Application of Rapid Manufacturing Technologies to Integrated Product Development in Clinics and Medical Manufacturing Industries.

by

Francis Owusu-Dompreh

Submitted in Partial Fulfillment of the Requirements

for the Degree of

Master of Science in Engineering

in the

Industrial and Systems Engineering

Program

YOUNGSTOWN STATE UNIVERSITY

December, 2013

Application of Rapid Manufacturing Technologies to Integrated Product Development in Clinics and Medical Manufacturing Industries.

Francis Owusu-Dompreh

I hereby release this thesis to the public. I understand that this thesis will be made available from the Ohio LINK ETD Center and the Maag Library Circulation Desk for public access. I also authorize the University or other individuals to make copies of this thesis as needed for scholarly research.

Signature:

Francis Owusu-Dompreh, Student Date

Approvals:

Dr. Martin Cala, Thesis Advisor Date

Dr. Hojjat Mehri, Committee Member Date

Dr. Brett P. Conner, Committee Member Date

Dr. Salvatore Sanders, Associate Dean Graduate Studies and Research Date

Abstract

This study examines the possible application of reverse engineering and rapid prototyping technologies to the manufacture of customized implants from scanned anatomical images.

This thesis is composed of five chapters. The first chapter provides a brief overview of the rapid prototyping technologies, statement of the problem, purpose of this research and the question this research seeks to answer.

The second chapter is concerned with reverse engineering in relation to the medical field. It describes ways in which anatomical images can be obtained from a patient. It also highlights the file format that is required for rapid prototyping processes.

The third chapter discusses the FDM processes that were selected for this research, the materials that are biocompatible for the manufacture of implants and the general process in RE and RP technologies.

Chapter four shows the processes that scanned anatomical images should go through so that they can be 3D printed using applicable software with Z Corp and MakerBot printers. It demonstrates the step-by-step method of converting a scanned image into a CAM file that can be 3D printed.

Chapter five discusses the outcome of the research and the conclusions drawn. Further research recommendations are outlined in this chapter.

Acknowledgement

It is a pleasure to acknowledge the assistance of many people in the preparation of this thesis.

I am very grateful to Dr. Martin Cala, Coordinator of the Industrial and System Engineering Program, as chairman of the thesis committee and as my advisor for his guidance and enthusiastic help in the preparation of this thesis. He supported me in developing my financial aid, and above all gave me fatherly love throughout my stay at the Youngstown State University.

Many thanks to members of my thesis committee, Dr. Hojjat Mehri, Professor of Industrial and System Engineering and Dr. Brett P. Conner, Associate Professor of Industrial and Systems Engineering and Director, Advanced Manufacturing and Workforce Initiatives, College of STEM, for their time, suggestions, and constructive criticisms for the production of this thesis.

I gratefully acknowledge the help of Carrie Sinkele, an engineering instructor at Chaney High School for allowing me to use their laboratory equipment. I appreciate the help of Applied Systems & Technology Transfer, 'AST2' for their support and allowing me to use their laboratory equipment.

It is a gain with great joy that I acknowledge a friend, sister and mother in the person of Ernestine Marshall for her great assistance she offered during the course of my study at Youngstown State University.

Table of Contents

Chapter One

1.0 Project overview

1.1 Introduction

This thesis examines the impact of combining rapid technologies on performance outcomes in clinical activities and implant manufacturing industries. At present, most research focusing on this relationship consists of small case studies on the individual rapid prototyping technologies. As a result, manufacturing managers and medical officers have little guidance as to which types of rapid technologies when combined lead to greatest likelihood of enhanced performance.

Modern work organization patterns require high effectiveness of designers' work and full utilization of their creative potential while aiming toward competitive advantages such as short cycle time, low cost of order realization and high quality of products. These requirements may only be realized with complete integration of methods, models and information during development of a product, from the conceptual phase, through its manufacturing processes and on to post-manufacturing phases of service and recycling. Currently, shorter product life cycles, lower prices, and ever improving fulfillment of consumer needs causes ever increasing competition at the local and global levels. The need for reducing planning and design time encouraged the development of a set of new methods called rapid technologies or time compression technologies. This thesis seeks to undertake a comprehensive investigation of skills and processes required to maximize the potential of rapid prototyping and reverse engineering in the manufacturing of implants and anatomical modules. The combination of these two methods is capable of reducing the development stage, from the expression of needs to the introduction into the market. Rapid prototyping and reverse engineering also address the attainment of required product quality; these methods extend the concept of quality from production floor to the whole product life cycle. An object's mathematical model is considered to be a basic element of every rapid prototyping and reverse engineering application. This model must correctly describe the geometrical shape of the three dimensional object. A model may be obtained either from a CAD system, where the object may be designed from scratch, or

from an existing artifact by using a reverse engineering technology to find a mathematical model for a measured physical object. In many cases technical data that is available is not current or sufficient. Often unavailable technical data needed to maintain and repair equipment was never furnished or purchased. Examples of such situations include handmade prototypes, reproduction of old engineering objects and sculptured bodies found in medical and dental applications. In order to facilitate Computer-Aided Manufacturing (CAM), it is essential to establish CAD models for these items. RE is the quickest way to get the digital data for representing these items. Technical data is critical to the smooth and continuous operation of any production or manufacturing facility. The term Rapid Prototyping means a set of processes that realizes parts and components with layer-by-layer material addition and usually starts from an STL computer file generated from a three-dimensional mathematical model. Rapid Tooling processes are used in manufacturing. Although they do not replace traditional manufacturing techniques, they meet a need for quick production of prototype parts and tooling. Examples of their application is the direct production of an injection mold by using a metal sintering machine or by producing a mold cavity manufactured as a sprayed metal shell.

1.2 Rapid Manufacturing

Rapid Manufacturing (RM) is the latest approach for the manufacture of small quantities or complex individual items such as prostheses and hip replacement components. RM is a process that employs additive fabrication technology to produce end-use items, directly from Computer Aided Design (CAD) data. Components are manufactured without molding, casting or machining. Rapid Manufacturing is an extension of Rapid Prototyping and Rapid Tooling – the idea behind RM is to manufacture final products in processes similar to RP but in materials required in production of these parts.

Rapid Prototyping may deliver a first prototype in a matter of hours; a time frame for the first series of products may be days with Rapid Tooling, while months if they are manufactured traditionally.

The impact of RM is far-reaching and the opportunities and advantages are extensive. Implications are significant for the medical field which is ready to take advantage of developments in the use of RM.

1.3 Reverse Engineering

The process of duplicating an existing component, subassembly, or product, without the aid of drawings, documentation, or computer model is known as reverse engineering. In industrial practice new product designs are usually created in a CAD system from the beginning. Geometric models are digital and may be used in further computer aided stages of product development. There are cases, however, when product geometry must be created from an existing physical object, e.g. to re-engineer a design of a product without any technical documentation or to transform an artist's view into industrial design. This is the job for Reverse Engineering, where physical artifact is digitized into a computer model. The input to RE technologies is a material object, and the output is a CAD model. This can be achieved using contact and non-contact technologies. Among contact technologies most widely used are measurements with a Coordinate Measuring Machine (CMM), among non-contact methods – laser scanning and computed tomography. Contact and non-contact methods using visible light allow for reconstruction of geometry of outer surfaces of objects. Models representing objects with uniform internal structure may be recreated – this is a sufficient approximation for some applications.

1.4 Rapid Prototyping

Rapid prototyping broadly indicates the fabrication of a three-dimensional (3D) model from a computer-aided design (CAD), traditionally built layer by layer according to the 3D input [1]. Rapid prototyping has also been indicated as solid free-form, computer-automated or layer manufacturing [2]. The term rapid prototyping refers to the automatic construction of physical objects directly from a geometric solid or surface model.

According to *Wohler's Report 2000,* RP is defined as: a special case of machine technology that quickly produces models and prototype parts from 3-D data

using an additive approach to form the physical models [5].While several different rapid prototyping (RP) technologies have emerged since the 1980s, all of them start with a virtual CAD model. The model geometry is then transformed into cross sections, and the prototype is additively fabricated one physical cross section at a time.

Unlike part production using numerical control (NC) machine tools, rapid prototyping is fast and simple. Rapid prototyping does not require process planning, tooling, or material handling. Whereas NC machine tools can work with most materials, including metals, rapid prototyping is currently restricted to the use of specific materials e.g acrylonitrile butadiene styrene(ABS) plastic. For this reason, RP physical objects are often used as prototypes or patterns for other manufacturing procedures.

Rapid prototyping is used for (i) design evaluation, (ii) function verification, (iii) aiding in the creation of models for other manufacturing processes, and (iv) producing construction-quality parts in relatively small numbers. A physical model, particularly one that can be quickly generated, enables all parties involved in the development process to visualize, discuss, and intelligently evaluate a particular design. In this way, potential problems and misunderstandings are uncovered and resolved, thus avoiding costly mistakes that go undetected until late in the product's development cycle.

Rapid prototypes are also used to verify that a design will function as intended. Common function verification tasks include:

- Demonstrating the practicality of an assembly. Many products are difficult—or even impossible—to assemble.
- Evaluating the kinematic performance of an assembly. Do moving parts perform as intended? Are there any unexpected interferences?
- Assessing aerodynamic performance. Here the geometric shape is of primary importance; a prototype made from a different material may be sufficient.

In the event that such characteristics as the strength, fatigue, operational temperature limits, or corrosion resistance of a part are to be tested, the prototype must be made of the same material as the actual part. In this case, RP prototypes are sometimes used as patterns for other fabrication processes.

The most significant benefits of RP technology are a compressed design cycle and improved product quality. Rapid prototyping dramatically reduces the time and expense required to take a new product from initial concept to final production, and it is also helpful in identifying design flaws.

1.5 Technology Overview

The methods used for manufacturing a physical model by rapid prototyping can be generally divided into two major categories: “additive” and “subtractive”. Additive manufacturing indicates the fabrication of a part by adding materials to a substrate. On the other hand, a subtractive process involves machining using high-speed spindles and fairly machinable aluminum alloys in order to provide fast turnarounds for tooling and functional parts [5]. The choice between additive and subtractive rapid prototyping requires the evaluation of parameters such as speed of manufacturing, desired accuracy and budget [9]. In the clinical context, since subtractive techniques have the limitation of reduced ability in printing complex geometries and of requiring hard materials, additive techniques are more commonly employed. Currently, the most commercially successful RP technologies are stereolithography, fused deposition modeling (FDM), and selective laser sintering (powder bed binder jet printing).

1.5.1 Stereolithography: A stereolithographic system includes a bath of photosensitive resin, a model-building platform and an ultraviolet laser for curing the resin [3]. The input image is divided into slices and such data is fed to the stereolithography machine. Layers are cured in sequence, the laser guided onto the surface of the resin by means of a PC-controlled mirror. The support platform is lowered following the completion of each layer. Further curing occurs in an opposite cabinet once the model is removed from the resin bath. Stereolithography requires a support structure when the part being built has

undercuts—that is, when the upper cross section overhangs a lower R cross section Support structures are added to the model in order to aid layers adhesion and then removed once the model is printed. It is regarded that stereolithography provides the most accurate 3D models with best surface finishing. A wide variety of photosensitive polymers are available for making parts, including clear, water-resistant, and flexible resins.

1.5.2 Fused deposition modeling (FDM). Similarly to stereolithography, this is a layer-by layer process, the main difference between the two being that the layers are deposited as a thermoplastic that is extruded from a fine moving tip [1]. Once a complete layer is deposited, the table drops down and another layer begins. As for stereolithography, support structures are necessary and are extruded with a second nozzle. The supporting elements are often printed in a different color or using soluble material [3]. Fused deposition modeling is office-friendly and fairly fast when making small parts. FDM parts have good mechanical properties, to the point that functional parts can be produced.

1.5.3 Selective laser sintering (SLS) employs a powder material that is selectively fused by a laser. After a roller spreads the powder, the laser is used to solidify a single layer of material. In this case an infrared laser is used to cure a thermoplastic powder. This technique does not require supporting structures because the unprocessed powder serves this purpose, facilitating the cleaning process of the models [4].

This process repeats until the part is complete. Parts can be produced from a wide range of commercially available powder materials, including nylon and polystyrene. The key advantage of SLS is its ability to make functional parts.

1.5.3 Computerized numerically controlled milling: In this case the printing process consists in removing a layer at a time from a block of material. Albeit the complexity of the surfaces and the detail of internal finishing are limited, this subtractive technology has been applied to medical modeling. One example is the construction of custom titanium implants for cranioplasty [6].

1.6 Statement of the Problem

Food and Drug Administration (FDA) proposed new rules that may stop manufacturers from selling faulty all-metal hip implants. The FDA's proposal comes after an estimated 500,000 people in the United States received hip implants that can fail early – one of the biggest device failures in decades. FDA stressed that "metal-on-metal implants have unique risks in addition to the general risks of all implants." Specifically, FDA refers to adverse reaction to metal debris (ARMD).This condition occurs when "tiny metal particles [that] wear off of the device around the implant, which may cause damage to bone and or soft tissue surrounding the implant and joints. This research is focused on adopting various reverse engineering approaches that replicate original human body part which will serve as an implant using materials other than metals. This thesis also bases on the FDA recommendation to used rapid prototyping and reverse engineering technology to develop with plastics and composite materials which is biocompatible, high resistant to wear , and its debris will not cause any damage to the tissues.

Clinics are always faced with challenges concerning replacements of bones, organs, and tissues that are not readily available for surgery. This thesis seeks to discover how RP and RE technique in the clinical world can be rendered possible by the concomitant advances in all its three fundamental steps: i. Medical imaging (data acquisition), ii. Image processing (image segmentation and reconstruction by means of appropriate software) and iii. Rapid prototyping itself (3D printing). These approaches may have provided some success in supporting manufacturers of medical implants to stay in business; and preventing patients from soft tissue damage; preventing implant loosening; preventing device failure; and preventing the need for revision surgery. This research may provide the possibility of observing, manipulating or manufacturing an anatomical model can

serve a range of significant functions. For instance, it can lead to the development of customized for a patient; it can address visualization issues that virtual examination cannot always resolve. Also, it can be adopted as a simulation tool or a teaching device. Moreover, it allows medical practitioners and researchers to fully make use of the "patient-specific" concept, in terms of prosthesis design and implant fitting but also in terms of *ad hoc* simulations.

1.7 Purpose of Research

Majority of research on Advance Manufacturing Technologies (AMTs) has been either conceptual in nature or based on individual rapid prototyping technologies. These studies which are all geared towards reducing product development times have yielded significant insight and laid a firm foundation for further research .There is the need to expand on the existing research to integrate the RP technologies to enhance product development in medical industries.

Anatomical parts can be complicated in shape but a CAD model is needed to enable the manufacturing of such part. As the part become more and more complicated in shape, designing CAD, formation of tool and dies may be challenging or take a long time. There is no guarantee that CAD model will be acceptably close to the anatomical model. There has been a mandatory need for 3D reconstruction of objects from existing components by the medical industries and research facilities.

This research seeks to develop techniques that assist medical manufacturers and designers to meet the demands of reducing product development time for them to be in competition with the global market by shortening lead- time to market new product. This will also assist medical practitioners to produce implants without waiting for a patient to die to get an implant for another patient. This thesis also bases on the FDA recommendation to used rapid prototyping and reverse engineering technology to develop implants with plastics and composite materials which is biocompatible, high resistant to wear , and its debris will not cause any damage to the tissues.

As part of the methodology used to test hypothesis which the researcher is interested in, this study develops and tests the combination of AMTs in terms of (i) time (ii) product quality (iii) Accuracy. This thesis describes a complete prototyping process using the Reverse Engineering techniques to capture the geometry of an anatomical part using medical scanners and Reverse Engineering (RE) software. The Rapid prototyping process used is Fused Deposition Modeling (FDM) system. It also describes the step-by-step procedure for making the prototype (ABS Pattern) as well as the hardware and software used for making the prototype model.

1.8 Method of Research

This section provides brief overview of the research methodology used in this research. Data is collected using experimentation and observation in the laboratory.

The goal of reverse engineering an object is to successfully generate a 3D CAD model of an object that can be used for future modeling of parts where there exists no CAD model. The aim is to generate clean, smooth 3D models, which are free of noise and holes. The geometry of a medical implant is captured using MRI/CT scanning machine and Reverse Engineering (RE) software. The Rapid prototyping process used is Fused Deposition Modeling (FDM) system and Powder jet Binder Bed 3D printing. It also describes the step-by-step procedure for making the prototype (ABS Pattern) as well as the hardware and software used for making the prototype model.

1.9 Research Objectives and Questions

1. An important objective of this research is to provide information on AMTs and their use which is of practical significance to managers of implant manufacturing industries who make decisions regarding these technologies. In order to accomplish this, there must be a specific example of which infrastructural programs effectively support AMTs and how these programs can best be implemented. Therefore, this study aims:

1. To provide managers of implant manufacturing firms that use AMTs with practical insight to guide the implementation process and the use of these technologies.

2. To examine the interrelationship between AMTs and Medical activities which provide clinics the fast and easy way to develop and produce their own implants without wasting time to the detriment of the patient.

3. To empirically examine the effect of integrating two or more rapid prototyping technologies on quality and time of product development

There are three questions which will be answered by this research:

1. What rational can be used to explain performance differentials due to combination of rapid prototyping technologies and product development?

2. Do some clinical activity lead to the development of model for rapid prototyping similar to reverse engineering processes which could possibly lead to the development of implants for surgical operations?

3. Do the combination of reverse engineering and rapid prototyping actually increase the quality of product and reduce the time of getting product to the market?

Several approaches will be utilized in the examination of these questions.

Firstly, reverse engineering processes will be used to acquire the model of components and anatomical data and image of implants.

Secondly, the model will be converted into STL and finally into Computer Aided Manufacturing CAM format by generation of code using a software.

Finally, the CAM model will be fabricated using rapid prototyping

techniques “additive and subtractive” which will be followed by testing.

Chapter Two

2.0 Literature Review

2.1 Introduction

Reverse engineering (RE) is the science of taking the existing physical model and reproducing its surface geometry in three-dimensional (3D) data file on a computer-aided(CAD) system. Reverse engineering is the general process of analyzing a technology specifically to ascertain how it was designed or how it operates. This kind of inquiry engages individuals in a constructive learning process about the operation of systems and products. RE as a method is not confined to any particular purpose, but is often an important part of the scientific method and technological development. The process of taking something apart and revealing the way in which it works is often an effective way to learn how to build a technology or make improvements to it. Reverse engineering is the process of generating a Computer Aided Design (CAD) model from an existing part. It enables the reconstruction of an object by capturing the components physical dimension and geometrical features. It is a converse product design approach where the designer begins with the product and works through the design process in an opposite sequence to arrive at product specifications such as dimensions and form. This enables the designer to mentally simulate design ideas that occur during the design of the original product.

2.12 Preparation of geometric data for the RP Process

Physical prototypes made by incremental or decremental RP techniques are based on the 3D-CAD model. Depending on the RP method, proper computer data processing is required. The generation of the prototype is possible on the basis of a geometric (volumetric) CAD model. Computer processing begins in the CAD environment, from which the model is exported into the proper format of the RP system.

In this research, the prototype is fabricated on the basis of data directly from the RE process. It should be remembered, however, that data of this type is less accurate than data processed in 3D-CAD programs. Programs dedicated to RP devices verify the correctness of models. Further file processing comes down to defining the right parameters of the device operation (the layer thickness for the incremental systems or the

path for the CNC **(**decremental systems). It is the so-called program post-processing, which consists in the preparation of the final data, essential to the construction of the physical model (files in the RP device format). The process of data preparation has a significant influence on the accuracy of the model received in the rapid prototyping process. Computer-aided design systems have a certain accuracy of mapping the 3D-CAD model geometry (e.g. the linear accuracy of the model made in the CATIA system is 0.001mm). At the current stage of technological development, this accuracy is higher than the accuracy of mapping the geometry of the prototype produced with the use of rapid prototyping systems. The parameters of geometric data exported from CAD systems should be adjusted to the assumed accuracy of the physical prototype fabrication. In general, the accuracy of the 3D-CAD model should be higher than the accuracy of the mapping of the RP device geometry. Thanks to this, in the process of the physical model construction, the RP device does not repeat program errors [10].

2.20 Reverse Engineering and Rapid Prototyping in Medical Field

2.21. Introduction

This chapter will present a brief overview of the possible applications of rapid prototyping in the medical context. Different options of clinical inputs will be discussed, which will demonstrate the flexibility and clinical usefulness of this technique. The section also demonstrates some medical activities will lead to the acquisition of 3d model of a tissue, organ, or system that can be printed using rapid prototyping technique. Rapid prototyping broadly indicates the fabrication of a three-dimensional (3D) model from a computer-aided design (CAD), traditionally built layer by layer according to the 3D input (1). Rapid prototyping has also been indicated as solid free-form, computer-automated or layer manufacturing [2].

2.2 Reverse Engineering Processes in Medical Field

The development of this technique in the clinical world has been rendered possible by the concomitant advances in all its three fundamental steps:

1. Medical imaging (data acquisition),
2. Image processing (image segmentation and reconstruction by means of appropriate software) and
3. Rapid prototyping itself (3D printing).

2.2.1. Anatomical data and image acquisition

The clinical input for rapid prototyping is represented by all the information contained in imaging data. Most commonly, magnetic resonance (MR) imaging and computerized tomography (CT) imaging are used for this purpose. Other sources include laser surface digitizing, ultrasound and mammography. Unfortunately, Laser surface digitizing is a technique that permits acquisition only of external data, while MR and CT comprise both internal and external data, thus reducing scanning time and file size [12]. The output of the imaging acquisition process and input of the rapid prototyping following appropriate processing is a DICOM image (Digital Imaging and Communications in Medicine), which is the outcome of virtually all medical professions utilizing images, including endoscopy, mammography, ophthalmology, orthopedics, pathology and even veterinary imaging [11].

2.2.1.2 Magnetic resonance imaging

MR imaging is an imaging technique based on detecting different tissue characteristics by varying the number and sequence of pulsed radio frequency fields, taking advantage of the magnetic relaxation properties of different tissues [12]. MR imaging has the crucial advantage of not emitting X-ray radiations. Instead, the MR scanner provides a strong magnetic field, which causes protons to align parallel or anti-parallel to it. MR measures the density of a specific nucleus, normally hydrogen, which is magnetic and largely present in the human body, approximately 63% [13], except for bone structures. The speed at which protons lose their magnetic energy varies in different tissues allowing detailed representation of the region of interest. This measurement system is volumetric, producing isometric 3D images (i.e. the same resolution in all directions).

Figure2.1. Magnetic resonance imaging

2.2.1.3 Computerized tomography

Hard tissues and bony structures, which are assessed less well by MR imaging, can be captured by means of CT. This is a radiographic technique that uses a narrow fan X-ray beam to scan a slice of tissue from multiple directions. The absorption of different tissues is calculated and displayed according to gray-scale values. The resolution of CT data can be increased by decreasing the slice thickness, producing more slices along the same scanned region. However, the resulting longer scanning time has to be weighed by the clinician against the consequence of increased radiation dose [12]. The technology known as spiral CT allows for shorter scanning time and small slice intervals with respect to previous scanners. In this case the patient is translated continuously through the gantry as the X-ray tube and detector system are continuously rotating, the focus of the X-ray tube essentially describing a spiral.

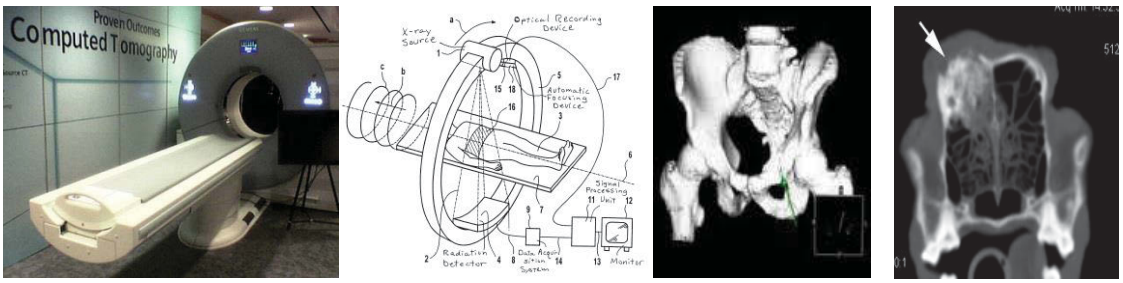


Figure 2.2 Computerized tomography

2.2.2 Advantages of CT/MRI scan for implant manufacturing

Recent advancements in the areas of Rapid Prototyping (RP), Reverse Engineering (RE) and Image Processing (IP), lead to the emergence of the field of Medical Applications of Rapid Prototyping (MARP). Soon after the introduction of Rapid Prototyping to industry, the advantages of this new technique were realized and researchers started to look at the medical community to implement new applications. With improvements in the medical imaging, it is now feasible more than ever to produce a physical model "directly" from Computed Tomography (CT) scan or Magnetic Resonance Image (MRI) with great accuracy. RP requires that CAD files be provided in layers. Since medical data resulting from CT/MRI is usually provided in a slice format, it seemed natural to be able to produce physical models directly by the new layered-manufacturing technique. By combining RP, RE and Image processing, the medical applications took off and have been under constant development ever since.

Coordinated Measuring Machine is a technique that permits acquisition only of external data, while MR and CT comprise both internal and external data, thus reducing scanning time and file size (Liu et al., 2006).

2.2.3 Data formats for the CAD/RP process

Rapid prototyping systems require that the files of 3D-CAD digital models be saved in the proper formats. The most popular 3D-RP formats include: STL format (Stereolithography Language), SLC format (Sliced Layer Contour), CLI format (Common Layer Interface), HPGL format (Hewlett Packard Graphic Language) and The MGX format– a format of the Magic RP program. In the process of data processing by means of 3D-CAD/3D-RP there are also universal 3DCAD formats applied, such as STEP, IGES or 3DS. By way of example, Z Print, a program for operating three-dimensional printers, makes it possible to read in the CAD model with colored texture saved in the 3DS format. The universal Magic RP program allows for the reading in of files in most formats applied in CAD systems, depending on the installed translators. The formats that used in this research are STL, STEP or IGES.

2.2.4 Conversion of Anatomical Data into STL Format

Robiony et al. recently showed an integrated process involving maxillofacial surgeons, radiologists and engineers for dental virtual surgical planning [16]. In this case, the input data for the printing process is represented by CT images. Once the images are imported in the dedicated software (Mimics®), the anatomical region of interest is contoured by segmentation algorithms and the 3D structure is described by a triangle mesh which is exported as STL file for rapid prototyping. The printing process is a standard 3D printing technique using PLA or ABS material. While acknowledging the importance of the physical 3D model *per se*, this study also stressed the importance of being able to simulate a surgical procedure on the digital model. Manipulation of the STL file, rather than other formats such as IGES, appeared to be the best solution. Surgeons and engineers were thus able to import the skull model in the digital environment and replicate a surgical procedure.

2.2.5 Product Development

The methods used for manufacturing a physical model by rapid prototyping can be generally divided into two major categories: “additive” and “subtractive”. Additive manufacturing indicates the fabrication of a part by adding materials to a substrate. On the other hand, a subtractive process involves machining using high-speed spindles and fairly machinable aluminum alloys in order to provide fast turnarounds for tooling and functional parts [5]. The choice between additive and subtractive rapid prototyping requires the evaluation of parameters such as speed of manufacturing, desired accuracy and budget [9]. In the clinical context, since subtractive techniques have the limitation of reduced ability in printing complex geometries and of requiring hard
materials, additive techniques are more commonly employed. Several rapid prototyping processes were discussed in the first chapter, but in this research 3D printing is used in the development of the prototype.

2.2.6 3D Printing

The Three Dimensional Printing method consists in the building of the model in the form of layers with the use of a material heated by the head and fluidized, which is pumped through a nozzle also equipped with a mechanism controlling and cutting off the material supply. The nozzle is mounted in a holder having the possibility of moving horizontally and vertically, which enables the placement of a material layer in the working space in accordance with the defined geometry of the cross-section. The applied layer solidifies as soon as it flows out of the nozzle binding to the layer applied before. During the construction of the model, another nozzle pumps out a material supporting the proper model. This material also serves the purpose of joining the proper model with the working platform. The supporting structures generated together with the model are removed once the complete object has been built. It is possible to construct supports using a water-soluble material, which makes it easier to remove them. Several kinds of materials can be applied in the 3DP method, such as waxes, PLA, alkylbenzenesulfonates and polycarbonates as well as biocompatible materials.

Chapter Three

3.0 Rapid Manufacturing

3.1 History of Rapid Prototyping

Rapid prototyping (RP), which is part of Additive manufacturing (AM), improves upon the traditional material forming, removal and assembly methods of manufacturing. This eliminates restrictions in traditional manufacturing technology, with great impact on commercial and technological implications. The tremendous potential surrounding this technology led to the rapid development of RP, Magnus started in 1965 followed by Swainson in 1971. Thereafter the first stereolithography apparatus (SLA) by 3D Systems appeared in 1987,and then selective laser sintering (SLS) by EOS in 1990.Three new technologies were released in 1991; Fused Deposition Modeling (FDM) by Stratsys, Solid Ground Curing (SGC) by Cubical and Laminated Object Manufacturing (LOM) by Helisys. In 1996 the first 3D Print technology was released by Stratasys. These technology breakthroughs set the stage for the commercial integration of AM within manufacturing industry. [18]

3.2 Introduction to RP

The RP 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.

3.3 Methods and Applications of Medical RP

The applications of RP within the medical field are increasing and certain areas have been targeted. These areas include medical device prototyping, bio modeling and anatomical modeling. With the advancements in medical based rapid prototyping 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 patient's requirements. Models can be used to plan reconstructive surgery for maxillofacial, orthopedic, 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 medical devices. Currently areas of particular focus are the hearing aid and dental restoration industry. [19]

3.4 RP Principles.

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 analyze, 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

3.4.1 Input

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

3.4.2 Method

Presently the number of manufacturers of RP systems is increasing rapidly. The method applied by this manufacturer can be classified into the following categories:

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

3.4.3 Applications

Generically speaking applications can be grouped into the following areas:

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

3.4.4 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.

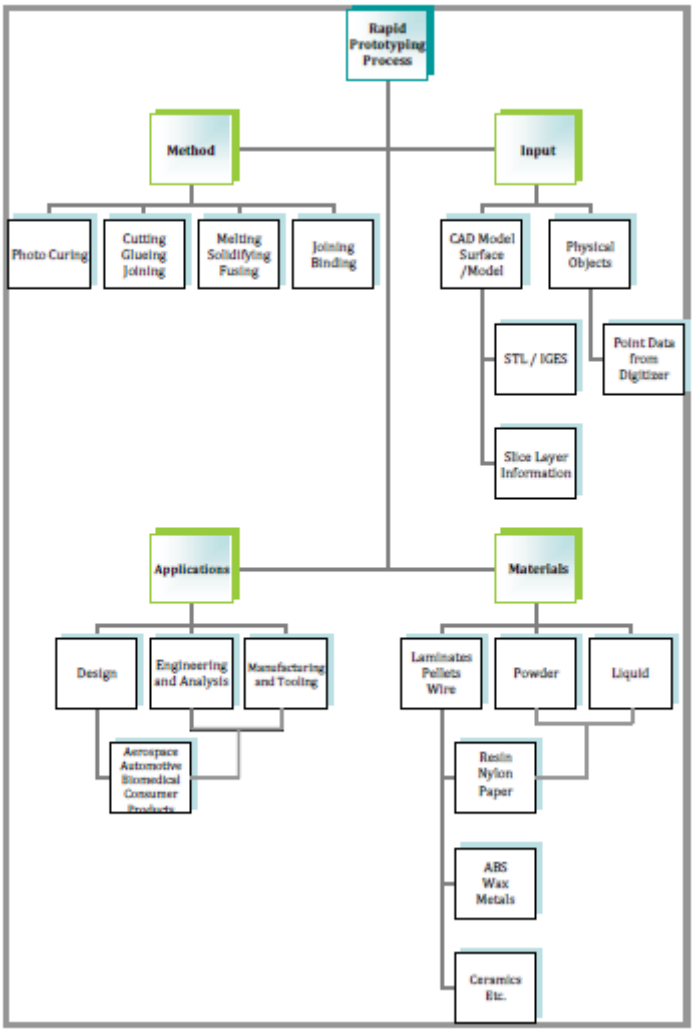


Fig 3.1 Overview of RP process. [22]

3.5 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].

3.6 RP Process

3.6.1 3D Modeling

Advanced 3D CAD modeling 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).

3.6.2 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).

3.6.3 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. Materialize Magic and 3-matic software can be used to produce a watertight solid model.

3.6.4 Building

Some software used for operating FDM machines more than on part to be built at the same time on the same platform. It is always advantageous to build as many parts as possible at the same time, this make the effective use of the build area of the platform. When complete the part should be handled carefully until post processing has taken place. [26]

3.6.5 Post Processing

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

3.7 Selected RP Processes

Many RP processes were mention in section 3.3 but in this research FDM method; polymers SLS and 3D Printing is used. These processes are discussed in the following sections.

3.7.3 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, acrylonitrile butadiene styrene (ABS), elastomers, and investment casting wax.

3.7.3.1 Process Overview

The modeling 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. [31]

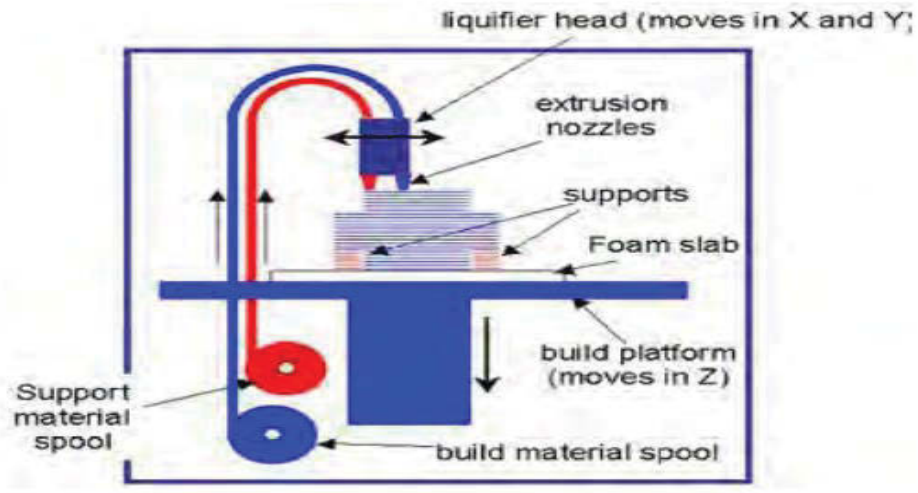


Figure 3.2 FDM process. [32]

3.8.4 3D Printing

The Z-Corp three dimensional printing Ink-jet based process prints the parts 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 color. 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.

3.8.4.1 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 infiltrates. [33]

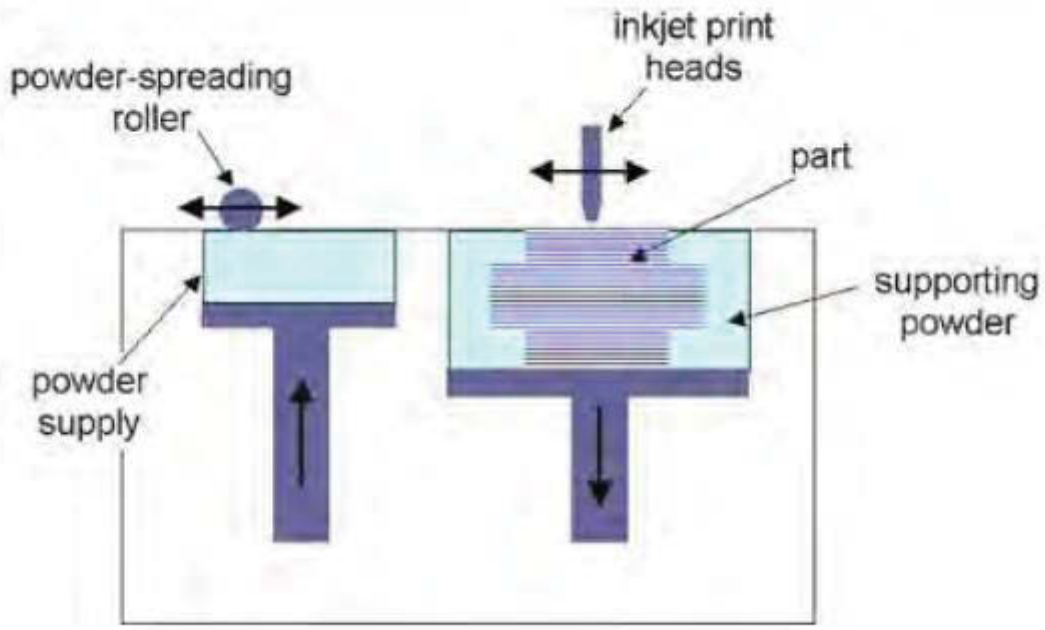


Figure 3.3 3D Printing process. [34]

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 molds.

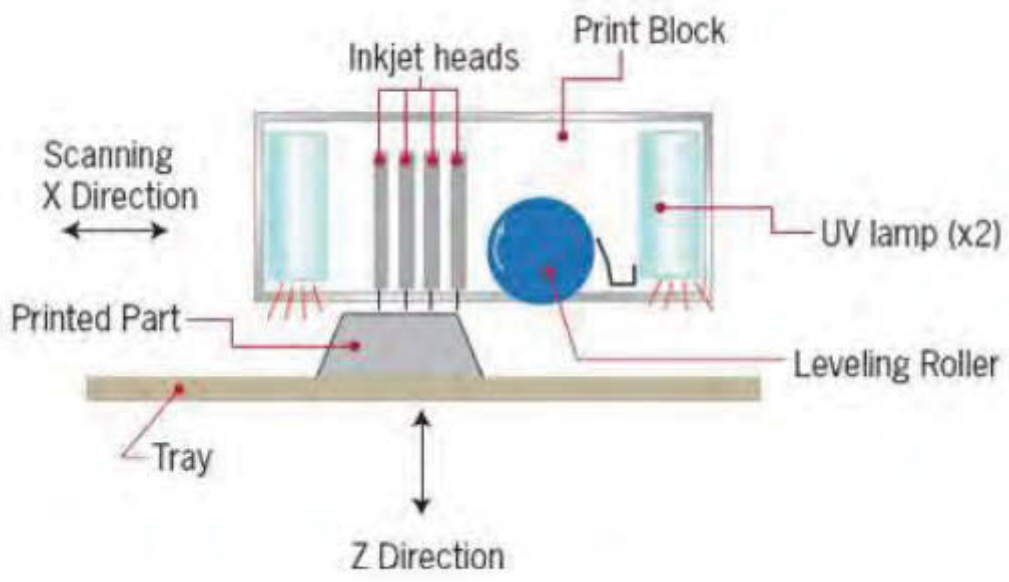


Figure 3.4. Objects Polyjet process uses UV lamps to cure the layers as they are been printed. [35]

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 colored materials are also available. The properties of the materials used can range from hard and tough to flexible depending on the application. [36]

3.9 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. [40]

Bone is considered to be a composite material; it has the capability of healing and remodeling 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 minimizes healthy tissue excision. [41]

3.1.0 Customized Implants

Customized implants are made for many parts of the human anatomy specifically for each individual patient to increase functionality, aesthetic appearance and reduce discomfort.

These implants includes:

- Scaffolding and Tissue Engineering
- Knee Implant
- Dental Implant
- Chin Implant
- Mandibular Implant

3.1.1 Bio-compatible materials

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 [43]

Owing to the increase in the average life expectancy of the general population, implants especially orthopedic 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 utilized 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.

3.1.1.1 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. 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. [44]

3.1.2 Approved Biomaterials

3.1.2.1 Metals:

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. Metallic materials accepted to be used for medical implant are; 316L Stainless Steel, Co-Cr Alloys, and Titanium

3.1.2.2 Ceramics:

Ceramic materials are designated where resistance to wear is of primary importance. 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 [47]

Examples of ceramics currently used for medical implants are: Alumina (AL2O3) and Zirconia which are mainly used for orthopedic and dental implants, and Hydroxyapatite (HA) which 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.

3.1.2.3 Polymers:

Polymeric materials are used where stability, flexibility and controlled porosity are required. 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 behavior 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. [51]. Polymers used for medical implants include: Ultra High Molecular Weight Polyethylene (UHMWPE) which is a preferred material when performing arthroplasty procedure for spine and orthopedic implants. [53] and Poly(methyl methacrylate)(PMMA).In orthopedic 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. [55]

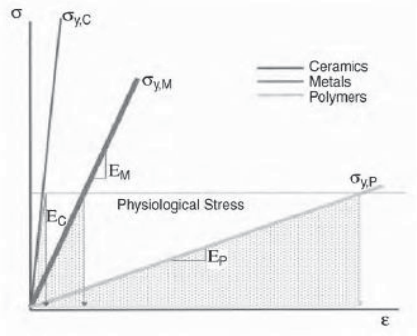


Figure 3.5 Compares strain on a ceramic, metal and polymer implant subjected to given physiological stress. [52]

Figure 8 A complete hip replacement using UHMWPE as the acetabula cup with Co-Cr femur head. [54]

3.1.3 Performance of Polymer Implants

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

Factors are:

- Implant design
- Structural Requirements
- Clinical Issues
- Processing Treatments
- Material Selection

In terms of degradable polymeric biomaterials, typical applications include sutures, drug delivery devices, orthopedic fixation devices, temporary vascular graphs and tissue engineering for guided tissue regeneration scaffolds. [56]

Chapter Four

4.0 Methodology

This chapter explains how an acetabula cup is produced using RE and RP manufacturing technologies.This case study demonstrates how medical problems can be given attention with medical design software and RP technology to produce reliable medical solutions.All anatomical data used in this thesis are from the researcher.

4.1 Systematic Approach

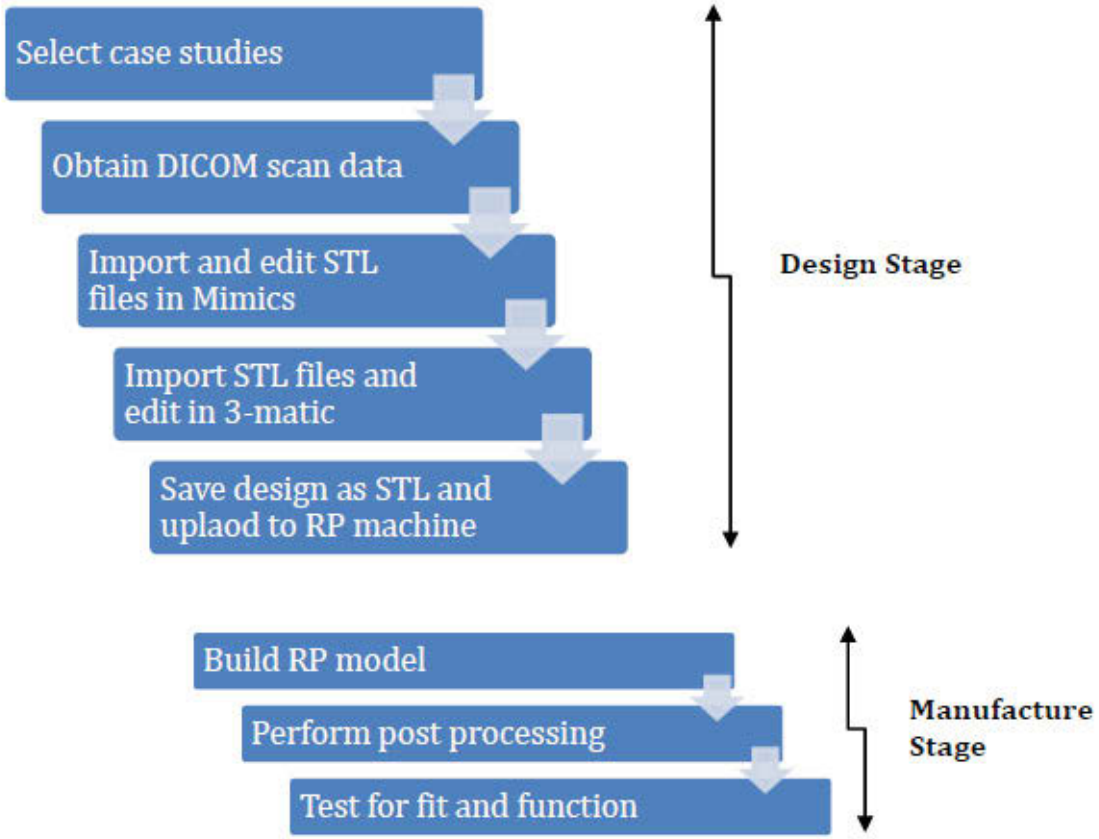


Figure 4.1 Systematic approach applied to case studies.

4.2 Case Study – Design an Acetabular Cup Implant

Researcher's DICOM data, Materialise Mimics and makerware design are used in this thesis to produce a customised acetabular cup implant using RP technology. The process selected to produce the acetabula cup is FDM.Specifically 3D Systems SLS machine and makerBot Replicator 2 printer are used to produce the cup. GD&T will be done on the cup produced and comparison will be made between the actual acetabula cup and the implant produce, finally the result discussed.

4.3 Acquisition of CT-scan

The most commonly used techniques for capturing internal medical data are the Computed Tomography (CT) and the Magnetic Resonance Imaging (MRI). Either of the techniques provides cross sectional images of a scanned part of the human body. The main difference is that the CT scanner uses radiation in the process while MRI does not. The quality of the finished model totally depends on the accuracy of the scanning machine and the resolution of the data. Decreasing the scan distance, which produces more slices along the scanned region, can increase resolution. The longer scanning period required for a high-resolution scan, however, must be weighted against increasing the patient's exposure to radiation, scan time and cost, and patient discomfort. The new spiral CT-scan technology allows faster acquisition of smaller scan distances compared to traditional scanners that must translate the patient for each transverse section. In either of the techniques, the output of the scanning process is a set of cross-sectional data images. CT-data is most suitable for modeling bone structures and MRI-data is best suited for modeling of soft tissues.

4.4 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

3-matics – used for the manipulation of line geometry, editing and processing of files

Makerware – used for the manipulation and processing of files into computer aided manfacturing CAM file.

4.4.1. Conversion of CT-data and CAD Model Generation

The following three steps summarizes the conversion process:

4.4.1 Process Steps

4.4.1.1 Mimics Process Steps

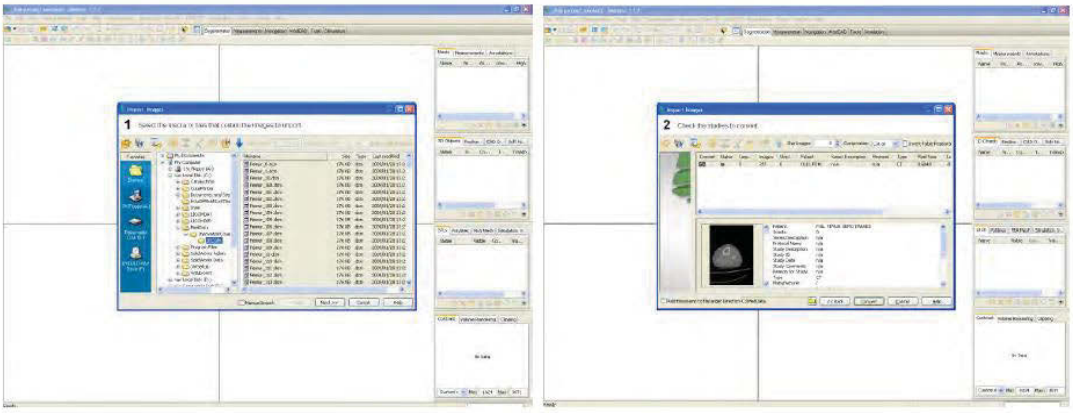


Figure 4.2 (a), (b) CT data has been loaded into Mimics. CT compression is selected to compress the files and then select convert to load images into Mimics.

Figure 4.3 (a), (b) Select orientation must by clicking on x.

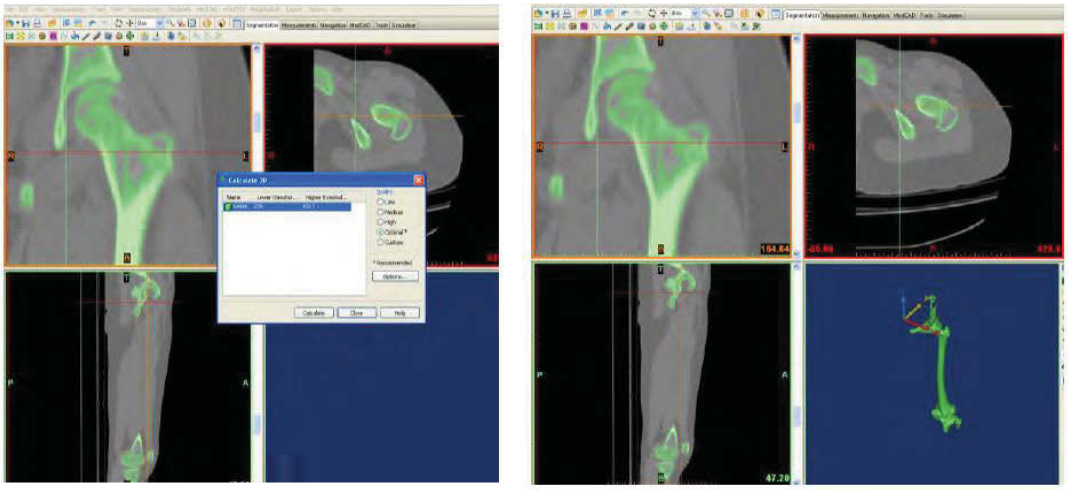


Figure 4.4 (a), (b) Threshold selection.

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.

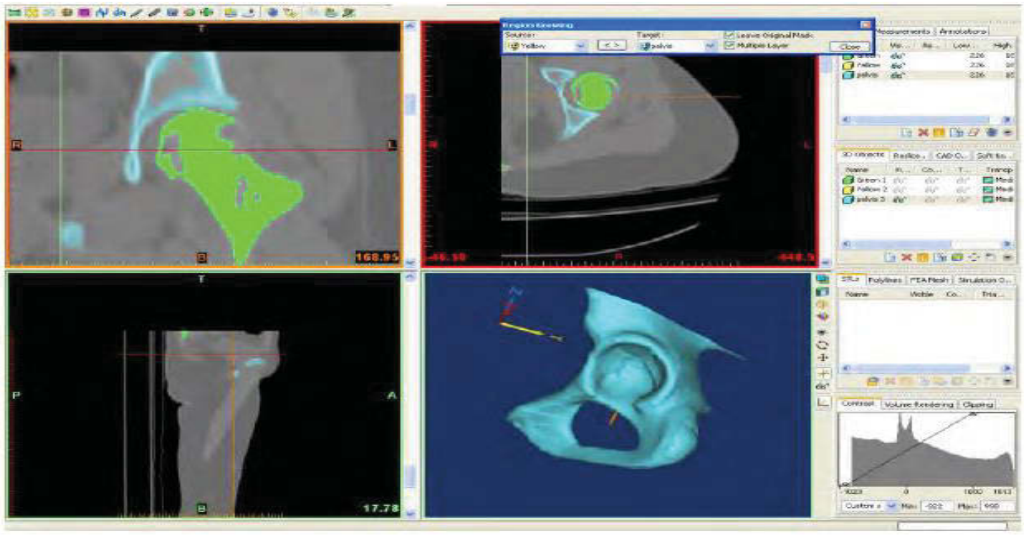


Figure 4.5(a) and (b) Region growing.

Selecting the femur and clicking on region growing tool with high quality tab the femur will be separated from the neighboring 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.

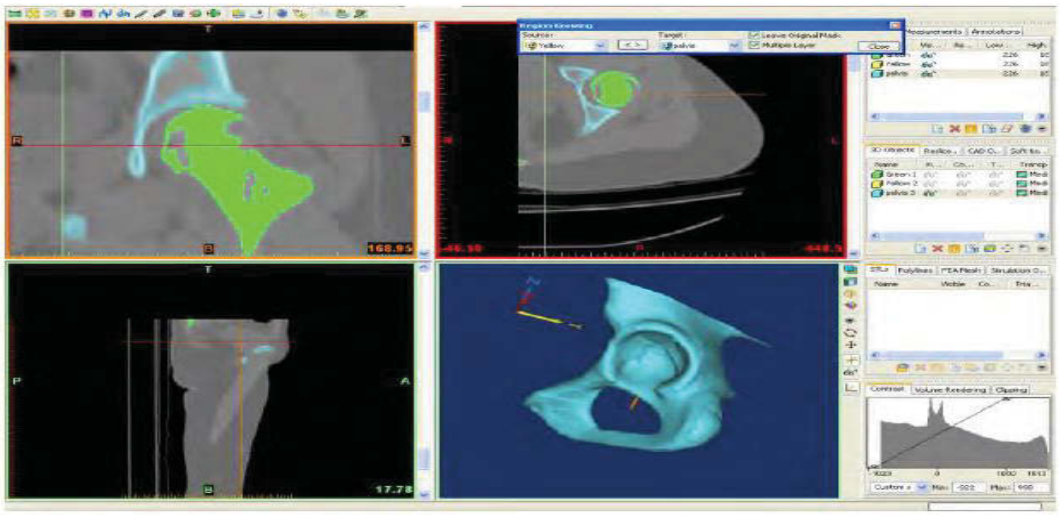


Figure4.6 Pelvic bone separated.

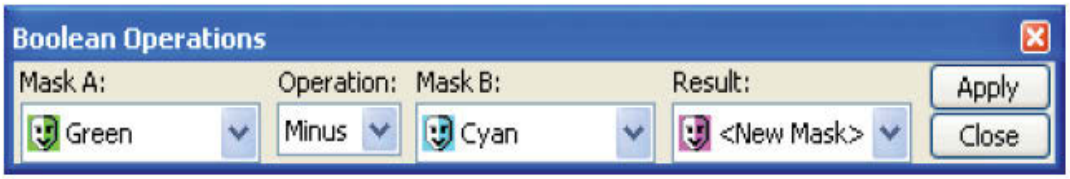


Figure 4.7 Boolean subtractions.

The pelvis has to be separated from the femur this can be achieved by subtracting the cyan from the green mask.

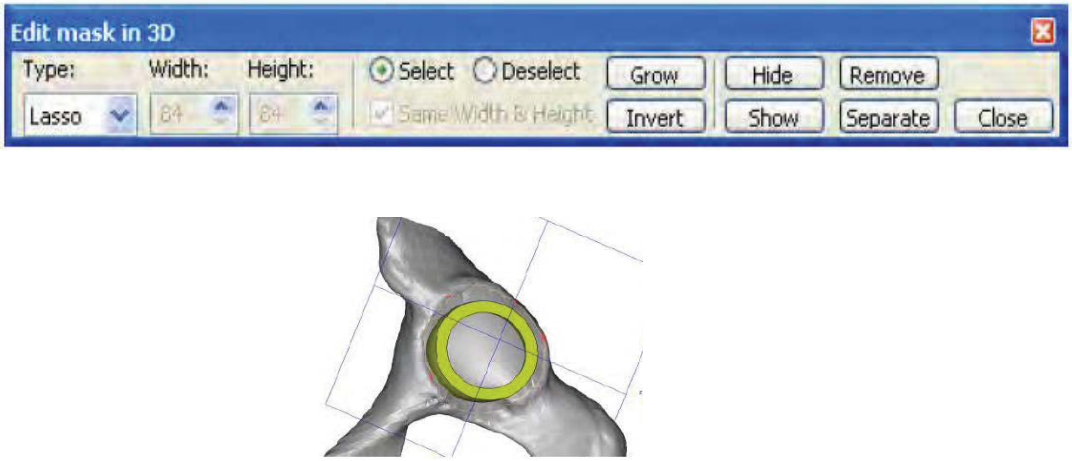


Figure 4.8 (a), (b) Mask editing.

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.

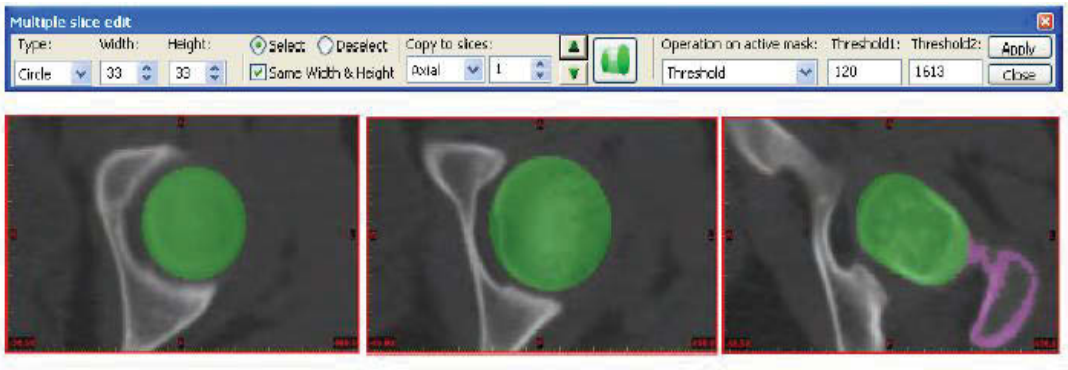


Figure 4.9 (a), (b) Slicing.

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".

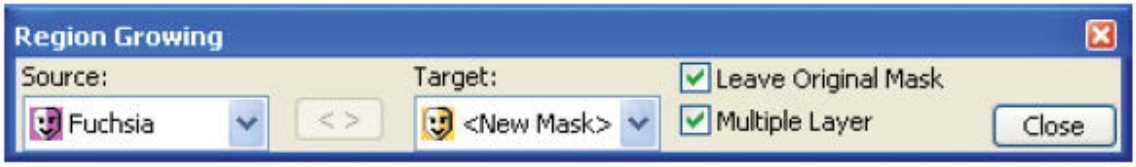


Figure 4.10 Region growing.

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.

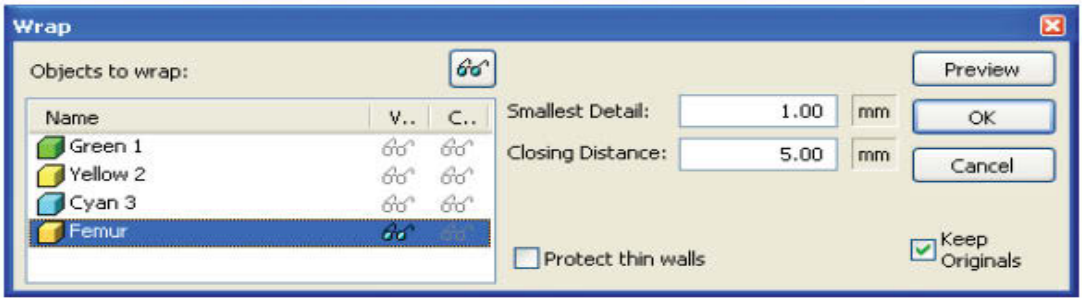


Figure 4.11 Wrapping operations.

There may still be some small holes visible. These holes can be removed using the "Wrap" function using the values above.

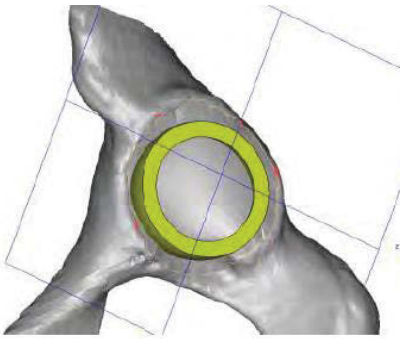


Figure 4.12 pelvis as separate identities.

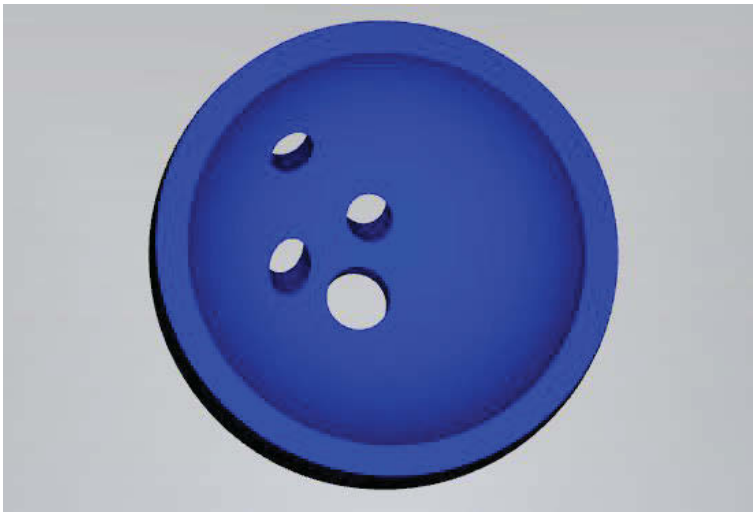


Fig. 4.13 Acetabula cup separated and saved in STL

4.9.1.2 Process and Material Selection

All applicable rapid protptyping processes have been discussed in the previou chapter. Based on the resources at the disposal of the resercher, the most convienient process for this study is FDM method and Powder Jet Binder Bed 3D printing Method using makerbot Replicator2 and Z Corp 3D printers respectively.

Figure 4.14 Replicator 2 Makerbot

4.5 Conversion of STL File to CAM File

4.5.1 Makerware process

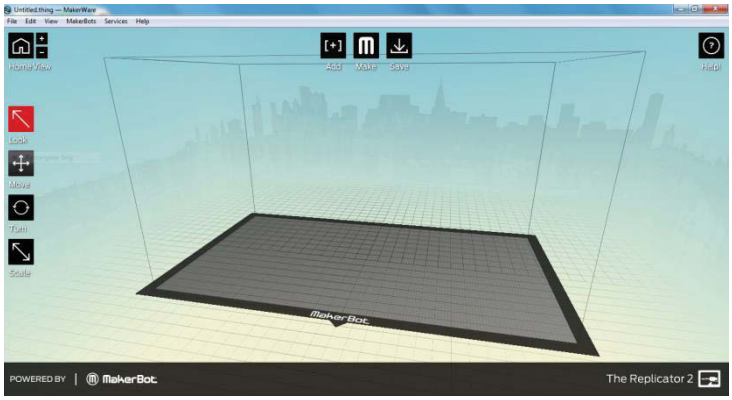


Figure 4.15 makerware software

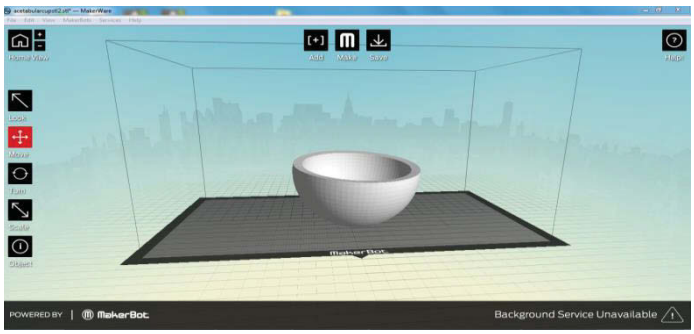


Figure 4.16 STL acetabula cup imported into makerware software

4.5.1.1 Orientation

Once the part has been deemed an appropriate build size, the part should be oriented in an optimum position for building. The shape of the part plays a major role in this, in that some orientations may require less supporting of overhangs than others.The skull must be properly oriented to avoid support materials as much as possible, since support materials reduces the surface quality of the part being built. The arrows X, Y , Z is used for that purpose.

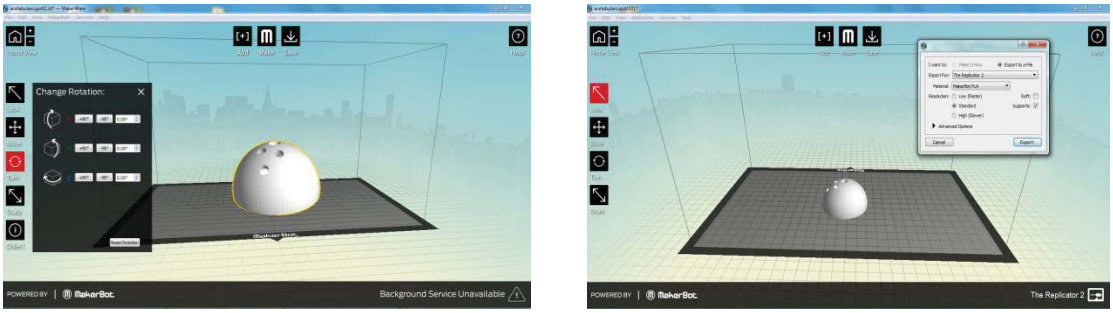


Figure 4.17 acetabula cup placed on the platform of the makerware software. Proper orientation is needed to avoid too much support materials.

4.5.1.2 Slicing

Once the part has been properly oriented and /or scaled it must be sliced. Slicing is a software operation that creates thin, horizontal cross sections of the STL file that will later be used to create the control code for the machine. In catalyst the slice thickness can be changed before slicing, the typical slices range from .005 inches to .015 inches. Thinner slices can be used for higher definition models.

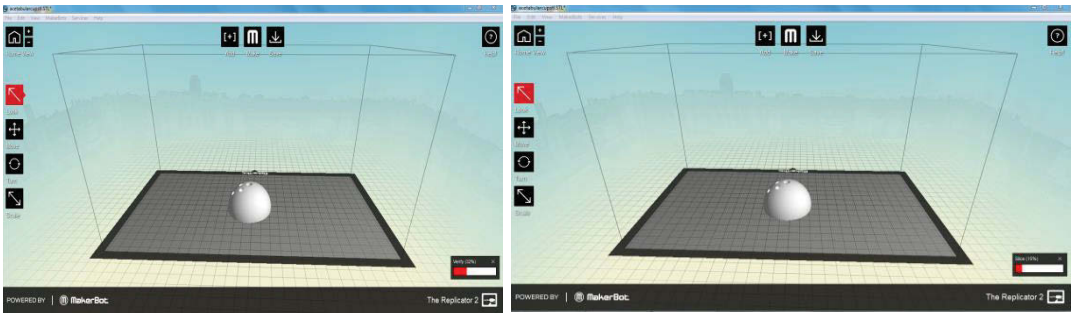


Figure 4.18 (a)Makerware slicing the femur bone (b) Acetabula cup going through varifcation process.

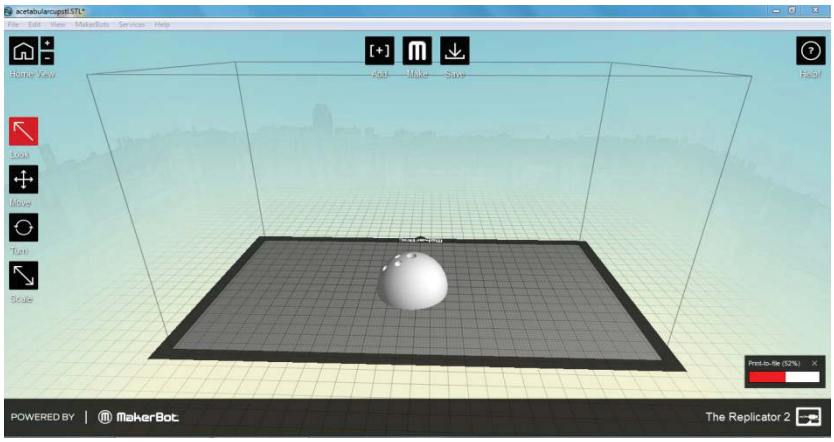


Figure 4.19 makerware creating the CAM file for printing on the makerbot Replicator2.

Built file saved on SD card which needs to be slotted into makerware replicator2

4.5.2 Z print process

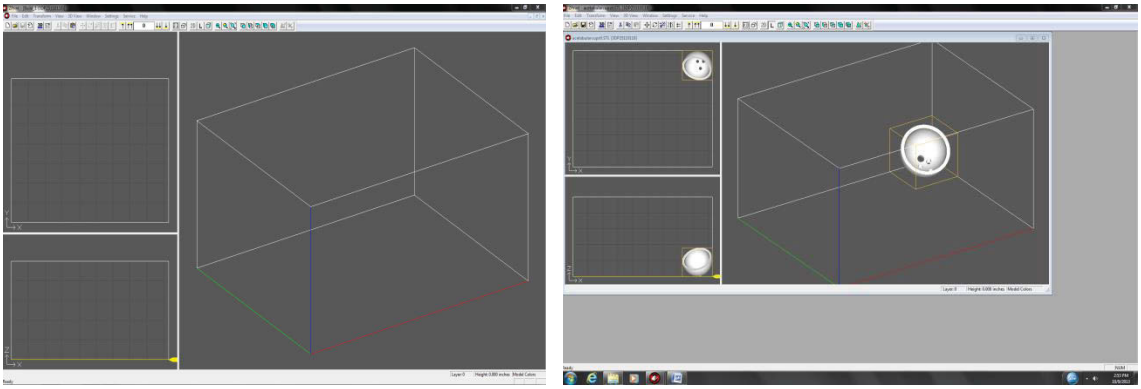


Fig.4.20 (a) Zprint software (b) acetabula cup imported onto Zprint

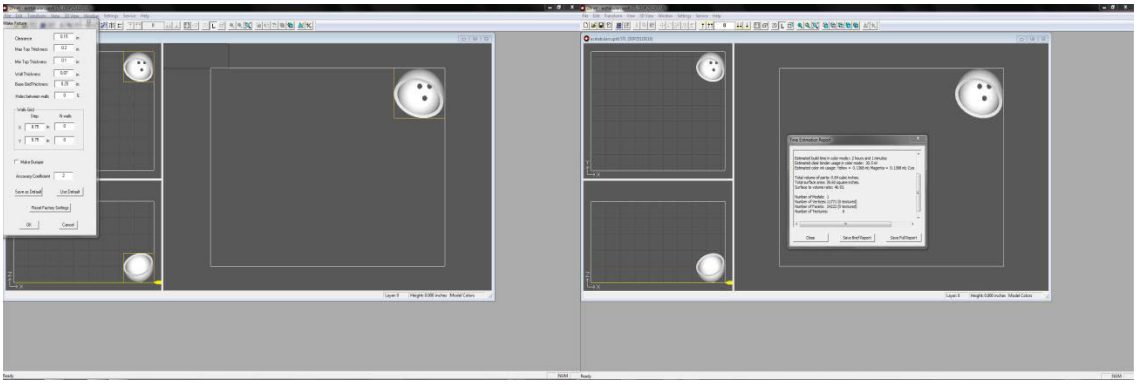


Fig 4.21(a) going through the process of creating support

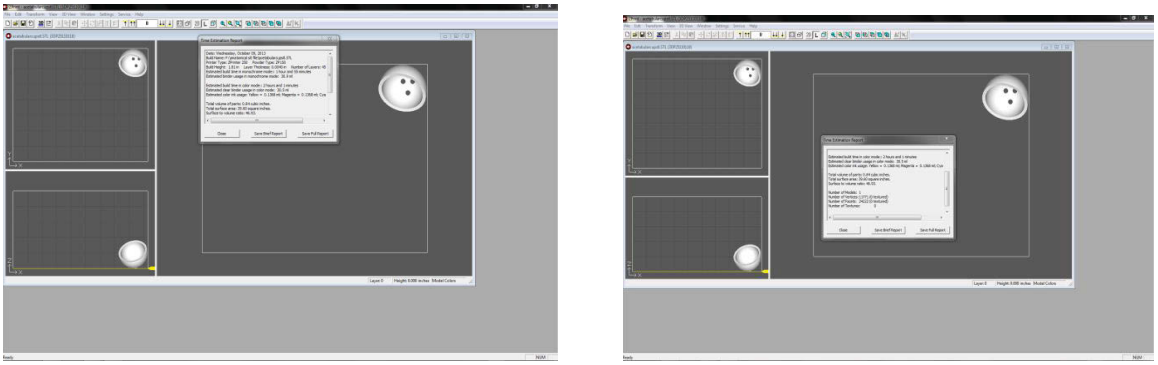


Fig.4.22 (a) and (b) showing production statistics.

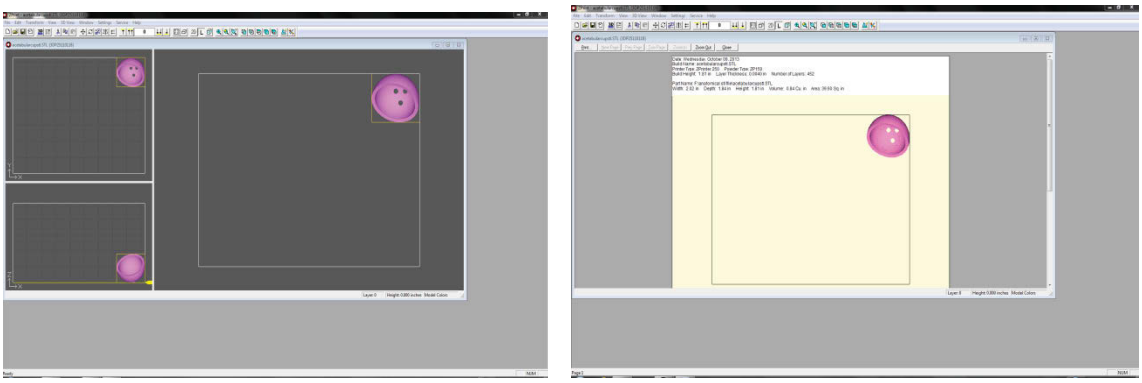
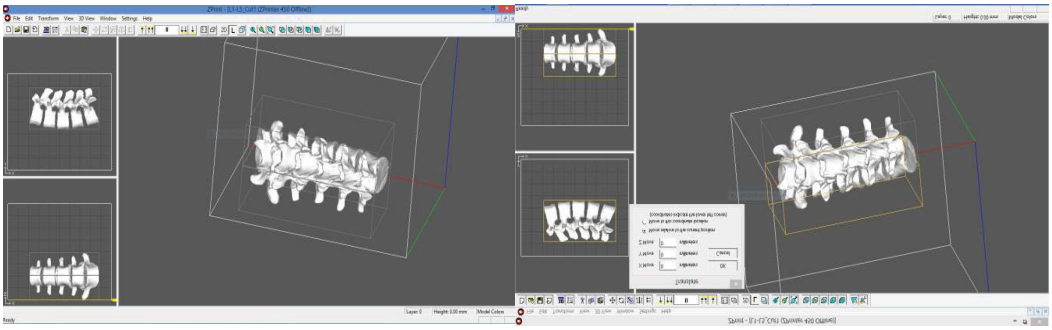


Fig. 4.23 (a) acetabula cup colored on Zprint (b) generated code ready to print

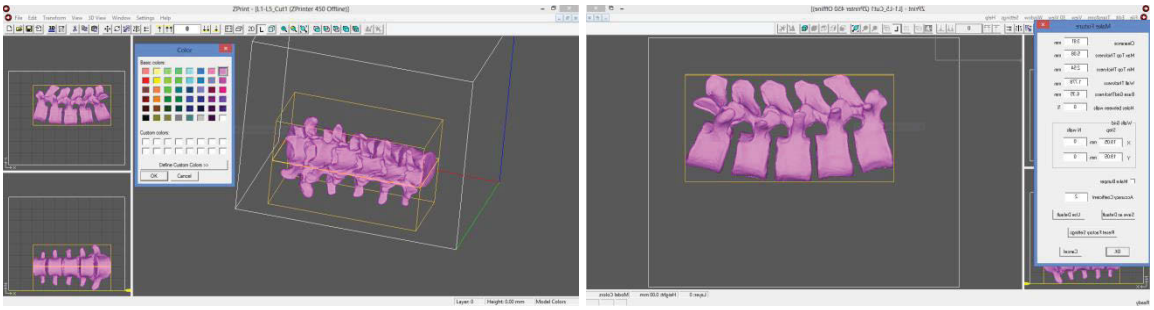
4.5.3 Vertebral bone reproduction

The process of obtaining the STL for the acetabula cup and the vertebral bone is the same.



(a) (b)

Fig.4.24 (a) Vertebral bone imported onto Zprint software (b) vertebral bone undergoing orientation.



(a) (b)

Fig.4.25 (a)Color changes , (b) generation of support structure for the part.

The ZCorp printer has the color printing capabilities so parts can be built using the best color it requires.

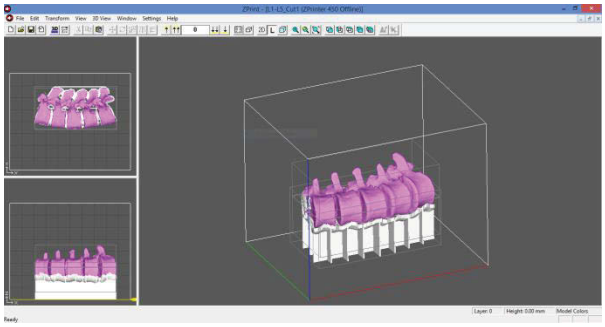


Fig4.26 Support structures generated

The part showing in a white color is the suppor structure for the verteral bone .

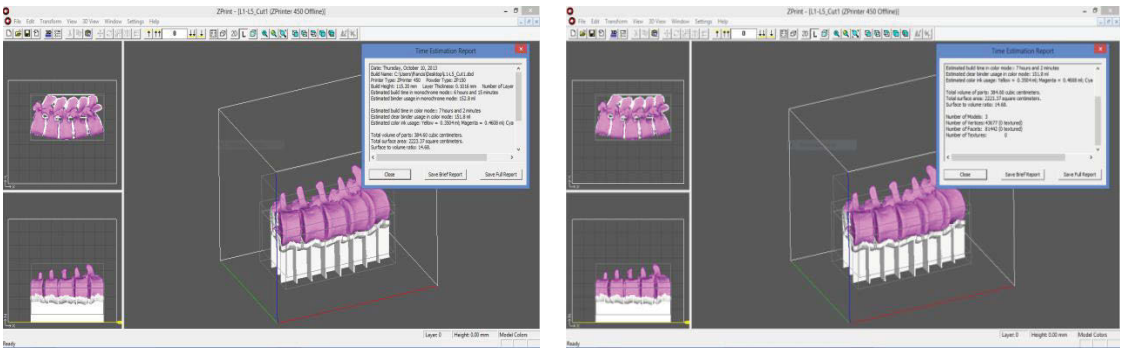


Fig.4.27 Statistics of Z Corp print of Vertebral bone

ZC printer show the estimated time of build, and cost of the part built after the G code is generated.

4.5.4 Z-Corp 3D Printing

Z-corp 3D printing uses the same principles as SLS but the only difference is laser used in SLS to sinter the material together is replaced by a printer head which dispenses a solution to bind the powder together. The Z-corp system has the following parts: feed piston, build piston and spread apparatus and print head gantry. The feed head measures and dispenses powder that is spread across the build piston by means of spreading apparatus. Once the initial layer is spread, the lowest cross section of the part is printed by praying the binder on the powder substrate by means of inkjet print head on the print gantry head. After the initial part is printed the feed piston raises on layer thickness and the build piston lowers one layer thickness and the spreader spreads the next layer over the existing cross section. The print head is then used to print the next layer. This process continuous until the part is completely built. When the part is completed and allowed to dry, the part is removed and the powder is then blown off the part. Like SLS, no support material is needed; excess powder is used as support structure during the build process. Once the part is de-powdered, the part can be finished using infiltrates, varying from wax, cyanoacrylate and epoxy material to increase strength and achieve a desirable finish.

Fig.4.28 Lab setup for the ZCorp Printing machine at Chaney.

4.5.5 Materials

The material used for the building of the acetabula cup and vertebral bone on the ZCorp printer is High performance ZP® Composite .It consists of plaster, vinyl polymer and carbohydrates which are biocompatible. High performance ZP® Composite is strong, high definition, best resolution, whitest whites, excellent color accuracy and also low cost material. Part build with High performance ZP® Composite material can be sanded, drilled, tapped, painted and electroplated. The binding material is Z-B bond 63 which is made up humectant and water and the post process material is Z-Bond 90 which is basically cyanoacrylate.

Time

PART	MACHINE	PRINTING TIME
Acetabula Cup	MakerBot Replicator 2 (FDM)	1 Hour
Acetabula Cup	Z Corp (Powder Jet Binder Bed)	2hr 1mins.
Vertebra bone	MakerBot Replicator 2 (FDM)	5hrs 15mins.
Vertebra bone	Z Corp (Powder Jet Binder Bed)	7hrs 2mins

Fig.4.30 Printing Time

4.5.6 Surface Quality measurement

Surface profilometer was used to determine the surface roughness of the part produced from both processes. The surface roughness was described by using arithmetic mean (Ra) and root mean square (Rq) value and these values were compared with the surface roughness of the actual bone and the FDA requirements on implants.

The implants produced were compared with the actual STL file and tolerances were determined on each of the implants manufactured.

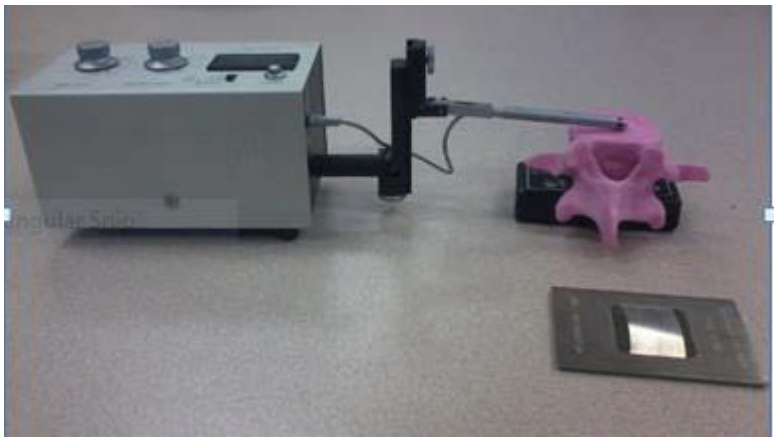


Fig.4.31Vertebra bone surface roughness measurement using the surface profilometer

Surface Quality (x-y)

Part	**Machine**	**Surface Quality(x-y)**		**Tolerance**
		R_a	**R_q**	
Acetabula Cup	MakerBot Replicator 2 (FDM)	1.69µm	1.86 µm	± 75
Acetabula Cup	Z Corp (Powder Jet Binder Bed)	0.47µm	0.32 µm	± 0.34
Vertebra bone	MakerBot Replicator 2 (FDM)	1.69µm	1.86 µm	± 0.75
Vertebra bone	Z Corp (Powder Jet Binder Bed)	0.47µm	0.32 µm	± 0.34

Fig.4.32 Surface Quality (x-y)

Surface Quality z-direction

Part	Machine	Surface Quality(z)		Tolerance
		R_a	R_q	
Acetabula Cup	MakerBot Replicator 2 (FDM)	1.71µm	1.89 µm	± 75
Acetabula Cup	Z Corp (Powder Jet Binder Bed)	0.49µm	0.35 µm	± 0.34
Vertebra bone	MakerBot Replicator 2 (FDM)	1.71µm	1.89 µm	± 0.75
Vertebra bone	Z Corp (Powder Jet Binder Bed)	0.49µm	0.35 µm	± 0.34

Fig.4.33 Surface Quality (z) direction

Surface quality measured in x-y direction to the built plane demonstrated that both processes differed in surface roughness as shown in fig.4.32. The Z Corp printed parts surface showed recorded average surface roughness (R_a =0.47 µm) and (Rq=0.32) which was significantly lower than the MakerBot printed surfaces (Ra=1.69) and (Rq=0.75). Measurement taken in z direction showed a significant increase in surface roughness as shown in fig.4.33. The difference between the surfaces of implants produced from the FDM and the powder bed jet printer is due to the fact that, the composite material used on the ZCorp printer used the same powder as a support material which does not stick to the actual part that is been built. With reference to the FDM 3Dprinting the support material sticks to the actual part and removing the increases the surface roughness. Another reason for these differences could be due to the thickness of the layers that is extruded. The thicker the material extruded from the nozzle of the 3D printer the greater will be the surface roughness produced. All these measurement were taken in the length of 15mm.

Weight

The weights of the bones printed were measured and the values were recorded in the table below.

Weight

Part	**Machine**	**Weight**
Acetabula Cup	MakerBot Replicator 2(FDM)	14.8g
Acetabula Cup	Z Corp (Powder Jet Binder Bed)	24.5g
Vertebra bone	MakerBot Replicator 2(FDM)	22.7g
Vertebra bone	Z Corp(Powder Jet Binder Bed)	70.6g

Fig.4.35 weight

Comparing the weights, the weights of the bones printed on using the Powder jet Binder bed is significantly higher than the bones printed on the using the FDM printer.

Chapter five

5.1 Discussion of findings

On completion of this research it became apparent that the combination of RE and RP technologies has an immense contribution in the medical field. Increased used of the technology (AMT) in production of customizes implant is possible through the use of and software such as Materialize, Mimics and 3-matic, MakerWare, Zprint. The RE and RP technologies applied in implant manufacturing industries positively affect organizational performance as cost , time , and labor are reduced .Cost is reduced because only one person can go through all the processes since machines and equipment involved in these operations are computer numerically controlled (CNC). The total time used in the 3d printing (MakerBot Replicator2) was 1hour to get the acetabula cup produced. It took the ZCorp printer approximately 1hr 55min to complete the acetabula cup production. In terms quality the bones produced on MakerBot Replicator2 is much lighter in weight than that produced on the ZCorp printer; this may be due the fact that PLA is less dense than the composite polymer. Although it took much longer time to complete the printing on the ZCorp printer the surface quality of the parts produced was much better than those produced on the MakerBot Replicator 2. The implant produced on the ZCorp printer is resistant to corrosion, degradation, and wear. Therefore, they will retain their strength and shape for a long time. Resistance to wear is particularly significant in maintaining proper joint function and preventing the further destruction of bone caused by particulate debris generated as the implant parts move against each other. They can very durable for implants used where there is more movement, like the ball and socket joints.

In general they both have mechanical properties that duplicate the structures they may be intended to replace. For example, they are strong enough to withstand weight-bearing loads, flexible enough to bear stress without breaking, and able to move smoothly against each other as required. These technologies have numerous advantages to offer the medical professionals and patients with regard to preoperative planning models and customized medical implants and avoidance of pains that can be endured by patients after surgery due debris falling from the implants. This research shows step by step

procedure of how CT/MRI scans can be converted into 3D module and STL file that can be printed using FDM method. This can serve as an inroad to the implant manufacturing industries to optimize their system to reduce their process lead time from day to hours which in the long ran could assist them to introduce product to the market.

5.2 Conclusions.

i. The processes and the methodology demonstrated depict that with further development and regulatory approvals could print customized implants.

ii. Rapid Prototyping and Reverse Engineering technologies can be applied in the medical field to enhance activities such as surgery, diagnostics, teaching and learning.

iii. Combination of rapid prototyping and reverse engineering reduce lead time, cost and improved the quality of implants to the advantage of implants manufacturing industries

iv. Implant (Acetabula Cup) produced using Z Corp 3D printer with the composite material satisfies most of the current FDA requirement on implant production.

v. The research makes it clear that CT/MRI scanning is basically a reverse engineering process since anatomical images are generated from physical organs, systems, tissues and bones.

vi. The time taken to build the implants on the FDM 3D printer (makerBot) is less than the time taken to build the same implants on the Powder Jet Binder Bed printer (Z Corp printer).

vii. The surface quality of implants produced on the powder jet binder bed printer (Z Corp) is much better than those produced on the FDM (makerBot.)

5.3 Recommendations

With reference to the weight of the implant CT/MRI machine designers should improve incorporate into their system the ability of their machine to estimate the weight or density of the anatomical image they scan. 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.

Although there is a similar method of designing an acetabula 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. 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, and acetabula cup design. The capability of the software appeared very proficient and highlighted the degree of flexibility it offers users.

The 3D printers should be design to include the ability to set the actual density of the part to produce. This will make it easier to print different types of bones with different densities.

It is recommended that that material with the right mechanical properties such as stiffness, tensile strength and right geometrical accuracy must be used in subsequent research.

5.4 Further work

This research is an exploratory framework which geared in the direction of better understanding the application of reverse engineering and Rapid prototyping technologies in industrial and medical field. The results acquired from this study suggested the capabilities of the application of reverse engineering and rapid prototyping technologies

in terms of production of customized implants and the effects of these technologies in the organizational performance.

Future research should broaden this examination to include new materials that are biocompatible, other RP technologies, redefine measurement procedure and address related research questions. With reference to new materials, future researchers should include research into new material that meet the current recommendation of FDA and can be used on existing and emerging 3D machines.

Future research should include subtractive manufacturing technology using the CNC machines. Limitation of time and resources did not permit these areas to be included in this study. As a framework research, the relationships between variables have not been fully determined. Researcher interested in this area of research should extend their research to cover the relationship between individual RP technologies to ascertain if combination of some of these technologies better increase organizational performance in the implant production industries.

Suggested future questions for researchers should be that; will the improvement in CT/ MRI scanning machines to include the weight of the specific bone, organ, tissue, scanned by these equipment increase the accuracy and durability of the implants that will be produced. This is because some of the software that are used to operate some of these printers has a feature whereby the weight and density of the part to build can be controlled.

Further research should delve into materials that can be used for delicate organs like the kidney, liver etc. so that customized implant can be produced for patients that need it without waiting for someone to die or donate these organs.

References

1. Laoui, T. & Shaik, S.K. (2003). Rapid prototyping techniques used to produce medical models/implants, *Proceedings of the 4th national conference on rapid and virtual prototyping and applications*, pp. 23-32, ISBN 1-86058-411-X, Centre for rapid design and manufacture, Buckinghamshire Chilterns University College, UK, June 20, 2003

2. Rengier et al. (2008).Beyond the eye – Medical applications of 3D rapid prototyping objects. *European medical imaging review,* Vol.1, (December 2008), pp. 76-80, ISSN 1759-7722

3. Winder, J. & Bibb, R. (2005). Medical rapid prototyping technologies: state of the art and current limitations for application in oral and maxillofacial surgery. *Journal of oral and maxillofacial surgery,* Vol.63, No.7, (July 2009), pp. 1006-1015, ISSN0278-2391

4. Berry et al., (1997). Preliminary experience with medical applications of rapid prototyping by selective laser sintering. *Medical engineering & physics,* Vol.19, No.1, (January1997), pp. 90-96, ISSN 1350-4533

5. Destefani, J. (2005). Additive or subtractive? What rapid prototyping process is right for your job? *Manufacturing engineering,* Vol.134, No.4, (April 2005), pp. 2-5, ISSN 0361-0853

6. Joffe et al., (1999). A prospective study of computer-aided design and manufacture of titanium plate for cranioplasty and its clinical outcome. *British journal of neurosurgery,* Vol.13, No.6, (December 1999), pp. 576-580, ISSN 0268-8697

7. Chang, K. H., ADCS Program Final Report, CASI Summer Research Program 2003, OC-ALC, October 30, 2003.

8. Kim et al. (2008). Rapid prototyping: a new tool in understanding and treating structural heart disease. *Circulation,* Vol.117, No.18, (May 2008), pp. 2388-2394, ISSN 0009-7322

9. Mishek, D. (2009). How and when to choose between additive and subtractive prototyping, In: *Mold making technology,* Available from http://www.vistatek.com/pdfs/Choosing-Between-Additive-and-Subtractive-

Prototyping-manufacturing.pdf

10. Budzik, G., Kozik, B., Pacana, J., Żmuda, B. (2010). Modeling and Prototyping of Aeronautical Planetary Gear Demonstrator, Journal of KONES Powertrain and Transport, Vol. 17, No. 3/2010, pp. 49-54.

11. Lim, J. & Zein, R. (2006). The Digital Imaging and Communications in Medicine (DICOM): description, structure and applications, In: Rapid prototyping: theory and practice, A.K. Kamrani & E.A. Nasr, (Ed.), 63-86, Springer, ISBN-10 0-387-23290-7, New York, NY, USA

12. Liu, Q.; Leu, M.C. & Schmitt, S.M. (2006). Rapid prototyping in dentistry: technology and application. The international journal of advanced manufacturing technology, Vol.29, No.3-4, (June 2006), pp. 317-335, ISSN 0268-3768

13. Hornak, J.P. (1996). The basics of MRI, Available from http://www.cis.rit.edu/htbooks/mri, Rochester, NY, USA

14. Ching, L.S.; Kai, C.C. & Meng, C.S. (1998). A novel technique for fabricating facial prosthetic model, Proceedings of the 20th annual International Conference of the IEEE Engineering in Medicine and Biology Society, pp. 2746-2749, ISBN 0-7803-5164-9, Hong Kong SAR, China, October 29-November 1, 1998

15. Werner, H.; Fontes, R.C.; Campbell, S. & Santos, J.R.L. (2010). Rapid prototyping models of foetuses built from ultrasound 3D and magnetic resonance files, Innovative developments in design and manufacturing: advanced research in virtual and rapid prototyping – Proceedings of VR@P4, pp. 89-94, ISBN 978-0-415-87307-9, Leiria, Portugal, October 2009

16. Robiony, M.; Salvo, I.; Costa, F.; Zerman, N.; Bandera, C.; Filippi, S.; Felice, M. & Politi, M. (2008). Accuracy of virtual reality and stereo lithographic models in maxillo-facial surgical planning. The journal of craniofacial surgery, Vol.19, No.2, (March 2008), pp. 482-489, ISSN 1049-2275

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

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

19. Wohler, 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. Redeye Express (2005) Stereolithography Apparatus [WWW] Available from: http://www.xpress3d.com/SLA.aspx [Accessed 8/17/2013].

24. Stereolithography Apparatus Process Diagram (2005) [Online Image]Available from: http://www.xpress3d.com/SLA.aspx [Accessed 8/25/2009].

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

26. Selective Laser Sintering Process Diagram (2005). [Online image].Available from: http://www.xpress3d.com/SLS.aspx [Accessed 06/12/2013].

27. 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

28. Fused Deposition Model Process Diagram (2008). [Online image] Available from: http://www.xpress3d.com/FDM.aspx [Accessed 7/15/2013].

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

30. 3 Dimensional Printing Process Diagram [2007]. [Online image] Available from: http://home.att.net/~castleisland/3dp.htm [Accessed 8/01/2013].

31. Objects polyjet RP machine [2009]. [Online image] Available from: http://medicaldesign.com/mag/prototyping1009-fig02.jpg [Accessed 8/01/2013].

32. Radtech Europe (2010) Inkjet 3D Printing of Photopolymer Materials [WWW] Available from:

33. Maxillofacial 3d Printed model (2008). [Online image] Available from: http://www.3dventures.com/wp-content/uploads/2009/

35. Rapid Manufacturing Technologies (2010) Direct Metals Manufacturing Technology Available from: http://www.mtt-group.com/selective-laser- melting.html [Accessed 06/02/2013].

36. Schematic of SLM process SLM process (2010) [Online Image] Available from: http://www.twi.co.uk/content/laser_slm.html [Accessed 08/02/2013].

37. Technion, Israel Institute of Technology, Types of Bone Tissue [WWW] Available from: http://www.technion.ac.il/~mdcourse/274203/lect5.html [Accessed 8/05/2013].

38. S.F Khan, K.W. Dalgarno, Design of Customized Medical Implants by Layered Manufacturing, (2007). [WWW] Available from:http://scholar.google.com/scholar?hl=en&q=Design+of+Customized+Medical+Implants+by+Layered+Manufacturing.S.F+kHAN+and+K.W+Dalgarno&btnG=Search&as_sdt=2000&as_ylo=&as_vis=1 [Accessed 05/03/2013].

39. 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 08/03/2013].

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

41. Williams, 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&_orig=search&_sort=d&_docanchor=&view=c&_searchStrId=1435640341&_rerunOrigin=scholar.google&_acct=C000056897&_version=1&_urlVersion=0&_userid=2322584&md5=bf4d3247fc7cdf3cb338a5ab66544fc4 [Accessed 9/03/2013]

42 Arcam, ASTMF75 Co Cr Alloy.[WWW] Available from: http://www.arcam.com/CommonResources/Files/www.arcam.com/Documents/EBM%20Materials/Arcam-ASTM-F75-Cobalt-Chrome.pdf [Accessed 10/03/2013].

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

44. Morgan Technical Ceramics, Advanced ceramics for medical implants [WWW] Availablefrom:http://www.azom.com/details.asp?ArticleID=4265#_Advanced_Ceramics_for [Accessed 10/10/2013].

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

46. 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

47. Frame, John. W., 1987 Hydroxyapatite as a biomaterial for alveolar ridge construction, [WWW], Available from:http://www.sciencedirect.com/science?_ob=ArticleURL&_udi=B7GHW4WSRF561&_user=2322584&_coverDate=07%2F31%2F2010&_rdoc=1&_fmt=high&_orig=search&_sort=d&_docanchor=&view=c&_searchStrId=1338015772&_rerunOrigin=google&_acct=C000056897&_version=1&_urlVersion=0&_userid=2322584&md5=0cd7e7a8c7788f3df8e10d51ad4427f3#secx2` [Accessed 10/03/2013]

47. 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 10/04 2013]

48. Biomaterial stress/strain comparison graph, [Online image] Available from: http://www.tms.org/pubs/journals/JOM/0909/fig1.jpg [Accessed10/5/2013]

49. Quadrant Engineering, Technical data sheet [WWW] Available from: http://www.alperton.com/alperton/Files/PDS_CESTITECH_7000_EN.pdf [Accessed 04/04/2013]

50. Hip implant (2009). [Online image]. Available from; http://www.tms.org/pubs/journals/JOM/0909/fig7.jpg [Accessed 05/04/2013]

55. 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 09/04/2013]

56. Ratner, D. Buddy. et al. (2004), Biomaterials Science 2nd Edition, San Diego, Elsevier Inc., pp. 819-823

57. Ratner, D. Buddy. et al. (2004), Biomaterials Science 2nd Edition, San Diego, Elsevier Inc., pp. 819-823.

Appendix List of Terms

i. Additive Manufacturing : (AM)

ii. Computer Aided Design : (CAD)

iii. Computer Numerically Controlled : (CNC)

iv. Computerized Tomography : (CT)

ix. Design for Manufacture and Assembly : (DFMA)

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

vi. Direct Metal Laser Sintering : (DMLS

vii. Fused Deposition Model : (FDM)

viii. Hydroxyapatite : (HA)

x. International Graphics Exchange System : (IGES)

xi. Laminated Object Manufacture : (LOM)

xii Magnetic Resonance Imaging : (MRI)

xiii. Polymethylmethacrlate : (PMMA)

xiv. Rapid Prototyping : (RP)

xix. Rapid Tooling : (RT)

xv. Reverse Engineering : (RE)

xvi. Selective Laser Sintering : (SLS)

xvii. Standard Triangle Language : (STL)

xviii. Stereo lithography Apparatus (SLA)