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JUDUL: **DESIGN AND FABRICATION OF ANKLE-FOOT ORTHOSES THROUGH 3D SCANNING AND RAPID PROTOTYPING**

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DESIGN AND FABRICATION OF ANKLE-FOOT ORTHOSES THROUGH 3D SCANNING AND RAPID PROTOTYPING

ENGKU ERSYAD BIN ENGKU ABAS

Thesis submitted in partial fulfillment of the requirements

for the award of the degree of

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EXAMINER APPROVAL DOCUMENT

We certify that the thesis entitled "DESIGN AND FABRICATION OF ANKLE-FOOT ORTHOSES TRHOUGH 3D SCANNING AND RAPID PROTOTYPING" is written by ENGKU ERSYAD BIN ENGKU ABAS. We have examined the final copy of this thesis and in our opinion; it is fully adequate in terms of scope and quality for the award of the "Bachelor of Manufacturing engineering" . We are here with recommend that it be accepted in fulfillment of the requirement for the degree of Engineering specializing in Manufacturing.

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I hereby declare that the work in this project is my own except for quotations and summaries which have been duly acknowledged. The project has not been accepted for any degree and is not concurrently submitted for award of other degree.

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DEDICATION

To my beloved family and friends

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ABSTRACT

This project aims to tackle the problem of current manufacturing method of production Ankle-Foot Orthoses (AFO). AFO is needed for people who experience foot-drop, limited ability or inability to raise the foot at the ankle joint. There are two ways of acquiring these AFOs, first is by getting on the shelves, prefabricated AFO, which are affordable and designed to fit a range of patients. However, due to this features, it will not provide individualized comfort and functionality. Second method of obtaining AFO is by using traditional custom-made technique which is laborious and time-consuming manual process and can only be accomplished by expert orthotists. Nonetheless it does provide better fit and function. This research explore the possibilities of using current technology in bring the manufacturing process of AFO much faster and reliable. By using 3D scanner to obtain the geometric data of the foot, the process of fabricating patient-specific orthotic devices has the potential to deliver outstanding comfort due to the accurate polygon data. The process of designing orthoses using reverse engineering software would permit changes in the standard design to meet the exact needs of each patient. In order to test the effectiveness of the AFO made using the new modern method, gait analysis was conducted and comparison was made. It was concluded that the fabricated able to perform its intended function which is to restrict ankle motion and prevent drop-foot symptoms. The design made based on the scanned cloud point data also prove to fit excellently and comfortably on the subject's foot using velcro strap.

ABSTRAK

Projek ini bertujuan untuk menangani masalah kaedah pembuatan “Ankle-foot Orthoses” (AFO). AFO diperlukan untuk orang yang mengalami “Drop-foot”, iaitu keupayaan terhad atau ketidakupayaan untuk meningkatkan kaki di sendi buku lali. Terdapat dua cara untuk memperolehi AFOs, pertama ialah dengan mendapatkan AFO sedia ada di kedai. AFO yg dipasang siap mempunyai harga yang berpatutan dan direka untuk memenuhi pelbagai saiz. Walau bagaimanapun, disebabkan ciri-ciri ini, ia tidak akan memberi keselesaan dari segi individu dan fungsi yang baik. Kaedah kedua mendapatkan AFO adalah dengan menggunakan cara tradisional yang memakan masa dan hanya boleh dicapai oleh pakar orthotists. Walau bagaimanapun, ia menyediakan keselesaan yang lebih baik dan memberi fungsi yang lebih berkesan. Kajian ini meneroka cara menggunakan teknologi masa kini dalam membawa proses pembuatan AFO lebih cepat dan berkesan. Dengan menggunakan pengimbas 3D untuk mendapatkan data geometri kaki, proses fabrikasi peranti ortotik pesakit tertentu mempunyai potensi untuk memberikan keselesaan yang luar biasa disebabkan oleh data polygon yang tepat. Proses mereka bentuk orthoses menggunakan perisian kejuruteraan terbalik akan membenarkan perubahan dalam reka bentuk yang standard untuk memenuhi keperluan sebenar setiap pesakit. Dalam usaha untuk menguji keberkesanan AFO yang dibuat menggunakan kaedah moden ini, analisis gaya berjalan telah dijalankan dan perbandingan telah dibuat. Kesimpulan telah dibuat bahawa AFO tersebut dapat direka untuk melaksanakan sebagai fungsi yang dimaksudkan iaitu untuk menyekat pergerakan buku lali dan mencegah gejala “drop-foot”. Reka bentuk yang dibuat berdasarkan diimbas data titik awan juga membuktikan ia dapat memberi keselesaan yang baik kepada pengguna AFO tersebut.

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LIST OF SYMBOLS

T_g	Glass Transition Temperature
T_m	Melting Point
%	Percentage
^oC	Degree Celsius
^oF	Fahrenheit
N/m^2	Newton’s per Square Metre
Lbf/In^2	Pounds-Force per Square Inch
lb/in3	Pound per cubic inch
MPa	Mega Pascal
mm	millimeter
N	Newton’s
mm^2	Square millimeter

LIST OF ABBREAVIATIONS

ABS	Acrylonitrile-Butadiene-Styrene
AFO	Ankle-foot Orthoses
ATOS	Advanced Topometric Sensor
ASTM	American Society for Testing and Materials
CAD	Computer-aided design
CT	Computed (Axial) Tomography
MRI	Magnetic Resonance Imaging
EMG	Electromyography
FDM	Fused deposition modeling
FF	Foot flat
HS	Heel-strike
HR	Heel rise
MS	Mid-stance
RP	Rapid Prototyping
SLA	Stereolithography
SLS	Selective laser sintering
TO	Toe-off
US	United States

CHAPTER 1

INTRODUCTION

1.1 PROJECT BACKGROUND

In modern competitive world, manufacturers have to release a new and improved product to the market as fast as possible to be able to compete in the global market. The introduction of rapid prototyping in the early stages of product development has greatly reduced the development time frame and cost involved in prototype manufacturing. Rapid prototyping (RP) is the process of producing a three-dimensional parts or models directly from CAD drawings.

The applications of rapid prototyping are advancing at rapid pace. They have moved from creating prototypes for parts to several engineering applications. Among the evolving RP applications are the making of molds for die casting, and making of parts to be used in the assembly of products. In terms of medical use, RP is employed to make models using three-dimensional graphics from X-ray equipment and these models are used to study and plan surgery Techniques are being developed to conduct remote surgery by virtual reality using RP models. In addition to the previous application, rapid prototyping is also being used to make body parts known as orthotics and prosthetics.

This project is focused on designing ankle foot orthoses (AFO) through reverse engineering and fabrication by rapid prototyping. An orthosis is defined by the International Standards Organization as an externally applied device used to modify the structural and functional characteristics of the neuromuscular and skeletal system. Ankle Foot Orthoses are orthoses that encompass the ankle joint and the whole or part of the foot. AFOs are intended to control motion, correct deformity and/or compensate for weakness of the leg.

With our current technology, we can speed up the manufacturing process by using reverse engineering to collect 3D CAD data on the patient's foot. Medical Reverse Engineering is aimed to use the Reverse Engineering technology to reconstruct 3D models of the anatomical structures and biomedical objects for design and manufacturing of medical products. Reverse Engineering is generally defined as a process of analyzing an object or existing system, to identify its components and their interrelationships, and investigate how it works in order to redesign or produce a copy without access to the design from which it was originally produced.

Through reverse engineering, we can analyze the 3D scanned data and design the most suitable orthoses for the patient. The process of designing orthoses using reverse engineering software would permit changes in the standard design to meet the exact needs of each patient. Additionally, the use of 3D scanner and computerized software in fabricating patient-specific orthotic devices has the potential to deliver outstanding comfort due to the accurate data provided through 3D scanning.

1.2 PROBLEM STATEMENT

Presently, prefabricated orthotic devices are affordable and designed to fit a range of patients. Due to this limited designs, it will not provide customized comfort and functionality. However, producing a custom-fit orthosis is a laborious and time-consuming manual process accomplished only by expert orthotists. The procedure to create a cast can take up as much as 4 hours of fabrication time per unit if performed by an experienced technician. To create the orthotics based on the cast itself will take days. The cast will also takes space when storing and can only be kept for a few months and then a new cast has to be made.

1.3 OBJECTIVES

1. To design ankle foot orthoses through reverse engineering software and fabrication by rapid prototyping.
2. To study the effectiveness of the ankle-foot orthoses design on human walking pattern through gait analysis.

1.4 PROJECT SCOPES

This project is focused on developing and designing custom-made ankle-foot orthoses through three-dimensional scanning and reverse engineering software followed by a fabrication process using fused deposition modeling. The project scope is as follow:

1. Take a 3D scan of a foot from a healthy subject using ATOS 3D digitizer
2. Design ankle-foot orthoses based of scanned data through ATOS and Geomagic Software.
3. Fabricate ankle-foot orthoses using Fortus 360MC rapid prototyping machine.
4. Conduct gait analysis to test the AFO effectiveness on human walking pattern using Kinovea Software.

CHAPTER 2

LITERATURE REVIEW

2.1 INTRODUCTION

This chapter discusses the principle behind rapid prototyping, type of rapid prototyping and its application. We take a look at how the process of 3D scanning of the foot works, and the use of ATOS, GOM Inspect and Geomagic software and the rapid prototyping machine use to fabricate the orthotics. In addition to that, we discuss design considerations and the material which is suitable for this application. Drop foot which is a symptom cause by stroke is further discussed in this chapter and how AFOs are used to treat them. Gait analysis is explained regarding its purpose of being used to analyze the after effect of wearing ankle-foot orthotic.

2.2 OVERVIEW OF RAPID PROTOTYPING

The term rapid prototyping refers to a class of technologies that can automatically construct physical models from CAD data. RP has also been referred to as solid free-form manufacturing, computer automated manufacturing, and layered manufacturing (Nyaluke, P.A., An D., Leep, H.R., & Parsaei, H.R., 1995). To substantially shorten the time for developing patterns, molds, and prototypes, some manufacturing enterprises have started to use RP methods for complex patterns making and component prototyping.

2.3 RAPID PROTOTYPING PROCESSES

Rapid prototyping processes can be classified into three major groups: subtractive, additive and virtual. Subtractive processes involve material removal from a work piece that is larger than the final part (Nyaluke, P.A. et al., 1995). Virtual processes use advanced computer-based visualization technologies. Additive processes build up a part by adding material incrementally to produce the part. Examples of technologies that use additive processes are stereolithography, selective laser sintering, modeling. In this project we will focus on additive manufacturing, specifically fused-deposition modeling process in view of the fact that it will be used to fabricate the orthotic in this project.

2.3.1 Fused-Deposition Modeling

In fused-deposition modeling (FDM) process, a gantry robot-controlled extruder head moves in two principal directions over a table, which can be raised and lowered as needed. A thermoplastic filament is extruded through the small orifice of a heated die (Gu, P., & Yan, X., 1996). The initial layer is placed on a foam foundation by extruding the filament at a constant rate while the extruder head follows a predetermined path as shown in **Figure 2.1**. When the first layer is completed the table is lowered so that subsequent layers can be superimposed.

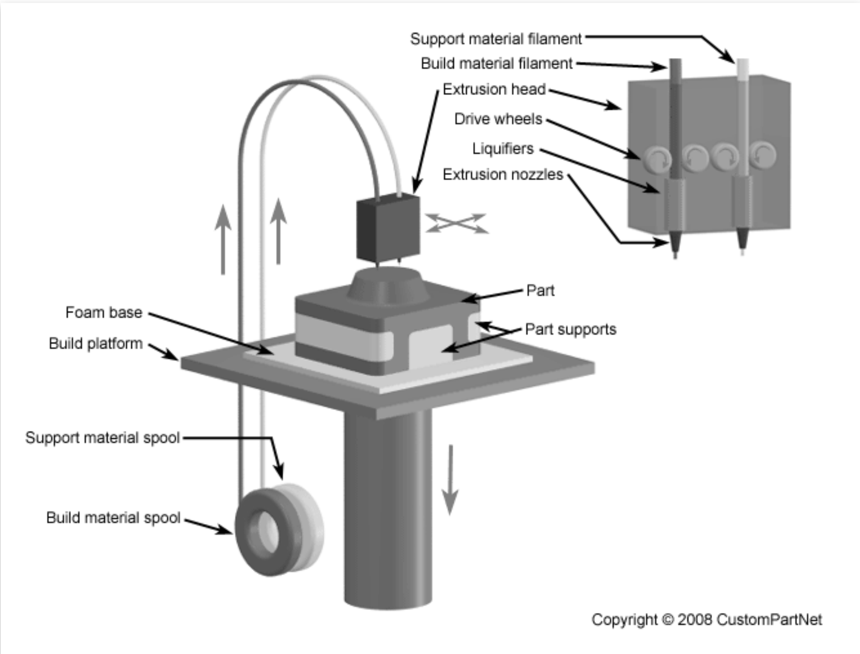

Figure 2.1 Fused-Deposition Process

Source: http://www.stratasys.com/3d-printers/technology/fdm-technology

To fabricate a complex part such as shown in **Figure 2.2 (a)**, support material will be extruded separately from the modeling material. As a result, the use of support structures allows all of the layers to be supported by the material directly beneath them as shown in **Figure 2.2 (b)**. The support material is produced with less dense filament spacing on a layer, so it is weaker than the model material and can be broken off easily after the part is completed (Abdullah, J., & Hassan, A.Y., 2003).

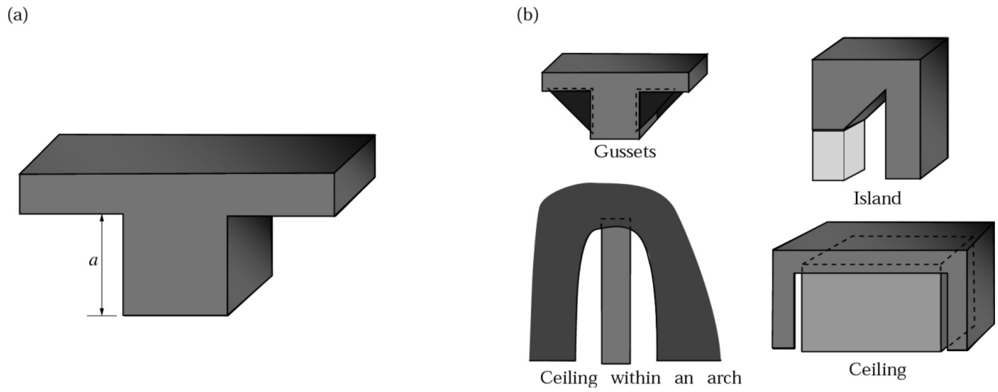

Figure 2.2 Support materials for complex part

Source: Kalpakjian, S. (2009)

2.4 APPLICATION OF RAPID PROTOYPING IN MEDICAL SECTOR

In the beginning of its inception, rapid prototyping was mainly used for product development in the manufacturing industry. The applications of RP were growing very fast. They progressed from making prototypes for parts to several engineering applications (Nyaluke, P.A. et al., 1995). It was used to speed up design process for household products, toys, tools and mechanical components. Among the evolving RP applications are the makings of molds for die casting, making of several parts required for medical applications. RP is widely used in many other science and engineering applications, with the medical sector representing 10% in 1999 and the usage is increasing (Abdullah, J., & Hassan, A.Y., 2003).

Based on the pioneering research that we have studied, we can see that there have already been applications of custom-made orthoses using RP. However, those researches do not specified or demonstrate the full manufacturing process of creating an AFO. In addition to that, most of the studies do not include gait analysis experiments to assess the mechanical effect of different design of orthoses. Comparing the efficiency and performance of different AFO's design would lead to an optimal standard design ideal for wide range of patients.

2.5 3D SCANNING IN MEDICAL FIELD

Instead of using the conventional method of pouring liquid plaster-of-Paris to create a hydrocolloid impression of the healthy anatomy, or the use of CT/MRI digitizer to capture both internal and external data of the healthy anatomy during the pre-process for prosthesis design, an alternative approach is to use the laser surface digitizer. Unlike CT/MRI digitizer, the data captured by the laser surface digitizer only consist of the external data of the healthy anatomy and not the internal tissue structure of the anatomy. By scanning only the external data, it will reduce the size of the image file and the processing time to convert the scanned data to CAD data (Kai, C.C., Meng, C.S., Ching, L.S., Teik, L.S., & Aung, S.C., 2000).

In addition, the laser scanner takes only seconds to capture images of the patient's healthy facial anatomy, and the usual file size is less than one megabyte. This is much better than the time needed to capture CT/MRI data. Furthermore, with the use of digitized data, it is easy to generate a mimic impression, reverse engineering, in the CAD environment, which is not possible by conventional technique (Kai, C.C., et al. 2000).

Another type of 3D scanner is based upon stereoscopic photogrammetry. 3D photogrammetric scanners use images captured from different points of view. Given the camera locations and orientations, lines are mathematically triangulated to produce 3D coordinates of each unobscured point in both pictures necessary to reproduce an adequate point cloud for shape and size reproduction.

2.5.1 ATOS 3D Scanner

Using the digitizing system ATOS (Advanced Topometric Sensor), objects can be measured quickly and with high local resolution. The ATOS system is based on the triangulation principle: The sensor unit projects different fringe patterns onto the object to be measured which are then recorded by two cameras. Each single measurement generates up to 4 million data points (ATOS III / 4M).

Reference points are self-adhesive or magnetic marks (measuring markers) which are applied to the measuring object. They have a defined geometry and a high contrast (white circle on a black back-ground). In addition, the reference points serve as connection points for the individual measurements and take care that these individual measurements can be transformed into a common coordinate system. The measuring data are made available as point cloud, sections or STL data.

2.6 GRAPHICAL SOFTWARES

In CAD, models are planned and conceived entirely on the computer screen, then converted to physical reality. In bio scientific applications, the objects already exist physically. Building models of them essentially involves reverse engineering, starting with acquiring data such as a stack of cross- sectional CT images (Zolikofer, P.E.C., & Leon, M.S.P., 1998).

In a case study by Chrisoph P.E Zollikofer, he used FoRM-IT (Fossil Reconstruction and Morphometry In teractive Toolkit) software to combine virtual reality and CAD data. The term real virtuality is used to define an environment where a user interacts with physical models of 3D objects generated or modified by a computer and produced with RP technologies. Data from natural objects must pass several preprocessing steps, such as feature extraction, 3D object reconstruction, reorientation, and modification. **Figure 2.3** shows the process flow of creating virtual object through 3D scanning

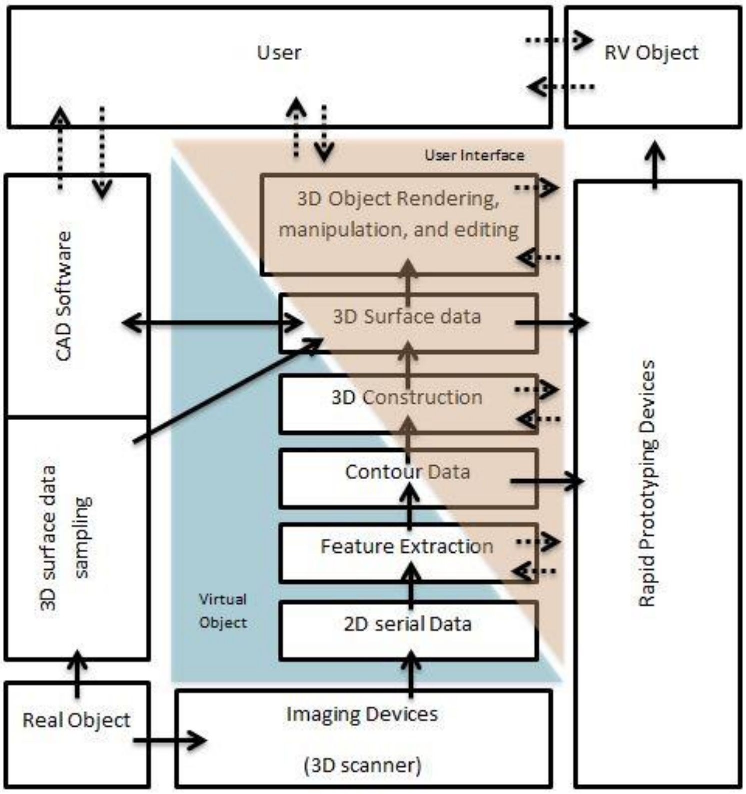

Figure 2.3 : Black arrows show possible pathways for data flow from the real object to the real virtuality replica. Virtual objects can be manipulated through a user interface (dashed arrows) at different levels of data representation.

Source: Zolikofer, P.E.C., & Leon, M.S.P., (1998)

2.6.1 ATOS V6.2

ATOS software is available for Windows operating systems for evaluating finished ATOS measuring projects. The functions of this software is to generate of STL or CAD data, Transfer of model modifications to CAD and making comparison of nominal/actual values between measured object and computer data (CAD model, point clouds or STL data).

2.6.2 GOM Inspect v75 SR1

GOM Inspect is a free 3D inspection and mesh processing software for dimensional analysis of 3D point clouds from white light scanners, laser scanners, CTs and other sources. In addition GOM Inspect is a free viewer for GOM Inspect Professional, ATOS and TRITOP Professional data.

2.6.3 Geomagic Studio 2012

Geomagic Studio is the complete toolbox for transforming 3D scanned data into highly accurate surface, polygon and native CAD models. A vital component in a range of manufacturing workflows, Geomagic Studio provides the industry's most powerful point cloud editing, mesh editing, and advanced surfacing functions in an intelligent, easy-to-use application. In addition to its precise 3D data processing functions, Geomagic Studio incorporates incredible automated tools, all of which enable users to produce the highest quality models in significantly less time and reduce costly man-hours. For reverse engineering, product designs, rapid prototyping, analysis and CAD export, Geomagic Studio is the core 3D creation tool.

2.7 ANKLES-FOOT ORTHOSES

Ankle Foot Orthoses (AFOs) are orthoses that encompass the ankle joint, the whole or part of the foot. AFOs are intended to control motion, correct deformity and/or compensate for weakness. AFOs can be designed with sufficient mechanical lever arms to control the ankle complex directly and to influence the knee joint indirectly (The Use of Ankle Foot Orthoses in the Management of Stroke, 2008). AFOs are presently the most widely used orthoses in the United States (US), accounting for 26% of clinical practice by certified orthotists, double that of any other type of orthosis. There are many types of AFOs, which may vary in their biomechanical design (including desired mechanical force systems, any joint or articulation, alignment and range of motion), materials and components (Practice Analysis of Certified Practitioners in the Discipline of Orthotics and Prosthetic, 2007).

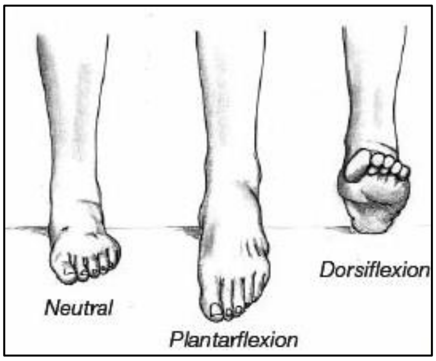

Figure 2.4: Dorsiflexion and plantarflexion of the foot

Source: http://www.studyblue.com/notes/note/n/musculoskeletal-systems/deck/5319192

To understand how AFOs work, we must first understand two standard motions that occur at the ankle joint “dorsiflexion” and “plantarflexion” shown in **Figure 2.4**. Plantarflexion is the motion the ankle joint makes when the toes point downward. Dorsiflexion is the motion the ankle joint makes when the foot points upward. This motion needs to occur when the foot comes off the ground so that the patient does not drag their toes. Patients with dropfoot usually have a partial or complete weakness of the muscles that dorsiflex the foot at the ankle joint.

Whatever types of orthoses are recommended or fitted, they share many common design points and try to provide some or all of the elements below:

i. Hind foot stability
ii. Mid-forefoot stability
iii. Contoured sole plates to assist in foot stabilization (tone reduction)
iv. Promotion of a stable base
v. Encouragement of good standing position with equal weight bearing on both feet.

The International Committee of the Red Cross published its manufacturing guidelines for ankle-foot orthoses in 2006. Its intent is to provide standardized procedures for the manufacture of high-quality modern, durable and economical devices to people with disabilities throughout the world. The guideline stated that there are four types of AFOs, each with their own unique characteristic (Manufacturing Guidelines – Ankle Foot Orthoses, 2003). **Figure 2.5** shows the manufacturing process done by Mavroidis, C, Ranky, R, G, 2011, where they used modern 3D scanning to fabricate an AFO

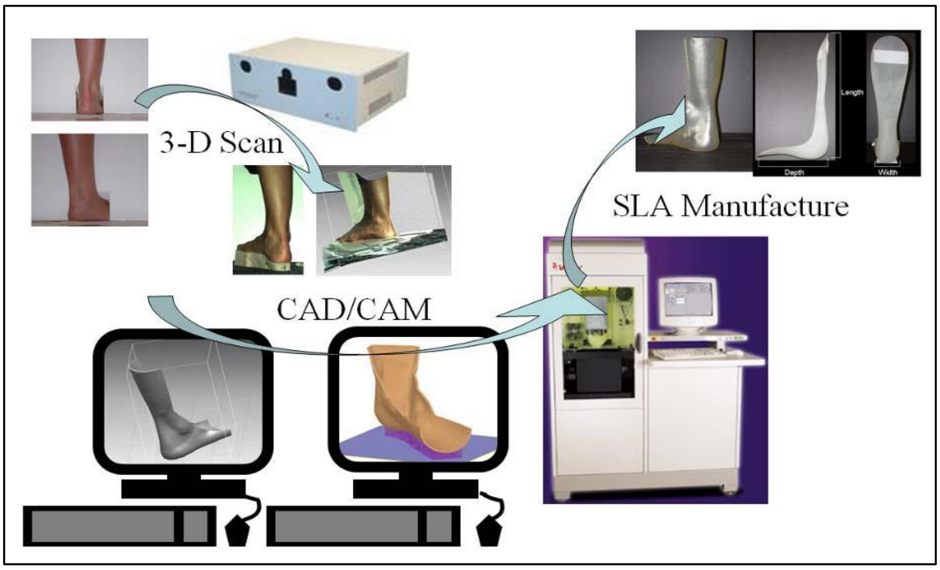

Figure 2.5: AFO created based on 3D scanning and fabrication by rapid prototyping

Source: Mavroidis, C, Ranky, R, G. (2011)

2.7.1 Solid AFO

The solid or fixed hinge version of an AFO maintains the foot and ankle in a fixed position. Plastic is molded in one piece to cover the back of the calf and bottom of the foot. The ankle joint angle is set to neutral, or 90 degrees (Brehm, M,A, Harlaar, J, 2008). The advantage of a solid AFO is to provide assistance during the swing phase of gait by keeping an individual's toes from catching the ground. The disadvantage of a solid AFO is the fact that by limiting ankle movement an individual will have some abnormalities in gait. Also an AFO is a short leg brace and does not provide enough stability in a tall individual over six feet four inches or individuals over 250 pounds. **Figure 2.6** shows examples of solid and rigid AFOs.

Figure 2.6 Solid and rigid ankle-foot orthoses

Source: http://www.cascade-usa.com/products/orthotics/

2.7.2 VARIABLES THAT INFLUENCE ABILITY OF AFO

The ability of an AFO to address foot problems largely depends on the variables that influence the alignment and design of the AFO. These variables include acquisition of measurements/impression, sagittal alignment of the AFO–footwear combination, footplate length of the AFO, lateral/medial trim lines of the AFO, and posting considerations (Bryan, S.M., & MHPE. 2011). One must also consider data acquisition and impression technique process. Although the data acquisition and impression technique provides information necessary to properly align the AFO, the alignment of the AFO on the patient and in the shoe has the greatest impact. Proper alignment requires a clear distinction between a patient's existing ankle angle compared with the AFO alignment in the shoe and the alignment of the tibia relative to the floor. The former can be determined during the impression technique phase, whereas the latter can only be assessed when the patient is wearing the AFO.

The initial alignment should focus on stabilizing the proximal joints of the lower limb and ensuring proper postural alignment. This is often between 10 to 12 degrees of a forward incline of the SAF. Brayan S. Malas (2011) found that a full-length footplate can increase stance phase dorsiflexion and plantar flexion moments around the ankle when compared with no AFOs. he full footplate length of a solid AFO design not only provides stability around the ankle, but can indirectly stabilize the knee and influence the alignment of the hip during walking.

2.8 GAIT ANALYSIS

Gait analysis is the study of lower limb movement patterns and involves the identification of gait events and the measurements of kinetics and kinematics parameters (Abu Bakar, N., & Wahab, Y., 2009). These include for example, toe-off, landing, stance, swing, displacement, speed, acceleration, force, pressure and the pressure-time-integral. In sports, gait analysis can be used to improve athlete's performance and injury prevention. For patients, such as those suffering from diabetes, gait analysis can be used to screen for development of foot ulceration thus preventing them. In term of gait stability, gait analysis is proven to be very helpful in assessing and improving balance among the elderly, patients with diabetes or peripheral neuropathy and many other sicknesses. Clinical gait analysis usually consists of 5 elements; videotape examination, measurement of general gait parameters, kinematic analysis, kinetic measurement, and electromyography (EMG).

2.8.1 Gait Parameters

Three measurements give a general idea of how well a patient walks. They are the cycle time, stride length and speed. They may be measured by having the patient walk a known distance, while timing them and counting footfalls, or these measures may be provided by the kinematic system (Whittle, M.W., 1996). General gait parameters may be plotted to show how the patient's gait compares to normal individuals of the same sex and age, and to compare the gait under different conditions, such as before and after treatment.

2.8.2 Gait Cycle

The gait cycle provides a standardized frame of reference for the various events that occur during walking. The gait cycle is the period of time for two steps and is measured from initial contact of one foot to the next initial contact of the same foot (Wahab, Y, 2011). Gait cycle can be referred in **Figure 2.7**. The gait cycle consists of two phases: 1) stance (when the foot is in contact with the supporting surface) and 2) swing (when the limb is swinging forward, out of contact with the supporting surface). Along with providing forward momentum of the leg, the swing phase also prepares and aligns the foot for heel-strike and ensures that the swinging foot clears the floor

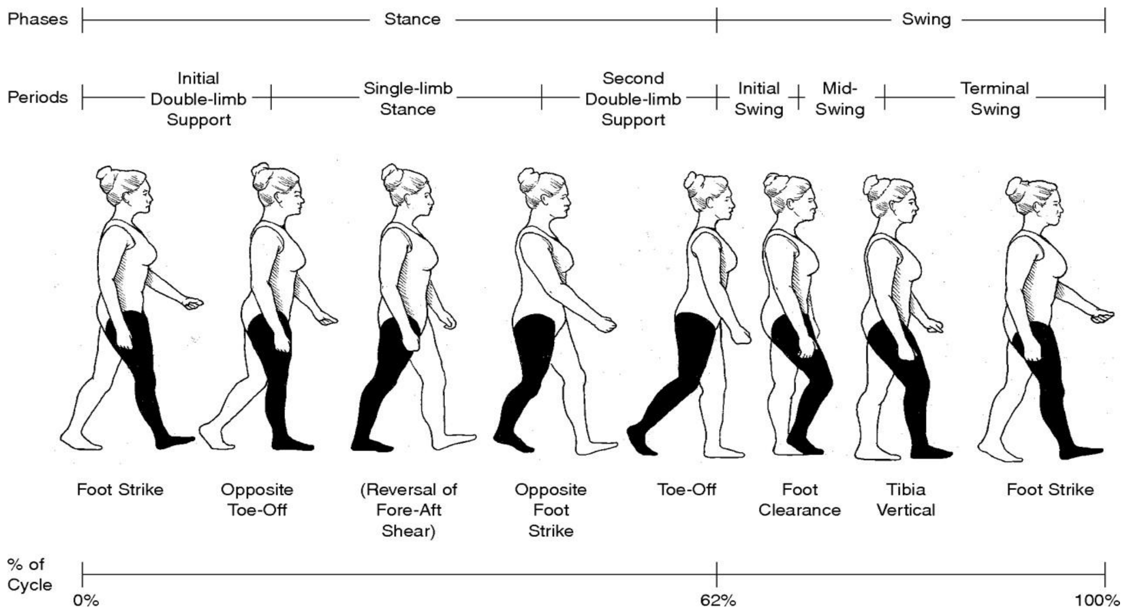

Figure 2.7 Gait Cycle

Source: http://www.jaaos.org/content/15/2/107/F1.expansion

Stance comprises about 60% of the total gait cycle at freely chosen speeds and functions to allow weight-bearing and provide body stability. **Figure 2.8** shows a case study by Mavroidis, C, Ranky, R,G, 2011, where they made two AFOs using 3D scanning using materials with different flexibility. Through the gait analysis, it is shown that the AFOs are able to restrict the ankle movement and perform just as well as prefabricated AFO.

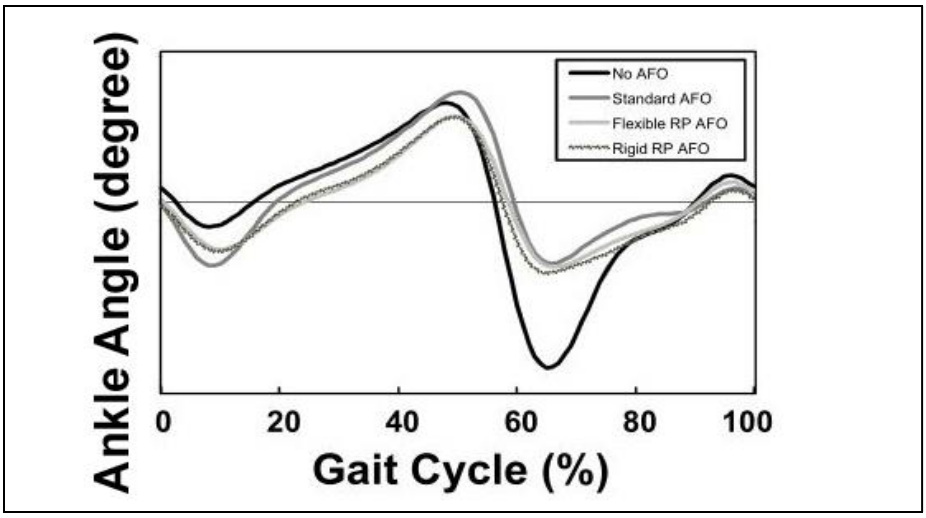

Figure 2.8 Gait Analysis using AFO made by 3D scanning and Prototyping

Source: Mavroidis, C, Ranky, R, G. (2011)

2.9 DROP FOOT DISORDER

Drop foot (also known as dropfoot, footdrop and foot drop) is a term that describes a disorder where a patient has a limited ability or inability to raise the foot at the ankle joint. This makes walking difficult as the toes tend to drag on the ground which leads to tripping and instability. Patients adapt to this by using their hip muscles to exaggerate lifting the foot above the ground or by swinging their leg outward so that the foot can clear the ground (Blaya, J.A., & Herr, H., 2004).

Treatment depends on the specific cause of foot drop. The most common treatment is to support the foot with light-weight leg braces and shoe inserts, called ankle-foot orthotics. Exercise therapy to strengthen the muscles and maintain joint motion also helps to improve gait. Devices that electrically stimulate the nerve during footfall are appropriate for a small number of individuals with foot drop. In cases with permanent loss of movement, surgery that fuses the foot and ankle joint or that transfers tendons from stronger leg muscles is occasionally performed. **Figure 2.9** shows a study by Chin, R, Wecksler, W (2009). In this study they made a pneumatic power harvesting ankle-foot orthosis to prevent foot drop experienced by the patient. The AFO greatly reduce the motion of ankle when reaching 70% of the gait cycle.

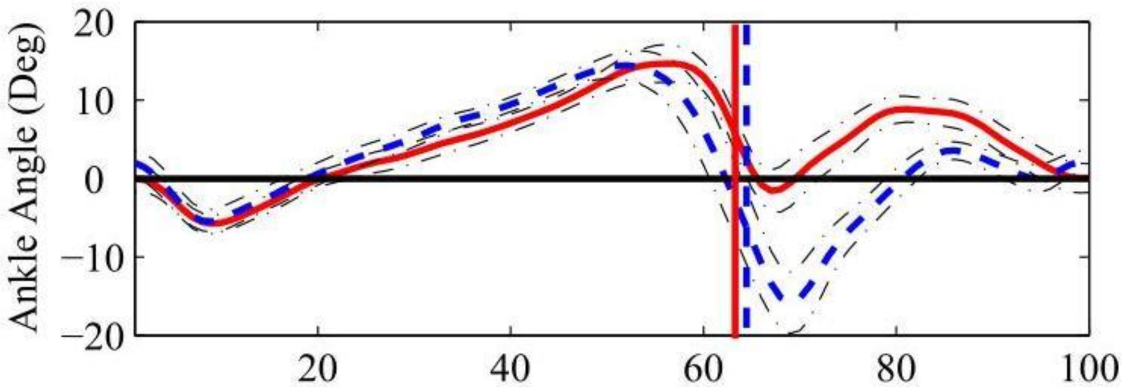

Figure 2.9: Gait Analysis from Drop foot patient

Source: Chin, R, Wecksler, W (2009)

CHAPTER 3

METHODOLOGY

3.1 INTRODUCTION

This chapter introduces the overall methodological approach that is used in the project. Process flow was created in order to ensure the smooth flow of each task in this project, followed by establishment of Gantt chart to make certain that this project was completed on time. Throughout this chapter, full detail explanation on how the project was conducted is explained. Below are the process flow charts for the project and methodology processes which focus on the manufacturing process of the orthotics.

3.2 METHODOLOGY FLOW CHART

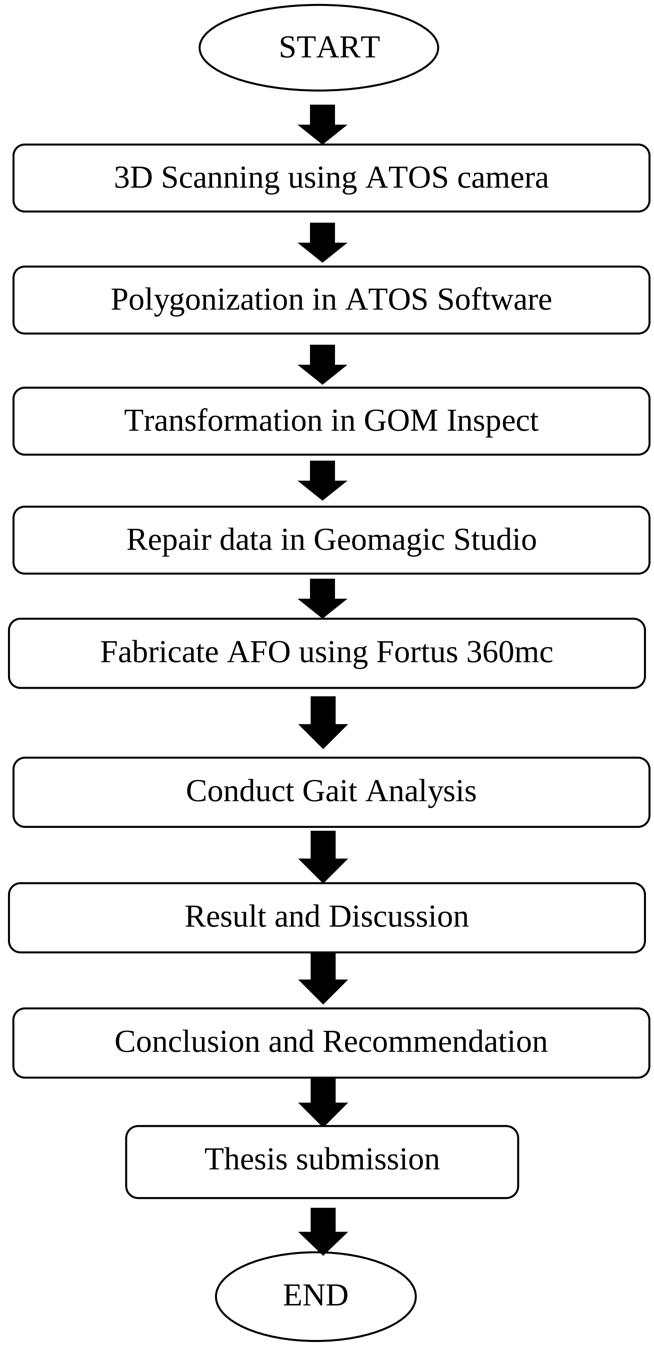

Figure 3.0: Methodology flow chart

3.3 3D SCANNING USING ATOS CAMERA

In order to digitize an object completely, several individual measurements are required from different angles. Based on reference points (circular markers), which are applied to the object directly or to the measuring plate or a fixture, ATOS transforms these individual measurements fully automatically into a common global coordinate system. **Table 3.1** shows ATOS 3D scanner capabilities. Figure X shows the ATOS camera used in this research.

Table 3.1 ATOS Configurations

System Configurations	ATOS I (0.8M)
Camera Pixels	800 000 pixels
Camera Frame	350 / 700 mm
Measured Points	800 000
Measurement Time	0.8 seconds
Measuring Area (min.)	125 x 100 mm²
Measuring Area (max.)	1000 x 800 mm²
Sensor Dimensions	440 x 140 x 200 mm³

Figure 3.1: ATOS 1 3D Digitizer

Firstly, the patient's foot is positioned in a way so that it was suitable for the scanning process to be conducted. The position should give the 3D scanner a room to create a full 3D point cloud of the ankle-foot complex and any other joint of interest. Data from below the knee and also to side of the foot is required for design purposes. The quality of data is directly by the camera locations for scans that were dictated by its range of field and view. To be able to digitize the feet completely, 26 images were captured from different angles. These individual measurements were transformed by ATOS fully automatically into a common global coordinate system based on 35 reference points, which were placed to the feet directly and to the base. The measured data are made available as point cloud, sections or STL data.

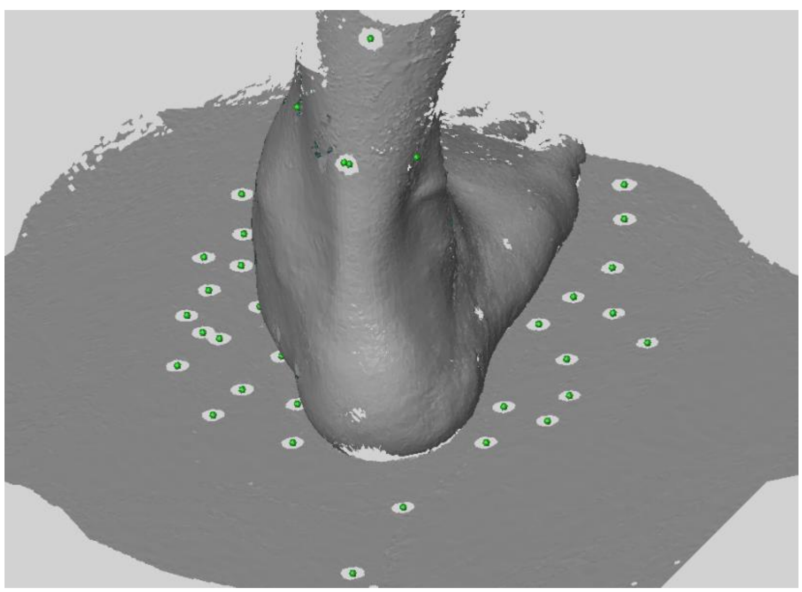

Figure 3.2: Scanned Data by ATOS

Titanium dioxide powder was sprayed at the measuring object as it does not provide sufficient contrast. This enabled the cameras to record the projected fringe pattern with better accuracy. A pattern of colored light was projected onto the target surface during scanning. To reconstruct the shape digitally, the reflected light from this pattern was captured at two different locations by camera lenses.

As soon as the measurements starts, the software calculates from the 3D coordinates of the reference points in the 2D camera image. The calculated 3D coordinates were then being calculated back again into the 2D camera images. For the position of the reference points, this results in the so-called reference point deviation. This value describes how well the second measurement suits the first one. An unstable object or a non-static measurement setup or a movement of the reference points with respect to each other will cause a high value of deviation. In this scenario, while the measurements were taken, the subject's leg might be moving.

Table 3.2: Data collected by ATOS 3D scanner

3D scanned measurement	
Reference Markers	35
Images Captured	26
Total Deviation	0.305mm

For each individual measurement, at least 3 reference points identified by the ATOS system in previous measurements must be recorded as well. 4 or more reference points are required that must not be in a line and, ideally, should be well distributed so that more optimum measurement could be required.

3.4 POLYGONIZATION IN ATOS SOFTWARE

Holes in the 3D data were caused by the reference point of an object being measured. By using the ATOS v6 software, these holes were later being filled automatically. The measuring points need to be transformed into an editable polygon mesh, right after the measuring have been digitized completely. This was achieved in the project mode by polygonization. Polygonization means that the measuring point cloud was converted into a mesh of non-overlapping triangles.

The mesh's densities are different, depending on the curvature of the object. This so-called polygonization raster can be adjusted. The individual measurements are fine adjusted to each other during the polygonization process and recalculated with the highest point resolution. The overlapping areas are deleted and stitched up to a polygon mesh.

3.5 TRANSFORMATION IN GOM INSPECT

First, the coordinate system in ATOS results arbitrarily. In order to be able to use the data, for example, for further processing by subsequent systems (CAD software) or to carry out inspection tasks, they need to be transformed into a defined coordinate system. In order to put a coordinate system in a defined condition, the nominal coordinates of some reference points or features need to be known. This might be CAD data, data of other measuring projects or data determined by coordinate measuring machines

. A method called 3-2-1 Transformation in **Figure 4.3** was used to define the coordinate system in this project. 3-2-1 means that three 3D points (Z1, Z2, Z3, located as far as possible from each other and not in a line) describe a plane, two additional 3D points describe a line (Y1, Y2, located as far as possible from each other in the X-axis) and one 3D point describes a point (X). **Figure 4.4** showed the scanned data that has been transform where its coordinate system has been defined.

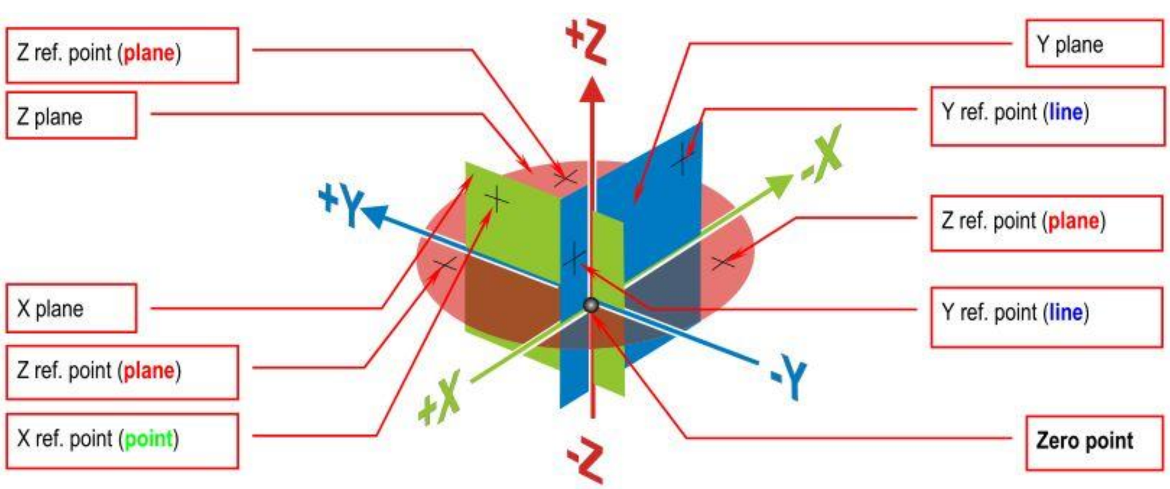

Figure 3.3: Transformation System in GOM Inspect

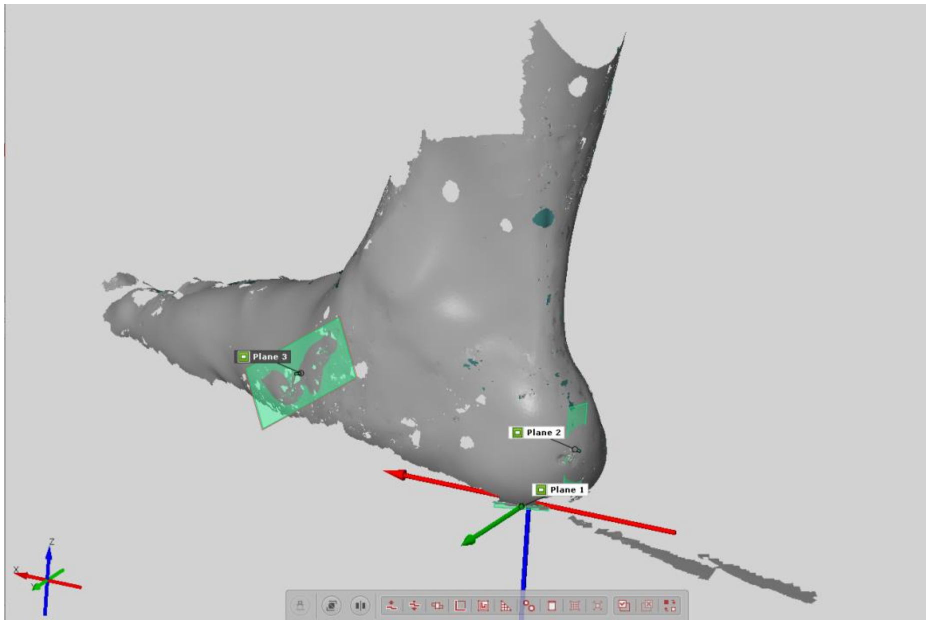

Figure 3.4: After the transformation process in GOM Inspect

3.6 REPAIR DATA USING GEOMAGIC SOFTWARE

In order to improve a polygon object's mesh in preparation for exact or parametric surfacing, it may be necessary to manually repair the mesh. Many different commands are provided for making all possible repairs.

3.6.1 Decimate

Decimate command allowed the reduction of the number of triangles in object's mesh without compromising surface detail or color. This command was used due to the object contains an excessive number of cloud points. This reduces the burden of the processing computer and fastens the repairing process.

3.6.2 Make Manifold

Make Manifold command were used to delete non-manifold triangles, which are triangles that are not connected to other triangles on all three sides, or on two sides if the triangle lies on an edge. These triangles are sometimes referred to as floating triangles. In some applications like rapid prototyping, a polygon object must be closed-manifold. A closed manifold object is a manifold object that encloses volume. Some applications like rapid prototyping require that a polygon object be closed-manifold. An open manifold object is a manifold object that does not enclose volume.

3.6.3 Enhancing the Subject Mesh

Using remesh command, the software retriangulate the polygon mesh to produce a more uniform tessellation, recreate the polygon mesh on a selected portion of a polygon object, or increases the number of polygons on the object. It is useful for converting coarse or sparse polygon meshes into dense, evenly distributed meshes for later processing. This command creates very regularly shaped triangles. The new mesh vertices will always lie on the original mesh, so it produced an accurate result. **Figure 3.5** shows the scanned data after it has been repaired

3.6.4 Trimming and creating thickness

After all the repairing process has been done, the scanned data was trimmed into the desired AFO's shape and shell command was used to create 3 mm thickness. The file is then saved in STL format and sent to rapid prototyping machine.

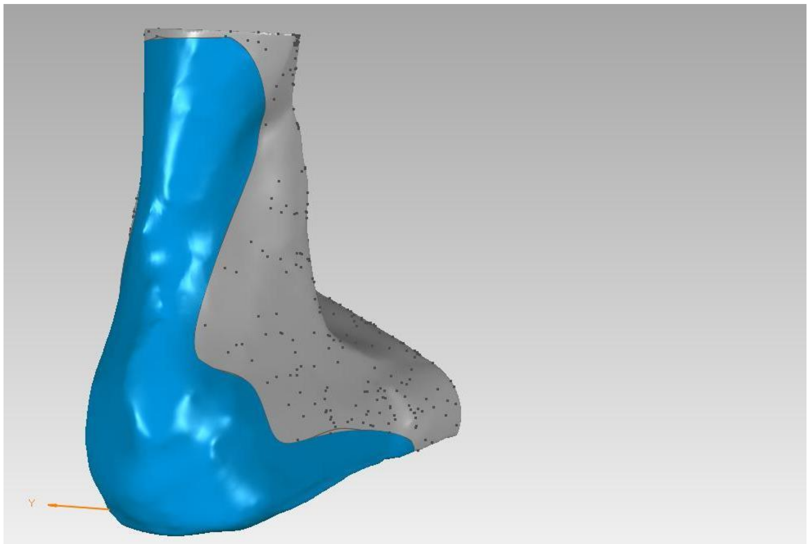

Figure 3.5: The Scanned data after it has been repaired

3.7 FABRICATE AFO USING FORTUS 360 MC

Fortus 360mc was used in this project as is suitable for high accuracy prototyping and direct digital manufacturing. Fortus 360mc capabilities are shown in **Table 3.2**. The system is equipped with an extrusion head and gantry that maintains tight positional accuracy and can produces parts with high tolerance. **Figure 3.6** shows the Fortus 360mc machine.

Table 3.3: Fortus 360mc Specifications

Fortus 360mc Specifications	
Build Envelope	(355 x 254 x 254 mm)
System Size/ Weight	50.5 x 35.3 x 77.3 in
	(1281 x 896 x 1962 mm)
Material Options	ABS-M30, PC-ABS, PC
Throughput Comparison	1.7 x
Achievable Accuracy	± .005 in (± .127 mm) or
	± .0015 in/in (± .0015 mm/mm)

Figure 4.6: Fortus 360mc rapid prototyping machine

Insight software prepares 3D digital part files (output as an STL) to be manufactured on a Fortus system by automatically slicing and generating support structures and material extrusion paths in a single push of a button. If necessary, users can override Insight's defaults to manually edit parameters that control the look, strength and precision of parts as well as the time, throughput, expense and efficiency of the FDM process.

3.7.1 Material ABS-M30

ABS-M30 was chosen as the material to be used in the orthotics as it is the only acceptable material in Fortus 360mc. ABS-M30 is up to 25-70 percent stronger than standard Stratasys ABS and is an ideal material for conceptual modeling, functional prototyping, manufacturing tools, and end-use-parts. ABS-M30 has greater tensile, impact, and flexural strength than standard ABS. Layer bonding is significantly stronger than that of standard ABS, for a more durable part. This results in more realistic functional tests and higher quality parts for end use. **Table 3.3** shows the properties of ABS-M30.

Table 3.3 ABS-M30 properties

Properties	Test Method	Metric
Tensile Strength	ASTM D638	36 MPa
Tensile Modulus	ASTM D638	2,400 MPa
Tensile Elongation	ASTM D638	4%
Specific Gravity	ASTM D792	1.04
Density	ASTM D792	0.0397 lb/in3
Rockwell Hardness	ASTM D785	109.5

3.8 GAIT ANALYSIS

Gait studies were conducted at Sports Department in mechanical engineering faculty, University Malaysia Pahang, Pekan. We collected video data from a healthy subject (the one for which scans were taken in order to manufacture the AFO) during the subject is walking on a treadmill. The subject will wear the AFOS on the right side. Two conditions will be tested;

I. Walking with without AFO

II. Walking with AFO

There were three parameters data that were collected;

I. Speed (m/s)
II. Step Length (m)
III. Double support (s)

Figure 4.7: AFO attach to the feet

The AFO were attached using Velcro strap slightly above the ankle and the tightness is adjusted according to the subject's comfort. Reference points were place right on top of the ankle; end of the foot and slightly higher than the Velcro strap so that it can be track in the kinovea software as shown in **Figure 4.7**.

3.8.1 Kinovea Software

The video captured was analyzed in kinovea software. To determine the speed of the subject, a tape with the length 0.50 was placed besides the treadmill to be calibrated in the software. The reference marker place on the leg was tracked and the speed was acquired in one full gait cycle. The stride length was obtained by drawing lines in the video software. By using a stopwatch feature, we obtained the amount of time for double support in seconds. **Figure 4.8** shows the tracking motion of kinovea software; it tracks and calculates the speed of the reference point based on the calibrated distance of 0.50 m

Figure 4.8: Calibrating distance and tracking the speed in Kinovea

Figure 4.9: Measuring ankle angle in Kinovea software

To compare the effectiveness of the custom-made AFO, the ankle angle measurement were taken for each phase in the gait cycle. This process is done manually frame by frame as the software was unable to track the angle of reference point efficiently. A total of 10 measurement angles were taken for the two tests in a complete gait cycle and the value were plotted in graph to obtain a clear difference between the two results. **Figure 4.9** shows how the measurements were taken in Kinovea Software. These measurements were later plotted into graph and comparisons are made side by side.

CHAPTER 4

RESULT AND DISCUSSIONS

4.1 INTRODUCTION

This chapter shows all the result obtained from this project. Table of results, graphs and figures are included. Detailed explanation of graphs and figures are also provided.

4.2 DEVIATION ANALYSIS

After the scanned data has been repaired, deviation analysis was conducted through Geomagic software to identify which part deviate the most with the original scanned data. Certain scanned data deviates when features such as auto repair mesh, remesh, rewrap were used in the process of repairing the creased edges and small holes.

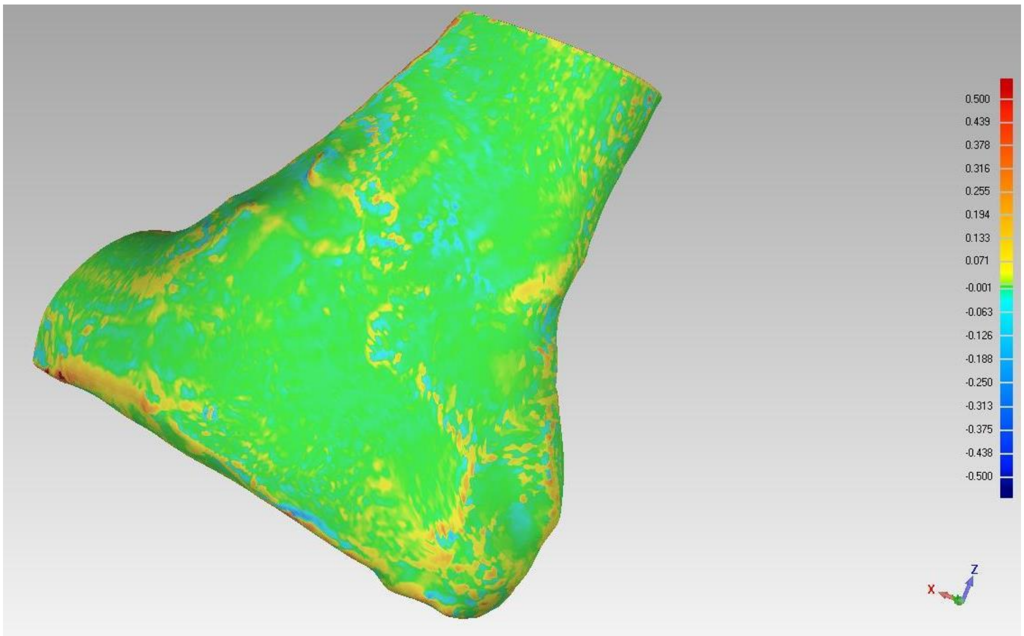

Figure 4.1: Deviation analyses of the scanned data

Deviation Analysis displays the graphical comparison of the current entities to original scanned data. The deviations do not necessarily indicate a problem. In this case, if the data deviates too much, the repairing process will be redone to ensure that any deviation is kept to the minimum. The Deviation analysis result is as follows;

i. Max Deviation : 0.009 mm

ii. Average Deviation : 0.001 mm

iii. Standard Deviation : 0.004 mm

As the figure shows, the maximum deviation is located at the beneath the feet. This is the area where Geomagic studio is used to fill the empty gap and create the structure for the sole. The Filling Holes commands detect the presence of holes, construct a polygon mesh over each hole, and provide additional commands for customizing the new polygon mesh. This features results in deviation of the scanned data with the maximum amount of 0.009 mm. Average Deviation of 0.001 mm is the result of the calculated average deviation for the whole scanned data.

4.2 AFO PROTOTYPE

The prototype built using the ABS-M30 filament is shown in Figure **X**. The model was built in an inclined orientation since it did not fit sideways to save up on support material. The build cycle consisted of hundreds layers of heated polymer and was built in the total time of 5 hours due to the large z-build dimension. Fitting of the rigid RP AFO prototype according to the subject was excellent. The optimal fit of the AFO geometry to the human subject anatomy was evident from visual inspection and the subject expressed great comfort whilst wearing it.

Figure 4.2: Fabricated Ankle-Foot Orthoses

4.3 TESTING AND VALIDATION

To ensure the two trials can be compared accurately, the conditions between the two trials were replicated as best as possible. The walking speed was considerably the same between the two tests as the subject walk according to the treadmill speed. Stride length and double support time was also measured to be the similar.

Table 4.1: Gait Parameters

Parameter	No AFO	With AFO
Speed (m/s)	0.463	0.465
Stride Length (m)	0.29	0.29
Double support time (s)	0.2	0.29

A total of 10 ankle angle measurements were taken for the two tests were plotted and compare side by sided. To give a clear picture of the results, the ankle angles have been divided into two parts; plantarflexion and dorsiflexion. The ankle angle is subtracted from the neutral angle position (90 degree) which gives the graph in **Figure 4.3**. The ankle kinematics showed the effect of the AFOs. The blue line in **Figure 4.3** shows the ankle measurement divided into plantarflexion-dorsiflexion for one gait cycle collected during the walking trials performed with-out AFO. This pattern is typical of individuals without gait abnormalities.

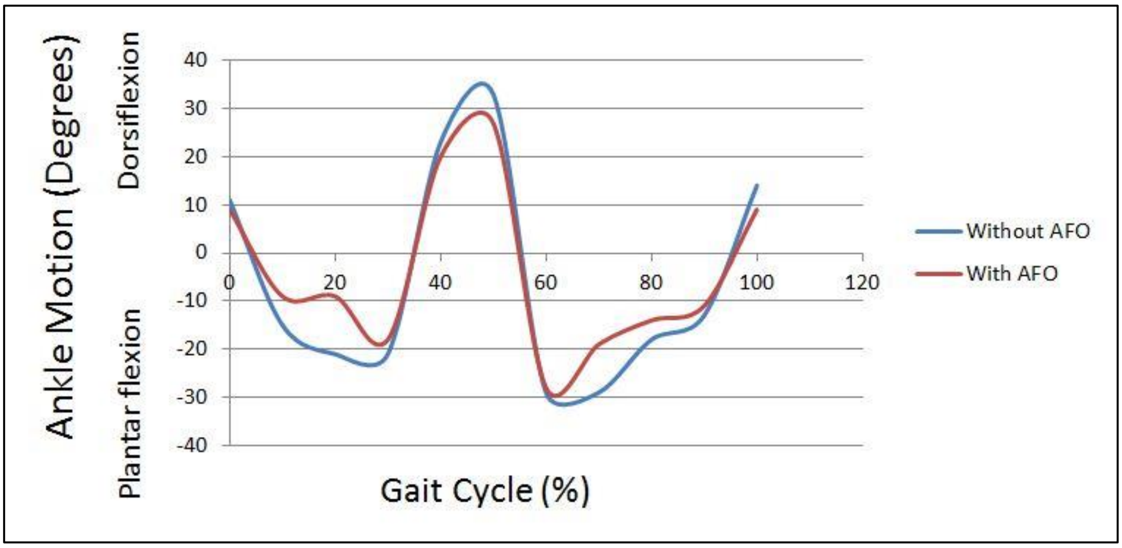

Figure 4.3: Ankle Motion in one complete gait cycle

The Gait analysis is break down into 6 major periods in order to see in details the effect of AFO towards the ankle range of motion.

I. Period 1: Initial Double Limb Support (0-12% of gait cycle)

   This period begins with the first foot strike and ends with the opposite foot's toe-off. During this period, the AFO doesn't show any restriction to the ankle motion. However the restriction starts at the end of the period. The ankle goes from a neutral position to plantarflexed until the foot is flat on the floor.

II. Period 2: Single Limb Support (12-50% of gait cycle)

   This period begins with the opposite toe off and ends with opposite foot strike. The AFO restrict the most in this period with the amount of 10 degrees at 20% of the gait cycle. At 50% of the gait cycle, it restricts more than 5 degree of the ankle motion. The ankle dorsiflexes throughout the phase but actively plantarflexes towards the end to resist this dorsiflexion.

III. Period 3: Second Double Limb Support (50-62% of gait cycle)

   This period begins with opposite foot strike and ends with toe off. The AFO performs considerable the same without wearing AFO. This is due to the fact that the AFO doesn't affect the swinging motion of the foot. The ankle plantarflexes during this time in order to prepare for the limb's lift off.

IV. Period 4: Initial Swing (62-75% of gait cycle)

   It begins when the foot is lifted off the ground (toe-off) and ends when the swinging foot clears the ground and is opposite the standing opposite foot. During this period, around 10 degrees of ankle motion were restricted by the AFO. The ankle continues to plantarflex but then begins to dorsiflex in order to clear the ground.

V. Period 5: Mid-Swing (75-85% of gait cycle)

   It begins with foot clearance where the feet are adjacent and ends when the swinging foot is in front of the body. Throughout this gait period, the AFO restrict around 5 degrees of ankle motion as the ankle continues to dorsiflex to neutral.

VI. Period 6: Terminal Swing (85-100% of gait cycle)

This is the last phase of the gait cycle. The foot is preparing for heel strike and repeats the cycle back to period 1. The AFO restrict close to 5 degrees as the gait approaches 100%. The ankle remains dorsiflexed to neutral.

CHAPTER 5

CONCLUSION AND RECOMMENDATIONS

5.1 INTRODUCTION

This chapter summarizes the whole project and suggested the ways to improve the project in the future. It concludes all the outcomes, observation of results and analysis, and discussion throughout the experiment. The conclusion is based on the results obtained from the Gait Analysis through Kinovea Software. Recommendations are also given to improve this study in the future**.**

5.2 CONCLUSION

As for conclusion, this project has achieved its target which was to design and fabricates ankle foot through 3D scanning and reverse engineering software. By designing the AFO based on exact 3D scanning of the subject's feet, the prototype able to provides appropriate comfort and fit. Analysis conducted on the AFO prototype also showed that it is able to perform its intended function, which is to restrict ankle range of motion. This characteristic is needed for patients who experience drop-foot disorder. The process of designing orthoses using reverse engineering software and 3D scanning would permit changes in the standard design to meet the exact needs of each patient. If the patient want to recreate another orthoses, another 3D scan is not required as the previous data already available. Compare to the traditional method of storing and keeping the cast of the leg for a few months, this new modern new method definitely saves space and time for patient who wanted to create AFO.

5.2 RECOMMENDATIONS

Throughout the project, there are several recommendations that can greatly improve the future of this research.

1. By scanning an object on a rotation table, the 3D measurement process can be simplified by making the 3D camera stationary. Hence, reducing the risk of disconnecting firewire cable from the camera to the ATOS software and enabling the scanning to be done in small spaces as the camera does not need to move around.

2. Designing AFOs with hinged should provide more flexibility and comfort to the foot and ankle. This design is a lot more complicated as it uses rivet to control the range of motion of the AFO. However, it will give better control for the user in controlling gait cycle.

3. Repairing scanned data without decimating the polygon data would preserve more detail of the feet. Thus, producing more accurate result of the structure of the feet. This will also increase the processing time taken to repair the object and would require computer with better performance to handle the burden.

4. By using different material for the rapid prototyping process, we could see how flexibility of materials could affect the performance of the AFO. Flexible materials could provide a much more comfortable experience during walking and gives a clear result of its effectiveness in gait analysis.

5. To gives more support towards the validity of the results, the use of EMG and force plate are recommended during the process gait analysis. EMG could show how AFO affect the muscle activities and force place can detect the power applied as the heel strike during the gait cycle.

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APPENDICES

APPENDIX A1

GANTT CHART FOR FYP 1

No	Items		SEPTEMBER			OCTOBER				NOVEMBER				DICEMBER		
			WEEK 1	WEEK 2	WEEK 3	WEEK 4	WEEK 5	WEEK 6	WEEK 7	WEEK 8	WEEK 9	WEEK 10	WEEK 11	WEEK 12	WEEK 13	WEEK 14
1	Kick-off meeting	Plan	■													
		Action		■												
2	Problem Statement	Plan			■											
		Action				■	■									
3	Objectives	Plan			■											
		Action				■	■									
4	Project Scope	Plan			■											
		Action				■	■									
5	Process Flow	Plan				■										
		Action					■	■								
6	Literature Review	Plan				■										
		Action					■	■	■	■						
7	Develop Methodology	Plan					■									
		Action						■	■	■	■	■	■			
8	Project Proposal Report	Plan											■			
		Action												■	■	
9	Project Presentation	Plan													■	
		Action														■

APPENDIX A2

GANTT CHART FOR FYP 2