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Production of Anatomical Models from CT Scan Data

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PRODUCTION OF ANATOMICAL MODELS FROM CT SCAN DATA

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Abstract

Rapid Prototyping (RP) technology was conceived in the mid 1980s as a method of manufacturing models, particularly to support the design of new motor vehicles. However as early as 1995 the potential to take data from medical scanners and generate models of patient anatomy to assist clinicians plan complex surgical procedures had been recognised, albeit by researchers rather than the mainstream medical industry. Over the last 15 years the production of preoperative planning models has increased dramatically and moreover, the potential to produce customised implants recognised.

Although RP technology is now established in the medical field work is still on going to develop new applications (the majority of cases still reside in craniomaxillofacial field), explore the use of different RP methods and overall improve the efficiency of the approach.

In this project the latest medical data processing software tools will be used to generate models for preoperative planning and also medical training and the results reviewed. A comprehensive literature review in the field has been conducted and publications in the medical scanning, RP, preoperative planning, biomaterials, customised medical implants and jigs are presented and discussed. Several case studies which are particularly pertinent to the trials undertaken by the author have been identified and incorporated into the report and explained in detail in order to illustrate the capability, potential and flexibility of this technology within the medical sector.

Acknowledgements

Declaration

I hereby declare that the material contained within this thesis and the practical work associated with it is the work of its author and is submitted in partial fulfilment in attaining a M.Sc. in Rapid Product Development, DE Montfort, University, Leicester, U.K.

Signed : ……………………………………………………………………..

Date : ………………………………………………………………………..

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Chapter 1.0 - Project Overview

1.1 Introduction

This project investigates the suitability of using RP technology and associated medical software solutions to transfer 2D Digital Imaging and Communications in Medicine (DICOM) data into 3d Standard Triangle Language (STL) data. This data is then utilised using medical software solutions to manufacture preoperative planning models and customised medical implants for the benefit of patients and surgical planning teams alike. The project also gives an overview of relevant subject matter such as medical scanning, RP, preoperative planning models, customised implants/jigs and biocompatible materials. Case studies are included as a method of illustrating how the different technologies integrate and function to produce tangible successful outcomes that make a significant difference in medical interventions.

Prior to RP the production of medical models of individual patients was very rare due to the difficulty and cost of generating (usually by CNC machining) complex geometry associated with anatomy. Medical implants were manufactured using pressing, forging, machining and casting processes. Unfortunately, due to the limitations of the manufacturing processes this often resulted in bulky, poorly fitting and costly implants. With the introduction of RP technology, these types of problems were solved using the additive manufacturing (AM) or "layer by layer" process. Building intricate geometrical parts suddenly became less problematic and cheaper this helped RP technology gain acceptance by the medical profession.

1.2 Project Aim

The aim of the project is to investigate the integration of RP manufacturing technologies in the production of medical models and in vivo medical implants using Materialise "Mimics" and "3-matic" software to generate medical models for several, quite diverse and demanding medical applications.

1.3 Project Stages

      i.   Literature search

     ii.   Identify areas for further investigation

    iii.   Produce virtual 3D anatomical reconstructions

    iv.   Produce virtual 3D implant geometry

     v.   Produce RP physical preoperative planning models

    vi.   Produce RP physical customised medical implant models

   vii.   Review and analyse the results of each case study

1.4 Structure of Thesis

In the next Chapter 2, medical scanning methods, data modalities and processing methods will be reviewed.

Chapter 3 presents RP manufacturing methods and its integration and application within the medical field.

Chapter 4 introduces the concept of preoperative planning models their association with RP technologies and the benefits they offer the medical profession.

Closely associated to preoperative planning models are customised medical implants and jigs. Chapter 5 explains their importance in current day medical interventions and compares existing and previous practices.

Chapter 6 introduces the area of bio-compatible materials and aspects such as applications, classification and ethical issues are explained.

In chapter 7 the subject matter of previous research is addressed. Topics discussed include the medical device market the RP industry at present, process advancements and medical applications.

Case study methodology, selection, systematic approach and evaluation of results are explained in chapter 8.

Chapter 9 focuses on the 5 case studies selected and each case is explained in detail.

Finally chapter 10 deals with discussion, conclusion, further work and recommendations.

Chapter 2 – 3D Data Processing

2.1 Medical Scanning

Medical Imaging generates a representation of a patient's anatomy in order to facilitate medical diagnosis. Techniques include Computerised Tomography (CT), Magnetic Resonance Imaging (MRI) and Ultrasound. These tools increase diagnostic accuracy hence reducing both risk and the recovery time of the patient. Specific technologies are outlined below. [1]

2.2 CT Scanning

A CT scan, also known as CAT (Computer Axial Tomography) is a non-invasive medical scanning technique. It uses x-ray technology to obtain geometric data of a body from different positions. A CT scan uses modified x-ray technology, selectively exposing sections of the patient to radiation. The data is then processed to generate a cross-section of the human body's tissues and organs [2]. In order to facilitate the tomography of certain organs, x-ray opaque material may be ingested or injected. Radiologists interpret tomographs, identifying trauma, diseases and determining the existence and impact of various pathologies.
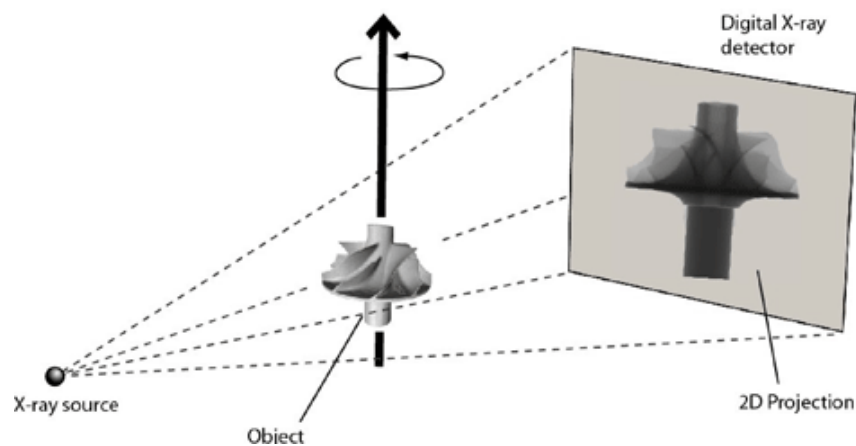
Figure 2.1 The workings of CT scanning. [3]

2.2.1 The CT Process

The X-ray tube emits a conic beam of electromagnetic radiation that selectively penetrates the part of the body being examined; the attenuated radiation is then encoded by a 2D detector and sent to the processing equipment as a digital radiograph image. The body is

positioned and a precision rotational stage device rotates. An image is generated one step at a time at intervals between 0.25^0 and 1^0. This produces 360 to 1440 images and covers a scan of 360^0 [4].

3D CT is a method that employs conventional 2D CT data to recreate an image that can be viewed in all three planes. Viewing these images in three different orientations throughout the body provides greater flexibility than conventional planar X-rays more importantly a 3D reconstruction can be generated which provides precise anatomical features. This is due to recent developments in 2D CT equipment and CAD software. The development of 3D CT data is primarily intended to simulate real life anatomical parts and is currently been used in areas such as trauma, tumours and craniofacial deformities. 3D rendering is also possible which lends to high quality 3D CT images.

2.2.2 Advantages and Disadvantages of CT Scanning

Advantages:
1. The process is non-invasive and accurate
2. CT scanning can produce high quality images of bone, blood vessels and soft tissue
3. The examination and diagnosis of CT scans are fast and facilitate short response times
4. More tolerant to patient movement than MRI
5. Tolerant to in vivo medical devices
6. Accurate imagery often obviates exploratory surgery

Disadvantages:
1. Radiation exposure
2. Inadvisable on pregnant women
3. Mothers breast feeding should wait 24 hours before resuming
4. Potential allergic reaction to the iodine contrast material
5. Potential imunocompromisation of children [5]

Figure 2.2 A C.A.T. scan machine. [6]
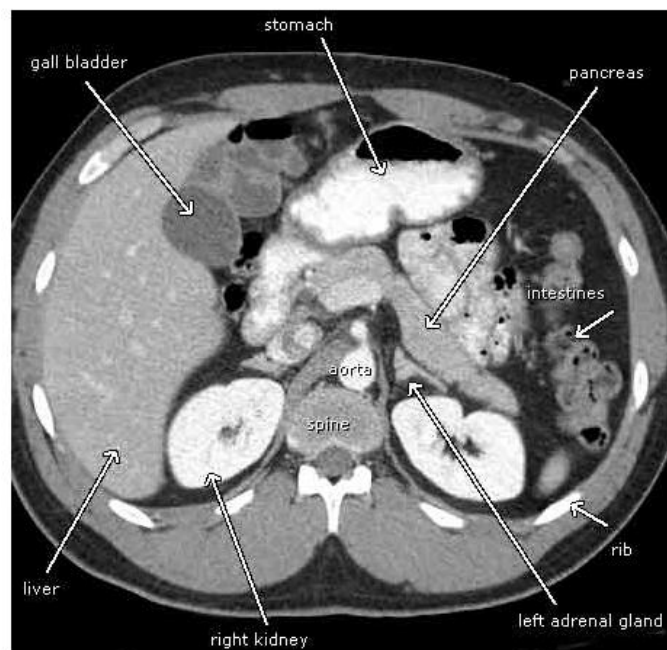
Figure 2.3 A 2D CAT scan slice of a patient's abdomen showing no abnormalities. [7]

Volumetric imaging samples generated
from CT (DICOM) images

Figure 2.4 A 3D CT scan of a mandible bone. [8]

2.3 MRI Scanning

In 1993 the first functional MRI machine was developed which displayed an image of the brain [9].

The MRI scanning technique generates pulsed radio frequency (RF) EMR via magnetic coils. The realignment time of displaced hydrogen atoms contained in the tissues is determined and processed to produce an image of the tissue.

Step1   Step2

Step3
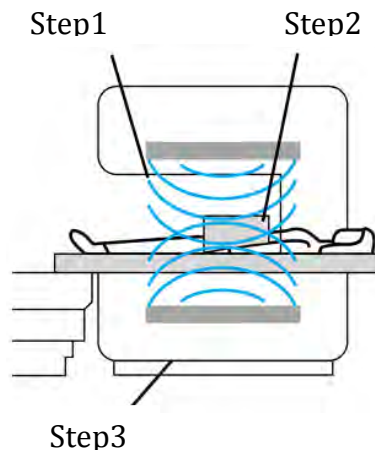
Figure 2.5 The working principle of an MRI Scanner. [10]

2.3.1 MRI Process

i. A magnetic field aligns the hydrogen protons in the body

ii. RF waves are absorbed by the protons and then emitted as a signal

iii. A RF coil picks up the signal and transmits it to the computer

iv. The computer processes the data and generates an image

Figure 2.6 2D image of the knee taken by MRI machine. [11]
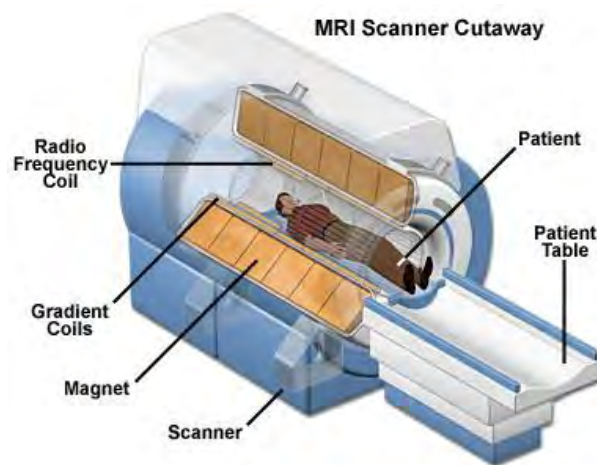
Figure 2.7 Essential parts of a modern MRI machine. [12]

2.3.2 Advantages and Disadvantages of MRI

Advantages:

1. MRI scans produce clear images of parts of the body that are encapsulated by bone tissue such as the brain and spinal chord

2. Its accurate imaging and ability to differentiate tissues facilitates diagnoses

3. There is no exposure to electromagnetic radiation

4. Facilitates visualisation of the structure of soft tissues such as cartilage

5. MRI scans identify blood flow through blood vessels hence facilitating circulatory system study and diagnosis

Disadvantages:

1. Intolerant of body motion

2. May induce claustrophobia

3. Intolerant of in vivo medical devices

2.4 Ultrasound

This technique uses the analysis of sound waves reflected within the human body to generate an image. In 1962 Joseph Holmes designed the first contact B-mode scanner [13].

2.4.1 Ultrasound Process

The ultrasound device emits ultrasonic sound waves when in contact with the body. These waves, partially reflected at anatomical interfaces, are received by a microphone in the device. The amplitude, frequency and interference profile of the reflected waves is a function of the anatomy under study. This profile is processed and displayed as an image. An interface gel may be used to enhance sound transmission.
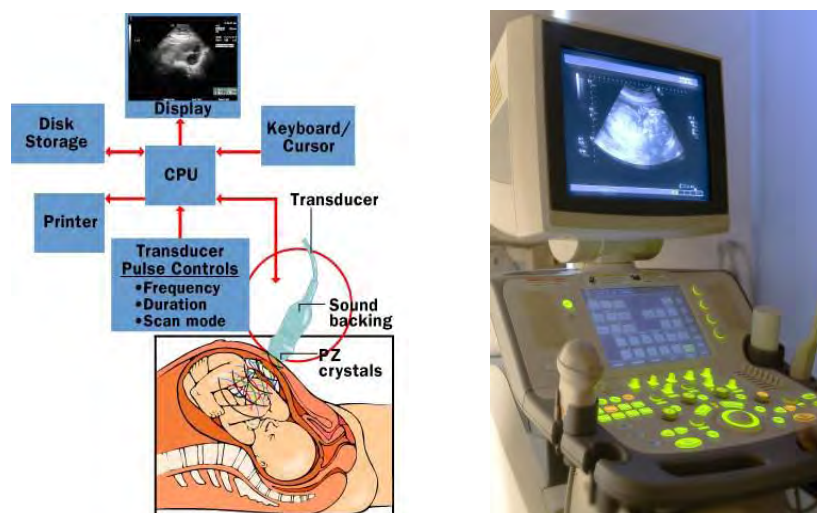
Figure 2.8, 2.9 The Ultrasound Scanning Process [14] and a modern Ultrasound Scanning Device. [15]

2.4.2 Advantages and Disadvantages of Ultrasound:

Advantages:

1. Is a non invasive procedure
2. Easy to use
3. No exposure to radiation
4. Used extensively in gynaecology

Disadvantages:

1. Can not detect all abnormalities
2. Some scans can appear abnormal and cause confusion
3. Many melanomas cannot be detected by ultrasound

2.5 Digital Imaging and Communications in Medicine (DICOM)

DICOM is a worldwide information technology standard established in 1993 [16]. The standard covers file format and transfer protocol, permitting exchange of data regardless of hardware origin. Devices that make up a DICOM system are:

a) Hardware modules, such as CT and MRI scanners
b) Picture Archiving and Communication Systems (PACS)
c) Reporting and post processing workstations
d) Printing services

2.5.1 DICOM Process

i. A CT scan is performed
ii. The scanner console generates a set of images from the unprocessed data
iii. The CT console forwards the study to a PACS
iv. Data is reformatted; this creates images from the original study
v. These images are returned to the archive and merged with the rest of the study
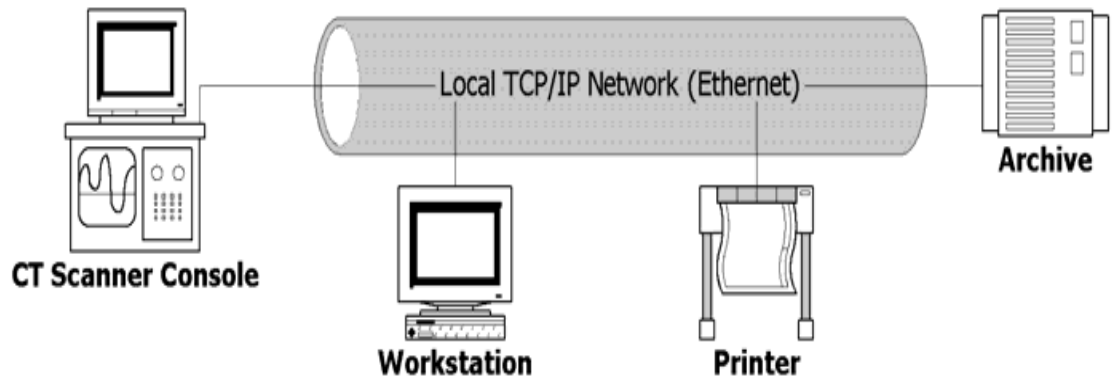
Figure 2.10 A standard DICOM Network. [17]

2.6 Summary

The above diagnostic techniques permit accurate analysis of patients' conditions and facilitate correct medical and surgical interventions. The technology is a critical link in the process of reducing patient morbidity and mortality rates.

Chapter 3.0 – Rapid Prototyping

3.1 Rapid Manufacturing

3.2 History of Rapid Prototyping

Additive manufacturing (AM), of which rapid prototyping (RP) is a subset, augments traditional material forming, removal and assembly methods of manufacturing. This overcomes traditional restrictions in manufacturing technology, with significant commercial and technological implications. The huge potential of this technology led to the rapid development of RP, firstly by Magnus in 1965 and then by Swainson in 1971. Thereafter the first stereolithography apparatus (SLA) by 3D Systems appeared in 1987 followed by selective laser sintering (SLS) by EOS in 1990. In 1991 three new technologies were released; Fused Deposition Modelling (FDM) by Stratsys, Solid Ground Curing (SGC) by Cubital and Laminated Object Manufacturing (LOM) by Helisys. In 1996 the first 3D Print technology was released Stratasys. These technology breakthroughs set the stage for the commercial integration of AM within manufacturing industry. [18]

3.3 Introduction to RP

The AM process generates physical models by depositing successive layers of material on top of each other. The profile of each layer is determined by processing CAD data, and the profiles of successive layers determine the overall geometry of the body. Materials include paper (LOM), photosensitive resins (SLA), polymers (SLS, 3D Printing) and powdered metals (SLS, SLM and EBM). Complex geometries can be formed, however part orientation, size and material are considerations. RP uses the above technologies to produce prototype models for analytical, marketing and investment decision purposes.

One of the most significant breakthroughs in recent years has been the identification and potential use of RP technology within the medical field. In this sector RP is used for generating preoperative models of the human anatomy for the cranial and maxillofacial regions. This area has been further developed to design and build custom fit implants for both in vivo and in vitro applications. The intention here is to increase the quality of patient's lives who are burdened with a defect caused by trauma, genetic defect or disease. Although RP has many advantages it does not solve all design problems. It does

conversely simplify problems in areas that are very difficult to overcome using existing conventional design and manufacturing techniques.

3.4 Integration of Medical Modelling and RP

3.4.1 Phidias Project

The Phidias project was initiated in 1998 and concluded in 2002. It was created to investigate the process and significance of constructing solid medical customised anatomical models. This was done in the context of preoperative planning, simulation and optimisation of intricate surgical interventions. The models developed were based on high resolution images taken from CT and MRI scans and developed into physical models built using RP processes. One of the findings of this project identified that the accuracy of the models are influenced by the accuracy of the medical images and scanning equipment used. Subsequently project networks were established between 40 different partners across 11 European countries which formed a research network. The network was primarily involved with performing specific research and commercialisation in the areas of medical modelling. This research became involved in all areas of medical modelling such as image generation and processing, clinical research and machine development.

3.5 Methods and Applications of Medical RP

The applications of RP within the medical field are increasing and certain niche areas have been focused on. These areas include medical device prototyping, bio modelling and anatomical modelling. With the advancements in medical based modelling technologies and Reverse Engineering (RE) it is possible to construct three dimensional (3D) models of anatomical structures of the human body. This is possible by collating scan data attained from CT, MRI and Ultrasound. These 3D models of anatomical structures can be used for preoperative planning, diagnosis of diseases, surgical simulation and medical device prototyping.

The application of RP in the medical sector is governed by the designs of custom made products. Each product design will vary in terms of functionality, shape and fit depending on the recipient's requirements. Models can be used to plan reconstructive surgery for maxillofacial, orthopaedic, spine and plastic surgery. The fact that RP is relatively cost effective and has manufacturing and performance advantages over conventional manufacturing techniques this consequently has become a very active area in terms of:

- ➢ In vivo devices
- ➢ In vitro devices
- ➢ Prosthesis
- ➢ Surgical jigs and tools
- ➢ Drug delivery devices

Currently areas of particular focus are the hearing aid and dental restoration industry. [19]

3.6 Principles of RP

A prototype is a fundamental part of the product development process. Getting the focus right at an early stage establishes the design intent and will help reduce the time and effort spent preparing the prototype for market. A prototype can be defined as **"The first or the original example of something that has been or will be copied or developed".** [20]

A prototype enables a design development team to analyse, plan, experiment and learn the process while designing the product. Material properties may limit the RP process capability. The four key points in any RP process are:

- ➢ Input
- ➢ Methods
- ➢ Applications
- ➢ Materials

3.6.1 Input

The term Input refers to the computer generated data (solid model or a surface model) required to describe the physical object.

3.6.2 Method

Presently there are more than 20 manufacturers of RP systems. The method applied by each manufacturer can be classified into the following categories:

- o Photo-Curing
- o Cutting and Gluing
- o Melting and Fusing
- o Joining and Binding

3.6.3 Applications

Generically speaking applications can be grouped into the following areas:

- Design
- Engineering Analysis and Planning
- Tooling and Manufacture [21]

3.6.4 Materials

Material used can come in either solid, liquid or powder form. In the solid state it can exist as pellets, wire or laminates. The material type can come in the form of nylon, wax, resins, metals, and ceramics. One of the more convenient ways of classifying these processes is with reference to the initial form of the material, these are;

- Liquid Based
- Solid Based
- Powder Based

These options are shown in Fig 3.1 as part of the overall RP process chain.
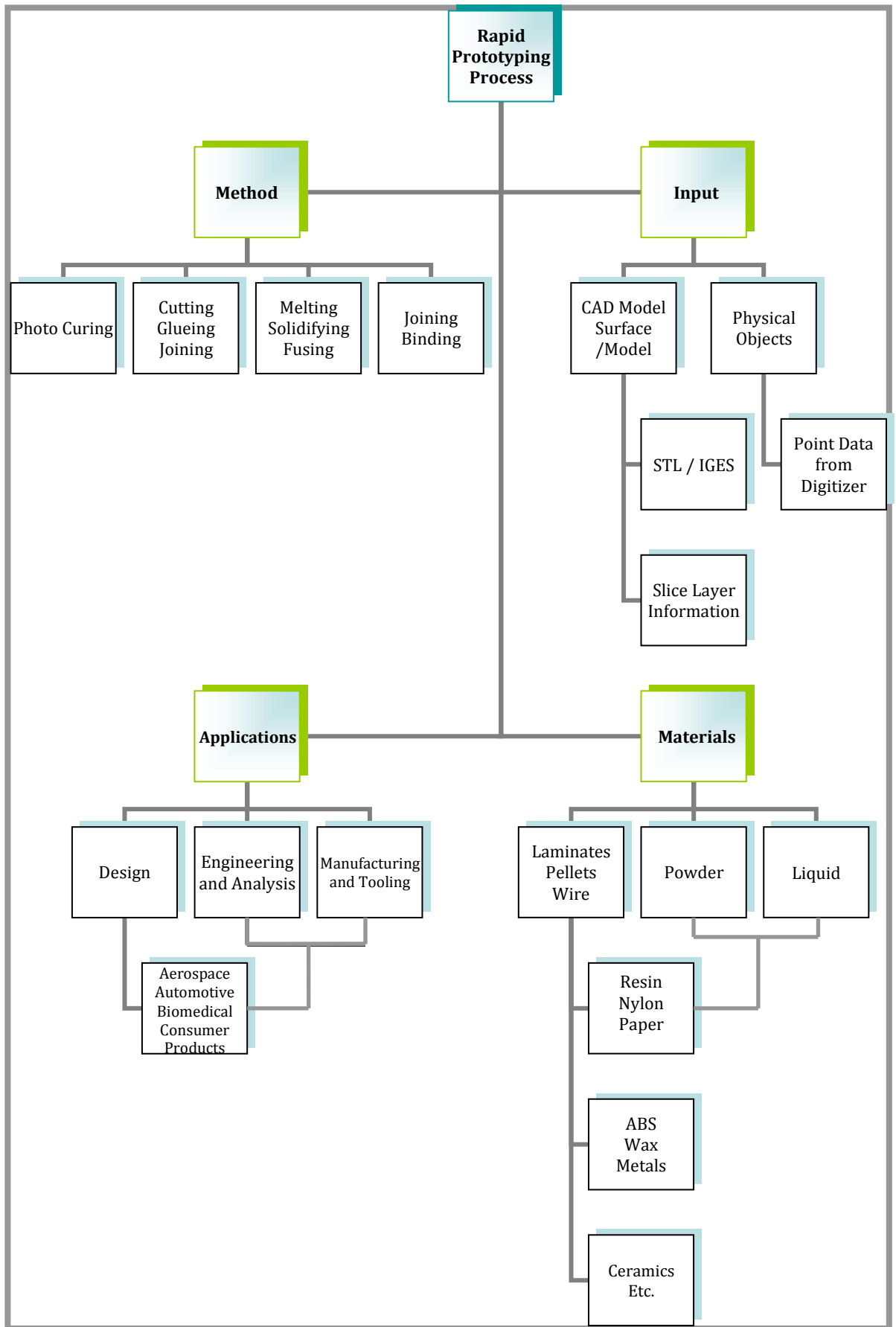
Fig 3.1 Overview of RP process. [22]

3.7 Benefits of RP

Benefits include:

- Part Complexity
- Product Reliability
- Product Liability
- Short product life cycle
- Diverse range of products
- Lead Time to market
- Integration of CAD with manufacturing systems [23]

Processes such as SLS, SLA, SLM and EBM are capable of producing small intricate components. Multiple models are possible as parts can be arranged to cover the entire build area and stacking parts is also an option [24]. Rapid tooling (RT) are tools made by the RP process and can be used to make part quantities ranging from one to several thousand [25].

3.8 RP Process

3.8.1 3D Modelling

Advanced 3D CAD modelling is a general prerequisite in the RP process and is usually the most time consuming part of the entire process chain. It is important that these 3D geometric models can be viewed by the entire design team for reasons such as form and fit, stress analyses, Finite Element Method (FEM) analysis, detailed design, drafting, design for manufacture and assembly (DFMA).

3.8.2 Data Conversion and Transmission

The solid or surface model built is converted into an STL file format. The STL file format approximates the surfaces of the model using triangulation. The data transmission must take place under agreed data formats such as Standard Triangle Language (STL) or Initial Graphics Exchange Specification (IGES).

3.8.3 File Processing

The STL file must be checked for flaws within the file. This can be caused by errors within CAD models or the non robustness of the CAD-STL interface. Materialise Magics and 3-matic software can be used to produce a watertight solid model.

3.8.4 Building

It is good practice to build as many parts as possible at the same time, this utilises the build area of the platform. When complete the part should be handled carefully until post processing has taken place. [26]

3.8.5 Post Processing

This includes manual preparation and cleanup. Depending on the process used it could involve removing resin, powder or some other support material.

3.9 RP Process Description

The processes discussed are commonly used in the RP sector for medical models and implants.

3.9.1 SLA

The SLA process uses photosensitive resin materials. The resins are cured by a laser that traces the part's cross section layer by layer. SLA produces accurate, intricate models, with a variety of materials.

3.9.1.1 Process Overview

The build platform reciprocates vertically and is located in a vat of liquid resin. Before the build commences the build platform is placed slightly below the surface of the resin surface. The recoating blade passes over the build area to help discard any excess resin and generates a homogenous layer of resin. A laser beam passes over the layer and cures the resin. The laser will scan the part being built in addition to the support material. The support material maintains the position of the structure in its build orientation, including any overhanging features. When the first cross section has been completed the platform will be lowered one layer thickness into the vat. The recoating blade recoats the build area. This process repeats itself until the component is complete.

When complete the build platform is raised out of the bath of resin and allowed to drain. The component is detached from the surface and the support material is removed. The part is then washed with alcohol solvent (isopropyl alcohol (IPA)). Finally it is washed in water, dried and allowed to cure to strengthen the finished part. [27]
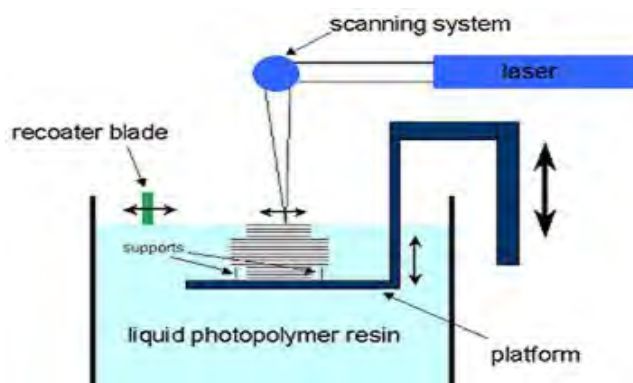
Figure 3.2 The SLA process. [28]
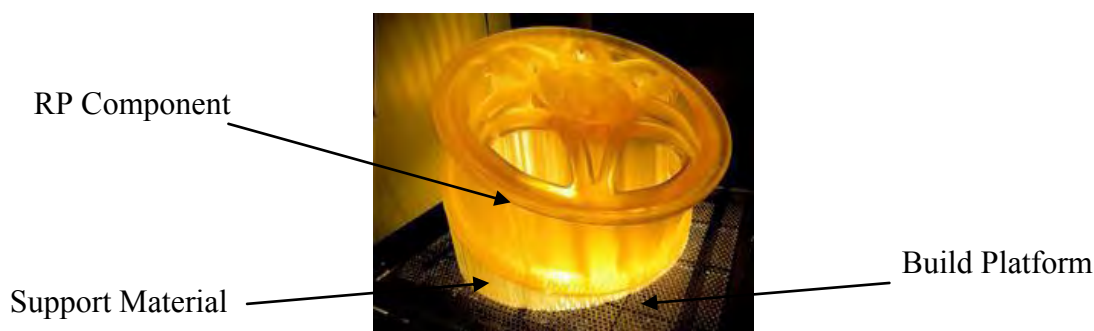
Figure 3.3 A component made by the SLA process suspended on support material which is attached to the build area. [29]

The SLA process provides a good combination of speed, accuracy and surface finish. The main drawback is the limited selection of materials for use as functional models but new materials are now being used to create colour highlighted models.

3.9.2 SLS

The SLS process uses a CO_2 laser to fuse or sinter a powder material. The laser traces the parts cross sectional profile layer by layer. SLS creates accurate and durable parts but surface finish is relatively poor. Factors such as z axis height, enclosed pockets or build orientation can greatly affect the surface finish and geometry, especially with circular parts.

3.9.2.1 Process Overview

The SLS method uses fine powders that are exposed to a laser beam that fuses the powder granules together. Slice file data is fed to the CO_2 laser and the laser scans the image onto a preheated hyphenate bed.

The feed piston is used to measure and feed powder that is spread over the build platform by a spreading apparatus, usually a roller. Once a layer is spread onto the build chamber, a laser, controlled by a scanning device usually a galvanometer sinters the material together. After the first cross sectional area is complete the feed elevator raises one layer thickness and the build chamber lowers one thickness. The roller spreads the next layer of powder over the first layer. The next cross section is sintered which bonds the current layer to the previous layer. This process is continued until the part is completed. When the build is completed the part is left for post curing to take place. When this time has expired any excess powder is carefully removed and the part is extracted from the build chamber. The part is then coated with special epoxies that protects the surface and prevent overhanging features and delicate parts from breaking off.

The advantages of this process are that the unfused powder acts as a support material to help stabilise the part during the build process. Unused material can be partially recycled which helps to reduce material costs. Material densities ranging from 75% to 98% are achievable. [30]
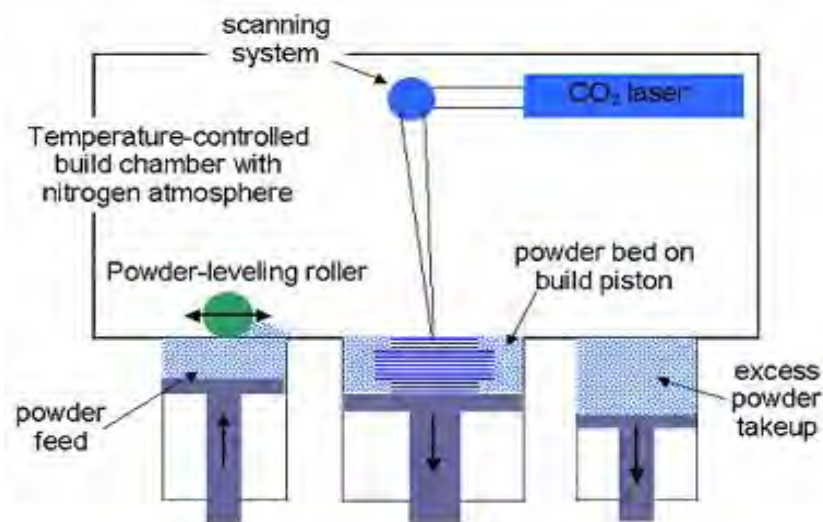
Figure 3.4 The SLS process identifying the main components. [31]

One disadvantage of SLS is that the parts have a rather porous surface finish due to sintering. This can be a drawback for some applications and may require infiltrating with other materials to fill any voids present. Materials available include:

- o Polyamide
- o Glass filled polyamide
- o Elastomers
- o Polystyrene
- o Foundry Sand
- o Stainless Steel

Figure 3.5 A Stryker knee implant made from cobalt chrome using an EOS SLS process. [32]

Figure 3.6 A Direct Metal Laser Sintering (DMLS) dental implant fitted to a SLS mandible model. [33]

3.9.3 FDM

The FDM process involves heating a filament of thermoplastic polymer that is forced through a circular nozzle to form the RP layers. The materials include polyester, acrylonytrile butadiene styrene (ABS), elastomers, and investment casting wax.

3.9.3.1 Process Overview

The modelling material is contained on spools and is fed into an extrusion head and heated to a semi liquid state. The semi liquid material is extruded through the head, and is deposited in very fine layers from the extrusion head one layer at a time. Since the ambient air temperature is maintained at a point below the melting point of the materials, the material quickly solidifies. As the X-Y plane moves, the head follows the tool path generated by the software, and the next layer is dispensed. The width of the bead can vary between 0.250mm to 0.965mm depending on the model of FDM machine.

Thermoplastics, such as ABS, can be used to produce structurally functional models. Two build materials can be used, and latticework interiors are an option. [34]
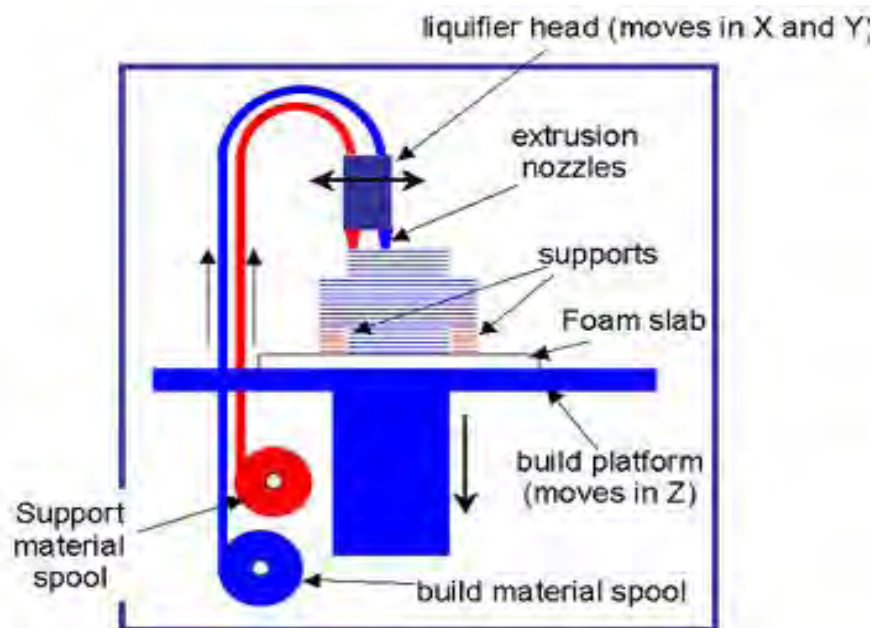

Figure 3.7 FDM process. [35]

Figure 3.8 [36] and 3.9 [37] components manufactured by the FDM process.
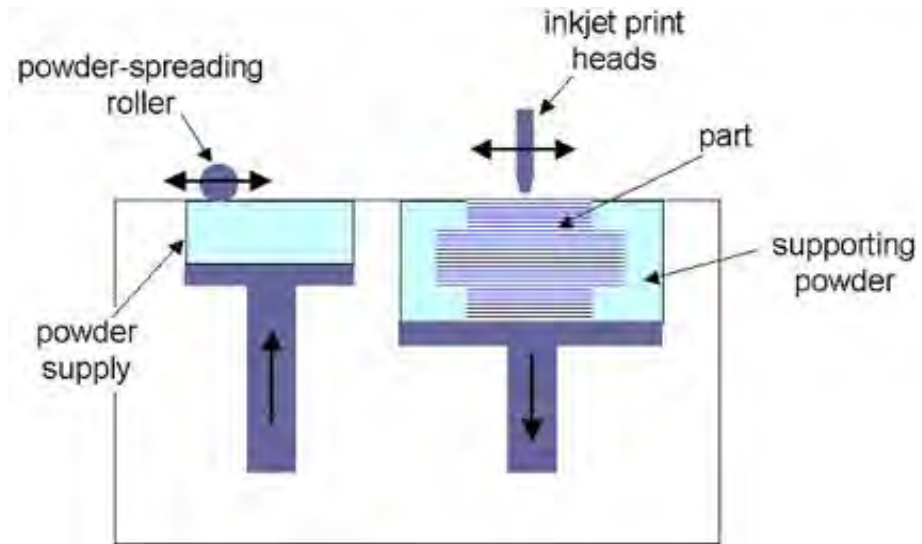
3.9.4 3D Printing

The Z-Corp three dimensional printing Ink-jet based process prints the part's cross sectional geometry on layers of powder spread over each other. This process enables models to be built quickly and affordably. Models may also be printed in colour. Z-Corp 3D printing is similar to the SLS method except instead of using a laser to sinter material a print head dispenses a solution to bind the powder together.

3.9.4.1 Process Overview

The feed piston measures and dispenses powder that is spread across the build area by means of a spreading apparatus. Once the initial layer is spread, the lowest cross section of the part is printed by spraying a binder solution on the powder substrate by means of an inkjet print head located on the print head gantry. After the initial layer is printed, the feed piston raises one layer thickness and the build piston lowers one thickness and the spreader disperses a layer of powder over the first cross section. The print heads then print the next layer. This process continues until the part is completed. Once complete and the binder has dried, the part can be removed and excess powder blown off. No support structures are needed because the excess powder on the build platform acts as a support during the build. Once the part is de-powdered, the part can be finished using infiltrants. [38]

Figure 3.10 3D Printing process. [39]

The 3D Printing technology allows parts to be built very quickly and inexpensively. This makes these types of models excellent for visual aids and concept models. Some limitations of this technology is the surface finish, accuracy and strength are poor compared to other methods. The material selection is limited to plaster or starch. It is recommended that the plaster based system be used where possible as it is more durable and gives better resolution. The starch should be used only if one is making investment moulds.
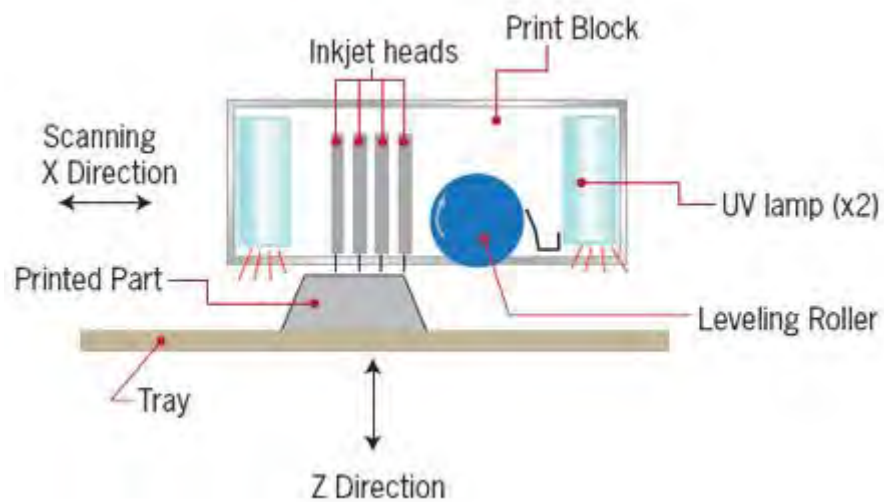
Figure 3.11 Objects Polyjet process uses UV lamps to cure the layers as they are been printed. [40]

The advancements made in the 3D printing process and the addition of UV curing allows a greater variety of materials to be used such as ABS. Materials used can be transparent, but coloured materials are also available. The properties of the materials used can range from hard and tough to flexible depending on the application. [41]

Figures 3.12 3D printing mandible model. [42]

Figure 3.13 Skull model used for placement and fit of implant. [43]

Figure 3.14 A medical preoperative planning model of a human spine. [44]

3.9.5 SLM

SLM is a relatively new RP process. This process has been specifically targeted at the medical sector and is currently been used to produce customised implants and jigs.

3.9.5.1 Process Overview

The workings of the process are very similar to the SLS or SLA process. In this process a high powered laser is used to melt powder metal particles and fuse them together. When the laser has fused one complete layer another fresh layer of powder is dispersed across the build chamber. The thickness of this layer can vary from a minimum of 20 to a maximum of 100 microns. The parts produced are dense metal parts and are available in materials such as tool steel, stainless steel, cobalt chrome and titanium. When reactive materials such as titanium or aluminium are being used the oxygen content within the sealed chamber must be reduced to prevent oxides forming with consequent material defects. This is achieved by charging it with a high purity argon gas. [45]
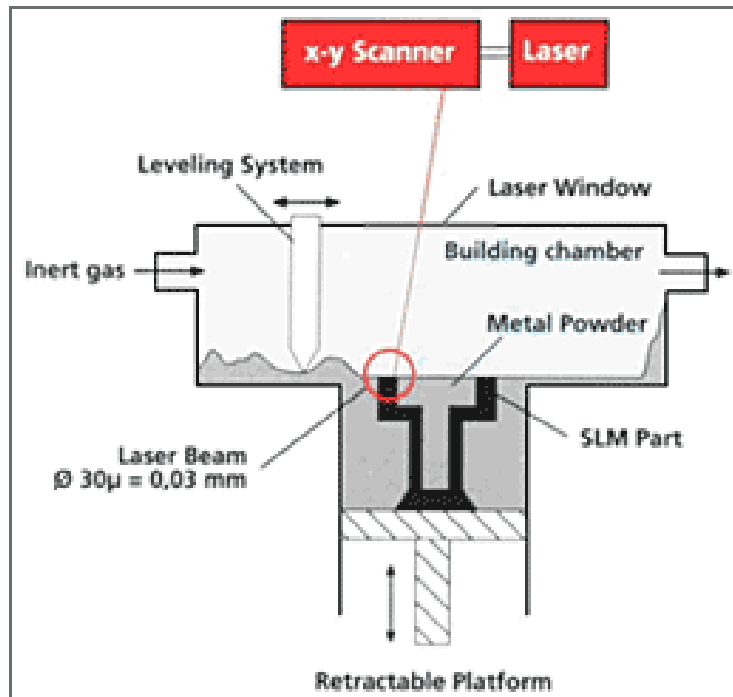
Figure 3.15 The SLM process. [46]

Figure 3.16 A range of medical implants produced by the SLM process. [47]

3.10 Summary

New process and material releases are taken place on a regular basis due to constant R&D within the AM sector. Contributions made by R&D now allow the building of more intricate parts such as custom designed implants for the medical industry. This along with the consumer product and aerospace industry will help develop AM technology for the foreseeable future. The variation in material selection is also increasing the impact of this industry and is one of the main factors helping to sustain it.

Chapter 4.0 – Preoperative Planning Models

4.1   Introduction

Due to the complex nature of the human anatomy good preparation and accurate patient data are fundamental in achieving precise and repeatable results. Preoperative planning models have been used since the early 1980's for maxillofacial, orthopaedic and oral applications. Anatomical models were traditionally manufactured using a five axis CNC machines but had limitations in terms of undercuts and thin cross sections. These short comings were eliminated by RP technology and were subsequently identified as a suitable manufacturing method for preoperative planning models.   The previously mentioned Phidias Project was initiated to develop and integrate RP technology into the medical sector. The project's recommendations led to developments in data acquisition technologies. This, combined with improved RP, has led to the availability of preoperative models that are fit for purpose. Preoperative planning models have become one of the preferred tools available to surgeons. [48]

4.2 Physical Modelling

In complex medical cases it can be difficult for surgeons to ascertain a patient's medical condition. However this can be overcome at least in part by having a physical model of the patient's anatomy. This allows medical teams to intuitively understand complex anatomical details. Precise preoperative planning models also facilitate the accurate calculation of medical implant geometry and assist with proactive surgical planning and preoperative training. This helps to identify surgical risk and appropriate actions to reduce same. Overall surgical time and risk to the patient is therefore minimised. Review of medical research papers indicates that increasing use of preoperative planning models yields several advantages.

4.3 Benefits of Preoperative Planning Models

   i.   Improved patient confidence

  ii.   Improved communication, leading to reduced ambiguity

 iii.   Reduced operating times

  iv.   Decreased level of risk to patient

   v.   Faster recovery time

  vi.   Improved incision accuracy

 vii.   Reduced numbers of corrections

viii.   Physical models of dislocated elements facilitate predictable surgical outcomes

  ix.   Used as a reference during preoperative planning meetings

   x.   Benefits in terms of diagnosis, treatment planning, as a reference during surgery and in the fabrication of custom made implants and surgical jigs and fixtures [49]

Alternatives to preoperative planning models are virtual or augmented 3D models. Virtual and augmented 3D models have been used with the aid of head mounted displays and holograms which are a significant improvement over 2D images. One of the major benefits of using this technology is the ability to overlay images. Limitations associated with this technology, include:

   i.   Deformed anatomical geometry can be difficult to understand

  ii.   2D visual displays do not provide an intuitive interpretation of 3D geometry

 iii.   Planning complex 3D interventions based on 2D data can be complicated and misleading [50]

Surgeons vary in systems preference, but it is always beneficial to have a physical model during medical interventions.

SLA models of the cranium have proven in many cases to be very useful for preoperative planning models and surgery simulation. The material characteristics of SLA models allow various mechanical procedures to be performed such as removing burrs, drilling and the location and installation of fasteners. Another advantage of the process is its ability to produce enclosed voids. The fact that the model is transparent allows internal canals and structures to be visible. This permits the modelling of other medical conditions such as tumour expansion and reduction of arteries which lead to reduced blood flow.

In terms of legal defence surgeons are now seeing the benefit of having preoperative planning models at their disposal when performing complex interventions that have a high risk. In some cases surgical complications may lead to litigation. Medical staff may use models for legal defence. [51]

4.4 RP Processes and Preoperative Planning Models

The processes mainly used for the generation of preoperative planning models are:

- SLA
- FDM
- 3D Printing
- SLM, although this process is mainly used for producing custom medical implants

4.4.1 Process advantages

SLA	i. High quality surface finish ii. Good resolution iii. Sterilisation tolerant iv. Multi-coloured models aid anatomy identification
FDM	i. A variety of materials can be used ii. Robust models are produced iii. ABS plastic can be sterilised
3D Printing	i. Coloured models can be produced ii. Process is cheap and fast iii. 3D models can be produced including hollow features iv. Additives increase model durability v. Models can be electroplated to resemble the appearance and texture of metals[52]

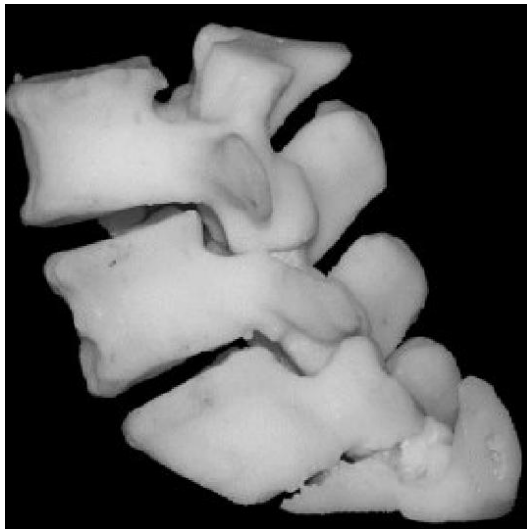**Figure 4.1 RP process advantages for preoperative planning models.**

4.5 Preoperative Planning Model Examples
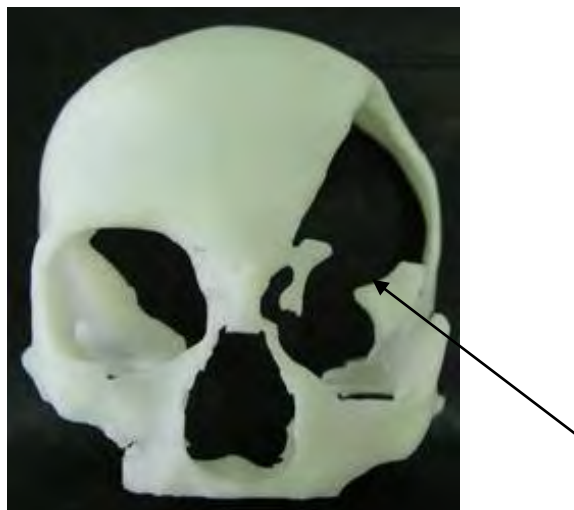
Figure 4.2 FDM 3D human skull model showing a severe cranial defect. [53]

Figure 4.3 SLA model of a mandible bone fitted with a customised implant. [54]

Figure 4.4 FDM partial spine model. [55]

Figure 4.5 A 3D Printing biomedical and translucent preoperative planning model.

The above model was built on a Connex 350 machine, by Objet. Constructed of transparent FullCure 720 material and FullCure Vero material and allows the generation of 3D translucent medical models. This model shows details such as nerves, arteries and tumours and displays the full versatility of preoperative planning models. [56]

Figure 4.6 A 3D SLA model of a pelvis and femur. [57]

These models are very accurate, strong and relatively light. Surface coating may also be applied to improve the aesthetics of the model.

Figure 4.7 A right forearm FDM model with a broken radius bone. [58]

The bone based on this model had to be reset 9 times due to the fact that the surgeons had poor radiological 2D data. Therefore bad alignment resulted in multiple surgeries. Normally the recovery time for this fracture would take 6 weeks but took 54 weeks and extensive physical therapy. Successful alignment was eventually achieved using a CT scan from which a 3D RP model was made.

4.5 Summary

Although there have been considerable advancements in medical reconstructive surgery certain fundamentals have not changed. Surgeons use their hands to control operating tools and rely on their eyes to provide closed loop feedback in relation to the movement and adjustment of their hands. Therefore the more data they have at their disposal before an intervention takes place the higher the success rate, preoperative planning models being a critical part of this data. [59]

Chapter 5.0 - Customised Medical Implants and Jigs

5.1 Introduction

Applications for customised medical implants include maxillofacial, cranial, knee and hip implants. Implant profile determination is a limiting factor, leading to implant categorisation as "standard" and "custom". The use of iterative design differentiates custom from standard implants. [60]

In certain circumstances anatomical complexity indicates the use of a custom implant. AM technology is ideal for the production of complex geometries, and hence is the method of choice for implant and orthotic device manufacture. These geometrically accurate implants have become a proven technology and are preferred by surgeons to traditionally manufactured devices.

Surgeons fit customised implants for the following reasons:

- Reduced operating time
- Reliable and relatively low cost
- Reduction in time between diagnosis and surgery
- Reduced infection rates
- Minimal excision of good tissue [61]

5.2 Customised Implants

Customised implants are made for many parts of the human anatomy specifically for each individual patient to increase functionality, aesthetic appearance and reduce discomfort. Some examples are provided in this section.

5.2.1 Scaffolding and Tissue Engineering

Tissue engineering requires *inter alia* the implantation of customised permeable implants (scaffolds) to support tissue regeneration. One of the main characteristics of a scaffold is that it must contain micro channels with a high degree of porosity. This property allows the generation and diffusion of tissue cells and nutrients which facilitates the speedy generation of new cell tissue. In existence since the 1980s, original scaffold manufacturing processes yielded poor pore size and geometry repeatability. Contemporary AM technology obviates this problem.
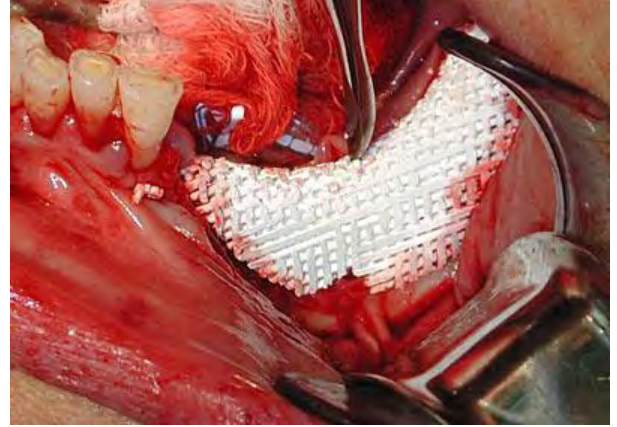
<center>(a)   (b)</center>

Figure 5.1 (a), (b) A post machined FDM hydroxyapatite manufactured scaffold used in the reconstruction of a mandibular implant. [62]
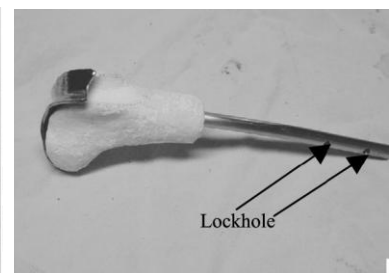
5.2.2 Knee Implant

Knee implant procedures are performed on a regular basis due to the breakdown of the joint induced by cyclical loading causing wear and degradation.


<center>(a)   (b)   (c)</center>

Figure 5.2 (a) SLA pattern of a hemi-knee joint, (b) a master for the titanium joint, (c) implant for the femur bone. [63]

5.2.3 Dental Implant

Dental implantations are a difficult procedure to perform accurately due to varying geometry. The diagrams below show surgical guides used to accurately identify the drilling points for dental implants. The 3D CAD model can be used to optimise these positions before the guide is manufactured.

| (a) | (b) | (c) |
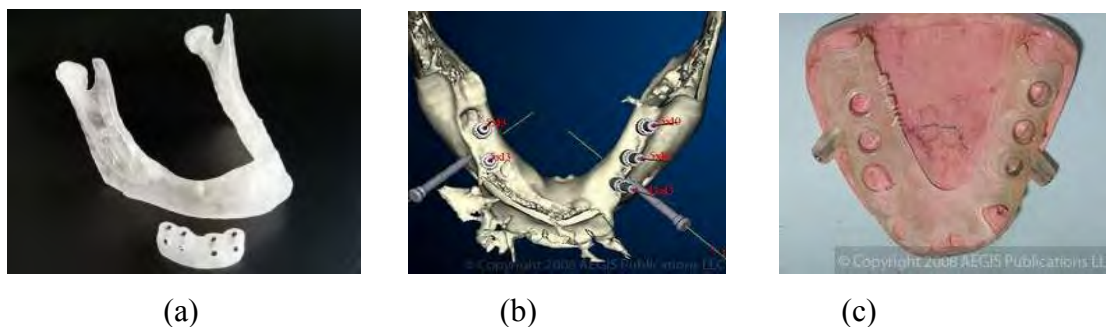
Figure 5.3 (a) SLA surgical guide, (b) 3D model, and (c) fabricated guide. [64]

5.2.4 Chin Implant

The RP chin implant below was used to generate the positive prototype from which a silicone rubber mould was made. The silicone mould was then used to manufacture a wax pattern, which used the lost wax process to fabricate the titanium implant.

| (a) | (b) | (c) |
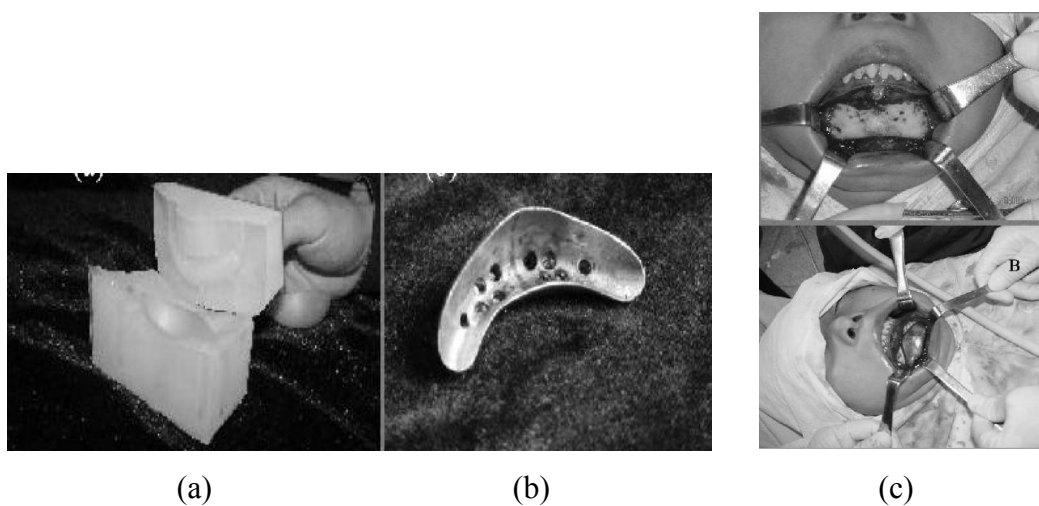
Figure 5.4 (a) silicone mould, (b) titanium implant, (c) implant been placed in position. [65]

5.2.5 Mandibular Implant

A common maxillofacial trauma is mandibular bone fracture. Accurate design and positioning of the implant facilitates aesthetic and functional recovery.

(a)   (b)
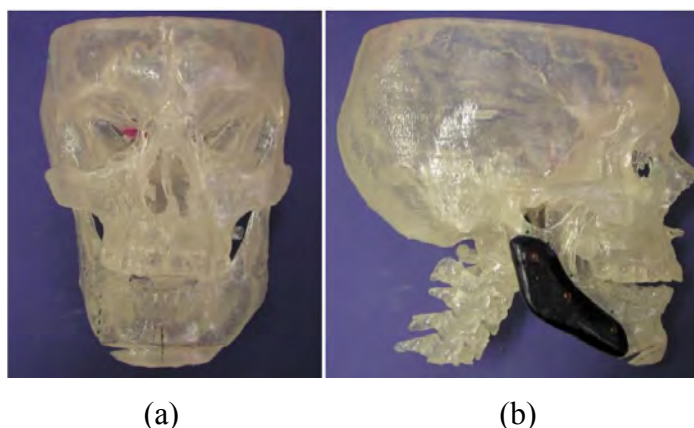
Figure 5.5 (a) SLA model of a patients skull, (b) a side elevation showing the cast titanium mandibular implant. [66]

5.3 Implant Design

Medical CAD software has streamlined the design and manufacture of complex bone replacement implants.

Bone is a living connective tissue and is the main constituent of the human skeleton. It solidifies due to calcification, becoming hard and brittle, but with low density. Bone also changes over the course of a person's life, continually being produced as the body grows. Factors that affect the formation of bone growth include metabolic causes, endocrine changes, mechanical stimuli and exposure to drugs. [67]

Bone is considered to be a composite material; it has the capability of healing and remodelling itself. However, severe blunt force trauma, disease or congenital abnormalities prevents this. In these instances bone repair is achieved by grafting, using either a part of the patients own bone (autographs) or a donor's bone (allographs).

Synthetic substitutes exist, comprised of materials such as ceramics, metals, polymers and composites used to help bridge this shortcoming. Bio-ceramic materials are one of the main groups of materials used as they have a chemical composition similar to that of human bone.

When designing an implant points that must be considered are:

       a) Mechanical properties

       b) Biocompatibility

       c) Cost effectiveness of manufacture

       d) Geometric accuracy

The implant must exhibit the mechanical properties of the bone being replaced so as to facilitate function and perform satisfactorily at the point of substitution. The material chosen for the implant must be biocompatible, i.e. must not produce a toxic or chemical reaction which may lead to further medical complications. Accuracy of the part must be ensured, as this reduces the risk of infection, increases the functionality of the implant and minimises healthy tissue excision. [68]

5.4 Customised Medical Jigs

Customised jigs assist the surgeon with the accurate placement of medical implants.

AM processes (e.g. SLA, SLS) produce accurate, robust parts that are sterilisation tolerant. In certain circumstances AM produced implants may require reinforcement to become fit for purpose, leading to the use of reinforcing elements. However, new processes such as SLM and Electron Beam Melting (EBM) produce non porous metal parts, overcoming the limitations of other AM technologies. With the introduction of these new metals, surgical guides can be made smaller with a reduced cross sectional area and still retain sufficient stiffness. This reduction in size allows the surgeon greater visibility, permitting the surgeon to make smaller and more accurate incisions. [69]

5.5 Existing and previous practice

The positioning of osseointegrated implants for the retention of prosthesis is important in terms of aesthetics, function and comfort.

Previous methodological steps include:

    a) Patient brought to clinic for preoperative planning session

    b) Planning performed on patient and the ideal prosthesis location marked on patients skin

    c) The markings transferred to a transparent plastic template

d) The template is then used to transfer the location of the implant onto the patients bone using a hypodermic needle and sterile ink.

e) The skin is then cut and folded back to show the ink marks for the implant locations.

Although this procedure works, problems can occur with soft tissues movement when used as a reference surface leading to inaccurate positioning of the implant hence producing poor aesthetics. Since this procedure provides no diagnostic data on the quality or thickness of the bone at the point of implantation this could increase the operating time if the bone quality is not sufficient and the fixing points have to be altered.

Existing methodological process steps for producing a SLM process surgical guide:

a) A CT scan made of the patients relevant anatomy. Includes software formatting and manipulation to produce STL files

b) Computer aided surgical planning and design. Includes using CAD software to perform functions such as mirroring and Boolean operations, assessing quality of bone at the location point. All soft tissue data is removed before the surgical guide is designed and then located onto the bone

c) Surgical guide manufactured by the SLM process

d) Finishing involves removing support material used in the construction of the guide to maintain dimensional accuracy and post surface finishing processes such as bead blasting which reduces the surface roughness (Ra value) caused by the layering process

e) Evaluation, comprising fitting the guide onto a preoperative planning model of the patients anatomy to guarantee a good fit. The location of the osteotomies and drilling locations are checked by surgeons and confirmed before the surgery takes place [70]

(a)   (b)   (c)
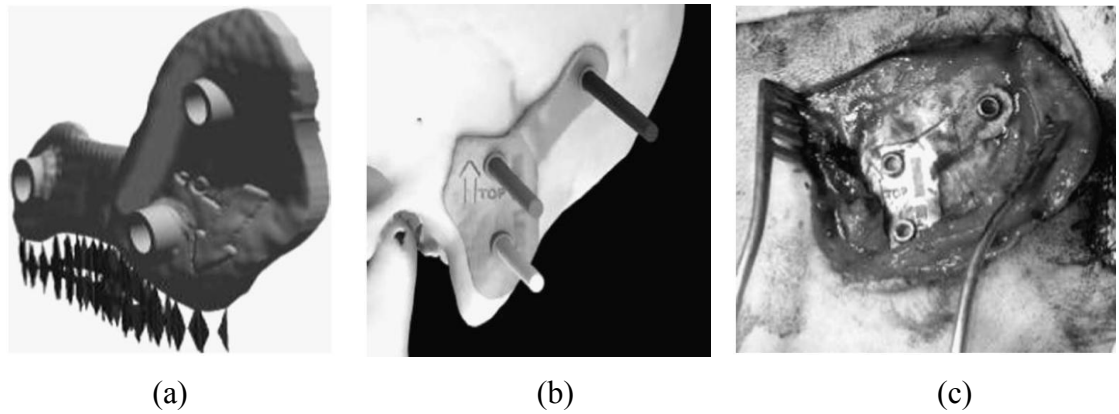
Figure 5.6 (a) Surgical guide showing support structures for rapid manufacture, (b) surgical guide being used in preoperative planning showing drilling locations, orientation and patient's name,(omitted for privacy reasons) (c) Surgical guide in use. [71]

Figure 5.7 A surgical guide containing embossed features with orientation details and drill size to aid with the implantation procedure. [72]

(a)   (b)   (c)
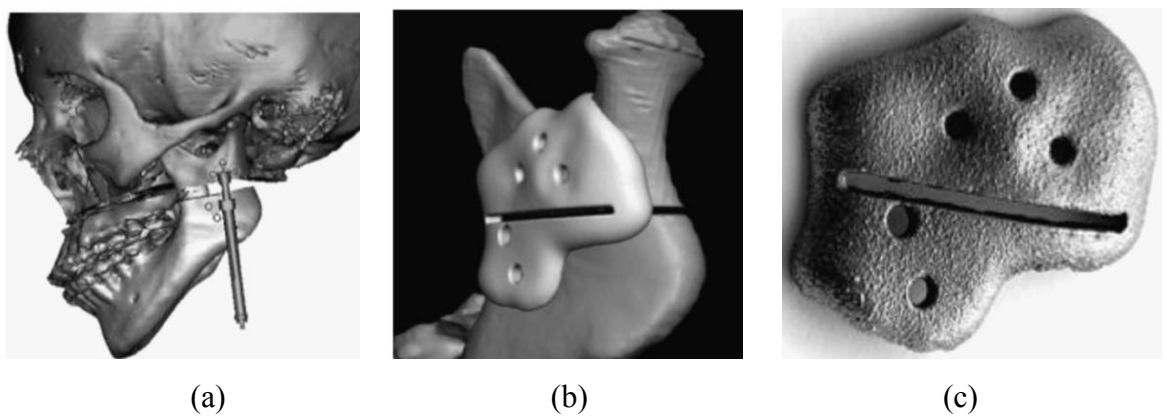
Figure 5.8 (a) A software surgical planning screen capture identifying the location of a distraction device, (b) a distraction guide design, (c) a SLM distraction guide. [73]

<div align="center">(a)   (b)</div>

Figure 5.9 (a) 2 surgical guides used in the correction of a cleft lip and palate, (b) shows the guides in use. [74]
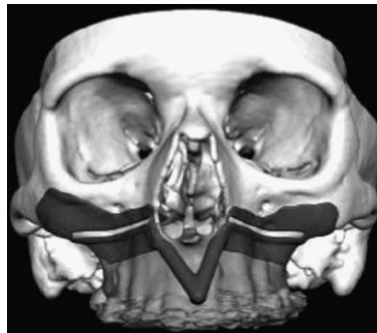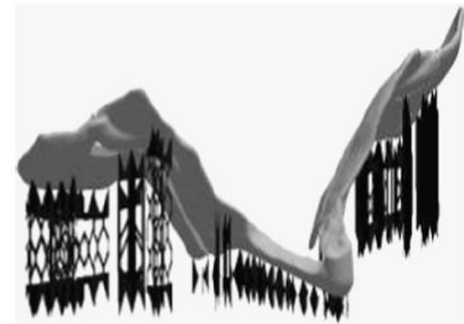
<div align="center">(a)   (b)</div>

Figure 5.10 (a) the 3D surgical guide design, (b) the surgical guide design with support structure. [75]
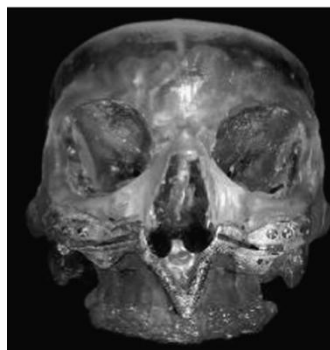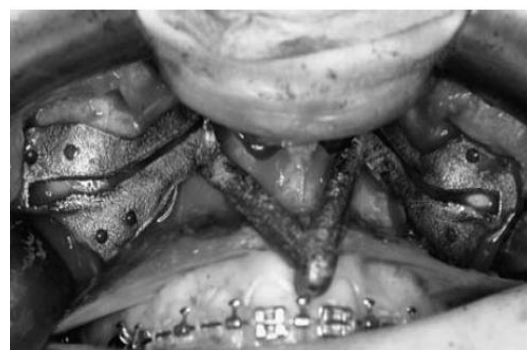
<div align="center">(a)   (b)</div>

Figure 5.11 (a) A surgical guide fitted to an SLA preoperative planning model, (b) the guide being fitted to patient during surgery. [76]

5.6 Requirements of a Medical Guide

Desired requirements when designing a medical guide:

a) Good rigidity so the guide will retain its profile when being handled and worked

b) Good wear resistance capabilities to prevent damage from surgical tools

c) High temperature resistance, which enables high temperature sterilisation

d) Increased freedom of movement for surgeons to reduce line of sight complications
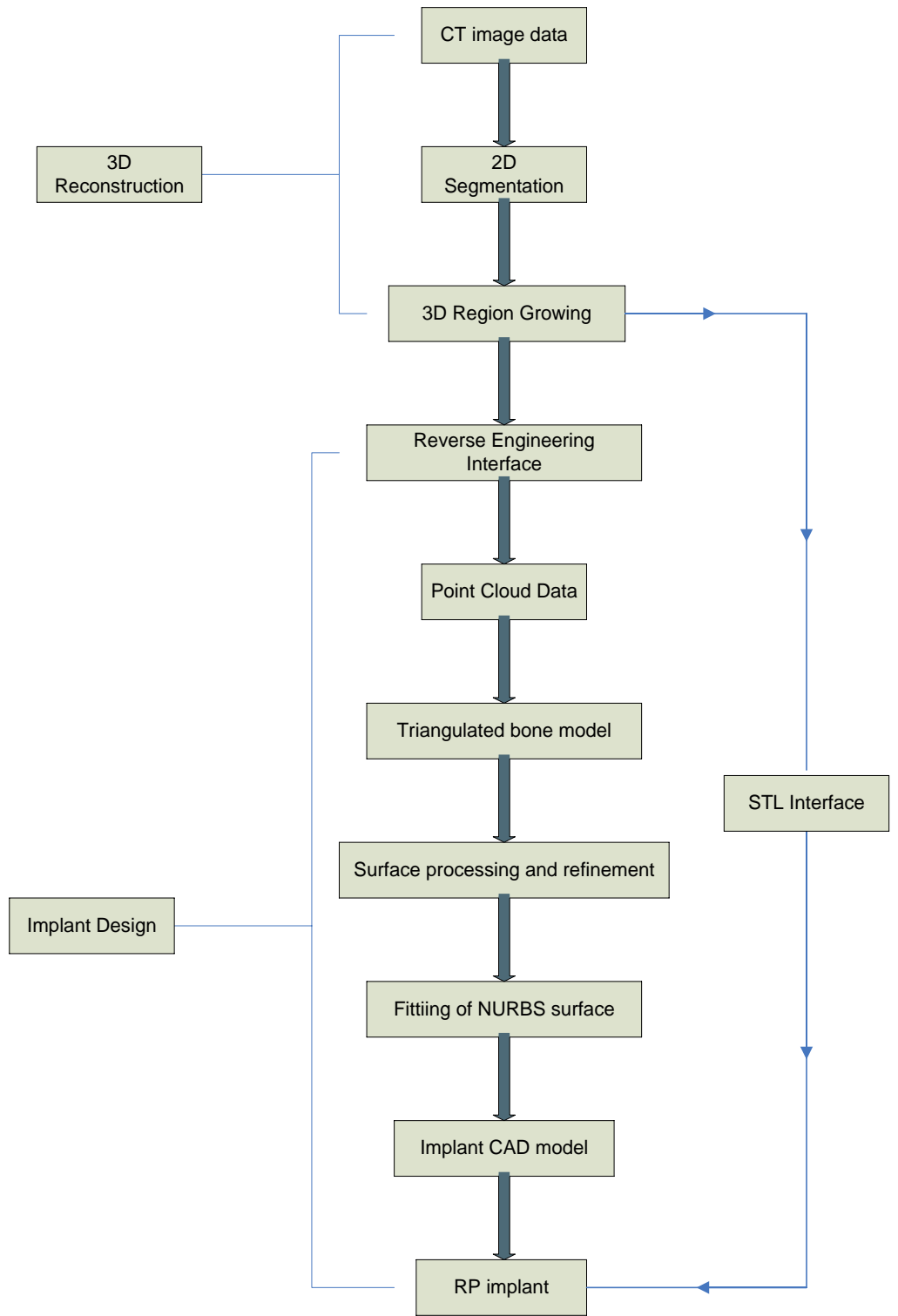
Figure 5.12 RP and CAD methodology procedure for generating customised designed implants. [77]

Chapter 6.0 Bio-compatible materials

6.1 Introduction:

The primary aim of medical intervention is to restore the human anatomy to its original state after it has undergone some form of physical trauma, disease or genetic defect. Biocompatibility and custom manufacturability are significant indicators of successful implant surgery.

Biomaterials have emerged over the years through constant research and development and have permeated many fields of the medical profession. A biomaterial is classified as "any material used to manufacture devices that replace a part or a function of the body in a safe and reliable way". [78]

Owing to the increase in the average life expectancy of the general population, implants especially orthopaedic implants, are being installed on a more frequent basis. As patients become older their joints degrade leading to decreased mobility and associated pain. This indicates the need for implant surgery in an increasing proportion of the population. This need has become one of the key drivers for research and development in medical implant and biomaterials technology.

Therefore it is essential that the application of biomaterials extends to as many regions of the body as possible. This will play an important part in creating a permanent solution to issues such as mobility and function.

Although the range of experimental biomaterials is expanding, only approved biomaterials can be utilised for the manufacture of biomedical implants. Materials can only be classified as approved after extensive medical testing has been performed in order to ascertain the biocompatibility of the material with the human body. Problems such as bacterial infection, blood clots and tissue trauma are possible medical problems when a material is used in the design of a medical implant. Hence the material in question must undergo rigorous clinical trials to establish its biocompatibility and become FDA or equivalent compliant. A suitable surface coating may be applied to allow the implant to be fitted in vivo.
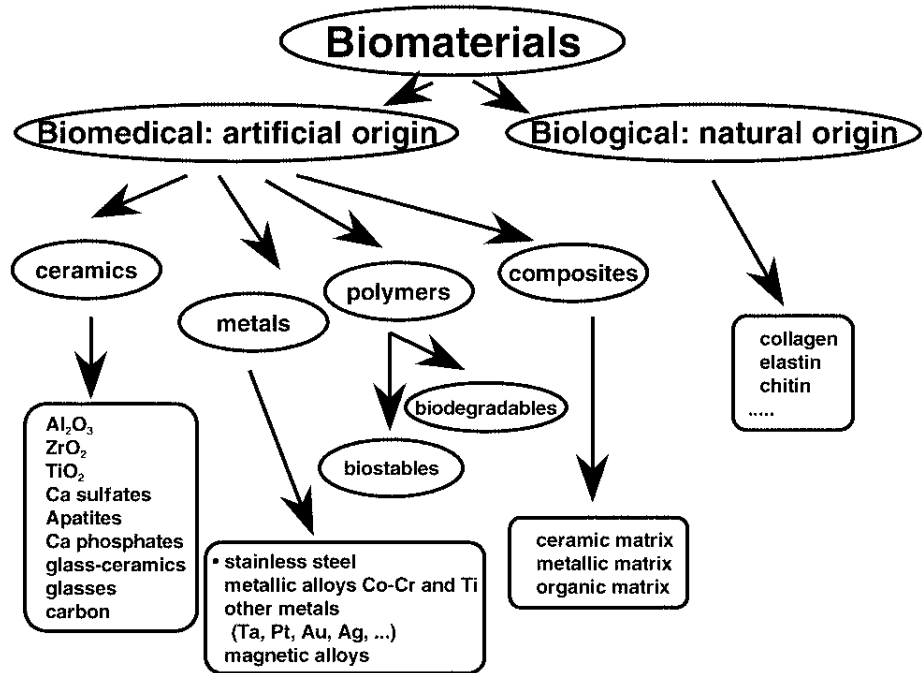
Figure 6.1 the classification of biomaterials. [79]

6.2 Biocompatibility

"The biocompatibility of a long-term implantable medical device refers to the ability of the device to perform its intended function, with the desired degree of incorporation in the host, without eliciting any undesirable local or systemic effects in that host." [80]

6.3 Biomaterial Applications

Examples are:

- Bone plates
- Heart valves
- Contact lenses
- Skin repair devices
- Blood vessel prostheses
- Dental implants
- Orthopaedic replacements
- Customised medical implants

6.4 Biomaterial Classification:

Biomaterials can be classified into three main groups: metals, ceramics and polymers.

Metals	Ceramics	Polymers
316L stainless steel	Alumina(Al_2O_3)	Ultra high molecular weight polyethylene
Co-Cr Alloys	Zirconia	Polyurethane
Titanium	Carbon	
Ti6Al4V	Hydroxyapatite	

Figure 6.2 Categorized approved biomaterials. [81]

Metallic biomaterials are indicated for use in areas of high static or cyclic stress. Such activities include lifting, running, bending or chewing. All of these actions will transfer stresses to the implant, and metallic materials are best suited to these applications. Ceramic materials are designated where resistance to wear is of primary importance, and polymeric materials are used where stability, flexibility and controlled porosity are required. [82]

Careful selection of material is vital in ensuring that the implant:

      a) Functions correctly

      b) Is biocompatible

      c) Is degradable or absorbable if required

If these fundamental selection criteria are satisfied this will increase the probability of a successful biomedical implant design. [83]

6.5 Approved Biomaterials

6.5.1 Metals:
6.5.1.1 316L Stainless Steel

This material demonstrates high strength, high corrosion resistance and improved biocompatibility when compared to other grades of stainless steel. This material is used for pins, plates and screws for locating and fixing. [84]

6.5.1.2 Co-Cr Alloys

Cobalt chrome alloys have extensive industrial applications and are also used for medical implants. EBM is a process capable of producing such implants using CoCrMo ASTM 75. In terms of medical applications this material is used for orthopaedic and dental implants. [85]

6.5.1.3 Titanium

Titanium Alloy Ti6Al4V contains properties that are desirable for medical implants, these are:

      a. High strength
      b. Bio-compatibility
      c. Low density
      d. Good corrosion resistance

This material can be used in conjunction with the EBM or SLM process to produce good quality accurate medical implants such as cranial plates and acetabular implants. [86]

6.5.2 Ceramics:

Ceramic materials are typically solid inert compounds; they offer many advantages in the manufacture of medical implants, including:

- They are bioactive, inert and absorbable
- Surfaces can be polished to a high degree
- High rigidity, required in certain applications
- Improved cell and tissue bonding [87]

Examples of ceramics currently used for medical implants are:

6.5.2.1 Alumina (AL$_2$O$_3$)

This material is mainly used for orthopaedic and dental implants. Alumina can be polished to a high degree having a low average roughness value (Ra) with a high hardness value. Due to these properties Alumina is used in load bearing applications such as total hip arthroplasties as the femoral head. [88]

6.5.2.2 Zirconia

Biomedical grade zirconia was first used in the 1980s to solve the problem of alumina brittleness and ultimately the failure of medical implants. Although this material is extremely hard it is susceptible to age hardening when in contact with water which leads to crack propagation and failure. In 2001 approximately 400 zirconia Prozyr femoral heads failed in application. This had a catastrophic effect on this material as an approved biomaterial. Since then detailed R&D has been undertaken which shows that the failure of these femoral heads was due to two factors:

      a) Accelerated ageing of the ceramic

      b) A change in the heating process technique

Tests carried out have concluded that zirconia with a grain size above 0.6 microns reduces the ageing dramatically. One solution was to add yttria as a dopant which increased the toughness and reduced the signs of aging in the implant. Zirconia toughened alumina may be another alternative as the addition of alumina to zirconia reduces the effect of ageing dramatically. For the immediate future, alumina and zirconia composites appear to be the solution and are currently been introduced to the area of dental implants. [89]

6.5.2.3 Hydroxyapatite (HA)

HA is a naturally occurring mineral form of calcium apatite also found in bone and teeth. Medical applications include the replacement of amputated bone and bone growth promotion (osseoconductivity) in prosthetic implants.

SLS is capable of producing medical implants from this material because the powders are subjected to low compression forces which naturally produce porous components. This is a key characteristic for some in vivo medical implants such as drug delivery devices. HA

has been used in several in vivo applications such as dense sintered ceramics for middle ear implants, alveolar ridge reconstructions and augmentation, orbit implants for orbital floor fractures and general volume augmentation. HA is also used as a biocompatible surface coating for metals. [90]

6.5.3 Polymers:

Medical grade polymers are used in various medical applications including tissue repair, drug delivery devices, wound healing and medical implants. Polymers have an extensive range of controllable structural properties including molecular weight, entanglement density, degree of crystallinity, and degree of crosslinking. In general polymers exhibit time-dependent mechanical behaviour and are said to be viscoelastic. When polymers are subjected to sustained loads this can result in time-dependent strain or creep. Time-dependent material properties make the prediction of in vivo performance difficult, especially when the loading conditions become complex. During use, load bearing medical devices may subject their polymer components to their fatigue, fracture and wear limits. [91]
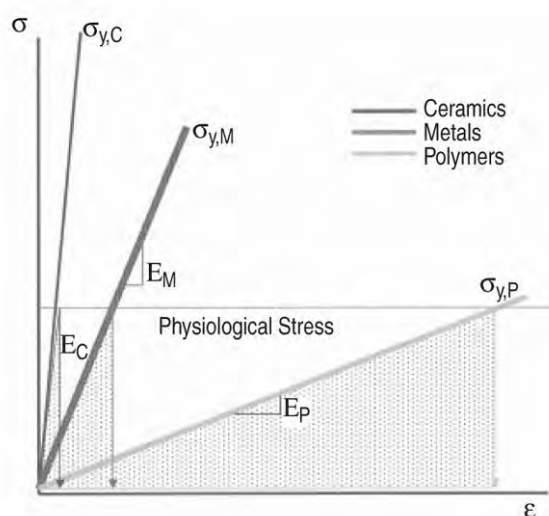
Figure 6.3 Compares strain on a ceramic, metal and polymer implant subjected to a given physiological stress. [92]

6.5.3.1 Ultra High Molecular Weight Polyethylene (UHMWPE)

UHMWPE is a material better known as high performance polyethylene which is a thermoplastic polyethylene. Owing to its long chain like structure it can distribute loads more efficiently helping to reduce wear and increase stability. It has a high resistance to

chemical attack and absorbs only minute amounts of moisture. In terms of medical applications UHMWPE is the preferred material when performing arthroplasty procedure for spine and orthopaedic implants. [93]

Figure 6.4 A complete hip replacement using UHMWPE as the acetabular cup with Co-Cr femur head. [94]

6.5.3.2 Poly(methyl methacrylate) (PMMA)

PMMA is a material that is highly biocompatible and is commonly used in the production of intraocular lenses. This material is better known as Vitroflex, Acrlyex or Perspex. This material can be used in RP to produce medical implants such as scaffolds and bioactive implants in conjunction with the SLS process. In orthopaedic surgery PMMA is used as bone cement to locate and fix implants and to remodel and replace damaged or lost bone. PMMA is also used in the production of dentures and in cosmetic surgery to reduce the appearance of visible scar tissue. [95]

6.6 Performance of Polymer Implants

For a medical implant or device to function correctly it is important that the following factors are discussed and analysed prior to material selection.

Factors are:

- Implant design
- Structural Requirements
- Clinical Issues
- Processing Treatments
- Material Selection
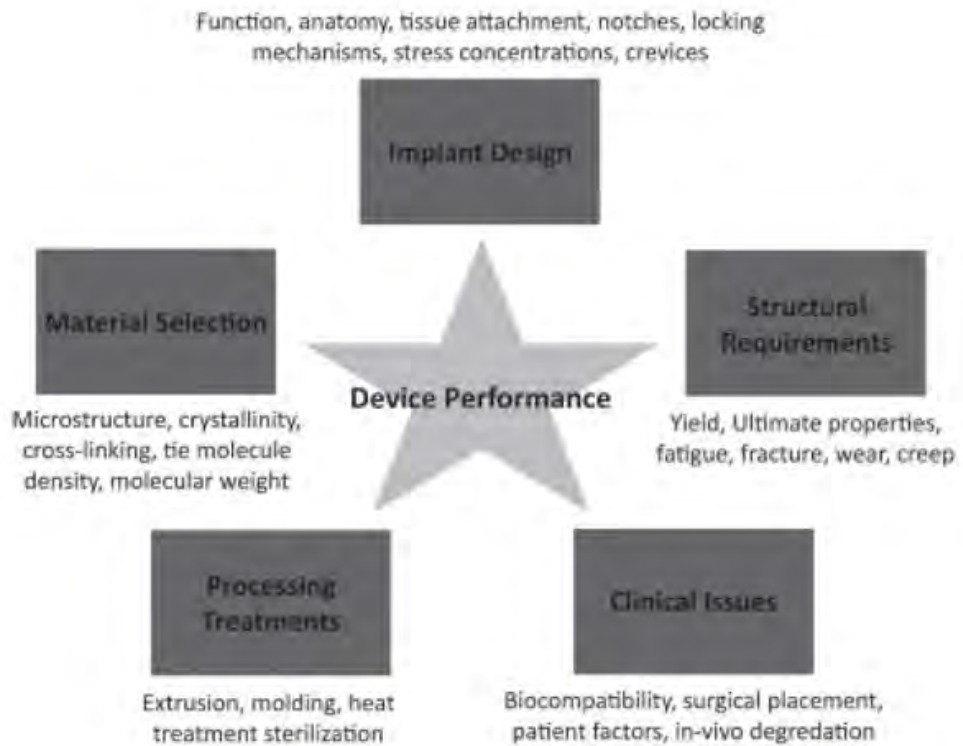
Figure 6.5 Key factors influencing the performance of a polymer in a medical device or implant. [96]

6.7 RP Biomedical materials

In terms of RP there are several processes that can produce medical implants. These are:

    i.   SLS

    ii.   SLA

    iii.   EBM (Electron Beam Melting)

    iv.   SLM

    v.   LENS (Laser Net Shaping)

SLS and SLA normally focus on polymers and ceramics whereas EBM, SLM and LENS deal with producing metal implants.

6.8 Biocompatible materials and medical applications

Material	Medical Application
Low density polyethylene (LDPE)	Tubing , Shunts, Catheters
High density polyethylene (HDPE)	Plastic surgery implants
Ultrahigh molecular weight polyethylene (UHMWPE)	Acetabulum in total hip prostheses, artificial knee prostheses
Polypropylene	Heart valve structures
Polyvinylchloride (PVC)	Catheters, Maxillofacial prostheses
Polytetrafluoroethylene (PTFE)	Catheter coatings, facial prostheses, heart valves
Polydimethylsiloxane	Shunts, Maxillofacial prostheses heart valve structures
Poly(methyl methacrylate) (PMMA)	Bone cement, Middle Ear Prosthesis, intraocular lenses

Figure 6.6 Biocompatible polymers used in biomedical applications.

In terms of degradable polymeric biomaterials, typical applications include sutures, drug delivery devices, orthopaedic fixation devices, temporary vascular graphs and tissue engineering for guided tissue regeneration scaffolds. [97]

Material	Medical Application
Stainless Steel AISI316Llvm, 319L	Customised medical implants
Stainless Steel F745 (Cast stainless steel)	Location and fixing devices, screws and pins
Co-Cr-Mo F75 (Vitallium)	Dental implants
Co-Cr-Mo F799 (Forged Co-Cr-Mo)	Coatings on artificial joints
Co-Cr-W-Ni F90	Surgical fixation wires
Co-Ni-Cr-Mo-Ti F562	Customised medical implants
Pure Ti, grade 4 F67	Spinal fixation devices, femoral components
Ti-6Al-4V ELI F136-79	Orthopaedic Implants and prosthesis

Figure 6.7 Biocompatible metals used in biomedical applications.

Ceramics	Medical Application
Alumina (AL_2O_3)	Total hip arthroplasties (Femoral Head)
Zirconia	Dental implants and crowns
Hydroxyapatite (HA)	Middle ear implant Alveolar ridge reconstruction Orbit implants for orbital floor fractures

Figure 6.8 Biocompatible ceramics used in biomedical applications. [98]

6.9 Ethical issues in the development of new biomaterials

6.9.1 Biocompatibility

Materials specified for implant production must be biocompatible. Non biocompatible materials can cause infections, create toxins which cause illness and in certain cases be fatal.

6.9.2 Osseointegration

This is the direct relationship between osseo or calcium tissue e.g. bone and the surface of a biomaterial used in a medical implant. Two biomaterials that demonstrate osseointegration are hydroxyapatite and titanium. This material characteristic helps to

63

increase the rigidity of the recovery site and promotes bone growth in the affected area therefore reducing the recovery time and improving the integration of the implant. [99]

Titanium Plate
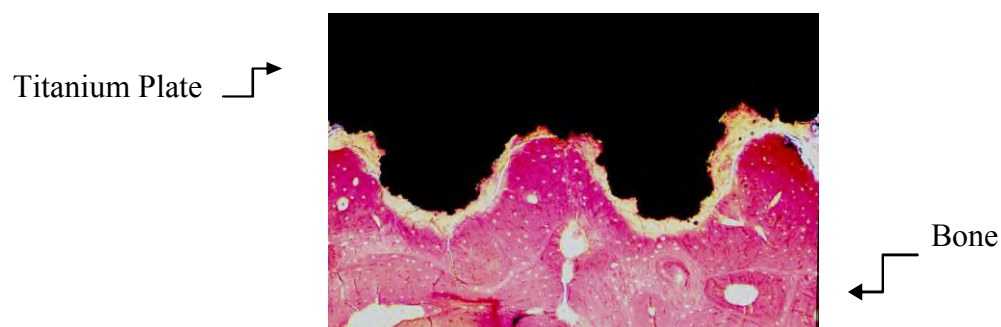
Bone

Figure 6.9 A titanium implant (black) integrated into bone shown in red. [100]

Osseointegration is important in craniofacial, ear, nose and orbital prosthesis in increasing rigidity and is especially useful for bone anchored hearing aids which rely on the transmission of vibration to hear.

6.9.3 Clinical trials:

Clinical trials are performed to ascertain the safety and efficacy data required for biomaterials and medical devices. These trials can only be performed when satisfactory data has been collated and trials are in compliance with FDA or similar medical regulatory bodies. Clinical trials are mandatory and must be conclusive before materials are allowed to be used as approved biomaterials.

Clinical trials are put in place to achieve a number of outcomes. Some of these are:

a) Assess the safety and biocompatibility of the material

b) Assess the risk of infection

c) Assess the long term stability of the material in terms of mechanical properties e.g. age hardening in zirconia. [101]

Once the clinical trials are successful, and meet the specifications required the material can be categorised as an approved biomaterial.

Chapter 7.0 – Growth of RP in the medical sector

7.1 Medical Device Market

Due to the global economic downturn there has been a decline in the UK's gross domestic product (GDP) for the first half of 2009. Nevertheless in the last quarter of 2009 there has been a 0.4% growth which indicates there is an economic upturn. In terms of the healthcare sector the medical device industry is recovering at a faster pace. This is mainly due to the fact that the demand for healthcare products is not directly related to consumer spending and therefore tends to remain more stable during times of economic difficulty.
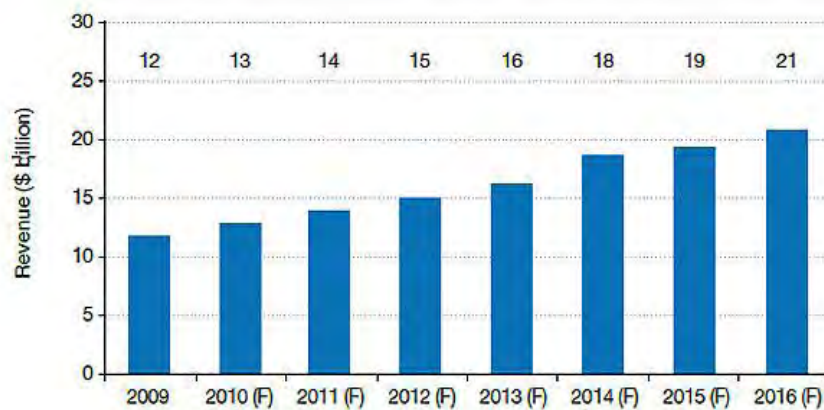
Figure 7.1 U.K medical devices industry projected forecast. [102]

In 2009 the U.K medical device industry was valued at £8.2 billion. The main driving element was the fact that there was an increase in the average age and decrease of average health in the population. Forecasts expect that the market will grow by 8.2% annually over the next seven years to reach £14.2 billion ($21 billion) by 2016.

Another area that is forecast to see extensive growth is the orthopaedics device market. The primary driver been an increase in the number of incidents related to arthritis and musculoskeletal disorders. Arthritis affects one fifth of the adult population in the U.K.

It was reported that an estimated 539,000 cases related to musculoskeletal was recorded between 2007 and 2008. This increase coupled with the improvements in related implant technologies and superior products such as hip resurfacing implants the orthopaedic device market estimated at £665million ($997 million) in 2009 and is forecast to grow by 8% annually over the next seven years to a value of £1.14 billion ($1.76 billion) by 2016.

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The medical device industry in the U.K will undergo significant challenges due to the policy adopted by the National Health Executive (NHS) in its attempt to implement "efficiency- saving measures". It is estimated that 39.5 million people have related contact with a medical device on a daily basis in the U.K and with the increase in demand for medical devices that save and increases the quality of life this sustained growth is expected to continue on an upward trend. [103]

7.2 Current state of play of RP industry

The Wohler's report is a document published annually since 1995 that gives a global account and analysis of the current state of the RP industry. The report also highlights a number of elements within RP including industries investing in RP technology, the integration of applications, annual revenues, industry growth and predicted forecasts. This thesis outlines some of these areas and focuses on the biomedical sector where RP technology is been harnessed to increase the accuracy and confidence of surgeons.

The last year has been a rather steady one for RP industry in terms of new material and processes releases. Although the economic downturn has had an effect on the sector direct part production from RP technologies continues to grow especially in the dental area which has been the strongest area of growth for the past four years.

The RP industry, which includes products and services, had a worldwide annual growth of 3.7% from $1.141 billion in 2007 to $1.183 billion in 2008. This is set to continue in 2009. [104]

7.3 Processes Advancements

Some recent advancement contributed by equipment and material manufacturers in the RP industry over the past 2 years is listed below.

(a) Direct Metal Sintering/Melting is now been investigated as an alternative process capable of performing satisfactorily in the biomedical and aerospace industries.

(b) EOS in May 2008 introduced its high elongation polyamide PrimePart DC for plastic laser sintering and Stainless PH1 for its direct metal laser sintering platforms.

(c) In May 2008 Arcam released its Titanium Grade 2 material for electron beam melting systems.

(d) 3D Systems released their new large frame iPro 9000 XL SLA Centre and the iPro 8000 MP SLA Centre aimed directly at the hearing aid, dental and medical sectors.

(e) In December 2008, Stratasys introduced a vapour-honing product called Fortus Finishing Stations for finishing FDM parts made form ABS.

(f) In February 2009 EOS and Victrex revealed a new PEEK material, PEEK HP3 for use in their high temperature EOSINT P800.

(g) In March 2009 3D Systems formed an alliance with Dreve GmbH to develop and market dental application solutions. [105]

7.4 Current Applications of RP Technology in Industry

The industries availing of RP technology are numerous, but the sectors benefiting from it most can be seen below.
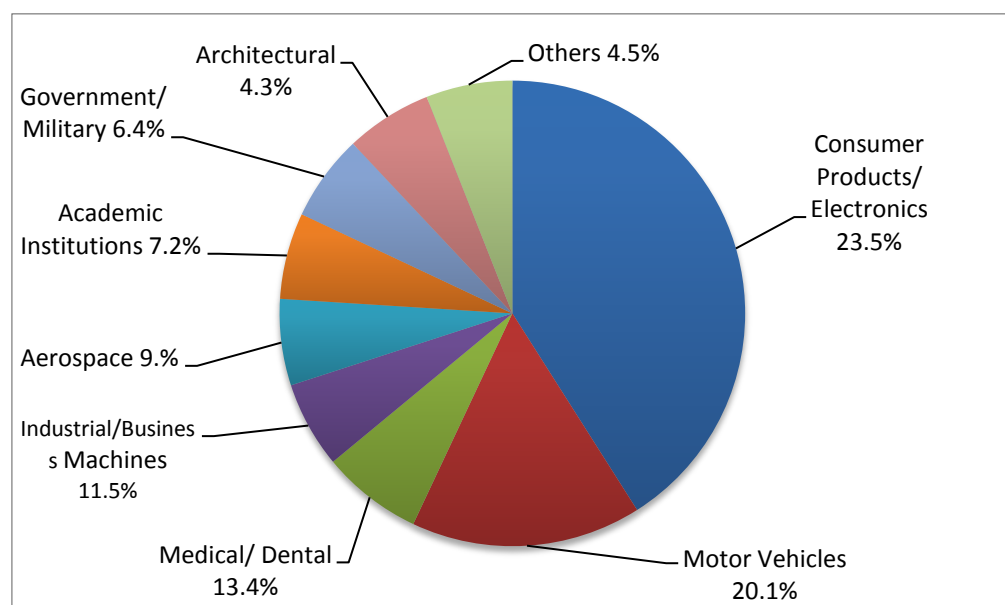
Figure 7.2 Results carried out by 65 system manufacturers in relation to sectors they service and revenues generated. [106]

7.5 Potential of RP

The applications of RP are quite extensive and its boundaries are continuing to be tested. Current areas of integration are:

a) Castings for microsurgery tools
b) Reconstructive surgery for victims with skull traumas
c) Drill guides for Jigs and fixtures
d) Finite Element Analysis (FEA) using colour models to reveal stress levels
e) Aerospace and motorsport wind tunnel design [107]

7.6 Medical Applications

With the increased access to medical imaging technology due to using small office type cone-beam CT (CBCT) scanners, high quality images are been produced on a more frequent basis at a fraction of the original cost. This is mainly due to orthodontic processes that require dental data to produce accurate implants and dentures. As discussed there are a number of processes available but two in particular have developed a niche market in the medical sector. These are EBM by Arcam and DMLS by EOS. These processes can produce parts from stainless steel, cobalt-chrome alloys and titanium alloys. Both EBM and DMLS has become recognised processes for producing medical implants due to the extensive compliance carried out with relation to regulatory affairs in Europe for CE certification of implants. [108]

7.7 RP Medical Developments

7.7.1 Background

Cleft lip and palate is a deformity frequently seen in infants worldwide. One of the methods used for reversing this deformity is achieved by fitting a Dento Maxillary Appliance (DMA). This process requires surgical pinning of an implant to the roof of the mouth and tightening by means of screws on a daily basis to close the opening.
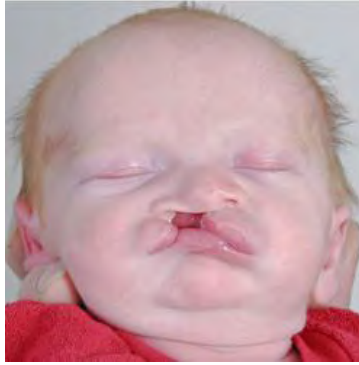
Figure 7.3 Baby with cleft lip and palate. [109]

7.7.2 New Procedure Process steps

   i.   Obtain a profile of patients palate using a 3D laser scanner

  ii.   Using Geomagic software to design the final palate shape

 iii.   Produce a series of progressive implants from start to finish using SLS RP system
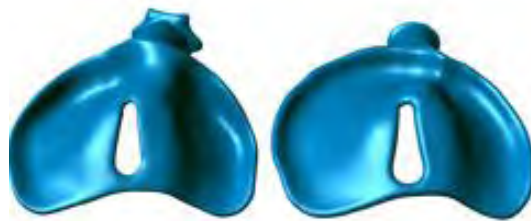
Figure 7.4 First and final customised implant. [110]

Figure 7.4 Dr Stoddard examining a complete range of RP inserts. [111]

Figure 7.5 One of the original patients to be treated using this process. [112]

7.7.3   Process Advantages

i.   Less invasive

ii.   Aesthesia not required

iii.   Process repeatable and results are more consistent

iv.   Cost efficient [113]

Chapter 8.0 - Case Study Methodology

In this chapter five separate case studies were selected. These cases illustrate how medical problems can be addressed with medical design software and RP technology to produce reliable medical solutions.

8.1 Systematic Approach
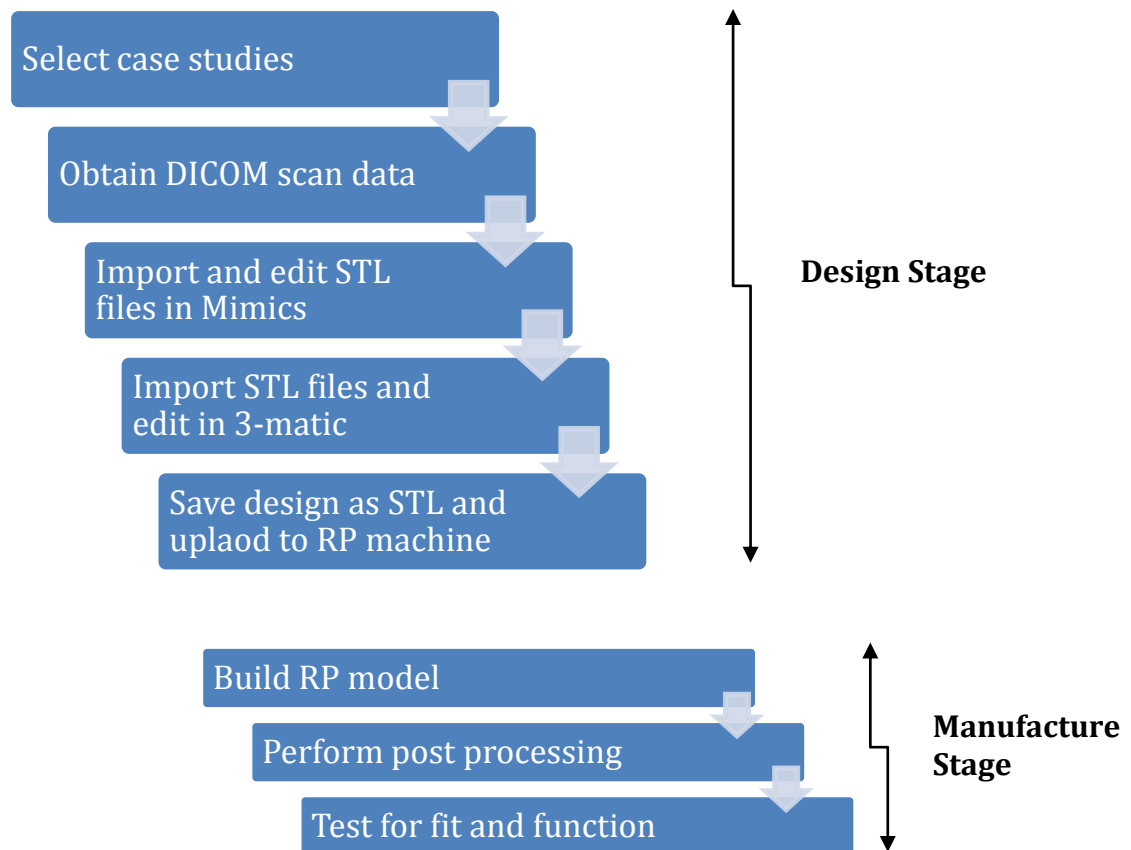
Figure 8.1 Systematic approach applied to case studies.

8.2 Methodology

  i. Identification and selection of medical test cases

  ii. Identification of relevant software solutions

  iii. Identify a systematic approach for each case

  iv. Evaluation of methodology and results

8.3 Case Study Selection

8.3.1Case study one – Cranial defect comparison of methods

Build a partial skull model from a Z-Corp 3D printer and design and build 2 model cranial plates using two different methods using a 3D Systems SLA machine. Compare the two methods of producing a cranial plate using CT DICOM data, Materialise Mimics and Materialise 3-matic software and discuss the results.

8.3.2 Case study two – Right Hand Cranial Defect of Skull

Produce a RP model of a patient's skull with a side cranial defect using a Z-Corp 3D printer and subsequently design a completed cranial plate implant using Materialise Mimics and 3-matics software to produce a SLA model of the cranial plate.

8.3.3 Case study three – Acetabular Fracture Reconstruction

Process data using Materialise 3-matic software to reconstruct an acetabular fracture and build the reconstructed parts on a Z-Corp 3D printer and discuss results.

8.3.4 Case study four – Design an Acetabular Cup Implant

Using a patient's DICOM data and Materialise Mimics and 3-matic software to design and produce a customised acetabular cup implant using RP technology.

8.3.5 Case study five – Aorta Segmentation, Aneurysm Design and Alignment of Heart Valve

Using a patient's DICOM data, Materialise Mimics and 3-matics software solutions to analyse an aorta under varying conditions including the alignment and fitting of a heart valve.

8.4 Software Solutions

To integrate DICOM data with the finished RP product, software solutions programmes are necessary to make this link. These are:

- Materialise Mimics – used to convert 2D DICOM data from MRI/CT scans to 3D data
- Materialise, Magics and 3-matics – used for the manipulation of line geometry, editing and processing of files

8.5 Evaluation of results

The results obtained overall were good in all cases but should be evaluated by consulting an expert in the area or a surgeon who performs interventions on a regular basis. Only then can the results be evaluated properly.

Chapter 9.0 - Case Studies

9.1 Case Study 1- Cranial Defect Comparison of Methods

This case study required a cranial plate to be designed and manufactured due to sustained blunt force trauma to a patient's right hand side of the craniofacial region. A model of the patient's skull was converted from CT scanned data and manipulated using Mimics and 3-matics software to produce a 3D image file in STL format. Using 3-matic software two cranial plates were designed and manufactured on a 3D Systems SLA machine. The first cranial plate was designed using the "Create Cranioplasty" prosthesis tool. This method generates the plate automatically using the existing geometry of the patient's skull and the algorithms within the software. This method is generally used when the surface area concerned is reasonably uniform.

The second plate was designed using the "Create Spline" command. This allows a cross section of the patient's skull to be viewed and a spline created through the skull intersecting the affected area. Inserting control points along the spline, the position of the spline can be manipulated by moving each point individually to match the profile of the opposite side of the skull. Therefore this is a subjective method of achieving the profile of the cranial plate.

9.1.1 Process steps

9.1.1.1 Mimics Process Steps

The data in this case study had already been converted from DICOM 2D data to 3D data and saved in STL format.

Mimics steps include:

- DICOM data images imported into Mimics software
- Project loaded and orientation selected
- Threshold set to default; 226 points and first mask will appear
- Selecting a particular area on the skull and selecting region grow will produce a new mask in yellow and eliminate background interference
- By selecting "Calculate 3D" a 3D model will appear. When the mask has been edited the file must be saved as a binary STL file, for file transfer

9.1.1.2   3-matic Automatic Method
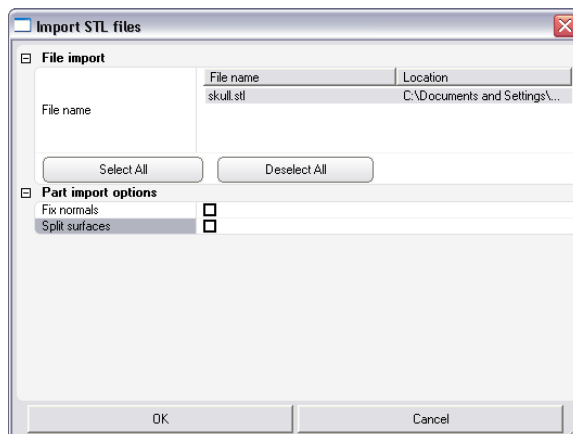
Figure 9.1. Part imported as STL file.
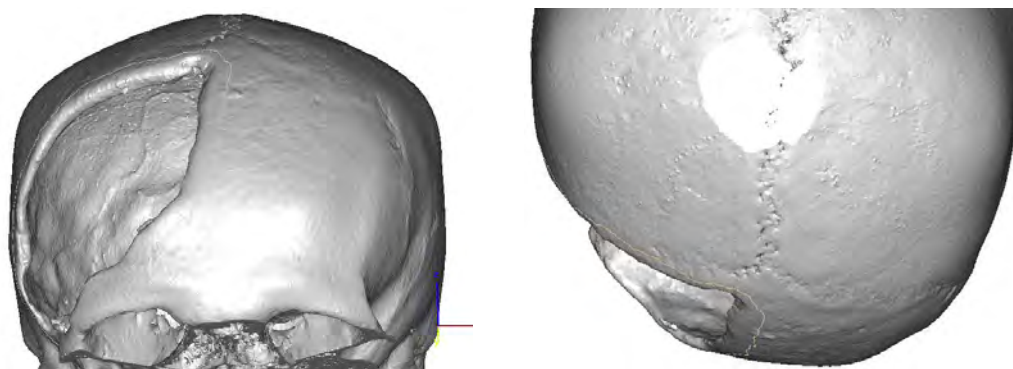
Figure 9.2. (a), (b) Curve tool selected and polyline plotted around the cranial defect.
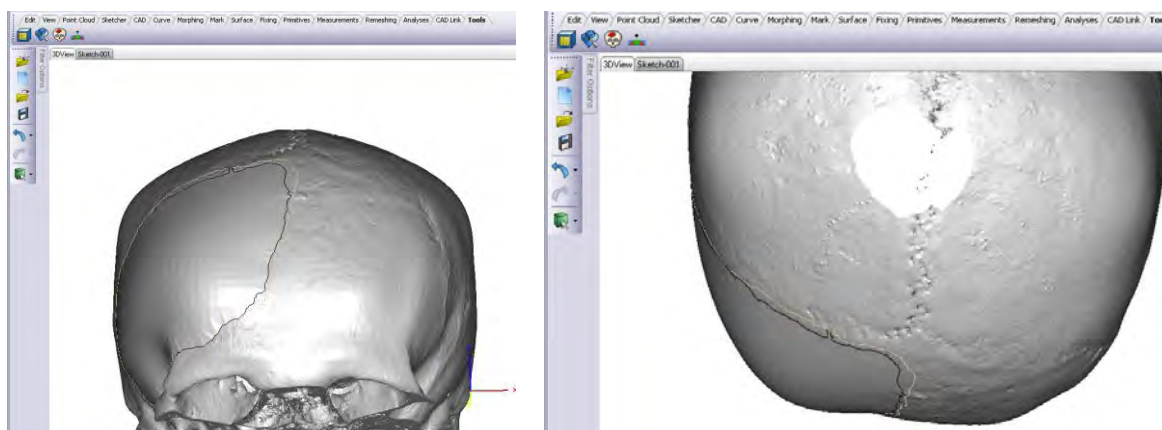
Figure 9.3 (a), (b) Front and plan view of cranial plate generated by selecting "Create Cranioplasty" tool.

A more pronounced profile is generated by this method. The create cranioplasty tool automatically creates tangency to the existing shape of the skull edge and uses algorithms in the software to generate profile.

9.1.1.3 3-matic Manual Method
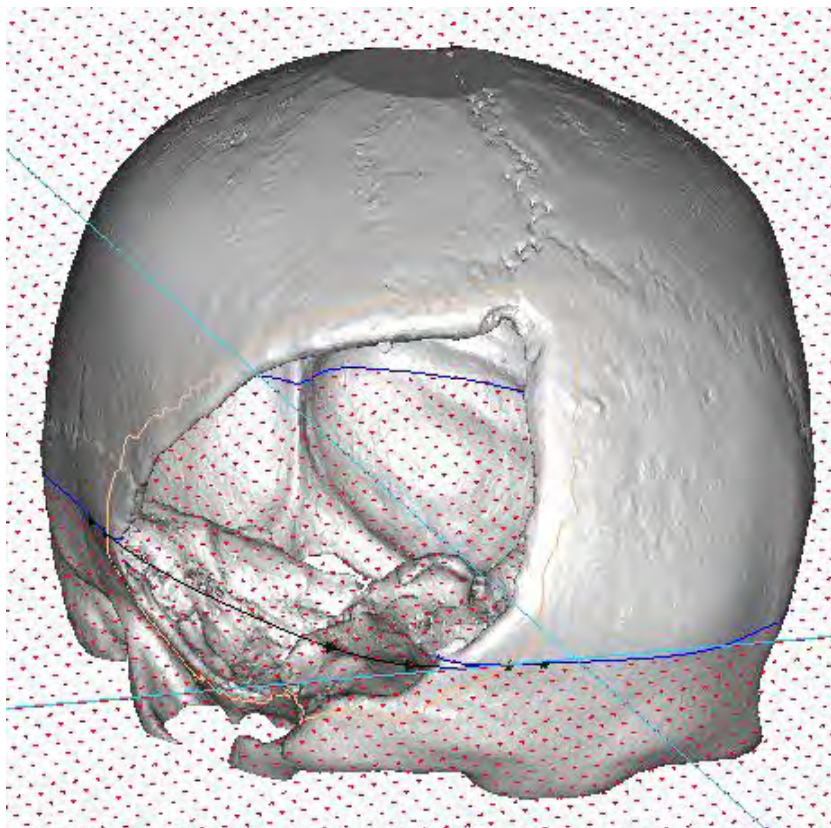
Figure 9.4 3D skull cross section.

A spline is fitted through a cross section of the skull and control points fitted so the profile of skull can be adjusted to generate a corresponding match. (Select sketcher, new sketch, import an intersection of skull into sketch)
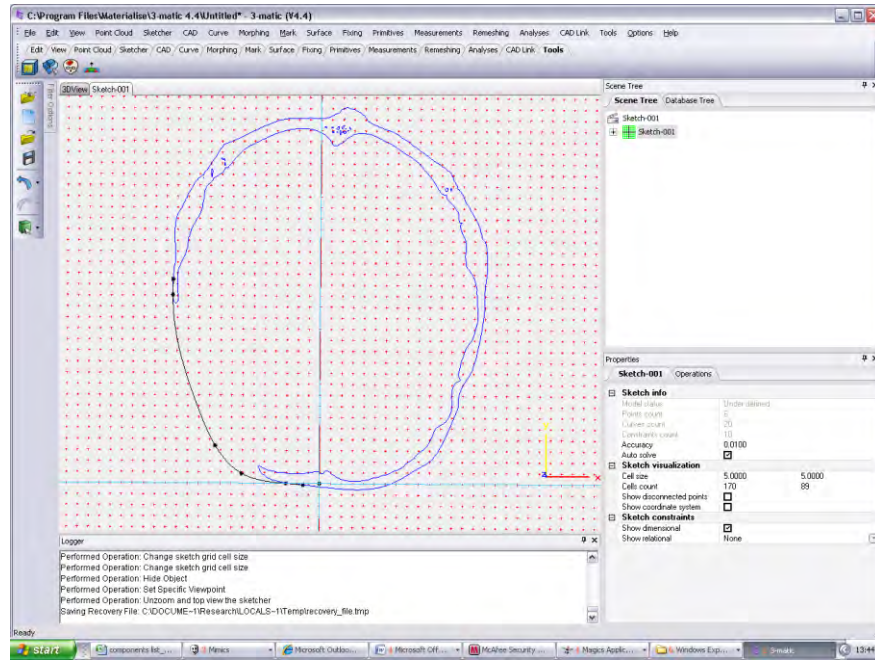
Figure 9.5 A 2D skull cross section.

A cross section of the skull is inserted into a new sketch and a spline created and manipulated by control points to generate symmetry. (Select sketcher, create spline and drag control points)
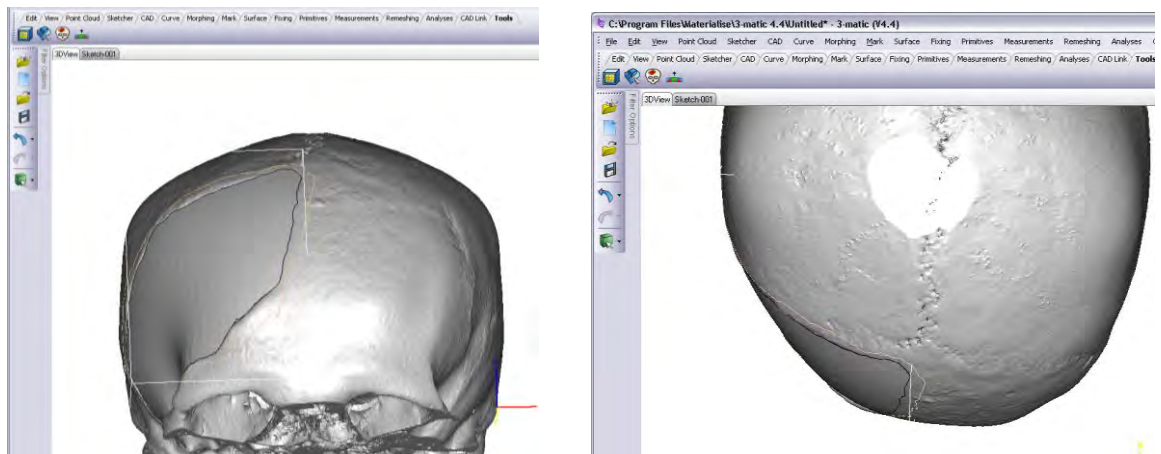
Figure 9.6 (a), (b), skull front and top view.

Under the tools tab select "Create Cranioplasty" icon and select the guide curve defined in sketch. A cranial plate is generated using software algorithms for the surrounding edge and

the inserted spline. It can be seen that the profile of the cranial plate is relatively symmetrical with the opposite side due to the inserted spline controlling the profile. The file is then saved as an STL file.

Cranioplasty tool

Cranial plate made from automatic cranial plate tool

Cranial plate made from spline method
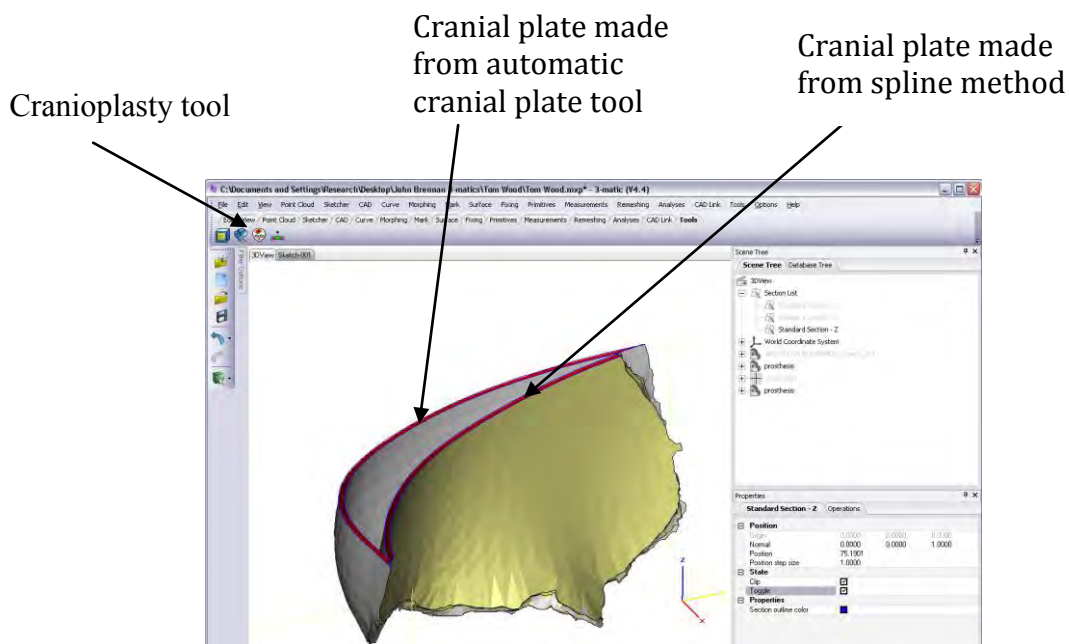
Figure 9.7 Differences between cranial plates generated by two different methods.
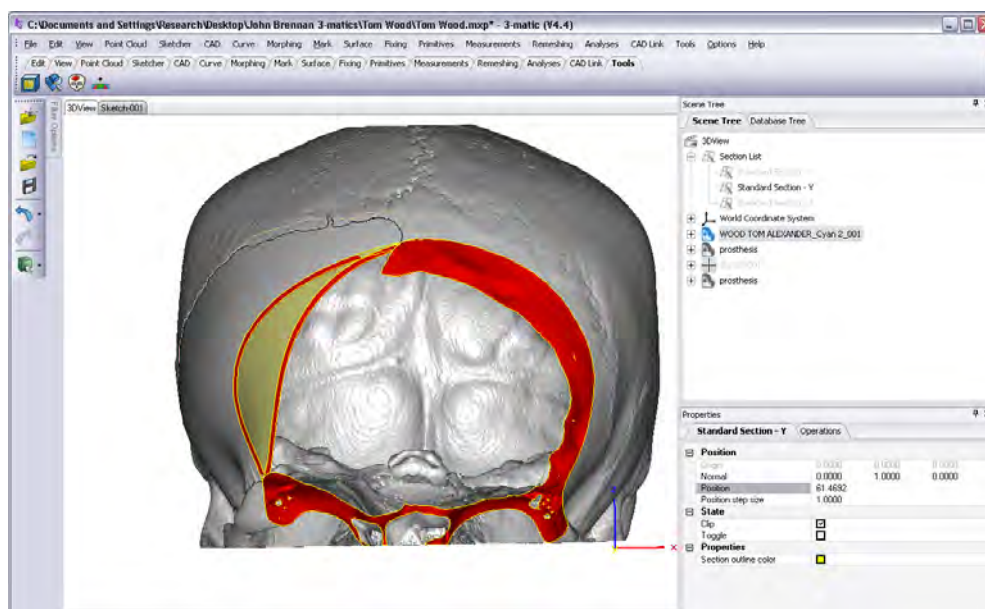
Figure 9.8 Front view of both cranial plates showing their different profiles.

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Figure 9.9 A sliced 3D Z-Corp case study skull model.

Figure 9.10 Cranial plates rapid prototyped on 3D Systems 250 SLA machine.

Cranial plate and skull model. Radius of curvature is not as uniform when compared to manual method.
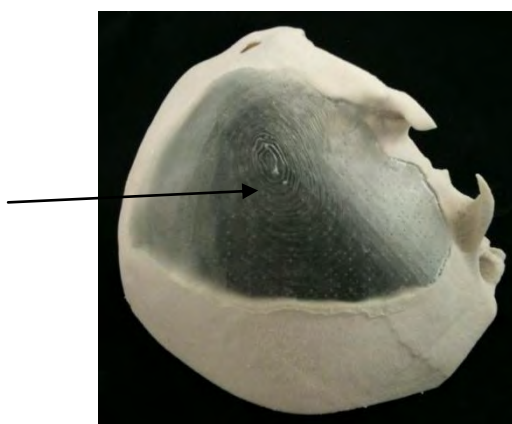
Figure 9.11 A partial RP generated skull with cranial plate made by the automatic "Cranioplasty Tool" in 3-matics. The concentric pattern denotes a greater change in curvature.

Cranial plate and skull model. Radius of curvature is more uniform.
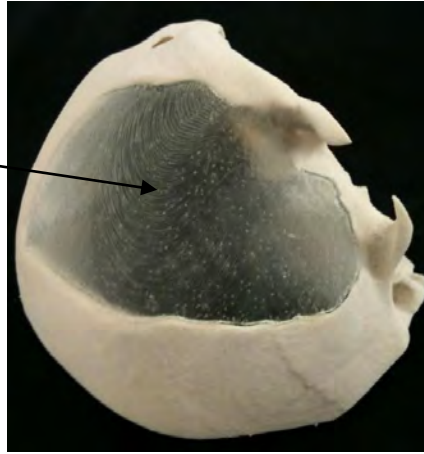
Figure 9.12 Section of skull with cranial plate made from inserting spline, manual method.

9.1.2 Summary:

Both plates, although designed from the same data, have different profiles but give a satisfactory fit. However the shape of the plate designed from the manual method is more symmetrical and therefore would look more aesthetically pleasing if designed and manufactured out of a biocompatible material such as titanium and fitted as a custom designed implant. However using the "Create Cranioplasty tool" is more time efficient.

9.2 Case Study 2- Cranial defect on right hand side of skull

This case study required a cranial plate to be designed and manufactured due to a sustained blunt force trauma to the frontal area of the right craniofacial region. The skull model was made on the Z-Corp 3D printer and the cranial plate was made on the 3D Systems 250 SLA machine. This method involved the use of Materialise Mimics and 3-matic software. In this case Boolean subtractions and extrude commands were required. Four tabs were also designed and attached to the cranial plate to provide a method of fixing the plate in position.

9.2.1 Process steps

9.2.1.1 Mimics Process Steps
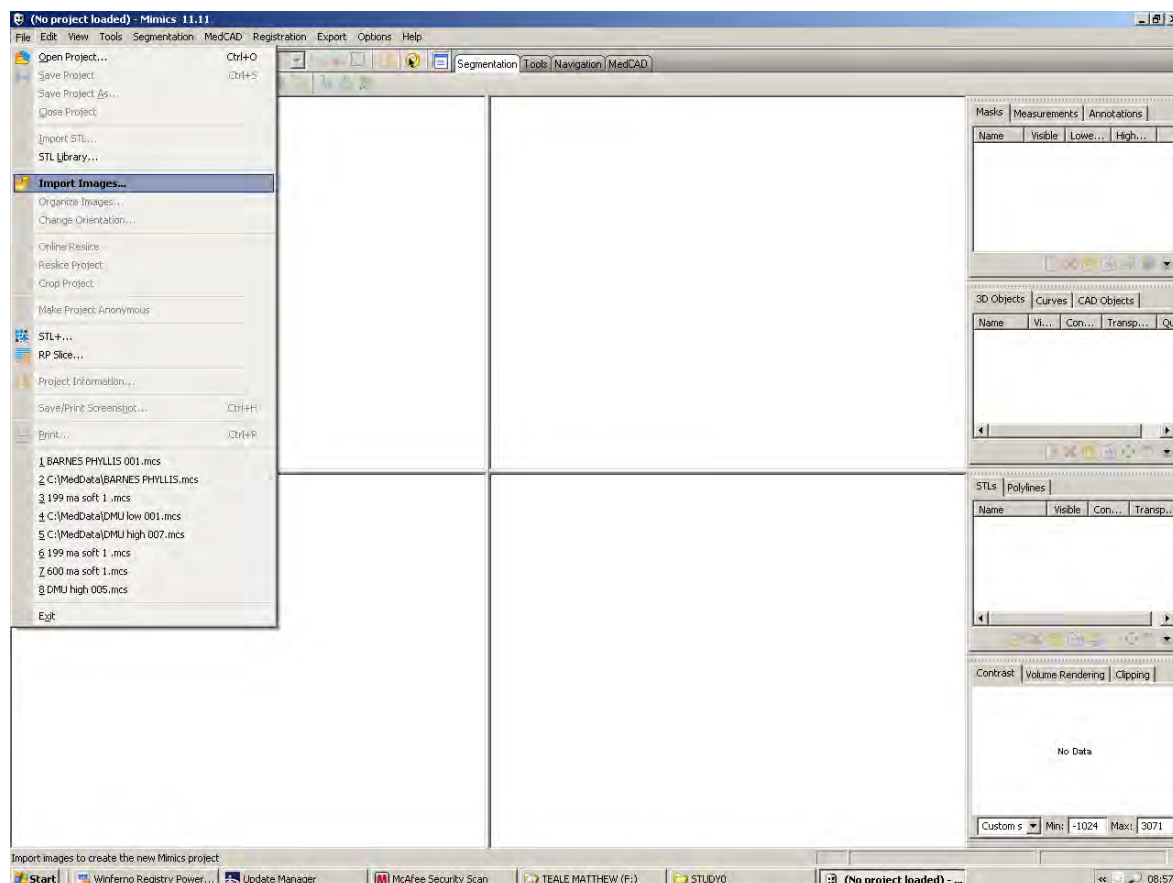
Figure 9.13 DICOM data images been imported into Mimics software.
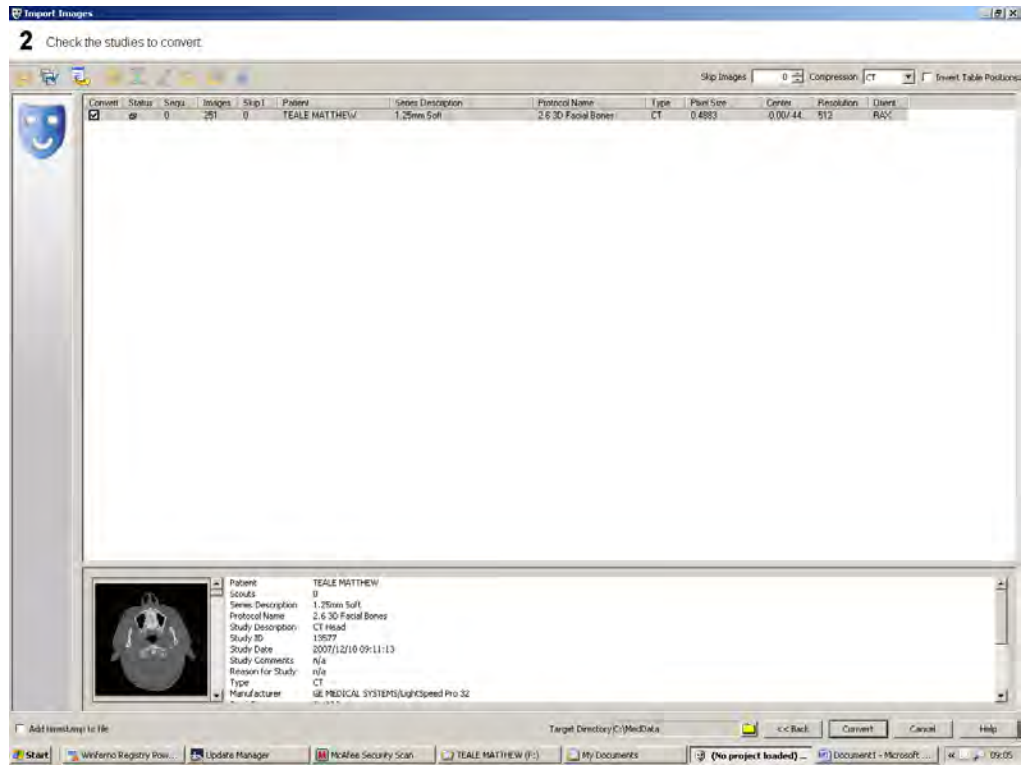
Figure 9.14 DICOM data being converted.
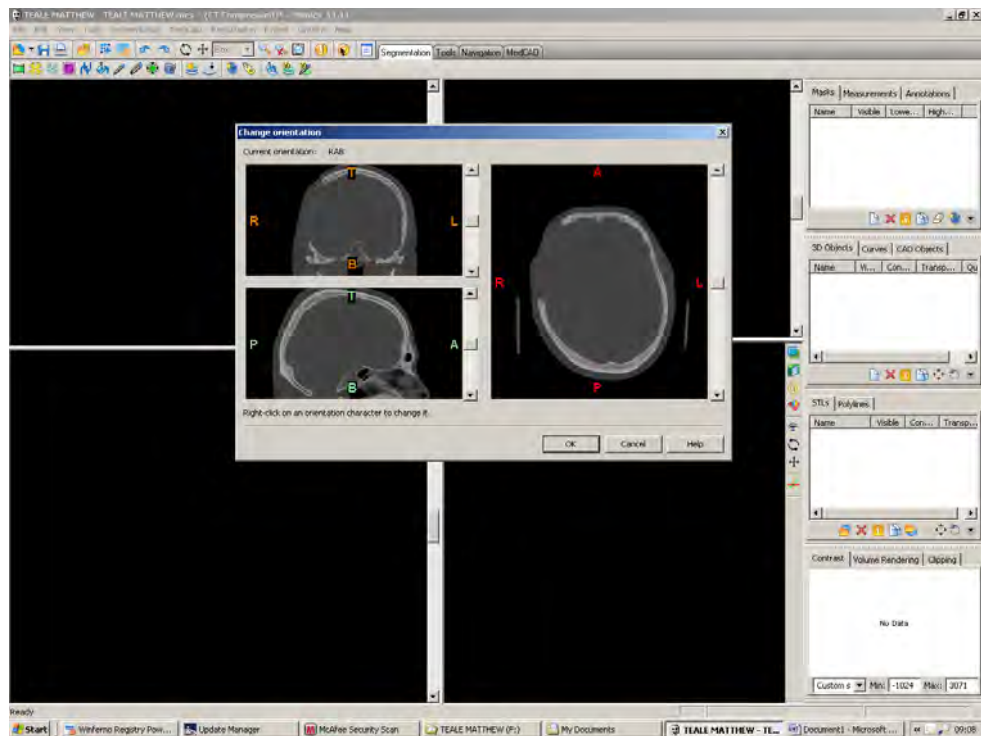
Figure 9.15 Orientation of project is selected.
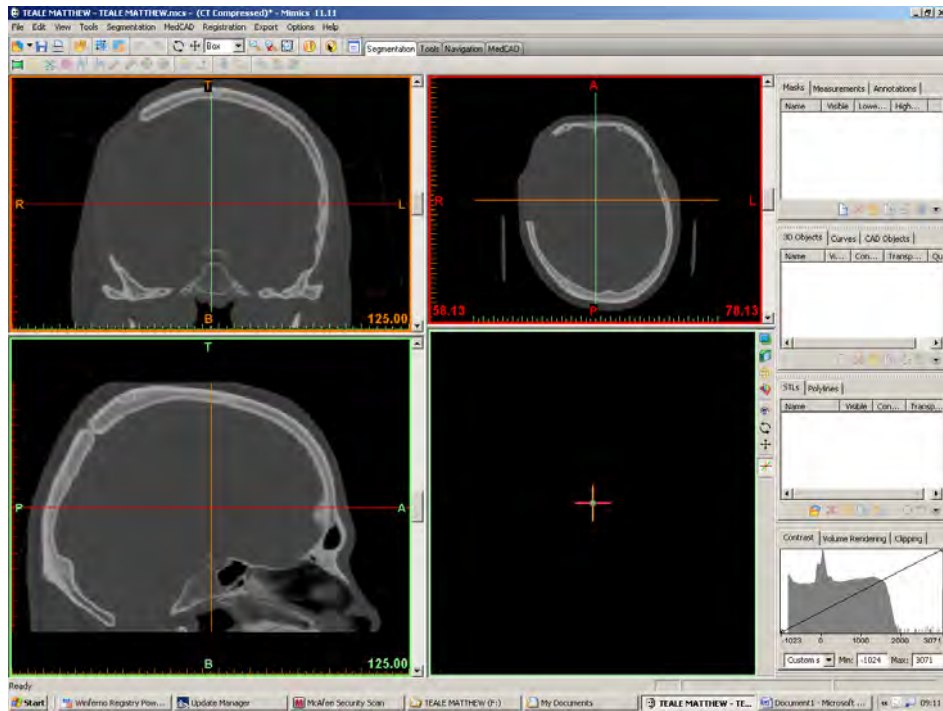
Figure 9.16 Screen above will appear when orientation has been selected.
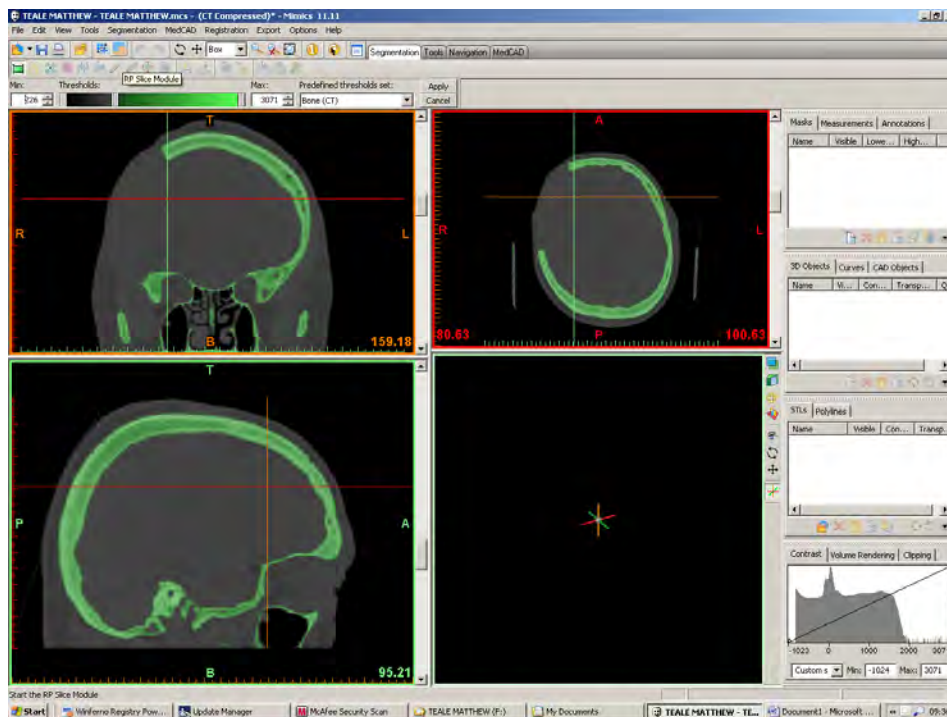
Figure 9.17 Setting the threshold for mask.

The threshold button should be set to 226 points and select region grow button for first mask to appear.
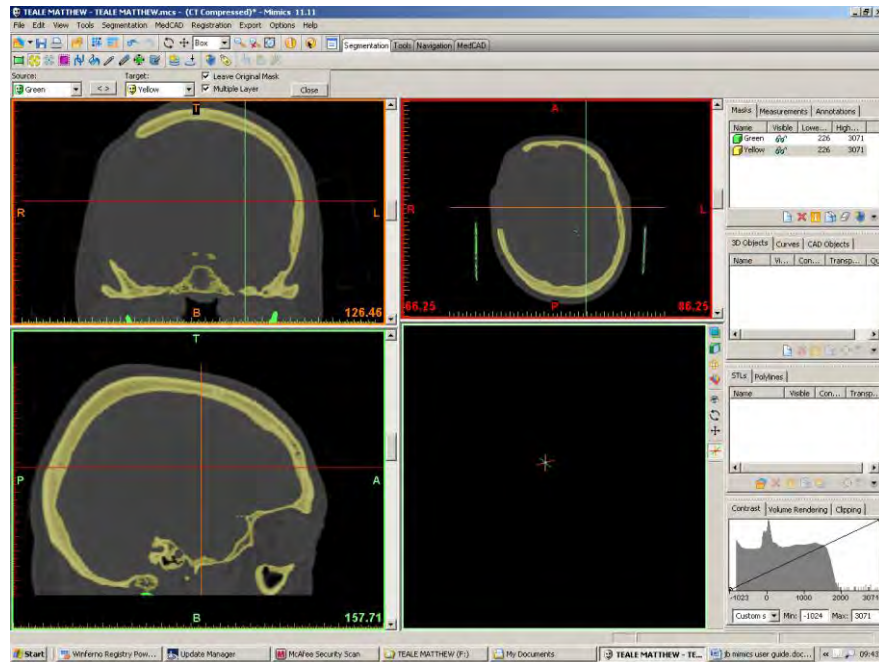
Figure 9.18 Skull area selection.

Select a particular area of the skull and select region grow this will reduce the interference around the skull and a new mask will be generated in a different colour.
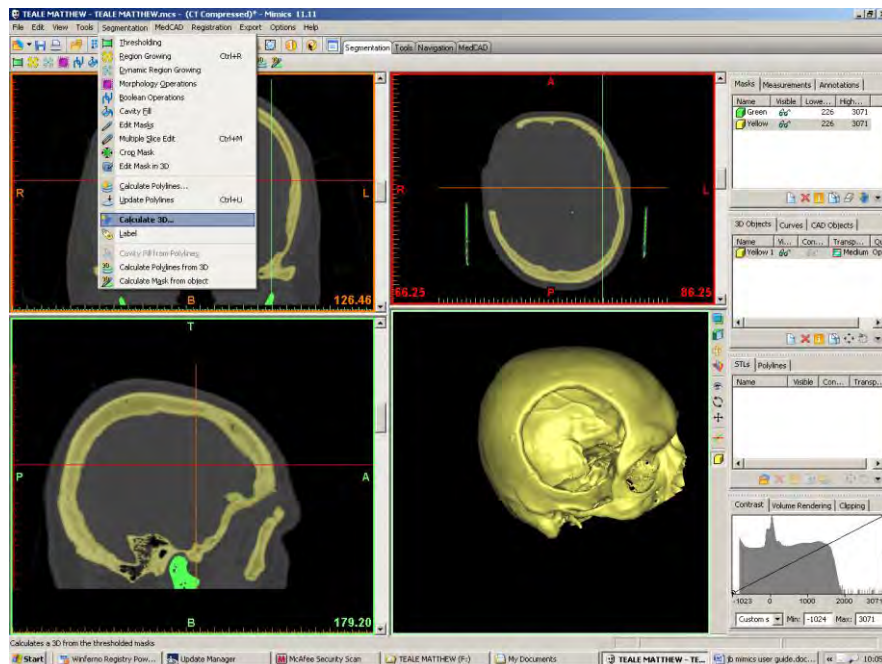
Figure 9.19 3D calculation.

Select "calculate 3D" button and select yellow file, 3D image of skull will appear.
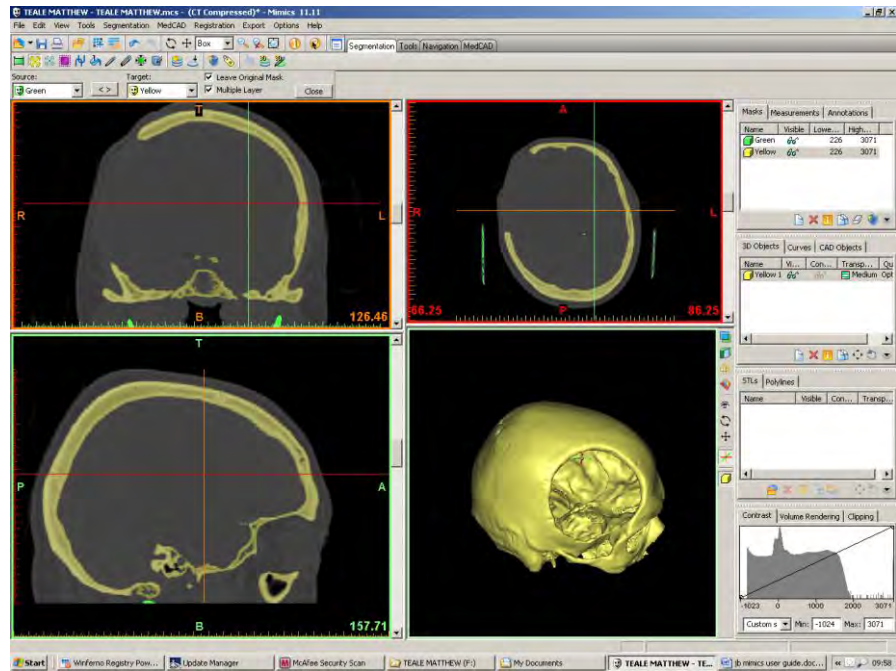
Figure 9.20 Mask editing process.

Mask will need editing to separate mandible bone from skull as it is not required this is done by selecting the erase tool and erasing all points in contact with the skull on each slice.
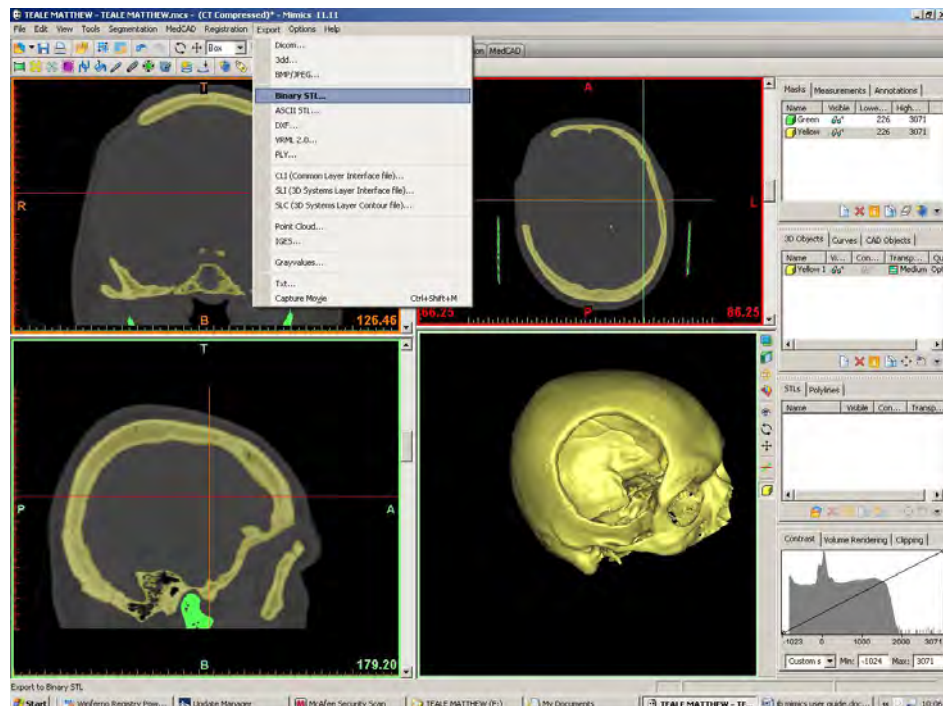
Figure 9.21 File saved as a binary STL file.

9.2.1.2 3-matic Process Step
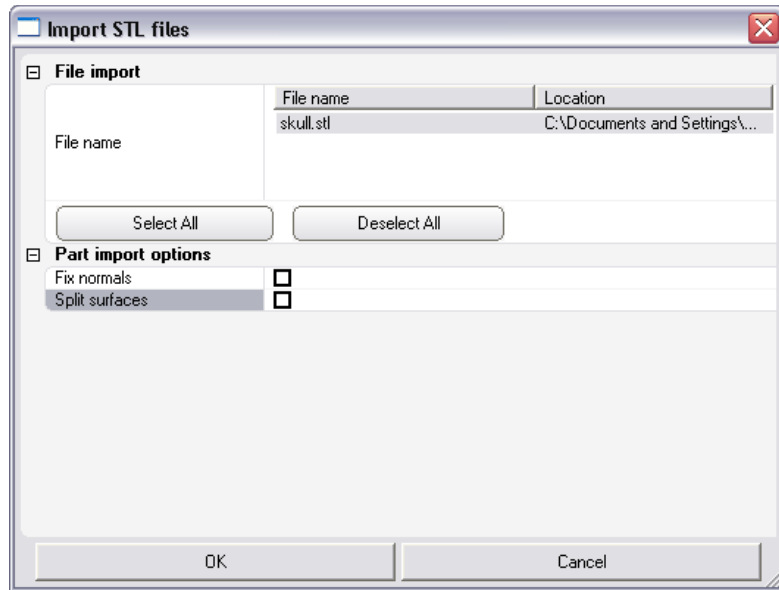
Figure 9.22 Project file imported into 3-matic in STL format.
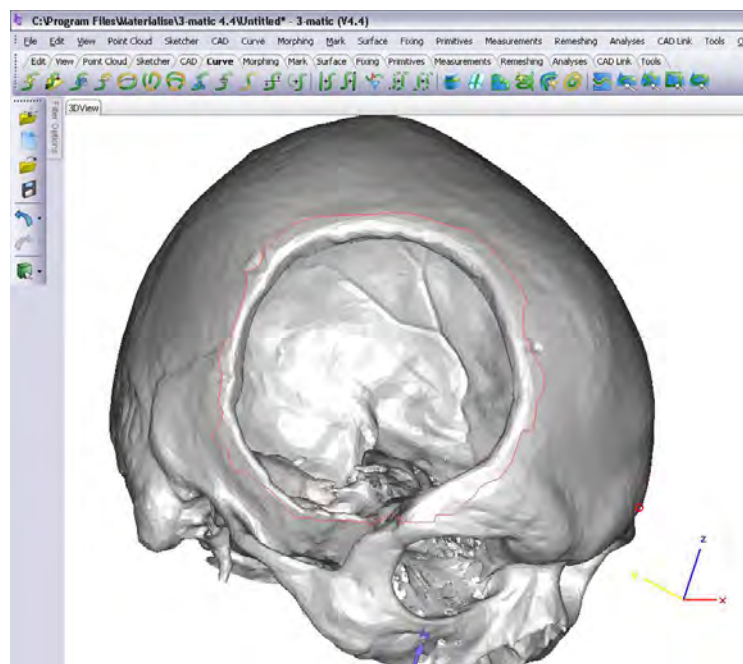
Figure 9.23 Curve tool selected and polyline is plotted around the cranial defect.
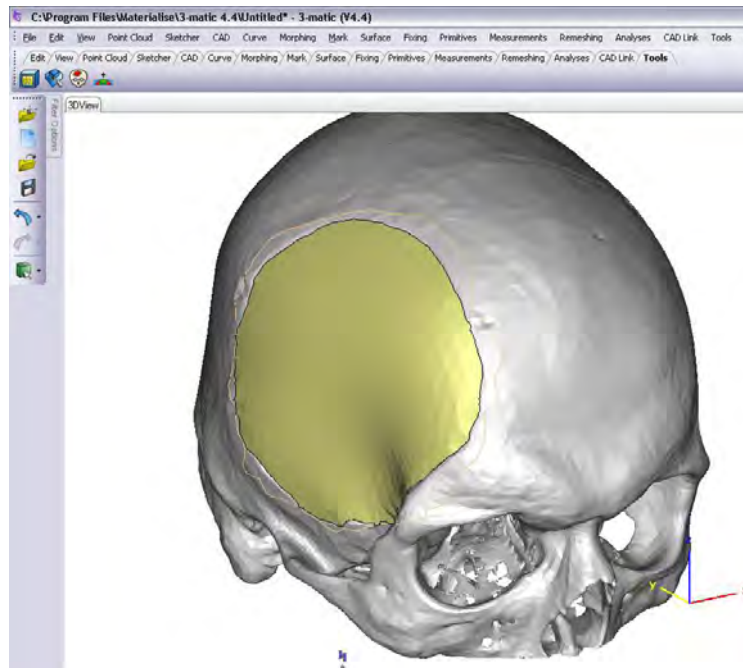
Figure 9.24 Cranial plate creation.

The "Create Cranioplasty" icon is selected and a cranial plate is automatically generated using algorithms in the software and the surrounding edges.

When the cranial plate is generated some editing might be required and any undercuts will need to be trimmed and surface repaired. The red section represents a hole and must be repaired to create a complete surface for RP.
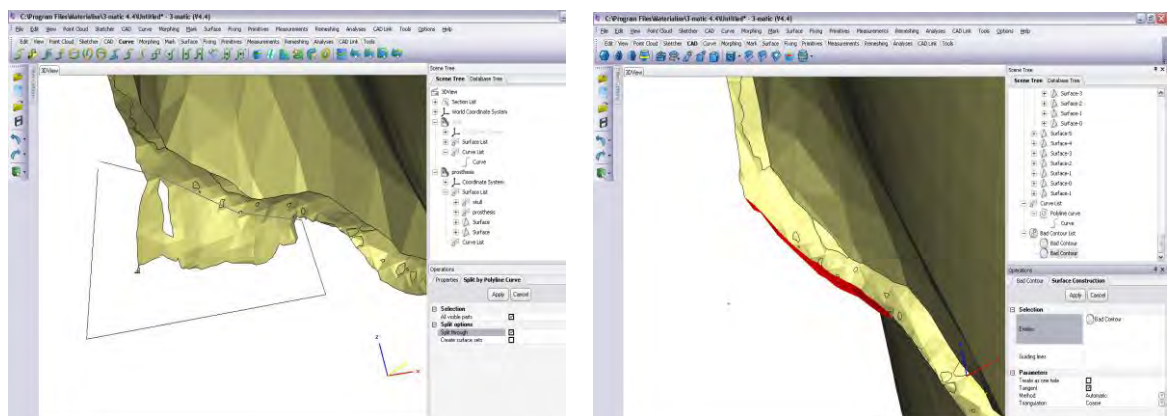
Figure 9.25 (a) and (b) polylines are used to cut away protruding edges and bad surfaces are repaired by selecting the CAD command, selecting bad surface and repairing.

The next stage is to create a location point for fixing tabs. This is achieved by evenly spacing the number of tabs required. This will depend on the extent of the trauma. Under the "Mark" tab a triangle is selected at the point of reference. Then a new sketch is selected. This generates a sketch plane parallel to the selected triangle. The tab geometry is drawn, using grid points as reference.
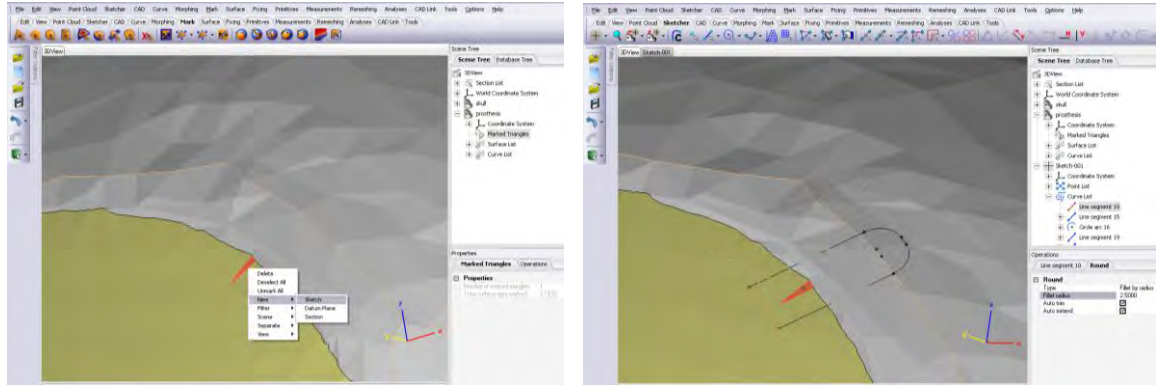
Figure 9.26 (a), (b) Triangle selected onto which is placed a sketch plane for tab. The grid tool is selected and the profile of the tab is drawn.

When the sketch geometry is completed it is extruded in both directions using the "Extrude" command the required amount and additional features such as fillet radii added.
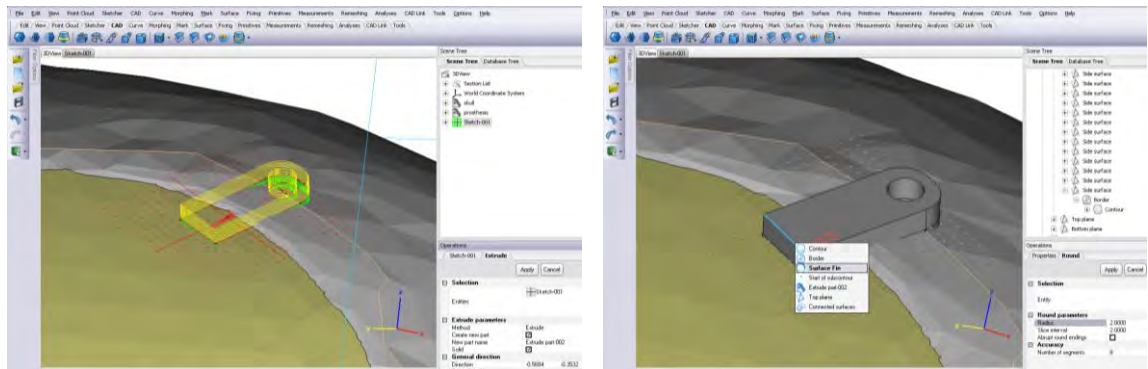
Figure 9.27 (a), (b) Sketch is selected and extruded 2mm upwards and 1mm downwards ensuring complete surface contact.

Other features added include a surface fin. By right clicking on the edge highlighted in blue and applying a value of 2mm the fin is created.
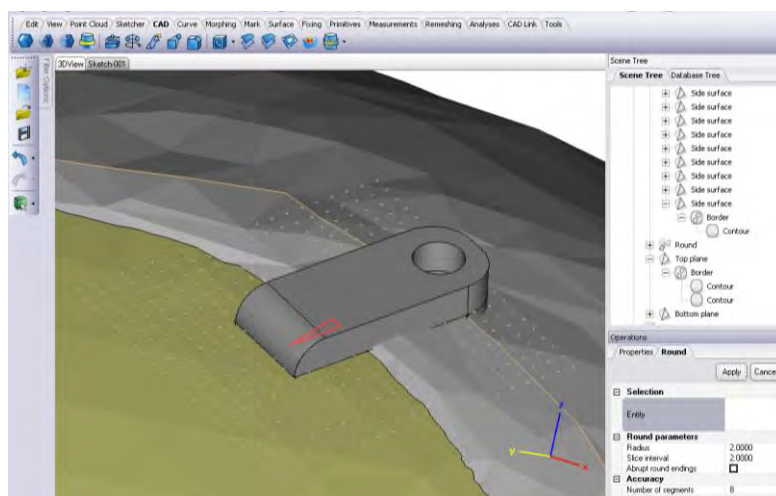
Figure 9.28 Shows the creation of a surface fin.
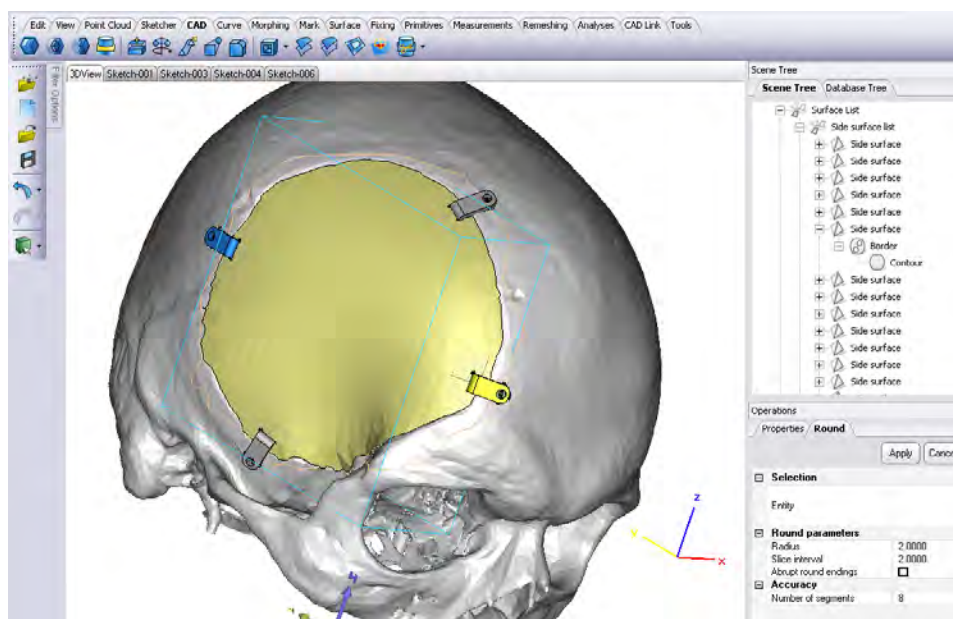
Figure 9.29 Four tabs are constructed in the same method and evenly placed around the periphery of the cranial plate.

Once the four tabs have been drawn and constructed they must be permanently joined to the cranial plate to become one complete part. Under the "CAD" tab "Boolean Union" command is highlighted. All tabs and plate are selected and the Boolean union performed.
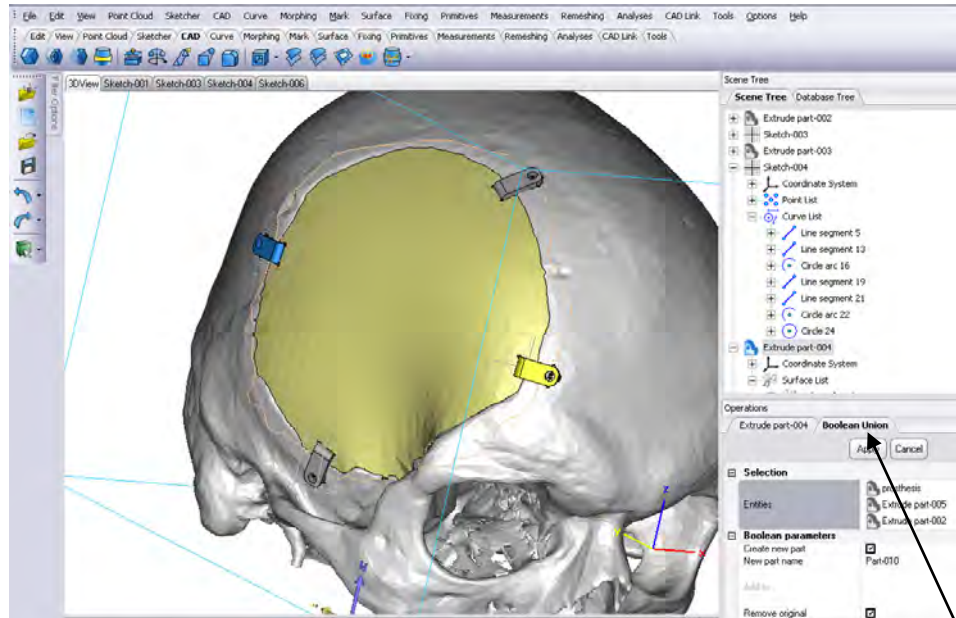
Figure 9.30 Four tabs are then permanently joined to the plate using the Boolean union tool.
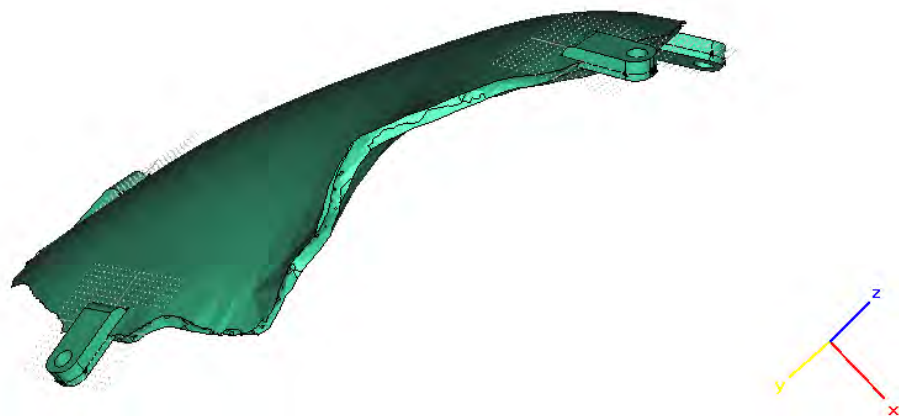
Figure 9.31 Cranial plate and tabs unioned into one part.

To aid with the location of the cranial plate a "Union Subtraction" is performed. The cranial plate is selected as the entity and the skull as the subtraction entity and operation applied.
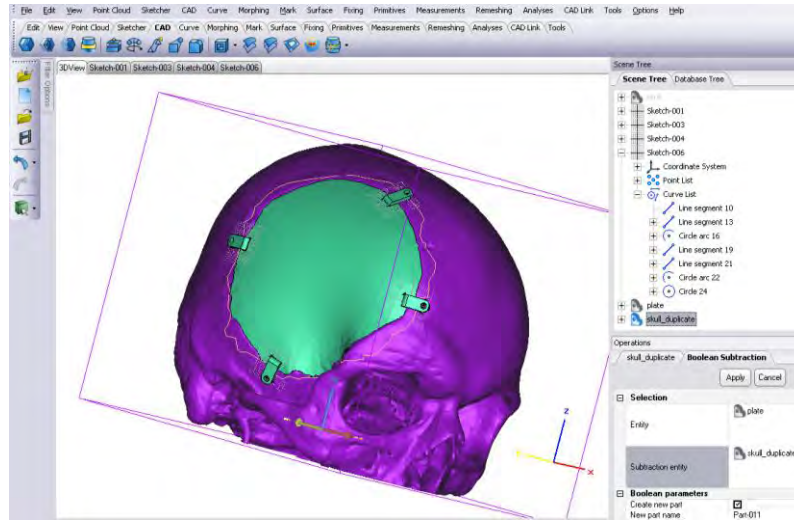
Figure 9.32 Cranial plate and tab assembly undergoes a Boolean Subtraction; this allows the tabs to sit neatly onto the surface geometry of the cranial plate.
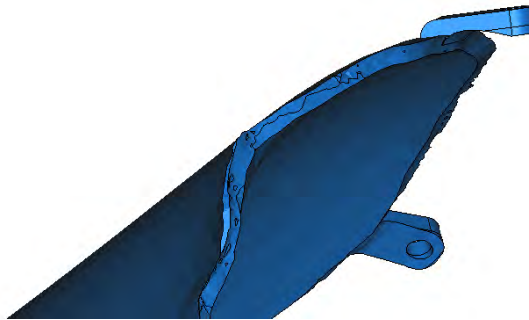
Figure 9.34 A Boolean subtraction can be seen on tabs.
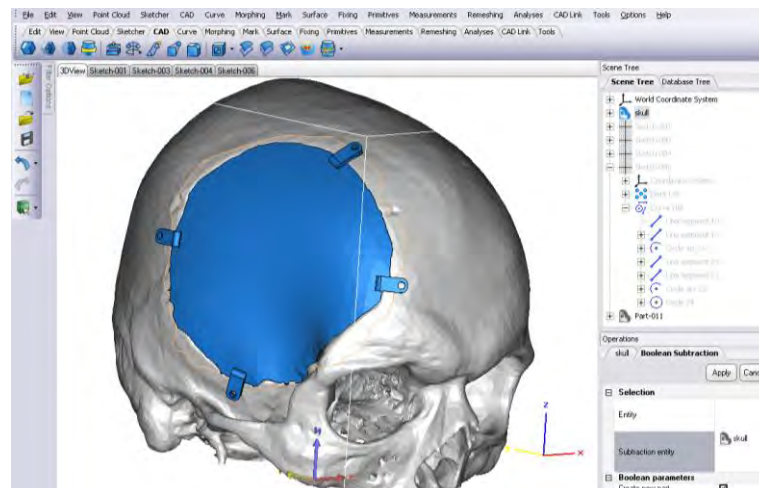
Figure 9.35 A completed cranial plate and skull model.

Figure 9.36 Completed skull model produced on Z-Corp 3D printer and cranial plate model produced on EOS 250 SLA RP machine.

9.2.2 Summary

As in case study 1 the procedure of processing DICOM 2D data to 3D data is identical, using Mimics and 3-matic software. Generating the cranial plate in 3-matic is faster when compared to Magics due to "Create Cranioplasty" tool. The cranial plate produced a good fit and the Boolean subtraction performed on the tabs provided better location. The STL file for the cranial plate required supports to be generated in Magics before it was downloaded to SLA machine.
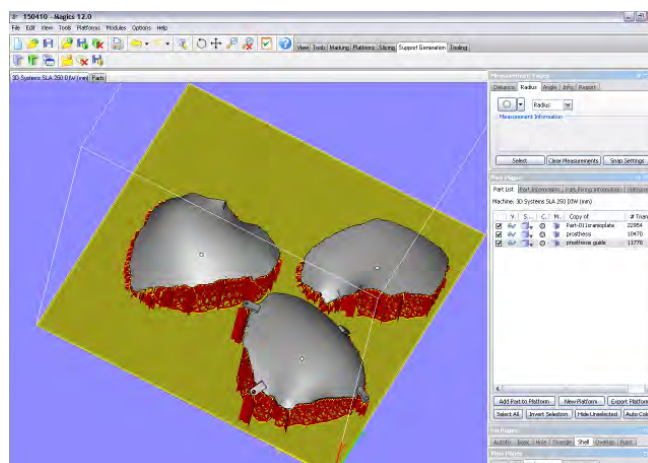
Figure 9.37 Generation of support material in Magics for cranial plates in case study one and two.

9.3 Case Study 3 - Acetabular Fracture Reconstruction

The acetabular is part of the pelvis bone that forms the hip socket. An acetabular fracture is a common injury that requires reconstruction or replacement. An acetabular fracture occurs when the socket of the hip joint fractures. This joint is covered internally with cartilage which provides a load bearing surface on which the ball of the femur can rotate. This fracture can happen due to trauma or weakening of the bone from osteoporosis. The extent of the treatment to repair an acetabular fracture depends upon the quantity of cartilage movement and the volatility of the hip. The method of restoring the functionality to the joint involves a surgical procedure which takes place in three steps:

- Good alignment of the cartilage surface
- Removing bone debris lodged in the hip joint
- Re-establish stability to the hip

If the joint cannot be repaired a custom made acetabular cup implant and femur head may be required. Depending on the severity of the fracture, the joint may be allowed to heal itself without any invasive surgery, although the alignment may not be ideal, this is sometimes applied to elderly people so as to prevent the patient undergoing the trauma of surgery and recovery which can be very demanding.

9.3.1 Process Steps

9.3.1.1 3-matic Process Steps

In this case study the data had already been processed through Mimics software and the data converted from 2D to 3D therefore required editing in 3-matics.
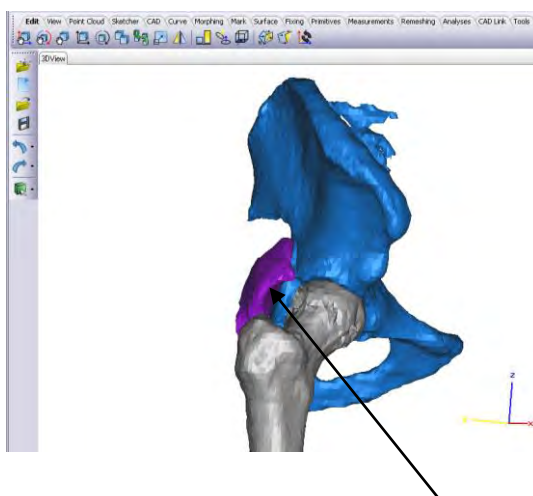
Figure 9.38 view of a hip joint indicating fragment out of position.

As part of the implant construction process the following steps are required.
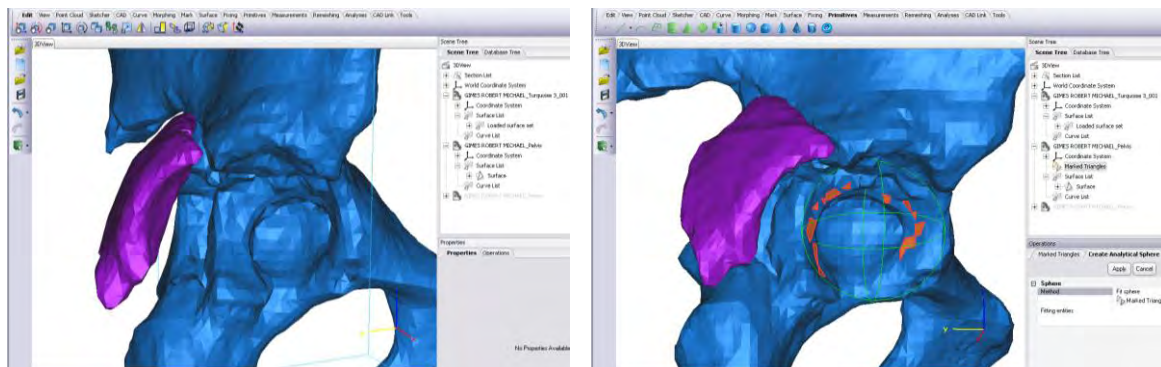
Figure 9.39 (a), (b) Femur hidden and mark plane icon is selected to mark triangles on socket surface so an analytical sphere can be fitted to marked triangles.
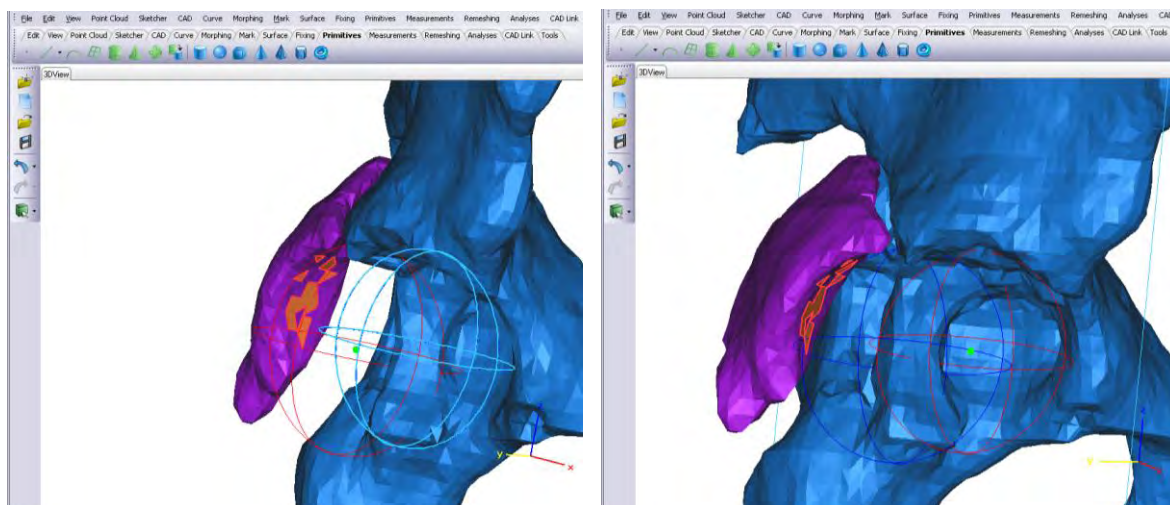
Figure 9.40 (a), (b) Mark plane icon selected to mark triangles on fragment surface. Create analytical sphere selected and fitted to marked triangles.
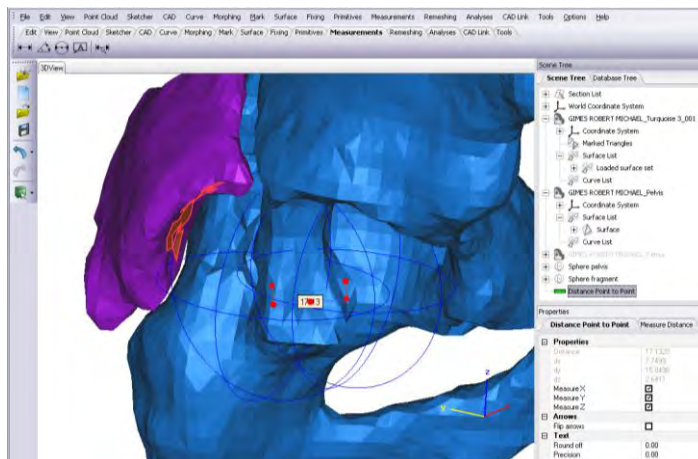
Figure 9.41 Acetabulum sphere measured radius is 25.4516 mm and bone fragment measured radius is 27.16mm error offset by 1.5mm.
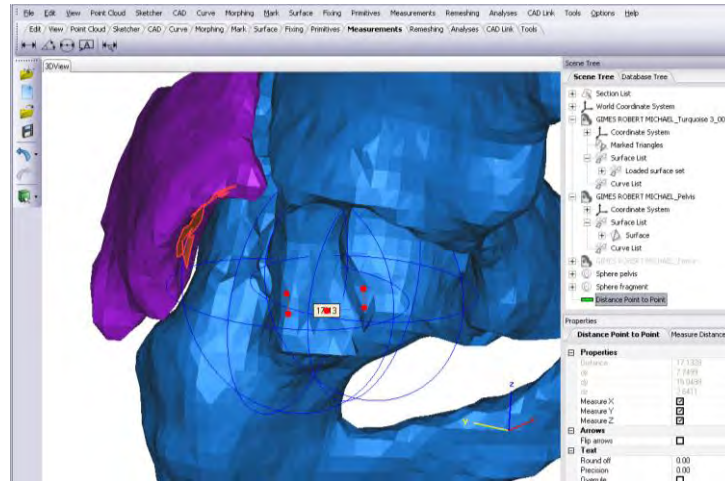
Figure 9.42 Distance between centres of spheres is measured using the measure point to point command. The displacement error is 17.13mm.
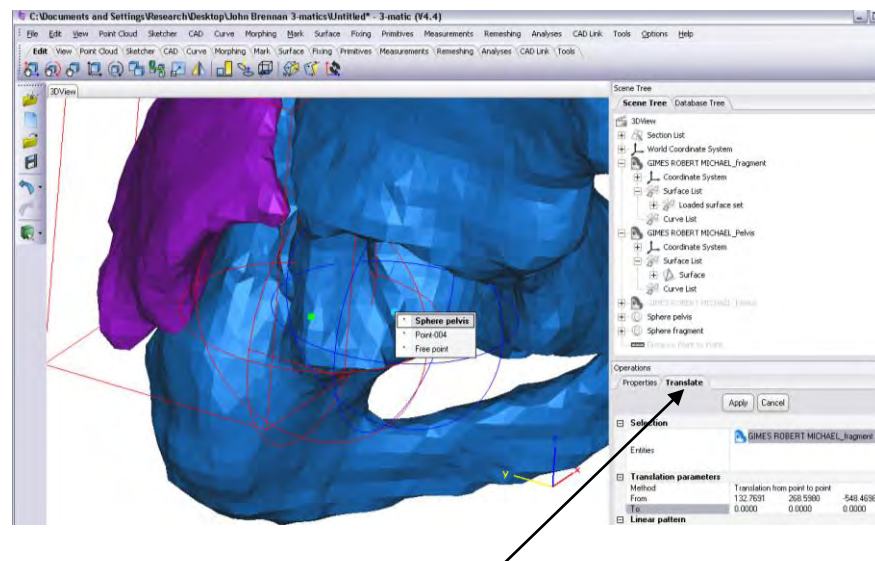
Figure 9.43 Under the edit tab the translate option and point to point option is selected which makes the centre points coincident.

Figures 9.39(a) to 9.43 explains the process required to reconstruct an acetabular fracture. The process involves selecting the surface of the acetabular cup, fitting an analytical sphere to these points and the radius recorded. The same process is performed for the fragment. The distance between the two sphere centres is noted. Using the translate option and selecting point to point the fragment sphere is made coincident with the cup sphere. The fragment also required adjustment in the z and y axis to complete alignment. This was performed using the revolve command.

Translate Option

Revolve Option
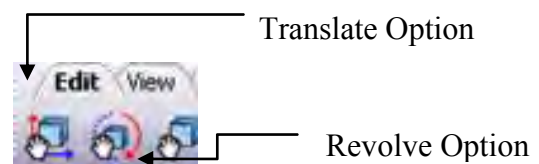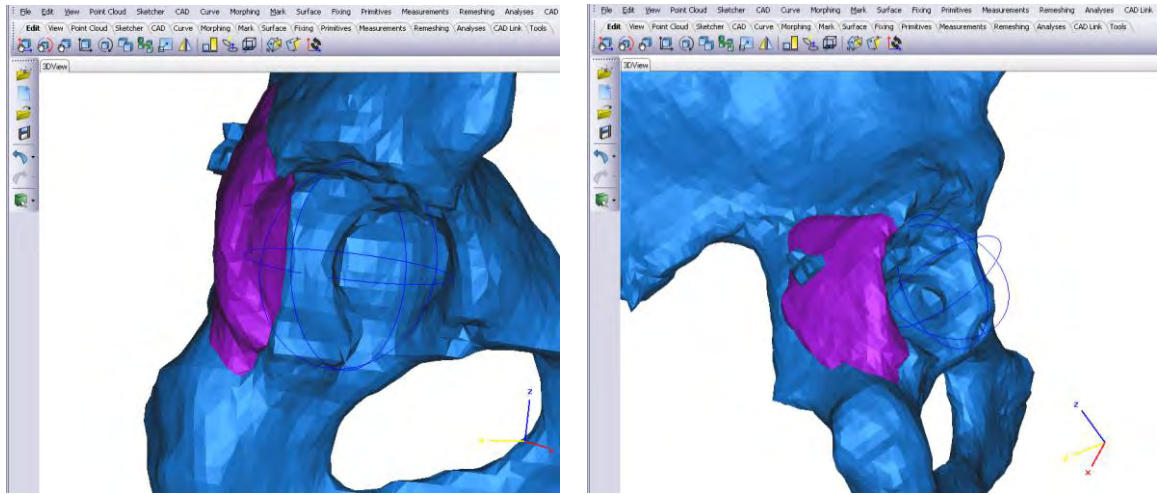
Figure 9.45 (a), (b) Fragment requires rotation using interactive rotate tool based on pelvis sphere fitted centre. (Z=15^0, Y=10^0)
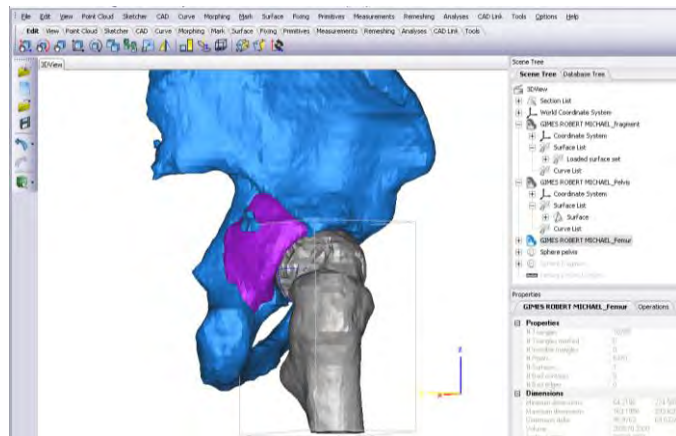
Figure 9.46 Reconstructed acetabular joint with femur in position.
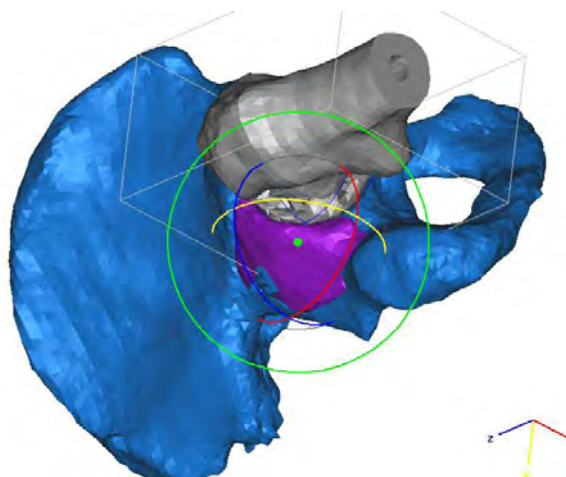
Figure 9.47 Bottom view of reconstructed acetabular joint.

9.3.2 Additional Work

Research carried out at De Montfort University, test data has been collated that allows the Z-Corp 3D printer to produce parts more accurately.

Build Orientation	Average Offset Error(mm)	Offset Compensation Values (mm)	Average Scaling Error	Rescaling Factor
X	0.5165	0.25825	0.002	1-0.002=0.998
Y	0.6285	0.31415	0.000	1-0.1
Z	0.3775	0.18883	0.004	1-0.004=0.996

Figure 9.48 Table containing parameter values for x, y, and z axis.
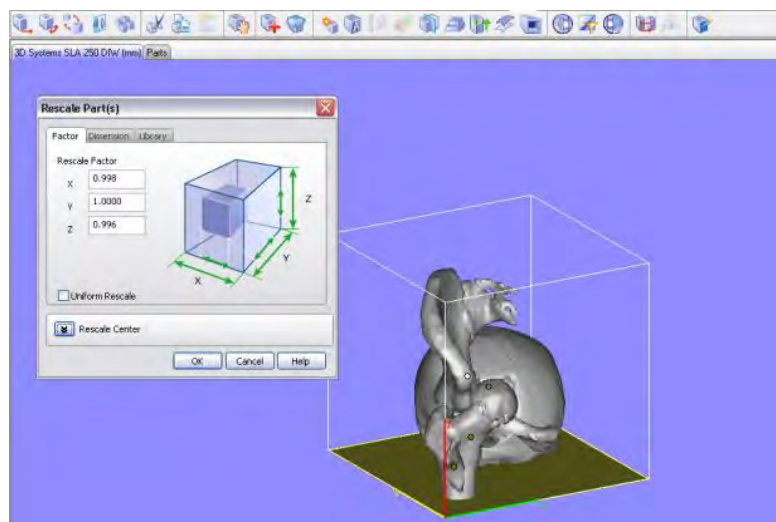
Figure 9.49 Under "Tools" option, rescaling values can be entered into Magic's before building commences.
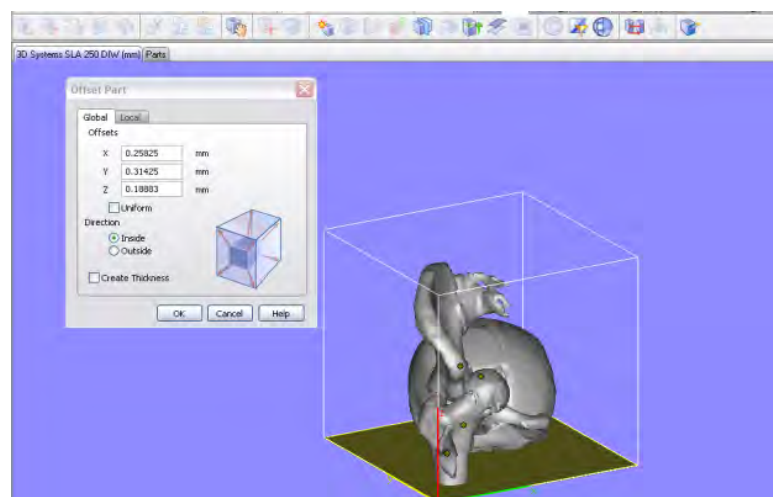
Figure 9.50 Under "Tools" option, offset values can be entered into Magic's before building commences.

Figure 9.51 Pelvis, femur and fragment built on Z-Corp 3D printer.

Figure 9.52 (a), (b) Z-Corp model of pelvis and femur head.
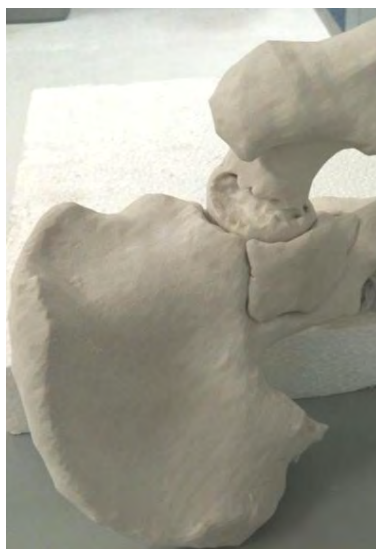
Figure 9.53 Reconstructed hip joint. Cavities shown on femur head can be caused by selecting the incorrect threshold value when converting 2D data to 3D data in Mimics or could also represent anchorage or cartilage.

9.3.3 Summary

Using 3matic and Magics software demonstrated the flexibility of the software to manipulate STL files. Selecting the correct threshold level in Mimics can play a significant feature in part geometry and accuracy. Although rescaling and offset values were entered into Magics to produce parts with greater dimensional accuracy, some finishing operations were required to achieve a good fit. Waxing of the parts was also required to increase part stability.

9.4 Case Study 4- Design of an Acetabular Cup Implant

The previous case study was a reconstruction of an acetabular fracture. This case study takes the process a step further and produces an acetabular cup implant based on the existing geometry of the acetabular cup and femoral head.

9.4.1 Process Steps

9.4.1.1 Mimics Process Steps
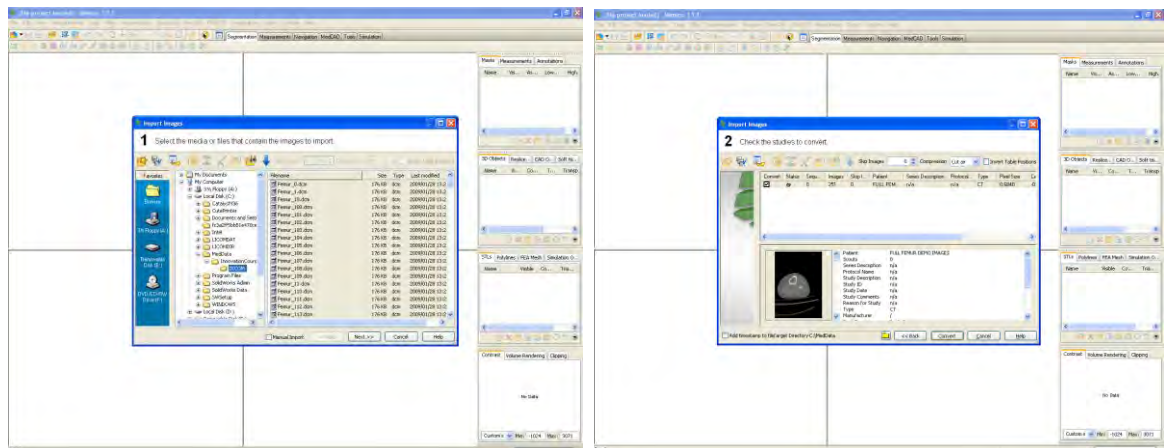
Figure 9.54 (a), (b) CT data is been loaded into Mimics. CT compression is selected to compress the files and then select convert to load images into Mimics.
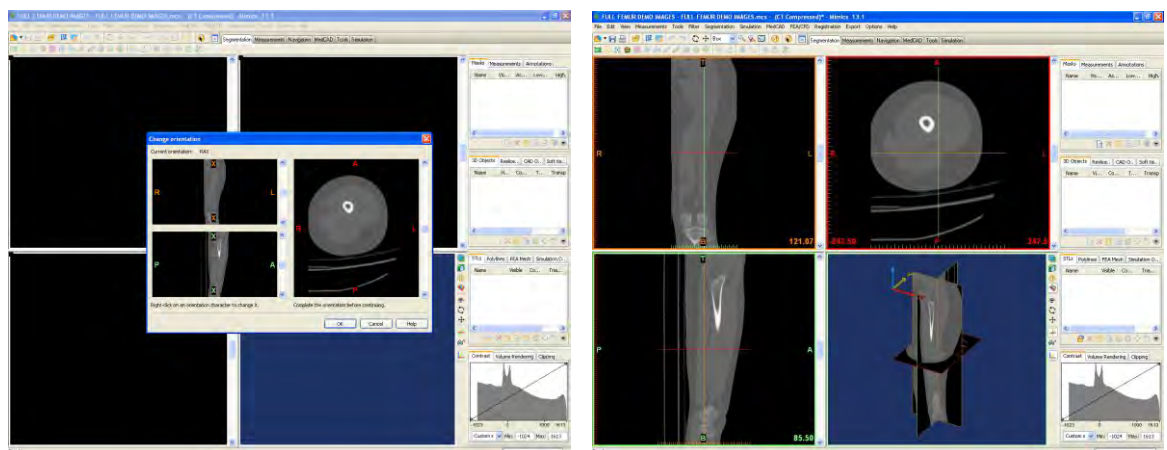
Figure 9.55 (a), (b) Orientation must also be selected by clicking on x.
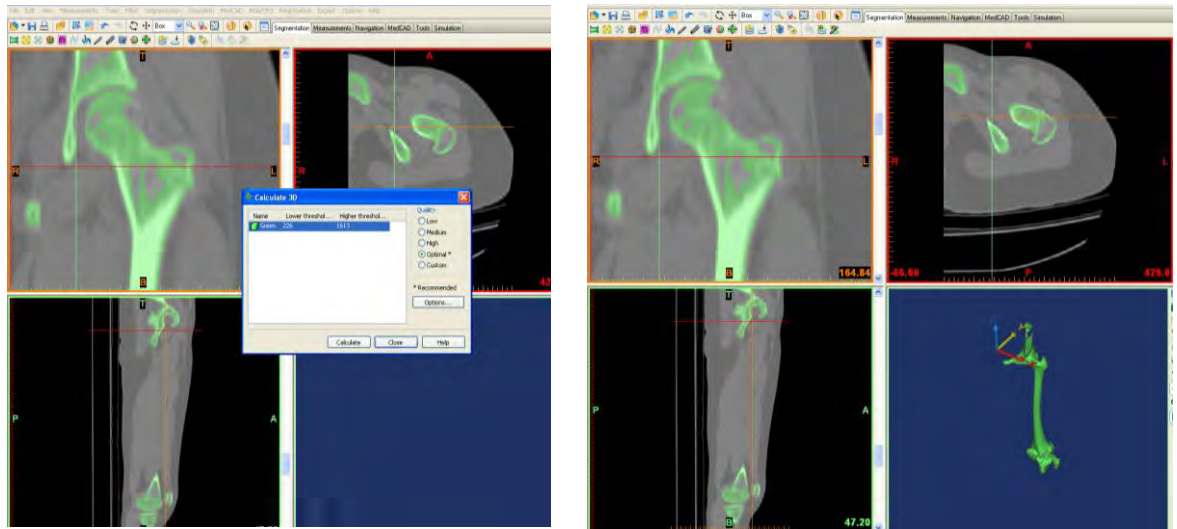
Figure 9.56 (a), (b) Threshold selection.

Selecting the "Threshold" tab and select the predefined threshold value for bone CT, 226 points and choose high quality, multiple parts will be selected and green mask will be generated.
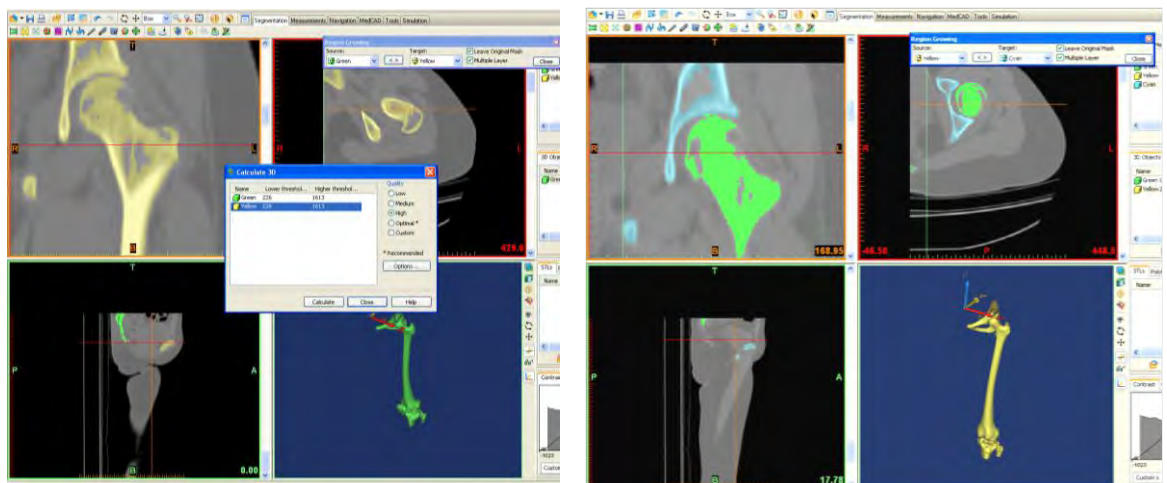
Figure 9.57 (a) and (b) Region growing.

Selecting the femur and clicking on region growing tool with high quality tab the femur will be separated from the neighbouring bones. Selecting "Calculate 3D" with high quality a new yellow mask will. This region growing operation excluded the coccyx and the patella from the mask, but the pelvic bone and tibia are still connected to the femur. To separate the pelvic bone certain editing operations using the lasso tool is required.
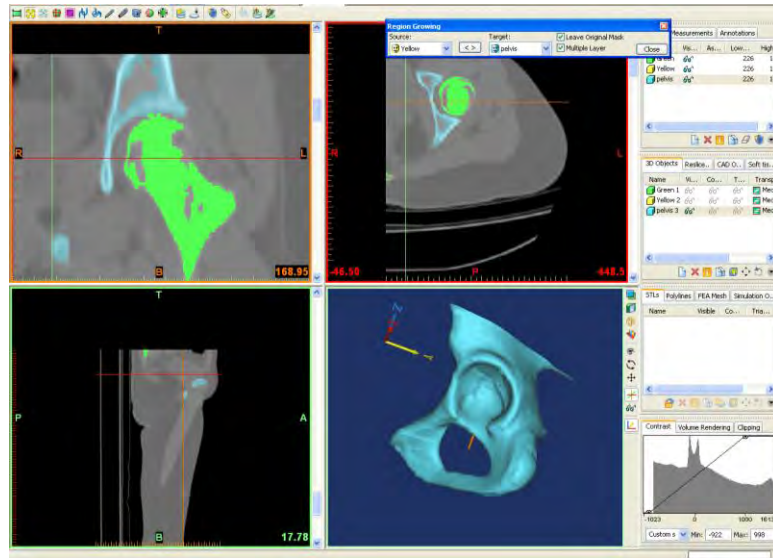
Figure 9.58 Pelvic bone separated.
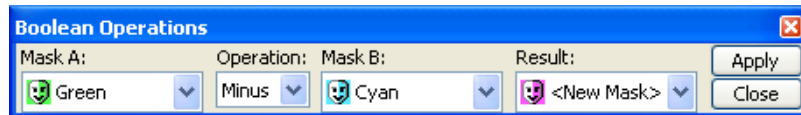
Figure 9.59 Boolean subtraction.

The femur has to be separated from the Tibia this can be achieved by subtracting the cyan from the green mask. The fuchsia mask contains the femur, tibia, fibula and the patella.
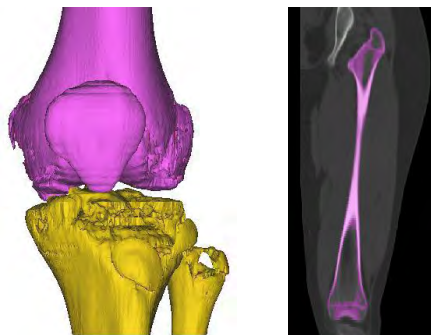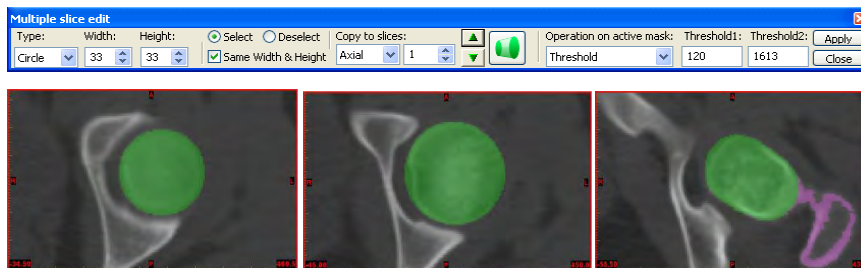



Figure 9.60 (a), (b) Mask editing.

Activate the "Edit Mask in 3D" function and select the lasso tool. Then select the Tibia and Fibula and click on "Remove" to exclude these pixels from the Fuchsia mask.

Figure 9.61 (a), (b) Slicing.

Select axial view and select slice 460.5 and select the complete femoral head, repeat this for slices 450 and 436.5 and select "Interpolate".

A temporary mask must be created on the distal extremity for slices 87, 69 and 60 to aid with femur extraction. Click on "interpolate" and set the threshold valve to 120 and select "Apply".
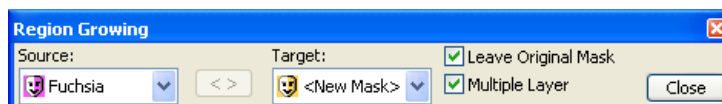
Figure 9.62 Region growing.

Select the region growing tool. Select the new orange mask and rename it "Femur". Then calculate the 3d object of this mask with optimal quality.
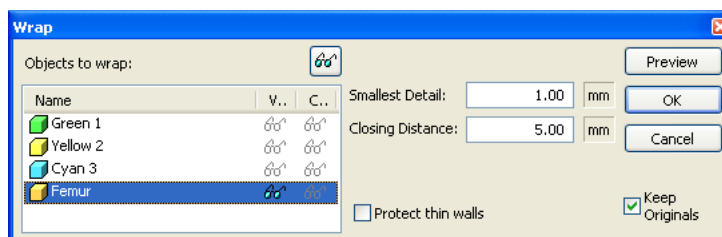
Figure 9.63 Wrapping operation.

There may still be some small holes visible. These holes can be removed using the "Wrap" function using the values above.
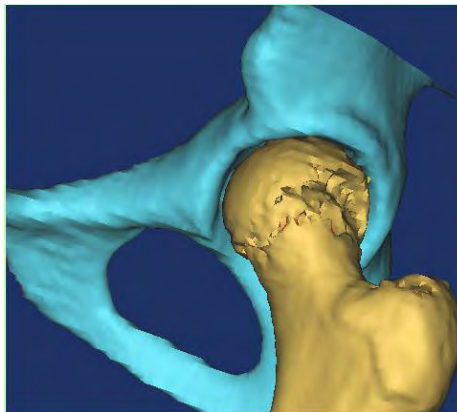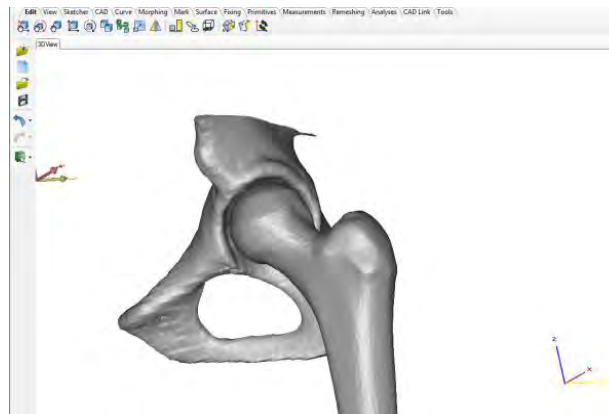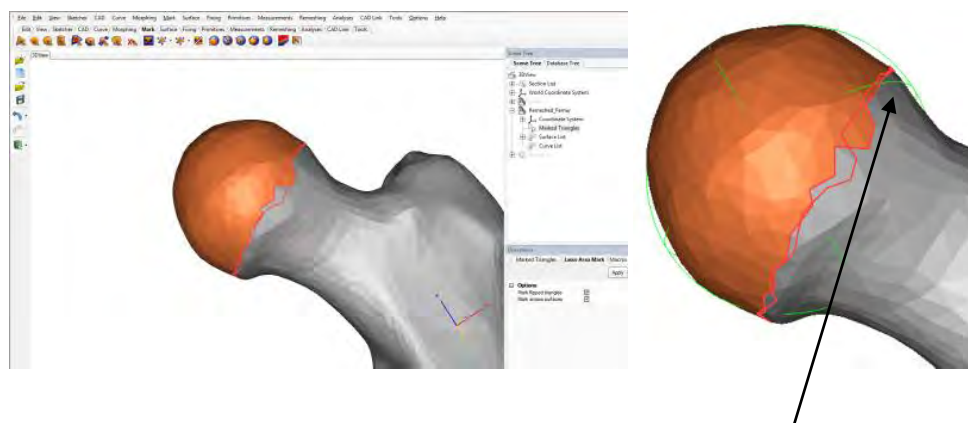
Figure 9.64 Femur and pelvis as separate identities.
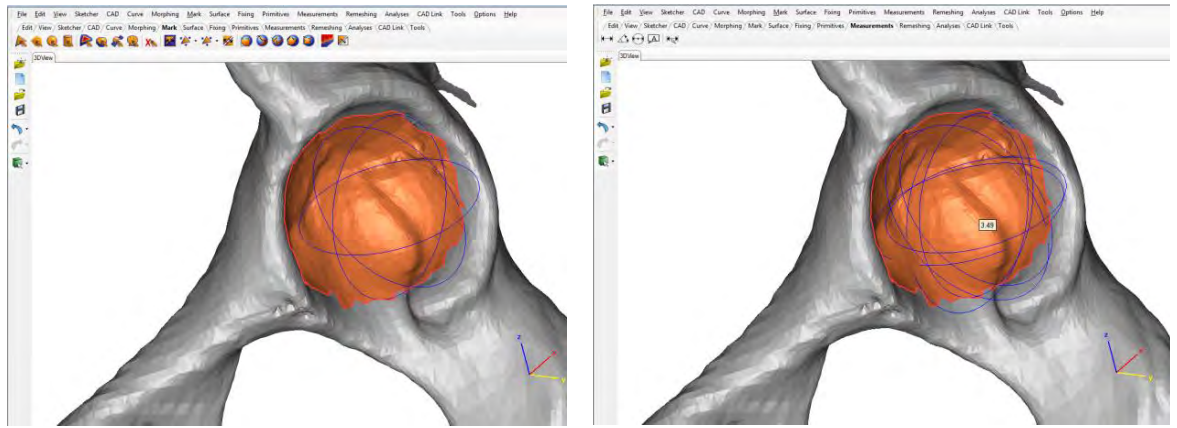
9.4.1.2 3-matic Process Steps

Similar to the previous case studies the STL file from Mimics is imported into 3-matic. This is achieved by selecting "Import part" and browsing to c:\MedData\FemurCaseStudy.
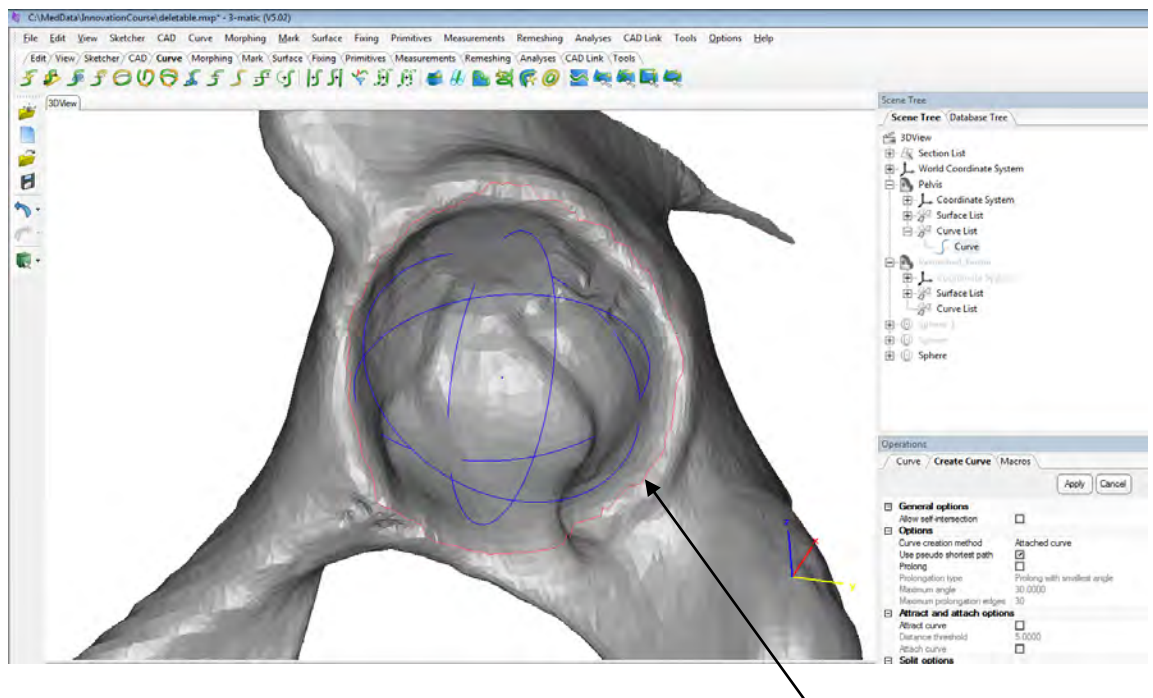

Figure 9.65 Parts loaded into 3-matic.

Figure 9.66 (a), (b) Triangles are marked on femur head and an analytical sphere is fitted to the marked triangles.

Figure 9.67 (a), (b) An analytical sphere is fitted to marked triangles on cup surface. The centre points of both the spheres are noted. The pelvic cup is used as it is stationary.


Figure 9.68 The "Curve" tool is used to define the edge of the pelvic cup rim.
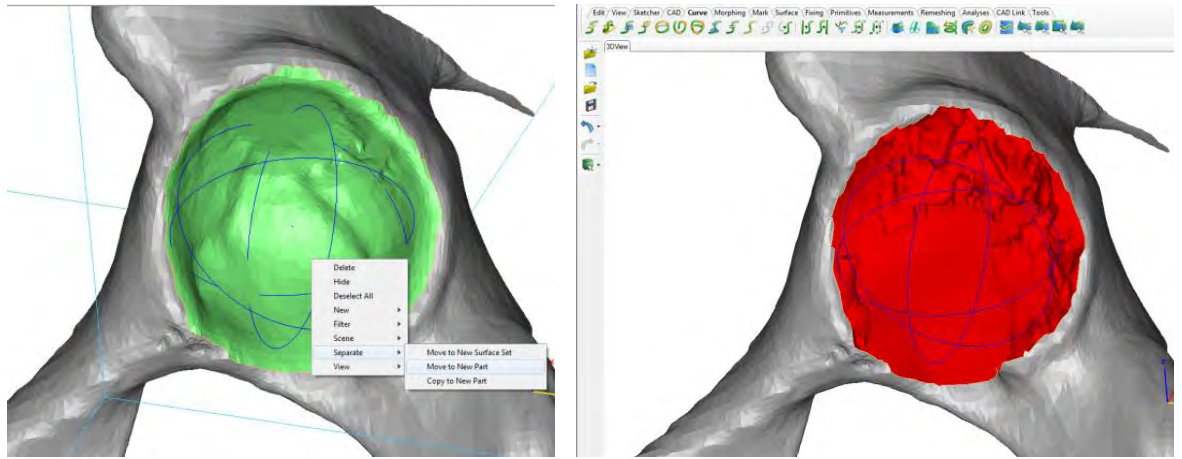
Figure 9.69 (a), (b) The cup surface is selected, separated and deleted. This allows a new flat surface to be fitted to aid in the design of implant.
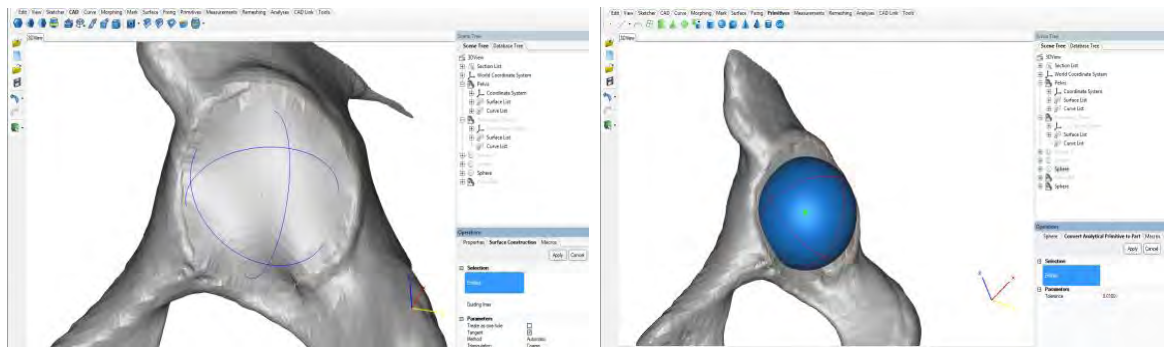

Figure 9.70 (a), (b) A new flat surface is inserted this prevents the cup flanges from entering into the original cup. A new sphere is generated from the original pelvis cup.
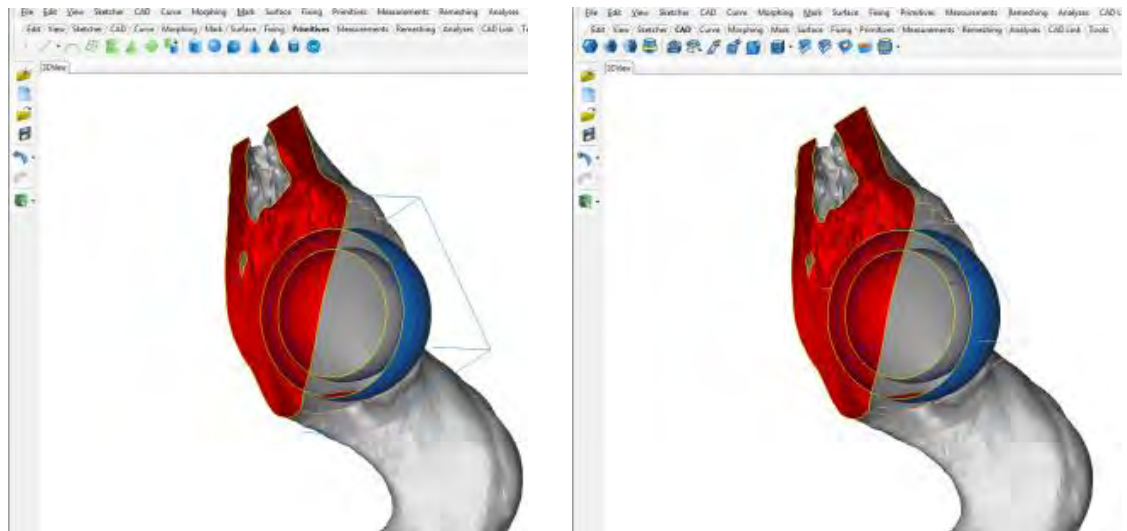

Figure 9.71 (a), (b) The external sphere is offset to get the inner surface of cup and a Boolean operation performed to subtract the inner sphere from the outer sphere to give a thin wall section.
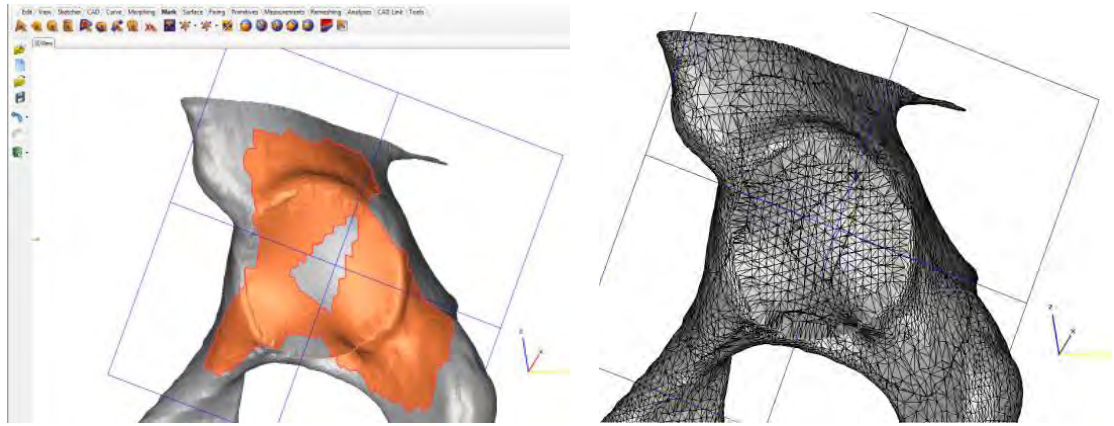
106
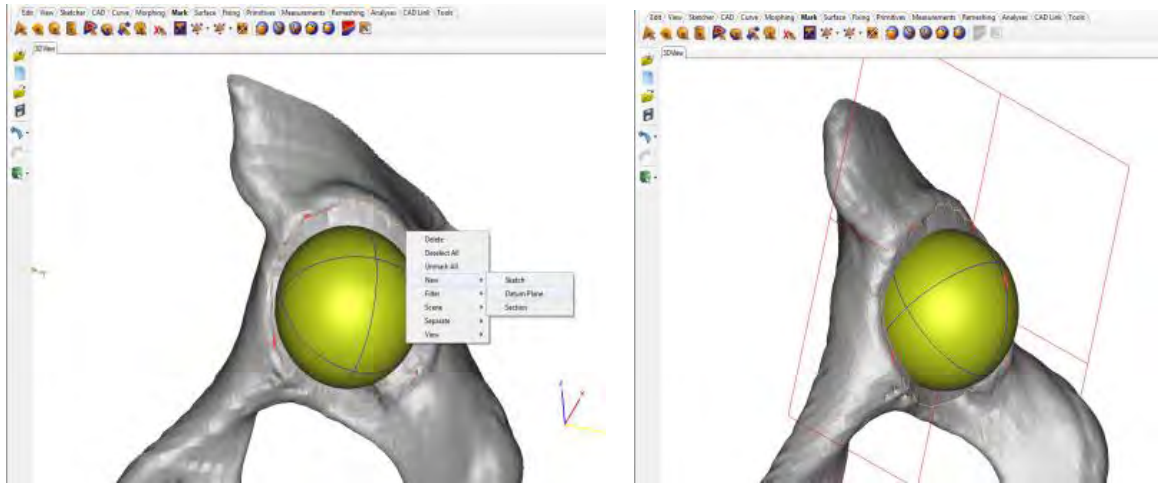
Figure 9.72 (a), (b) Using the "Mark" tool, triangles are selected to define datum plane for hemisphere alignment.
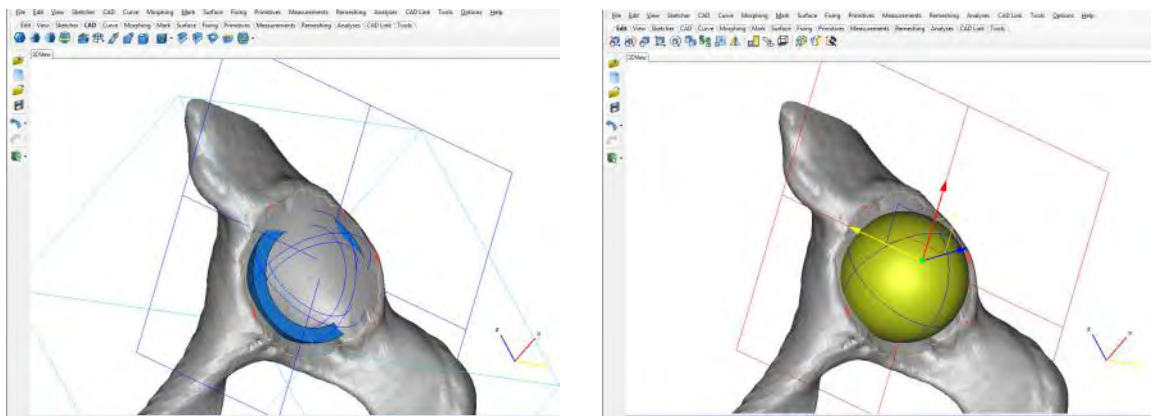
Figure 9.73 (a), (b) The "Cut" command is used to cut the sphere along the plane. Hemisphere is to low and is moved in the Z+ direction using the "Interactive Translate" tool.
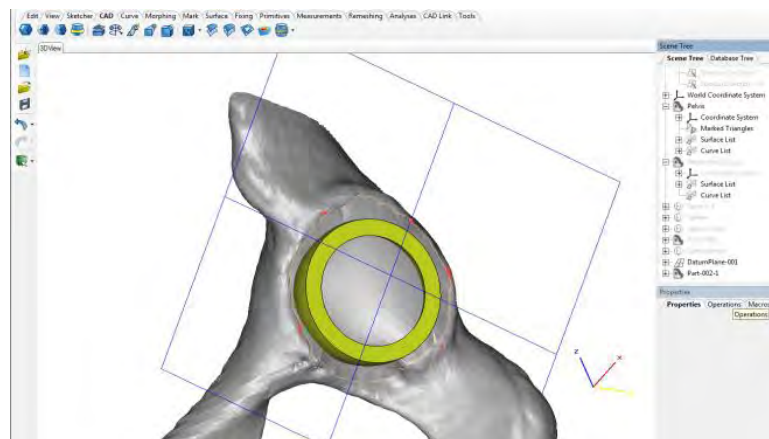
Figure 9.74 Acetabular cup in position.

Figure 9.75 (a), (b) Area for flanges marked using "Lasso" area mark tool. Edges of marked area are smoothened. Triangles fit along perimeter edge.
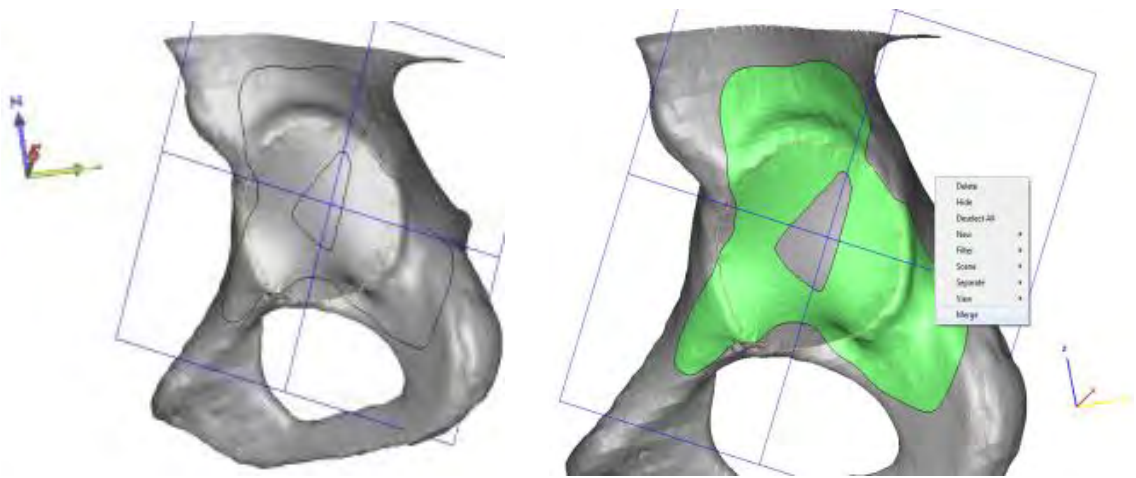
Figure 9.76 (a), (b) Smoothened outer edges and merging of different marked regions.
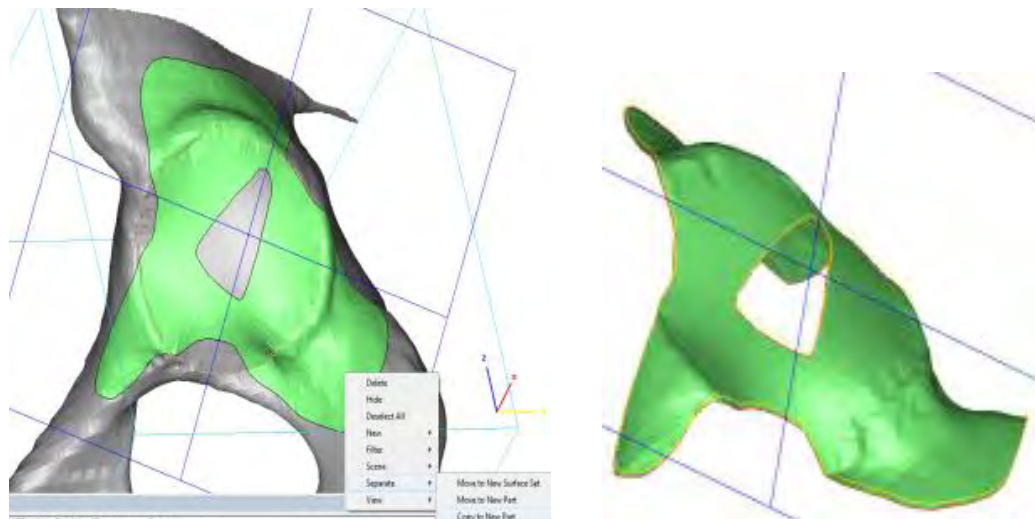
Figure 9.77 (a), (b) Separation of the new surface, copied as a new part and a thickness applied.
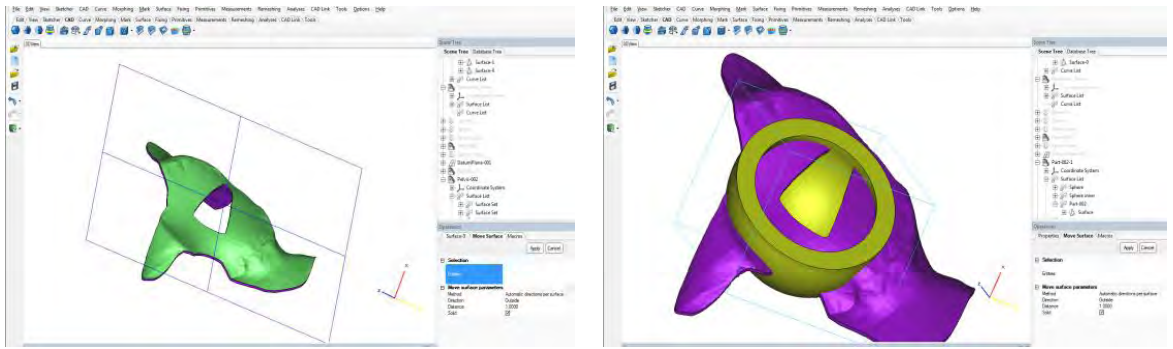
Figure 9.78 (a), (b) Solid flange after creation and flange and cup in position.
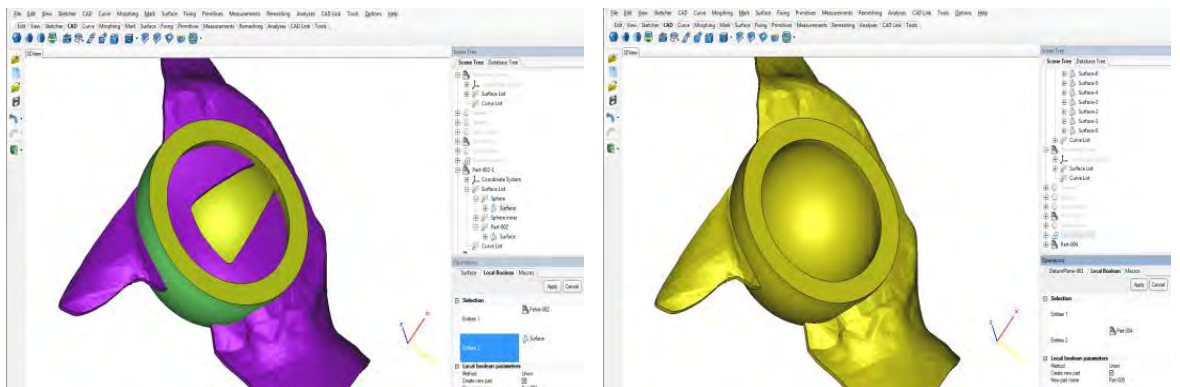
**Figure 9.79 (a), (b) Flange requires trimming to outer cup surface shown in green.
Completed solid part shown in yellow.**
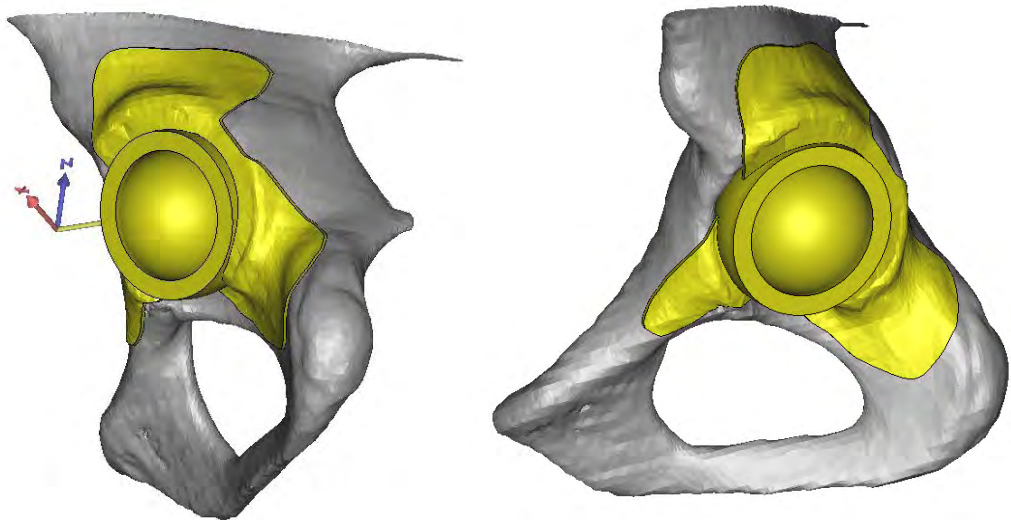
Figure 9.80 (a), (b) Two alternative views of implant and pelvis.
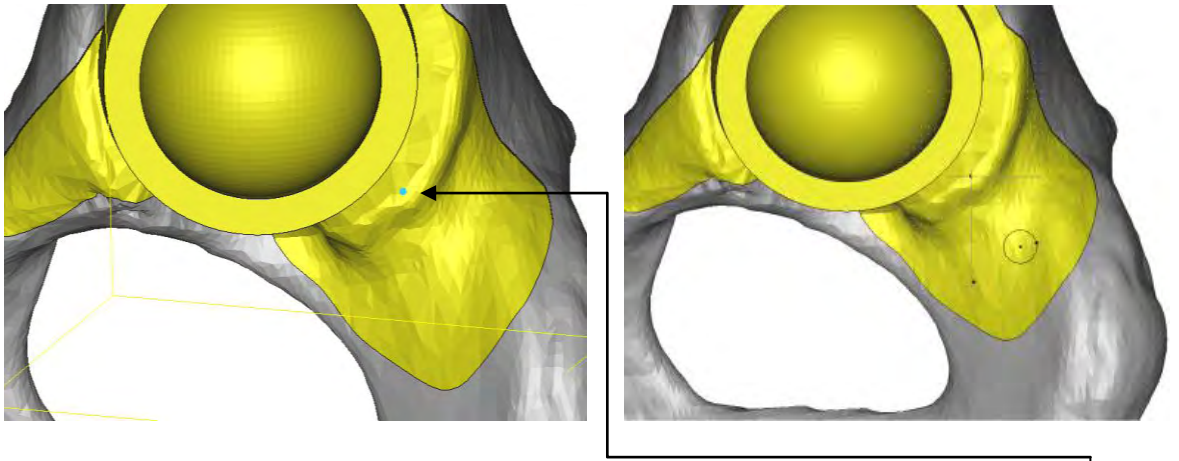
Figure 9.81 (a), (b) Generation of a sketch plane parallel to screen view; the blue dot represents the height and circle sketched on plane.
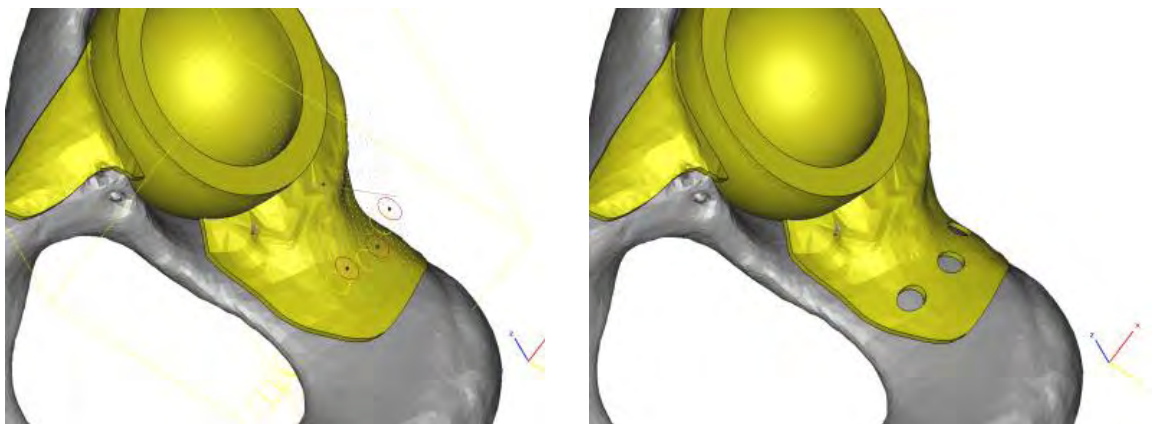
Figure 9.82 (a), (b) Sketch circles for fixing holes extruded, diameter 2mm.
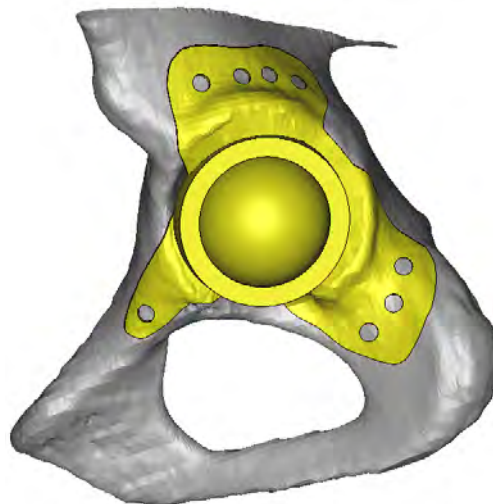
Figure 9.83 Completed acetabular implant in position.

Figure 9.84 (a), (b) Acetabular cup model implant shown with support material on FDM machine. Pelvis 3d printer model with acetabular cup model assembled.

Figure 9.85 (a), (b) Femur, pelvis and model implant. Original Femur and pelvis assembled.

9.4.2 Summary

This case study contained the process steps of extracting DICOM data and converting it to STL format. Designing an acetabular cup model implant in 3-matic, building the 3 components, two on a Z-Corp 3D printer and one on Stratasys FDM machine. This case study demonstrates to a high degree the feasibility of using medical software solutions and RP manufacturing methods for the design of an in vivo medical model implant. Some post finishing was required to maintain the integrity of the components.

9.5. Case Study 5 - Aorta Segmentation, Aneurysm Design and Valve Alignment

This case study involves the conversion of DICOM data from 2D to 3D. The aim of this case study is to get a 4D data set of a human aorta at different points in time during the cardiac cycle. Two sets of data are required, one for diastole and one for systole. In achieving this, identification of the important features of the aorta is required. In addition how to model the characteristics of an aortic aneurysm and the insertion of a heart valve is also included.

9.5.1 Process Steps

9.5.1.1 Mimics Process Steps

The file is loaded into and converted in Mimics. The file is then opened in Mimics by browsing C:\MedData/Aorta.mcs.

Figure 9.86 Aorta case study imported into Mimics.
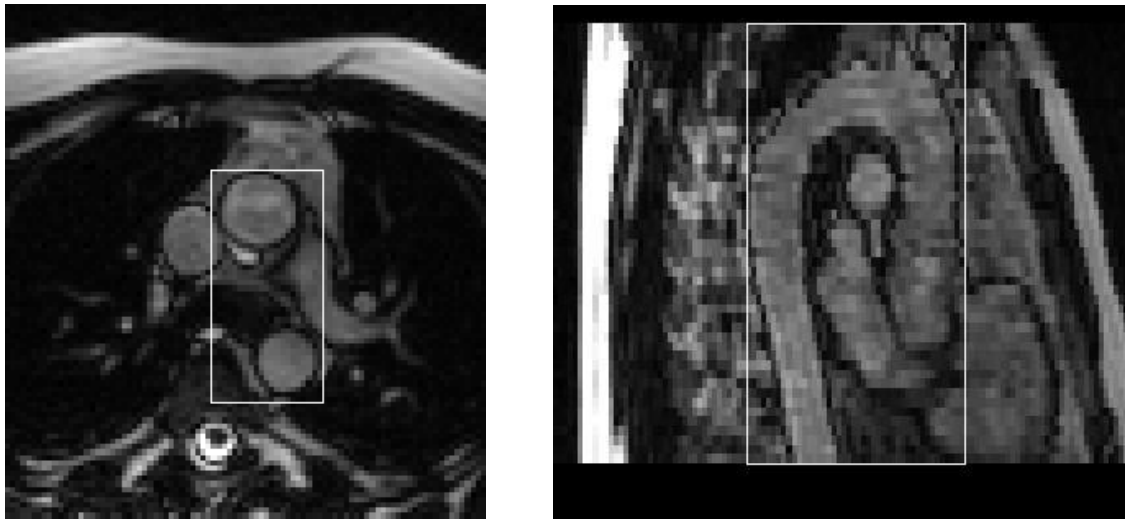
Figure 9.87 (a), (b) Dynamic region growing is selected the region of interest is cropped. Outer boundaries must be identified by scrolling through each slice.
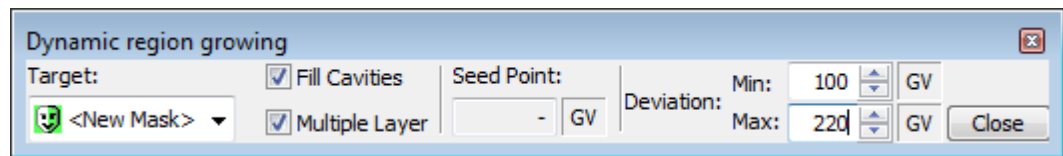
Figure 9.88 Select the "Fill Cavities" and "Multiple Layer" setting deviation points to 100 and 220 respectively. The seed point must be set by selecting a point on the Aorta in the arch.

Figure 9.89 Segmentation of the Aorta.
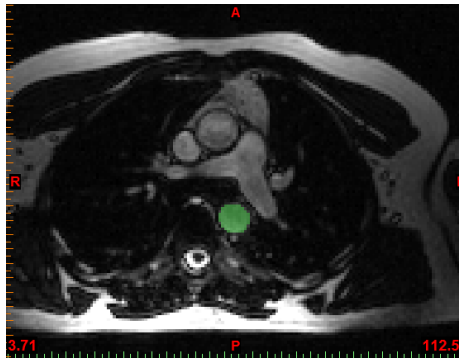
Figure 9.90 Starting at slice 112.5 everything must be erased except the aorta, this will remove any connection to surrounding tissue.
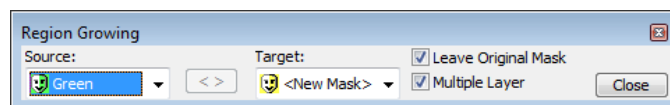
Figure 9.91 Choose "normal region growing" to select aorta.
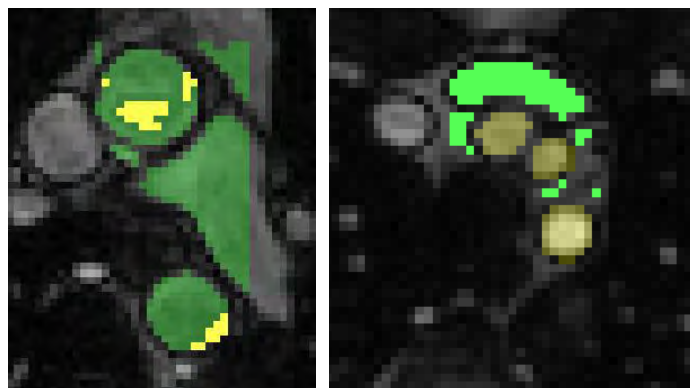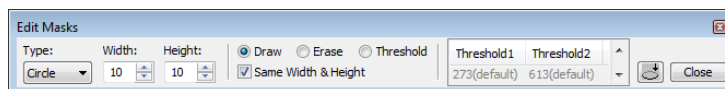
Figure 9.92 Select the manual editing option to erase parts not required or fill parts that should be included.
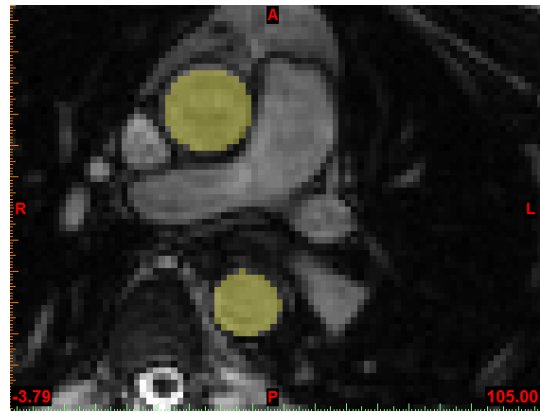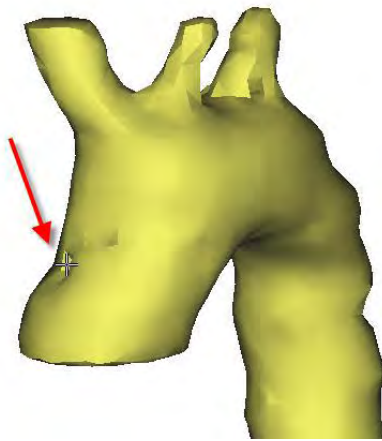
Figure 9.93 (a), (b) Calculating a 3D view of the mask is useful when identifying irregularities. Aorta is added from slice 93.75 to 112.5 to the mask using manual drawing.
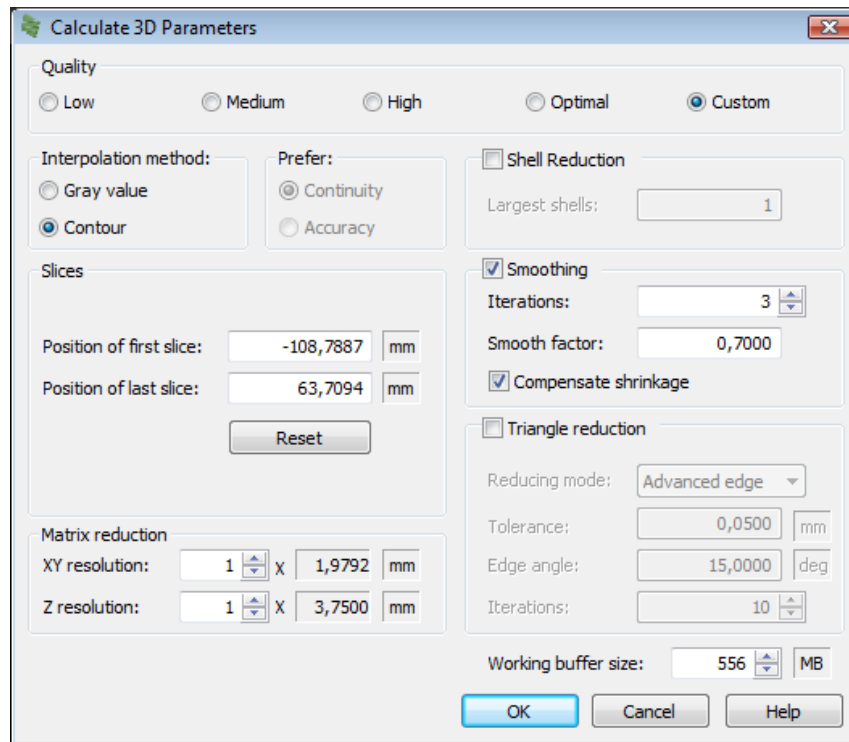
Figure 9.94 When editing is complete select "Calculate 3D" and select the aorta with the above settings.

Figure 9.95 Final segmented aorta.
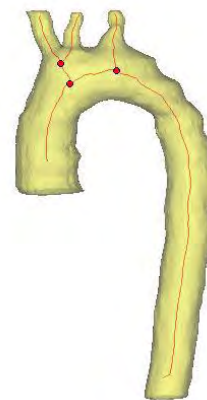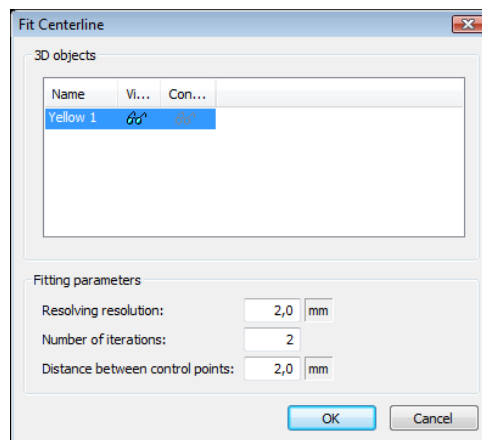
Figure 9.96 (a), (b) Selecting the "Fit Centreline" option, choosing the values shown and turn on transparency the centreline of the aorta can be viewed.
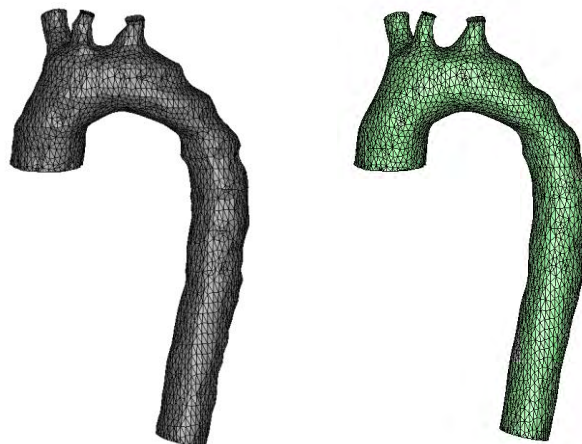
Figure 9.97 (a), (b) Aorta re-meshing.

The aorta before and after the surface mesh has been optimised and smoothened. This is achieved by selecting the "Smooth" icon, selecting the aorta surface and applying. The number of triangles can also be reduced by selecting "Reduce Triangle" icon and performing a "Quality Preserving "triangle reduction.
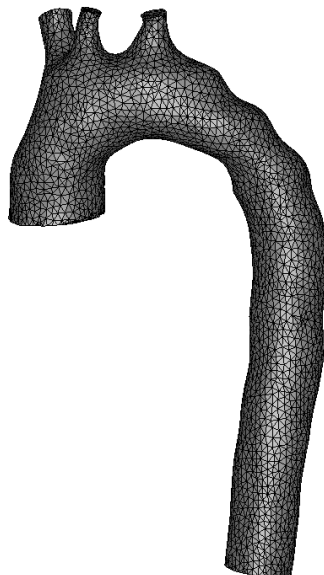
Figure 9.98 Aorta with optimised mesh.

The same procedure is followed for "Aorta 2" so as to obtain the 2 data sets required for comparison.

9.5.1.2 3-matic Process Steps
9.5.1.2.1 Comparison Analysis:
The aorta files are now imported into 3-matic by selecting the STL "Aorta1" and "Aorta 2".
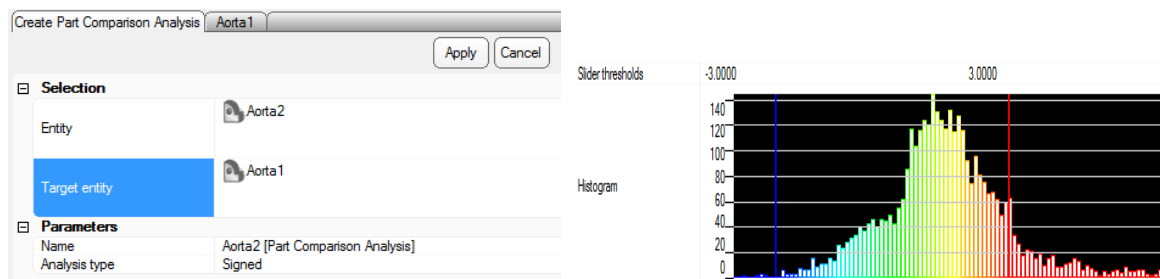
Figure 9.99 (a), (b) Comparison analysis.

The analysis tab is selected to create a part comparison analysis. This compares the aorta at diastole (Aorta1) and systole (Aorta2). The slider is set to analyse the movement of surfaces between -3mm and +3mm. Red indicating positive and green representing negative.
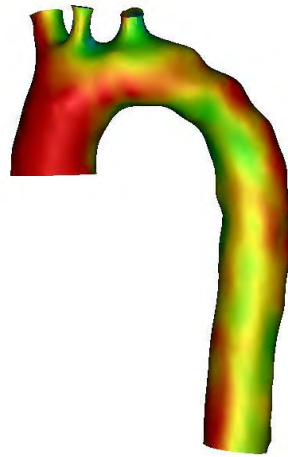
Figure 9.100 Analysis of aorta.

9.5.1.2.2 Aneurysm Design:

Aneurysms are a common medical problem that leads to many fatalities every year. Understanding their effect on the aorta in terms of pressure and blood flow could potentially save lives. The following section demonstrates how an aneurysm can be designed in 3-matics software and how the variation in size and shape effect pressure and blood flow.
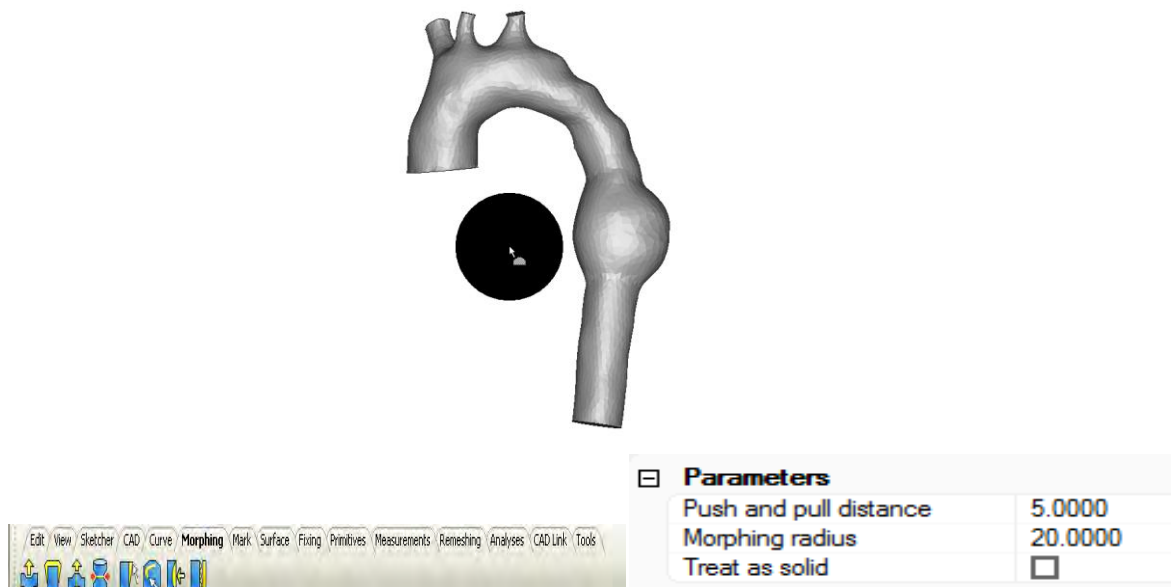
Figure 9.101 (a), (b) Selecting the "Morphing" tab and using the settings shown, hold the Ctrl button to pull on the surface and rotate aorta to complete.
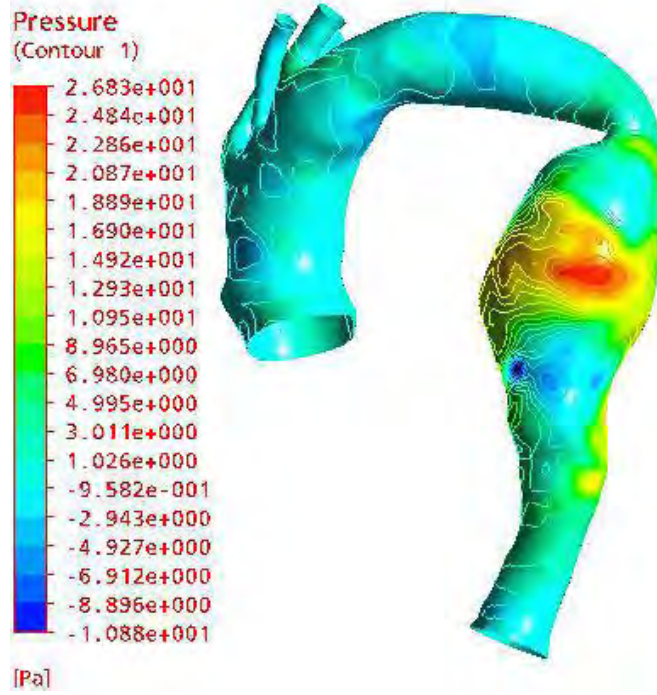
Figure 9.102 Example of CFD blood pressure analysis on a similar aorta.
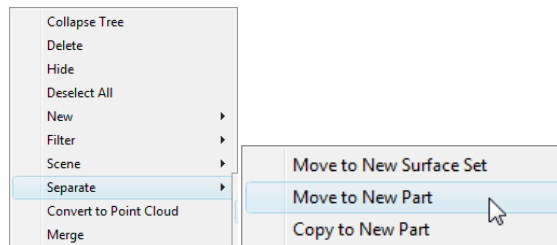
Figure 9.103 (a), (b) Aorta prototype.

For the aorta to be rapid prototyped and in flow analysis performed the aorta must be given a wall thickness. This is achieved by separating the inlet and outlet surfaces to another part. Therefore the aorta consists of the outer surface only.
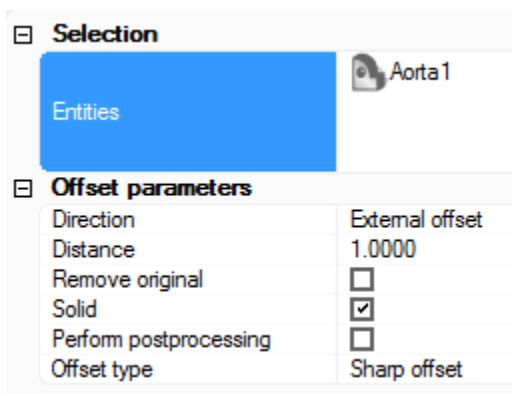
Figure 9.104 (a), (b) Select the offset option from the CAD toolbar and using the values shown to create an aorta with a wall thickness.

9.5.1.2.3 Fitting Heart Valve
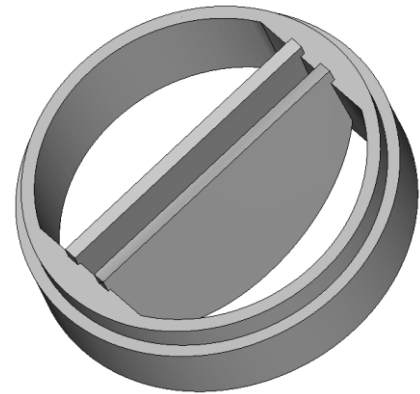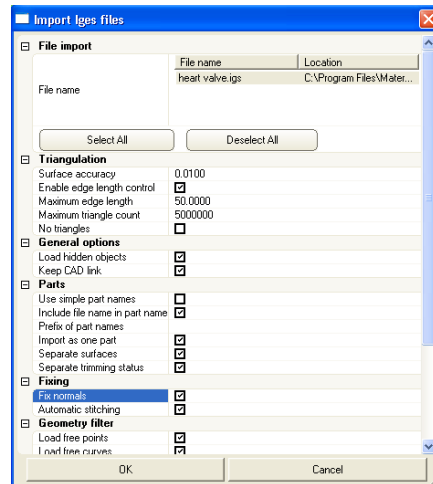
Figure 9.105 (a), (b) IGES file of a heart valve is imported.

In the "Import Dialog Box" enable "Fix Normals" and "Automatic Stitching".
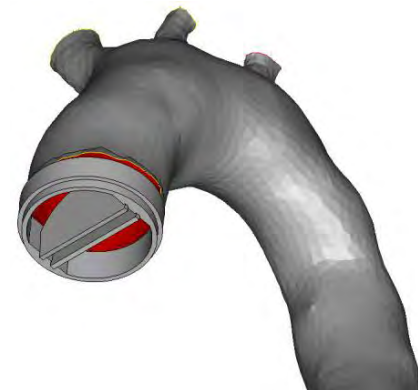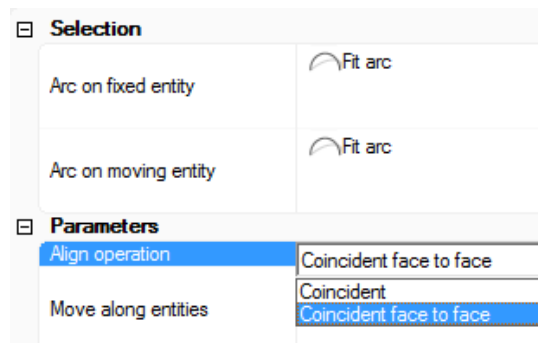
Figure 9.106 Valve alignment.

Selecting the properties above for aligning the valve and the aorta ensuring the arrow orientation is correct (arrow not shown)
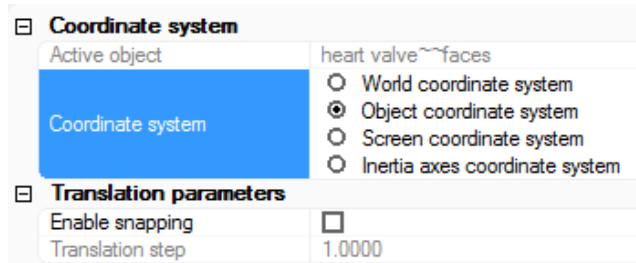
Figure 9.107 Interactive translate option is selected to accurately position the valve.
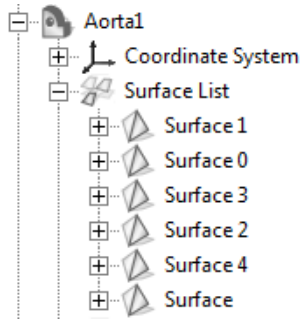
Figure 9.108 Aorta modification.

The aorta inlet requires to be modified to fit the valve. This is achieved by moving the surfaces back to the active scene.
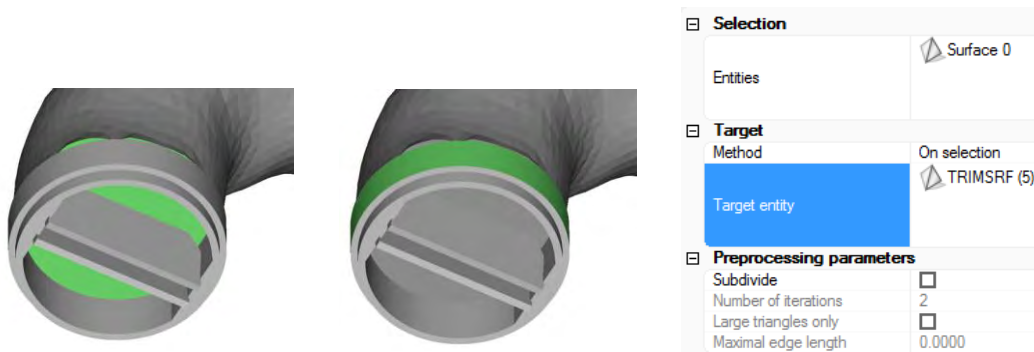
Figure 9.109 (a), (b) Part stitching.

Selecting the "Fixing Tab" and clicking "Project Mesh" then selecting the inlet surface as entity and select valve outer surface as target entity. The aorta surface will be altered.
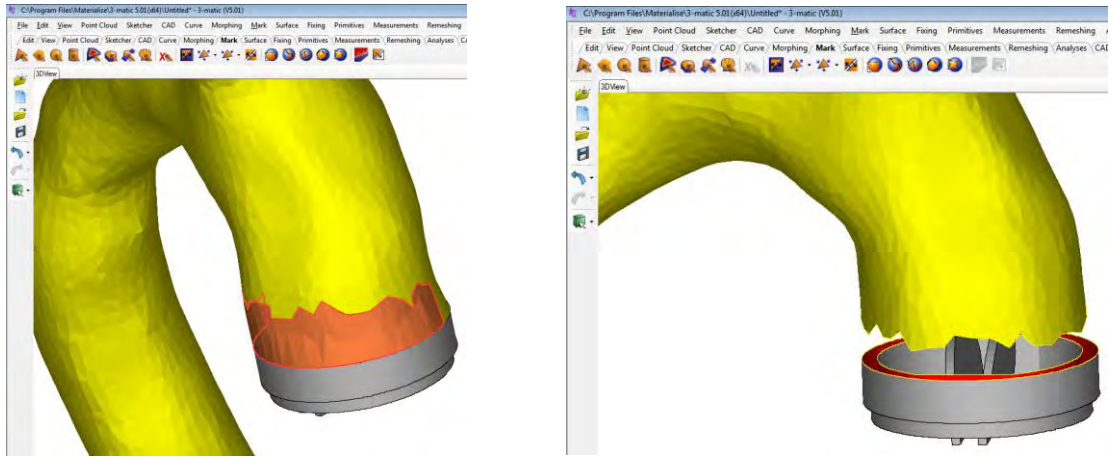
Figure 9.110 (a), (b) Alternative method.

Another method of meshing aorta to valve is the end of the Aorta is marked using the "Mark" tool it is deleted to give a definite gap so the valve edge can be correctly joined to the aorta body.
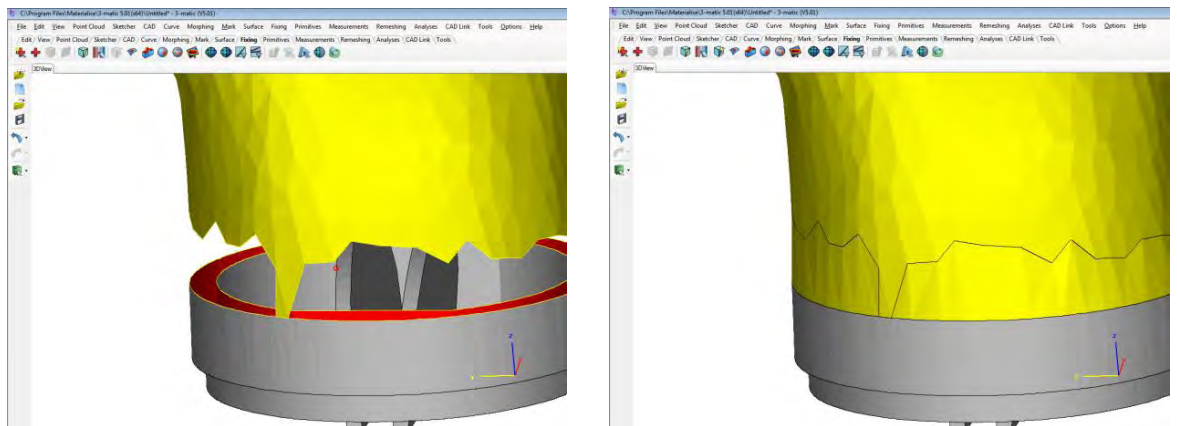
Figure 9.111 (a), (b) Gap bridging.

Using the create triangle the gap is bridged between the Aorta and the valve. This crates one hole that can be filled using automatic hole fill. This process was repeated for the internal wall also.
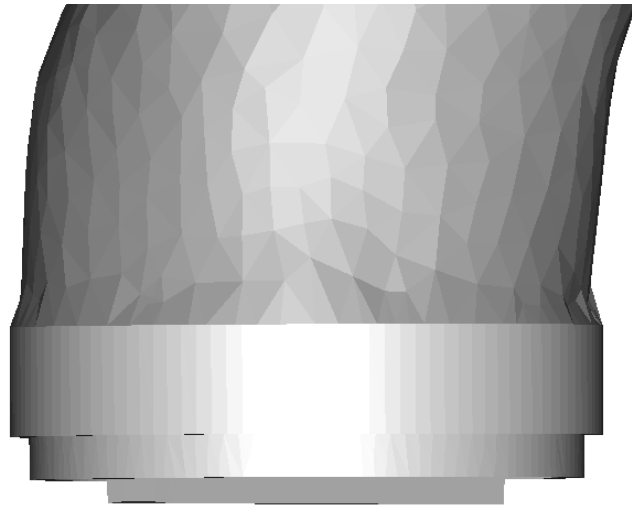
Figure 9.112 Result after meshing.

Figure 9.113. (a), (b) Final aorta prototype.

Z-Corp 3D prototype model illustrating a heart valve and the three branches of the aortic arch, brachiocephalic, left common carotid and left subclavian.

Figure 9.114 Combined Z-Corp RP model of aorta and heart valve.

9.5.2 Summary

This case study illustrates how medical software solutions can be used to edit STL files, compare analysis, design aneurysms and integrate in vivo components such as heart valves. CFD can also be performed on the prototype to evaluate the effects of valves on blood flow and pressure fluctuations within the aorta. While the aorta model was built on the Z-Corp 3D printer, a better option would be to build it on an SLA machine so as blood flow could be observed during analysis.

Chapter 10.0 – Conclusions, Further Work and Recommendations

10.1 Discussion

On completion of this project it became apparent that certain RP technologies and associated software such as Materialise, Mimics and 3-matic has indeed many advantages to offer the medical profession with regard to preoperative planning models and customised medical implants. Although not fully accepted by all, constant research and development in RP technology, biomaterials and software solutions, means that medical implant technology will continue to improve.

10.2 Conclusions

Case Study 1

i. Generating the cranial plate using the two methods produced 2 plates of similar fit.

ii. The profiles of the two plates were considerably different

iii. Using the "Create Cranioplasty" tool was significantly easier and faster than the manual method.

iv. The two cranial plates should have been made 0.5mm thicker to provide better location on the skull.

v. The manual method is subjective by nature and allows the designer to intuitively control the final design

Case Study2

i. The cranial plate was generated using the automatic method.

ii. The preoperative planning model produced on the 3D printer clearly depicted the nature and extent of the patient's trauma.

iii. Performing a Boolean subtraction on the tabs improved the fit and location of the plate on the skull model.

Case Study 3

i. The components produced on the 3D printer were satisfactory.

ii. The offset compensation values and rescaling factors entered into Magics 12.0 produced components of increased dimensional accuracy.

iii. Finished components required post processing to increase component rigidity.

Case Study 4

    i.   Producing an acetabular cup implant using 3-matic software was intuitive and efficient.

    ii.   The 3D Z-Corp print models produced were of good quality.

    iii.   The design and fit of the cup implant was sufficient but could have been refined if produced by the SLA process, due to process accuracy.

    iv.   The flange thickness was a little thin in two specific areas and should have been made 0.5mm thicker to increase part stability

Case Study 5

    i.   Aorta segmentation, aneurysm design and alignment of a heart valve were all achieved.

    ii.   A combined model of the aorta and valve were satisfactorily built on the Z-Corp 3D printer.

    iii.   Ideally this model should have been built on the SLA machine so blood flow could be observed and changes noted when performing CFD analysis and the effect of the valve recorded.

10.3 Recommendations

With reference to case study one the automatic method should be used on areas where the skull geometry is relatively constant. In contrast the manual method should be used where the rate of change of skull geometry is high. This allows the cranial plate profile to be designed in a subjective manner yielding more accurate results in terms of replicating a mirror image and achieving symmetry.

The approach taken in case study two is the standard method used by Materialise experts for designing a cranial plate in 3-matic software. Although the process involved a considerable number of steps the design process was systematic and produced very good results. Therefore based on the results obtained the approach adopted should be maintained until changes in software provide a more efficient alternative.

Case Study three was a straight forward process. The anatomical reconstruction produced good results but consultation with a surgeon would have proven beneficial in terms of ascertaining a professional medical opinion on the quality of the models. Furthermore,

explaining possible reasons for the irregularities or cavities on the femoral head and possible methods of reducing such.

Case study four was similar to case study two in terms of time and process steps. The method applied again is standard and is used by Materialise experts. Although there is a similar method of designing an acetabular cup implant model, the method chosen was more efficient in terms of time. Therefore the approach taken should be maintained unless the case characteristics or experts demand otherwise.

Case Study five differed from the other four cases in so far as this case focused primarily on software capabilities. Using Mimics software to extract complex anatomical part geometries and 3-matic demonstrated its flexibility and scope in coping with various design situations. This was achieved in terms of component attachment, aneurysm design and analysis of the aorta in reference to systolic and diastolic pressure characteristics. The capability of the software appeared very proficient and highlighted the degree of flexibility it offers users.

10.4 Further work

With reference to case study one, a series of test cases could be selected and a range of cranial plates produced. Based on the results obtained with respect to profile and fit the cranial could be categorised into areas particularly suited to each method.

In case study two, research could be conducted into the different designs of cranial plates currently available and examine why these particular designs exist. Thereafter, analysis could be conducted on each design and a determination made regarding which design would be the most suitable to address the vast majority of cases.

In case study three, although the parts were of good quality further research into offset compensation values and rescaling could be performed to yield increased part accuracy. Furthermore research into CT tissue recognition and classification would greatly improve the geometrical accuracy of anatomical models produced giving rise to better diagnosis of patients' pathologies.

Case study four involved the production of an acetabular cup implant and although the design was good, investigation into the design methodology applied could be examined and alternative approaches investigated.

Finally in case study five the aorta model produced could be prototyped by the SLA process to provide transparency to visualise fluid flow during CFD analysis. In addition to

this, design and build a number of aortic models each incorporating different medical implants devices such as heart valves, stents and catheters. Then analyse the results in terms of resistance to fluid flow and pressure fluctuations. A similar process could be conducted for aneurysm design.

References

References - Chapter 2

[1]   Medical Imaging and Technology Alliance (2010), Medical Imaging Primer
        [WWW] Available from: http://www.medicalimaging.org/medical-imaging-primer/
        [Accessed 12/11/2009]

[2]   American College of Radiology (2010) The radiology information resource for
        patients [WWW] Available from:
        http://www.radiologyinfo.org/en/info.cfm?pg=bodyct#part_three
        [Accessed 13/11/2009]

[3]   How computer Tomography works (2008). [Online Image].Available from:
        http://www.xviewct.com/assets/images/how-ct-works.gif
        [Accessed 13/11/2009]

[4]   North Star Imaging (2008). How computer Tomography works [WWW] Available
        from: http://www.xviewct.com/computed-tomography-technology/how-ct-works
        [Accessed 13/12/2009]

[5]   Chartered Medical Group (2007). CT overview [WWW] Available from:
        http://www.chartermedical.ie/diagnostic-imaging/ct [Accessed 19/11/09]

[6]   American College of Radiology (2010) Computed Tomography (CT) equipment
        [Online Image] Available from:
        http://www.radiologyinfo.org/en/photocat/gallery3.cfm?image=to_ct.jpg&pg=bodyct&pid=1 [Accessed 13/12/2009]

[7]   American College of Radiology (2010) CT scan of body [Online Image] Available
        from:
        http://www.radiologyinfo.org/en/photocat/gallery3.cfm?image=00276077_appy_AP.jpg&pg=bodyct&pid=1 [Accessed 13/12/2009]

[8]   Simplant Israel (2009) Volumetric imaging samplesgenerated from CT images
        [Online Image] Available from:
        http://www.dmfiua.com/resources/_wsb_465x349_Slide3.PNG
        [Accessed 14/12/2009]

[9]   Oracle Education Foundation (2006), History of the MRI [WWW], Available
        from: http://library.thinkquest.org/TQ0312532/thinkquestH1/history.html
        [Accessed 13/12/2009]

[10]   How MRI works (2009), [Online image], Available from:
        http://www.bitterrootimaging.com/images/mri-diagram.png
        [Accessed 18/12/2009

[11]   MRI of Knee joint (2010), [Online image], Available from:
        http://blog.remakehealth.com/Portals/11143/images//knee_mri_picture.jpg
        [Accessed 14/12/2009]

[12]   MRI Scanner Cutaway (2010), [Online Image], Available from:
        http://www.magnet.fsu.edu/education/tutorials/magnetacademy/mri/images/mri-
        scanner.jpg [Accessed14/12/2009]

[13]   American College of Radiology (2009), General Ultrasound Imaging [WWW]
        Available from: http://en.wikipedia.org/wiki/Medical_ultrasonography
        [Accessed 14/12/2009]

[14]   Ultrasound Scanning Process (2001), [Online Image] Available from:
        https://honors.rit.edu/amitraywiki/images/9/9d/Ultrasound-parts.jpg
        [Accessed 16/12/2009]

[15]   Modern Ultrasound machine (2010), [Online Image] Available from:
        http://www.yourultrasound.com/wpcontent/uploads/2007/06/ultrasoundmachine.
        jpg [Accessed 16/12/2009]

[16]   Whitby, Jonathan. (2007), White Paper the DICOM standard [WWW] Available from: http://www.barco.com/barcoview/downloads/TheDICOMstandard_v2.pdf [Accessed 12/11/2009]

[17]   Whitby, Jonathan. (2007), White Paper the DICOM standard [Online Image] Available from: http://www.barco.com/barcoview/downloads/TheDICOMstandard_v2.pdf [Accessed 13/11/2009]

References - Chapter 3

[18]   Bralla, J.G., (1986), Handbook of Product Design for Manufacturing, 1st ed, p54, New York: McGraw-Hill.

[19]   Wohlers, T., Wohler's Report 2009, Part 7, Other Developments, p. 179, Fort Collins, Colorado, U.S., Wholers Associates, Inc.

[20]   Chua, C.K., Leong, K.F., Kai, C.C. (1998), Rapid Prototyping Principles and Applications in Manufacturing, New York. John Wiley and Sons.

[21]   Liou, Frank.W., (2008), Rapid Prototyping and Engineering Applications, pp. 223-233, 1st ed, Florida, U.S.A, Taylor and Francis Group.

[22]   Chua, C.K., Leong, K.F., Lim, C.S., (2003), Rapid   Prototyping Principles and Applications, 2nd ed, p.13, Singapore, World Scientific Publishing Co.Pte.Ltd.

[23]   Chua, C.K., Leong, K.F., Lim, C.S., (2003), Rapid   Prototyping Principles and Applications, 2nd ed, p.13, Singapore, World Scientific Publishing Co.Pte.Ltd.

[24]   Chua, C.K., Leong, K.F., Lim, C.S., (2003), Rapid   Prototyping Principles and Applications, 2nd ed, p.13, Singapore, World Scientific Publishing Co.Pte.Ltd.

[25]   Chua, C.K., Leong, K.F., Lim, C.S., (2003), Rapid   Prototyping Principles and Applications, 2nd ed, p.12, Singapore, World Scientific Publishing Co.Pte.Ltd,

[26]   Chua, C.K., Leong, K.F., Lim, C.S., (2003), Rapid   Prototyping Principles and
         Applications, 2nd ed, pp 26-32, Singapore, World Scientific Publishing Co.Pte.Ltd.

[27]   Redeye Express (2005) Stereolithography Apparatus [WWW] Available from:
         http://www.xpress3d.com/SLA.aspx [Accessed 28/12/2009].

[28]   Stereolithography Apparatus Process Diagram (2005) [Online Image]Available
         from: http://www.xpress3d.com/SLA.aspx [Accessed 28/12/2009].

[29]   Stereolithography Apparatus Sample Component (2005) [Online Image] Available
         from: http://www.xpress3d.com/SLA.aspx [Accessed 28/12/2009].

[30]   Liou, Frank.W., (2008), Rapid Prototyping and Engineering Applications, 1st ed,
         pp. 270-272, Florida, U.S.A, Taylor and Francis Group.

[31]   Selective Laser Sintering Process Diagram (2005). [Online image].Available from:
         http://www.xpress3d.com/SLS.aspx [Accessed 28/12/2009].

[32]   Stryker knee implant (2009). [Online image]. Available from:
         http://www.eos.info/fileadmin/user_upload/downloads_presse/Medizin/Stryker/Knee_Implant_Stryker_01.jpg [Accessed 28/12/2009].

[33]   DMLS teeth implants and SLS jaw prototype bone (2009). [Online Image]
         Available from: http://www.3trpd.co.uk/dmls/medical.htm [Accessed 28/12/2009].

[34]   Chua, C.K., Leong, K.F., Lim, C.S., (2003), Rapid Prototyping Principles and
         Applications, 2nd ed, pp. 124-133, Singapore World Scientific Publishing
         Co.Pte.Ltd

[35]   Fused Deposition Model Process Diagram (2008). [Online image] Available from:
         http://www.xpress3d.com/FDM.aspx [Accessed 29/12/2009].

[36]   FDM Sample Component, (2009). [Online image] Available from:
        http://home.att.net/~castleisland/fdm.htm [Accessed 29/12/2009].

[37]   FDM Sample Component, (2009). [Online image] Available from:
        http://home.att.net/~castleisland/fdm_int.htm [Accessed 29/12/2009].

[38]   Liou, Frank.W., (2008), Rapid Prototyping and Engineering Applications, 1st ed,
        pp. 275-279 ,Florida, U.S.A., Taylor and Francis Group.

[39]   3 Dimensional Printing Process Diagram [2007]. [Online image] Available from:
        http://home.att.net/~castleisland/3dp.htm [Accessed 2/01/2010].

[40]   Objects polyjet RP machine [2009]. [Online image] Available from:
        http://medicaldesign.com/mag/prototyping1009-fig02.jpg [Accessed 2/01/2010].

[41]   Radtech Europe (2010) Inkjet 3D Printing of Photopolymer Materials [WWW]
        Available from:
        http://www.radtecheurope.com/files_content/august%20papers%202005/napadensk
        ypaperaugust2006.pdf [Accessed 01/02/2010].

[42]   Maxillofacial 3d Printed model (2008). [Online image] Available from:
        http://www.3dventures.com/wp-content/uploads/2009/05/skull-2.jpg Available at:
        http://www.3dventures.com/?p=25 [Accessed 02/02/2010].

[43]   Cranial Implant (2008). [Online image] Available from:
        http://c0388982.cdn.cloudfiles.rackspacecloud.com/6657_31120693359.jpg
        [Accessed 06/02/2010].

[44]   Spinal Medical model (2007). [Online image], Objet Geometries Ltd. Available
        from: www.answers.com/topic/3d-printing-technology [Accessed 06/02/2010].

[45]   Rapid Manufacturing Technologies (2010) Direct Metals Manufacturing
        Technology [WWW] Available from: http://www.mtt-group.com/selective-laser-
        melting.html [Accessed 06/02/2010].

[46]   Schematic of SLM process SLM process (2010) [Online Image] Available from:
        http://www.twi.co.uk/content/laser_slm.html [Accessed 02/02/2010].

[47]   SLM medical implants (2010) [Online image] Available from:
        http://www.mtt-group.com/selective-laser-melting_01.html [Accessed 03/02/2010].

References - Chapter 4

[48]   Gale (1996) Preoperative planning with rapid prototyping [WWW] Available from:
        http://www.thefreelibrary.com/_/print/printarticle.aspx?id=18916139
        [Accessed 08/02/2010].

[49]   Erickson, Douglas (1999) Benefits of Stereolithography models [WWW]
        Available from: http://www.joms.org/article/S0278-2391(99)90322-1/abstract
        [Accessed 08/02/2010].

[50]   Potamianos, P. et al. (2009) Rapid Prototyping for Orthopaedic surgery [WWW]
        Available from: http://pep.metapress.com/content/7864473822g50067/
        [Accessed 09/02/2010].

[51]   Wouters, K. (1998) What is the Phidias newsletter [WWW] Available from:
        http://ss1.spletnik.si/000/000/15e/56a/PH1_ok.pdf [Accessed 09/02/2010].

[52]   Ryan, V. (1996) Advantages of 3D modelling [WWW] Available from:
        http://www.technologystudent.com/cam/prn3d4.htm [Accessed 06/02/2010].

[53]   FDM skull model (2002). [Online image] Available from:
        http://dml.chania.teicrete.gr/ereuna/3dmedical/skull-3d-medium.jpg
        [Accessed 09/02/2010].

[54]   Torro, Corrado. et al.(2005) SLA mandible model (2003). [Online image]
        Available from:
        http://www.biomedcentral.com/imedia/1564237097111784_manuscript.pdf
        [Accessed 09/02/2010].

[55]   FDM spinal model (2001). [Online image] Available from:
        http://www.emeraldinsight.com/Insight/ViewContentServlet?Filename=Published/
        EmeraldFullTextArticle/Articles/1560070506.html
         [Accessed 11/02/2010].

[56]   Translucent 3D Printer model (2004). [Online image] Available from:
        http://www.objet.com/Portals/0/LiveContent/2661/Images/medical800.jpg
        [Accessed 14/02/2010].

[57]   SLA model of femur and pelvis (2009). [Online image] Available from:
        http://ddi-inc.net/images/medical-model-pelvis-femur.jpg [Accessed 14/02/2010].

[58]   FDM forearm model (2007). [Online image] Available from:
        http://www.ablesw.com/3d-doctor/armmod0.jpg
        [Accessed 14/02/2010].

[59]   WU, Ted. (2001) From CT image to 3D model [WWW] Available from:
        http://www.ablesw.com/3d-doctor/surgmod.html [Accessed 15/02/2010].

References - Chapter 5

[60]   ZHU Xiao-feng (2005), Digital Geometry Processing Applied in Customizes
        Medical Implant Design. [WWW] Available from:
        http://ieeexplore.ieee.org/stamp/stamp.jsp?arnumber=01615869
        [Accessed 22/2/2010]

[61]   S.F Khan, K.W. Dalgarno, Design of Customised Medical Implants by Layered
        Manufacturing, (2007). [WWW] Available from:
        http://scholar.google.com/scholar?hl=en&q=Design+of+Customized+Medical+Imp

lants+by+Layered+Manufacturing.+S+F+Khan%2C+K+W+Dalgarno&as_sdt=200
0&as_ylo=&as_vis=0 [Accessed 22/02/2010].

[62]   Sterling, B. Rapid prototyping evolves into custom manufacturing, (2004). [WWW]
        Available from:
        http://www.laserfocusworld.com/display_article/227426/12/none/none/Feat/Rapid-
        prototyping-evolves-into-custom-manufacturing [Accessed 20/02/2010].

[63]   He J, Li D, Lu B, Custom fabrication of a composite hemi-knee joint based on
        rapid prototyping (2006). [WWW] Available from:
        www.emeraldinsight.com/1355-2546.htm [Accessed 20/02/2010]

[64]   Orentlicher, G., The Future of Implant Dentistry, (2007). [WWW] Available from:
        http://www.dentalaegis.com/Publications/Inside_Dentistry/article.aspx?id=54667
        [Accessed 05/03 2010].

[65]   Singare.S., Customised design and manufacturing of chin implant based on rapid
        prototyping, (2005). [WWW] Available from:
        http://www.emeraldinsight.com/Insight/ViewContentServlet?Filename=Published/
        EmeraldFullTextArticle/Articles/1560110207.html [Accessed 02/03/2010].

[66]   RP Course Work Module, Lecture Notes, Professor David Wimpenny, De Montfort
        University, Leicester , PowerPoint presentation [Accessed 15/02/2010].

[67]   Technion, Israel Institute of Technology, Types of Bone Tissue [WWW] Available
        from: http://www.technion.ac.il/~mdcourse/274203/lect5.html
        [Accessed 22/02/2010].

[68]   S.F Khan, K.W. Dalgarno, Design of Customised Medical Implants by Layered
        Manufacturing, (2007). [WWW] Available from:
        http://scholar.google.com/scholar?hl=en&q=Design+of+Customized+Medical+Imp
        lants+by+Layered+Manufacturing.S.F+kHAN+and+K.W+Dalgarno&btnG=Search
        &as_sdt=2000&as_ylo=&as_vis=1 [Accessed 05/03/2010].

[69]   Bibb, Richard, (et al), (2009), Rapid Prototyping Journal, Rapid manufacture of custom-fitting surgical guides. Available from: http://www.emeraldinsight.com/Insight/viewContentItem.do?contentType=Article&contentId=1811844 [Accessed 05/03/2010].

[70]   Bibb, Richard, (et al), (2009), Rapid Prototyping Journal, Rapid manufacture of custom-fitting surgical guides. Available from: http://www.emeraldinsight.com/Insight/viewContentItem.do?contentType=Article&contentId=1811844 [Accessed 05/03/2010].

[71]   Bibb, Richard, (et al), (2009), Rapid Prototyping Journal, Rapid manufacture of custom-fitting surgical guides. Available from: http://www.emeraldinsight.com/Insight/viewContentItem.do?contentType=Article&contentId=1811844 [Accessed 05/03/2010].

[72]   Bibb, Richard, (et al), (2009), Rapid Prototyping Journal, Rapid manufacture of custom-fitting surgical guides, Available from: http://www.emeraldinsight.com/Insight/viewContentItem.do?contentType=Article&contentId=1811844 [Accessed 06/03/2010].

[73]   Bibb, Richard, (et al), (2009), Rapid Prototyping Journal, Rapid manufacture of custom-fitting surgical guides, Available from: http://www.emeraldinsight.com/Insight/viewContentItem.do?contentType=Article&contentId=1811844 [Accessed 06/03/2010].

[74]   Bibb, Richard, (et al), (2009), Rapid Prototyping Journal, Rapid manufacture of custom-fitting surgical guides, Available from: http://www.emeraldinsight.com/Insight/viewContentItem.do?contentType=Article&contentId=1811844 [Accessed 06/03/2010].

[75]   Bibb, Richard, (et al), (2009), Rapid Prototyping Journal, Rapid manufacture of custom-fitting surgical guides, Available from:

http://www.emeraldinsight.com/Insight/viewContentItem.do?contentType=Article&contentId=1811844 [Accessed 06/03/2010].

[76]   Bibb, Richard, (et al), (2009), Rapid Prototyping Journal, Rapid manufacture of custom-fitting surgical guides, Available from: http://www.emeraldinsight.com/Insight/viewContentItem.do?contentType=Article&contentId=1811844 [Accessed 07/03/2010].

[77]   Hieu, L.C., Zlatov.N. (2005), Medical rapid prototyping applications and methods, [WWW] Available from: http://demo1.emeraldinsight.com/Insight/ViewContentServlet;jsessionid=709EA197B453A0508B397407FF50F733?contentType=Article&Filename=Published/EmeraldFullTextArticle/Articles/1560150102.html [Accessed 08/03/2010].

References - Chapter 6

[78]   Park, Joon, Lakes, R.S. (2007) Biomaterials An Introduction, Third Edition, page 2, New York, U.S.A, Springer.

[79]   Vallet-Regi, Maria, (2001) Ceramics for medical applications, Available from: http://www.rsc.org/delivery/_ArticleLinking/DisplayArticleForFree.cfm?doi=b007852m&JournalCode=DT   [Accessed 11/03/2010].

[80]   Wiliams, David. F, (2008) On the mechanisms of biocompatibility Biomaterials, [WWW] Available from: http://www.sciencedirect.com/science?_ob=ArticleURL&_udi=B6TWB-4SCTN0N-1&_user=2322584&_coverDate=07%2F31%2F2008&_rdoc=1&_fmt=high&_origin=search&_sort=d&_docanchor=&view=c&_searchStrId=1435640341&_rerunOrigin=scholar.google&_acct=C000056897&_version=1&_urlVersion=0&_userid=2322584&md5=bf4d3247fc7cdf3cb338a5ab66544fc4 [Accessed 14/03/2010]

[81]   Czernuszka, J., Materials World, vol. 4, pp. 452-53, 1996 "Biomaterials under the microscope" Available from: http://www.azom.com/details.asp?ArticleID=108 [Accessed 08/03/2010].

[82]   Czernuszka, J., Materials World, vol. 4, pp. 452-53, 1996 "Biomaterials under the microscope" Available from: http://www.azom.com/details.asp?ArticleID=108 [Accessed 08/03/2010].

[83]   Park, Joon, Lakes, R.S. (2007) Biomaterials An Introduction, Third Edition, page 3, New York, U.S.A, Springer.

[84]   Walter, Michael. J., Stainless Steel for medical (2006), [WWW] Available from: http://www.veridiam.com/articles/article3.pdf [Accessed 15/03/2010].

[85]   Arcam, ASTMF75 CoCr Alloy.[WWW]Available from: http://www.arcam.com/CommonResources/Files/www.arcam.com/Documents/EBM%20Materials/Arcam-ASTM-F75-Cobalt-Chrome.pdf [Accessed 15/03/2010].

[86]   Titanium Alloy Technical Datasheet, [WWW] Available from: http://cartech.ides.com/datasheet.aspx?i=101&E=269 [Accessed 18/03/2010].

[87]   Morgan Technical Ceramics, Advanced ceramics for medical implants [WWW] Available from: http://www.azom.com/details.asp?ArticleID=4265#_Advanced_Ceramics_for [Accessed 15/03/2010].

[88]   Cordingley, R. (et al), Alumina as an Orthopaedic Biomaterial, (2003) [WWW] Available from: http://www.azom.com/details.asp?ArticleID=2160 [Accessed 20/03/2010]

[89]   Chevalier, Jerome., What future for Zirconia as a biomaterial [WWW] Available from: http://www.sciencedirect.com/science?_ob=ArticleURL&_udi=B6TWB-4H21NC5-2&_user=2322584&_coverDate=02%2F28%2F2006&_rdoc=1&_fmt=high&_orig

=search&_sort=d&_docanchor=&view=c&_searchStrId=1351488689&_rerunOrig
in=scholar.google&_acct=C000056897&_version=1&_urlVersion=0&_userid=232
2584&md5=7d4f5ffc6bf11cc9ec5de74ebaa458b9 [Accessed 22/03/2010]

[90]   Frame, John. W., 1987 Hydroxyapapite as a biomaterial for alveolar ridge
       construction, [WWW], Available from:
       http://www.sciencedirect.com/science?_ob=ArticleURL&_udi=B7GHW-
       4WSRF561&_user=2322584&_coverDate=07%2F31%2F2010&_rdoc=1&_fmt=hi
       gh&_orig=search&_sort=d&_docanchor=&view=c&_searchStrId=1338015772&_
       rerunOrigin=google&_acct=C000056897&_version=1&_urlVersion=0&_userid=2
       322584&md5=0cd7e7a8c7788f3df8e10d51ad4427f3#secx2`
        [Accessed 24/03/2010]

[91]   Pruitt, Lisa., (et al), Polymeric Biomaterials for Load-bearing Medical Devices,
       [WWW] , Available from: http://www.tms.org/pubs/journals/JOM/0909/pruitt-
       0909.html [Accessed 01/04 2010]

[92]   Biomaterial stress/strain comparison graph, [Online image] Available from:
       http://www.tms.org/pubs/journals/JOM/0909/fig1.jpg [Accessed29/03/2010]

[93]   Quadrant Engineering, Technical data sheet [WWW] Available from:
       http://www.alperton.com/alperton/Files/PDS_CESTITECH_7000_EN.pdf
       [Accessed 04/04/2010]

[94]   Hip implant (2009). [Online image]. Available from;
       http://www.tms.org/pubs/journals/JOM/0909/fig7.jpg [Accessed 04/04/2010]

[95]   Lee, D.C, (et al) (1998), Preparation and characterization of PMMA–Clay hybrid
       composite by emulsion polymerization, [WWW], Available from;
       http://onlinelibrary.wiley.com/doi/10.1002/(SICI)10974628(19960815)61:7<1117::
       AID-APP7>3.0.CO;2-P/abstract [Accessed 09/04/2010]

[96]   Factors influencing the performance of a polymer in a medical device, (2009)

           [Online image] Available from:

           http://www.tms.org/pubs/journals/JOM/0909/fig2.jpg [Accessed 09/04/2009]

[97]   Ratner, D. Buddy. et al. (2004), Biomaterials Science 2nd Edition, San Diego,

           Elsevier Inc, pp 819-823.

[98]   Ratner, D. Buddy. et al. (2004), Biomaterials Science 2nd Edition, San Diego,

           Elsevier Inc, pp 819-823.

[99]   Leow. Natalie, (2001), Osseointegration, [WWW], Available from:

           http://members.aos.org.au/files/Implant-bone%20interface%20FINAL.pdf

           [Date Accessed 14/04/2010]

[100]   Histologic section of osseointegrated Titanium implant, [Online image], Available

           from: http://en.wikipedia.org/wiki/File:Osseointegration_Histology.jpg [Accessed

           14/04/2010]

[101]   U.S National Institute of Health (2007), Understanding clinical trials, [WWW]

           Available from: http://clinicaltrials.gov/ct2/info/understand#Q01

           [Accessed 14/04/2010]

References - Chapter 7

[102]   U.K medical devices industry, (2010). [Online image]. Available from:

           http://www.medicaldevice-network.com/features/feature90272/feature90272-
           1.html [Accessed 20/07/2010].

[103]   Padhi, Jyoti, Ranjan., (2010), Medical Devices for UK Lifestyles Disorders

           [WWW] Available from:

           http://www.medicaldevice-network.com/features/feature90272/

           [Accessed 20/07/2010]

[104] Wohlers, T., Wohler's Report 2009, Part 2, Industrial Growth, p. 43, Fort Collins, Colorado, U.S., Wohler's Associates, Inc.

[105} Wohlers, T., Wohler's Report 2009, Part 1, Background, p. 22, Fort Collins, Colorado, U.S., Wohler's   Associates, Inc.

[106] Wohlers, T., Wohler's Report 2009, Part 1, Background, pp. 22-26, Fort Collins, Colorado, U.S., Wohler's Associates, Inc.

[107] Wohlers, T., Wohler's Report 2009, Part 1, Background, p. 42, Fort Collins, Colorado, U.S., Wohler's Associates, Inc.

[108] Wohlers, T., Wohler's Report 2009, Part 7, Other Developments, p. 179, Fort Collins, Colorado, U.S., Wohler's Associates, Inc.

[109] Baby with cleft lip and palate, (2010) [Online Image] Available from: http://www.pddnet.com/news-Treatment-Uses-Geomagic-Studio-to-Bring-Smiles-to-Babies-Faces-060710/ [Accessed 01/09/2010]

[110] First and final customised implant, (2010) [Online Image] Available from: http://www.pddnet.com/news-Treatment-Uses-Geomagic-Studio-to-Bring-Smiles-to-Babies-Faces-060710/ [Accessed 01/09/2010]

[111] Dr Stoddard examining a complete range of RP inserts, (2010) [Online image] Available from: http://www.pddnet.com/news-Treatment-Uses-Geomagic-Studio-to-Bring-Smiles-to-Babies-Faces-060710/ [Accessed 01/09/2010]

[112] One of the original patients treated by this process, (2010) [Online image] Available from: http://www.pddnet.com/news-Treatment-Uses-Geomagic-Studio-to-Bring-Smiles-to-Babies-Faces-060710/ [Accessed 01/09/2010]

[113] Treatment Uses Geomagic Studio to Bring Smiles to Babies' Faces, (2010) Industry News Today, [WWW] Available from: http://www.pddnet.com/news-Treatment-Uses-Geomagic-Studio-to-Bring-Smiles-to-Babies-Faces-060710/ [Accessed 01/09/2010]

References - Chapter 9

[114] Ladher. Jasvir, PHD thesis, To develop a route for the generation of accurate 3Dprinted preoperative models for the treatment of acetabular fractures De Montfort University (2010).

Appendix - List of terms:

i. Rapid Prototyping : (RP)

ii. Digital Imaging and Communications in Medicine : (DICOM)

iii. Standard Triangle Language : (STL)

iv. Computer Numerically Controlled : (CNC)

v. Computerised Tomography : (CT)

vi. Magnetic Resonance Imaging : (MRI)

vii. Archiving and Communication Systems : (PACS)

viii. Computer Axial Tomography : (CAT)

ix. Additive Manufacturing : (AM)

x. Computer Aided Design : (CAD)

xi. Stereolithography Apparatus (SLA)

xii. Fused Deposition Model : (FDM)

xiii. Solid Ground Curing : (SGC)

xiv. Laminated Object Manufacture : (LOM)

xv. Computational Fluid Diagnostics : (CFD)

xvi. Rapid Tooling : (RT)

xvii. Direct Metal Laser Sintering : (DMLS)

xviii. Reverse Engineering : (RE)

xix. Solid Creation Systems : (SCS)

xx. Multi-jet Modelling Systems : (MJM)

xxi. Three Dimensional Printing : (3DP)

xxii. Direct Shell production Casting : (DSPC)

xxiii. Selective Laser Sintering : (SLS)

xxiv. Electron Beam Melting : (EBM)

xxv. Polymethylmethacrlate : (PMMA)

xxvi. Design for Manufacture and Assembly : (DFMA)

xxvii. International Graphics Exchange System : (IGES)

xxviii. Ultra High Molecular Weight Polyethylene (UHMWPE)

xxix. Poly(methyl methacrylate) : (PMMA)

xxx. Hydroxyapatite : (HA)

xxxi. Laser Net Shaping : (LENS)

xxxii. Cone-beam CT : (CBCT)