into consideration: the preoperative planning and surgical procedures can be performed on the same day, there is no need to take an intraoral impression, and these systems can be used in patients with reduced mouth opening. Furthermore, dCAIS also allows to confirm the accuracy several times during the surgical procedure, the clinicians can adapt or change their surgical planning during surgery, there is no need for a specific set of drills or instruments, and the drill irrigation and visibility are better.

On the other hand, dCAIS systems also present some drawbacks. The cost of the equipment is high and a license is needed to plan each case. In addition, these systems require a certain degree of experience, since the learning curve plateau is not reached

until the surgeon has placed at least 15-20 dental implants with dCAIS (70,71). Other important limitations are the increased surgical time (due to the registration and calibration processes) and the difficulties associated with fully edentulous patients.

Moreover, the lack of a rigid guide might lead to some deviations since the implant is placed freehand. Indeed, clinically relevant deviations can occur when using dCAIS systems (32,72). This is particularly relevant when assessing the apex depth, since these inaccuracies can lead to major complications (for example, inferior alveolar nerve injury) (73). For this reason, a 2 mm. safety margin should always be applied when performing virtual implant placement planning (56). Table 1 lists the main advantages and limitations of dCAIS.

Table 1: Advantages and limitations of dynamic computer-assisted implant surgery.

sCAIS: Static Computer Assisted Implant Surgery.

Dynamic computer-assisted surgery	
Advantages	**Limitation**
High accuracy	Longer surgical time
Possibility to do minimally invasive surgery	More complex intraoperative procedures than in a non-guided approach
Simple workflow. Generally, all procedures completed in one day	High costs
Reduced risk of complications	Learning curve
Ability to modify the surgical planning intraoperatively	Intraoral and/or extraoral devices could be uncomfortable for the patient.
Flexibility and freedom as in a non-guided freehand approach. Good visibility	Registration process very sensitive. Must be performed accurately.
In general, no need for lab, stent design or surgical stent production	Possible inaccuracies. A security margin of 2mm should be maintained.

Table 1: (Continued).

Dynamic Computer-assisted surgery	
Advantages	**Limitation**
Does not require special drill kits	Limited evidence in fully edentulism
Applicable to all dental implant brands, lengths, and diameters	
Better drill irrigation in comparison with sCAIS	

Considering the observed results in the meta-analysis published by Jorba-Garcia *et al.* (58), which is part of the present thesis, dCAIS systems can be considered a reliable and accurate option for implant placement. Nevertheless, the number of well designed randomized clinical trials (RCT) is still scarce.

Accuracy assessment of dynamic computer–aided implant placement: a systematic review and meta-analysis

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REVIEW

Accuracy assessment of dynamic computer–aided implant placement: a systematic review and meta-analysis

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Abstract

Objectives To assess the accuracy of dynamic computer–aided implant surgery (dCAIS) systems when used to place dental implants and to compare its accuracy with static computer–aided implant surgery (sCAIS) systems and freehand implant placement.

Materials and Methods An electronic search was made to identify all relevant studies reporting on the accuracy of dCAIS systems for dental implant placement. The following PICO question was developed: "In patients or artificial models, is dental implant placement accuracy higher when dCAIS systems are used in comparison with sCAIS systems or with freehand placement? The main outcome variable was angular deviation between the central axes of the planned and final position of the implant. The data were extracted in descriptive tables, and a meta-analysis of single means was performed in order to estimate the deviations for each variable using a random-effects model.

Results Out of 904 potential articles, the 24 selected assessed 9 different dynamic navigation systems. The mean angular and entry 3D global deviations for clinical studies were 3.68° (95% CI: 3.61 to 3.74; I^2 = 99.4%) and 1.03 mm (95% CI: 1.01 to 1.04; I^2 = 82.4%), respectively. Lower deviation values were reported in in vitro studies (mean angular deviation of 2.01° (95% CI: 1.95 to 2.07; I^2 = 99.1%) and mean entry 3D global deviation of 0.46 mm (95% CI: 0.44 to 0.48 ; I^2 = 98.5%). No significant differences were found between the different dCAIS systems. These systems were significantly more accurate than sCAIS systems (mean difference (MD): −0.86°; 95% CI: −1.35 to −0.36) and freehand implant placement (MD: −4.33°; 95% CI: −5.40 to −3.25).

Conclusion dCAIS systems allow highly accurate implant placement with a mean angular of less than 4°. However, a 2-mm safety margin should be applied, since deviations of more than 1 mm were observed. dCAIS systems increase the implant placement accuracy when compared with freehand implant placement and also seem to slightly decrease the angular deviation in comparison with sCAIS systems.

Clinical Relevance The use of dCAIS could reduce the rate of complications since it allows a highly accurate implant placement.

Keywords Dynamic computer-assisted surgery · Navigation systems · Computer-guided implantology · Dental implants

Introduction

Nowadays, dental implants are a predictable treatment option for treating both partially or totally edentulous patients [1]. However, some complications can occur, leading to implant failure. The risk factors associated with these complications can be related to the surgical technique, the patient, the restoration, and the implant itself [2].

Implants may become osseointegrated and be considered successful despite not attaining an ideal prosthetically driven position. However, this optimal position should be a treatment goal since it facilitates restoration and maximizes esthetics.

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Indeed, achieving an ideal three-dimensional (3D) implant position prevents surgical complications (such as sinusitis, nerve injuries, or bleeding), esthetic problems (i.e., buccal dehiscence due to the resorption of the buccal plate), prosthetic complications (i.e., difficulty in inserting a restoration), and marginal bone loss [3–7]. It is estimated that around 7% of complications might be related to implant malposition [8]. Moreover, another study has reported that the distance to the neighboring teeth/implant was incorrect in almost 1/5 of the implants and that one third of the implants presented perforation of adjacent structures [9].

Cone-beam computed tomography (CBCT) has become a widely used examination technique for adequate planning of any implant surgery [10–12]. Furthermore, CBCTs make it possible to simulate a prosthetically driven implant placement with specific software. This information, in turn, can be transferred to the patient, facilitating more accurate implant positioning.

Computer-aided implant surgery (CAIS) has recently been introduced into dental implantology to reduce deviations from the virtually planned implant position. According to Hämmerle et al. [13], static computer–aided implant surgery (sCAIS) systems use stereolithographic templates supported by teeth, bone, or mucosa during drilling and insertion of the implant, while dynamic computer–aided implant surgery (dCAIS) systems perform real-time tracking of the drills and implants through an optimal marker and relate this information to the 3D preoperative virtual plan drawn up with CBCT [13–16]. In 2009, Jung et al. [14] published a systematic review in which dCAIS delivered promising results. However, at that time, the available information on this technology was scarce and most published studies used an "in vitro" setting [14].

Considering the rapid development of these technologies and the large number of studies on navigation systems published in recent years, it is of great importance to gather together all the information related to the accuracy of the available dCAIS systems. Hence, the main aim of this meta-analysis was to determine the accuracy of dCAIS systems for dental implant placement in relation to the position planned preoperatively. The secondary objective of this review was to compare dCAIS systems with sCAIS systems and freehand placement.

Methods

This systematic review complied with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Statement [17]. The protocol was registered in PROSPERO (CRD42020175829).

The following PICO questions were formulated:

- Population: Patients or artificial models treated with dental implants placed using a dCAIS
- Intervention: Implant placement using dCAIS
- Comparison: Implant placement using sCAIS and/or freehand
- Outcome: Accuracy of dental implant placement measured with the angular deviation between the central axes of the planned and final position of the implant
- Studies: Randomized or non-randomized controlled trials, retrospective or prospective cohort studies, case-control studies, case series with more than 10 patients, and "in vitro" studies

Eligibility criteria

All primary studies including clinical (i.e., randomized clinical trials (RCTs), prospective and retrospective cohort studies, case-control studies, and case series with more than 10 patients), "in vivo", and "ex vivo" studies that reported the accuracy of dynamic computer–assisted implant systems were included. Only studies reporting the exact amount of deviation between the presurgical planning and the final implant position were included. No language restriction was applied.

Case reports and studies assessing virtual augmented reality were excluded. Studies evaluating sCAIS systems without comparing them with dCAIS systems were also excluded. Likewise, studies involving accuracy assessment in zygomatic or pterygoid implants and papers published before 2010 were excluded. The date restriction was applied to avoid including potentially outdated systems.

The main outcome variable was the angular deviation of the implant, defined as the largest angle between the longitudinal axis of the planned implant position and the placed implant position, measured in sexadecimal degrees (°). The secondary variables were entry global (3D) and lateral (2D) deviations (i.e., deviation at the implant connection), apex global (3D) and lateral (2D) deviations (i.e., deviation at the implant apex), and deviation in depth both at the apex and at the implant connection (Fig. 1).

Search strategy

An electronic search in MEDLINE (PubMed), the Cochrane Library, Scopus (Elsevier), and Web of Science (Thomson Reuters) databases up to December 13, 2020 was performed to identify all potentially eligible articles regarding dCAIS accuracy. The search strategy can be observed in Table 1.

Additionally, OpenGrey and www.greylit.org were searched for gray literature and ClinicalTrials.gov for relevant unpublished data, and manual screening of articles published in the last 10 years was carried out in the following journals: *Clinical Oral Implants Research*,

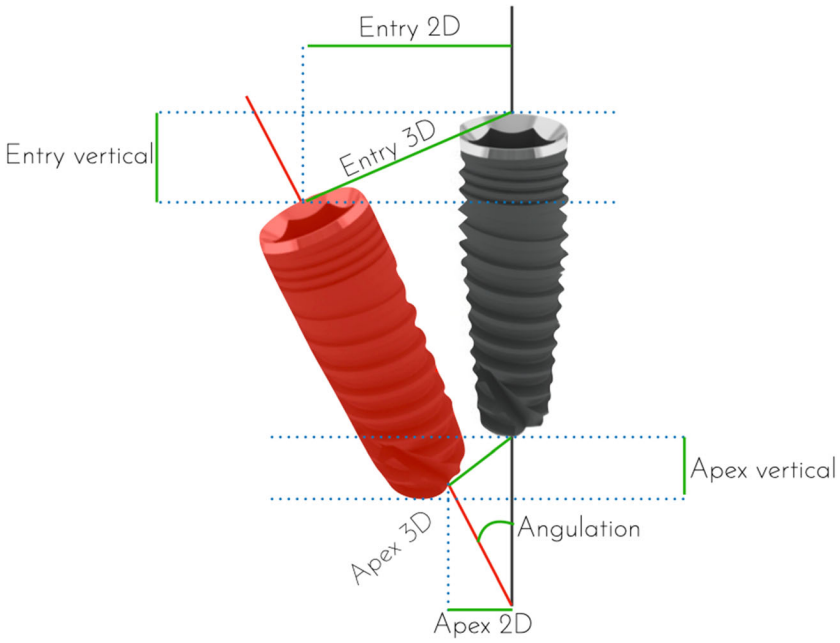

Fig. 1 Deviation outcomes: deviation between the planned position and the final position. 2D: two dimensions (lateral); 3D: three dimensions (global). Entry 2D: deviation of the implant platform in the *x* and *y* dimensions of space in an occlusal view, without taking deviation in depth (*z*-axis) into account, in millimeters (mm). Entry 3D: deviation of the implant platform in the three dimensions of space (*x*, *y*, and *z*), in millimeters (mm). Entry vertical: deviation of implant platform depth (*z*-axis), in millimeters (mm). Apex 2D: deviation of the implant apex in the *x* and *y* dimensions of space in an occlusal view, without taking deviation in depth (*z*-axis) into account, in millimeters (mm). Apex 3D: deviation of the implant apex in the three dimensions of space (*x*, *y*, and *z*), in millimeters (mm). Apex vertical: deviation of implant apex depth (*z*-axis), in millimeters (mm). Angulation: angular deviation between the central axes of the planned position and the final position, in sexadecimal degrees (°)

Table 1 Search strategy for each database

PubMed
("Surgery, Computer-Assisted"[Mesh] OR "navigation system" OR "navigation systems" OR "dynamic computer aided" OR "dynamic computer guided" OR "dynamic computer assisted") AND (dental implants OR dental implant OR "Dental Implants"[Mesh] OR implantology)
Scopus
TITLE-ABS-KEY ("Surgery, Computer-Assisted" OR "navigation system" OR "navigation systems" OR "dynamic computer aided" OR "dynamic computer guided" OR "dynamic computer assisted") AND TITLE-ABS-KEY (("dental implants" OR "dental implant" OR implantology))
Web of Science
TOPIC: (("Surgery, Computer-Assisted" OR "navigation system" OR "navigation systems" OR "dynamic computer aided" OR "dynamic computer guided" OR "dynamic computer assisted") AND ("dental implants" OR "dental implant" OR implantology))
Cochrane Library
#1: "Surgery, Computer-Assisted"[Mesh]
#2: "navigation system" OR "navigation systems" OR "dynamic computer aided" OR "dynamic
computer guided" OR "dynamic computer assisted"
#3: "Dental Implants"[Mesh]
#4: "dental implants" OR "dental implant" OR implantology
(#1 OR #2) AND (#3 OR #4)

International Journal of Oral & Maxillofacial Implants, *Journal of Oral and Maxillofacial Surgery*, *Clinical Implant Dentistry and Related Research*, and *European Journal of Oral Implantology*. The references in the selected articles and reviews were also searched. Finally, the bibliography recommended by the main manufacturers of navigation systems was analyzed.

Study selection

Two examiners with experience in meta-analysis (A.J-G. and A.G.-B.) independently selected the studies in accordance with the inclusion criteria. Initially, duplicates were merged and two reviewers (A.J-G. and A.G-B.) independently read the titles and abstracts of the potential studies to exclude irrelevant publications. After this stage, the reviewers individually assessed the full-text articles to decide on the eligibility of the remaining articles. The studies removed at this stage and the reasons for their exclusion were recorded. Any disagreement was resolved by consensus. If no consensus was achieved, a third reviewer with broad experience in statistics and meta-analysis (O.C.-F.) decided on the eligibility of the article. Cohen's kappa coefficient was calculated and showed a high degree of agreement between the reviewers (kappa= 0.977).

Data extraction

Two reviewers (A.J-G. and A.G-B.) independently used a data extraction table to gather the relevant data from the articles included. The tables were evaluated by a third reviewer (O.C.-F.), and in the event of inconsistencies, the item was referred back to the reviewers to confirm or correct data. The data included the following: (1) study characteristics: authors, year, country, and study design and settings; (2) participants' characteristics: number of patients/models, number of implants, age, gender, and type of edentulism; (3) intervention: dCAIS system, operator experience, and assessment of implants or holes; (4) comparison; and (5) outcomes of interest: deviations. The declared conflicts of interest were also registered for each individual study.

Authors were contacted in case of missing information or a need for clarification. If the reviewers identified multiple reports on the same patients, only the study with the largest sample was included.

Quality and risk of bias assessment

As part of the data extraction process, 2 reviewers (A.J.-G. and A.G.-B.) independently assessed the quality of the clinical studies.

For the RCTs, the Cochrane's risk-of-bias tool (RoB 2) was used according to the method described in the Cochrane Handbook for Systematic Reviews of Interventions (version 6.0) [18]. Hence, the following domains were evaluated: (1) randomization process, (2) deviations from intended interventions, (3) missing outcome data, (4) measurement of the outcome, and (5) selection of the reported result. The publications were grouped into the following categories: low risk of bias if the trial is judged to be at low risk of bias for all domains, some concerns if the trial is judged to raise some concerns in at least one domain for this result without having high risk of bias for any domain, and high risk of bias when the trial is judged to be at high risk of bias in at least one domain or is judged to have some concerns for multiple domains in a way that substantially lowers confidence in the result [18].

The quality assessment for observational studies was assessed using the Newcastle-Ottawa scale [19]. The following items were evaluated: (1) selection, (2) comparability (taking into consideration the type of edentulism and implant site location), and (3) outcome, and the maximum score for each study was 9 points.

Summary measures and synthesis of results

A descriptive analysis of the articles included was performed, and the following data were recorded in a descriptive summary: (1) author, (2) year, (3) country, (4) study design, (5) clinical setting, and (6) details of population, interventions, comparison, and outcomes.

The following outcome variables were analyzed (Fig. 1):

- Entry (2D) lateral: deviation between the planned position and the final position of the implant platform in the x and y dimensions of space in an occlusal view, without taking deviation in depth (z-axis) into account, in millimeters (mm)
- Entry (3D) global: deviation between the planned position and the final position of the implant platform in the three dimensions of space (x, y, and z), in millimeters (mm)
- Entry depth: vertical distance (depth) between the planned position and the final position of the implant platform (z-axis), in millimeters (mm)
- Apex (2D) lateral: deviation between the planned position and the final position of the implant apex in the x and y dimensions of space in an occlusal view, without taking deviation in depth (z-axis) into account, in millimeters (mm)
- Apex (3D) global: deviation between the planned position and the final position of the implant apex in the three dimensions of space (x, y, and z), in millimeters (mm)
- Apex depth: vertical distance (depth) between the planned position and the final position of implant apex (z-axis), in millimeters (mm)
- Angulation: angular deviation between the central axes of the planned position and the final position of the implant, in sexadecimal degrees (°)

If the studies reported the outcome data by subgroups, the mean and standard deviation (SD) were weighted by the size of each subgroup as recommended in the Cochrane Handbook for Systematic Reviews, version 6.0 [18].

The single mean meta-analysis involved estimating the mean deviations for each variable using a random-effects models based on the inverse variance method. Stratified analyses were made based on the type of study (i.e., clinical and "in vitro") and navigation system. The mean deviations and 95% confidence interval (95% CI) of each study were reported as well as the overall values. Subgroups ("in vitro" and "in vivo" studies) were isolated and subjected to linear meta-regression with adjustment for multiple comparisons (i.e., random permutations based on Monte Carlo simulation) to identify them as possible sources of covariance.

Pairwise meta-analyses were used to compare the accuracy of dCAIS with sCAIS and freehand implant placement, respectively. Meta-analyses were only performed when studies compared similar techniques and reported the same outcome measures. Stratified analysis was made based on the type of study (i.e., clinical and "in vitro"). Mean differences (MD) were combined using random-effects models.

Statistical heterogeneity was estimated by means of χ^2 (Q value) and I^2 analyses. A χ^2 P-value of <0.10 and an I^2 value of >50% were interpreted as significant heterogeneity [20].

Statistical analysis was carried out with Stata 14 software (StataCorp, College Station, TX, USA), and forest plots were performed with another software package (Review Manager version 5.3; The Cochrane Collaboration, Copenhagen, Denmark). The level of significance was set at $P < 0.05$ for all analyses.

RESULTS

Out of 907 potential articles, 24 were included in the quantitative and qualitative analysis. Twenty-two reports were excluded after full-text assessment [21–42]. Figure 2 shows the complete flowchart of the study selection process. Of the 24 articles, 10 reported on clinical studies involving humans [43–52] and 14 reported on preclinical "in vitro" studies [53–66]. The types of studies included for each system can be observed in Table 2.

In the final screening stage, the study by Kang et al. [21] testing the Cbyon system (CBYON, Inc., Mountain View, CA, USA) was excluded because the surgical technique and employed instruments were not comparable to all other studies. Furthermore, the software used in this study had important limitations (for example, it did not have a visual accuracy tool to enhance the guidance).

Nine navigation systems were evaluated. One system was not identified, and another study only reported the brand of the optical system used. Navident (Navident®, ClaroNav Technology Inc.®, Toronto, Canada) was assessed by 10 studies (5 of which were clinical studies), followed by AqNavi (AQNavi, TITC Ltd, Kaohsiung, Taiwan) with 4 studies. ImplaNav (ImplaNav; BresMedical, Sydney, Australia), AqNavi (AQNavi, TITC Ltd, Kaohsiung, Taiwan), and X-guide (X-Guide, X-Nav Technologies, LLC, Lansdale, Pa) were each used in 1 clinical study, whereas the remaining systems were only tested in an "in vitro" setting.

Table 2 Types of studies included, by system

System	Human	"In vitro"	Total
Navident	5	5	10
Iris-100	2	0	2
ImplaNav	1	1	2
AqNavi	1	3	4
X-Guide	1	1	2
Polaris Vicar	0	1	1
StealthStation Treon	0	1	1
Yizhimei	0	1	1
Others	0	1	1
Total	10	14	24

One randomized clinical trial (RCT) with a split-mouth design compared the accuracy of the Navident system with freehand implant placement [45], while two RCTs (2 parallel groups) assessed the Iris-100 system and compared it with a static guided system [47, 52].

The quality and risk of bias assessments are summarized in Table 3 and Fig. 3. The main limitations detected in the non-randomized clinical studies were limited sample sizes, which may hamper the generalization of the results [45, 49, 50], and that some articles did not specify whether the outcomes were assessed by an independent blinded researcher [20, 46–48]. Regarding the included RCT, the main limitations were associated with the allocation concealment and the blinding of the outcome assessor [47, 52].

Summarized descriptions of the studies included are presented in Table 4 and Table 5 for clinical and preclinical studies, respectively. The mean overall angular deviations were 3.68° (95% CI: 3.61 to 3.74; $I^2 = 99.4\%$) in clinical studies and 2.01° (95% CI: 1.95 to 2.07; $I^2 = 99.1\%$) in "in vitro" settings. The global (3D) entry deviation was 1.03 mm (95% CI: 1.01 to 1.04; $I^2 = 82.4\%$) in "in vivo" scenarios and 0.46 mm (95% CI: 0.44 to 0.48 ; $I^2 = 98.5\%$) in the papers that used "in vitro" designs. The mean overall accuracy of dCAIS for all the variables retrieved is summarized in Table 6. Meta-regression only revealed statistically significant differences between preclinical and clinical studies in the apex depth deviation variable ($P = 0.047$), while for all the other outcome variables, no significant differences between preclinical and clinical studies were found ($P >0.05$ for all analyses). The forest plots can be observed in Figs. 4, 5, 6 and 7.

All dCAIS systems had similar results regarding deviations ($P>0.05$). The lowest angular deviations (mean angulation deviation of less than 2°) were achieved with the Yizhimei (Yizhimei, Suzhou, China), the StealthStation Treon (Medtronic, Minneapolis, MN), and the X-guide (X-Guide, X-Nav Technologies, LLC, Lansdale, Pa) systems in "in vitro" settings. In a clinical scenario, the highest deviations were reported by Pellegrino et al. [46] and Aydemir and Arisan [44], using ImplaNav (ImplaNav; BresMedical, Sydney, Australia) and Navident (Navident®, ClaroNav Technology Inc.®, Toronto, Canada), respectively. Navident (Navident®, ClaroNav Technology Inc.®, Toronto, Canada), Iris-100 (IRIS-100, EPED Inc., Kaohsiung, Taiwan), and AqNavi (AQNavi, TITC Ltd, Kaohsiung, Taiwan) reported similar mean angular deviations of around 3°. Finally, the ImplaNav system (ImplaNav; BresMedical, Sydney, Australia) had a mean angular deviation of 4.38° (95% CI: 3.92 to 4.83; $I^2 = 81.3\%$). The forest plot can be observed in Fig. 4b.

The angular deviation was used to compare dCAIS, sCAIS, and freehand implant placement, since this variable was reported in all studies. Only 10 papers reported data from a control group that could be analyzed in a meta-analysis [45, 47–49, 52, 54, 55, 59, 63, 66]. MD meta-analysis comparing

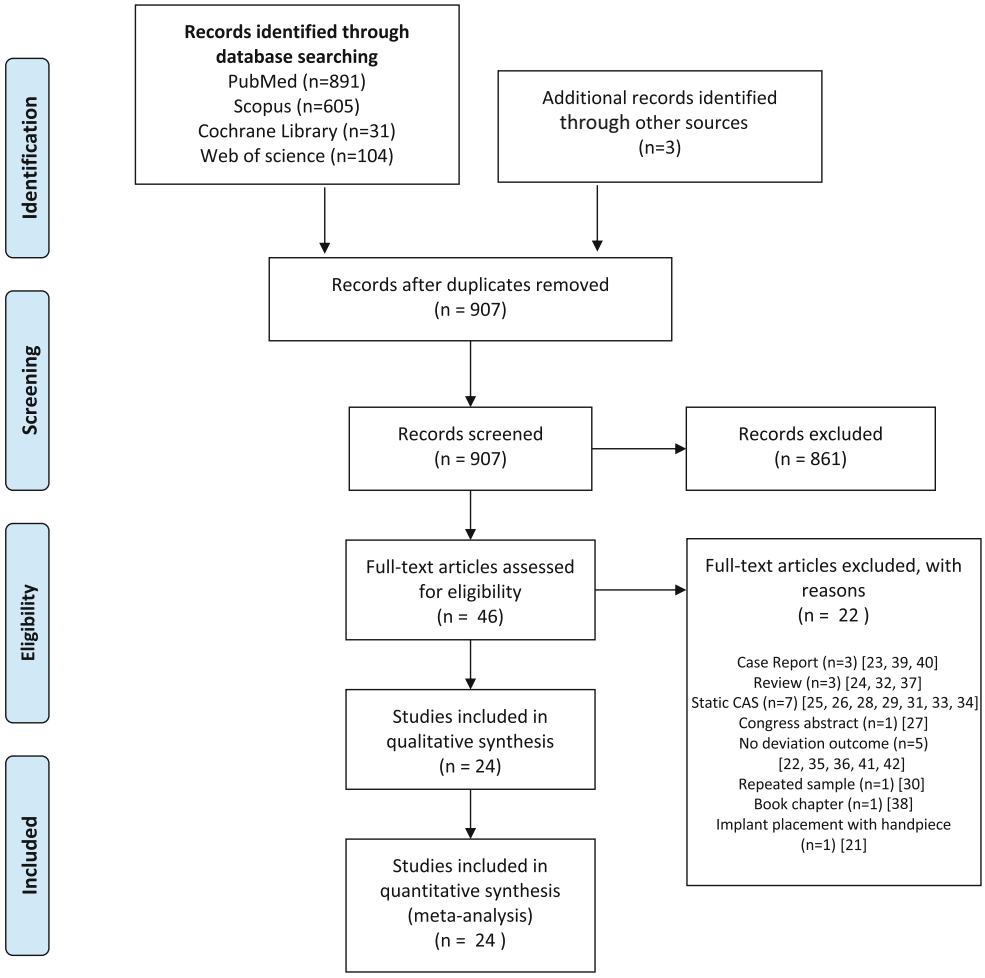

Fig. 2 Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) flowchart summarizing the screening process [17]

dCAIS with freehand implant placement reported statistically significant differences favoring dCAIS (MD: −4.33°; 95% CI: −5.40 to −3.25; $P < 0.001$; $I^2 = 97\%$). On the other hand, statistically significant differences were also found between dynamic and sCAIS systems (MD: −0.86°; 95% CI: −1.35 to −0.36; $P < 0.001$; $I^2 = 88\%$). These differences were only

Table 3 Quality assessment of the selected non-randomized studies

	Selection				Comparability	Outcome			TOTAL
Study	Representativeness of the exposed cohort (Maximum: ★)	Selection of the non-exposed cohort (Maximum: ★)	Ascertainment of exposure (Maximum: ★)	Demonstration that outcome of interest was not present at start of study (Maximum: ★)	Comparability of cohorts on the basis of the design or analysis (Maximum: ★★)	Assessment of outcome (Maximum: ★)	Was follow-up long enough for outcomes to occur (Maximum: ★)	Adequacy of follow up of cohorts (Maximum: ★)	
Stefanelli 2020c [29]	★	-	★	★	--	★	★	★	6★
Stefanelli 2020b [28]	★	-	★	★	--	★	★	★	6★
Sun 2020 [27]	★	★	★	★	★★	-	★	★	8★
Stefanelli 2020a [22]	★	-	★	★	--	★	★	★	6★
Pellegrino 2019 [24]	★	-	★	★	--	★	★	★	6★
Stefanelli 2019[21]	★	-	★	★	--	-	★	★	5★
Block 2017 [26]	★	★	★	★	★-	-	★	★	7★

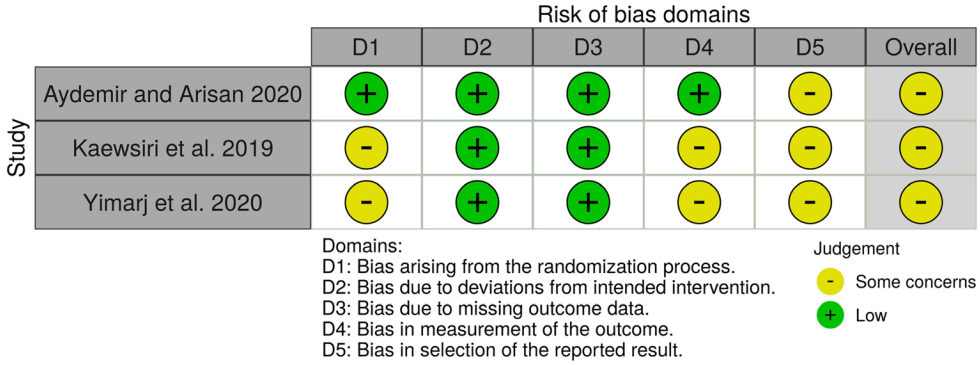

Fig. 3 Risk of bias of the selected randomized clinical trials

significant in the "in vitro" studies (MD: −1.12°; 95% CI: −1.97 to −0.28; $P = 0.009$; $I^2 = 82\%$), while clinical reports found no significant differences between groups (MD: −0.52°; 95% CI: −1.58 to 0.54; P = 0.34; $I^2 = 89\%$) (Fig. 8).

Discussion

dCAIS systems for implant dentistry have been developed to help clinicians obtain a more accurate match between implant placement and the preoperative plan. The results of the present review demonstrate that these systems are reliable and achieve clinically undetectable angular deviations (95% CI: 2.84° to 2.93°). However, it is important to stress that a 2-mm safety margin should always be applied when implants need to be placed near important anatomic structures like the inferior alveolar nerve, since deviations of slightly over 1 mm were registered on some occasions. The present meta-analysis also showed that both dCAIS and sCAIS systems are predictable options that allow clinicians to place dental implants accurately.

Comparing the different systems, Navident was assessed in 5 clinical [43–45, 50, 51] and 5 "in vitro" studies [53, 54, 57, 59, 60]. Nevertheless, it should be taken into account that 4 of the 5 clinical studies [43, 44, 50, 51] were conducted by the same research group. A similar situation was found for several systems (AqNavi system [49, 59, 62], Iris-100 system [47, 52], and ImplaNav [46, 53]) since most published studies were performed by the same authors. X-guide (X-Guide, X-Nav Technologies, LLC, Lansdale, Pa) had the largest cohort of patients (almost 500 cases with more than 700 implants placed) [48], and some clinical data was also available for AqNavi (AQNavi, TITC Ltd, Kaohsiung, Taiwan) and ImplaNav (ImplaNav; BresMedical, Sydney, Australia), as they each had at least one clinical study.

Some variables might increase inaccuracies and therefore should be controlled. Misfit of the radiological fiducial markers (which are usually tooth-supported), movements of the patient or of the fiducial markers during CBCT imaging, low quality/resolution of the CBCT, or problems during registration of the radiological markers by the planning software are possible sources of inaccuracies. Some intraoperative complications, such as movement of the optical markers placed on the patient's jaw or on the handpiece, incorrect calibration of the drill axis or tip, and imprecise manipulation of the drills, should also be considered. Finally, postoperative assessment errors (distortion of the CBCT caused by the implant and inaccuracies when overlapping the pre- and postoperative CBCTs) might affect the outcomes of the studies, although usually they are not clinically relevant. Thus, it is of utmost importance to ensure accuracy at each step, since errors accumulate.

A dCAIS system that does not need radiological fiducials has recently become available [44]. It registers the CBCT by tracing at least 3 predefined points on the remaining teeth. This could reduce inaccuracies caused by movement of the radiological fiducials. Furthermore, this system allows the clinician to register the CBCT again in case of errors. Nevertheless, it is important to stress that the available data on this system are quite scarce and further research is needed.

The results of the present review were similar to those of previous systematic reviews assessing the accuracy of sCAIS [21, 66]. These papers reported slightly higher angular and linear deviations at the entry and apex points, whereas depth deviations were lower [67, 68]. Nevertheless, their results must be interpreted with caution since Tahmaseb et al. [67] only included clinical studies, which generally report slightly higher deviations in comparison to "in vitro" studies. On the other hand, Bover-Ramos et al. [68] included both clinical (22 studies) and preclinical (12 studies) studies. The findings of both reviews are summarized in Table 7.

Our report shows that dCAIS had more accurate results compared with sCAIS only in "in vitro" settings and both systems seemed to provide similar results in a clinical scenario. Thus, in our opinion, sCAIS systems should be considered the first-line option in guided implant surgery due to the available scientific data and the reduced cost of the equipment. Nonetheless, dCAIS systems also have some advantages that need to be taken into consideration:

Table 4 Description of the selected clinical studies

Study	Country	Settings	Study design	Edentulism	N patients	N implants	Age (years)	Gender male/female	Operator experience	Intervention (dCAIS system)	Comparator	Conflict of interest
Yimarj P 2020 [52]	Thailand	University	RCT parallel	Partial (two neighboring implants)	30	60 (30/30)	60	7/23	Trained surgeon	Iris-100	sCAIS (VisiJet MP200)	No
Stefanelli 2020 c [51]	Italy	University	Case series	Fully edentulous	13	77	68.15 (SD=9.22)	7/6	Trained surgeon	Navident 2.0 TaP	None	No
Stefanelli 2020 b [50]	Italy	University	Retrospective case series	Fully edentulous	14	56	NR	NR	Trained surgeon	Navident 2.0 TaP	None	No
Sun 2020 [49]	Taiwan	NR	Non-RCT	NR	NR	128 (32/32/32/32)	NR	NR	Trained surgeon	AqNavi	- sCAIS - d+sCAIS Freehand	Yes
Stefanelli 2020a [44]	Italy	Private practice	Retrospective case series	Partial	59	136	NR	NR	Trained surgeon	Navident 2.0 TaP	None	Partial yes
Aydemir 2020 [44]	Turkey	University	Split-mouth RCT	Partial (posterior bilateral edentulism)	30 (15/15)	86 (43/43)	48.4 (21-78)	7/25	Trained surgeon	Navident	Freehand	NR
Pellegrino 2019 [46]	Italy	University	Case series	Partial and total (8/2)	10	18	57 (38-69)	3/7	NR	ImplaNav	None	Yes
Kaewsiri 2019 [47]	Thailand	University	RCT parallel	Single tooth missing	60 (30/30)	60 (30/30)	53 (21–74)	16/44	Trained surgeon	Iris-100	sCAIS (VisiJet MP200)	NR
Stefanelli 2019[43]	Italy	Private practice	Retrospective observational	Partial and total (61/28)	89 (arches)	231	NR	NR	Trained surgeon	Navident	None	No
Block 2017 [48]	USA	Private practice	Prospective cohort	Partially edentulous	478	714 (219 FG; 373 PG; 112 FH)	59 (21-89)	242/236	Trained surgeons	X-Guide	Freehand	Yes

SD standard deviation, *TaP* trace and place, *NR* not reported, *RCT* randomized clinical trial, *dCAIS* dynamic computer–aided implant surgery, *sCAIS* static computer–aided implant surgery, *FG* fully guided, *PG* partially guided, *FH* freehand

Table 5 Description of the selected preclinical studies

Study	Country	Phantom	Type of model	Edentulism	N models	N implants	Operator experience	Intervention (dCAIS system)	Comparator	Conflict of interest
Zhou 2020 [21]	China	Yes	Resin 3D printed	Partial	20 (10/10)	80 (40/40)	NR	Yizhimei	sCAIS (VisiJet M3)	No
Pellegrino 2020 [53]	Italy	No	Plaster	Total	16	112	4 operators • Experienced in implantology and dCAIS • Experienced in implantology • Experienced in dCAIS No experience	ImplaNav	None	Yes
Jorba-García 2019 [54]	Spain	Yes	Resin	Partial	6	36 (18/18)	2 operators • Experienced in implantology • No experience	Navident	Freehand	No
Sun 2019 [59]	Taiwan	No	Plaster	Partial	30	150	5 operators without dCAIS experience but with different degrees of implantology experience	AqNavi	None	No
Golob Deeb 2019 [61]	USA	Yes	Polymethylmethacrylate 3D printed	Partial	84	294	14 dental students (no experience in implantology or dCAIS)	Navident	None	NR
Mediavilla Guzman 2019 [60]	Spain	No	Polyurethane	Total	20 (10/10)	40 (20/20)	NR	Navident	sCAIS (NemoStudio®/ProJet 6000)	No
Jiang 2018 [62]	China	No	3D printed	Total	12 (6/6)	96 (48/48)	NR	dCAIS NR	Augmented reality	No
Sun 2018 [63]	Taiwan	Yes	Plaster	Partial	50	150	NR (but calculating the learning curve implies no experience with dCAIS)	AqNavi	None	No
Chen 2018 [64]	Taiwan	NR	Plaster	Partial	30 (10/10-/10)	150 (50/50/-50)	NR	AqNavi	sCAIS Freehand	No
Emery 2016 [65]	USA	Yes	Polyurethane	Partial and total	27	47	One surgeon experienced in CAIS	X-Guide	None	Yes
Kim 2015 [66]	Korea	Yes	Model	Partial	20	110	NR	Polaris Vicar (camera)	None	NR
Somogyi-Ganss 2015 [55]	Canada	Yes	Resin	Partial	50	2000 (400/16-00)	Surgeons experienced in sCAIS	Navident	4 sCAIS • Straumann • Nobel • Simplant Laboratory	Yes
Widmann 2010 [57]	Austria	No	Plaster	Total	14	104 (only osteoto-my)	NR	StealthStation Treon Plus	None	Yes
Golob Deeb 2020 [58]	USA and Slove-nia	NR	Polyurethane	Partial	12	42 (21/21)	Two residents experienced in dCAIS	Navident (Drills)	Navident (Trephine)	No

NR not reported, *dCAIS* dynamic computer–aided implant surgery, *sCAIS* static computer–aided implant surgery, *CAIS* computer-aided implant surgery

Table 6 Overall mean deviations grouped by the type of study

	Angular (°) Mean [95% CI]	Lateral (2D) entry (mm) Mean [95% CI]	Global (3D) entry (mm) Mean [95% CI]	Lateral (2D) apex (mm) Mean [95% CI]	Global (3D) apex (mm) Mean [95% CI]	Apex depth (mm) Mean [95% CI]	Entry depth (mm) Mean [95% CI]
"In vitro"	2.01 [1.95 to 2.07]	0.8 [0.77 to 0.83]	0.46 [0.44 to 0.48]	0.97 [0.94 to 1.01]	0.81 [0.79 to 0.83]	0.61 [0.59 to 0.64]	0.76 [0.68 to 0.84]
Clinical	3.68 [3.61 to 3.74]	0.69 [0.67 to 0.72]	1.03 [1.01 to 1.04]	0.9 [0.83 to 0.97]	1.34 [1.32 to 1.36]	0.73 [0.7 to 0.76]	0.50 [0.43 to 0.57]
Overall	2.84 [2.80 to 2.89]	0.74 [0.72 to 0.76]	0.75 [0.73 to 0.76]	0.96 [0.93 to 0.99]	1.09 [1.08 to 1.11]	0.66 [0.64 to 0.68]	0.61 [0.56 to 0.67]
	P=0.453	*P*=0.197	*P*=0. 163	*P*=1	*P*=0.7	*P*=0.047*	*P*=0.487

the preoperative planning and surgical procedures can be performed on the same day, there is no need to take an intraoral impression, and the dental laboratory is not involved. Furthermore, dCAIS allows real-time verification of position accuracy, clinicians can adapt their surgical planning during surgery, there is no need for a specific set of drills or instruments, and the surgeon's perception of the drilling sequence and implant placement is not affected by a splint. Another important advantage is related to the fact that these systems can be used in almost all patients, whereas static systems might not be suitable in cases with limited mouth opening. Some authors have also used dCAIS systems to place zygomatic and pterygoid implants with good results [50, 69]. This might be an interesting indication for dCAIS systems, since these implants can be associated with important complications.

On the other hand, dCAIS technology also presents some drawbacks. Expenditure increases due to the cost of the equipment and the license needed to plan each case. In addition, these systems require a certain degree of experience since the learning curve plateau is not reached until the surgeon has placed at least 15 dental implants with these systems [62]. Other important limitations are that the surgical time increases and that, in the present authors' opinion, these dCAIS tools are not at all suitable for treating fully edentulous patients.

The professional's experience is a key factor for increasing the success rate of most treatments in implant dentistry. Even though the present review did not analyze the role of the

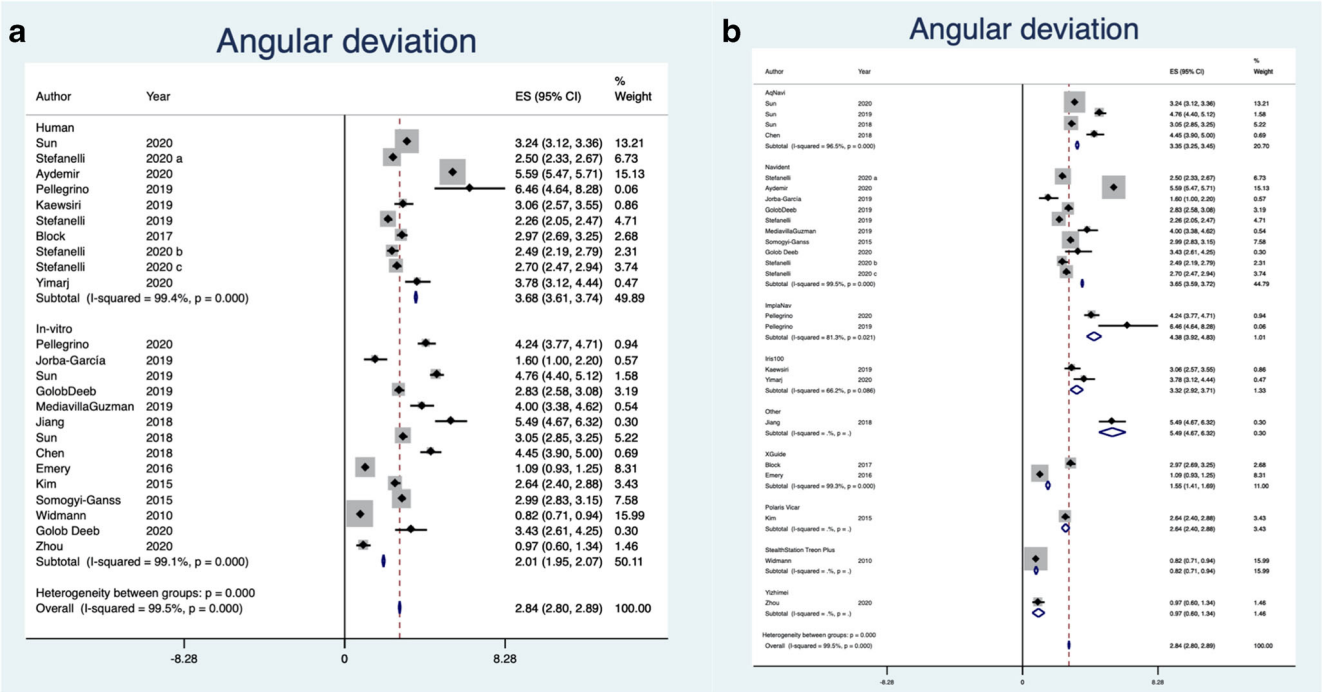

Fig. 4 Forest plot showing angular deviation measured for all selected articles. **a** Grouped by clinical and "in vitro" studies. **b** Grouped by dCAIS system. dCAIS dynamic computer–aided implant surgery

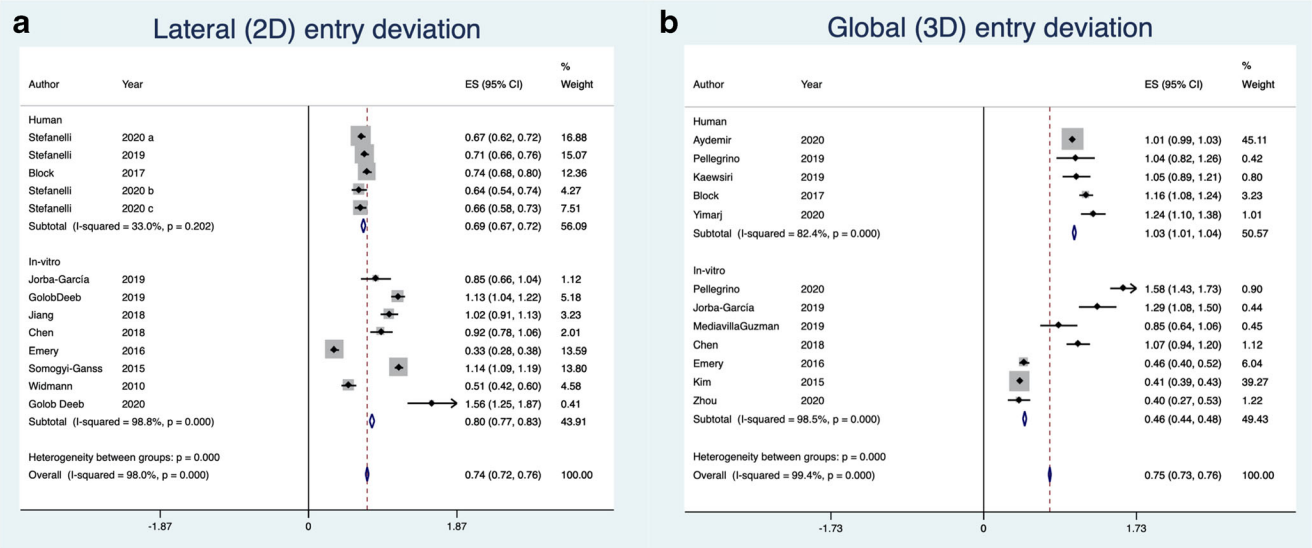

Fig. 5 Forest plot showing **a** lateral (2D) and **b** global (3D) entry deviation measured for all selected articles grouped by clinical and "in vitro" studies

surgeon's experience, some "in vitro" studies have reported that these systems might be especially useful for novice clinicians, since both experienced and novice professionals obtained a similar degree of accuracy with this technology [53, 54, 58, 60].

Despite the recommendation to use patient-reported outcome measures (PROMs) in all clinical studies dealing with rehabilitation with dental implants, they were not reported for any of the clinical studies included [70]. One systematic review included 14 studies that evaluated PROMs in patients undergoing sCAIS implant placement, but the authors were unable to issue recommendations due to the heterogeneity of the studies regarding PROM measurement, treatment modalities, and trial designs [71].

The short-term outcomes of the implants placed using dCAIS seem to be excellent. Jokstad et al. [22], after 1 year of follow-up, observed that all implants could be restored without any adverse event or prosthetic complication after loading. Furthermore, the mean marginal bone loss was less than 1 mm, and the probing depth was less than 2 mm for all sites. To confirm that these results are stable over time, further studies with longer follow-ups are needed.

New technologies have been developed every day. Augmented reality (AR) eyeglasses have already been used by clinicians to view the dCAIS computer screen next to the patient's mouth [72]. AR has also been employed to project the virtual implant plan onto the patient's jaw [61, 73]. Very recently, in 2020, robot-assisted dental implant placement has been performed with promising results, with small deviations (apical global deviation of 0.8 mm, coronal global deviations of 0.9 mm, and an angular deviation of 0.53°)[74].

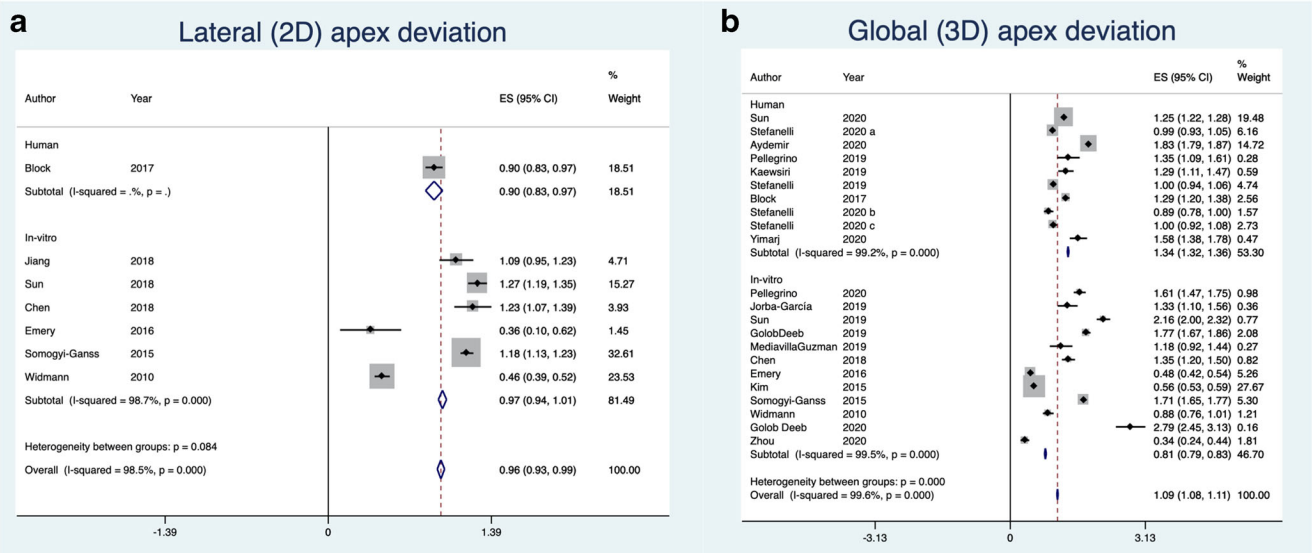

Fig. 6 Forest plot showing **a** lateral (2D) and **b** global (3D) apex deviation measured for all selected articles grouped by clinical and "in vitro" studies

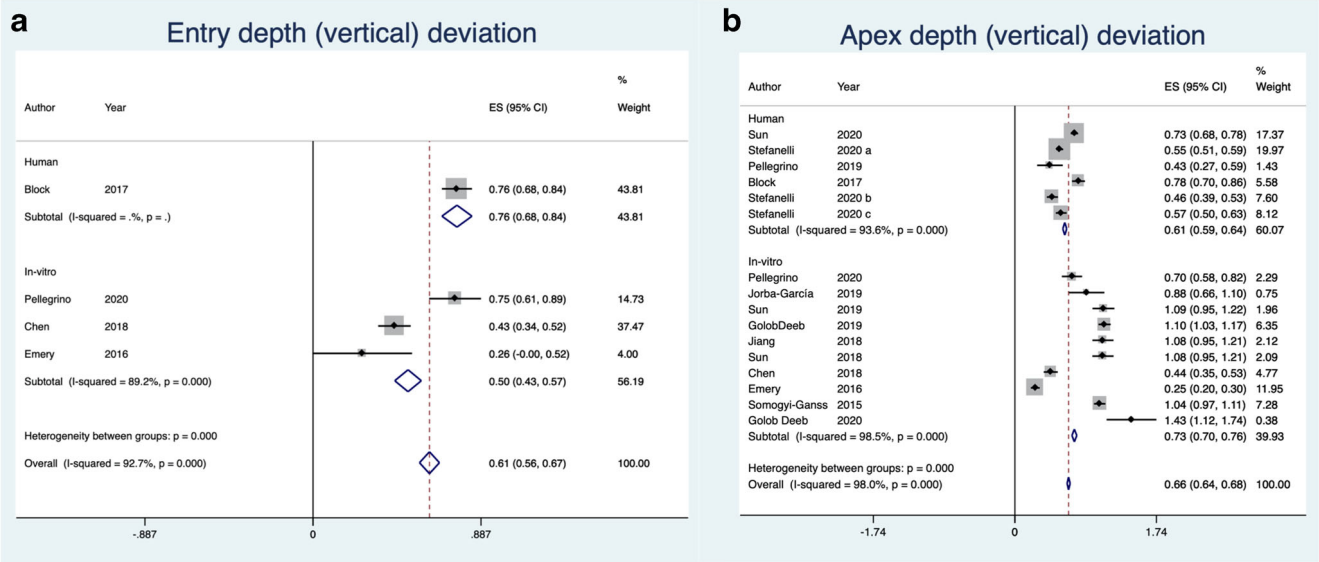

Fig. 7 Forest plot showing **a** entry depth and **b** apex depth deviation measured for all selected articles grouped by clinical and "in vitro" studies

The present review presents some limitations that need to be considered. The low number of clinical studies and the lack of homogeneity of the papers included make it difficult to determine the real accuracy of dCAIS systems. More clinical trials that evaluate patient satisfaction through the use of PROMs and have longer follow-up times are necessary to confirm the published "in vitro" data. Finally, the results related with the secondary aim (comparisons between dCAIS, sCAIS, and freehand placement) should be interpreted with caution due to the high heterogeneity found.

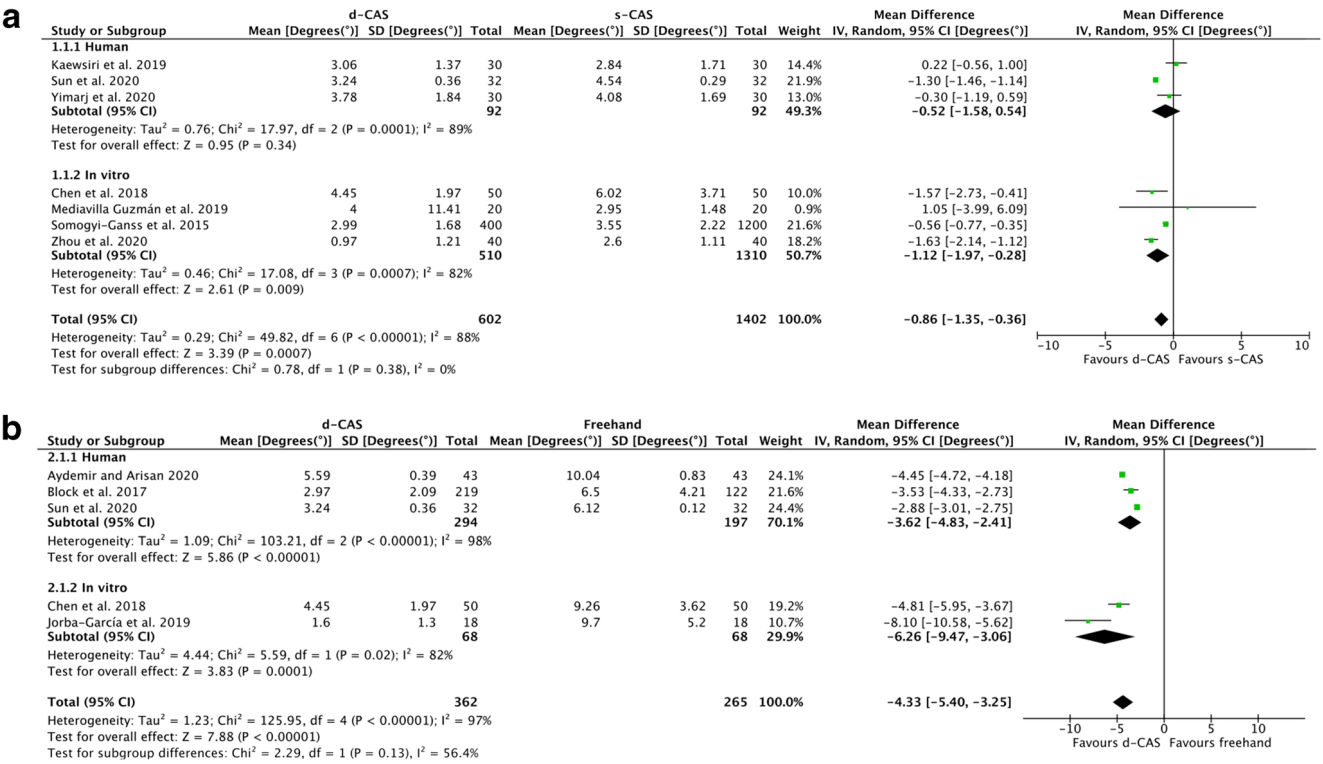

Fig. 8 Forest plots for angular deviation comparing **a** dCAIS versus sCAIS and **b** dCAIS versus freehand implant placement. sCAIS static computer–aided implant surgery, dCAIS dynamic computer–aided implant surgery, SD standard deviation, CI confidence interval

Table 7 Summary of results of meta-analysis of sCAIS

	Angular (°) Mean [95% CI]	Lateral (2D) entry (mm) Mean [95% CI]	Global (3D) entry (mm) Mean [95% CI]	Lateral (2D) apex (mm) Mean [95% CI]	Global (3D) apex (mm) Mean [95% CI]	Apex depth (mm) Mean [95% CI]	Entry depth (mm) Mean [95% CI]
sCAIS (clinical setting) Tahmaseb et al. 2018 [67]	3.5 [3.00 to 3.96]		1.3 [1.09–1.56]		1.4 [1.28 to 1.58]	0.5 [−0.08 to 1.13]	0.2 [−0.25 to 0.57]
sCAIS (clinical and "in vitro" settings) Bover-Ramos et al. 2018 [68]	3.48 [2.96 to 3.99]	1.03 [0.88 to 1.18]		1.29 [1.11 to 1.48]		0.64 [0.47 to 0.82]	

sCAIS static computer–aided implant surgery

Conclusion

dCAIS systems allow highly accurate implant placement with a mean angular deviation of less than 4°. However, a 2-mm safety margin should be applied, since deviations of more than 1 mm were observed in some studies. Most of the dCAIS systems tested achieved similar performance levels. Also, dCAIS systems increase the implant placement accuracy when compared to freehand implant placement and also seem to slightly decrease the angular deviation in comparison with the sCAIS systems.

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Author contribution Adrià Jorba-García and Albert González-Barnadas: Conception of the review; literature search and data acquisition; article drafting; approval of the final version of the manuscript and agreement to be accountable for all aspects of the work.

Octavi Camps-Font: Conception of the review; analysis and interpretation of the data; critical review of the article; approval of the final version of the manuscript and agreement to be accountable for all aspects of the work.

Rui Figueiredo and Eduard Valmaseda-Castellón: Conception of the review; interpretation of the data; critical review of the article; approval of the final version of the manuscript and agreement to be accountable for all aspects of the work.

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Declarations

Ethics approval This article does not report on any studies with human participants or animals performed by any of the authors.

Informed consent For this type of study, formal consent is not required.

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4. JUSTIFICATION

Dental implants are considered a reliable solution for treating both partially and totally edentulous patients. Nowadays, most dental implants are still placed with a conventional freehand approach which might lead to implant deviations, thus compromising the ideal prosthetic design and increasing the risk of complications.

In the last years, the development of new digital technologies has led to significant improvements. For example, dCAIS has allowed a more accurate and less invasive implant placement. However, this technology is relatively new and the available literature on this topic remains limited. In fact, when the present thesis project started, only one systematic review (69), and a limited number of clinical studies had been published. Today, more data are available but the number of randomized clinical studies assessing dCAIS systems remains scarce. Moreover, there is no information regarding the perception and satisfaction of patients that undergo implant placement with dCAIS. In our opinion, it would be of great interest to perform a randomized clinical trial (RCT) to determine the accuracy of dCAIS and to report patient perception through Patient-Reported Experience (PRE) and Patient-Reported Outcome Measures (PROMs) .

On the other hand, the registration process is a crucial step when dCAIS systems are involved. Without a correct overlaying of the data obtained in the CBCT and the patient's anatomy, the results can be seriously compromised. Up to date, mainly two registration methods (RMR and MTR) are available but there is no information regarding their impact on dental implant deviations. Thus, it is of paramount importance to determine which method is more accurate.

Also, in some occasions, the visualization of the remaining teeth might not be optimal in the CBCT (27,74–76) due to the presence of radiographic artifacts, which might compromise the tracing of fiducial markers. Hence, it is necessary to develop additional techniques to reduce innacuracies in this process, such as the introduction of a surface scan from an IOS during the patient registration process.

For all the above-mentioned reasons, this thesis is comprised by a meta-analysis to review all data published on this topic and two preclinical studies to determine the most suitable registration method and if an intraoral scanner improves dental implant accuracy. Finally, this project also included a randomized clinical trial to validate the results of a dCAIS system in a clinical setting.

5. HYPOTHESIS

Main hypothesis

- Ha_0: The use of dCAIS system allows to place dental implants with a mean angular deviation of less than 5° and mean linear deviations at platform and apex levels of less than 1mm.
- Ha_1: Implant placement with dCAIS systems reports a mean angular deviation over 5° and a mean linear deviation at the platform and apex of more than 1mm.

- Hb_0: Implant placement with dCAIS systems is as accurate as the conventional freehand non-guided method (difference of less than 5° in angular deviation and less than 1mm in linear deviations at the platform and apex levels).
- Hb_1: Implant placement using a dCAIS system is significantly more accurate than the conventional freehand non-guided method (reduces the mean angular deviation in at least 5° and 1mm the linear deviation at the platform and apex).

- Hc_0: The registration method (i.e markerless pair-point registration and radiographic marker registration) does not affect the implant placement accuracy when using a dCAIS system.
- Hc_1: The markerless pair-point tracing registration is more accurate than the radiographic marker registration method when placing implants using a dCAIS system (improves the mean platform linear deviation in at least 0.5mm).

- Hd_0: Superimposing a STL file obtained with an intraoral scan onto the DICOM, files of a CBCT and performing the registration on the STL file does not increase the implant placement accuracy when using a dCAIS system, in comparison with the standard registration on the DICOM file.
- Hd_1: Superimposing a STL file obtained with an intraoral scan onto the DICOM, and performing the registration on the STL file improves implant placement accuracy when using a dCAIS system, compared to the standard registration on the DICOM file (reduces the linear platform deviation in at least 0.5mm).

Secondary hypothesis

- Ha_0: The use of a dCAIS system during implant placement surgery does not improve the patient's perception and satisfaction (measured with PROM and PRE) in comparison with a conventional freehand non-guided approach.
- Ha_1: Patients undergoing dental implant surgery using dCAIS report worse patient perception and satisfaction (measures with PROMs and PRE) in comparison with patients undergoing the same surgical procedure using a conventional freehand non-guided approach.

- Hb_0: The implant placement accuracy using a dCAIS system is not affected by implant location or operated jaw.
- Hb_1: Implant placement using a dCAIS system is more accurate in the maxilla and in the anterior region.

6. AIMS

Main aim

1. To determine the accuracy of dynamic computer-assisted implant surgery systems for implant placement in relation to the preoperatively planned position.
2. To compare the accuracy of dental implant placement with a dynamic computer-assisted implant surgery system and the conventional non-guided freehand method in partially edentulous patients.
3. To assess and compare the accuracy during implant placement with two different registration methods for a dynamic computer-assisted implant surgery system (i.e. markerless pair-point registration and radiographic marker registration).
4. To assess if superimposing Standard Tessellation Language files from an intraoral scanning of the teeth and soft tissues with the cone-beam computed tomography images and performing the patient registration on the intraoral scan, improves the implant placement accuracy when using a dynamic computer-assisted implant surgery system.

Secondary aim

1. To compare patient's perception and satisfaction when undergoing dental implant placement using a dynamic computer-assisted implant surgery system or a conventional freehand non-guided approach.
2. To assess if dental implant placement accuracy when using a dynamic computer-assisted implant surgery system is affected by different clinical scenarios and surgical site locations (i.e. maxilla vs. mandible, anterior vs. posterior region).

7. PhD CANDIDATE CONTRIBUTIONS

The following work has been carried out by the doctoral student during this doctoral thesis as a compilation of articles:

1. Conceptualization and design of the studies, including metholodological aspects and reviewing of existing literature.
2. Preparation of the study protocols.
3. Preparation of all documents required to apply for a financial aid for doctoral and postgraduate students given by the Faculty of Medicine and Health Sciences (Dentistry teaching and research unit) of the Universitat de Barcelona.
4. Study protocol drafting and preparation of all documents required by the Ethical board committee of the Quiron Salut Hospital in relation with the randomized clinical trial.
5. Registration of the study protocol in clinicaltrials.gov.
6. Monitoring of the clinical study workflow
7. Accuracy measurements in the clinical trial.
8. Collection of all the study variables and data curation.
9. Performing all the simulated preoperative and surgical procedures of the two pre-clinical studies.
10. Registration of the meta-analysis protocol in the PROSPERO database.
11. Design of the search strategy of the meta-analysis.
12. Participation in the selection of studies, data extraction, and assessment of the quality and risk of bias in the meta-analysis.
13. Interpretation and formal analysis of all the results.
14. Writing of the published manuscripts.
15. Writing of this doctoral thesis as a compendium of papers.

8. MATERIAL, METHODS AND RESULTS

8.1. Study 1.

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

- Authors: Jorba-García A, Bara-Casaus JJ, Camps-Font O, Sánchez-Garcés MÁ, Figueiredo R, Valmaseda-Castellón E.
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ORIGINAL ARTICLE

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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; $p = .036$),

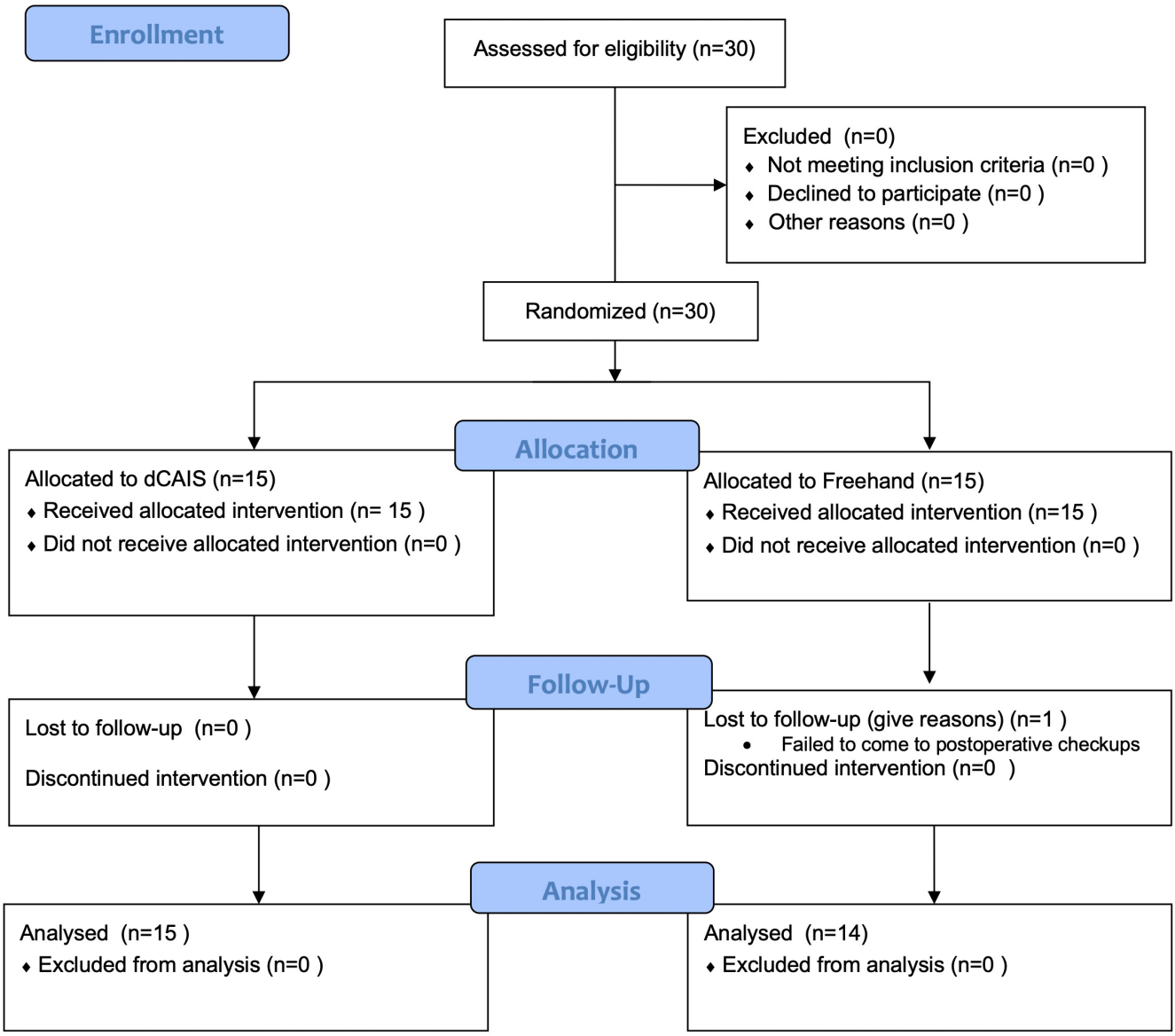

FIGURE 2 Consolidated standards of reporting trials (CONSORT) flow diagram. dCAIS: Dynamic computer-assisted implant surgery.

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.

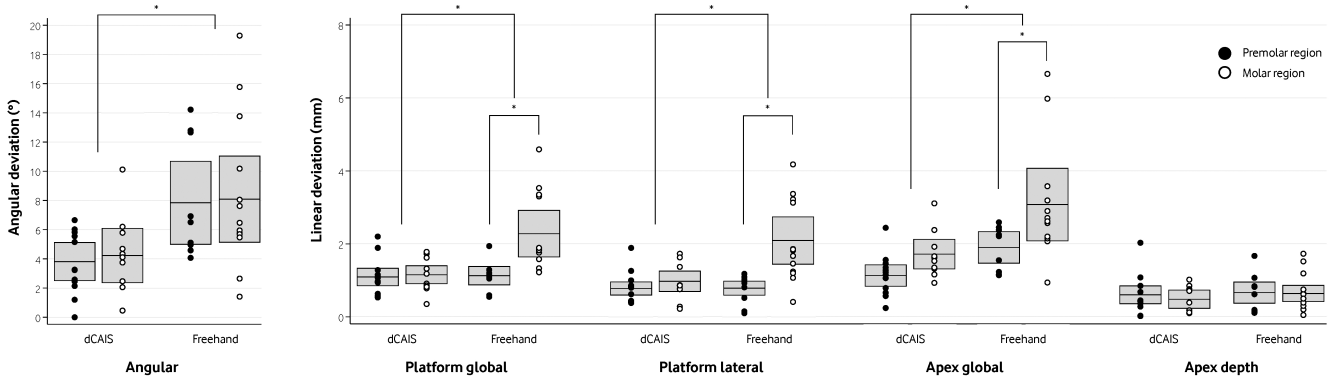

FIGURE 3 Box and scatter plots of angular and linear deviations for dCAIS and Freehand groups in premolar and molar regions. For each box, the interior line in bold shows the mean, and the edges of the box are estimates of the lower and upper 95% CIs. dCAIS: Dynamic computer-assisted implant surgery.

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

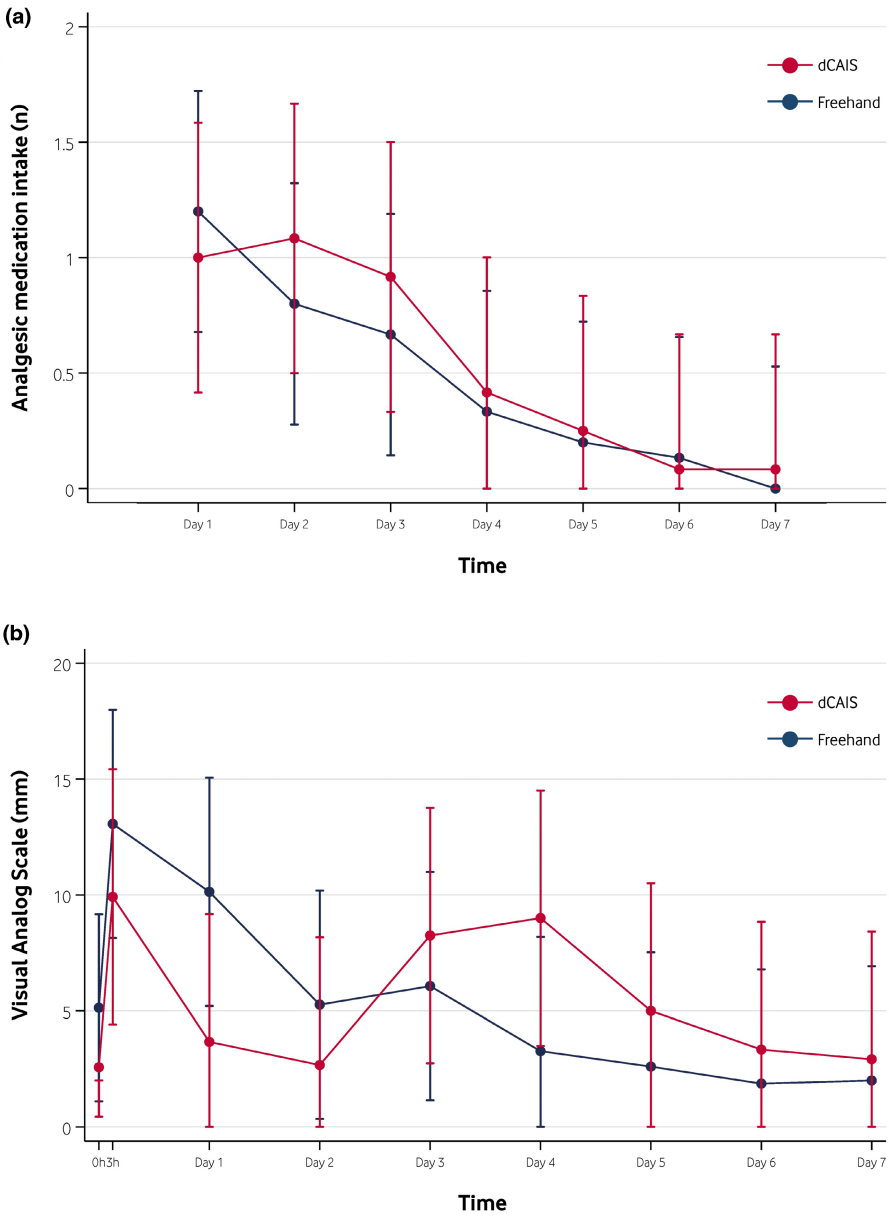

FIGURE 4 Postoperative analgesic medication intake (a) and pain evolution (b) diagram. The mean and IC 95% bars are plotted for each time point for the patients in the dCAIS group and the Freehand group. dCAIS: Dynamic computer-assisted implant surgery; h: hours.

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.

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CONFLICT OF INTEREST STATEMENT

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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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8.2. Study 2.

The effect on the performance of a dynamic navigation system of superimposing a standard tessellation language (STL) file obtained with an intraoral scan on a cone beam computer tomography (CBCT). An experimental *in vitro* study.

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The effect on the performance of a dynamic navigation system of superimposing a standard tessellation language (STL) file obtained with an intraoral scan on a cone beam computer tomograph (CBCT). An experimental in vitro study

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ABSTRACT

Objectives: To compare the accuracy and operative time of implant placement using a dynamic computer assisted implant surgery (dCAIS) system based on a cone beam computer tomography (CBCT) image, with and without superimposing a standard tessellation language (STL) file of an intraoral scan of the patient.
Methods: Ten identical resin models simulating an upper maxilla with posterior edentulism were assigned to two groups. In the CBCT+STL group, a CBCT file and an intraoral STL file were superimposed and used for registration; in the CBCT group, registration was performed using CBCT images. Six implants were placed in each model using the Navident® dynamic navigation system. Anatomy registration was performed by tracing fiducial points on the CBCT or STL image, depending on the group. Preoperative and postoperative CBCT images were overlaid to assess implant placement accuracy.
Results: Sixty implants were analyzed (30 implants in each group). 3D platform deviation was significantly lower (mean difference (MD): 0.17 mm; 95 % confidence interval (CI): 0.01 to 0.23; $P = 0.039$) in the CBCT+STL group (mean: 0.71 mm; standard deviation (SD): 0.29) than in the CBCT group (mean: 0.88 mm; SD: 0.39). The remaining accuracy outcome variables (angular deviation MD: -0.01; platform lateral deviation MD: 0.08 mm; apex global MD: 0.01 mm; apex depth MD: 0.33 mm) and surgery time (MD: 3.383 min.) were similar in both groups ($p > 0.05$).
Conclusions: The introduction of an intraoral scan (STL) seems to reduce deviations slightly in dental implant placement with dCAIS systems. However, the clinical repercussion of this improvement is questionable.
Clinical significance: Superimposing an intraoral scan on the CBCT image does not seem to increase the accuracy of dCAIS systems but can be useful when radiographic artifacts are present.

1. Introduction

The use of cone beam computer tomography (CBCT) in implant dentistry has allowed surgeons to make accurate assessments of the available bone and the position of anatomic structures. Thus, the use of CBCT has reduced the risk of complications and has facilitated preoperative prosthetic-driven implant planning [1-3].

Nowadays, computer assisted implant surgery (CAIS) is a reliable treatment approach for dental implant placement. Several studies have shown that these techniques are accurate, predictable, and allow a minimal approach in implant dentistry [4-9]. Two CAIS approaches should be differentiated: Static CAIS (sCAIS) uses a rigid guide with

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sleeves to transfer the planned position of the dental implants to the mouth, while dynamic CAIS (dCAIS) uses tomographic images in a computer display to show the real-time position of the burs and the implant relative to the virtual preoperative plan [10-12].

Both approaches require a CBCT scan to plan the implant position preoperatively. Although CBCT provides excellent bone anatomy detail, the anatomy of the teeth and soft tissues is not shown precisely enough to manufacture a surgical guide [10,13]. Thus, sCAIS systems require the CBCT images to be merged with the information acquired through scanning the intraoral anatomy, either with an intraoral scan or by scanning a stone cast [14]. This process achieves an adequate fit of the guide in the mouth and, therefore, an accurate drilling sequence and implant placement [13].

In contrast, dCAIS systems generally do not require preoperative models of the dental anatomy or the soft tissues. The registration concept in dCAIS systems is slightly different, as an "image-to-patient registration" is performed [10,15]. This process, which consists of virtually merging the CBCT images with the real patient's anatomy, can be carried out by using a radiographic marker placed on the patient's teeth before the CBCT, or by selecting different fiducial points (usually teeth) on the CBCT and then tracing them on the patient (markerless pair-point registration). Specific software will then recognize the patient's position in relation to the CBCT images [15]. This tracing registration can be done on CBCT images or in a merged standard tessellation language (STL) file.

Since the visualization of the anatomy of the remaining teeth is usually not excellent in CBCT [16-19], the tracing of fiducial markers might be imprecise, and this could affect the accuracy of dCAIS systems. Nevertheless, there appear to be no studies on this topic. Thus, the aim of this in vitro randomized study was to assess the accuracy of implant placement using a dCAIS system with and without overlaying an intraoral scan (STL file) of the model on the CBCT registration. The main hypothesis was that superimposing a STL file obtained with an intraoral scan onto the CBCT files would increase the accuracy of the dCAIS system during implant placement.

2. Materials and methods

A randomized in-vitro study was performed to assess the accuracy of Navident® navigation system v. 3.0.3 (Navident®, ClaroNav Technology Inc.®, Toronto, Canada) using 2 different registration methods: in the CBCT group, only the CBCT images were used for patient registration, while in the CBCT+STL group, registration was performed using CBCT images overlaid with an STL file of the model. The CONSORT guidelines [20] were followed whenever possible throughout the study. Fig. 1 shows the implant placement steps for each group.

Ten identical customized resin models (BoneModels®, Castellón de la Plana, Spain) simulating bilateral posterior maxillary edentulism (from the first premolar to the second molar) were employed in this study. Five models were allocated to each group. All the models were placed in a preclinical learning dental simulator with limited mouth opening and with facial soft tissues simulating a real clinical scenario (Frasaco GmbH, Tettnang, Germany) (Fig. 2).

The sample size was calculated using G*Power v.3.1.3 software (Heinrich- Heine Universität, Dusseldorf, Germany), based on the assumption that a difference of 0.5 mm in the depth deviation would be clinically significant. Considering a common standard deviation (SD) of 0.47 mm [21], an allocation ratio of 1:1, a risk of 0.05, and a power of 80 %, 30 implants (15 implants per group) were required. Since the implants were not independent due to the two-level data structure (model and implant), the number of models needed to be corrected. Assuming an intrasubject correlation of 0.5 (moderate) and six implants for each model, 60 implants (10 models) were placed.

2.1. Intervention

A preoperative CBCT scan (Vistavox S, Dürr Dental, Germany) of every model was acquired (94 kV, 9 mA, 0.2 × 0.2 × 0.2 mm voxel size, 110 × 80 mm FOV). The models were fixed with a customized platform to avoid movement during scanning. Additionally, the 5 models allocated to the CBCT + STL group were scanned with an intraoral device (3Shape TRIOS® 3D scanner, 3Shape A/S® Copenhagen, Denmark).

All the procedures were performed by a clinician with 4 years' prior experience in dCAIS (A.J-G). The surgeon placed a total of 60 implants (Ocean 4 × 10 mm dental implants, Avinent Implant System, Santpedor, Spain) following the drilling protocol recommended by the manufacturer (guide drill, pilot drill ø1.6 mm, ø1.6–2.4 mm drill, ø 2–3.3 mm drill and ø 2.2–3.8 mm drill).

Six implants were planned in each model (3 per side) in the first premolar, first molar and second molar positions [implant positions (FDI World Dental Federation notation): 14, 16, 17, 24, 26 and 27]. The position of the virtual crowns was considered when deciding the implant positions and a virtual wax up was made using software tools.

2.1.1. CBCT group

Digital imaging and communication in Medicine (DICOM) files of the

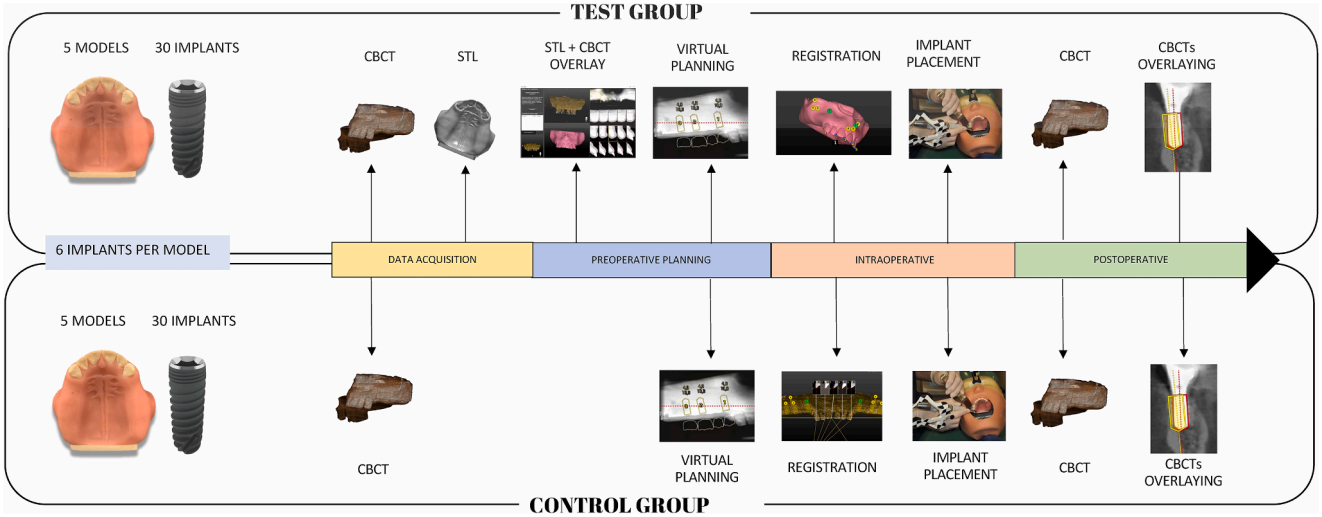

Fig. 1. Infographic showing all the steps for each study group (CBCT group and CBCT + STL group). A total of 60 implants were placed in 10 models. STL: Standard Tessellation Language (intraoral scan files); CBCT: cone beam computer tomography.

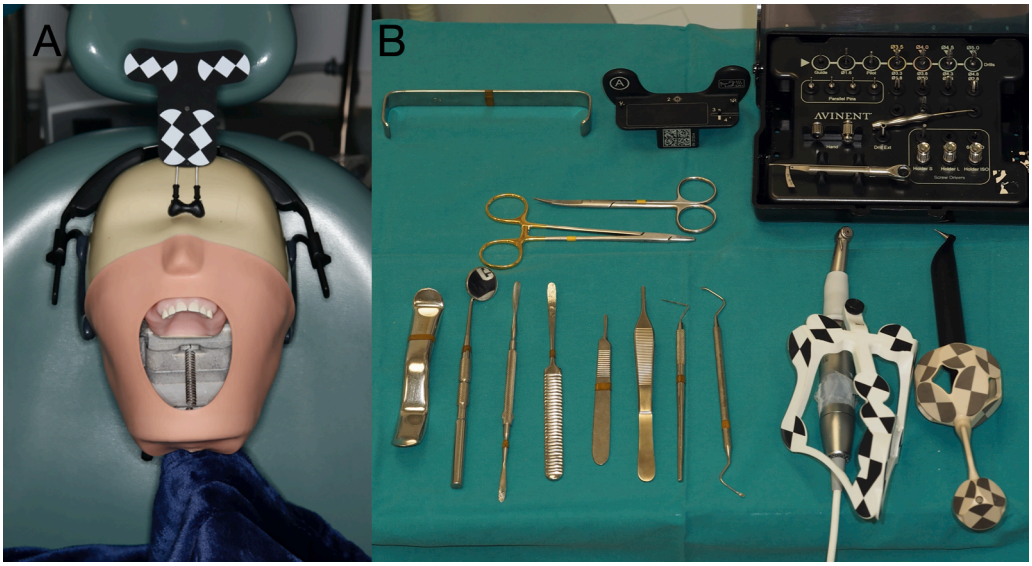

Fig. 2. Preclinical simulation scenario. A. Phantom head with optical markers. The patient optical marker was a head mounted device supported on the nasion, head, and ears. B. Surgical field with oral surgery instruments, handpiece with optical marker, tracer with optical markers and drill axis and tip calibrator.

CBCT scans were uploaded to the navigation system software (Navident ®, ClaroNav Technology Inc. ®, Toronto, Canada).

Optical markers were attached to the handpiece and dental simulator before the procedure (Fig. 2). The optical marker on the patient was a head mounted device supported on the nasion, top of the head, and ears; while the handpiece optical marker was screwed onto a metallic abutment attached to the handpiece. In the registration process, the clinician could select any five fiducial points on the clearest incisal edges or cusp tips of the remaining teeth in the CBCT image. To achieve accurate registration for all the implants, the fiducial points were selected as far apart as possible. Using a probe with an optical marker (tracer) (the instrument on the right in Fig. 2B), the fiducial points were then traced on the resin model. Following successful completion of registration, its accuracy was assessed by touching several points with the tracer on the model and checking the real time feedback from the navigation system (Fig. 3 and Fig. 4A).

2.1.2. CBCT + STL group

In this group, both the CBCT (DICOM) and intraoral scan (STL) data files were uploaded to the Navident ® software. Dental implant planning and the placement of the optical markers were performed following the method described for the CBCT group (Fig. 2).

The registration process consisted of selecting five fiducial points on the STL file and tracing them on the dental model with the tracer (Figs. 3 and 4B).

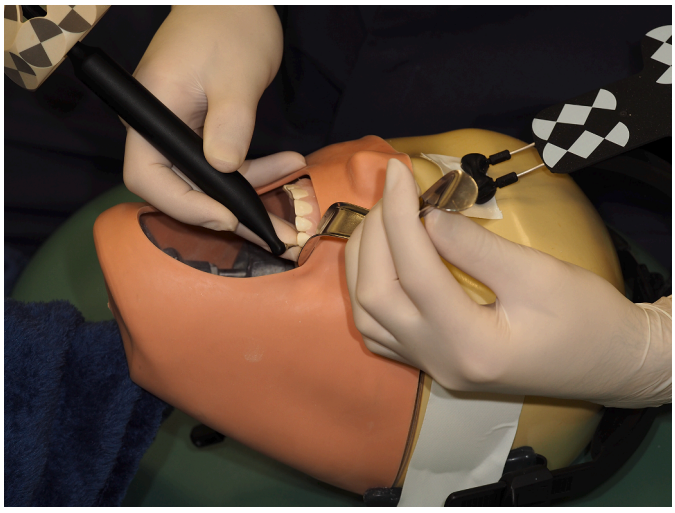

Fig. 3. Markerless pair-point trace registration, touching several model teeth with the tracer with optical markers.

2.1.3. Surgical procedure

A crestal incision was performed and an envelope flap was raised. The drill tip and axis were calibrated with a specific device and the implant site was prepared using the navigation system (Figs. 5A and 5B). Accuracy was checked by placing the drill tip on a cusp before each step in the drilling sequence. If any inaccuracy was detected, most probably due to involuntary optical marker movements, re-registration was performed, and the fiducial points were traced anew. Implant placement was also guided by the dCAIS system.

A postoperative CBCT scan was performed on all the models with the same settings as in the preoperative scan. A second blinded researcher (V.R-R) overlaid the two CBCT scans (pre- and postoperative), using EvaluNav software (Navident®, ClaroNav Technology Inc.®, Toronto, Canada), to check the implant placement accuracy (planned position vs. final position).

2.2. Blinding and randomization

Due to the nature of the study, it was not possible to blind the surgeon, as the navigation images were different. The researcher responsible for overlaying the preoperative and postoperative CBCTs and gathering the accuracy data was blinded, since the group variable was coded.

The treatment sequence (CBCT or CBCT + STL) was randomized using the www.randomization.com website (accessed in December 2021).

2.3. Outcomes

For each implant, five accuracy variables were registered:

- Platform three-dimension (3D) deviation (in mm): global deviation at the entry point of the dental implant, measured in the three spatial dimensions.

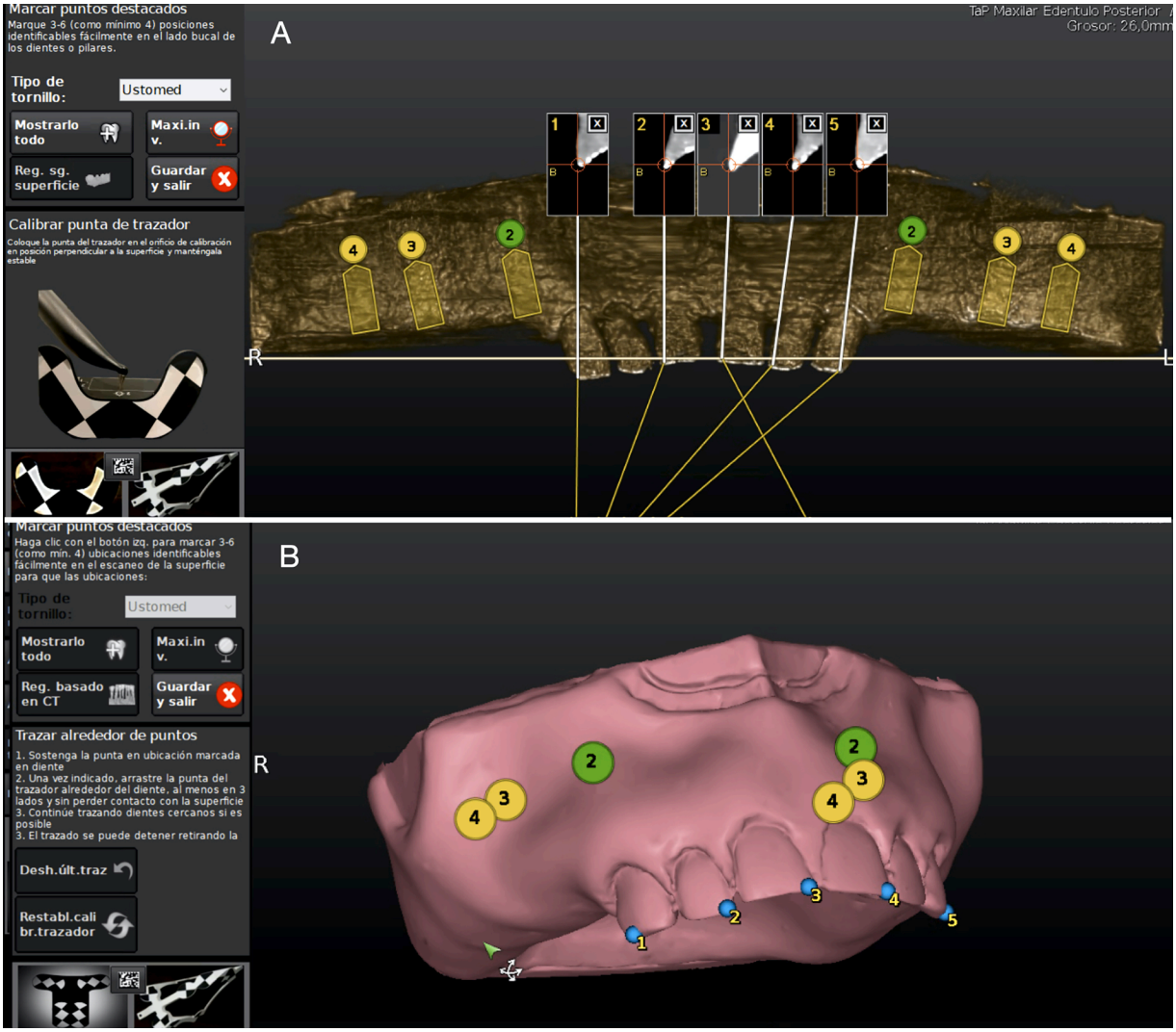

Fig. 4. Screen view of markerless pair-point trace registration with Navident ® software. A. Cone beam computer tomography (CBCT) pair-point trace registration. B. Standard Tessellation Language (STL) pair-point trace registration.

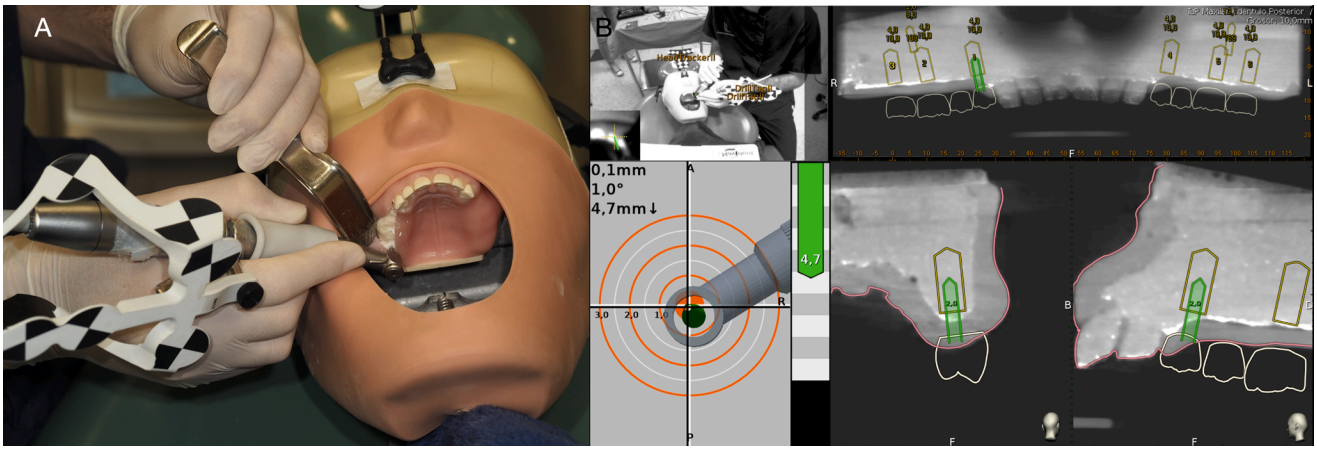

Fig. 5. Implant placement using the Navident dynamic computer assisted guidance (dCAIS) system. A. View of the surgical procedure using artificial models and the phantom head with optical markers. B. Computer software interface during the surgical procedure.

- Platform two-dimension (2D) deviation (in mm): horizontal deviation of the dental implant at the entry point in 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.

Since manual selection of several points is required to overlap the preoperative and postoperative CBCT images, intraexaminer agreement and consistency were tested in 3 randomly selected models (90 measurements). The measurements were repeated after 2 weeks. The intraclass correlation coefficient (ICC) was 0.82 (95 %CI: 0.71 to 0.88; $P < 0.001$) for absolute agreement.

The time spent performing the following procedures was also registered: CBCT + STL overlaying, registration and implant placement. The number of additional registrations needed due to any inaccuracy was also recorded.

2.4. Statistical analysis

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 in the same model. Group (CBCT or CBCT+STL), region (premolar or molar), implant position (first premolar, first molar and second molar) and the interaction between them were included as predictor variables. Adjusted beta coefficients for linear regression models including 95 % confidence intervals (CIs) were obtained from the Wald $\chi 2$ statistic.

SPSS version 27 (SPSS Inc., Chicago, IL, USA) was used for the statistical analyses. The level of significance was set at $P < 0.05$.

3. Results

Thirty dental implants were analyzed in each group. The results of the accuracy variables are summarized in Table 1. A statistically significant reduction in deviation was found in the CBCT+STL group regarding the mean global 3D platform deviation (Mean difference (MD): 0.17 mm; 95 % CI: (0.01 to 0.34); $P = 0.039$). No statistically significant differences were observed in the remaining accuracy variables (Table 1, Fig. 6). The CBCT group had a mean angular deviation of 2.29° (SD: 2.33), a mean platform lateral deviation of 0.63 mm (SD: 0.34), a mean apex global deviation of 0.97 mm (SD: 0.48) and a mean apex depth deviation of 0.50 mm (SD: 0.55). The CBCT + STL group had a mean angular deviation of 2.30° (SD: 1.91), a mean platform lateral deviation of 0.54 mm (SD: 0.30), a mean apex global deviation of 0.95 mm (SD: 0.35) and a mean apex depth deviation of 0.33 mm (SD: 0.25).

Table 1
Summary of accuracy variables.

Accuracy variable	CBCT Mean (SD)	CBCT+STL Mean (SD)	MD (95 %CI)	P-value
Angular (°)	2.29 (2.33)	2.30 (1.91)	−0.01 (−1.09 to 1.07)	0.989
Platform global (mm)	0.87 (0.38)	0.69 (0.27)	0.17 (0.01 to 0.34)	0.039*
Platform lateral (mm)	0.63 (0.34)	0.54 (0.30)	0.08 (−0.06 to 0.23)	0.259
Apex global (mm)	0.97 (0.48)	0.95 (0.35)	0.01 (−0.19 to 0.22)	0.893
Apex depth (mm)	0.50 (0.55)	0.33 (0.25)	0.17 (−0.05 to 0.40)	0.401

CBCT: Cone beam computer tomography (CBCT); STL: Standard Tessellation Language; SD: Standard deviation; MD: Mean difference (CBCT – CBCT+STL); 95 %CI: 95 % Confidence interval.
Note: MD adjusted according to generalized estimating equations (GEE), considering other covariates.

The interaction between group (CBCT or CBCT+ STL) and implant site (premolar, first molar or second molar) did not yield any statistically significant difference for any of the accuracy variables assessed ($P > 0.05$), and similar results were obtained in the different implant site positions (Fig. 6).

The time employed in placing the 6 implants in each model was similar in both groups ($P = 0.748$). A mean of 29.2 min (SD: 5.04) was necessary in the CBCT group and a mean of 28.1 min (SD: 5.56) in the CBCT+STL group. Likewise, the registration time was also similar in both groups (CBCT+STL group: 1.83 min vs. CBCT group: 1.56 min; $P = 0.459$). A mean of 2.44 min (SD: 0.46) was needed to superimpose the CBCT and the STL file. *Re*-registration due to inaccuracies was required in 4 models (3 out of 5 in the CBCT group and 1 out of 5 in the STL+CBCT group; $P = 0.17$) (Table 2).

4. Discussion

The main aim of this trial was to assess whether performing an intraoral scan improves the accuracy of dCAIS systems. To the best of our knowledge, it is the first study to address this issue. It has shown that this procedure improves the location of the implant platform ($P = 0.039$) in comparison with the standard technique. Nevertheless, since the improvement in accuracy was only 0.17 mm (95 %CI: 0.01 to 0.34), it cannot be considered clinically relevant in the present simulation scenario. Thus, in the authors' view, the accuracy outcomes of both groups are similar, indicating that there is no need to merge the CBCT images with STL files. Nevertheless, the introduction of an STL file could significantly increase the accuracy of dCAIS if low quality CBCT scans are used or when radiographic artifacts are present.

In sCAIS and dCAIS, the registration process is crucial to achieve precise results. Nevertheless, this procedure is performed in totally different ways. In sCAIS, registration consists in merging STL files (intraoral scan data) and a DICOM file (radiographic data from the CBCT scan) to accurately reproduce the dental anatomy, in order to fabricate splints that fit the patient perfectly [22]. This process has been described thoroughly in the literature [13,23]. A potential problem is that radiographic artifacts, such as metallic restorations, orthodontic appliances, or other dental implants, can distort the images [13,14,24,25]. However, dCAIS registration requires space coordinates of the patient's position to merge this virtually with the CBCT images [15]. Hence, an intraoral scan is not mandatory. Instead, fiducial markers or points must be selected and placed [26]. In general, dCAIS systems use radiographic fiducial markers, attached to intraoral splints or devices, which are automatically detected by the software. During the surgical procedure, the splint with the optical markers must be placed in exactly the same location so that the software automatically registers the patient's position [27,28].

Recently, the introduction of a tracing technology that does not require radiographic fiducial markers has enabled registration using different anatomical fiducial points on the patient (usually located on the remaining teeth). Thus, this process does not require placing an intraoral device, and prior CBCT scans of the patient (without markers) can be used to perform the guided surgery [29,30]. Nevertheless, certain limitations need to be considered. Firstly, in fully edentulous patients, it might be difficult to select fiducial points. In these situations, placement of three to six miniscrews before the CBCT scan allows point-to-point registration using the head of the screw as a reference [31]. Another option is to fabricate a radiographic splint with at least three

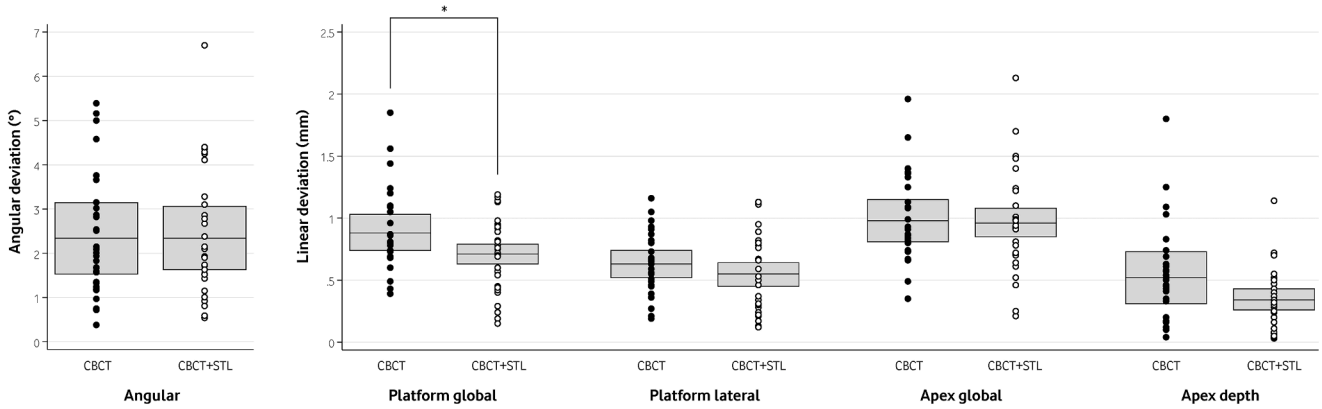

Fig. 6. Box and scatter plots of angular and linear deviations for the CBCT and CBCT+STL groups. For each box, the bold interior line shows the mean, and the edges of the box are estimates of the lower and upper 95 % confidence intervals. STL: Standard Tessellation Language (intraoral scan files); CBCT: cone beam computer tomography. °: degrees, mm: millimeters.

Table 2
Mean time recording for overlapping, registration, surgery, and recalibration.

Accuracy variable	CBCT Mean (SD)	CBCT+STL Mean (SD)	MD (95 %CI)	P-value
Overlaying (minutes) Mean (SD)	–	2.4 (0.47)	–	–
Registration (minutes) Mean (SD)	1.6 (0.5)	1.8 (0.6)	0.253 (−1.004 to 0.498)	0.459
Surgery (minutes) Mean (SD)	26.9 (4.5)	23.52 (2)	3.383 (−3.125 to 9.925)	0.265
Recalibrations (minutes) Mean (SD)	1.2 (0.2)	1.6*	–	–
TOTAL (minutes) Mean (SD)	29.2 (5.0)	28.1 (5.6)	1.113 (−5.521 to 8.862)	0.748

CBCT: Cone beam computer tomography (CBCT); STL: Standard Tessellation Language; SD: Standard deviation; MD: Mean difference (CBCT – CBCT+STL); 95 %CI: 95 % Confidence interval.

* SD and 95 % CI could not be calculated since only one case in the CBCT+STL group required recalibration.

radiographic fiducial marker points.

Several factors could limit the quality and definition of a CBCT scan. Radiographic artifacts are especially relevant and might hinder correct registration, since the tooth anatomy (edges and cusps) and microscrews might not be fully recognizable. Thus, in patients with reconstructions, brackets or prosthetic rehabilitations, a specific device with radiopaque landmarks or at least three microscrews might be placed before performing the CBCT scan and then traced during surgery. In these cases, overlaying the STL and DICOM files corrects radiographic artifacts and allows point-to-point registration without the introduction of any specific device. Ideally, for accurate overlay, at least three points should be selected in both files, creating a wide triangle (for example, points located on one anterior tooth and two posterior teeth) [25]. Hence, if only unilateral or anterior teeth remain, the placement of additional landmarks (bone anchored or adhesive) should be considered [32,33]. In addition, it should be noted that tooth mobility might also result in inaccurate registration [29].

Pei et al. [34] compared 3 different markers (micro-screws, tooth cusps and intraoral devices) in an in vitro study and concluded that intraoral devices seem to be more accurate (angular deviation of 1.36 (SD:0.54)). It is important to stress that these authors reported high deviations in all groups, in contrast with the outcomes of our study.

The findings of this study confirm that the use of an intraoral scan has limited clinical repercussion, since the accuracy improvement was imperceptible (less than 0.2 mm). Moreover, the alignment between the STL file of the dentition and the CBCT data might be an additional source of inaccuracies. However, this technique can provide additional information (soft tissue thickness and emergence profile) that might improve prosthetic planning [35,36]. The use of an STL file could also present some advantages when radiographic artifacts hinder correct registration on CBCT images. Additionally, while neither statistically significant nor significantly increasing the overall procedure time, re-registration due to inaccuracies was required in 3 out of 5 models in the CBCT group but in only 1 out of 5 in the CBCT + STL group.

It is important to point out that, on some occasions, clinically relevant deviations can occur when using dCAIS systems [5,29]. In the present study, some implants presented angular deviations of more than 5° and lineal deviations of more than 1.5 mm. This is particularly relevant when assessing the apex depth, since these inaccuracies might lead to major complications (for example, inferior alveolar nerve damage). For this reason, a safety margin should always be applied when performing virtual implant placement planning.

This in vitro study has some limitations that should be discussed. In a real clinical scenario, CBCT image quality might be affected by the patient's movements or the presence of metallic artifacts. Also, this study only addressed a specific situation (posterior maxillary edentulism). Thus, future research should assess whether these findings are affected by variables like the number and location of the missing teeth (anterior versus posterior; maxilla versus mandible, single implants versus multiple implants, fully edentulous versus partially edentulous patients, etc.) or by the presence of adjacent metallic elements. Generalization of the results should also be treated with caution if other dCAIS systems are used or less experienced surgeons are involved.

5. Conclusions

Performing an intraoral scan (STL file) of the patient seems to reduce deviations slightly in dental implant placement with dCAIS systems. However, the clinical repercussion of this improvement is questionable. Nonetheless, this procedure might be of interest when radiographic artifacts are present or when information on the soft tissues can provide useful data for prosthetic planning.

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CRediT authorship contribution statement

Adrià Jorba-García: Conceptualization, Methodology, Formal analysis, Investigation, Writing – original draft, Visualization. **Víctor Ruiz-Romero:** Investigation, Writing – original draft, Visualization. **Jose Javier Bara-Casaus:** Conceptualization, Resources, Writing – review & editing, Funding acquisition. **Octavi Camps-Font:** Conceptualization, Methodology, Formal analysis, Data curation, Writing – review & editing, Visualization. **Maria Ángeles Sánchez-Garcés:** Methodology, Resources, Writing – review & editing, Supervision. **Rui Figueiredo:** Conceptualization, Methodology, Resources, Writing – review & editing, Project administration, Funding acquisition. **Eduard Valmaseda-Castellón:** Conceptualization, Methodology, Resources, Writing – review & editing, Supervision, Project administration, Funding acquisition.

Declaration of competing interest

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

The authors declare no conflict of interest directly related with this study. However, the authors would like to state the following conflicts outside the submitted work:

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8.3. Study 3.

The influence of radiographic marker registration versus a markerless trace registration method on the implant placement accuracy achieved by dynamic computer-assisted implant surgery. An in-vitro study

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The influence of radiographic marker registration versus a markerless trace registration method on the implant placement accuracy achieved by dynamic computer-assisted implant surgery. An in-vitro study

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ABSTRACT

Objectives: This study aimed to compare the effect the radiographic marker registration (RMR) and markerless tracing registration (MTR) on implant placement accuracy using a dynamic computer-assisted implant surgery system (dCAIS). Additionally, this study aimed to assess the surgical time and whether the implant location influences the accuracy of the two registration methods.
Methods: 136 dental implants were randomly allocated to the RMR or MTR group and were placed with a dCAIS in resin models. Preoperative and postoperative Cone Beam Computer Tomograms (CBCT) were overlaid and implant placement accuracy was assessed. Descriptive and multivariate analysis of the data was performed.
Results: Significant differences ($P < 0.001$) were found for all accuracy variables except angular deviation (RMR:4.30° (SD:4.37°); MTR:3.89° (SD:3.32°)). The RMR had a mean 3D platform deviation of 1.53 mm (SD:0.98 mm) and mean apex 3D deviation of 1.63 mm (SD:1.05 mm) while the MTR had lower values (0.83 mm (SD:0.67 mm) and 1.07 mm (SD:0.86 mm), respectively). In the MTR group, implant placement in the anterior mandible was more accurate ($p < 0.05$). Additionally, MTR did not significantly increase the surgical time compared with RMR ($P = 0.489$).
Conclusions: MTR seems to increase the accuracy of implant placement using dCAIS in comparison with the RMR method, without increasing the surgical time. The operated area seems to be relevant and might influence the implant deviations.
Clinical significance: Considering the limitations of this *in-vitro* study, MTR seems to provide a higher accuracy in implant placement using dCAIS without increasing the surgical time. Furthermore, this method does not require radiographic markers and allows re-registration during surgery.

1. Introduction

Dynamic computer-assisted implant surgery (dCAIS) or navigation systems are used to provide clinicians with a real-time guidance during implant placement without the need for any guide or splint. During the surgical procedure, a stereoscopic camera and different optical trackers attached to the patient and handpiece enable the software to provide real-time feedback on the relative position of the bur or implant and the patient's anatomy in the Cone-beam Computer Tomography (CBCT) images [1–3].

These systems work with an "image-to-patient registration" which consists of virtually overlaying the 3D images of the planned implant position on those of the real patient's anatomy. This step – also known as the registration process – is critical since any inaccuracy will lead to

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deviations between the planned and final position of the dental implant. Currently, two registration methods have been described in dCAIS: radiographic marker-registration and markerless tracing registration [4]. The first of these methods consists of attaching a radiographic marker to the patient, usually by means of an intraoral splint or clip, which will be used during CBCT data acquisition and will be automatically recognized by the dCAIS software. This device will be placed in the same position during the surgical procedure and, together with the patient's optical tracker, will allow the software to identify the relative position of the patient's anatomy on the CBCT images [5]. The second method, markerless tracing registration, works by selecting different fiducial points on the CBCT scan images (usually on the cusps and edges of the remaining teeth) and then tracing them on the patient's anatomy using a specific probe with optical trackers, which allows the navigation system to recognize the patient's position in relation to the CBCT images [6,7].

Since two registration methods are available and no data to evaluate their impact on dental implant deviations have been published, it is of paramount importance to determine which method is more accurate. Thus, the main aim of this *in-vitro* study was to compare the effect of the two different registration methods (radiographic marker registration and markerless tracing registration) on the accuracy of implant placement using a dCAIS system. The secondary objectives of this research were to assess whether the location (maxilla versus mandible; anterior versus posterior) influenced the accuracy results of these registration methods and to compare the surgical time required with both registration approaches.

2. Methods

An *in-vitro* randomized study was performed using the Navident® dynamic CAS system (ClaroNav Technology Inc. ®, Toronto, Canada). Twenty-eight resin models that simulated different clinical situations were randomly allocated to one of the 2 study groups. In the radiographic marker-registration (RMR) group, registration was performed using a specific radiographic marker placed in a thermoplastic splint during the CBCT. In the markerless tracing registration (MTR) group, registration was performed by tracing at least 3 fiducial points on the preoperative CBCT and then on the model, using a specifical probe with optical trackers. An adaptation of the CONSORT guidelines [8] was followed whenever possible throughout the study. Fig. 1 shows the study flowchart.

2.1. Resin models

Four types of artificial model (BoneModels®, Castellón de la Plana, Spain) were specifically developed for this study to simulated 4 different clinical situations (Fig. 2):

- Maxillary anterior partial edentulism.
- Maxillary posterior partial edentulism.
- Mandibular anterior partial edentulism.
- Mandibular posterior partial edentulism.

The resin models had artificial soft tissues simulating the oral mucosa and were placed in a preclinical learning dental simulator to reproduce a clinical setting (limited mouth opening and latex face to limit visibility and to mimic the pressure of the facial soft tissues).

2.2. Sample size calculation

The sample size was calculated with G*Power v.3.1.3 (Heinrich-Heine Universität, Düsseldorf, Germany), considering that the primary outcome variable was depth deviation (in mm). Depth deviation data were extracted from a previously published study [9]. An alpha value of 0.05 and a statistical power of 80 % were established. Considering that a clinically significant difference would be a reduction of 0.5 mm in depth deviation, the sample size calculation yielded a total of 15 implants for each group.

2.3. Allocation and blinding

The models were randomly allocated to each group (RMR and MTR) using a webpage random generating sequence (www.randomization.com). The allocation ratio was 1:1, and the surgeon was unaware of the group assigned during the preoperative planning.

The outcome assessment was done by a third researcher that was unaware of the group allocation. However, blinding was not possible in all cases since the splint could be observed on some occasions.

2.4. Interventions

An oral surgeon (AJ-G) with more than 5 years of clinical experience in Implant Dentistry and familiar with dCAIS performed all the interventions of the study.

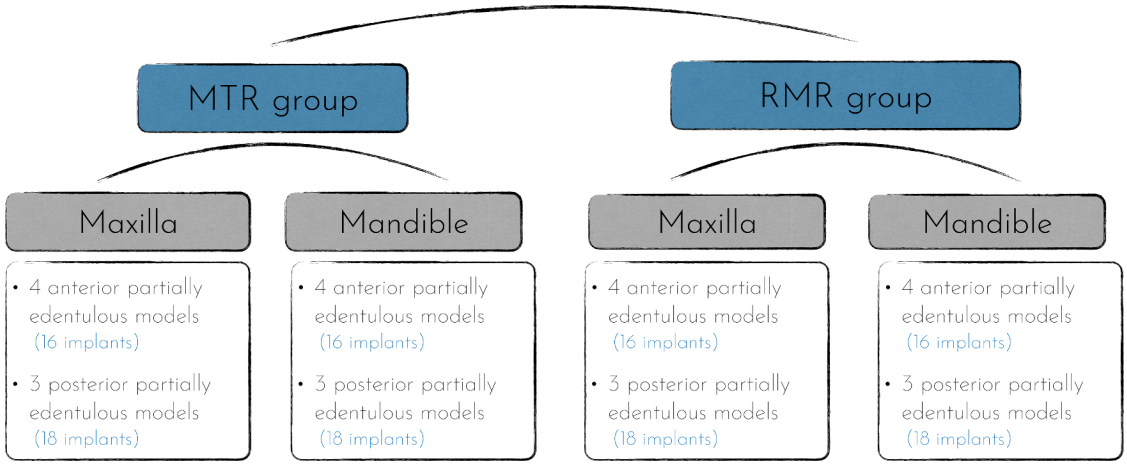

Fig. 1. Study flowchart.
MTR: Markerless tracing registration; RMR: Radiographic marker registration.

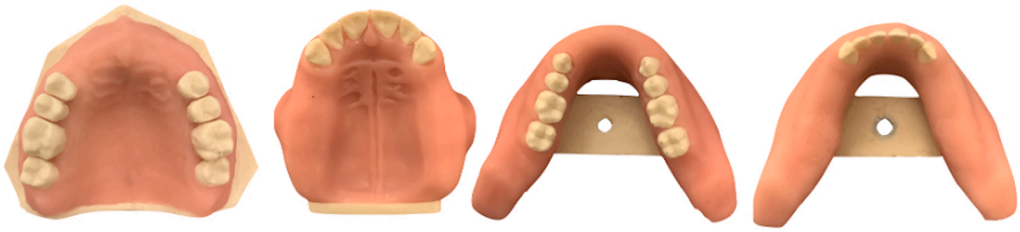

Fig. 2. Resin models simulating different clinical situations.

2.5. Radiographic marker-registration (RMR) group

For each model, a thermoplastic splint (Navistent; ClaroNav Technology Inc. ®, Toronto, Canada) was adapted to the remaining teeth. A marker with a specific radiopaque pattern was then attached to the splint and a CBCT scan (Morita®, Veraview X800; settings: 90 kV, 5 mA, 0.25 × 0.25 × 0.25 mm, voxel size, 10 × 10 cm FOV) was obtained. (Fig. 3A)

All the DICOM data were imported into the Navident 3.0 software (ClaroNav Technology Inc. ®, Toronto, Canada). The software automatically detects the radiographic marker pattern when importing the scan (Fig. 3B). Manual delimitation is not required unless inaccuracies are detected.

Prosthetically driven virtual placement of the implants was made and virtual crowns were also designed. The implant positions (FDI World Dental Federation notation) were as follows:

- Maxillary anterior partially edentulous model: 1.3, 1.1, 2.1 and 2.3.
- Maxillary posterior partially edentulous model: 1.4, 1.6, 1.7, 2.4, 2.6 and 2.7.
- Mandibular anterior partially edentulous model: 3.3, 3.1, 4.1 and 4.3.
- Mandibular posterior partially edentulous model: 3.4, 3.6, 3.7, 4.4, 4.6 and 4.7.

During the surgical procedure, the radiographic marker attached to the splint was replaced by an optical tracker (Fig. 3C). Then, the splint with the optical tracker was firmly positioned on the remaining teeth in the exact same position and the drill axis and bur lengths were calibrated.

The clinician used the specific drilling protocol of the implant system (Bioner TopDM; Bioner®, Barcelona, Spain). Drill tip calibration was performed for each bur. The following drilling sequence was employed:

- Dental implants Ø 3.5mm:
  - Initial drill
  - Drill Ø 1.5–2.0 mm
  - Drill Ø 2.2–3.3 mm
- Dental implants Ø 4mm:
  - Initial drill
  - Drill Ø 1.5–2.0 mm
  - Drill Ø 2.4–2.8 mm.
  - Drill Ø 3.4 – 3.8 mm

The implants were also calibrated before being inserted at 15 rpm with a maximum torque of 50 N.cm. The following dental implants diameters and lengths were used:

- Anterior implants: Bioner TopDM 3.5 × 11.5 mm.
- Posterior implants: Bioner TopDM 4 × 10 mm.

2.6. Markerless tracing registration (MTR) group

All the models were scanned (Morita®, Veraview X800; settings: 90

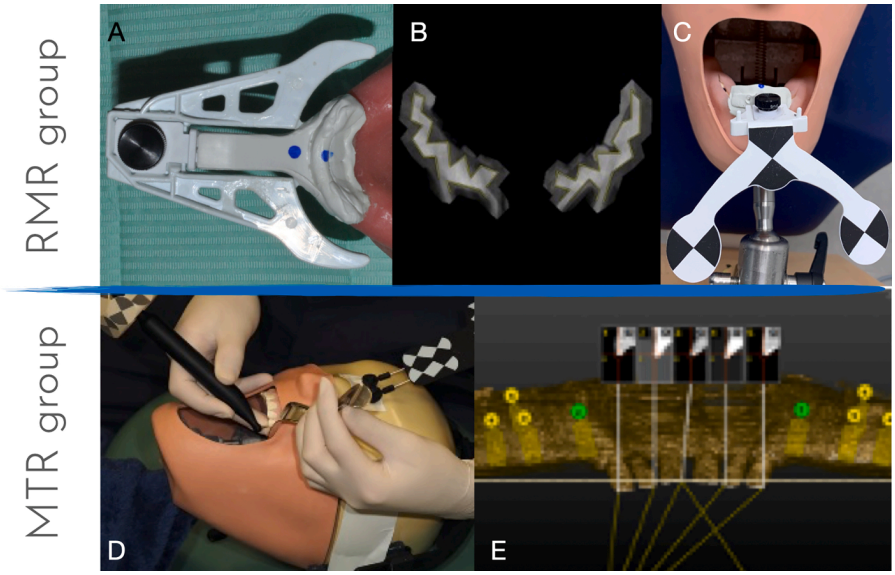

Fig. 3. Summary of the registration process in both groups. A. Thermoplastic stent adapted to the remaining teeth and radiographic marker fixed to the stent. B. dCAIS software automatically detecting radiographic marker on CBCT scan. C. Thermoplastic stent with the optical tracker attached to the remaining teeth. The optical tracker is placed in the stent after removing the radiographic marker. D. Pair point registration by tracing fiducial points on tooth anatomy. E. Fiducial points selected on the CBCT reconstruction in the dCAIS software.
MTR: Markerless tracing registration; RMR: Radiographic marker registration.

kV, 5 mA, 0.25 × 0.25 × 0.25 mm, voxel size, 10 × 10 cm FOV) without any specific splint or radiographic marker. The DICOM data were then uploaded to the Navident 3.0 ® software and the implants were planned in the same way as for the RMR group.

Before starting the surgical procedure, the optical tracker was placed on the phantom (i.e. intraoral tooth-supported optical tracker for the lower jaw, and extraoral head-supported optical tracker for the maxilla). Then, 4 fiducial points located on well-defined cusps or edges of the remaining teeth were chosen on the CBCT panoramic reconstruction. These points were selected by the clinician trying to draw the largest possible geometric form. Then, a specific probe was used to spot these fiducial points on the model and trace the surface around it until 100 points were automatically detected (Fig. 3D and E). The process had to be repeated for each fiducial point. Once the markerless registration was completed, accuracy was confirmed by touching different teeth with the optical probe and confirming their position on the CBCT images.

A schematic workflow of the interventions in each group can be consulted in Fig. 4. The employed optical trackers can be seen in Fig. 5.

2.7. Outcome measurements

A second CBCT scan of each model was performed after implant placement (Morita®, Veraview X800; settings: 90 kV, 5 mA, 0.25 × 0.25 × 0.25 mm, voxel size, 10 × 10 cm FOV). The implant accuracy variables were assessed, using EvaluNav® software (ClaroNav Technology Inc. ®, Toronto, Canada), by overlaying the preoperative and postoperative CBCTs and comparing the planned position with the final position of the dental implant.

The following accuracy outcome variables were measured for each implant by a second independent investigator [7]:

- 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 in 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.

Additionally, the surgical time was recorded for each model. Surgical time was defined as the time elapsed between placing the stent and finish placing the dental implants in the RMR group; and from the beginning of the registration process (i.e. selection of fiducial points) until the implants were placed in the MTR group.

To test intraexaminer reliability, an assessment of 36 randomly selected measurements was repeated after 4 weeks. The intraclass correlation coefficient (ICC) was 0.94 (95 %CI: 0.89 to 0.97; $P < 0.001$), indicating excellent absolute agreement. Specifically, the magnitude of errors of the repeated measurements were 0.22º (95 %CI: 0.16 to 0.28) and 0.33 mm (95 %CI: 0.27 to 0.40) for angular and linear outcome variables, respectively.

2.8. Statistical analysis

A third blinded researcher performed the statistical analysis using Stata14 software (StataCorp, College Station, TX, USA) and SPSS version 27 (SPSS Inc., Chicago, IL, USA). The level of significance for all statistical tests was set at 5 % ($P < 0.05$), using the Bonferroni correction for multiple comparisons.

The normality of scale variables (Entry 3D, Entry 2D, Apex 3D, Apex vertical, Angulation and Surgical time) was explored using the Shapiro-Wilks test and the visual analysis of normal P-P graphics and box diagrams. Descriptive analysis using the median and interquartile range (IQR) was calculated when normality was rejected. Where the distribution was compatible with normality, the mean and the standard deviation (SD) were used. Descriptive analysis for bivariable categoric variables was performed through absolute and relative frequency tables.

Multilevel linear regression models were constructed to evaluate accuracy outcomes based on the registration method, using generalized estimating equations (GEE). The GEE method was used to account for the fact that repeated observations (several implants) were made in the same model. Registration (MTR or RMR), location (maxilla or mandible), and region (anterior or posterior), and the interaction between them, were included as predictor variables. Adjusted beta coefficients for linear regression models including 95 % confidence intervals (CIs) were obtained from the Wald $\chi 2$ statistic. Pairwise comparisons between groups were performed.

3. Results

In total, 136 implants were placed in 28 resin models: 68 implants using radiographic marker registration (RMR group) and 68 implants employing markerless tracing registration (MTR group).

Significant differences ($P < 0.001$) between the 2 groups were found for all the accuracy variables except angular deviation (Table 1). The mean 3D platform deviation was 1.53 mm (SD: 0.98 mm) for RMR group, and 0.83 mm (SD: 0.67 mm) for the MTR group (Mean difference (MD): 0.69 mm (95 % CI: 0.41 to 0.98), $P < 0.001$). Regarding apex 3D deviations, the mean values of the RMR and MTR groups were 1.63 mm

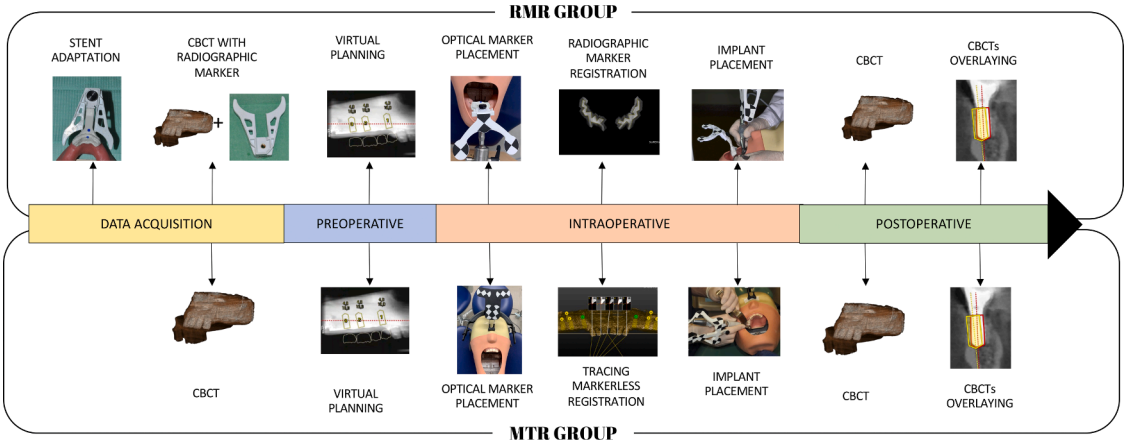

Fig. 4. Illustration showing the workflow in both study groups.

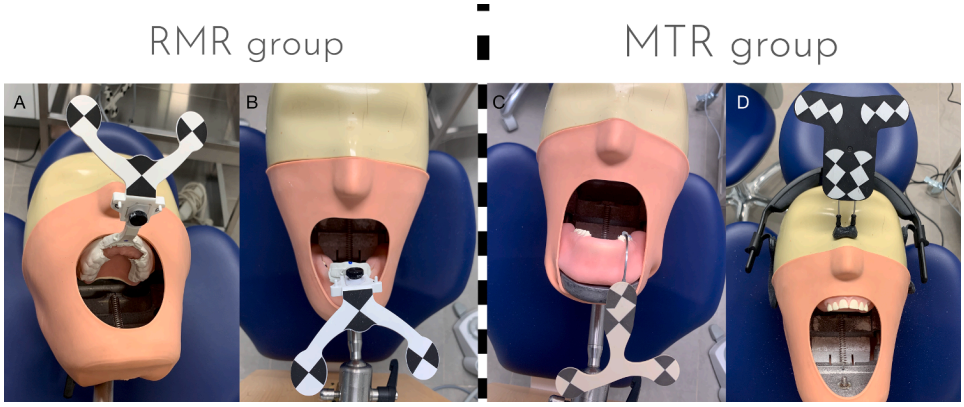

Fig. 5. Fixation of the optical trackers in both groups. A. Maxilla in the RMR group. B. Lower jaw in the RMR group. C. Maxilla in the MTR group. D. Upper jaw in the MTR group.

Table 1
Differences between the 2 study groups (RMR and MTR) for all accuracy variables.

	RMR Mean (SD)	MTR Mean (SD)	Mean difference [95 % CI]	P-value
Platform 3D (mm)	1.53 (0.98)	0.83 (0.67)	0.69 [0.41 to0.98]	<0.001*
Platform 2D (mm)	1.22 (0.92)	0.72 (0.71)	0.50 [0.23 to0.78]	<0.001*
Apex 3D (mm)	1.63 (1.05)	1.07 (0.86)	0.55 [0.23 to0.88]	<0.001*
Apex Depth (mm)	0.79 (0.50)	0.32 (0.39)	0.47 [0.33 to0.60]	<0.001*
Angle (°)	4.30 (4.37)	3.89 (3.32)	0.41 [−0.90 to1.73]	0.537

SD: Standard deviation; 3D: 3 dimensions; 2D: 2 dimensions; RMR: radiographic-marker registration group; MTR: markerless tracer registration group; CI: confidence interval.

(SD:1.05 mm) and 1.07 mm (SD: 0.86 mm), respectively (MD: 0.55 mm (95 % CI: 0.23 to 0.88), $P < 0.001$). The angular deviation did not yield significant differences, being the MD of 0.41° (95 % CI: −0.90 to 1.73; $P = 0.537$), with a mean deviation of 4.30° (SD: 4.37°) for the RMR group and of 3.89° (SD: 3.32°) for the MTR group. The results for all the outcome variables are summarized in Table 1 and Fig. 6.

Table 2 shows the deviations observed according to the arch (maxilla or mandible) and location (anterior or posterior). In general, the MTR group implants were placed more accurately in all areas in comparison with the RMR group. The MTR registration method seems to be specially recommendable in the anterior mandible, where significant differences were found for all the deviation variables (Table 2).

Intragroup comparisons were also performed (Table 2). Implant placement with MTR was significantly less accurate in the posterior mandible compared to the anterior mandible (platform 3D; platform 2D; apex 3D) and in the anterior maxilla compared to the anterior mandible (platform 3D; platform 2D; angular deviation) ($P < 0.001$). Deviations between maxillary and mandibular and between anterior and posterior implants were also analyzed (Table 2). In this regard, the arch did not seem to affect the accuracy significantly for either of the groups. However, the posterior implants presented higher 3D apex deviations in the MTR group and lower apex depth deviations in the RMR group (Table 2).

The markerless tracing registration method (MTR group) did not significantly increase the overall surgical time [RMR= 14.05 min (SD=3.63); MTR=15.50 min (SD=8.28) $P = 0.489$] (Table 3). A significantly higher surgical time was only found when placing implants in the posterior region of the mandible with the markerless tracing registration system [RMR= 15.31 min (SD=0.53); MTR=20.43 min (SD=1.58) $P = 0.046$] (Table 3).

4. Discussion

The radiographic marker (RMR) and markerless tracing (MTR) methods are the most common registration techniques in dCAIS systems. To the best of the authors' knowledge, this is the first study to evaluate the impact of these registration methods on implant placement accuracy when navigation devices are used. The present outcomes indicate that markerless tracing registration seems to be preferable since more accurate results are obtained without increasing the surgery time.

Registration is a crucial step when using static or dynamic CAIS systems since an error can lead to clinically relevant discrepancies between the virtual and real implant placement. Indeed, when dCAIS is involved, incorrect registration will impede a precise overlap between the patient's jaw and the preoperative CBCT [4]. Hence, several papers have been published recently to determine which registration method for dental implant placement is most accurate [10–14]. Some in-vitro studies have compared different fiducial points such as tooth areas,

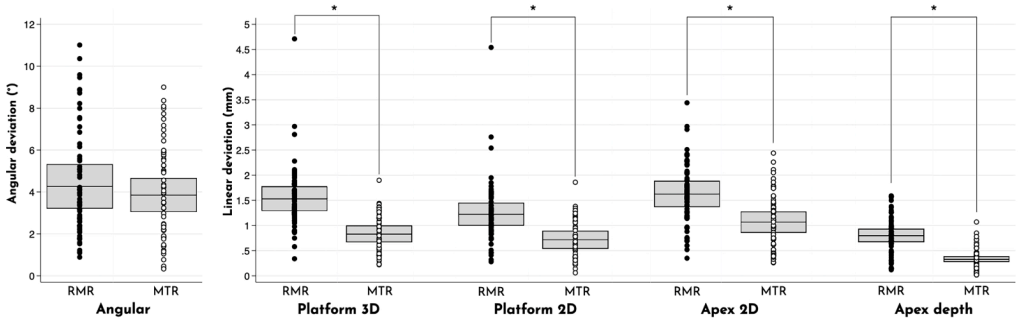

Fig. 6. Box and scatter plots of angular and linear deviations in the RMR and MTR groups. For each box, the interior line in bold shows the mean and the edges of the box are estimates of the lower and upper 95 % confidence intervals (CI).
MTR: Markerless tracing registration, RMR: Radiographic marker registration, °: degrees, mm: millimeters, 3D three dimensions, 2D two dimensions.

Table 2
Accuracy variables of the 2 study groups stratified by arch (maxilla and mandible) and location (anterior and posterior).

Arch and location	Platform 3D (mm) Mean (SD)			Platform 2D (mm) Mean (SD)			Apex 3D (mm) Mean (SD)			Apex Depth (mm) Mean (SD)			Angle ° Mean (SD)		
	RMR	MTR	P-value	RMR	MTR	P-value	RMR	MTR	P-value	RMR	MTR	P-value	RMR	MTR	P-value
Anterior maxilla	1.53 (0.44)	1.20 (0.41)	0.185	1.12 (0.78)	1.13 (0.43)	1.000	1.75 (0.56)	1.01 (0.68)	0.005*	0.93 (0.41)	0.36 (0.17)	0.000*	2.84 (1.64)	4.09 (2.66)	0.667
Posterior maxilla	1.29 (0.75)	0.69 (0.45)	0.018*	1.11 (0.61)	0.57 (0.51)	0.025*	1.71 (1.32)	1.20 (0.69)	0.887	0.59 (0.46)	0.29 (0.06)	0.037*	5.08 (5.47)	5.45 (3.26)	1.000
P-value	1.000	0.003*		1.000	0.004*		1.000	1.000		0.126	0.715		0.591	1.000	
Anterior mandible	1.43 (0.64)	0.49 (0.29)	0.000*	1.07 (0.57)	0.35 (0.29)	0.000*	1.68 (0.85)	0.60 (0.28)	0.000*	0.87 (0.25)	0.30 (0.14)	0.000*	5.10 (2.74)	1.63 (1.17)	0.000*
Posterior mandible	1.85 (1.36)	0.95 (0.15)	0.030*	1.57 (1.16)	0.82 (0.14)	0.039*	1.40 (1.00)	1.41 (0.91)	1.000	0.82 (0.66)	0.35 (0.19)	0.020*	4.11 (4.08)	4.15 (3.92)	1.000
P-value	1.000	0.000*		0.641	0.000*		1.000	0.002*		1.000	1.000		1.000	0.055	
Maxilla	1.41 (0.68)	0.93 (0.74)	0.038*	1.11 (0.69)	0. 83 (0.77)	0.711	1.72 (1.03)	1.11 (0.71)	0.026*	0.75 (0.58)	0.32 (0.15)	0.000*	4.03 (4.83)	4.81 (3.36)	1.000
Mandible	1.66 (1.15)	0.73 (0.52)	0.000*	1.34 (1.08)	0.60 (0.56)	0.003*	1.53 (0.98)	1.03 (1.13)	0.310	0.85 (0.51)	0.33 (0.17)	0.000*	4.57 (3.68)	2.96 (4.07)	0.520
P value	1.000	1.000		1.00	0.951		1.000	1.000		1.000	1.000		1.000	0.245	
Anterior	1.48 (0.55)	0.84 (0.79)	0.001*	1.09 (0.68)	0.74 (0.85)	0.401	1.71 (0.72)	0.81 (0.66)	0.000*	0.90 (0.35)	0.34 (0.17)	0.000*	3.97 (3.19)	2.86 (3.21)	0.983
Posterior	1.57 (1.29)	0.82 (0.46)	0.006*	1.34 (1.08)	0.69 (0.48)	0.007*	1.55 (1.23)	1.30 (0.85)	1.000	0.70 (0.63)	0.32 (0.16)	0.002*	4.59 (4.97)	4.80 (3.94)	1.000
P value	1.000	1.000		1.000	1.000		1.000	0.040*		0.677	1.000		1.000	0.151	

SD: SD: Standard deviation; 3D: 3 dimensions; 2D: 2 dimensions; RMR: radiographic-marker registration group; MTR: markerless tracer registration group; *: $P < 0.05$.

Table 3
Surgical time outcomes for both study groups, stratified by arch and location.

	RMR Median (IQR) (minutes)	MTR Median (IQR) (minutes)	P-value
Anterior maxilla	12.81 (1.51)	14.5 (2)	0.110
Anterior mandible	12.74 (1.64)	12 (1.1)	0.236
Posterior maxilla	21.83 (3.5)	21.75 (2.66)	0.827
Posterior mandible	15.0 (0.93)	21.28 (2.81)	0.046*
TOTAL	**14.05 (3.63)**	**15.5 (8.28)**	**0.489**

IQR: interquartile range. RMR: radiographic-marker registration group; MTR: markerless tracer registration group.

miniscrews, or the use of specific devices (clips, tubes, or bite indices) with radiopaque markers. More research is needed on this topic since the results are inconsistent. While one study has shown more accurate results when using bone-anchored miniscrews as fiducial points, other authors have failed to find differences between specific regions of teeth or devices provided by manufacturers [10,12]. Nevertheless, it is important to stress that all these studies have focused only on markerless tracing registration and have not provided comparisons with the traditional radiographic marker registration process. dCAIS usually increases the surgical time in comparison with a conventional non-guided free-hand approach since several additional steps are required [7]. In this regard, the number of drills affects the length of the procedure since each drill must be calibrated before use. On the other hand, the markerless registration (MTR) process might be time-consuming since it requires the tracing of 100 points on the surface of the chosen landmarks (3 or 4 teeth). However, the present study showed that this registration method does not significantly increase the operation time in comparison with the standard procedure (RMR).

A new navigation system offers the possibility of using the patient's scan virtually to design and print an individual tray on which to attach markers. During surgery, this tray is placed on the patient's jaw according to the planned position and the dCAIS system automatically detects its relative position, achieving successful registration. However, currently this system seems to be less accurate than the conventional radiographic marker registration protocol [14]. Nevertheless, it might be an interesting concept to develop since it avoids the use of radiographic markers and tracing devices. Wu et al. [13,15] propose a registration device with radiographic markers and infrared light emission. In that study, the radiographic marker is placed during CBCT acquisition and an optical tracker with infrared light emission is attached to the marker during the surgical procedure. The system proposed by Wu et al. [13] seems to provide slightly more accurate outcomes, as it reduced the platform and apex linear deviations in comparison with the RMR group.

Recent studies appear to support the use of pair-point tracing markerless registration in the clinical setting [6,7]. Stefanelli et al. [6] retrospectively analyzed a total of 136 implants placed using dCAIS with markerless tracing registration and reported highly accurate results. A recently published randomized clinical trial using the same registration method also obtained good clinical outcomes with a mean angular deviation of 4.02° (SD = 2.80) and a linear 3D platform deviation of 1.12 mm (SD = 0.38) [7]. It is important to stress that the markerless tracing registration process offers several other important advantages. Firstly, it allows the use of any recent CBCT scan of the patient. Secondly, the surgical procedure is usually more comfortable for both patient and surgeon since there is no need to wear a splint with an optical tracker. Thirdly, the splint can present small movements that might affect the implant placement accuracy, especially when the distance between the patient optical tracker and the surgical site is large. This might explain why higher SD values for almost all accuracy variables were observed in the posterior implants of the RMR group. Finally, this method makes it possible to perform new registration if any inaccuracy is detected during the surgical procedure. Thus, taking into consideration the accuracy results obtained in the present in vitro study, markerless tracing registration should be used whenever possible.

The distance between the fiducial points is an important factor. Indeed, the connection between these points should generate a large geometric form to provide a more accurate registration [16]. In this regard, the distribution of bone anchored miniscrews as fiducial points during dCAIS for zygomatic implants has recently been assessed. The authors concluded that registration was more accurate when wide geometric forms connected the screws [17]. Hence, clinicians should avoid localized or unilateral fiducial markers, and in case of large edentulous areas, clinicians should consider adding artificial markers (i.

e., miniscrews or adhesive devices) [18]. Also, increasing the number of reference points seems to increase the accuracy [6,19,20]. This might explain the worse results obtained in the MTR group in implants placed in the posterior mandible in comparison with implants located in the anterior mandible. The simulated bilateral posterior edentulism situation did not allow a large geometric form to be drawn since the model only included canines and incisors. Rutkunas et al. [20] reported similar findings and concluded that bilateral posterior free-end edentulism yielded the worst results. Another report concluded that the distance from the radiographic marker (i.e., U-shaped tube registration device) to the surgical site did not influence the accuracy of the procedure [21].

Another important factor to consider could be the distance between the patient optical tracker and the surgical site. In the MTR group, the dCAIS system employed a head-mounted device on the patient's forehead for upper arch surgeries, while a tooth-supported tracker attached to remaining teeth using light-curing resins is used on the mandible. Thus, the distance from the dental arch to the optical tracker is greater in the maxilla, which could explain the less accurate results observed in this arch. This limitation could be reduced by using an intraoral tooth-supported optical tracker for maxillary surgeries. However, extraoral optical trackers are easier to place and less time-consuming. More research is needed to identify which additional factors might affect the implant placement accuracy.

The use of markerless pair-point registration might be challenging in fully edentulous patients since these cases usually lack clear anatomical landmarks to be used as fiducials. Therefore, additional radiopaque markers should be placed prior to the CBCT scan and traced during the registration process [22]. In this regard, Jaemsuwan et al. [23] propose to stabilize the registration stent containing the radiopaque fiducial markers with mini-implants [23].

A recent study compared 2 registration methods in static CAIS (MTR and RMR) measuring the registration accuracy during the overlaying of an intraoral scan and a CBCT scan in the presence of radiographic artifacts. Interestingly, the authors concluded that the radiographic fiducial marker-based registration should be considered when 4 or more radiopaque restorations are present [24].

The results of the present report should be interpreted with caution, especially considering that this was an *in-vitro* experimental study and that only four scenarios were tested. Also, the accuracy of the 2 registration methods was assessed indirectly since this study focused on the effect of RMR and MTR on the implant placement accuracy, which might be affected by other variables. Another possible limitation is related to the models employed. Even though these models successfully simulated different radiographic densities, it is essential to acknowledge that certain disparities may exist when comparing them to the radiological characteristics of the human tissues. Hence, further investigation comparing different registration methods in diverse scenarios (types of edentulism, location, presence of radiological artifacts, etc.) must be conducted in a clinical setting to confirm these findings.

5. Conclusions

Taking into consideration the limitations of this *in-vitro* study, markerless tracing registration seems to improve the accuracy of implant placement using dCAIS systems in comparison with the radiographic marker registration method, without increasing the surgical time. The operated area appears to be a relevant variable and might have an effect on the implant deviations.

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CRediT authorship contribution statement

Adrià Jorba-García: Writing – original draft, Visualization, Methodology, Investigation, Formal analysis, Conceptualization. **Jose Javier Bara-Casaus:** Writing – review & editing, Resources, Investigation, Funding acquisition, Conceptualization. **Octavi Camps-Font:** Writing – review & editing, Visualization, Methodology, Formal analysis, Data curation, Conceptualization. **Rui Figueiredo:** Writing – review & editing, Resources, Project administration, Methodology, Investigation, Funding acquisition, Conceptualization. **Eduard Valmaseda-Castellón:** Writing – review & editing, Supervision, Resources, Project administration, Methodology, Funding acquisition, Conceptualization.

Declaration of competing interest

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. 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 (Zürich, Switzerland), 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).

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9. DISCUSSION

The present thesis consists of 4 papers and aims to shed light into the relevance and accuracy of dCAIS. This thesis shows that the accuracy of dental implant placement is significantly higher when a dCAIS system is used in comparison with the traditional freehand non-guided approach. Moreover, the 2 *in vitro* studies also indicate that the pair-point markerless tracing registration process seems to be more precise without increasing the surgical time and that superimposing a STL file has a questionable clinical relevance. Therefore, the latter should only be considered in specific situations (for example, when radiographic artifacts are present).

The 4 included papers have different methodological design and provide different levels of scientific evidence. The randomized clinical trial, along with the meta-analysis, allows us to establish a clinical recommendation of using dCAIS systems to improve the accuracy outcomes without any major drawbacks or safety issues. On the other hand, the conclusions of the two *in vitro* studies should be interpreted with caution since further research, preferably in a clinical setting, is required to confirm the findings.

As described in the introduction section, the amount of literature on this topic is rapidly increasing. Today, the available evidence seems to indicate that dCAIS systems are accurate, predictable, and safe. Furthermore, since this is considered a very interesting topic among the implantology scientific community, the available data is expected to increase in the upcoming years. Indeed, only in the year 2021, 5 very similar systematic reviews and meta-analyses were published (58,77–80).

Our systematic review (58), besides the single mean meta-analysis to calculate the mean deviation of the dCAIS systems, also included two pairwise meta-analysis that compared accuracy of dCAIS vs. sCAIS, and dCAIS vs. the non-guided freehand approach. To the knowledge of the authors, this pair-wise meta-analysis was the first attempt to compare these techniques in a meta-analysis. As expected, the dCAIS system was significantly more accurate than the free-hand approach. On the other hand, no differences were found when comparing the 2 guided methods (sCAIS and dCAIS) in clinical settings.

These findings seem to be supported by recently published papers involving single implant placement (81,82), immediate implant placement (83), partial edentulism (two adjacent implants) (84), or full edentulism (85,86). Likewise, the results of our meta-analysis were similar to those of previous systematic reviews assessing the accuracy of sCAIS (87,88). These papers reported slightly higher angular and linear deviations at the entry and apex points, whereas depth deviations were lower. These data should be interpreted with caution, since the majority of studies in our review were pre-clinical, while Tahmaseb et al. (87) only included clinical studies, and Bover-Ramos et al. (88) included both clinical (22 studies) and pre-clinical (12 studies) studies. In general, clinical studies usually report slightly higher deviations in comparison to research performed in *in vitro* settings.

The registration process is a critical step, yet it differs between both static and dynamic CAIS approaches. In sCAIS, the intraoral scan anatomy (or STL file) is superimposed to the CBCT images. Conversely, dCAIS performs a virtual overlaying of the real patient anatomy with the 3D images of the CBCT. An error in the registration step can lead to

clinically relevant discrepancies between the virtual and actual implant placement (61). If the registration is not correct, deviations will be present during the additional steps and will lead to an inaccurate implant placement which can cause safety issues like bone dehiscences/fenestrations and injuries to important anatomic structures.

Most dCAIS systems started using a radiographic marker-based registration, which detects the position of the patient and surgical tools through specific radiopaque patterns present in the CBCT scan. The RMR has a solid scientific background supporting its accuracy in clinical and preclinical scenarios (62,89).

One of the largest cohort studies testing dCAIS was published by Block et al. (89) who placed 219 totally guided and 373 partially guided implants (meaning that, in at least 50% of the implants and the drilling was done using the dCAIS system but some additional steps were done manually). The dCAIS X-Guide system (X-Guide, X-Nav Technologies, LLC, Lansdale, Pa, USA), with a radiographic marker registration (X-Clip; X-Nav Technologies, LLC, Lansdale, Pa, USA) was used and a high accuracy was reported (mean angular deviation of 2.97^{o} (SD: 2.09 ^{o}) and mean platform and apex global 3D deviation of 1.00mm (SD: 0.49 mm) and 1.13mm (SD: 0.53 mm), respectively) (89). This registration approach was also tested by Aydemir and Arisan (62) in 2020 in a split-mouth randomized controlled clinical trial. These authors employed the same system tested in the present thesis (i.e. Navident®, ClaroNav Technology Inc.®, Toronto, Canada) with a RMR approach using a thermoplastic stent called Navistent (Navident®, ClaroNav Technology Inc.®, Toronto, Canada), with the following findings: linear platform

deviation of 1.01 mm (SD: 0.07 mm); angular deviation of 5.59º (SD: 0.39 º); and apex 3D deviation of 1.83mm (SD: 0.12 mm).

Recently, some manufacturers have introduced a markerless pair-point registration approach, since this method seems to provide additional advantages. This procedure consists of the selection of different anatomical landmarks or fiducial points in the CBCT and then matching them to the corresponding point in the patient's dental arch. Stefanelli et al. (63), in one of the first studies using this approach, reported a high accuracy, with apparently better outcomes than the ones obtained with the radiographic marker registration method. In a sample of 136 implants, a mean angular deviation of 2.5º (SD: 1.04º), a mean platform deviation of 0.67mm (SD: 0.29mm), and an mean apical deviation of 0.99mm (SD: 0.33mm) were observed (63).

The two above-mentioned methods are the most common registration techniques in dCAIS systems, and to the best of the authors' knowledge, the *in vitro* study of the present thesis was the first study to evaluate their impact on implant placement accuracy (64). Markerless tracing registration seemed to provide better outcomes, as accuracy was higher, without increasing the surgery time. In our opinion, the markerless tracing registration will gradually replace radiographic markers (63,72,90.91) since this approach offers several advantages. Firstly, with this method, previously made CBCTs can be used, as there is no need to include a custom splint or clip holding a radiographic marker attached to the jaw or teeth during the CBCT adquisition (92). The markerless tracing registration also allows to repeate the registration process by tracing of the fiducial points or adding new ones (i.e. re-registration), if innacuracies are detected

during the surgical procedure. Finally, surgery is usually more comfortable for both patient and surgeon, since the intraoral devices are smaller, and registration does not appear to significantly increase the overall surgery time. Thus, in our opinion, the markerless tracing registration should be used whenever possible.

Selecting appropriate fiducial points is an important aspect since their number and distribution play a key role during the registration. Stefanelli et al. (63) showed that tracing 5 to 6 landmarks significantly improved the accuracy in comparison with tracing only 3-4 teeth. Another important factor is the distance between the fiducial points: the connection between these points should generate a large geometric figure to increase accuracy (93). Figure 18 highlights the critical importance of strategically distributing fiducial points along the dental arch to ensure accurate spatial referencing, avoiding localized or unilateral fiducial points selection. The same findings seem to be applicable when bone anchored miniscrews are used as fiducial points during zygomatic implant placement with dCAIS (94). Hence, clinicians should scatter fiducials points throughout the dental arch and avoid unilateral locations. Also, in patients with large edentulous areas, artificial markers might be useful (i.e., miniscrews or adhesive devices) (95).

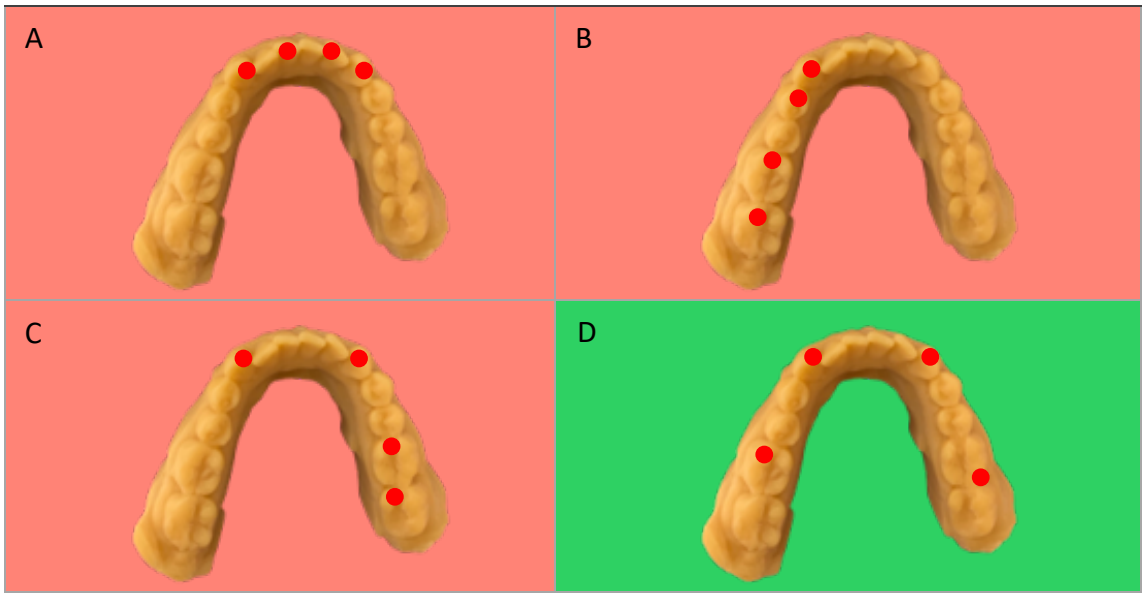

Figure 18: Different simulations of fiducial points distribution: A. Localized fiducial points in the anterior area. B: Unilateral fiducial points distributed in a lineal pattern. C: Missing fiducial point in the posterior left area. D: Well distributed fiducial points in a scattered manner.

Another relevant variable to consider is the type of fiducial points (96–99). Some in-vitro studies have compared tooth areas, miniscrews, or the use of specific devices (clips, tubes, or bite indices) with radiopaque markers. More research is needed on this topic, since the results are inconsistent. While one study reported higher accuracy when bone-anchored miniscrews were used, another did not find any differences between specific regions of teeth or devices provided by manufacturers (96,98). It is also important to stress that teeth with mobility might be a source of inaccuracies (63).

The distance between the patient optical marker and the surgical site might also affect the accuracy of dCAIS. For example, the system employed in the present thesis uses a head-mounted device on the patient's forehead for upper arch surgeries, while a tooth-supported marker is used on the mandible. Consequently, the distance from the dental

arch to the optical marker is greater in the maxilla, which could lead to greater deviations due to any undesirable movement of the optical marker during surgery. Thus, the further the optical marker is from the surgical site, the more pronounced the deviation will be in the event of optical marker movement. Figure 19.

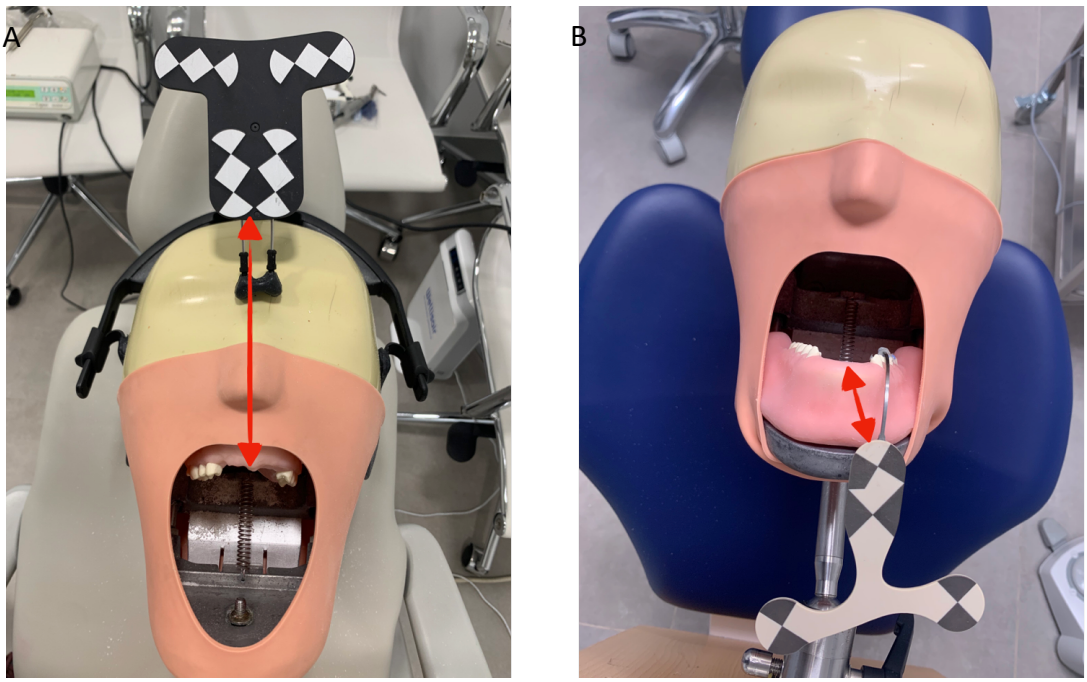

Figure 19: Pictures showing the fixation of optical markers in the upper (A) and lower (B) jaw. Red arrow shows the distance between the surgical field and the optical marker.

The above-mentioned aspect could explain the lower accuracy observed in the anterior maxilla in one of the *in vitro* studies (64). Stefanelli et al. (63) also reported more accurate results in the mandible in comparison with the maxilla using the same dCAIS system in a clinical environment. This limitation could be reduced by using a tooth-supported optical marker for upper arch surgery even though extraoral optical markers are easier to place, less time-consuming (do not require stabilization with a light curing

resin or polyvinyl siloxane additive silicone), and do not affect the visibility of the surgical field.

When using markerless pair-point registration, high definition CBCTs are required to allow an accurate selection of the anatomical landmarks. MTR process could be impaired by low definition, image noise, and distortion, for example due to patient motion during scanning or metallic artifacts. If the margins of the teeth are poorly defined, selection of the fiducial points on the 3D reconstruction might be inaccurate. For these specific situations, we believe that performing the registration on the STL file, instead of the 3D CBCT reconstruction, could be advisable. According to our study (100), in general, superimposing the STL and the CBCT files slightly increases the implant placement accuracy. However, these improvements do not seem to be clinically significant as the 3D plaform deviations decreased a mean of 0.17 mm (95% CI: 0.01 to 0.23).

In our opinion, MTR registration on the STL file should only be indicated if a low quality CBCT scan is used or when radiographic artifacts are present (100). Additionally, it is important to note that the alignment between the STL file of the dentition and the CBCT data might be an additional source of inaccuracy. However, adding the dental and soft tissue information (i.e. STL file) can provide additional information (soft tissue thickness and emergence profile) that might improve the prosthetic planning (101,102).

Nowadays, freehand implant placement is still the most common approach in the daily clinical practice. As expected, the RCT included in the present thesis showed that dCAIS improved all accuracy variables except depth deviation in comparison with the

traditional method. The fact that implant depth can be easily controlled because the alveolar bone margin is used as a reference point during the freehand approach could probably explain this outcome.

Implant location is also a variable to consider. According to our results, implants placed in a freehand non-guided aproach in molars had larger differences than in premolars probably because the gap is wider and sometimes the distal tooth is missing. In these conditions, a non-guided approach has more risk of inaccuracy. Besides, the reduced visibility, the limited access and the lack of reference points seem to favor dCAIS in the molar area (Figure 20) (32).

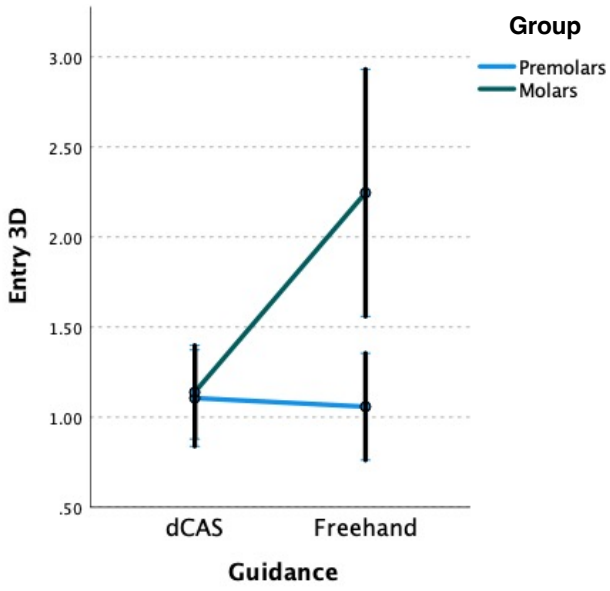

Figure 20: Diagram showing the entry 3D linear deviation in the molar and premolar region of the implants placed using a dCAIS system and a freehand non-guided approach.

Nowadays, PROMs and PREs are considered to be relevant outcome variables and should be registered in clinical trials. Indeed, the 4th Consensus Conference of the European Association for Osseointegration (EAO) (103), and the 6th ITI Consensus Conference report (104), recommended to record PROMs in all clinical studies dealing with dental implant rehabilitations. In this regard, Joda et al. (105), analyzed a total of 14 studies that used sCAIS but were unable to issue recommendations due to the heterogeneity regarding PROM measurement, treatment modalities and trial designs. In the systematic review of the present thesis (58), none of the included studies evaluated PROMs nor PREs, hence we decided to perform a randomized clinical trial to evaluate not only accuracy variables, but also patient related outcomes and experiences during the treatment and their effect upon quality of life (QoL). Patient satisfaction and subjective perception were similar in both treatment modalities (dCAIS and freehand) (32). Likewise, Engkawong et al. (106) reported no differences between static or dynamic CAIS and freehand implant placement. A recent critical review (107) also seems to be in line with these results, since no differences were detected in terms of patient reported outcomes and experience. Furthermore, this paper showed no direct improvement in implant survival, peri-implant diseases risk and intraoperative and early healing events (107). However, 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 a prosthetic-driven implant placement.

The use of navigation surgery increases surgery time in comparison with the conventional freehand approach, with a mean difference of almost 14 minutes (32). This finding has been reported in several studies and, on some occasions, the time required

for implant placement doubled (56,108). 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, PROMs and PRE.

CAIS systems seem to be specially useful when novice clinicians are involved. In a pre-clinical study published in 2019, a fifth-year dental student was able to obtain very similar results in comparison with an experienced clinicians when placing implants with a dCAIS system. However, when both professionals used the free-hand method, deviations were significantly higher for the unexperienced professional (56). In this regard, several papers have shown the usefulness of the dCAIS system as a training tool for novice clinicians or dental students (109–111).

New technologies are being developed every day. Augmented reality (AR) eyeglasses have already been used by clinicians to view the dCAIS computer screen next to the patient's mouth(112). AR has also been employed to project the virtual implant planning onto the patient's jaw (113,114). Recently, a robot-assisted dental implant placement has shown promising results with small deviations (apical global deviation of 0.8mm, coronal global deviations of 0.9mm and an angular deviation of 0.53º). Since that initial report of robotic computer-assisted implant surgery (rCAIS), more trials have been published (115,116). A very recent meta-analysis on the topic showed an extremely high accuracy using rCAIS during implant placement (117).

Over the last year, some novel dCAIS systems and registration methods for dCAIS systems have been developed and evaluated. One of these approaches involve a recently developed navigation system with a 3D stereotactic camera attached directly to the hand piece, which considerably reduces the dimensions of the system and facilitates transport and storage of the device. The initial reports on this system called Falcon (Institut Straumann AG, Basel, Switzerland) or Denacam (Mininavident, Basel, Switzerland) seem encouraging. Moreover this system offers the possibility to virtually designing and fabricating a custom template to support the patient marker based on the patient's intraoral scan (STL file) and CBCT using a specific planning software. Then, the planning data, along with the custom template design, is uploaded into the dCAIS system. Prior to surgery, the marker is attached to the 3D printed template that will be securely placed on the patient's teeth according to the planned position, achieving succesfull registration (118,119). Although this system seems to be less accurate than the conventional radiographic marker registration protocol (118), it might be an interesting concept, since it does not require the use of either radiographic markers or tracing devices.

Another interesting navigation system consists of an automatic registration through a surface approach (61) using a mixed reality device like the HoloLens 2® (Microsoft, Redmond, WA, USA). Preoperatively, blue resin dots are attached to the buccal surfaces of the teeth. These dots serve as markers and, after being detected by the headset cameras, the software automatically performs the patient registration. The surgeon, wearing the mixed reality headset, can then see a holographic projection overlaid onto the patient's real anatomy. This projection includes the entire set of images, such as the intraoral scan, bone model from CBCT, and a holographic guide/target facilitating

accurate placement of the implants in terms of position, angulation, and depth (120). Nevertheless, the supporting evidence for these approaches is still scarce and is limited to *in vitro* and proof of a concept studies.

9.1. Limitations of the studies

As reported in the discussion of the papers included in the present review some limitations should be taken into account when interpreting the results of the present thesis.

9.1.1. Study 1. Systematic review and meta-analysis

In this systematic review, due to the limited available evidence, we decided to include a broad range of study designs, comprising both clinical and pre-clinical studies, randomized clinical trials, non-randomized studies, and single-cohort studies. This decision affected the overall quality of the evidence and heterogeneity but, it also allowed to increase the external validity of the results.

Among the included studies in the meta-analysis, some raised concerns regarding the risk of bias or exhibited limited quality. In randomized clinical trials, the primary limitations were associated with the allocation concealment and blinding of the outcome assessor. Non-randomized trials also faced limitations, such as inadequate blinding of the researchers, specially the outcome assessors, and the small sample size of some studies, which may hamper generalization of the results.

Furthermore, a significant heterogeneity was detected in the meta-analysis. Nonetheless, meta-regressions only revealed statistically significant differences between preclinical and clinical studies in terms of apex depth deviation. Indeed, the pairwise meta-analysis combined randomized clinical trial and non-randomized retrospective or prospective studies in the same analysis. This approach may restrict the generalization of results, but was made because only 3 randomized clinical trials were available at that time.

9.1.2. Study 2. Randomized controlled clinical trial.

In this randomized controlled clinical trial, limitations were related to blinding of both the surgeon and patient. Due to the nature of study and given the inherent differences in surgical procedures between the two groups, achieving complete blinding of the surgeon was impossible. To solve this issue, allocation concealment was ensured by keeping the surgeon unaware of the patient's group assignment until the start of the surgery. Blinding of the patient was also challenging, as two distinct interventions were tested and optical markers were used during surgery. However, efforts were made to avoid this bias as the patients eyes were covered during the procedure and the surgeon was instructed to avoid providing information regarding the employed technique.

Another limitation was related with the lack of validated questionnaires specifically designed to evaluate PROMs and PREs in the context of dCAIS in partially edentulous patients. Consequently, a specific questionnaire with a Likert scale was made to evaluate patient’s perceptions and experiences immediately after the surgery, which makes comparisons more difficult.

Finally, this study tested a dCAIS system (i.e. Navident 2.0) which uses a markerless tracing pair-point registration in partial edentulism. Therefore, the findings of this study may not be directly applicable to fully edentulous cases or to alternative registration methods, such as radiographic marker registration.

9.1.3. Study 3 and 4. In- vitro pre-clinical studies

In vitro preclinical studies provide a low level of evidence and should be considered the least suitable for establishing causal relationships. Also, all studies performed outside a clinical scenario might overlook important variables. In these particular studies, CBCT image quality was not affected by possible patient movements or by the presence of metallic artifacts. Besides, these studies only addressed very specific clinical situations and types of edentulism. Thus, future research should assess whether these findings are affected by variables like the number and location of the missing teeth (anterior versus posterior; maxilla versus mandible, single implants versus multiple implants, fully edentulous versus partially edentulous patients, etc.) or the presence of adjacent metallic elements. Furthermore, these results should be interpreted with caution if other dCAIS systems are used or if less experienced surgeons are involved.

Finally, another possible limitation is related with the models. Even though these models successfully simulated different radiographic densities, disparities may exist when comparing them to the radiological characteristics of the human tissues. Hence, all the present findings should be confirmed and validated in further investigations in a clinical setting.

9.2. Future investigations and clinical aplicability

The current thesis demostrates the effectiveness of dCAIS systems in dental implant placement through a comprehensive exploration of both pre-clinical and clinical studies. The documented low deviations and high accuracy provide compelling evidence favouring the incorporation of these technologies in clinical practice.

Nonetheless, dCAIS is rapidly evolving, with new features and innovations being launched into the market everyday that need to be validated. To substantiate its effectiveness across diverse scenarios and facilitate comprehensive comparisons among techniques, it is imperative to conduct new, well-designed randomized controlled clinical trials, since the majority of published data relies on case series or cohort studies.

On the other hand, it is essential to broaden the scope of evaluation of dCAIS beyond accuracy. Patient satisfaction using PROMs, PRE, and the evaluation of QoL should be assessed, contributing to a more comprehensive understanding of its clinical implications. Also, economic evaluations should be performed focusing not only on the costs of the equipment but also on the impact on other factors, such as safety and surgical time.

The registration procedure stands out as a crucial step in dCAIS. Consequently, it is imperative to promote comparative clinical investigations of different registration methods across diverse clinical scenarios, including several types of edentulism and locations, and the presence of radiological artifacts. These clinical studies will help validate the findings observed in the present pre-clinical studies.

Furthermore, our review highlighted a notable gap in the scientific evidence of some of the available dCAIS systems. While the Navident system (Navident®, ClaroNav Technology Inc.®, Toronto, Canada) has several clinical and pre-clinical studies, other dCAIS systems seem to have less supporting evidence. It is also important to avoid extrapolating results obtained with a particular dCAIS system to the remaining devices. Therefore, there is a pressing need for additional clinical studies to validate the performance and reliability of all dCAIS systems available in the market to guarantee patient safety.

Additionally, future research should also explore the application of dCAIS in other surgical fields. Potential areas of study include the use of dCAIS in the placement of zygomatic implants, canine fenestration, orthodontic corticotomies, osteotomies in orthognathic surgery, and the placement of orthodontic miniscrews. Evaluating these applications could provide valuable insights into the versatility, accuracy, and benefits of dCAIS in improving outcomes and reducing complications across a broader range of surgical procedures.

10. CONCLUSIONS

1. The dynamic computer-assisted implant surgery systems enabled highly accurate implant placement with an average angular deviation of 4.02° (SD: 2.80°). However, a safety margin of 2 mm should be respected, as lineal deviations exceeding 1 mm were observed either in the platform (1.12mm (SD: 0.38mm)) and apex (1.42mm (SD: 0.52mm)) of the implants.
2. Dynamic computer-assisted implant surgery significantly increased accuracy in implant placement compared to freehand placement.
3. Regarding different registration methods and considering the limitations of the *in vitro* design, markerless registration was more accurate than radiographic marker-based registration.
4. The introduction of an intraoral scan overlaid on the cone-beam computed tomography image did not increase the accuracy of dynamic computer-assisted implant surgery systems.
5. When compared with non-guided freehand implant placement, dynamic computer-assisted implant surgery increased surgical time (MD = 13.83 min; 95% CI: 6.43 to 21.24; $p < .001$).
6. Dynamic computer-assisted implant surgery did not appear to improve patient satisfaction or reduce postoperative pain in comparison with freehand implant placement.
7. The implant location seemed to be relevant and might have an effect on the implant accuracy. Implant placement using dynamic computer-assisted implant surgery with markerless pair-point tracing registration was more accurate in the anterior mandible.

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