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Accuracy of navigation guided implant surgery for immediate loading complete arch restorations: Prospective clinical trial

Alessandro Pozzi[1,2,3,4] | Paolo Carosi[1,5] | Andrea Laureti[5] | Nikos Mattheos[6,7] | Atiphan Pimkhaokham[6] | James Chow[8] | Lorenzo Arcuri[9]

[1]Department of Clinical Science and Translational Medicine, University of Rome Tor Vergata, Rome, Italy

[2]Department of Periodontics and Oral Medicine, University of Michigan School of Dentistry, Ann Harbor, USA

[3]Department of Restorative, Sciences Augusta University, Augusta, Georgia, USA

[4]Department of Restorative Dentistry and Biomaterials Sciences, Harvard School of Dental Medicine, Boston, Massachusetts, USA

[5]Department of Chemical Science and Technologies, University of Rome Tor Vergata, Rome, Italy

[6]Department of Oral and Maxillofacial Surgery, Faculty of Dentistry, Chulalongkorn University, Bangkok, Thailand

[7]Department of Dental Medicine, Karolinska Institute, Stockholm, Sweden

[8]Brånnemark Osseointegration Centre, Hong Kong, China

[9]Department of Odontostomatological and Maxillofacial Sciences, Sapienza University of Rome, Rome, Italy

Correspondence
Alessandro Pozzi, Department of Clinical Science and Translational Medicine, University of Rome Tor Vergata, Rome, Italy.
Email: apozzi@augusta.edu

Abstract

Objectives: To assess navigation accuracy for complete-arch implant placement with immediate loading of digitally prefabricated provisional.

Materials and Methods: Consecutive edentulous and terminal dentition patients requiring at least one complete-arch FDP were treated between December 2020 and January 2022. Accuracy was evaluated by superimposing pre-operative and post-operative cone beam computed tomography (CBCT), recording linear (mm) and angular (degrees) deviations. T-tests were performed to investigate the potential effect of the registration algorithm (fiducial-based vs. fiducial-free), type of references for the fiducial-free algorithm (teeth vs. bone screws), site characteristic (healed vs. post-extractive), implant angulation (axial vs. tilted), type of arch (maxilla vs. mandible) on the accuracy with p-value <0.05.

Results: Twenty-five patients, 36 complete-arches, and 161 implants were placed. The overall mean angular deviation was 2.19° (SD 1.26°). The global platform and apex mean deviations were 1.17 mm (SD 0.57 mm), and 1.30 mm (SD 0.62 mm). Meaningful global platform ($p = 0.0009$) and apical ($p = 0.0109$) deviations were experienced only between healed and post-extraction sites. None of the analyzed variables significantly influenced angular deviation. Minor single-axis deviations were reported for the type of jaw (y-axis at implant platform and apex), registration algorithm (y-axis platform and z-axis deviations), and type of references for the fiducial-free algorithm. No statistically significant differences were found in relation to implant angulation.

Conclusions: Within the study limitations navigation was reliable for complete-arch implant placement with immediate loading digitally pre-fabricated FDP. AI-driven surface anatomy identification and calibration protocol made fiducial-free registration as accurate as fiducial-based, teeth and bone screws equal as references. Implant site characteristics were the only statistically significant variable with healed sites reporting higher accuracy compared to post-extractive. Live-tracked navigation surgery enhanced operator performance and accuracy regardless of implant angulation and type of jaw. A mean safety room of about 1 mm and 2° should be considered.

KEYWORDS
accuracy, complete-arch, dental implants, dynamic navigation, guided surgery, immediate loading

Summary Box

What is known

Although the accuracy of dynamic computer-assisted implant surgery (CAIS) is shown to be at least equal to static CAIS, there is a scarcity of prospective studies investigating complex clinical scenario as terminal dentition and edentulous jaws to be rehabilitated with immediate loading digitally prefabricated provisionals. In addition, the level of accuracy required from implant placement to allow for adequate fit of such prefabricated fixed dental prosthesis (FDP) is at present unknown.

What this study adds

Dynamic CAIS might provide adequate accuracy for complete-arch implant placement to facilitate immediate loading with prefabricated FDP. AI-driven surface anatomy identification and calibration protocol made fiducial-free calibration registration as accurate as fiducial-based. Dynamic navigation guidance improved operator performance and accuracy regardless of implant angulation and type of jaw. The implant site characteristics were the only variable shown to affect deviation, with implants at healed sites reaching higher accuracy than in post-extractive sockets.

1 | INTRODUCTION

Complete-arch implant fixed dental prostheses (FDP), represent a surgical and prosthetic challenge to the clinician, even when empowered by digital technologies.[1,2] Technological advancements have significantly improved data acquisition and integration with a highly realistic overview of residual anatomy and his relationship with future prosthetic rehabilitation.[3–6] Artificial intelligence[7] (AI) driven automatic superimposition and 3-dimensional rendering of the facial skeleton, soft tissue, and remaining dentition by fusing different digital data sets (digital imaging and communications in medicine [DICOM]) and stereolithography (STL) files, simplified the creation of virtual dental patient. Bone segmentation and mandibular joint movement allowed to plan the implant placement and design the immediate temporary FDP according to a 3-dimensional evaluation of centric relation, vertical dimension, and skeletal relationship between the jaws.[8,9] However, the lack of anatomical references and strategic teeth, bone, and soft tissue architecture deformities, full thickness flap elevation may infringe template stability affecting the overall accuracy of static computer-assisted implant surgery (CAIS) for complete arch implant placement.[1,2,8,10–14] The major limitation of static CAIS is the lack of real-time visualization of recipient site preparation.[15] No intraoperative position changes can be made with a fully guided static system.[16,17] Dynamic CAIS or navigation implant surgery allows constant visual inspection of implant site characteristics, live tracking full guidance and "real-time" adjustments in case any deviation may occur, with no template hiding the surgical field or hampering the soft tissue handling.[1,8,18] The sophisticated algorithms of modern CAD/CAM software integrated surgical plan with digital design of a prefabricated prosthetically and biologically driven complete arch temporary FDP, to be delivered immediately.[19] This integration extended the guided concept to the positioning of the temporary immediate FDP in the

3-dimensional planned position, to act as a prosthetic scaffold and enhance soft tissue interface reconfiguration and maturation.[6] The optimal design of the prosthesis is an important key to long-term peri-implant tissue health and successful clinical outcomes and must consider optimal implant position, the soft tissue height, and the distance to the bone, aiming to achieve a healthy restorative interface.[9,20,21] To limit the intraoperative adjustments of the prefabricated immediate temporary FDP, an accurate implant placement is mandatory. At present, most of the investigated navigation systems have demonstrated similar performance levels and potential clinical applications,[22–28] with significantly higher accuracy than freehand implant placement and at least as much as static CAIS.[29–34] However, a scarcity of well-designed clinical trials investigating dynamic CAIS in complex clinical scenarios such as terminal dentition and edentulous patients remained to be addressed (Data S1).

The primary aim of this study was to investigate the accuracy of dynamic CAIS for complete-arch implant placement with immediate loading of digitally prefabricated FDPs. Secondary aims were to assess the influence on accuracy of certain dichotomous variables of the process: (a) calibration registration algorithm (fiducial-based vs. fiducial-free), (b) type of references for fiducial-free algorithm (teeth vs. bone screws), (c) implant site (healed site vs. extraction socket), (d) implant intended angulation (axial vs. tilted) and (e) type of arch (maxilla vs. mandible). The null hypothesis was that no significant difference in the overall linear and angular deviations would be found between all five pairs of characteristics.

2 | MATERIALS AND METHODS

The study was approved by the ethical committee of the University of Rome Tor Vergata (202.20) and registered with protocol number ISRCTN95404312. The study was conducted in compliance with the Declaration of Helsinki for biomedical research involving human subjects as amended in 2008 and revised in Fortaleza in 2013 and, according to the industry regulations (the International Conference for Harmonization Guideline for Good Clinical Practice and ISO14155). Patients of both sexes, aged 18 years, requiring at least one complete-arch implant-supported FDP, in either jaw, after signature of the informed consent were enrolled. Patients were informed of the nature of the study, benefits, risks, and possible alternative treatments and provided consent prior to inclusion in the study, as well as any follow-up evaluations required for the clinical study. Patients were recruited and consecutively treated in one rehabilitation center between December 2020 and January 2022.

2.1 | Sample size calculation

The sample size was calculated using Wilcoxon-Mann–Whitney test based on means and standard deviation (SD) of 3-dimensional deviations at implant platform and apex of dynamic guided surgery previously published in a randomized clinical trial (RCT) study[24] (1.24; SD 0.39 and 2.27; SD 0.56 mm). With a significance level (alpha) of 0.05 and 90% power test, the minimum required sample size was $n = 92$ implants (G*Power version 3.1.9.7).

2.2 | Inclusion and exclusion criteria

The following inclusion criteria were used: (1) Healthy patients. (2) Adequate bone height for placement of at least 10 mm-long implants. (3) Healed sites with bone width of at least 5 mm and 6 mm for narrow (NP 3.75 mm) and regular (RP 4.3 mm) implants, respectively. (4) Fresh extraction sockets with at least 4 and 5 mm of bone beyond the root apex in the mandible and maxilla. (5) Minimal insertion torque of 40 Ncm. (6) Minimal ISQ mean value of 64 per each implant. Exclusion criteria were general medical (American Society of Anesthesiologists [ASA] class III or IV) and/or psychiatric contraindications; pregnancy or nursing; any interfering medication such as steroid therapy or bisphosphonate therapy; alcohol or drug abuse; heavy smoking (>10 cigarettes/day), radiation therapy to head or neck region within 5 years, untreated periodontitis; acute and chronic infections of the adjacent tissues or natural dentition; severe maxillo-mandibular skeletal discrepancy; high and moderate parafunctional activity,[35] absence of opposite teeth; unavailability to attend regular follow-up visits.

2.3 | Digital workflow

All patients received a comprehensive examination including an intraoral optical surface scanning (IOS) (IS 3800W, Dexis, Quakertown, PA, USA) and a high-speed cone beam computed tomography (CBCT) (i-CAT FLX V17 Dexis) with large field of view (FOV 160 mm height, 130 mm width) and high resolution (voxel size 0.25 mm). The

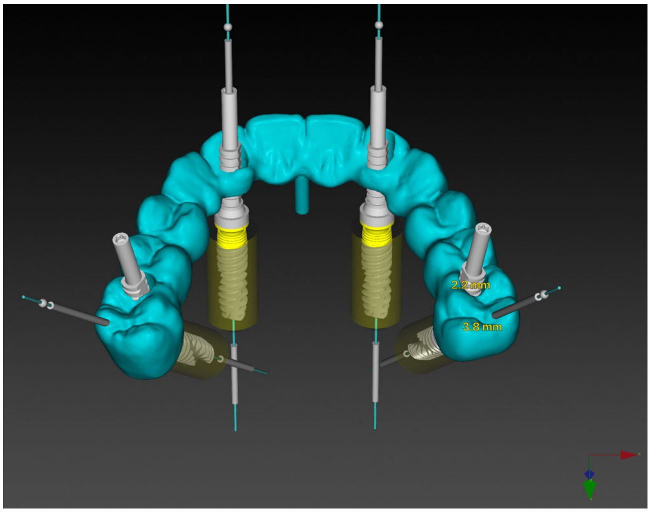

FIGURE 1 Three-dimensional planning file including implant coordinates, prosthetic components, and personalized CAD/CAM immediate temporary FDP.

implant planning software (DTX Studio™, Nobel Biocare AG, Kloten, Switzerland) with an AI algorithm process automatically detects the remained dentition, design any missing teeth, overlay DICOM with STL data and a virtual dental patient (VDP) according to the "Smiling Scan Technique"[5] was created. The approved 3-dimensional planning file including the implant coordinates was exported into the dynamic navigation system (X-Guide, X-Nav Technologies, LLC, Lansdale PA, USA) to execute the surgery and into prosthetic software (DTX Studio™ Lab 1.10.6, Nobel Biocare AG) to produce a personalized CAD/CAM immediate temporary FDP (Figure 1).

2.4 | Calibration and registration protocol

The surgical navigation system dynamically tracked the motion of two dynamic reference frames (DRFs), 1 firmly secured to the patient's anatomy (teeth or bone) and 1 rigidly attached to the surgical handpiece. The Navigation system algorithm tracked data to compute guidance information, displayed in real-time to assist surgical drilling according to the CBCT implant planned coordinates. According to the intraoral status of the jaw to be treated, two different registration protocols were performed.[8] In case of terminal dentition with stable subsequent residual adjacent teeth >3 and located in an area of the dental arch not infringing the implant drilling a fiducial-based registration protocol was executed. Otherwise, in the case of edentulous patients or terminal dentition with subsequent residual teeth <3, a fiducial-free registration protocol was conducted and the CBCT scan was taken without any clip in the mouth.

2.5 | Fiducial-based registration

Fiducial-based registration protocol used a prefabricated thermoplastic device (clip) with three radiopaque fiducials (X-Clip, X-Nav Technologies) positioned on the residual teeth of the dental arch involved in the implant surgery or prior to the acquisition of the CBCT scan. The clip device was removed after the CBCT, appropriately labeled, and stored for later use during implant surgery to hold the patient tracking array. Thereafter, the clip with the fiducial markers and the connected patient tracking array cylinder, properly oriented extraorally, was secured onto the teeth in the same location as during CBCT acquisition. Fiducial-based registration related the geometry of the patient tracking array to the CBCT images of the clip fiducials represented by the three radiopaque landmarks of the prefabricated thermoplastic device positioned in the patient mouth before CBCT acquisition.

2.6 | Fiducial-free registration

In the case of edentulous patients or terminal dentition with subsequent residual teeth <3, a fiducial-free registration protocol was executed with a dedicated software algorithm (X-mark, X-Nav Technologies). The CBCT examination was performed without any clip in the mouth, with patient wearing wax rims or complete removable dental prostheses to stabilize the jaws in centric relation. The navigation software allowed to identify digital landmarks onto the DICOM and STL 3-dimensional surface anatomy, that were numbered and coupled with the real patient anatomy touching with a dedicated calibration probe the equivalent points onto the bone or tooth surface. In case of edentulous patients or terminal dentition with not adequate tooth stability, 3 to 5 self-drilling titanium bone screws (1.5 mm diameter, 4 to 5 mm in length) (Maxdrive screws, KLS Martin SE & Co. KG, Tuttlingen, Germany) were placed into the bone along the arch to be treated prior the CBCT to act as landmarks for the fiducial-free registration. The navigation algorithm automatically related the patient tracking array geometry to the CBCT or STL images of the landmarks coupled with the corresponding tooth and bone-screw references in the patient's mouth. Therefore, the registration process aligned the virtual patient including the planned implant coordinates to the live patient's anatomy. Moreover, in case of complete edentulism of one or both dental arches the integration of the planned prosthesis within the craniofacial model was achieved through the double scan technique.

2.7 | Surgical protocol

Calibration of the surgical handpiece and patient tracking arrays was performed prior to surgery. The handpiece calibration determined the relationship between the geometry of the handpiece tracking array and the axis of the drill. In the case of edentulous patients or dentate patients with high tooth mobility the patient tracking array was connected to the bone with a dedicated metal arm secured with self-tapping bone fixation screws. In the case of dentate patients with stable teeth, the tracking array was connected to the clip. The surgical handpiece and patient tracking arrays must be within the line of sight of the overhead stereo cameras to be accurately tracked on the monitor. Hence, a link between the preoperative planning coordinate system and the tracking coordinate system is automatically generated. This stereo tracking algorithm triangulated the two arrays continuously, to determine their precise position and orientation in a common coordinate frame during the surgery. The dynamic connection of the drill body and tip with the patient's CBCT anatomy and the implant coordinates pre-planned into the software is visualized with high magnification on a dedicated screen to guarantee an accurate navigation through a real-time coordination of the surgeon's hands and eyes[22] (Figure 2). One expert clinician performed all the surgical and prosthetic procedures after having received two full days of over-the-shoulder training and completed 20 dynamic navigation implant surgeries. All the implants were positioned by means of a dynamic navigation surgery system (X-Guide, X-Nav Technologies). Depending on the recipient site characteristics, conventional (with flap) or flapless surgical procedure was performed. The drilling protocol and sequence for healed and post-extractive sites followed the criteria described by the authors in the previously published study.[36]

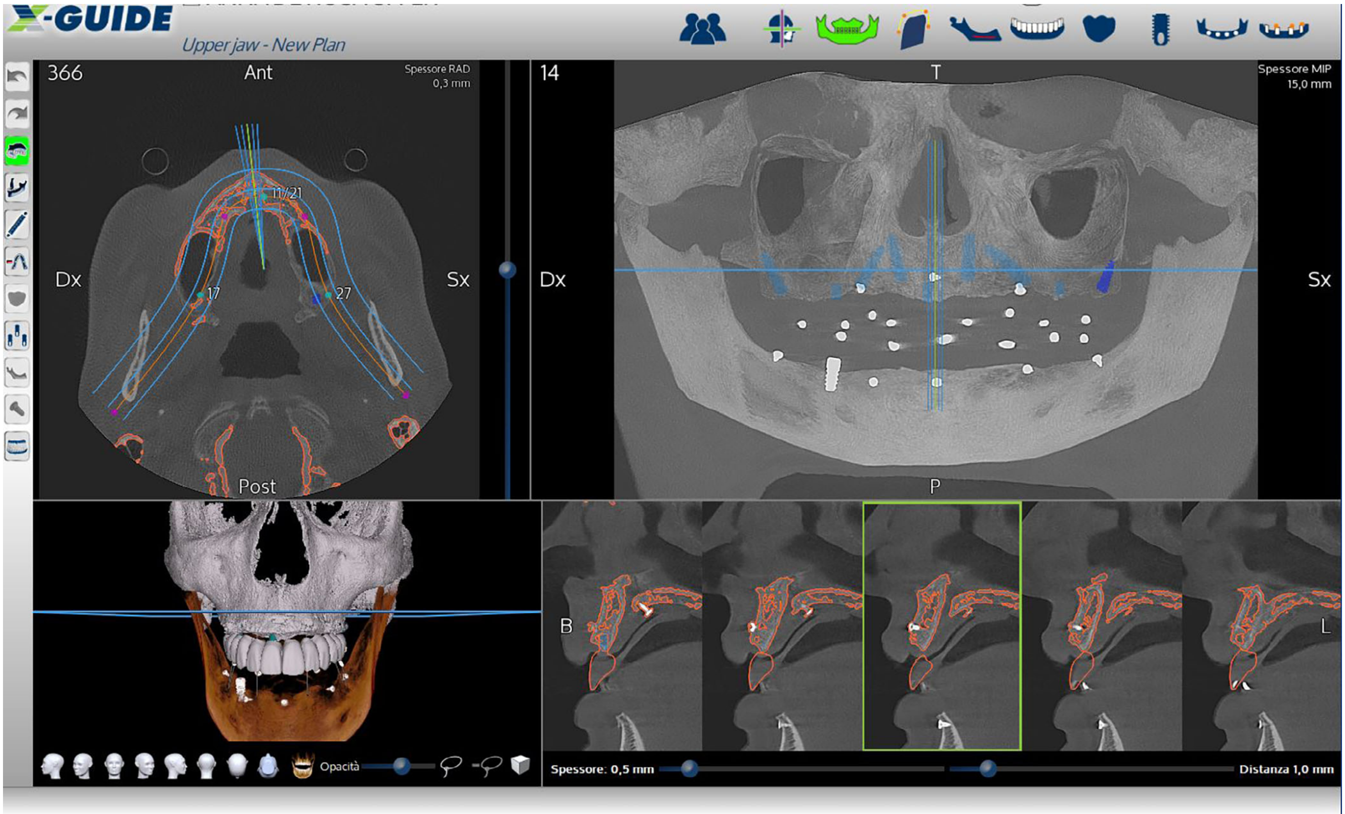

FIGURE 2 Fiducial-free calibration registration in a complete edentulous patient.

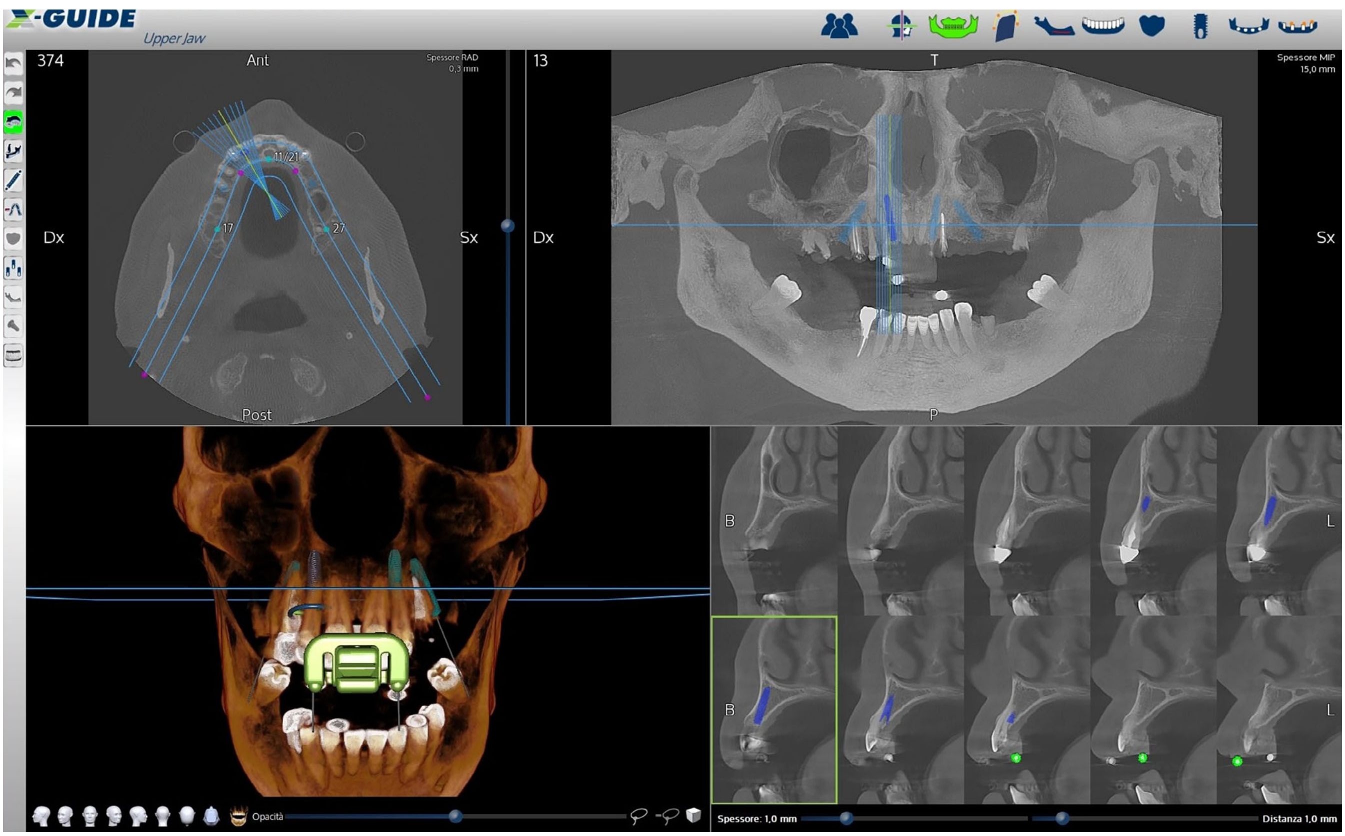

FIGURE 3 Accuracy evaluation Step 1: Pre-operative implant planning.

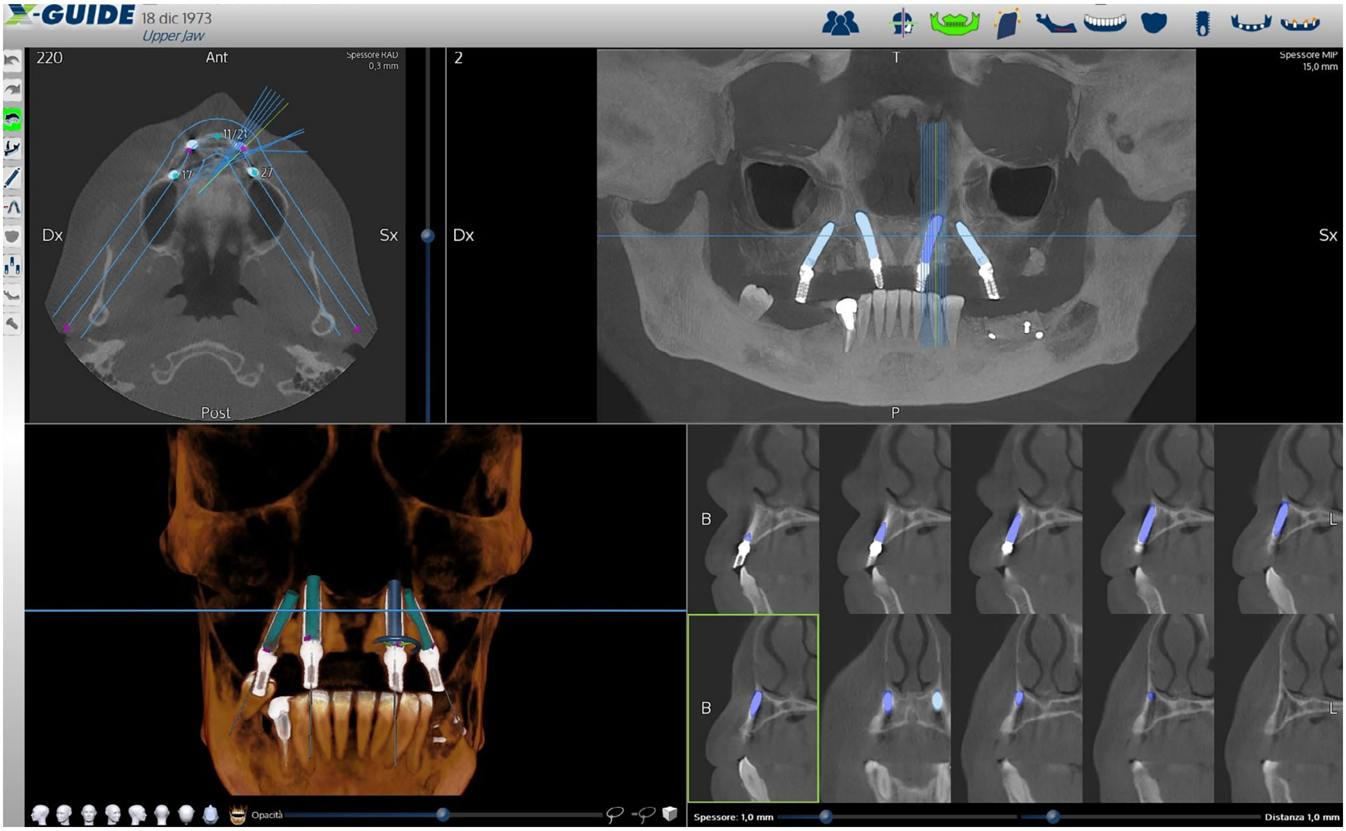

FIGURE 4 Accuracy evaluation Step 2: Implant library geometries were aligned in the postoperative cone beam computed tomography (CBCT) to the respective images of the placed implants.

2.8 | Prosthetic protocol

The temporary screw-retained complete arch FDP was milled out by a five-axis milling machine (DWX-51D, Roland DG, Shizuoka-ken, Japan) from a multilayered polymethylmethacrylate (PMMA) disk (Whitepeaks, Whitepeaks Dental Solutions GmbH & Co). The temporary prosthesis was digitally designed according to the XYZ coordinates of the planned implants and their angulation eventually adjusted using multi-unit abutments. The FDP prosthetic channels were digitally designed with a diameter of 4.5 mm to preserve the occlusal surface and at the same time house the temporary cylinders and facilitate the chairside relining.[37]

2.9 | Accuracy evaluation

After the surgery, a post-operative CBCT scan was executed with the same FOV and resolution of the pre-operative CBCT examination. The accuracy analysis required two meshes (STL files) to be superimposed: the first one was represented by the implant planning (Figure 3) and the second was achieved from the postoperative CBCT scan (Figure 4).

The first mesh file was obtained exporting from the X-Guide software (X-Guide, X-Nav Technologies) the implant planning including the XYZ implant coordinates as a standard tessellation language (STL) file. Using the X-Guide Accuracy Analysis software tool, the implant characteristics (diameter and length) and position were detected and recorded. The second mesh file was obtained uploading the postoperative CBCT into the X-Guide software, then digital geometries of the placed implants were aligned to the respective radiopaque images, and finally exported as an STL file.

The exported preoperative and postoperative mesh files (Figure 5) were then merged with a "point based gluing" function in a dedicated software (MeshLab, Visual Computing Lab, ISTI-CNR, Italy). Common anatomic references made by thick cortical bone were selected on both meshes to achieve an accurate superimposition. Visual feedback of the alignment was performed aiming to obtain a marble-like appearance of the merged file (Figure 6). The file was then exported in a MLP format (MeshLab file format) and opened in X-Guide.

The tool "X-Guide Accuracy Analysis" allowed to select and open the three files (the preoperative plan, the postoperative plan, and the merged file) to analyze the case and produce a .txt file with implant deviation data.

Finally, the .txt file was launched in a programming language for scientific computing software (GNU Octave, GNU General Public License, University of Texas, TX, USA) that converted the script in a spreadsheet (Microsoft Excel, Microsoft, Redmond, WA, USA)

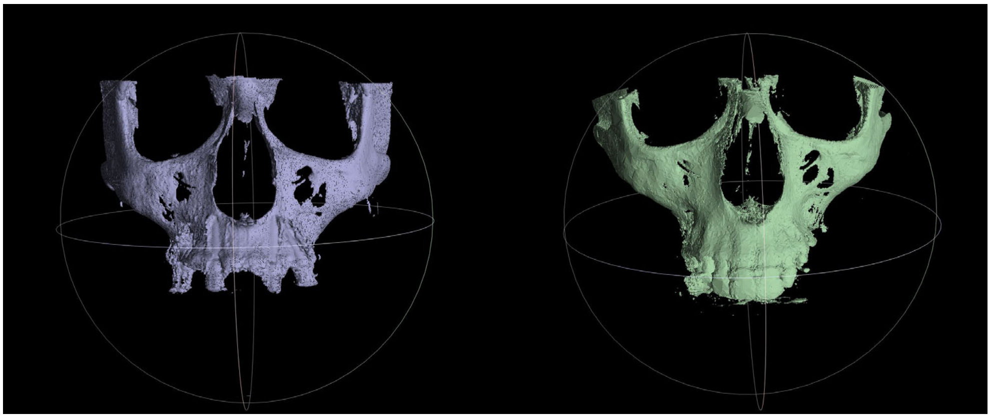

FIGURE 5 Pre-operative and post-operative meshes (STL files) segmented from the respective cone beam computed tomography (CBCT) examinations (DICOM files).

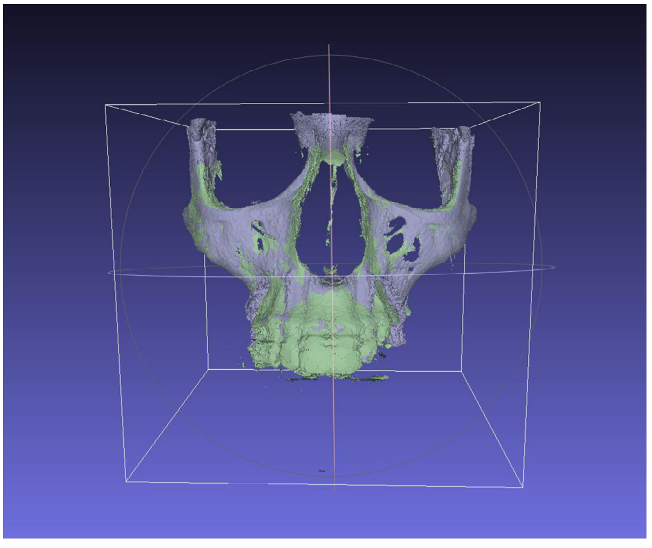

FIGURE 6 Pre-operative and post-operative meshes are properly aligned with a marble-like appearance.

containing the angular (°) and linear deviations (mm) of each implant.

2.10 | Outcomes

The following outcomes were then analyzed:

- Angular deviation (°): angle formed by the vertical axes of the planned and placed implants.
- Global platform deviation (mm): overall 3-dimensional distance between the platform centroids of the planned and placed implants.
- Platform bucco-lingual (B/L) deviation (mm): buccolingual distance between the platform centroids of the planned and placed implants on the x-axis.
- Platform mesiodistal (M/D) deviation (mm): mesiodistal distance between the platform centroids of the planned and placed implants on the y-axis.
- Platform depth deviation (mm): depth distance between the platform centroids of the planned and placed implants on the z-axis.
- Global apical deviation (mm): overall 3-dimensional distance between the apex centroids of the planned and placed implants.
- Apical B/L deviation (mm): buccolingual distance between the apex centroids of the planned and placed implants on the x-axis.
- Apical M/D deviation (mm): mesiodistal distance between the apex centroids of the planned and placed implants on the y-axis.
- Apical depth deviation (mm): depth distance between the apex centroids of the planned and placed implants on the z-axis.

2.11 | Statistical analysis

Statistical analysis was performed using IBM SPSS Statistic software. The normality of the distribution of the data was controlled with Kurtosis test. Descriptive analysis, including mean and standard deviation (SD) was calculated. The sample was divided into five dichotomous variables (fiducial-based vs. fiducial-free; teeth vs. bone-screw; healed vs. post-extractive; axial vs. tilted; maxilla vs. mandible) to investigate potential effect by means of independent samples *t* tests on calibration registration algorithm, implant site characteristic, implant angulation, type of jaw for each outcome value. p-value <0.05 was considered the threshold for statistical significance.

This study is reported in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement for improving the quality of observational studies (http://www.strobe-statement.org).[38]

3 | RESULTS

One hundred and sixty-one implants (59 NobelParallel TiUltra, 55 NobelActive TiUltra, 47 N1, Nobel Biocare) were placed in 25 patients (mean age 59.72). A total of 36 complete arches were treated and immediately loaded. No deviations from the original digital, surgical, and prosthetic protocol occurred and all the prefabricated complete-arch FDPs were delivered with no or minimum adjustments at the prosthetic channel level. The main characteristics of the sample

TABLE 1 Sample size characteristics.

No. of patients (female, male)	25 (15, 10)
Mean age (y)	59.72
Implants evaluated	161
Complete arches rehabilitated	36
Fiducial-free: implants + (No. of arches)	107 (22)
Fiducial-based: implants + (No. of arches)	54 (14)
Post-extractive implants	73
Healed site implants	88
Axial implants	90
Tilted implants	71
Maxilla: implants + (No. of arches)	59 (16)
Mandible: implants + (No. of arches)	102 (20)

were summarized in Table 1. The mean and SD of all the platform and apex linear (Global, B/L, M/D and depth) and angular deviations stratified according to the analyzed variables are reported in Table 2. The results related to potential effect of five dichotomous variables (calibration registration algorithm, implant site characteristic, implant angulation, type of jaw) are reported in Tables 3–6. The fiducial-based algorithm implants showed significant differences in the y-axis platform deviations (−0.18 mm SD 0.63 mm, $p = 0.0066$), compared to the fiducial-free algorithm (0.18 mm SD 0.84 mm) (Figure 7). For what it concerns depth z-axis deviation, the fiducial-based algorithm implants showed significant differences (−0.64 mm SD 0.78 mm, $p = 0.0118$) compared to the fiducial-free algorithm (−0.31 mm SD 0.77 mm) (Figure 8). Moreover, the fiducial-free algorithm did not report any significant differences in terms of global linear ($p = 0.610$ and $p = 0.918$) and angular (0.833) deviations between teeth and bone-screws landmarks (Table 7). For the site characteristics, significant differences were found at the global platform ($p = 0.0009$) and global apical deviation ($p = 0.0109$) levels between healed and post-extraction sites. In healed sites, significant deviations were found on the y-axis platform deviations (−0.31 mm SD 0.73 mm, $p = 0.0272$) compared to implants placed in fresh extraction sockets (−0.03 mm SD 0.81 mm). Post-extractive implants resulted significantly different in the depth z-axis deviations (0.61 mm SD 0.89 mm, $p = 0.0046$) than implant placed in healed sites (−0.26 mm SD 0.67 mm). (Figures 9–11) For implant angulation (axial vs. tilted), no significant differences were found concerning x- y- and z-axis and angular deviation. For what it concerns the type of jaw, significant differences were found on the y-axis at implant platform and apex ($p = 0.0405$ and $p = 0.0410$, respectively) (Figures 12, 13).

4 | DISCUSSION

The harmonic integration of miniaturized video-optical navigation trackers and a comprehensive 3-dimensional implant planning software may lead to a more efficient and accurate dynamic CAIS in the daily routine with a temporary FDP to be delivered immediately.[8]

However, the paucity of well-designed clinical trials investigating dynamic navigation-guided surgery for complete-arch, advised the need to assess its accuracy in these complex clinical scenarios. Therefore, the primary aim of this study was to investigate the accuracy of dynamic CAIS for complete-arch implant placement with subsequent immediate loading with a prefabricated fixed dental prosthesis. To the best of the authors' knowledge, this is the first in vivo prospective study investigating dynamic CAIS accuracy in such a complex clinical procedure, based on an a priori sample size calculation.

The overall results of this study indicate the maturity of the technology, workflow, and clinical protocol, as all implants were placed as planned with adequate stability and accuracy to allow for the immediate loading with prefabricated complete-arch FDPs. Accurate and predictable implant placement is fundamental not only to avoid damage to sensible anatomical structures but also to streamline the temporary prosthetic workflow. The high correspondence between the planned and placed implants, reported in the present study, allowed to prefabricate congruous temporary FDPs with narrow diameter prosthetic channels, facilitating the chairside relining with minor adjustments and reducing the amount of relining material.

However, the results of the present study should be seen under the light of the limitations of the protocol and technology utilized. The reported outcomes are inherent to the investigated navigation system and specific workflow and shall be extrapolated with caution to any other devices. Furthermore, one expert clinician performed all the surgeries, which might inhibit generalization of such outcomes to operators of different experience levels. Moreover, in the investigation method the accuracy analysis was based on a manual superimposition of specific implant library geometries on the placed implants silhouettes of postoperative CBCT scan. This manual matching could be considered a limitation, even though the same procedure was adopted by other accuracy studies and performed by a well-trained operator.[1–40]

In the present study, the global platform and apex deviation were 1.17 mm (SD 0.57 mm) and 1.30 mm (SD 0.62 mm) and an overall mean angular deviation was 2.19° (SD 1.26°). A total of 36 complete arches were treated and immediately loaded with no deviations from the original digital, surgical, and prosthetic protocols. Such positive outcomes may be related to the specific navigation software target that allow a dynamic and easy-to-follow live tracking of the linear and angular trajectories during the drilling, facilitating a fast adjustment in case deviation occurs. A recent systematic review on static complete-arch computer-guided implant surgery showed average global platform deviation, global apex deviation, and angular deviation of 1.23 mm (95% CI 0.97–1.49), 1.46 mm (and 95% CI 1.17–1.74) and 3.42° (95% CI 2.82–4.03) suggesting that dynamic CAIS accuracy could be similar or even higher compared to static CAIS.[17] Nevertheless, accuracy data on dynamic navigation for complete-arch scenarios are scarce with only two prospective clinical studies having investigated the dynamic CAIS for such clinical cases. A prospective study by Jaemsuwan and colleagues[1] compared the accuracy of implant placed in 13 completely edentulous patients by means of freehand (6 patients), static (4 patients), and dynamic (3 patients)

TABLE 2 Mean and SD of all the platform and apex linear (Global, B/L, M/D, and depth) and angular deviations stratified according to the analyzed variables.

	Overall	Fiducial-based	Fiducial-free	Healed	Post-ex	Axial	Tilted	Maxilla	Mandible
Angular deviation mean (SD)°	2.19 (1.26)	2.13 (1.30)	2.30 (1.26)	2.25 (1.30)	2.25 (1.28)	2.10 (1.22)	2.42 (1.36)	2.38 (1.42)	2.09 (1.15)
Global platform deviation mean (SD) mm	1.17 (0.57)	1.27 (0.58)	1.17 (0.58)	1.07 (0.52)	1.37 (0.61)	1.24 (0.57)	1.19 (0.63)	1.26 (0.67)	1.21 (0.54)
Platform BL mean (SD) mm	0.05 (0.55)	0.06 (0.60)	0.05 (0.53)	0.03 (0.52)	0.09 (0.58)	0.06 (0.56)	−0.01 (0.63)	0.15 (0.67)	−0.01 (0.45)
Platform MD mean (SD) mm	−0.18 (0.78)	−0.18 (0.63)	0.18 (0.84)	−0.31 (0.73)	−0.03 (0.81)	−0.14 (0.80)	−0.27 (0.76)	−0.02 (0.82)	−0.27 (0.69)
Platform depth mean (SD) mm	−0.39 (0.78)	−0.63 (0.77)	−0.30 (0.77)	0.25 (0.66)	−0.60 (0.88)	−0.14 (0.80)	0.34 (0.82)	0.47 (0.75)	−0.35 (0.80)
Global apical deviation mean (SD) mm	1.30 (0.62)	1.37 (0.70)	1.32 (0.65)	1.22 (0.65)	1.49 (0.68)	1.38 (0.64)	1.33 (0.77)	1.35 (0.71)	(1.27 (0.57)
Apical BL mean (SD) mm	0.09 (0.65)	0.16 (0.71)	0.07 (0.64)	0.15 (0.65)	0.04 (0.68)	0.06 (0.66)	0.07 (0.78)	0.10 (0.78)	0.08 (0.56)
Apical MD mean (SD) mm	−0.12 (0.93)	−0.09 (0.87)	−0.13 (1.03)	−0.23 (0.94)	0.02 (1.02)	- 0.08 (0.98)	−0.18 (0.98)	0.09 (0.98)	−0.23 (0.89)
Apical depth mean (SD) mm	−0.41 (0.79)	−0.64 (0.78)	−0.31 (0.77)	−0.26 (0.67)	0.61 (0.89)	−0.44 (0.80)	−0.36 (0.82)	−0.49 (0.75)	−0.35 (0.80)

TABLE 3 Potential effect of calibration registration algorithm (fiducial-based vs. fiducial-free) (independent sample *t* test) on each outcome value.

Fiducial-based versus fiducial-free	Angular deviation	Global platform	Platform BL	Platform MD	Global Apical	Apical BL	Apical MD	Depth
Mean difference	−0.170	0.100	0.010	−0.360	0.050	0.090	0.039	−0.330
SE	0.215	0.097	0.093	0.131	0.112	0.112	0.165	0.129
95% CI	−0.5937; 0.2537	−0.0918; 0.2918	−0.1742; 0.1942	−0.6184; 0.1016	−0.1705; 0.2705	−0.1308; 0.3108	−0.2868; 0.3648	−0.5857; −0.0734
p-value	0.4293	0.3048	0.9148	**0.0066**	0.6548	0.4220	0.8134	**0.0118**

Note: Bold indicates statistically significant values.

TABLE 4 Potential effect of implant site characteristics (healed vs. post-extractive) (independent sample *t* test) on each outcome value.

Healed versus post-extractive	Angular deviation	Global platform	Platform BL	Platform MD	Global apical	Apical BL	Apical MD	Depth
Mean difference	−0.010	0.300	−0.050	−0.270	0.270	0.100	−0.250	−0.350
SE	0.203	0.089	0.087	0.131	0.105	0.105	0.154	0.122
95% CI	−0.4109; 0.3909	0.1247; 0.4753	−0.2225; 0.1225	−0.5092; −0.0308	0.0630; 0.4770	−0.1070; 0.3070	−0.5546; 0.0546	−0.5906; −0.1094
p-value	0.9608	**0.0009**	0.5678	**0.0272**	**0.0109**	0.3414	0.1070	**0.0046**

Note: Bold indicates statistically significant values.

TABLE 5 Potential effect of implant angulation (axial vs. tilted) (independent sample *t* test) on each outcome value.

Axial versus tilted	Angular deviation	Global platform	Platform BL	Platform MD	Global apical	Apical BL	Apical MD	Depth
Mean difference	0.320	−0.050	0.060	−0.130	−0.050	−0.010	−0.100	0.070
SE	0.205	0.095	0.095	0.124	0.112	0.114	0.156	0.128
95% CI	−0.0843; 0.7243	−0.2381; 0.1381	−0.1280; 0.2480	−0.3758; 0.1158	−0.2709; 0.1709	−0.2355; 0.2155	−0.4081; 0.2081	−0.1827; 0.3227
p-value	0.1200	0.6002	0.5293	0.2978	0.6554	0.9303	0.5223	0.5850

TABLE 6 Potential effect of type of jaw (maxilla vs. mandible) (independent sample *t* test) on each outcome value.

Maxilla versus mandible	Angular deviation	Global platform	Platform BL	Platform MD	Global apical	Apical BL	Apical MD	Depth
Mean difference	−0.290	−0.050	0.150	−0.250	−0.080	0.020	−0.310	0.130
SE	0.205	0.097	0.088	0.121	0.102	0.106	0.150	0.128
95% CI	−0.6955; 0.1155	−0.2408; 0.1408	−0.0247; 0.3247	−0.4891; −0.0109	−0.2818; 0.1218	−0.1896; 0.2296	−0.6072; −0.0128	−0.1227; 0.3827
p-value	0.1598	0.6055	0.0918	**0.0405**	0.4348	0.8508	**0.0410**	0.3111

Note: Bold indicates statistically significant values.

computer-assisted navigation systems. Average global platform deviation, global apex deviation, and angular deviation for dynamic navigation were 1.73 (0.43) mm, 1.86 (0.82) mm, and 5.75° (2.09°). No significant difference was found between static and dynamic surgery in terms of accuracy, while the freehand protocol expressed significantly higher deviation values. However, within the sample, the edentulous patients treated with dynamic CAIS were less represented. Another proof-of-concept prospective study by Pomares and colleagues,[2] merging static and dynamic computer-guided surgery, was executed on 12 complete-arch cases, reporting global platform deviation, global apex deviation, and angular deviation of 1.42 mm (SD 0.64), 1.25 MM (SD 0.55), and 3.74° (SD 2). Even though the accuracy was similar to the present study, a direct comparison is not advisable as the implant placement was performed with a combination of static and dynamic surgery instead of a pure navigation protocol.

It is not surprising that dynamic CAIS can reach high levels of accuracy of implant placement in the light of recent systematic reviews, which have shown not only superior accuracy compared to freehand placement but also slight decrease the angular deviation in comparison with the static CAIS.[33,40] The present study results of accuracy are in line with the ones described by a recent systematic review with meta-analysis, which evaluated five clinical and five simulation studies in terms of average global platform deviation, global apex deviation, and angular deviation.[26] According to the average accuracy values, dynamic CAIS could be considered as acceptable for most situations. Still, the maximum deviation measurements recorded by Wei and colleagues[26] (4.55 mm and 11.94°) must be considered with caution to prevent damage to vital anatomical structures. In the present study, the maximum linear and angular deviations (3.08 mm and 5.3°) were considerably lower. This could be attributed to the placement of all the implants by only one skilled operator with a long experience in computer-guided surgery. In fact, the operator experience and learning curve in dynamic navigation was found to be a significant factor in influencing the implant placement accuracy.[17] Furthermore, the maximum deviation reported by Wei and colleagues,[25] are related to an old in vitro study testing a prototype dynamic CAIS system, which might be not of relevant with current protocols.[41] Moreover, the systematic review with meta-analysis by Yu and colleagues[40] assessing the accuracy of dynamic CAIS in clinical studies reported only one complication (failed osseointegration in four implants), while more serious complications (e.g., nerve damage and large-scale deviations) were not observed. In the present study, no complications during the navigation-guided implant surgery were reported, all the implants were placed, and the digitally prefabricated prosthesis fit on the temporary cylinders with minor or no adjustments at the prosthetic channel level.

The secondary aim was to evaluate the potential influence of certain variables as calibration registration algorithm, type of reference for fiducial free registration, implant site characteristics, implant angulation, and type of jaw on the on the linear and angular accuracy. The null hypothesis that no significant difference in the overall linear and angular deviations would be found between fiducial-based versus fiducial-free registration algorithms, teeth versus bone screws

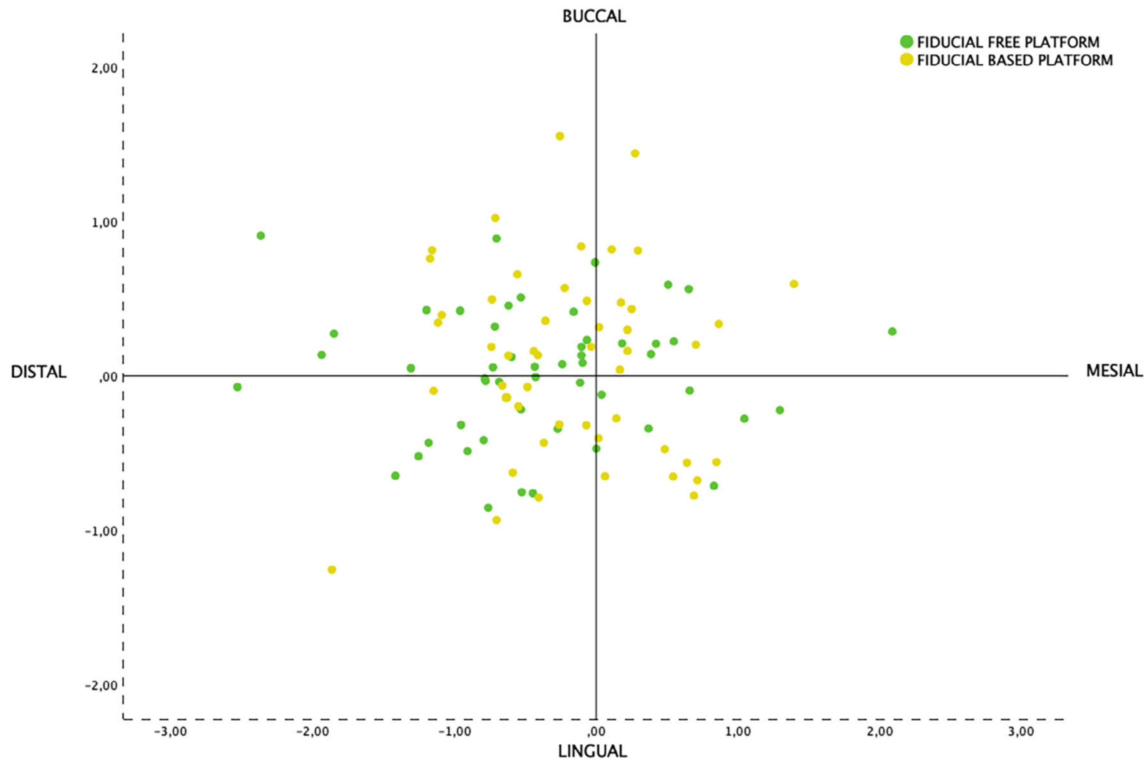

FIGURE 7 Platform deviation distributions on M/D, B/L stratified per calibration registration algorithm (green dots = fiducial-free; yellow dots = fiducial-based). M/D shifting was statistically significant toward the distal side ($p = 0.006$).

FIGURE 8 Depth deviation distributions stratified per calibration registration algorithm (green dots = fiducial-free; yellow dots = fiducial-based). Implants with fiducial-based protocol were placed deeper than the pre-planned coordinates ($p = 0.011$).

TABLE 7 Independent sample *t* test to assess significant differences in fiducial-free subgroup between tooth-based and bone screw-based calibration algorithm.

Tooth based versus bone-screw based	Angular deviation	Global platform	Platform BL	Platform MD	Global apical	Apical BL	Apical MD	Depth
Mean difference	0.051	−0.057	−0.0630	−0.495	−0.012	0.058	−0.602	−0.136
SE	0.244	0.111	0.102	0.155	0.125	0.124	0.190	0.149
95% CI	−0.4322; 0.5354	−0.2792; 0.1646	−0.2670; 0.1408	−0.8045; 0.1865	−0.2626; 0.2367	−0.1871; 0.3046	−0.9808; −0.2236	−43 068; 15 786
p-value	0.833	0.610	0.541	**0.002**	0.918	0.637	**0.002**	0.363

Note: Bold indicates statistically significant values.

references for fiducial free protocol, maxilla versus mandible, healed versus post-extractive and axial versus tilted implants was partially rejected. Significant differences were found only between healed and post-extraction sites at the global platform ($p = 0.0009$) and global apical deviation ($p = 0.0109$) levels. For implant angulation, no significant differences were found concerning global x- y- and z-axis and angular deviation.

However, even though no other significant differences were found at global level between the investigated dichotomous variables, navigation tracking algorithm showed a partial significant effect as M/D platform ($p = 0.006$) and apical depth ($p = 0.012$) deviations and the type of jaw as M/D platform ($p = 0.040$) and M/D apical ($p = 0.041$) deviations levels.

Considering the global platform and apex deviations, implants in healed sites were more accurate than those in post-extraction sockets ($p = 0.0009$ and 0.0109, respectively). However, the M/D shifting toward the distal side was more pronounced in the healed sites at platform ($p = 0.0272$), and in the mandibular implants at platform ($p = 0.0405$) and at apex ($p = 0.0410$) levels. This may be related to the drill tip engagement to the cortical zone of the bone, which may provoke a displacement caused by the drill rotation itself, while it is not affecting the drilling trajectory in post-extraction sockets. On the contrary, implants placed by means of fiducial-free algorithm slightly tending on the mesial shifting of the platform ($p = 0.0066$) than implants placed by means of fiducial-based algorithm. Moreover, the fiducial-free algorithm was divided into tooth-based and bone screw-based calibration protocol, reporting no significant differences in terms of global linear ($p = 0.610$ and $p = 0.918$) and angular (0.833) deviations between the two groups. Such outcome was related to the latest implementation of the AI machine learning process in the fiducial-free registration algorithm, that allowed to automatically detect the screws into the bone without the need to of a physical calibration probe-based marking. Other significant differences were related to implant depth. Implants placed in post-extraction sites tended to be deeper than implants in healed sites ($p = 0.0046$), most likely because of the need to achieve higher primary stability by engaging more native bone. Despite that, the fiducial-based implants were placed deeper ($p = 0.0118$) than the fiducial-free ones.

Different variables have been reported to influence the overall deviation of the implant positioning compared to the digital planning.[33] These factors are linked to the preoperative dynamic navigation workflow (misfit of the radiological fiducial markers, patient and/or fiducial markers movement during CBCT, CBCT low quality/resolution, or registration issues of the radiological markers through the planning software), to intraoperative procedures (patient and/or handpiece optical marker movement, improper drill axis and/or tip calibration) and to patient and implant factors (number/lack of teeth, type of jaw, implant site characteristics, implant type and length).[26,42–44] Thus, the control of each step of the dynamic navigation workflow is strongly advised, in particular the use of a large CBCT FOV to avoid stitching procedures that could potentially decrease the accuracy of the anatomical information included in the DICOM file.

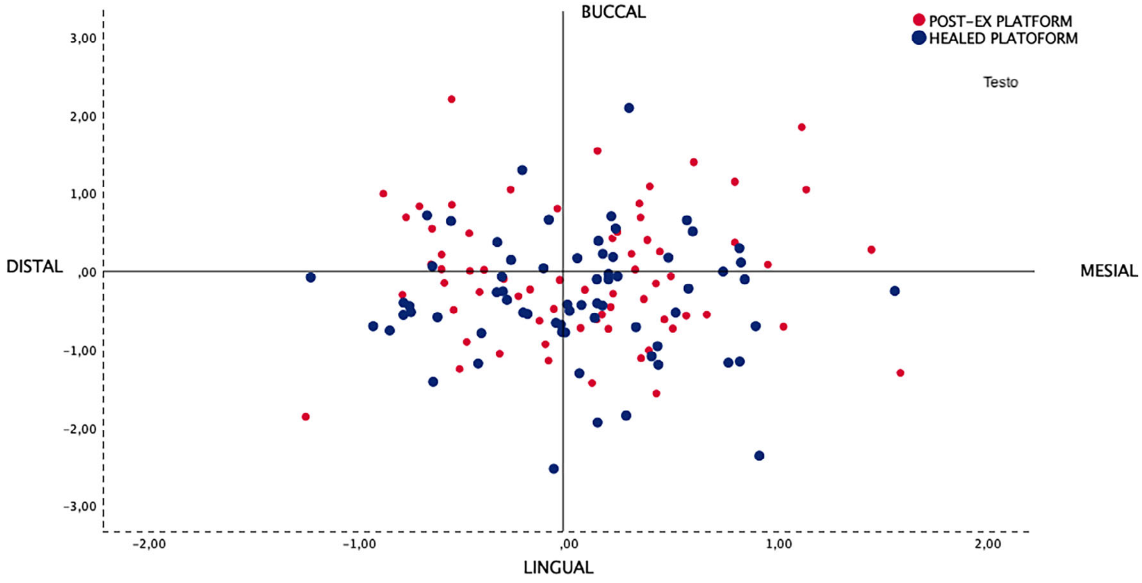

FIGURE 9 Platform deviation distributions on M/D, B/L stratified per implant site characteristic (red dots = post-extraction sites; blue dots = healed sites). M/D shifting was statistically significant toward the mesial side ($p = 0.027$).

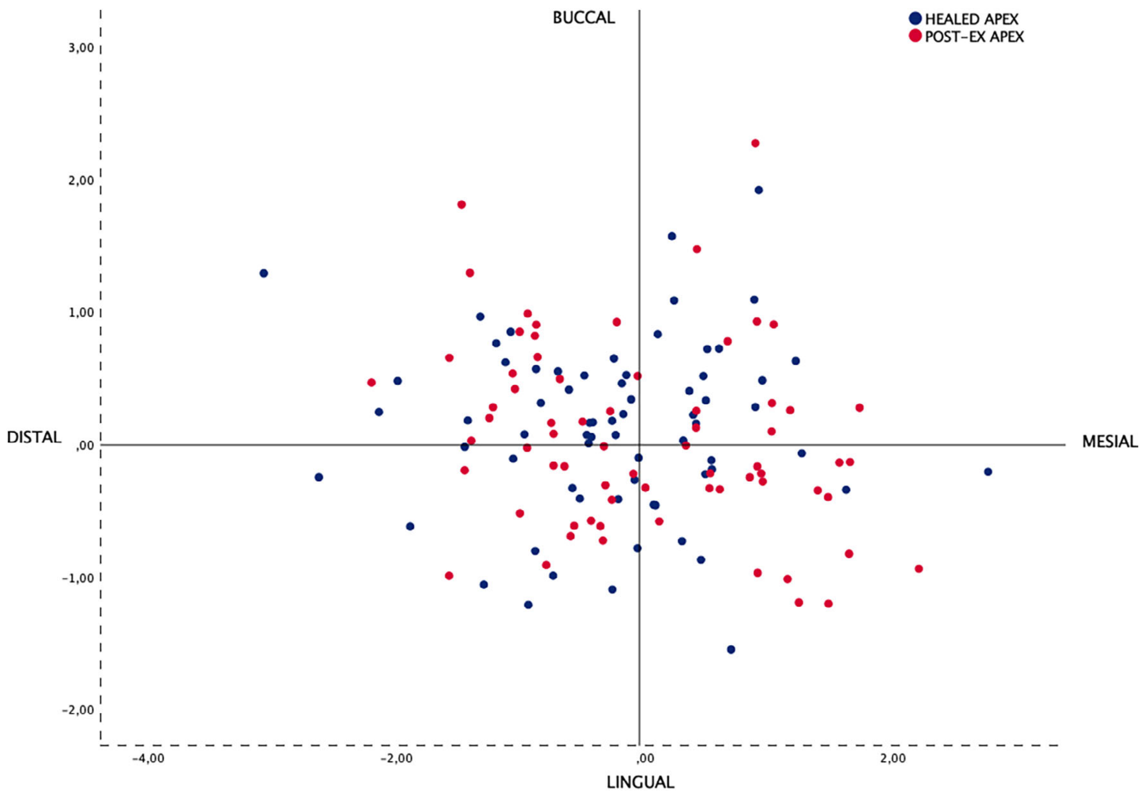

FIGURE 10 Apical deviation distributions on M/D, B/L stratified per implant site characteristic (red dots = post-extraction sites; blue dots = healed sites). M/D shifting was statistically significant toward the mesial side ($p = 0.010$).

Considering the reported outcomes in terms of global linear angular deviations and all the disclosed limitations of this study, a mean safety room of about 1 mm and 2 degrees should be take into account by the expert operator to execute navigation-guided complete arch surgery with immediate loading of digital prefabricated FDP.

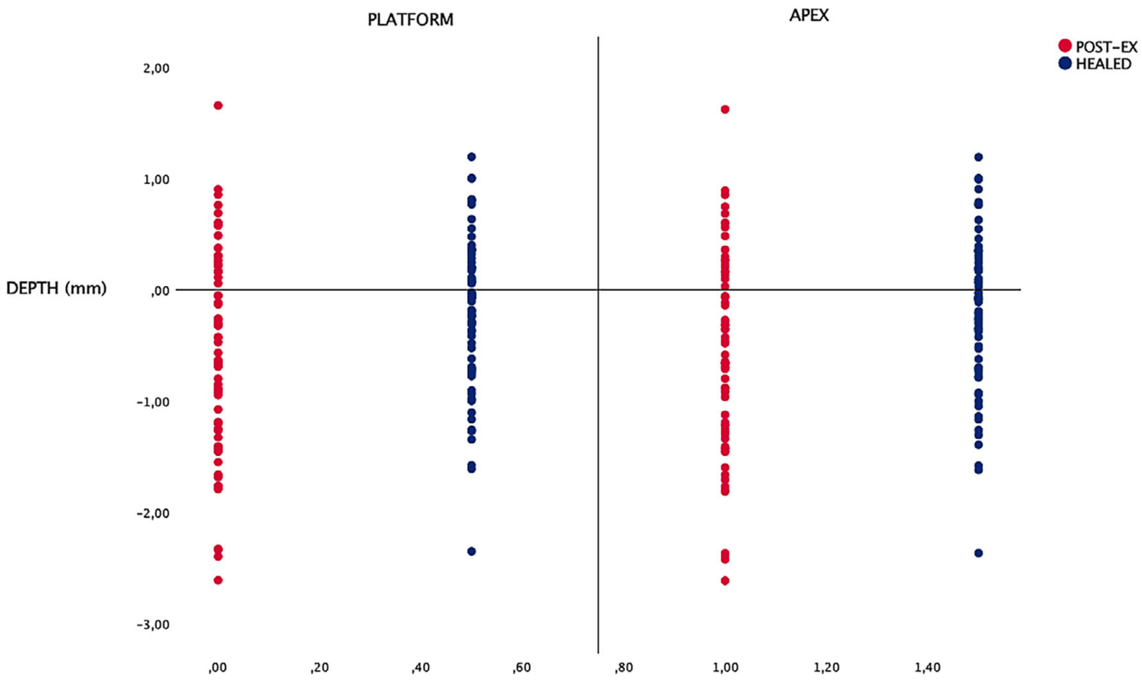

FIGURE 11 Depth deviation distributions stratified per implant site characteristic (red dots = post-extraction sites; blue dots = healed sites). Post-extraction implants were placed deeper than the pre-planned coordinates ($p = 0.004$).

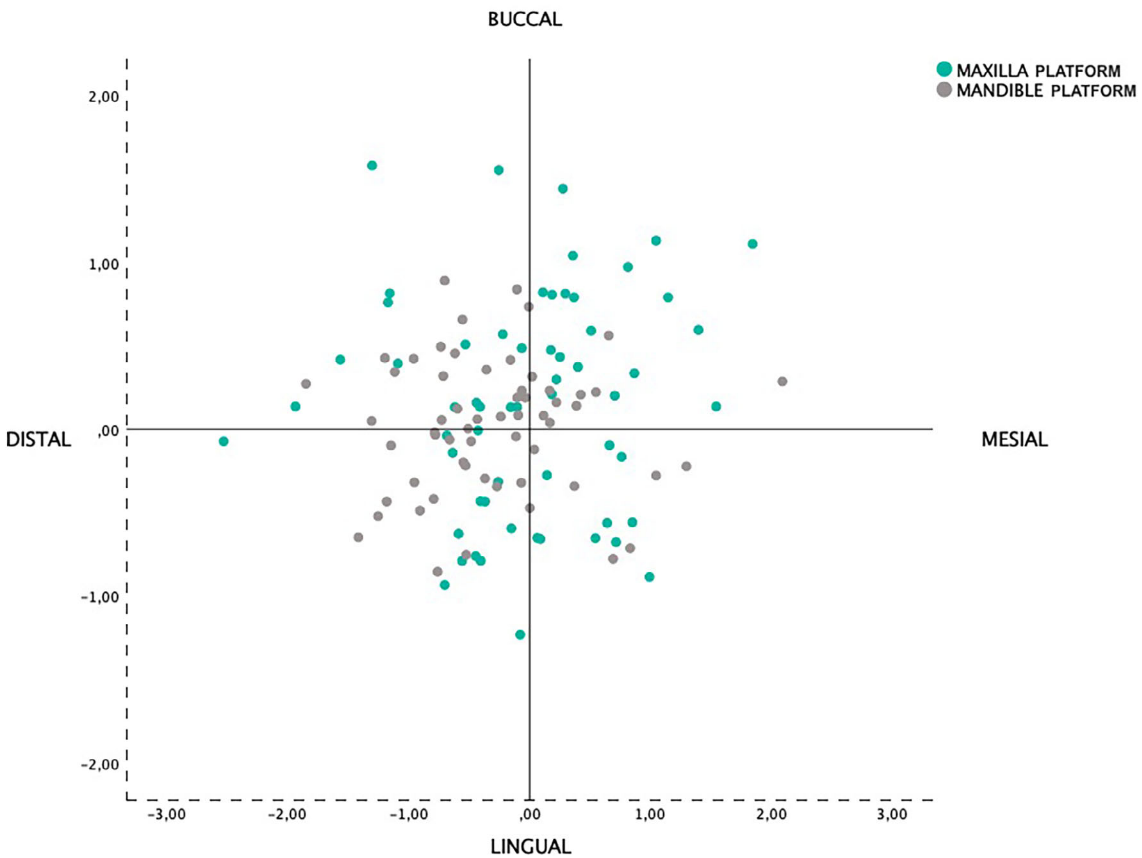

FIGURE 12 Platform deviation distributions on M/D, B/L stratified per type of jaw (light blue dots = maxilla; gray dots = mandible). M/D shifting was statistically significant toward the distal side ($p = 0.040$).

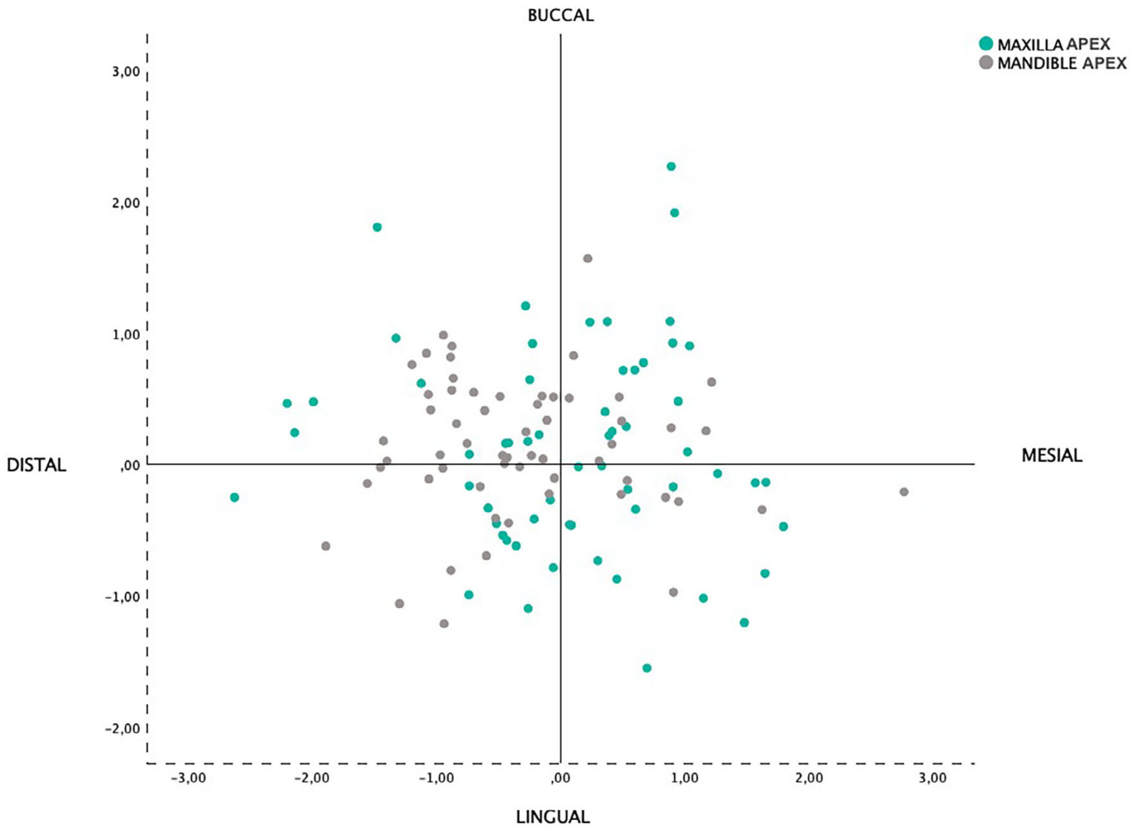

FIGURE 13 Apical deviation distributions on M/D, B/L stratified per type of jaw (light blue dots = maxilla; gray dots = mandible). M/D shifting was statistically significant toward the distal side ($p = 0.041$).

5 | CONCLUSIONS

Within the study limitations, dynamic CAIS was reliable for complete-arch implant placement and immediate loading of digitally pre-fabricated FDP. AI-driven surface anatomy identification and calibration protocol made fiducial-free registration as accurate as fiducial-based and teeth and bone screws equal as references. Implant site characteristics were the only statistically significant variable affecting global platform and apical deviation, with healed sites reporting higher accuracy compared to post-extractive. Live-tracked dynamic navigation contributed to enhanced operator performance and accuracy regardless of implant angulation and type of jaw. A mean safety room of about 1 mm and 2° should be considered.

AUTHOR CONTRIBUTIONS

A.P., P.C., L.A. conceived study aims and design; A.P., A.L. L.A., P.C. collected the data; A.L. and P.C. analyzed the data; A.P., P.C., A.L., N.M., A.P., J.C., and L.A. led the writing.

CONFLICT OF INTEREST STATEMENT

The authors have stated explicitly that there are no conflicts of interest to disclose in connection with this article.

DATA AVAILABILITY STATEMENT

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

ORCID

Paolo Carosi https://orcid.org/0000-0002-2442-1091
Nikos Mattheos https://orcid.org/0000-0001-7358-7496
Atiphan Pimkhaokham https://orcid.org/0000-0002-0170-243X

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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