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Reliability and accuracy of dynamic navigation for zygomatic implant placement

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Abstract

Objectives: To assess the accuracy of a real-time dynamic navigation system applied in zygomatic implant (ZI) surgery and summarize device-related negative events and their management.

Material and methods: Patients who presented with severely maxillary atrophy or maxillary defects and received dynamic navigation-supported ZI surgery were included. The deviations of entry, exit, and angle were measured after image data fusion. A linear mixed-effects model was used. Statistical significance was defined as $p < .05$. Device-related negative events and their management were also recorded and analyzed.

Results: Two hundred and thirty-one zygomatic implants (ZIs) with navigation-guided placement were planned in 74 consecutive patients between Jan 2015 and Aug 2020. Among them, 71 patients with 221 ZIs received navigation-guided surgery finally. The deviations in entry, exit, and angle were 1.57 ± 0.71 mm, 2.1 ± 0.94 mm and 2.68 ± 1.25 degrees, respectively. Significant differences were found in entry and exit deviation according to the number of ZIs in the zygomata ($p = .03$ and .00, respectively). Patients with atrophic maxillary or maxillary defects showed a significant difference in exit deviation ($p = .01$). A total of 28 device-related negative events occurred, and one resulted in 2 ZI failures due to implant malposition. The overall survival rate of ZIs was 98.64%, and the mean follow-up time was 24.11 months (Standard Deviation [SD]: 12.62).

Yiqun Wu and Baoxin Tao have contributed equally to this work.

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Conclusions: The navigation-supported ZI implantation is an accurate and reliable surgical approach. However, relevant technical negative events in the navigation process are worthy of attention.

KEYWORDS
dental implants, dental prosthesis, jaw, edentulous, surgery, computer-assisted, zygoma

1 | INTRODUCTION

Zygomatic implants (ZIs), described by PI Brånemark, are an effective and promising solution for patients who suffer from severely atrophic maxilla and maxillary bone defects, with a long-term survival rate of up to 95.2% for these patients (Chrcanovic et al., 2016).

Due to the limited intraoperative visibility and anatomical intricacies of zygoma processes, zygomatic implant (ZI) surgery is considered a "semi-blinded" surgery, and the difficulty and the rate of surgical complications sometimes increased (Block et al., 2009), such as orbital cavity penetration accompanied by extraocular injury (Krauthammer et al., 2017; Tran et al., 2019), intracranial placement (Reychler et al., 2010), infraorbital nerve and zygomaticofacial nerve paresthesia (Bedrossian & Bedrossian, 2018), and globe penetration (Topilow et al., 2020). To avoid these complications, Wu et al. proposed eyelid incision to expose inferolateral orbital rim to avoid orbital cavity penetration complication (Wu et al., 2015). Topilow et al. recommend inserted steel shoehorn into the inferior conjunctival fornix to protect orbital contents (Topilow et al., 2020). Optimal positioning of ZIs is crucial and related to surgical morbidity. Current advancements and improved digital technology in implant dentistry have significantly enhanced the clinician's ability to improve the predictability of implant surgery. Many efforts have been made to increase the drilling accuracy and reduce the risks of ZI surgery.

However, unlike conventional implants, which are approximately 10 mm in length, ZIs are much longer, and their drilling path is angled; both lead to deviation accumulation with a static template as insertion guidance (Chow, 2016; Chrcanovic et al., 2010; Vrielinck et al., 2003). Moreover, insufficient bone in the maxilla cannot provide stable support to the template. Therefore, traditional static guidance does not seem to be a predictable guiding aid for ZI placement in previous studies. It has always been the pursuit of clinicians to find a method that can achieve the precise placement of ZIs in accordance with preoperative virtual planning.

In terms of digitally guided surgery, in addition to static guides, navigation-guided surgery is an option. Navigation surgery has two main advantages: visualization and instant modifiable solutions. In the past 20 years, navigation has been proven to gain high accuracy, similar to static surgical guides in conventional dental implant placement (Kaewsiri et al., 2019; Guzmán et al., 2019; Ruppin et al., 2008; Yimarj et al., 2020; Zubizarreta-Macho et al., 2020). The application of navigation in ZI surgery was first proposed in 2000, which was later than conventional implant placement (Schramm et al., 2000). Compared with static guided surgery, the application of navigation in zygomatic implantation seems not affected by factors such as excessive implant length, implantation angle, and poor guide plate retention. Therefore, in the preliminary model and skull experiments, ZIs have achieved good accuracy. In addition to decreasing and avoiding critical anatomical damage, accurate placement of ZIs has additional significance. It is fundamentally important to locate the optimal position for the apical ZI where maximum bone-to-implant contact can be achieved. This contact area largely determines the initial stability of the ZI and the possibility of delivering immediate loading after surgery. Navigation can help to establish anchorage points provided by implants placed wherever potentially suitable bone exists. Meanwhile, the precise positioning of the starting point of ZI is also conducive to the actualization of the concept of "prosthesis-driven surgery".

However, compared with static guided surgery, previous studies report a steeper learning curve when applying navigation in surgery, and the period of training is inevitable. Navigation-based surgery requires 25% more time than conventional surgery due to the intricate preparation and manipulation steps of this technology (Dai et al., 2016).

In our previous studies, the feasibility and workflow of ZI navigation-guided surgery have been reported (Wu et al., 2019). In the quad approach to ZI placement, navigation-guided ZI placement is promising and has demonstrated a high level of accuracy with minimal planned-placed deviations, irrespective of the lengths or locations of the implants (Hung et al., 2017).

The present study focused on the application and accuracy of a dynamic navigation system in ZI surgery in various clinical situations, including severely atrophic jaw and maxillectomy patients, and device-related negative events as well as their management were also summarized and analyzed.

2 | MATERIALS AND METHODS

2.1 | Patient selection

Patients from January 2015 to August 2020 who were ≥18 years old and had severely atrophic maxilla or maxilla defects with good general condition seeking implant-supported prostheses were included (Zhao et al., 2018). Those who had acute sinus pathology, contraindications for surgery, or severely systemic disorders or received freehand ZI surgery were excluded (Zhao et al., 2018). All patients gave informed consent prior to inclusion into the study. All surgeries were conducted at the Department of Second Dental Center and Department of Oral Implantology of Ninth People's Hospital Affiliated with Shanghai Jiao Tong University, School of Medicine. This study was conducted based on the Helsinki Declaration which was revised in 2008 and gained approval (ethical approval number: SH9H-2020-T95-2) from the Ethics Committee of the Ninth People's Hospital Affiliated with Shanghai Jiao Tong University, School of Medicine. This study was performed according to the STROBE statement.

2.2 | Planning procedure

Before surgery, each patient received CBCT (cone beam computed tomography) or MSCT (multislice computed tomography) scanning after seven to ten mini-screws (CIBEI; A-1; Shuangyang) were placed dispersedly into the remaining maxilla as fiducial markers. For general consideration, screws were placed in the anterior nasal spine, mid-palatal suture, and bilateral maxillary tuberosity on the severely atrophic maxilla. When patients had maxillary defects, fiducial screws were usually placed in the maxilla on the intact side and extraoral positions, such as the mastoid process, superciliary arch, and posterior zygomatic arch (Figure 1) (Zhou et al., 2020). Barium sulfate dentures were constructed and trimmed to avoid blocking fiducial screws. Then, patients were asked to wear the denture to undergo CBCT or MSCT. The goal of this barium sulfate dentures was to achieve the prosthesis-driven surgery, which was not used during surgery. The Planmeca ProMax (Planmeca Oy) and i-CAT 3D Imaging System (Imaging Sciences International) were used to obtain CBCT scans, while the MSCT scan was acquired by Philips/Brilliance 64 (Philips), with settings as in previous studies (Tao, Wang, et al., 2020; Zhao et al., 2018). Then, files were imported into planning software such as Nobel Clinician (Nobel Biocare AB), coDiagnostiX® (Dental Wings) or an in-house software named Dental-Helper (Shanghai Jiao Tong University) in the DICOM format (Digital Imaging and Communications in Medicine) for preliminary implant planning.

A single ZI on each side of the zygomata combined with conventional implants was planned when the bone was adequate only in the anterior maxilla (Chrcanovic et al., 2013). Bilateral two ZIs were considered when the whole maxilla encountered insufficient bone (Davo & David, 2019; Weyh et al., 2020). Two or more ZIs were planned in a unilateral zygoma to treat patients who suffered from maxillectomy or large bone defects (Bothur et al., 2003; Hung et al., 2016).

For single ZI placement, the intraoral coronal entry points were at the second premolar or the first molar region, accompanied by 2 to 4 conventional implants in the anterior maxilla (Brånemark et al., 2004). For the bilateral two ZIs approach, the distal ZIs were designed with the entrance at the second premolar or the first molar region, while the mesial ZIs usually originated from the canines or lateral incisors according to the denture (Brånemark et al., 2004; Davo & David, 2019). Data from the previous plan were exported as a standard tessellation language (STL) file and overlapped with the DICOM file in iPlan CMF planning software (BrainLAB), and then the new trajectories were duplicated (Figure 2). All fiducial screws were then marked in an easy to remember order.

2.3 | Surgical implant placement procedure

After trajectories were designed, planning files were imported to navigation software (VectorVision2, BrainLAB AG). Then, the patient received general anesthesia, and then a skull reference base that loaded three reflective spheres was firmly placed on the head with a titanium screw (Figure 3). After the stability of each fiducial screw was checked, a probe was used to contact each fiducial screws for few seconds in the former order to achieve the registration procedure. This

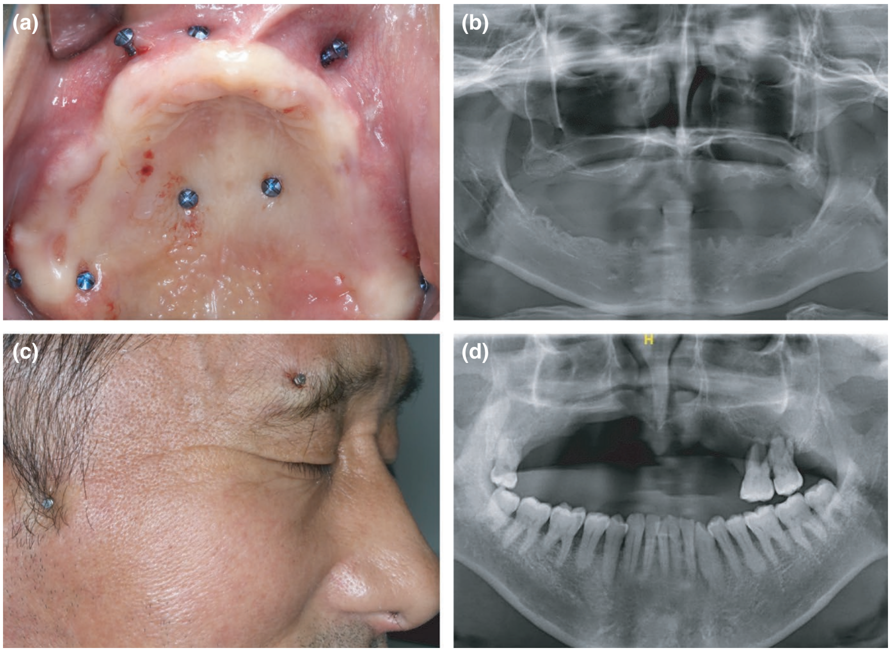

FIGURE 1 Position of the fiducial screws in patients with severely atrophic maxilla or maxillary defect. (a and b: the position of fiducial screws that were placed on severely atrophic maxilla and corresponding panoramic radiographic image of the patient; c and d: mini-screws attached to the superciliary arch and posterior zygomatic arch and panoramic radiographic image of the patient)

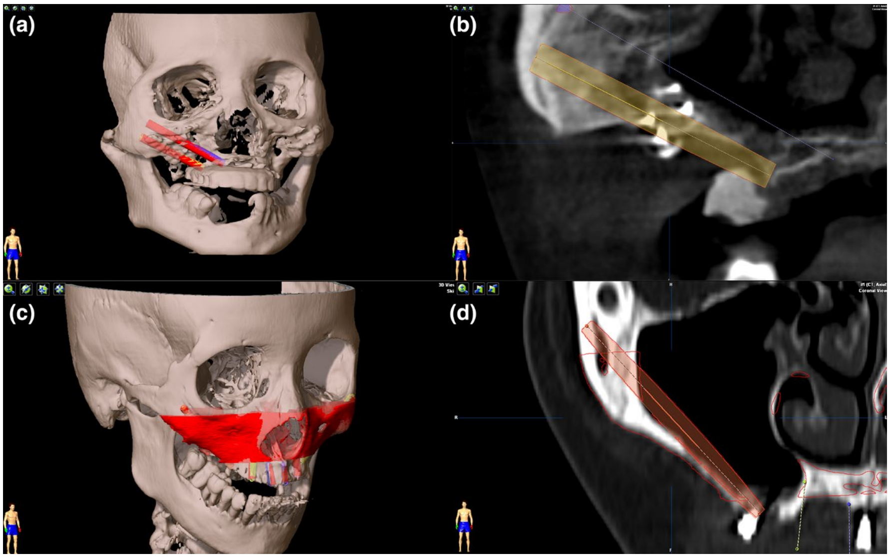

FIGURE 2 Previous plan as standard tessellation language (STL) file was merged with DICOM file in iPlan CMF and the new trajectories were duplicated. (a: The previous trajectories were designed in in-house Dental-Helper planning software and then exported with the same reference frame as the iPlan CMF, so only implant trajectories were exported and merged with the DICOM file at the right position automatically. c: The initial plan made by coDiagnostiX software, which contains implant information and bone information, was exported and merged with the DICOM file manually based on the outline of the maxilla and find the right position of implants. b and d: New plans were created accordingly)

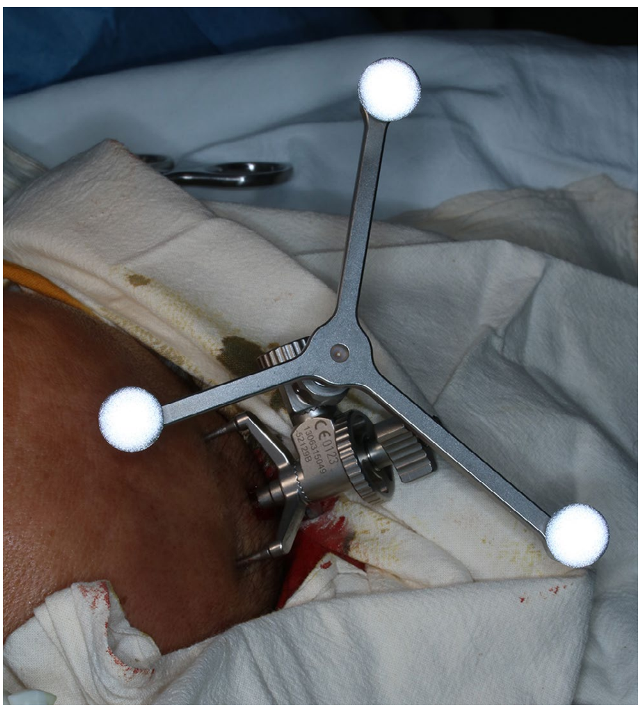

FIGURE 3 Skull reference base which loads three reflective spheres was placed in the hairline firmly with a titanium screw

procedure is used to establish a connection between the patient and the image. Once the procedure was accomplished, it was supposed to check the registration accuracy by using the probe to contact each fiducial screw again. In addition, the target registration error (TRE) is displayed on the computer screen then. After registration, mid-crestal incisions were made and accompanied by vertical releasing incisions in the midline and at the maxillary tuberosity region. The mucoperiosteal flap was elevated to expose the lateral sinus wall and the bottom rather than the medial part of the zygomatic body thanks to the extended virtual view from the navigation system. A palatal flap was also raised to disclose the alveolar crest and hard palate.

The size of the lateral sinus window was made depending on the path of the virtually planned ZIs, that is, the relationship between the conceived trajectory and the maxilla sinus. For the intrasinus path, a bone window in the lateral aspect of the sinus wall was created and then the sinus membrane was dissected meticulously (Davo & David, 2019). The preparation of the bone window was also conducive to intraoperative direct cooling of the internal cortex of the zygomatic bone. For the virtual extrasinus path, a smaller bone window close to the entry point of zygoma bone was prepared. Before sinus window preparation, the location of the window at the infrazygomatic crest could be identified with the navigation probe according to the planned path and then prepared by the surgeon (Figure 4).

The handpiece was later calibrated for real-time tracking. First, a round bur of 2.9 mm was inserted into the handpiece, which loaded a reference array with 3 reflective spheres. Then, after selecting the corresponding hole in the calibration block, the surgeon inserted the drill into the hole to the end so that the offset and direction vector could be obtained and calculated. Then, the tip of the drills was placed on each fiducial screw to assess the TRE of the instrument. After that, the probe or calibrated instrument could be used to detect the entrance of each drilling path (Figure 5).

When intraoperative conditions could not meet the predesigned ZI location, angulation of the drilling path could not be achieved due to limited mouth opening, or the CBCT/MSCT image was different from the real surgical situation, the preoperative virtual plan could

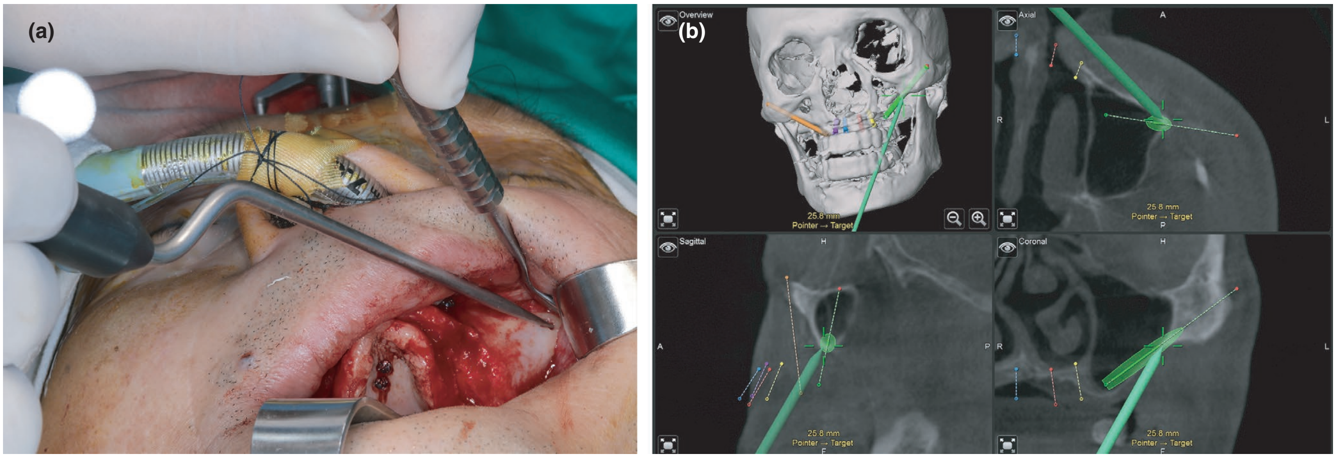

FIGURE 4 Navigation probe was used to identify the location of the window at infrazygomatic crest according to the planned path. (a and b: The probe was used to contact the point where the trajectory entered the zygoma bone and the corresponding computer interface)

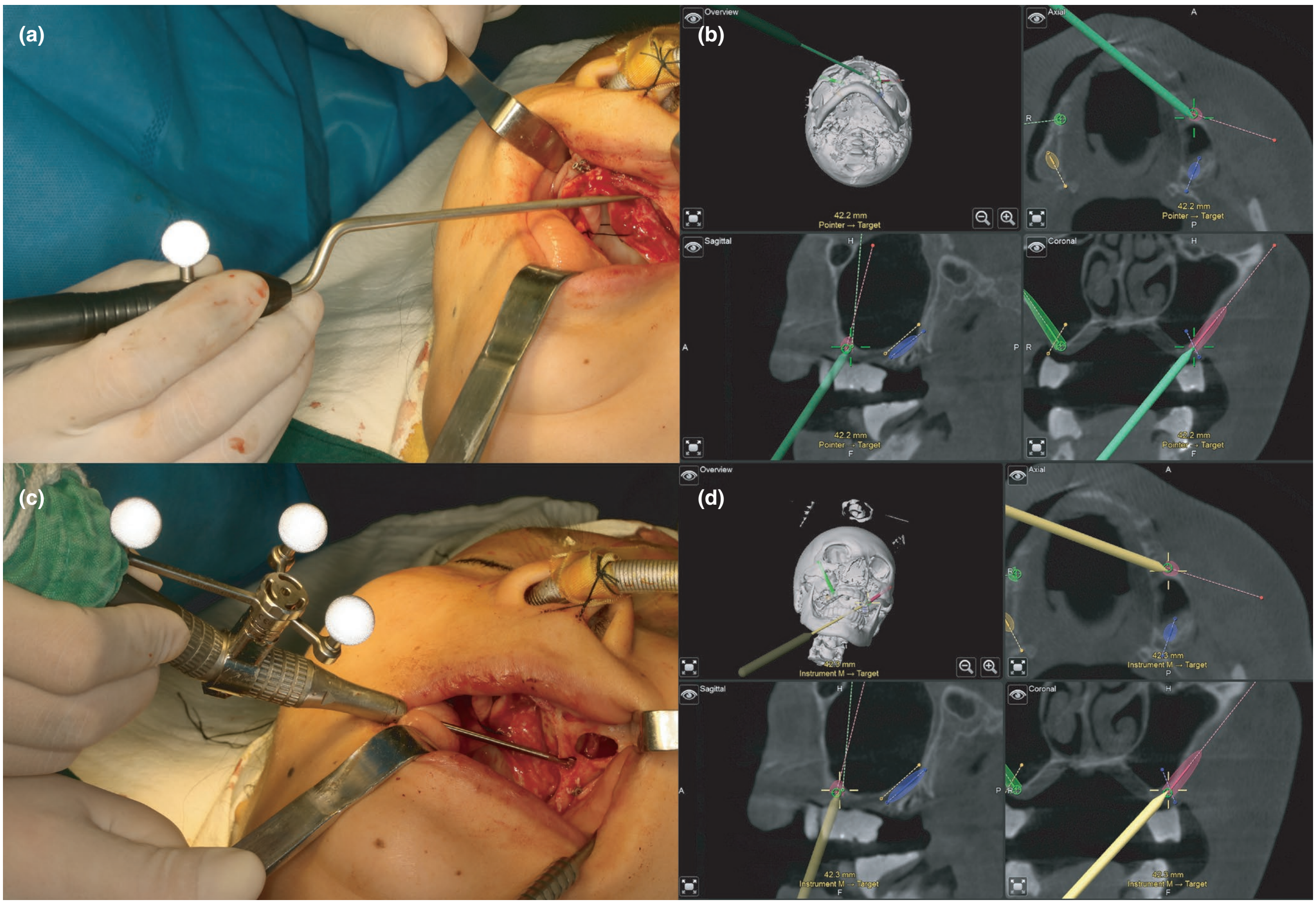

FIGURE 5 Probe or calibrated instrument were used to detect the entrance of the trajectory. (a and b: The probe was used to contact the entry point of the trajectory and the corresponding computer interface; c and d: the calibrated instrument detected the entry point and the corresponding computer interface)

be changed in the navigation software instantly. Using the probe to touch the newly designed entry point and clicking on "Navigate entry point" and "Set entry," the entry point could be newly defined. The entry point to the zygomatic bone could also be detected by the probe in patients with concave lateral sinus walls, giving surgeons direct trajectories for ZIs. Once the entries of residual maxilla and those of the zygomatic bone were defined, the direction of trajectory was clearly observed by surgeon. So, a contra-angle handpiece with short twist drills could be used to prepare the distal zygomatic implant by connected pre-marked points if the mouth opening was limited.

All of the drilling procedures during implant bed preparation followed the planning trajectories on the screen under the guidance of a navigation device. In this process, when the surgeon kept the instrument still for a few seconds, the computer automatically enlarged the interface three times to provide a clearer view. The recalibration procedure was inevitable when changing the drills every time, and recalibration took approximately 20 s to repeat these steps during surgery. A constantly displayed distance between the drill tip and the exit point could remind the surgeon when the drill tip was close to the exit point. Abundant irrigation was vital for the crest as well as the zygomatic bone to avoid overheating concerns. In the process of osteotomy, the stability of all reference frames should be checked at all times to ensure navigation accuracy.

After implant bed preparation, ZIs (Brånemark system Zygoma; Nobel Biocare) with corresponding lengths were inserted with zygoma handles or handpieces under the guidance of navigation. For the latter approach, a custom-made ZI substitute was placed on the carrier, and calibration was executed to make the system track the tip of the ZI. Then, ZI could be inserted with the handpiece (Figure 6). If the insertion torque reached more than 35 Ncm for each ZI, immediate loading was applied to the patient. Impression and occlusal relationship record were done, and an acrylic resin prosthesis reinforced by an interim metal was fabricated within 2 days after surgery in some immediate loading cases. In other cases, a prefabricated acrylic resin prosthesis reinforced by an interim metal was secured to the implants along with tightened prosthetic screws after relining and modification (Wang et al., 2021). Delayed loading was performed when the ZI could not acquire sufficient anchorage, patients presented with obvious parafunctional activity and patient suffered from maxillary defect. Postoperative MSCT or CBCT was performed within 72 h after surgery.

2.4 | Image fusion and accuracy measurement

The iPlan CMF planning software was used to conduct image fusion and accuracy evaluation. After importing postoperative data to the software, a surface-based fusion method was conducted to perform image fusion. A coarse manual adjustment of the postoperative image to a position similar to the preoperative image was needed first. Then, a fusion ROI (region of interest) was selected, and it usually included the maxilla and skull. After clicking the "Auto Fusion" button, pre- and postoperative image fusion was achieved automatically. If obviously mismatched conditions were detected, delicate manual adjustment was required. The distance deviations at the entry and exit points between the placed and planned implants were measured and documented in millimeters. The distance deviation was described as the linear displacement between the entry (or exit) centers of implants in a three-dimensional world. The three-dimensional angle between the axes was considered the angle deviation. All deviations were calculated by two surgeons independently (Tao and Lan), and the final mean values were obtained and recorded.

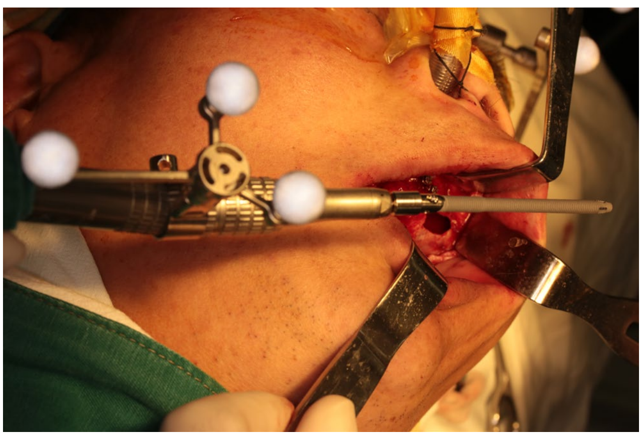

FIGURE 6 Zygomatic implant (ZI) was loaded on handpiece and inserted under guidance of the navigation system

2.5 | Statistical analysis

SAS 9.4 (SAS Institute Inc., SAS Campus Drive) was used for statistical analysis. Intraclass correlation coefficients were calculated to verify interrater reliability. According to the number of ZIs in the zygomata (single ZI approach, bilateral two ZIs approach, and triple ZIs in a unilateral zygoma), the ZIs were classified into three groups. Based on the bone defect type (severely atrophic maxilla or maxillary bone defect) and sex, patients were then classified into two groups. The mean, standard deviation, median, interquartile range, and minimum–maximum deviations were calculated. The Shapiro–Wilk test and Levene's test were used to test the normality and homogeneity of variance of the variables, respectively. A linear mixed-effects model, which is a robust model for analyzing clustered observations (Schielzeth et al., 2020), with random intercept was applied to evaluate the accuracy of ZI among three groups, between the bone defect types and between whether fiducial screws were loose. The covariance structure was unstructured structure (UN). Normality transformation of the angle deviation was applied, as Equation (1) shows:

$$\text{Newangle} = \sqrt{\text{Max}\left(\sqrt{\text{angle}}\right) + 1 - \sqrt{\text{angle}}}. \tag{1}$$

The homogeneity of residual variance was evaluated by the plots of residuals vs. fitted values. $p < .05$ was defined as statistically significant.

3 | RESULTS

In total, 74 patients were included in the study, including 10 patients with maxillary bone defects and 64 patients with severely atrophic maxilla. Two hundred and twenty-one ZIs in 71 patients were placed uneventfully under the guidance of navigation, while 10 ZIs in 3 patients were finally placed freehand due to navigation system breakdown during surgery. The patients' characteristics are described in Table 1. The entry, exit, and angle deviations of 221 ZIs were calculated, and the intraclass correlation coefficients were 0.9, 0.94, and 0.92, respectively. The mean, standard deviation, median, interquartile range (P_{25}–P_{75}), minimum and maximum entry, exit, and angle deviations of these 221 ZIs are presented in Table 2. These parameters of the three classified groups are also shown in Tables 3, 4, and 5.

Because the number of ZIs were different in each patient and the lack of independence of ZIs, a linear mixed-effects model was applied. The *p* values of Shapiro–Wilk test for the angle deviation of the three groups after the normality transformation were 0.07, 0.21, and 0.94, respectively. Even spread of values around the centered line was found in the evaluation of homogeneity of residual variance. There was no significant difference in angle deviations ($p = .12$); however, significant differences were found in entry deviations (single ZI approach: 1.51 ± 0.59 mm; bilateral two ZIs approach: 1.57 ± 0.69 mm; triple ZIs in a unilateral zygoma: 0.99 ± 0.31 mm; $p = .03$) and exit deviations (2.56 ± 1.17 mm, 2.01 ± 0.81 mm, and 1.38 ± 0.75 mm, respectively, $p = .00$) among the three groups. The results of the multiple paired comparison are shown, and a significant difference was found in the entry and exit deviation between the single ZI approach and triple ZIs in a unilateral zygoma approach (Table 6, Figure 7).

The entry, exit, and angle deviations in the severely atrophic maxilla group and the maxilla defect group are shown in Table 7. No significant difference was found in entry and angle deviations ($p = .11$ and $p = .37$); however, in the exits, a significant difference in deviation was detected (patient with severely atrophic maxilla: 2.18 ± 0.95 mm; patient with maxillary defect: 1.64 ± 0.76 mm; $p = .01$).

Three surgeries were terminated, and 10 ZIs were placed freehand finally because the navigation system broke down unpredictably. In total, 21 patients with 27 ZI trajectories were modified during surgery, and the details are shown in Table 8. The most common reasons were a limited mouth opening or a better entry point than the virtual position during surgery. The skull reference was loose in 7 patients. This situation was found in time in 6 patients, and re-registration was conducted after retightening the reference frame. The loosened reference in one patient was not observed in time, which led to large deviations and implant malposition and later implant failure in the healing phase.

Twelve fiducial titanium screws became loose in 10 patients. Deviations of ZIs in patients with and without loosening of fiducial titanium screws were calculated (Table 9). No significant difference was found in entry, exit, and angle deviations ($p = .17$, .1, and .15, respectively). There were always two to three screws inserted as fiducial markers in the anterior nasal spine, mid-palatal suture, and bilateral maxillary tuberosity areas in case of any loss during surgery. Reflective spheres were loose or contaminated by blood in 8 patients, and all of them were detected in time and were retightened or replaced with a new sphere (Figure 8).

The mean follow-up time was 24.11 months (Standard Deviation [SD]: 12.62). The total survival rate of ZIs was 98.64%, with 3 ZIs failing in 2 patients. Two ZIs in one patient had micromovement during the immediate loading procedure 10 months after surgery. The reason was that the surgeon failed to detect the loose skull reference in time, resulted in both ZIs on the right side to deviate to the buccal side, and there was almost no bone around the ZIs. Finally, two conventional implants were implanted in the place where an intraoperative sinus bone grafting was conducted and aforementioned two ZIs were remain in zygoma without loading and a metal-acrylic resin implant-supported fixed prosthesis was delivered. One ZI in a patient was detected mobile during immediate loading procedure after surgery. The ZI was later removed, and a short-arch metal-ceramic implant-supported fixed prosthesis was mount on 4 conventional implants and left ZI finally.

TABLE 1 Characteristics of the patient included ($n = 71$)

Characteristics	Patients	Implant number
Gender		
Male	38 (53.5%)	118 (53.4%)
Female	33 (46.5%)	103 (46.6%)
Age (years)	46.8 ± 15.02 (range: 18–79)	
Male	47.4 ± 14.83 (range: 18–79)	118 (53.4%)
Female	46.2 ± 15.45 (range: 21–75)	103 (46.6%)
Type of patients		
Severely atrophic maxilla	61 (85.9%)	188 (85.1%)
Maxillary bone defect	10 (14.1%)	33 (14.9%)
Number of ZI		
Dual approach	26 (36.6%)	52 (23.5%)
Quad approach	35 (49.3%)	140 (63.3%)
Other approaches		
Single ZI	1 (1.4%)	1 (0.4%)
Dual ZIs in unilateral zygoma	1 (1.4%)	2 (0.9%)
Triple ZIs in bilateral zygomata	3 (4.2%)	9 (4.1%)
Triple ZIs in unilateral zygoma	4 (5.6%)	12 (5.4%)
Quintuple ZIs in bilateral zygomas	1 (1.4%)	5 (2.3%)
Image acquisition		
Planmeca ProMax	40 (56.34%)	116 (52.49%)
I-CAT 3D Imaging System	15 (21.12%)	57 (25.79%)
Philips/Brilliance 64	16 (22.54%)	48 (21.72%)

Abbreviations: ZI, zygomatic implant.

4 | DISCUSSION

For patients suffering from severely atrophic maxilla (Aparicio et al., 2014) and maxillary bone defects (Goker et al., 2020; Hackett et al., 2020), the ideal number and distribution of conventional implants

TABLE 2 Deviations between the planned and placed zygomatic implants

	Mean (SD)	Median	Interquartile range (P_{25}–P_{75})	Min-max	Shapiro–Wilk (*p* Value)
Entry deviation	1.57 (0.71)	1.50	1.10–2.02	0.15–4.65	<.01**
Exit deviation	2.10 (0.94)	1.95	1.50–2.60	0.20–5.85	<.01**
Angle deviation	2.68 (1.25)	2.45	1.75–3.60	0.15–5.80	<.01**

Note: ***p* < .01.

TABLE 3 Entry deviations between the planned and placed zygomatic implants of the three groups

	Mean (SD)	Median	Interquartile range (P_{25}–P_{75})	Min-max	Shapiro–Wilk (*p* Value)	Levene's test
Single ZI approach	1.51 (0.59)	1.43	1.10–2.00	0.40–3.15	.43	0.04*
Bilateral two ZIs approach	1.57 (0.69)	1.58	1.15–2.03	0.15–3.7	.09	
Triple ZIs in a unilateral zygoma	0.99 (0.31)	1.05	0.70–1.23	0.45–1.45	.59	

Note: **p* < .05.
Abbreviations: ZI, zygomatic implant.

TABLE 4 Exit deviations between the planned and placed zygomatic implants of the three groups

	Mean (SD)	Median	Interquartile range (P_{25}–P_{75})	Min-max	Shapiro–Wilk (*p* Value)	Levene's test
Single ZI approach	2.56 (1.17)	2.58	1.80–3.28	0.70–5.85	.16	0.00**
Bilateral two ZIs approach	2.01 (0.81)	1.95	1.55–2.44	0.20–4.5	.06	
Triple ZIs in a unilateral zygoma	1.38 (0.75)	1.30	0.78–1.73	0.45–3.05	.35	

Note: ***p* < .01.
Abbreviations: ZI, zygomatic implant.

TABLE 5 Angle deviations between the planned and placed zygomatic implants of the three groups

	Mean (SD)	Median	Interquartile range (P_{25}–P_{75})	Min-max	Shapiro–Wilk (*p* Value)	Levene's test
Single ZI approach	3.02 (1.42)	3.00	1.80–4.08	0.75–5.60	.04*	0.01*
Bilateral two ZIs approach	2.64 (1.17)	2.45	1.81–3.60	0.45–5.75	.04*	
Triple ZIs in a unilateral zygoma	2.11 (0.73)	1.95	1.70–2.70	0.90–3.35	.89	

Note: **p* < .05.
Abbreviations: ZI, zygomatic implant.

may be hindered due to limited or no residual bone in the bilateral anterior and posterior maxilla. ZI is, therefore, regarded as a promising approach due to its attractive advantages. To improve the overall accuracy and obtain a safe, precise, and reliable outcome, several methods have been conceived and tried in ZI surgery.

Several attempts have been made to apply surgical templates in ZI placement. Vrielinck et al. inserted 18 ZIs using customized surgical template and found mean entry, exit, and angle deviations were 2.77 mm, 4.46 mm, and 5.1 degrees, respectively (Vrielinck et al., 2003). Schiroli et al. and Vosselman et al. also designed and fabricated surgical template specific for ZI surgery and gained high accuracy in ZI placement (Schiroli et al., 2016; Vosselman et al., 2021). Seldom study reported the accuracy in freehand ZI surgery, Gao et al. applied digital ZI planning but conducted ZI surgery by freehand, the entry, exit, and angle deviations of 14 ZIs were 4.99 ± 2.66 mm, 6.11 ± 4.28 mm and 8.36 ± 5.3 degrees, respectively (Xing Gao et al., 2021). Compared with freehand surgery, the accuracy was improved in static guided ZI surgery. However, when applied in ZI surgery, the surgical template may not acquire acceptable stability in drastically inadequate residual bone. Moreover, the angle between the zygoma and maxilla is oblique rather than vertical. To overcome these shortcomings, Chow designed a retractable drill sleeve for ZI

TABLE 6 *p*-Values obtained the solution of fixed-effect for multi-comparison among the different groups (from top to bottom means *p* value of entry and exit deviation in each grid)

	Single ZI approach	Bilateral two ZIs approach	Triple ZIs in a unilateral zygoma
Single ZI approach	1	.53 .07	.03* .01*
Bilateral two ZIs approach	.53 .07	1	.32 .35
Triple ZIs in a unilateral zygoma	.03* .01*	.32 .35	1

Note: *$p < .05$.
Abbreviations: ZI, zygomatic implant.

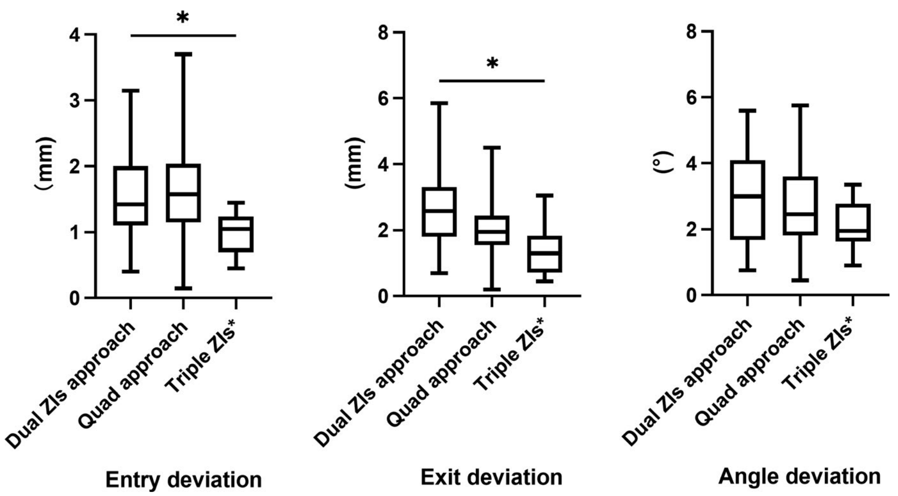

FIGURE 7 Box plots representing median, quartile, and minimum–maximum deviation of three groups. *:$p < .05$, Triple ZIs*: Triple ZIs in a unilateral zygoma. ZI, zygomatic implant

TABLE 7 Deviations between the planned and placed zygomatic implants according to the type of patients

	Patient with severely atrophic maxilla		Patient with maxilla defect	
	Entry deviation	Exit deviation	Entry deviation	Exit deviation
Linear deviations, mm				
Mean (± SD)	1.61 ± 0.72	2.18 ± 0.95	1.37 ± 0.66	1.64 ± 0.76
Median	1.55	2.05	1.30	1.65
P_{25}–P_{75}	1.15–2.05	1.6–2.68	0.93–1.73	1.15–2.25
Minimum-maximum	0.15–4.65	0.2–5.85	0.45–3.1	0.4–3.1
Angle deviations, degrees				
Mean (± SD)	2.71 ± 1.28		2.47 ± 1.03	
Median	2.45		2.55	
P_{25}–P_{75}	1.75–3.65		1.83–3.30	
Minimum-maximum	0.45–5.8		0.15–4.45	

guide surgery (Chow, 2016) and Takamaru et al. proposed an indicator to guide the direction of drill (Takamaru et al., 2016). To some extent, these modifications could improve the accuracy and reliability of template-guided ZI surgery; however, massive instruments or complex installation procedures may impede its applications.

The real-time navigation system was first applied in in vitro ZI surgery attempts. Watzinger and colleagues precisely placed 10 endosteal implants in the zygomata of 5 cadavers with the help of the VISIT system (Watzinger et al., 2001). Fifteen skull models underwent ZI placement via an image-guided oral implant system (IGOIS) developed by Chen et al., and the results showed high insertion accuracy (Xiaojun et al., 2009). Other navigation systems, such as VoXim (Kreissl et al., 2007), AccuNavi (Chen et al., 2011), ImplaNav (Pellegrino et al., 2015) and some without certain names (Franco, 2017; Gasparini et al., 2017), have also been employed in ZI surgery, achieving gratifying outcomes with high accuracy. Recently, the X-Guide navigation system has been applied in both conventional dental and ZI surgery (Lopes et al., 2020; Panchal

TABLE 8 Summary of dynamic navigation system-related complications

	Intraoperative trajectories modification	Operation was carried free hand due to navigation system problem	Loosen of skull reference	Loosen of fiducial titanium screws	Reflective spheres loosen or contaminated by blood
Single approach	9 (12 ZIs)	1	4	4 (5 screws)	2
Bilateral two ZIs approach	10 (12 ZIs)	2	3	5 (6 screws)	4
Other approaches	2 (3 ZIs)	0	0	1 (1 screw)	2

Abbreviations: ZI, zygomatic implant.

TABLE 9 Deviations of ZIs in patients with and without loosening of fiducial titanium screws

	Patient without loosening of fiducial titanium screws (*n* = 61,190 ZIs)		Patient with loosening of fiducial titanium screws (*n* = 10, 31 ZIs)	
	Entry deviation	Exit deviation	Entry deviation	Exit deviation
Linear deviations, mm				
Mean (± SD)	1.54 ± 0.72	2.04 ± 0.93	1.77 ± 0.65	2.46 ± 0.96
Median	1.45	1.95	1.75	2.3
P_{25}–P_{75}	1.09–1.96	1.45–2.55	1.25–2.15	1.8–3.05
Minimum-maximum	0.15–4.65	0.2–5.85	0.45–3.15	1.25–4.7
Angle deviations, degrees				
Mean (± SD)	2.62 ± 1.19		3.02 ± 1.5	
Median	2.45		3.1	
P_{25}–P_{75}	1.7–3.5		1.85–4.05	
Minimum-maximum	0.15–5.75		0.65–5.8	

Abbreviations: ZI, zygomatic implant.

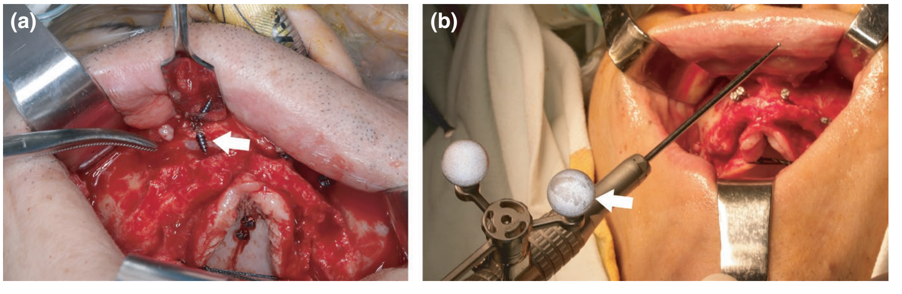

FIGURE 8 Some devices related negative events (a: Fiducial titanium screws were loose after the flap elevation; b: one reflective sphere on handpiece reference frame was contaminated by blood)

et al., 2019). The drill tip is tracked in real time, indicating a high-accuracy transformation from preoperative planning to patients and a predictable location as well as the angle of ZIs, which is essential for both esthetic and functional prosthetic outcomes. It enables patients who have previously not been able to get quad approach or triple zygomatic implants due to their deviation-intolerant thin zygoma bone to also undergo accurate and safe zygomatic surgery. Another advantage of the navigation system is that a real-time drill display and foreseeable clinical outcome make surgeons more confident in carrying out ZI surgery, which is beneficial to the popularization of this method. Navigation surgery also has instant modifiable solutions. Twenty-seven (27/221, 12.2%) ZI trajectories were modified during surgery due to mismatch between images and the actual situation and limited mouth opening. In these situations, the entrance and exit points of the ZI could be changed immediately, and no extra time was spent. At the same time, replanning the path did not affect the registration accuracy. This is a unique advantage that guided template surgery lacks. During the operation, the path of the ZI, including the positional relationship between it and the maxillary sinus, could be well predicted. Therefore, clinicians can use the navigation probe to indicate the position and size of the bony window precisely.

However, few studies have reported the accuracy of in vivo ZI surgery. Our previous study reported 40 ZIs in a quad approach with guidance of a real-time navigation system, in which high accuracy was gained with 1.35 ± 0.75 mm, 2.15 ± 0.95 mm, and 2.05 ± 1.02 degrees for entry, apical, and angle deviations, respectively (Hung et al., 2017). Another study using a novel extraoral registration method in 4 patients who were maxillary defect with 14 ZIs showed 1.56 ± 0.54 mm (entry deviation), 1.87 ± 0.63 mm (exit deviation), and 2.52 ± 0.84 degrees (angle deviation) (Zhou et al., 2020). In the present study, the entry, exit, and angle deviation of 221 ZIs were 1.57 ± 0.71 mm, 2.1 ± 0.94 mm, and 2.68 ± 1.25 degrees, respectively. When three ZIs were inserted in a unilateral zygoma, the entry, exit, and angle deviations were the lowest among the three groups. This type of implantation of multiple ZIs on one side of the zygomatic bone usually occurs in patients with large maxillary bone defects. The distance between the entry and exit of ZIs in these patients was usually much shorter than that in severely atrophic maxilla, helping to avoid human error accumulation. Adding extraoral regions for registration screws in these patients with maxillary defects brings the position of the registration center closer to the exit of the ZI, which improves the accuracy.

Factors that can influence image-guided navigation implant surgery mainly include image error, technical error, registration, calibration error, and human error (Widmann et al., 2009). Image quality highly depends on the model of imaging and corresponding imaging parameters. Our previous study showed that CBCT rather than CT may result in higher accuracy in real-time ZI navigation surgery, and this is mainly attributed to the small voxel size in the former (Tao, Shen, et al., 2020). In this study, the voxel size of Planmeca ProMax and i-CAT 3D Imaging System was 0.4 mm and 0.25 mm, respectively, and the pixel size and slice thickness of Philips/Brilliance 64 were 0.45 mm and 0.8 mm, respectively. In addition, 55 patients received CBCT scanning and 173 ZIs were then placed, so the accuracy result was reasonable and reliable. The technical error is generated from navigation-related hardware and software associated with the working principle and algorithm within it. The position-measuring accuracy of optical navigation systems is in the range of 0.1 mm–0.4 mm (Khadem et al., 2000), which can be regarded as an intrinsic error and is hard to avoid. Then, although we applied zygoma handpiece instead of conventional dental implant handpiece, little flexion of long drills still exits, which may cause loss of accuracy sometimes. Three types of preoperative planning software were applied, but the planning procedure was in the same steps: image importation, image reconstruction, occlusion plane definition, arch curve drawing, prosthesis-driven implant planning, and implant fine adjustment. And also, all planning files were imported in the same STL format and overlapped with the image in iPlan CMF planning software (BrainLAB) and then the new trajectories were duplicated. Although the overlapped method may different based on whether the coordinate frame of STL and images in iPlan CMF is pre-unified, all previous planning can be precisely transferred to iPlan CMF.

Registration is the key factor for the overall accuracy (Wu et al., 2019), and it is responsible for accurately linking the virtual coordinate system and patient coordinate system. Titanium screw markers as rigid registration are still the most accurate method (Metzger et al., 2007). To minimize pain and discomfort in patients, the interval between screw placement and the beginning of ZI surgery should be as short as possible. In the calibration process, a customized calibration block is used to establish the spatial relationship between the handpiece with different lengths of drills and the skull reference (Gao et al., 2020). When the navigation system is applied in zygomatic implant surgery, the mode of skull reference frame secured by a titanium screw within the hairline determines the reliability of this method. Error from registration and calibration has been reported as TRE, the deviation between the corresponding point on CBCT/CT image and surgical field other than the points used for registration (Fitzpatrick & West, 2001). Our previous study showed that the TRE value in the zygoma could be decreased to 0.44 ± 0.1 mm with 10 well-distributed fiducial markers intraorally (Fan et al., 2019). The TRE of image-guided surgery systems is within 1.5 mm–2.0 mm (Citardi & Batra, 2007). Another study noted that TRE <1.5 mm could be considered an acceptable accuracy in image-guided surgery (Mohagheghi et al., 2014). Because there is no standard value for the minimum accuracy in dynamic navigation zygomatic implant surgery, a TRE value of drills of <1.5 mm could be a satisfactory accuracy. Human error runs through the entire process. Inaccurate perception and slight hand tremors both influence application accuracy (Widmann et al., 2009). The lateral force of drills, knife-shaped alveolar crest, and oblique ZI insertion path may contribute to the formation of an ellipse entry, increasing the entry deviation.

During navigation surgery, a few device-related negative events occurred in the present study. The breakdown of the infrared cameras, data cable, or monitor cart may cause the whole navigation system stop working, which can terminate the dynamic navigation-supported ZI surgery and is considered as the most serious negative events. Preoperative and routine devices' check is necessary. Undiscovered loose fiducial titanium screws, skull reference, handpiece reference, and reflective spheres were the main issues resulting in poor accuracy during surgery. When reflective spheres were contaminated by blood, the navigation system might fail to detect the location of references, influencing the whole accuracy. Therefore, checking the skull, handpiece references, and reflective spheres as often as possible during the whole process of surgery to ensure their fixation is of vital importance (Tao, Wang, et al., 2020). It is also essential to use a periodontal probe to ensure the stability of each fiducial screw both preoperatively and intraoperatively, especially for those in the tuberosity area, because of poor bone quality for solid screw anchorage.

Once the operation began, if any registration screws were detected to be loose before registration, it was better to remove the loose screws and check the TRE value using the remaining screws. If the TRE value was acceptable (<1.5 mm) with the remaining fiducial screws, the navigation surgery could be executed as planned. In contrast, if the TRE value was higher than the threshold, the accuracy of the navigation system could not be guaranteed, and freehand surgery had to be performed under these circumstances. Two of 3 ZI failures in the present study were the results of an undetected loose skull reference during surgery. This reminds us that problems related to navigation system accessories can cause serious errors during the operation.

Except for errors and problems related to navigation system, there are still several disadvantages. The registration fiducial screws and skull reference are still invasive. Aside for its higher cost, human studies considering its clinical applications are still scare (Gargallo-Albiol et al., 2019). Also, the challenge still exists in dynamic navigation minimally invasive flapless ZI surgery, a conservative incision is recommended currently (Ramezanzade et al., 2021). A frequent view shift between computer screen and surgical field is needed, which may interpret essential cues and feedback obtaining and causes surgeon's fatigue (Shrestha et al., 2021). It has been evaluated that the learning curve of the navigation system in conventional dental implant surgery showed a learning plateau after 5 attempts in a phantom study (Sun et al., 2018). For ZI surgery, due to the difficulty from ZI surgery itself and the navigation procedure, more attempts may need to master dynamic navigation surgery for ZI than conventional implant. For some surgeons who are lack of related experience, the preparation and navigation-related procedure may complex and time-consuming and the surgery is prolonged. It is worth noting that the navigation device used in this study is not specifically designed for conventional dental implants or ZIs. This equipment is primarily used in neurosurgery, orthognathic surgery, orthopedics, and other clinical fields. In the software interface, we could only mimic the cylindrical column as ZI, and there is no real virtual zygomatic implant that could be used. In the hardware, the reference connected to the handpiece was customized. We believe that the improvement of navigation equipment and its accessories may further improve the accuracy of ZI surgery.

Although a few errors and negative events, this approach for ZIs placement has achieved high ZI survival rate (98.64%). Only 3 surgeries (4.23%) changed to freehand surgery due to the navigation system problem, and the final accuracy has been less affected when minor fiducial screws loosen. What's more, when skull reference frame and reflective spheres become loose, rapid remedial measures still exist that fixing them again and re-registration. In computer-aided implant placement surgery, besides success rate implant placement, accuracy is another evaluation index. In this study, high accuracy of ZIs was achieved in both atrophic maxilla and maxilla defect patients and in different ZI surgical approaches. So, the reliability of the navigation system in ZI surgery can be ensured.

One limitation of this study is the monocentric nature of the research. More multicenter and prospective studies need to be conducted to further evaluate the navigation accuracy in ZI surgery with different kinds of navigation devices.

5 | CONCLUSION

The navigation-supported ZI implantation is an accurate and reliable surgical approach, and it allows clinicians to accurately transfer preoperative planning to patients during surgery. This actualization of the preplanned position reduces the risk of damaging the critical anatomical structures and fully leverages the limited amount of zygomatic bone. This technology has become a bridge between virtual design and the real world. However, relevant device-related negative events in the navigation process are worthy of attention. A series navigation operative standard needs to be established to prevent any possible complications. More navigation systems and multicentric studies should be performed to evaluate this result further.

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CONFLICT OF INTEREST

No conflict of interest.

AUTHOR CONTRIBUTIONS

Yiqun Wu: Conceptualization (lead); Formal analysis (lead); Funding acquisition (lead); Methodology (lead); Project administration (lead); Supervision (lead); Validation (lead); Writing – review & editing (equal). **Baoxin Tao:** Conceptualization (supporting); Data curation (lead); Investigation (equal); Software (lead); Writing – original draft (lead). **Kengliang Lan:** Data curation (supporting); Formal analysis (equal); Methodology (equal); Software (supporting); Supervision (supporting); Validation (equal); Visualization (supporting). **Yihan Shen:** Data curation (equal); Formal analysis (supporting); Resources (supporting); Software (supporting); Visualization (equal). **Wei Huang:** Conceptualization (equal); Methodology (supporting); Project administration (equal); Visualization (equal); Writing – original draft (equal); Writing – review & editing (equal). **Feng Wang:** Conceptualization (equal); Methodology (lead); Project administration (equal); Supervision (equal); Visualization (lead); Writing – review & editing (lead).

DATA AVAILABILITY STATEMENT

Author elects to not share data.

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SUPPORTING INFORMATION

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