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Evaluation of dynamic computer-assisted implant placement accuracy by means of a novel digital method: a feasibility clinical study / Pera, Francesco; Gibello, Umberto; Dalmaso, Lorenzo; Menini, Maria; Pesce, Paolo; Molinero-Mourelle, Pedro; Rocuzzo, Andrea. - In: JOURNAL OF DENTISTRY. - ISSN 0300-5712. - ELETTRONICO. - 162:(2025), pp. 1-8. [10.1016/j.jdent.2025.106021]

Availability:

This version is available at: 11583/3002374 since: 2025-08-08T15:53:47Z

Publisher:

Elsevier

Published

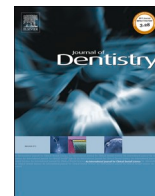
DOI:10.1016/j.jdent.2025.106021

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Evaluation of dynamic computer-assisted implant placement accuracy by means of a novel digital method: A feasibility clinical study

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ARTICLE INFO

Key words:

Dynamic navigation system
Navigated implantology
Dental implants
Accuracy
Trueness
dCAIS

ABSTRACT

Purpose: To present a novel digital method to evaluate dynamic computer-assisted implant surgery (dCAIS) accuracy comparing digital implant planning to real implant position.

Methods: Twenty patients in need of implant supported single unit-crowns (SUC), were consequently treated following a standardized digital protocol encompassing (1) a diagnostic digital intra-oral scan (IOS), (2) a cone beam computed tomography (CBCT), (3) 3D digital implant planning, (4) dynamic navigated implant placement (X-Guide, X-Nav Technologies, LLC, Lansdale, PA, USA) and (5) a post-operative IOS with the scan body in situ. Implant position accuracy was evaluated by superimposing the post-operative IOS with the pre-operative digital planning and calculating the resulting angular deviation (°), global head deviation (mm) and global tip deviation (mm).

Results: From the original 30 installed implants, 29 could be analyzed. All surgical procedures were successfully completed without any complication. The calculated mean angular deviation was $4.50^\circ \pm 2.59^\circ$, while the mean deviation at the implant head was 1.18 ± 0.52 mm. Finally, the global tip deviation was 1.43 ± 0.78 mm. Flapless implant placement was significantly associated with a reduction in both head and tip linear deviations ($p = 0.026$; $p = 0.007$), as well as with a significant reduction in angular deviation ($p < 0.001$). Implants placed in the anterior region showed a mean statistically significantly higher deviation at the implant head compared to those in posterior sites (difference: 0.39 mm; $p = 0.043$).

Conclusions: Despite its limitations, the proposed digital method does represent a promising and patient friendly approach to evaluate dCAIS accuracy.

Clinical significance: The proposed digital method represents a promising workflow for the evaluation of dCAIS implant placement avoiding the need of post-operative radiations.

1. Introduction

Tooth loss remains a global public health issue despite a significant

decline in the prevalence of edentulism has been reported over the past three decades [1,2]. Tooth loss negatively impacts quality of life [3,4] affecting essential daily functions such as chewing, swallowing, speech,

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aesthetics and social interactions [5,6]. Consequently, to address this issue, implant-supported oral rehabilitations have widely become the gold standard of care, significantly improving masticatory function, aesthetics and patient-reported quality of life [4,7,8]. From a clinical perspective, the success of implant placement, is mainly dependent on the precision of implant positioning, which must respect anatomical structures, optimize prosthetic outcomes, and ensure osseointegration [9–12]. Achieving optimal implant positioning can be particularly challenging, especially in patients with narrow alveolar ridges, thin bone margins or in anatomical sites where critical structure (e.g. mandibular nerve or maxillary sinus) must be preserved [13]. Historically, a free-hand approach has been widely practiced, despite the intrinsic limitations related to operator experience, intra-operative visibility, and manual dexterity, often resulting in deviations from the ideal implant position [9]. To overcome these problems, the implementation of new digital technologies, such as computer-assisted implant surgery (CAIS), has been adopted to improve surgical precision and predictability [14]. This approach relies on preoperative cone-beam computed tomography (CBCT) and a specific three-dimensional implant planning software allowing for accurate digitalized implant placement [15].

CAIS techniques are generally categorized into two main modalities: static and dynamic navigation [16]. The first modality, static CAIS (sCAIS), uses a pre-fabricated surgical guide based on the pre-operative planning. The guide is fabricated to fit precisely onto patient's teeth, mucosa or bone, and contains sleeves that direct the drilling instruments along the planned trajectory [17]. The reliability of this procedure has been clinically validated [18,19]. Nevertheless, several studies have highlighted that various factors may affect its accuracy, including the lack of direct visual control of the surgical site, challenges in intraoral guide positioning and impossibility to perform intra-operative adjustments based on anatomical findings and unexpected conditions [19]. It is to overcome such limitations that dynamic CAIS (dCAIS) was launched to the market, allowing for real-time feedback on the position, angulation and depth of the drilling instruments within the three-dimensional surgical field. During this procedure, the dynamic navigation system continuously tracks the position of both the surgical instruments and the patient's anatomy using cameras and optical markers. The pre-operative plan is displayed on a monitor, allowing the clinician to visualize and guide the operation with precision, adapting intra-operatively whenever necessary [16,20].

Until today, the assessment of the accuracy of dCAIS has been evaluated by superimposing two STL files gathered from two CBCT scans (i.e., pre-operative and immediately post-operative) [20]. However, performing a post-operative 3D scan seems limited to scientific purposes only due to adjunctive radiations for the patient as well as due to the increased financial cost.

Consequently, it is of paramount clinical importance to explore alternative digital measures to verify implant placement accuracy by means of a novel digital method to evaluate dCAIS accuracy performed with X-Guide, X-Nav Technologies, LLC, Lansdale PA, USA.

2. Materials and methods

This manuscript adheres to the STROBE guidelines for observational studies [21]. The study was conducted according to the Helsinki Declaration, as revised in 2018, and all participants signed a written informed consent. The study protocol was submitted to and approved by the Institutional Ethics Committee (Nr. 0001,448).

2.1. Study population

Patients of both sexes, requiring the replacement of at least one tooth by means of implant supported single unit crowns, were consecutively enrolled at Department of Implant Prosthodontics at the CIR Dental School, University of Turin, Turin, Italy between June 2022 and June 2025, following the fulfillment of the following inclusion and exclusion

criteria:

2.2. Inclusion criteria

- Absence of local or systemic conditions that could represent a contraindication to implant surgery (i.e., ASA (American Society of Anesthesiologists) physical status classification of ≤ 2)
- Healed sites (4C) [22]
- Presence of at least 3 adjacent teeth in the arch to hold the clip (X-Clip, X-Nav Technologies, Lansdale, PA, USA), which contains the fiducials necessary to register the jaw to the navigation computer system
- Radiographically confirmed bone availability sufficient to allow the placement of implants with a minimum length of 8 mm evaluated through CBCT and panoramic x-ray

2.3. Exclusion criteria

- Untreated periodontitis
- Heavy smoking (>10 cigarettes/day)
- Pregnancy or breast feeding
- Unavailability to attend regular follow-up visits

2.4. Digital work-flow planning

All patients underwent a comprehensive diagnostic assessment, which included an intraoral optical surface scan (IOS) using an intraoral scanner (Aorascan 3, Shining 3D, Hangzhou, China) and high-resolution cone beam computed tomography (CBCT) imaging (NNT—Medical Suite®; NewTom, Imola, Italy. Setting: 110 kV, 1.94 mA, 3.6 s exposure time, 685.41 DAP (mGy $\times m^2$), field of view (FOV) of 100 \times 140 mm, a voxel size of 0.25 mm). In this study, a fiducial-based calibration protocol was used, therefore, during the CBCT scan, the patient wore a clip (X-Clip, X-Nav Technologies, Lansdale, PA, USA), fitting onto his teeth. This clip contains the fiducials necessary to register the jaw to the navigation computer system, ensuring accurate tracking and alignment during the procedure. The digital data from the CBCT (DICOM files) were combined with intraoral IOS files (STL files) using an AI algorithm process within the implant planning software (DTX Studio™, Nobel Biocare AG, Klotten, Switzerland), creating a Virtual Dental Patient (VDP). This software allows to plan a prosthetically guided implant placement, providing a comprehensive view of all structures above and below the bone and mucosa. The software contains an implant library, ensuring that the planned implant precisely matches the implant to be placed in the patient (Fig. 1). Finally, the approved three-dimensional planning file, including the implant coordinates, was exported to dynamic navigation system (X-Guide, X-Nav Technologies, LLC, Lansdale PA, USA) for surgical execution. The whole workflow was performed in accordance with a previously published methodology [23].

2.5. Calibration and surgical procedure

All surgical procedures were performed by an expert clinician (F.P.), after completion of a two days of over-the-shoulder training and hands-on to achieve a proficiency level. Prior to surgery, calibration of the surgical handpiece and patient tracking arrays was performed according to the manufacture instructions and as previously reported [20]. Briefly, each drill was calibrated by the surgeon and utilized according to the standard sequence for implant site preparation. Continuous real-time monitoring was performed through patient's CBCT anatomy and implant pre-planned coordinates, ensuring tracking accuracy, using the navigation screen on the monitor. Based on implant site characteristics (i.e., amount of keratinized tissue) either a conventional or flapless surgical procedure was chosen. Irrespective of the surgical approach implemented, implants were placed at bone level.

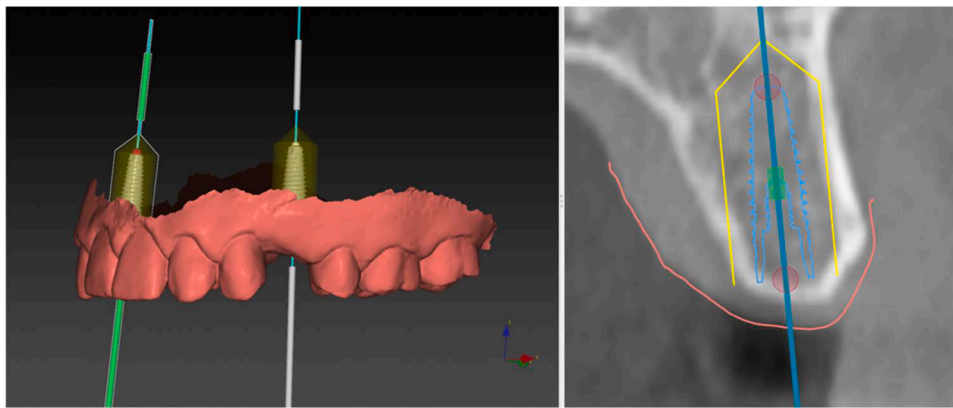


Fig. 1. Representative virtual scenarios of the 3D implant planning.

2.6. Accuracy evaluation analysis process

Immediately after surgery, a postoperative intraoral conventional optical surface scan (IOS) was performed using the intraoral scanner Aorascan 3 (Shining 3D, Hangzhou, China). A dedicated scan body (Mech and Human, Vicenza, Italy) was used to accurately record the implant position. The proper fitting of the scan body was assessed with an intra-oral bidimensional x-ray according to a previously published methodology [24].

Thereafter, the obtained STL files were imported in a dedicated software (Exocad; Exocad GmbH, Darmstadt, Germany), by an experienced dental technician not involved in any part of the clinical study and a virtual reproduction of the placed implant was precisely positioned as an analog in correspondence of the placed implant head, resulting in the implant position (Fig. 2). The resulting STL file obtained from this procedure was imported into the implant planning software (DTX Studio™, Nobel Biocare AG, Kloten, Switzerland) and supported by the AI algorithm process, it was superimposed onto the implant planning file (file NCLE) (Fig. 3). Consequently, using a dedicated tool for implant planning, a new implant with the same characteristics of the placed implant was added and aligned with the implant analog obtained from the second STL file. This step allowed the identification of two implants: one representing the planned implant and the other representing the

placed implant (Fig. 4). This configuration enabled the 3D visualization of the two implants (Fig. 5).

2.7. Study outcome measures

All measurements were performed in duplicate by two calibrated operators (U.G., L.D.) and considered the following outcomes:

1. Angular deviation ($^{\circ}$): angle resulting by the vertical axes of the planned and placed implant (Fig. 6). This measure was automatically provided by the implant planning software (DTX Studio™)
2. Global head deviation (mm): 3-D distance between the head centroids of the planned and placed implant (Fig. 7)
3. Global tip deviation (mm): overall 3D distance between the tip of the planned and placed implant (Fig. 8).

2.8. Statistical analysis

The statistical analysis was performed by a professional statistician not involved in the study. For each variable, the mean of the two operators' measurements was calculated. The descriptive analysis was subsequently performed on these mean values (i.e., mean, standard deviation, range). The association between clinical variables and mean

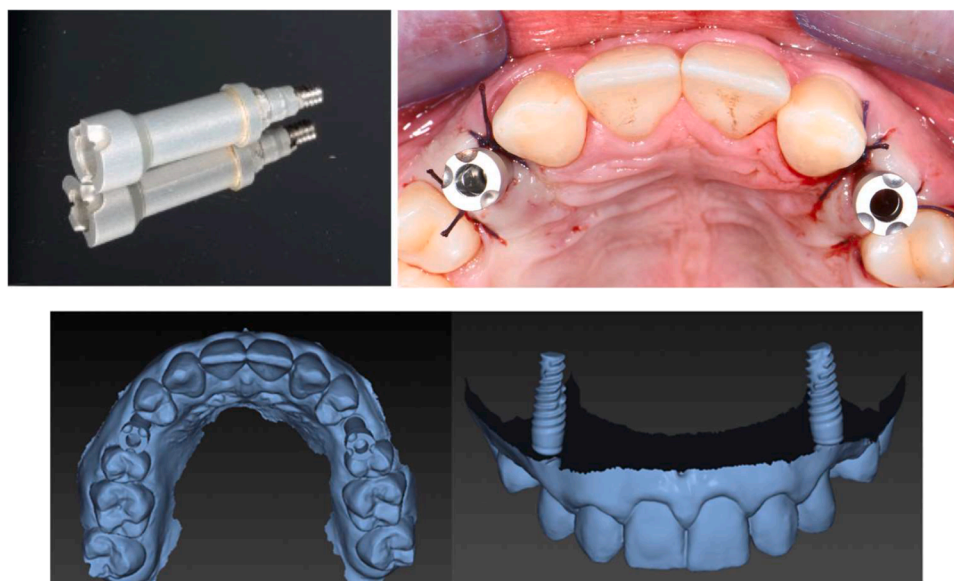


Fig. 2. Clinical view of the used scan body prior (a) and immediately after (b) intra-oral scan. STL files of the clinical scenario with scan bodies in situ (c) and of the two virtually matched implants (d).

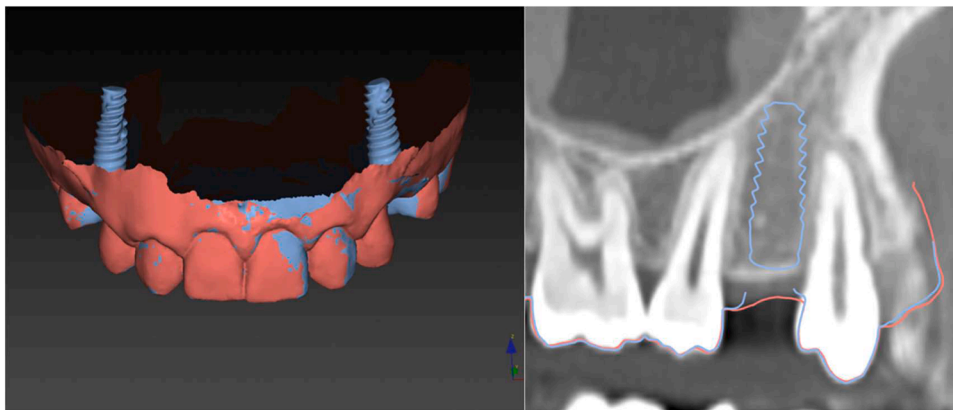


Fig. 3. Superimposition of the post-operative STL file (blue) on the pre-operative STL with the digital planning (red).

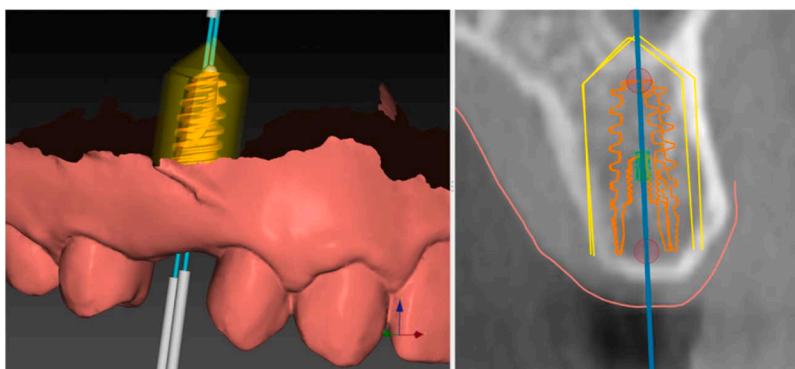


Fig. 4. Appearance of the two superimposed implants (planned vs. placed implant).

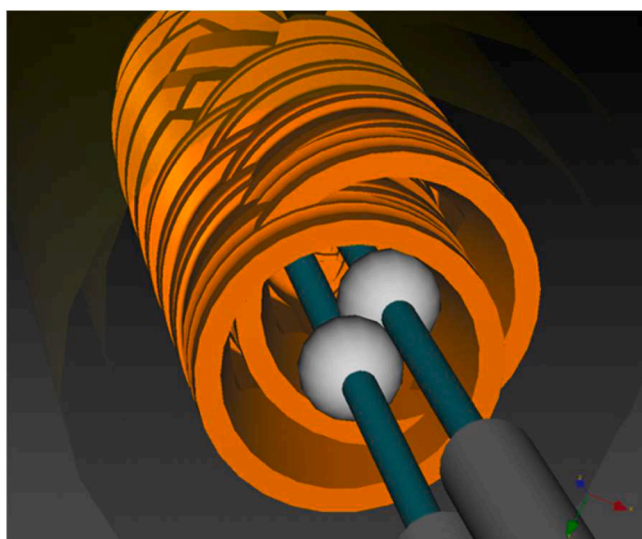


Fig. 5. Visualization of two superimposed implants in the 3D scenario where the measurements were taken.

deviations was investigated using the statistical tests, selected according to the nature of the independent variable: Spearman's correlation for continuous variables (e.g., age) and Student's *t*-test for dichotomous variables (e.g., sex, flapless). To assess the agreement between the two operators, Intraclass Correlation Coefficient (ICC) was calculated for each evaluated variable. All analyses were performed using R (version 4.2.1), and $p < 0.05$ was considered statistically significant.

3. Results

3.1. Patient and implant characteristics

The study sample consisted of 20 patients (11 men and 9 women; age: range 23–69 years; non-smokers), who received 30 implants (21 NobelActive, 9 NobelReplace Conical Connection PMC, (Nobel Biocare, Zürich-Flughafen, Switzerland). Implant length and diameter ranged between 8 and 13 mm and from 3.5 to 4.3 mm, respectively. Twenty-free implants were placed in the maxilla (13 anterior; 10 posterior) while 7 were placed in the posterior mandible. Twenty-six implants were placed following an open-flap approach, while 4 implants were placed flapless. A non-submerged healing was adopted in all cases. All surgeries proceeded without early or late complication. The performed digital analysis included 29 implants since the intraoral scan of one implant was not available for analysis.

3.2. Inter-examiner reliability

The agreement between the two examiners revealed an intraclass correlation coefficient (ICC) of 0.931 for deviation at the implant head and 0.983 for deviation at the implant tip, respectively.

3.3. Descriptive deviation analysis

The mean deviation at the implant head was 1.18 ± 0.52 mm, while at the implant tip was 1.43 ± 0.78 mm. Finally, the mean angular deviation was $4.50^\circ \pm 2.59^\circ$. Details of the calculated mean deviations are presented in Table 1 while a comprehensive graphic representation of the deviation for each implant is provided in Fig. 9.

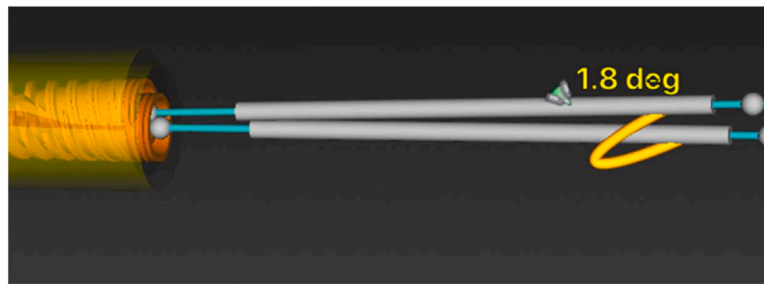


Fig. 6. Visualization of the 3D performed angular deviation measurement.

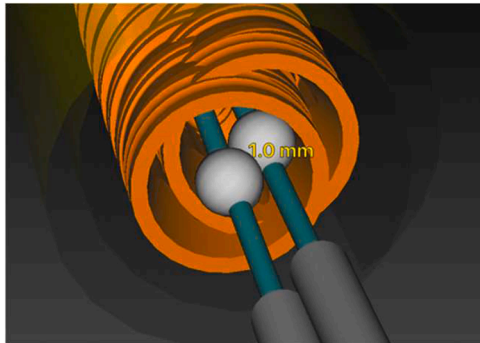


Fig. 7. Visualization of the 3D performed global head deviation measurement.

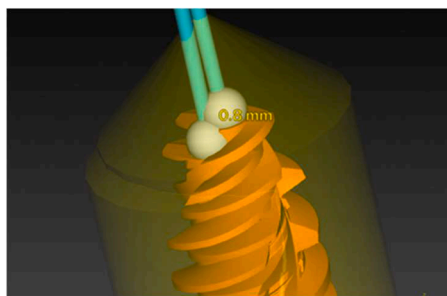


Fig. 8. Visualization of the performed 3D global tip deviation measurement.

Table 1

Mean, standard deviation, minimum and maximum values of the calculated differences.

	Deviation Head (mm)	Deviation Tip (mm)	Angular deviation (degrees)
Mean	1.18	1.43	4.50
Standard Deviation	0.52	0.78	2.59
Minimum	0.25	0.15	1.20
Maximum	2.25	3.30	13.20

3.4. Influencing factors analysis

The analysis of associations between patient demographic and clinical variables (age, sex, smoking status, surgical technique, anterior/posterior implant site, implant brand, and cause of tooth loss) and average deviations yielded the following results: flapless implant placement procedure was significantly associated with a reduction in linear deviation, both for at implant head (difference: 0.57 mm; $p = 0.026$), implant tip (difference: 0.76 mm; $p = 0.007$), as well as in angular deviation (difference: 3.07° ; $p < 0.001$). Moreover, implants placed in the anterior region showed a mean statistically significantly

higher deviation at the implant head compared to those in posterior sites (difference: 0.39 mm; $p = 0.043$). None of the other investigated parameters was found statistically significant affecting linear or angular accuracy ($p > 0.05$). A graphical representation of the significant association is displayed in Fig. 10.

4. Discussion

The present study was designed to explore the possibility of assessing dynamic computer-assisted implant placement accuracy introducing a new digital method. The scientific rationale behind it is based on the clinical need of an innovative method not based on the use of post-operative CBCT image: indeed, even though the direct comparison on two CBCT dataset (i.e., planning vs. post-operative) has been widely used and it is nowadays considered the gold standard to evaluate implant placement accuracy, it is clear that its implementation should be limited to few research cases only due to ethical reasons. On the other hand, the proposed methodology, adhering to the ALARA principles (As Low As Reasonably Achievable) [25], encompasses a new digital workflow to allow the superimposition of the 3D planned implant with the real implant position based on the scan body position.

Since the inception of implant dentistry, a great effort has been made to optimize prosthetically driven implant placement [26]. In this context, the last introduction of three-dimensional imaging and visualization (dynamic guided surgery) does represent the most modern approach [17]. On this topic, several studies have investigated the reliability of this new technology by assessing linear and angular deviations between the planned and the real implant position; however, at the time being most of the available evidence is derived from in vitro investigations. Ma et al., comparing the accuracy of dynamic navigation-based dental implant placement, reported an angular deviation of $3.29 \pm 0.17^\circ$, an entry deviation of 1.29 ± 0.07 mm and an apex deviation of 1.43 ± 0.08 [27]. More recently, Wu et al. reported a mean angular deviation of $2.01 \pm 0.74^\circ$, while the mean global deviation at the implant platform and apex was 0.53 ± 0.27 mm and 0.62 ± 0.27 mm, respectively [28]. Finally, a systematic review by Matvijenko et al. detected a mean angular deviation of 2.01° , a mean 3D coronal deviation of 0.46 mm and a mean 3D apical deviation of 0.81 mm [29].

When focusing on the data gathered from in vivo studies, it should be underlined how these findings are more heterogeneous due to clinical variability. More specifically, Block and Emery reported a mean angular deviation of $2.97 \pm 2.09^\circ$, a mean global platform position deviation of 1.16 ± 0.59 mm, and a mean global apical position deviation of 1.29 ± 0.65 mm, concluding that dCAIS approach demonstrated significantly less deviation from the virtual plan compared to freehand approach [16]. Similar results were presented by Pellegrino et al. where the mean deviation measured at the insertion point was 1.04 ± 0.47 mm, while at the apical point it was 1.35 ± 0.56 mm. Finally, the mean axis deviation was $6.46 \pm 3.95^\circ$ [30]. On the contrary, Stefanelli et al. in a retrospective in vivo study, reported better results in terms of mean global head (0.67 mm), global tip (0.9 mm) and angular deviation (2.50°) [31]. These results were consistent with those previously reported by the same

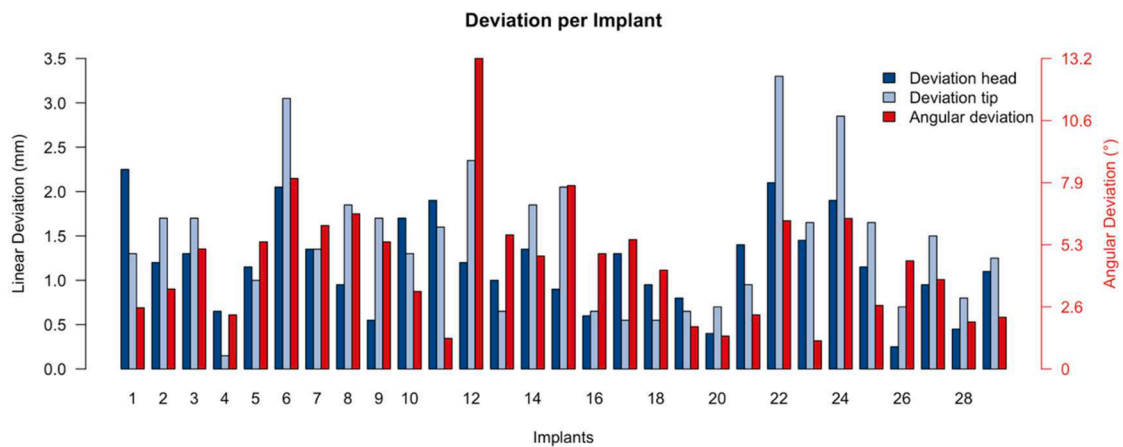


Fig. 9. Visualization of the deviations for each implant: head (blue), tip (light blue), and angular (red). The right axis indicates the degree of deviation; these values have been proportionally scaled (up to a maximum of 2.5) to enable their visualization alongside the linear deviations on the same vertical axis. The right side of the graph displays the angular deviation values.

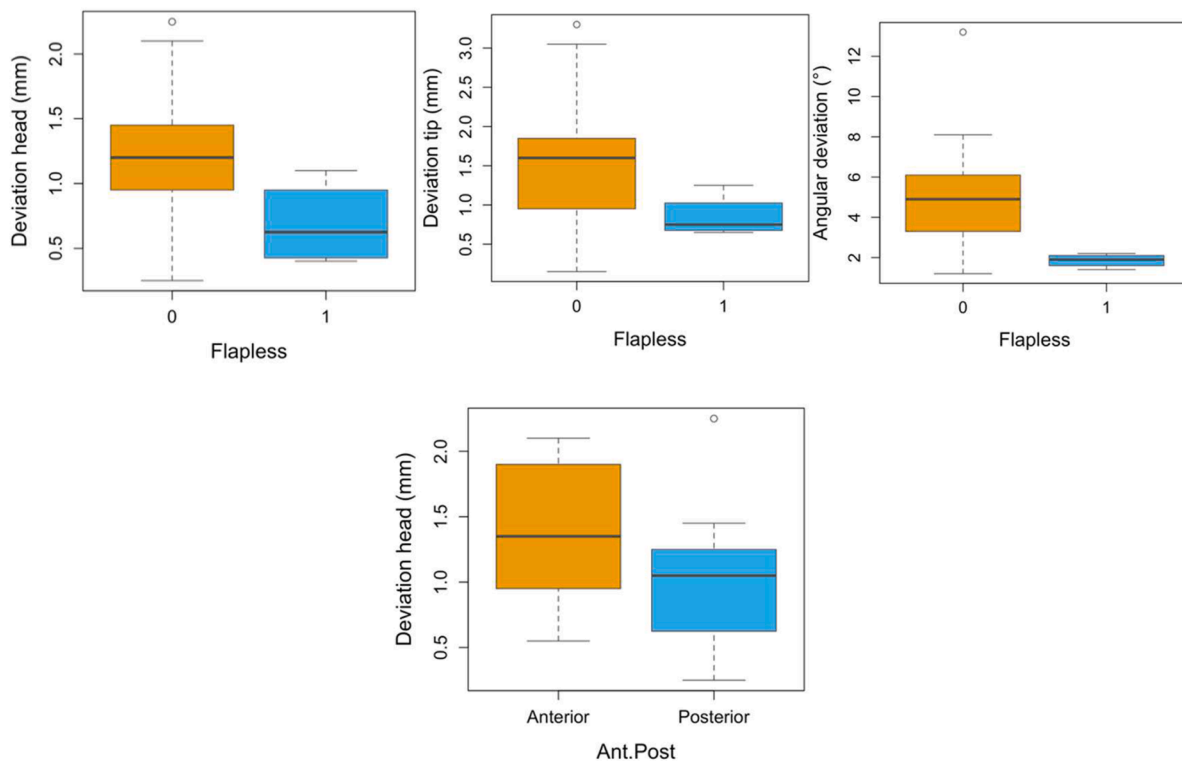


Fig. 10. Boxplots of implant deviations. The y-axis displays the specific unit of measurement for each outcome: linear deviations in millimeters (mm) and angular deviations in degrees (°). The plots show the median, quartiles and range. From left to right: deviation head, deviation tip and angular deviation are compared between “flapless” vs. “non-flapless” procedure, followed by deviation head compared between implants placed in “anterior” vs. “posterior” sites.

group [32].

An attempt to compare in vitro and in vivo results was done by Gorba-Garcia et al. who conducted a meta-analysis including 24 articles, and reported a mean angular deviation of 3.68°, a global entry deviation of 1.03 mm and a mean global apex deviation of 1.34 mm for clinical studies. Furthermore, the authors underlined that lower deviation values were observed in vitro studies, with a mean angular deviation of 2.01°, a mean global coronal deviation of 0.46 mm and a mean global apex deviation of 0.81 mm [33]. When comparing the reported measurements with those obtained from our study, it can be stated that they are consistent (i.e., 1.18 ± 0.52 mm mean global coronal deviation, 1.43 ± 0.78 mm - mean global tip deviation and $4.50^\circ \pm 2.59^\circ$ - mean angular

deviation), providing consequent indirect evidence of the reliability of the proposed methodology.

Additional interesting findings are that the type of surgical protocol performed (open-flap vs. flapless) as well as the operated area (i.e., anterior vs. posterior) had a statistically significant impact on both linear and angular deviations values: these results are in accordance with previous studies showing how minimizing the surgical trauma as well as placing implants in the posterior area are associated with a higher degree of accuracy [34]. Specifically, on the latter aspect, our findings suggest that the detected discrepancies may reflect the more often need for intra-operative adjustments in the aesthetic zone. However, it should be pointed out how the detected discrepancies resulting

from the different applied surgical protocol (i.e., open flap vs. flapless), might have been influenced by post-operative factors during the scanning procedure such as the presence of bleeding and surgical sutures.

The present study, despite some elements of novelty, presents several limitations which must be disclosed: first, due to the exploratory nature and in light the lack of previous similar studies, a power analysis could not be performed, consequently the obtained results should be interpreted with caution. Secondly, the investigated methodology, applied to one implant system within a dCAIS workflow only, relies on a perfect positioning of the scan body on the implant head, precluding from any generalizability of the obtained data to other implant systems and digital workflows. Finally, all implants were placed in healed sites, therefore the reliability of the obtained data is limited to such clinical scenario.

5. Conclusions

Despite its limitations, the proposed digital methodology does represent a reliable and patient friendly approach to evaluate dynamic computer-assisted implant placement accuracy. Additional clinical studies are encouraged to verify its reliability in more complex clinical scenarios such as full-arch rehabilitations.

CRedit authorship contribution statement

Francesco Pera: Writing – review & editing, Investigation, Funding acquisition, Data curation, Conceptualization. **Umberto Gibello:** Writing – review & editing, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Lorenzo Dalmasso:** Methodology, Formal analysis, Data curation. **Maria Menini:** Writing – review & editing, Data curation. **Paolo Pesce:** Writing – review & editing, Conceptualization. **Pedro Molinero-Mourelle:** Writing – review & editing, Data curation. **Andrea Rocuzzo:** Writing – original draft, Validation, Supervision, Methodology, Investigation, Formal analysis, Data curation, Conceptualization.

Declaration of competing interest

The authors do not report any conflicts of interest related to the present study.

Acknowledgements

The authors thank Nobel Biocare for the precious support during the whole study.

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