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DESIGN AND FABRICATION OF PATIENT SPECIFIC ORBITAL FLOOR IMPLANT USING 3D METAL PRINTING

RINGKASAN: Implan khusus kepada seorang pesakit bagi pembinaan semula kecacatan maksilofasial telah memperoleh kepentingan disebabkan oleh prestasinya berbanding dengan implan generik yang lain. Keretakan pada bahagian *orbital* adalah kecederaan trauma terhadap tulang pada bahagian soket mata, yang mana biasanya disebabkan oleh daya yang kuat dikenakan pada sekelilingnya. Kecederaan *orbital rim* merujuk kepada kecederaan di tulang pada bahagian luar soket mata dan ia disebabkan oleh daya yang sangat kuat dikenakan pada bahagian tersebut seperti kemalangan kereta. Penulisan ini akan membentangkan kajian mengenai rekabentuk dan fabrikasi implan *orbital* menggunakan teknologi percetakan logam 3-Dimensi (3D), penggunaan perisian perubatan untuk menterjemahkan data pesakit daripada *CT Scan* kepada data pemodelan 3-Dimensi, membantu kaedah pakar bedah membuat perancangan pembedahan dan jurutera rekabentuk merancang rekabentuk *orbital* implan yang khusus untuk pesakit. Kemajuan dalam proses pembuatan seperti teknologi percetakan logam 3D untuk menghasilkan implan khusus pesakit telah menghapuskan kekangan yang dihadapi untuk menghasilkan implan yang memenuhi keperluan dari segi bentuk, saiz, struktur dalaman seseorang pesakit dan sifat-sifat mekanik yang membolehkan implan tersebut dihasilkan memenuhi keperluan fizikal dan mekanikal implantasi. Titanium asli digunakan untuk menghasilkan implan lantai orbit khusus pesakit. Proses pengesahan dilakukan dengan menggunakan model bercetak 3D di kawasan kecacatan orbital dengan pembinaan model implan khusus lantai orbit. Analisis sisihan dijalankan untuk mengkaji ketepatan implan khusus yang dibuat. Pelaksanaan teknologi percetakan logam 3D untuk pembentukan implan dan penilaian pembinaan semula intraoperatif membantu kepada peningkatan penampilan estetik seseorang pesakit.

ABSTRACT: Patient Specific Implants for the reconstruction of maxillofacial defects have gained importance due to better performance over their generic counterparts. An orbital fracture is a traumatic injury to the bone of the eye socket, usually occurring because of blunt force trauma to the area surrounding the eye. Orbital rim fractures refer to injury to the bony outer edges of the eye socket and it takes a great deal of force to make them occur, such as in car accidents. This paper will present the study of design and fabrication of orbital implant using 3D metal printing technology. Application of Medical Software to translate patient's Computed Tomographic Scanning (CT Scan) data into 3D modelling is assisting the way surgeons are planning surgeries and design engineers are designing the Patient Specific Implant of the orbital fractures. Advances in manufacturing process such as 3D metal Printing technology for custom implant production has eliminated the constraint of shape, size and internal structure and mechanical properties making it possible for the fabrication of custom implants that conform to the physical and mechanical requirements of the region of implantation. Pure titanium is used for the fabrication of patient specific orbital floor implant. The validation process is done using a 3D printed model of the orbital defects area with the reconstruction of orbital floor custom implant model. The deviation analysis is carried out to study the accuracy of the manufactured custom implant. The implementation of the 3D metal printing technology for implant shaping and intraoperative assessment of reconstruction leads to improve aesthetic appearance which could essentially improve patient outcomes.

Keywords: 3D modelling; Patient Specific orbital floor implant; 3D Titanium Printed; 3D printing technology

INTRODUCTION

Fractures of the orbital floor are common and it was estimated that about 10 % of all facial fractures are isolated orbital wall fractures (the majority of these being the orbital floor), and that 30 – 40 % of all facial fractures involve the orbit. The anatomy of the orbital floor predisposes it to fracture. The inferior orbital neurovascular bundle (comprising the infraorbital nerve and artery) courses within the bony floor of the orbit; the roof of this infraorbital canal is only 0.23 mm thick, and the bone of the posterior medial orbital floor averages 0.37 mm thick. By contrast, the bone of the lateral portion of the orbital floor averages 1.25 mm thick, over 5 times the thickness of the bone over the neurovascular bundle. As one might suspect, it is this very thin area of the orbital floor overlying the neurovascular bundle where isolated orbital floor fractures invariably occur.

In the great majority of floor fractures, a fracture can be localized above, or just medial to, the course of the infraorbital nerve. A fracture in this location leads either to a "trap door" displacement of the orbital floor, or, if a second fracture is present at the junction of the floor and medial wall, to a completely depressed, separate bony fragment (Paul D. Langer, 2018). Reconstruction of the orbital wall by mirroring data from the normal side has been described by several authors (Bell RB *et al.*, 2009; Tang W *et al.*, 2010; Zhang *et al.*,2010; Kokemueller H *et al.*, 2008). 3D printed models have been used as a template to pre- surgically adapt a customized implant to precisely fit the defects of the orbital wall, a procedure that helps to reduce surgical time.

In this paper, a case study of a patient suffering from an orbital floor fracture was conducted. Surgical repair of orbital fractures was done with the aid of implant with the best fit for the patient to reconstruct the defect. The implant design was based on CT Scan data received from the Pusat Perubatan Universiti Malaya (referred case HUKM). The Patient Specific implant was fabricated using the 3D Metal printing technology. When dealing with 3D printing manufactured parts, it is important to realize that acquiring an accurate and precise scale of measurement to validate the parts play an integral role in the production cycle. The validation of an orbital floor was done by using a software tool such as Geomagic Studio. Industrial Scanning can also serve manufacturing projects that require 100 % validation of high value printed parts during production. Finally, if there are failed parts or errors during production due to temperature change or stress, such as broken or chipped parts, an industrial CT Scan can be analyzed to identify these internal failures quickly and accurately in 3D. The design procedure and fabrication of the orbital floor implant are described as below.

MATERIALS AND METHOD

Orbital Floor Implant Design Methodology

Generally, the design process for orbital floor implant starts with data conversion from CT scan to 3D model. The 3D model will visibly show the defect area. The design of the orbital floor implant was done in CAD software. The details of the design process are described below.

3D Model

The 3D Model was imported into Geomagic Studio software to examine the patient condition. The 3D model shows that the zygomatic bone and maxilla at the orbital floor have deformed and circled in white (Figure 1).

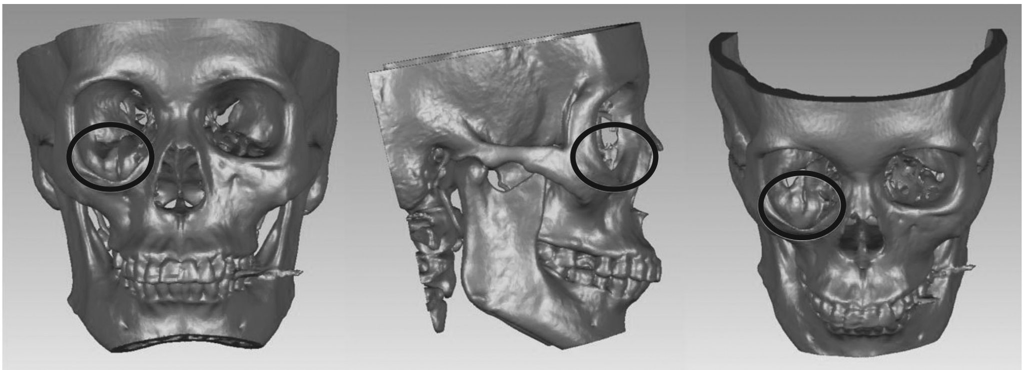


Figure 1. *Defect area of the orbital floor*

Alignment of 3D Model

The 3D Model was then imported into Geomagic Studio software to do alignment and making sure the skull was positioned in a vertical direction from axial view. An approximate middle plane was constructed for mirroring technique which is shown in Figure 2.

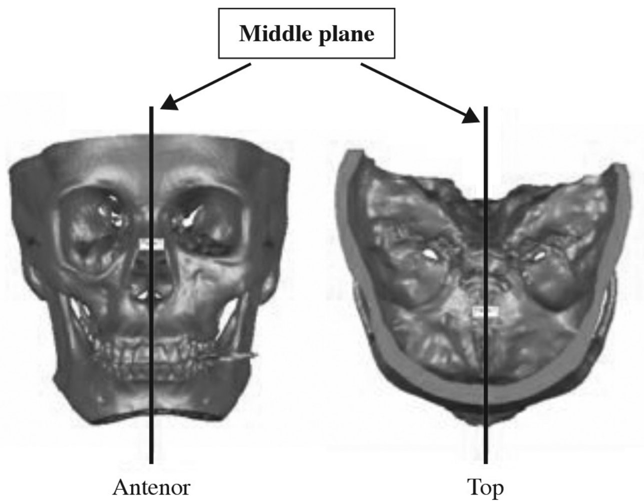


Figure 2. *Alignment and middle plane construction*

Prepare 3D Model for Digital Reconstruction

Once the alignment of the skull has been fixed, the skull was wrapped to get a smooth surface. Any unnecessary pixel will be deleted to simplify the model. The wrap parameter was set within 0.3 mm compared to original skull (Figure 3). A deviation analysis was carried out to check for accuracy (Figure 4).

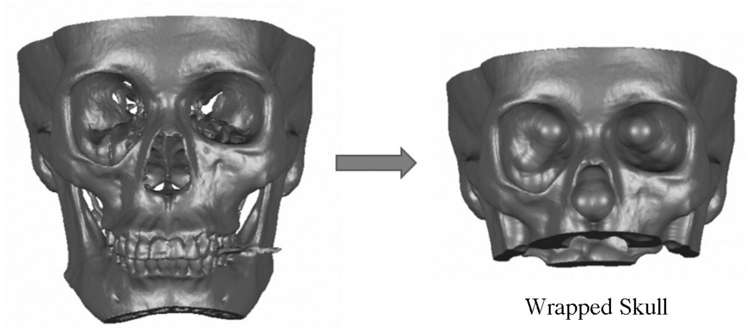


Figure 3. *Wrapped model of the skull*

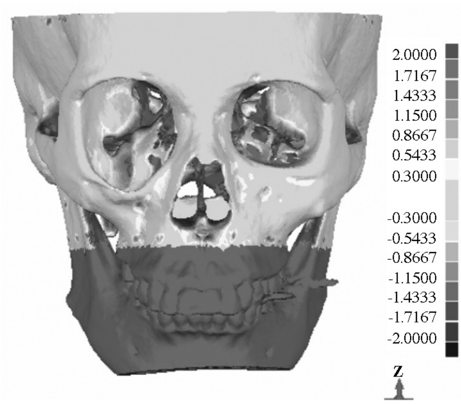


Figure 4. *Deviation analysis*

The healthy orbital floor was mirrored to the deformed orbital floor (Figure 5). The mirrored orbital was checked against the original skull model. An adjustment of the mirrored skull was made based on the deviation analysis results (Figure 6).

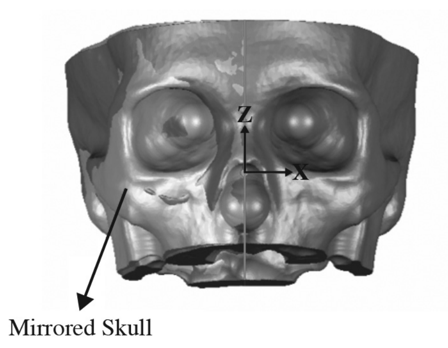


Figure 5. *Mirror technique*

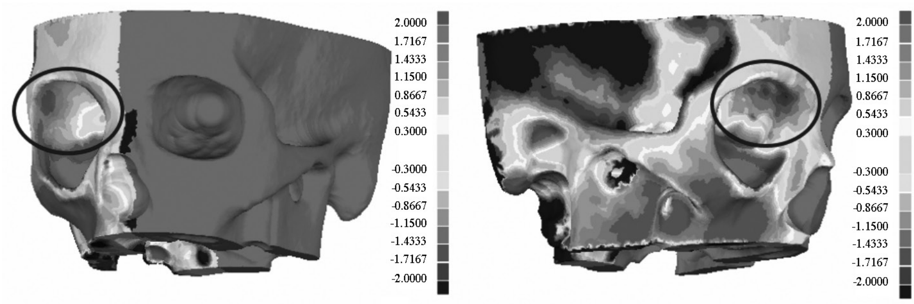


***Figure 6.** Deviation analysis of the mirrored skull*

Adjustment was made by referring to deviation analysis results in comparison between the original skull and the mirrored skull. It was observed that the top portion of the mirrored eye socket was much closer to the original skull.

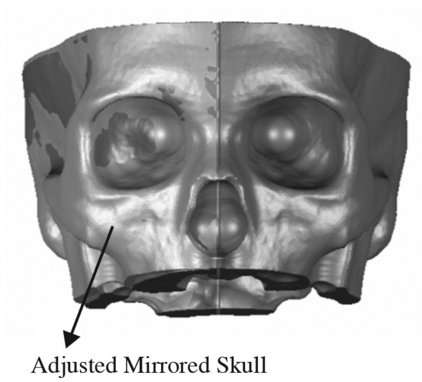


***Figure 7.** Adjusted mirrored skull*

Digital Reconstruction of Orbital Floor

The mirrored orbital floor was sculpted to make sure that it flashed with the original skull. The sculpted orbital floor was then subtracted from the original skull. The design sequences are shown in Figure 8.

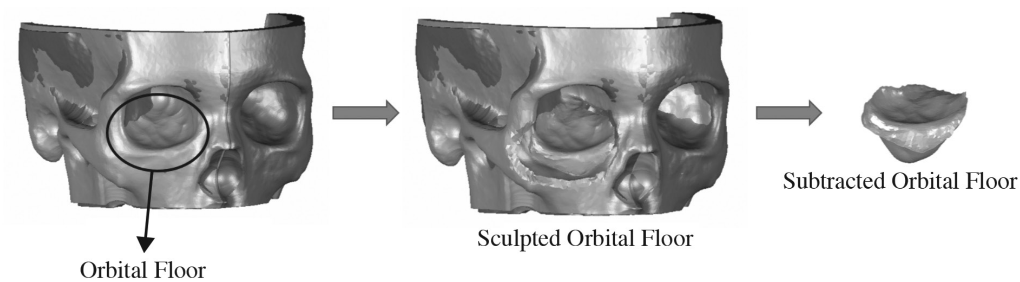


***Figure 8.** Sequences of the orbital floor subtraction*

The subtracted orbital floor was placed back to the original skull of patient to validate the position and visualize the outcome of the design (Figure 9).

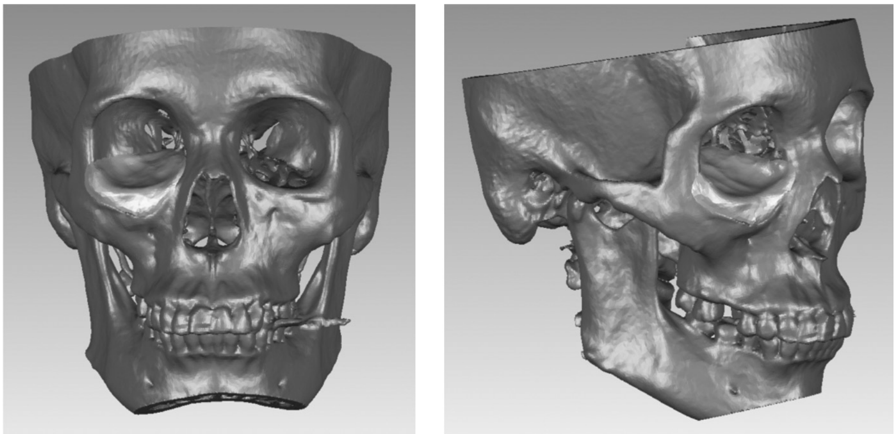


Figure 9. *Virtual positioning of the orbital floor design*

Cross Section tool was done to check the placement and shape of the reconstructed orbital floor (Figure 10). Position of the implant was validated to confirm that the design suit with patients anatomy.

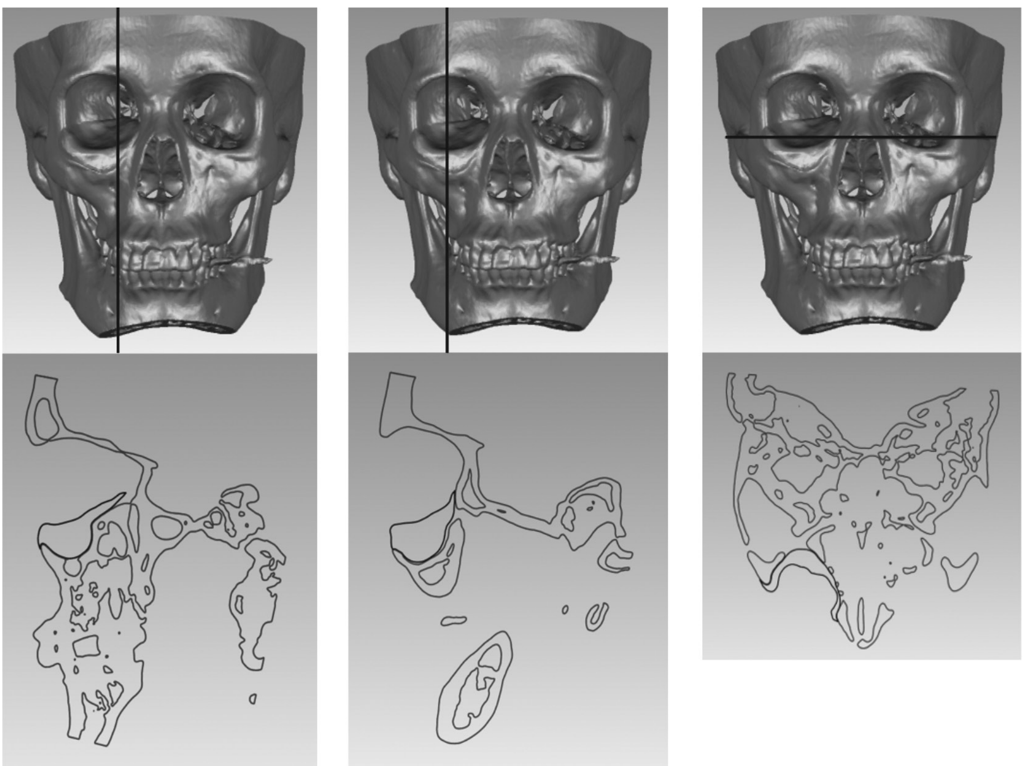


Figure 10. *Cross section view in sagittal plane of the subtracted orbital floor.*

Orbital Floor Implant Design

The design of the orbital needs to be completed by adding two flanges where the mounting holes will be constructed on these flanges (Figure 11). The orbital floor with flanges were then converted to NURBS surfaces (Figure 12). The Non-Uniform Rational B-Spline (NURBS) surfaces were imported into Siemens NX software to design a 3D printed implant with a thickness of 0.6 mm.

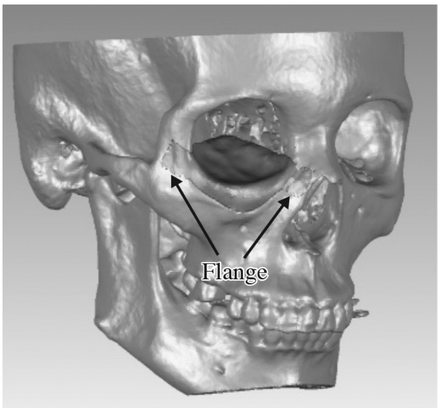


Figure 11. *Flange design*

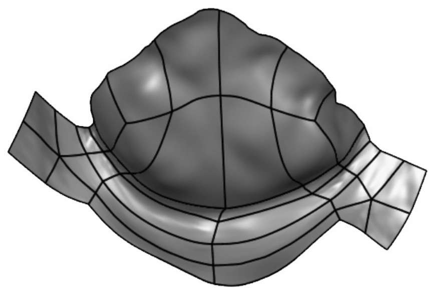


Figure 12. *NURBS surface of the orbital floor with flanges*

The design of the flanges was changed to a round shape in order to eliminate sharp edges. Two mounting holes were added to each flange. The implant was perforated with mesh at the floor area and three navigation points in semi-sphere shape were added on the implant.

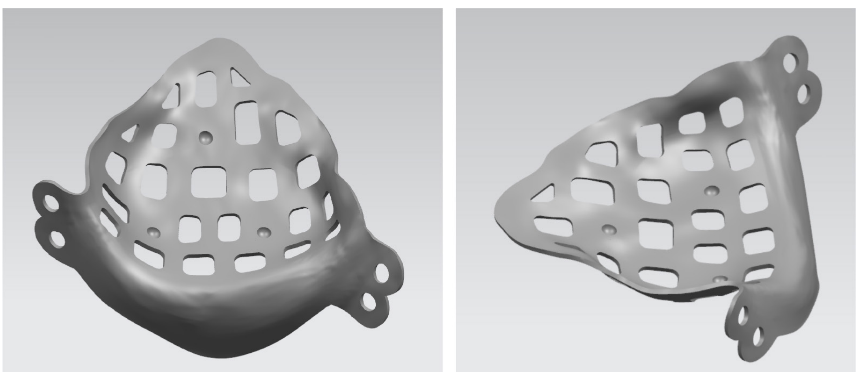


Figure 13. *3D design of the orbital floor implant*

The design of the orbital floor implant was positioned on to the patient skull 3D model to confirm that it matches with patient anatomy (Figure 14). Once the validation was agreed with the surgeons, the patient specific orbital floor implant was sent for fabrication using 3D metal printing.

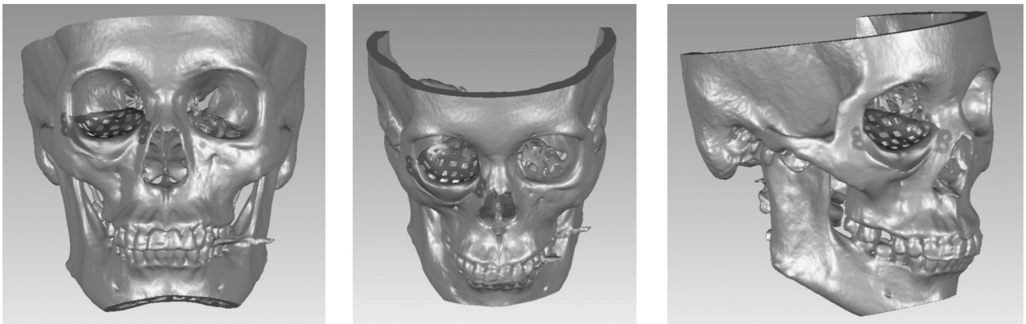


Figure 14. *Orbital floor implant validation with patient skull*

RESULTS AND DISCUSSION

Implant Verification and Validation

The design process for medical devices is highly regulated to ensure the safety of patients and healthcare practitioners. The medical device directive is developed to regulate medical devices. It is a document that is legally binding, enforceable in law with penalties for non-compliance. In order to comply with the regulations, companies that manufactured implants are required to have Quality Management System in place to ensure that the whole design and verification process are managed and planned in a systematic and repeatable manner (Figure 15).

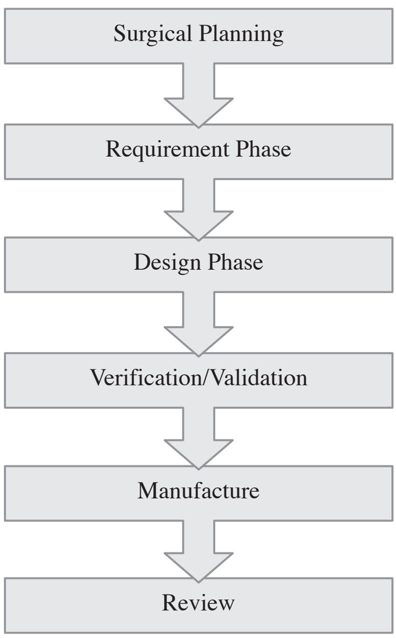


Figure 15. *Implant verification and validation process flow*

3D model printing is a very effective technique for verifying implant as it aids communication between engineers and surgeons. The model of skull with customized implant were produced within hours using Stereolithography (SLA). Surgeon could then inspect the model with the implant to verify the implant fitting and shape. This has allowed the communication between surgical devices such as screws, plate, screw driver thus minimizing the opportunity for components incompatibility. Once the surgeon confirmed the implants design, the Computer Aided Design (CAD) data will be sent for manufacture.

Data Preparation for 3D metal printing

Generally, the laser sintering process begins with the creation of 3D CAD data. Most of the software are capable of producing 3D data and the most important function is the capability of converting the 3D data to STL file format. This file format is widely used for 3D printing technology. Materialise Magics software was used for data pre-processing based on STL data. It provides effective visualisation of part in STL format besides using it for repairing and editing the STL data.

Once the design was completed, the CAD data must be converted to a readable machine format. This conversion will create the Specific Layer Interface (SLI) data which are required for the building process. At this stage, 3D data was converted into a sequence of 2D data called "slices" consisting of many layers. Before sintering the geometry part, a support structure was built on the tray and then the bottom of the part was developed before building the part from bottom up. The absence of a support structure over an appropriate area causes parts to severely warp. The geometry of the part, which in this case, an orbital floor implant, was carefully analysed, giving more attention to all down facing surfaces and the area where there is a large volume of material. The support structure was placed manually rather than automatically to avoid unnecessary and massive support structures which lead to longer production time. The implant was first oriented in different positions in order to get the best possible building orientation. The part and the support structures were sliced at 30 µm intervals and saved in .sli format. This was done by using the EOS RP tools software. The process flow is illustrated as below (Figure 16).

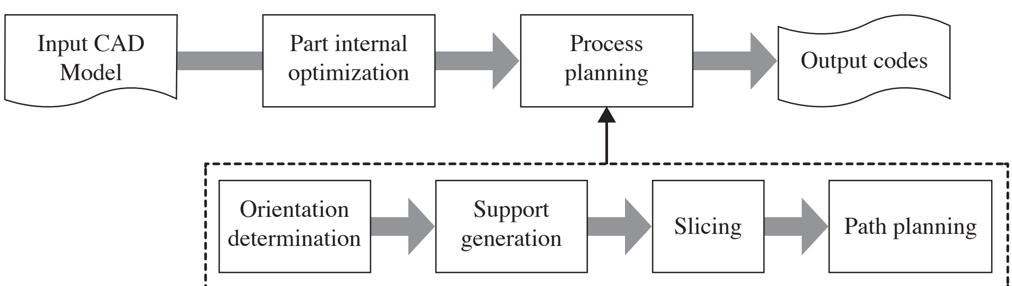
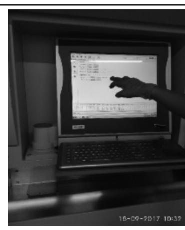
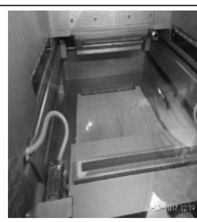


Figure 16. *The internal optimization method process flow*

Implant Fabrication Procedure

The detail procedure and technique used to fabricate the orbital implant are illustrated as Table 1 below. The patient specific orbital floor implant was manufactured using SLM machine by utilizing the titanium powder material. The machine uses the layered manufacturing principles by fusing various metallic powders layer by layer into a solid part by melting it locally using a focused laser beam.

Table 1. 3D Metal Printing for orbital implants

PROCESS	
1. Material loading in the material bottle	
2. Placing material bottle in the material tank	
3. Protective glass cleaning	
4. Define first layer of powder	
5. Build process	

6. Remove excess powder	
7. Remove part from build platform	
8. Peening process	
9. Post processing	
10. Final part	

The fabrication of Patient Specific Implant orbital floor using 3D metal printing technology requires many critical steps. It begins with design stage and goes through intricate data preparation before the 3D metal printing process. Good data preparation would determine the successful fabrication of the parts. This involves placement of support structure, part orientation and processing parameters. There are four important parameters in Direct Metal fabrication process: laser power, layer thickness, scan speed and scanning pattern. The values of these parameters determined the energy density absorbed by the titanium powder.

The process of 3D metal printing for the patient specific implant took approximately 5 hours. The implant was successfully fabricated with no defects and no crashing while printing. The implant was sent for heat treatment for stress relief on the formed titanium implant for 3 to 4 hours to avoid unwanted deformations before removing the support structure. Then it must go through intricate cleaning process to remove burrs and trapped powder using ultrasonic bath. The implant was then tested with the anatomical model for fitting test.

CONCLUSION

IIt can be concluded that 3D Design using CAD software and 3D metal printing technology along with biocompatible materials give opportunities to medical implant companies to 3D print patient-specific orbital floor implants faster than traditional manual forming process. Hence the use of 3D Metal printing and 3D bio-model adaptation can significantly reduce the operative time taken while improving patient outcome.

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REFERENCES

Bell RB and Markiewicz MR (2009). Computer-assisted planning, stereolithographic modeling, and intraoperative navigation for complex orbital reconstruction: A descriptive study in a preliminary cohort. J Oral Maxillofac Surg. 67: pp 2559–70.

Christopher G.T.Lim, Duncan I.Campbell, and Don M.Clucas. (2014). Rapid Prototyping in Orbital Floor Reconstruction: Application in Three Patients. Cranimaxillofac Trauma Reconstr. 7(2): pp 143-146.

Kokemueller H, Tavassol F, Ruecker M and Gellrich NC. (2008). Complex midfacial reconstruction: A combined technique of computer-assisted surgery and microvascular tissue transfer. J Oral Maxillofac Surg. 66: pp 2398–406.

M.Giarda, A.Tavolaccini, F.Arcuri, and A.Benech. (2015). Surgical approach to isolated bilateral orbital floor fractures. Acta Otorthinolaryngol Ital. 35(5): pp 362-364

Orbital Floor Fractures. http://eyewiki.aao.org/Orbital_Floor_Fractures

Takahiro Kanno, Masaaki Karino, Aya Yoshimo, Takashi Koike, Taichi Ide, Hiroto Tatsumi, Koji Tsunematsu, Hideki Yoshimatsu and Joji Sekine. (2017). Feasibility of Single Folded Unsintered Hydroxypatite Particles/ Poly-l-Lactide Composite Sheet in Combined Orbital Floor and Medial Wall Fracture Reconstruction. Journal of Heard Tissue Biology 26(2) pp 237-244.

Tang W, Guo L, Long J, Wang H, Lin Y, Liu L, et al (2010). Individual design and rapid prototyping in reconstruction of orbital wall defects. J Oral Maxillofac Surg. 68: pp 562–70.

Zhang Y, He Y, Zhang ZY and An JG. (2010). Evaluation of the application of computer-aided shape-adapted fabricated titanium mesh for mirroring-reconstructing orbital walls in cases of late post-traumatic enophthalmos. J Oral Maxillofac Surg. 68: pp 2070–5.