© Med Sci Monit, 2010; 16(Suppl.1): 75-79

WWW.MEDSCIMONIT.COM
Supplement 1

Received: 2010.02.26
Accepted: 2010.03.31
Published: 2010.05.20

Patient specific implants, designed using Rapid Prototyping and diagnostic imaging, for the repair of orbital fractures

Marcin T. Elgalal[1], Marcin Kozakiewicz[2], Piotr Loba[3], Bogdan Walkowiak[4], Marek Olszycki[1], Ludomir Stefańczyk[1]

[1] Department of Radiology and Diagnostic Imaging, Medical University of Lodz, University Hospital No 1, Lodz, Poland
[2] Department of Cranio-Maxillofacial and Surgery, Medical University of Lodz, University Hospital No 2, Lodz, Poland
[3] Department of Ophthalmology, Medical University of Lodz, University Hospital No 1, Lodz, Poland
[4] Department of Biophysics, Institute of Materials Science and Engineering, Faculty of Mechanical Engineering, Technical University of Lodz, Lodz, Poland

Source of support: This study was supported by grant KBN 3627/B/T02/2008/34 and UM503-1088-1

Author's address: Marcin Elgalal, Department of Radiology and Diagnostic Imaging, Barlicki Memorial Teaching Hospital, Kopcińskiego 22 Str., 90-153 Lodz, Poland, e-mail: telgalal@yahoo.co.uk

Summary

Background: *Craniofacial trauma affects orbital structures in approximately 40% of all cases. Over the years, there has been a marked increase in applying preformed implants for the reconstruction of orbital fractures. Such implants significantly shorten operating times and decrease trauma to intraorbital structures during surgery. This study sought to create anatomic models of the bony orbit based on MSCT images, and use them as templates to form titanium mesh into custom, patient-specific implants for the reconstruction of orbital wall defects. Furthermore, the aim was to compare this new technique with a conventional method of treatment.*

Material/Methods: *A total of 30 patients with facial trauma and orbital fractures were included and divided into 2 groups. The first group of 15 subjects was treated with custom implants formed before surgery. The second group of 15 patients had been previously treated using a conventional method of manual implant formation during surgery. Both groups underwent ophthalmic evaluation and were statistically compared.*

Results: *Significant improvement in all cases was seen after surgery based on ophthalmic examination. There is a statistically significant superiority of RP (rapid prototyping) treatment method over CM (conventional method) when the area of diplopic vision (binocular single vision loss) and upgaze VVD (vertical visual disparity) reduction are considered.*

Conclusions: *With this new method of treatment, it is possible to use MSCT imaging to create accurate, individual implants. Such implants allow for precise reconstruction of tissue defects and better outcome.*

Key words: computerized tomography • rapid prototyping • computer models • orbital fractures • orbital implants

Background

Although several different surgical approaches have been described regarding the repair of orbital floor defects, all of these methods results are in a very narrow operating field. This makes the process of fitting and aligning implants to anatomic landmarks within the orbit time-consuming [1] and operator-dependant. In addition to this, the complex anatomy of the orbit makes the process of shaping and cutting the titanium mesh very difficult, and it is almost impossible to achieve a "true-to-original" 3-dimensional shape.

Multislice computed tomography can provide accurate images of the facial skeleton, and is routinely used to image trauma of the bony orbit. These images can be reconstructed into detailed 3-dimensional images. Nowadays, it is possible

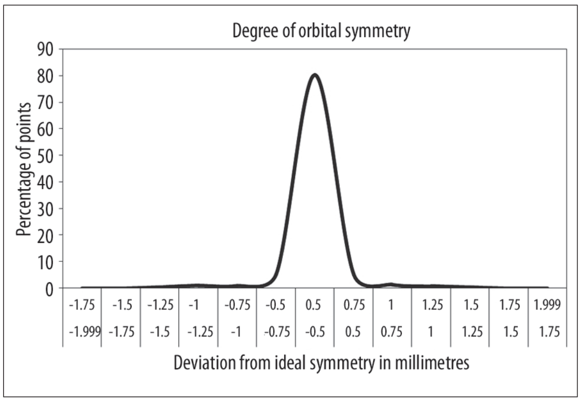

Figure 1. Symmetry of the human orbits. The degree of symmetry tolerance was divided into classes: 80% of data points are in the range ±0.5 mm, and 90% in range ±0.75 mm

to convert these DICOM images into different formats that are compatible with software and equipment used for industrial purposes. With this technology, it is possible to make accurate 3-dimensional physical models of very complex structures in a relatively short space of time. In this study, rapid prototyping was used to build accurate physical anatomic models of the bony orbit. Such models allow for presurgical planning and serve as templates that are used to create individual implants. The ideal template would be an exact model of the orbit that is to undergo reconstruction. However, this would only be possible if the patient had a preinjury MSCT scan. Trauma of the bony orbits results in changes to their dimensions and therefore, they cannot be used for this purpose. To achieve accurate templates of the injured bony orbit, it is necessary to mirror a 3D model of the uninjured contralateral orbit. This results in a 3D model of the injured orbit that reflects its premorbid anatomy. This technique is very effective; however, it must be assumed that an innate symmetry of the orbits exists. Although this is a reasonable assumption, there has been no data available in the literature to date on this subject [2]. For this reason, it was necessary to compare several orbits in patients with no orbital pathology to assess their level of symmetry.

To form individual implants for each of the patients treated, titanium mesh was bent and cut to size using the orbit models as templates. This resulted in implants with a 3D "true-to-original" shape that best reflected the contours of the orbital wall. These models were further used during surgery as guides to help identify anatomic landmarks and correctly position the implant.

The aim of this study was to present a novel method of orbital bone surgery that significantly increases the degree of reconstruction precision.

Material and Methods

Orbital symmetry

MSCT studies of the paranasal sinuses were chosen to assess the degree of orbital symmetry in subjects with no orbital pathology. All studies were performed on a Multi-slice VCT, GE Lightspeed 64-slice scanner according to the following protocol: 0.6 mm layers, gantry tilt 0°, matrix 512×512. The

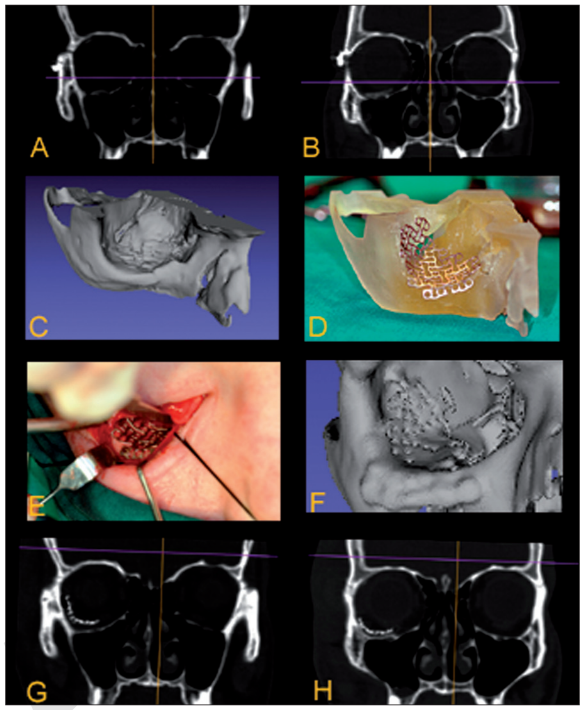

Figure 2. (**A**) Coronal MPR of retrobulbar area before individual implant application. The patient was previously treated for a fracture of the right orbit. The increased volume of the orbit was not corrected by bone graft situated on lower wall. (**B**) Coronal MPR at the level of the eye globe; thin bone graft between the globe and lower orbital wall; right orbit has increased volume. (**C**) Virtual model. (**D**) Physical model with formed custom titanium implant which corrected the contour of the lateral and lower walls. (**E**) Position of implant – intrasurgical view. (**F**) Post-operational 3D CT showing position of the implant in the orbit. (**G**) Coronal MPR of retrobulbar area after individual implant application. Globe position has shifted superiorly, medially and anteriorly. (**F**) Coronal MPR; the correction of globe position is less directly below the globe and the insertion of lower rectus muscle.

CT data was imported into specialist software [MIMICS, Materialize, Belgium] and converted into 3-dimensional models of the orbits. These were next exported in STL format and imported into Geomagic Qualify inspection software, which is used in industry to compare reference CAD models and scanned data of production parts for quality purposes. The left orbit was treated as the reference model and mirrored model of the right orbit was compared with it. Data were acquired regarding differences between the 2 models for a maximum deviation range of ±2 mm.

Study group

A total of thirty patients who had sustained facial injuries and orbital fractures were included in the study, and divided into 2 groups. Each case consisted of either an isolated orbital floor fracture or such a fracture constituted part of a larger trauma pathology. The first group of 15 subjects was treated with custom implants formed before surgery (presurgical stage). The second group consisted of 15 patients who had been previously treated using a conventional method

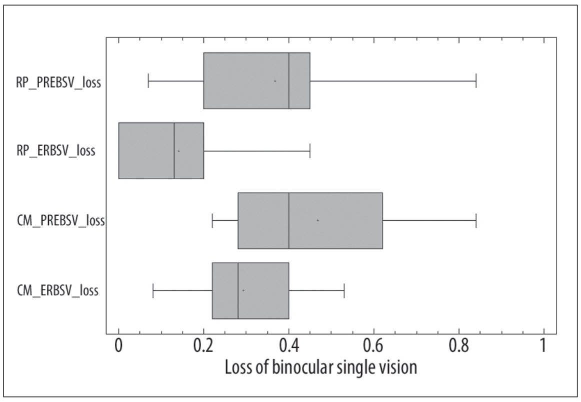

Figure 3. Loss of binocular single vision (0=best; 1=worst) in both patients groups [treated with individual implant – RP, and conventional method – CM] before and after surgical treatment.

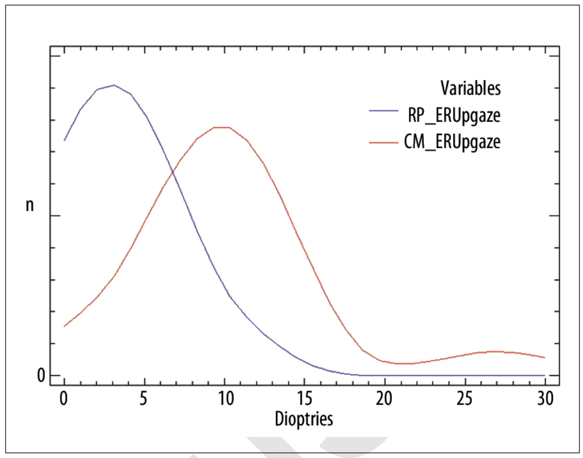

Figure 4. Post-operational residual eyeball motility restriction (n – number of patients, RP – treatment with individual implants, CM – conventional method of treatment).

of manual implant formation during surgery. All patients in the custom implant group had a CT study performed that was later converted into a virtual model of the bony orbit and a physical model was later produced.

The ethics committee at the Medical University of Lodz approved the procedures for this study, which was conducted in accordance with the principles set by the Helsinki Convention. Informed consent was obtained from all participants.

CT scanning protocol for anatomic models

Multislice VCT, GE Lightspeed 64-slice scanner, 0.6 mm layers, gantry tilt 0°, and matrix 512×512 was performed for all patients on the day of admission to hospital.

CT data processing, virtual model creation, and physical model production was done by rapid prototyping

The CT studies were evaluated and the area of interest i.e. both orbital cavities and the surrounding bone structures were assessed. CT data were imported into MIMICS and 3D virtual models were created. The unaffected orbit was mirrored onto the contralateral side i.e. the injured orbit. Such models contained numerous pseudoforamina which is typical for CT studies because of the very thin bone structures of the orbit. In order to create rigid physical models that would be stiff enough to be used as templates, all the empty spaces (air) surrounded the mirrored orbits in the virtual models were filled in. This resulted in virtual models of the orbit that were surrounded by hard tissue only. The resulting physical models were much more rigid than if they had been built containing hollow structures i.e. maxillary and ethmoid sinuses. Next, the virtual model data were converted to STL format and solid physical models were created from polyacrylic resin using a 3D photopolymer technique [Objet Geometries, Israel].

Presurgical stage

A simple protocol for forming the titanium mesh was established. A 0.4-mm – thick titanium mesh was used to prepare reconstructive plates for orbital wall reconstruction. The surgeon cut to size and formed an implant based on clinical symptoms, data from CT scans, and shape of the orbital walls in the physical model. The aim was to precisely cover the area of bone defect and produce a supporting structure for the globe. Careful attention was paid to omit anatomic structures such as the lacrimal sac.

Surgical procedure

Under general anaesthesia, transconjunctival approach was used in all patients and revision of lower orbital wall was performed. Herniated tissue was reduced to restore proper positioning of the intraorbital structures. Bone fragments were reduced if possible. The pre-bent titanium mesh was positioned, and the globe was supported on this. Passive movement of the globe was evaluated at the end of the surgical procedure.

Postsurgical follow-up

Ophthalmic examination was used to assess eye globe motility and binocular single vision test. MSCT studies to evaluate the position of intraorbital implants were performed 2 weeks after surgery for both groups and compared statistically.

Results

Orbital symmetry analysis showed that a high degree of symmetry exists between individual bony orbits. An example of such an analysis is shown in Figure 1. In this case, more than 16000 data points were analyzed for the 2 orbits. In each corresponding model, symmetrical points were established, and the distance between them was recorded. The average positive deviation was 0.216 mm, average negative deviation was –0.332 mm, while the average standard deviation was 0.417 mm. The figure below shows the deviation distribution for a maximum range of ±2 mm. In this analysis, 80% of the data points were within the range ±0.5 mm and 90% were in the range ±0.75 mm.

Significant improvement in all cases was observed after surgery based on ophthalmic examination (Table 1). Owing to the fact that *P* value for the *t* test is less than.05, there is a statistically significant superiority of RP treatment method over CM

Table 1. Functional results [ophthalmic] comparison, treatment of orbital fractures with individual implant [RP] and conventional method [CM].

Groups	PRE BSV loss	PRE Upgaze	PRE Primary position	PRE Downgaze	ER BSV loss	ER Upgaze	ER Primary Position	ER Downgaze
RP	0.37±0.21	11.37±5.32	3.80±3.57	8.67±9,73	0.14±0.14*	3.47±2.88*	0.87±1.12*	4.93±4.80
CM	0.47±0.21	16.27±9.09	5.33±5.98	4.93±8.34	0.29±0.13*	10.07±5.97*	2.00±2.38	5.10±7.46
	NS	NS	NS	NS	P<.01	P<.0001	NS	NS

PRE – pre-operational; ER – early post-operational; BSV loss – loss of binocular single vision (0=best; 1=worst). * Improvement compared to preoperational state.

when the area of diplopic vision (Figure 3) and upgaze VVD reduction (Figure 4) are considered at 95.0% confidence level. Correction of VVD in downgaze and primary position in early results are the same for both methods of treatment, however a greater improvement for primary position was demonstrated after application of individual implants (Figure 2, Table1).

Discussion

Craniofacial trauma affects orbital structures in approximately 40% of all cases [3]. Many orbital cavity fractures occur medial to the infraorbital groove and canal and are commonly combined with fractures of the medial wall [4–6]. Such trauma affects the bony structures and results in changes in the orbital dimensions. This alters the position and function of intraorbital contents and leads to serious complications such as diplopia, enophthalmos, and visual acuity disturbances [6]. Surgical repair of orbits and restoration of the preinjury anatomy is frequently necessary to prevent these complications from developing [7]. Multiple surgical approaches have been described in literature (transconjunctival, subciliary, transcutaneous), and different types of materials have been used for reconstruction (bone, cartilage, titanium, resorbable mesh) [3,8–11]. Many studies have been published on this subject, and different methods have been demonstrated to repair these defects [3,7,12,13]. Nevertheless, these injuries still continue to be some of the most complex and demanding reconstructive challenges in maxillofacial surgery [2].

Multislice computed tomography can provide accurate images of the facial skeleton and is used routinely to image trauma of the bony orbit. These images can be reconstructed into detailed 3-dimensional images. It is nowadays possible to convert these DICOM images into different formats that are compatible with software and equipment used for industrial purposes. Rapid prototyping is a technology that became commercially available in the mid 1980s and was almost instantly adopted by the car manufacturing and aerospace industries. With this technology, it is possible to make accurate, 3-dimensional, physical models of very complex structures in a relatively short space of time. As a result of this, the use of rapid prototyping soon became very popular in many different and varied industries.

This paper demonstrates the results of an uncomplicated method of creating very precise orbital wall implants, which can be successfully used in daily maxillofacial practice and prevent complications developing due to changes in orbital dimensions. The use of the mirroring technique is very effective as it provides a means of creating an accurate replica of a bony orbit. Our preliminary studies have shown the orbits to have a high degree of symmetry. This suggests that is justifiable to the use of the mirroring technique and that it is the method of choice to create an accurate model of an injured orbit.

A review of the advantages and disadvantages should be the starting point of a discussion regarding this treatment method. The disadvantages are the length of time required to build models, need for cooperation between a number of people in different locations (radiology department, surgical ward, IT services, hospital management, rapid prototyping service provider), and the difficulty of using this method in panfacial fractures-problem of indentifying stable orbital margins [before surgery] for virtual planning of the model and establishing accurate placement of the pre-bent plates. On the other hand greater accuracy, straightforward planning and model construction, better understanding of orbital injury morphology, shortened operation time, decreased number of attempts at positioning implant in the orbital cavity and assessing the shape and fit, excellent technique for large wall defects, favorable method for retreatment, model available to surgeon during operation, and low costs are undeniably the advantages of this method [14].

It is necessary to apply this method to a larger population of patients. It is also essential to acquire accurate data regarding the level of precision achieved in reconstructing the orbital walls and the dimensions of the bony orbit. To do this, repeat MSCT studies will have to be done. However, due to the high radiation doses involved, this is not immediately possible and will be performed over time.

Conclusions

This study has shown a new method of orbital bone surgery that improves the precision of reconstruction and results in better functional outcome. With this new method of treatment, it is possible to use MSCT imaging to create accurate, individual implants. Such implants allow for precise reconstruction of tissue defects and better outcome in patients with orbital wall fractures. The use of the mirroring technique is justifiable because preliminary results indicate a high degree symmetry for the bony orbits.

References:

1. Schön R, Metzger M C, Zizelmannn C et al: Individually prefromed titanium mesh implants for true-to-original repair of orbital fractures. Int J Oral Maxillofac Surg, 2006; 35: 990–95

2. Metzger MC, Schön R, Weyer N, Rafii A: Anatomical 3-dimensional prebent titanium implant for orbital floor fractures. Ophthalmology, 2006; 113: 1863e–68
3. Hoffmann J, Cornelius CP, Groten M et al: Orbital reconstruction with individually copy-milled ceramic implants. Plast Reconstr Surg, 1998; 101: 604e–12
4. Nolasco FP, Mathog RH: Medial orbital wall fractures: classification and clinicalprofile. Otolaryngol Head Neck Surg, 1995; 112: 549–56
5. Burm JS, Chung CH, Oh SJ: Pure orbital blowout fracture, new concepts and importance of medial orbital blowout fracture. Plast Reconstr Surg, 1999; 103: 1839–49
6. Manolidis S, Weeks BH, Kirby M et al: Classification and surgical management of orbital fractures: experience with 111 orbital reconstructions. J Craniofac Surg, 2002; 13: 726–37 (discussion 738)
7. Hammer B, Prein J: Correction of post-traumatic orbital deformities: Operative techniques and review of 26 patients. J Craniomaxillofac Surg, 1995; 23: 81
8. Burnstine MA: Clinical recommendations for repair of orbital facial fractures. Curr Opin Ophthalmol 2003;14: 236-40
9. Hoffmann J, Cornelius CP, Groten M et al: Biomaterials for reconstruction of the internal orbit. J Oral Maxillofac Surg, 2004; 62: 1280–97
10. Burm JS: Internal fixation in trapdoor-type orbital blowout fracture. Plast Reconstr Surg, 2005; 116: 962–70
11. Buchel P, Rahal A, Seto I, Iizuka T: Reconstruction of orbital floor fracture with polyglactin 910/polydioxanon patch (Ethisorb): a retrospective study. J Oral Maxillofac Surg, 2005; 63: 646–50
12. Parsons GS, Mathog RH: Orbital wall and volume relationships. Arch Otolaryngol Head Neck Surg, 1988; 114: 743–47
13. Eufinger H, Wittkampf AR, Wehmoller M, Zonneveld FW: Single-step fronto-orbital resection and reconstruction with individual resection template and corresponding titanium implant: a new method of computer-aided surgery. J Craniomaxillofac Surg, 1998; 26: 373–78
14. Kozakiewicz M, Elgalal M, Loba P et al: Treatment with individual orbital wall implants in human-one year observation. J Craniomaxillofac Surg, In press