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Research Article

Modelling of customized cranial implants for decompressive craniectomy

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Abstract

Cranioplasty is one of the oldest and lifesaving surgical procedures to repair cranial defects and is extremely challenging for most experienced neurosurgeons. Cranioplasty often performs an aesthetic purpose, improves the neurological function of brain tissue, and arrests cerebrospinal fluid leak (CSF). These surgical procedures are gradually improved and enhanced with the help of computer-aided design (CAD) and computer-aided manufacturing (CAM) technologies. Recently, these surgical procedures are notoriously enhanced with 3D printing technology which helps to manufacture large-sized cranial defects with contour surfaces. The main objective of this research work is to develop customized cranial implants for severely injured patients. The computer-aided modelling and reconstruction techniques are creating an essential role in various cranial defects such as symmetrical and asymmetrical defects respectively. The symmetrical defects are modelled through the mirroring technique, however, the modelling of cranial implants for asymmetrical defects is quite difficult such as beyond midline deformities, multipoint defects, and frontal bone defects. The complexity depends upon the surface area of the implant and curvature. The skull is damaged in the frontal, parietal, and temporal regions and a small portion of the frontal region is damaged away from the sagittal plane. The cranial bone thickness is calculated at different regions such as temporal and parietal regions etc. The implant is modelled at a thickness of 2.5mm and the edges of the implant are corrected to arrest the CSF leak. Finally, the 3D printed model is useful for planning surgery, modelling implants, and estimating skull damage.

Keywords: *Cranial Implant, CSF, 3D Printing, decompressive craniotomy*

Introduction

Skull provides structure to head and face while protecting brain. The bones in skull can be divided into several types of cranial bones namely, frontal, parietal, temporal, occipital, sphenoid and ethmoid bone, which form the cranium, and facial bones make up the face. The Head accommodates one of the most vital parts of the body, the brain. Although it is well protected in a bony cranial cage, it still remains one of the most vulnerable parts of the body. Cranial bones are unique shapes and together by unique joints called sutures. Any break or defect of cranial bone is known as a skull fracture. A fracture can be defined as an abnormal break in the continuity of a structure [2]. The severity of the fracture relies on the blow's power, the skull's impact point, the object's form, and the location of the impact [1]. Intra cranial hematoma (ICH), or blood clots, may take many different forms in or around the brain.

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The various varieties are categorized according to where they are found in the brain. These may vary in severity from minor head injuries to very severe, even life-threatening, wounds. Different fracture types result in varying degrees of stress and harm. Head injury is a common term that is actually craniocerebral damage. Some defects in the skull can fatally threaten human life.

When a direct blow to the head, shaking of the child (as observed in many cases of child abuse), or an injury similar to whiplash occurs, a process known as coup-countercoup results, which damages internal tissue and blood vessels as well as bruises the brain (as seen in car accidents). A bruise that is directly related to trauma and is seen at the place of impact is known as a coup (pronounced COO) lesion. If it hits the other side of the skull, it might cause a countercoup lesion, which is a bruise. The brain's impact on the sides of the skull may tear or shear the inside lining, tissues, and blood vessels, which might cause internal bleeding, bruising, or swelling of the brain.

The technique to correct cranial bone defects is known as cranioplasty. A bone substitute can be used to fill the missing bone, depending on the dimension and location of the defect [3]. The purpose of reconstruction of the cranial defects using individual implants is to replace the missing and damaged anatomical bone structures, restore their function and aesthetic. Customized implants can be created with 3-D printing technology with better cosmetic and functional outcomes [3].

Cranioplasty with varied materials was performed by many ancient civilizations; and a number of these procedures date back to 3000 BC [12] particularly the Inca period in Peru. Ancient surgeons from different geographical sites and cultures performed both practices with remarkable survival rates [6]. Different types of materials were used throughout the history of cranioplasty [10] many efforts have been taken to repair defects in the skull, among which cranioplasty is the most prominent technique. To repair the injury, numerous natural and artificial materials have been adopted by neurosurgeons [7]. The cranioplasty was first documented by Fallopius who described repair using gold plates; the first bone graft was documented by van Meekeren [8][11][12]. The aim of cranioplasty is not only a cosmetic issue also, the repair of cranial defects gives relief to psychological drawbacks and increases the social performance [10].

During the decompressive craniectomy, the autologous bone flap was removed and stored at a -27^{0}C temperature in a refrigerator. If the repositioning of the autologous bone flap failed to owe to infection or bone flap resorption, a prosthetic material was used. The autologous bone flap was not accessible because of the etiology of the cranial deficit. In such cases, we used hand-made implants whenever a bone deficit needed to be swiftly corrected. When the time of the cranioplasty may be extended or when a hand-made prosthesis could not provide appropriate results because of the shape and size of the bone defect, a custom-made implant was preferred [14]. The individualized prosthesis was made of hydroxyapatite, a biological component, or polyether ether ketone-PEEK, two synthetic materials

The modeling of cranial implant is difficult because of skull is having variable thickness at different cross sections and depends on age and sex. The implant material should be durable, biocompatible, widely available and with low incidence of infection. To analyze the effect of early surgery, implant material and method of flap preservation on cranioplasty infections and to perform a sub analysis of the effect of early surgery on overall complications associated with cranioplasty [9]. The department of neurosurgery, SKIMS, Kashmir has been performing the procedure of cranioplasty since 1982 [11].

The use of bone from diverse donor sites, such as the tibia or ribs, became widely accepted in the 19th century [15]. New materials are now accessible for surgeons to employ thanks to the developing new biomedical technologies. Skull bone flaps may be stored in a variety of ways (alcohol, formalin, boiling, freezing, autoclaving, freeze-drying, and even intracorporeally). Drug-resistant high intracranial pressure is now often treated by decompressive craniectomy. After the patient has healed from the initial damage, cranioplasty offers protection and aesthetics while restoring fluid dynamics and enhancing neurological status [14].

Cranial surgeries: Based on dimension and location of the defect, Implants/substitutes are used fill the missing bones. The purpose of reconstruction of the skeletal defects using individual implants is to replace the missing and damaged anatomical bone structure, restore their function and aesthetic.

The following characteristics are essential for a good cranioplasty material such as It must fit the cranial defects and achieve complete closure, Radiolucency, Resistance to infections, Not dilated with heat, Strong in biomechanical process, Easy to shape, not expensive, and Ready to use

Three-dimensional (3D) printing is an additive manufacturing technique that may be used to finish a three-dimensional volumetric structure by layering materials like metal or plastic to form an object. The products are produced using images obtained using computer-aided design (CAD) software, magnetic resonance imaging (MRI), or computed tomography (CT) [2]. There are different classification methods for the different printing modalities. printing methods based on material used are solid, liquid and solid based printings.

The usage of 3D printing technology in medicine has increased, ranging from disease detection and instructional models for teaching [3] to medical equipment and surgical applications for patient-specific needs. Researchers are looking at the prospect of utilizing 3-D printing to repair or replace damaged organs like the heart, kidneys, or skin. Furthermore, it is capable of creating whole new organs that would carry out the same biological functions as sick or damaged organs, such as the pancreas in the case of diabetes. 3D printing technology used as Counter models, guides, Splints and implants. In clinical applications 3D printing used as surgical 3D models, surgical guides and implants. These are printed with Selective laser Melting (SLM), Selective Laser Sintering (SLS) or Electro Discharge Machining (EBM). Donelson et al. examined the use of 3-D models in preoperative planning, included the creation of model and the integration of the model into a presurgical planning. In medicine, there is increasing awareness that outcome must be evaluated in terms of quality of life and cost effectiveness.

The objective of the present work is to pre plan a surgery with cranial implant with accurate shape for injured portion by available software's (Invesalius & Rhino3D) with different tools. Finally reduces the surgery time and overcome the cerebrospinal fluid (CSF) leakage with good results.

Methodology

Data collection: A CT-scan of 45 years old patient fractured skull was collected from the hospital. Number of slices was 16, and thickness of each slice is 5mm. the skull got damaged in parietal, temporal and sphenoid region by an accident. And brain was swelling, doctors were removed damaged portion of the skull.

In this research, a 3D (Dimensional) modelling software called Invesalius is used for creation of 3D model skull from CT data. A DICOM (Digital image Communications in Medicine) image consists of two main components, an array contains the pixels of the image and set of meta -information. Computer tomography specifies the radio density of tissues (absorption of an average X-ray by the tissues). Radio density reading is converted in to an image grey level is called as the Hounsfield (HU) scale.

The DICOM format files are imported into Invesalius software. The process of converting anatomical data from 2D CT images to 3D models is called segmentation. It consists of some main tools like thresholding, region growing and so on. Thresholding tool bar had predefined scale (range 226 to 3071) for bone, soft tissue, compact bone, spongy bone & fat tissue etc. this cranial implant is modelled based on bone of threshold value 226. Region growing is used to separate the masks into different parts. Broken bone particles were erased at different layers of CT images. After erasing 3D model was prepared and this image data is exported in Standard Triangular Language (STL) file format for further creation of implant.

Fig 1: 3D model from Invesalius.

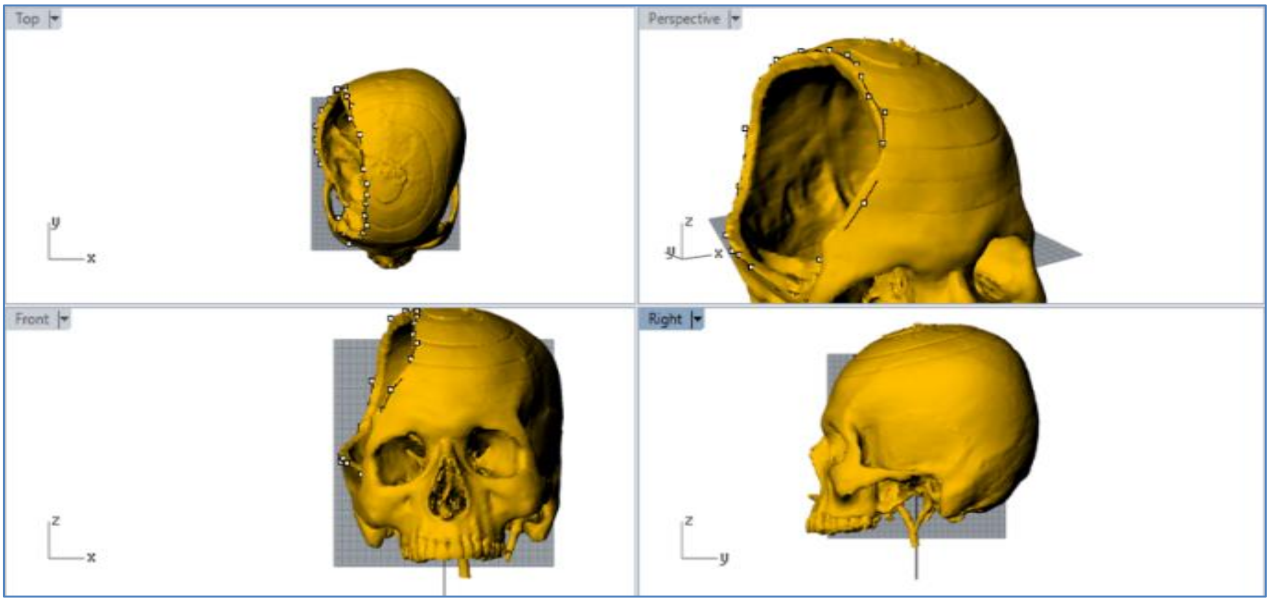

Fig 2: Front, top and right views of curve on outer layer of damaged skull.

The cranial implant is modelled using patient data in Rhinoceros. The damaged section of the skull's thickness in the parietal, temporal, and sphenoid regions was first calculated before modelling the cranial implant. Afterward, an implant was developed.
In this implant creation, anatomical reconstruction or free form modelling technique was used. In this technique implant can be designed with the help of a supporting geometry, the residual geometry of the patient's bone and free form modelling tools such as lines, planes and curves. A solid in Rhino is constructed using NURBS, as opposed to a solid created using mesh 3D modelling. For a good 3D printable model, it is crucial to understand the differences between these two 3D modelling techniques.

The first step is Extract the STL file, which is obtained from Invesalius, into Rhino 3D. free form modelling technique was used. As per this implant method, opened the file or image in perspective view, click on curve from menu bar Curve select free from then select sketch on polygon mesh, then draw the curve on the outer part layer of the skull and attached at ends. These curves are manually adjustable.

In standard option selected the patch then selected the curve which is drawn on the outer layer of the broken part. Select the patch button from menu option, after click on enter patch was created and draw a perpendicular line to the patch Finally extruded the patch, with the help of solid extrusion (both sides). Extrusion is exhibited up to getting the average thickness of the skull.

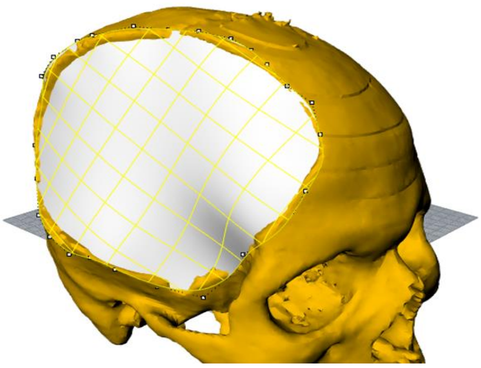

Fig 3: Patch created on damaged portion.

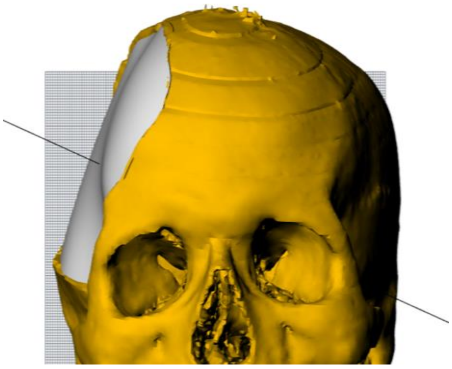

Fig 4: extrusion in both sides.

Results

Both physical models and 3D photos were useful for preoperative assessment of the unique implant design and surgical planning. The bespoke implants proved to be a less intrusive method and were effective for cutting down on procedure time. Preoperative planning was done using the printed 3-D model. Finally, the implant is utilized to stop CSF leakage and modelling this implant relied heavily on 3D models (pictures) and software. After completion, this model was used in pre-operative planning. because during surgery less of the skull had to be exposed. The 3-D surgical templates were placed and cut in an efficient, straightforward, repeatable manner.

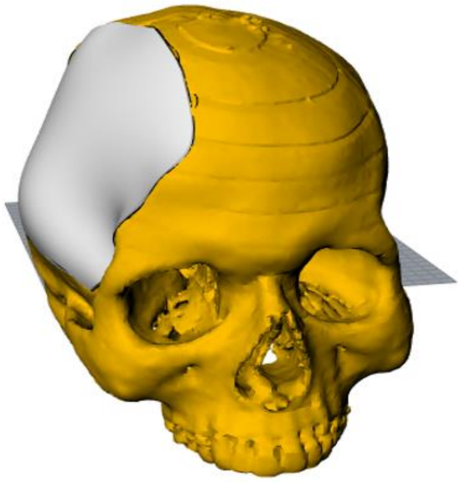

Fig 6: Final cranial implant

Discussion

Physical models include, but are not limited to, surgical guides, implants, and anatomical models for surgical planning [3]. While implants are often made using SLS, SLM, or EBM, models and surgical guidance may be printed using Stereolithography (SLA) and Fused Deposition Modelling (FDM) [4]. When a cranial implant is necessary, these printed models are useful. Individuals who had bilateral flaps rapidly re-implanted after removal were more likely to use their craniotomy flap, which had a low infection rate [5]. In this instance, a flawless model of the cranial implant is produced using the Invesalius and Rhinoceros software. The surgeon can precisely pinpoint the location of the skull injury with the aid of a 3D printed model. Additionally, there are ways to shorten operations, enhance surgical results, and lessen radiation exposure.

The goal of cranial restoration is not only purely ornamental; it also alleviates psychological suffering and improves social function [10]. Additionally, it has been shown that cranioplasty may enhance cardiovascular functioning and increase cerebral blood flow by accelerating the blood flow via the ipsilateral middle cerebral and internal arteries [11]. However, if carried done correctly, at the right time, and using an aseptic approach, excellent outcomes may be obtained with cranioplasty.

Conclusion

Rhinoceros software is used to construct an implant, and Invesalius is used to convert CT scan data into a 3D model of the skull. It was finally manufactured using PLA material in an FDM machine. The 3D printed models might be valuable, particularly when a cranial implant is required, for the assessment of damaged skulls, implant modelling, and operation planning. Our results show that the therapy is successful. It is vital to use standardized procedures for gathering information on infections, complications, and the timing of cranioplasty surgery. The field of 3D printing is quickly developing in many areas of our life, including the medical sector.

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