Custom implant design and surgical pre-planning using rapid prototyping and anatomical models for the repair of orbital floor fractures

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Purpose

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

Orbital structures are affected in approximately 40% of all craniofacial trauma. Such trauma affects the bony structures of the orbit and results in changes to orbital dimensions. This may result in serious complications such as diploplia, enophthalmous and visual acuity disturbances due to the altered position and disrupted function of intraorbital contents. It is frequently necessary to surgically repair such damaged orbits in order to restore pre-injury anatomy and function. To date multiple surgical approaches have been described and different types of materials have been used for the reconstruction of tissue defects. However, all of these procedures result in a narrow operating field with limited access to the orbital floor. This makes the process of fitting and aligning implants within the orbit time consuming and operator dependant. Moreover, 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' 3 dimensional shape. Although numerous studies have been published on this subject and different techniques have been described, these injuries nevertheless continue to be some of the most complex and demanding reconstructive challenges in maxillofacial surgery.

Rapid Prototyping is a phrase that was coined in the 1980s to describe new technologies that could produce physical models directly and in a relatively short space of time from 3 dimensional CAD (Computer Aided Design) objects. Different phrases have also been used in the past to describe this technology including solid freeform fabrication, layer additive manufacturing, 3D printing and advanced digital manufacturing.

Initially this technology was adopted by the automotive and aerospace sectors but has since been implemented by almost all industries. The first studies demonstrating the use of rapid prototyping in medicine appeared in Medline in 1984. Since then there has been a marked increase in the number of papers published on this subject (fig.2). It is now possible to create accurate anatomical models of anatomical structures from MDCT study images.

In order to create a physical model of an anatomical structure it is first necessary to convert this into a virtual model using specialist software that uses the technique of segmentation and can isolate tissues on the basis of their density. Consequently, it is possible to separate bone tissue and create a 3D model of a structure such as the bony orbit. This virtual model is a polygonal mesh and may be exported as an STL file, which is the industry standard format and is recognised by different types of rapid prototyping machines.
Such anatomical models of the orbit are used as templates on which it is possible to shape and from standard titanium mesh. Consequently, creating 'custom' or 'patient specific' implants that accurately fit the orbital floor of a specific patient. For the implant to accurately reflect the shape and dimensions of the orbital floor it is necessary to create a 'true-to-original' anatomical model. This can be achieved by mirroring the virtual model of the unaffected orbit onto the contralateral side producing a model that represents the premorbid anatomy of the injured orbit.

Images for this section:

![Anatomical model of the left orbit made using a photopolymer rapid prototyping apparatus.](image)

**Fig. 1:** Anatomical model of the left orbit made using a photopolymer rapid prototyping apparatus.
Fig. 2: Graph showing the number of articles on the subject of rapid prototyping in medicine.
**Methods and Materials**

Twelve 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. MDCT was performed for all patients and these data were then converted into virtual and physical models of the orbit.

CT scanning protocol: Multi-slice VCT, GE Lightspeed 64-slice scanner [GE Healthcare, United Kingdom], 0.6mm layers, gantry tilt 0°, matrix 512x512 was performed for all patients.

CT data processing and virtual model creation: CT studies were assessed by both a radiologist and a maxillofacial surgeon. The area of interest i.e. both orbital cavities and the surrounding bone structures was evaluated (fig.3). DICOM data from these studies were prepared and sent via the internet to the Centre for Advanced Manufacturing Technology, Wroclaw University of Technology.

CT data were imported into the medical data manipulation software MIMICS [Materialise, Belgium] and 3-D virtual models were created (fig.4). The unaffected orbit was mirrored onto the contralateral side (fig.5). 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 models were exported as STL files and solid physical models were created from acrylic resin using a Jetting Head Technology rapid prototyping system [Objet Geometries, Israel] (fig.6). The resulting physical models were stronger and more rigid than if they had been built containing hollow structures i.e. maxillary and ethmoid sinuses.

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 with a suitable concave shape and produce support for the globe. Careful attention was paid to omit anatomical structures such as the lacrimal sac and lower orbital fissure (fig. 7,8).

The models were also used intraoperatively as guides to aid correct implant placement in the orbitas

Post-surgical follow-up consisted of orthoptic examination to assess function and MDCT scans to assess the position of implants.

**Images for this section:**
Fig. 2: Virtual model of both orbital cavities
**Fig. 3:** The left orbit is 'mirrored' onto the right side i.e. each point in the model is rotated through 180 degrees around a common axis.
Fig. 4: Physical model of the right orbit.
Fig. 5: Physical model of the right orbit with a pre-formed implant
**Fig. 6:** Physical model of the right orbit with a pre-formed implant.

**Fig. 7:** fixed implant covering a defect of the lorbital floor.
Results

The study group consisted of 12 patients who had sustained facial trauma that resulted in orbital fractures. The results of their treatment and their clinical assessment at 0 and 12 months are presented in Table 1. In this study pre-formed implants accurately reflected the shape and dimensions of the orbital floor (Fig 10-14). The use of such implants reduced operating times by 15-20 min and resulted in less soft tissue manipulation, fewer trial fittings, decreased likelihood of damaging intraorbital structures, more precise fit and repair.

Images for this section:

![Table 1 Patients treated using pre-shaped titanium orbital implants.](image)

Fig. 1
Fig. 2: Coronal view with implant in-situ.
Fig. 3: Coronal view with implant in-situ.
Fig. 4: Post-op MPR in the orbital axis.

Fig. 5: 3D reconstruction of right orbit showing custom implant
Conclusion

Rapid prototyping methods have become cheaper and their use in medicine is financially feasible. It is now possible to build accurate anatomical orbital models on the basis of MDCT images at a relatively low cost (under 300 Euros). These can be used for pre-surgical planning and may serve as templates to create custom pre-formed implants that precisely reflect the orbital dimensions of a specific patient. The use of the mirroring technique allows us to create a virtual model of a contralateral structure that represents the damaged structure's premorbid anatomy.