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Primary orbital reconstruction with selective laser melted core patient-specific implants: overview of 100 patients

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Abstract

Contemporary advances in technology have enabled the transfer of industrial laser melting technology to surgery, and its use can improve the accuracy of orbital restoration. The aim of this study therefore was to evaluate the accuracy of primary orbital reconstruction with the use of selective laser melted, patient-specific implants and navigation. A total of 100 patients with complex orbital fractures were included. Planned orbital volumes were compared with those achieved, and angles were compared with the unaffected side. Analysis included the overlay of postoperative on planned images (iPlan® 3.0.5, Brainlab). The mean (SD) orbital volume of the unaffected side was 27.2 (2.8) ml in men and 25.0 (2.6) ml in women. Fractures that involved the posterior third of the orbital floor and comminuted fractures showed significant orbital enlargement ($p = 0.026$). The mean (SD) reconstructed orbital volume was 26.9 (2.7) ml in men and 24.26 (2.5) ml in women. Three-dimensional analysis of the colour mapping showed minor deviations when compared with the unaffected side. The results suggest that a high degree of accuracy can be routinely achieved in these complex cases.

Keywords: Orbital reconstruction; Selective laser melting; Customized implant; 3D mesh; orbital wall fracture; intraoperative navigation

Introduction

Fractures of the facial skeleton are often the centre of attention because of their frequency and the complexity of surgical reconstruction. The orbit is susceptible to injury, and up to 40% of craniomaxillofacial traumas are associated with orbital fractures.[1,2] These can be sustained as a result of violent assaults, motor vehicle accidents, or sports-related injuries,[3–5] and external impacts seem to cause a so-called "blowout".[6] Depending on the type of impact (commonly as a result of sporting accidents), fractures of the orbital floor may be isolated injuries,[7] and it is generally agreed that early treatment, usually within two weeks, is necessary.[6,8] The clinical presentation depends largely on the extent of the injury and any other associated fractures of the facial skeleton. To treat or even to prevent severe complications such as diplopia, hypoglobus, or changes in facial geometry, fractures must be reduced as closely as possible to the original anatomy.[9,10] The

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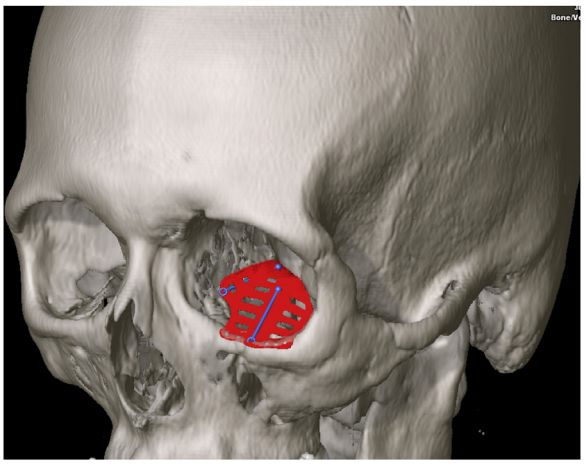

Fig. 1. A selective laser-melted, patient-specific implant designed for the left orbit (two-wall reconstruction). A horizontal drainage system was incorporated throughout. Landmarks and guides facilitated placement with intraoperative navigation. Screw holes were placed anteriorly for fixation to the inferior orbital rim.

goals are to reconstruct the midface and re-establish normal function and aesthetics.[9]

Standard treatment in many institutions consists of restoration with individually bent or preformed meshes.[11,12] High-resolution preoperative computed tomography (CT) and digital planning could help to prevent an asymmetrical outcome,[5,13,14] and patient-specific 3-dimensional mesh fabrication with image-guided navigation are options that can be used in complex cases.[10] Advances in these techniques and a detailed knowledge of the anatomy have made it possible to improve the accuracy of orbital reconstructions, control the position of the implant, and reduce operating times.[15,16] Preliminary results have indicated that they have the potential to lessen the deviation from the angle and orbital volume of the unaffected side.[17]

The focus of this single-centre prospective analysis therefore was to present our experience, and the potential advantages, of selective laser melted patient-specific orbital implants in the primary reconstruction of complex orbital fractures, and to help clinicians optimise their digital and clinical workflows.

Patients and methods

We analysed the results after treatment of unilateral orbital fractures using patient-specific orbital implants at the Department of Craniomaxillofacial Surgery, Hannover

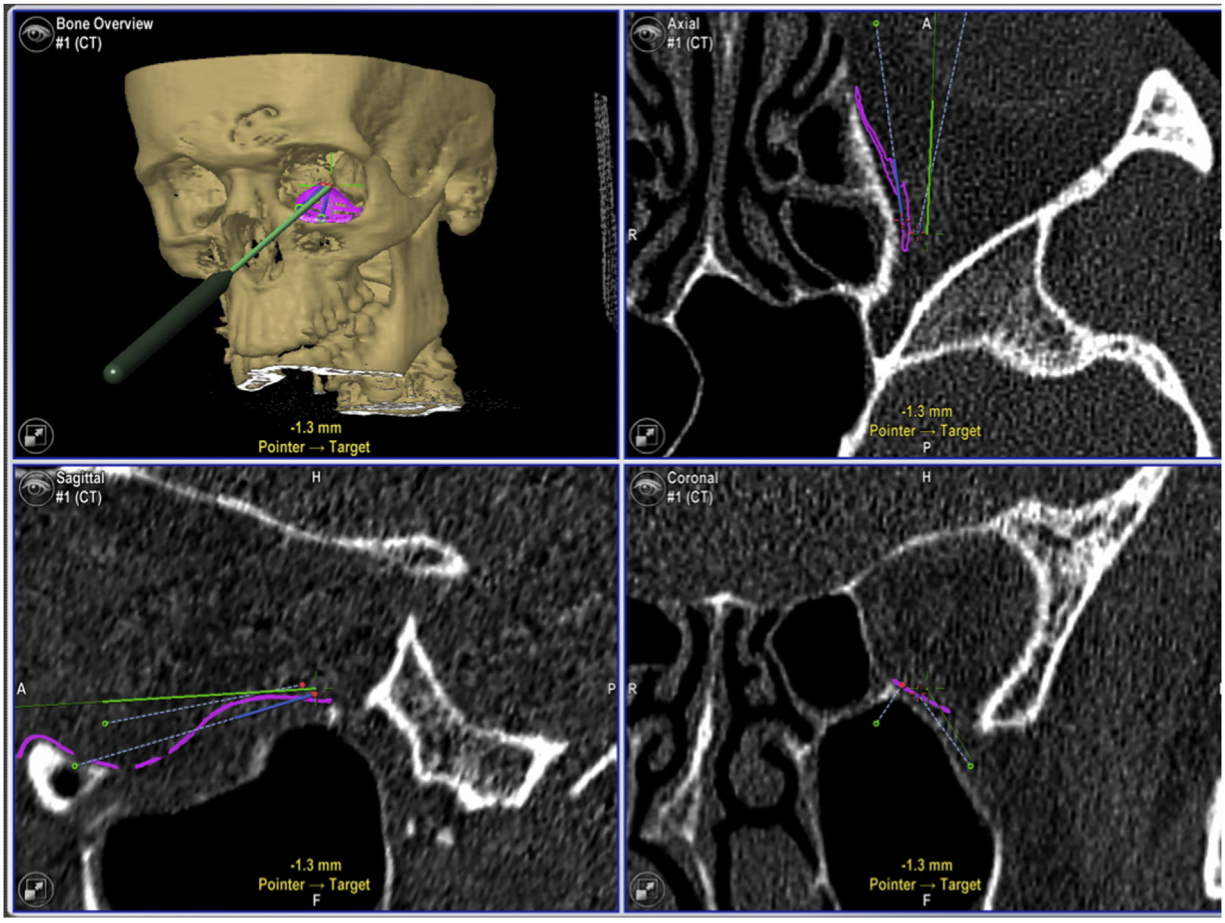

Fig. 2. Intraoperative navigation used to confirm the correct position of the implant (upper left: pointer resting on a navigational landmark of the implant).

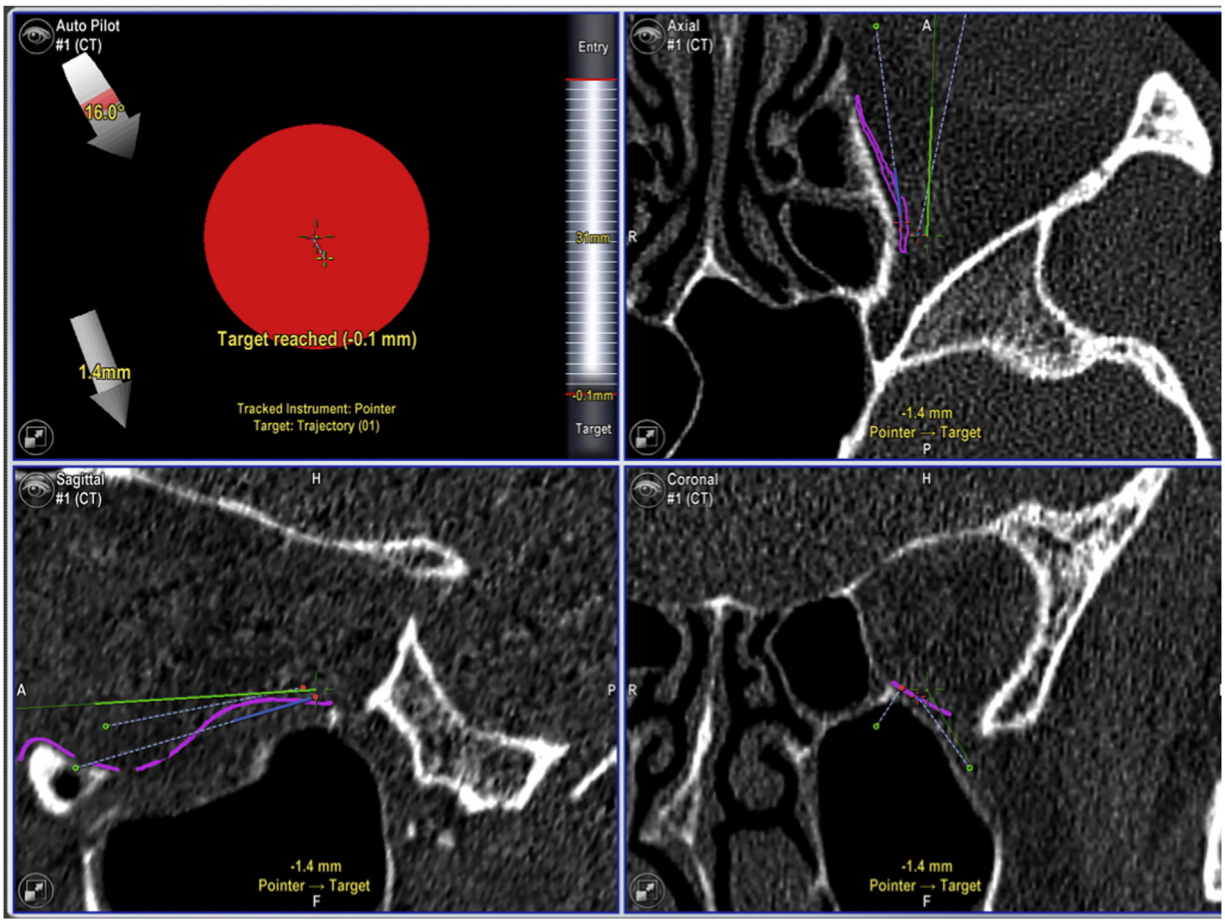

Fig. 3. Upper left: screenshot showing that the pointer has reached the navigational landmark. Lower right and left: screenshots showing position of the pointer in sagittal and coronal views (tip of pointer is represented by the centre of the green cross).

Medical School, and the Department of Oral and Maxillofacial Surgery, Heinrich Heine University of Duesseldorf, Germany, between October 2013 and December 2017. All patients were treated using the same method of orbital reconstruction by the same primary surgeon (MR).

Patients were included if they were over 18 years of age, had existing vision in the affected eye, and had had intraoperative image-controlled reconstruction of complex primary unilateral orbital deformities secondary to traumatic injury during the study period (Figs. 2 and 3). They had also had a preoperative CT or cone-beam CT, had agreed to take part, and been given adequate follow-up care and examination. Computer-assisted navigation at the Hannover Medical School is used to treat patients with fractures of the medial orbital wall and posterior third of the orbital floor, as well as complex comminuted orbital fractures, and fractures of the orbital wall that include the transition zone between the medial wall and orbital floor.

The two outcome variables were orbital volume and intraorbital angulation of the implant. As a guide, we based the planned orbital restoration on the unaffected side (in terms of size and shape). We looked at details of the final position of the implant, quantified the preoperative and postoperative orbital volume to validate accuracy, and measured the angles (anterior, medial, and posterior) in the coronal view of the 3-dimensional images. Placement of the plate and measurement of the volume were evaluated using atlas-based 3-dimensional software (iPlan® 3.0.5, Brainlab). The absolute mean difference was calculated for final statistical calculation.

Table 1 shows the study variables. We noted if there was a double operation (such as positioning of the midfacial bony frame followed by restoration of the orbit with the implant).

Preoperative conventional high-resolution CT or cone-beam CT and its DICOM-scan data were generated. To create the implant we used iPlan® CMF 3.0.5 (Brainlab) and the program Geomagic - Freeform® Plus (Fig. 1), as previously described.[10] Most of the planning was done by the surgeon without the need to communicate with medical engineers or prepare a web meeting.[13] For the most complex cases, we liaised closely with the engineers (KLS-Martin®) by web meetings or telephone calls. After planning, the production process itself took up to a maximum of five days.

All operations were done through a retroseptal, transconjunctival incision without lateral canthotomy. During the procedure, intraoperative navigation (Kick®, Brainlab) was used to place the implant within less than 1 mm of the tar-

Table 1
Study variables and surgical data.

Demographic variables*	No. of patients (n = 92)
Sex:	
Female	28
Male	64
Types of wall for reconstruction:	
Simple (single wall)	11
More than one wall	81
Cause of defect:	
Traffic accident	12
Assault or violence	28
Horse-associated accident	7
Hit by golf ball	1
Syncope	11
Fall from bike	16
Fall	17
Type of injury:	
Isolated orbital fracture	38
Zygomaticomaxillary complex, naso-orbitoethmoidal, panfacial	53
If zygomaticomaxillary complex, naso-orbitoethmoidal, panfacial, during:	
One procedure	19
Later	35
Indication for operation:	
Double vision	15/91
Enophthalmos	10/91
Hypoglobus	3/91
Size of defect and degree of dislocation	63/91
Surgical access:	
Transconjunctival, retroseptal	91/91
Navigation tools:	
Calvarial screws	6/91
Dental cusps	85/91
Mean (SD) size of defect (mm):	
Coronal	22.6 (7.5)
Sagittal	25.0 (6.3)

* Note: the same patient can contribute to more than one category.

geted area (Figs. 2 and 3). Proper positioning of the bony segments and internal orbit was confirmed using the following protocol: infraorbital rim, lateral rim, orbital floor, medial internal orbit or posteromedial orbital bulge, lateral internal orbit, posterior orbit, and projection of the globe. The implant was secured into position with one or two 1.3 mm titanium microscrews (DePuy Synthes).

All patients had a postoperative cone-beam scan (NewTom DVT 9000) or CT. We superimposed the postoperative images on to the preoperative images and analysed them, noting the differences in orbital contour, position of the implant, and angle. Every patient was evaluated for disorders of ocular motility, projection of the globe, diplopia, and neurological signs. If a patient had moved during the scan or was returned to the operating theatre it was considered a complication.

Patients with full data were followed up for up to one year (after about one week and again up to 12 months after operation). Additional information (such as adverse events) was recorded at all unscheduled visits.

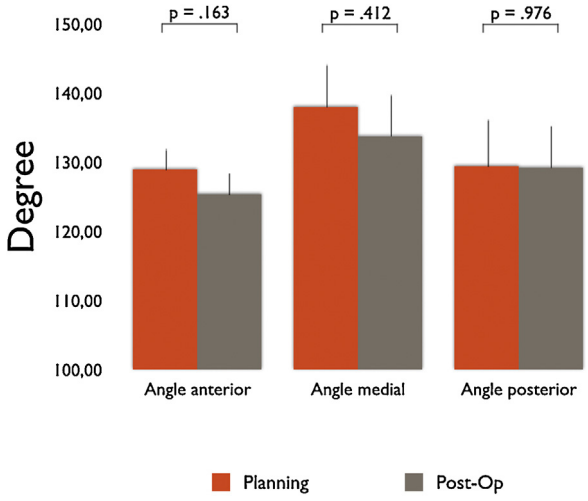

Fig. 4. Bar graph showing the postoperative angular deviation from the unaffected orbit (planned reconstruction).

The data were analysed with the help of IBM SPSS for Windows, version 23.0 (IBM Corp). Descriptive statistics were used for the study variables and matched-pair *t* tests to assess the significance of differences between the planned and achieved orbital volumes and the three angles (anterior, medial, posterior). An α-level of 0.05 was set as the level of statistical significance. All p values were two-sided.

Results

A total of 100 patients had repair of complex, unilateral, primary, post-traumatic orbital fractures with selective laser melted implants and the use of intraoperative navigation. Of them, 92 (64 men and 28 women) met the inclusion criteria. Patients' details are shown in Table 1. The mean (range) age was 45 (18–84) years. Of the 100 patients, 62 were followed for up to one year.

Diagnosis was confirmed by CT or cone-beam CT. A total of 38 had isolated orbital fractures; all the others had combined zygomaticomaxillary fractures. Fractures were simple (one wall) in 10 and complex in the rest.

The mean (SD) size of the defect (measurement taken at the widest diameter in the coronal and sagittal views) was 22.6 (7.5) mm and 25 (6.3) mm, respectively. The mean (SD) orbital volume of the unaffected side was 27.2 (2.8) ml in men and 25.0 (2.6) ml in women (CT or cone-beam CT). There was significant orbital enlargement in fractures that involved the posterior third of the orbital floor and in comminuted fractures ($p = 0.026$). The mean (SD) orbital volume was 27.9 (4.0) cm^3 before operation and 27.5 cm^3 (4.1) postoperatively ($t = 0.959$; $p = 0.338$). In the coronal view, the mean (SD) planned and achieved angulations of the implant were 123.7° (8.1) and 122.8° (8.2), respectively, for the anterior

Table 2
Duration of operation with navigation in minutes (n = 92 patients).

Operation	Median (range)
One-wall fracture	65 (42–139)
Multiwall fracture	78 (45–385)
Simultaneous panfacial and orbital restoration	401 (112–445)

Table 3
Adverse events* (directly postoperatively).

	No. of patients (n = 92)	95% CI† (%)
Patients with one or more adverse event:	17	17.0 (10.2 to 25.8)
Malpositioning of implant	5	5.0 (1.6 to 11.3)
Bleeding	1	1.0 (0.0 to 5.4)
Superficial wound infection	0	0.0 (0.0 to 3.6)
Deep wound infection	0	0.0 (0.0 to 3.6)
Intraorbital haematoma	0	0.0 (0.0 to 3.6)
Muscle tethering	0	0.0 (0.0 to 3.6)
Impaired motility	1	1.0 (0.0 to 5.4)
Mydriasis	0	0.0 (0.0 to 3.6)
Numbness	1	1.0 (0.0 to 5.4)
(Extra-) ocular muscle entrapment	1	1.0 (0.0 to 5.4)
Bulbus dislocation$	0	0.0 (0.0 to 3.6)
Diplopia	0	0.0 (0.0 to 3.6)
Restricted gaze / myopia	0	0.0 (0.0 to 3.6)
Pain	0	0.0 (0.0 to 3.6)
Cardiac complications	1	1.0 (0.0 to 5.4)
Other	11	11.0 (5.6 to 18.8)
Enophthalmos¥, ectropion, amaurosis, impairment of sight, optical nerve injury, infraorbital nerve anaesthesia	0	0.0 (0.0 to 3.6)

* Note: the same patient can contribute to more than one category.
† CI for percentages were calculated using the exact method.
$ Exophthalmometry measurement of >21 mm or a difference of >2 mm between the two eyes was considered abnormal, values of <14 mm were defined as enophthalmos[18].
¥ Enophthalmos measurement of <14.

angle ($t = 1.066$; p = 0.288); 135.8° (11.6) and 136.1° (10.3), respectively, for the medial angle ($t = -0.248$; p = 0.804); and 123.3° (11.5) and 122.9° (10.8), respectively, for the posterior angle ($t = 0{,}333$; p = 0.739).

The mean (SD) reconstructed orbital volume was 26.9 (2.7) ml in men and 24.26 (2.5) ml in women (cone-beam CT). Three-dimensional analysis of the colour mapping showed minor deviations when compared with the unaffected side (Fig. 4).

Table 2 shows the operating times and Table 3 the number of postoperative adverse events.[18]

Discussion

The correct use of imaging, accurate restoration of the orbital volume, and early repair can produce desirable long-term outcomes with good cosmetic and functional results.[19–22] Digital planning and computer-assisted surgery can be particularly helpful in large and complex deformities.[16,23,24] Our study has shown the importance of "true-to-origin" primary orbital reconstruction with patient-specific implants.

Navigational guides and rulers can be built into the implant, and these target points enable better spatial orientation and feedback about its exact position.[10] As the pointer traverses the trajectory guides, the navigation system can confirm that both the position of certain points and the trajectory are correct. This enables the accurate positioning of the implant without the need for intraoperative CT (and the additional exposure to radiation).

The treatment of complex orbital deformities aims to avoid complications such as visual disturbances, compromised facial aesthetics, extraocular muscle restriction, and enophthalmos, which can prolong recovery and affect a patient's health-related quality of life. Intraoperative navigation can help in the repair of large defects, as the posterior ledge, which often provides adequate footing in the deep orbit for the appropriate placement of the implant, can be difficult to visualise.[25] The use of selective laser melted, patient-specific implants could prevent damage to the soft or hard tissues from sharp edges or displacement of the mesh, which can occur with the use of trajectory guides and rulers.[17]

Our long-term results, which are consistent with other centres, show no disadvantage when compared with other procedures.[6,26] We think that long-term complications such as diplopia, hypoglobus, enophthalmos, facial asymmetry, and reduced motility of the globe, cannot always be prevented. Surgeons have no influence on the positioning of fat or muscle, or on atrophy of the connective tissues, but contemporary clinical investigations give the potential, at least, for the accurate rebuilding of the orbit.

This prospective study has shown that complex orbital fractures can be reconstructed with a high degree of accuracy. The use of digital workflows and computer-assisted surgery (analysis, preoperative planning, and production, as well as intraoperative navigation) could become standard practice. We have used this approach for several years and think that it is now suitable for routine use by clinical teams in trauma centres. The cost, however, may preclude this, and so we recommend that it is used only for complex orbital deformities or traumas when the highest degree of accuracy is essential to avoid serious complications.

Conflict of interest

We have no conflicts of interest.

Ethics statement/confirmation of patients' permission

All procedures in the study that involved human participants were in accordance with the ethical standards of the ethics commission of Hannover Medical School, Germany (No.

2281-2014), and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. The study was registered at the German clinical trials register

(DRKS-ID: DRKS00006549). The paper does not include the personal details of the patients.

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