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Trueness of fully guided versus partially guided implant placement in edentulous maxillary rehabilitation: a split-mouth randomized clinical trial

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Abstract

Background This study aimed to evaluate the trueness of implant placement with fully guided (FG) implant placement protocol versus partial-guided (PG) protocol.

Methods The study recruited 16 fully edentulous patients with adequate maxillary bone volume. Each patient received six implants; three were planned for each side of the maxilla to support a full-arch implant-supported fixed prosthesis 3 (FP3). Patients were randomly assigned to one of two intervention groups: Group 1 (PG group), drilling was done using a surgical guide, but implant placement was done without the guide. In group 2 (FG group), both drilling and implant placement were done through the surgical guide. The spatial relationship (entry, apex, and angle deviation) between planned and placed implants was evaluated using pre- and postoperative CBCT data.

Results The FG approach resulted in statistically significantly higher overall trueness in entry, apex, and angle deviation across multiple implant sites, with a statistically significant difference of 0.030, 0.013, and 0.036, respectively, though differences at individual implant sites were not consistently significant.

Conclusion This trial supported the fully guided implant placement protocol for enhancing the trueness of implant positioning in the rehabilitation of edentulous maxillary arches. Clinicians should weigh the benefits of this increased trueness against practical considerations.

Trial registration The current study was registered at ClinicalTrials.gov (NCT06542562) on August 5, 2024.

Keywords Trueness, Dental implant, Edentulous maxilla, Fully-guided, Partial-guided, Implant placement

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Background

Precise 3D implant positioning is crucial in the rehabilitation of edentulous maxillary arches using implant-supported fixed prostheses, as it is essential for achieving optimal esthetic and functional outcomes [1]. The fabrication of FP3-type implant-supported fixed prostheses requires a high level of precision to attain a passive fit and ensure long-term success (Fig. 1). It is essential to carefully consider the number, angulation, and distribution of dental implants in order to provide sufficient biomechanical support and effective load distribution for the prostheses [2, 3]. Discrepancies in the planned and placed implant have the potential to compromise the fit of prostheses and result in biomechanical complications, such as peri-implantitis, which can often be attributed to mispositioning of the implant [4].

Prosthetically driven implant surgery employing the computer-guided surgical approach is recommended to guarantee long-term stability of hard and soft tissue and reliable outcomes that are both aesthetically pleasing and functionally effective [5, 6]. The introduction of guided implant surgery ensures optimal 3D implant placement in accordance with the anatomic and prosthetic considerations, especially in cases with anatomic limitations such as insufficient bone encountered in the edentulous maxilla [1, 7, 8].

However, many variables affect the accuracy of guided implant surgery, including the quality of data acquisition (DICOM and STL files), surgical guide construction and fixation, the form of support (mucosa-supported, tooth-supported, and bone-supported), surgical protocol (PG or FG), and implant installation procedure (guided placement or freehand placement) [9–14].

Some of the surgical guides utilized in implant placement facilitate FG implant placement, whereas others necessitate their removal at the moment of implant placement and freehand implant placement (PG protocol). In this context, the potential deviations associated with freehand implant placement may be unavoidable [1, 5].

The use of FG surgery in implant placement has been associated with significantly higher accuracy compared to PG surgery, as reported in two systematic reviews [8, 15]. However, a fundamental limitation of these reviews is the exclusion of randomized controlled trials (RCTs), which are considered the gold standard for evaluating clinical interventions. Furthermore, while some studies reported higher accuracy with the FG protocol, other studies have recommended the PG protocol, highlighting the advantage of allowing clinicians to adjust the implant location slightly during insertion when necessary [16]. This conflicting evidence underscores the need for further investigation, including RCTs, to provide a more comprehensive and reliable assessment of the trueness and clinical benefits of FG versus PG surgery. Therefore, this study is necessary to fill this gap and contribute to more explicit clinical guidelines on implant placement techniques.

Fig. 1 Full-arch implant-supported FP3

According to ISO 5725-1, accuracy encompasses both trueness and precision. Trueness refers to the closeness of agreement between the average of test results and the true or accepted reference value, while precision is defined as the degree of agreement among independent test results obtained under specified conditions [17]. This study aimed to compare the trueness of the FG protocol, in which both drilling and implant placement were performed through the guide, with the PG protocol, where drilling was guided but the implant fixture was placed after guide removal, in patients with an edentulous maxilla to provide insights into the optimal approach to ensure accurate implant placement and, consequently, optimal aesthetic and functional outcomes. The null hypothesis is a statistically non-significant difference between the PG and FG protocols.

The research question of the study was "For patients with an edentulous maxilla rehabilitated using the full-arch implant-supported FP3, does PG implant placement influence the trueness compared to FG implant placement protocol?

Materials and methods

Study design and ethical approval

The split-mouth randomized clinical trial obtained approval from the ethics committee of MSA University with a number REC-D 4147-4 and was conducted in accordance with the Helsinki Declaration of 1975, as revised in 2013. The study protocol was registered on clinicaltrials.gov under the number NCT06542562. This study, conducted and reported herein, adheres to the CONSORT guidelines and is presented following the Extension to the CONSORT 2010 checklist for reporting within-person randomized trials.

Calculation of the sample size

Due to the limited number of available studies that could serve as a representative sample, we relied on mean linear deviation values from previous research [18, 19].

Specifically, prior studies reported mean linear deviations at the implant shoulder ranging from approximately 0.8 mm in PG protocol to around 0.56 mm in FG protocol. This corresponds to an estimated relative difference of roughly 30%. Using these values, we calculated the required sample size at the implant level with G*Power software. Assuming a two-tailed test, a significance level (α) of 0.05, and a power of 80%, we determined that a minimum of 86 implants would be needed to detect this effect size. To account for potential dropouts or data loss, we increased the planned sample to 96 implants, which were distributed among 16 patients.

Recruitment of patients and eligibility criteria

Patients were included if they were 18 years or older, fully edentulous in the maxilla, had sufficient bone volume for six implants (3.7 mm diameter, 10 mm length) to support a full-arch implant-supported FP3, and had fully healed ridges (≥ 6 months' post-extraction) to ensure standardized bone healing. Exclusion criteria were systemic conditions contraindicating implant surgery (e.g., uncontrolled diabetes, recent myocardial infarction), prior head and neck radiation, poor oral hygiene or noncompliance, pregnancy or lactation, smoking over five cigarettes daily, and psychiatric or cognitive disorders affecting consent or follow-up. All Participants provided written consent.

Preoperative planning, imaging, and software planning

Maxillary and mandibular diagnostic casts were mounted on an articulator for comprehensive examination. A diagnostic wax-up was performed to visualize the anatomical structures and optimal implant placement. This wax-up was then duplicated and converted into a radiographic guide. Radiopaque materials were embedded into prepre-pared holes on the guide's surface. A dual-scan protocol was conducted using a CBCT device (I-CAT, Imaging Science International, Hatfield, PA, USA), with standardized exposure parameters (170 × 230-mm FOV, 120 kVp, and 18.7 mAs). The first scan involved the patient wearing the radiographic guide, while the second focused exclusively on the guide itself. The CBCT data were then imported into the BlueSky Software (BlueSkyPlan 4; BlueSky Bio) for further planning. Six implants (S-clean tapered dental implants, Dentis, Korea) were planned—three on each side of the maxilla to support a full-arch implant-supported FP3. The planned implant sites included the upper right central incisor, the upper right canine, the upper right second premolar, the upper left central incisor, the upper left canine, and the upper left second premolar. Figure 2A.

The virtual implant planning was executed by a single expert with over 10 years of experience in guided implant procedures. After finalizing the plan, it was sent to the

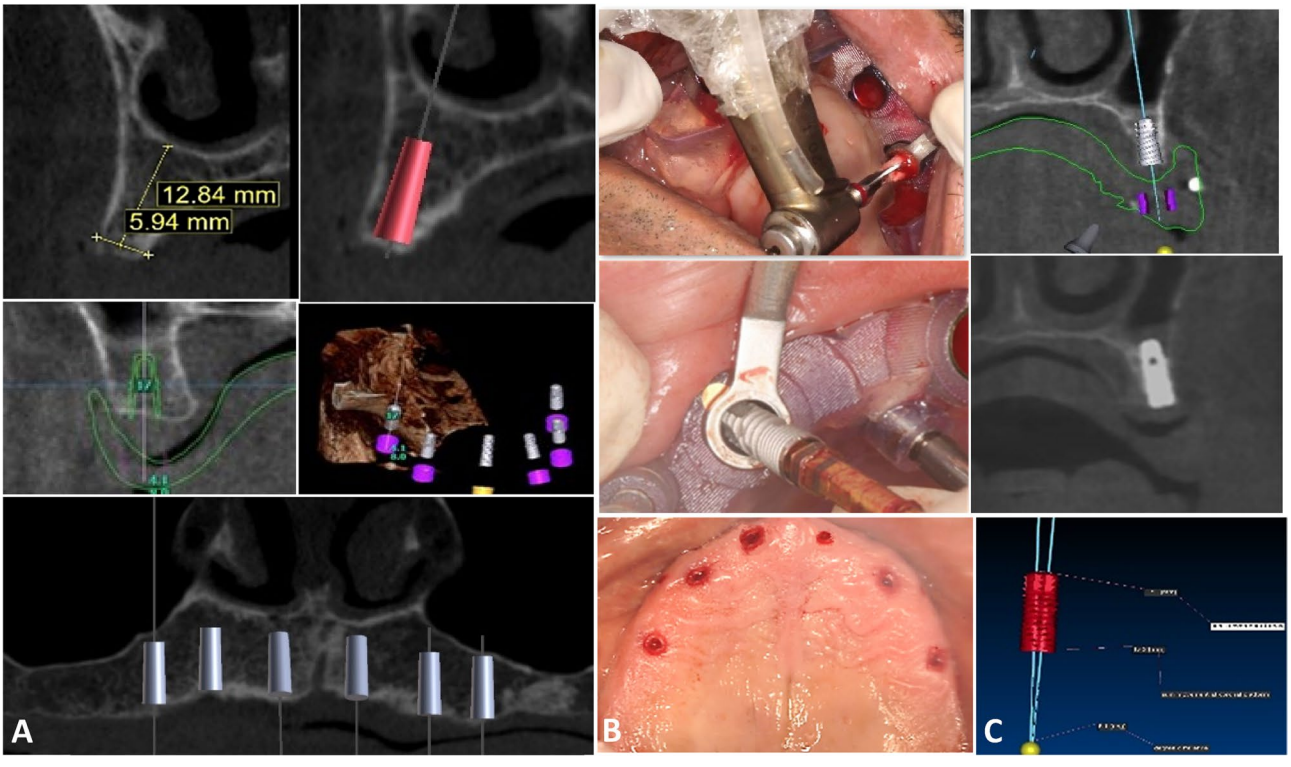

Fig. 2 (**A**) virtual implant planning using CBCT and software showing implant positions in the edentulous maxilla; (**B**) clinical view of implant placement with fully guided (FG) and partial-guided (PG) protocols; (**C**) comparison of planned versus actual implant positions using postoperative CBCT to assess entry, apex, and angular deviations

manufacturer for the production of the surgical template, fabricated using a 3D printer (Envision Tech Gmbh) with a transparent, FDA-approved, biocompatible material (E-Guard) The same guide design was used consistently across all cases. A mucosa-supported surgical guide was used in all cases, as all participants were fully edentulous. The guide was fabricated as a single-piece design and stabilized intraorally using fixation pins in a tripod arrangement, two buccal and one palatal, to prevent movement during surgery.

Randomization, allocation concealment, and blinding

Patients were randomly assigned to one of two intervention groups for the right or left side of the maxilla using a computer-generated system (https://www.randomizer.org/.) assigning each patient to receive both interventions in a split-mouth design (one side treated with the PG protocol and the other with the FG protocol):

- Group 1: Partial guided (PG) – The drilling sequence was performed using a surgical guide, but implant placement was done without the guide.
- Group 2: Fully guided (FG) – Both the drilling sequence and implant placement were performed using the surgical guide.

Each patient received three PG implants on one side and three FG implants on the other.

Randomization was concealed by placing numbered cards into sealed opaque envelopes, which were prepared by an investigator not involved in patient care. These envelopes determined the specific intervention to be performed on each side of the maxilla. They were opened immediately following the drilling of the implant site on one side, thereby ascertaining which intervention would be administered; consequently, the opposite side received the alternative intervention. While it was not possible to blind the surgeon during implant placement, the outcome assessors were kept unaware of the group assignments to ensure unbiased evaluation. To minimize performance bias, all surgeries were performed by a single experienced surgeon trained in both techniques, using standardized protocols and equipment for both groups.

Implant surgical procedures

All surgeries were performed by a highly experienced surgeon specializing in guided implant techniques. Local anesthesia (Optocaine, 20 mg/ml with adrenaline at 1:80,000) was administered to the maxilla. The computer-guided stent was then secured intra-orally with anchor screws, according to the preoperative plan, using a surgical kit provided by In2Guide. Drilling was performed following the kit's protocol, with irrigation throughout the process. The surgery began with soft tissue removal, followed by drilling using computer-guided keys that matched the planned dimensions. Osteotomies were completed using the surgical tray's pilot, twist, and final drills. In Group 1 (PG), the stent was removed before implant placement, while in Group 2 (FG), implants were inserted through the stent's sleeves at the pre-planned positions. Both groups used the same type and dimensions of implants (S-clean tapered dental implants, 3.7-mm diameter, 10-mm length). After implant placement, covering screws were placed over all the implants. Figure 2B.

Evaluation of trueness

Post-surgery, all patients were re-scanned using the same CBCT machine and exposure settings. Preoperative and postoperative CBCT scans were imported into the BlueSky Software, where an overlay of the preoperative plane onto the postoperative scan allowed for precise evaluation of implant positioning. Implant deviations were measured in three directions: angular deviation (difference in the implant axis angle between the planned and actual positions), entry deviation (deviation at the coronal platform), and apex deviation (deviation at the apical portion) (Figs. 2C and 3). The software generated coordinates for the necessary calculations, with coronal and apical deviations reported in millimeters and angular deviation in degrees.

To ensure reliability, multiple assessments of trueness were conducted. The first two analyses, performed one week apart, were executed by the same investigator, who remained blinded to the interventions. A third analysis was conducted by an independent examiner. Intra-class correlation coefficients were calculated to evaluate reliability. Prior to the assessments, both examiners underwent training and calibration using data from five previous patient scans.

Prosthetic rehabilitation

After a four-month healing period, patients underwent prosthetic rehabilitation with screw-retained full-arch implant-supported FP3. For the second-stage surgery, the implants were uncovered, and transmucosal titanium abutments were screwed into place. An open-tray impression technique was used, and implant analogs were attached to the impression copings. After pouring the impression, the framework was milled using CNC technology, and the final prosthesis was processed and fitted.

Statistical analysis

The statistical analysis entailed the calculation of the mean, standard deviation (± SD), range, and 95% confidence intervals (CIs). The normality of the data was assessed utilizing the Shapiro-Wilk test, and paired

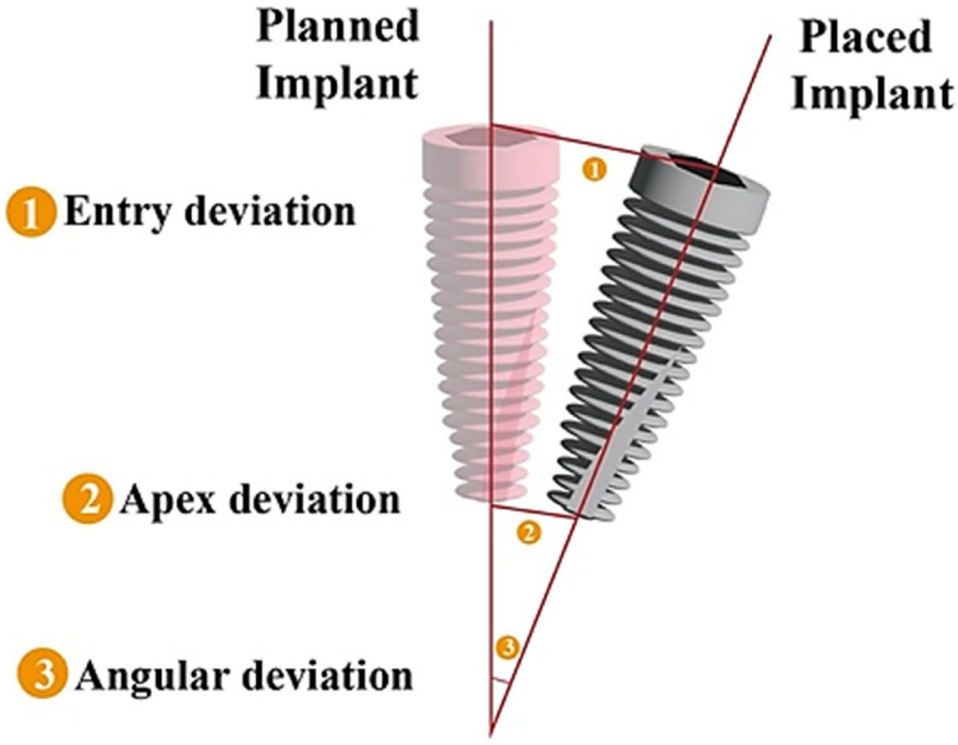

Fig. 3 Illustration of deviation parameters: entry deviation (at the coronal platform), apex deviation (at the apical portion), and angular deviation (difference in implant axis angle between planned and actual positions)

t-tests were employed for group comparisons. A two-sided p-value of less than 0.05 was established as the threshold for statistical significance. All analyses were conducted using IBM SPSS, version 22 for Microsoft Windows (IBM Corp, Armonk, NY, USA).

Results

This split-mouth randomized clinical trial involved a cohort of 16 participants, consisting of 10 male patients and 6 female patients, with an average age of 42.60 ± 12.83. All participants included in the study were included in the analysis (Fig. 4). Table 1 provides the gender, age, and bone density of each eligible patient.

All 96 implants were successfully placed according to the predetermined plan. Throughout this study, there were no instances of implant failure, resulting in a 100% success rate for early-term implantation. Furthermore, no significant deviations or instances of collision with critical anatomical structures were observed in any of the patients.

Table 2 presents a summary of the findings relating to entry, apex, and angle deviation. These variables were divided into two categories for further analysis: the PG study group and the FG study group. Upon comparing the various implant positions, it was observed that the FG group demonstrated superior outcomes compared to the PG group. Notably, no statistically significant differences were observed in terms of entry, apex, and angle deviation between the two groups ($P > 0.05$). In terms of overall entry deviation, apex deviation, and angle deviation, the FG group exhibited greater trueness than the PG group, with statistically significant differences of 0.030, 0.013, and 0.036, respectively. Box plots depicting the results for both the PG and FG groups can be found in Fig. 5.

The intra- and inter-observer intraclass correlation coefficients (0.94–0.98) confirm the precision of the measurement process, ensuring consistent and reliable evaluation of implant positioning.

Discussion

This trial aimed to compare the trueness of the FG protocol, in which both drilling and implant placement were performed through the guide, with the PG protocol, where drilling was guided but the implant fixture was placed after guide removal, in patients with an edentulous maxilla. The FG protocol demonstrated significantly higher overall trueness, confirming its superiority in enhancing implant positioning accuracy and rejecting the null hypothesis.

Although the improvements may not be conclusive at each site due to the lack of statistically significant differences in entry, apex, and angle deviation, the cumulative trend toward higher trueness in the FG group supports its recommendation. Therefore, clinicians should consider the enhanced trueness of the FG approach when

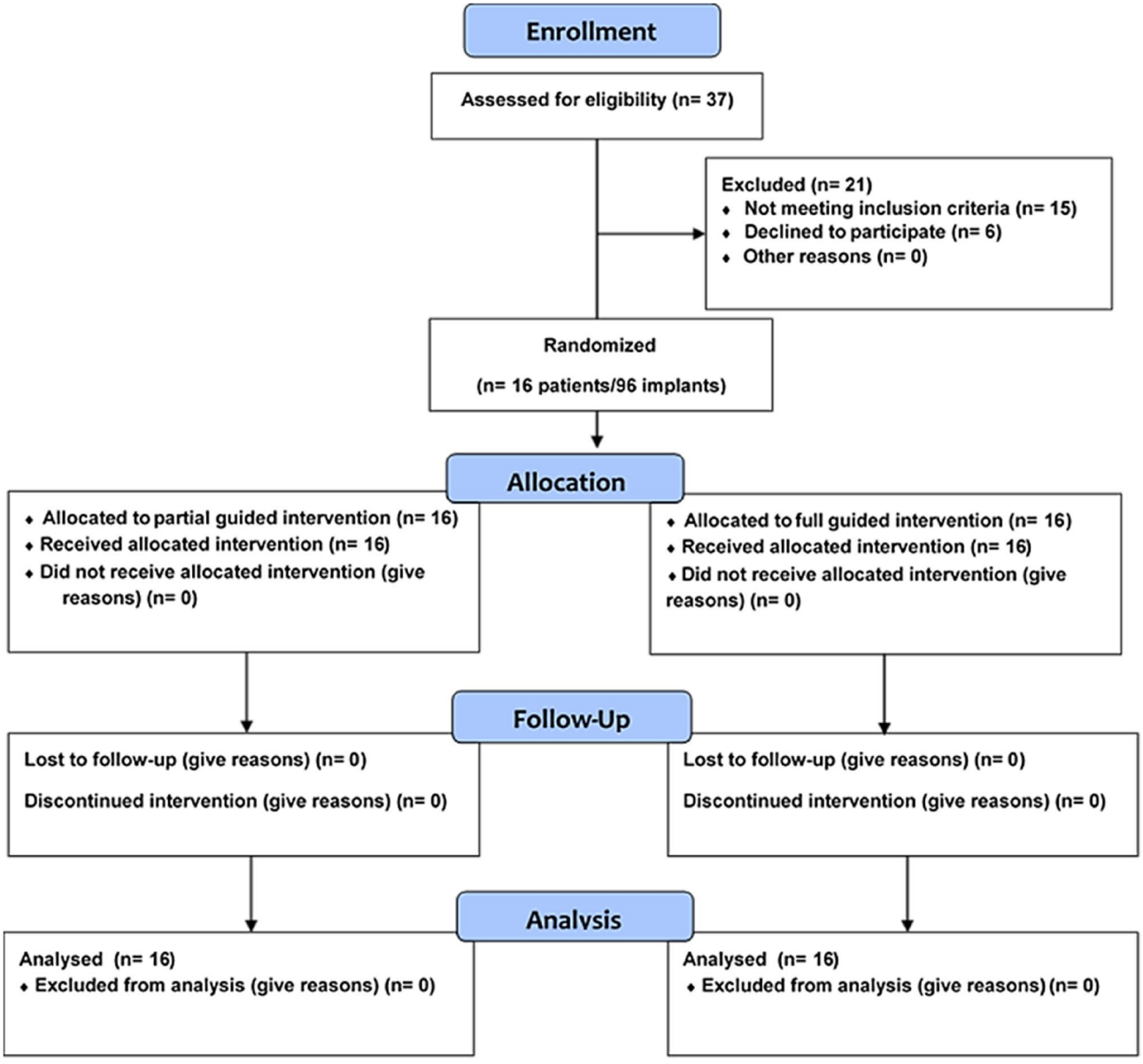

Fig. 4 Study design and CONSORT flow diagram illustrating participant recruitment, randomization, intervention allocation, and analysis for the PG and FG groups

Table 1 Demographic and anatomical characteristics of participants in the Partial-Guided (PG) and Fully-Guided (FG) groups ($n=16$)

		Partial guided (PG)	Full guided (FG)	*P* value
Age (year)		42.60 ± 12.83	42.60 ± 12.83	1
Sex	Male	10 (62.5%)	10 (62.5%)	1
	Female	6 (37.5%)	6 (37.5%)	
Bone density (HU)*		587.75 ± 97.4	569.14 ± 102.6	0.06

Bone density classification based on Misch: D1 (> 1250 HU), D2 (850–1250 HU), D3 (350–850 HU), D4 (150–350 HU), and D5 (< 150 HU). [20]

*HU: Hounsfield units

selecting a guided surgery protocol for edentulous maxillary cases.

All surgical procedures were conducted by a single experienced surgeon specializing in guided implant surgery techniques, ensuring that the skill and experience of the surgeon did not influence the results. Different operators might achieve varying levels of accuracy with either method, potentially affecting the outcomes [21].

The split-mouth design in this trial enhanced the reliability and validity of the results [22] as it provides a controlled comparison between the planned and placed implant position, where the variability in the factors that might enhance the trueness of implant placement is

Table 2 Comparison of implant placement trueness between Partial-Guided (PG) and Fully-Guided (FG) protocols based on deviation parameters ($n=48$ implants per group)

		Partial guided (PG) ($n=48$)		Full guided (FG) ($n=48$)		*P* value
		Mean ± SD	CI, 95%	Mean ± SD	CI, 95%	
Entry deviation (mm)	Central incisor	1.006 ± 0.5	0.74 to 1.27	0.881 ± 0.27	0.74 ± 1.03	0.253
	Canine	0.956 ± 0.32	0.78 to 1.13	0.897 ± 0.18	0.8 ± 0.99	0.310
	Premolar	1.178 ± 0.44	0.94 to 1.41	0.991 ± 0.32	0.82 ± 1.16	0.133
	Overall	1.047 ± 0.43	0.92 to 1.17	0.923 ± 0.26	0.85 ± 0.99	0.030*
Apex deviation (mm)	Central incisor	1.803 ± 0.43	1.57 to 2.03	1.584 ± 0.32	1.41 ± 1.76	0.141
	Canine	1.744 ± 0.48	1.48 to 2	1.4925 ± 0.41	1.27 ± 1.71	0.088
	Premolar	1.894 ± 0.27	1.72.041	1.821 ± 0.23	1.7 ± 1.94	0.367
	Overall	1.814 ± 0.4	1.696 to 1.93	1.633 ± 0.35	1.53 ± 1.73	0.013*
Angle deviation (^{0})	Central incisor	3.717 ± 1.26	3.05 to 4.39	3.293 ± 1.19	2.66 ± 3.93	0.301
	Canine	3.03 ± 0.84	2.58 to 3.48	2.574 ± 1.21	1.93 ± 3.22	0.268
	Premolar	4.73 ± 2.1	3.61to 5.85	3.738 ± 1.7	2.83 ± 4.64	0.163
	Overall	3.826 ± 1.62	3.35 to 4.3	3.202 ± 1.44	2.78 ± 3.62	0.036*

*Statistically significant (*P* value <0.05)

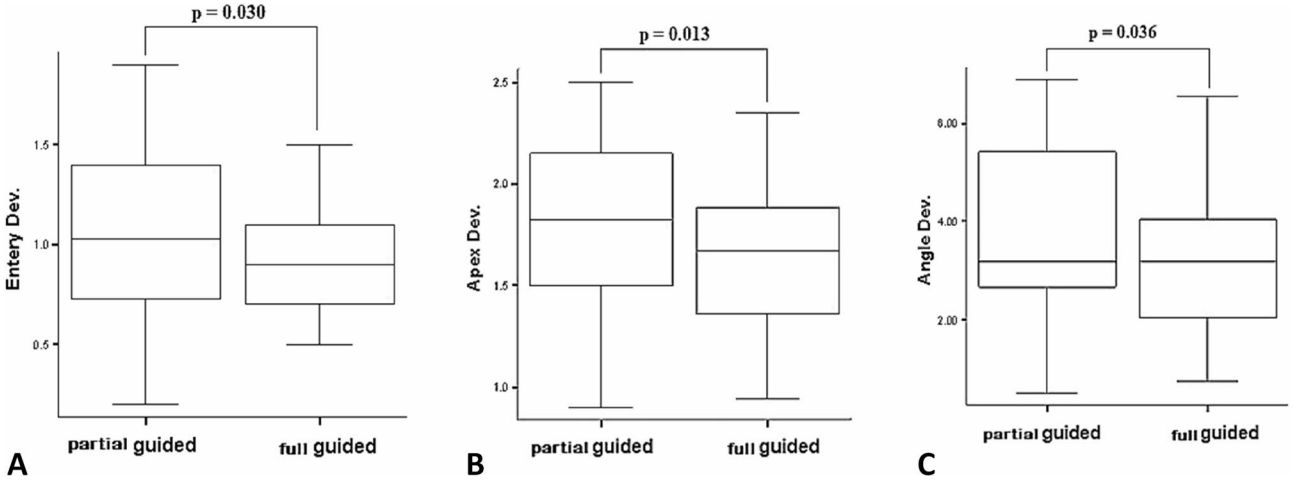

Fig. 5 Box plots showing the range value for the entry (**A**) apex (**B**) and angle (**C**) deviations

minimized. The anatomical structures, quality of bone, and the confounders such as age, gender, and overall health status are consistent since each patient serves as their control, decreasing any influences on the outcome. Moreover, a direct and more straightforward evaluation of the trueness of implant placement techniques at corresponding sites is provided.

The importance of achieving optimal implant placement for long-term success is supported by earlier work that outlined criteria for implant success emphasizing accurate positioning to avoid complications [23]. The accuracy of implant placement is influenced by many factors, including the bone quality and quantity, anatomical consideration, surgical technique, and guided surgery system [24, 25].

The edentulous maxilla is particularly affected by these factors, as reduced bone volume and quality, along with anatomical limitations such as the proximity of the maxillary sinus and nasal cavity, may compromise implant accuracy [26]. Furthermore, the 3D anatomy of the maxilla is more complex than that of the mandible, which can also impact the positioning of implants and subsequently influence prosthetic design. Additionally, there are esthetic demands associated with the apparent areas of the maxilla, necessitating precise implant positioning and optimal integration of soft tissues to achieve satisfactory prosthetic outcomes [26, 27].

Achieving accuracy in dental implant placement is particularly critical in cases characterized by low bone density, as this factor significantly impacts the overall success of the procedure. Low bone density is correlated with increased implant deviation, particularly when it is compounded by narrow bone width and reduced cortical bone thickness [28]. These conditionsincrease the likelihood of implant fixture deviation toward areas of softer bone during placement , especially during PG surgical protocols. Such deviations may jeopardize implant stability and potentially inflict damage on adjacent anatomical

structures, thereby underscoring the necessity for meticulous planning and the consideration of FG surgical protocols to enhance accuracy in these complex cases [28]. Consequently, PG protocols may render the procedure more susceptible to errors, as the removal of the guide can lead to decreased precision and increased variability in outcomes, particularly in the maxilla [29].

The success of the PG protocol heavily depends on the surgeon's experience and skill, particularly in low-density bone situations. Less experienced surgeons may struggle to achieve the same level of trueness without the continuous guidance of a surgical template and are more prone to placement errors [30]. Incorrect seating of the guide or an unstable guide can lead to deviation from the planned implant position. Similarly, patient movement with or without guide can contribute to inaccuracies in implant placement [31].

Potential shifts during the transition from drilling to implant insertion may be encountered in PG protocol. In the present study, the FG group demonstrated a lower incidence of deviation values in comparison to the PG group. This difference is likely attributable to the meticulous control of all drilling steps and implant placement, which effectively eliminated the need for manual orientation and handling of the dental implant fixture during placement [32]. Within each group, deviations were found to vary according to implant position, with premolar sites demonstrating greater deviations than incisor and canine sites. This disparity may be attributed to several factors, including restricted access, inadequate visibility, and diminished bone density in the posterior maxilla. Collectively, these factors may increase the likelihood of deviations during dental implant placement, particularly following the removal of surgical guides in PG procedures [33–35].

Therefore, the edentulous maxilla may derive the most significant advantage from the implementation of FG surgery to optimize the positioning of dental implants in both the desired 3D anatomical and prosthetic locations, as evidenced by our study. This is crucial for achieving higher precision and improved clinical outcomes, especially in the implant-supported FP3, which were used to rehabilitate the patients enrolled in this trial. This type of prosthesis requires a high level of precision to attain a passive fit and ensure long-term success [2, 3, 25, 36].

A recent study compared the trueness of implant placement in the edentulous maxilla using PG, pilot-drill guided (PG), and FG surgery. The authors recommended the FG surgery as a gold standard approach [18]. Another 2 systematic reviews reported a significantly higher accuracy of implant placement using FG compared to PG surgery [8, 15],; however, these reviews lacked the inclusion of RCTs, which recommends the conduction of this study.

An important clinical factor influencing the trueness of guided implant placement is the type of surgical guide support. In this study, a mucosa-supported guide was used, commonly applied in fully edentulous cases for its non-invasive nature and ease of use [37, 38]. Although it may be prone to minor displacements in areas with compressible soft tissues, evidence shows mucosa-supported guides provide greater accuracy than bone-supported guides, can reduce angular and linear deviations compared with bone-supported guides, and represent a reliable and predictable treatment choice in complete-arch restorations [11, 38–40]. In contrast, bone-supported guides exhibit significantly greater deviations than mucosa-supported guides, likely due to the need for flap elevation, which can interfere with the stability and positioning of the surgical guide [8, 37, 41]. Future studies should compare guide types to assess their impact on accuracy and outcomes.

Given that all participants were rehabilitated with full-arch implant-supported FP3, it is important to outline the clinical rationale behind this choice. FP3 is a fixed metal-acrylic restoration supported by multiple implants, designed to replace a full arch of missing teeth. It offers functional and esthetic benefits, especially in cases requiring lip support, improved speech, or with increased intra-arch space. Originally developed to overcome the limitations of unstable dentures, FP3 are cost-effective, absorb occlusal forces well, and deliver high esthetic results—though challenges such as food impaction, hygiene maintenance, and occasional speech issues may arise [42].

There are some limitations to this study. First, the sample size was relatively small, with only 16 patients and 96 implants. This may affect the generalizability of the findings and increase the risk of type II errors, where significant differences might go undetected. Although the outcome assessors were blinded, the surgeon was not, which may introduce performance bias, as knowledge of group allocation could influence the surgical approach. This limitation is inherent in implant surgery due to procedural differences between protocols. To minimize bias, sealed envelopes were used and only opened after the final drill preparations.

To further investigate the clinical impact of the observed differences in implant placement trueness, future research should focus on larger sample sizes and extended follow-up periods to provide more robust evidence. Incorporating long-term outcomes such as implant survival rates, peri-implant bone loss, and prosthetic complications would offer a more comprehensive assessment of implant success. Additionally, including patient-reported outcome measures would provide valuable insight into the functional and esthetic implications from the patient's perspective.

Conclusion

Within the limitations of the study, this trial supports the fully guided implant placement protocol to enhance the trueness of implant positioning in the rehabilitation of edentulous maxillary arches. Clinicians should carefully evaluate the advantages of this increased trueness in relation to practical considerations when selecting the most suitable guided surgery technique for their patients.

Abbreviations

CBCT	Cone Beam Computed Tomography
CI	Confidence Interval
CNC	Computer Numerical Control
CONSORT	Consolidated Standards of Reporting Trials
FDA	Food and Drug Administration
FG	Fully Guided
FOV	Field of View
FP3	Fixed Prosthesis Class 3
PG	Partial Guided
SD	Standard Deviation

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Authors' contributions

AYA and RSA made substantial contributions to the conception and design of the study. AYA, RSA, and WII collected data. WII and DE analyzed and interpreted data. The manuscript was drafted by DE and critically reviewed by AYA, RSA, and WII. All authors read and approved the final version of the manuscript.

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Data availability

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

This study obtained approval from the ethics committee of MSA University with a number REC-D 4147-4 and was conducted in accordance with the Helsinki Declaration of 1975, as revised in 2013. The study protocol was registered on clinicaltrials.gov under the number NCT06542562. All participants provided written informed consent.

Consent of publication

Written informed consent was obtained from all patients for the publication of their photographs included in this study.

Competing interests

The authors declare no competing interests.

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