3D PRINTED SKULL SCAFFOLDING AND ORTHOPAEDICS

Major Project Report
submitted in partial fulfilment of
the requirements for the award the degree of

BACHELOR OF ENGINEERING AND TECHNOLOGY
IN
MECHANICAL ENGINEERING

BY
ISMAEL WASIM (14BME0033)
YASH CHATURVEDI (14BME0042)
UDIT AGARWAL (14BME0054)

under the tutelage of

PROF. ABID HALEEM
DEPARTMENT OF MECHANICAL ENGINEERING
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JAMIA MILLIA ISLAMIA
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DECLARATION

We, ISMAEL WASIM (Roll No: 14BME0033), YASH CHATURVEDI (Roll No: 14BME0042) , and UDIT AGARWAL (Roll No: 14BME0054) student of B. Tech. in Mechanical Engineering, hereby declare that the project report titled “3D PRINTED SKULL SCAFFOLDING AND ORTHOPAEDICS”, which is submitted by us to the Department of Mechanical Engineering, Faculty of Engineering and Technology, Jamia Millia Islamia, New Delhi in partial fulfillment of the requirement for the award of the degree of Bachelor of Technology in Mechanical Engineering, has not previously formed the basis for the award of any Degree or Diploma and that this work has been carried out exclusively on our own effort under the supervision of Prof. ABID HALEEM, Department of Mechanical Engineering, Jamia Millia Islamia New Delhi.

Place: New Delhi

Date: 30 May, 2018

ISMAEL WASIM (14BME0033)

YASH CHATURVEDI (14BME0042)

UDIT AGARWAL (14BME0054)

CERTIFICATE

DEPARTMENT OF MECHANICAL ENGINEERING
FACULTY OF ENGINEERING & TECHNOLOGY
JAMIA MILLIA ISLAMIA
NEW DELHI-110025

May 30th , 2018

On the basis of declaration submitted by **ISMAEL WASIM(Roll No: 14BME0033), YASH CHATURVEDI(Roll No: 14BME0042), UDIT AGARWAL(Roll No: 14BME0054)** student of B. Tech. in Mechanical Engineering, I hereby certify that the project report titled **"3D PRINTED SKULL SCAFFOLDING AND ORTHOPAEDICS"** which is submitted to the Department of Mechanical Engineering, Faculty of Engineering and Technology, Jamia Millia Islamia, New Delhi in partial fulfillment of the requirement for the award of the degree of Bachelor of Technology in Mechanical Engineering is an original work carried out by them under my guidance and supervision.

To the best of my knowledge this work has not been submitted in part or full for any Degree or Diploma to this University or elsewhere.

(Prof. J.A. USMANI)
Head
Department of Mechanical Engineering,
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ACKNOWLEDGEMENT

We express our gratitude to God, our Parents, Department of Mechanical Engineering, Faculty of Engineering and Technology, Jamia Millia Islamia and Dr. J.A. Usmani for providing us with the facilities and infrastructure needed for the successful completion our project work.

A sincere appreciation goes to our supervisor Dr. Abid Haleem, Professor, Department of Mechanical Engineering, Jamia Millia Islamia, for his immense guidance and support during the project work.

We are also grateful to our family and friends and also to all the staff members and Ph.D. scholars of Mechanical Engineering Department for their support. They have been a rich source of knowledge regarding the project.

We also want to acknowledge JAMIA MILLIA ISLAMIA for providing us a great horizon to stand in front of this competitive world.

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ABSTRACT

Additive Manufacturing (AM) is emerging as a clinically promising technology for rapid prototyping of surgically implantable products. With this commercially available technology, computed tomography, magnetic resonance images can be used to create graspable objects from 3D reconstructed images. Customized implants and casts can be made to match an individual's anatomy. With advances in both medical imaging and computer programming, two-dimensional axial images can be processed into other reformatted views (sagittal and coronal) and three-dimensional (3D) virtual models that represent a patients' own anatomy. This processed digital information can be analyzed in detail by orthopaedic surgeons to perform patient-specific orthopaedic procedures and enhance patients' understanding of their pathology. The use of 3D printing is rising and has become more prevalent in medical applications over the last decade as surgeons and researchers are increasingly utilizing the technology's flexibility for manufacturing objects. 3D printing is a type of manufacturing process in which materials such as plastic or metal are deposited in layers to create a 3D object from a digital model. This additive manufacturing method has the advantage of fabricating objects with complex freeform geometry, which is impossible using traditional subtractive manufacturing methods. Specifically, in surgical applications, the 3D printing techniques can not only generate models that give a better understanding of the complex anatomy and pathology of the patients and aid in education and surgical training but can also produce patient-specific surgical guides or even custom implants that are tailor-made to the surgical requirements. As the clinical workflow of the 3D printing technology continues to evolve, orthopaedic surgeons should embrace the latest knowledge of the technology and incorporate it into their clinical practice for patient-specific orthopaedic applications.

The 3D printing technology has been reported to be beneficial in patient-specific orthopaedics, such as in the creation of anatomic models for surgical planning, education and

surgical training, patient-specific instruments, and 3D-printed custom implants. Besides being anatomically conformed to a patient's surgical requirement, 3D-printed implants can be fabricated with scaffold lattices that may facilitate osteointegration, proper load bearing, stress shielding and reduce implant stiffness which has been one of the major challenges in overcoming post-operative problems in orthopaedics. However, limitations including high cost of the implants, the lead time in manufacturing, and lack of intraoperative flexibility need to be addressed. New biomimetic materials have been investigated for use in 3D. To overcome this, a novel technique of reverse engineering to create artificial scaffolds was designed and tested. Our project study 1) presents the necessary steps to prepare the medical images that are required for 3D printing, 2) reviews the current applications of 3D printing in patient-specific orthopaedic procedures, 3) discusses the potential advantages and limitations of 3D-printed custom orthopaedic implants, and 4) suggests the directions for future development. We used DICOM file editor to extract the 3D models from Magnetic Resonance (MR) scans and Computed Tomography (CT) scans and printed prototypes of scaffolds and internal nerves to accentuate the prominence of Additive Manufacturing in biological sciences and biomechanics. Further studies are needed to investigate the real clinical efficacy of 3D printings in orthopaedic applications.

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CHAPTER I

INTRODUCTION

1.1. Introduction

In various fields of medicine – from cranial prostheses for skull defect reconstruction [1,2] to titanium artificial jaw replacement [3,4] to human earlobes to dermal skin grafts to tracheas dimensional (3D) printing has emerged as a clinically promising technology for rapid prototyping of graspable products. Recent advances in 3D printing have provided orthopaedic surgeons with a new technology that has the potential to revolutionise preoperative planning, surgical instrument development, and custom orthopaedic implant creation. Surgical planning has gone through many different stages in the evolutionary history of modern medicine, moving simultaneously with the progression of the available technologies for diagnostic imaging. From the simple radiographs of the early 1900s, we arrived at modern acquisition systems such as computed tomography (CT) and magnetic resonance imaging (MRI) which provide the surgeon with detailed reconstructions of the patient anatomy, in combination with advances in image processing. Today, thanks to Additive Manufacturing technology, we can make a further step, moving from the virtual world to the physical one.

To date, 3DP has begun to have an emerging role in some medical fields, such as dentistry, orthopaedics and traumatology. Its enormous success in these fields stems from the ease of medical image processing as it mainly involves bone structures, offering clear visibility and contrast. The segmentation process that allows translation from medical images to the virtual model consists of extracting the specific structure in each layer of the image dataset. Once this process is completed, the final model is exported to a suitable format for 3DP and prototyped. At the end of a post-processing phase articulated according to the specific production technology, it is possible to provide a replica of the anatomy of interest. The advent of minimally-invasive techniques such as laparoscopic surgery, or - more recently - robotics, have completely changed surgeons' approach to intervention. There is a need for greater understanding of the specific anatomy to plan not only the various phases of the intervention but also the access of surgical instruments. For this reason, it is necessary to provide surgeons with facilities that allow them to investigate the clinical situation properly. Moreover, in the orthopaedic or traumatology fields, it is possible to let the surgeon test in advance the specific procedure on a 3D printed model, applying for screws or plates, or testing the drilling path.

1.2. Need for The Study

Three-dimensional printing allows for anatomic model creation so surgeons can examine patient anatomy more concretely compared with traditional 2-dimensional radiological images [5]. The insight provided by a 3D printed model may be helpful to both patients and surgeons. Epps [6] described how directly comparing usual anatomic models with custom printed models of complex deformities undergoing surgical correction can be used to deepen patients' insight into their condition as well as the surgical repair process. Bizzotto et al. showed that the preoperative analysis of 3D printed models of patient bone fractures, compared with analysis of 2D and 3D reconstruction on screens alone, resulted in surgeons and residents reporting a significant improvement in understanding fracture patterns. The model was able to accurately display features such as dislocation of the articular surface and joint fragmentation. These elements aided in the surgical planning, such as screw measurement and plate positioning [7]. Additionally, intraoperative guidance with templates is possible with models printed with thermoplastics (e.g., ULTEM 1010; Stratasys, Eden Prairie, Minnesota) that can be autoclave sterilized.

L.C. Hieu along with his colleagues presented design methods of cranioplasty implant using medical rapid prototyping technology. The skull formed with the help of CT data and reverse engineering is used to construct the 3D model. It is based upon two types of data first is Stereo Lithography files (STL) and bone slice contours (Strata Sys Layer files (SSL) and Initial Graphics Exchange Specification (IGES) [8]. This data was acquired is more achievable in easy construction and reverse engineering of medical implants. He also reviewed additive manufacturing in medical and methods which based on medical imaging data and reverse engineering. 3D models for anatomical studies were constructed. These methods are successful for design and manufacturing of medical devices, surgical aid tools, implant and bio-models and was presented in the write up titled, '**Medical rapid prototyping applications and methods**' [9].

Similarly, J. Domanski in his study, '**Rapid prototyping in the intervertebral implant design process**' [10], presented his methodology to create new lumbar intervertebral disc implants with specific emphasis on the use of rapid prototyping technologies. The design process was based on the computed tomography (CT) scan data, the lumbar spine bone tissue anatomical parameters were achieved, which were the basis for the design and manufacturing process carried out with the use of computer-aided designing/computer-aided manufacturing systems/computer-aided engineering. The achievement was accurate solutions to problems related to the reconstruction of geometry and the functionality of disc using the three rapid prototyping technologies FDM, 3DP and SLM.

Many more scientists have been working on these processes to build up a strong uphold of the prevalence of Additive Manufacturing in medical sciences, especially, in surgical planning and prosthetics.

1.3. Problem Objectives

With a wide variety of tasks that AM perform it is very much visible to assess that its contributions will disrupt the manufacturing industry. Moreover, Am combines with 3D scanning will pervade every engineering and medical domain possibly known to humankind. There have been many cases, which are discussed later in this report which was fatal and needed extreme care to operate and other postoperative measures. Products infused with bio-ink and created with AM have been used to attenuate patients’ sufferings.

Through this project, we tend to bridge the gap between and express possibilities which might have been taken for granted by people due to inappropriate information about the domain.

1.4. Problem definition

Cranial nerves are a set of each of twelve pairs of nerves which arise directly from the brain, not from the spinal cord, and pass through separate apertures in the skull. These nerves form the underlying circuitry of the brain, which is protected by a hard skull. It is because of this skull we evade neural injuries. However, in doing so, some damage is sustained to the skull.

So, we propose to create a prototype of a damaged skull and its prototype scaffold using additive manufacturing processes. Also, we created a successful clear map of human cranial nerves and enhanced the prominent areas, which will be very useful for neurological surgery and practices.

1.5. Scope of Work

This project aims to unfold the studies that have been performed all over the world and applied to real life instances. The issues raised in this study will have a great significance for the upcoming researchers and will form a base of study for future innovations. Growing demand for prosthetics, high surgical mortality rate and the anatomical prosthetic rejection are compelling researchers to get involved in creation of these products. Moreover, there have been issues and limitations on the application of these products.

1.6. Research Limitations

In this project the things that are taken into account are cranial nerves and skull, which are one of the most delicate parts of the human body and people are more than conscious while treating them. There have cases where people have denied for neurological treatment.

The only limitations to this technology are the application of inappropriate biomaterials and the patient's confidence on the technology. Apt researchers can accomplish the above limitation for biomaterials and latter by education and informing people of the new technology.

1.7. Conclusion

In this chapter, we discussed the introduction of Additive Manufacturing technology and its application in orthopaedics. We also discussed why we needed to do this study, what has been till now in the study, what is our project problem and definitions. Moreover, the scope of our work, research limitations have also been discussed.

CHAPTER II

LITERATURE REVIEW

2.1. Introduction

In this chapter, we will be discussing additive manufacturing in detail. Questions about AM will be answered. And not only AM will be reviewed but also the where it is used (its applications) and other specific examples of the processes that have been crucial to classify AM as disruptive Manufacturing.

2.2. Additive Manufacturing

Additive manufacturing processes take the information from a computer-aided design (CAD) file that is later converted to Standard Tessellation file (STL) file. In this process, the drawing made in the CAD software is approximated by triangles and sliced containing the information of each layer that is going to be printed. There is a discussion of the relevant additive manufacturing processes and their applications. The aerospace industry employs them because of the possibility of manufacturing lighter structures to reduce weight. Additive manufacturing is transforming the practice of medicine and making work easier for architects. In 2004, the Society of Manufacturing Engineers did a classification of the various technologies, and there are at least four additional significant technologies in 2012. Studies are reviewed which were about the strength of products made in additive manufacturing processes. However, there is still a lot of work and research to be accomplished before additive manufacturing technologies become standard in the manufacturing industry because not every commonly used manufacturing material can be handled. The accuracy needs improvement to eliminate the necessity of a finishing process. The continuous and increasing growth experienced since the early days and the successful results up to the present time allow for optimism that additive manufacturing has a significant place in the future of manufacturing.

Types of Additive Manufacturing Processes

a. VAT Polymerization

b. Power Bed Fusion

c. Fused Deposition Modelling

d. Material Jetting

e. Binder Jetting

f. Direct Energy Deposition

g. Laminated Object

2.3 Applications

2.3.1 Lightweight Machines

With additive manufacturing technologies it is possible to manufacture lightweight parts which can be used in automotive and aerospace industry, where the primary goal is to make the lightest practical car or aircraft while securing safety. Additive manufacturing technologies have enabled the manufacturing of complex cross-sectional areas like the honeycomb cell or every other material part that contains cavities and cut-outs which reduce the weight-strength relation. It is possible to create lightweight structures; they are methods to get a shape that has a minimum weight of the hanging method and the soap film method. The hanging method and the soap fill method produce a complicated form of a structure which has been used for civil construction, but with additive manufacturing, it is possible to create structural parts for machines using the shape described by these methods and reducing the total weight. Selective laser sintering and electron beam are now used in the aircraft and aerospace industries. Engineers perform design within the manufacturing constraints but this process expands the limits. With SLS and EBM, the limit will be the engineer's imagination. They open a whole new dimension of possible designs with almost any pre-alloyed metal powder. With the traditional process, these complex shape structures will be expensive to do it at all possible. With additive manufacturing printing technologies like selective laser sintering or electron beam melting, hollow structures, which are less expensive than a solid one, can be made since less material is used.

2.3.2 Architectural Modeling

Creating an architectural model can be very difficult for architects. Architects usually build their models with hand techniques, but when complex models are on their minds making a physical model can be an arduous task. Modelling is essential for the architects to study the models and their functionality. They are also needed for architects to explain them to their customers and convince them to make the project a reality. Additive manufacturing technologies can provide architects with a potent tool for their business, by being able to create a physical model faster without worrying about the complexity of their design. It also achieves a better resolution than other processes used in architecture. Architects work with CAD software, so there is no need for them to adapt to anything because the STL file is created from a CAD file. Stereolithography is a process very suitable for the architectural modelling because of the materials used and the printing resolution.

2.3.3 Medical Applications

Additive manufacturing printing technologies have vast applications in the medical world. They are transforming the practice of medicine through the possibilities of making rapid prototypes and very high-quality bone transplants and models of the damaged bone of the patients for analysis. Additive manufacturing printing methods permit to scan and build a physical model of broken bones from patients and give doctors a better idea of what to expect and plan better the procedure, and this will save cost and time and help achieve a better result. Bone transplants now can be done by printing them, and additive manufacturing methods make it possible to have a transplant that is practically identical to the original. Because of the limitless form or shape of what could be built, doctors have the option to create a porous-controlled material that will permit osteoconductivity or to create a precise metal transplant identical to the original depending on the bone to be replaced. Characteristics of the transplants such as density, pore shape and size, and pore interconnectivity are essential parameters that will manipulate tissue ingrowth and mechanical properties of the implant bone. The mechanical strength of these implants are three to five times higher than others produced by other processes, and the possibility of inflammation caused by micro debris that breaks during the procedure is reduced. Additive manufacturing is an excellent tool for dentists because they can quickly build a plaster model of a patient's mouth or replace the teeth, which have a unique form with a process like stereolithography, selective laser sintering and electron beam melting.

Figure 1. Worlds' first Jaw transplant

According to PC Magazine, an 83-year-old Belgian woman became the first-ever person to receive a transplant jawbone tailor-made for her face using a 3D printer and the surgery time and recovery were a lot less than other patients that received the same procedure. The shapes of bones differ too much between each person, and additive manufacturing printing produces transplants that fit better, and are more comfortable to insert and secure, reducing the time for the procedure and produce a better cosmetic result.

Stereolithography is being used to manufacture prosthetic sockets. By using this technology to ensure that the form of the socket adapts better to the patient while being more cost-effective than hand or machined methods. Not only hard parts like bones can be produced, also it is possible to print cells in a 3D array that with the possibility of printing complex shapes and arrays human tissue can be printed. This technology will help patients that have lost tissue in accidents or from other reasons to recover faster and with better cosmetic results. Also, 3D cell printing technologies offer the possibility of printing artificial blood vessels that can be used in the coronary bypass surgery or any other blood vessel procedure or diseases, like cardiovascular defects and medical therapy. The application of this printed blood vessels is in the future. Research in this area, also called bioprinting organs, will eventually lead to printed organs, but this could take 20 years until someone achieves it.

Cell printing is not limited to print human tissue; it is also used in the field of molecular electronics. The precision of high-resolution processes like nanolithography and photolithography permits the creation of biochips and biosensors.

2.3.4 Strength Comparison

Studies have been made to analyse the properties of the product in each process. Kim and Oh compared the properties of nonmetal additive manufacturing processes. They tested the specimens in the building direction and perpendicular to the building direction, and they found very little influence in the building directly in 3DP but an enormous influence in LOM. The figure is a comparison of the strength for LOM, Polyjet, SL, SLS, FDM, and 3DP.

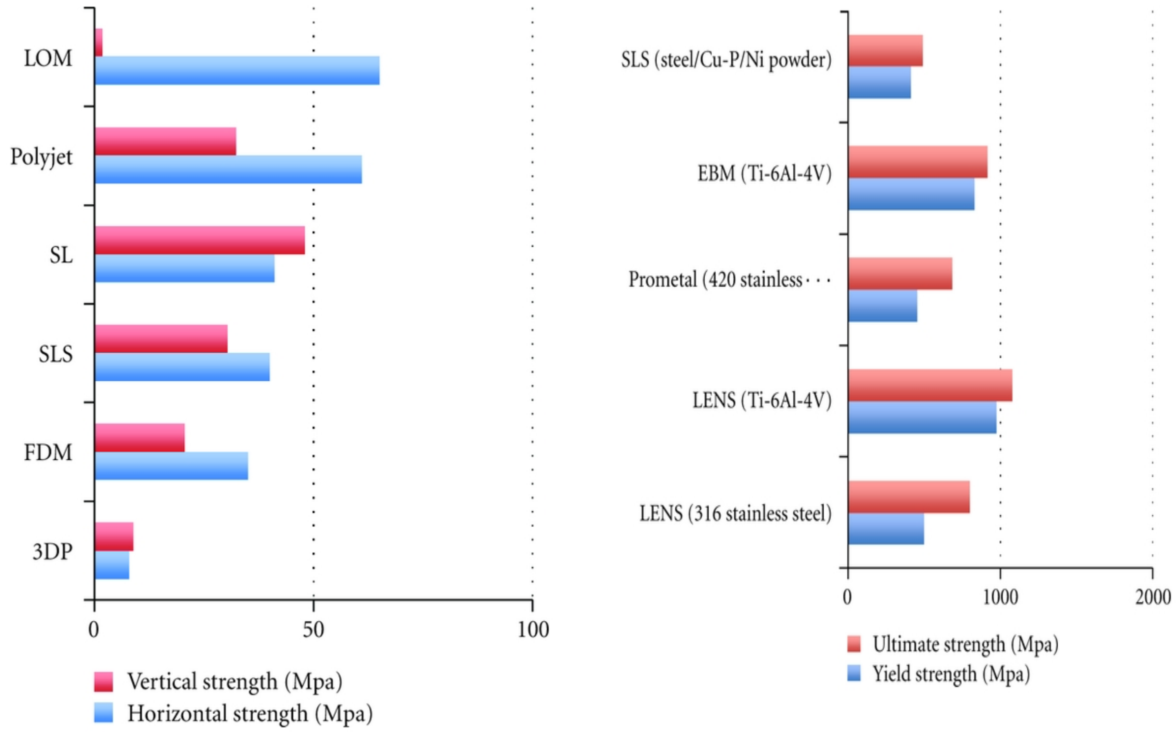

Figure 2. Comparison of the strength for LOM, Polyjet, SL, SLS, FDM, and 3DP.

A 22-year-old woman from the Netherlands who suffers from a chronic bone disorder -- which has increased the thickness of her skull from 1.5cm to 5cm, causing reduced eyesight and severe headaches -- has had the top section of her skull removed and replaced with a 3D printed implant.

A team of neurosurgeons performed the operation at the University Medical Centre Utrecht, and the university claims this is this first instance of a successful 3D printed cranium that has not been rejected by the patient.

The operation, which took 23 hours, was led by Dr Bon Verweij. The patient's skull was so thick, that had the operation not been performed, severe brain damage or death may have occurred in the near future. "It was only a matter of time before critical brain functions were compromised and she would die," said Dr Verweij. Major surgery was inevitable, but before the 3D printing technique, there was no ideal effective treatment.

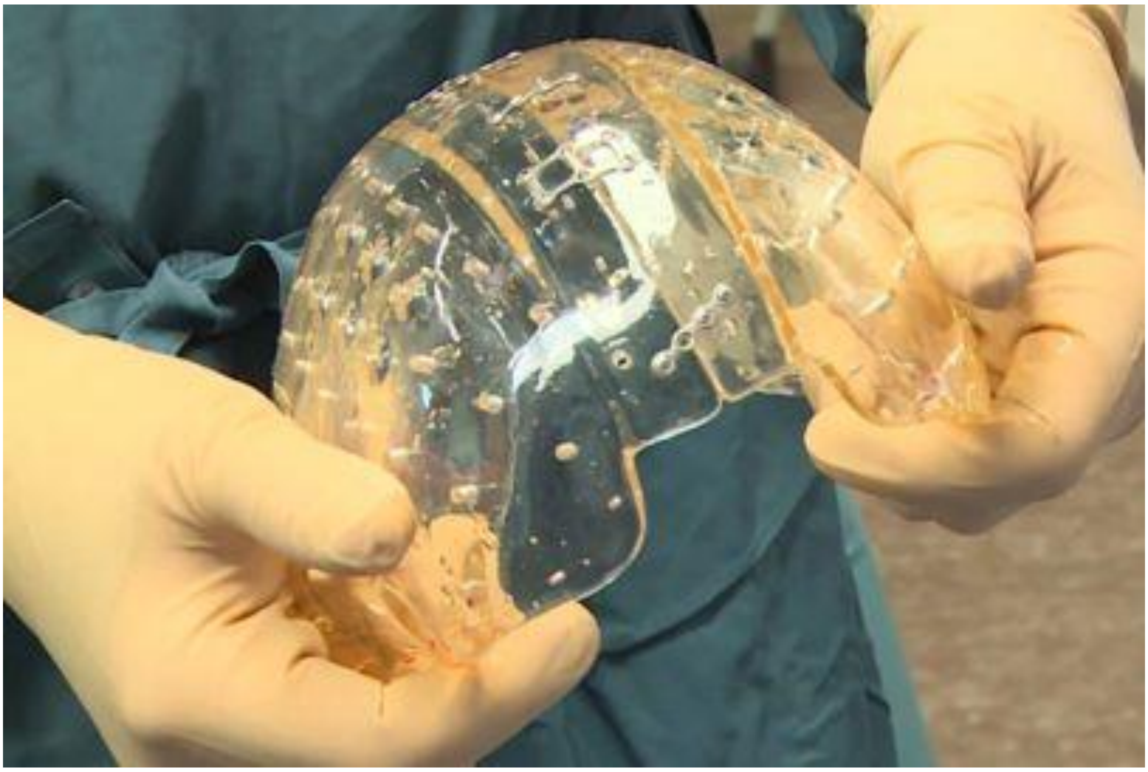

Figure 3. 3D printed Skull Implant (UMC Utrecht)

The skull was made especially for the patient using an unspecified durable plastic. Since the operation, the patient has gained her sight back entirely, is symptom-free and back to work. It is not known whether the plastic will require replacing at a later date or if it will last a lifetime.

2.4 Cases

A team of South Korean surgeons has successfully transplanted a 3D printed skull into a patient. The 60-year-old woman went to Chung-Ang University Hospital in Seoul after she developed a sudden headache, and a CT scan showed that she was suffering from a subarachnoid brain haemorrhage, a rare condition that involves bleeding between the brain and the tissues that cover it [12]. It is apparently a life-threatening condition and one that required immediate surgery.

Figure 4: The surgical team, led by Professors Kwon Jeong-tek and Lee Mu-yeol from CAUH's neurosurgery department, first had to block the blood supply to parts of the brain to prevent further bleeding. They then removed a portion of the patient's skull to relieve pressure caused by the swelling of the brain. As if things were not dire enough for the poor woman, her brain then collapsed in the portion of the skull that had been removed, requiring a skull transplant.

Though it sounds unbelievable, surgeons have replaced large portions of patients' skulls via 3D printing before. Recently doctors were able to save the life of a baby with hydrocephalus by 3D printing and implanting a titanium skull in three pieces, and a young woman was able to return to normal after a terrible accident thanks in no small 3D printed plate that surgeons attached to her damaged skull. For the Korean woman, help came from the Korea Institute of Industrial Technology (KIIT) in Gangwon, where technicians used her CT scans to model a customised reproduction of her skull, which they then 3D printed in pure titanium. The new skull fits the woman perfectly, and the operation was concluded successfully.

While surgeons have been replacing portions of patients' skulls with synthetic implants and plates for some time, the technology has always been imperfect. Figure

Figure 5: Jim Boysen with Worlds first skull transplant

Texas doctors say they have done the world’s first partial skull and scalp transplant to help a man with a large head wound from cancer treatment. MD Anderson Cancer Center and Houston Methodist Hospital doctors announced Thursday that they did the operation on May 22 at Houston Methodist. The recipient — Jim Boysen, a 55-year-old software developer from Austin, Texas — expects to leave the hospital Thursday with a new kidney and pancreas along with the scalp and skull grafts. He said he was stunned at how well doctors matched him to a donor with similar skin and colouring.

"It is kind of shocking how good they got it. I will have way more hair than when I was 21," Boysen joked in an interview with The Associated Press.

Last year, doctors in the Netherlands said they replaced most of a woman’s skull with a 3-D printed plastic one. The Texas operation is thought to be the first skull-scalp transplant from a human donor, as opposed to an artificial implant or a simple bone graft.

Boysen had a kidney-pancreas transplant in 1992 to treat diabetes he has had since age 5 and has been on drugs to prevent organ rejection. The immune suppression drugs raise the risk of cancer, and he developed a rare type — leiomyosarcoma.

Cancer can affect many types of smooth muscles, but in his case, it was the ones under the scalp that make your hair stand on end when something gives you the creeps.

Radiation therapy for cancer destroyed part of his head, immune suppression drugs kept his body from repairing the damage, and his transplanted organs were starting to fail — "a perfect storm that made the wound not heal," Boysen said.

Yet doctors could not perform a new kidney-pancreas transplant as long as he had an open wound. That is when Dr Jesse Selber, a reconstructive plastic surgeon at MD Anderson, thought of giving him a new partial skull and scalp at the same time as new organs as a solution to all of his problems.

Houston Methodist, which has transplant expertise, partnered on the venture. It took 18 months for the organ procurement organisation, LifeGift, to find the right donor, who provided all organs for Boysen and was not identified.

2.5 Conclusion

This chapter discusses Additive Manufacturing, the scope of Additive Manufacturing and the essential applications that had made Additive Manufacturing as the topic of this project.

CHAPTER III

RESEARCH

3.1 Introduction

This chapter gives you a detailed overview about what we has already been done and what we have done in our project, different tools that we have used while doing this project and a detailed discussion on them.

3.2 What has already been done?

3D printing has had and will continue to have impact on many areas. One of the most hotly anticipated areas for 3D printing to impact is medicine. By 3D printing medical models, student, doctors and other staff members can get a hands-on learning experience of a pathology, organ or a part of human anatomy. These models can be touched, passed around, discussed and are used as a learning tool worldwide. Initially 3D printed medical prototypes were high end and often hand-painted affairs. They cost hundreds or thousands of dollars and competed with handmade models. Now desktop 3D printed medical prototypes are providing for an extremely low cost alternatives. In surgical planning medical models have been used to guide extensive through complex surgeries. In cases such as conjoined twins or other high risk or highly complex procedures models can help teams to train or prepare. Though

3D printing CT,MRI or other scanning data can be converted into a unique 3D print that shows the surgical team the actual organ that they will operate on. Blood vessels and veins can be identified, specific problems can be shown right in front of the team's eyes. Stratasys has shown how its Objet PolyJet technology can be used to make patient-specific vascular flow models, while 3D Systems' healthcare facilities can bring 3D printed medical models right into the operating room.

3.2.1. Titanium Orthopedic Implants

More than 10,000 titanium orthopedic hip implants are implanted in patients every year. These implants are cheaper to produce than conventionally made ones. Acetabular cups are usually made with the Arcam EBM process but can also be made with DMLS (powder bed fusion, SLM). EBM was often criticized for having a rough surface texture. It is this texture plus the ability of the acetabular cup to be changed in order for its pore size and density to promote bone growth that means that these cups outperform those made with conventional means, at lower cost.

Patient-specific titanium implants are a research area of great interest to many orthopedics companies. In the extremities, knees, neck, femur, tibia etc. companies are looking to patent, develop and launch suitable 3D printed orthopedic implants. We’ve reported on titanium jaw implants and spinal devices.

3.2.2 Plastic Patient-Specific Implants

PEEK is a very exciting material, also for implantology. Xilloc Medical and other companies have been 3D printing and implanting PEEK patient-specific implants in a (limited) number of test patients. The ability to quickly create a custom implant that is safe to use in the patient and comparatively low cost is the key factor here.

Xilloc’s Interfix technology also predetermines the number and positioning of locations for screws. This can reduce the number of screws needed. Xilloc will even 3D print the screw length next to the right hole so the surgeon remembers to use the right screws.

MedCAD lets you upload the file and receive your medical implant within one day. Essentially it is a Shapeways for cranial implants, or Amazon Prime for PEEK implants. For CMF and other surgeries custom 3D printed implants have been used for years and the scope of the application area is widening.

3.3. What we had done?

Our main objective to print and analyse the femur and the human skull. So following are the steps that we have followed to perform our work:

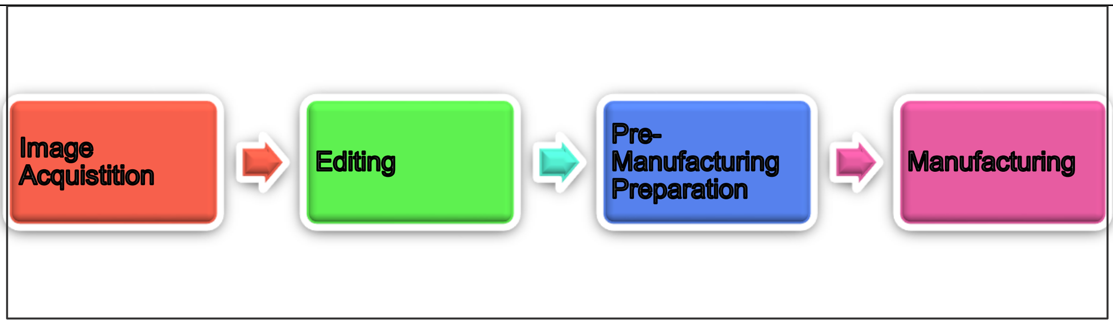

Figure 6. Process Flow to accomplish our objectives

Step1. Image Acquisition

Using the DICOM viewer and editor 3D slicer acquired and converted .dcm file from the MRI/CT scans to scalable rough 3D model. This method works as combination of regular image processing and 3D model generation.

First, the file import . **Second**, the file is volume rendered using the volume rendering tool. **Third**, it is given bone color preset and then converted to solid model using the model maker option. The figures given below are depicted in this order.

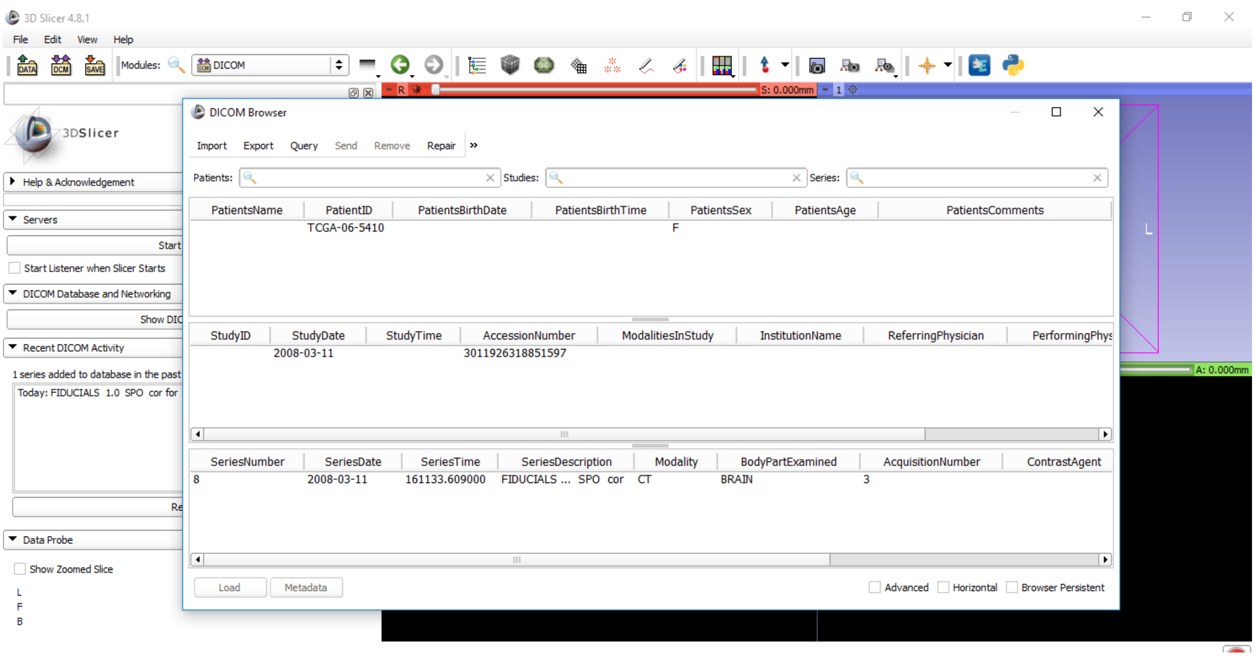

Figure 7: Screenshot of 3D Slicer Window

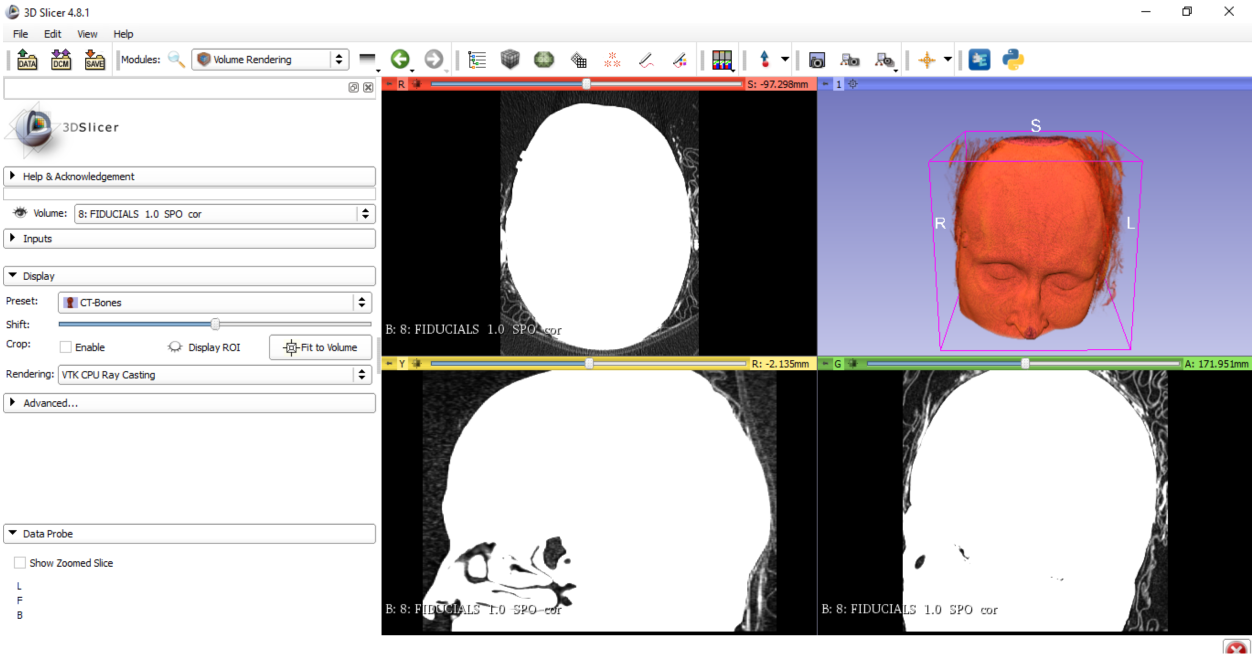

Figure 8: Acquiring Data from the MR Scan

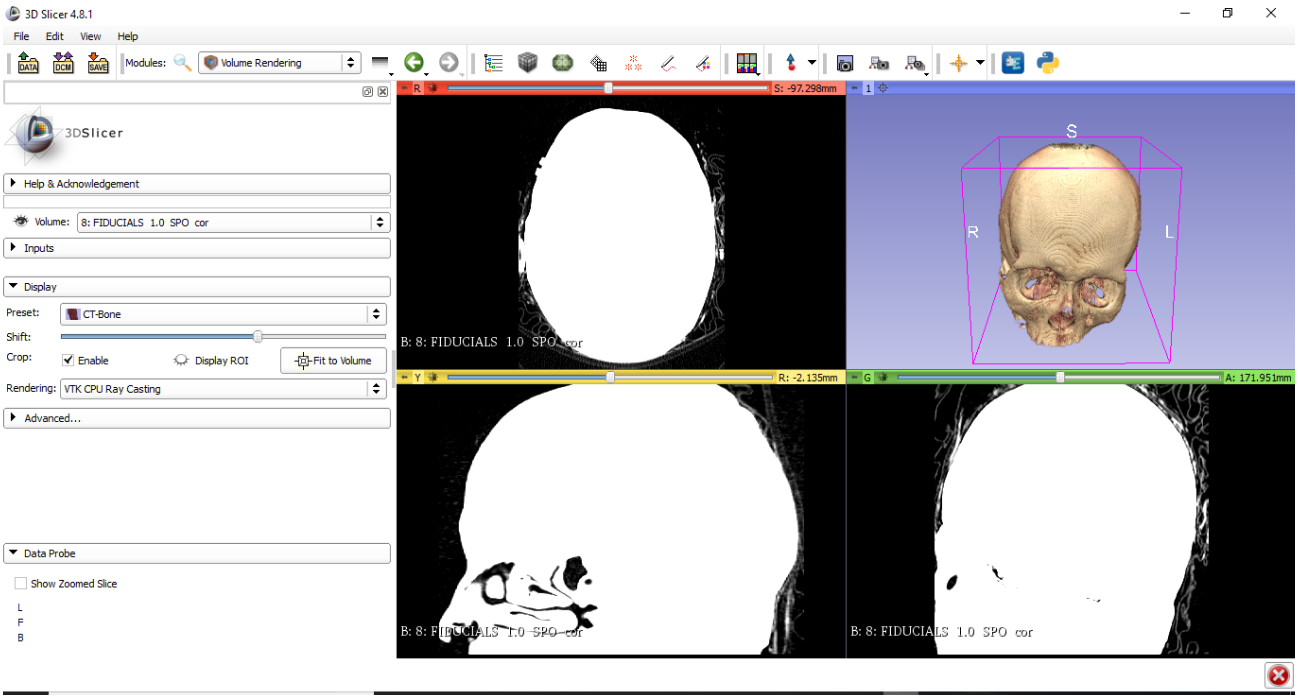

Figure 9: Initialization of Model

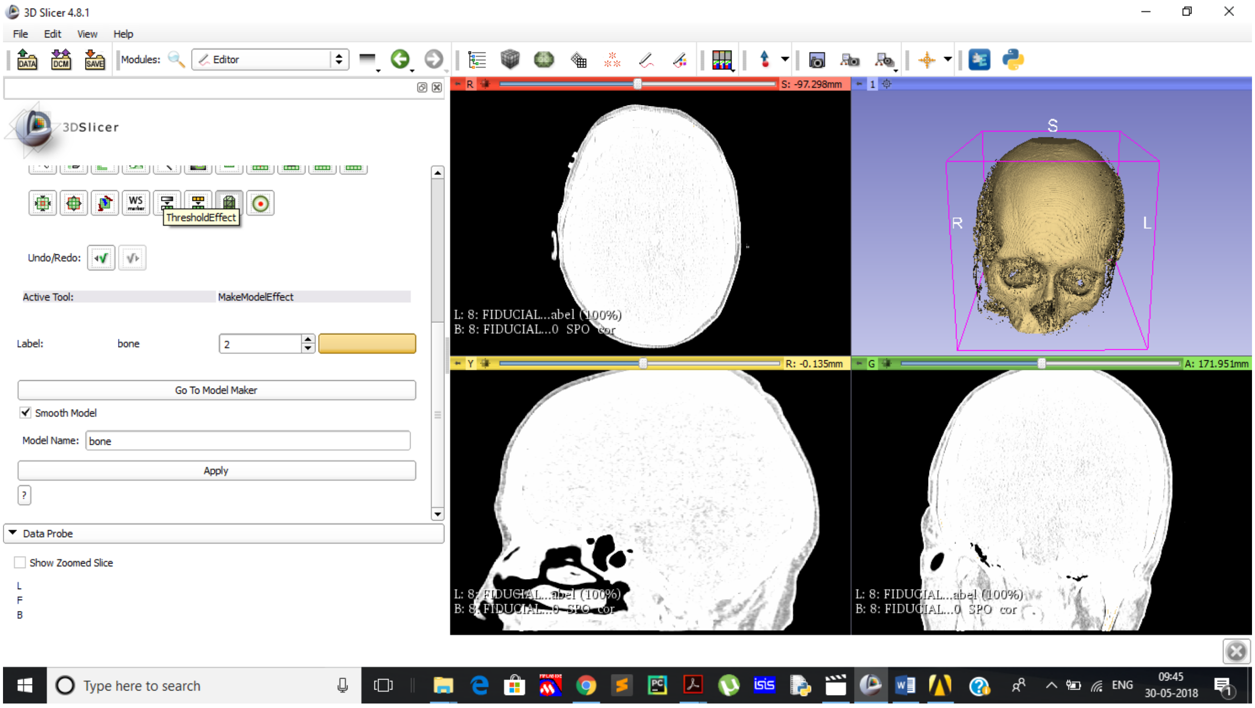

Figure 10: Final Model Creation

Step2. Editing

Using blender the features of the models was intensified.

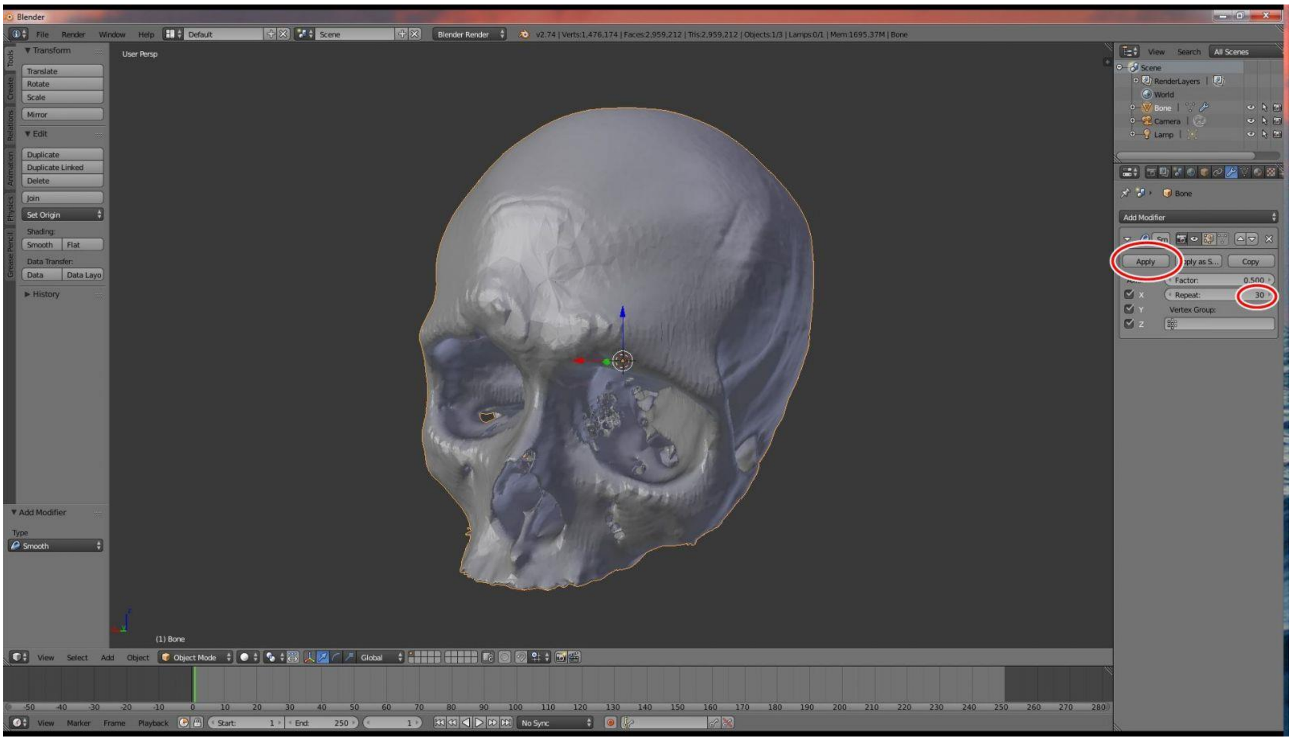

Figure 11. Blender Window with our Model

3.3.2.1 BLENDER

Blender is a professional, free and open-source 3D computer graphics software toolset used for creating animated films, visual effects, art, 3D printed models, interactive 3D applications and video games. Blender's features include 3D modeling, UV unwrapping, texturing, raster graphics editing, rigging and skinning, fluid and smoke simulation, particle simulation, soft body simulation, sculpting, animating, match moving, camera tracking, rendering, motion graphics, video editing and compositing. It also features an integrated game engine.

a. System Requirements

Processor: 32-bit dual-core 2 GHz CPU with SSE 2 supr

Memory: 2GB RAM

Graphic Card: Open GL, compatible card with 512 MB video card

Display: 1280*768 pixel, 24- bit colour

Input: Mouse & Track-pad

Step3. Pre-manufacturing Preparation

Finally, using Autodesk Meshmixer the model was repaired for any discontinuities. It is tool for working with meshes and mixing them up. As per the website, it is a state of art software used for working with meshes [13]. It helps us to clean 3D scanned models to make them more printable.

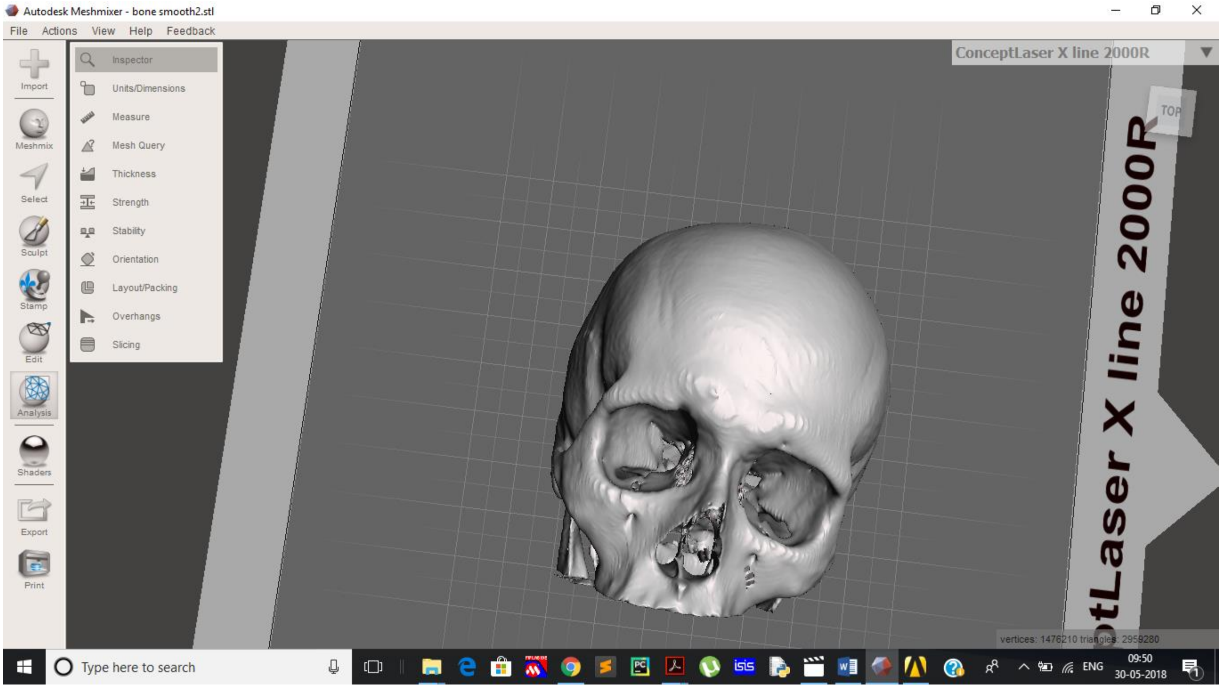

Figure 12. Meshmixer Window (Analysis)

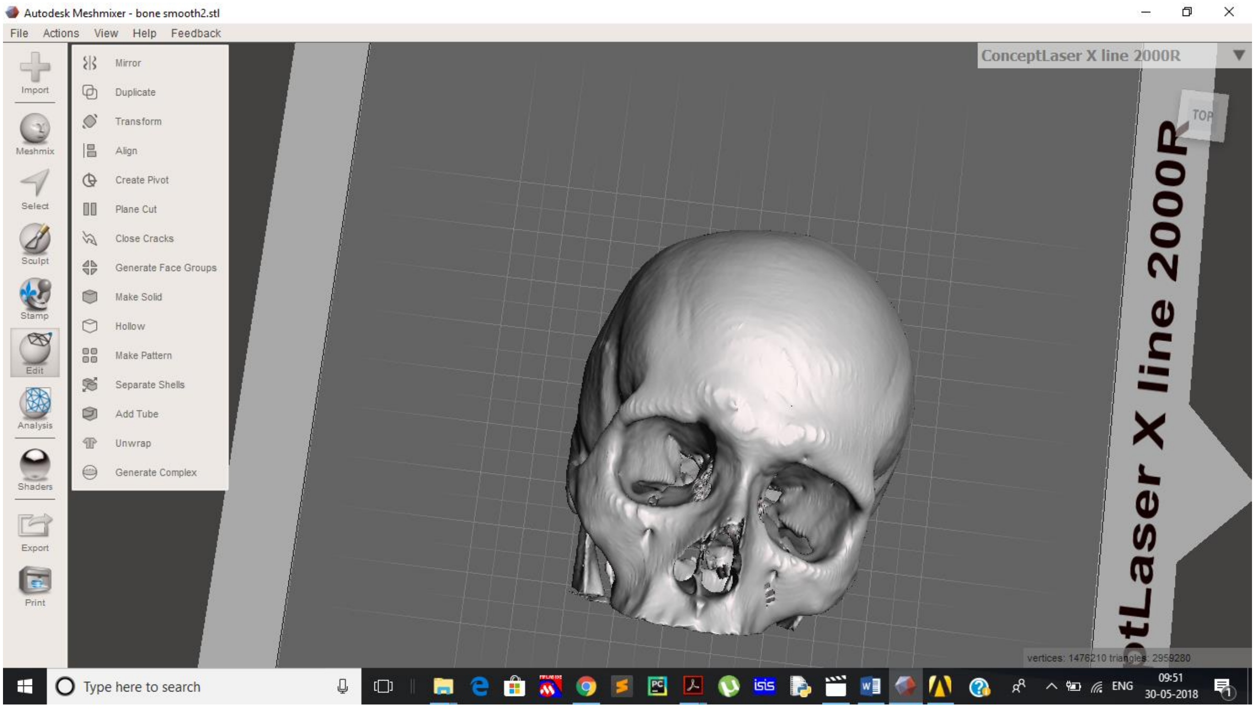

Figure 13. Meshmixer Window (Edit Menu)

Step4. Manufacturing

Using 3D Print software, the data was fed to 3D systems' Projet 460 machine for the manufacturing.

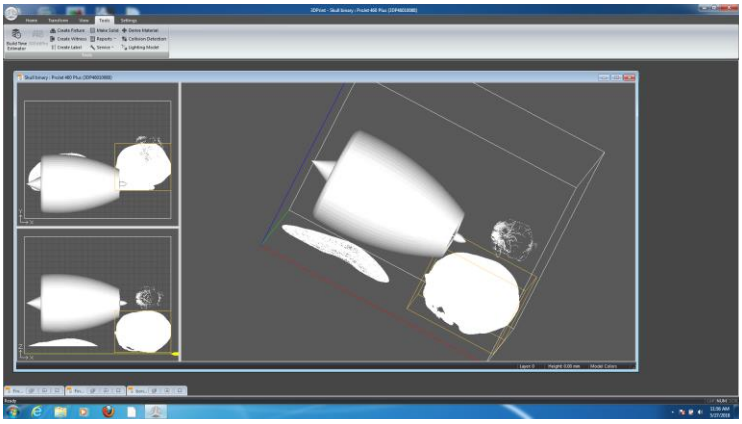

Figure 14. 3D print Software Window

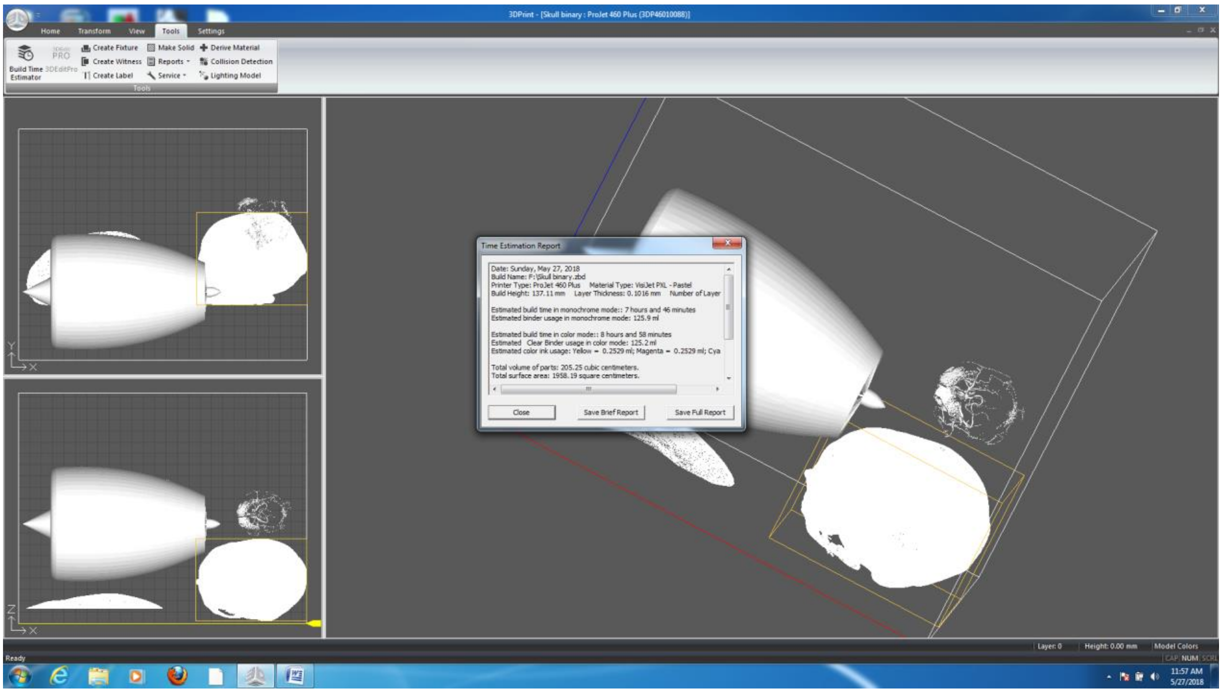

Figure 15. Software window showing Print time

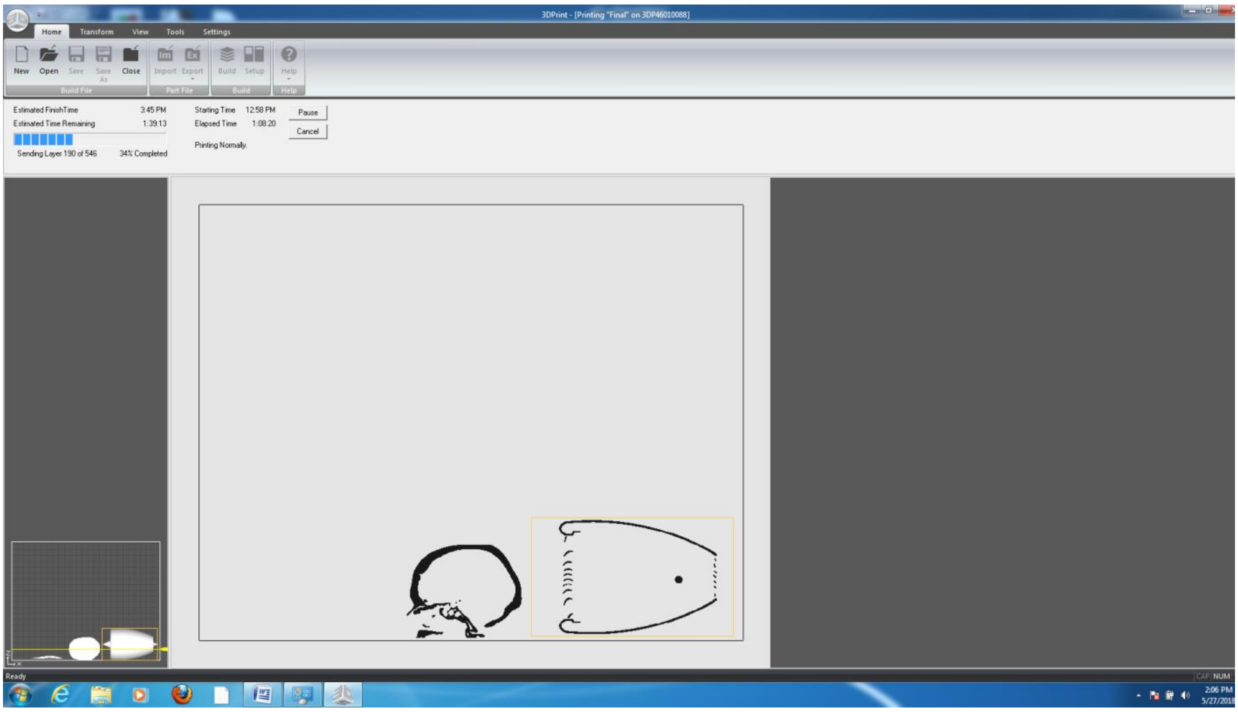

Figure 16. The Print process

3.3.4.1 3Ds PROJET 460

Incorporating advanced 3-channel CMY full-color 3D printing and integrated cleaning station, the ProJet CJP 460 operates with safe build materials, active dust control and zero liquid waste, making it an ideal office companion for a wide range of applications.

a Color 3D printing

Use the ProJet CJP 460 to create beautiful, photo-realistic parts in CMY colour with the ability to use full texture/UV mapping to evaluate the look better, feel, and style of product designs, without paint. Stakeholders can better visualise design intent and can make faster and more effective decisions.

b **High throughput**

The ColorJet printing technology allows the fastest print speeds, 5x–10x faster than all other technologies, to deliver models in hours, not days. Its high throughput supports an entire department with ease.

Figure 17: 3Ds ProJet 460

c **Low part cost**

Based on reliable and affordable CJP technology, the ProJet CJP 460 prints parts at up to 7x lower cost than other technologies. Featuring efficient material use, you will eliminate waste and reduce finishing time as no supports are necessary and the unused core material is recycled.

3.3.4.2 APPLICATIONS:

a. Concept modelling

i. Communication, sales and marketing models

ii. Rapid design iteration

iii. Display/art models

b. Simulation models

i. Surgery practice

ii. FEA analysis

iii. Assemblies visualization

iv. Ergonomics

c. Colour and texture validation

3.3.4.3 FEATURES:

a. ColorJet Printing technology

b. Max build envelope capacity
(W x D x H): 8 x 10 x 8 in
(203 x 254 x 203 mm)

c. Printing in CMY colour

d. Using natural products based build materials

e. Conveniently integrated part cleaning station

f. Effective, safe and easy models infiltration with the down-draft workbench (optional)

3.3.4.4 BENEFITS:

a. Unique professional quality colour

b. Fast print speed

c. Low operating costs

d. Safe and eco-friendly

e. Easy post-processing with no supports to remove

f. Choose from a range of part finishing options to meet your application requirements

3.3.4.5 Magnetic Resonance Imaging

Magnetic resonance imaging (MRI) uses a large magnet and radio waves to look at organs and structures inside your body. Healthcare professionals use MRI scans to diagnose a variety of conditions, from torn ligaments to tumours. MRIs are very useful for examining the brain and spinal cord.

a. What is MRI of the Head?

Magnetic resonance imaging (MRI) is a noninvasive medical test that physicians use to diagnose medical conditions.

MRI uses a powerful magnetic field, radio frequency pulses and a computer to produce detailed pictures of organs, soft tissues, bone and virtually all other internal body structures. MRI does not use ionising radiation (x-rays).

Detailed MR images allow physicians to evaluate various parts of the body and determine the presence of certain diseases. The images can then be examined on a computer monitor, transmitted electronically, printed or copied to a CD or uploaded to a digital cloud server.

Currently, MRI is the most sensitive imaging test of the head (particularly the brain) in routine clinical practice.

b. Benefits of MRI

- MRI is a noninvasive imaging technique that does not involve exposure to ionising radiation.
- MRI can help physicians evaluate the structures of the brain and can also provide functional information (fMRI) in selected cases.
- MR images of the brain and other cranial structures are clearer and more detailed than with other imaging methods. This detail makes MRI an invaluable tool in early diagnosis and evaluation of many conditions, including tumours.
- MRI enables the discovery of abnormalities that might be obscured by bone with other imaging methods.
- The contrast material used in MRI exams is less likely to produce an allergic reaction than the iodine-based contrast materials used for conventional x-rays and CT scanning.

- A variant called MR angiography (MRA) provides detailed images of blood vessels in the brain—often without the need for contrast material. See the MRA page for more information.
- MRI can detect stroke at a very early stage by mapping the motion of water molecules in the tissue. This water motion, known as diffusion, is impaired by most strokes, often within less than 30 minutes from the onset of symptoms.

c. Risks Involved

- The MRI examination poses almost no risk to the average patient when appropriate safety guidelines are followed.
- If sedation is used, there are risks of excessive sedation. However, the technologist or nurse will monitor your vital signs to minimise this risk.
- Although the strong magnetic field is not harmful in itself, implanted medical devices that contain metal may malfunction or cause problems during an MRI exam.
- Nephrogenic systemic fibrosis is currently a recognised, but rare, a complication of MRI believed to be caused by the injection of high doses of gadolinium-based contrast material in patients with inferior kidney function. Careful assessment of kidney function before considering a contrast injection minimises the risk of this infrequent complication.
- There is a very slight risk of an allergic reaction if contrast material is injected. Such reactions are usually mild and easily controlled by medication. If you experience allergic symptoms, a radiologist or other physician will be available for immediate assistance.

3.4. Conclusion

This chapter was focused on our research. It explains the methodology and tools we used and the software we learnt to execute this project. Everything starting from image acquisition to the completion and the machine we used has been discussed in this chapter.

CHAPTER IV

RESULTS AND DISCUSSIONS

4.1. Introduction

This Chapter provides results and discussion about the whole project and discusses the scope of Additive Manufacturing.

4.2. DISCUSSION

This technology provides a means for surgeons to prepare for difficult surgeries, allowing them to practice on a model with a patient’s exact anatomy. This method permits them to plan the surgery procedure precisely, which then improves the patient outcomes and treatments.

Being able to practice on an identical model has allowed surgeons to complete their operations faster and with less patient trauma. It also allows surgeons to prepare for problems that might arise during the surgery and decide how to handle them accurately.

In actual practice, the skulls can be corrected to scale or as required and can take anywhere from 2 to 40 hours to print, depending on the size of the skull and degree of accuracy required. The skulls are made out of Acrylonitrile-Butadiene-Styrene plastic. In our project, we used Calcium Sulphate powder and an Epoxy jet binder to accomplish this task.

Merging the use of additive manufacturing to the field of surgery has produced models which replicate patient’s bony anatomy, where the surgeon can perform pre-operative planning surgery on these models. Throughout the centuries, surgeons have been trying to make changes in the field of maxillofacial surgery in understanding complex anatomical details of the maxillofacial region for the benefit of patients.

For the current case study, AM medical model of the patient is fabricated using the readily available Polyjet machine, which reduced the cost of the preplanning medical model. The other advantage of the medical model is adapting or bending of mesh plate before the surgery.

With the exact fit of the orbital mesh plate, surgery time is reduced by 40 minutes. The reduced surgery time improved the safety of the patient. The accuracy of the FDM model can be further improved using specific algorithms.

Determination of the important anatomical structures or landmarks for plastic surgery was complicated before the advent of 3D models. These models have given an added perfectionism and ease to the surgeon in efficiently shaping the mesh/ replacement for operation, which in the absence of 3d technology would've required multiple try-ins on the patient, thereby resulting in a considerably higher risk of trauma to essential structures in close vicinity to the target structure.

By testing the replacement which may be a mesh or bio-acceptable plastic over the 3d replica will facilitate in the optimal, precise and accurate placement of the replacement on the patient. Minimal or no corrections may be required, thereby minimizing the chances of failure of fitting and risk of damage to nearby structures.

In this project’s case, a smaller sized replica was manufactured using Projet 3D printer so as to understand the rough degree of accuracy offered by the printer in comparison to the actual MRI scan.

Recent advances in 3D printing have enabled biocompatible materials to be applied to regenerative medicine in order to address the growing need for tissues and organs, including the bone. The aging population, with its concomitant increased risk of osteoporosis, osteoarthritis, bone injuries, and obesity, are significant contributors to orthopedic implant failure. Due to its ability to be tailored for patient-specific needs, the demand for 3D-printed bone will only increase in the coming years. By utilizing low-cost material, such as Gypsum powder in our study, we can further show its biocompatibility and cellular response, the road to custom created bone graft substitutes is easier and more affordable. Moreover, Gypsum powder has good absorbent properties, which makes it a better choice of material than plastics. It can easily incorporate biomaterial aptly and produce a bone like structure. Further, this property of it makes it identical to bone structure, as bones are also made of calcium sulphate and its structural strength can be easily enhanced by similar methods.

4.3. RESULT (OUR WORK)

The prototypes we produced and the scalable models were printed using 3Ds' Project 460 machine. The results suggested that the 3d printed model was optimally accurate and provided sufficient details of the skull so as to evaluate possible injuries (which may result from radiation from cancer treatment (Abnormal growth of bone), high speed accidents which may fracture the skull beyond the scope of recovery, genetic abnormality among children caused by premature births, radioactive radiation or physical impact on foetus) and by noting these details a plastic surgeon can conveniently plan a course of surgery so as to cater to all problems present with efficiency.

The largest impediment to the implementation of 3D printers in orthopedics is the cost associated with the time it takes for medical staff to operate the machinery—the building material itself is relatively inexpensive, and printer prices are continually dropping. Three-dimensional printer technology may advance to the point that even an untrained user could operate a 3D printer efficiently, or better yet, the entire process of printing from image acquisition to rapid prototyping may become automated. A solution to the labor costs of printing may be the outsourcing of medical 3D printing operations to a dedicated third-party company. That way, medical staff would not need 3D printing training, and economical advantages of scale could provide access to inexpensive, customized 3D printed products.

Figure 18. The model just after Manufacturing

Figure 19. Model and Scaffolding just before post-processing

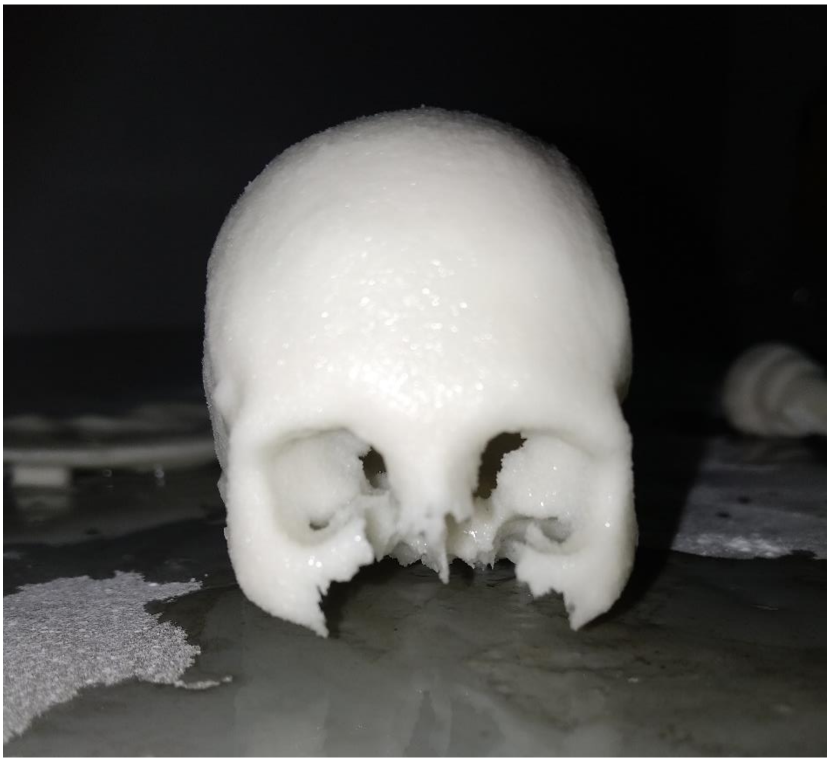

Figure 20: Just After Post Processing

Figure 21. Post Processed Model (Image of Scaffolding Unavailable)

4.4. Our future work

In near future we plan to create more and more body parts, especially related to medical sciences such as the true map of cranial nerves, ankle bone repairs and the lumbar spine.

Theses 3D printable models are ready to be printed.

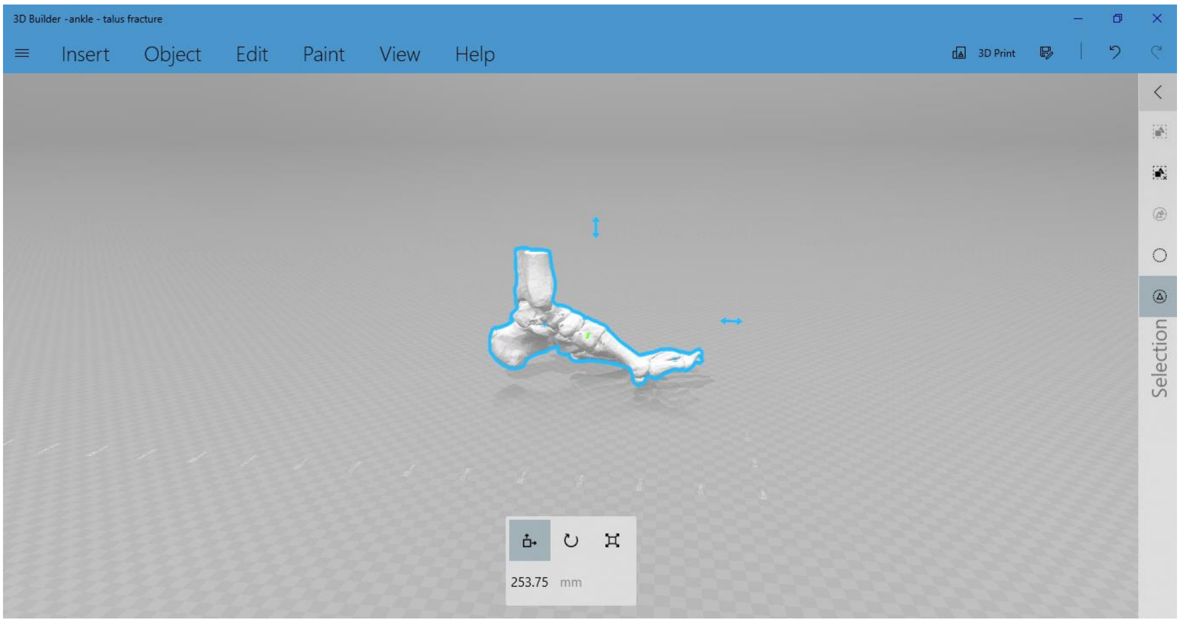

Figure 22. Repaired Ankle joint

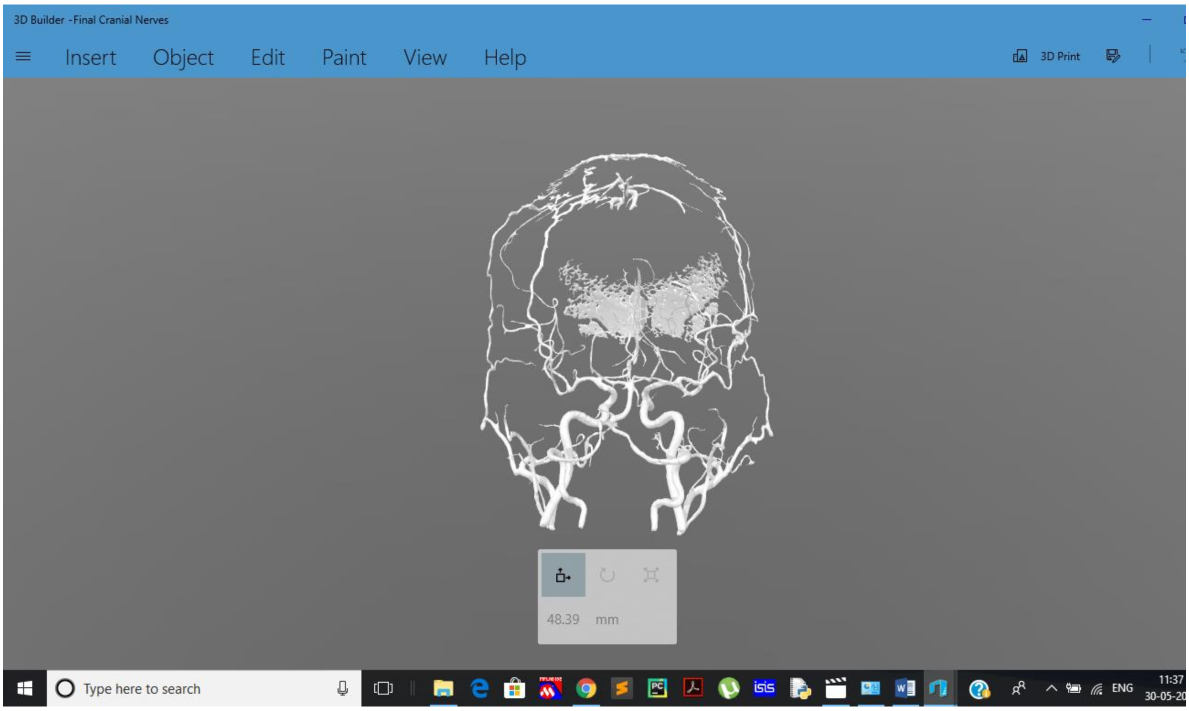

Figure 23. Mapped Cranial Nerves

4.5. Conclusion

This chapter discussed the results we received after performing our project tasks and the future of Additive Manufacturing in our domain.

CHAPTER V

CONCLUSION AND FUTURE SCOPE

5.1. Introduction

In this chapter we conclude our work and project with note of summary of limitations we faced and the future scope of our work.

5.2. Major contribution of work

The use of physical models for treatment planning and visualization, instead of the sole use of CT, MRI data or virtual reconstruction, has a number of distinct advantages. Software methods which give the illusion of 3D volumes on a 2D screen can cause problems regarding the viewing angle, depth, transparency and lighting anomalies that manifest as viewing orientation uncertainties[10]. Successful surgical correction of deformities such as of the hip joint before the onset of osteoarthritis requires the accurate characterization of anatomical deviations as the first step in the planning of a corrective osteotomy. Pedicle screws inserted with a standard surgical technique have sometimes penetrated the outer bony wall or even missed the pedicle [14]. Complex anatomical relationships (bone fragments in the vicinity of fracture sites, for example) can be better appreciated on 3D solid models 'in hand'. Touch seems to recalibrate the visual perception so that it is better able to infer depth from the retinal projection [15]. The sensory information exploited by the haptic system for the recognition of real objects is made by kinesthetic and cutaneous inputs. While kinesthetic inputs refer to the perception of the spatial configuration of the hand and fingers, the cutaneous inputs deal with the perception of the contact conditions between the human hand and the real object [16]. Vision and touch generate functionally overlapping, but not necessarily equivalent, representations of 3D shape. Within the orthopaedic and traumatology field, 3DP also enables advance testing of the surgical procedure; this possibility can lead to a better intervention outcome and a reduction of operation time. 3D-printed models can be a useful tool for the teaching and training of novice surgeons, improving the quality of training and the learning curve.

As 3D printing technology advances and the cost of printing drops, the speed of printing increases, and the operation of printers becomes easier, the use of custom 3D printed models of patient bone may become standard in preoperative planning, surgical simulation, intraoperative guidance, and implant development.

Should 3D printer technology advance to the point that 3D printer use is widely accepted in a sterile hospital environment, one potential use of readily available 3D printers could be the on-demand manufacturing of customized surgical instruments that would otherwise be unavailable due to prohibitive costs or rare use.

Another possible application is in operations requiring reconstruction of large bone defects. A “negative” mold of the required implant would enable the surgeon to shape the implant to the proper dimensions for optimal fit even before the surgery is performed. Three-dimensional printed biologic and bone-like implants may be used to optimize restoration of original structure and function.20 Three-dimensional printers also have the potential to rapidly increase the number of tools available to surgeons. With the aid of a designer, surgeons could modify mass-produced instruments to suit their particular needs and preferences. The availability of rapid prototyping may spur instrument innovation because surgeons can easily produce novel tools to satisfy unmet needs during an operation.

5.3. Limitations:

There were some limitation we faced. The limitation in any project arise due to either inept knowledge or unavailability of resources. We had the following limitations:-

a. We were not able to gather enough number of MR or 3D scans of patients who were injured to present what we intended to

b. Due to boundary and limited connected we were able to present and discuss out project work with higher authority medical officials

c. We were not able to complete our Additive Manufacturing process because of the unavailability of the best condition of machine tool

5.4. Future scope:

With 3D printed organs, the problem of donor shortage for transplant organs could be diminished as patients would no longer have to wait for donors. This is a potential innovation of 3D printing, in addition to providing more accurate and planned surgery, reduced surgery time and new teaching methods in residency [11].

"This is the tip of the iceberg of where 3D printing is going to venture into medicine," Plastic Surgeon Dr Jonathan Black said. "We are going to see … 3D printers that print bones … And that'll be the first stage of where we'll start implementing 3D printed stuff, and it will go all the way up to a point in 10-30 years we will see 3D printed organs we have transplanted in."

The advent of image processing and 3D printing technology is opening up many opportunities in patient-specific applications in orthopedics. The modern high-resolution medical imaging data can further be processed to create 3D images that are essential for 3D printing of physical objects [17]. The 3D printing technology has been reported to be beneficial in patient-specific orthopedics, such as for the creation of anatomic models for surgical planning, education and surgical training, PSIs, and 3D-printed custom implants. Besides being anatomically conformed to a patient’s surgical requirement, 3D-printed implants can be fabricated with scaffold lattices that may facilitate osteointegration and reduce implant stiffness. Early results in revision hip arthroplasty and bone tumor surgery have been promising. However, limitations including high cost of the implants, the lead time in manufacturing, and lack of intraoperative flexibility need to be addressed. Materials like PEEK, which are biocompatible and have superior strength and heat resistance, have been investigated for use in 3D printing. In addition, 3D printing has been incorporated into drug delivery systems that may restore bony anatomy and deliver therapeutic compound to the target tissue. To increase utilization of 3D printing technology in orthopedics, an all-in-one computer platform should be developed for easy planning and seamless communication among different care providers. Further objective investigation into the clinical efficacy of the technology is needed before one can put the technology into routine clinical practice in orthopedics.

5.5. Concluding remarks

Our project deals with the Medical application of Additive Manufacturing and its future.

Throughout centuries, surgeons have been trying to make changes in the field of maxillofacial surgery (relating to the jaw and face) in understanding complex anatomical details of the maxillofacial region for the benefit of patients.

By merging the use of additive manufacturing to the field of surgery, models have been developed that replicates the patient's bony anatomy, where the surgeon can perform pre-operative planning surgery on these models.

Medical models which are customized and sourced from the data of an individual patient. Details may vary from patient to patient can well be modified and printed.

An advantage is a reduced cost of preplanning a medical model, being able to adapt the mesh plate or replacement before the surgery, hence having the exact fit and also reducing the time of surgery which improves the safety of the patient.

REFERENCES AND BIBLIOGRAPHY

1. Biomedical devices. http://www. oxfordpm.com/biomedical_parts. php. Accessed May 30, 2015.
2. Eng J. Medical first: 3-D printed skull successfully implanted in woman. http://www. nbcnews.com/science/science-news/medical-first-3-d-printed-skull-successfully-implanted-woman-n65576. Accessed May 29, 2015.
3. Richmond S. 3D printer builds new jaw bone for transplant: an 83-year-old woman has become the first person to have a 3D printer-created jaw fitted. The Telegraph. February 7, 2012. http://www.telegraph.co.uk/ technology/news/9066721/3D-printer-builds-new-jaw-bone-for-transplant.html. Accessed May 30, 2015.
4. Singare S, Liu Y, Li D, Lu B, Wang J, He S. Individually prefabricated prosthesis for maxilla reconstruction. J Prosthodont. 2008; 17(2):135-140.
5. Starosolski ZA, Kan JH, Rosenfeld SD, Krishnamurthy R, Annapragada A. Application of 3-D printing (rapid prototyping) for creating physical models of pediatric orthopaedic disorders. Pediatr Radiol. 2014; 44(2):216-221.
6. Epps HR. 3-D printing helps with complex hip surgery: pediatric orthopaedists find it helpful for patient education tool. AAOS Now. July 2014. http://www.aaos.org/news/aaosnow/jul14/clinical4.asp.
7. Bizzotto N, Sandri A, Regis D, Romani D, Tami I, Magnan B. Three-dimensional printing of bone fractures: a new tangible realistic way for preoperative planning and education. Surg Innov. pii:1553350614547773. Epub ahead of print
8. L.C. Hieu, E. Bohez, J. Vander Sloten, et al.Design for medical rapid prototyping of cranioplasty implants, Rapid Prototyp J, 9 (2003), pp. 175-186
9. L.C. Hieu, N. Zlatov, J. VanderSloten, et al.Medical rapid prototyping applications and methods, Assembly Automation, 25 (2005), pp. 284-292
10. 3D printing: clinical applications in orthopaedics and traumatology
11. https://www.huffingtonpost.com/peter-mellgard/medical-3d-printing-future_b_7088994.html
12. https://3dprint.com/128423/3d-printed-skull-surgery/
13. http://www.meshmixer.com/

14. Brown GA, Firoozbakhsh K, DeCoster TA, Reyna JR., Moneim M. Rapid prototyping: the future of trauma surgery? J Bone Joint Surg Am 2003;85-A(suppl 4):49-55. PMID:14652393.
15. Pietrabissa A, Marconi S, Peri A, et al. From CT scanning to 3-D printing technology for the preoperative planning in laparoscopic splenectomy. Surg Endosc 2016;30:366-71.doi: 10.1007/s00464-015-4185-y. Epub 2015 Jul 3.
16. Frisoli A, Solazzi M, Reiner M, Bergamasco M. The contribution of cutaneous and kinesthetic sensory modalities in haptic perception of orientation. Brain Res Bull 2011;85:260-6.
17. 3D-printed patient-specific applications in orthopedics by Kwok Chuen Wong