Primary orbital reconstruction with selective laser melting core (SLM) patient specific implants (PSI): overview of 100 surgical treated patients

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Abstract

Purpose

Contemporary advances in technology allowed the transfer of knowledge from industrial laser melting systems to surgery; such an approach could increase the degree of accuracy in orbital restoration. The aim of this study was to examine the accuracy of selective laser melted PSI and navigation, in primary orbital reconstruction.

Methods

One hundred patients with complex orbital fractures were included in this study. Planned vs. achieved orbital volumes (a) and angles (b) were compared to the unaffected side (n = 100). Analysis included the overlay of post-treatment on planned images (iplan 3.0.5, Brainlab®, Feldkirchen, Germany).

Results

Orbital volume of the unaffected side ranged from 27.2 ml ± 2.8 ml in male and 25.0 ml ± 2.6 ml in female. Significant orbital enlargement was found in orbital fractures with involvement of the posterior third of the orbital floor and in comminuted fracture pattern. Reconstructed orbital volume ranged from 26.9 ± 2.7 ml in male and 24.26 ± 2.5 ml in female. 3D Analysis of the colour mapping showed minor deviations compared to the mirrored unaffected side.

Conclusion

The results suggested that primary reconstruction in complex orbital wall fractures can be routinely achieved with a high degree of accuracy by using selective melted orbital PSIs.

Keywords

Orbital reconstruction, Selective laser melting, Customized implant, 3 D mesh, orbital wall fracture, intraoperative navigation

Introduction

Fractures of the facial skeleton are often the center of attention, due to their frequency and the complexity of the surgical reconstruction. The orbit is a susceptible region in the midface. Over all, up to 40% of craniomaxillofacial traumas are associated with orbital fractures.[1, 2] The mode of action is variable, but orbital fractures may result from violent assaults, motor vehicle accidents or sports- related injuries.[3-5] External impact forces seem to cause a so-called 'blowout'.[6] Dependent on the type of impact - commonly following sports related injuries- orbital floor fractures may be isolated injuries.[7] There is a general agreement that these fractures should receive an early treatment usually within two weeks.[6, 8] The clinical presentation, following an orbital fracture, is largely dependent on the extend and any other associated fractures of the facial skeleton. To treat or even prevent severe complications like diplopia, hypoglobus, changes in facial geometry, a fracture reduction as close as possible to the original anatomy is mandatory.[9, 10] The goals are to reestablish normal function, aesthetics and an appropriate reconstruction of the midface.[9] Contemporary standard in many institutions is a surgical restoration with individually bent or preformed meshes.[11, 12] To avoid inadequate surgical treatment, a high resolution preoperative CT-scan and digital planning could be useful and could prevent post procedure asymmetry.[5, 13, 14] To deal with these issues, patient specific 3-dimensional mesh fabrication and image guided navigation is an option to perform complex orbital rehabilitations.[10] Advances in these technologies have made it possible to achieve increasing degrees of accuracy in the treatment of orbital deformities. This tactic is associated with knowledge of specific anatomical circumstances, decreased operative times and a precise control of implant-position.[15, 16]

Preliminary results indicated that this technique has the potential to decrease the angle and orbital volume deviation from unaffected to the distracted orbital space.[17] The focus of this single center prospective analysis is to present our experience and potential advantages of orbital SLM PSIs in primary reconstruction of complex orbital fractures. This could help clinicians towards the optimization of the digital and clinical workflow for orbital SLM PSIs.

Material and Methods

This review is analyzing the results of unilateral orbital fractures treated at the Department of Craniomaxillofacial Surgery, Hannover Medical School, Germany, between October 2013 and December 2015 using orbital PSIs. There was only one primary surgeon for all patients (author MR). No other method of orbital reconstruction was used at that time.

Patients were included if they had reconstruction for complex primary unilateral orbital deformities secondary to traumatic injury using computer assisted treatment during the study period. In addition, the patients should fulfill the following inclusion criteria: (a) patients older than 18 years, (b) indication for orbital reconstruction (true to origin planning), (c) intraoperative image-controlled reconstruction (Fig. 2 and 3), (d) existence of a pre-surgery CT or CBCT, (e) patient letter of agreement, (f) adequate follow-up care and examination and (g) existing vision at the affected eye. In addition to that, the indications for using computer-assisted navigation, used in Hannover Medical School, Germany, including the following, had to be fulfilled:

- Fractures of the medial orbital wall
- Fractures of the posterior third of the orbital floor
- complex comminuted orbital fractures
- Orbital wall fractures including the transition zone between medial wall and orbital floor

The two outcome variables were orbital volume and intraorbital implant angulation. As a guiding aim, we planned the orbital restoration based on the unaffected side (in terms of size and shape). We looked at details of the final implant position and we quantified orbital pre- and postoperative volume to validate accuracy. In addition to that, we measured the angles (anterior, medial and posterior angle) in the coronal view of the 3-dimensional imaging. Plate placement and volume- measurement was evaluated using atlas-based 3-dimensional software iplan 3.0.5 (Brainlab®, Feldkirchen, Germany). The absolute mean difference was calculated for final statistical calculation.

Additional study variables included the following (table 1): Gender, Age, etiology of injury, type of fracture (isolated orbital fracture, zygomaticomaxillary complex (ZMC), naso-orbital-ethmoid fracture (NOE), panfacial fracture), number of injured orbital walls (simple: one wall, multi-wall: more than one wall). We noted if there was a double operation procedure (e.g. first positioning of midfacial bony frame and then, secondary the orbital restoration with PSI). Table 2 gives an overview about additional findings like diplopia, ectropion or entropion.

Preoperative conventional high resolution computed tomography (CT) and/or Cone Beam computed tomography (CBCT) and its DICOM-scan data were generated. For implant creating procedure we used iPlan® CMF 3.0.5 (Brainlab®, Feldkirchen, Germany) and the program Geomagic - Freeform® Plus (Morrisville, NC, USA) as previously described (Fig. 1).[10] An accurate transfer of virtual plan to a precise PSI is very prone for the success. Most of all planning processes were done by the surgeon, without the need of communicating with medical engineers or prepare a web meeting.[13] For very complex cases, we hold up a close liaison to the engineers (KLS-Martin®, Tuttlingen, Germany), like web meetings or telephone calls. After planning, the production process itself took up to a maximum of 5 days.

At the time of surgery, all patients were approached via a retroseptal, transconjunctival incision without a lateral canthotomy. During the procedure, intraoperative Navigation (Kick, Brainlab®, Feldkirchen, Germany) was in use to assess the correct implant position within less than 1mm of targeted reconstruction area (Fig. 2 and 3). Proper position of the bony segments and internal orbit were confirmed with the following protocol: infraorbital rim, lateral rim, orbital floor, medial internal orbit/ postero-medial orbital bulge, lateral internal orbit, posterior orbit and globe projection. The previously manufactured and inserted PSI was locked after position control with one or two 1,3mm titanium microscrews (DePuy Synthes, Switzerland).

All patients received a postoperative Cone beam scan (NewTom DVT 9000, Deutschland AG, Marburg, Germany) or a CT-scan. The postoperative images were superimposed onto the preoperative images and got analyzed if the reconstituted position is equal to the planned position. Differences in orbital contour, definitely PSI position and the angular deviations were noted. Every patient was evaluated for presence of ocular motility disorders, globe projection, diplopia and neurological signs. Complications were defined as suboptimal placing resulting from the procedure itself or a return to the operation room.

Acting within the scope of orbital follow-up care, we examined the patients with full data available posttreatment up to one year long term, T1 about one week and T2 up to 12 month after operation. Additional information (e.g. adverse events) was documented at all unscheduled visits.

The data were analyzed with IBM SPSS for Windows, Version 23.0 (IBM Corp., Armonk, NY, USA). Each study variable was computed by descriptive statistics. For testing differences between the planned vs. achieved orbital volume and three angles (anterior, medial, posterior), a matched pairs t-test was used to assess the differences. An α-level of 0.05 was set as the level of statistical significance. All p-values were two sided.

Results

One hundred patients with complex orbital, unilateral primary post-traumatic bone fractures got SLM-implants with intraoperative navigation. 91 patients fulfilled whole inclusion criteria by having all therapy data available. An overview about patient demographics, injury causes and measurements is demonstrated in Table 1. The study cohort (included patients) was composed of 63 males and 28 females. The average age was 28.9 years. 62 out of the 100 patients got a follow-up post treatment up to one year long (19 females, 43 males).

Diagnosis was validated by imaging (CT/ CBCT). 41,8 % of all included patients had an isolated orbital fracture, all others a combined zygomaticomaxillary fracture. 10 out of 91 patients (11 %) had a simple (one-wall fracture), all the others had complex (more than one wall) fractures.

Concerning orbital fractures, the average defect size (measurement was performed at the largest fracture-diameter in coronal and sagittal view) was 22,6 mm (SD 7,5) and 25 mm (SD 6,3). Table 2 shows pre-surgical parameters and intraoperative conditions.

Orbital volume of the unaffected side ranged from 27.2 ml ± 2.8 ml in male and 25.0 ml ± 2.6 ml in female (CT/CBCT). Significant fracture-associated orbital enlargement was found in orbital fractures with involvement of the posterior third of the orbital floor and in comminuted fracture pattern ($p=0.026$). The mean difference in orbital volume between digital planned and operated orbit post-operatively was 27.9 cm^3 (SD 4.0; pre-surgical) to 27.5 cm^3 (SD 4.1; post-surgical; $p=0.352$). The mean difference between planned and reached implant angulation (in coronal view) was 123.7° (SD 8.1) to 122.8° (SD 8.2) for the anterior angle ($p=0.163$), 135.8° (SD 11.6) to 136.1° (SD 10.3) for medial angle ($p=0.412$) and 123.3° (SD 11.5) to 122.9° (SD 10.8) for the posterior angle ($p=0.976$).

Reconstructed orbital volume ranged from 26.9 ± 2.7 ml in male and 24.26 ± 2.5 ml in female (CBCT). 3D Analysis of the color mapping showed minor deviations compared to the mirrored unaffected side.

Table 3 compares operation times between different extended fractures and table 4 shows the number of adverse events after operation.

Discussion

Desirable long-term clinical outcomes could be achieved with the use of the correct radiographic modality and with restoring the exact orbital contoured volume.[18-20] This work showed the importance of the 'true-to-origin' primary orbital reconstruction with patient-specific implants. Good cosmetic and functional results can be achieved with an early repair.[21] The digital planning and computer assisted surgery are particularly helpful in large and complex facial deformities.[16, 22, 23] However, navigational guides and rulers can be built into the implant. These navigational target points enable much better spatial orientation and feedback about whether the implant is actually where it is supposed to be.[10] As the pointer traverses along the trajectory guides, the navigation system can confirm that certain points are in the correct position and also that the trajectory is correct. These advantages lead to an exceedingly accurate implant position that can be placed without additional intraoperative CT scans, so there is no additional intraoperative radiation. The goals of treatment for complex orbital deformities are multiple and include avoiding complications such as visual disturbances, compromised facial esthetics, extraocular muscle restriction and enophthalmus. Such complications can prolong the recovery journey and can affect the health-related quality of life. In very large defects, very often the posterior ledge generates adequate footing in the deep orbit, that can facilitate the appropriate placement of the implant. To reach this poorly visualized anatomic area can be very challenging and intraoperative navigation can lead to success.[24] In addition to that, the use of SLM could prevent possible inserting adverse effects on soft or hard tissues, because of sharp edges or displacing mesh, while using the so called trajectory guides and rulers.[17] Our long-term results are consistent with other centers and showed no disadvantage when compared with other surgical procedures.[6, 25] We believe that possible long term complications like diplopia, hypoglobus, enophthalmos, facial disproportion and decreased globe motility, could not always be prevented by any medical procedure known today; surgeons have no influence on fat positioning, muscle or connective tissue atrophy. But the contemporary clinical work up, has the potential -at least- to rebuilt as best as possible the pre-accidental orbital bone position. This prospective study showed that complex orbital fractures can be reconstructed with a high degree of accuracy concerning the planned and post-operative implant fit. The digital workflow and computer assisted surgery (analysis, preoperative planning and production as well as intraoperative navigation), can provide a standard procedure. However, the costs of the implant as well as the navigation system costs may preclude its widespread use. After a few years of clinical use, we believe that this technique is now suitable for daily use by clinical teams in trauma centers.

Additional data

Competing interests

The authors declare that they have no competing interest.

Author's contribution

MR and NCG conceived of the study and participated in its design and coordination. MR, HH and MR made substantial contributions to conception and design of the manuscript as well as data acquisition. MR, HH, MR, AK and DDS have been involved in drafting the manuscript. NCG, CKS and NRK were involved in revising the manuscript. All authors read and approved the final manuscript.

Ethical standard

All procedures performed in the presented study involving human participants were in accordance with the ethical standards of ethic commission of medical school of Hanover, Germany (No. 2281-2014), and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

References

1. Manolidis S, Weeks BH, Kirby M, Scarlett M, Hollier L. Classification and surgical management of orbital fractures: experience with 111 orbital reconstructions. The Journal of craniofacial surgery. 2002;13(6):726-37; discussion 38.

2. Jank S, Schuchter B, Emshoff R, et al. Clinical signs of orbital wall fractures as a function of anatomic location. Oral surgery, oral medicine, oral pathology, oral radiology, and endodontics. 2003;96(2):149-53.
3. Tong L, Bauer RJ, Buchman SR. A current 10-year retrospective survey of 199 surgically treated orbital floor fractures in a nonurban tertiary care center. Plastic and reconstructive surgery. 2001;108(3):612-21.
4. Shere JL, Boole JR, Holtel MR, Amoroso PJ. An analysis of 3599 midfacial and 1141 orbital blowout fractures among 4426 United States Army Soldiers, 1980-2000. Otolaryngology--head and neck surgery : official journal of American Academy of Otolaryngology-Head and Neck Surgery. 2004;130(2):164-70.
5. Chi MJ, Ku M, Shin KH, Baek S. An analysis of 733 surgically treated blowout fractures. Ophthalmologica Journal international d'ophtalmologie International journal of ophthalmology Zeitschrift fur Augenheilkunde. 2010;224(3):167-75.
6. Gosau M, Schöneich M, Draenert F, et al. Retrospective analysis of orbital floor fractures—complications, outcome, and review of literature. Clinical oral investigations. 2011;15(3):305-13.
7. Antoun JS, Lee KH. Sports-related maxillofacial fractures over an 11-year period. Journal of oral and maxillofacial surgery : official journal of the American Association of Oral and Maxillofacial Surgeons. 2008;66(3):504-8.
8. Burnstine MA. Clinical recommendations for repair of isolated orbital floor fractures: an evidence-based analysis. Ophthalmology. 2002;109(7):1207-10; discussion 10-1; quiz 12-3.
9. Gellrich NC, Schramm A, Hammer B, et al. Computer-assisted secondary reconstruction of unilateral posttraumatic orbital deformity. Plast Reconstr Surg. 2002;110(6):1417-29.
10. Rana M GM, Gellrich NC. Customized orbital wall reconstruction & engineering of selective laser melted implants (Core Implants SLS) - A technical note -. The British journal of oral & maxillofacial surgery. 2014.
11. Kozakiewicz M, Szymor P. Comparison of pre-bent titanium mesh versus polyethylene implants in patient specific orbital reconstructions. Head & face medicine. 2013;9:32.
12. Huempfner-Hierl H, Doerfler HM, Kruber D, Hierl T. Morphologic comparison of preformed orbital meshes. Journal of oral and maxillofacial surgery : official journal of the American Association of Oral and Maxillofacial Surgeons. 2015;73(6):1119-23.
13. Rana M, Essig H, Ruecker M, Gellrich NC. Development and demonstration of a novel computer planning solution for predefined correction of enophthalmos in anophthalmic patients using prebended 3D titanium-meshes--a technical note. Journal of oral and maxillofacial surgery : official journal of the American Association of Oral and Maxillofacial Surgeons. 2012;70(11):e631-8.
14. Zizelmann C, Gellrich NC, Metzger MC, et al. Computer-assisted reconstruction of orbital floor based on cone beam tomography. The British journal of oral & maxillofacial surgery. 2007;45(1):79-80.
15. Wan KH, Chong KKL, Young AL. The Role of Computer-Assisted Technology in Post-Traumatic Orbital Reconstruction: A PRISMA-driven Systematic Review. Scientific Reports. 2015;5:17914.
16. Schmelzeisen R, Gellrich NC, Schoen R, et al. Navigation-aided reconstruction of medial orbital wall and floor contour in cranio-maxillofacial reconstruction. Injury. 2004;35(10):955-62.
17. Rana M, Chui CH, Wagner M, et al. Increasing the accuracy of orbital reconstruction with selective laser-melted patient-specific implants combined with intraoperative navigation. J Oral Maxillofac Surg. 2015;73(6):1113-8.
18. Sidebottom AJ, Sissons G. Radiographic screening for midfacial fracture in A&E. The British journal of radiology. 1999;72(858):523-4.
19. Schuknecht B, Graetz K. Radiologic assessment of maxillofacial, mandibular, and skull base trauma. European radiology. 2005;15(3):560-8.

20. Dempf R, Hausamen JE. [Fractures of the facial skull]. Der Unfallchirurg. 2000;103(4):301-13.
21. Girotto JA, MacKenzie E, Fowler C, et al. Long-term physical impairment and functional outcomes after complex facial fractures. Plastic and reconstructive surgery. 2001;108(2):312-27.
22. Markiewicz MR, Dierks EJ, Bell RB. Does intraoperative navigation restore orbital dimensions in traumatic and post-ablative defects? Journal of cranio-maxillo-facial surgery : official publication of the European Association for Cranio-Maxillo-Facial Surgery. 2012;40(2):142-8.
23. Bell RB, Markiewicz MR. Computer-assisted planning, stereolithographic modeling, and intraoperative navigation for complex orbital reconstruction: a descriptive study in a preliminary cohort. Journal of oral and maxillofacial surgery : official journal of the American Association of Oral and Maxillofacial Surgeons. 2009;67(12):2559-70.
24. Schramm A, Suarez-Cunqueiro MM, Barth EL, et al. Computer-assisted navigation in craniomaxillofacial tumors. The Journal of craniofacial surgery. 2008;19(4):1067-74.
25. Holtmann H, Eren H, Sander K, Kubler NR, Handschel J. Orbital floor fractures--short- and intermediate-term complications depending on treatment procedures. Head Face Med. 2016;12:1.

Tables

Table 1: Study variables (for included patients).

Demographic variables (n =91)	
Self- reported sex Female Male	 28 63
Wall types for reconstruction Simple (single wall) Multi-wallx (> one wall)	 10 81
Etiology of defects Traffic accident Assault or Violence Horse associated accident Golf ball hit Syncopes Bike spill Stumble spill	 11 28 7 1 11 16 17
Type of traumatic injury Isolated orbital fracture Zygomaticomaxillary complex, naso-orbital-ethmoidal, panfacial If Zygomaticomaxillary complex, naso-orbital-ethmoidal, panfacial, during: one procedure later	 38 53 19 34

Table 2: Surgical data.

Indication for surgery (n= 91) Double vision Enophthalmos Hypoglobus Defect size and degree of dislocation	 15 10 3 63
Surgical access Transconjunctival, retroseptal	 all
Navigation tools Calvarian screws Dental cusps	 6 85
Average defect size in mm (SD) Coronal sagittal	 22,6 (7,5) 25 (6,3)

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

Table 3: Median procedure timing with navigation (in minutes, range)

n (%)	92		
One-wall fracture	65 (42, 139)		
Multi-wall fracture	78 (45, 385)		

Combination panfacial and orbital restoration simulataneously	401 (112, 445)

Table 4: Adverse events (directly postoperative)

	Patient specific Implant	
Adverse events*	**n**	**% (95% CI†)**
Patients with one or more adverse events	17	17.0 (10.2;25.8)
Implant malposition	5	5.0 (1.6;11.3)
Bleeding complications	1	1.0 (0.0;5.4)
Superficial wound infection	0	0.0 (0.0;3.6)
Deep wound infection	0	0.0 (0.0;3.6)
Intraorbital haematoma	0	0.0 (0.0;3.6)
Muscle tethering	0	0.0 (0.0;3.6)
Motility impairment	1	1.0 (0.0;5.4)
Mydriasis	0	0.0 (0.0;3.6)
Numbness	1	1.0 (0.0;5.4)
(Extra-) ocular muscle entrapment	1	1.0 (0.0;5.4)
Bulbusdislocation$	0	0.0 (0.0;3.6)
Diplopia	0	0.0 (0.0;3.6)
Gaze restriction / Myopia	0	0.0 (0.0;3.6)
Pain	0	0.0 (0.0;3.6)
Cardial complications	1	1.0 (0.0;5.4)
Other	11	11.0 (5.6;18.8)
Enophthalmos¥, Ectropion, Amaurosis, Impairment of sight Optical nerve injury, Infraorbital nerve anesthesia,	0	0.0 (0.0;3.6)

*Note: the same patient can contribute to more than one category.
† Confidence intervals for percentages were calculated using the exact method
$ Exophthalmometry measurement >21 mm or a difference of > 2 mm between the two eyes was considered abnormal, values < 14 mm were defined as enophthalmos *(Cline and Rootman, 1984)*
¥ Enophtalmetry measurement of <14 mm