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Manufacturing of Customized Implants for Orbital Fractures Using 3D Printing

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Abstract:

An orbital fracture is a traumatic damage to the bone in the eye socket. These fractures modify the orbital bone dimensions and the working of the intra-orbital contents. It is difficult to achieve an original three-dimensional orbital shape through the process of forming and cutting implants. Customized implants are created using computed tomography (CT) images of the patient. CT images of the patient are used to create a computer-aided design (CAD) model of orbital floor implants. The designed implants are manufactured through a material extrusion process with biocompatible material. The application of the material extrusion process with biocompatible material resulted in the fabrication of implants at a minimal cost and time, also at the same time maximized surgical safety.

Keywords: Computed tomography, Computer-aided design (CAD) model, additive manufacturing.

1.Introduction

Growing demands of man has led to invention of new technologies. 3D printing is one such advancement in manufacturing industry which uses computer-aided design (CAD) to create three-dimensional objects through a layering method. In medical field, 3D printing can be used to create perfect scale models of patient-specific anatomy and structures.With 3D printing in healthcare, doctors can create tools that accurately follow a patient's unique anatomy. 3D printed tools are used to make the placement of restorative treatments (screws, plates and implants) more precise, resulting in better post operative results.**3D bioprinting** is the utilization of 3D printing–like techniques to combine cells, growth factors, or biomaterials to fabricate biomedical parts, often with the aim of imitating natural tissue characteristics.

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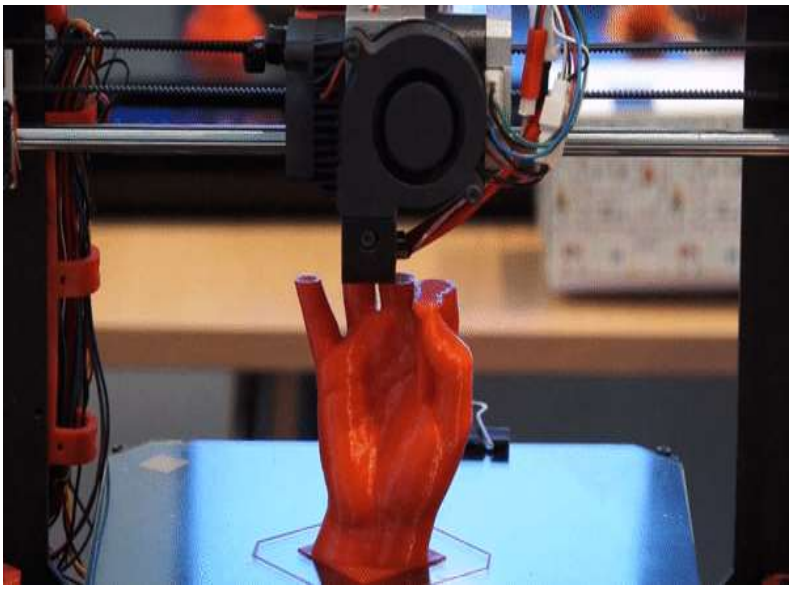
3D printing.



3D printing or additive manufacturing is a process of making three dimensional solid objects directly from a digital file. The creation of a 3D printed object is achieved using additive processes in which an object is created by laying down successive layers of material until the desired shape is obtained. Each of these layers can be seen as a thinly sliced cross-section of the object. 3D printing enables production of complex shapes using less material than traditional manufacturing methods.

3D printing in medical industry

3D printing, commonly referred to as rapid prototyping (RP) or additive manufacturing (AM), is a manufacturing method in which materials are solidified in the form of layers to create three-dimensional (3D) physical objects from a 3D virtual model.In medical industry 3D printing is widely used in the fields, such as orthopedics, plastic surgery, neurosurgery, pulmonology (respiratory system)etc.In the field of oral and maxillofacial surgery (Dentistry), 3D printed objects are used to reconstruct the deformed bone.But the reconstruction of the orbital fracture is challenging, and it is extremely difficult to regain its original structure.

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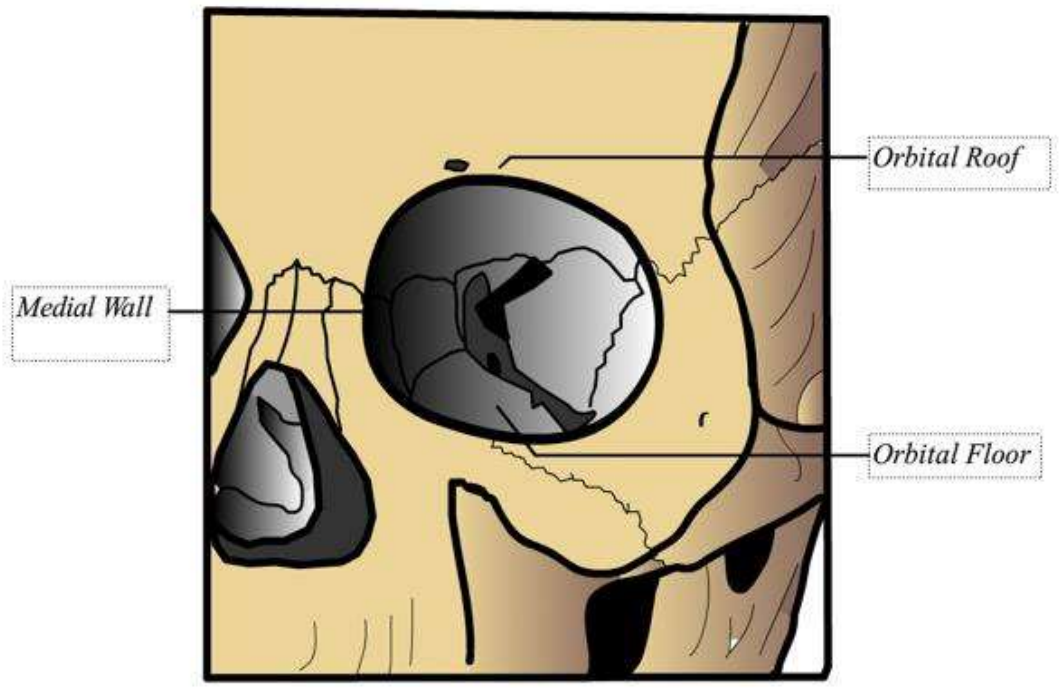
Case study

The study considered a 40-year-old male patient who was diagnosed with orbital floor fracture and designated and fabricated a customized implant. The patient was treated at the Department of Oral and Maxillofacial Surgery, Panineeya Institute of Dental Science and Research Centre, Hyderabad, India. The surgical procedures for the patient were performed with the approval of the Institutional Ethical Committee (IEC).

Orbital floor fracture



Orbital floor fracture refers to the breakage of one or more bones surrounding the eye socket. Orbital fractures affect the position and function of intra-orbital substances, leading to problems such as diplopia and other visual acuity problems. To avoid these difficulties, it is necessary to surgically restore the fractured orbits and repair the pre-injury anatomy. CT(computed tomography) data acquisition

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The study was carried out according to the following steps:

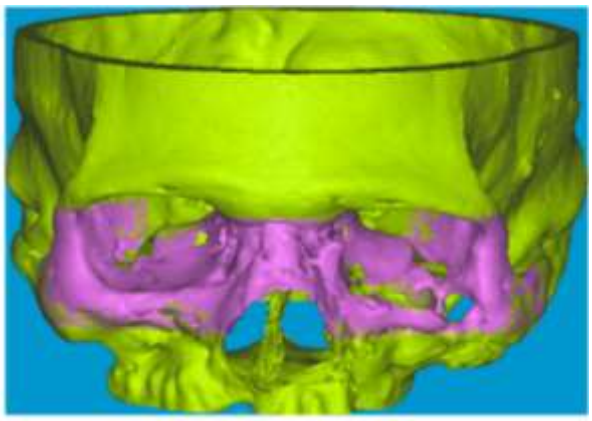
1. CT data processing and design of an implant
2. Manufacturing of medical models by 3D printing
3. Pre-surgical planning
4. Surgical procedure
5. Post-surgical follow-up

CT data acquisition

The patient's CT images were obtained using a 64-slice spiral CT scanner.The patient's skull (orbital cavity and the surrounding bone structure) was scanned with parameters of:

1. Tube current = 500 mA
2. Tube voltage =80 kV
3. Pitch =1.34
4. Gantry rotation time= 0.4 s

CT data processing and design of an implant



With the help of **Mimics software** (Materialise Interactive Medical Image Control System), CT images in the form of Digital Imaging and Communications in Medicine (DICOM)

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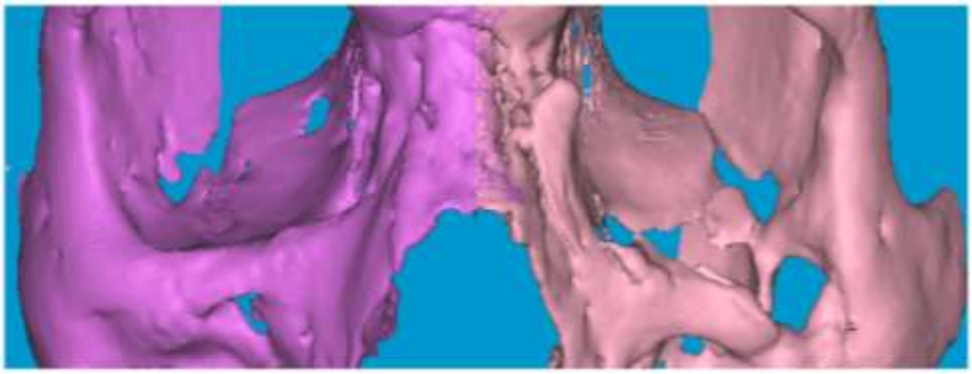
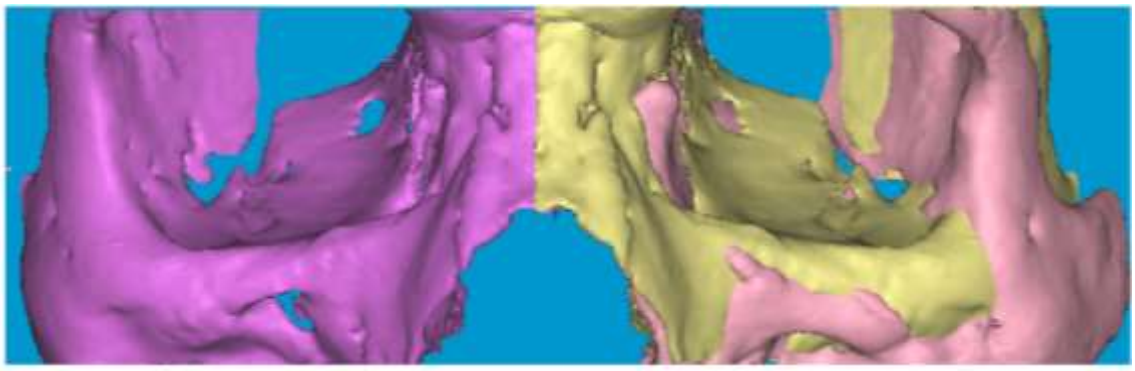
standard were processed to develop a 3D CAD model.In the generated 3D CAD model the orbital's were indicated in a violet colour showing damaged(right) and healthy(left) orbital's.



A mask editing tool was used to select and deselect pixels in the 2D view which intern added and removed voxels in their respective 3D CAD models. Two orbital's CAD model was extracted from the maxillary CAD model using the mask editing tool and the left and right orbital anatomical models were separated using the axis of symmetry. The healthy orbital (left side) CAD model was used to design the implant using a mirror tool. Using a mirror tool, the 3D CAD model of the healthy orbital side was mirrored by the midsagittal plane to maintain the symmetry of the orbital counter and the mirrored part is indicated in yellow color.The mirrored orbital CAD model was used to design the implant.This CAD model was then subtracted from the initially developed right-sided orbital CAD model and the inner surface of the subtracted CAD model was exactly aligned on the top surface of the initially developed right-sided orbital model.



The area of the subtracted portion was reduced to provide a curved linear shape and a uniform surface on a fractured orbital and the designed implant (red color model) maintained symmetry and improved the surface of the fractured orbital. The 3D CAD models of the maxilla and designed implants were converted into Standard Triangle Language (STL) file format to produce 3D printed models.

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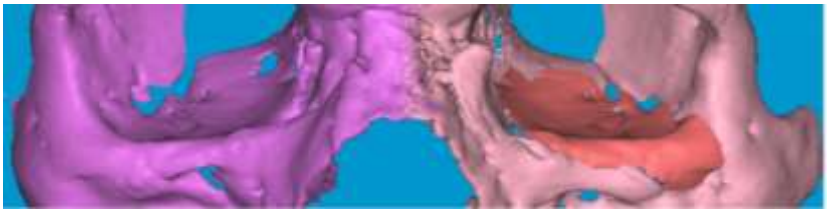
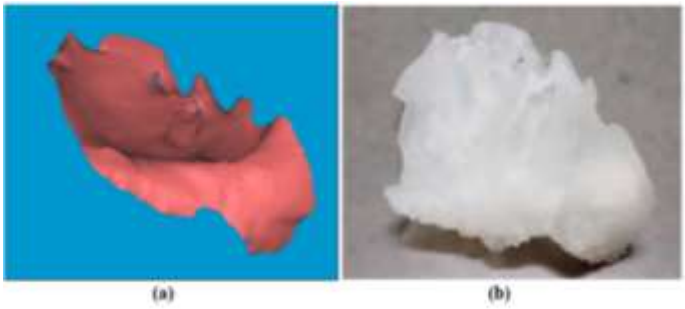
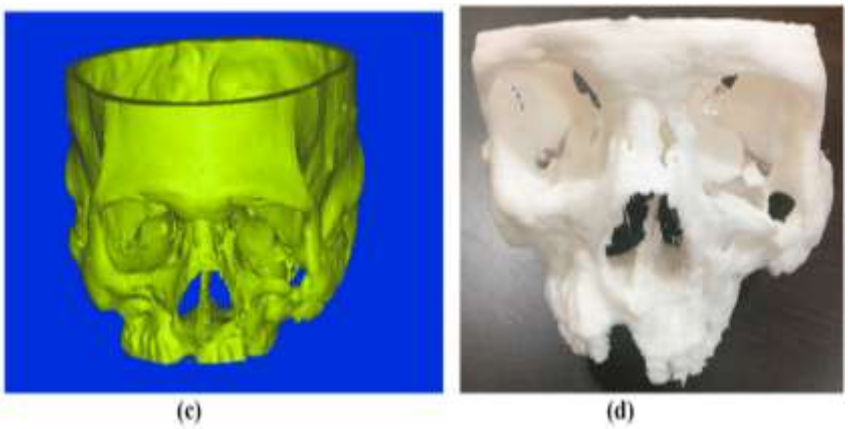


Manufacturing of medical models by 3D printing

In a 3D printing process, the STL file was divided into multiple layers and controlled by a computer, based on which the printer fabricates medical models.The designed implant model was manufactured using a Stratasys Fused Deposition Modeling (FDM) fortus 900mc machine with a biocompatible PC-ISO material.The PC-ISO material is used for making ABS filaments with a diameter of 1.75 mm, which are wound in the form of coils and then extruded as a thin filament from a heated nozzle, deposited on top of a printer base plate where it solidifies.The bottom layer on the base plate is formed by a controlled extrusion head, which deposits thin layers of material onto the plate. Likewise a layer by layer deposition of the material finally results in the desired model.



(a). Implant 3D CAD model (b). 3D printed implant



(c).Maxilla 3D CAD model (d). 3D Printed maxilla

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Pre-surgical planning

Virtual pre-planning surgery was performed.Surgeons obtained information on the position of the implant and the positions of screw placement. Rigid fixation can be achieved through a 3D printing technique.

Surgical procedure

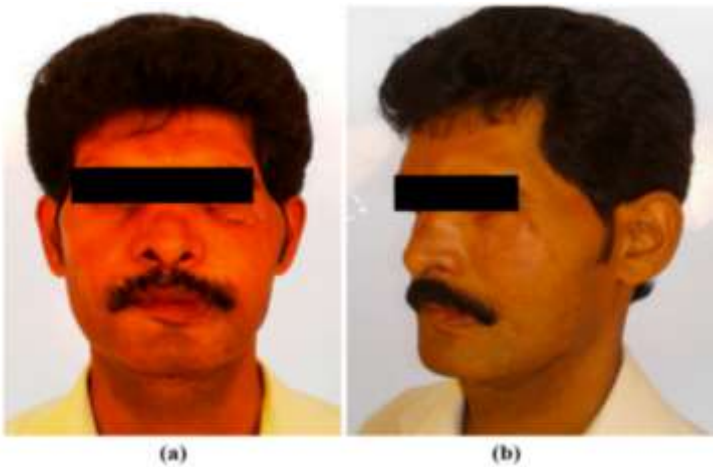
3D printed manufactured implant was sterilized in an iodine solution for 8 h. Transconjunctival approach was used for the patient and a review of the lower orbital wall was performed. Herniated orbital tissue was reduced to restore intra-orbital structures.3D printed implant was properly aligned with the orbital floor and fixed with titanium screws.

Fig: Reduction of orbital tissues

Fig: Fixing the implant with titanium screw

Post-surgical follow-up

Based on the orthotic observation, the patient's globe position and visual disturbances were noticed. Significant development was detected after implanting the 3D printed model and eliminating diplopia. The patient eventually regained a reasonable orbital floor and a better facial appearance.



(a) (b)

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Conclusion

- The use of thermoplastic polymer implants in treatment is affordable and economical.
- 3D printing technology is a simple and reliable method for designing, manufacturing, and placing implants for the treatment of orbital fractures.
- Computer-assisted surgical tools were taken into consideration, which reduced the operational time and provided an accurate design along with positioning of orbital implants.
- The application of FDM 3D printing technology in the medical industry using a combination of biocompatible materials resulted in fabrications of implants at a minimal cost and less production time.
- Depending on the appropriate pre- planned surgical procedures, a perfect fit can be obtained during surgery, with 3D printed medical models being effective.
- 3D printing technique and CAD models are used together in orbital floor restoration to provide satisfactory aesthetic results.Customized models used in the patient's intra-operation can minimize the operational time and maximize surgical safety.

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