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Randomized controlled trial on the efficacy of a custom-made, fully guided implant system for flapless crestal sinus floor elevation: Accuracy and patient-reported outcomes

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Abstract

Objective: To compare fully guided flapless implant surgery using a light-cured surgical guide (FG group) with partially guided open flap surgery (PG group) in the posterior maxilla when performing simultaneous sinus floor elevation in terms of the accuracy, time requirements, and patient/clinician-reported outcomes (PROMs and CROMs).

Materials and Methods: In this study, 56 tissue-level implants were placed with crestal sinus floor elevation in 56 patients at single-tooth sites, with 28 implants allocated to the PG group and 28 to the FG group. The deviations of the placed implants from the virtually planned positions were measured at the implant platform and apex and for the angular deviation. The presurgical preparation time and the duration of surgery were measured. PROMs and CROMs were made by administering questionnaires at multiple time points.

Results: Horizontal deviations at the platform and apex and the angular deviation were significantly smaller in the FG group than the PG group ($p < .05$). Presurgical preparation and surgery times were significantly shorter in the FG group ($p < .001$). Patient satisfaction and willingness to receive repeat treatment were significantly better in the FG group than in the PG group ($p < .005$ and .025, respectively). Clinicians were more satisfied in the FG group than the PG group ($p < .05$).

Conclusion: When placing an implant with sinus floor elevation, the flapless approach using a fully guided surgical system can be more accurate, faster, and increase the satisfaction of both the clinician and patient compared to the partially guided surgery.

KEYWORDS
clinical trial, dental implants, maxillary sinus floor elevation, randomized controlled trial, surgical techniques

Jongseung Kim, Jin-Young Park and Joo-Yeon Lee contributed equally to the writing of this manuscript.

1 | INTRODUCTION

Placing an implant in the correct restoration-driven position is crucial for preventing biological and aesthetic complications and thereby enhancing the longevity of the implant restoration (Furhauser et al., 2022; Saleh et al., 2022). The traditional free-hand method of implant placement has been the domain of a skilled surgeon. However, regardless of the surgeon's skill level, the clinical situation can easily result in the implant position deviating from the planned position (Gargallo-Albiol et al., 2020; Putra et al., 2020; Yogui et al., 2021). Fully guided implant systems have been developed by applying CAD/CAM technology and digital fabrication methods, including three-dimensional (3D) printing and milling (Zhu et al., 2019). These advancements have allowed more-accurate and less invasive implant placement (D'Haese et al., 2017), reduced surgery times, reduced patient discomfort, the possibility of immediate provisional restoration (Sancho-Puchades et al., 2019; Schneider et al., 2018; Schneider, Sancho-Puchades, Mir-Marí, et al., 2019; Schneider, Sancho-Puchades, Schober, et al., 2019), and improved implant survival rates (Pedrinaci et al., 2023).

Additional time spent at the dentist while the surgical guide is being fabricated can be inconvenient for the patient. For the clinician, extra steps and time spent in impression-taking, shipping, and guide fabrication may reduce the overall benefit–cost ratio. A fully guided implant system has been introduced recently (Song et al., 2021) that can be manufactured immediately at the chairside without visits to the laboratory by incorporating moldable light-cured composite resin as the main material for the surgical guide body. According to preclinical studies (Park et al., 2021; Song et al., 2021), the in-house, model-free features of this system may substantially improve clinician satisfaction. However, this system has yet to be tested in clinical situations.

The main advantage of using a full surgical guide is that the relative ease of accurately placing the implant in the planned position provides the surgeon with extra time and stamina for performing simultaneous procedures such as sinus floor elevation and soft-tissue augmentation even when placing multiple implants (Park et al., 2020; Romandini et al., 2023). However, the literature lacks well-designed clinical trials that have tested this assumption. This study hypothesized that using a fully guided implant system in the posterior maxilla requiring sinus floor elevation allows implants to be placed with greater accuracy, more quickly, and with higher patient and clinician satisfaction compared with the conventional procedure using a partially guided surgical stent.

Therefore, the aim of this study was to compare fully guided flapless implant surgery with partially guided open flap implant surgery in the posterior maxilla requiring transcrestal sinus floor elevation, in terms of accuracy, overall time, and patient- and clinician-reported outcome measurements (PROMs and CROMs).

2 | MATERIALS AND METHODS

2.1 | Study design and participants

This study was designed as a two-center, single-blinded, prospective, randomized controlled clinical trial and was conducted in accordance with the Declaration of Helsinki and the Good Clinical Practice Guideline. The protocols for this study were approved by the Institutional Review Board for Clinical Research at the Dental Hospital of Yonsei University (Approval no. 2–2020-0053). The present study was prepared based on the CONSORT guidelines and registered in the Clinical Research Information of National Research Institute of Health in South Korea (No. KCT0005465) (Data S2).

The participants were enrolled at the Department of Periodontology, Research Institute for Periodontal Regeneration, Yonsei University College of Dentistry (Seoul, South Korea), and at the Department of Periodontology and Dental Research Institute, School of Dentistry, Seoul National University (Seoul, South Korea) from 2020 to 2022.

2.1.1 | Inclusion criteria

The following inclusion criteria were applied for the study:

- Male or female patients with age over 19 years.
- Partially edentulous in the posterior maxilla, with a need for implant placement. This includes both free-end sites and sites between teeth.
- A minimum of 12 weeks of healing following tooth extraction.
- Adequate residual ridge height (4–8 mm) to facilitate sinus floor elevation via the crestal approach.
- No requirement for ridge augmentation procedures.

2.1.2 | Exclusion criteria

The following exclusion criteria were applied for the study:

- Presence of cystic lesions or infection in the maxillary sinus.
- Uncontrolled systemic diseases such as diabetes.
- Pregnant or lactating.
- History of radiation or chemotherapy in the head and neck area.
- Bisphosphonates taken within the previous 4 months.
- Smoking more than 20 cigarettes daily.
- Considered unsuitable by the clinician due to lack of compliance or ability to cooperate.

2.2 | Group allocation, randomization, and blinding

In this two-center trial, randomization was stratified by center to ensure balanced allocation across the sites. Participants were first screened based on the predefined inclusion and exclusion criteria. Upon meeting these criteria, written informed consent was obtained from each participant before their enrollment in the study. Based on a computer-generated random number created with a block size of 4, the enrolled patients were randomly assigned to one of the following treatment groups: (1) fully guided surgery group using a light-cured-composite-resin-based full guide (VAROguide, Neobiotech, Seoul, South Korea) (FG group) or (2) partially guided surgical stent group (PG group). Throughout the course of the study, the information regarding group allocation was kept undisclosed to the participants. The operator could not be blinded due to the distinct differences between the two groups.

2.2.1 | Presurgical procedure: Surgical stent and guide fabrication

Prior to proceeding with the study, a calibration meeting was conducted for education of study protocols and instructions on guide fabrication and application during surgery using models. On the day patients visited the centers for the pre-surgical procedure, a computer-generated randomization list and sealed envelopes were used to determine which of the two surgical guide fabrication protocols would be applied. In the FG group, a ready-made preguide (PGM13, Neobiotech) constructed from uncured composite resin (dimethacrylate and diurethane) inside a clear acrylic impression tray was seated in the region of the missing teeth at the chairside. A polyvinyl alcohol sheet covered the preguide to prevent the uncured resin from sticking to the teeth and also to prevent the formation of undercuts within the resin impression. With the preguide in situ, light polymerization was carried out for 15 s each toward the buccal and palatal sides. The partially polymerized preguide was retrieved from the oral cavity, and then the inner and outer surfaces were light cured for an additional 30 s. The polymerized preguide was placed back in the mouth and checked for fit and stability. Then, cone-beam computed tomography (CBCT) was performed with the preguide seated in the mouth. The preguide contained six radiopaque dots for transferring the position of the preguide onto the CBCT images using implant planning software (VARO Plan, Neobiotech). Virtual planning of the implant position was performed using this software. The planned data were saved on a USB flash drive and transferred to a milling machine (VARO Mill, Neobiotech). Finally, the preguide was placed inside the milling machine, and the drill sleeve was created at the precise location to complete the fabrication of the full surgical guide.

In the PG group, alginate impressions were taken of both jaws, and the interocclusal relationship was recorded (Blu-Mousse Bite Registration, Parkell, NY, USA) at the chairside. In the laboratory, study casts were made and a radiographic stent was fabricated using acrylic resin. A drill sleeve was punctured at the prosthetically driven location and filled with gutta-percha. CBCT (Q-FACE, HDXWILL, Seoul, South Korea) was performed with the radiographic stent in situ (85 kV, 8 mA, and exposure time of 24 s). The implant position was planned with reference to the position of the radiopaque gutta-percha using 3D imaging software (Dental System, 3Shape, Copenhagen, Denmark). The position of the gutta-percha was reviewed to ensure that it accurately represented the desired implant position. If the radiographic stent was considered unsuitable, the drill sleeve location was corrected, and CBCT was repeated. Once the implant was correctly positioned, the gutta-percha was removed from the drill sleeve. The surgical stent was then disinfected and delivered to the clinic for use in the surgery.

2.2.2 | Surgical procedure

Prophylactic antibiotic (1 g of amoxicillin) was prescribed 1 h before the surgery. Perioral areas of skin were disinfected using BETADINE swabs, and 0.2% chlorhexidine mouth rinse was administered for 30 s. Infiltrative anesthesia was performed at the surgical site using 2% lidocaine and 1:100,000 epinephrine.

Serial photography of the overall procedure of the surgery is shown in Figure 1. In the FG group, flapless surgery was performed using a sinus floor elevation kit (VAROguide Sinus Kit, Neobiotech). A resin-based full surgical guide was seated in the mouth until the implants were placed. A soft-tissue punch from the kit was used to expose the alveolar bone at the drilling site.

In the PG group, open flap surgery was performed using a surgical kit for freehand crestal sinus floor elevation (Neo Master Kit, Neobiotech). Flap elevation was performed with the aid of a mid-crestal incision in the edentulous region to check the exact drilling position, and sulcular incisions were made around the adjacent teeth to elevate a full-thickness mucoperiosteal flap. Initial drilling was performed using the surgical stent in situ. The stent was then removed for the remaining procedural steps.

Sequential drilling was performed using the sinus drill and stoppers at the anticipated length reaching just beneath the sinus floor. An S-Reamer, which has a non-cutting end, was then used to elevate the sinus floor. The vertical distance from the expected drilling point on CBCT planning to the sinus floor was measured. In the PG group, a stopper was installed on the S-Reamer based on the distance from the bone crest to the sinus floor, and drilling was performed without tearing the Schneiderian membrane. In the FG group, drilling was performed with an S-Reamer and stopper based on the distance from the top of the guide sleeve to the sinus floor, ensuring safe drilling without directly visualizing the bone crest through a flapless approach. The sinus membrane was checked for integrity using a depth gauge and the Valsalva maneuver, and was then further elevated using hydraulic pressure induced by injecting saline through a tube attached to a syringe included in the kit.

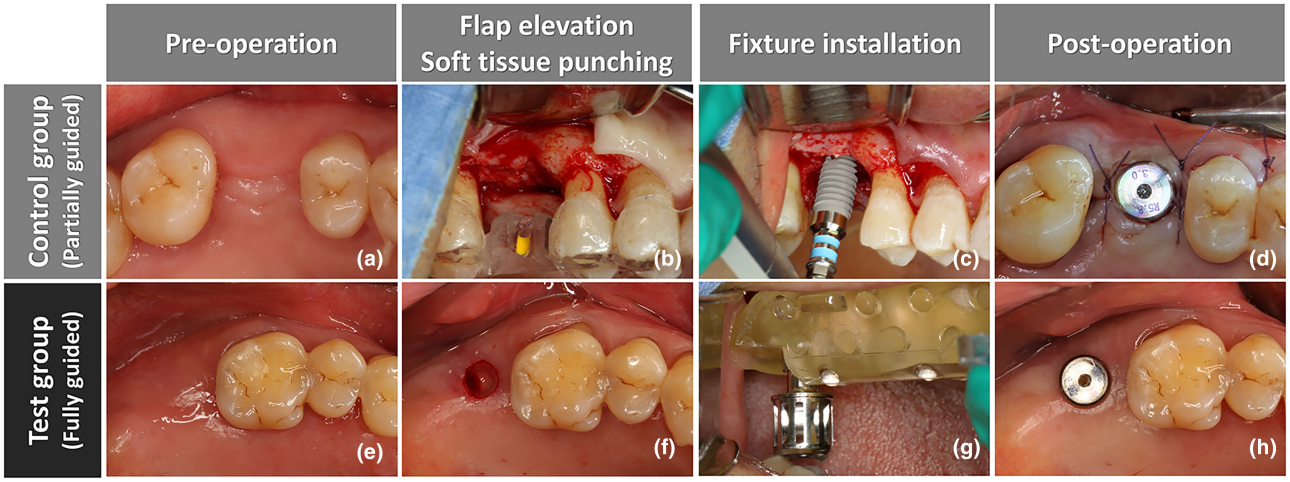

FIGURE 1 Simultaneous crestal sinus grafting procedures with implant installation using the partially guided system (PG group, a–d) and fully guided system (FG group, e–h). (a, e) Clinical situation before implantation. (b) After flap elevation and surgical stent application. (c) Implant fixture installation after the crestal sinus grafting procedure. (d) Postoperative situation in the PG group. (f) Soft-tissue punching using a full surgical guide in the correct position. (g) Implant fixture installation at the correct depth and position using the fully guided surgical system after crestal sinus floor elevation and the grafting procedure. (h) Postoperative situation in the FG group.

A particulate bovine bone substitute (Bio-Oss, Geistlich Pharma, Wolhusen, Switzerland) was applied to the sinus using a carrier. Finally, a tissue-level implant (Neo IT-III, Neobiotech) was placed. Guided implant placement was performed using a full surgical guide in the FG group, whereas freehand implant placement was performed in the PG group.

The implant position after placement was recorded using intraoral scanning with a scan body attached to the implant. A healing abutment was connected to the implant. In the PG group, the flap was repositioned and sutured using 4–0 Monosyn sutures (B. Braun, Seoul, South Korea).

2.2.3 | Follow-up examinations

Wound dressing was performed using 3% hydrogen peroxide on day 1 and day 10 following the surgery. The sutures were removed in the PG group on day 10. Follow-up examinations were performed at 4 and 12 weeks after the surgery.

2.3 | Measurements

All raw data, including details of implant positions, implant planning files, pre-surgical preparation times, surgery durations, PROMs, and CROMs from Centers 1 and 2, were forwarded to a blinded, trained outcome assessor at the Center 1 (J.S.K).

To ensure reproducibility, all measurements were performed twice by a single outcome assessor, and intra-examiner reliability evaluation was performed. Intra-class correlation coefficient was 0.95 for the primary outcome (deviation at the implant shoulder).

2.3.1 | Deviation between virtually planned and actually placed implant positions

Based on the virtually planned position of the implant, a STL (Standard Triangle Language) file of the virtual abutment was created and provided to a blinded outcome assessor. These two raw data sets were superimposed using 3D analysis software (Geomagic Verify, SculptCAD, Dallas, TX, USA), which was used to measure the deviation between the virtually planned and actually placed positions (Figure 2).

Measurements of the linear deviations

The following parameters were measured to assess the placement accuracy (a detailed schematic diagram is in Figure S1):

- Horizontal platform deviation, corresponding to the horizontal distance between the virtually planned and actually placed implant platforms.
- Horizontal apex deviation, corresponding to the horizontal distance between the virtually planned and actually placed implant apices.
- Angular deviation, corresponding to the angle between the virtually planned and actually placed implant axes.
- Vertical platform deviation, corresponding to the vertical distance between the virtually planned and actually placed implant platforms.
- Vertical apex deviation, corresponding to the vertical distance between the virtually planned and actually placed implant apices.

Subgroup analysis of the linear deviations in the FG group

In the FG (Fully Guided) group, a detailed subgroup analysis was conducted based on the following criteria:

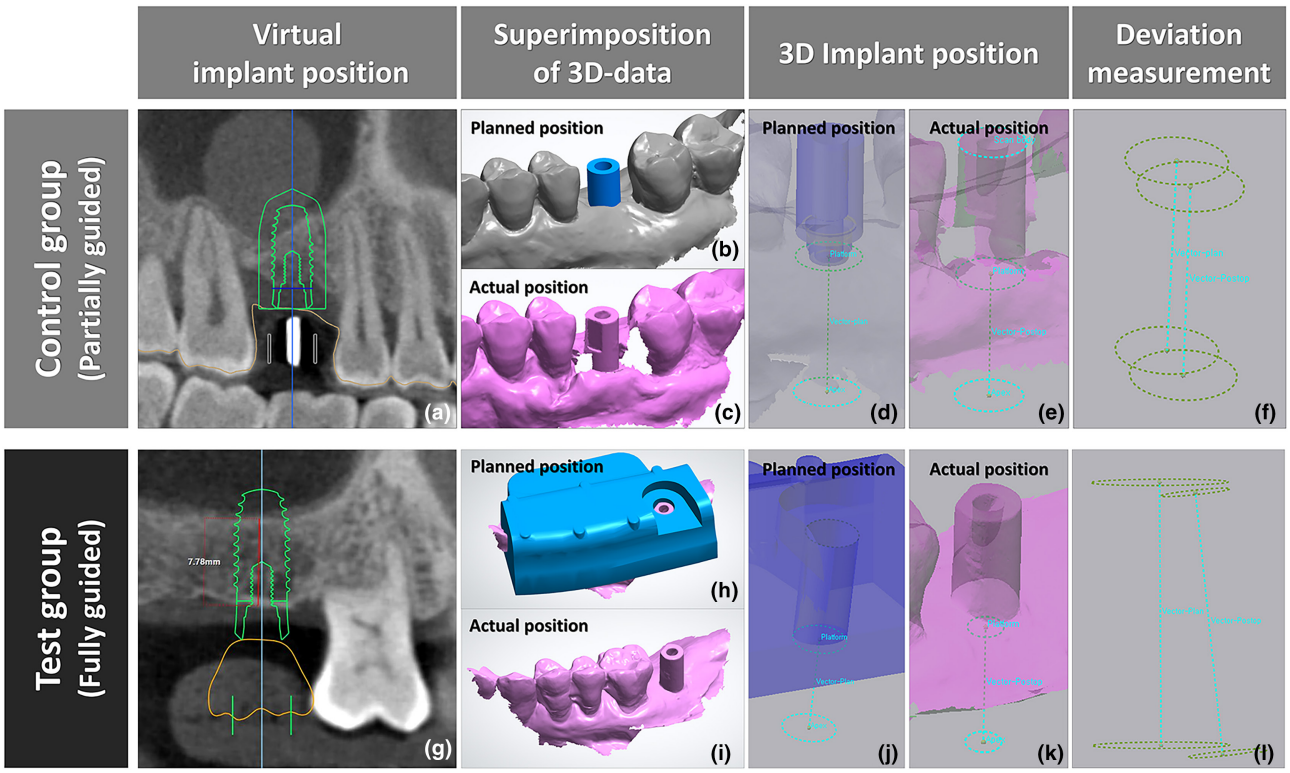

FIGURE 2 Schematic images showing measurement procedures for the deviations in implant fixture positions in the PG group (a–f) and FG group (g–l). (a, g) Virtual planning of implants on a CBCT image. (b) Virtual abutment derived with the virtually planned fixture position in the PG group. (h) Superimposed STL file of the virtual surgical guide at the virtually planned implant position in the FG group. (c, i) STL file after connecting a ready-made scan body to the actually placed implant. (d, e, j, k) After superimposing the two STL files in (b) and (c), implant positions were derived using computer software. (f, l) Deviations of positions and angles were measured.

- Type of support: distinguishing between tooth-supported and free-end extension sites.
- Surgeon's experience with the fully guided system: categorized by the number of cases handled using this system (<5 cases, ≥5 and <10 cases, or ≥10 cases).
- Residual bone height (RBH) at the implant placement site: divided into three groups based on RBH measurements: group 1 with RBH ≥ 2.93 mm and ≤4.58 mm, group 2 with RBH ≥ 4.71 mm and ≤7.64 mm, and group 3 with RBH ≥7.83 mm and ≤9.95 mm.
- Centers: comparison between Center 1 and Center 2.

Scatter plots of the deviations from virtually planned implant positions

The directions of the deviations from the virtually planned positions for the apex and platform and for the angular deviations were marked on scatter plots to allow qualitative evaluations of the error distributions (for a detailed explanation, refer to Figure S2 in the supplement file and appendix A in Data S1). Briefly, a two-dimensional (2D) coordinate system was used to determine the direction of deviation for the horizontal platform and apex and for the angular deviation. The mesiodistal axis was defined by the line connecting the central fossae of the adjacent teeth and the center of the virtually planned implant at either the platform or apex. The buccopalatal axis was perpendicular to the mesiodistal axis and originated from the center of the virtually planned implant at either the platform or apex:

- Horizontal platform deviation position (A'_p), corresponding to the position of the actually placed implant platform on the 2D coordinates.
- Horizontal apex deviation position (A'_a), corresponding to the position of the actually placed implant apex on the 2D coordinates.
- Angular deviation position (A'_θ), corresponding to the actual amount of angular deviation from the origin position and the direction of the actual deviation.

A one-dimensional (1D) coordinate system was used to determine whether the direction of vertical deviation was either coronal (a negative value) or apical (a positive value) relative to the virtually planned position (Figure S2):

- Vertical platform deviation position (A''_p), corresponding to the vertical distance between the virtually planned and actually placed implant platforms.
- Vertical apex deviation (A''_a), corresponding to the vertical distance between the virtually planned and actually placed implant apices.

Five scatter plots were drawn using these five accuracy parameters, and the FG and PG groups were compared qualitatively by a blinded outcome assessor.

2.3.2 | Time evaluations

The times taken for presurgical preparation and the surgery were recorded for both groups. The presurgical preparation time included the chair time (curing and fitting of the preguide for the FG group vs. impression-taking and stent fitting for the PG group) and office preparation time (virtual planning and guide milling for the FG group vs. stent fabrication and shipping time for the PG group).

The times taken for the entire surgery were measured for both groups based on video recordings of every surgery. The times required for the different steps of the surgery were also measured to allow a detailed analysis between groups. These included the times taken for flap elevation or tissue punching, osteotomy, sinus floor elevation and grafting, implant installation, healing abutment connection, and suturing.

2.3.3 | PROMs and CROMs

PROMs were made by administering a questionnaire at the times of guide making or impression-taking, implant surgery, postoperative dressing, and suture removal after 10 days, 1 month, and 12 weeks. The following questions were answered using a numerical rating scale (NRS) ranging from 0 to 10: (Q1) pain in the area where the treatment was performed, (Q2) the amount of swelling in the area where the treatment was performed, (Q3) the adequacy of the time required for treatment, (Q4) discomfort in the area where the treatment was performed, (Q5) satisfaction with the treatment, and (Q6) the intention to be treated again in the same way.

CROMs were made by administering a questionnaire at the time of implant surgery. The following questions were answered on an NRS ranging from 0 to 10: (Q1) ease of guide application, (Q2) improvement of surgical effectiveness, (Q3) improvement of positional accuracy, (Q4) clinician's satisfaction, (Q5) patient's convenience from the clinician's perspective, (Q6) tolerability of the surgery time, and (Q7) willingness to use the same type of surgical guide again.

2.4 | Statistical analyses

Data management and statistical analyses were conducted using SPSS software, version 28 (IBM). The Shapiro–Wilk test indicated that the data did not follow a normal distribution ($p < .05$), necessitating non-parametric tests for all comparisons. Specifically, the Mann–Whitney U test and the Kruskal–Wallis test were employed. Descriptive statistics such as the linear deviation of implant placement accuracy, pre-surgical preparation times and surgery times, patient-reported outcome measures (PROMs), and clinician-reported outcome measures (CROMs) were reported using the mean, median, and interquartile range.

A *p*-value of less than .05 was considered statistically significant for all analyses. The primary outcome of the study was the deviation of the placed implant from the planned position, measured at the implant shoulder.

2.5 | Sample size calculation

The sample size for this study was determined using G*Power 3.1, based on the findings from Schneider, Sancho-Puchades, Mir-Marí, et al. (2019), Schneider, Sancho-Puchades, Schober, et al. (2019), which assessed the accuracy of implant placement post-surgery compared to preoperative planning, utilizing different protocols. The primary outcome was the implant placement accuracy at the level of the implant shoulder, which was deemed most clinically significant.

In the cited study, the deviation at the implant shoulder was observed to be 1.25 ± 0.62 mm in the control group (free-handed approach) and 0.72 ± 0.31 mm in the test group (computer-assisted planning). The null hypothesis was that there is no difference between the two groups regarding the deviation at the implant shoulder. To reject this hypothesis with a significance level of 0.05 and a power of 0.95, an effect size (*d*) of 1.08 was calculated. This led to a minimum required sample size of 24 participants per group. Factoring in a dropout rate of 10%, the total sample size was determined to be 54 participants, with 27 in each group.

3 | RESULTS

3.1 | Description of the patient population and demographics

In this study, 56 implants were placed with simultaneous crestal sinus floor elevation in 56 patients: 28 in the Partially Guided (PG) group and 28 in the Fully Guided (FG) group. However, one patient from the PG group was excluded due to inadequate primary stability of the implant. Additionally, osseointegration failure at 12 weeks led to the removal of one implant in the PG group and three implants in the FG group. Consequently, for the statistical analysis of implant positional accuracy, time evaluation, and clinician-reported outcome measures (CROMs), 27 implants in the PG group and 28 implants in the FG group were included. For the patient-reported outcome measures (PROMs) analysis, data from 26 implants in the PG group and 25 implants in the FG group were used.

All patients enrolled in this study were in good general health. The distribution of the implant site, center, age, and gender is detailed in Table 1.

3.2 | Deviations in implant fixture positions

3.2.1 | Measurements of linear deviations

In the FG group, the actually placed implants exhibited 1.37 [1.15–1.59] mm of horizontal platform deviation, 1.85 [1.54–2.16] mm of horizontal apex deviation, 4.69 [3.96–5.41]° of angular deviation, 0.85 [0.62–1.08] mm of vertical platform deviation, and 0.87 [0.64–1.10] mm of vertical apex deviation.

In the PG group, the actually placed implants exhibited 2.02 [1.69–2.36] mm of horizontal platform deviation, 2.57 [2.16–2.99] mm of horizontal apex deviation, 6.65 [5.32–7.99]° of angular deviation, 1.01 [0.67–1.34] mm of vertical platform deviation, and 1.04 [0.70–1.38] mm of vertical apex deviation.

The deviations were significantly smaller in the FG group than in the PG group in terms of the horizontal platform and apex and for the angular deviation ($p < .05$) (Table 2, Figure 3).

3.2.2 | Subgroup analysis of the linear deviations in the FG group

The support type (free-ending vs. tooth-bound) and the surgeon's experience (<5 cases, ≥5 and <10 cases, or ≥10 cases) made no difference to the implant placement accuracy ($p > .05$). There were no significant differences in terms of accuracy between the centers 1 and 2. According to the RBH, the vertical platform deviation was significantly lower in Group 3 than in Group 2 (0.51 [0.18–0.83] mm vs. 1.11 [0.71–1.51] mm, respectively, $p = .04$), as was the vertical apex

TABLE 1 Demographic table.

		PG	FG	
Total 18+		27	28	
	Frequency *N* (%)	**SD *N* (%)**	**Frequency *N* (%)**	**SD *N* (%)**
Gender				
Male	12 (44.4%)	3.1 (9.6)	8 (28.6%)	2.6 (8.5)
Female	15 (55.6%)	3.3 (9.6)	20 (71.4%)	3.6 (8.5)
Age				
Mean ± SD	52.8 ± 14.3		59.8 ± 13.6	
18–29	3 (11.1%)	1.7 (6.0)	2 (7.1%)	1.4 (4.9)
30–49	5 (18.5%)	2.1 (7.5)	4 (10.7%)	1.7 (5.8)
50–64	13 (51.9%)	3.2 (9.6)	13 (50.0%)	3.2 (9.4)
65+	6 (18.5%)	2.1 (7.5)	9 (32.1%)	2.7 (8.8)
Site				
Tooth supported	18 (66.7%)	3.5 (9.1)	14 (50.0%)	3.2 (9.4)
Free end	9 (33.3%)	2.7 (9.1)	14 (50.0%)	2.2 (9.4)
Center				
Center 1	15 (55.6%)	3.3 (9.6)	15 (53.6%)	3.3 (9.4)
Center 2	12 (44.4%)	3.1 (9.6)	13 (46.4%)	3.2 (9.4)

TABLE 2 Accuracy analyses of the implant positions in the FG and PG groups.

	Platform deviation (mm)	**Apex deviation (mm)**	**Angular deviation (°)**	**Platform vertical deviation (mm)**	**Apex vertical deviation (mm)**
FG group ($N = 28$)	1.37, 1.41 (0.83–1.74)	1.85, 1.88 (1.24–2.47)	4.69, 4.93 (3.11–5.93)	0.85, 0.66 (0.36–1.15)	0.87, 0.71 (0.37–1.19)
PG group ($N = 27$)	2.02, 1.94 (1.38–2.60)	2.57, 2.47 (1.87–3.09)	6.65, 6.38 (4.17–8.52)	1.01, 0.65 (0.37–1.48)	1.04, 0.72 (0.34–1.60)
p	**.004**	**.025**	**.026**	.775	.807

Note: Data are mean, median (interquartile range, Q1–Q3) values.
Boldface indicates statistically significant in the Mann–Whitney *U* test ($p < .05$).

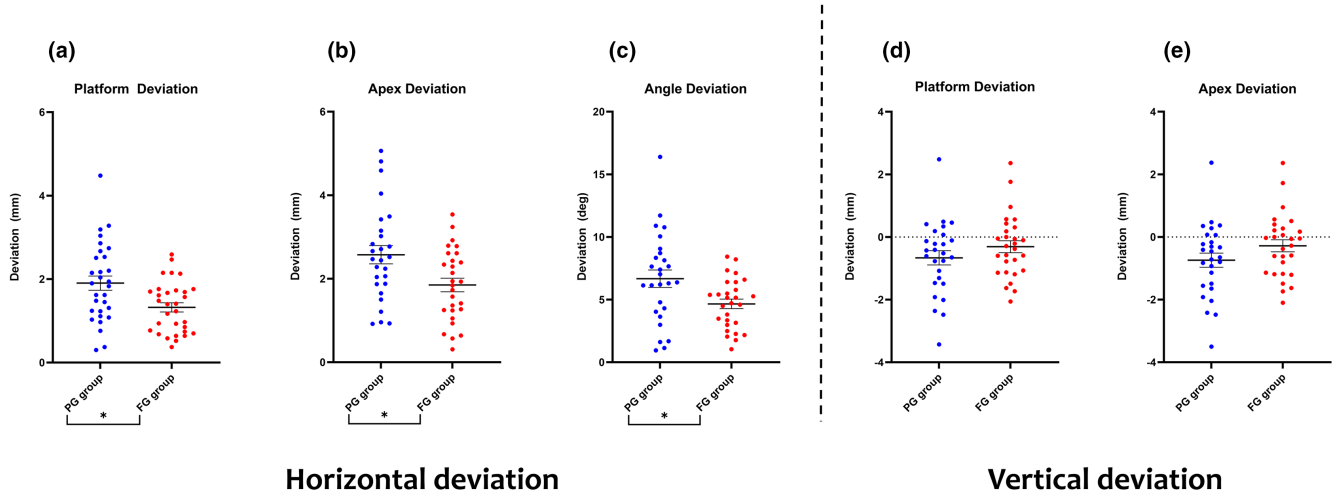

FIGURE 3 Positional accuracy of the implant fixtures. In each scatter plot, the long horizontal line indicates the mean, the short horizontal line indicates the 95% confidence interval, and the scattered dots indicate the analyzed individual deviation of the actually placed implants. (a) Horizontal platform deviation. (b) Horizontal apex deviation. (c) Angular deviation. (d) Vertical platform deviation. (e) Vertical apex deviation. An asterisk (*) indicates a statistically significant difference between groups.

deviation (0.54 [0.21–0.87] mm vs. 1.11 [0.70–1.52] mm, respectively, $p = .022$) (Table 3, Figure 3).

3.2.3 | Scatter plot of the implant deviation position

At the platform level, scatter plots for the FG group appeared to be more concentrated toward the virtually planned position, while those for the PG group were uniformly distributed in all directions (Figure 4). In the PG group, the deviation was more pronounced in the buccopalatal than the mesiodistal direction.

At the apex level, the FG group exhibited a greater concentration toward the virtually planned position compared with the PG group. There was a greater tendency for deviation toward the distal aspect in both groups.

In terms of the angular deviation, the FG group exhibited a greater concentration toward the virtually planned position compared with the PG group. In both groups, there was a tendency for mesial tilting, with this being more pronounced in the PG group.

Vertically, both FG and PG groups revealed a tendency of coronal positioning compared with the virtually planned position, and the variations appeared to be greater in the PG group (Figure 3).

3.3 | Time evaluations

3.3.1 | Presurgical preparation time

The chair time was significantly shorter in the FG group than the PG group ($p < .001$) (Table 4). Curing and fitting of the preguide took 7:24 min:s in the FG group on average, while impression-taking and stent fitting resulted in a collective chair time of 11:05 min:s in the PG group.

The office preparation time was significantly shorter in the FG group than the PG group ($p < .001$). Office preparation took 14:59 min:s in the FG group, which included virtual planning and guide milling. Stent fabrication and shipping took 6.1 days in the PG group.

3.3.2 | Surgery time

The mean surgical time was significantly shorter in the FG group than in the PG group (10:21 min:s vs. 16:27 min:s, respectively) ($p = .001$) (Table 5). This was due to tissue punching in the FG group taking significantly less time than flap elevation in the PG group (1:02 min:s vs. 2:51 min:s, respectively, $p < .001$), in addition to the times spent on suturing (0:00 min:s vs. 3:15 min:s, respectively, $p < .001$). There were no significant differences in the times taken for drilling, sinus floor elevation, and grafting ($p > .05$).

3.4 | PROMs and CROMs

In terms of the PROMs (Table 6), patient satisfaction and willingness to receive repeat treatment were significantly better in the FG group than in the PG group ($p < .005$ and .025, respectively) (Figures 5 and 6). Regarding the CROMs (Table 7), the FG group performed significantly better than the PG group across all parameters ($p < .05$).

4 | DISCUSSION

The purpose of this study was to determine the accuracy as well as the time, PROMs, and CROMs when using this system for flapless surgery in the posterior maxilla, compared to open flap surgery using a partially guided surgical stent. The main findings were as follows:

TABLE 3 Accuracy analyses of the implant positions in the FG group.

Contributing factor	Platform deviation (mm)	Apex deviation (mm)	Angular deviation (°)	Platform vertical deviation (mm)	Apex vertical deviation (mm)
Support type					
Tooth ($N=14$)	1.15, 0.95 (0.70–1.61)	1.70, 1.60 (0.81–2.65)	4.57, 5.15 (2.44–5.70)	0.85, 0.57 (0.39–1.13)	0.86, 0.53 (0.38–1.18)
Free-end extension ($N=14$)	1.58, 1.64 (1.40–1.75)	2.00, 2.04 (1.45–2.42)	4.80, 4.54 (3.56–6.14)	0.85, 0.83 (0.38–1.16)	0.87, 0.83 (0.36–1.19)
p	.294	.822	.918	.951	.886
Experience of using FG					
<5 cases ($N=14$)	1.37, 1.32 (0.81–1.76)	1.86, 1.88 (1.25–2.56)	4.82, 5.27 (3.56–5.70)	0.88, 0.66 (0.34–1.13)	0.90, 0.72 (0.30–1.18)
≥5 and <10 cases ($N=9$)	1.45, 1.61 (0.97–1.70)	1.95, 1.94 (1.24–2.61)	4.60, 4.60 (3.15–5.27)	0.85, 0.96 (0.38–1.19)	0.86, 0.99 (0.38–1.21)
≥10 cases ($N=5$)	1.21, 0.85 (0.74–1.67)	1.65, 1.57 (1.36–2.34)	4.45, 4.49 (2.17–6.40)	0.77, 0.57 (0.56–0.78)	0.78, 0.56 (0.51–0.81)
p	.712	.829	.880	.977	.988
Vertical RBH (mm)					
Group 1 (≥2.93 and ≤4.58, $N=9$)	1.42, 1.61 (0.94–1.70)	1.92, 2.14 (1.24–2.61)	4.04, 4.60 (2.26–5.15)	0.97, 0.78 (0.42–1.49)	0.98, 0.81 (0.38–1.49)
Group 2 (≥4.71 and ≤7.64, $N=9$)	1.43, 1.23 (0.93–1.76)	1.92, 1.84 (1.41–2.34)	5.12, 5.41 (3.81–6.40)	1.11, 1.13 (0.59–1.19)	1.11, 1.18 (0.60–1.21)
Group 3 (≥7.83 and ≤9.95, $N=10$)	1.27, 1.41 (0.77–1.69)	1.72, 1.42 (0.96–2.39)	4.87, 4.73 (3.10–6.71)	0.51, 0.30 (0.19–0.69)	0.54, 0.33 (0.20–0.77)
p	.867	.797	.435	**.040**[a]	**.044**[a]
p (post hoc)	.720 (group 1 vs. 2)	.905 (group 1 vs. 2)	.356 (group 1 vs. 2)	.315 (group 1 vs. 2)	.278 (group 1 vs. 2)
	.661 (group 2 vs. 3)	.447 (group 2 vs. 3)	.780 (group 2 vs. 3)	**.017 (group 2 vs. 3)**[b]	**.022 (group 2 vs. 3)**[b]
	.661 (group 1 vs. 3)	.780 (group 1 vs. 3)	.356 (group 1 vs. 3)	.079 (group 1 vs. 3)	.079 (group 1 vs. 3)
Center					
Center 1 ($N=13$)	1.25, 1.23 (0.85–1.66)	1.76, 1.84 (1.14–2.36)	4.84, 4.71 (3.39–5.94)	0.77, 0.73 (0.40–1.10)	0.79, 0.82 (0.39–1.16)
Center 2 ($N=15$)	1.51, 1.67 (0.85–2.13)	1.95, 2.14 (1.36–2.78)	4.51, 5.14 (3.15–5.77)	0.94, 0.57 (0.29–1.73)	0.95, 0.56 (0.37–1.72)
p	.387	.467	.683	.928	.821

Note: Deviation measurements are sorted by contributing factors. Data are mean, median (interquartile range, Q1–Q3) values.

[a]Boldface indicates statistically significant in the Kruskal-Wallis test ($p<.05$).

[b]Boldface indicates statistically significant in the Mann–Whitney *U* test ($p<.05$).

(i) Accuracy was greater in the FG group than the PG group as measured by horizontal and angular deviations. (ii) The overall treatment time, including guide fabrication and surgery, was shorter in the FG group compared to the PG group. (iii) Both patients and clinicians reported higher satisfaction levels in the FG group compared to the PG group.

This study found that the linear deviation values in the FG group were similar to those reported in the literature using other 3D printed guides (Bover-Ramos et al., 2018; Jung et al., 2009; Putra et al., 2020, 2022; Tahmaseb et al., 2018). However, the angular deviation of 4.7° was larger than the typical values of 3–4° reported previously (Bover-Ramos et al., 2018; Jung et al., 2009; Putra et al., 2020, 2022; Tahmaseb et al., 2018). This difference could be attributed to several factors: First, most previous studies investigated pristine ridges requiring no additional procedures, whereas the present study focused on ridges with deficient heights, necessitating sinus floor elevation. The lack of bone in the apical region of the implant may negatively affect stability during drilling and fixture installation, which could result in greater angular deviation. Second, the current guide system utilizes a universal product for all patients containing a uniform drill sleeve height. In the circumstance where the implant shoulder has to be placed deeper than usual due to vertical ridge resorption or a longer

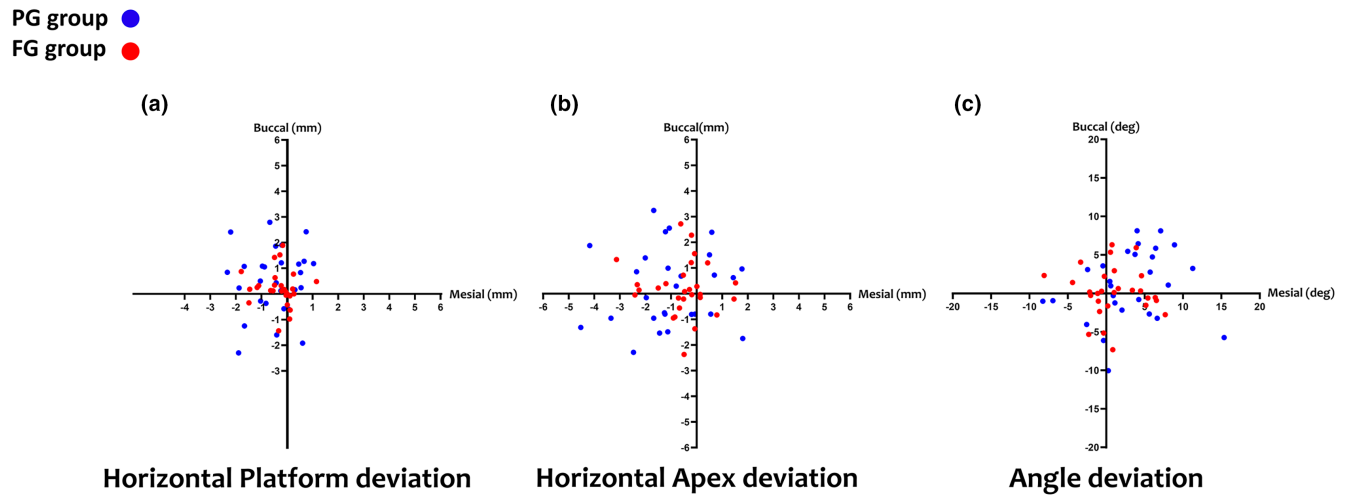

FIGURE 4 Scatter plots showing the positions of the horizontally deviated platform, horizontally deviated apex, and direction and the magnitude of the angular deviation. (a) Horizontally deviated platform position of the actually placed implants. (b) Horizontally deviated apex position of the actually placed implants. (c) Direction and amount of angular deviation of the actually placed implants. Vertically deviated platform and apex positions are shown in Figure 3d,e.

TABLE 4 Contributions to the presurgical preparation time (mean, median (95% confidence interval)).

	Chair time	Office preparation time
FG group ($N = 28$)	**Curing and fitting (min:s)**	**Virtual planning and guide milling (min:s)**
	7:24, 7:14 (4:57, 8:44)	14:59, 15:07 (11:53, 17:36)
PG group ($N = 27$)	**Impression-taking and stent fitting (min:s)**	**Stent fabrication and shipping time (days)**
	11:05, 10:59 (7:43, 14:11)	6.1, 6 (5, 8)
p	**.001**	**<.001**

Note: Data are mean (mean, median (interquartile range, Q1–Q3)) values.

Boldface indicates statistically significant in the Mann–Whitney *U* test ($p < .05$).

crown height of the adjacent teeth, the vertical dimension of the guide has to be reduced by milling so that it conforms to the drill cylinder height. This would result in a reduction in the height of the drill sleeve that can negatively affect the accuracy of fixture installation (Kessler et al., 2021; Wang et al., 2020). Third, this study was the first clinical trial using this type of surgical guide. As with any surgical instrument, there might be a learning curve for the clinicians to become fully proficient in its use. Nevertheless, the linear deviation of the FG group in this study was within the safety margin of 2 mm that has been suggested for avoiding anatomical risks (Tahmaseb et al., 2018).

It was particularly interesting that the present qualitative analysis of the direction of the implant deviation revealed a tendency to place implants too shallow, buccally, and with a mesial angulation in both groups, and that using the full surgical guide significantly reduced the variation. These findings were understandable given that all of the implants were placed in the posterior region, and hence the drill head was likely to approach from the mesial and buccal aspects, especially when the mouth opening was restricted. Also, implants might have been placed too shallow due to the lack of vertical ridge height combined with the surgeons' attempts to gain as much support and stability as possible from the available ridge.

The present subgroup analysis of the implant placement accuracy according to different risk factors in the FG group revealed that the magnitude of deviations can be affected by the remaining ridge height. It can be assumed from this finding that a smaller ridge height in the posterior maxilla may reduce the stability in the apical region of the implant that protrudes into the maxillary sinus, resulting in the implant deviating from the virtually planned position even when using a full surgical guide. It is noteworthy that only a borderline significant difference was found between groups 1 and 3, for which the difference in remaining ridge height was the largest. This might be explained by the greater variance of data in group 1 and the small sample size in each group.

On the other hand, the type of guide support was shown not to influence accuracy. A previous study found that guides with free-end extensions in the shortened dental arch provided less stability and lower implant placement accuracy compared with tooth-supported sites (Behneke et al., 2012). Another study found that free-end extensions of a single tooth site produced the same placement accuracy as tooth-supported sites (Schnutenhaus et al., 2016). A recent study using a non-metal-sleeved full surgical guide found that when there were multiple implantation sites in the posterior free-end extensions, the deviation from the virtually planned position was greater for the third and fourth sites from the most posterior tooth than for the first and second sites (Park et al., 2020). In the present study, all cases were conducted at single tooth sites; therefore, the results can be considered consistent with those of previous studies. In addition, the surgical guide used in this study had a bulky body and was less flexible than regular 3D-printed guides, and so the influence of the free-end-extension support could be expected to be less.

TABLE 5 Contributions to the surgery time.

	Tissue punching (FG group) flap elevation (PG group)	Drilling	Sinus augmentation and grafting	Implant installation	Healing abutment connection	Suturing (PG group)	Total
FG group ($N=28$)	1:02, 0:56 (0:18, 1:22)	2:35, 2:58 (0:53, 3:45)	4:41, 4:08 (2:27, 6:45)	1:39, 1:22 (1:05, 1:51)	0:23, 0:20 (0:15, 0:30)	0:00 ± 0:00	10:21, 10:13 (6:20, 13:39)
PG group ($N=27$)	2:51, 2:24 (1:47, 3:20)	3:37, 3:30 (1:39, 5:31)	4:51, 4:05 (2:22, 6:43)	1:31, 1:13 (0:48, 1:39)	0:22, 0:21 (0:16, 0:24)	3:15, 3:00 (2:35, 3:48)	16:27, 16:14 (9:39, 21:18)
p	**<.001**	.075	.987	.204	.799	**<.001**	**.001**

Note: Data are mean (mean, median (interquartile range, Q1–Q3)) values.
Boldface indicates statistically significant in the Mann–Whitney *U* test ($p < .05$).

TABLE 6 NRS scores for PROMs.

	Impression-taking		Surgery		1 day		10 days	
	Q1	Q2	Q1	Q3	Q1	Q2	Q1	Q2
FG group ($N=25$)	1.5, 0.0 (0.0, 3.5)	8.3, 10.0 (6.8, 10.0)	1.1, 0.0 (0.0, 1.3)	8.7, 10.0 (7.8, 10.0)	2.4, 1.0 (0.0, 4.3)	2.1, 1.0 (0.0, 4.0)	1.0, 0.0 (0.0, 1.0)	0.8, 0.0 (0.0, 1.0)
PG group ($N=26$)	1.8, 1.0 (0.0, 2.0)	8.4, 9.0 (7.8, 10.0)	1.5, 0.0 (0.0, 2.0)	8.2, 9.0 (7.0, 10.0)	1.6, 1.0 (0.0, 2.0)	1.7, 1.0 (0.5, 2.0)	0.5, 0.0 (0.0, 1.0)	0.6, 0.0 (0.0, 1.0)
p	.117	.201	.759	.465	.961	.697	.876	.756

	4 weeks				12 weeks		
	Q1	Q2	Q4	Q5	Q4	Q5	Q6
FG group ($N=25$)	0.3, 0.0 (0.0, 0.0)	0.1, 0.0 (0.0, 0.0)	8.6, 10.0 (9.0, 10.0)	8.7, 10.0 (9.0, 10.0)	0.2, 0.0 (0.0, 0.0)	**9.8, 10.0 (10.0, 10.0)**	**9.5, 10.0 (10.0, 10.0)**
PG group ($N=26$)	0.1, 0.0 (0.0, 0.0)	0.0, 0.0 (0.0, 0.0)	8.4, 10.0 (9.0, 10.0)	9.2, 10.0 (0.0, 10.0)	0.5, 0.0 (0.0, 1.0)	8.8, 9.0 (9.0, 10.0)	8.5, 9.0 (8.0, 10.0)
p	.354	.284	.413	.940	.360	**.005**	**.025**

Note: Data are mean (mean, median (interquartile range, Q1–Q3)) values.
Boldface indicates statistically significant in the Mann–Whitney *U* test ($p < .05$).

This study observed that the operator's experience did not affect the placement accuracy in the FG group. It is noteworthy that significant deviations have been found for novice surgeons with no previous experience in implant surgery even when they use a full surgical guide (Marei et al., 2019). However, for surgeons with a high degree of expertise in implant dentistry, implants were placed with high accuracy, regardless of their experience in using surgical guides (Cassetta & Bellardini, 2017). In the present study, all surgeons were capable of freehand implant placement and had past experience in using surgical guides. Therefore, it can be inferred that for the surgeons included in this study, the accuracy was not affected by the experience level in the FG group.

Furthermore, the analysis indicated that the type of center (Center 1 vs. Center 2) where the implant placement occurred did not significantly impact the accuracy of implant placement within the FG (Fully Guided) group. This finding suggests that the implant placement protocol was uniformly applied and well-calibrated across both centers, ensuring consistent results within the FG group.

Surgical guides were fabricated faster in the FG group than for the conventional stent. This could be attributed to the convenience of the preguide containing a light-cured composite resin, which can be rapidly converted to a full surgical guide after planning and milling at the clinic. The fabrication of the conventional stent took longer because the PG group requiring digital impressions of both jaws and communications with the laboratory until the surgical stent was finally delivered to the clinic.

The surgery duration was shorter in the FG group compared to the PG group, a difference largely attributable to the steps of incision, flap elevation, and suturing. What is noteworthy is that the difference in surgical time was not statistically significant in terms of drilling, sinus floor elevation, and implant installation. Nevertheless, the overall time difference was due to the fact that the use of the full guide in the FG group enabled safe crestal sinus floor elevation without tearing of the Schneider membrane even with a blind technique. This shortened the time required for flap elevation and suture. Although the time saved was approximately 5 min, this may not significantly impact the overall clinical experience. Despite the minimal difference in time, the use of a fully guided surgical approach facilitated a minimally invasive procedure with greater accuracy, eliminating the need to expose the alveolar bone. Conversely, the

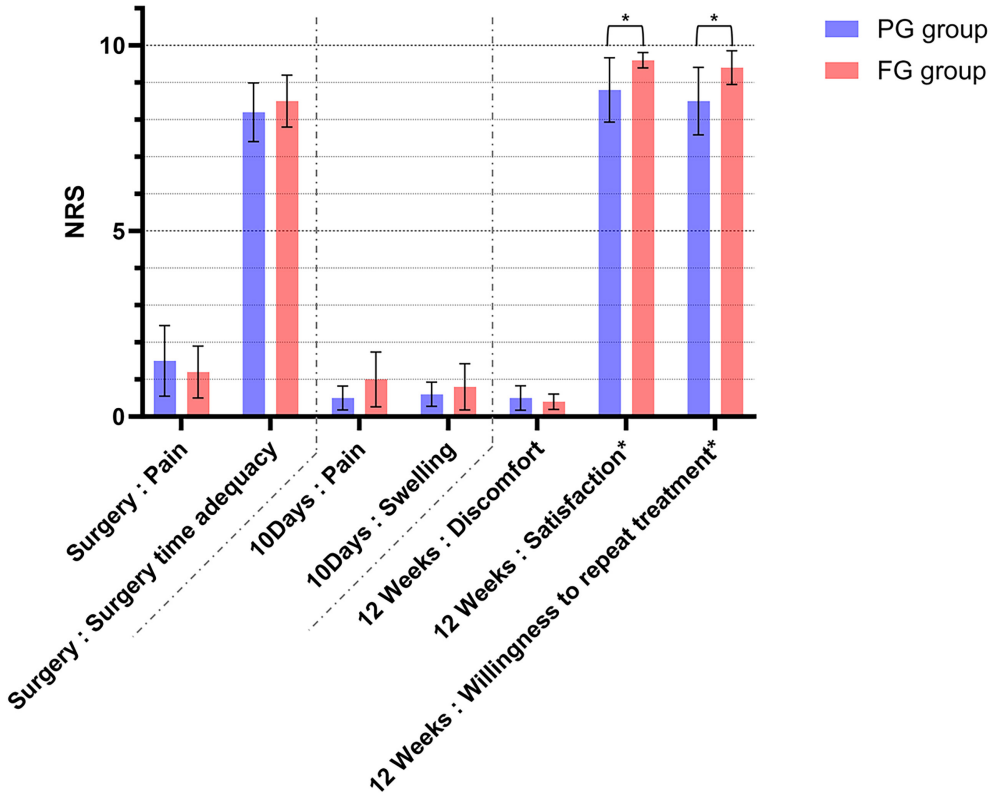

FIGURE 5 PROMs from a questionnaire with seven questions answered on an NRS from 0 to 10. Data are means and 95% confidence intervals. Patient satisfaction and willingness to receive repeat treatment at 12 weeks after surgery differed significantly between the two groups ($p < .05$).

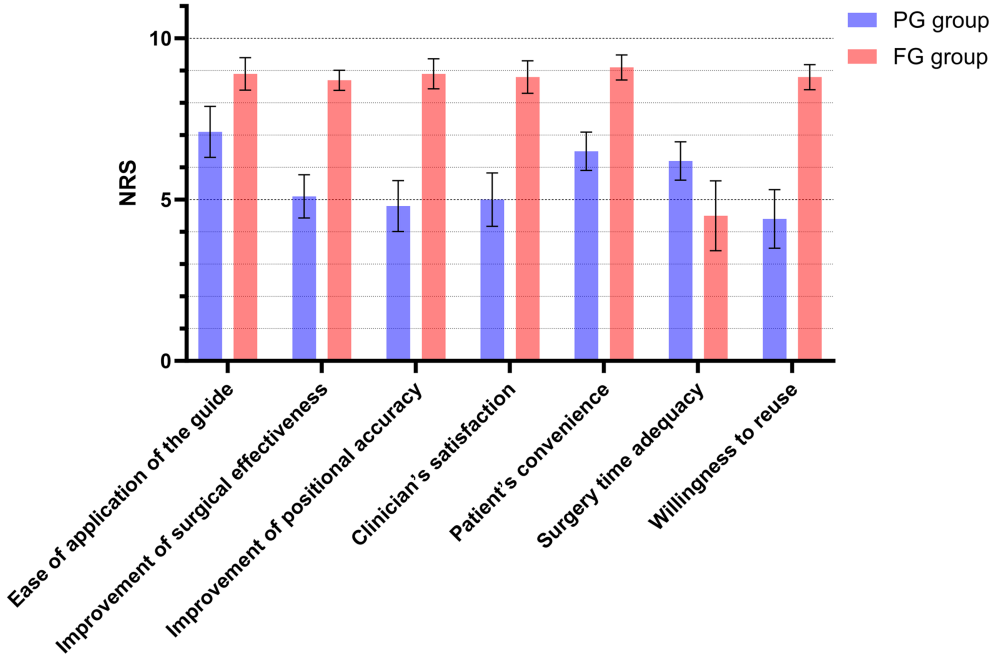

FIGURE 6 CROMs from a questionnaire with seven questions answered on a NRS from 0 to 10. Data are means and 95% confidence intervals. All data values differed significantly between the two groups ($p < .05$).

use of a partially guided stent was associated with less accurate implant placements, necessitating flap elevation to mitigate the risk of incorrect implant positioning.

The results from the PROMs revealed greater satisfaction and willingness to receive repeat treatment in the FG group 12 weeks after surgery. This finding could reflect the fast, convenient, and

TABLE 7 NRS scores for CROMs.

	Q1	Q2	Q3	Q4	Q5	Q6	Q7
FG group ($N=28$)	**9.0, 9.0 (9.0, 10.0)**	**8.9, 9.0 (8.0, 9.0)**	**9.2, 9.0 (9.0, 10.0)**	**9.1, 9.0 (9.0, 10.0)**	**9.2, 9.0 (9.0, 10.0)**	**4.5, 5.0 (2.0, 8.0)**	**8.8, 9.0 (9.0, 10.0)**
PG group ($N=27$)	7.0, 7.0 (6.5, 9.0)	4.9, 5.0 (4.0, 6.0)	4.6, 5.0 (4.0, 6.0)	4.9, 5.0 (4.0, 6.3)	6.6, 7.0 (5.8, 8.0)	6.3, 6.5 (5.0, 7.0)	4.1, 5.0 (3.5, 5.3)
p	**<.001**	**<.001**	**<.001**	**<.001**	**<.001**	**.018**	**<.001**

Note: Data are mean (mean, median (interquartile range, Q1–Q3)) values.
Boldface indicates statistically significant in the Mann–Whitney U test ($p < .05$).

minimally invasive features of the FG group. However, it was surprising that there was no intergroup difference in patient satisfaction regarding pain and swelling. Given that the PG group also showed a satisfactory results, any such differences may be negligible from the patients' perspective. These findings are consistent with a recent randomized controlled clinical trial that found no difference in patient satisfaction between freehand surgery, dynamic navigation, and static guided implant placement (Afrashtehfar, 2021).

On the other hand, the clinicians considered all aspects of surgery were better in the FG group than in the PG group. From the surgeon's point of view, flapless surgery can shorten the operation time and prevent complications such as bleeding, and the precise 3D positioning of implants, which prevents membrane perforation, seems to have greatly impacted surgeon satisfaction throughout the procedures.

This study had some limitations. First, the full surgical guide applied in the FG group was a new system that has not been used before, and so the proficiency in surgery using the guide may have differed between the early and late stages of the study. The guide used in this study was rather bulky due to it being provided as a ready-made product. Also, the length of the drill sleeve can end up being short depending on the situation, which can reduce the accuracy. This issue could have been addressed by performing hands-on calibration before the study began.

Second, various errors may have occurred during the analysis of the accuracy of implant placement. Accurate raw data could be obtained from both the FG and PG groups using the scan body and planning data (excluding errors in the scanning and guide production processes). However, since an evaluator was involved in the overlapping and measurement processes, measurement errors may have occurred. Also, interpreting the scatter plots allows only qualitative assessments rather than objective statistical analysis. This also requires careful consideration due to such interpretations possibly being affected by examiner bias.

Third, this study did not establish selection criteria based on the presence of site-bounding teeth. It has been demonstrated that distal free-ending sites may exhibit greater placement discrepancies compared to tooth-borne sites. This is due to the creation of a fulcrum axis along the most distal tooth of the arch, which can lead to a tipping movement of the guide along this axis. Additionally, when using a partial guide for implant placement, having adjacent teeth on either side can offer more accurate positioning as these teeth can serve as "visual guidance." Despite the participants being randomly allocated to each group, there was an even distribution of distal free-ending sites and tooth-borne sites within each group. Consequently, it is unlikely that the characteristics specific to each site type influenced the outcome of the intergroup comparisons.

Finally, due to the distinct shapes of the surgical guides used in the experimental and control groups, achieving complete blinding during the surgical procedures was not possible. Although the group allocation had been kept undisclosed to the participants, the clinician-reported outcome measurements were subject to a high risk of bias. Nevertheless, individual operators had no conflicts of interest and were fully entitled to their own opinion and evaluation of the surgical experience.

5 | CONCLUSION

Within the limitations of this study, when placing an implant simultaneously with crestal sinus floor elevation, the flapless approach using a fully guided system can be more effective than the open flap approach using a partially guided stent. The application of fully guided surgery can be more accurate and faster and can enhance the satisfaction of both clinician and patient compared to the partially guided surgery.

AUTHOR CONTRIBUTIONS

Jongseung Kim: Software; data curation; investigation; formal analysis; visualization; writing-original draft; writing-review & editing. Jin-Young Park: Investigation; validation; formal analysis; visualization; writing-original draft. Joo-Yeon Lee: Software; data curation; investigation; validation; formal analysis; visualization; writing-original draft. Da-mi Kim: Data curation; investigation. Jungwon Lee: Methodology; software; investigation; supervision; project administration. Ui-Won Jung: Conceptualization; methodology; investigation; resources. Young-Jun Lim: Conceptualization; methodology; funding acquisition; writing-review and editing. Jae-Kook Cha: Conceptualization; methodology; software; investigation; supervision; funding acquisition; project administration; visualization; resources.

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CONFLICT OF INTEREST STATEMENT

The authors have no conflict of interest to declare.

DATA AVAILABILITY STATEMENT

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

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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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