Three-Dimensional Accuracy of Bone Contouring Surgery for Zygomaticomaxillary Fibrous Dysplasia Using Virtual Planning and Surgical Navigation

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Purpose: Fibrous dysplasia (FD) is a benign condition in which normal cancellous bone is replaced by immature woven bone and fibrous tissue. The present study aimed to estimate and compare the 3-dimensional (3D) accuracy of bone contouring surgery for zygomaticomaxillary FD performed using virtual planning and surgical navigation versus surgeon's intraoperative assessment.

Patients and Methods: This is a retrospective cross-sectional study. Patients with zygomaticomaxillary FD who underwent bone contouring surgery between 2012 and 2019 were reviewed. They were divided into 2 groups: group A underwent bone contouring surgery using virtual planning and surgical navigation, and group B underwent bone contouring surgery by surgeon's intraoperative assessment. The predictor variable was surgical technique. The other variables were gender, age, and operative region. The primary outcome variable was 3D accuracy, which was indicated by root mean square, calculated as a measure of the deviation of the postoperative computed tomography from the preoperative virtual plan. The other outcome variables were patient satisfaction with the outcome by self-evaluation score and operative times. Correlation analysis between the predictor variables and outcome variables was performed.

Results: The sample comprised 24 patients (17 males and 7 females, mean age, 25.7 ± 10.45 years), 13 patients in group A and 11 patients in group B. The mean root mean square was significantly lower in group A than in group B (P = .007). Patient satisfaction with facial symmetry was significantly better in group A (P = .015). Mean operative time was comparable between the 2 groups (P = .918). Surgical technique (P = .011) and operative region (P = .01) were significant influence factors in 3D accuracy of surgery.

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Conclusions: Virtual planning and surgical navigation can significantly improve the 3D accuracy and patient satisfaction of bone contouring surgery for zygomaticomaxillary FD, without prolonging operative time.

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Fibrous dysplasia (FD) is a benign condition in which normal cancellous bone is replaced by immature woven bone and fibrous tissue.[1] It was first recognized by Lichtenstein in 1938[2] and described in detail by Lichtenstein and Jaffe in 1942.[3] FD may affect only single bone (monostotic) or multiple bones (polyostotic), and may sometimes be associated with skin pigmentation and endocrine disturbances—the McCune-Albright syndrome.[4] In the craniofacial region, the zygomaticomaxillary region is most commonly affected, followed by the mandible, frontal bones, sphenoidal bones, ethmoidal bones, parietal bones, temporal bones, and occipital bones.[5] Lesions in the zygomaticomaxillary region often involve adjacent bones, that is, the sphenoid, nasal, or frontal bones,[6] causing severe deformities and functional problems. Management of zygomaticomaxillary FD is by complete removal of dysplastic bone and bone recontouring surgery.[7,8] In the past, the bone contouring was very challenging and outcomes depended on the surgeon's experience and judgment. Now, computer-assisted design and manufacture techniques have made the surgery much more straightforward to perform.

Virtual planning, rapid prototyping, reverse engineering, and surgical navigation have been used for different types of craniofacial surgery, including tumor resection, jaw reconstruction, trauma repair, and orthognathic surgery.[9-12] Several authors have reported the use of computer-assisted techniques in bone contouring surgery for patients with zygomaticomaxillary FD,[13-18] but only a few studies[19] have investigated the 3-dimensional (3D) accuracy of bone contouring surgery for zygomaticomaxillary FD in quantitative analysis.

The purpose of this study was to estimate and compare the 3D accuracy of bone contouring surgery for zygomaticomaxillary FD performed using virtual planning and surgical navigation versus the traditional method (ie, with the extent bone resection and contouring based solely on the surgeon's intraoperative judgment). The investigators hypothesized that virtual planning and surgical navigation can improve the 3D accuracy of bone contouring surgery for zygomaticomaxillary FD without prolonging operative time. The specific aims of the study were to estimate and compare the 3D accuracy, patient satisfaction, and operative time of bone contouring surgery for zygomaticomaxillary FD performed using virtual planning and surgical navigation versus traditional method.

Patients and Methods

STUDY DESIGN

To address the research purpose, we designed and implemented a retrospective cross-sectional study. The study population comprised patients with zygomaticomaxillary FD who underwent bone contouring surgery at the Department of Oral and Maxillofacial Surgery in Peking University School and Hospital of Stomatology between May 2012 and July 2019. To be included in the study sample, patients had to have the following: *1)* pathologically confirmed diagnosis of FD; *2)* unilateral lesion involving the zygomaticomaxillary region; and *3)* computed tomography (CT) performed preoperatively and at 1 month after surgery. Patients were excluded as study participants if *1)* patients had craniofacial disease on the unaffected side, such as cleft lip and palate, or a history of fracture; and *2)* medical records and CT data were incomplete.

Patients were divided into 2 groups: group A underwent bone contouring surgery by computer-assisted techniques (virtual planning and surgical navigation), and group B underwent bone contouring surgery by the traditional method (ie, extent bone resection and contouring solely based on the surgeon's judgment). Demographic and clinical characteristics, intraoperative parameters, and outcomes were compared between the 2 groups.

The primary predictor variable was surgical technique, and the other study variables included age, gender, and operative region. The primary outcome variable was 3D accuracy. The other outcome variables were patient satisfaction with the outcome by self-evaluation score and operative times.

The institutional review board approved this study. All procedures were carried out in accordance with the Code of Ethics of the World Medical Association (Declaration of Helsinki) for experiments involving humans. Informed consent was obtained from each patient before the surgery.

SURGICAL TECHNIQUE

All patients underwent spiral CT scanning of the head and neck region preoperatively (field of view, 20 cm; pitch, 1.0; slice, 1.25 mm; 120 to 280 mA). Preoperative virtual plan was performed for group A. The scan data, in digital imaging and communications in medicine format, were imported into ProPlan CMF

3.0 (Materialise, Leuven, Belgium). We chose the median sagittal plane as the reference plane and mirrored the unaffected side onto the affected side as the contouring template (Fig 1). The extent of resection and the contour lines were designed and displayed on multiplanar views. Then, the CT images of the virtual plan in stereolithography (STL) format were imported into iPlan CMF (BrainLAB AG, Feldkirchen, Germany) for registration with the original CT images.

For all patients, an intraoral vestibular approach was used to expose the lesion. In group A patients, bone contouring was performed according to the virtual plan, fully guided by the surgical navigation system (BrainLAB AG). The navigation frame was fixed to the patient's head with screws inserted through small incisions in the scalp. Then the operator registered a series of points on the face with the CT data set to match the actual maxillofacial skeleton. Intraoperative navigation was used to implement the virtual plan for bone contouring. The extent of resection and the contour lines were displayed on the multiplanar sagittal, coronal, axial, and 3D reconstruction images. With the help of a surgical probe and by real-time comparison with the preoperative virtual plan, the surgeon estimated the degree of bone recontouring required and the exact location of important anatomic structures (Fig 2).

In group B patients, bone contouring was performed in the traditional way, with the extent of resection based on the surgeon's clinical judgment.

OUTCOME EVALUATION

Patients in both groups underwent postoperative CT examination within 1 month of surgery. The data in digital imaging and communications in medicine format were imported into ProPlan CMF 3.0 and a 3D model in STL format was generated. The ideal and postoperative 3D models in STL format were imported into Geomagic Control 2015 (Geomagic, Cary, NC) for comparison. For group A, the ideal 3D model was obtained from the preoperative virtual plan. For group B, the preoperative virtual plan was simulated, mirroring the unaffected side onto the affected side, to get ideal 3D model. The ideal 3D model was set as the reference object, whereas the postoperative 3D model was set as the test object. The 2 models were aligned by optimal fitting, and the surgical area was selected. Then, 3D analysis was used to evaluate the accuracy of the superimposition in the surgical area to get a color-coded map and the root mean square (RMS) values between the 2 models (Fig 3).

The RMS was calculated using the equation $\mathrm{RMS} = \sqrt{\sum_{n}^{i=1}(x_{1,i}-x_{2,i})^2/n}$, in which $x_{1,i}-x_{2,i}$ is the distance between point pairs in the reference model and the corresponding point pairs with the closest Euclidean distance in the test model during the registration process, and n is the total number of point pairs measured (calculated automatically by the software). The greater the difference in distance between point pairs in the reference model and the corresponding point pairs in the test model, the greater is the difference between the 2 models. The RMS represents the direct mean deviation between the ideal and postoperative 3D models and, thus, reflects the 3D accuracy of the bone contouring surgery.

All measurements were carried out independently by 2 investigators, and the values were averaged. If the difference between the measurements was greater than 10%, an additional measurement from a third investigator was obtained and the mean value was calculated.

Facial symmetry also was self-evaluated by patients at 3 months after the surgery; satisfaction with outcome was scored by the patient on a scale of 0 to 10. The scores were categorized as follows: fully satisfied (8 to 10), fairly satisfied (4 to 7), and not satisfied (0 to 3).

The operative times were collected from the anesthesia notes.

STATISTICAL ANALYSIS

The χ^2 test was used to compare the binary study variables (gender and operative region) with the predictor variable and the primary outcome variable. Pearson correlation was used to analyze the relationship between age and the primary outcome variable. Continuous variables (age, RMS, and operative time) were summarized as the means $\pm$ standard deviation and compared between groups using the Student t test. The categorical variable (self-evaluation score) was compared by Wilcoxon rank sum test. Multiple linear regression analysis of predictor variables versus primary outcome variable was used to adjust for potential confounders or effect modifiers identified. The consistency between investigators in the measurement of RMS was assessed by calculating the intraclass correlation coefficient. IBM Statistical Product and Service Solutions Statistics 21.0 (IBM, Armonk, NY) was used for statistical analysis. $P < .05$ was considered statistically significant.

Results

A total of 24 patients (17 males and 7 females) were included in this study, with an average age of 25.7 $\pm$ 10.45 years (range, 9 to 57 years). Group A comprised 13 patients, and group B comprised 11 patients. There were no significant differences in gender, age, or operative region between the 2 groups (Table 1).

As for univariate survival analysis, study variables (gender, age, and operative region, except the primary

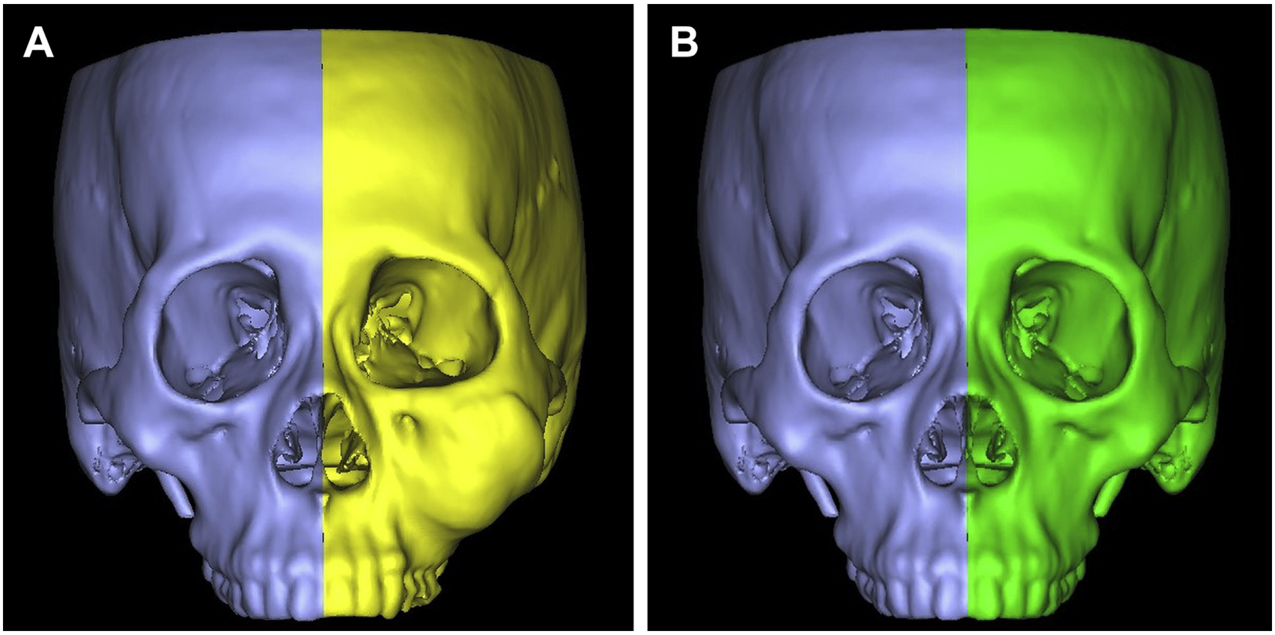

FIGURE 1. Preoperative virtual planning. *A*, The median sagittal plane was designed as the reference plane. *B*, Mirror image of the unaffected side used as the contouring template for the affected side.

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predictor variable) versus the primary outcome variable, we found that female patients and patients with the operative region only in the maxilla had lower RMS (P = .012 and P = .01, respectively), indicating higher 3D accuracy. Age of the patient had no correlation with the RMS (P = .743), showing age had no influence on 3D accuracy of surgery (Table 2).

Postoperative 3D reconstructed images showed excellent outcomes for facial symmetry in group A (Fig 4). The mean RMS was significantly lower in group A than in group B (P = .007), indicating higher 3D accuracy of bone contouring surgery in the former group (Table 3).

Mean operative time did not differ significantly between group A and group B (P = .918; Table 3).

All patients expressed satisfaction (fully satisfied or fairly satisfied) with the facial symmetry achieved (Figs 4, 5). However, comparison of the scores by the Wilcoxon rank sum test showed that satisfaction was significantly better in group A than in group B (P = .015; Table 3).

After adjusting for potential confounders and effect modifiers identified, multiple linear regression analysis showed that surgical technique (P = .011) and operative region (P = .01) were significant influence factors in 3D accuracy of bone contouring surgery for zygomaticomaxillary FD (Table 4).

All measurements between the 2 investigators were less than 10%, and the result of intraclass correlation coefficient (0.93, >0.9) showed a high degree of consistency and reliability between investigators.

The wounds healed well in all patients. Although 14/24 (58.3%) patients complained of suborbital numbness after surgery, all recovered within 2 weeks to 6 months. There were no serious surgical complications (ie, tooth root injury, eye injury, or suborbital nerve rupture). The follow-up period ranged from 6 to 72 months (mean, 35.3 months). Four (4/24, 16.7%, 2 patients in each group) patients had local relapse 11 to 18 months after surgery, but most of them were not serious. Only 1 patient underwent a second bone contouring surgery.

Discussion

The purpose of this study was to estimate and compare the 3D accuracy of bone contouring surgery for zygomaticomaxillary FD performed using virtual planning and surgical navigation versus the traditional method. We hypothesized that virtual planning and surgical navigation can improve the 3D accuracy of bone contouring surgery for zygomaticomaxillary FD without prolonging operative time. The specific aims of the study were to estimate and compare the 3D accuracy, patient satisfaction, and operative time of bone contouring surgery for zygomaticomaxillary FD performed using virtual planning and surgical navigation versus the traditional method.

In this study, we found that virtual planning and surgical navigation can significantly improve the 3D accuracy and patient satisfaction of bone contouring surgery for zygomaticomaxillary FD and the operative time was not significant between the 2 groups. In

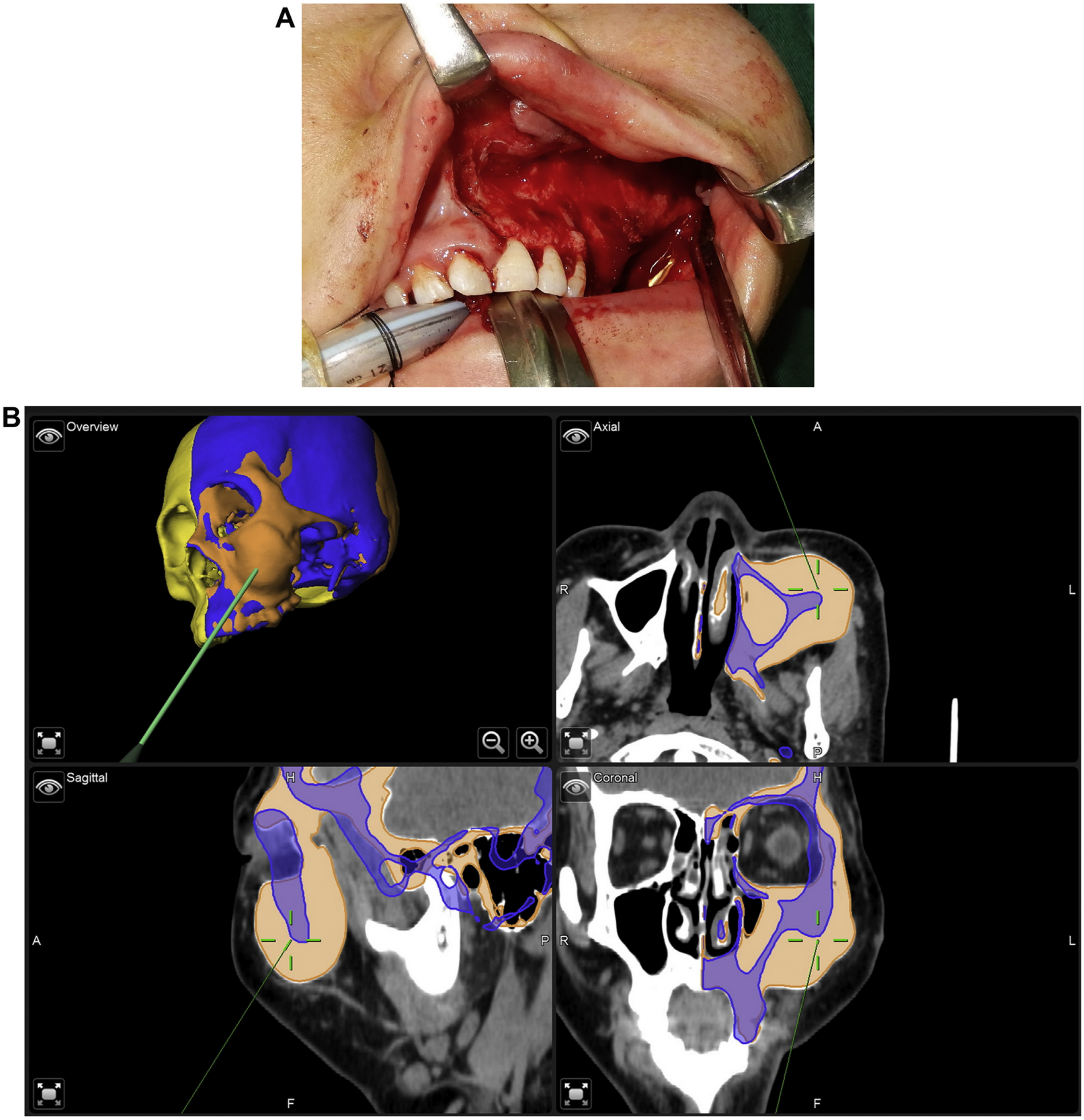

FIGURE 2. *A*, The lesion has been exposed using an oral vestibular approach. *B*, Bone contouring carried out under the guidance of navigation system.

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addition, operative region can influence the 3D accuracy of surgery, that is, patients with FD affecting only the maxilla had a higher 3D accuracy of surgery than patients in whom the whole zygomaticomaxillary region was affected.

The most common clinical sign of zygomaticomaxillary FD is painless swelling or deformity of the affected bone.[7,20,21] In some cases, an eye may be vertically displaced or exophthalmic because of pressure from the expanding bone.[22] The aim of treatment is to remove excess bone, achieve esthetic improvement, and restore function. Conservative bone contouring and radical resection are the 2 main surgical approaches. Some scholars favor radical surgical therapy, with extended resection and reconstruction with free flap, to avoid relapse.[7] However, several studies have shown that the pathology does not develop after adolescence.[20,23,24] It may therefore be reasonable to perform bone contouring surgery after the patient has reached adulthood.[25] According to Valentini

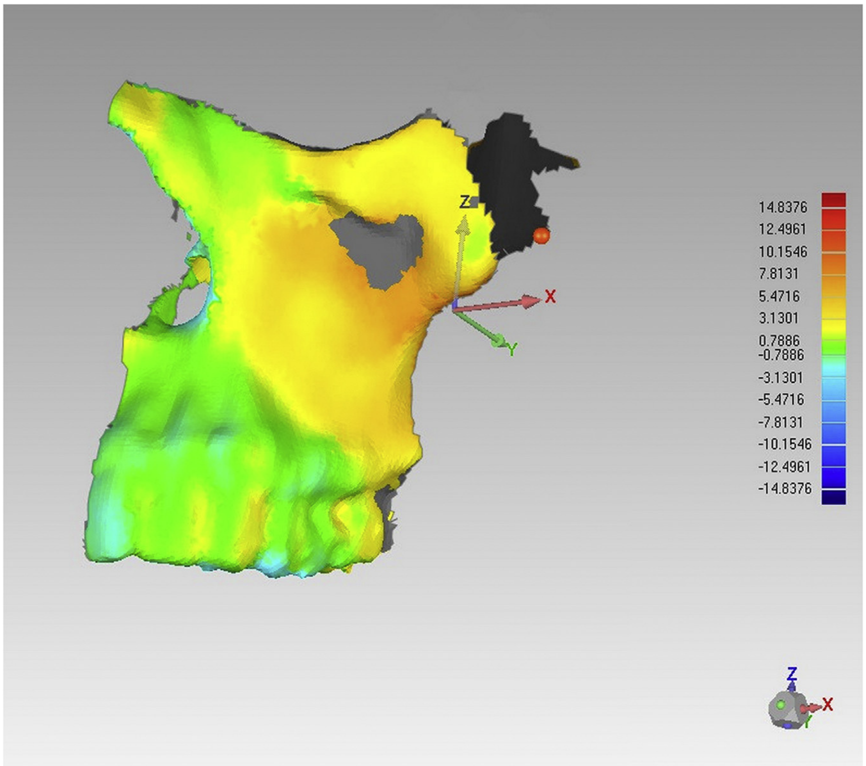

FIGURE 3. Accuracy evaluation. The color-coded map shows the degree of discrepancy between preoperative design and postoperative CT. CT, computed tomography.

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et al,[8] the number of patients undergoing radical resection has decreased in the past 10 years, whereas the number of patients undergoing bone recontouring has increased.

Medical treatments may help in some cases; for example, bisphosphonates can inhibit osteoclastic activity, alleviate pain, and improve the radiological appearance, whereas corticosteroid drugs may provide temporary relief to patients with optic canal involvement and sudden visual loss. However, medical therapy cannot cure or halt the progression of FD.[26,27] Meanwhile, radiotherapy is contraindicated in FD because of the potential for malignant transformation, and chemotherapy is ineffective.[6]

At our center, we prefer conservative bone contouring for most adult patients and reserve extended resection for patients with repeated relapse or malignant changes.[28] For adolescents, we usually prefer to perform bone contouring surgery when the patient reaches adulthood. But for adolescent patients with severe functional impairment, we choose to perform immediate surgery, taking care to be as conservative as possible to prevent growth alteration. In the present study, 23 of the 24 patients were adults when they

Table 1. PATIENT DEMOGRAPHIC AND CHARACTERISTICS

Characteristics	Total	Group A	Group B	*P* Value
Gender				.078
Male	17	7	10	
Female	7	6	1	
Age (yr) (mean ± SD)	25.7 ± 10.45	26.4 ± 9.57	24.9 ± 11.84	.739
Operative region				1.000
Zygomaticomaxillary	13	7	6	
Maxilla	11	6	5	

Abbreviation: SD, standard deviation.

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Table 2. STUDY VARIABLES VERSUS 3-DIMENSIONAL ACCURACY OF SURGERY

Variables	*n*	RMS (mm) (Mean ± SD)	*P* Value
Gender			.012*
Male	17	4.4 ± 1.09	
Female	7	3.1 ± 0.94	
Operative region			.01*
Zygomaticomaxillary	13	4.5 ± 1.03	
Maxilla	11	3.3 ± 1.05	
Age	24	0.071 (−0.042, 0.058)†	.743

Abbreviations: RMS, root mean square; SD, standard deviation.

* Statistically significant.

† Pearson correlation coefficient (95% confidence interval).

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received surgery. One patient received surgery at the age of 9 years because the deformity was progressing rapidly and seriously affecting the patient's life.

Conventional bone contouring surgery for zygomaticomaxillary FD, which relies solely on the surgeon's experience and judgment, can be very challenging, and outcomes are never entirely satisfactory. Many important nerves, vessels, and organs in the maxillofacial region (eg, orbital nerve, maxillary artery, eye, and tooth root) are vulnerable to damage during conventional surgery. Computer-assisted surgery—with techniques such as virtual planning, rapid prototyping, reverse engineering technology, and surgical navigation—can substantially improve esthetic and functional outcomes of various surgical procedures.

Mirroring technology is a form of reverse engineering in which left and right symmetrical 3D images are processed, and 1 image is then used as a template to complete the reconstruction of defects on the other side. Although the anatomy of the zygomaticomaxillary region is complex, it is bilaterally symmetrical and therefore suitable for application of the mirroring technology.

Surgical navigation systems build a "virtual-reality" bridge for the surgeon, especially during performance of bone surgeries, providing direct, precise, 3D, and instant feedback about the operation.[9] The basic principle of surgical navigation is as follows: the preoperative medical image information obtained by digital scanning (CT or magnetic resonance imaging) is input into specialized software to reconstruct the 3D model image, and then the preoperative design and simulation of the operation are carried out using relevant software. During the actual surgery, infrared ray or a laser probe is used to dynamically display the operation area and track the real-time position of the surgical instrument, so as to realize the unification of the dynamic positioning of the surgical area, the instrument, and the virtual environment. With the progress of registration technology, the accuracy of navigation systems has improved markedly.[29] The accuracy of some registration methods can reach 1 mm.[30]

There is research on the 3D accuracy of bone contouring surgery for zygomaticomaxillary FD performed using virtual planning and surgical navigation. Pan et al[31] used reverse engineering and rapid prototyping technology to design and manufacture individualized navigation templates, but they did not use a navigation system and also did not objectively evaluate outcomes. Wang et al[14] reported the benefits of the navigation system in 13 patients of craniofacial FD who received bone contouring surgery assisted by computer techniques. Gui et al[32] used the mirroring tool in patients with unilateral craniofacial FD, and used virtual planning to draw new anatomic contours at the workstation in the patients with bilateral lesions; they reported better predictability and effectiveness with computer-assisted treatments. Kang et al[33] implanted screws of predetermined lengths into surgical sites as a guide for bone shaving surgery of craniofacial FD affecting the maxilla and zygoma. By using screws, the exact amount of bone could be removed, as determined preoperatively. However, the authors did not compare the 3D accuracy between patients undergoing computer-assisted surgery and conventional surgery. Bao et al[19] compared the symmetry after recontouring of zygomatic FD between navigation-guided surgery and conventional surgery, showing the use of a surgical navigation system during zygomatic FD recontouring improved the surgical outcome, but the 3D accuracy of the surgical area was not directly assessed.

The difference between the preoperative CT data and the computer-assisted design reflects the accuracy of the surgery. In our study, the RMS was significantly lower in group A than in group B (P = .007). Although the mean difference of the RMS between the 2 groups was 1.3 mm (Table 3), and it may not be necessarily discernible clinically by naked eyes, it was significant in statistical analysis. The result of patient satisfaction with the outcome by self-evaluation score also showed that the satisfaction was significantly better in group A than group B (P = .015). All these results showed that the better 3D accuracy is achieved with the use of virtual planning and surgical navigation. Both the precision and the safety of the surgery are remarkably improved. Surgical navigation can clearly identify safety margins, help in preserving vital structures,

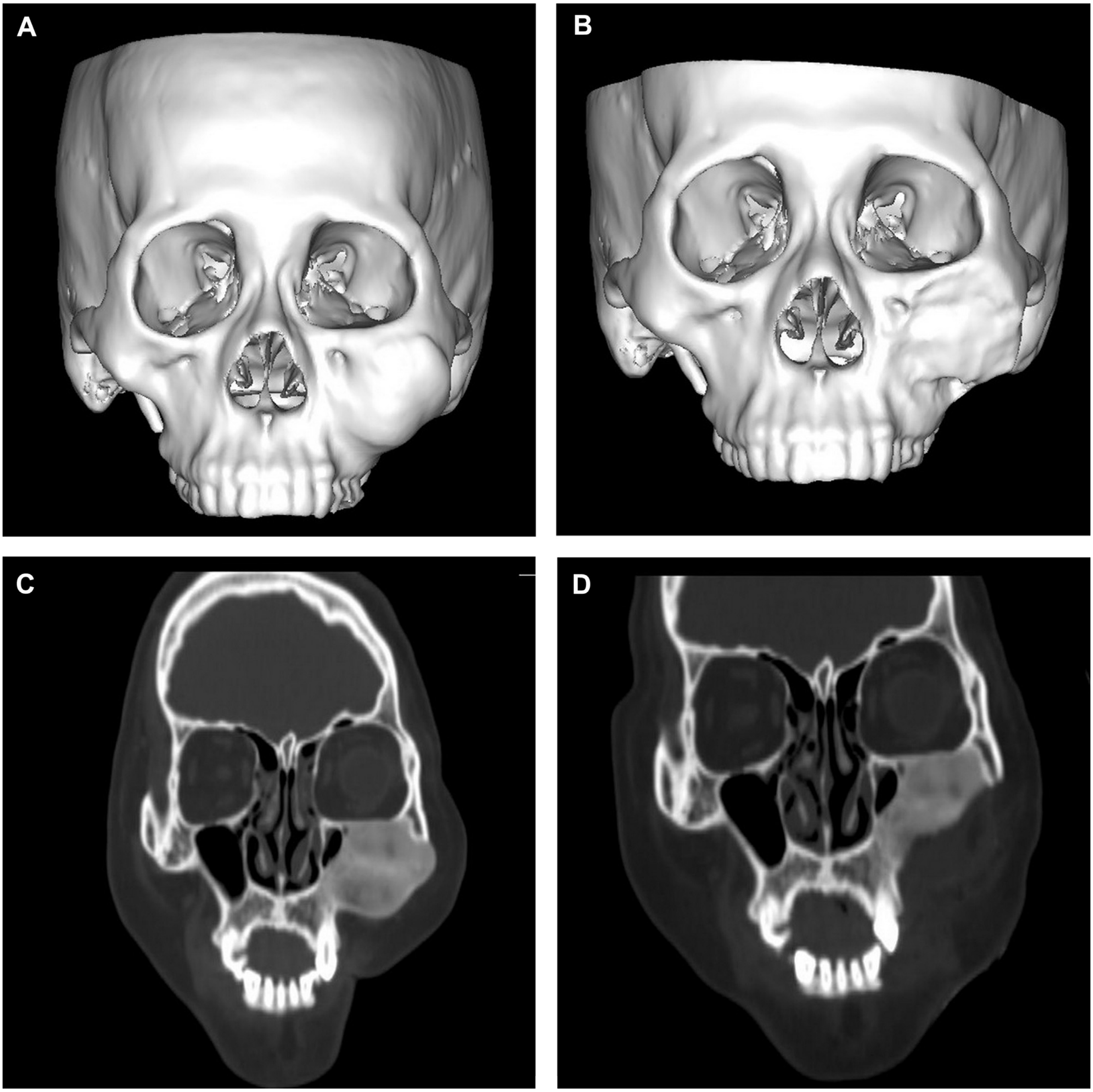

FIGURE 4. Preoperative (*A*, *C*) and postoperative (*B*, *D*) CT images. Postoperative CT shows good facial symmetry. CT, computed tomography.

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Table 3. SURGICAL OUTCOMES IN GROUP A AND GROUP B

Groups	RMS (mm) (Mean ± SD)	Self-Evaluation Score (Median ± Interquartile Range)	Operative Time (min) (Mean ± SD)
Group A	3.4 ± 0.98	8 ± 1	111.5 ± 43.04
Group B	4.7 ± 1.09	7 ± 1	109.6 ± 42.22
P value	0.007*	0.015*	0.918

Abbreviations: RMS, root mean square; SD, standard deviation.
* Statistically significant.

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FIGURE 5. Preoperative photographs show facial asymmetry (*A*, *B*). Postoperative photographs show improved facial symmetry (*C*, *D*).

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Table 4. MULTIPLE LINEAR REGRESSION ANALYSIS OF PREDICTOR VARIABLES VERSUS 3-DIMENSIONAL ACCURACY OF SURGERY

	RMS		
Variables	β	95% CI (Lower, Upper)	*P* Value
Surgical technique*	−0.463	−0.809, −0.117	.011§
Gender†	0.157	−0.211, 0.524	.384
Age	−0.081	−0.419, 0.257	.623
Operative region‡	0.493	0.132, 0.853	.01§

R^2: 0.487.

Assignment of categorical variables.

Abbreviations: CI, confidence interval; RMS, root mean square.

* Computer-assisted technique = 1, traditional method = 0.

† Male = 1, female = 0.

‡ zygomaticomaxillary = 1, maxilla = 0.

§ Statistically significant.

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and in achieving optimal symmetry (Figs 4 and 5). As far as we know, this is one of the few quantitative analyses of 3D accuracy of bone contouring surgery for zygomaticomaxillary FD performed with computer-assisted techniques.

Operative region, registration precision, stability of the navigation frame during the surgery, and computer algorithm accuracy may all affect the accuracy of surgery navigation.[14] In our study, the RMS was significantly lower in patients with FD affecting only the maxilla than in patients in whom the whole zygomaticomaxillary region was affected (*P* = .01, Table 2). Multiple linear regression analysis also showed that operative region was a significant influence factor in 3D accuracy of bone contouring surgery for zygomaticomaxillary FD (*P* = .01, Table 4). We found that the red region in the color-coded map was mainly in the zygomatic region or the maxillary tuberosity in most cases. To avoid surgical scarring, all our patients were treated with an oral vestibular approach. Because of the restricted visual field and the limited range of pulling, the 3D accuracy of bone contouring surgery is less than ideal for patients with a lesion involving the zygomatic region, especially the root of the zygomatic arch. Some surgeons have used the Weber-Ferguson incision to approach FD of the zygomaticomaxillary complex.[24] Although this approach provides better visualization, it will leave visible scars on the face. In our study, most patients were young and were particularly concerned about facial scars. Although the 3D accuracy of bone contouring surgery was slightly lower in patients with zygomaticomaxillary lesions, all our patients were satisfied with the facial symmetry achieved.

Framework loosening can cause image drift and influence the accuracy of surgery navigation.[14] There are 2 types of navigation frames: noninvasive and invasive. The noninvasive frame is head-mounted, but because the head is often moved during surgery, there is a risk of loosening of the frame. In the present study, the invasive type was used; the navigation frame was fixed rigidly to the patient's head with screws to ensure stabilization of the infrared tracking camera throughout the surgery.

Nowinski et al[13] reported that the operative time tends to be relatively longer when the navigation system is used in the bone contouring surgery of zygomaticomaxillary FD. Unfamiliarity with the equipment may have been responsible, as installation of the frame of the navigation system and performing navigational confirmation during surgery can take some time. In our study, the mean operative time was not significantly different between the 2 groups (*P* = .918). In our hospital, the navigation system is widely used in various types of surgeries and so all surgeons are very familiar with the technology. With the preoperative virtual plan and surgical navigation, hesitation during surgery and the need for repeated comparison with the unaffected side are avoided. Thus, virtual planning and surgical navigation may actually reduce the operative time.

This study estimated and compared the global 3D accuracy, patient satisfaction, and operative time of bone contouring surgery for zygomaticomaxillary FD performed using virtual planning and surgical navigation versus the traditional method in quantitative analysis. Similar studies were few in the past. Because this study was a retrospective study and not a randomized controlled study, some samples were unevenly distributed. In this study, male patients had higher RMS than female patients (*P* = .012, Table 2), it may be because of the poor accuracy of the conventional group (group B), which involves more male patients. But multiple linear regression analysis showed that the gender was not a significant influence factor in 3D accuracy of bone contouring surgery for zygomaticomaxillary FD.

In conclusion, virtual planning and surgical navigation can significantly improve the 3D accuracy of bone contouring surgery for zygomaticomaxillary FD, without prolonging operative time. The technology is worth promoting. A randomized controlled and in-depth study is needed in the future.

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