Customizing Prosthetic Leg Socket by using Rapid Prototype with Reverse Engineering

by

Leong Song Seng

Dissertation submitted in partial fulfilment of
the requirements for the
Bachelor of Engineering (Hons)
(Mechanical Engineering)

December 2008

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CERTIFICATION OF ORIGINALITY

This is to certify that I am responsible for the work submitted in this project, that the original work is my own except as specified in the references and acknowledgements, and that the original work contained herein have not been undertaken or done by unspecified sources or persons.

LEONG SONG SENG

CERTIFICATION OF APPROVAL

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Approved by,

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ABSTRACT

The demand of using prosthetic leg keeps on increasing due to unpredictable of certain diseases or physical trauma such as accident and war. Prosthetic devices can help, but making a prosthetic leg can be a long and difficult process. Standard made prosthetic leg come ready-made in various standard sizes, though they are often not as realistic as their custom-made counterparts. Custom-made prosthetic legs are generally more expensive which costing thousands of US dollars, depending on the level of detail. This case study describes implementation of rapid prototyping and reverse engineering technology on customizing the prosthetic leg socket. A negative mold was obtained from the amputee stump with plaster of paris. The positive mold is generated from negative mold and taken to the 3D Renishaw Digitizer machine for reverse engineering. 3D Renishaw Digitizer machine will produce 3D point cloud data from the scanning result. Unigraphics is used to fix, repair and customize the 3D point cloud data into 3D solid modeling and convert into STL file format before send to the Rapid Prototype machine to produce the rapid prototype part. Final rapid prototype part is in wax form, therefore Rapid tooling is needed in order to make the socket of the prosthetic leg more realistic by using the thermoplastic or engineering plastic material. For this FYP project, due to the cost budget of a FYP student is limited the real size of the prosthetic leg socket for this project has been scale down into 80mmX50mmX45mm in order to show the rapid tooling process. The different between the final part of the prosthetic leg of the rapid tooling with the rapid prototype is plastic material which can sustain high strength compare with wax. Therefore, a scale down of this project is essential to save material cost of the rapid tooling process.

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TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

APPENDIX

CHAPTER 1
INTRODUCTION

1.1 Background of the project

Artificial leg or prosthetic leg intended to restore a degree of normal function to amputees. Mechanical devices that allow amputees to walk again have probably been in use since ancient times, but the process of making prosthetic leg can be long and difficult process. Twentieth century, with advance manufacturing technology such as Rapid Prototype machine, 3D Digitizer machine and CAD/CAM software exist able to advance the ordinary prosthetic leg making process. This project is mainly focus on customizing the prosthetic leg socket by using Rapid Prototype with reverse engineering method.

1.2 Problem Statement

World statistics report that 200 to 500 amputations per 1 million of population are performed each year [1].This happen due to some unpredictable of certain diseases or physical trauma such as accident and war. This impact the market demand of using prosthetic leg keeps on increasing and result the price of the prosthetic leg keep on increase which the price may reach thousands of US dollars. Moreover, making a prosthetic leg can be a long and difficult process. The most important part of the prosthetic leg is 'socket'. The socket of the prosthetic leg functioned as the medium to fit between the leg and the artificial stump, which helps reduce wear on the stump. Therefore, it is important for prosthetic leg manufacturer to be able to measure, design and manufacture the socket according to the shape of the amputees stump. As the shape, size and bone location of the stump of an amputated stump vary from one to another, the fabrication of a prosthetic leg socket has to be customized, which is currently a very time consuming and laborious process. Besides, the process of manufacturing prosthetic leg also need expertise to measure the stump of the amputee before the mold of the socket is molded out. If errors occur during measurement of the stump, the consequences will make the prosthetic leg socket unable to fit according to the patient residual stump or stump thus result the patient feels uncomfortable and difficult to use due to easily rubbing between the stump and socket. This can be painful and cause breakdown of tissue.

Typical manufactured prosthetic leg using the following steps:

1. Measurement of the stump
2. Measurement of the body to determine the size required for the artificial stump
3. Creation of a model of the stump
4. Formation of thermoplastic sheet around the model of the stump – This is then used to test the fit of the prosthetic
5. Formation of permanent socket
6. Formation of plastic parts of the artificial stump – Different methods are used, including vacuum forming and injection molding
7. Creation of metal parts of the artificial stump using die casting
8. Assembly of entire stump

The typical manufactured prosthetic leg process required long process cycle time, high cost for tooling such as injection molding, vacuum forming and die casting. Beside that, it also required expertise in pattern maker for die casting and injection molding.

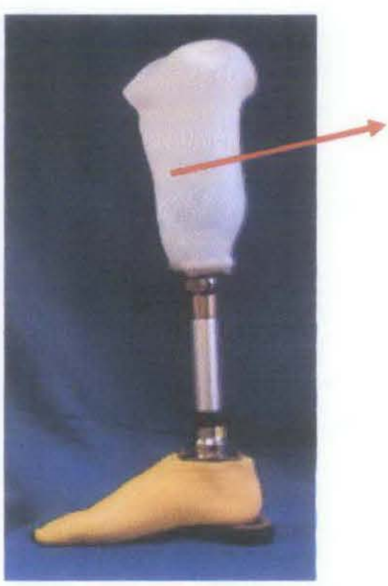


Figure 1: Overview of the Prosthetic Leg

Figure 2: Overview of the Prosthetic Leg

1.3 Objectives

- To digitize the mold of the amputee stump by using 3D scanning digitizer such as **Renishaw Cyclone Digitizer** (available in UTP lab).
- Fix, repair and customize the socket of the prosthetic leg by using high end CAD/CAM/CAE/PLM software such as **Unigraphics** (currently using NX5 version).
- To fabricate the socket of the prosthetic leg by using rapid prototyping machine such as **Thermojet 88 3D printer** (available in UTP lab)
- Rapid tooling of the prosthetic leg socket.
- Fitting-test of conceptual mechanism of the socket prosthetic leg by amputee.

1.4 Scope of the Project

- **Digitize the mold of the amputee stump by Renishaw Cylone Digitizer with reverse engineering.**

  This process is to scan and digitize the actual mold of the amputee stump and generated the initial geometry data into 3D point cloud data. The purpose of the process is to transfer shape, dimension of the mold into the 3D point cloud data which the 3D point cloud data able to be read and convert the file format for use in Unigraphics and rapid prototype machine. This process is a method of Reverse Engineering process.

- **Fix, repair and customize the socket of the prosthetic leg by using Unigraphics NX5**

  It is to improve the functional and practical for the socket of the prosthetic leg. By using the high end CAD/CAM/CAE/PLM software with reverse engineering method, the 3D point cloud data able to be fix, repair and customize according to the patient needs. This will make the process of customizing socket able to create in a fast and precise which able to fit the amputees' leg very well. Besides, it is use to generate 3D solid model from the 3D point cloud data.

- **Fabricate the socket of the prosthetic leg by using 3D Thermojet Printer**

  The socket of the prosthetic leg will be fabricated by using rapid prototype machine 3D Thermojet 88, which available in UTP with the combination of reverse engineering processes. The rapid prototype machine able to fabricate the socket of the prosthetic leg fast compare with the typical manufacturing process.

- **Rapid Tooling of the prosthetic leg socket**

  The prosthetic leg socket will be rapid tooling in order to produce the strong plastic part which will be use to test by the amputee.

- **Test the conceptual mechanism of the prosthetic leg**

  The fabricated design of the prosthetic leg will be fitting-tested by the amputee for recommendation and feedback.

CHAPTER 2
LITERATURE REVIEW

The purpose of this chapter is to provide a better understanding about prosthetic leg making process, rapid prototyping, reverse engineering, CAD/CAM/CAE/PLM software process and application towards the development of the customizing prosthetic leg manufacturing process.

2.1 Prosthetic leg

The socket of the prosthetic leg act as an important feature and function due to the socket is the medium for amputees to fit between the leg and the artificial stump. It is very crucial to make sure the leg can fit with the socket of the prosthetic leg according to Prosthetist Dennis Clark, Walter Reed Army Medical Center, Washington. [2]. This problem can be solved by customizing the diameter and length of the socket according to the patient stump size. Thus, the socket plays a very important role in order to make sure the patient comfortable with the prosthetic leg.

2.11 Interview with the Prosthetic & Orthotics Centre

For this project, research, survey and interview have been done. The writer has visited Prosthetics & Orthotics Centre, hospitals, medical supplies company in Ipoh, Perak. Those company that have been visited are as below:

- Total Medical Supplies Prosthetic & Orthotics Centre in IPOH, Perak.
- Integrated Medical Supplies Sdn. Bhd, Ipoh, Perak.
- Hospital Pantai Putri Ipoh, Perak
- General Hospital Ipoh, Perak

The purpose of the visits is to understanding regarding the process of making the prosthetic leg and the criteria that need to consider in fabricating the prosthetic leg.

According to the prosthetic leg maker Mr. Allen Ho from Total Medical Supplies Prosthetic & Orthotics centre in Ipoh, the process of making a prosthetic leg is a complicated and difficult process. The Prosthetist need to determine the bone location of the stump and measure the size of the stump correctly in order to prevent the final prosthetic meet the requirement and satisfied the patient since the bone location is the main support for the socket of the prosthetic leg with the stump of the amputee. Beside that, when measure the size of the stump, the amputee should be advise in a relax position for sitting and standing position in order to measure the exact dimension of the stump.[3]

According Dr. Ravindran from general Hospital Ipoh from General Surgery Department, the weight of the Prosthetic leg also criteria to consider in designing the prosthetic leg. This is because the weight of the prosthetic leg will make the stump need high power to move or swing when walking with the prosthetic leg. On the other hand, the socket of the prosthetic leg should not too tight due to the size of the stump will grow much bigger size when the stump has fully recovered. It also advises the amputee should maintain their own diet in order to fit with the prosthetic leg. [4]

2.12 Interview with the Prosthetic leg user and maker

An interview have been carried out with Mr. Kumaran A/L Ganasan whom is an employee of the Total Medical Supplies in Ipoh have lost his right leg in an accident occur in June 2003. Currently Mr. Kumaran has worn the 'above knee' prosthetic leg for 5 years. According to Mr. Kumaran, the socket of the prosthetic leg is most important consideration in making the prosthetic leg. Thus the socket of the prosthetic leg is custom made others parts of the prosthetic leg such as feet, pylons are manufactured in a factory, sent to the prosthetist, and assembled at the prosthetist's facility in accordance with the patient's needs. Beside that in order to satisfy and comfort the amputee, the socket of the prosthetic leg should be make fit with the stump in order to be able to walk, sit, squat, knee and etc with the prosthetic leg. [5] Below show the pictures taken from Mr. Kumaran with his prosthetic leg.

Figure 3: Prosthetic leg user and maker, Mr. Kumaran A/L Ganasan with his equipped prosthetic leg in standing position.

Figure 4: Overview of Mr. Kumaran's prosthetic leg.

Typical process of making prosthetic leg according to Mr. Kumaran who work as an prosthetic leg maker in Total Medical Supplies Ipoh as below:

For Measuring and casting:

1) Accuracy and attention to detail are important in the manufacture of prosthetic stumps, because the goal is to have a stump that comes as close as possible to

being as comfortable and useful as a natural one. Before work on the fabrication of the stump is begun, the prosthetist evaluates the amputee and takes an impression or digital reading of the residual stump.

2) The prosthetist then measures the lengths of relevant body segments and determines the location of bones and tendons in the remaining part of the stump. Using the impression and the measurements, the prosthetist then makes a plaster cast of the stump. This is most commonly made of plaster of paris, because it dries fast and yields a detailed impression. From the plaster cast, a positive model, an exact duplicate of the stump is created.

For Making the socket:

3) Next, a sheet of clear thermoplastic is heated in a large oven and then vacuum-formed around the positive mold. In this process, the heated sheet is simply laid over the top of the mold in a vacuum chamber. If necessary, the sheet is heated again. Then, the air between the sheet and the mold is sucked out of the chamber, collapsing the sheet around the mold and forcing it into the exact shape of the mold. This thermoplastic sheet is now the test socket; it is transparent so that the prosthetist can check the fit.

4) Before the permanent socket is made, the prosthetist works with the patient to ensure that the test socket fits properly. In the case of a missing leg, the patient walks while wearing the test socket and the prosthetist studies the gait. The patient is also asked to explain how the fit feels; comfort comes first. The test socket is then adjusted according to patient input and retried. Because the material from which the test socket is made is thermoplastic, it can be reheated to make minor adjustments in shape. The patient can also be fitted with thicker socks for a more comfortable fit.

5) The permanent socket is then formed. Since it is usually made of polypropylene, it can be vacuum-formed over a mold in the same way as the test socket. It is common for the stump to shrink after surgery, stabilizing approximately a year later. Thus, the socket is usually replaced at that time, and thereafter when anatomical changes necessitate a change.

For fabrication of the prosthetic leg:

6) There are many ways to manufacture the parts of a prosthetic stump. Plastic pieces including soft-foam pieces used as liners or padding are made in the usual plastic forming methods. These include vacuum-forming, injecting molding which forcing molten plastic into a mold and letting it cool and extruding, in which the plastic is pulled through a shaped die. Pylons that are made of titanium or aluminum can be die-cast; in this process, liquid metal is forced into a steel die of the proper shape. The wooden pieces can be planed, sawed, and drilled. The various components are put together in a variety of ways, using bolts, adhesives, and laminating, to name a few.
7) The entire stump is assembled by the prosthetist's technician using such tools as a torque wrench and screwdriver to bolt the prosthetic leg together.

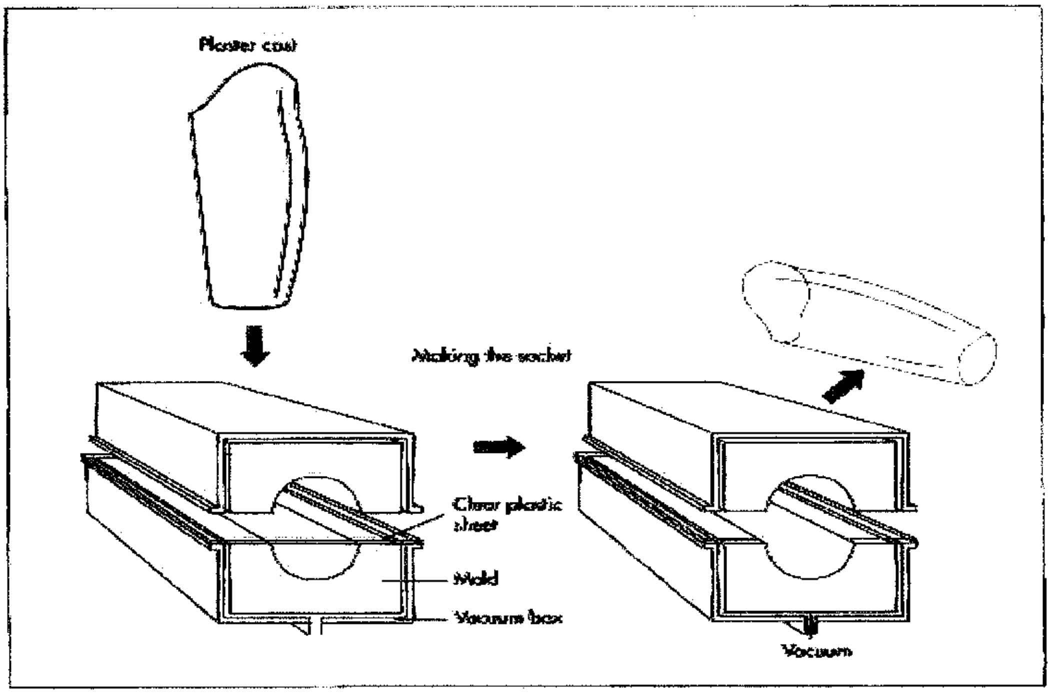


Figure 5: The Vacuum forming process for the prosthetic leg socket

8) A typical artificial stump, in this case an above-the-knee prosthesis. The foam cover is covered with artificial skin that is pointed to match the patient's natural skin color.

9) Prosthetic device together. After this, the prosthetist again fits the permanent socket to the patient, this time with the completed custom-made stump attached. Final adjustments are then made.

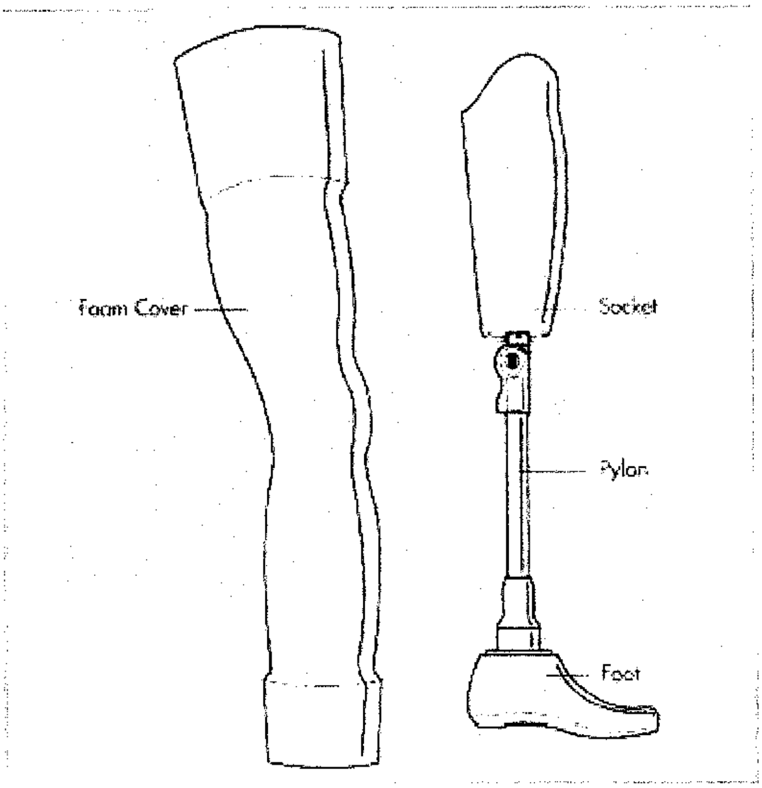


Figure 6: The above knee prosthetic leg ready cover with the foam cover.

2.13 Case Study-The Jaipur Foot

The Jaipur foot case study which done by Nothing About Us Without Us, Developing Innovative Technologies For, By and With Disabled Persons by David Werner. The Jaipur Foot, now world famous, was developed by an orthopedic surgeon, Dr. P.K. Sethi in India. Dr. Sethi developed a design that was more suited to the traditions, poverty, and environment of rural India. The Jaipur foot-piece is heat-molded in iron forms in which pieces of wood are covered with vulcanized rubber. It is very flexible, water-proof, and looks real with toes, veins, and skin color. The foot is fixed to a lightweight aluminum shank crafted by traditional tinsmiths. The above-the-knee stump has a swivel knee joint that permits comfortable squatting and cross-legged sitting. Beside that, the Jaipur foot is so practical and low-cost.[6]

Below pictures show the step by step of making jaipur foot:

Figure 7: A local limb maker measure amputee's stump

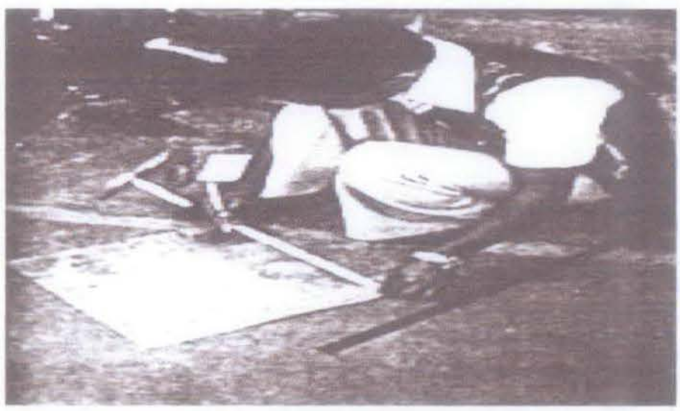


Figure 8: the limb maker draw measurements on a sheet of aluminum and cut them out

Figure 9: The limb maker hammer the tube to took like a leg and correctly fix the stump

Figure 10: After adding the foot to the tube, the limb maker add padding and a strap and try it on amputee's leg.

Figure 11: The amputee walk with the Jaipur limb

2.2 Rapid Prototyping

Rapid prototyping (RP) is a relatively new class of technology used for building physical models and prototype parts from 3D computer-aided design (CAD) data. Rapid Prototyping is Computer Controlled Additive Fabrication. Unlike CNC machines tools, which are subtractive in nature, RP systems join together liquid, powder and sheet materials to form complex parts.

Rapid prototyping able to reduce the prosthetic leg manufacturing process cycle time compare with the typical manufacturing process by using the injection molding, vacuum forming and die casting. Beside that, Rapid prototyping is freeform fabrication where rapid prototyping is largely 'geometrically independent' in that any increase in the complexity of form does not necessarily make it more difficult to build. [7]

Beside that, by using rapid prototyping, low volume of mass production able to manufactured in lower price compare with others conventional manufacturing process such as injection molding and die casting which required expertise and high tooling cost. The general advantages of using rapid prototype are:

- Time Compression
- Reduce cost of design iterations
- Addictive Process
- Minimal human intervention
- Complex intricate geometric forms
- Simultaneous fabrication of multiple parts into a single assembly
- Multiple materials or composite materials in the same part

2.21 Rapid Prototype Machine – 3D Thermojet 88

The 3D Thermojet 88 rapid prototype machine able to quickly produce superior quality, low-cost models and evaluate design alternatives. It also able to deliver improved products to market and reduce product development cycle time and costs.

3D Thermojet 88 Machine Specification:

Technology	Multi-Jet Modeling (MJM)
Resolution	300 DPI
Maximum Model Size	250mm X 190mm X 200mm (10 X 7.5 X 8 in)
Modeling Material	Thermolet 88 Thermopolymer
Material Color option	Neutral, Grey or Black
Material Capacity	5.9kg (13 lb)
Material Loading	2.3kg cartridge (5 lb)

Interface	Ethernet 10/100 Base-TX, RJ-45 Cable,TCP/IP protocol
Platform Support	Silicon Graphics IRIX v6.5.2, Hewlett Packard HP-UX v10.2 ACE, Sun Microsystems Solaris v2.6.0, IBM RS 6000 AIX v4.3.2, Windows NT v4.0
Power Consumption	230 VAC, 50/60 Hz, 6.3 amps
Dimension	W1.37 x D0.76 x H1.12 m (W54 x D30 x H44 in)

Table 1: Specification of the 3D Thermojet 88 rapid prototype machine

2.3 Reverse Engineering

Reverse engineering is important in the process of making customizing socket for the prosthetic leg. Generally, reverse engineering involves producing 3-D images of manufactured parts when a blueprint is not available in order to remanufacture the part. To reverse engineer a part, the part is scan with the 3D digitizer machine such as 3D Thermojet 88 or measured by a coordinate measuring machine (CMM). As it is measured, a 3-D wire frame image is generated and displayed on a monitor and it is called the 3D point cloud data. After the measuring is complete, the wire frame image is dimensioned. Any part can be reverse engineered using these methods. By implemented the reverse engineering in the process of making the socket of the prosthetic leg, the process manufacturing cycle time can be reduced compare with conventional manufacturing process.

2.31 3D Digitizer-Renishaw Cyclone Digitizer

Renishaw's Cyclone Digitizer machine provides a complete stand-alone system for users who require the ultimate in high speed and fine detail scanning. It can be supplied with a low-force analogue contact probe for the very best accuracy or with a non-contact laser probe for scanning delicate materials. The Cyclone system is designed for users who require the ultimate in high speed or fine detail scanning.

The advantage of using the Renishaw's Cyclone Digitizer are:

- High speed scanning reduces lead times from pattern to finished part.

- Available with both contact and non-contact (Laser) scanning probes.
- Quiet and clean in operation - allows installation in an office-like environment.

For setting data capture parameters, data manipulation and machining the Cyclone system includes Tracecut. This powerful software enables you to machine parts totally independently of the scanning strategy and the probe styli which were used.

Figure 12: Mechanical probe

Figure 13: Laser probe

3D Digitizer Renishaw Cyclone Digitizer Machine Specification:

Length	1273 mm
Width	966 mm
Height	2113 mm
Weight	162 kg
Principal application	High speed digitizing and fine detail scanning
Axis travels	600 x 500 x 370 mm (23.6 x 19.7 x 14.6 in)
Max. work piece weight	200 kg (441 lb)
Repeatability	5 µm (0.0002 in)
Axis resolution	1 µm (0.00004 in)

Scanning speed	Up to 3 metres / min (9.83 ft / min)
Rapid speed	6 metres / min (29.66 ft / min)
Scanning rate	400 points per second
Working range (Z axis)	391 mm ± 5 mm with a 100 mm stylus
Software	Tracecut

Table 2: Specification of the Renishaw Cyclone Digitizer

2.4 Application of CAD/CAM/CAE/PLM software

CAD/CAM/CAE/PLM software Unigraphics NX5 is essential for the application towards the prosthetic leg design. The Unigraphics file format required to convert into STL file format in order for rapid prototyping machine can read it. Unigraphics software is high end CAD/CAM/CAE/PLM software which developed by Siemens PLM software which programmable to enhance the software capability. Unigraphics NX5 is essential to build the solid model from point cloud data and modify the dimension of the socket point cloud data before convert the socket point cloud data into STL file format and send to the rapid prototype machine "3D Thermojet 88

CHAPTER 3
METHODOLOGY

3.1 Identify the Problems

3.11 Limitation of the Renishaw Cyclone Digitizer

The Renishaw Cyclone Digitizer got limitation of scanning the deep dimension for generated the 3D point cloud data. Due to the specimen of the amputee mold have a deep hollow this may make the Renishaw Cyclone Digitizer mechanical probe having limitation to scan the hollow dimension of the mold. The available length of the mechanical probe in UTP is from 2cm till the highest to 6cm. But the major limitation for this mechanical probe is the width of the body of the mechanical probe which got limitation in using for scanning the hollow dimension. For instance, in scanning the mold of the amputee, before the mechanical probe able to scan the deepest of the hollow of the amputee mold, the body of the mechanical probe already touch the side surface of the hollow before reach the deepest hollow of the amputee mold.

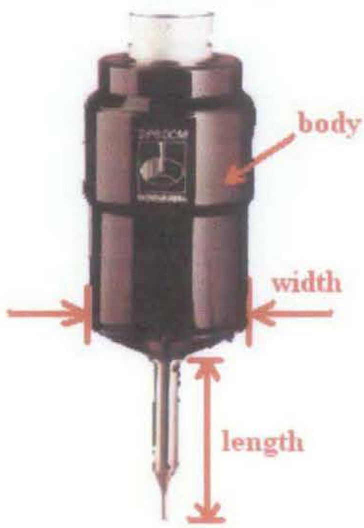


Figure 14: Overview of the mechanical probe.

Beside of the limitation of the mechanical probe, the 3D laser probe also got its' limitation. Where the 3D laser probe need to be at least 3cm distance from the specimen in order to get the good quality of the 3D surface scanning result. Thus, if the specimen got deep hollow shape, the scanning 3D surface quality may not in good quality and not clear enough for the deep surface.

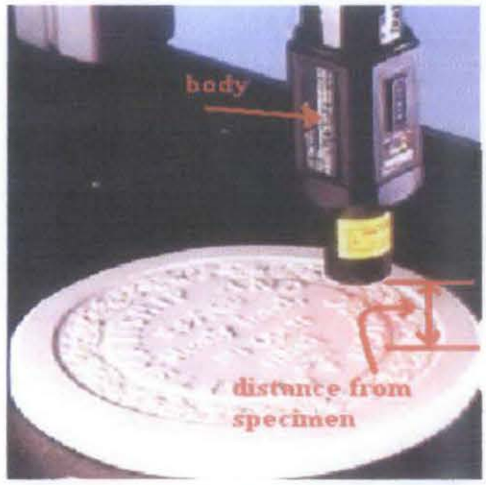


Figure 15: Overview of the laser probe

Beside that, no angle probe is available in UTP, thus the probe only can be digitizer in 90^0. Thus if the specimen have deep dimension and various shape it will make the process of scanning more difficulty.

3.12 Limitation of the Rapid Prototype Machine (3D Thermojet Printer)

The Rapid Prototype machine which available in UTP has limitation in produce the maximum size of the product. The maximum size which the 3D Thermojet Printer can produce is 250mm X 190mm X 200mm (10 X 7.5 X 8 in). For this project, the dimension of the positive mold is 310mmX 235mm X180mm, due to the length of the mold is 31cm and biggest diameter of the hollow reach 23cm. Therefore, the 3D Thermojet Printer will not able to produce the whole prosthetic socket of this project in one time due to the maximum limitation of the size. Beside that, due to the final product is in wax form, thus in order to produce the exact prosthetic leg socket which is in plastic form, rapid tooling is needed.

3.2 Learning and familiarize with Renishaw Cyclone Digitizer, Unigraphics, and 3D Thermojet Printer.

In order to proceed and completed this project, these equipment and software should be well learned and expertise.

3.3 Mold the stump by using Plaster of Paris

First step to start the project is to find an amputee which is willing to be taken as the reference for the prosthetic leg. Where a mold or cast will be molded according to the amputee stump. The mold will be done by using the Plaster of Paris to bandage the area of the stump. Before the mold is carried out, an exact dimension of the stump will be carefully measure and record. Then the wet bandages of the Plaster of Paris will be rolled over the stump. After finish rolled over the stump will be leave the Plaster of Paris to be hardened to be the mold of the stump. This is called the testing mold socket. In this project, the writer has invited Mr. Kumaran A/L Ganasan whom has lost his right leg in an accident occur in June 2003 and currently is a prosthetic leg user to join this project. Mr. Kumaran is categorized as the above knew prosthetic leg user.

Process of molding the stump are describe as below:

Material needed are:

a) Wrist measurement tape (To measure the stump dimension)

b) 2 bags of Plaster of Paris (each bag dimension15cmX 2.7m) (To make negative mold of the stump)

c) Colour pencil (To mark the location of the bone on the POP mold)

1) Measurement of the stump by using the wrist tape

For fabrication of the socket, the measurements of the stump are recorded. The amputee is made to stand as comfortably as possible with support of a parallel bar or a chair. Stump length is measured from the perineum to the end of the stump, along the long axis of the femur. With the measuring tape still held from the perineum to the end of the stump, the medial side of the stump is marked at 2" intervals. The circumference and length of the stump are recorded; upper circumference of stump is measured at the level of perineum. Care is taken to ensure that too much tension is not applied on the measuring tape and that it is kept horizontal as viewed from front and perpendicular to the long axis of the stump as viewed from the side. The lower circumference of the stump is similarly measured at the lower end of stump. Length of the stump is measured starting from the upper end of the greater trochanter along the long axis of the femur up to the lower end of stump.

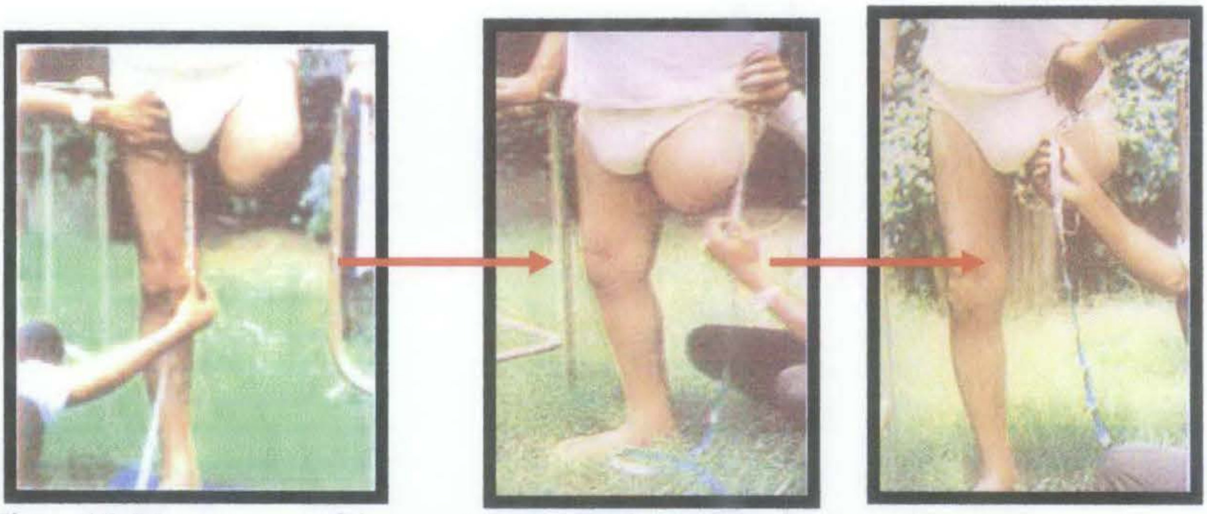


Figure 16: Measurement of the amputee stump using wrist measurement tape

Here plaster of Paris has been used because of many advantages.

The advantages offered by plaster of Paris over wood and other materials are:-

- Accuracy: Original patterns, models and molds can be made to extremely close tolerance.
- Dimensional stability: Molds are unaffected by normal change in temperature and humidity and therefore will not shrink and warp.
- Economy: It is characterized by substantial savings in time because of its simplicity.
- Adaptability : Plaster of Paris patterns are adaptable to complex contours and intersections of both original patterns and models and also in the reproduction of molds having irregular and intricate shapes.

2) Wrapping of Plaster of Paris:

Following this a negative plaster mold of the stump is taken. To ensure that the socket will be of correct size, it is best to take the measurements early in the morning as soon as patient arises. If the amputee is already using a prosthesis he should take it off just before the procedure of taking plaster mold starts. If he is not using any prosthesis, then he should come with the stump correctly wrapped. For this project taking the plaster impression of the stump, 2 bags of Plaster of Paris with each dimension 15cm X 2.7m was used to wrapped on Mr. Kumaran above knee stump. The Plaster of Paris need to wet in the water before wrapped on the amputee stump. Figure 8 below show the way of wrapping the above knee method.

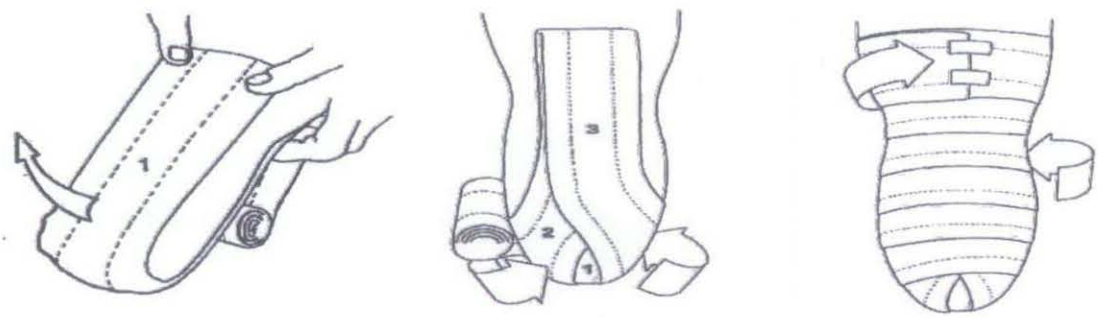


Figure 17: The method of wrapped the above knee stump

Figure 18: 2 bags of Plaster of Paris (Each dimension17cmX2.1m)

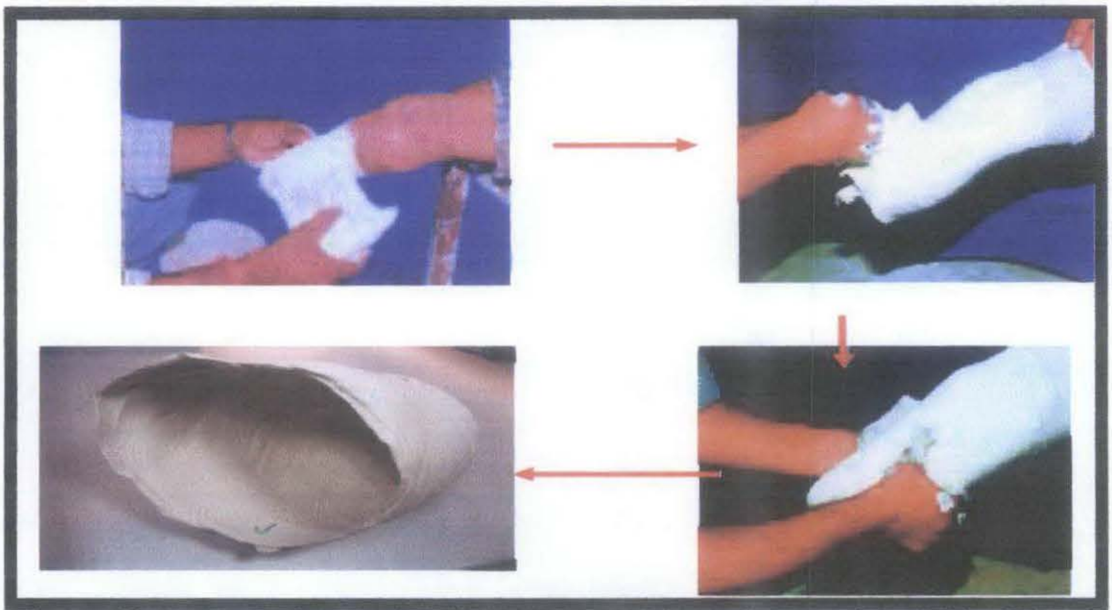


Figure 19: Process of wrapping the POP to mold out the negative mold of the above knee of the stump

3) Left for 3-4 minutes to harden the mold

After completed wrapped the above knee of the stump, the Plaster of Paris is left to be hard for few minutes. During this time, the amputee is not allowed to move to prevent any error of the mold dimension.

4) Taken out the negative mold

After the Plaster of Paris which wrapped on the amputee stump harden, the negative mold of the stump is finally mold out. The location of the bone is being mark with color pencil. The negative mold then is being taken out slowly and carefully to avoid the dimension of the mold being enlarge and to prevent the negative mold broken.

Figure 20: The Final negative mold of the stump

6) Filled the negative mold with cement powder to mold out the positive mold

In order to get the exact dimension and shape of the above knee know dimension from the negative mold. The negative mold is being filled with cement with a wood stick insert in it to have the positive mold. The cement is then being left to be hardened. After the cement been harden, the negative mold is being cut in order to take out the positive mold to be use to digitized with the Renishaw Cyclone digitizer.

3.4 Scanning the mold of the stump with Renishaw Cyclone Digitizer

The next step is taken the positive mold of the stump to scan by the 3D digitizer-Renishaw Cyclone Digitizer which available in UTP lab. The Renishaw Cyclone will capture the mold of the stump shape, dimension and surface just like the exact shape and dimension of the mold of the stump and generated the initial geometry data as 3D point cloud. Then, the 3D point cloud data will be converted into file format of IGES/DXF which the file format can read by the Unigraphics. Due to the limitation size of the length of the mechanical probe of the 3D Renishaw to scan deep hollow length, the writer purpose to cut the mold of the amputee into section by section in order to scan this positive prosthetic mold socket.

Figure 21: Overview of the Renishaw Cyclone Digitizer machine

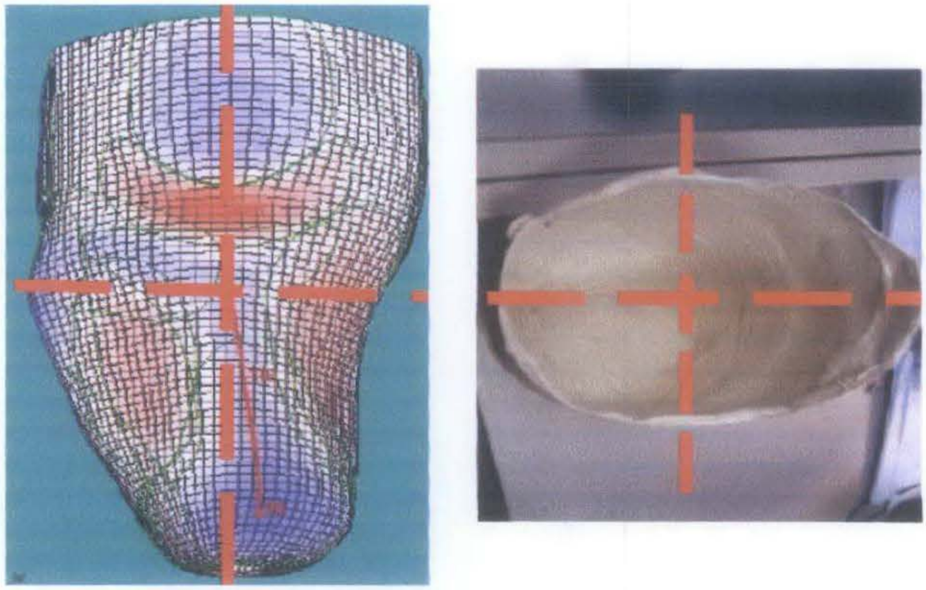


Figure 22: The amputee mold is cut into 4 sections to overcome the limitation of the 3D Reninshaw digitizer

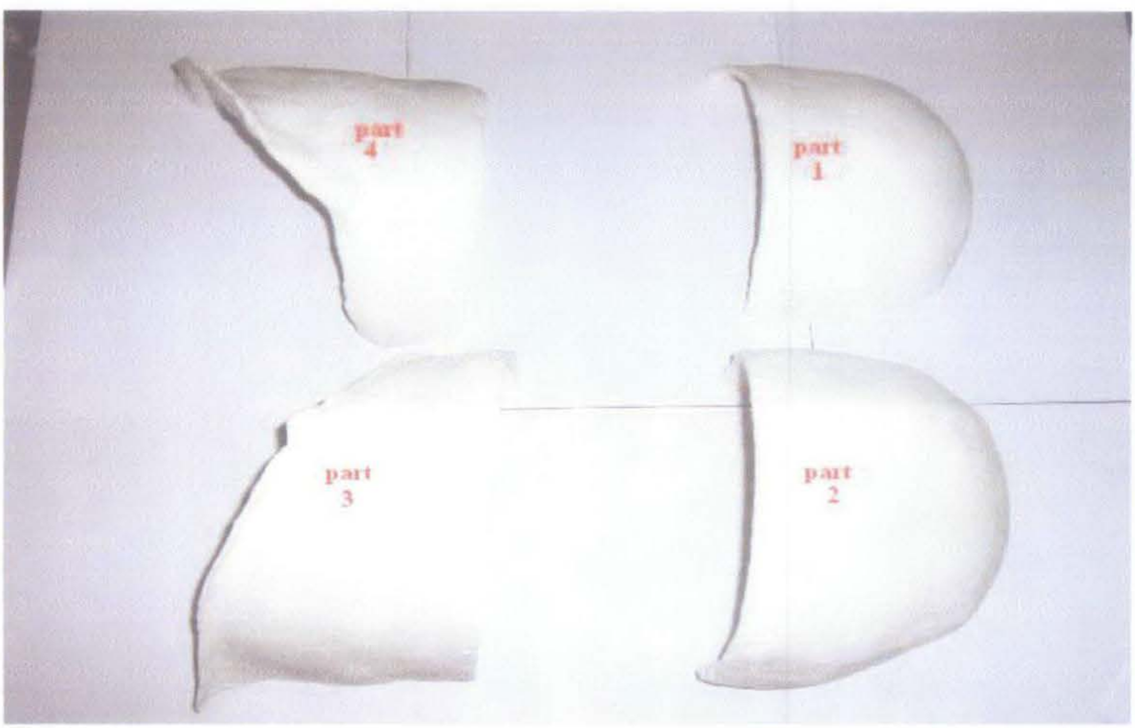


Figure 23: The amputee mold cut into 4 sections.

The operation of the Renishaw Cyclone Digitizer as below:

The item to be scanned is secured on the work table to prevent moving during scanning process.

For 2D scanning process:

1. Select program > trace cut > 2D Scanning process
2. Job datum > set size probe > initialize machine

   Depending on the probe sized that is currently used, the data of probe type, its diameter and length is input. This will then be compared to the result derived from the machine's calibrating block where it will estimate the diameter.
3. Set X,Y and Z datum plane

   This step is to tell the machine on where the workpiece is placed on the work table. The probe is moved by bare hand to the nearest location of the workpiece. This step will set the X,Y and Z datum for the positive mold.
4. Select 2D profile operation > capture > create > job
5. Set profile parameters > SI or metric unit
6. Set initial direction > positive or negative

   This step will tell the machine on the direction that the probe will take initially
7. Scanning speed > 1000 to 15000

   This step is to set the speed of the probe movement
8. Receive > display graphic to display the scanned images

For 3D scanning process:

1. Change the probe with the laser Probe.
2. Select 3D Scanning profile
3. 3D surface > capture > create > jog > ok
4. Laser probe calibration > 3D > Initialize machine
5. Profile > job > save
6. Generate 3D > Capture >Receive > estimate time

   The machine can estimate the completion job time where the machine can be left unattended.

3.5 Customize and correcting the 3D cloud point data of the positive mold

Customizing and correcting the 3D cloud point data of the positive mold is done by using CAD/CAM/CAE/PLM software-Unigraphics NX5. After the positive mold of the amputee leg has been scanned with 3D Digitizer, the 3D point cloud data is obtained. The 3D point cloud data will be converted to IGES/DXF file format in order for the Unigraphics to read. Due to current rapid prototype machine which available in UTP have the limitation of maximum dimension work piece produce up to 250mm X 190mm X 200mm (10 X 7.5 X 8 in) only thus research and survey has been done on how to solve the limitation of the product size which product by the current rapid prototype machine which available in UTP to produce largest part. Unigraphics is the solution in order to solve this problem. After the Renishaw Cyclone Digitizer produce the 3D point cloud data in IGES/DXF file format. Unigraphics then is used to convert the IGES/DXF file format into solid model. Besides that due to the amputee mold has been cut into section thus Unigraphics is using to combine again all the parts together to form the exact socket which needed later to send to the Rapid Prototype machine. In this section also Unigraphics is used to fix, repair and customize the require dimension of the product which is needed and convert into STL file format to suit with the current rapid prototype machine which available in UTP to produce the require product.

STL files are format models made up of triangles (facets). Figure below showed the format a good and bad STL model is created.

Good STL Bad STL

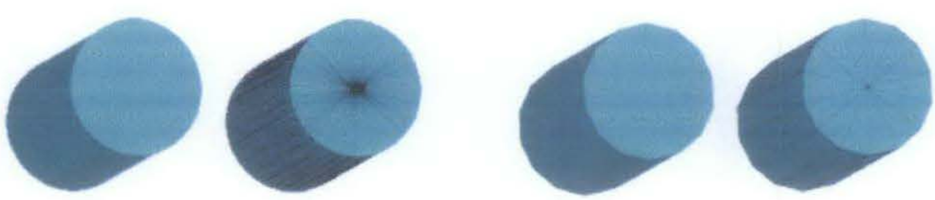


Figure 24: Comparison of good STL and bad STL file format

When possible, STL files should be output in Binary format. This will reduce the size dramatically and make file transfers much faster. The operation in Unigraphic to convert the current 3D point cloud data into STL file format as below:

1) File > Export > Rapid Prototyping
2) Set Output type to Binary
3) Set Triangle Tolerance to 0.0025
4) Set Adjacency Tolerance to 0.12
5) Set Auto Normal Gen to On
6) Set Normal Display to Off
7) Set Triangle Display to On

3.6 Fabricating the socket of the prosthetic leg by using 3D Thermojet 88 Printer

After Unigraphics has been used to fix, repair and divide the positive mold of the above knee into sections, those parts will be converted into STL file format by Unigraphics in order to send to the rapid prototype machine 3D Thermojet 88 Printer to manufacture out the prototype of the prosthetic leg socket part by part due to the limitation of the machine size. Then the 3D Thermojet 88 Printer will print out the rapid prototype according to the STL file dimension and shape. The 3D Thermojet 88 printer which available in UTP will only able to print out the 3D wax model or prototype. The material using by the 3D Thermojet is Thermojet 88 and Thermojet 2000. Then all rapid prototype which been printed out by addictive process from bottom of the part till finish printed out the entire part as showed in figure 26. Due to the limitation of the maximum size the Thermojet 88 Printer is 250mm X 190mm X 200mm. This prosthetic leg socket of dimension of 310mmX235mmX180mm need to separate printed out. For this project, the part has been separated printed out. After printed out all the 4 part will be combined together to make the exact above-knee prosthetic socket wax prototype by using superglue.

Figure 25: Overview of the 3D Thermojet 88 Printer

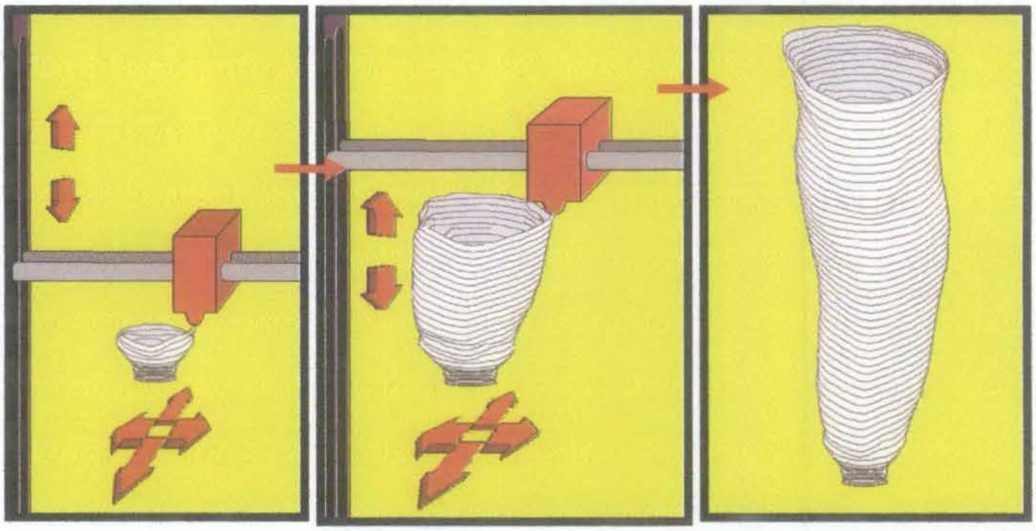


Figure 26: Addictive process by 3D Thermojet 88 printer

3.7 Rapid Tooling

Rapid tooling will be done after the rapid prototype process in order to make the socket of the prosthetic leg more realistic by using the thermoplastic or engineering plastic material. Rapid Tooling is the result of combining Rapid Prototyping techniques with conventional tooling practices to produce parts of a functional nature from electronic CAD data in less time and at lower cost relative to traditional machining methods.

Advantages of Rapid Tooling are:

- Shorten the tool making time
- Direct transfer of CAD data
- Functional test of the parts in early design make possible
- Low cost

For this project, due to the final part of the prosthetic leg socket is in plastic form, therefore plastic mould or RTV Silicon Rubber Mould is used to produce the final plastic parts.

3.8 Testing

The socket of the prototype will be tested by amputee in order to make sure the prototype able to work functional and able to fit the patient leg.

3.9 Analysis and Discussion and Documentation.

When testing the prototype, the functions of it will be analyze. Discussions will be done for future improved the prototype in future. The research and results must be properly documented for future references. In addition, the resources are also documented.

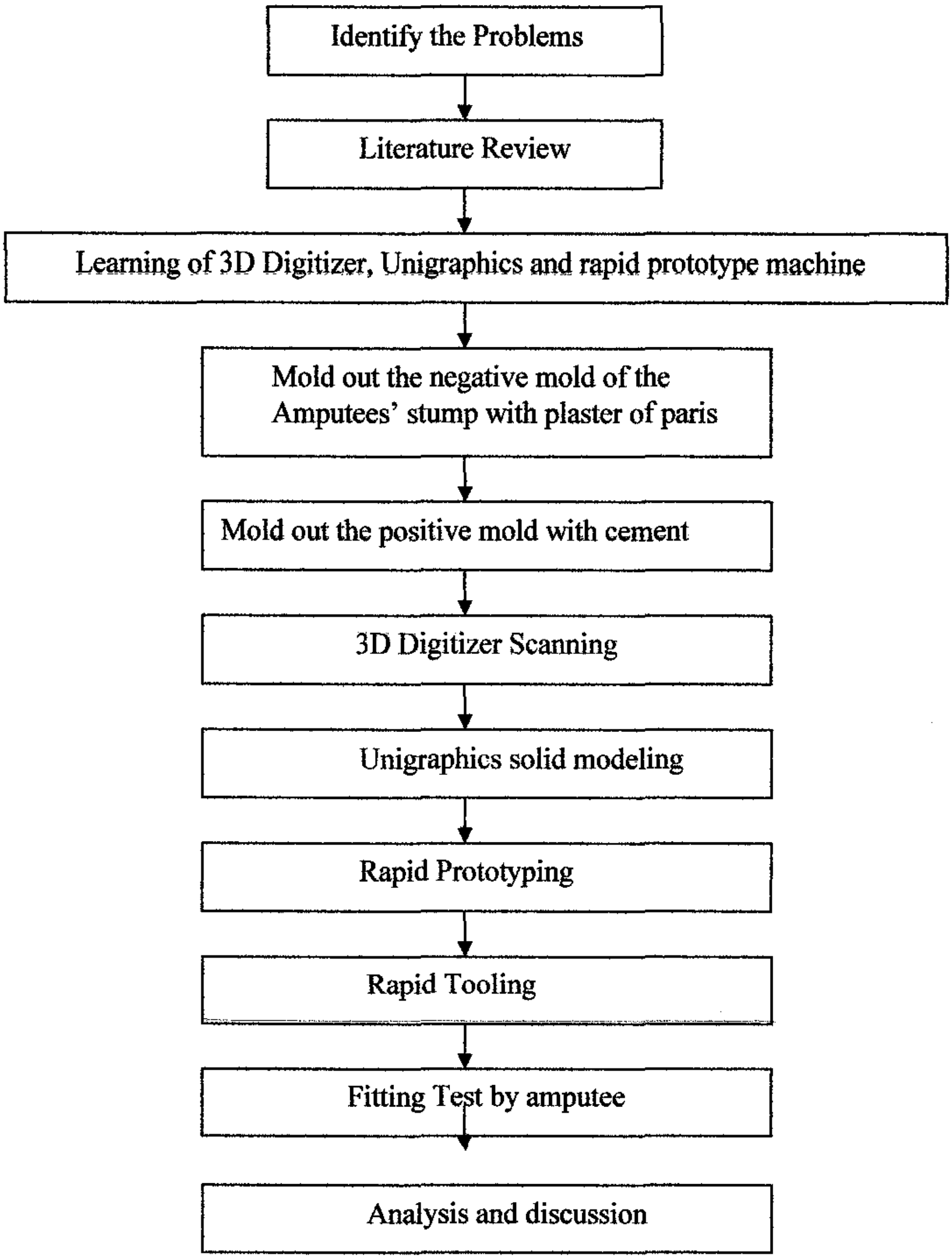


Figure 27: Schematic of flow chart of the completed methodology

CHAPTER 4
RESULT AND DISCUSSION

4.1 Renishaw Cyclone Digitizer

The Renishaw Cyclone Digitizer will generated 3D point cloud data from the specimen. Here is the step by step process of digitizing the amputee mold section. Figure 28 is the mold part 1 which is used to illustrate the 3D digitizing process. Figure 29a, 29b, 29c showed the 3D scanning process with Traceut 24 software of the Renishaw Cyclone Digitizer. Figure 30 showed the completed scanning of part 1.

Figure 28: Part 1 of the amputee stump

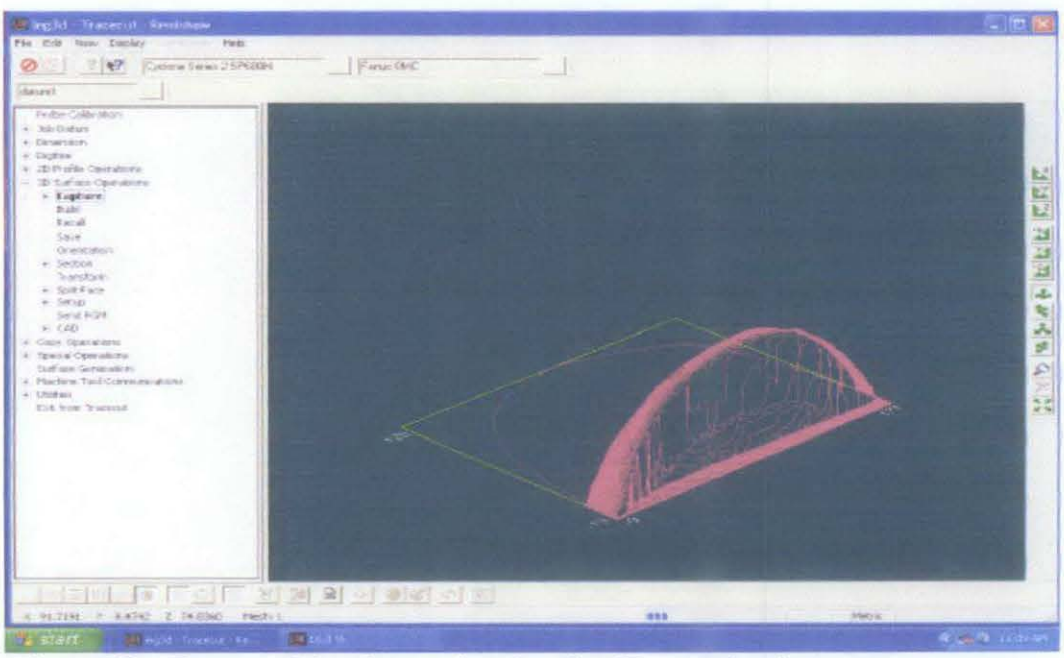


Figure 29a: Tracecut 24 software showing the 3D scanning in progress

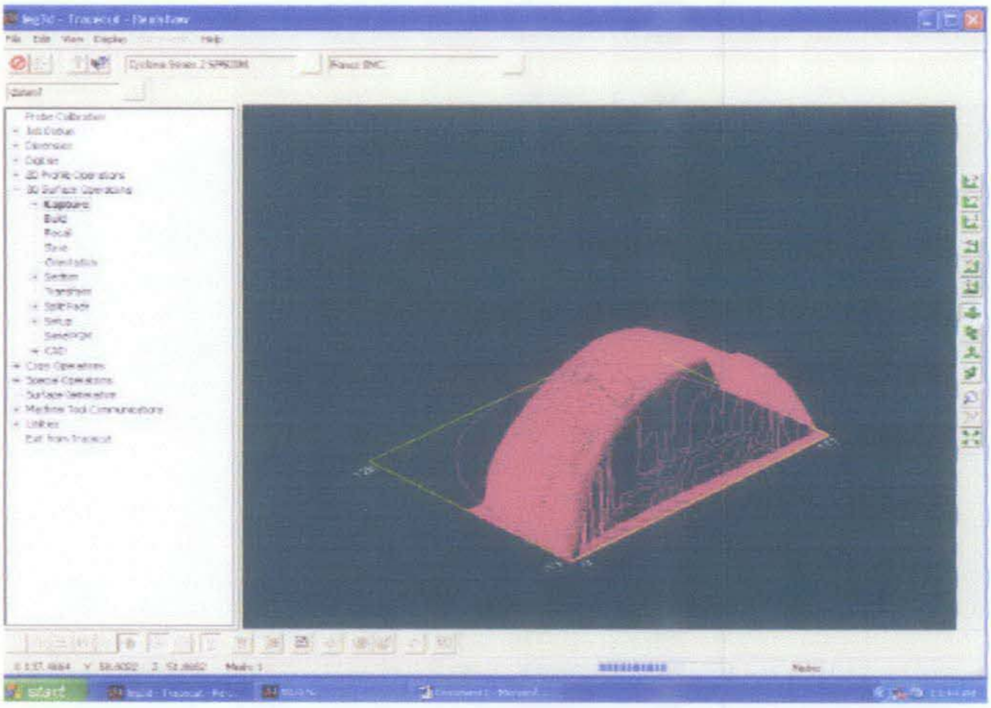


Figure 29b: Tracecut 24 software showing the 3D scanning in progress

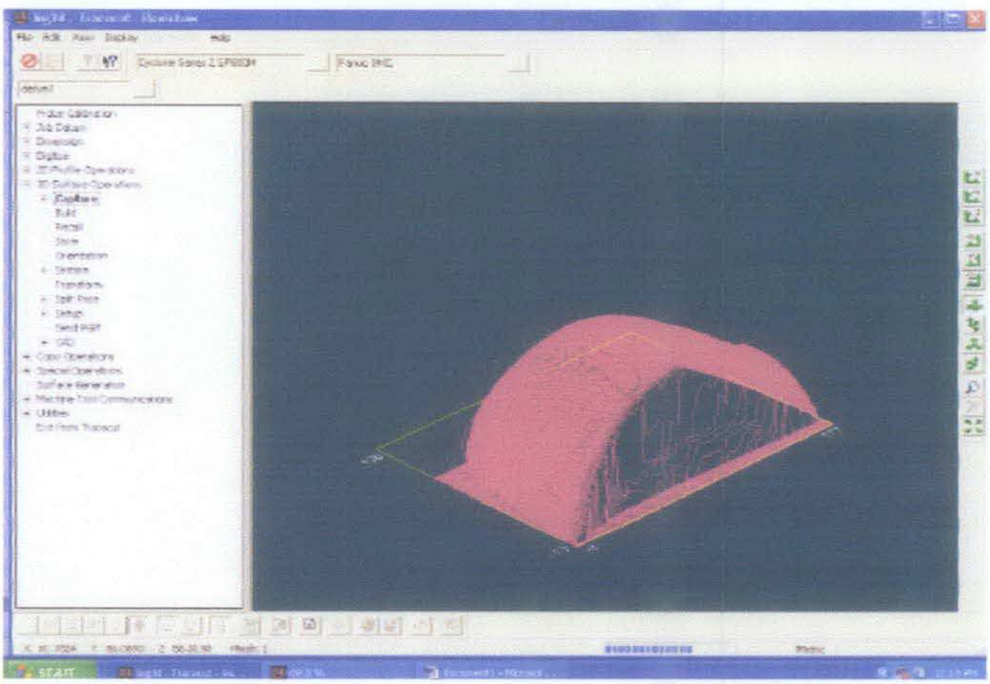


Figure 29c: Tracecut 24 software showing the 3D scanning in progress

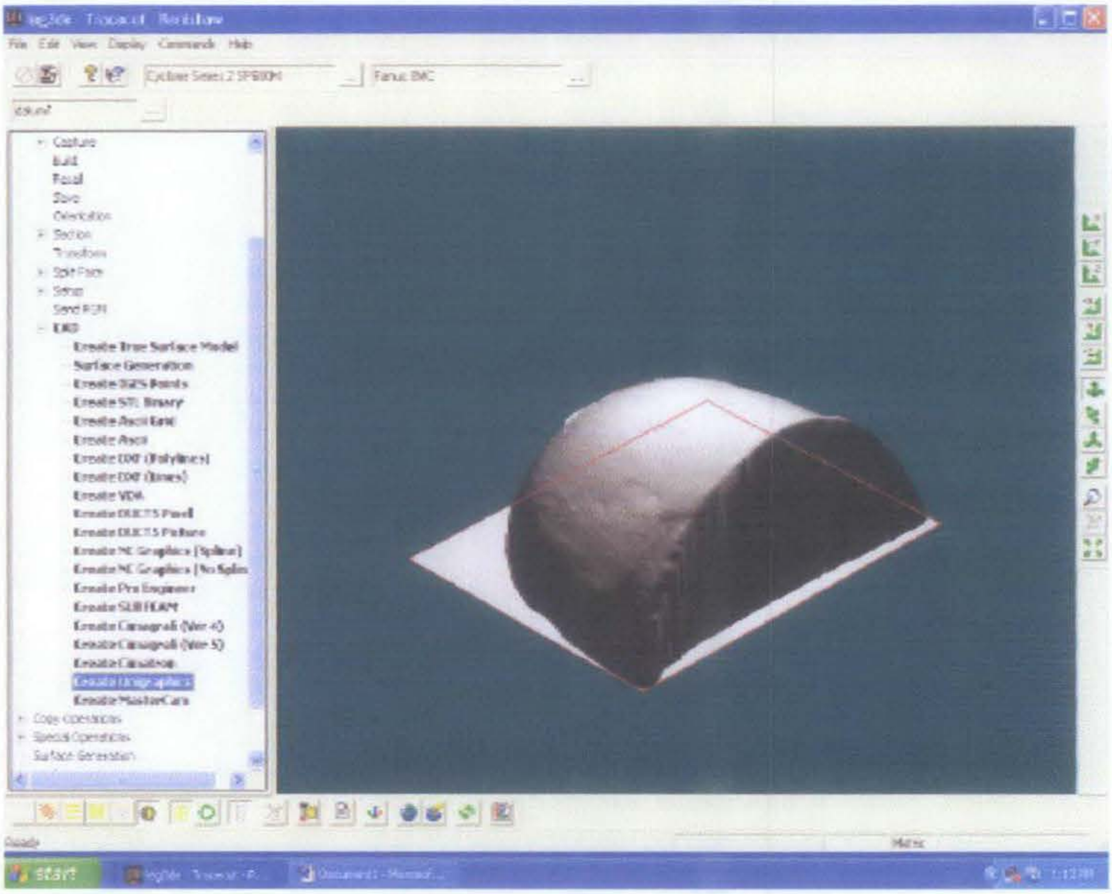


Figure 30: Tracecut 24 software showing the completed 3D scanning process

4.2 Unigraphics (NX5)

The Unigraphics will be used for the purpose of fix, repair and modify the 3D point cloud data from the 3D Renishaw Cyclone Digitizer. The 3D point cloud data from the 3D Renishaw Cyclone digitizer will be saved in IGES/DXF file format in order for Unigraphics software to open it. Then, Unigraphics will be used to open the IGES/DXF file format and converted the 3D point cloud data into solid modeling into to fix, repair and modify the 3D point cloud data. Figure 31, 32, 33 and 34 showed the 4 different parts in solid modeling. Figure 35 showed the completed part of mold stump after combined all the 4 parts together by using Unigraphics. In order to combine all the 4 parts, 'notches' at every part have been added for combination.

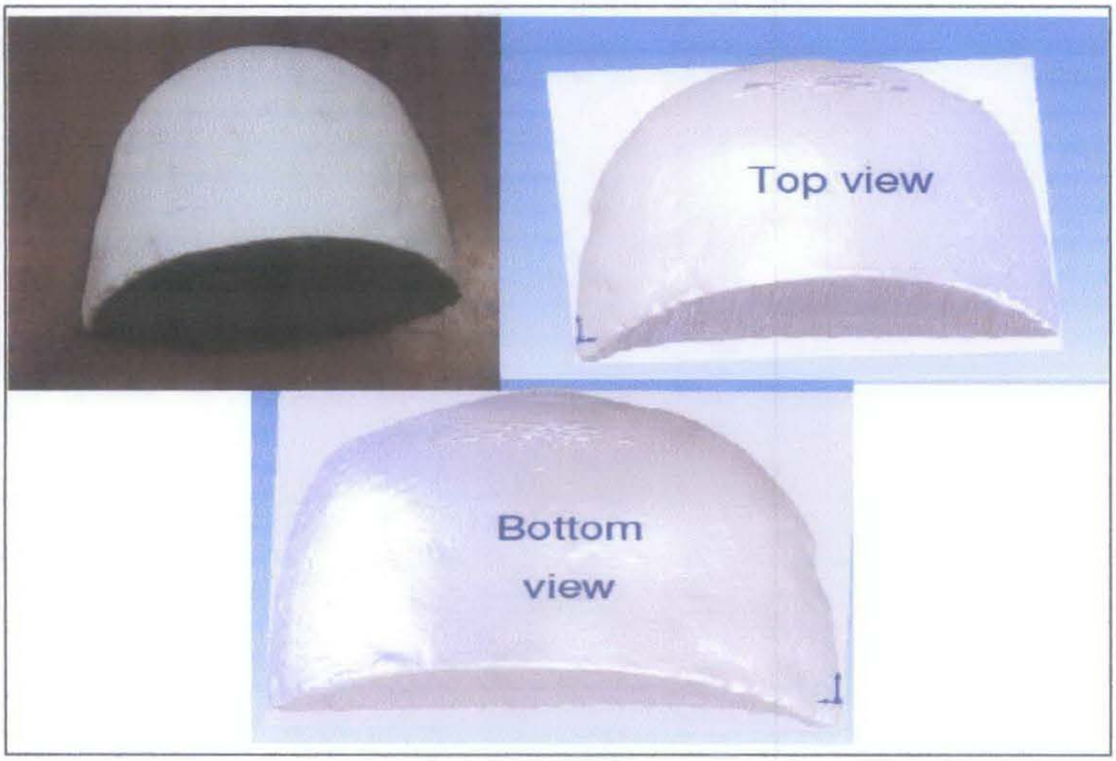


Figure 31: part 1 of the amputee stump with the solid modeling in Unigraphics.

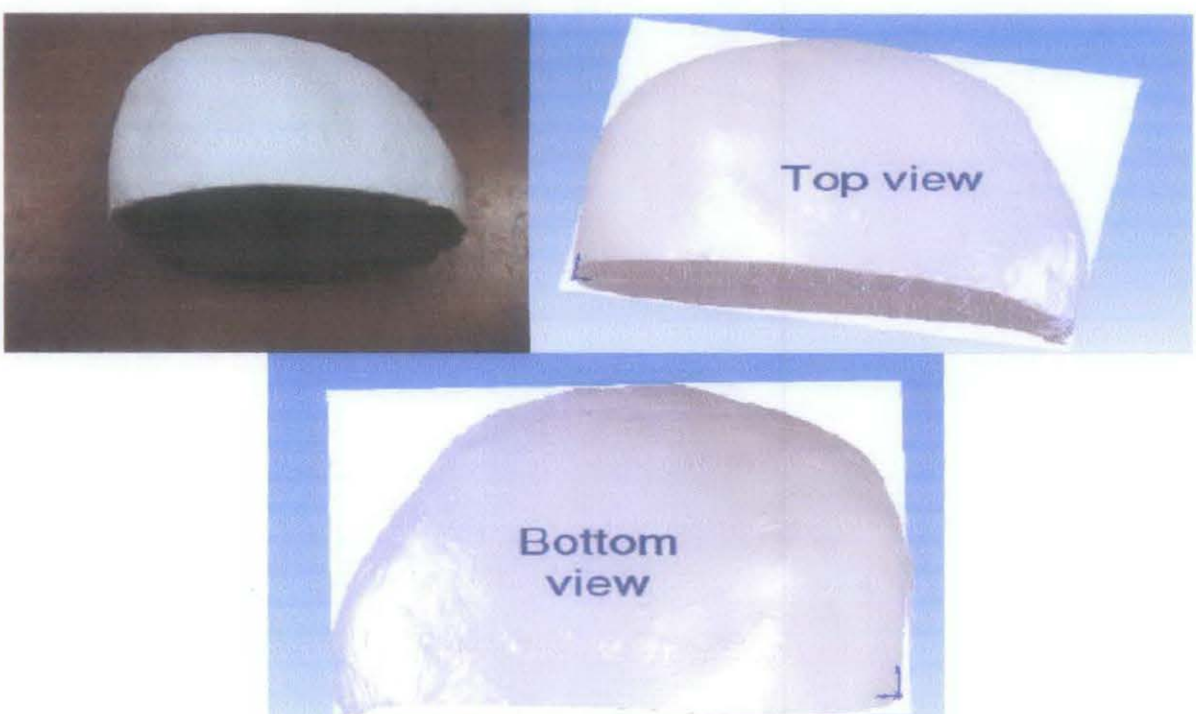


Figure 32: part 2 of the amputee stump with the solid modeling in Unigraphics.

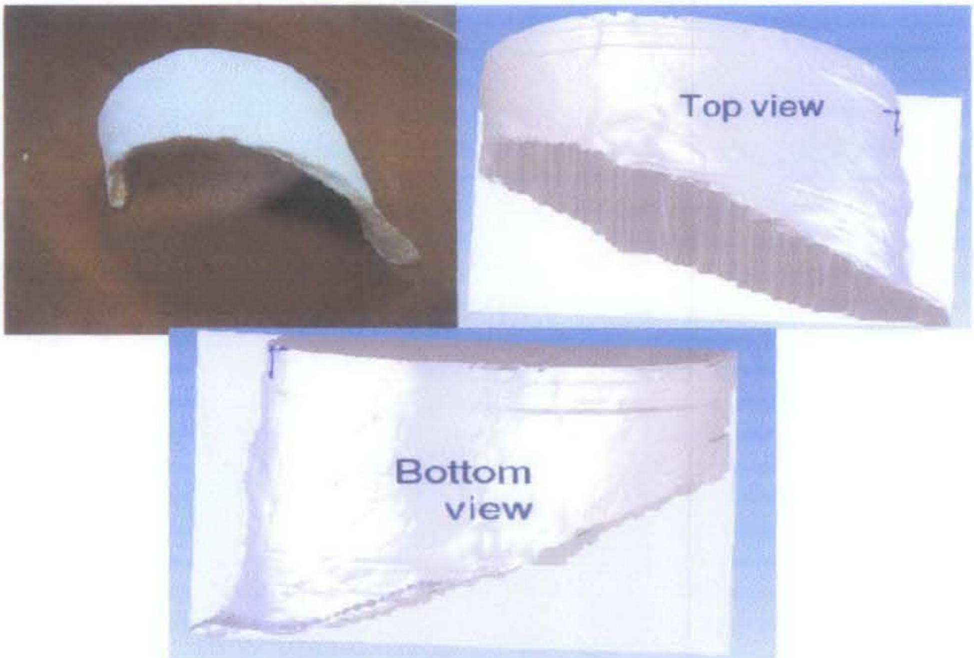


Figure 33: part 3 of the amputee stump with the solid modeling in Unigraphics.

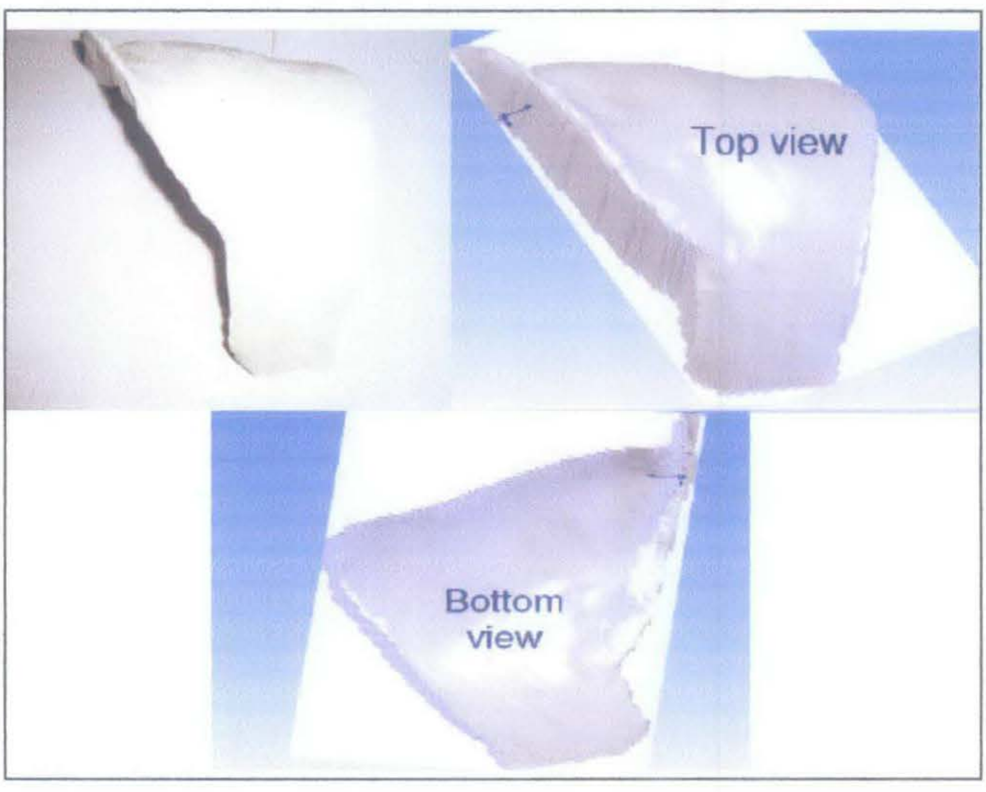


Figure 34: part 4 of the amputee stump with the solid modeling in Unigraphics.

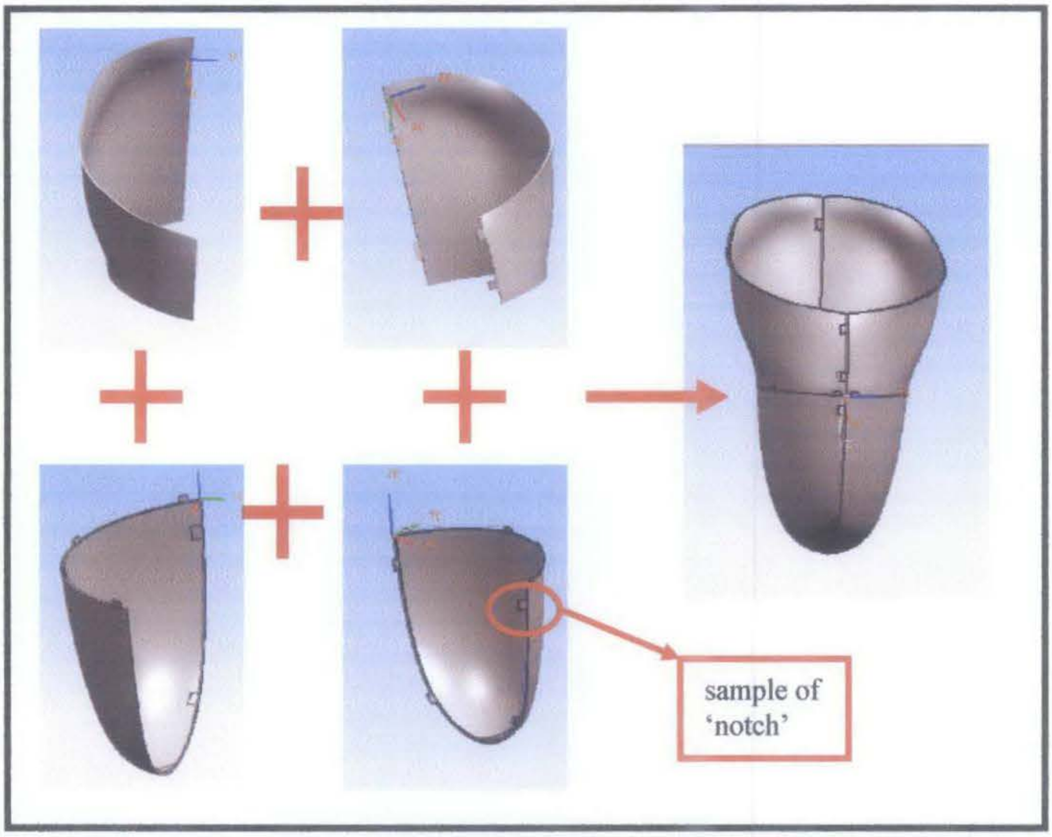


Figure 35: 'Notches' are design at every parts in order to combine all the 4 parts together.

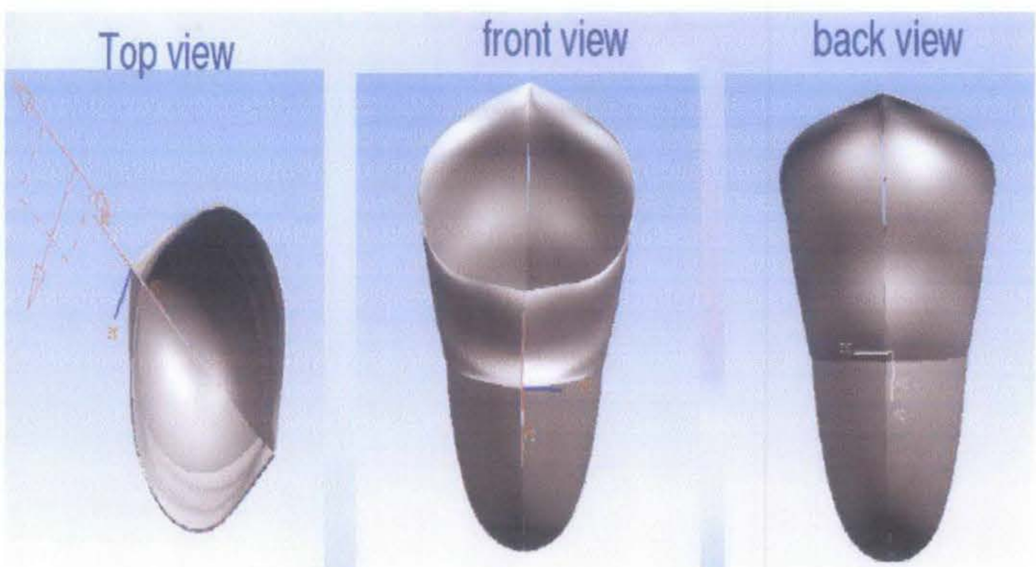


Figure 36: The completed part of mold stump after combined all the 4 parts together by using Unigraphics.

4.3 Rapid Prototype

The 3D Thermojet 88 printer will produce the maximum size of dimension 250mm X 190mm X 200mm. But for this project due to the entire part dimension is 310mmX235mmX180mm, therefore the part also will be separate in to 4 parts to print out and then combined all the 4 parts together with the 'notches' that are created with Unigraphics. The process of combining all the 4 parts is easy by using superglue due to the entire parts is from wax form. Wax can be easy shaped and combined together.

Figure 36: Side view of the completed rapid prototype prosthetic leg socket after combined with the superglue.

Figure 37: Top view of the completed prototype rapid prototype prosthetic leg socket after combined with the superglue.

4.4 Rapid Tooling

Rapid tooling is done for the purpose of having the final product of the prosthetic leg in plastic form. The process of the rapid tooling is done as below:

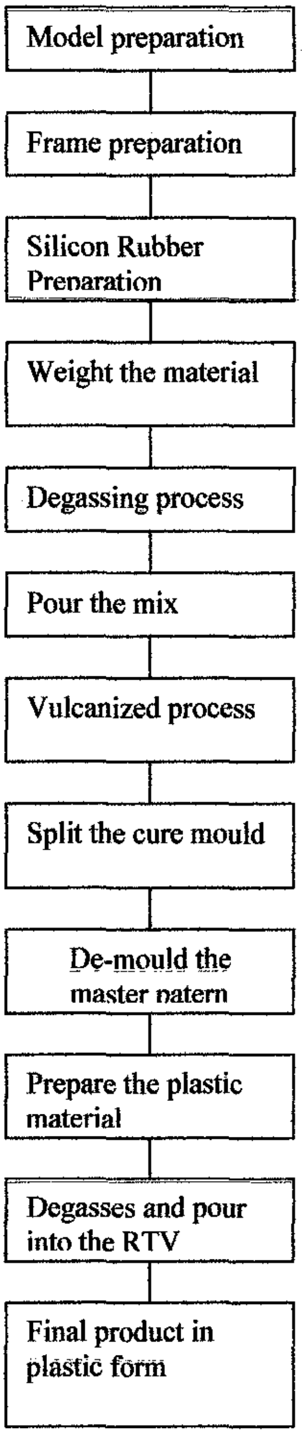


Figure 38: The schematic diagram of the Rapid Tooling process flow

For this Final year project, after discussing with the writer supervisor and others lecturer the final part of the prosthetic leg will be scaled down in order to save cost due to every student is only giving limited budget in order to complete their final year project. Therefore, the real size of the prosthetic leg socket for this project has been scale down into 80mmX50mmX45mm in order to show the rapid tooling process. The different between the final part of the prosthetic leg of the rapid tooling with the rapid prototype is plastic material which can sustain high strength compare with wax. Therefore, a scale down of this project is essential to save material cost of the rapid tooling process.

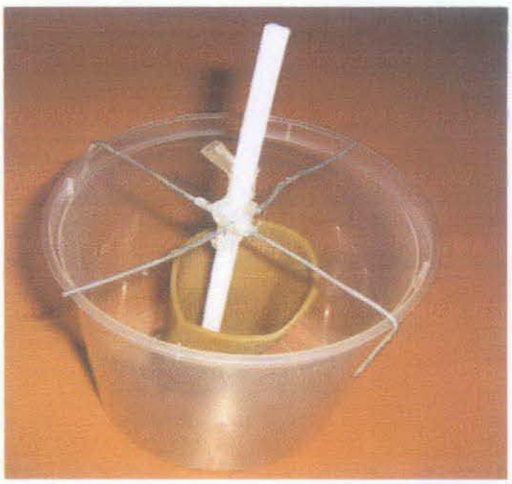


Figure 39: The scale down prosthetic leg in hanging position inside a box prepare for rapid tooling process.

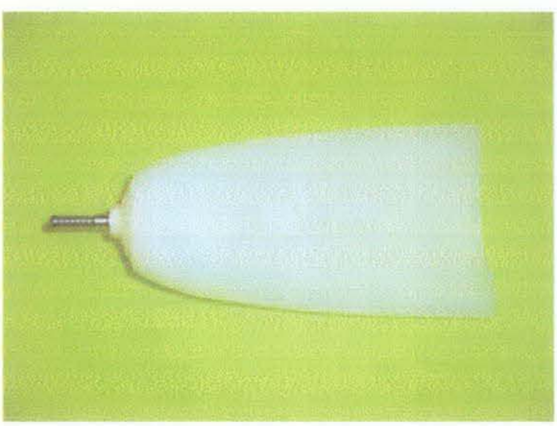


Figure 40: The final plastic part of the prosthetic leg socket after rapid tooling process.

CHAPTER 5
CONCLUSION

By using 'Customizing Prosthetic Leg Socket by using Rapid Prototype with Reverse Engineering' method, although the cost of the 3D Thermojet material is higher due to new technology but by using this method the tooling cost involved injection molding and vacuum forming can be excluded Besides that, reverse engineering is essential when there is no blue print available. 3D Scanning Digitizer machine able to scan in fine detail with high speed scanning up to 3 meter/s and the Rapid Prototype machine is time compression and able to produce complex intricate geometric forms and simultaneous fabrication of multiple parts into a single assembly compare to injection molding process which need expertise and experience to handle the process of making the prosthetic leg. Due to the limitation size which Rapid Prototype machine can be produced therefore Rapid Prototype machine is essential for producing small size of the part rather than big size of the part. Unigraphics is essential to fix, repair and customize the 3D point cloud data. Besides, the user may have preference on the thickness and shape of the prosthetic leg socket by customizing the 3D point cloud data with Unigraphics. This study concludes that Reverse Engineering and Rapid Prototype able to produce prosthetic leg socket. In future, prosthetic leg socket manufacturer able to consider this new method and the traditional method which applicable to them.

CHAPTER 6

REFERENCES

[1] www.belsurg.org/imgupload/RBSS/wasiak.pdf

[2] http://www4.army.mil/ocpa/read.php?story_id_key=5784

[3] Allen Ho, Total Medical Supplies, 7 Medan Istana 7, Bandar Ipoh Raya, 30000 Ipoh, Perak.

[4] Dr. Ravindran, General Surgery Department, General Hospital Ipoh, Jalan Hospital 30990 Ipoh, Perak.

[5] Mr. Kumaran A/L Ganasan, Prosthetist from Total Medical Supplies, 7 Medan Istana 7, Bandar Ipoh Raya, 30000 Ipoh, Perak.

[6] David Werner(1998), Nothing about us without us, developing innovative technologies for, by and with disabled persons, HealthWrights.

[7] Ian Gibson (2005), Advance Manufacturing Technology For Medical Applications, Wiley.

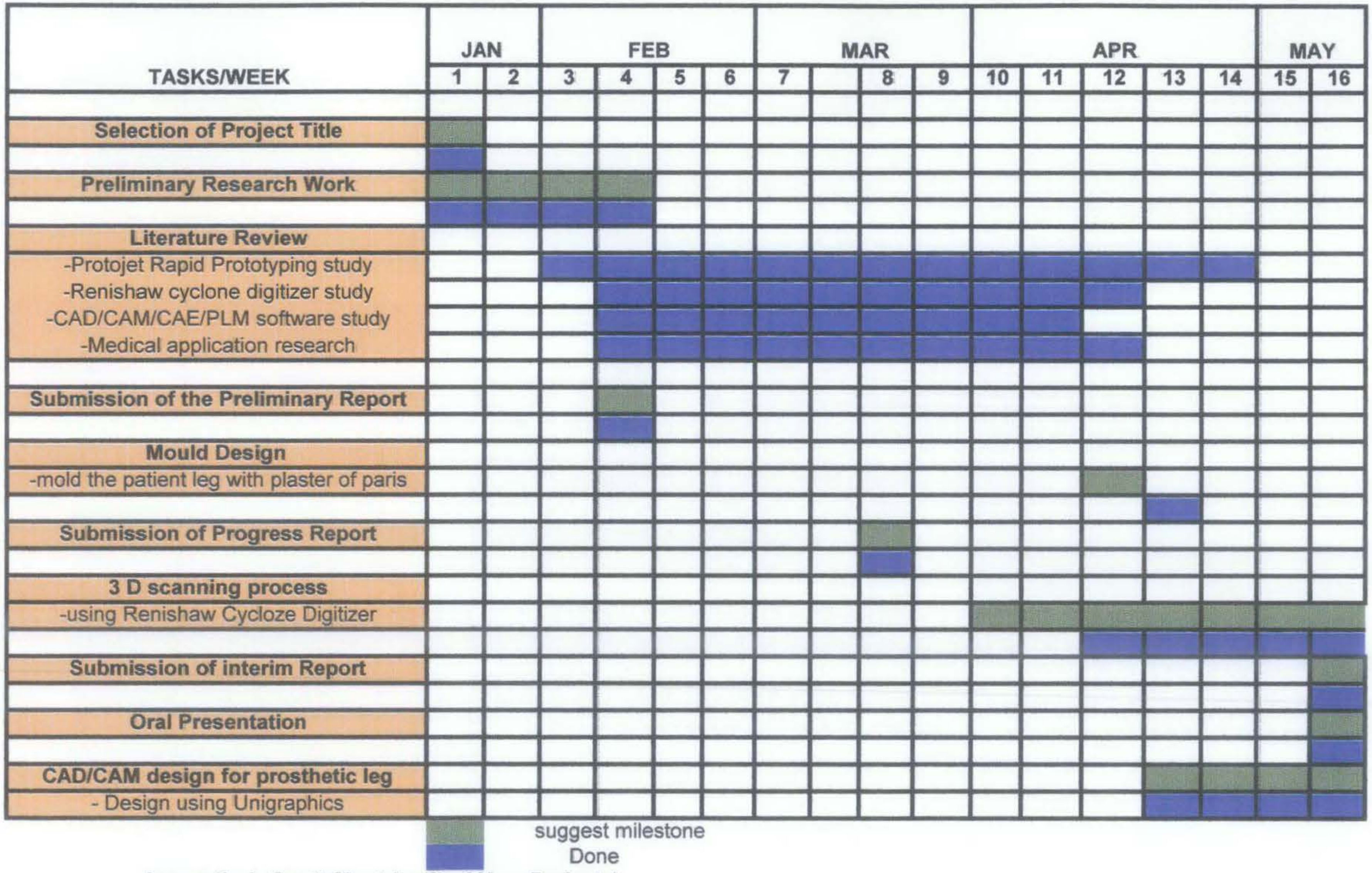
Others references:

- Journal: Immediate prosthesis fitting and comprehensive rehabilitation following lower

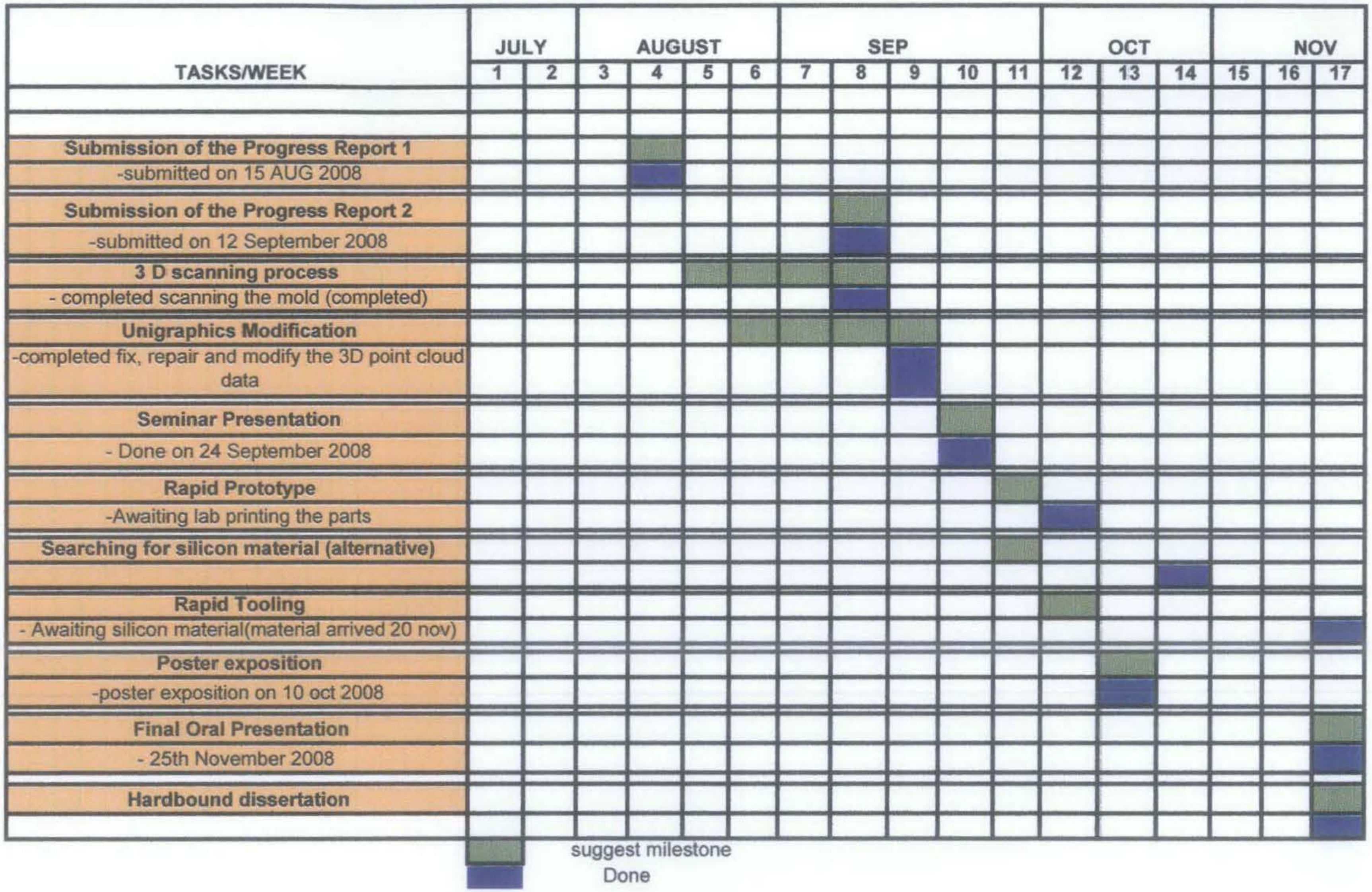
  limb amputation – the most important components of physiotherapy by Aneta Pirowska,

  Tomasz Włoch and Roman Nowobilski (30.12.2005).

- Journal: Prosthetic Leg Design by Daniel Rihs and Ivan Polizzi (2001), from Victorian University of Technology .
- JAMcDonald, CJRyall and DIWimpenny (2001), Rapid Prototyping Casebook, Professional Engineering Publishing Limited London and Bury St Edmunds, UK.
- Rafiq Noorani (2006), Rapid Prototyping Principles and Applications, Wiley.
- Teoh Swee Hin (2004), Engineering material biomedical application, World Scientific.
- Anthony Holms-Walker (2005), Life Enhancing Plastic, imperial college Press.



Appendix 1: Gantt Chart for Final Year Project 1



Appendix 1: Gantt Chart for Final Year Project 2