Application of a Computer-Assisted Navigation System (CANS) in the Delayed Treatment of Zygomatic Fractures: A Randomized Controlled Trial

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Purpose: The delayed treatment of zygomatic complex (ZMC) fracture presents a difficult challenge to surgeons. The aim of this study was to compare the treatment effects of delayed surgery of ZMC fractures with and without a computer-assisted navigation system (CANS).

Materials and Methods: In this observer-blinded single-site randomized clinical trial, patients with unilateral ZMC fracture were included and randomized 1:1 to delayed treatment with or without CANS. The primary outcome measurement was the absolute bilateral differences of the ZMC eminence and width based on computed tomographic (CT) measurements 48 to 72 hours after surgery.

Results: One hundred three patients with unilateral ZMC fracture without immediate treatment were enrolled, and 78 were randomized to each group. Postoperative CT measurements showed that the bilateral difference in ZMC eminence was significantly less for the navigation group than for the control group (1.24 vs 2.22 mm; $P < .001$). The bilateral difference in ZMC width was not significantly different between the 2 groups (0.94 vs 1.36 mm; $P = .061$). The percentage of patients exhibiting a morphologically symmetrical face (bilateral differences ≤2 mm in ZMC eminence and width) was 71.8% (28 of 39) for the navigation group and 35.9% (14 of 39) for the control group ($P = .001$). Photogrammetry showed that the average difference between the postoperative CT data and the preoperative design was smaller in the navigation group (1.30 vs 2.40 mm; $P = .012$).

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Conclusions: Use of CANS improved ZMC symmetry in patients with unilateral ZMC fracture who had delayed treatment by allowing for more accurate implementation of the preoperative plan.

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Zygomatic complex (ZMC) fracture is used to describe the clinical entity characterized by fracture(s) of the zygoma or adjacent bones, such as the maxilla, orbit, or temporal bone. ZMC fracture is second in frequency after nasal fractures.[1] If treatment is delayed or the reduction is inadequate, secondary deformities can result, leading to a badly disfigured facial appearance and dysfunctions such as limited mouth opening, diplopia, enophthalmos, unequal pupillary level, and abnormal nerve sensibility.[1] For ZMC fractures treated in a delayed manner, the loss of normal anatomic landmarks, caused by the malunion of the fracture lines and resulting remodeling of the bony contour, makes it difficult to determine the correct positions of the zygomatic bones. In such cases, ideal outcomes with satisfactory midface symmetry have been difficult to obtain.[2,3]

Owing to the development of computer technology, there are many computer-assisted surgical techniques available to treat oral and maxillofacial trauma. Surgical planning software and computer-generated stereolithographic (STL) models[4-6] have already helped many surgeons perform accurate preoperative simulations that provide ideal 3-dimensional (3D) surgical simulation plans. However, before the use of intraoperative navigation systems, favorable results were difficult to achieve, because accurate translation of these computer-based surgical plans into real-world surgical outcomes is a major challenge. Intraoperative navigation systems[7] delivered an effective solution to the problem. However, prior studies have focused only on the navigation methods and ways to improve their accuracy. These studies also had limitations such as small samples, a retrospective design, absence of control groups, and homogeneity between experimental and control groups,[2,3,5,7,8,9,10,11,12,13,14,15,16,17,18,19,20] so that whether computer-assisted navigation system (CANS)-assisted surgery really improves the treatment effect on ZMC fractures treated in a delayed manner versus other computer-assisted technologies (measurement or guide plate technology) remains controversial. Therefore, the authors carried out a prospective randomized controlled clinical trial to assess the treatment effects of CANS-assisted surgery on ZMC fractures treated in a delayed manner.

Materials and Methods

STUDY DESIGN AND PARTICIPANTS

This was a prospective single-center randomized, control trial with blinded adjudication of outcomes. The study was conducted at the Department of Oral and Maxillofacial Surgery at the Peking University School and Hospital of Stomatology (Beijing, China) from December 2011 to February 2015. This trial was approved by the medical ethics committee of Peking University (review document, IRB00001052-11076). Potential participants were provided with written and oral information about the trial in Chinese.

PRELIMINARY EXPERIMENT

Seven patients in the navigation group and 28 patients in the control group participated in the preliminary experiment; the sample size of the control group was larger because of its greater standard deviation. The comparison of the bilateral difference in zygomatic eminence between the 2 groups (nonparametric correction) was used to estimate the sample size using PASS 11.0 (NCSS, Kaysville, UT). The threshold for type I error (α) was 5%, and 90% was considered the power of the test ($1-\beta$). The results indicated an estimated sample size of 71 (the bilateral difference in zygomatic eminence was 1.5 ± 0.5 mm in the navigation group and 2.6 ± 1.9 mm in the control group). Taking into account the loss to follow-up and other reasons, the estimated sample size was expanded by 10%, so that the final sample size was 78 (39 in each group).

PARTICIPANTS

The inclusion criteria were unilateral ZMC fracture(s) of type B (complete mono-fragment zygomatic tetrapod fracture) or type C (multi-fragment comminuted type B zygomatic fracture), as proposed by Zingg et al[21]; a delay from injury to surgery of at least 21 days; and patient age from 16 to 60 years. The following exclusion criteria were applied: mild esthetic problems without dysfunction (which could be treated using grafts of alloplastic implants such as porous polyethylene); did not accept treatment; or was unwilling to participate in the study. The following dropout criteria were used: accidents from

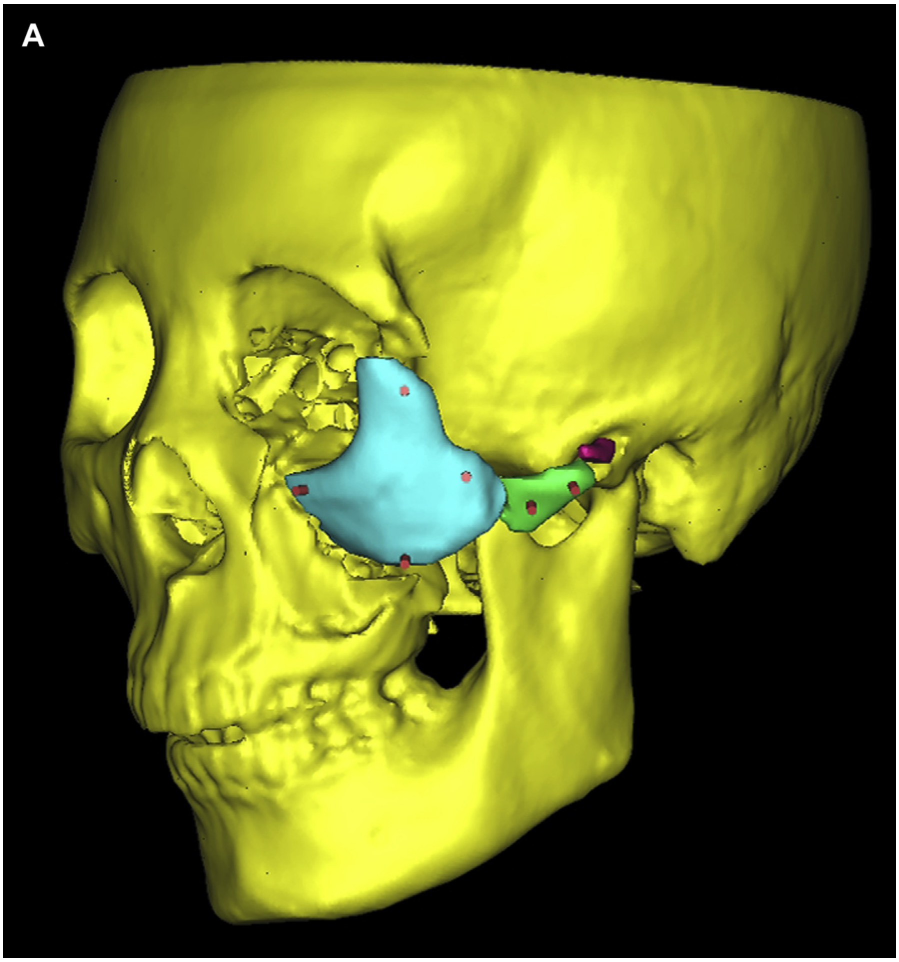

FIGURE 1. Design flow for the navigation group. *A*, A cylinder marker was placed for 3-dimensional maxillofacial reconstruction and zygomatic complex fracture segmentation (localization plan). **(Fig 1 continued on next page.)**

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instrument failure or failed navigation registration or the participant asked to drop out.

RANDOMIZATION METHOD

After giving consent, patients were randomized by an external statistician who used dynamic randomization techniques to generate a random allocation sequence according to the disequilibrium measures of main unbalanced nonexperimental factors for group assignment.[22] According to the results of the preliminary experiment, the main unbalanced nonexperimental factors were ZMC fractures (type B or C), fracture time (≥21 days, ≥3 months, or ≥6 months), gender (male or female), and surgeon (A or B).

INTERVENTIONS

All patients underwent preoperative spiral computed tomography (CT), which was repeated 2 weeks after surgery (helix with 1.25-mm slice thickness; Bright Speed 16, GE Healthcare, Buckinghamshire, UK). For preoperative surgical planning and postoperative evaluation, CT data were processed and imported to SurgiCase CMF 5.0 (Materialise, Leuven, Belgium) and iPlan CMF (BrainLAB, Feldkirchen, Germany) software using Digital Imaging and Communications in Medicine (DICOM) files.

NAVIGATION GROUP INTERVENTIONS

For patients in the navigation group, the intervention was completed according to the method of marker-assisted surgical navigation.[20] After 3D image construction and segmentation, 3D cylindrical objects (STL format) were positioned in specific locations on the surface of the digital model of the ZMC fragments. Then, the cylindrical object data were merged with the skull data to create “the localization plan” (Fig 1A). The data also were merged with the ZMC fracture segments and the simulated reduction was performed according to the mirrored image, thus yielding “the

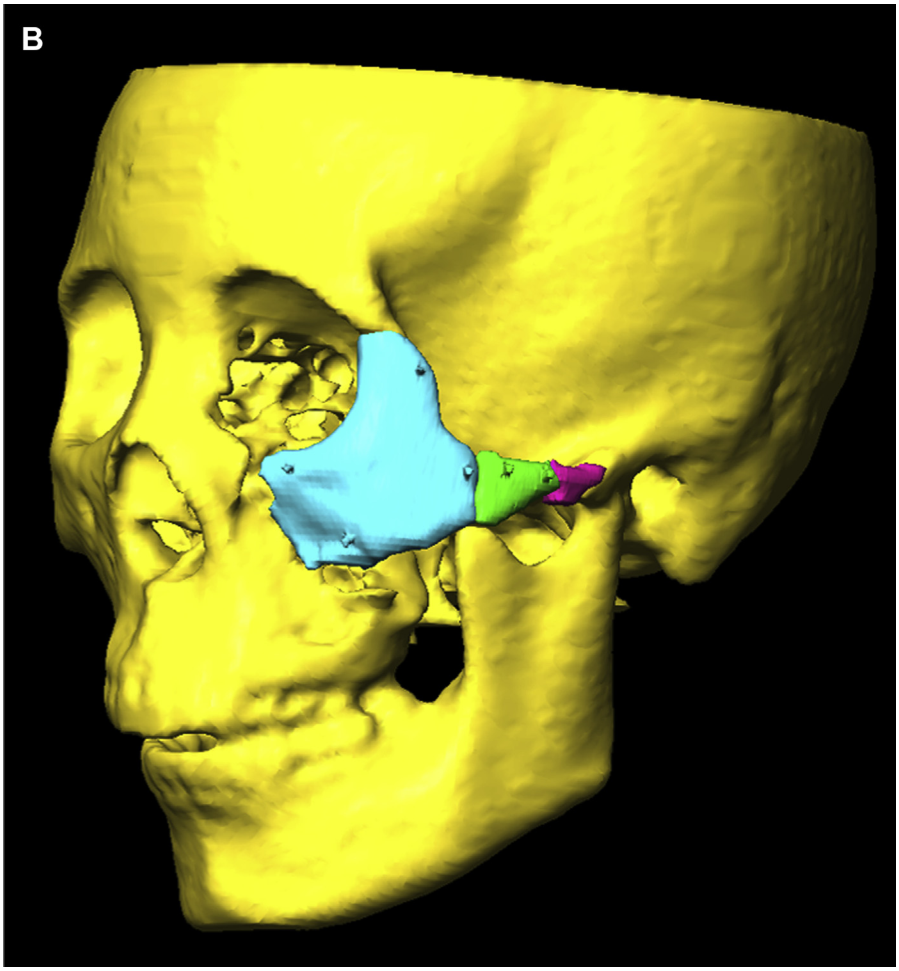

FIGURE 1 (cont'd). *B*, Simulated surgery was conducted according to the mirrored data (non-fractured side); the bone segments with the markers were moved; and the bone segments were smoothly connected with the fixed bone segment to form the target position of bone fracture reduction (reduction plan). **(Fig 1 continued on next page.)**

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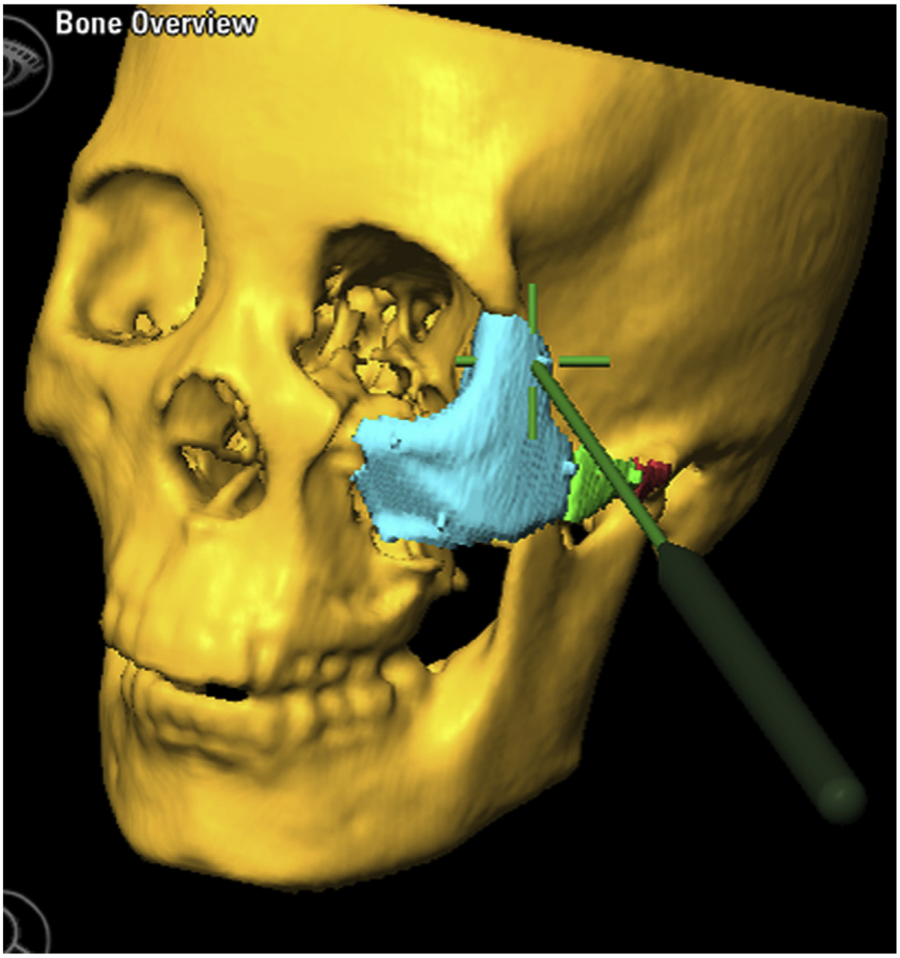
reduction plan" (Fig 1B). The VectorVision navigation system (BrainLAB) was used for intraoperative navigation. After the induction of general anesthesia, a reference frame with 3 light-reflecting balls was rigidly fixed to the patient's skull to identify the patient's position. Subsequently, the registration was completed through facial surface scanning using a Z-touch wireless laser pointer; this software automatically verified the registration accuracy of the surgical area in all patients, and the registration error was smaller than 1.0 mm in all cases. The surface markers were added by drilling holes in the fractured bones before osteotomy according to the localization plan. Then, the segments were reduced to the planned positions according to the reduction plan (Fig 1C, D).

CONTROL GROUP INTERVENTIONS

For the control group, the computer-assisted design steps were similar to those of the navigation group but without the markers. For type B ZMC fractures, the bilateral differences for the zygomatic eminence and width were measured before surgery to assist ZMC fracture reduction using CT measurement techniques.[23] For type C fractures, the intraoperative reduction was guided by prefabricated titanium plates. More specifically, the repositioned fracture segments were merged with the skull data after simulation of the reduction to create the plan (Fig 2B). The plan was printed out as an individualized 3D skull model using a rapid prototyping machine (MakerBot Industries, Brooklyn, NY). Then, 2.0-mm titanium plates (Synthes, Zuchwil, Switzerland) were fabricated along the zygomatic arch or the lateral orbital margin to fit with the surface of the 3D skull model (Fig 2C). After complete loosening of the osteotomy segments, the 2 ends of the titanium plate were fixed with screws to the unaffected bone, and the fractures were adjusted to the appropriate location and fixed on the template (Fig 2D).

C



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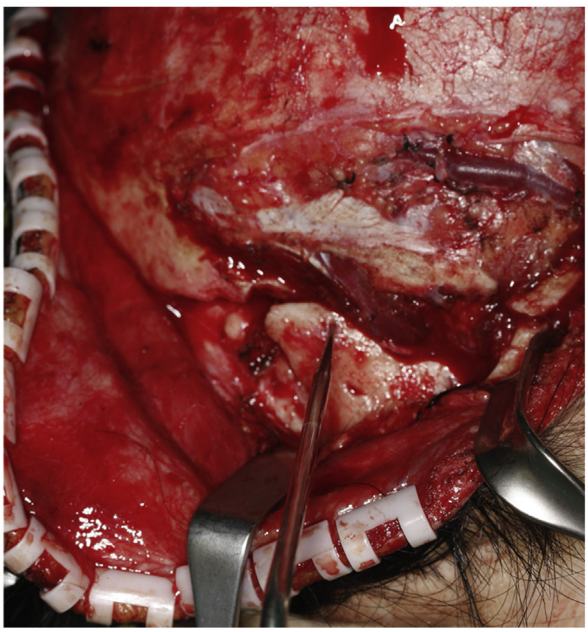

FIGURE 1 (cont'd). *C*, *D*, Real-time intraoperative navigation. The reduced zygomatic complex navigation verification position was designed according to the preoperative plan.

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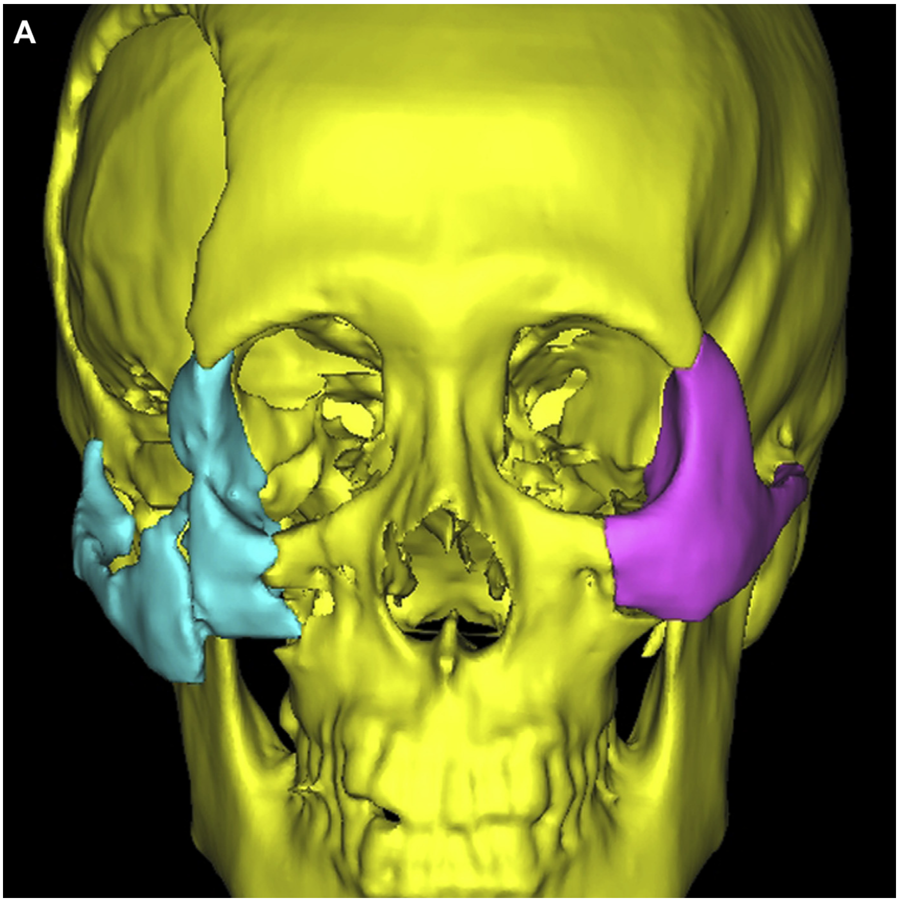

FIGURE 2. Treatment flow for patients with type C zygomatic complex fracture in the control group. *A*, Three-dimensional reconstruction of maxillofacial bone segments. **(Fig 2 continued on next page.)**

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OUTCOME MEASUREMENTS

The symmetry of the ZMC eminence and width was assessed by spiral CT and photogrammetric analysis 48 to 72 hours after surgery. The patients were followed for 6 months to finalize the visual analog scale (VAS) score and to observe clinical symptoms and signs in a blinded manner. The CT measurement and follow-up clinicians were maxillofacial surgeons with clinical experience who used related software. The following effect indicators were evaluated.

First, the symmetry of the postoperative ZMC eminence and width was evaluated using 3D CT measurements (primary outcome); its accuracy and repeatability for evaluation of midfacial symmetry have been shown.[23] Using iPlan CMF, the CT data were used to construct a 3D coordinate system based on the exact craniofacial midsagittal plane. After selecting the ZMC slice in the 3D coordinate system, the most prominent point on the zygomatic contour was identified and verified in the sagittal and coronal views. The zygomatic eminence was defined as the linear distance between the most prominent point and the origin of the coordinate axis. The linear distance between the most lateral point of the zygomatic arch and the final midsagittal plane was defined as the ZMC width. Absolute bilateral differences were calculated for the ZMC eminence and widths. These parameters were measured 3 times by each of 3 separate examiners (blinded method). The minimum measurement interval was 1 week.

Second, the accuracy of the CANS surgery (secondary outcome) was evaluated by comparing the postoperative (CT) model and the digital model of the reduction plan (Fig 3).[20] The postoperative and digital models of the reduction plan were outputted as STL files, imported into Geomagic Qualify 12.0 (Geomagic, Morrisville, NC), and then superimposed. The outside surfaces of the zygoma and zygomatic bone from the 2 models were selected for comparison. The program automatically identified the points that corresponded between the models and overlaid the superimposed image with different colors according to the degree to which their positions differed between models (linear distance). After the comparison, a color-graded

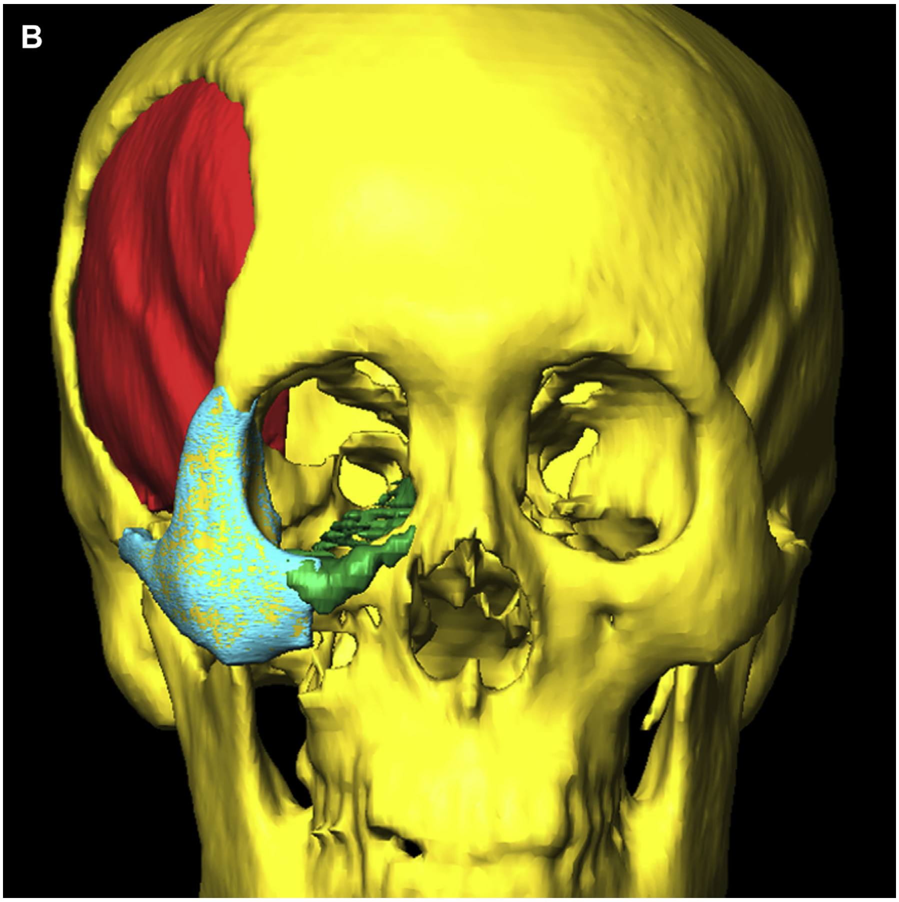

FIGURE 2 (cont'd). *B*, Simulated surgery according to the mirrored data (non-fractured side), which were matched to the zygomatic contour. **(Fig 2 continued on next page.)**

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error map was generated to show the matching deviation between the 2 models, with each grade of deviation indicated by a specific color. The distances between the identified points on each model also were measured and analyzed automatically; then, they were compared between the 2 models. Average deviations were used to evaluate the navigation accuracy. Pre- and postoperative data were input into the Geomagic Qualify 12.0, and the 2 sets of 3D coordinates were aligned after facial multipoint registration. The affected zygomatic region was selected as the target region and the mean value of the absolute ZMC deviation was analyzed.

Third, bilateral ZMC region symmetry was evaluated by the patients and by a physician from the study group (blinded) using the VAS. The following clinical evaluation criteria were used: poor, 0 to 2; general, 3 to 5; good, 6 to 8; excellent, higher than 8.

Fourth, impaired mouth opening, diplopia, enophthalmos, infraorbital numbness, and other symptoms and signs were recorded and evaluated. The hospitalization time (days) and cost (renminbi), amount of bleeding (milliliters), and operation time (minutes) also were recorded.

STATISTICS

Data entry was managed using EpiData 3.1 (EpiData Association, Christiansminde, Denmark) and accuracy was ensured by double entry and validation. The normality of numerical variables was assessed using a Shapiro-Wilk test. The mean and standard deviation were used to describe normally distributed numerical values, and an independent-samples *t* test was used to compare the 2 groups. Non-normally distributed numerical values were described using the median and interquartile range (25th percentile, 75th percentile). The difference between the 2 groups was compared using a Mann-Whitney *U* test. For categorical variables, the fraction of the treatment group that belonged to the given category was used, and the difference between the 2 groups was compared using a χ^2 test (Fisher exact probability method). All statistical analyses were carried out using SPSS 19.0 (SPSS, Inc,

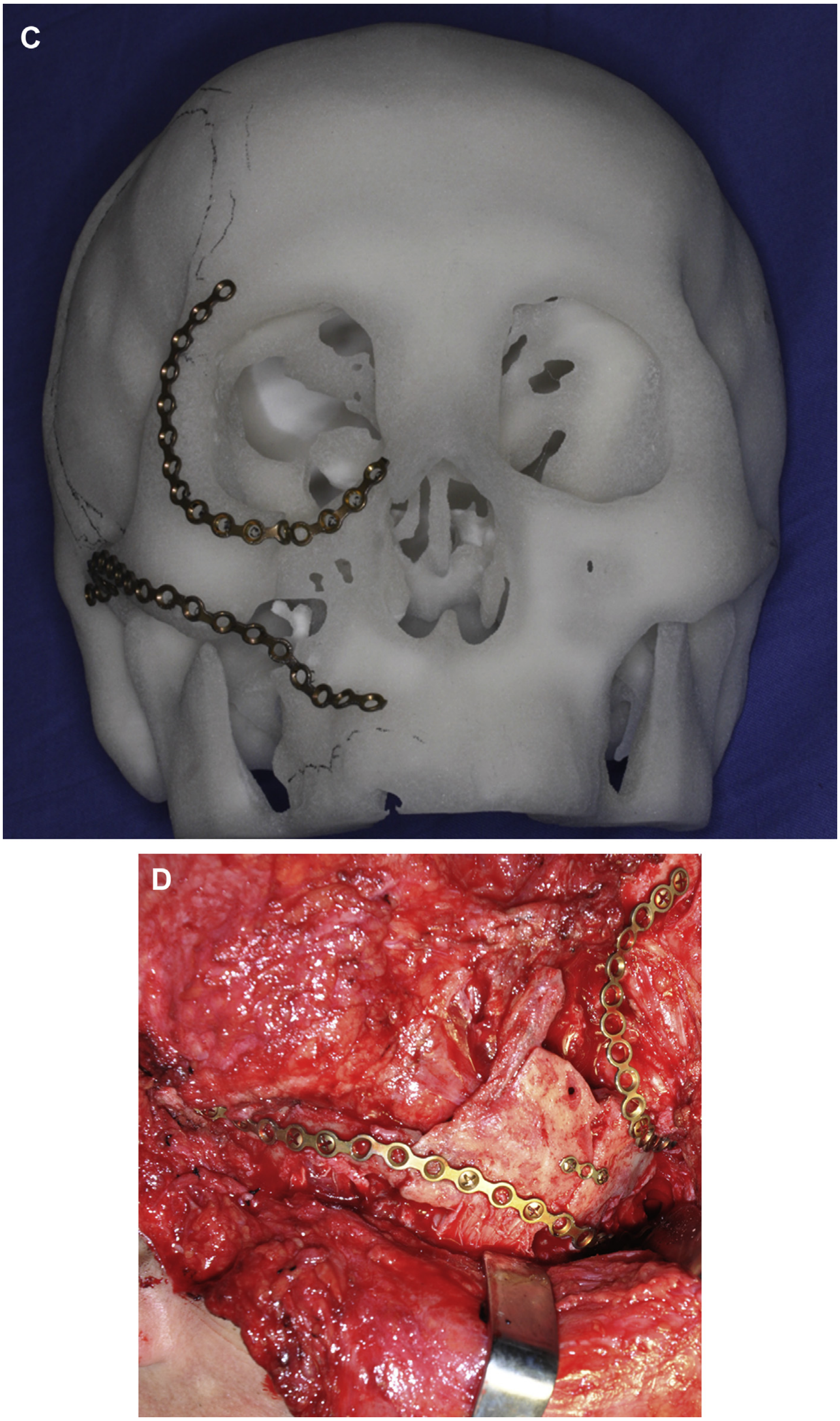

FIGURE 2 (cont'd). *C*, The reduced fracture segments were fused with the skull data without the zygomatic complex fracture to generate the stereolithographic data. The data were transmitted to the rapid prototyping machine to produce the patient's individualized 3-dimensional skull model. A 2.0-mm pre-springing titanium plate was fitted to the surface of the skull model along the affected zygomatic arch, infrazygomatic crest, or lateral orbital margin. *D*, Osteotomy was conducted; and after complete loosening of the osteotomy segments, the location of the 2 ends of the pre-springing plate was determined on the normal bone surface.

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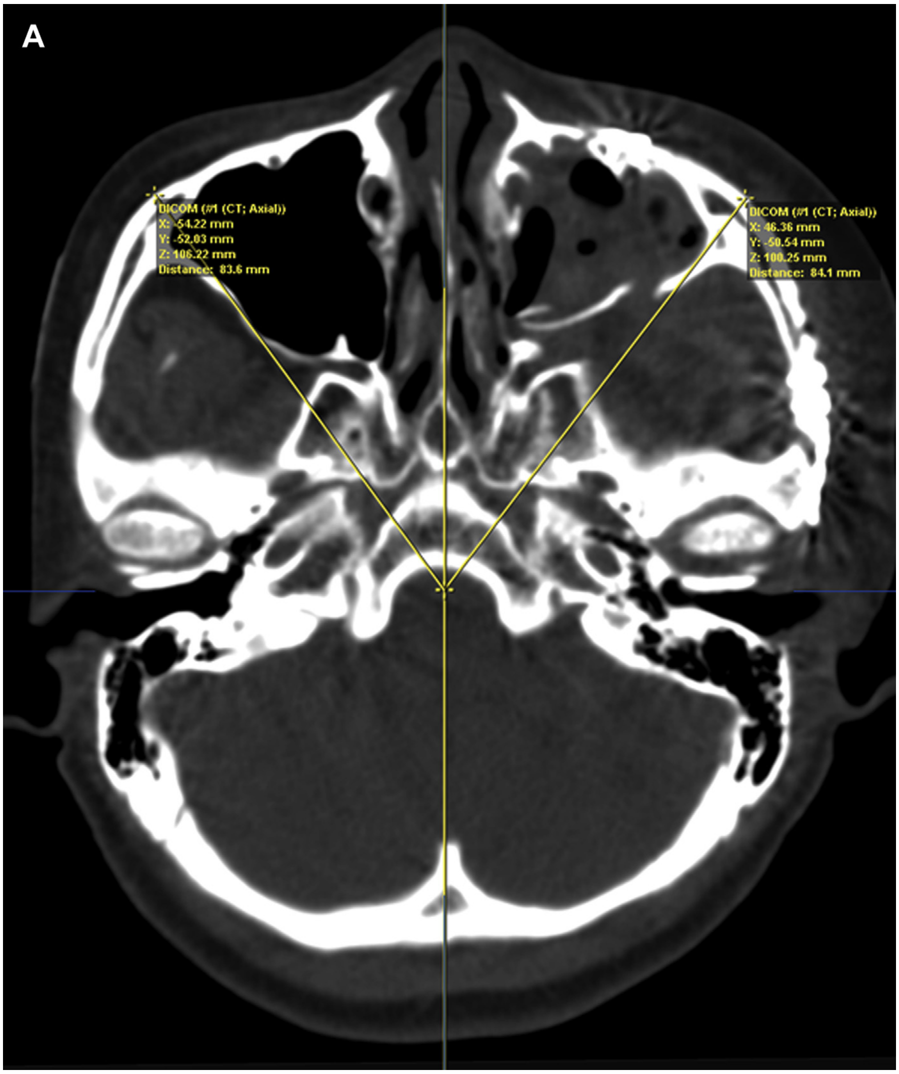

FIGURE 3. Evaluation indicators. *A*, Measurement of zygomatic complex eminence. The most prominent points of the zygomatic contours were identified on the zygomatic complex slice (axial slice covering most of the bilateral zygomatic complex region) determined by the final cephalo-facial midsagittal plane. The zygomatic complex eminence was measured as the linear distance between the most prominent point of the zygomatic contour and the origin of the 3-dimensional coordinate system. The bilateral differences in the zygomatic eminence were calculated for the navigation and control groups. **(Fig 3 continued on next page.)**

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Chicago, IL). A 2-tailed *P* value less than .05 was considered to indicate a statistically significant difference. Data were analyzed by the Research Center of Clinical Epidemiology (Peking University, Beijing, China).

Results

The final study sample consisted of 78 patients divided between 2 treatment groups, navigation and control. There were 62 men and 16 women and the average age was 33.7 years (range, 18 to 60 yr). The following were the causes of injury: accident, 50 (64.1%); occupational injury, 14 (17.9%); violent injury, 5 (6.4%); fall damage, 5 (6.4%); crush injury, 3 (3.8%); and athletic injury, 1 (1.3%). In addition to unilateral ZMC fracture, 71 patients exhibited other fracture types: 48 (61.5%) cases of orbital-wall fracture, 25 (32.1%) cases of maxillary fracture, and 8 (10.3%) cases of mandibular fracture.

Of the 39 patients in the navigation group, 33 underwent marker-assisted CANS surgery. Four underwent ZMC fracture reduction using navigation to check the position of the ZMC surface profile and anatomic eminence because of invalid markers that resulted from ZMC displacement before drilling of the holes in the fractured bones according to the localization plan. Two patients underwent reduction guided by mirrored data because of severely comminuted fractures. In the control group, the reduction positions

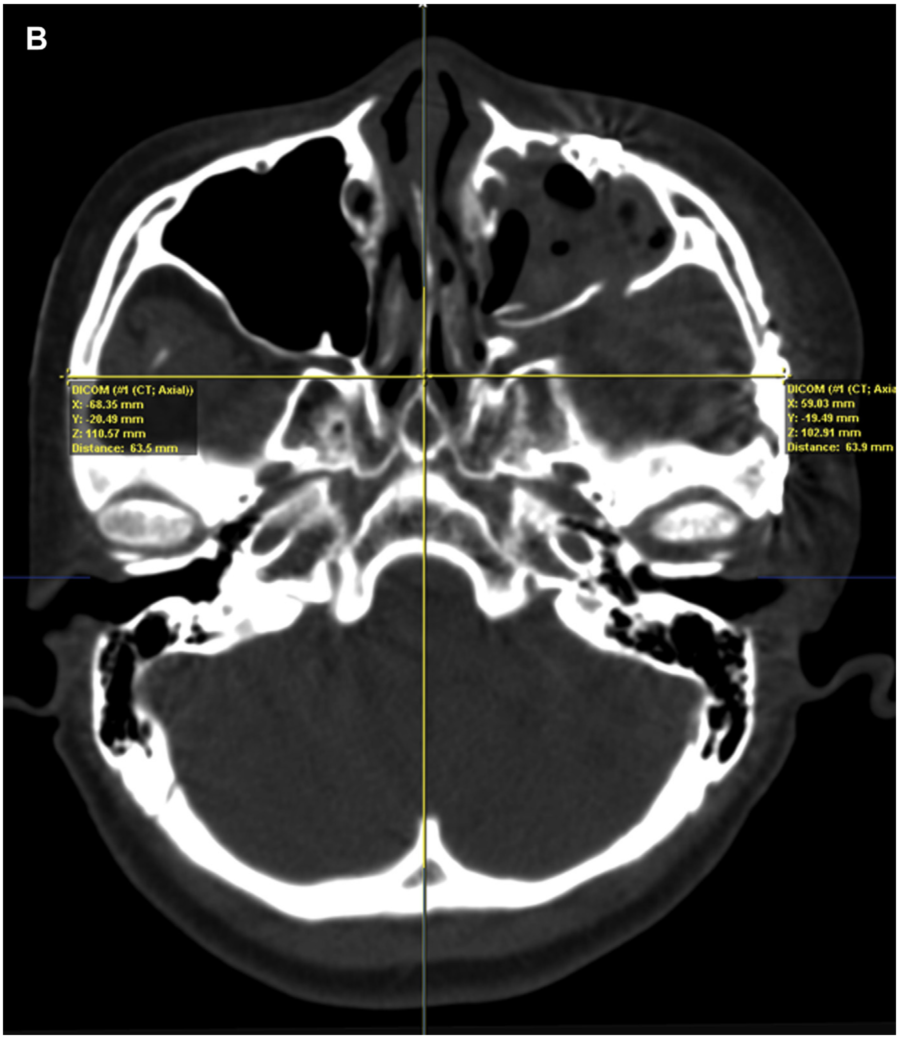

FIGURE 3 (cont'd). *B*, Measurement of zygomatic complex width. The most lateral points of the zygomatic arches were identified on the zygomatic complex slice (axial slice bilaterally covering most of the zygomatic complex) and the width of the zygomatic complex was measured as the linear distance between the most lateral point of the zygomatic arch and the final midsagittal plane. The bilateral differences in the zygomatic width were calculated for the navigation and control groups. **(Fig 3 continued on next page.)**

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in 22 patients with type B ZMC fracture were determined according to the preoperative CT measurements and anatomic reduction. Seventeen patients with type C fracture underwent ZMC reduction guided by a prefabricated titanium plate. The main clinical characteristics were balanced in the 2 groups (Table 1).

Postoperative CT measurements showed that the median bilateral difference in ZMC eminence was 1.24 mm (0.80 to 1.86 mm) in the navigation group and 2.20 mm (1.58 to 3.66 mm) in the control group (P < .001). The bilateral difference in ZMC width was not significantly different between the 2 groups (navigation group, median, 0.94 mm [0.73 to 1.57 mm]; control group, 1.36 mm [0.93 to 2.13 mm]; P = .061). The percentage of patients exhibiting a morphologically symmetrical face (bilateral differences ≤2 mm in ZMC eminence and width) was 71.8% (28 of 39) for the navigation group and 35.9% (14 of 39) for the control group (P = .001). The photogrammetric results, based on fitting the postoperative CT data to the preoperative design, showed that the average deviation of the reduced ZMC was smaller in the navigation group (1.30 mm [0.40 to 2.40 mm] vs 2.40 mm [1.40 to 4.10 mm]; P = .012). Median VAS score from the physician assessment of facial symmetry (6 months postoperatively) was higher for the navigation group (8 [6 to 9] vs 7 [5 to 9]; P = .043). No significant differences were seen for the other indicators at 6 months after surgery, including limitation of mouth opening (2 vs 2; P = 1.000), diplopia (0 vs 0; P = 1.000), enophthalmos (10 vs 8; P = .591), infraorbital region numbness (4 vs 7; P = .329), and self-assessment of ZMC symmetry (9 [8 to 9] vs 8 [8 to 9]; P = .328; Table 2).

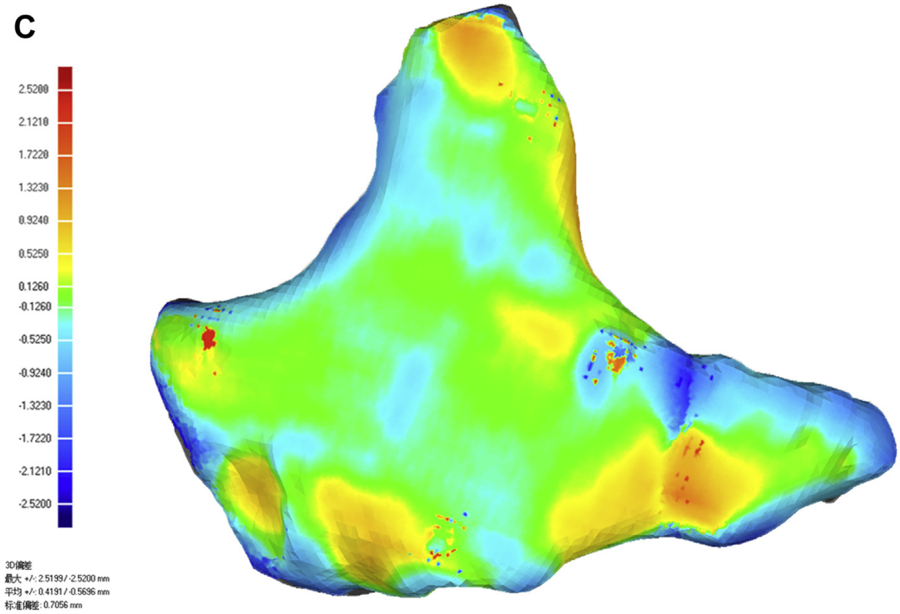

FIGURE 3 (cont'd). *C*, The postoperative computed tomographic data and preoperative planning data of the patients were imported into Geomagic Qualify 12.0 in stereolithographic format. The 2 sets of 3-dimensional coordinates were aligned after facial multipoint registration. The affected zygomatic complex region was selected as the target area. The mean value of the absolute deviation of the zygomatic complex region was analyzed.

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Discussion

The central location and forward projection of the ZMC make its contribution to facial form considerable. These features also expose the ZMC to frequent injuries that can seriously affect facial symmetry. Therefore, ZMC fracture reduction usually focuses on recovery of symmetry (primary outcome). A previous study found that bilateral facial differences smaller than 2 mm are visually imperceptible, and the face is considered visually symmetric.[24] In the present study, the average bilateral difference in ZMC eminence was 1.24 mm for the navigation group, with a dispersion (interquartile range) of only 0.80 to 1.86 mm; therefore, a morphologically ideal result (bilateral difference ≤2 mm for ZMC eminence and width) was achieved for most patients (71.8%) in the navigation group. In contrast, only 35.9% of patients in the control group achieved this ideal outcome. For them, the average bilateral difference in zygomatic eminence was 2.20 mm, which was almost twice that of the navigation group; the dispersion also was much greater (1.58 to 3.66 mm). This suggests that CANS technology can improve the accuracy and stability of ZMC fracture reduction. In the present study, all patients were operated on by 2 senior surgeons; however, it is likely that less experienced surgeons would find the technology even more helpful.

For ZMC fractures, the traditional reduction method, based entirely on the surgeon's experience and skills without any assisted methods such as guide or preformed guide plates, cannot achieve a stable and accurate therapeutic effect, which can result in secondary deformity and might require repeat surgery[5,7]; therefore, this method is rarely used. Besides the traditional method, preoperative prediction using preoperative computer-assisted planning and measurement is the most straightforward method with costs the same as those for the traditional method and can provide some guidance to surgeons during surgical planning. However, its accuracy is limited because it is difficult to translate preoperative planning into the actual surgery without the assistance of guide templates or navigation. It might be used for simple type B ZMC fractures and depend on the surgeon's experience. Use of preformed patient-specific guide plates for osteotomy and repositioning might achieve better accuracy than preoperative prediction alone, but might be relatively more expensive. The guide plate's positioning requires coronal incisions; hence, it might be used for type C ZMC fractures. In addition, accuracy of the guide plate is limited by data deviation and the intraoperative shift in positioning of the plate. In the present study, the preoperative prediction method and the guide plate method were used for type B and C ZMC fractures, respectively, in the control group, although the navigation group still achieved better therapeutic effects. Navigation-assisted surgery could not only achieve point-to-point

Table 1. BASELINE AND OPERATIVE DATA

Variables	Navigation Group (n = 39)	Control Group (n = 39)	*P* Value
Age (yr)	31.0 (25.0, 38.0)	31.0 (24.0, 41.0)	.487
Women*	9	7	.575
Caused by traffic accident (main cause)	28	22	.480
Left affected	16	17	.819
Time from injury to surgery (days)*	60 (30, 118)	37 (24, 126)	.244
Dysfunction			
Limited mouth opening	25	24	.815
Diplopia	5	3	.738
Enophthalmos	26	22	.352
Infraorbital region numbness	20	16	.364
Type B* (remaining percentage, type C)	22	22	1.000
Treated by surgeon A*	27	25	.631
Surgical approach			
Maxillary vestibular sulcus approach	38	39	1.000
Inferior eyelash approach	34	30	.238
(Half) coronary valve approach	29	24	.225
Exterior superciliary arch approach	11	13	.624
Anterior tragus approach	7	5	.530
Original approach	7	5	.530
Hospitalization time (days)	14 (12, 15)	14 (11, 19)	.916
Cost (RMB)	45,077 (29,265, 53,398)	43,219 (32,361, 58,677)	.614
Operation time (minutes)	390 (240, 510)	325 (250, 470)	.450
Amount of bleeding (mL)	300 (150, 500)	300 (180, 500)	.813

Note: Indicator values are presented as median (25th percentile, 75th percentile) based on Mann-Whitney *U* test. The χ^2 test was used to compare categorical variables.

Abbreviation: RMB, renminbi.

* Important randomly selected nonexperimental factors.

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ZMC reduction, but also provide real-time intraoperative verification. The degree of deviation between postoperative CT data and preoperative design was statistically smaller in the navigation group, indicating that the CANS method could achieve better accuracy with preoperative planning. Moreover, in the present study, the CANS method was not more time consuming compared with the non-CANS method. Compared with the non-CANS surgery, approximately 40 minutes was required in the CANS surgery to fix the reference frame without registration. However, during surgery, it helps surgeons to achieve repositioning of the fragment and confirm the final result of fracture reduction, which saves the time required to repeat and the hesitation in fragment repositioning and checking the final result.

Intraoperative imaging using a 3D C-arm system also has been used to assist reduction of zygomatic orbital fractures. Compared with CANS, the C-arm system can help surgeons immediately know and check the reduction effect during surgery and is commonly used to check results of reduction in locations that are difficult to explore during surgery, such as the deep orbit and zygomatic arch. However, it cannot guide reduction in real time or achieve certain complex surgical planning for severe and delayed fractures. In addition, it might be relatively more time consuming and might lead to additional radiation exposure.[25,26]

When CANS is used for ZMC fractures, access through the zygomatic surface is the most commonly used approach for intraoperative navigation.[27,28] In this method, the preoperative surgical plan is easy to develop, but the zygomatic surfaces are not regular and lack landmarks, making it difficult and time consuming to identify the planned positions, particularly when the bone has multiple fractures. In

Table 2. EVALUATION INDICATORS BASED ON CT MEASUREMENTS AND HOSPITALIZATION INFORMATION

	CT Measurement (mm)	Navigation (n = 39) vs Control (n = 39) Group		Visual Analog Scale Score	Navigation (n = 36) vs Control (n = 35) Group
	Difference of Bilateral Zygomatic Eminence	Difference of Bilateral Zygomatic Width	Accuracy Evaluation	Self-Assessment*	Other Assessments†
Navigation group	1.24 (0.80, 1.86)	0.94 (0.73, 1.57)	1.30 (0.40, 2.40)	9 (8, 9)	8 (6, 9)
Control group	2.20 (1.58, 3.66)	1.36 (0.93, 2.13)	2.40 (1.40, 4.10)	8 (8, 9)	7 (5, 9)
P value	<.001	.061	.012	.328	.043

Note: Indicator values are presented as median (25th percentile, 75th percentile) based on Mann-Whitney *U* test.

Abbreviation: CT, computed tomographic.

* Self-assessment of bilateral zygomatic symmetry 6 months postoperatively: poor, 0 to 2; general, 3 to 5; good, 6 to 8; excellent higher than 8.

† Blinded assessment of bilateral zygomatic symmetry by physician 6 months postoperatively: poor, 0 to 2; general, 3 to 5; good, 6 to 8; excellent, higher than 8.

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the present study, a different strategy was used for intraoperative navigation, which was described in the authors' previous study.[20] Briefly, the authors artificially created 4 new landmarks on the surface of the zygomatic bone. Using geometry, the location of 4 points on a 3D object can determine the position of the object. Thus, the authors needed to locate these 4 landmark points alone on the zygomatic bone to determine its position. This point-to-point intraoperative navigation strategy provided more accuracy with less time expenditure. In the present study, no significant differences were observed in the surgical time between the navigation group and the control group (P = .450).

Of the 78 patients, 48 (26 in the navigation group and 22 in the control group) exhibited orbital fracture and enophthalmos (4.35 mm [2.87, 6.76 mm]). Fifteen of them had different degrees of diplopia or eyeball dyskinesia. In this study, all orbital reconstructions were guided by CANS. An orbital-wall titanium mesh was used for 31 of these patients (16 in the navigation group and 15 in the control group). The basic details of this procedure were as follows. The healthy orbit of the patient was mirrored onto the fractured side and a 3D polymer model of this repaired skull was produced. The model was used to shape a titanium mesh, which was intraoperatively positioned at the appropriate site with guidance from CANS. Another 12 patients undergoing orbital reconstruction were treated by inserting sliced bone chips or alloplastic implants into the orbit to reduce the volume of the expanded orbital cavity fracture. The remaining 5 such patients underwent these 2 procedures. The postoperative CT measurements showed that 30 patients (62.5%) had good postoperative globe projection (≤2 mm), 9 (18.8%) had mild enophthalmos (≤3 mm), 4 (8.3%) had moderate enophthalmos (≤4 mm), and 5 (10.4%) required ocular prostheses.

The primary limitation of this study was the absence of a soft tissue symmetry evaluation. However, owing to the uncertainty about the mechanism of soft tissue healing, current techniques cannot provide accurate prognoses for postoperative soft tissue symmetry. Moreover, there is no well-accepted objective evaluation method for soft tissue symmetry. This study adopted the VAS to subjectively evaluate the postoperative recovery of facial soft tissue symmetry. Clinician assessment of VAS resulted in a higher median value for the navigation group (8 vs 7; P = .043), whereas patient self-assessment scores were not significantly different between groups (9 vs 8; P = .328). This could be the result of the observer (Hawthorne) effect.[29]

In conclusion, this randomized controlled trial provides evidence that the CANS allows for more accurate implementation of preoperative plans for fracture reduction, thereby yielding substantial improvements in the postoperative bilateral symmetry of the ZMC region.

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