

Primary reconstruction of orbital fractures using patient-specific titanium milled implants: the Helsinki protocol

M. Kärkkäinen^{a,b,*}, T. Wilkman^b, K. Mesimäki^b, J. Snäll^{a,b}

^a Department of Oral and Maxillofacial Diseases, University of Helsinki, Helsinki, Finland

^b Department of Oral and Maxillofacial Diseases, Helsinki University Hospital, Helsinki, Finland

Accepted 14 August 2018

Available online 13 September 2018

Abstract

Preoperative virtual planning and the use of patient-specific implants enable exact reconstruction of orbital fractures. We present our results and experience of reconstruction of isolated orbital fractures with patient-specific implants, according to the Helsinki protocol, in 15 patients who were followed up for at least three months postoperatively. The mean (range) difference between the positions of virtually planned, and postoperative, implants was 1.9 (0.5–5.6) mm. The postoperative volume of the fractured orbit was 1.34 ml less than that of the non-fractured side, but this was not clinically relevant. None of the patients required reoperation and none had any implant-related complications during follow up. We conclude that patient-specific implants are an adaptable and reliable treatment for primary orbital trauma, and that the Helsinki protocol may have wider applications in the treatment of facial fractures.

© 2018 The British Association of Oral and Maxillofacial Surgeons. Published by Elsevier Ltd. All rights reserved.

Keywords: patient specific implant; virtual planning; orbital fracture; facial fracture

Introduction

Fractures of the orbital floor and wall are challenging because of the demanding three-dimensional anatomy and limited operative view. Ill-fitting implants and poor surgical technique may lead to visual disturbance and an unattractive outcome, and the expanded orbital volume leads to asymmetry in the position of the eyeball (dystopia). The area of the fracture and the volume of herniated soft tissue have been associated with primary¹ and late-onset² enophthalmos. In

the surgical management of such fractures, dissection to the posterior margin and reconstruction of the slope of the orbital floor are key factors in the prevention of residual enophthalmos and recurrent diplopia.³

Stock titanium meshes are available, but the anatomy of human orbits is not identical, and the morphology of fractures differs. Stock meshes therefore need to be cut and shaped at the time of operation. Conventional, manually-bent plates have been found to be less accurate than pre-bent implants in the reconstruction of fractures with a 3-dimensional printed prototype of a skull.^{4,5} Pre-bent plates have similar results to polyethylene-titanium hybrid implants and there is no difference in complication rates.⁶

* Corresponding author at: Department of Oral and Maxillofacial Diseases, Helsinki University Hospital, 00029 HUS, Finland.

E-mail address: matti.karkkainen@hus.fi (M. Kärkkäinen).

Computer-aided-design (CAD) combined with patient-specific implants has previously been used in the reconstruction of facial fractures, but with polyethylene or titanium materials in delayed primary or secondary operations,^{7–10} so they have not been considered suitable for immediate primary reconstruction of fractures of the orbital wall.

Precise and immediate primary reconstruction of fractures of the orbital wall has not been used because we lacked a convenient protocol. To our knowledge, there have been no reports of standardised protocols that describe virtual planning and primary reconstruction of orbital fractures using patient-specific implants, so we present here our experience with primary reconstruction of orbital fractures with titanium-milled, patient-specific implants.

Patients and methods

Study design

This retrospective study includes patients from a cohort of isolated orbital fractures who presented between 1 January and 30 November 2017 and who had had an isolated orbital fracture reconstructed with a titanium patient-specific implant at the Department of Oral and Maxillofacial Surgery, Töölö Hospital, Helsinki University Hospital. Patients who were operated on with a Nordic Classification of Surgical Procedures (NCSP) operative code CAC10 (which stands for “Reconstruction of orbital wall using bone graft or plate”) were included. Three months’ postoperative follow-up was required. All patients had an ophthalmological examination. Exclusion criteria were: extension of the orbital fracture to the orbital rim, secondary reconstruction, and reconstruction associated with treatment of a tumour. We also excluded patients who had reconstructions with a non-customised titanium mesh.

Both the preoperative and postoperative assessments were made with a high-resolution 16-slice computed tomography (CT) scanner (Siemens, or GE Medical Systems) and bone and soft tissue algorithms with 0° tilt of the gantry. The data were reformatted into axial, coronal, and sagittal images 1.0 mm thick. Volume was measured on reformatted axial images 1.0 mm thick with a bone algorithm.

Outcome was evaluated using a computer. The size of the fracture and measurements of the orbital volume before and after operation were made by Disior Ltd, Helsinki, Finland. The measurements comparing the preoperative plan and the postoperative outcome of the implants were made by Planmeca Ltd.

Virtual planning

Patient-specific implants were designed preoperatively with the two surgeons (JS and MK) and engineered using the CAD of the Planmeca ProModel™ system (Planmeca Ltd). We

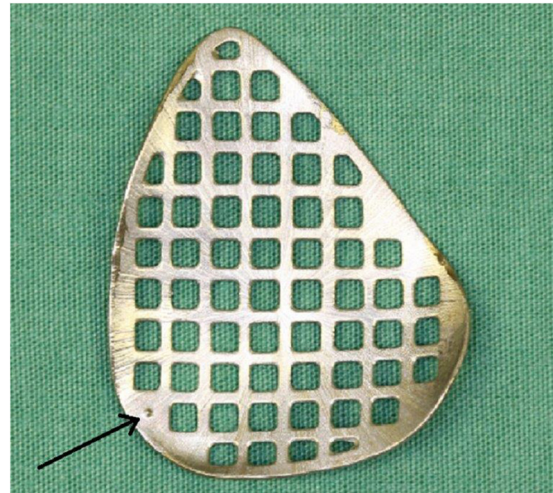


Fig. 1. Complete design of the implant was confirmed by surgeon. A small eminence on the anteromedial side of the plate next to the lacrimal foramen (arrow) was designed for better orientation during the operation.

used mirroring of the unaffected contralateral side as reference for the virtual reconstruction.

The borders of the fractures were localised and implants designed to rely on at least three intact shelf structures of the orbital structures: anteromedial, anterolateral, and posterior. The implant was extended at least 3 mm beyond these supporting edges. Anteriorly it was supported on the inner surface of the anterior orbital rim. The lateral side of the implant was extended to the infraorbital groove, but not in it or over it. The implants were designed to rely on the bony support points and orbital shape with sufficient stability, so eliminating the need for further fixation. The final design was confirmed by the surgeon (Fig. 1). The virtually planned design and fit of the implant was confirmed on a 3-dimensional model of the skull before operation.

Manufacture of the implant

The patient specific implants were CNC (Computer Numerical Control)-milled from titanium (grade 2) alloy blocks to a thickness of 0.3–0.4 mm. Apertures of 2.0–3.0 mm with 1 mm spaces were used for reconstruction of the frame. Implants were heat-sterilised before operation. The implants were manufactured by Planmeca Ltd.

Operation

The orbits were reconstructed by the authors (JS and MK) at Töölö Hospital, Helsinki University Hospital. Neither perioperative CT nor navigation was used, but CT images were obtained within 24 hours postoperatively in all the patients.

Measurements of the orbital volume

The one-click method developed by Disior Ltd and in this department the orbital volume is defined by marking the outer

orifice of the optic canal in the apex of the orbit. The accurate location of this point is further adjusted with an algorithm using the predefined form of the canal. A virtual sphere is inserted in the middle of the orbital cavity. This is allowed to expand until its surface is aligned with the boundaries of the orbital cavity. Its volume therefore consists of the optical canal in the apex and the orbital rim anteriorly. The true and pseudoforamina in the orbit are controlled by a stabilisation coefficient of the virtual expanding sphere.

The expansion of the sphere must stop on the boundary of the true orbit. This is done by applying certain stopping criteria that are based directly on the DICOM-data. In this study, the orbital volumes were analysed using proprietary algorithms (Disior Ltd) and solved numerically.

Measurement of the position of the implant

Virtual 3-dimensional models of the patients (Planmeca Promodel™) from before and after the operation were superimposed. Differences between the postoperative position of the implant and the virtually planned position were measured in three sites: anteromedial, anterolateral, and posterior in three dimensions (lateral, posterior, and superior).

Statistical analyses

The data were analysed with the aid of IBM SPSS Statistics for Windows (version 24, IBM Corp) The results are given as mean (SD) or range, and the significance of differences calculated with the chi squared test or Fisher's exact test, as appropriate. We used Pearson's correlation coefficient where necessary.

Results

Of the 35 patients who were treated by orbital reconstruction during the study period, 15 (six women and nine men) had isolated orbital fractures treated with titanium-milled, patient-specific implants (Table 1). Nine other patients had traditional mesh reconstruction (for wide fractures extending to the medifrontal area (n = 2); emergency surgery for a trapdoor fracture (n = 1); they were treated during holidays

Table 1
Patients studied.

Patients	No.
Patients with orbital reconstruction	35
Those with associated fractures of the midface or upper third, or both	8
Those having reconstructions for cancer	2
Those having secondary reconstruction	1
Patients with isolated orbital fractures	24
Those who had non-customised reconstruction with titanium mesh	9
Patients with isolated orbital fracture treated by patient-specific implant	15

Table 2
Descriptive statistics of the 15 patients.

Variable	No.
Sex:	
Male	9
Female	6
Median (range) age (years)	36 (21–71)
Median (range) delay in treatment (days)	9 (5–11)

when there was no possibility of producing the implants; or there was uncertainty about the treatment for patient-related factors (n = 4)).

All 15 patients who had patient-specific implants were followed up for at least three months. Indications for surgery were a fractured area of more than 1.5 cm² with dislocation of 4 mm or more, and diplopia during daily activities (Table 2). The transconjunctival approach was used in all patients, and none had bilateral reconstruction or reconstruction of the medial wall. No patient required reoperation. The planning, processing, and delivery of the implant ranged from 1–4 days, which did not influence the timing of the planned operation. None of the 15 patients had any complications related to the implant during the follow-up period. The position of the globe was clinically acceptable in all patients (less than 2 mm vertical or posterior displacement of the eye). None of the patients required operation on the eyelid, other ophthalmic surgery, or treatment of strabismus.

One patient was unconscious until after the operation but of the other 14, eight were found to have diplopia preoperatively. At three months postoperatively 6 of 15 patients had minor diplopia at the extremities of the visual field. One of these six had minor diplopia as a result of the operation, which subsided during follow-up. The remaining five patients with postoperative diplopia had also had it preoperatively. However, none of these patients had any trouble with daily activities.

The details of the volumes of the fractured and non-fractured orbits are shown in Tables 3 and 4 and the differences in the preplanned and postoperative positions of the implants in Table 5.

Discussion

This is to our knowledge, the first protocol that describes the use of titanium-milled, patient-specific implants for the pri-

Table 3
Volume (ml) of the 15 fractured and non-fractured bony orbits.

Orbit	Mean (SD)	Range
Fractured:		
Preoperative	29.24 (3.92)	20.61–34.82
Postoperative	24.30 (2.64)	18.81–29.52
Not fractured:		
Preoperative	25.70 (2.87)	19.46–31.84
Postoperative	25.64 (2.97)	19.34–31.99

Table 4
Correlations of postoperative volume (ml) of 15 fractured and non-fractured orbits.

Orbit	Mean (SD)	Range
Fractured	24.30 (2.64)	18.81–29.52
Not fractured	25.64 (2.97)	19.34–31.99

Pearson correlation coefficient between fractured and non-fractured orbit: 0.952, $p < 0.0001$.

Table 5
Measurements of difference between preplanned and postoperative position of the implant in 15 patients with orbital fractures.

Case No.	Difference (mm)		
	Anteromedial	Anterolateral	Cranial
1	0.7	1.5	1.3
2	1.7	2.2	1.6
3	0.8	1.2	0.6
4	1.5	2.1	0.8
5	2.1	1.3	2.5
6	1.7	3.1	2.4
7	2.6	3.8	5.0
8	1.1	3.4	3.0
9	5.6	2.9	3.8
10	0.4	0.6	0.6
11	2.7	2.1	2.2
12	2.3	2.2	1.9
13	2.0	1.5	1.3
14	0.6	0.5	0.7
15	1.0	1.3	1.0
Mean	1.8	2.0	1.9
Range	0.4–5.6	0.6–3.8	0.6–5.0

mary reconstruction of orbital fractures. They were planned purely virtually, without unnecessary delays to reconstruction. The protocol has been used in our department since January 2017.

Currently we use patient-specific implants for repair of all isolated fractures of the orbital floor except for emergencies, or when the need for operation is uncertain, or in children in whom we prefer to use resorbable materials. None of our patients had their treatment delayed by the production of the implant. The design takes about 15 minutes of the surgeon's time, and the implant can be manufactured in one day. Local planning and manufacturing make considerable savings.

The implants were inset precisely, and there was no need for reoperation. None of the patients had any complications related to their implant, or postoperative infections, during the three months' follow-up, and none complained of clinically relevant deviation in the position of the globe postoperatively. The actual postoperative volume of the fractured orbit correlated closely with the volume of the non-fractured side. A previous study comparing intact right and left orbital volumes of patients, showed a mean SD difference of 0.44 (0.31) ml.¹¹ The postoperative volume of the fractured side was 1.34 ml less than that of the intact side so the over-correction in orbital volume of 5.2% did not matter clinically, because the implant is placed as an onlay, on top the bone, instead of between the edges of the fracture.

All the patients had isolated blow-out fractures, and the orbital floor was reconstructed exclusively. We assume that the primary reconstruction of fractures of the medial wall (and particularly combined fractures of the medial wall and floor) with such implants would be more challenging because of the thin bone in the medial area. The definition of the edges of the fracture may be difficult, and some of its morphology cannot be detected on preoperative CT because of the limited accuracy of the imaging, which has been discussed previously in orbital reconstructions with patient-specific implants.¹² Perioperative dissection might break or bend the non-dislocated medial wall, and it is not always predictable. One of our patients presented with a challenge posed by a 5 mm deviation of the virtually planned position of the implant. The implant was, however, positioned well in other areas of the orbit, and the patient had no symptoms from the position. Improvements in imaging techniques and the development of computer-aided fracture planning will improve our ability to identify areas of thin bone in the near future.

Recently, the mirroring of the unaffected contralateral bony orbit has been considered to be an acceptable reference in orbital reconstruction,¹¹ but it can be used only to define bony structures. When using mirroring as a reference for virtual planning, the possible chance of a previous fracture of the contralateral side must be considered. One of our patients had had a blow-out fracture of the floor on the contralateral side, and possibly a parallel fracture on the ipsilateral side. The body of the orbit did not form the typical anatomical shape, and that complicated preoperative planning, so consequently the implant did not fit exactly. The implant was misplaced, but this was noticed and corrected in the operating theatre. To ensure correct positioning of the plate during operation we designed a small eminence on the anteromedial side of the plate to improve orientation during the operation.

Two implants did not fit exactly, but the misfits were noted purely radiologically and did not cause any clinical consequences to the patients. Nevertheless, we did not use intraoperative navigation or CT, which would have confirmed the correct position of the implant. However, from experience we know that customised implants settle most accurately, and this reduces the need for additional checking. Apart from the two previously-mentioned patients, the virtually planned and postoperative positions of the implants showed precise fitting. We found that the positioning of the implant and the outcome in these patients were superior to those of other types of orbital reconstructions with patient-specific implants.¹²

We have found that a prominent orbital rim provides better support for the implant than a flatter rim, and this is important when considering the design of the implant. If the rim is flatter the implant may be misplaced laterally, and to avoid this it should be extended more laterally to get adequate bony support. Preoperative errors in planning should be carefully avoided, as milled titanium is a rigid material that does not allow intraoperative bending. At present titanium is the material of choice for customised implants. However, after recurrent orbital trauma, implants can cause a severe threat to

adjacent anatomical structures.¹² The optimal reconstruction material, therefore, should be resorbable, osseointegrative, and should integrate with bone, and for the personalised implants it should be possible to manufacture as printable or milled. Development of new materials is therefore needed in the future.

In earlier studies of orbital reconstructions using preformed titanium meshes compared with sheets bent intraoperatively the reported differences in outcome were minor.⁶ However, it has been postulated that patient-specific implants give precise results and are therefore superior to manually-bent titanium mesh implants.¹³ Individual dual planning has been shown to reduce the amount of manipulation of tissue and duration of operation.¹⁴ Customised individually-made implants have also been shown to reduce the number of adverse events in orthopaedics,¹⁵ and the better outcomes were achieved without increasing costs. In the near future, cost-effectiveness must also be evaluated with regard to implants for orbital fractures. Our results suggest that they should not be limited to secondary reconstructions, but be used for primary trauma, too.

Optimal reconstruction of increased orbital volume may be challenging because of possible later changes in soft tissues, which may be unpredictable.¹⁶ Despite adequate bony reconstruction, the changes in the soft tissues may limit the aesthetic and morphological outcomes.¹⁷ We think, based on our clinical experience, that slight overcorrection is appropriate in fractures with a wide prolapse of soft tissue. Virtual planning and customised orbital reconstruction will allow accurate overcorrection in the future. However, predictors for late-onset dystopia need to be studied in further detail.

Conclusion

We have shown that exact fitting of customised implants is possible in primary facial fractures. We think that preoperative virtual planning is an important tool in the management of fractures, and measurements of orbital volume should be included in preoperative planning. Computer-aided techniques, virtual planning, and use of patient-specific implants enable anatomically exact reconstruction of the orbital floor in primary trauma. These methods should be considered for larger studies in primary reconstruction of facial fractures.

Conflict of interest

We have no conflicts of interest.

Ethics statement/confirmation of patients' permission

The study was approved by the Internal Review Board of the Division of Musculoskeletal Surgery. Patients' permission has been obtained.

Acknowledgements

We thank MSc Alexander Brink, Planmeca Ltd., Finland, for assistance with measurements of the position of implants and virtual planning, and MSc Sakari Soini and MSc Arto Poutala, Disior Ltd, Finland, for measurements of volume. Finnish Cultural Foundation, North Savo Regional Fund (MK).

References

- Jin HR, Shin SO, Choo MJ, et al. Relationship between the extent of fracture and the degree of enophthalmos in isolated blowout fractures of the medial orbital wall. *J Oral Maxillofac Surg* 2000;**58**: 617–21.
- Choi J, Park SW, Kim J, et al. Predicting late enophthalmos: differences between medial and inferior orbital wall fractures. *J Plast Reconstr Aesthet Surg* 2016;**69**:e238–44.
- Park J, Kim J, Lee J, et al. Secondary reconstruction of residual enophthalmos using an endoscope and considering the orbital floor and medial wall slope. *J Craniofac Surg* 2016;**27**:992–5.
- Kim YC, Jeong WS, Park TK, et al. The accuracy of patient specific implant prebent with 3D-printed rapid prototype model for orbital wall reconstruction. *J Craniomaxillofac Surg* 2017;**45**: 928–36.
- Raisian S, Fallahi HR, Khiabani KS, et al. Customized titanium mesh based on the 3D printed model vs. manual intraoperative bending of titanium mesh for reconstructing of orbital bone fracture: a randomized clinical trial. *Rev Recent Clin Trials* 2017;**12**:154–8.
- Peng MY, Merbs SL, Grant MP, et al. Orbital fracture repair outcomes with preformed titanium mesh implants and comparison to porous polyethylene coated titanium sheets. *J Craniomaxillofac Surg* 2017;**45**:271–4.
- Tarsitano A, Badiali G, Pizzigallo A, et al. Orbital reconstruction: patient-specific orbital floor reconstruction using a mirroring technique and a customized titanium mesh. *J Craniofac Surg* 2016;**27**: 1822–5.
- Zhang Y, He Y, Zhang ZY, et al. 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**:2070–5.
- 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**:126–30.
- Stoor P, Suomalainen A, Lindqvist C, et al. Rapid prototyped patient specific implants for reconstruction of orbital wall defects. *J Craniomaxillofac Surg* 2014;**42**:1644–9.
- Jansen J, Dubois L, Schreurs R, et al. Should virtual mirroring be used in the preoperative planning of an orbital reconstruction? *J Oral Maxillofac Surg* 2018;**76**:380–7.
- Foletti JM, Scolozzi P. Severe distortion of an orbital titanium mesh implant after recurrent facial trauma: a potential threat to the orbital contents? *Br J Oral Maxillofac Surg* 2017;**55**: 836–8.
- Oh SA, Aum JH, Kang DH, et al. Change of the orbital volume ratio in pure blow-out fractures depending on fracture location. *J Craniofac Surg* 2013;**24**:1083–7.
- Callahan AB, Campbell AA, Petris C, et al. Low-cost 3D printing orbital implant templates in secondary orbital reconstructions. *Ophthalmic Plast Reconstr Surg* 2017;**33**:376–80.
- Culler SD, Martin GM, Swearingen A. Comparison of adverse events rates and hospital cost between customized individually made implants

- and standard off-the-shelf implants for total knee arthroplasty. *Arthroplast Today* 2017;**3**:257–63.
16. Jung S, Lee JW, Kim CH, et al. Postoperative changes in isolated medial orbital wall fractures based on computed tomography. *J Craniofac Surg* 2017;**28**:2038–2041.
 17. Clauser L, Galiè M, Pagliaro F, et al. Posttraumatic enophthalmos: etiology, principles of reconstruction, and correction. *J Craniofac Surg* 2008;**19**:351–9.