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Accuracy of dental implant placement using augmented reality-based navigation, static computer assisted implant surgery, and the free-hand method: An *in vitro* study

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ABSTRACT

Objectives: This *in vitro* study aimed to compare the accuracy of implant placement in model surgeries carried out by implementation of three different methods.

Methods: An *in vitro* study was conducted on 3D printed study models randomly assigned to three study groups. In Group 1, model surgeries were assisted by augmented reality (AR)based dynamic navigation (Innooral System, Innoimplant Ltd, Budapest, Hungary). In Group 2, implants were placed with a free-hand method, and in Group 3, static Computer Assisted Implant Surgery (CAIS) was used (coDiagnostiX software, version 10.4 Dental Wings, Montreal, CA, USA). A total of 48 dental implants (Callus Pro, Callus Implant Solutions GmbH, Hamburg, Germany) were placed (16 implants in four models per study group). The primary outcome variables were angular deviation, coronal, and apical global deviation. These were calculated for all implants based on pre-operative registration of the surgical plan and postoperative cone beam computed tomography (CBCT) reconstruction.

Results: The accuracy of implant placement using AR-based dynamic navigation showed no significant difference compared to static CAIS (angular deviation, 4.09 ± 2.79° and 3.21 ± 1.52°; coronal deviation, 1.27 ± 0.40 mm and 1.31 ± 0.42 mm; and apical global deviation 1.34 ± 0.41 mm and 1.38 ± 0.41 mm). Global deviation results were significantly lower with AR-based dynamic navigation than with the free-hand approach (coronal and apical global deviation of 1.93 ± 0.79 mm and 2.28 ± 0.74 mm, respectively).

Conclusions: Implant positioning accuracy of AR-based dynamic navigation was comparable to that of static CAIS and superior to that obtained by the free-hand approach.

Clinical Significance: Implementing Augmented Reality based dynamic Computer Assisted Implant Surgery (CAIS) in model surgeries may allow to obtain an implant positioning accuracy comparable to that provided by static CAIS, and superior to that obtained through the free-hand approach. Further clinical studies are necessary to determine the feasibility of AR-based dynamic navigation.

1. Introduction

Computer-assisted implant surgery (CAIS) allows the surgeon to reproduce the planned implant position during surgery with clinically adequate accuracy [1, 2]. Guided implant placement involves a minimally invasive surgical procedure, reduces surgical time and postoperative morbidity, and helps the clinician avoid roots of adjacent teeth, major blood vessels, nerves, the nasal cavity, and the maxillary sinuses during the intervention, compared to the free-hand approach. This approach could ensure optimal aesthetics, function, and ideal biomechanics of the prosthesis, while facilitating the long-term stability of the peri-implant soft and hard tissues. CAIS can be classified into

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dynamic and static navigation [1–5].

During static CAIS, a surgical template is manufactured using computer-aided design and computer-aided manufacturing (CAD/CAM) technology to guide the drills for implant bed preparation and implant placement [1, 5-9]. According to the Group 5 ITI Consensus Report: Digital technologies, the accuracy of static-CAIS was 1.2 mm (1.04, 1.44, 95% confidence level [CL]) at the entry point and 1.5 mm (1.29, 1.62 mm, 95% CL) at the apical position, with an angular deviation of 3.5° (3.00, 3.96, 95% CL) [8]. Fernández-Gil et al. found that the angular deviation of implant placement using static CAIS by experienced surgeons in model surgeries was 1.96 ± 0.91° [10].

Dynamic navigation allows real-time monitoring of implant bed preparation during surgery. Registration of the dentition and the reconstruction of the computed tomography (CT) or cone beam computed tomography (CBCT) data is carried out and the surgeon can monitor the position of the surgical drills on the CT reconstruction with the help of the specialized software and tracking methods to follow the movement of the surgical field and instruments [1, 5, 7, 11, 12]. In the existing literature, there are a few randomized controlled clinical trials assessing the accuracy and possible complications of dynamic CAIS [12, 13]. According to the systematic review and meta-analysis by Wei et al., average global coronal deviation, global apical deviation, and angular deviation of dynamic CAIS were 1.02 mm, 95% CI (0.83, 1.21), 1.33 mm, 95% CI (0.98, 1.67), and 3.59°, 95% CI (2.09, 5.09) [12]. Systematic reviews suggest that dynamic CAIS enables the clinician to place implants with better accuracy than the free-hand and half-guided static CAIS methods [1, 11, 14, 15]. Higher cost and iatrogenic complications arising due to the surgeon's increased attention to the monitor instead of the surgical field are the disadvantages associated with this surgical modality [1, 5, 7].

Augmented reality (AR) is a technology in which computer-generated content is superimposed on the real environment to enhance the user's sensory perception [16–19]. AR utilizes a set of technologies to integrate the digital world with the real world. The main components of the AR system are the display, the technology for registration and tracking and a computer software. The display enables the user to perceive the real environment and the digitally supplied information simultaneously, while the technology for registration and tracking makes sure that the digital information is adequately aligned with the real objects in real time [17, 20]. According to previous reports, primary areas of application of AR include the education of undergraduate and postgraduate dental students, oral and maxillofacial surgeries, and dental implant surgeries [16-19, 21-23]. There are only a few *in vitro* studies [20, 24-27] and even fewer clinical studies [28] in the available literature on the composition of AR-based dynamic CAIS systems, let alone on the accuracy of the implant positioning achieved by the application of this technique. However, according to these studies, the accuracy of implant placement using this surgical method is clinically adequate [20, 24, 25, 27, 28]. In their *in vitro* study, Jiang et al. observed that there was an angular deviation of 5.04 ± 2.83° during implant placement using AR-based dynamic navigation [24]. Pellegrino et al. have reported the successful application of AR-based dynamic CAIS in clinical settings [28]. To the best of our knowledge, this is the only clinical study on AR-based CAIS so far.

This *in vitro* study aimed to compare the accuracy of implant placement in model surgeries carried out with three different navigational methods (AR-based dynamic CAIS, static CAIS, and free-hand implant placement). Our null-hypothesis was that both the AR-based dynamic and static navigation allow more accurate implant positioning compared to the free-hand approach. In addition, we hypothesized that there is no significant difference in the accuracy of implant placement achieved using the two different CAIS modalities.

2. Materials and methods

2.1. Study design

This *in vitro* study was approved by the Regional, Institutional Scientific and Research Ethics Committee (109/2020). The sample size was determined based on the results of previous *in vitro* studies in this subject area using the G*Power 3.1 software (v.3.1.9.3, 2017, Institut für Experimentelle Psychologie, Heinrich-Heine-Universität, Düsseldorf, Germany). Our calculation was based on the results of Jiang et al [24]. and Fernández-Gil et al [10]., according to which if α (false positive rate) was set at 0.05, to reach a power of 95% with a 1:1 distribution ratio between study groups the minimal sample size should be at least 11 (dental implants placed) per study group.

In Group 1, model surgeries were assisted by AR-based dynamic navigation. In Group 2, implants were placed with a free-hand method. In Group 3, static CAIS was used to place the implants.

Participant bias was minimized by assigning different examiners and clinicians to individual tasks. The surgeon performing the model surgery (M.K.) was not involved in surgical planning (D.P.) and evaluation of the accuracy of implant placement (A.T.). The examiner carrying out the measurements of the outcome variables (A.T.) was blinded to the surgical modality used during the model surgeries.

2.2. Preparation of the models

From an open-source Standard Tessellation Language (STL) file of a lower jaw, 12 models were 3D printed using Flashforge Hunter Digital Light Processing 3D Printer (Zhejiang Flashforge 3D Technology Co., Ltd, Jinhua City, China) composed of FHD 1300 Carnation Dental Model Resin material (Zhejiang Flashforge 3D Technology Co., Ltd, Jinhua City, China). Models were randomly assigned to three study groups.

2.3. Pre-operative CBCT and implant planning

CBCT scans (Green X, Vatech, Hwaseong, Korea) were carried out prior to the model surgeries (preoperative CBCT). The scanning conditions were as follows: a 15 × 8 cm field of view field of view (FOV), 200 μm voxel size, 360° rotation, exposure time of 9 s, tube voltage of 94 kV, and tube current of 7.2 mA.

Implant positions and surgical guides for static CAIS were planned to simulate the clinical scenario of delivering four parallel Callus Pro (Callus Implant Solutions GmbH, Hamburg, Germany) implants (4.2 mm in diameter, 10 mm length) in the interforaminal region of the mandible for an implant borne overdenture. Planning was carried out by digital planning using coDiagnostiX software, version 10.4 (Dental Wings, Montreal, CA, USA). The STL file of the mandible was registered with the Digital Imaging and Communications in Medicine data of the preoperative CBCT reconstruction. The two distal implants were planned in the most distal position with a 5 mm safety zone from the mental foramina mesially. The two mesial implants were planned as far apart as possible in a manner that no axis of rotation is created on the fulcrum line linking these implants. In the orthoradial direction, implants were planned in such a way that a cortical bone thickness of at least 1.5 mm would remain on both the lingual and the labial sides [29]. A surgical template for the pilot-guided intervention was designed with sleeves of 2 mm diameter (Article number HN001, Hager & Meisinger GmbH, Neuss, Germany) to guide the pilot drill (Article number HN011, Hager & Meisinger GmbH, Neuss, Germany) and three guide fixation pins (Straumann Template Fixation Pin, Article number 034.282, Straumann GMBH, Basel, Switzerland) were planned to stabilize the surgical guide.

Implant positions were exported using the Virtual Planning Export option of the coDiagnostiX (Dental Wings, Montreal, CA, USA) software in STL format, which served as the input data for the AR-based dynamic navigation system, Innooral System (Innoimplant Ltd, Budapest, Hungary). The AR-based dynamic navigation system consisted of a

head-mounted virtual retinal display (VRD) (Magic Leap One, Magic Leap Inc, Miami, USA) and a contra angle handpiece (WS-56 L, W&H, Bürmoos, Austria) mounted with the pilot drill (2 mm in diameter) of the Callus Pro (Callus Implant Solutions GmbH, Hamburg, Germany) surgical tray. This system was also equipped with a marker for tracking purposes.

2.4. AR-based CAIS system

The Innooral system creates a virtual coordinate system that is used to keep track of the headset, drill marker, and patient marker. The headset position is tracked by an accelerometer, gyroscope, and IR dot projector to gather data on the headset's position and momentum in 3D space. The gathered data is combined via sensor fusion. The drill and the patient are each tracked using a marker. The position of the drill marker is calculated by perspective distortion and distance. Before the operation, the offset of the drill is recorded and used to calculate the position of the drill bit that will give the exact point of the drill tip.

The software enables the operator to modify the opacity of each displayed object (dentition, drill indicator, drill bit) or to turn off the rendering completely.

The system requires a VRD (Magic Leap One) and a computer to upload the surgical plan to the VRD. The required softwares are Innooral (Innooral System, Innoimplant Ltd, Budapest, Hungary), MagicLeap - The Lab (Magic Leap One, Magic Leap Inc, Miami, USA), Net 4.6 (Microsoft Corporation, Redmond, Washington, USA) or newer, and Microsoft Windows 10 Microsoft Corporation, Redmond, Washington, USA) operating system or newer.

Any drill bit or other rigid tool can be used with the software if the length and diameter of the bit are known, these must be specified during the planning phase.

The rendering delay of the headset is within 10 ms; however, a computation time of 100–150 ms is added to this delay due to image recognition, resulting in a total delay of 110–160 ms. This is quite high for fast movements; however, it is adequate for the relatively slow movements of dental implant placement. Magic Leap One comes with two six-layer waveguide photonic lightfield chip displays (one for each eye) with a resolution of 1280 * 960 (4:3), a refresh rate of 122 Hz, and 4° horizontal, 30° vertical, and 50° diagonal FOV.

The VRD may induce visual fatigue, including eye strain, and the headset does not fit prescription glasses, which may limit its use. The use of image recognition requires close to ideal lighting conditions, preferably not too bright, diffused lighting.

2.5. Model surgery

The surgery was performed by a clinician (M.K.) who was well-experienced in the clinical use of free-hand and static CAIS modalities and had carried out numerous model surgeries using the AR-based dynamic CAIS system. Surgical interventions were performed in a randomized order over the course of three days with four model surgeries (16 implants placed) each day to avoid operator fatigue. Prior to the interventions, the models were stabilized to avoid any intraprocedural movements. All osteotomies were carried out at a drill rotation speed of 800 rpm with external cooling.

In Group 1 (test group), registration of the surgical plan and the model was carried out in the real environment by landmark registration using three points marked on the model (the mental foramina and a specific bone irregularity) for the AR-based dynamic navigation procedure. The Innooral System superimposed the planned implant position on the model using the VRD. The Innooral System also followed up on the progress of the pilot drilling. During the osteotomy preparation, three separate dots represented the entry point, the angle, and the depth of the drill. When the operator placed the tip of the drill on the entry point the first indicator turned from red to green. If the surgeon deviated from the correct angulation, the second indicator turned from green to red. The third dot alerted the operator when the correct depth was reached. Following the pilot drilling, the operator removed the VRD and finalized the implant bed preparation in a free-handed manner according to the manufacturer's instructions.

In Group 2, implant osteotomies were carried out using a free-hand method bearing in mind the general considerations for the placement of four parallel implants for an overdenture [29].

In Group 3, the fit of the surgical templates was checked, and the templates were stabilized on the models using three guide fixation pins. The pilot drill was used as the first step of implant bed preparation. After creating the pilot osteotomies, the surgical template was removed, and osteotomies were finalized in a free-handed manner according to the manufacturer's instructions Fig. 1.. presents the experimental setup in the three study groups.

2.6. Outcome variables

In the present study, primary outcome variables describing the difference between planned and executed implant positions were angular deviation, coronal global deviation, and apical global deviation.

2.7. Postoperative CBCT

Postoperative CBCT examination was performed using the same scanning conditions as those used for the preoperative CBCT scan.

2.8. Trueness evaluation

The primary outcome variables (angular deviation, coronal global deviation, and apical global deviation) were calculated by an investigator (A.T.) blinded to the modality used for implant placement during the model surgery. Variables were calculated using the treatment evaluation plug-in of the coDiagnostiX software, version 10.4 (Dental Wings, Montreal, CA, USA), following the registration of postoperative and preoperative CBCT scans into the system Fig. 2.. presents the measurement of the primary outcome variables in the planning software.

2.9. Statistical analyses

Statistical analyses were performed using IBM SPSS Statistics software, version 25 (IBM Corporation, New York, NY, USA). Shapiro–Wilk's test of the primary outcome variables was carried out depending on the surgical modality used (AR-based dynamic CAIS, static CAIS, and free-hand) to reveal that all primary outcome variables were approximately normally distributed. One-way ANOVA with a post-hoc test (Tukey) was carried out to compare angular deviation, coronal global deviation, and apical global deviation data between the three study groups. Values of $p < 0.05$ were considered as statistically significant.

3. Results

In each study group, four models were used for implant placement and four implants were placed per model. Therefore, a total of 48 dental implants were placed in this study.

There were no significant differences between the primary outcome variables of the AR-based CAIS and static CAIS groups (angular deviation of 4.09 ± 2.79° and 3.21 ± 1.52°, coronal global deviation of 1.27 ± 0.40 mm and 1.31 ± 0.42 mm, and apical global deviation of 1.34 ± 0.41 mm and 1.38 ± 0.41 mm for the AR-based CAIS and static CAIS groups, respectively). Static CAIS produced significantly lower values of all three primary outcome variables than the free-hand approach (angular deviation, 5.85 ± 2.60°; coronal global deviation, 1.93 ± 0.79; and apical global deviation, 2.28 ± 0.74). The coronal and apical global deviations in the AR-based CAIS group were significantly lower than those in the free-hand group. However, regarding angular deviation, no

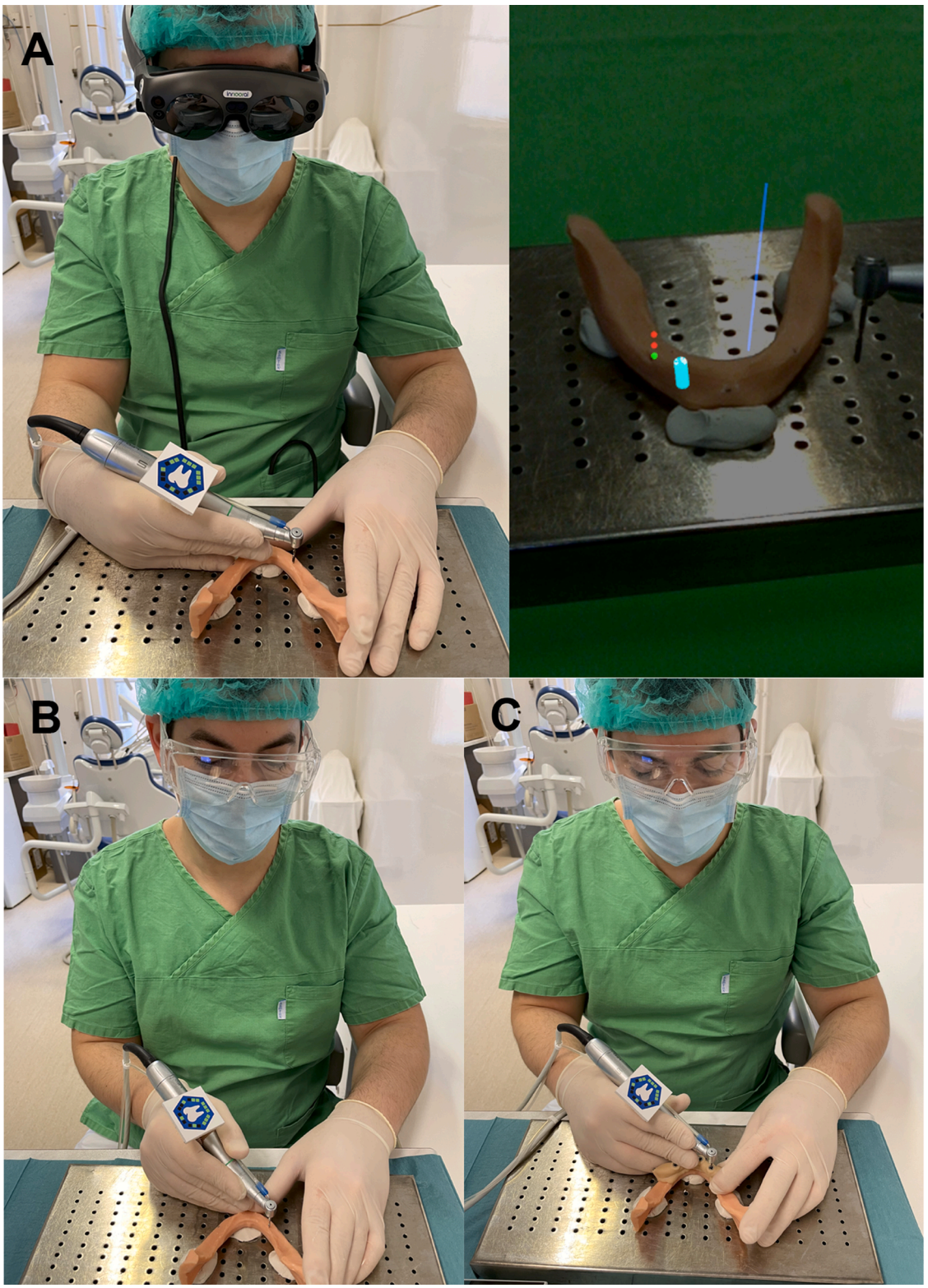

Fig. 1. The experimental setup in the AR-based CAIS group (A), the free-hand group (B), and the static CAIS group (C).

significant differences were found between the AR-based dynamic CAIS and free-hand groups.

Descriptive statistics and results of the statistical analysis are displayed in Table 1 and Fig. 3.

4. Discussion

AR-based dynamic CAIS is a novel navigational method. Therefore, it is paramount to assess implant positioning accuracy achieved by AR-based navigation compared to more conventional navigational methods prior to clinical testing. To the best of our knowledge, the present study is the first to compare the accuracy of implant placement

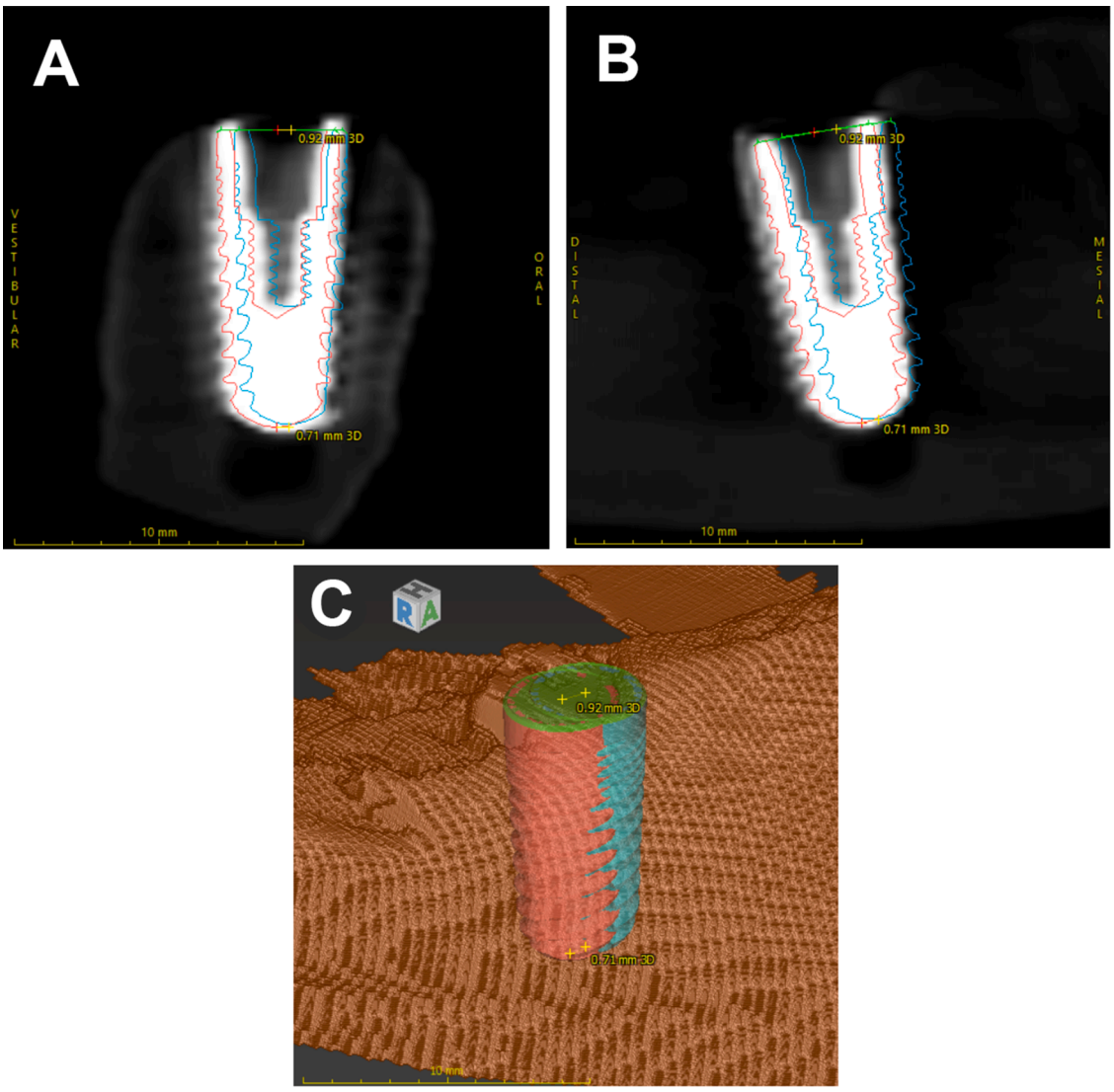

Fig. 2. Measuring angular deviation, coronal, and apical global deviation of planned (outlined in blue) and achieved (outlined in red) implant positions in the Treatment Evaluation plug in of the coDiagnostiX software, version 10.4 (Dental Wings, Montreal, CA, USA). Orthoradial (A), tangential (B) cross sections, and three-dimensional visualization (C).

Table 1
Descriptive statistics of for the primary outcome variables and the results of one-way ANOVA test, * $p<0.05$.

	Unit	Test group AR-based dynamic CAIS		Free-hand group free-hand implant placement		Static CAIS group static CAIS		
		Mean	Standard deviation (SD)	Mean	Standard deviation (SD)	Mean	Standard deviation (SD)	p value of One Way ANOVA
Angular deviation	°	4.09	2.79	5.85	2.60	3.21	1.52	0.010*
Coronal global deviation	mm	1.27	0.40	1.93	0.79	1.31	0.42	0.000*
Apical global deviation	mm	1.34	0.41	2.28	0.74	1.38	0.41	0.002*

using AR-based dynamic CAIS, static CAIS, and free-hand implant placement. No significant differences were noted in the coronal global deviation or apical global deviation between implant positions achieved using AR-based navigation or static CAIS, whereas both the approaches performed significantly better than the free-hand method. In the present study, the coronal and apical global deviations following use of AR-based CAIS were 1.27 ± 0.40 mm and 1.34 ± 0.41 mm respectively, which were similar to the results of previous *in vitro* studies. According to the results of the present study, angular deviation between the planned and achieved implant positions using AR-based CAIS was 4.09 ± 2.79°, which was similar to the results of previous *in vitro* studies and was not significantly different from the angular deviation data achieved using the free-hand and static CAIS approaches.

In their *in vitro* study, Lin et al. used AR as an auxiliary visualization method for static CAIS with clinically adequate results [26]. Another *in vitro* study by Ma et al. reported a mean target error of 1.25 mm and a mean angle error of 4.03° with a solely AR-based CAIS method [27]. Wang et al., in their *in vitro* study, described an AR-based navigation system with an average error of less than 0.5 mm and tracking within 0.5 second [20]. In their pig cadaver study, Katić et al. achieved less than 2.5 mm deviation while placing implants using AR-based navigation [25]. In their *in vitro* study, Jiang et al. reported mean linear deviations of <1.5 mm and angular deviations of <5.5° when placing implants using AR-based navigation [23]. Pellegrino et al. reported a clinical

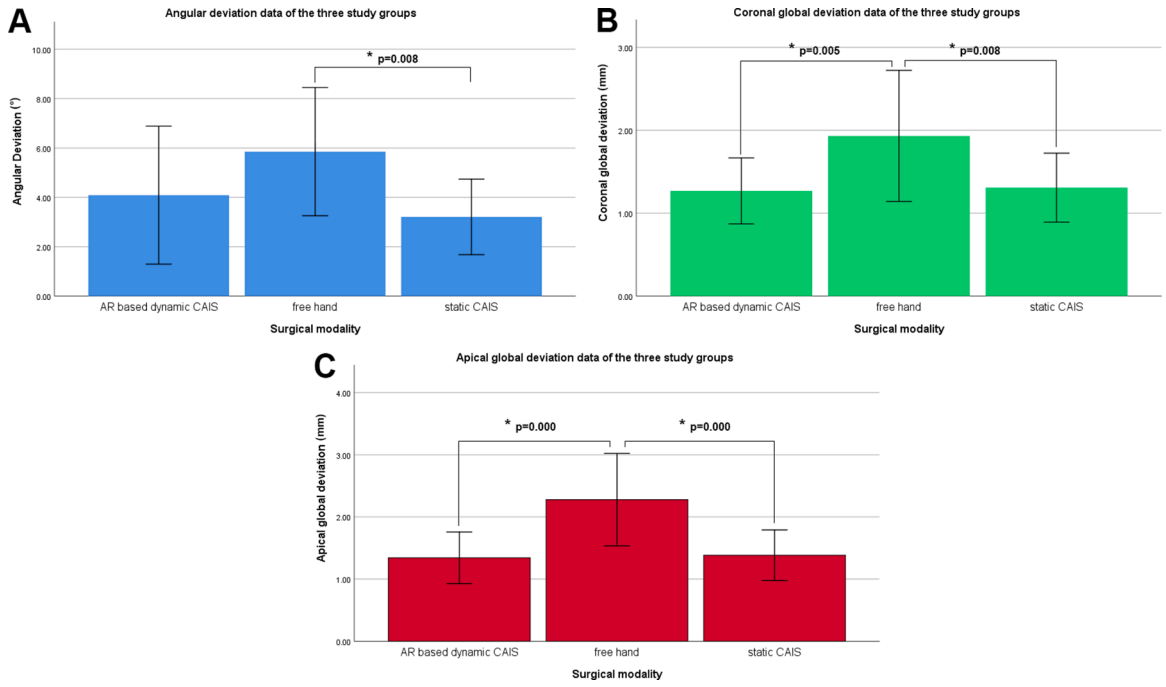

Fig. 3. Bar graphs representing the angular deviation (A), coronal global deviation (B), and apical global deviation (C) data with the results of the Tukey post-hoc test, * $p<0.05$.

study on two cases in which AR-based CAIS was performed with adequate clinical implant positioning accuracy [28].

AR-based dynamic navigation allows the surgeon to visualize the surgical plan superimposed on the actual surgical field, using a VRD enabling full visual control of both the surgical plan and the surgical field at the same time. The surgeon is not required to alternate their attention between the monitor and the surgical area, which may prove to be a significant advantage of the AR-based navigation compared to the conventional dynamic navigation in clinical settings and may prevent iatrogenic complications. Another advantage of AR-based dynamic navigation compared to static CAIS is that there is no need to fabricate a template; it is possible to load the surgical plan into the system instantly. Thereby, template caused inhibition of cooling of the drill and the need for additional space to accommodate both the drill and the template in the molar region are eliminated. However, there are hardly any *in vitro* and clinical studies evaluating the advantages and disadvantages of such a surgical modality [20, 24-28].

The limitation of the present study is that by stabilizing the models during surgery, the AR-based system was only left with the drill to track. However, the Innooral System has the capacity to track movements of the patient as well, which could not be put to test in the present study. The bulky headset that precludes the wear of prescription glasses and the limited FOV are disadvantages associated with the use of the VRD. The latter together with the need to keep the markers and the surgical field in the FOV simultaneously may force the surgeon to operate in an uncomfortable posture [28]. Delay and imprecision of the superimposition are the limitations of AR technology the surgeon must be aware of to avoid iatrogenic complications. The additional cost and time of setup are the disadvantages of most CAIS modalities. Connected technologies, including AR, are vulnerable to security risks and unauthorized access. Users and developers must follow precautionary measures to avoid severe surgical complications and invasion of personal privacy.

Further limitations of the study are that it was carried out with only one implant system and that implant positioning accuracy was evaluated by registering the preoperative plan with postoperative CBCT data, instead of the STL data of optical scanning. Intraoral and desktop scanning enable mapping of surfaces with higher accuracy than CBCT reconstruction. The use of optical scanning to calculate primary outcome variables in the present study may have led to more accurate evaluation of implant positioning accuracy. Nevertheless, CBCT data-based assessment of implant positioning accuracy is more widely supported by implant planning software. The few implants placed per study group may be another limitation of this study. Sample size calculation was carried prior to the model surgeries; it was based on the results of previous *in vitro* studies on AR-based navigation, which had small sample sizes. Further, the results of the present *in vitro* study should be carefully applied to the more complex clinical environment. Further clinical studies are required to determine the feasibility of AR-based dynamic CAIS.

5. Conclusions

According to the results of this preclinical study, implant positioning accuracy of AR-based dynamic CAIS was comparable to that provided by static CAIS and superior to that obtained using the free-hand approach.

The primary outcome variables for AR-based CAIS were an angular deviation of 4.09 ± 2.79°, coronal global deviation of 1.27 ± 0.40 mm, and apical global deviation of 1.34 ± 0.41 mm; using static CAIS, there was an angular deviation of 3.21 ± 1.52°, coronal global deviation of 1.31 ± 0.42 mm, and apical global deviation of 1.38 ± 0.41 mm; and using the free-hand method, there was an angular deviation of 5.85 ± 2.60°, coronal global deviation of 1.93 ± 0.79 mm, and apical global deviation of 2.28 ± 0.74 mm.

The limitations of the study are that it was carried out using only one implant system with a small sample size and that implant positioning accuracy was evaluated by registering the preoperative plan with postoperative CBCT data, instead of data acquired from optical scanning. The results of this *in vitro* study should be carefully applied to the more complex clinical environment.

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CRediT authorship contribution statement

Márton Kivovics: Methodology, Investigation, Writing – original draft, Project administration. **Anna Takács:** Formal analysis, Investigation, Data curation. **Dorottya Pénzes:** Investigation, Visualization. **Orsolya Németh:** Formal analysis, Resources, Writing – review & editing. **Eitan Mijiritsky:** Conceptualization, Writing – review & editing, Supervision.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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