Proceedings of the IASTED International Conference
Biomedical Engineering (BioMed 2017)
February 20 - 21, 2017 Innsbruck, Austria

ORBITAL WALL RECONSTRUCTION BY SELECTIVE LASER SINTERED MOULD

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ABSTRACT
Diagnosis and treatment of orbital wall fractures are based on both physical examination and computed tomography scan of the orbital cavity. The present paper reports on the secondary reconstruction of the skeletal orbit following untreated orbital floor fracture in a patient wearing an ocular prosthesis because of an orbital trauma.
A computer-assisted approach, based on anatomical modelling and custom-made mould fabrication via selective laser sintering, is proposed for manufacturing a preformed orbital implant. Such a procedure offers precise and predictable results for orbital reconstructions. This protocol proved an effective reduction of operating time, patient morbidity and a fast and low-cost preoperative planning procedure. Such an approach can be used for immediate and in-office manufacturing of custom implants in trauma and reconstructive patients.

KEY WORDS
Orbital wall reconstruction; ocular prosthesis; surgical tools; computer aided surgery.

1. Introduction

The success of reconstructive orbital surgery depends on diverse aspects related to the preoperative evaluation of the traumatic deformity, the design and manufacturing of the implant, and the surgical protocol. Patients who suffered disruption of the eyeball following direct or indirect ocular trauma often present an untreated fracture of one or more orbital walls. Usually the fracture involves the floor and/or the medial wall of the orbit, with consequent vertical dystopia and asymmetry of the ocular prosthesis compared to the controlateral side. Ocular and orbital volume are critical in these cases. The primary goal for orbital reconstruction is repairing the fractured wall by restoring the skeletal cavity and the orbital volume [1, 2]. In this regard, image-guidance technology is useful for the design of anatomic orbital implants, particularly for two-walled defects involving the floor and medial wall [3]. Custom implants can also be utilized for reconstruction of irregular defects or when there is a significant bone loss [4, 5]. The problems connected with the previous cited approach are related to the high cost of the surgical procedure due both to the planning phase and, particularly, to the manufacturing of a preformed titanium orbital implant. The present paper reports on a case of secondary reconstruction of the orbital cavity due to a 35-year-old displaced fracture of the orbital floor.
The paper consists of a computer-assisted approach, based on anatomical modelling and custom-made mould fabrication via selective laser sintering, for manufacturing a preformed orbital implant. Such in-office procedure offers precise and predictable results of orbital reconstruction. Moreover, it reduces at the same time the surgical time, morbidity, and it is a low-cost surgical procedure. Such an approach is suggested for achieving accurate results both in secondary and primary reconstruction of the orbital wall.
To date, surgeons have three main choices for the reconstruction of orbital walls: (1) to shape the implant directly on the patient orbital wall during the surgery, (2) to implant a preformed titanium plate or a 3D printed, custom-made titanium mesh, and (3) to model the implant on the 3D printed mould of the pathological orbital wall (with the fracture virtually closed). The three diverse procedures show some disadvantages. In the first case, the repetitive trial fitting of the implant can be traumatic to the periorbital tissues and the geometry and placement of the implant could be not accurate. In the second case, the main problem is related to the costs connected with the manufacturing of the implant. In fact, to date 3D printed titanium orbital implants, manufactured via electron beam melting (EBM) o direct metal sintering (DMS), have costs between 3000€ and 5000€. The costs of prefabricated titanium orbital plates or meshes range between 250€ (KLS Martin) and 600€ to 800€ (Synthes, West Chester, PA) [5]. In the last case, the main issue is the time required to the surgeon to manually model the implant on the mould and then re-adjust the shape of the plate on the patient. An example of this methodology is reported in [5], where Vehmeijer et al. created a virtual

individualized mould of the defect site, which was manufactured using an inkjet printer. The tangible mould was subsequently used during surgery to sculpture an individualized autologous orbital floor implant. In the past autogenous bone graft has been considered the gold standard in orbital wall reconstruction [5,7]. However, a major drawback of autologous bone compared with prefabricated titanium meshes is that autologous bone is cumbersome to sculpture and can easily break if bent beyond its capacity [5]. On the other hand, although titanium meshes are biocompatible, malleable and therefore easily adapted to the shape of the orbital defect [7], they are not osteoinductive and resorbable and they can shift in case of trauma. Each material has advantages and disadvantages and, for this reason, it would be appropriate to leave the choice of the implant material to the surgeon during surgery, without precluding any chance. The procedure presented in this paper solves several of the problems described above because the manufactured mould is low-cost, precisely defines the geometry and the placement of the implant and it can be used in order to form diverse materials that can be conveniently chosen by the surgeon during the surgical procedure.

2. Materials and methods

2.1 Orbital wall modelling

The procedure presented in this paper is valid for the 3D virtual reconstruction of any orbital wall (i.e. orbital floor, medial and lateral walls), and is performed as shown in Fig.1.

The CT (computed tomography) images of the patient are necessary for the reconstruction of the 3D model of the skull (step 1). Firstly, the bony areas are extracted from each slice using the commercial software *Mimics* (*v. 12.11 by Materialise NV*), to obtain the 3D images of the skull. The 3D visual models are then obtained by stacking the segmented slices (step 2). In order to allow the design of a mould, the *Mimics Simulation* module is then used to mirror the healthy orbital cavity on the pathological one (step 3). Therefore, the output of the orbital 3D reconstruction process in *Mimics* are two tessellated geometries in *.stl* format: one containing the mesh of the pathological orbital cavity and the other containing the mesh of the mirrored healthy orbital cavity. These files are imported in *Rhinoceros 3D* (*v.5.0 by McNeel Inc.*), where the fractured orbital bones are reconstructed by means of reverse engineering techniques. Firstly, the adjustment and fitting of the mirrored healthy orbital cavity on the pathological one is performed, so that the highest number of points corresponds over the two overlapped orbital cavity (fig. 2) (step 4).

Indeed, the human face is not symmetric, especially in people who had a cranial trauma, therefore geometric variability between the two orbital cavities is possible [6]. For this reason, it is necessary to work first on the mirrored healthy orbital cavity and then on the pathological one. The mirrored healthy orbital wall is dissected through parallel planes, in order to identify the spline curves for the reconstruction of the pathological orbital wall (step 5). The spline interpolation offers the possibility of modelling the new orbital wall using the healthy bones as a reference [6]. The new orbital wall is reconstructed as a surface (step 6).

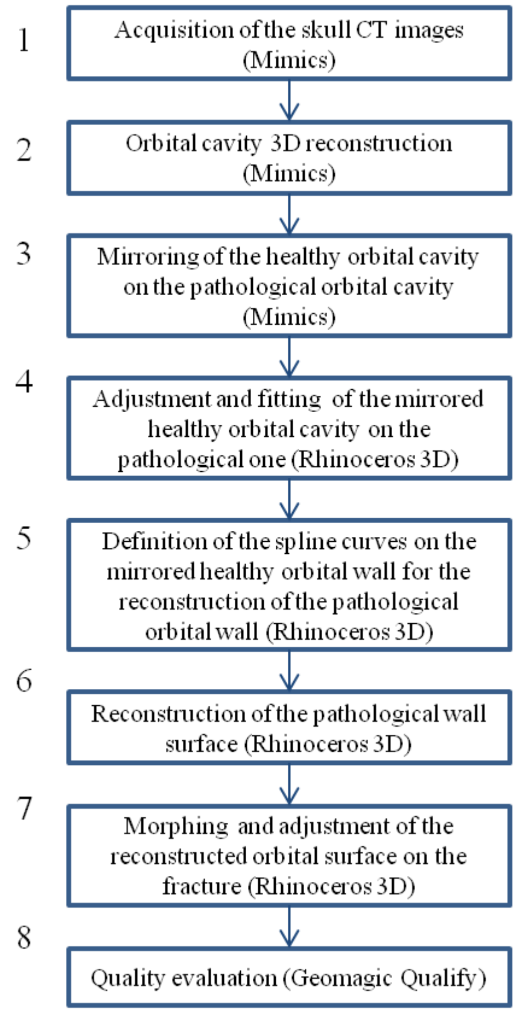

Fig.1: Flowchart of the virtual 3D reconstruction of orbital walls

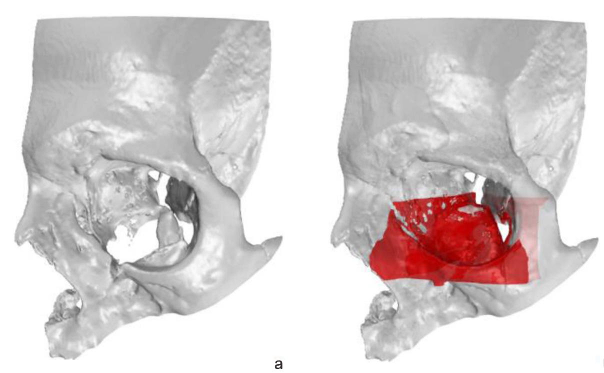

Fig.2: Pathological orbital cavity (fig.2a) and adjustment and fitting of mirrored healthy orbital cavity on the pathological one (fig.2b)

The next steps are focused on the pathological orbital cavity. The reconstructed orbital surface is modelled (in the orbital defect of the pathological orbital cavity) in order to create a proper continuity with the surrounding healthy bones. The reconstructed orbital surface is morphed and adjusted to the fractured site until the desired result is not achieved (step 7).
With this last step, continuity and tangency between the reconstructed orbital surface and the surrounding bones surfaces are achieved. The result of 3D orbital wall reconstruction is shown in Fig.3:

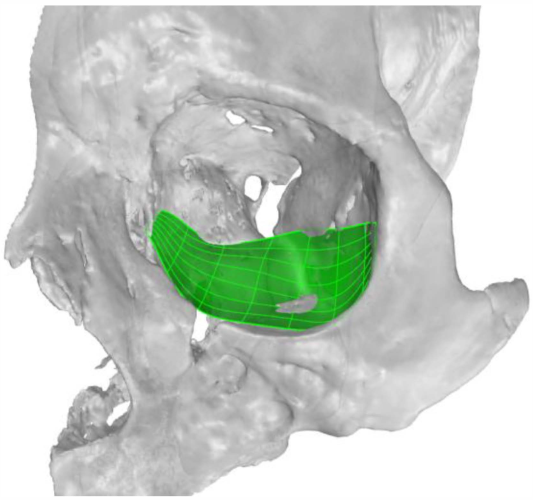

Fig.3: Orbital surface reconstruction

The orbital wall surface obtained through the previous steps is the input of the mould design process.
However, before starting the mould design, it is necessary to verify the accuracy and quality of the generated surface. The symmetry between the two orbits and the tangency between the modelled surface and the surrounding surfaces are evaluated through the use of *Geomagic Qualify* (*v.12 by 3D Systems*) (step 8). A detailed analysis of the modelled surface quality is obtained measuring the distance between the reconstructed orbital surface and the pathological orbital wall. If also the recreated symmetry of the orbits is acceptable, the custom-made mould can be designed.

2.2 Mould requirements

Before designing the mould, a list of medical and mechanical requirements must be defined in order to satisfy the clinical and technological needs. The clinical requirements about the mould include the adaptability to several prosthetic materials (i.e. titanium meshes, demineralized bone tissue, porous polyethylene sheets) in order to let the surgeon free to choose the implant material during the surgical procedure. The mould must be low-cost, affordable and realized in sterilizable material. The clinician needs to easily understand the cutting perimeter, thus the mould has to model the implant and suggest the cutting area. The ease of use of the mould must be assured. For this reason, the initial placement of the implant in the mould, the closing force and the orientation of the implant during the surgery must be taken into account and precisely defined. Moreover, the surface of the mould must have controlled roughness in order to avoid problems with the sliding of the implant upon the mould or with the result of modelling.
In order to prevent issues with the 3D printing technology, a list of mechanical requirements has to be defined. The structural strength must be guaranteed for making possible the modelling of various kinds of implant materials. The coupling tolerances on the different parts of the mould must be suitable for the additive manufacturing process. The absence of undercuts on the printable surfaces must be guaranteed. Furthermore, the overall dimensions of the mould must be minimum in order to limit the 3D printing costs.

2.3 Mould design and manufacturing

Mould manufacturing: selection of the technology and material

In the present case study, the choice about the manufacturing of the mould fell on SFF technology. SFF refers to the physical modelling of a design using a special class of machine technology. Using an additive approach to build shapes, SFF systems join liquid, powder or sheet materials to form physical object. Layer-by-layer, SFF machines fabricate plastic, ceramic, metal, and composite parts using thin, horizontal cross sections of the computer model. In the present paper, the selective laser sintering (SLS) technique has been selected for the manufacturing of the mould. In SLS, a laser beam is traced over the surface of a tightly compacted powder made of thermoplastic material. The powder is spread by a roller over the surface of a cylinder. A piston moves down-layer-by-layer to accommodate the layer of powder. Excess powder in each layer helps to support the part during the building. Heat from the laser selectively melts the powder where it strikes under the guidance of the scanner system. Sintering gives rise to formation and growth of necks between the particles, which are in fact surface contacts. The structure of discrete particles connected by relatively thin necks usually remains during and after SLS treatment. SLS has been selected for the manufacturing of the mould for the following advantages. Fast and economical process, durable, functional, large and complex parts, small series produced in one manufacturing process, no supports required since overhangs and undercuts are supported by the solid powder bed, all kinds of finishing degrees, as well as watertight, and, above all, the possibility to manufacture autoclave sterilizable parts connected to high accuracy and material versatility [8]. For these reasons, the mould has been manufactured in polyamide using SLS process.

Definition of the mould geometry
On the market there are several software with specific modules for the realization of moulds, developed for several applications such as plastic injection, drawing,

sheets forming [9, 10, 11]. However, these software are generally not optimized for additive manufacturing; furthermore, none of them was meant to be used in applications such as the one described in this article. For this reason, the authors chosen a general purpose CAD, system (*Rhinoceros v.5.0 by McNeel Inc*).
The mould is designed starting from the reconstructed orbital wall described in section 2.1 and following the requirements identified in section 2.2.
The result is shown in Fig.4:

Fig.4: The CAD model of mould

Before designing the mould, the absence of undercuts has been verified using a specific Rhinoceros function. The shape of the die and punch are defined in order to improve the mould usability and minimize costs. The die has a square base for ensuring a large contact area with the supporting surface below. The punch has a hollow shape for reducing the material consumption and improving the handling. In this way, the surgeon push the punch from above, applying the force required to reduce as much as possible the elastic return of the implant. Furthermore, the shape of the punch allows the side areas of the implant to deform freely, reducing the force needed.
For guaranteeing the correct alignment between die and punch, the mould has two lateral guides (pins with relative holes). Concerning the ease of use, the mould has a referencing system allowing the surgeon to easily understanding how orient the implant within the eye socket. In fig.4, the reference is the cylinder below the pin on the left.

3. Results and discussion

The case study presented in this paper is about a secondary reconstruction of an orbital floor due to a fracture healed in misplacement. The orbital wall reconstruction followed the steps of the flowchart shown in fig.1.
The reconstructed orbital floor surface has been morphed and adjusted to the fractured site and its quality has been evaluated in terms of symmetry and tangency between the modelled surface and the surrounding surfaces. The evaluation has shown that the maximum gap between the reconstructed surface and the pathological orbital wall was of +1,06 mm. Moreover, the recreated symmetry of the orbits was acceptable.
Starting from the modelled floor surface, the mould has been designed taking into account the medical and mechanical requirements defined in section 2.2.
The obtained mould, manufactured via SLS using PA-12, was used during the surgical procedure for realizing the preformed custom-made orbital floor implant. The mould defines precisely the geometry and the placement of the implant independently by the used prosthetic materials. So doing, the surgeon can conveniently choose the implant material directly during the surgical procedure. In fact, as shown in Fig.5 and 6, the surgeon can use the same mould in order to form both demineralized bone tissue membrane and net-shaped titanium sheet based on the difficulties and requirements encountered during the surgical procedure.

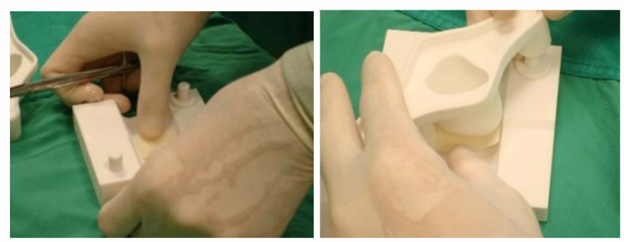

Fig.5: Modelling of the demineralized bone tissue membrane before the insertion in vivo using the custom-made mould

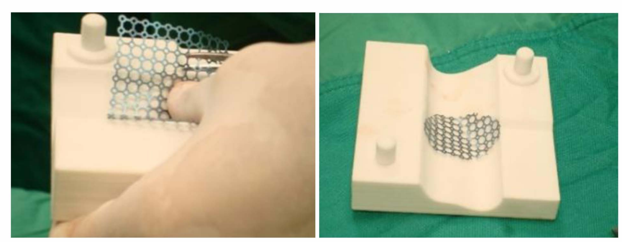

Fig.6: Modelling of the net-shaped titanium sheet before the insertion in vivo using the custom-made mould

In the specific case, due to the large extension of the bone fracture, the surgeon opted for the second solution (titanium mesh) in order to reconstruct a durable orbital cavity. In general, the use of demineralized bone tissue seems to be a less invasive approach. In fact, because of its bio-degradability and osteoinductivity, the membrane is gradually reabsorbed and replaced by newly formed bone tissue. In the present case, the surgeon has opted for a more stable solution, given the large extension of the bone loss. Fig.7 shows the preformed implant positioned in the orbital site.

Fig.7: Custom-made titanium prosthesis positioned in vivo

As shown in Fig.8, the obtained results, in terms of aesthetic rehabilitation of the patient, are satisfactory.

Fig.8: Pre-post surgical orbital floor reconstruction

The proposed surgical procedure solves several of the problems described in the introduction. In fact, the SLS manufactured mould allows:

- decreasing the costs related to the surgical procedure;
- reducing the surgical time (50 minutes vs 2 hours);
- minimal morbidity for the patient;
- low-cost of the final prosthesis compared with other solution proposed on the market;
- accurate definition of the geometry and the placement of the implant. It allows both the surgical treatment of secondary defects, as in the present case, and the primary reconstruction of the orbital cavity, if necessary;
- the preforming of diverse prosthetic materials that can be conveniently chosen by the surgeon on the basis of specific requirements encountered during the surgical procedure.

4. Conclusion

Orbital floor fractures, which are caused by blunt trauma to the periorbital and zygomatic region, have been occurring more often, from the increasing number of traffic and industrial accidents, social activities, and the events of violence. These fractures clinically occur with diplopia, extraocular movement limitation, and enophthalmos. As the failure of prompt recognition and treatment of these fractures may result in notable cosmetic and functional problems, such as enophthalmos, restriction in ocular motility, diplopia, and hypoesthesia of extended through the territory of the second trigeminal bran.

Immediate diagnosis and treatment of orbital wall fractures are important and they are based on both physical examination and computed tomography scan of the orbit. A computer-assisted approach, based on anatomical modelling and custom-made mould fabrication via selective laser sintering, is necessary in order to manufacture a preformed orbital implant and to obtain accurate outcome for orbital reconstruction. Our procedure has the following advantages: 1) it provides effective decrease of surgical time, and patient morbidity; 2) the technique is low-cost for patient; 3) it involves a fast preoperative planning procedure. This protocol can be used for immediate and in-office manufacturing of custom implants in trauma and reconstructive patients.

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