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Accuracy of globe-sparing orbital reconstruction using individually bent titanium mesh: A comparative study

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Summary Accurate reconstruction of orbital and midfacial defects following extensive globe-sparing maxillectomy is challenging, due to the complex anatomy of facial skeleton. The aim of this study is to evaluate the outcomes of individually bent titanium mesh in navigation-assisted reconstruction of post-ablative orbits in comparison with that without intraoperative navigation.

Forty-one patients undergone globe-sparing maxillectomy and orbital floor reconstruction using individually bent titanium mesh with or without intraoperative navigation were assessed. Pre- and postoperative orbital projection and volume measurements were performed on both orbits. The unaffected orbit was used as a control for comparison.

True-to-original orbital reconstruction was achieved in this study. The average difference of globe projection and orbital volume between unaffected and reconstructed orbits was 0.8 ± 0.5 mm and 0.9 ± 1.2cm[3], respectively, in navigation-assisted group. In non-navigation-assisted group, the average difference of globe projection and orbital volume of unaffected and reconstructed orbit was 0.7 ± 0.5 mm and 1.3 ± 1.3cm[3], respectively. There was no statistical significance in mean differences between unaffected and affected globe projection ($P = 0.744$) and orbital volume ($P = 0.677$) in both groups. There was also no significant difference observed when comparing the mean differences between pre- and postoperative globe projection ($P = 0.659$) and orbital volume ($P = 0.582$) in both groups.

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While intraoperative navigation system was shown to be effective in orbital reconstruction in the past decade, equal satisfactory post-ablative orbital reconstruction can be achieved with individually bent titanium mesh with or without intraoperative navigation.

Introduction

Oral and maxillofacial defects following head and neck tumor resections often result in substantial physiological, psychological, and financial impacts in oncology patients as it adversely affects the aesthetics and functions of the face. Accurate and symmetrical reconstruction of orbital and midfacial defects following extensive globe-sparing maxillectomy is taxing, due to the unique and complex anatomy of facial bone. Inadequate reconstruction often led to substandard aesthetics and functions of the face and changes in orbital volume can contribute to significant postoperative enophthalmos and diplopia. The large orbital defects following extensive maxillectomy often lack reliable anatomical landmarks that serve as references for reconstruction, thus, preformed titanium meshes are often insufficient for reconstruction. Computer-assisted surgery technique and intraoperative navigation are particularly advantageous in reconstruction of orbital defects.

Our previous study has shown the satisfactory functional and aesthetics outcomes can be achieved using navigation-assisted technique in orbital reconstruction.[1] Most studies published also demonstrated and substantiated the role of intraoperative navigation and its reliability in restoring orbital volume and projection.[2,3] Nevertheless, our daily practice often revealed that orbital reconstruction with personalized titanium mesh without utilizing navigation system yielded equal optimal outcome. Hence, whether intraoperative navigation system has any added values in orbital reconstruction using individualized titanium mesh remains debatable. The aim of this study is to assess the outcomes of individually bent titanium mesh in reconstruction of post-ablative orbits with or without intraoperative navigation.

Materials and methods

Forty-one consecutive patients who have undergone globe-sparing maxillectomy with orbital floor reconstruction under single surgical team at Department of Oral and Maxillofacial Surgery from January 2011 to December 2019 were reviewed. Thirty-five patients were identified and included in this retrospective study, in which 21 patients underwent navigation-assisted orbital floor reconstruction, while 14 patients underwent orbital reconstruction via conventional method (without navigation). The demographic data and surgical details were summarized in Table 1. Patients' computed tomography (CT) Digital Imaging and Communications in Medicine (DICOM) datasets were retrieved from the radiology database. Patients' data, including gender, age, diagnosis, surgical procedure, and the use of intraoperative navigation were also obtained. Six patients for whom no complete postoperative CT datasets were excluded. The tumor extension was classified based on Brown's maxillary defects classification.

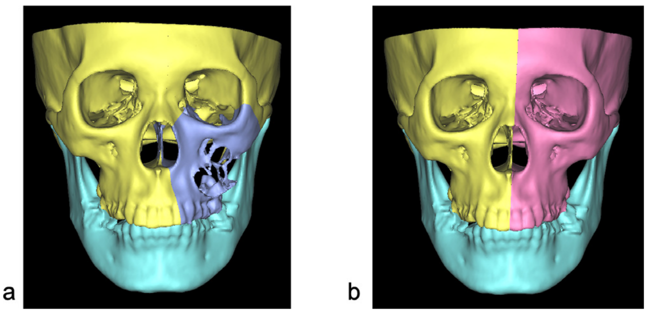
a  b

Figure 1 a: Virtual osteotomy of the left maxillary tumor
b: Mirroring technique was used to reconstruct the affected side.

Preoperative thin-slice (field of view, 20 cm; pitch, 1.0; slice, 0.75 mm; 120–280 mA) DICOM image dataset was acquired and imported into image-guided surgery (IGS) software iPlan® CMF 3.0 (BrainLAB, Feldkirchen, Germany) and third-party surgical planning software in navigation-assisted and conventional groups, respectively, for data conditioning, segmentation and reconstruction of orbital defect using mirroring function (Figure 1a-b). In both groups, the reconstructed models were exported in Standard Tessellation Language (.stl) format and stereolithographic models were printed. The titanium mesh was adapted manually on the 3D-printed model prior to sterilization (Figure 2). In this study, titanium mesh plate 1.3, 0.4, or 0.6 mm (DePuy Synthes, Switzerland) was used. In navigation-assisted group, virtual surgical plan was exported into navigation workstation Kick® (BrainLAB, Feldkirchen, Germany) to facilitate tumor resection, reconstruction and to verify the position of the titanium mesh. (Figure 3a-b) The operative techniques of maxillectomies and orbital reconstruction were similar in both conventional and navigation-assisted groups.

Standard postoperative orbital monitoring and 3D imaging were performed to detect early signs of increased intraorbital pressure or retrobulbar hemorrhage. All patients were subjected to standard oncological follow-up at 1-month, 3-month, 6-month, and annual intervals postoperatively. Postoperative outcome parameters, including postoperative diplopia, enophthalmos, restriction of ocular motility, titanium mesh exposure, and the need for secondary surgery, were recorded in follow-up visits.

Pre- and postoperative orbital projection and volume measurements were performed on both orbits. The unaffected orbit was used as a control for comparison. Using iPlan CMF 3.0, the postoperative CT datasets were aligned according to predefined symmetry planes prior to measurement of orbital projection. A tangent line was drawn con-

Table 1 Demographic and surgical data of the patients.

	Navigation-assisted ($n = 21$)	Without navigation ($n = 14$)
Age (years)	37.8 ± 19.7	60.2 ± 13.3
≤ 50 years old	16	5
≥ 50 years old	5	9
Gender		
Male	16	10
Female	5	4
Diagnosis		
Benign		
Odontogenic myxoma	5	1
Ossifying fibroma	5	0
Adenomatoid odontogenic tumor	1	0
Ameloblastoma	2	0
Ameloblastic fibroodontoma	1	0
Pleomorphic adenoma	1	0
Dentinogenic ghost cell tumor	0	1
Malignant		
Squamous cell carcinoma (SCC)	2	8
Adenoid cystic carcinoma (ACC)	0	1
Osteosarcoma	3	2
Myoepithelial carcinoma	1	0
Spindle cell sarcoma	0	1
Types of reconstruction		
Free fibula flap	14	0
Anterolateral thigh flap	6	13
Deep circumflex iliac artery flap	1	0
Radial forearm free flap	0	1
Mean follow-up duration (months)	33.6 ± 25.2	17.9 ± 11.9

necting both lateral and medial orbital walls, crossing the equator of the globe and the distance from the most prominent part of the orbit to this tangent line is defined as the orbital projection (Figure 4). The projection will be given in millimeter (mm) while orbital volume will be expressed in cubic centimeter (cm^3). The orbital volume was calculated via automatic segmentation and manual adjustments were performed using Smart Shaper and Eraser tools in cases presented with apparent errors, such as inclusion of frontal or ethmoidal sinuses. (Figure 5a-b) Examples of orbital volume and orbital projection measurements of navigation-assisted and without navigation cases were demonstrated in Figure 6a-j.

All data were analyzed using SPSS 24.0 (SPSS Inc., Chicago, IL, USA). Comparison between pre- and postoperative globe projection, and orbital volume was performed using paired sample *t*-test. Independent sample *t*-test was used to analyze the differences of orbital volume and orbital projection between navigation-assisted group and without navigation group. A *p*-value less than 0.05 was considered as statistically significant.

Results

A total of 35 patients in the age of 9–75 years (46 ± 20.35 years) who underwent orbital reconstruction following maxillectomy were included in this study. Each of the orbitomaxillectomy defects was classified as Brown's Class III defects. The average follow-up period is 29.3 months (range from 6 to 81 months). There were 26 (74.3%) male and 9 (25.7%) female patients. Benign pathology constituted 17 cases while malignant tumor comprised of 18 cases. Nineteen cases underwent reconstruction with vascularized anterolateral thigh flap, 14 patients received vascularized free fibula flap, one patient underwent reconstruction with vascularized deep circumflex iliac artery (DCIA) flap and one patient received vascularized radial forearm free flap. The general surgical data were summarized in Table 1. A combination of Weber Ferguson and transoral approaches were used in all subjects. All free flap transfer surgeries were successful. The mean follow-up duration for navigation-assisted and without navigation group was 33.6 ± 25.2 months and 17.9 ± 11.9, months respectively.

In navigation-assisted group, the mean globe projection of unaffected and reconstructed orbit was 15.5 ± 2.4 mm and 15.5 ± 2.9 mm, respectively, while the average difference of globe projection between unaffected and reconstructed orbits was 0.8 ± 0.5 mm. The pre- and postoperative globe projections were 15.5 ± 2.8 mm and 15.5 ± 2.9 mm, respectively, with the mean difference of 1.5 ± 1.3 mm. The mean orbital volume of unaffected orbit was 28.2 ± 4.2cm[3], while the reconstructed orbit measured 27.8 ± 3.4cm[3], with a difference of 0.9 ± 1.2cm[3] between unaffected and reconstructed orbit. The mean orbital volume measured on preoperative orbits was 28.2 ± 3.4cm[3], while a slight reduction in mean volume was noted postoperatively, 27.8 ± 3.4cm[3]. The average difference of

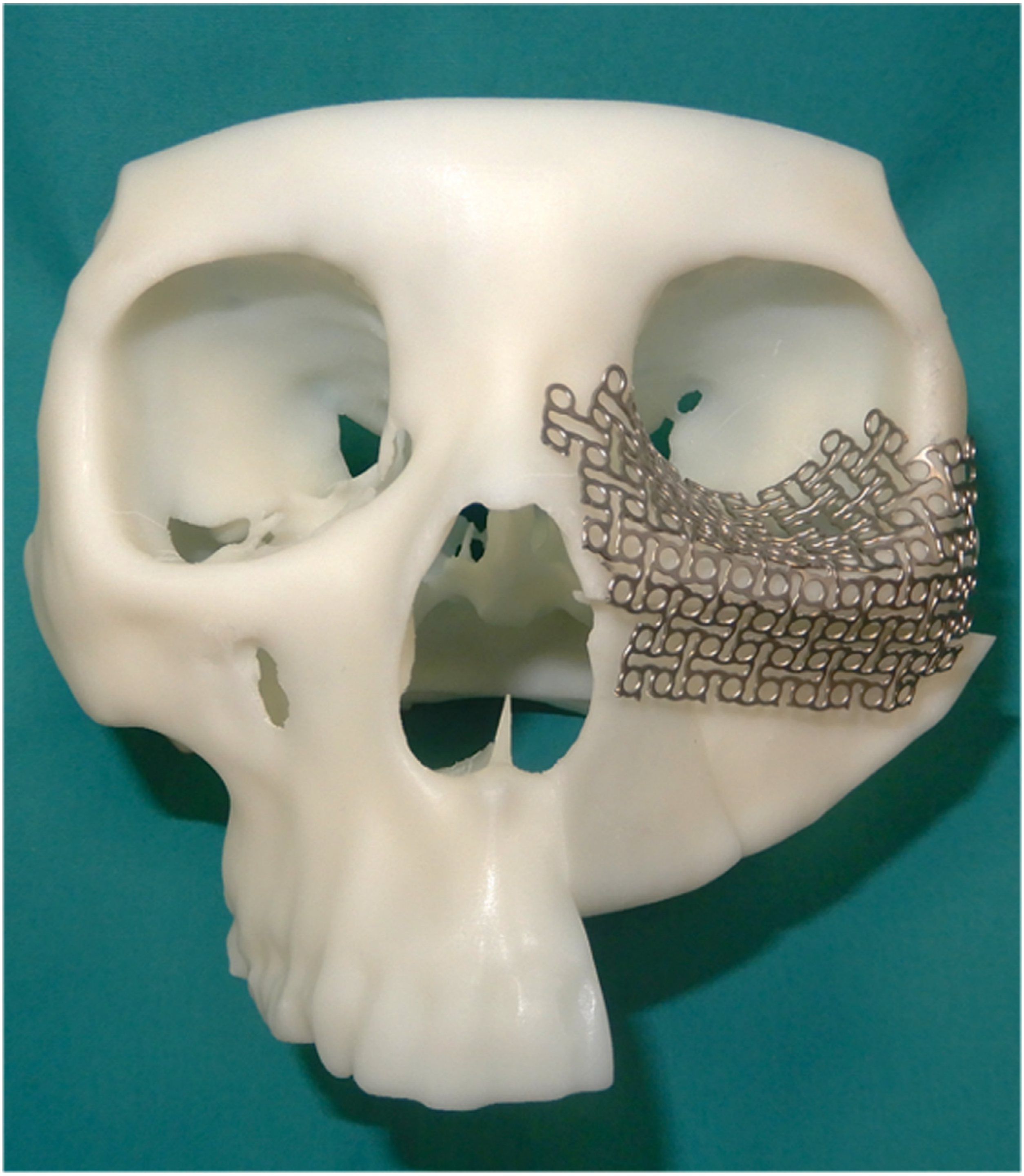


Figure 2 Titanium mesh was adapted manually on the 3D-printed skull model.

orbital volume between pre- and postoperative orbits was 1.2 ± 1.1cm[3]. (Tables 2 and 3)

In non-navigation-assisted group, the average globe projection of unaffected and reconstructed orbit was 16.4 ± 3.8 mm and 16.8 ± 3.3 mm, respectively, with a difference of 0.7 ± 0.5 mm between unaffected and reconstructed orbits. The average globe projection was 17.2 ± 3.7 mm preoperatively, and the mean projection was slightly reduced to 16.8 ± 3.3 mm postoperatively, with a difference of 1.6 ± 1.6 mm between pre- and postoperative globe projection. The mean orbital volume in unaffected orbits was 28.4 ± 5.4cm[3], while in reconstructed orbits, the mean volume was 27.8 ± 4.0cm[3]. The average difference between unaffected and reconstructed orbital volume was 1.3 ± 1.3cm[3]. Comparing orbital volume in pre- and post-operative orbits, the mean orbital volume was measured 28.6 ± 5.0cm[3] preoperatively and 27.8 ± 4.0cm[3] postoperatively, with a difference of 2.0 ± 2.9cm[3] (Tables 2 and 3).

Table 2 Unaffected and reconstructed orbital projection and orbital volume in both navigation-assisted and without navigation groups.

	Globe projection (mm)				Orbital volume (cm^3)			
	Unaffected	Reconstructed	Differences	*P*-value	Unaffected	Reconstructed	Difference	*P*-value
Navigation-assisted	15.5 ± 2.4	15.5 ± 2.9	0.8 ± 0.5	0.744	28.2 ± 4.2	27.8 ± 3.4	0.9 ± 1.2	0.677
Without navigation	16.4 ± 3.8	16.8 ± 3.3	0.7 ± 0.5		28.4 ± 5.4	27.8 ± 4.0	1.3 ± 1.3	

Table 3 Orbital projection and volume analysis between pre- and postoperative globes in both navigation-assisted and without navigation groups.

	Globe projection (mm)				Orbital volume (cm^3)			
	Preoperative	Postoperative	Differences	*P*-value	Preoperative	Postoperative	Differences	*P*-value
Navigation-assisted	15.5 ± 2.8	15.5 ± 2.9	1.5 ± 1.3	0.659	28.2 ± 3.4	27.8 ± 3.4	1.2 ± 1.1	0.582
Without navigation	17.2 ± 3.7	16.8 ± 3.3	1.6 ± 1.6		28.6 ± 5.0	27.8 ± 4.0	2.0 ± 2.9	

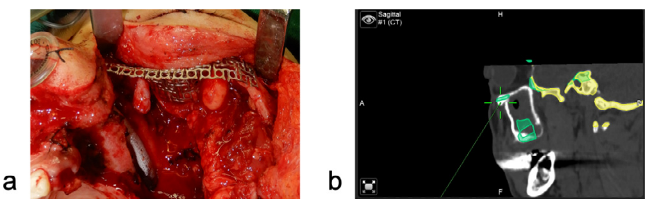


Figure 3 a: Precontoured titanium mesh in situ
b: Position of titanium mesh was confirmed using navigation probe in cases incorporated with intraoperative navigation.

True-to-original orbital reconstruction was achieved in this study, as there were no significant differences found between pre- and postoperative globe projection ($P = 0.126$), and orbital volume ($P = 0.878$), regardless of the navigation- or non-navigation-assisted group. Using independent *t*-test, there was no statistical significance in mean differences between unaffected and affected globe projection ($P = 0.744$), and orbital volume ($P = 0.677$) in both navigation-assisted and without navigation groups. There was also no significant difference observed when comparing the mean differences between pre- and postoperative globe projection ($P = 0.659$), and orbital volume ($P = 0.582$) in both groups.

Three out of 35 patients experienced titanium mesh exposure and one patient experienced ectropion of lower eyelid throughout the follow-up period, in which surgical revisions were performed subsequently. Two patients experienced titanium mesh exposure following external beam radiotherapy, while one patient experienced titanium mesh exposure following wound breakdown of the overlying lower eyelid. No postoperative diplopia, restriction of ocular motility, ocular dystopia, or visual disturbance was observed. All patients were satisfied with the globe position.

Discussion

Orbital and midfacial defects following radical globe-sparing maxillectomy is debilitating. Reconstruction of orbital floor is technically demanding as the anatomy is intricate and reconstruction failures may lead to diplopia, enophthalmos, exophthalmos, restriction of ocular motility. It was reported that 2 mm enophthalmos was associated with small changes in orbital volume of 0.9 mL.[4] True-to-original restoration of orbital volume therefore is particularly important to prevent unfavorable long-term sequelae. Nevertheless, most of the studies focused on post-traumatic orbital reconstructions, the literature comparing outcomes of reconstruction of post-ablative orbital defects with or without navigation is relatively limited.[5-7]

Optimal positioning and accurate shaped preformed implant for reconstruction of posteromedial region was shown to significantly improve the surgical outcomes of complex orbital fractures.[8] While preformed MatrixORBITAL plate (Synthes) provides ideal orbital floor contour and configuration, the size may be inadequate in larger orbital defects, particularly following globe-sparing maxillectomy, which often lack stable anatomical landmarks. Thus, preformed anatomic orbital implants are frequently insufficient to adequately reconstruct the defects.

To counteract the difficulties and reproduce symmetry with the unaffected side, computer-assisted design/computer-assisted manufacturing (CAD/CAM) technology was applied to facilitate true-to-original reconstruction of the affected orbital floor and to improve final surgical outcomes. Under 3D environment, virtual surgical planning can be executed preoperatively, and the mirroring technique permits ideal reconstruction of the affected orbital floor using the mirror image of unaffected side. Yelda et al. validated that the native orbital floor configuration is adequately symmetric to support mirroring technique in orbital reconstruction in the quantitative and volumetric analyses.[9] Consistent results were also reported by Blumer et al. in reconstruction of unilateral orbital fractures by combining both mirroring technique for virtual reconstruction and customization of commercial titanium mesh on 3D-printed model.[10]

Nevertheless, with current resolution limit of 3D CT scanning and stereolithographic techniques, it is almost impossible to precisely reproduce the thinness of orbital floor anatomy.[11] Intraoperative navigation has shown to be advantageous for the past decade, as it enables clearer spatial orientation of local anatomy and tumor margins. By providing real-time feedback, navigation aids to validate accurate

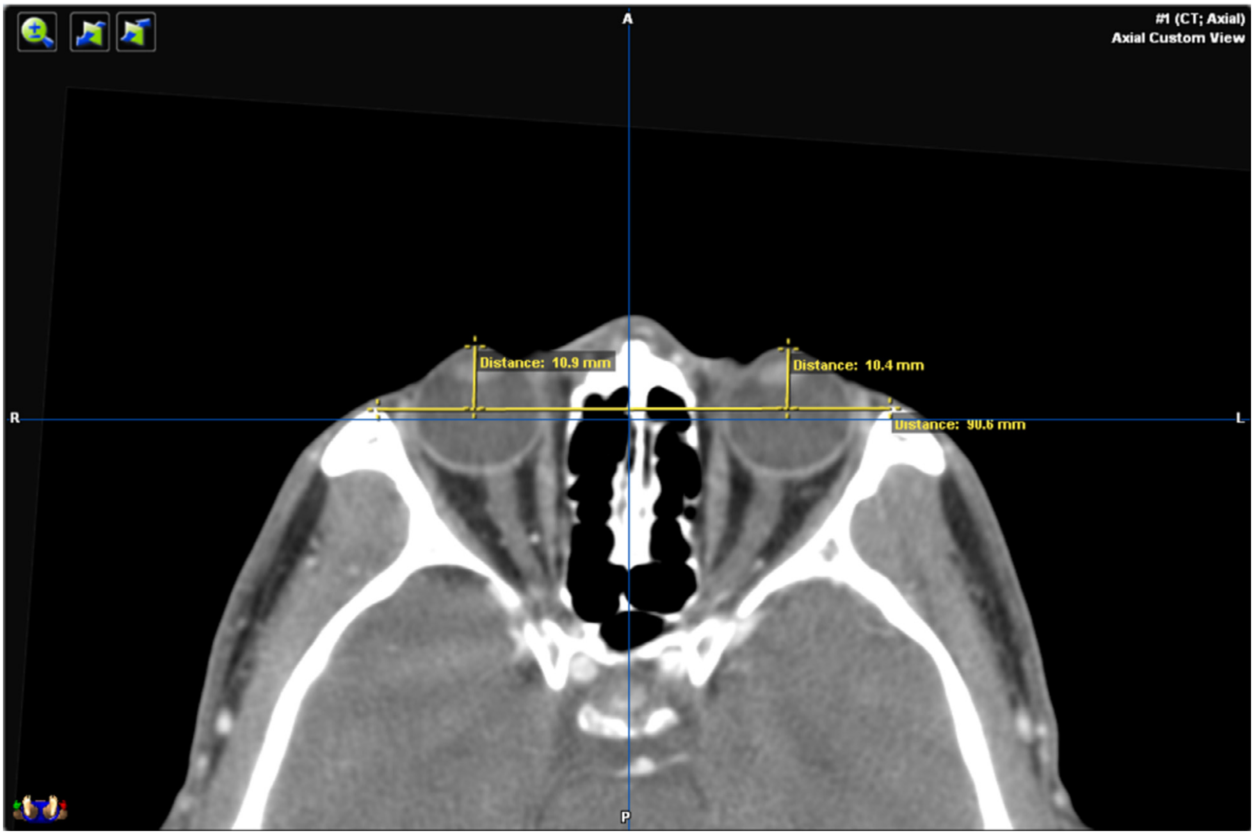


Figure 4 Orbital projection measurement. Following alignment of postoperative CT datasets according to predefined symmetry planes, a tangent line was drawn connecting both lateral and medial orbital walls, crossing the equator of the globe and the distance from the most prominent part of the orbit to this tangent line is defined as the orbital projection.

a b

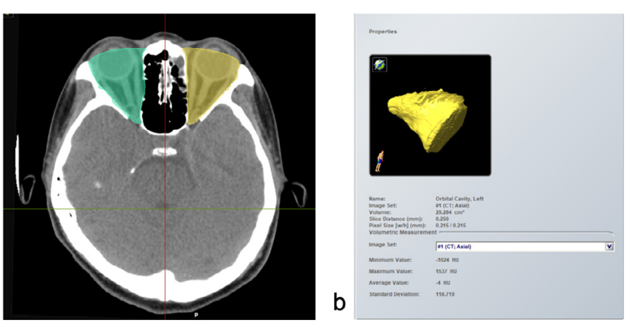


Figure 5 a: Orbital volume measurement. Orbital cavities were segmented automatically using iPlan CMF 3.0 software, followed by manual adjustments if presented with apparent errors, such as inclusion of frontal or ethmoidal sinuses.
b: Orbital volume was calculated automatically by the software.

implant placement without violating the orbital contents and the need for intraoperative CT scan. This is particularly useful in posttraumatic orbital reconstruction, where surgical access is often limited.[12,13] Metzger et al. demonstrated accuracy of approximately 1 mm in reconstruction of orbital fractures using mirroring technique in preoperative surgical planning, adaptation of titanium implants on 3D-printed resin models and incorporation of navigation system intraoperatively.[14]

While intraoperative navigation has shown to be invaluable in orbital reconstruction[2], the efficacy of navigation relies on the accuracy of the system and it is highly dependent on accurate registration. As re-registration is not always possible; registration errors may further contribute to inaccuracies. In this study, there are no significant differences observed between the projection and volume of both unaffected and affected orbits with or without the use of intraoperative navigation system. The postoperative projection and volume were comparable with that of the unaffected orbits regardless of application of navigation-assisted surgery. In contrast to study by Essig et al.[5], significant reduction of orbital volume was observed in complex orbital fractures in navigation group as compared with the conventional group. The substantial increase in orbital volume following complex orbital fracture may contribute to the significant reduction of orbital volume postoperatively. However, this is relatively different in oncological cases, where significant differences in orbital volume may be observed only in cases with massive tumor involvement.

With the prerequisite of thin-sliced CT data, 3D-printed STL models allow replication of the delicate framework of the orbital floor and native anatomical structures, such as posterior ledge. This enabled surgeon to accurately determine the extent of titanium mesh within safe limits of optic nerve, without the need for intraoperative navigation and

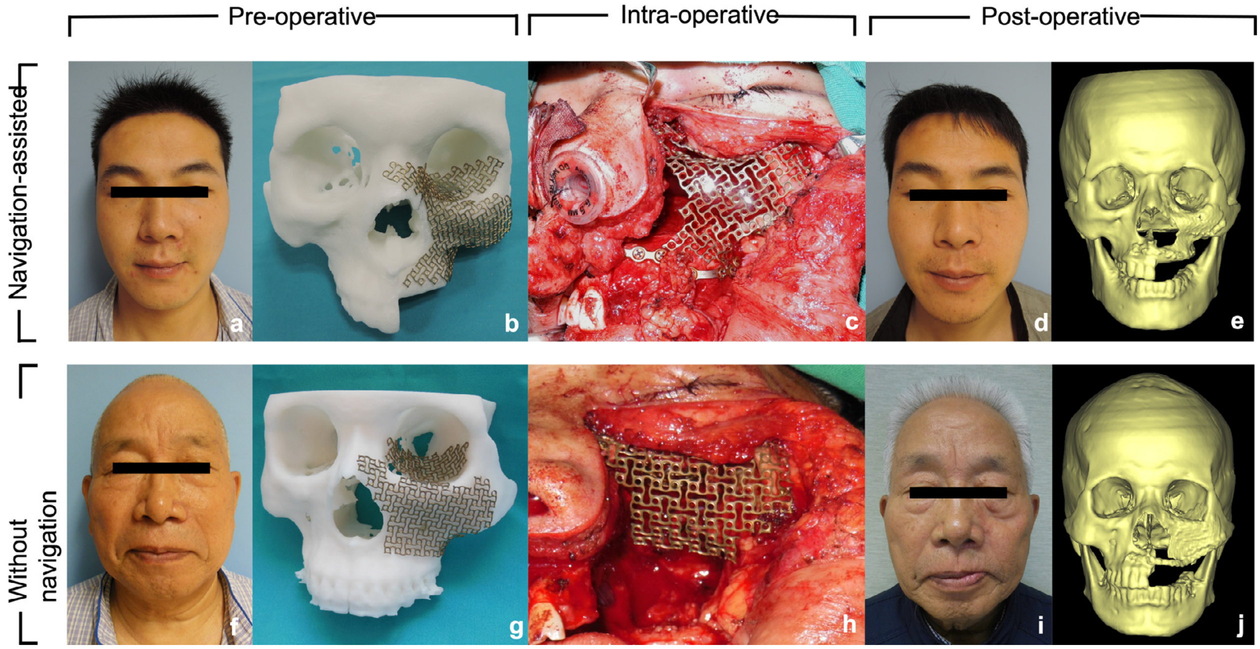


Figure 6 a: Preoperative clinical photograph of the patient with left maxillary ossifying fibroma.
b: Three-dimensional model was printed following virtual surgical planning a titanium mesh was adapted manually on the model preoperatively.
c: Pre-bent titanium mesh in situ following tumor resection and fixation of free fibula flap, verified using intraoperative navigation system.
d: Patient's frontal profile at postoperative 3-month review
e: Three-dimensional reconstruction of postoperative CT scan, demonstrating symmetrical orbital reconstruction.
f: Preoperative frontal profile of patient diagnosed with left maxillary low-grade myoepithelial carcinoma
g: Titanium mesh was adapted directly on the 3D model preoperatively.
h: Titanium mesh in situ following tumor resection via Weber Ferguson approach
i: Patient's frontal facial profile at postoperative 3-month review
j: Three-dimensional reconstruction of postoperative CT scan, showing satisfactory orbital reconstruction.

"overestimation" of the length and size of titanium mesh. Furthermore, the transfacial surgical access (Weber Ferguson approach) in post-ablative orbital reconstruction often enables surgeon to directly visualize the posterior limits of orbital walls. In contrast, the limited surgical access in orbital fractures may impede direct visualization and further manipulation. In case of implant overextension, manual adjustment and reduction can be made easily intraoperatively. Hence, in this study, there was no significant difference noted in both pre- and postoperative orbital volume, and projection. Additionally, the total operating time was also significantly reduced as intraoperative adaptation of the titanium mesh can be challenging and time-consuming.

The extension to medial orbital wall and zygomatic bone region during precontouring of the titanium mesh is crucial for its fixation intraoperatively. Due to the unique anatomical patterns in orbital region, the positioning of prebent titanium mesh can be relatively straightforward and the intraoperative offset should be minimal. Accuracy of the precontouring of the mesh is a prerequisite in this situation. The surgeons can verify the fitting of individualized titanium mesh by checking the degree of adaptation and by examining the intraocular pressure following positioning of the titanium mesh.

In our study, one patient experienced titanium mesh exposure following wound breakdown at the lower eyelid despite no history of radiotherapy. The discussion of potential predictive factors of titanium mesh exposure is beyond the scope of this article, however, our recent study suggested that robust soft tissue flap transfer is important to prevent titanium mesh exposure.[15]

However, individually bent titanium mesh is not without its weakness, the success is heavily reliant on surgeon's capability and ability to visualize the orbital defect three-dimensionally.[11] CAD/CAM-printed implants were recently introduced to maxillofacial reconstruction and had shown promising results. Accuracy of 3D-printed titanium mesh was reported to be within 1mm[16] while Rana et al.[13] demonstrated better reconstruction outcomes in patient-specific implant (PSI) group as compared with prebent titanium mesh. Although PSI could potentially enhance the surgical accuracy and reduce the total operating time, the cost, and time required for designing and manufacturing the implants may preclude its widespread use at present. The current study has demonstrated the manually adapted titanium mesh is adequate for accurate reconstruction of orbital defects following extensive maxillectomy without incorporating intraoperative navigation.

The inherent drawback of this study was that the study was retrospective in nature, the individualized titanium meshes were not scanned and incorporated into the virtual surgical plan, thus, we were unable to perform chromatographic analysis. Most postoperative CT scans were performed between 1 and 2 weeks postoperatively, both parameters measured in this study were unable to depict the long-term changes or volume deficit following cicatricial contractions postoperatively. Moreover, the study may be affected by the normal anatomical differences between orbits.

Adequate reconstruction of orbital anatomy is vital in restoring the native orbital volume and projection, to prevent undesirable postoperative complications. While intraoperative navigation system was shown to be effective in orbital reconstruction in the past decade, this study shows satisfactory post-ablative orbital reconstruction can be achieved with individually bent titanium mesh without intraoperative navigation. Nevertheless, surgeons should be reminded that, intraoperative navigation can only be omitted if there is accurate virtual surgical planning preoperatively, and high-resolution CT DICOM dataset and precise 3D-printed models are the fundamental prerequisite to producing an accurate pre-contoured titanium mesh implant.

Declaration of Competing Interests

None of the authors has a financial interest in any of the products, devices, or drugs mentioned in this manuscript.

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All co-authors have viewed and agreed to the submission.

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Ethical approval

The study was conducted according to the tenets of Declaration of Helsinki and approved by the Institutional Review Board of Peking University School of Stomatology, with the approval number PKUSSIRB-2013058. Written informed consent for medical photographs and publication of medical images was obtained preoperatively.

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