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Original Article

A retrospective study to compare the treatment outcomes with and without surgical navigation for fracture of the orbital wall

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A B S T R A C T

Purpose: To evaluate the outcomes with and without aid of a computer-assisted surgical navigation system (CASNS) for treatment of unilateral orbital wall fracture (OWF).

Methods: Patients who came to our hospital for repairing unilateral traumatic OWF from 2014 to 2017 were included in this study. The patients were divided into the navigation group who accepted orbital wall reconstruction aided by CASNS and the conventional group. We evaluated the surgical precision in the navigation group by analyzing the difference between actual postoperative computed tomography data and preoperative virtual surgical plan through color order ratios. We also compared the duration of surgery, enophthalmos correction, restoration of orbital volumes, and improvement of clinical symptoms in both groups systemically. Quantitative data were presented as mean ± SD. Significance was determined by the two-sample *t*-test using SPSS Version 19.0 A $p < 0.05$ was considered statistically significant.

Results: Seventy patients with unilateral OWF were included in the study cohort. The mean difference between preoperative virtual planning and actual reconstruction outcome was (0.869 ± 0.472) mm, which means the reconstruction result could match the navigation planning accurately. The mean duration of surgery in the navigation group was shorter than it is in the control group, but not significantly. Discrepancies between the reconstructed and unaffected orbital-cavity volume and eyeball projection in the navigation group were significantly less than that in the conventional group. One patient had remnant diplopia and two patients had enophthalmos after surgery in the navigation group; two patients had postoperative diplopia and four patients had postoperative enophthalmos in the conventional group.

Conclusion: Compare with the conventional treatment for OWF, the use of CASNS can provide a significantly better surgical precision, greater improvements in orbital-cavity volume and eyeball projection, and better clinical results, without increasing the duration of surgery.

Introduction

Orbital wall fracture (OWF) is usually caused by facial trauma, which can result in esthetic and functional impairments, such as enophthalmos, hypoglobus, diplopia, disturbed eye motility and even visual loss. The prevalence of OWF has been reported to be 18%–50% in all cases of craniomaxillofacial trauma.[1–3] Safe, rapid and precise reconstruction of the orbital wall is essential for restoring normal function and esthetics, but repair is hampered due to limited surgical exposure and complicated three-dimensional (3D) anatomic structures. Also, the reconstruction outcome is unpredictable because of soft-tissue edema, broken contours of the orbital wall, and difficulty of positioning the implant appropriately. The incidence rate of enophthalmos after repair of an orbital fracture by traditional methods varies between 8% and 72%, and the incidence rate of postoperative diplopia is 7%–85%.[4–6] The incidence rate of re-operation of an OWF has been reported to be 9%–20%,[7,8] which implies that appropriate surgical methods and precise manipulation are

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crucial to improve the surgical outcomes and to reduce the risk of complications.

Computer-assisted surgical navigation system (CASNS) is used widely in oral and maxillofacial surgery, especially in complex maxillofacial reconstruction, and orbital wall reconstruction is one of its indications.[1,2] CASNS can provide detailed preoperative analyses, virtual planning of a surgical procedure, intraoperative guidance and control, and postoperative validation. Several studies have shown that CASNS can provide good treatment outcomes and reduce second corrective procedure by restoring the volume and globe dimensions of the orbital cavity in complex defects of the orbital wall.[9–11] However, few published clinical studies contained a control group without application of a CASNS, or compared the difference in surgical results.

In a cadaver study, Dubois et al.[12] compared the effects of orbital reconstruction with and without the use of a CASNS. They showed that CASNS improved the satisfaction of the surgeon and accuracy of the implant position. However, they did not evaluate enophthalmos or diplopia. In another retrospective study, Yang et al.[10] compared the results of reconstruction of the medial wall of the orbit using a CASNS, endoscope, and conventional freehand under direct vision. They showed that CASNS was feasible (especially for complex orbital reconstruction) because it improved surgical predictability and outcomes. However, their study cohort was small (mean of six patients in each group) and the results were descriptive without statistical analyses.

Considering the additional time needed for preoperative planning, intraoperative manipulation and great medical expense, more evidences are needed to clarify that CASNS could be a routine procedure in repair of a unilateral orbital fracture. In China, the decision for applying CASNS appears to depend mainly on the surgeon's preference rather than evidence-based benefits of clinical outcomes.

We wish to assess the accuracy and treatment outcomes of CASNS in the repair of a unilateral OWF by direct comparison with the conventional method. The accuracy of reconstruction, duration of the surgical procedure, correction of enophthalmos, orbital-cavity volume (OCV), and improvements in clinical symptoms were evaluated.

Methods

Patients

Patients admitted to the department of oral and maxillofacial surgery within the School of Stomatology of the Fourth Military Medical University (Xi'an, China) from 2014 to 2017 for repair of unilateral traumatic OWF were included in our study. The study was conducted in compliance with the principles of the Declaration of Helsinki and approved by the ethics committee of the Fourth Military Medical University.

The inclusion criteria were: (1) unilateral OWF including the medial wall or floor or both, associated with clinically evident diplopia and enophthalmos; (2) surgery undertaken by the same senior surgeon; (3) complete preoperative and postoperative clinical and medical records; (4) preoperative and postoperative data for spiral multi-slice CT (slice thickness = 0.625–1.000 mm); (5) surgical procedure accepted by the patient < 1 month after injury. Syndromic and adolescent patients were excluded.

After careful analysis of the patients' medical record, we divided patients into the navigation group (in which CASNS was used) and the conventional group (in which freehand method based on the surgeon's experience was employed) according to different treatment methods.

Surgical navigation system

The optical navigation system used in this study is produced by Brainlab (Feldkirchen, Germany). This system is composed by two infrared emitting cameras, computer workstation, reflective markers, Z-touch, wireless handheld laser pointer and Brainlab optical adapter clamps.

Surgical protocol for the navigation group

Preoperative planning and simulation

The CT data of patients in the navigation group were processed with iPlan® CMF v3.0.5 (BrainLab, Feldkirchen, Germany). The mid-sagittal plane of the skull (which is necessary for mirroring) was generated automatically by this software. Then, the bony orbital wall of the unaffected side was auto-segmented and mirrored to the injured side to create a virtual template of the orbital wall. This final position of this template in 3D was determined by surgeons after a series of manual corrections using the fine adjustment tool in iPlan CMF v3.0.5. Then, the size and position of implants were determined and outlined according to this virtual template. The optic nerve was also marked (Fig. 1).

Procedure for intraoperative navigation

Under general anesthesia, a dynamic reference frame (DRF) was fixed to the skull with a 6 mm titanium screw. Then, surface matching was used for registration, and several points (e.g. nasion, medial and outer canthus, maxillary central incisal edge) were used to verify the accuracy of this registration. Thus, the position and anatomic information of the patient were matched to preoperative CT data and the virtual reconstruction plan.

After exposure of the OWF, the surgeon used a navigation probe to detect the OWF. This process could be shown on the screen of the CASNS. The optic nerve, bony nasolacrimal duct, and infraorbital fissure could also be shown clearly on the screen (which helped the surgeon to protect them from injury). After exposure of the fracture area and releasing the tissue hernia, a titanium orbital plate (MatrixMIDFACE Plating System, DePuy Synthes, Switzerland) was placed into the orbital cavity to cover the bony defect and to rebuild the curve of the orbital wall. Then, the surgeon used the navigation probe again to detect the location of the titanium mesh to see if it matched the virtual surgical plan (Fig. 2). If the position of the titanium orbital plate did not match the preoperative planning, it was adjusted until the appropriate orbital reconstruction was achieved. Finally, after repeated irrigation with physiologic (0.9%) saline, the wound was closed in layers.

Surgical protocol in the conventional group

In the conventional group, the CT data of all patients were also analyzed preoperatively by surgeons so that an appropriate surgery plan could be made. The surgical approach and procedure were the same as that described for the navigation group, except that the CASNS was not applied. The implant (titanium orbital plate, DePuy Synthes, Switzerland) was placed in the orbital cavity to repair the fracture according to the surgeon's view and experience. Before closing the wound, the mobility and position of the globe were checked by the forced reduction test, and the prominence of the globe was checked by the surgeon's finger.

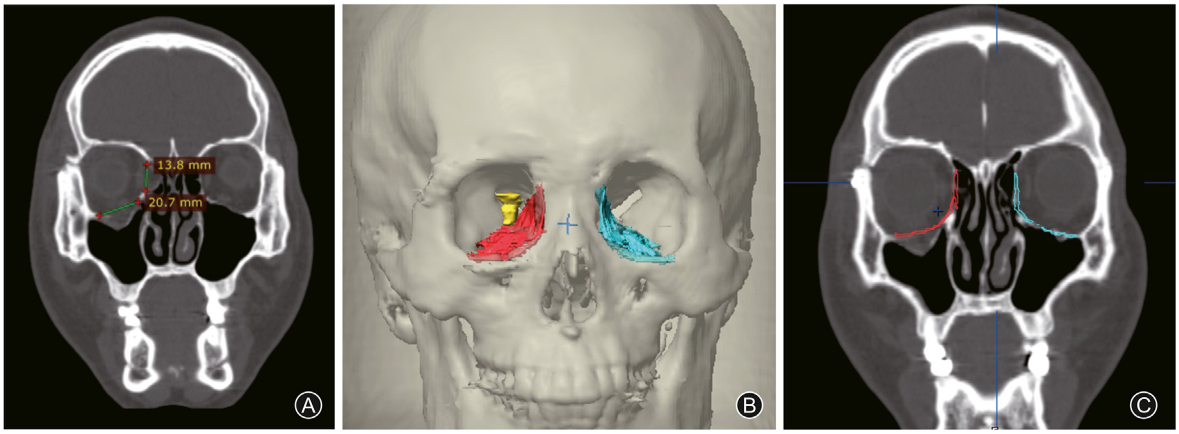

Fig. 1. The orbital-wall fracture was measured and analyzed in iPlan® CMF v3.0.5 before surgery. (A) The bony orbital wall of the unaffected side is auto-segmented and mirrored to establish a virtual surgical template. (B) & (C): the red areas show the virtual template.

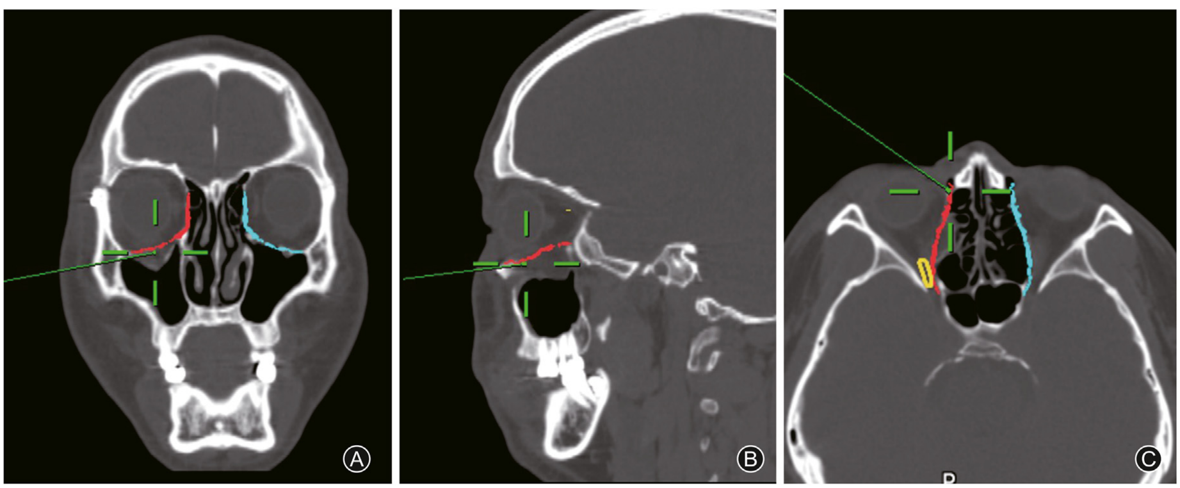

Fig. 2. After the implant had been positioned, a navigation probe was used to verify whether its location matched the preoperative plan (red line) in (A) coronal, (B) sagittal and (C) axis planes.

Parameters employed to evaluate outcome

The duration of the surgical procedure was recorded immediately at the end of surgery. The start time in the navigation group was recorded at the beginning of scalp incision to fix the DFR. The start time in the conventional group was recorded when the surgeon began to make the incision. The end time in both groups was recorded when all wounds had been sutured completely.

CT was undertaken 6 months after surgery for all patients. The accuracy of navigation was assessed by comparing the preoperative planning and actual postoperative results in the software of CMF Proplan 3.0 and 3-Matic Research 11.0 (Materialise, Leuven, Belgium). Analyses of the color order ratio were carried out to evaluate quantitatively the difference between virtual planning and true surgical results.[13,14] (Fig. 3).

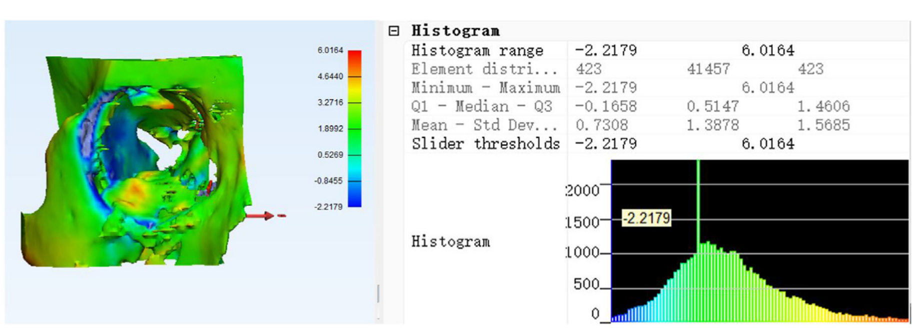

Fig. 3. In a fracture of the zygoma-orbit complex, data from virtual planning and postoperative CT data were superimposed in 3-Matic Research 11.0, and the difference in distance was also calculated.

The preoperative and postoperative CT data of the orbital wall were imported into iPlan CMF 3.0.5 (ver. 3.0.5, Brainlab, Feldkirchen, Germany). The OCV was calculated using the orbital cavity auto-segmentation tool, which can outline the orbital cavity automatically. If the margin was not outlined correctly, it was optimized manually through the fine adjustment tool in iPlan CMF 3.0.5 by surgeons. After the orbital cavity had been fully outlined precisely, its volume was calculated automatically (Fig. 4).

Enophthalmos correction was evaluated by the projection of the eyeball on preoperative and postoperative CT. The projection of the eyeball was measured using the Cabanis index.[15,16] The skull was aligned on the Frankfurt and sagittal planes on the computer. Then, the bicantal external plane (BCEP) was drawn on the axial view. Subsequently, a perpendicular line to the BCEP was drawn between the corneal surface point and BCEP: the anterior bicantal external segment (ABCES). The distance of the ABCES was measured in millimeters as the value for the eyeball projection (Fig. 5).

Clinical parameters (ocular motility, diplopia, orbital symmetry) were recorded preoperatively and 6 months after surgery. Ocular motility and diplopia (double vision in the primary gaze or within the 30° visual field of gaze as determined by a Hess chart) were determined based on ophthalmologic examinations. Orbital symmetry was evaluated by the subjective satisfaction of the patient.

Statistical analyses

Quantitative data were presented as mean ± SD. Significance was determined by the two-sample *t*-test using SPSS Version19.0 (IBM, Armonk, NY, USA), and $p < 0.05$ was considered significant.

Results

Forty patients (25 males, 15 females) were treated using a CASNS. Thirty patients (24 males, 6 females) were treated in the conventional method. The age ranged 18–56 years in the navigation group (mean 37.4 years) and 22–61 years in the conventional group (mean 40.6 years). The transconjunctiva or subciliary approach were used to access the orbital wall according to the location of the defect. The titanium mesh plate was used to reconstruct the orbit wall. Intraoral incisions were also made for patients with maxillary fractures. Patient demographics, fracture characteristics and surgical approach were summarized in Table 1.

Table 1
Summary of patient demographics, fracture characteristics and surgical approach.

Patient characteristics	Navigation group ($n = 40$)	Conventional group ($n = 30$)
Mean age (year)	37.4	40.6
Gender		
Female	25	24
Male	15	6
Fracture categorization		
Isolated orbital floor	11	8
Isolated medial wall	7	5
Combined	22[a]	17[b]
Surgical approach		
Transconjunctival	32	14
Subciliary	8	16

Data are presented as *n*, except age.
[a] 7 type II defect, 10 type III defect, 5 type IV defect.
[b] 6 type II defect, 7 type III defect, 4 type IV defect.

Duration of surgery

The mean time from making the incision to wound closure in the conventional group was (125.28 ± 40.73) min (range 65–148 min), whereas in the navigation group it was (117.41 ± 36.74) min (range 95–140 min), but the difference between these two groups was not significant ($p = 0.088$).

Surgical precision in the navigation group

In the navigation group, the mean maximal modulus and mean distance between the position of the reconstructive implant after surgery and preoperative virtual planning was (2.374 ± 0.454) mm and (0.869 ± 0.472) mm, respectively. This result implied that the reconstruction in the navigation group was undertaken faithfully according to virtual planning.

OCV evaluation

In the conventional group, the mean OCV of the unaffected side and affected side was (27.48 ± 3.01) mL and (30.17 ± 4.43) mL, respectively, whereas, in the navigation group, it was (27.35 ± 4.09) mL and (30.09 ± 4.25) mL. The mean OCV of the reconstructed side was (28.06 ± 3.51) mL in the conventional group and (26.85 ± 3.38) mL in the navigation group. The reconstructed side in both groups was not significantly different from the unaffected side, which implied that the surgical procedure in both groups achieved

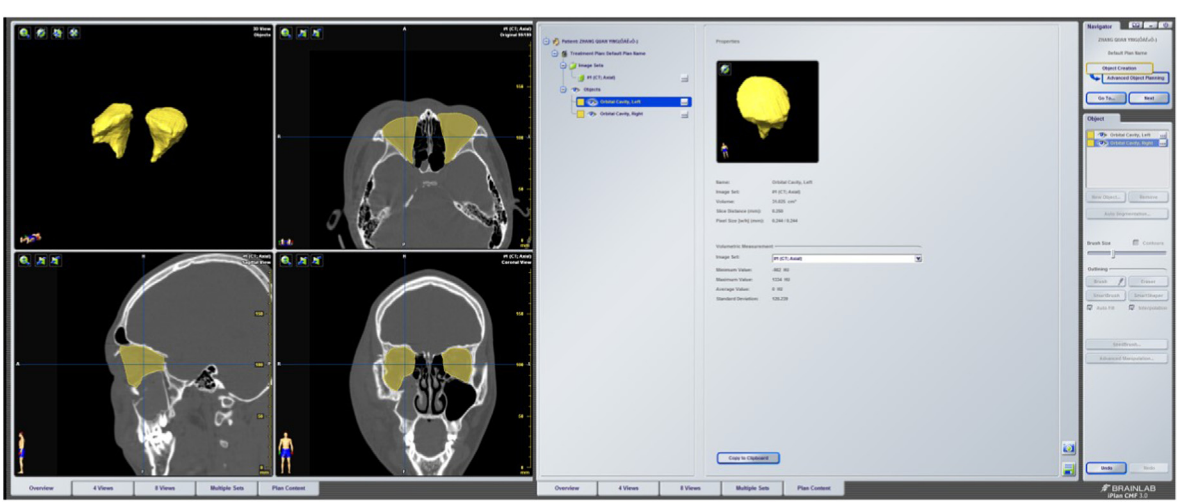

Fig. 4. Volumetric analyses of the orbital wall using the orbital cavity auto-segmentation tool within iPlan CMF 3.0.5.

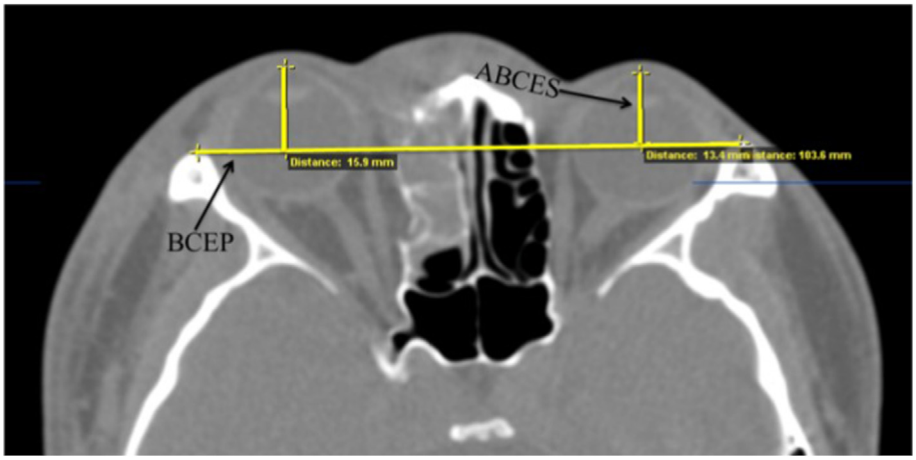

Fig. 5. Projection of the eyeball was measured using the Cabanis index. BCEP: bicantal external plane; ABCES: anterior bicantal external segment.

acceptable restoration of the OCV. However, the discrepancy of the OCV in the affected side before and after surgery (V_{R-A}) in the navigation group was significantly higher than that in the conventional group (4.15 ± 1.78 *vs.* 2.72 ± 1.50, $p = 0.001$). Examination of the discrepancy of the OCV between the reconstructed side to the unaffected side (V_{R-U}) in the two groups revealed that the navigation group had the lower value (0.57 ± 0.43 *vs.* 1.60 ± 0.78, $p = 0.022$). These results suggested that: (1) the navigation group achieved greater restoration of the OCV than the conventional group, (2) better anatomic reconstruction of orbital walls was achieved in the navigation group (Table 2).

Correction of enophthalmos

The distance of the eyeball projection measured by CT is displayed in Table 3. In the navigation group, the mean ABCES distance in the unaffected side and affected side was (16.81 ± 2.54) mm and (13.80 ± 2.69) mm, respectively. In the conventional group, the mean ABCES distance of the unaffected side and the affected side was (15.69 ± 2.94) mm and (12.96 ± 3.30) mm, respectively. After surgery, the mean ABCES distance of the reconstructed side changed to (15.82 ± 2.58) mm in the conventional group and to (16.65 ± 2.47) mm in the navigation group, and the difference was significant ($p = 0.031$). However, there was no significant difference regarding the ABCES distance between the unaffected side and the reconstructed side in the navigation group ($p = 0.53$) or the conventional group ($p = 0.32$). This likely indicated that the eyeball projection improved obviously in both groups. However, the discrepancy in the ABCES distance before and after surgery in the affected side (D_{R-A}) was significantly higher in the navigation group ((3.51 ± 1.45) mm) than that in the conventional group ((1.96 ± 0.82) mm) ($p = 0.028$), which indicated that greater correction of enophthalmos was achieved in the navigation group. The mean discrepancy in the ABCES distance between the reconstructed side and the unaffected side (D_{R-U}) was lower in the navigation group ((0.41 ± 0.27) mm) than that in the conventional group ((1.46 ± 0.78) mm), and this difference was significant ($p = 0.014$).

Clinical assessment

The wound healed very well without complications in both groups. After 6-month follow-up, one patient had diplopia and two patients complained of obvious orbital asymmetry after orbital-

Table 2
Evaluation of the orbital-cavity volume (mL) before and after surgery.

Orbital-cavity volume	Navigation group	Conventional group	*p* value
Unaffected side	27.35 ± 4.09	27.48 ± 3.01	0.815
Affected side	30.09 ± 4.25	30.17 ± 4.43	0.930
Reconstructed side	26.85 ± 3.38	28.06 ± 3.51	0.622
V_{R-A}	4.15 ± 1.78	2.72 ± 1.50	0.001*
V_{R-U}	0.57 ± 0.43	1.60 ± 0.78	0.022*

*$p < 0.05$: significant difference in the navigation group compared with the conventional group. V_{R-A}: the discrepancy of orbital cavity volume between the reconstructed side and the affected-side; V_{R-U}: the discrepancy of orbital cavity volume between reconstructed side and the unaffected side.

Table 3
Evaluation of eyeball projection (mm) before and after surgery.

Eyeball projection (ABCES)	Navigation group	Conventional group	*p* value
Unaffected side	16.81 ± 2.54	15.69 ± 2.94	0.671
Affected side	13.80 ± 2.69	12.96 ± 3.30	0.702
Reconstructed side	16.65 ± 2.47	14.82 ± 2.58	0.031*
D_{R-A}	3.51 ± 1.45	1.96 ± 0.82	0.028*
D_{R-U}	0.41 ± 0.27	1.46 ± 0.78	0.014*

*$p < 0.05$: significant difference in the navigation group compared with the conventional group. D_{R-A}: the discrepancy of the ABCES distance between the reconstructed side and affected side; D_{R-U}: the discrepancy of the ABCES distance between the reconstructed side and unaffected side; ABCES: anterior bicantal external segment.

wall repair in the navigation group. In the conventional group, two patients had persistent diplopia (one patient also had dysfunction of ocular motility) and four patients complained of obvious orbital asymmetry.

Discussion

Surgical navigation technology was introduced by Horsley and Clarke in neurosurgery in 1908.[17] Now, it is used widely in oral and maxillofacial surgery, such as reduction of zygoma-orbital fractures, zygomatic implantation, ankylosis of the temporomandibular joint, craniofacial fibrous dysplasia, removal of foreign bodies, resection of elongated styloid processes.[18,19] Since CASNS was firstly used for orbital-wall reconstruction in 2002, its advantages in orbital surgery have been demonstrated.[20] However, systematic assessment of a CASNS application in orbital-wall reconstruction has not been carried out. Evidence is required to convince surgeons and patients to choose a CASNS as a routine approach for treating OWFs because it is hampered by extra medical expense (which is not covered by basic health insurance in China), more time-consuming and prejudice from some surgeons. Hence, we conducted a retrospective study to compare treatment results with and without CASNS use in patients with a unilateral OWF for correction of enophthalmos, OCV and clinical symptoms.

When CASNS is applied in orbital-wall reconstruction, the first consideration is whether it can be used to help surgeon to carry out a surgical procedure precisely. With technology that fused CT images, it is showed that the mean distance difference between virtual planning and the true surgical outcome was (0.869 ± 0.472) mm. The mean discrepancy between the implant position and virtual planning varies from 0.3 to 1.6 mm in most studies on surgical navigation,[13,21–23] and perfect placement is defined as a positional error of 1–2 mm.[12–14] According to this criterion, our study indicated that a CASNS could precisely translate the virtual plan into true surgical manipulation and achieve precise reconstruction of the orbital wall.

Although the registration process expended additional time in the navigation group, the mean time consumption in the surgical procedure was not significantly different in the two groups. Usually, it takes an experienced team 10–20 min to accomplish preoperative planning using a CASNS.[3,24] Also, the time of registration process in the operating theater is usually 5–8 min. Hence, the use of a CASNS would not add too much time. We found that consumption of surgical time in the navigation group was even less. A possible reason might be that CASNS could guide the surgeon directly to reach the injured area with less dissection of adjacent structures, and help to place the implant in the correct position with less time needed for adjustment.

We calculated the OCV with iPlan CMF 3.0.5. Irrespective of whether a CASNS was used or not, the surgical procedure could decrease the increased OCV significantly. However, when we compared the extent of corrected OCV in the navigation group and conventional group, the difference between the reconstructed side and the unaffected side in the navigation group was significantly less, which indicated that the navigation group gained more precise reconstruction of orbital wall.

There are different methods for measurement of the eyeball projection. Hertel exophthalmometer is a classical method, but its reliance on the lateral orbital rims can lead to errors if soft-tissue edema or dislocation of the orbital rim are present.[16,25] One surgeon conducted clinical evaluation and assessed the position of the eyeball in a study can cause subjective errors unavoidably.[24] We used CT data, which allowed for more precise measurement of the eyeball projection by eliminating possible interference related to post-traumatic soft-tissue edema and lateral fracture of the orbital rim. Furthermore, we calculated the extent of correction of the eyeball projection in both groups. The navigation group gained more obvious correction than the conventional group, and the eyeball projection in the navigation group was more similar to the unaffected eye. The mean difference in the OCV between treated orbits using a CASNS and the unaffected side is < 1 mL in most studies, and the enophthalmos value is < 2 mm.[3,16,24,26] We obtained similar results, which further demonstrated that the use of a CASNS could achieve more accurate reduction in the OCV and correction of enophthalmos compared with that obtained using the conventional method.

The reason why the use of a CASNS could provide a better restoration of OWFs was that it enabled surgeons to detect the defect margin more accurately in a narrow surgical space and poor field of view. The effect of fracture reduction and the position of the implant can be verified in real time by a CASNS, which is very helpful for surgeons repairing OWFs accurately. Another reason is that the surgeon can undertake more aggressive dissection in the orbital cavity if a CASNS is employed. This is because navigation can show surgeons how deep they have reached into the orbital cavity, which will give them confidence when they identify the posterior or medial parts of the orbital wall.

The incidence rate of enophthalmos after surgical repair of a blowout fracture without navigation ranges from 7% to 27.5%, and the prevalence of diplopia ranges from 20% to 42.5% for isolated orbital-floor fractures and $\leq$85% for fractures involving multiple orbital walls.[27,28] In our study, the incidence rate of postoperative enophthalmos was about 10% in the navigation group, which was relatively lower than that reported by other studies. In the conventional group, the incidence rate of postoperative enophthalmos was 20%, which was similar to that in other reports. However, in terms of postoperative diplopia, we showed a significantly lower rate of incidence in the navigation group (5%). It was due (at least in part) to (1) more aggressive tissue dissection and better correction of herniation in the navigation group, and (2) the small sample size in our study.

Refractory enophthalmos in OWFs is not rare, and our study demonstrated this fact. The reason for enophthalmos is loss of the orbital-wall volume (bony volume and soft-tissue volume). Currently, the bony orbital structure can be reduced accurately using CASNS, computer aided design/computer aided manufacturing implants and endoscopy technologies.[9] However, relatively few researchers have investigated how to restore the soft-tissue volume. The soft tissue volume loss mainly come from resorption of peri-orbital fat, scar formation, and tissue herniation to sinuses. Unfortunately, a CASNS cannot be used to repair soft tissue, which is a major drawback of this technology. In recent years, more attention has been paid to virtual-surgery simulations of facial soft tissues, and convincing progress has been made. It has also been reported that 3D MD photogrammetry can be used to assess the esthetic outcome of soft tissues after orbital surgery.[29] We believe that, with the development in computer-aided surgery, precise restoration of orbital soft tissue will be realized soon, and the prevalence of postoperative enophthalmos will decrease considerably.

Several other methods and novel implants have been applied in combination with CASNS to achieve better surgical outcome in orbital-wall reconstruction.[26,30] Endoscopy has been used for treatment of fractures of the zygomatic arch, orbital reconstruction, frontal sinus fracture, reduction of condyle fractures. Endoscopy combined with CASNS could provide minimally invasive access with excellent visualization to achieve accurate reconstruction and stable fixation.[31.] Pre-bent or 3D printed patient-specific implants or 3D orbital models have also been used in combination with CASNS to improve treatment results, especially in complicated, delayed or secondary reconstruction of the orbit.[3,21,29,30,32,33] However, all of these adjuvant methods require extra instruments or much more time to accomplish preoperative planning or to produce patient-specific implants. According to our study, combination of a CASNS with other technologies may not be meaningful and may be less cost-effective, because a CASNS alone can do the job very well.

We compared the surgical outcomes with or without the aid of a CASNS for treatment of unilateral OWFs. The duration of the surgical procedure, correction of eyeball projection, OCV restoration, and clinical symptoms were analyzed to assess the benefits of CASNS for treatment of OWFs compared with the conventional method.

The navigation group achieved more accurate OCV reduction and enophthalmos correction, fewer patients had persistent diplopia or enophthalmos, and the duration of the surgical procedure was not significantly longer. Our study indicated that CASNS was a useful tool to improve outcome in unilateral orbital-wall reconstruction and should be regarded as a routine approach.

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Ethical statement

The study was conducted in compliance with the principles of the Declaration of Helsinki and approved by the ethics committee of the Fourth Military Medical University.

Declaration of competing interest

The authors report no conflicts of interest in this work.

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