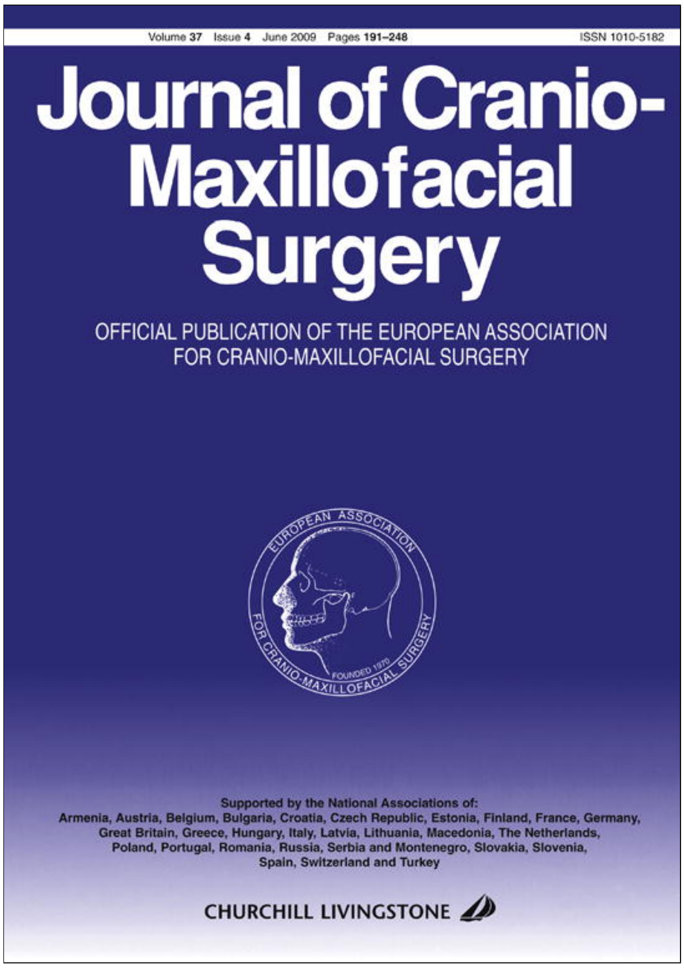
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Clinical application of 3D pre-bent titanium implants for orbital floor fractures☆

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SUMMARY. Introduction: **Orbital structures are affected in approximately 40% of all cases of craniofacial trauma. Changes in the bony orbital dimensions can alter the function of intraorbital contents and lead to serious complications. The unique anatomy of the orbit and the resulting surgical approaches make the process of fitting and aligning implants difficult, time consuming and operator dependent. It is now possible to make relatively inexpensive anatomical models on the basis of computed tomography images, using rapid prototyping. Such models can be used as templates to form titanium mesh implants, which are then used in the reconstruction of orbital floor defects.** Material and methods: **Six patients with facial trauma were included in this study. First, 3D virtual models and then physical models were created. These were used as templates to shape the titanium mesh and then intraoperatively as guides to aid correct implant placement in the orbit.** Results: **Significant improvement resulted in three cases and total recovery in three cases.** Conclusion: **It is financially viable to build anatomical models, on the basis of CT studies, that can be used in the repair of orbital floor fractures. © 2008 European Association for Cranio-Maxillofacial Surgery**

***Keywords:* orbital fractures, orbital implants, computer models, anatomical models, computed tomography**

INTRODUCTION

Orbital structures are affected in approximately 40% of all craniofacial trauma (*Hoffmann* et al., 1998). A large proportion of orbital cavity fractures occur medial to the infraorbital groove and canal and are commonly combined with fractures of the medial wall (*Nolasco* and *Mathog*, 1995; *Burm* et al., 1999; *Manolidis* et al., 2002). Such bony trauma results in changes to the orbital dimensions. This alters the position and function of intraorbital contents and may lead to serious complications such as diplopia, enophthalmos and visual acuity disturbances (*Manolidis* et al., 2002). Surgical repair of damaged orbits and restoration of the pre-injury anatomy are frequently necessary, in order to prevent these complications (*Hammer* and *Prein*, 1995). Multiple surgical approaches have been described in the literature (transconjuctival, subciliary, coronal) and different types of materials have been used for reconstruction (bone, cartilage, titanium, resorbable mesh) (*Hoffmann* et al., 1998, *Burnstine*, 2003; *Potter* and *Ellis*, 2004; *Burm*, 2005; *Buchel* et al., 2005). Numerous studies have been published on this subject demonstrating different methods of repair (*Parsons* and *Mathog*, 1988; *Hammer* and *Prein*, 1995; *Eufinger* et al., 1998; *Hoffmann* et al., 1998). Nevertheless, these injuries continue to be some of the most complex and demanding reconstructive challenges in maxillofacial surgery (*Metzger* et al., 2006).

Despite several different surgical approaches all result in a very narrow operating field. This makes the process of fitting and aligning implants within the orbit rather time consuming (*Schön* et al., 2006) and operator dependant. In addition, the complex anatomy of the orbit makes the process of shaping and cutting the titanium mesh intraoperatively very difficult, and it is almost impossible to achieve a 'true-to-original' 3D shape.

The use of rapid prototyping in medicine has become cheaper and financially feasible. It is now possible to build anatomical orbital models for less than 300 Euros, that can be used in pre-surgical planning and to serve as templates to create implants.

In this study, 0.4 mm thick titanium mesh [KLS Martin Group, Germany] was shaped and cut to size using these anatomical models to achieve a 3D shape that best fitted the contours of the orbit (floor). Furthermore, these models were used during surgery as guides to help identify anatomical landmarks and accurately position implants.

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Aim

The aim of this study was to present a method of repairing orbital floor fractures using pre-shaped titanium mesh implants that were formed on anatomical models of the orbit.

MATERIAL AND METHODS

Six patients who had sustained facial injuries were included in the study. Each case consisted of an orbital floor fracture either isolated or associated with other facial injuries. All patients had a CT study performed that was converted into both virtual and physical models of the bony orbit.

CT scanning protocol [effective time: 30 min]

Multi-slice VCT, GE Lightspeed 64-slice scanner [GE Healthcare, United Kingdom], 0.6 mm layers, gantry tilt 0°, matrix 512 × 512 was performed for all patients on the day of admission to hospital.

Table 1 − Patients treated with pre-shaped titanium orbital implants

Case	Status of orbital floor	Diagnosis	Note
1	Defect: 5.8 cm^2	Blow out	Retreatment
2	Defect: 2 cm^2	Lower wall and margin fracture	
3	Defect: 6 cm^2 Complete loss of the orbital floor	Midfacial fracture	Old untreated
4	Trap door Malunion	Blow out	Old untreated
5	Defect: 5 cm^2	Lower wall and margin fracture	Retreatment
6	Trap door	Blow out	

CT data processing and virtual model creation [effective time: 120 min]

Assessment of CT studies and the area of interest i.e. both orbital cavities and the surrounding bone structures. Relevant DICOM data from these studies were prepared and sent via the Internet to the Centre for Advanced Manufacturing Technology, Wroclaw University of Technology.

Model production by rapid prototyping [effective time: 8−12 h]

CT data were imported into the specialist software MIMICS [Materialise, Belgium] and 3D virtual models were created. The unaffected orbit was mirrored onto the contralateral side i.e. the injured orbit. This model contained numerous artefacts which is typical of CT studies because of the very thin bone structures of the orbit. In order to create a rigid physical model that would be strong enough to be used as a template, all the empty spaces (air) surrounded the mirrored orbit in the virtual model were filled in. This resulted in a virtual model of the orbit that was surrounded by hard tissue only. Next, the virtual model data were converted to STL format and solid physical models were created from acrylic resin using a 3D printer [Objet Geometries, Israel]. The resulting physical models were stronger and more rigid than if they had been built containing hollow structures

Table 2 − Orthoptic results of surgery with pre-bent titanium orbital implants

Case	Duction	Before surgery				After surgery			
		Diplopia	Ocular vertical deviation	Exophthalmometry		Diplopia	Ocular vertical deviation	Exophthalmometry	
				RE	LE			RE	LE
				mm				mm	
1	Up-gaze	Yes	VD− 19	15	15	No	VD− 2	15	15
	Primary	Yes	VD+ 8			No	VD+ 2		
	Down-gaze	Yes	VD+ 39			Extreme peripheral diplopia	VD+ 8		
2	Up-gaze	Yes	VD− 8	14	14	No	VD 0	14	14
	Primary	No	VD 0			No	VD 0		
	Down-gaze	No	VD+ 2			No	VD 0		
3	Up-gaze	Yes	VD− 15	11	14	No	VD− 2	14	14
	Primary	No	VD+ 1			No	VD 0		
	Down-gaze	Yes	VD+ 5			No	VD+ 3		
4	Up-gaze	Yes	VD+ 8	15	13	No	VD+ 2	15	15
	Primary	No	VD− 1			No	VD 0		
	Down-gaze	No	VD− 1			No	VD 0		
5	Up-gaze	Yes	VD− 8	12	15	No	VD− 2	14	15
	Primary	No	VD+ 2			No	VD 0		
	Down-gaze	Yes	VD+ 12			Extreme peripheral diplopia	VD+ 8		
6	Up-gaze	Yes	VD+ 14	13	13	Extreme peripheral diplopia	VD+ 5	13	13
	Primary	No	VD+ 2			No	VD 0		
	Down-gaze	No	VD+ 8			No	VD+ 1		

VD+, right hypertropia; VD, left hypertropia.

Fig. 1 − Appearance of face, before treatment of left side blow out orbital fracture. Lowered left eyeball, restricted upward movement and narrowed palpebral fissure.

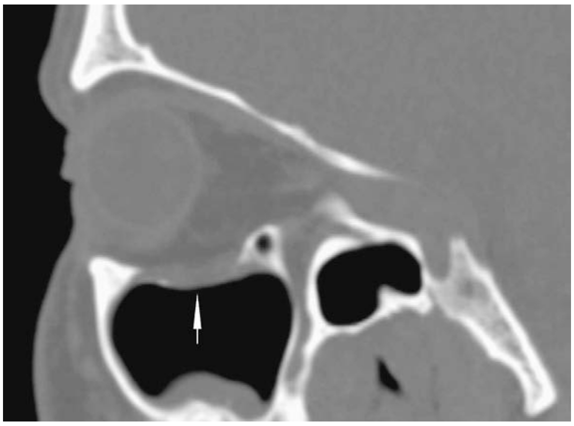

Fig. 2 − Computer tomography image of the left orbit with sagittal plane reconstruction. Damaged orbital floor (arrow).

i.e. maxillary and ethmoid sinuses. Finally, models were sent by courier to the hospital [24 h].

Pre-surgical stage [effective time: 30 min]

A simple protocol for forming the implants was established. 0.4 mm Thick titanium mesh was used to prepare reconstructive plates for lower orbital wall reconstruction. The surgeon cut to size and formed an implant based on clinical symptoms, data from CT scans and shape of the lower orbital wall in the physical model. The aim was to precisely cover the bony defect and produce support for the globe. Careful attention was paid to omit anatomical structures such as the lacrimal sac.

Surgical procedure [effective time: 60−120 min]

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

Additionally in case no. 3 intraoperative navigation was used for assistance due to the complete destruction of the orbital floor and lack of normal anatomical landmarks. Before the procedure a DICOM data set was imported into the surgical planning software iPLAN® [BrainLAB AG, Germany]. Important anatomical structures were identified and a surgical plan was transferred to the navigation hardware VectorVision® [BrainLAB AG, Germany] Intraoperational navigation allowed for the safe localisation of the displaced infraorbital neurovascular bundle and inferior rectus muscle. The shaped titanium mesh was inserted over the infraorbital bundle

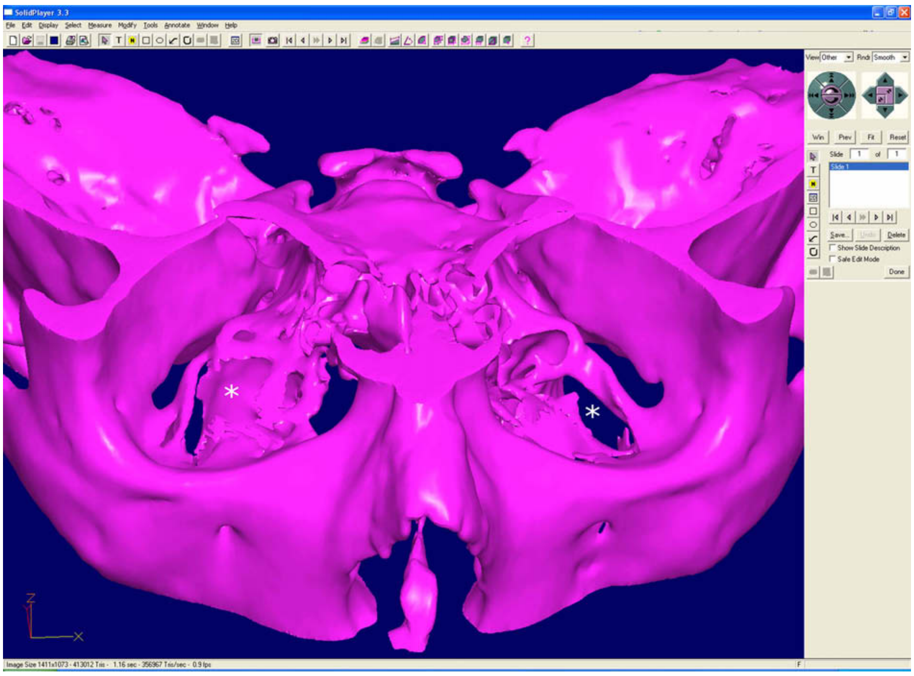

Fig. 3 − Virtual model constructed on the basis of DICOM data set. Numerous virtual defects (pseudoforamina) in orbital walls (asterisk).

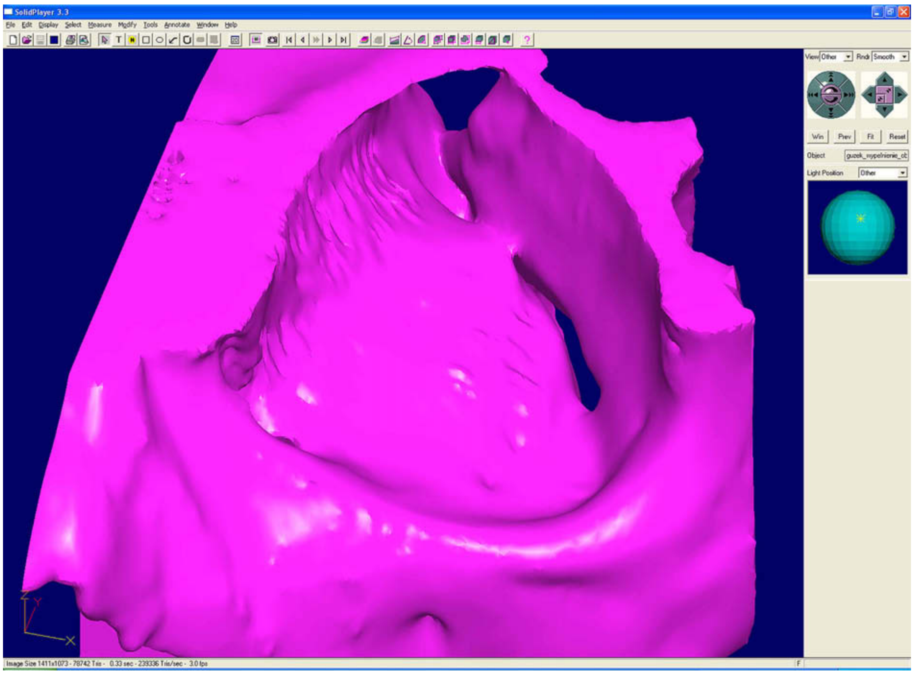

Fig. 4 – Cropped uninjured bony orbit (right) and mirrored to contralateral side. Final virtual model representing anatomical orbital floor (left), with maxillary and ethmoid sinuses filled in to resemble hard tissue.

Fig. 5 – Solid model of left orbital floor with formed titanium mesh.

and below the lower rectus muscle, and fixed to the inferior orbital margin to support orbital structures.

Post-surgical follow-up

Orthoptic examination to assess function and CT scans to check the position of intraorbital implants were performed. Patients were observed for globe position and visual disturbances.

RESULTS

On the basis of orthoptic examination, significant improvement in three cases and total recovery in three cases were observed after treatment. Improvement of vision was demonstrated by the elimination of diplopia and enophthalmos. Data are presented in Tables 1 and 2.

Morphology of the reconstructed orbital floors using the pre-shaped titanium implants clinical application is presented in Figs. 1–8.

DISCUSSION

Numerous articles have been published on the subject of orbital tissue reconstruction. Today, as a result of advances in diagnostic imaging and surgical approaches (*Nagasao* et al., 2007), knowledge of materials (*Kuttenberger* and *Hardt*, 2001), and registration methods (*Luebbers* et al., 2008) it is possible to produce individual, inexpensive implants and improve reconstruction of orbital wall defects.

The majority of presented cases were complicated: retreatment or old untreated fractures. Despite this, clinical results were satisfactory.

Vertical strabismus and diplopia are amongst the common sequelae of orbital trauma. The primary objective of non-surgical treatment of strabismus with resulting diplopia is single binocular vision in primary and downward-gaze. After treatment none of these patients exhibited this type of diplopia. Three patients did display extreme peripheral diplopia, but this was not clinically troublesome.

Enophthalmos was improved because the pre-shaped orbital floor implants had a more accurate 'true-to-original' shape [in particular their concavity] that better reflected the original shape of the fractured bone.

The ideal material for orbital reconstruction remains controversial (*Chang* and *Bernardino*, 2004). Numerous materials are available at present including lyophilized

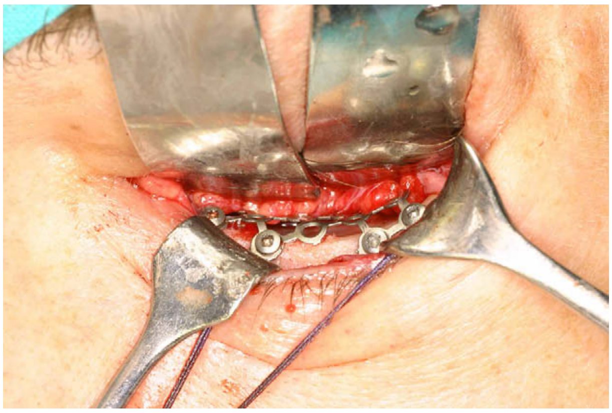

Fig. 6 – Left orbital floor reconstructed using pre-shaped titanium implant.

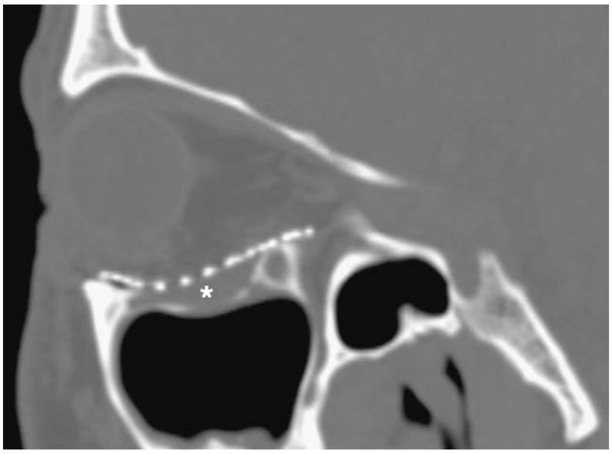

Fig. 7 – Computer tomography image of the left orbit with sagittal plane reconstruction, demonstrating reconstructed orbital floor and restored normal orbital volume. Change in position of orbital floor is indicated by the asterisk.

dura, polyethylene or polydioxanone sheets, hydroxyapatite blocks, titanium mesh, ceramic inlays and autogenous bone grafts (*Habal*, 1992; *Goldberg* et al., 1993; *Hoffmann* et al., 1998; *Ellis* and *Tan*, 2003; *Potter* and *Ellis*, 2004; *Kelly* et al., 2005; *Lee* et al., 2005). The more elastic materials are not capable of withstanding the (dynamic) stresses of large bony orbital defects (*Metzger* et al., 2006). Resorbable implants are prone to produce foreign body reactions, implant exposure may occur and only fibrous connective tissue remaining after resorption (*Hoffmann* et al., 1998; *Sevin* et al., 2000; *Buchel* et al., 2005). The disadvantages of autologous bone grafts include minimal contourability and donor site defects (*Chang* and *Bernardino*, 2004). Titanium mesh has a long track record in the reconstruction of large orbital defects and correction of globe malposition (*Habal*, 1992; *Potter* and *Ellis*, 2004). Advantages of titanium mesh plates are availability, biocompatibility, easy intraoperative contouring and rigid fixation. Disadvantages include difficulties with ease of insertion, as rough or irregular edges on the mesh tend to catch on adjacent soft tissues.

In case no. 3, due to extensive bony damage, it was impossible to identify anatomical landmarks. For this

Fig. 8 – Post-operative appearance of the face and correct level of pupils.

Table 3 – Summary of the proposed method of treatment

Advantages	Disadvantages
1. Greater accuracy	1. Length of time required to build model
2. Straightforward to plan and construct model	2. Surgeon needs to spend time cutting and shaping the implant before operation
3. Better understanding of orbital disruption	3. Cooperation required between a number of people in different locations
4. Shortened operation time	4. The use of this method in panfacial fractures is challenging – difficult to find any stable orbital margins for virtual planning of the model and to establish an accurate position for the pre-shaped plates
5. Decreased number of attempts at positioning implant in the orbit and verifying the shape and fit.	
6. Excellent for large wall defects	
7. Favourable method for retreatment	
8. Model can be used as a guide by surgeon during operation	
9. Relatively inexpensive method	

reason, computer-assisted surgery and intraoperative navigation were used. This system uses images from CT and MRI that act as a map of the patient's anatomy and makes it possible to pinpoint and identify orbital structures during surgery. Computer-assisted surgery can greatly improve the clinical outcome of reconstructive bone surgery and reduce the need for additional hard tissue procedures (*Lauer* et al., 2006). Intraoperative navigation is the one of the most valuable and effective tools available to surgeons today (*Luebbers* et al., 2008).

The disadvantages of this method are that the surgeon needs to spend time cutting and shaping the implant prior to surgery. The amount of work involved in this method of treatment is greater than in routine orbital wall reconstruction. In panfacial fractures, it is difficult to find any stable orbital margins and it is simply impossible to predict the final shape of the orbit. These are structures that are normally used to fix the titanium mesh to the orbit and in such cases the accuracy of a pre-shaped implant and its positioning significantly decreases.

Furthermore, in this study the total time needed to prepare such implants was prolonged due to the fact that the only centre capable of producing the anatomical models was in a different part of the country. The DICOM data were sent over the Internet and later the solid models were sent back to the hospital via mail courier. This was the most time consuming step in the entire process. However, this study does show that simple telemedicine techniques can be successfully used in daily clinical practice.

An evaluation of presented method of treatment orbital floor fractures by pre-shaped implants is shown in Tables 2 and 3.

CONCLUSION

New technical methods such as rapid prototyping are now easier to employ in medicine than before. The costs involved have been greatly reduced recently and techniques are now financially viable. Thanks to these innovations, different surgical procedures, in particular orbital floor reconstructions, can be significantly streamlined.

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