ISSN 2472-7040

Craniomaxillofacial Trauma & Reconstruction Open

AOCMF

Official scientific publication of AOCMF

www.thieme-connect.com
www.thieme.com/journals

Thieme

Reconstruction of Post-Traumatic Orbital Defects and Deformities with Custom-Made Patient-Specific Implants: Evaluation of the Efficacy and Clinical Outcome

Yurii Chepurnyi, DDS, PhD[1] Denis Chernogorskyi, DDS[1] Oksana Petrenko, MD, MScD[2] Andrii Kopchak, DDS, MScD[1]

[1] Department of Stomatology, O.O. Bogomolets National Medical University, Kyiv, Ukraine
[2] Department of Ophthalmology, Pl Shupik National Medical Academy of Postgraduate Study, Kiev, Ukraine

Address for correspondence Yurii Chepurnyi, DDS, PhD, Department of Stomatology, O.O. Bogomolets National Medical University, Zoologichna Street, 1 Kyiv 01601, Ukraine (e-mail: 80667788837@ukr.net).

Craniomaxillofac Trauma Reconstruction Open 2019;3:e9–e17.

Abstract

The main purpose of this article is to evaluate the efficacy of patient-specific implants (PSI) in treatment of patients with post-traumatic orbital defects and deformities. Twenty-three patients with post-traumatic orbital defects and deformities, who underwent subsequent reconstructive procedures using PSI, were included in the study. All the patients were examined according to the standard algorithm involving the local status examination, vision assessment, and computed tomography before and after surgery. The study findings show neither postoperative infectious complications nor decreased visual acuity or loss of visual fields. Functional disorders resolved in 65.2% of cases 1 month after the surgical intervention and in 86.96% of patients within a 3-month term. Positive aesthetic outcomes were seen in 95.7% of cases. Reconstruction with computer-aided design/computer-aided manufactured PSI is an effective procedure that allows accurate restoring of the complex orbital anatomy.

Keywords

- orbital defects
- patient-specific implants
- CAD/CAM
- reconstruction

Despite the notable advances in reconstructive surgery techniques, post-traumatic defects and deformities of the orbit remain a major challenge due to the complex anatomy, variable trauma patterns, and the need for an interdisciplinary approach. Injuries of the orbital walls are associated with significant facial disfiguration because of the eyeball displacement, and they cause functional deficit (diplopia, restricted globe motility, and a decrease or loss of vision). It complicates social adaptation of the patients, and affects the psychological state.[1–3]

Traditional methods for restoration of the orbital volume and anatomic shape include the usage of standard preformed titanium plates and meshes available in different sizes, polymeric implants of thin polyethylene membranes, and autologous bone grafts.[1,4] Bone grafts and standard titanium or polymeric implants usually require prebending or intraoperative bending and correction of the contours. It may be difficult because of the lost anatomical landmarks and changes in topographic anatomy of the orbit and its content. The proper insertion and positioning of the implants or grafts inside the orbit, especially in the region of the orbital ledge, remain challenging.[3,5] The problem could be solved with digital intraoperative navigation systems, but the high cost of the equipment limits their use. Moreover, these systems do not ensure a precise fit of the bone graft or implant if their geometry does not match the contours of the defect or individual orbital shape.[1,6,7]

In orbital reconstruction procedures, the location of implants or bone grafts and their conformity to the individual anatomy of the damaged structures in size and shape determine the surgical strategy and the integral success rate.

Recent developments of computer-aided design/computer-aided manufacturing (CAD/CAM) technologies and evidence of their effective clinical application in management of facial bone defects and deformities have generated an increased interest to their usage in reconstructive surgery of the orbit.

received
September 22, 2018
accepted after revision
November 14, 2018

DOI https://doi.org/10.1055/s-0039-1685505.
ISSN 2472-7512.

The above technologies have contributed to improved diagnostics and initial assessment of the clinical case, facilitated designing and manufacturing of orbital implants owing to the virtual simulation of the surgical procedures, and ensured highly predictable outcomes with significantly improved conditions postoperatively.[1,3,6,8,9] Previously, there were reports about successful experience of custom-made patient-specific implants (PSI) manufactured from either titanium by selective laser sintering (SLS) or polyether-ether-ketone (PEEK) for facial or cranial reconstructions.[1–3,10–12] The authors noted the complexity of conventional algorithms used for implant design and manufacturing with increased probability of errors and discrepancies.

One of the first orbital reconstructions with PSI was reported by Williams and Revington.[11] Later, the first series of cases was presented by Gander et al.[13] Several clinical studies have documented the efficacy of orbital reconstruction with PSI since then. Most of the articles describe the usage of titanium PSI. They differ in the number of patients involved, the algorithms of the CAD procedures, the evaluation criteria, and methods of implant manufacturing. Despite a considerable number of studies devoted to cranioplasty and frontal bone reconstructions with PEEK implants, only few reports present the outcomes of the orbital wall reconstructions with PEEK PSI.[14]

It conditions the need for evidence-based improvement of current approaches to the virtual simulation, manufacturing and installation of PSI in reconstructive surgery of the orbit.

The aim of this study was to evaluate the clinical efficacy of custom-made titanium and PEEK PSI in post-traumatic orbital defects and deformations.

Material and Methods

Twenty-three patients with unilateral post-traumatic defects and deformities of the orbit (15 males and 8 females, aged 16 to 54 years, mean age 37.9 $\pm$ 13.7 years), who underwent orbital reconstruction procedures with PSI at the Center for Maxillofacial Surgery and Stomatology, Kyiv Regional Hospital, Ukraine from January 1, 2016 to February 28, 2018, were included to this study. In all cases, an informed consent from patients for the treatment and participation in the present study was obtained. The research was approved by Bioethics Committee of Bogomolets National Medical University, Kyiv, Ukraine (Protocol No. 104). The exclusion criteria were the following: age under 16, bilateral orbital trauma, endocrine orbitopathy, anophthalmia, one or both side loss of vision, defects caused by gunshot injuries, defects and deformities after tumor resections, radiation or chemotherapy in anamnesis, mental illness, noncompliance with medical recommendations and lack of interaction with a doctor in the postoperative period, and refusal of the patient to participate in the study.

The diagnostics and treatment of the above patients were performed by a multidisciplinary team, which included oral and maxillofacial surgeons, ophthalmologists, and ENT surgeons.

All patients were examined preoperatively, first day after surgery, 1 and 3 months after surgery following the standardized algorithm, including local status examination (facial symmetry, scars, and position of the eyeball) and evaluation of vision (visual acuity, diplopia, and ocular mobility). Visual fields were also recorded. All patients underwent 64-slice computed tomography (CT; Philips Diamond Select Brilliance CT 64, Koninklijke Philips N.V.; slice thickness—0.5 mm) before and after surgery (►**Table 1**).

Efficiency evaluation criteria included the duration of the surgical intervention and the period of implant adaptation, orbital volume measurements, early and long-term postoperative complications, and changes in the aesthetics and ophthalmologic status. Aesthetic outcomes of the treatment were considered as unsatisfactory (where a residual cosmetic defect was significant, obvious to the patient, and requiring a secondary surgical correction), satisfactory (surgical repair of residual cosmetic defect was not necessary or only a small intervention on the paraorbital soft tissues was required), or good (where both the surgeon and patient were satisfied with the obtained result).

Design and Manufacturing of the Implants

Virtual simulation of surgical procedures and PSI designing were performed in close collaboration between surgeons and biomedical engineers. Preoperative CT data (Digital Imaging and Communications in Medicine [DICOM] files without compression) were provided to the manufacturer of the implants (Imatek-Esco Ltd., Kyiv, Ukraine 3D Systems [USA] reseller). Then, biomedical engineers analyzed the clinical case, created the design of the implant and defined its optimal position inside the orbit with the participation and under control of surgeons.

Computer-aided design procedures were performed in the software environment (SimPlant 10.03; Materialise Dental) by segmentation of the CT data, creating virtual models of the orbit and editing them. The models were edited in multiple slice modes (slice-by-slice) considering the contour of the mirrored healthy orbit after its superimposition on DICOM data of the damaged orbit using manual reposition. The purpose of the editing procedure was to restore the integrity of the orbital walls for creation of a constant surface in all slices without triangular mesh defects. STL model of the orbit after multiple slice editing was exported to design software (Geomagic Freeform Plus). Further processing of the model included wrapping, smoothing, and fixing procedures. The design of the implant was obtained by creating the required surface shape and its subsequent transformation into an object with defined thickness. Then, clearance of the object and holes for fixation were created using boolean operations.

The design of the implants was aimed at repairing the orbital wall defects and deformities of the orbital rim, thus restoring a true-to-original shape of the damaged structures. In all cases, retention points for precise intraoperative positioning of the implants and their stable retention after the installation as well as additional elements with holes for screw fixation to the orbital rim were modeled and created. The diameter and shape of the holes corresponded to the osteosynthesis system selected for fixation. In three cases, the design of the implant allowed correcting deformities of

Table 1 Patient demographic and clinical features

Patient	Age	Sex	Timing	Material	Aesthetic outcomes	Post-traumatic diplopia	Diplopia 3 months after surgery
1	18	M	> 1 month	PEEK	Good	Yes	No
2	46	M	> 1 month	Titanium	Satisfactory	No	No
3	16	F	> 1 month	Titanium	Satisfactory	Yes	Yes
4	27	M	> 1 month	Titanium	Good	No	No
5	25	M	> 2 weeks to < 1 month	PEEK	Good	Yes	No
6	48	M	> 2 weeks to< 1 month	PEEK	Good	Yes	No
7	28	F	>1 month	Titanium	Satisfactory	Yes	No
8	29	F	< 2 weeks	PEEK	Satisfactory	Yes	Yes
9	44	F	< 2 weeks	PEEK	Good	Yes	No
10	46	M	> 1 month	PEEK	Good	Yes	No
11	52	F	> 1 month	PEEK	Good	Yes	No
12	43	M	> 1 month	PEEK	Good	Yes	No
13	27	M	> 1 month	PEEK	Satisfactory	Yes	No
14	53	F	> 1 month	Titanium	Good	Yes	No
15	48	F	> 1 month	PEEK	Satisfactory	Yes	Yes
16	42	M	< 2 weeks	PEEK	Good	Yes	No
17	49	M	> 2 weeks to < 1 month	PEEK	Good	Yes	No
18	59	F	> 1 month	PEEK	Good	Yes	No
19	47	M	< 2 weeks	PEEK	Good	No	No
20	24	M	> 2 weeks to < 1 month	PEEK	Good	Yes	No
21	27	M	< 2 weeks	PEEK	Good	Yes	No
22	57	M	< 2 weeks	PEEK	Good	Yes	No
23	16	M	< 2 weeks	PEEK	Good	Yes	No

Abbreviation: PEEK, polyether-ether-ketone.

the orbital rims and defects of the bones adjacent to the orbit (►**Fig. 1**).

Virtual three-dimensional models of PSI in STL format were reimported to the software (SimPlant 10.03 with cranio-maxillo-facial module) for CT data analysis, where the surgeons performed the preoperative evaluation of PSI location inside the orbit in relation to the bone (orbital floor) and soft tissues (the optic and infraorbital nerves and muscles). After validation and correction by clinicians, STL file was sent for manufacturing. The implants were made by milling of radiopaque PEEK blocks (Merz Dental; 18 cases) on the machines with numerical control or by SLS of the titanium (Ti6Al4V) powder (DIN: 3.7165) according to ISO 5832-3 (in 5 cases). We preferred PEEK in cases where only orbital wall reconstruction was indicated. However, we considered titanium PSI as a method of choice in cases where the reconstruction of the orbitozygomatic complex with stabile fixation of the orbital rim fragments was performed simultaneously with orbital walls reconstruction. The implants were sterilized the day before operation by autoclaving at 132°C.

Virtual orbital models of the damaged and intact sides were generated for all cases before and after surgery. For this purpose, a threshold value segmentation of the CT data was performed with generation of the bony orbital model and models of the soft tissue content (orbital models). These orbital models were edited considering the contour of the bony orbit and orbital margins. Their volumes were measured in the computer software and compared for each individual case. Additionally, a superimposition of the virtual models (mirrored intact and damaged) was performed after trauma, after design of PSI, and after surgical treatment.[15,16]

Statistical analysis of the data included the calculation of mean values, and standard deviation for each parameter evaluated. Nonparametrical statistics was employed for analysis of the data. The Mann–Whitney *U* test was used to compare the differences between these parameters in the study group. The level of significance was set at $p < 0.05$. Statistical calculations were performed in SPSS Statistics software environment (IBM Inc.).

Results

Post-traumatic defects and deformities resulted from blow-out orbital fractures (five of them were combined with orbitozygomatic fractures and two with fractures of the orbital roof).

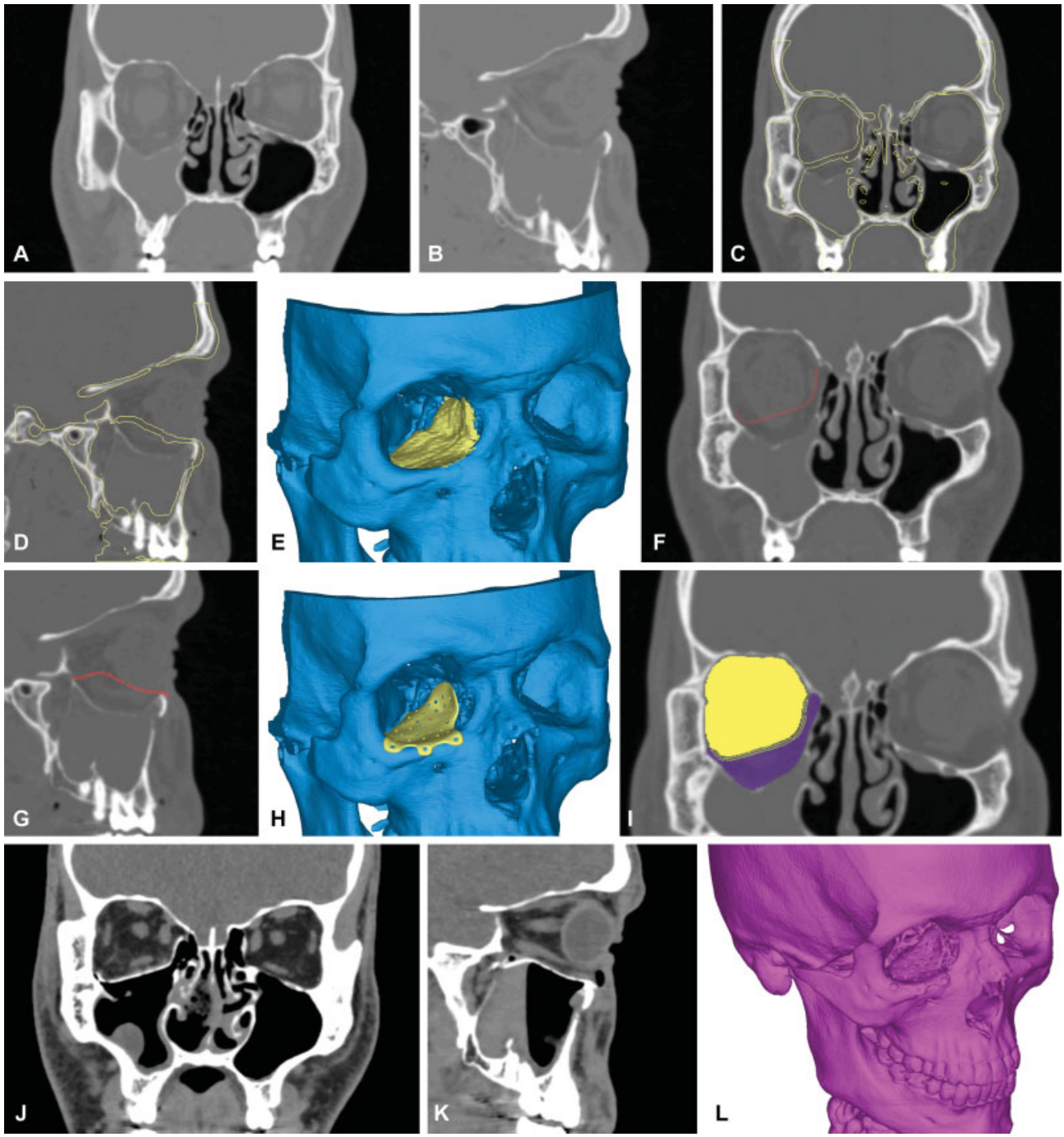

Fig. 1 Steps for patient-specific implant (PSI) design in orbital wall reconstruction. (**A, B**) Deformity of the orbital walls after blowout fracture: computed tomography (CT) data; (**C, D**) mirroring of the intact orbit and its comparison with the model of the damaged orbit; (**E**) editing of the CT-based three-dimensional virtual model of the orbit with the creation of a constant surface; (**F–H**) design and position of the PSI into the orbit; (**I**) evaluation and comparison of orbital volumes; (**J–L**) CT control after orbital reconstruction with PSI).

The preoperative examination revealed diplopia in all fields of view in 16 patients, diplopia in two fields of view (when looking downward and upward, or downward and inward) was found in 3 patients, and in one field of view (when looking downward) in 1 patient. In three cases, no functional disorders were observed.

Facial asymmetry caused by post-traumatic enophthalmos was noted in 17 cases; in five patients, it was associated with eyeball vertical displacement. In two cases, the aesthetic deficiency resulted from the deformity of the orbital rims. Concomitant post-traumatic deformities of the eyelids, lateral or medial telecanthus, in five cases also contributed to the worsening of the appearance and deterioration of the aesthetic condition.

In our series, the orbital floor was broken in all cases; the medial wall was damaged in 14 cases, orbital roof in two cases. Post-traumatic deformities of the orbital rims were recorded in five cases. Orbital floor or medial wall

reconstructions in all cases were performed via subciliary approach. Further reposition of the orbital content, implant insertion, and fixation to the orbital rim were accomplished by placing the eyeball to proper position. In three cases, we employed a coronal approach for reconstruction of the damaged orbitozygomatic complex and orbital roof.

Difficulties in proper positioning of the implant inside the orbit were seen only in two cases. They were associated with incomplete reposition of orbital content. In one case, the fixation hole was in the projection of the bone defect (in an area of incomplete osteogenesis).

In three cases, implants were used both for reconstruction of the orbital walls and correction of the orbital rim anatomic shape.

In this series, the average period of CAD procedures was 4.04 ± 2.9 days. The average time spent on manufacturing of the PEEK PSI was 1.8 ± 0.7 days vs. 23.7 ± 4.9 days spent on the manufacturing of the titanium PSI with delivery from the United States or European Union. The average duration of the surgical interventions was 58.8 ± 17.3 minutes.

In this series, no inflammatory complications, decreased visual acuity, or loss of visual fields were observed within the postoperative period. The average duration of hospital stay was 4.2 ± 1.6 days.

The aesthetic outcomes of the treatment were good in 17 cases and satisfactory in 6 cases. In five patients with satisfactory aesthetic outcomes, additional corrections of paraorbital soft tissues were indicated. Depending on the status, these patients underwent surgical repair of the eyelid deformities or ptosis, and reshaping the scars.

Mobility disorders were totally absent in 22 cases (95.7%) 1 month after surgery, and in only one case they were partially preserved; however, a significant improvement was seen.

One month after surgery, diplopia was present in 8 cases, but 3 months after surgery it was absent in 20 patients. Another three patients reported a significant decrease in diplopia.

Mydriasis was noted in three cases with recovery after a year follow-up. Sensory disturbances on the second branch of the fifth cranial nerve 3 months after surgery were present in nine patients but after a 6-month follow-up they resolved.

In one case, aesthetic and functional outcomes were unsatisfactory due to the restriction of the eyeball mobility, caused by compression of the medial rectus muscle with the edge of the implant. The patient underwent a secondary surgery to eliminate the compression of the muscle. The final functional and aesthetic outcomes were satisfactory.

Thus, in our series, positive aesthetic results were obtained in 95.7% of patients. Functional disorders resolved in 65.2% of cases in a month term after surgery, in 86.96% of patients within 3 months.

The measurements of the orbital volumes on the intact side before and after surgery (actually, this volume did not change) showed the minor differences in all cases, which can be recognized as measurement error. On average, they constituted 0.45 ± 0.35 cm^3 and were statistically nonsignificant ($U = 262$; $Z = -0.055$; $p = 0.956$).

The average volume of the orbit on the intact side was 25.6 ± 2.5 cm^3, whereas the average volume of the damaged orbits in our study significantly increased and constituted 29.8 ± 4.3 cm^3 ($U = 112$; $Z = -3.35$; $p = 0.001$). The mean difference was 4.2 ± 3.0 cm^3.

After reconstructive surgery in this series, the average volume of the damaged orbits reduced to 25.8 ± 2.6 cm^3. The average difference with intact orbits after the surgical interventions was only 0.77 ± 0.6 cm^3 and there were no significant differences between the mean volumes of the damaged and intact orbits ($U = 231$; $Z = -736$; $p = 0.462$) (►**Table 2**). Analysis of the orbital virtual model superimposition found a high degree of congruence between the shape of the mirrored intact and damaged orbits.

Discussion

Reconstruction of the orbit is always a challenge for surgeons due to the complexity of the anatomy, small size, and exceptional importance of the eye for the human life.[2] The main objectives to be solved in the treatment of orbital injuries are as follows: (1) the repair of the orbital wall defects by restoration of the orbital volume, (2) the reconstruction of the normal orbital shape, taking into account the individual anatomic features, and (3) the correction of the globe position.[3] The first objective is traditionally accomplished by the use of standard preformed implants made of different materials (titanium, polytetrafluoroethylene, silicone, polyethylene, etc.) or autologous grafts (bone and cartilage). The main problem is that the process of their adaptation to the parameters of the damaged orbit is complex and time-consuming.[3,4] The proper positioning of the standard implants or grafts inside the orbit is difficult to achieve, and it is the main reason for unsatisfactory treatment outcomes.[6,7] However, according to Zieliński et al,[17] the use of standard titanium meshes was not associated with worse functional outcomes as compared with PSI, but it required time-consuming intraoperative adaptation and demonstrated higher blood loss during surgery.

The most difficult task that conditions functional recovery and a high aesthetic outcome of treatment is the accurate restoration of the orbital shape, taking into account individual parameters of the anatomical structure. This is especially important for the lower and medial walls, which form a ledge near the orbital apex area.[3,5] Other important intraorbital structures which should be considered for proper reconstruction are the inferior orbital fissure (IOF), intraorbital buttress (IOB), and posterior ledge (PL). Their safety or damage is determined by the severity of trauma, surgical strategy, shape of the orbit after reconstruction (due to design and positioning of the implant or graft).[3,5,18]

Restoration of the orbital shape can be achieved by individualization of the standard implants (giving them a specific shape during or before operation, manually or with the use of special equipment). CAD/CAM technologies are one of the most effective approaches to solve these problems. The above technologies demonstrated significant benefits in reconstruction of facial and cranial bones. In orbital reconstruction, CAD/CAM technologies are used for accurate evaluation of the injury pattern, exact measurements of the orbital volume and its changes, designing and manufacturing

Table 2 Injury patterns in patients included in the study

Patient	Fracture	Damaged zone (according to AOCMF classification system for orbital fractures[16])	Damaged IOF[a]	Damaged IOB[b]	Damaged posterior ledge	Volume difference before surgery (damaged/intact) mm^3	Volume difference after surgery (damaged/intact) mm^3
1	Blowout	W2 (im) A(i)	Yes	Yes	Yes	8,913	440
2	Combined	R(li)W1(im)2(im)	Yes	Yes	Yes	5,148	935
3	Combined	R(im)W1(im) 2(im)	No	Yes	No	3,736	1,984
4	Combined	R(il)W2(il)	Yes	No	No	457	275
5	Blowout	W1(i)2(i)	No	Yes	No	3,708	48
6	Blowout	W1(mi)2(1) A(i)	Yes	Yes	Yes	7,605	625
7	Combined	W1(i)2(iml) A(i)	Yes	Yes	Yes	1,210	634
8	Blowout	W1(i)2(i)	No	Yes	No	1,553	1,385
9	Blowout	W1(i)2(i)	No	No	No	1,083	351
10	Blowout	W1(im)2(im) A(m)	No	Yes	No	9,737	909
11	Blowout	W1(is)2(i)	Yes	Yes	Yes	2,972	868
12	Blowout	W1(im)2(im)	No	No	Yes	2,294	174
13	Combined	R(il)W1(sm)2(lim)A(im)	Yes	Yes	Yes	9,838	2,408
14	Combined	R(li)W1(i)2(lm)	Yes	No	Yes	7,232	1,764
15	Blowout	W1(im)2(im)	No	Yes	Yes	1,830	428
16	Combined	W1(mi)2(im)	No	Yes	No	5,780	1,562
17	Blowout	W1(im)2(im)	No	Yes	No	5,463	654
18	Blowout	W1(i)2(i)	No	No	No	3,241	353
19	Blowout	W1(i)2(i)	No	No	No	1,145	240
20	Blowout	W1(im)2(im)	Yes	Yes	Yes	6,342	315
21	Blowout	W1(im)2(im)	No	No	No	429	280
22	Blowout	W1(i)2(i)	No	No	No	5,160	231
23	Blowout	W1(i)W(mi)	No	Yes	Yes	2,567	843

[a]Inferior orbital fissure.
[b]Intraorbital buttress.

of the implant for orbital shape restoration, considering the anatomical landmarks of the damaged orbit, and the geometry of the intact orbit. An implant designed in computer software can be created with specific elements and individually shaped to ensure fixation and placement inside the orbit only in one predetermined position. Thus, virtual design of the implants and the rapid prototyping become an effective alternative to traditional surgical methods of the orbital reconstruction.[3,19,20]

Our series of patients showed high efficiency of the offered algorithms of PSI modeling and manufacturing. In our experience, mirroring of the intact bony orbit enables virtual repair of bone defects of the damaged orbit only under the following conditions: the proper safety of IOF, IOB, PL, high CT resolution, sufficient thickness, and/or X-ray density of the bone walls of the intact orbit. The important role of these anatomical landmarks is to ensure an exact match between the mirrored model and the model of the damaged orbit. From the surgical and bioengineering points of view, PL assured the proper support for the distal edge of the PSI; the IOF conditioned the position of distal and lateral borders of the PSI. The IOB supported the medial border of the PSI and provided an exact reconstruction of the orbital shape.

In the absence of one or more of the above-mentioned conditions, the virtual model of the damaged orbit needed to be edited in automatic/semiautomatic or manual mode after the mirroring of the intact orbital model. The complexity of editing ("virtual sculpturing") depended on the severity of the injury. If the extent of the bony landmarks destruction was higher, the time spent on manual editing increased as well as the need for virtual sculpturing of such structures as IOB and PL. The destruction of the IOB resulted in increased implant surface due to the need to ensure its support in the area of the medial orbital wall. The use of anatomic landmarks in combination with mirroring of the contralateral orbit and "virtual sculpturing" assured accurate reproduction of the orbital anatomical shape in the software environment. Thus, the design of the implant was based on clinical status, geometry, and localization of the defect.

Some clinical trials report the outcomes of the PSI application for orbital reconstruction by the use surgical navigation and/or intraoperative CT to control the implant position inside the orbit.[14,21] However, in our study, the presence of specific elements (curves and legs) provided in each case allowed precise placement of the implants in the exact optimal/desired position with due consideration of specific clinical and anatomical conditions (►**Fig. 2**). However, in some cases it required

to increase the size of implants to fit an orbital anatomy, which demand more wide surgical approaches.

The use of different types of materials in treatment of our patients was conditioned by the different clinical goals and the limitations of manufacturing processes. Individualized titanium PSI provided the possibility of both orbital walls reconstruction and stabile fixation of the orbital rim fragments in cases of complex orbitozygomatic fractures. We also took into consideration the manufacturer's recommendations which made it possible to produce the implants with the thickness of 0.6 mm by milling of PEEK and of 0.9 to 1 mm (depending on geometry) by titanium sintering (►**Fig. 3**). For isolated orbital wall defects the thinner plates from PEEK were more appropriate. Thus, the shape and dimensions of the PSI influenced the choice of the material.

The only limitation in the production of PSI by milling was the presence of "a negative angle" in the region of the orbital rim when it was necessary to reshape it, which made it impossible to mill the inner surface of the implant. In such cases, we preferred SLS titanium implants. With respect to SLS technology, wall thickness conditioned the limitations for the manufacturing of thin sections of the implants (mostly retention points and fixing elements).

Our results did not allow us to give a comparative description of the titanium and PEEK PSI application due to the presence of significant individual variations in the trauma patterns, as well as different indications for their use. At the same time, we did not observe any complications or any significant differences in the accuracy of restoring the shape and volume of the orbits. The principles of modeling and the time spent on the CAD procedures were not different, as well as inquiries in time of manufacturing were determined by subjective factors. All this exclude the possibility to determine evidence-based recommendations of the material selection for PSI manufacturing.

According to the literary data, PEEK is a widely used biocompatible polymer with numerous physical characteristics that are favorable for craniofacial reconstruction.[2,12] It is a semicrystalline and thermoplastic material with good imaging properties, stiffness, durability, light weight, fatigue, and chemical resistance. PEEK implants can be repeatedly sterilized without the degradation of their structure and mechanical properties.

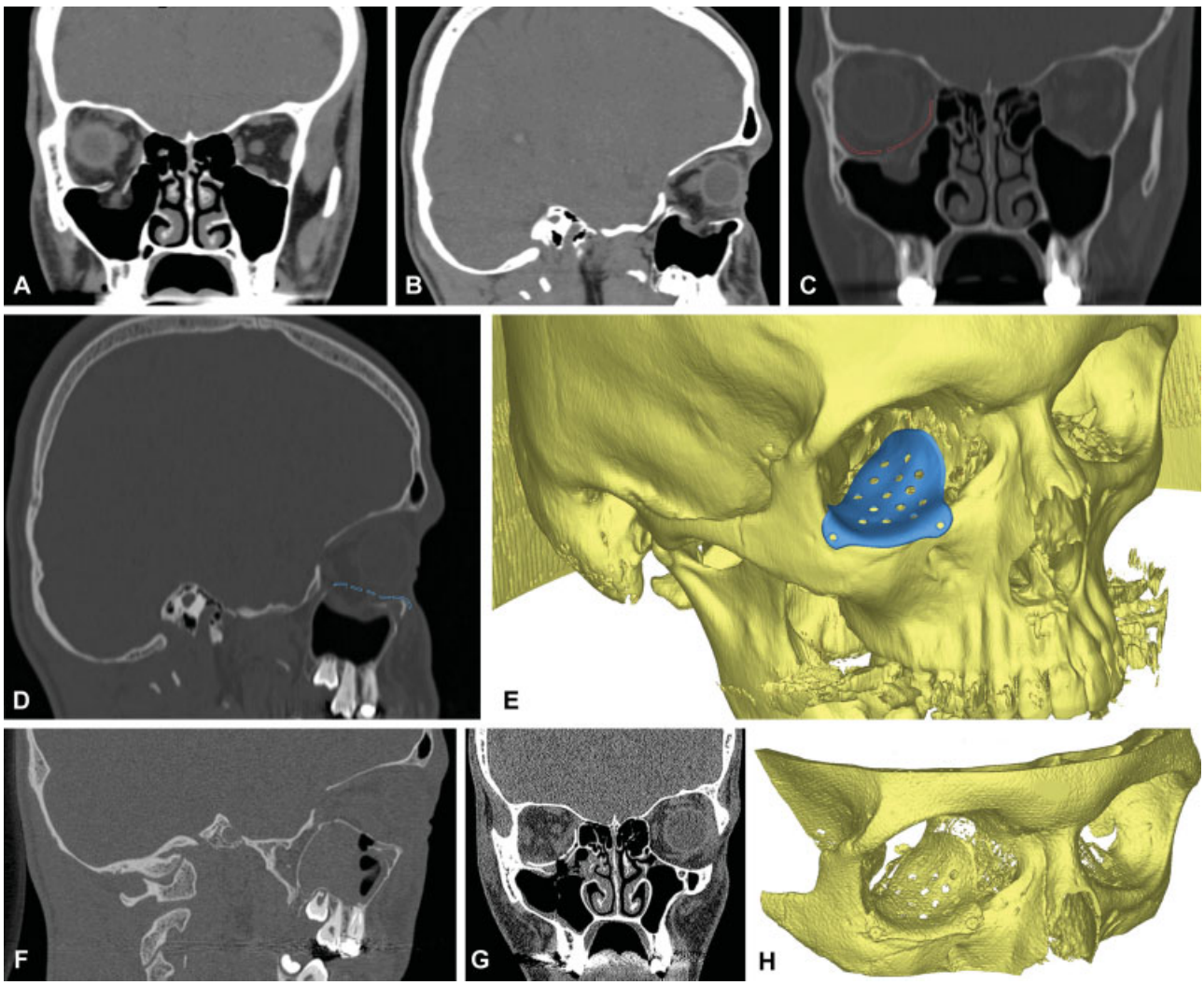

Fig. 2 Patient K with blowout fracture of the right orbit, 3 weeks after trauma (**A–C**) computed tomography (CT) slices of the damaged orbital walls; (**D, E**) virtual mode of the PSI, positioned into the orbit; (**F–H**) control CT of the reconstructed orbit with patient-specific implant.

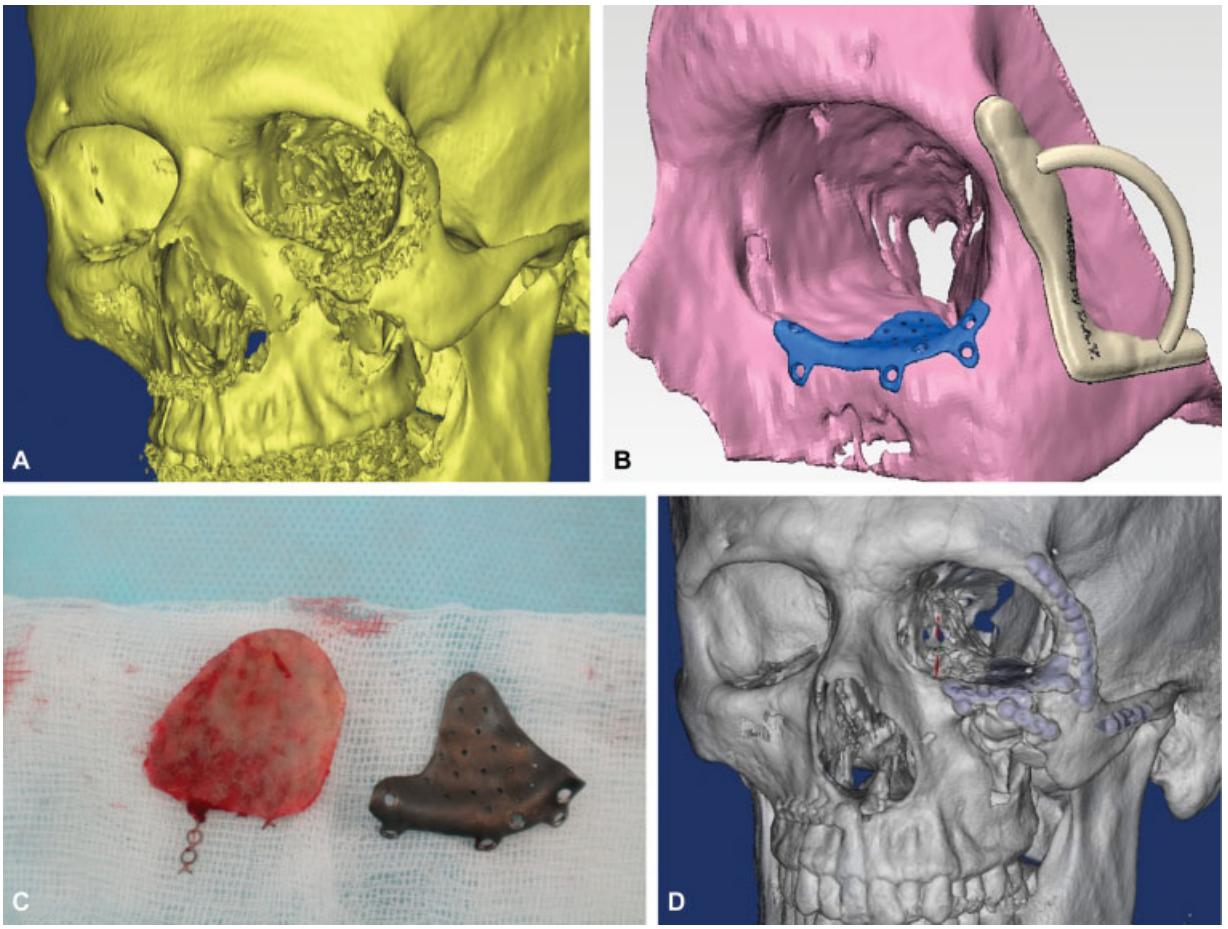

Fig. 3 Patient D with post-traumatic deformity of the left orbitozygomatical complex (**A**) three-dimensional (3D) computed tomography before surgery, (**B**) virtual model of the patient-specific implant (PSI) and surgical guide for zygoma reposition; (**C**) removed titanium + polyethylene implant and titanium PSI; (**D**) 3D after surgery).

In addition, the modulus of elasticity of this material is close to the cortical bone, thus avoiding stress shielding effect. Allergic reactions to PEEK are extremely rare. PEEK implants can be easily modified using high-speed burs and it is easy to fix them with conventional screws to the bone edges. In our series, neither clinical nor radiological manifestations of inflammatory complications, including sinusitis, caused by PEEK implants were observed (a maximum follow-up of 2 years).

Design and the way of implant insertion conditioned the choice of surgical approach. We used a subciliary approach as optimal one for mobilization of the orbital content, placement of the eyeball in the proper position, and insertion of the PSI into the orbit. According to our observations, the presence of a scar in the subciliary area did not affect the integral aesthetic outcomes of the treatment.

Virtual preoperative simulation was employed for the estimation of the implant position inside the orbit, and its interrelationships with bony structures, nerves, and oculomotor muscles. In the cases where collisions between the implant and anatomical structures were seen the design was changed. Preoperative planning allows the precise measurement of orbital volume and analysis of its changes caused by traumatic injury and surgical interventions. The results of this study demonstrated the effectiveness of the offered algorithm for PSI design and manufacturing. It enabled adequate recovery of the orbital volume and shape after reconstructive surgery so that the differences between volume of damaged and intact orbits became nonsignificant (►**Fig. 4**).

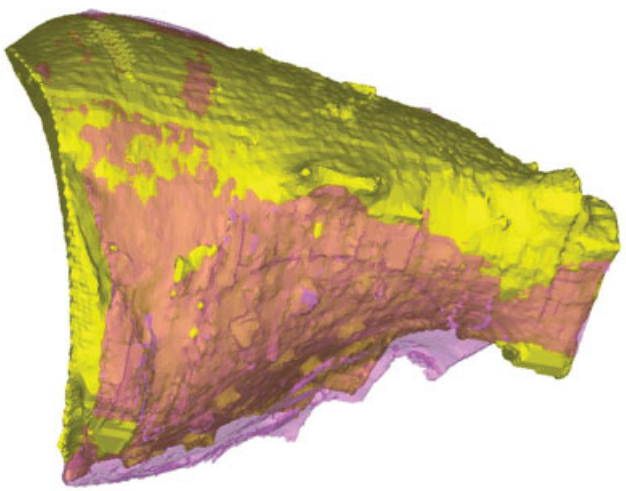

Fig. 4 Superimposition of the virtual models after surgery: mirrored intact and damaged orbits.

The main advantage of the offered surgical approach was accurate reconstruction of the orbital shape, especially in "the key area," according to Hammer,[22] which ensured high aesthetic outcomes of treatment. Postoperative CT images of patients, who were treated by the use of the offered algorithm, showed the high accuracy of implants positioning inside the orbit and the restoration of its anatomical structure in the vast majority of observations. PSI location was almost similar to the preoperative planning. The difficulties in positioning were due to scarring and presence of small bone fragments that were not adequately reflected on the CT slices.

The results obtained correlate with those reported by other authors. Zieliński et al[17] reported the presence of motility disorders after CAD/CAM-assisted orbital reconstructions in 29 and 13% of cases 1 and 6 months after surgery, respectively. According to the multicenter study by Zimmerer et al,[21] there was a statistically significant reduction in the time of surgical intervention when PSI were used. An average time of surgery in this study was $\sim$ 60 minutes, which correspond to the results obtained in present study. Motility disorders after orbital reconstruction with the use of PSI were in 15.8% of cases 1 month and in 3.3% 4 months after surgery. Diplopia was found in 35.8% of cases 1 month after surgery. The value decreased to 24.6% 4 months after surgery. These results are almost similar to those obtained in our study. However, our study had following limitation, such as subjective evaluation of the facial asymmetry and diplopia, absence of the control group with "hand-bent" implants and enophthalmos evaluation, as well as failure to determine the relationship between clinical and radiological objective data, absence of long-term follow-up, a relatively small number of observations with various trauma patterns. Accordingly, all these issues require further research and in-depth analysis.

Conclusion

The obtained results confirm the advantages of CAD/CAM technology and PSI in treatment of orbital defects and deformities. The use of anatomical landmarks in combination with mirroring of the contralateral orbit and "virtual sculpturing" ensured accurate reproduction of the anatomical shape of the orbit in the software environment. Both titanium and PEEK can be effectively used for PSI manufacturing, depending on clinical situation, surgical purposes, and geometry of the orbit.

Conflict of Interest
None.

References

1 Baumann A, Sinko K, Dorner G. Late reconstruction of the orbit with patient-specific implants using computer-aided planning and navigation. J Oral Maxillofac Surg 2015;73(12, Suppl): S101–S106
2 Patel N, Kim B, Zaid W. Use of virtual surgical planning for simultaneous maxillofacial osteotomies and custom polyetheretherketone implant in secondary orbito-frontal reconstruction: importance of restoring orbital volume. J Craniofac Surg 2017;28(02):387–390
3 Mommaerts MY, Büttner M, Vercruysse H Jr, Wauters L, Beerens M. Orbital wall reconstruction with two-piece puzzle 3d printed implants: technical note. Craniomaxillofac Trauma Reconstr 2016;9(01):55–61
4 Totir M, Ciuluvica R, Dinu I, Careba I, Gradinaru S. Biomaterials for orbital fractures repair. J Med Life 2015;8(01):41–43
5 Dubois L, Jansen J, Schreurs R, et al. Predictability in orbital reconstruction: a human cadaver study. Part I: endoscopic-assisted orbital reconstruction. J Craniomaxillofac Surg 2015;43(10):2034–2041
6 Dubois L, Schreurs R, Jansen J, et al. Predictability in orbital reconstruction: a human cadaver study. Part II: navigation-assisted orbital reconstruction. J Craniomaxillofac Surg 2015;43(10):2042–2049
7 Dubois L, Essig H, Schreurs R, et al. Predictability in orbital reconstruction. A human cadaver study, part III: implant-oriented navigation for optimized reconstruction. J Craniomaxillofac Surg 2015;43(10):2050–2056
8 Frodel JL Jr. Computer-designed implants for fronto-orbital defect reconstruction. Facial Plast Surg 2008;24(01):22–34
9 Soleman J, Thieringer F, Beinemann J, Kunz C, Guzman R. Computer-assisted virtual planning and surgical template fabrication for frontoorbital advancement. Neurosurg Focus 2015;38(05):E5
10 Goodson ML, Farr D, Keith D, Banks RJ. Use of two-piece polyetheretherketone (PEEK) implants in orbitozygomatic reconstruction. Br J Oral Maxillofac Surg 2012;50(03):268–269
11 Williams JV, Revington PJ. Novel use of an aerospace selective laser sintering machine for rapid prototyping of an orbital blow-out fracture. Int J Oral Maxillofac Surg 2010;39(02):182–184
12 Gerbino G, Zavattero E, Zenga F, Bianchi FA, Garzino-Demo P, Berrone S. Primary and secondary reconstruction of complex craniofacial defects using polyetheretherketone custom-made implants. J Craniomaxillofac Surg 2015;43(08):1356–1363
13 Gander T, Essig H, Metzler P, et al. Patient specific implants (PSI) in reconstruction of orbital floor and wall fractures. J Craniomaxillofac Surg 2015;43(01):126–130
14 Herford AS, Miller M, Lauritano F, Cervino G, Signorino F, Maiorana C. The use of virtual surgical planning and navigation in the treatment of orbital trauma. Chin J Traumatol 2017;20(01):9–13
15 Essig H, Dressel L, Rana M, et al. Precision of posttraumatic primary orbital reconstruction using individually bent titanium mesh with and without navigation: a retrospective study. Head Face Med 2013;9:18
16 Zhang Y, He Y, Zhang ZY, An JG. Evaluation of the application of computer-aided shape-adapted fabricated titanium mesh for mirroring-reconstructing orbital walls in cases of late post-traumatic enophthalmos. J Oral Maxillofac Surg 2010;68(09):2070–2075
17 Zieliński R, Malińska M, Kozakiewicz M. Classical versus custom orbital wall reconstruction: selected factors regarding surgery and hospitalization. J Craniomaxillofac Surg 2017;45(05):710–715
18 Kunz C, Audigé L, Cornelius CP, Buitrago-Téllez CH, Rudderman R, Prein J. The comprehensive AOCMF classification system: orbital fractures - level 3 tutorial. Craniomaxillofac Trauma Reconstr 2014; 7(Suppl 1):S092–S102
19 Jalbert F, Boetto S, Nadon F, Lauwers F, Schmidt E, Lopez R. One-step primary reconstruction for complex craniofacial resection with PEEK custom-made implants. J Craniomaxillofac Surg 2014;42 (02):141–148
20 Tarsitano A, Badiali G, Pizzigallo A, Marchetti C. Orbital reconstruction: patient-specific orbital floor reconstruction using a mirroring technique and a customized titanium mesh. J Craniofac Surg 2016;27(07):1822–1825
21 Zimmerer RM, Ellis E III, Aniceto GS, et al. A prospective multicenter study to compare the precision of posttraumatic internal orbital reconstruction with standard preformed and individualized orbital implants. J Craniomaxillofac Surg 2016;44(09):1485–1497
22 Hammer B. Orbital Fractures: Diagnosis, Operative Treatment, Secondary Corrections. Seattle, WA: Hogrefe & Huber Publishers; 1995:100