DESIGN AND TESTING OF PATIENT-SPECIFIC ANKLE FOOT ORTHOSIS

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DESIGN AND TESTING OF PATIENT-SPECIFIC ANKLE FOOT ORTHOSIS

by

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DECLARATION

This work has not previously been accepted in substance for any degree and is not being concurrently submitted in candidature for any degree.

Signed………………………………… (Muhammad Ahnaf Ataulah Bin Md Sukri)

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This thesis is the result of my investigations, except where otherwise stated.

Other sources are acknowledged by giving explicit references.

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Specially dedicated to
my beloved mother and father

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LIST OF ABBREVIATIONS

3D	Three Dimensional
ABS	Acrylonitrile Butadiene Styrene
AFO	Ankle Foot Orthosis
ALS	Amyotrophic lateral sclerosis
AM	Additive Manufacturing
CAD	Computer Aided Design
CI	Confidence of interval
CM	Conventional Manufacturing
CP	Cerebral palsy
CT	Computerized Tomography
DAFO	Dynamic Ankle Foot Orthosis
FDM	Fused Deposition Machine
FRAFO	Floor Reaction Ankle Foot Orthosis
GRAFO	Ground Reaction Ankle Foot Orthosis
HAFO	Hinged Ankle Foot Orthosis
HUSM	Hospital Universiti Sains Malaysia
MRI	Magnetic Resonance Imaging
PCL	Polycaprolactone
PLA	Polylactic acid
PLS AFO	Posterior Leaf Spring Ankle Foot Orthosis
SAFO	Solid Ankle Foot Orthosis
STL	Stereolithography
TBI	Traumatic Brain Injury
TPU	Thermoplastic Polyurethane

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REKABENTUK DAN PENGUJIAN ORTOSIS KAKI KHUSUS PESAKIT

ABSTRAK

Gaya berjalan yang tidak normal adalah kecacatan kaki yang biasa berlaku di mana pesakit tidak dapat menggerakkan kaki depannya semasa berdiri dan berjalan disebabkan oleh kecacatan kaki. Orthosis kaki (AFO) ialah peranti perubatan yang dipakai untuk membantu pergerakan harian pesakit yang mengalami kecacatan akibat strok. Walau bagaimanapun, produk sedia ada di pasaran adalah mahal, dan tidak sesuai untuk pesakit tempatan kerana iklim tropika yang panas dan lembap. Produk sedia ada juga tidak sesuai dengan profil kaki pesakit, yang menyebabkan ketidakselesaan. Dalam penyelidikan ini, dua jenis ortosis kaki telah berjaya dibangunkan, iaitu, Jenis 1 (AFO Hibrid) dan Jenis 2 (AFO berengsel) telah direka menggunakan mesin Creality Ender 5 yang menggunakan teknologi percetakan 3D dan pengimbasan 3D. Selain itu, dua lagi model Jenis 3 dan Jenis 4, daripada hasil kerja Yong Shien dalam penyelidikan sebelum ini juga telah diambil untuk tujuan analisis gaya berjalan yang menjadi minat utama dalam penyelidikan ini. Analisis gaya berjalan dijalankan sebagai perintis kajian klinikal untuk menguji prestasi ortosis dalam proses pemulihan di Hospital USM. Dalam kajian itu, dua pesakit telah diuji dengan ortosis kaki untuk menilai prestasi gaya berjalan. Didapati bahawa penggunaan mana-mana ortosis boleh memperbaiki kecacatan gaya berjalan pesakit semasa program pemulihan. Keputusan menunjukkan bahawa ortosis kaki Jenis 2 (AFO berengsel) meningkatkan masa kitaran berjalan [CI = 95%; Tanpa AFO vs. Dengan AFO; 3.58 ± 0.18 vs. 2.92 ± 0.21 s; $p = 0.0302$] untuk pesakit yang aktif, manakala tiada perbezaan ketara dalam keberkesanan AFO Berengsel dalam meningkatkan prestasi gaya berjalan pesakit pasif semasa terapi pemulihan (CI = 95%; Tanpa AFO vs. Dengan AFO; 4.05 ± 0.49 vs. 4.07 ± 0.63; $p = 0.32$). Oleh itu, hasil kajian mencadangkan bahawa bagi pesakit aktif, kedua-dua jenis ortosis adalah sesuai dan menghasilkan peningkatan yang ketara, manakala ortosis kukuh (Solid AFO) lebih sesuai bagi pesakit pasif dengan perbezaan ketara ($p = 0.025$). Percubaan klinikal selanjutnya akan diperlukan untuk menyiasat lebih lanjut keberkesanan ortosis kepada pesakit strok sub-akut dalam membangunkan ortosis kaki yang berfungsi sepenuhnya untuk terapi pemulihan gaya berjalan.

DESIGN AND TESTING OF PATIENT-SPECIFIC ANKLE FOOT ORTHOSIS

ABSTRACT

Abnormal gait is a common foot deformity where the patient is unable to move his forefoot during stance and walking position due to involuntary plantarflexion. An ankle-foot orthosis is a medical device worn to assist the daily mobility of patients suffering from ankle-foot deformity because of stroke or accident. However, the available product in the market was costly, and the design was not suitable for local patients due to the hot and humid tropical climate. The currently available product also does not fit perfectly to a specific patient's foot profile, resulting in discomfort and therefore less usage by the patient. In this research, two types of Ankle Foot Orthosis (AFO) devices have been successfully developed. Two AFO models, which are Type 1 (Hybrid AFO) and Type 2 (Hinged AFO) were fabricated by using Creality Ender 5 machine utilising 3D printing and 3D scanning technologies. Apart from that, two other models Type 3 and Type 4, from previous work by Yong Shien also have been taken for gait analysis purposes which is the main interest in this research. The gait analysis is conducted as a pilot clinical study of the AFO performance in the rehabilitation process in Hospital USM. In the study, two patients have been tested with the devices to evaluate the performance of each AFO. It is found that the use of any AFO devices can improve a patient's gait deformity during the rehabilitation program. The result shows that Type 2 (Hinged AFO) improved gait cycle time [CI = 95%; Without AFO vs. With AFO; 3.58 ± 0.18 vs. 2.92 ± 0.21 s; $p = 0.0302$] for active patients, while there is no significant difference between the effectiveness of the Hinged AFO in enhancing the gait performance of a passive patient during the rehabilitation therapy (CI = 95%; Without AFO vs. With AFO; 4.05 ± 0.49 vs. 4.07 ± 0.63; $p = 0.32$). This, suggests that in the case of an active patient, both types of AFO are suitable and produce a significant improvement, while solid AFO is more suitable to improve the gait parameters for the passive patient with a significant difference of ($p = 0.025$). A further clinical trial will be required to further investigate the efficacy of the devices to sub-acute stroke patients in developing a fully functional ankle foot orthosis for lower limb rehabilitation therapy.

CHAPTER 1

INTRODUCTION

1.1 Brief Overview

Ankle foot orthosis is foot support, commonly made of plastic polymer, worn by a patient with foot deformities to support one's foot and ankle in the appropriate position. An ankle foot orthosis is usually prescribed for a person with a peripheral neuropathy problem resulting in the body's nerve-ending damages that often cause body weakness, numbness, and pain contributing to gait problems [1]. Persons with hemiplegia are also commonly prescribed with foot orthosis to improve gait flaws such as weak points on the distal muscle which affected foot drop during the swing and inadequate push-off during walking possibly caused by extensor hypertonia in the lower limb which is generally found in a stroke patient [2].

Abnormal gait is a common foot deformity when a person has difficulties walking in the normal way which includes foot drops where the patient is unable to move his forefoot during stance and walking position. This causes involuntary plantarflexion and results in restriction in the range of ankle movement. The main cause of foot drop problems is the injury to the peroneal nerve that regulates muscle movement including foot lifting during walking [3]. Another cause of foot drop is musculoskeletal disorders and neuromuscular diseases such as amyotrophic lateral sclerosis (ALS), peripheral neuropathy, polio, and cerebral palsy (CP) which causes progressive muscle weakness [4]–[6]. Ankle foot orthoses are also known by other different names such as "Orthosis", "AFO" and "Foot brace".

Currently, there are two different ways of AFOs being made and sold in the market which include the typical off-the-shelf and custom-made AFOs. Typical off-the-shelf AFOs, usually have a rigid body with a fixed arc at the ankle, presuming that patient can get a normal ankle stance. This type of AFO is usually much cheaper and could come in handy for a person with minor to moderate foot deformity as off-the-shelf AFOs usually can be bought without any prescription from an orthotist or medical expert. However, for a patient with musculoskeletal impairments or peripheral neuropathy which limits the patient dorsiflexion and plantarflexion of the ankle, off-the-shelf AFOs might not be suitable for these patients due to the required effect on the foot and ankle might not be observed [7]. Additionally, poorly fitted AFOs may result in excessive pressure on the skin and awkward fitting which can lead to ulceration and skin wounds to further causing bacterial infections and discomforts [8].

On the other hand, there are custom-made AFOs in the market which are usually prescribed by medical experts before being made specific to each patient according to their needs. Custom-made AFOs are typically more expensive and require a medical expert to assess a patient's condition prior to the prescription of the AFO [9]. However, custom-made AFO is much more efficient for a patient with moderate to severe foot extremities due to its long-term effectiveness in improving foot deformities. Custom-made AFOs are designed to provide effective support for both dorsiflexion and plantarflexion stance as they are fitted well to the foot, which can be used as a relief for ambulation and provide support during the movement in various gait phases [10]. Numerous types of ankle joints and connectors are articulated to restrict and/or aid plantarflexion and dorsiflexion needed. According to Wang et al. [11], their study suggests that custom-made AFO significantly improves balance and reduces the fear of falling for older adults with poor coordination. Additionally, the study also stated that with a custom-made AFO, the patient is more likely to put higher commitment and devotion to using the AFO and will achieve more benefit and confidence during the rehabilitation process.

1.2 Project Background

Ankle foot orthosis (AFO) is a medical instrument that is used by patients worldwide to correct the function of a lower limb, improve gait flaws, and enhance walking anomalies that were caused by different chronic medical conditions such as peripheral neuropathy, polio, and cerebral palsy. In Malaysia, local patients often feel uncomfortable and discomfort during their rehabilitation process due to wearing unsuitable AFOs that fit poorly to their foot profile. Additionally, the tropical climate in Malaysia where the weather is hot and humid over the years caused excessive sweating and allergies which can lead to skin infection and blisters all over the contact area between the feet and the AFO [12]. On the other hand, according to a study in the US Army, researchers conclude that footwear could influence one's fatigue, injuries, and performance in unfavorable weather conditions where the common problem with footwear includes insufficient padding, support and ventilation could lead to higher risks of foot pain, back pain, and discomforts which eventually will reduce rehabilitation efficacy [13]. To improve the rehabilitation success and efficacy for local patients, custom-made AFO is required to be developed and sold in the market which suits local needs.

The traditional manufacturing method for producing an AFO that is still used in Malaysia in the present day involves a plastic thermoforming process. In general, thermoforming is a generic process that begins with thermoplastic sheets or films formed over the positive mould through the controlled range of heat and pressure applied to the thermoplastic sheet where it is soft and malleable [14]. The common procedure in traditional AFO production starts with plaster mould casting with a mixture of plaster slurry which includes gypsum (calcium sulphate), talc, silica flour, and water poured and carefully mould around the patient's lower limb to create a negative mould. Seconds after the plaster slurry is set and dried, the patient's limb is removed, and the plaster mould is filled with another plaster slurry to create a positive cast. The positive cast is then further dried at a higher temperature which ranges around $200°C - 300°C$. Then, a thermoplastic sheet is heated to a temperature above the glass-transition temperature where it is in soft and malleable condition. Then, the thermoplastic sheet is given enough force against the cast surfaces by vacuum forming to get the desired shape [15]. However, the main disadvantages of the traditional method of producing custom-made AFO include time-consuming, labour-intensive processes and requiring high skill expertise due to the complexity of the process. Additionally, the process also produces more waste materials, as the plaster cast and mould are discarded as the materials cannot be recycled. Zhen et al. (2019) in their study also state that the AFO made by using the traditional method is often huge and lacks customised comfort and functionality [16]. Thus, a new approach to AFO fabrication techniques should be further studied and implemented for the local market to improve the quality and user experience of using an AFO.

This project thesis will discuss the utilization of a new approach to AFO fabrication technique available such as the application of the Additive Manufacturing technique which involves the use of 3D scanning, 3D printing, and Fused Deposition Modelling technologies that have gained popularity in recent years. Additive Manufacturing (AM) presents numerous benefits compared to the traditional methods, especially in large-scale production where optimisation and customisation are preferred [17]. Additive manufacturing in AFO start with the acquisition of the geometrical data from the patient's lower limb: the process is done by using 3D scanning technologies integrated with several specific device and software to obtain the foot contours and surfaces. The second step in the technique is the foot data conversion to "stl" format and import to CAD compatible software: for this purpose, MediAce 3D software is used as the primary CAD software for the project. The third step is to model the AFO parametrically into the desired shape around the foot mesh and optimised thoroughly to withstand the imposed stresses. The AFO model is then 3D printed using a Fused Deposition Machine (FDM) and tested on the patient [18].

1.3 Problem Statement

Current AFOs sold in the market come in two ways which are off-the-shelf, and custom-made AFOs. Typical off-the-shelf AFOs are commonly made in bulk from overseas mainly from China. Usually, they are made in various design and sizes which comes with a solid and rigid body. These AFOs are much cheaper and can be adjusted to produce handy and functional devices. However, such AFOs are manufactured in bulk and follow general specifications and sizes which means it does not solve specific requirements as each patient requires certain needs according to their unique problems. On the other hand, custom-made AFOs may be able to solve the specific needs of each patient due to their customisation. However, the majority of the AFOs manufactured in the local market are still using the traditional and old technique which is not suitable for the modern demands as they are time-consuming, labour intensive, and require high skill expertise which can lead to a long lead time.

Additionally, the traditional technique also produces more wastage as the used materials are not suitable to be recycled. Numerous studies have shown that utilising the Additive Manufacturing technique as a modern approach in AFO fabrication might improve the quality and user experience. Also, customised AFOs that utilised modern technique available in the market are usually imported from overseas (mainly China and Europe) and have a high price tag of more than RM1500 per device. Finally, the majority of the AFOs sold in the market do not have a user monitoring system as an initiative to measure and predict the efficacy of the rehabilitation process.

1.4 Objectives

The main objectives of this project are as follows:

1) To develop and improve current AFO design by utilising the most recent technology development such as the Additive Manufacturing technology in the scope of healthcare and medical advancement.
2) To evaluate the performance and efficiency of four AFO designs on the improvement of the gait cycle in patients with stroke and foot drop conditions by using a gait analysis study.

1.5 Scope of the Project

The additive manufacturing method (3D printing technology) is utilised to develop an Ankle Foot Orthosis (AFO) for the usage of stroke and foot drop patients in rehabilitation therapy programs. Several parameters are taken into consideration in designing the AFO which include cost, structure flexibility, material selection, and comfortabilities. In the design phase, a custom 3D foot model is acquired to develop the AFO design by using a specific medical CAD software: Medi Ace 3D. Two (2) stroke patients are recruited to undergo the selected testing procedure with each of the gait parameters obtained during the rehabilitation exercise studied by using Kinovea software. The data obtained from the clinical testing is statistically analysed to evaluate the significant effect of each AFO design on the patient's gait.

CHAPTER 2

LITERATURE REVIEW

2.1 Introduction

This chapter underlines the study and research works that have been done by other researchers to investigate ankle foot orthosis (AFO), their customisation, the problems, manufacturing methods, current design, and improvements that have been made. Additionally, the issue regarding the main reason causes the need for AFOs including specific medical conditions and gait flaws and analysis are also discussed to find out the abnormalities of the biomechanical mechanisms during the gait cycle and their effect during the rehabilitation process. Finally, this chapter also discusses the common testing methods of AFO analysis and clinical testing that is related to AFO performance.

2.2 Ankle Foot Orthosis

Ankle foot orthosis (AFO) is a therapeutic device that facilitates the enhancement of the ambulation and gait cycle for people with hemiplegia such as severely hemiparetic stroke patients [19]. It is widely used in the world to ameliorate the effect of damage on the limb's neuromuscular motor system that impacts the gait system. Currently, available AFO technologies include a passive brace with fixed and interconnected joints, a semiactive brace that regulates the joint's damping mechanism and an active brace that utilised numerous modern technologies to aid the gait cycle of the foot [20]. Advancement in technologies gives the potential for a better AFO design that suits the custom needs of the patient. Nevertheless, the stringent AFO design requirements which include light weight, thin size, producing significant results and low noise possess substantial manufacturing and engineering barriers to having such devices realised as they will give opportunities for new clinical treatments for gait problems.

In the current market, there are numerous types of AFOs being manufactured and sold to patients throughout the world such as Solid (SAFO), Dynamic (DAFO), Hinged (HAFO), Floor Reaction (FRAFO), Ground Reaction (GRAFO) and Posterior Leaf Spring (PLS AFO) [21]. Additionally, Table 2-1 shows the variety of AFO designs and their specific characteristics for each type of AFO which includes the patient gait flexibility required during the rehabilitation, tolerance of ankle motion, stance phase and dorsiflexion/plantarflexion support. Therefore, some of the more complex and custom designs of AFOs are required to be prescribed by a medical expert or an orthotist to have a better understanding and proper prescription given on the exact needs of each patient who suffers from different chronic diseases.

Table 2-1: Typical AFO design in the market. [22]

Type of AFO	Description
 Solid AFO	Solid AFO allows no ankle motion during walking movement as it covers the lower limb completely and extends from just below the fibular head to metatarsal heads.
 Dynamic AFO	Dynamic AFO should be used where there are coronal or transverse plane deformities of the foot and ankle that can be passively corrected with minimal force.
 Posterior Leaf Spring AFO	Posterior Leaf AFO is a rigid and solid AFO where it is trimmed just behind the malleoli bone to provide flexibility at the ankle and allows passive dorsiflexion during the stance phase.
 Ground Reaction AFO	Ground Reaction AFO is made with a solid ankle in which the upper portion wraps around the anterior part of the tibia proximally with a solid front over the tibia. This rigid front provides strong ground reaction support for patients with weak triceps surae.

 Hinged AFO	It has a mechanical ankle joint usually preventing plantar flexion but allowing relatively full dorsiflexion. It permits dorsiflexion in the stance phase of the gait, thus making it easier to walk on uneven surfaces and stairs.

2.3 Foot Drop

Foot drop is a medical condition that is refer to weakness or permanent shortening of the muscle at the ankle and joint that produces walking abnormalities or distortion that may arise from many types of neuromuscular diseases [23]. Additionally, foot drop is considered an isolated peroneal neuropathy as it is usually caused by the difficulty of voluntary foot dorsiflexion and eversion where the patients experienced sensory loss in their lower limbs [24]. Furthermore, foot drop will cause patients to have difficulties actively lifting their foot against gravity, leading to an unusual gait cycle that affects both standing and swinging phases. To prevent the forefoot from touching the ground as an effect of spastic plantar flexor, the patient will compensate with hyperflexion in their knee and the hip joint which will shorten stance time which can cause improper gait cycle on the entire skeletal axis in the long term. This will affect the strain and shortening of the plantar flexors and tendons which will cause reduced quality of life in the later days [25].

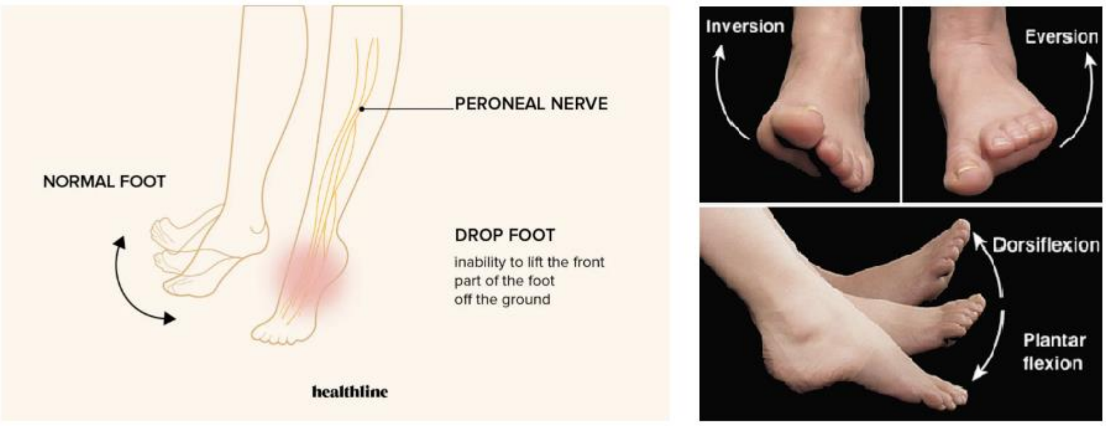

Figure 2-1: Illustration of foot drop Plantarflexion, Dorsiflexion, Inversion and Eversion of the foot. [26]

Dorsiflexion and plantarflexion are the movement of the ankle and joint that occur during the gait cycle. As shown in Figure 2-1, Dorsiflexion is the involuntary act of lifting the front foot to move the foot tip towards the interior limb while Plantarflexion is the involuntary act of lifting the heel off the ground and moving the toe downwards [27]. During the gait cycle, numerous muscles, and tendons act together to ensure that the body is stable and well balanced during these movements. In case of muscles and tendons failure, this will undermine the whole system which leads to damage and slow motion. All movements are required involuntarily for a good and balanced gait cycle during stance and walking movement.

2.4 Walking Cycle and Gait Analysis

The gait cycle is the cyclic configuration of a human movement that determines the body's position. In a normal and healthy condition, the walking cycle can be assumed constant, and the study of the gait cycle can be simplified into examining one type of gait cycle [28]. However, in certain medical diseases, the normal walking cycle can be distorted and abnormal depending on the problem that occurred. Gait cycle usually can be measured by using the same successive event that occurs on the same foot and can be measured using numerous parameters such as time and spatial measures. In general, the gait cycle can be divided into two different sub-phases of gait cycle which are the stance and swing phase which occur alternately between each foot. The stance phase begins when both legs are in contact with the ground and ends when one of the support limbs leaves the ground. On the other hand, during the swing phase, one of the limbs is standing on the ground as a supporting limb while the other is experiencing swinging.

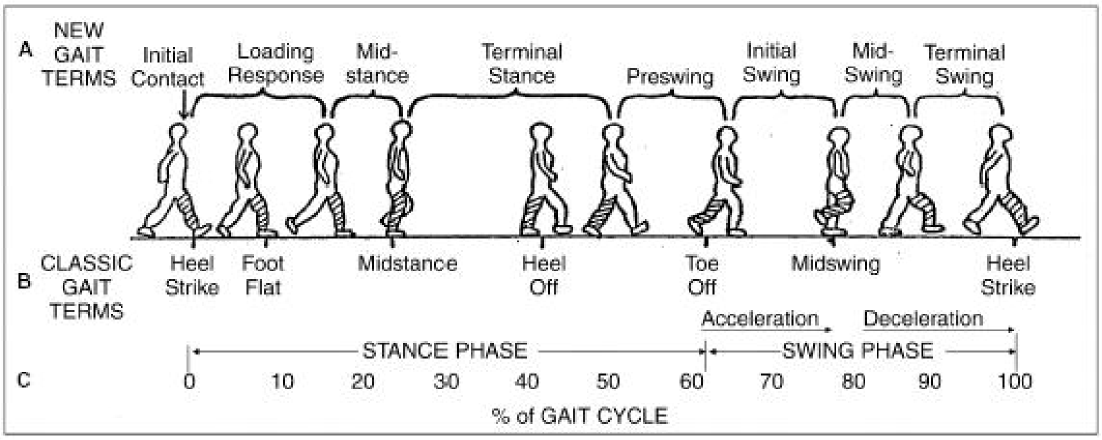

Figure 2-2: Gait cycle and its phases. [29]

As shown in Figure 2-2, assuming that the gait cycle begins on the right limb, it is observed that in the first step from the normal point of view, the right limb is moved forward and placed on the floor. While walking, the first step of gait involves lifting the right limb in a swing position for forwarding movement ahead while the left limb is positioned on the floor as a support for the right limb until the right limb is placed on the floor ending its swing phase. Then, the second step of the gait cycle is mostly similar to the first step, but with the use of an alternate foot as the support and a swing limb with the right limb placed on the ground as a supporting limb and the left limb moves forward in swing position until it touches the ground again. The continuous repetitions of a balanced walking movement result in a sustained movement of the gait cycle in the sagittal plane. In the normal walking cycle, the stance phase contributed up to 60% of the gait cycle while the swing phase contributed up to the other 40% [30]. Various parameters are used in the gait cycle analysis which include step length, stride length, foot angle, swing duration, cadence, and speed.

2.5 Conventional Fabrication Method of AFO

The conventional fabrication method of custom-made AFO that is commonly practiced in the market includes plaster moulding and thermoforming which is shown in Figure 2-3 and fully explained in the step shown in the figure below [31]. The conventional fabrication process of the AFO is divided into eight steps as follows: (A) Measurement of foot geometry: The crucial measurements of patient foot parameters include length, circumference, mediolateral and anteroposterior foot geometry. (B) A negative cast is filled with the powder slur to make a positive cast: The negative cast is commonly filled with different kinds of plaster slur and fibre resin. (C) The positive cast is created: After the liquid plaster is filled inside the negative cast, the positive cast started to come into shape and is embedded with resin tape to make it stronger and resistant.

Then, (D) the body of the positive cast is refined to get the desired shape: The cast is modified and rectified precisely according to the limb geometry. (E) Vacuum forming of the AFO: Thermoplastic sheet is heated until soft and then wrapped onto the positive cast by using the thermoforming method. (F) The plastic sheet is shaped as an AFO according to the cast and then the unwanted part is removed: As the plastic sheet cooled and hardened, the plastic is then trimmed and removed from the cast. (G)

Finishing and refining of the AFO: The AFO is refined and smoothed to remove any burr and sharp edges. (H) The AFO is assembled with accessories and fitted into the patient: The complete AFO is assembled with other relevant accessories and fitted into the patient foot for testing and observation to ensure the device fits perfectly and comfortably.

Figure 2-3: Conventional AFO fabrication method involving plaster moulding and thermoforming. [34]

2.6 Additive Manufacturing of AFO

Additive Manufacturing method (AM) offers a virtual way to design and manufacture customised AFO. This digitized technique of manufacturing provides exceptional results and promotes changes in the design criteria to achieve the precise requirements of each patient. 3D scanning and Rapid Prototyping (RP) is used to design and fabricate customised AFOs. This unique method was engineered to employ patient anatomical data, control and manipulate geometric information to an ideal form by using medical CAD software and convert it into a file that is compatible with a fabrication process in a rapid prototyping machine.

The fabrication process of the AFO by using Additive Manufacturing method is divided into three major steps. The first step usually involves the 3D scanning of the patient's foot anatomy by using a 3D scanner, MRI, or CT images. In this stage, geometrical foot data is obtained from the patient by using a 3D photogrammetric scanner to capture foot images from various positions to re-create the model virtually in the software [32]. The output file from the 3D model is usually in the format of standard tessellation language (STL) format which will be transferred to new CAD software for modelling and designing purposes of the AFO.

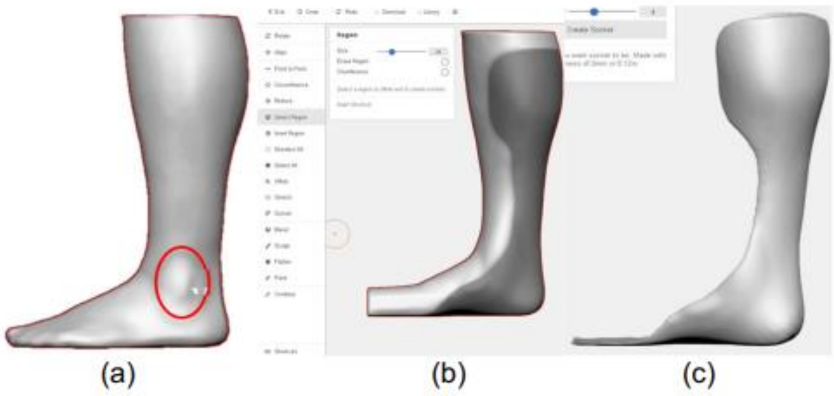

Figure 2-4: AFO Modelling in CAD software. (a) Identify the foot anatomical structure, (b) Model the AFO according to the 3D foot model, (c) Final AFO model created. [33]

The second step in fabricating AFOs by using the Additive Manufacturing method involved the use of medical CAD software which provides tools to model the desired AFOs as shown in Figure 2-4. The previously scanned foot and limb anatomy is uploaded into the design software where the orthotist will identify and mark the bone structure as shown in Figure 2-4 (a), From this, the orthotist will define the required force and pressure to be applied on a specific area on the foot by increasing or decreasing the gap allowance and thickness to accommodate custom needs. Figure 2-4 (b), it shows the process of modelling the AFO by applying the design directly onto the foot anatomical model specifically for each patient. In this phase, based on the machine, flexibility and strength required for the AFO, the orthotist will define the AFO parameters such as thickness and material to be used.

The last step in manufacturing AFO by Additive Manufacturing method is the 3D printing process. 3D printing process also known as Fused Deposition Modelling (FDM) is one of the Rapid Prototyping technologies in Additive manufacturing to fabricate a model. 3D printer automatically extrudes the melting thermoplastic filament, layer by layer to build a model structure by forcing the filament through the nozzle tip. Various types of filament materials are available in the market, which include Polylactic acid (PLA), Nylon, and Polycaprolactone (PCL). Additionally, some of these materials are embedded with carbon fibre which produces a composite polymer that significantly increases material strength, stiffness, and possesses a lightweight capability [34]. Post-processing of AFO involves cleaning and refining the body to remove any unwanted sharp edges and support structures from its body. Post-processing also includes assembly of AFO attachments such as Velcro tapes, shoe pad, buckle fasteners and shoe insole that was fitted into the AFO to maximise user experience [35].

2.7 Comparison between Conventional and Additive Manufacturing Methods

According to the article "*A Comparative Analysis between Conventional Manufacturing and Additive Manufacturing of Ankle-Foot Orthosis*" written by Shahar F, et al. [36], the Additive Manufacturing (AM) method of producing an AFO have more advantages when compared with the typical Conventional Method (CM). Their study has found that the major advantage of AM is the time taken for the production time is shorter significantly when compared to the CM method. According to Table 2-2 as shown below, their study state that the manufacturing of AFO by using AM method can be completed in just two days from whopping four weeks when manufactured by using the CM method [37], [38]. On the other hand, Shahar F, et al. also found that AM give better benefits in term of design option and optimisation that does not exist in the CM method, for example, AM method has various choices to model and optimise the design numerous times. Additionally, AM also provide flexibility that reducing material during design and rendering due to some mistake that occurs in the design phase that may cause material waste as in the CM method.

Table 2-2: Comparison of Conventional and Additive Manufacturing. [36]

Key Parameters	Conventional Method (CM)	Additive Manufacturing (AM)
Production time	4 weeks	2 days
Production cost	Expensive	Cheap
Required labour skills	▪ Physical dexterity ▪ Detail-oriented ▪ Physical stamina ▪ Problem-solving skills	▪ Operating 3D software designing skills
Manufacturing steps	1. Cast creation 2. Cast rectification 3. Polymer shaping using vacuum moulding method 4. Trimming and edge cutting 5. Accessory add-on	1. 3D scanning of ankle-foot 2. CAD/CAM designing 3. 3D Model printing

Table 2-3: Comparison of Conventional Manufacturing and Additive Manufacturing in term of material properties and cost. [36]

<table>
<tr><th>Material</th><th>Tensile Strength (MPa)</th><th>Young's Modulus (GPa)</th><th>Fabrication Method</th><th>Material Cost (RM/kg)</th><th>Material Characteristics</th></tr>
<tr><td>ABS</td><td>25.390</td><td>1.325</td><td>FDM (AM)</td><td>57.75 – 111.37</td><td rowspan="2">• No warping during 3D printing
• High impact resistant
• Excellent chemical, stress, and creep resistance
• Food grade thermoplastic
• Excellent fire and heat resistant
• Recyclable</td></tr>
<tr><td>ABS</td><td>29.600</td><td>1.790</td><td>Thermoformed polymer (CM)</td><td>184.64 – 637.25</td></tr>
<tr><td>PLA</td><td>42.660</td><td>3.930</td><td>FDM (AM)</td><td>61.87 – 111.37</td><td>• Minimal warping during 3D printing
• Odourless when used in 3D printing
• Eco-friendly (derived from corn starch or sugar cane)
• Biodegradable</td></tr>
<tr><td>PP</td><td>20.040</td><td>1.508</td><td>FDM (AM)</td><td>251.68 – 503.35</td><td rowspan="2">• High warping during 3D printing
• Chemical resistant
• Flexible
• Lightweight
• FDA approved</td></tr>
<tr><td>PP</td><td>20.000</td><td>1.000</td><td>Thermoformed polymer (CM)</td><td>40.40 – 1757.00</td></tr>
<tr><td>PETG</td><td>34.140</td><td>2.270</td><td>FDM (AM)</td><td>66.00 – 198.00</td><td rowspan="2">• No warping during 3D printing
• Extremely durable and odourless
• High impact resistant
• Water, chemical, and fatigue resistant</td></tr>
<tr><td>PETG</td><td>50.000</td><td>1.900</td><td>Thermoformed polymer (CM)</td><td>178.58 – 3066.56</td></tr>
<tr><td>Nylon</td><td>34.790</td><td>0.073</td><td>FDM (AM)</td><td>206.25 – 319.87</td><td>• Low odour when used in 3D printing
• Strong
• Lightweight
• Durable and Flexible
• Mechanical stability and hardness
• Fatigue resistance
• FDA approved</td></tr>
</table>

Additionally, their study also compares Conventional Manufacturing and Additive Manufacturing in terms of strength, stiffness, and material cost per kg. Shahar F, et al. in Table 2-3, compares the results of research done by other researchers by different types of materials and fabrication methods. It is shown in Table 2-3, that the tensile strength and Young's Modulus of the AFO manufactured by both methods Additive Manufacturing or Conventional Manufacturing can withstand nearly similar strength. However, it is observed from the Table 2-3, that the material cost per kg for AM is much cheaper compared to the CM for example for the same material of ABS in the first rows, the maximum cost of ABS for Additive Manufacturing is RM111.37 while ABS for Conventional Manufacturing is RM637.25 [39], [40]. From the calculation, the cost of material per kg for CM is six times higher than the same cost of material for AM. The fact of similar strength and stiffness while significantly reducing the production time and much cheaper production cost [41], shows that the Additive Manufacturing method is proved to be more beneficial to AFO production in the near future compared to Conventional Manufacturing method [42].

2.8 3D Printing Parameters

3D printing is the technique of creating a product by filling layers upon layers of extruded molten material typically plastic polymer on top of each other [43]. The 3D printing process greatly depends on its printing parameters. Literature study in this area reveals a lot of essential studies on different printing parameters which should be considered in the fabrication process to produce a specific outcome for the 3D printed products. Thus, various printing parameters can be considered accordingly to increase the material properties and printing efficiency of the product which include nozzle size, filament size, nozzle temperature, bed temperature, the printing speed, material feed rate, printing orientation, raster angle, infill density, infill structure, etc.

Studies on the effect of printing parameters on product outcomes have been conducted by numerous researchers in the field. According to a study by S, Lubis et al. [44], they mention that the best printing orientation to save printing time is horizontal orientation. They also mentioned that horizontal orientation produces a much smaller dimension error on PLA material when compared to ABS. Numerous other researchers had studied the different effects of printing parameters such as thickness layer, infill shape and filling angle. These studies are important because the printing parameters could directly affect the material properties of end products. In current days, 3D printing technology is not only used to fabricate a prototype but is also being used as one of the main methods to produce the product.

Hsueh M, et al. [45], conducted a study on the effect of printing angle and raster angle on the tensile properties of a material. His study found that both parameters highly impact the structural properties of the material as different effects were recorded on its tensile properties with different angle properties. The results of the study concluded that the printing angle strictly impacts the tensile properties of the product with the orientation of $X90°/Z0°$ having the strongest material properties among all orientations. On the other hand, the printing angle of $Y90°/Z0°$ and $Z30°$ was not recommended by the authors due to weaker layer bonding and can cause poor elongation resistance which could fail easily when experiencing tensile load.

Another pilot study conducted by Tanoto Y, et al. [46], investigates the effects of printing orientation on processing time, dimensional accuracy, and product structural strength as shown in Figure 2-5. From the study, Tanoto found that the processing time for the Third orientation is the fastest with 2432 seconds when compared to the First and Second orientations with 2688 and 2780 seconds, respectively. In the context of dimensional accuracy, the study has found that the Second orientation yields the smallest deviation in the thickness dimension with a 0.1mm error while the First orientation produces the product with the smallest deviation in the length dimension. Finally, the authors concluded that the Second orientation produces a product with the highest tensile properties at 7.66 Mpa of tensile strength.

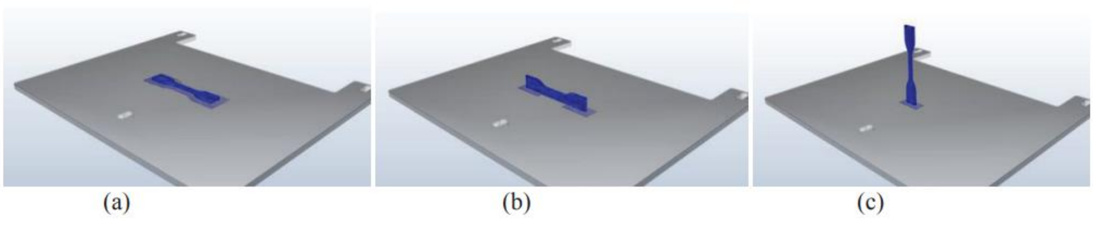

Figure 2-5: Printing Orientation (a) First orientation, (b) Second orientation, (c) Third orientation. [46]

2.9 Previous AFO Designs

Two AFO models will be discussed in this literature for the previous AFO design. These AFOs are designed by the previous Final Year Project (FYP) students which are Ong Xhin Jie (2019) [47] and Ong Yong Shien (2021) [22]. This section will briefly discuss their design and highlight the pros and cons of each AFO design which could give an insight into the area of improvement that should be focused on in this project. Figure 2-6 illustrates the AFO model designed by Ong Xhin Jie (Xhin J.) in 2019. In his design, Xhin J. emphasise several necessary criteria to be considered in his prototype which include having good ventilation, lightweight, flexible joint, easy to wear and an adjustable strap to fit the AFO on the user’s foot. The AFO is divided into four major components which are calf, back support, feet and shoe components.

Figure 2-6: AFO model designed by Ong Xhin Jie (2019). [48]

The prototype was fabricated using 3D printing technology and was printed using PLA material due to its lower melting temperature, high flexibility, and resulting in better surface finish compared to ABS material. Xhin J also mentioned that the printing time for his design is about 52 hours and could be delivered in just three days including finishing and assembly time. The AFO prototype is also assembled with a monitoring system, straps, shoe cushion and insole for comfortability purposes which yields the total cost for the AFO is about RM 118.11. However, some limitation in this design is the lack of customisation for design to fulfill the specific needs of the patient. Thus, this AFO design needs further improvement in term of customisation to ensure the best quality of AFO produced in the industry which fulfill customers’ needs.

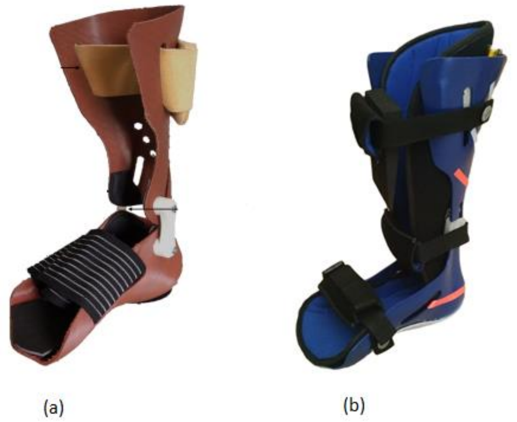

Figure 2-7: AFO model designed by Ong Yong Shien (2021). (a) AFO model fabricated by using Creatbot machine in School of Mechanical Engineering using PCL material, (b) AFO model fabricated by using industrial 3D printing machine by using PLA material. [22]

On the other hand, Ong Yong Shien (Y. Shien) has done some improvements to the model and come up with a new design and fabrication method. His research is more focused on the improvement in the fabrication process which allows for more customisation for the AFO design. Figure 2-7 shows the final prototype of Y. Shien AFO design which was made by using Polycaprolactone (PCL) material in Figure 2-7 (a) which is considered soft and biodegradable material that is made from petrochemical feedstock [48]. However, PCL material requires more attention and understanding due to its lower melting temperature which is much harder to print in the 3D printing machine. Additionally, the AFO model in Figure 2-7 (a) has a flexure joint which could allow ankle movement and provides better movement in the gait cycle. On the other hand, the model in Figure 2-7 (b) is the model fabricated by using PLA material using an industrial 3D printing machine. This AFO is a solid AFO that does not have any joint ankle to allow free movement of the ankle during the gait cycle.

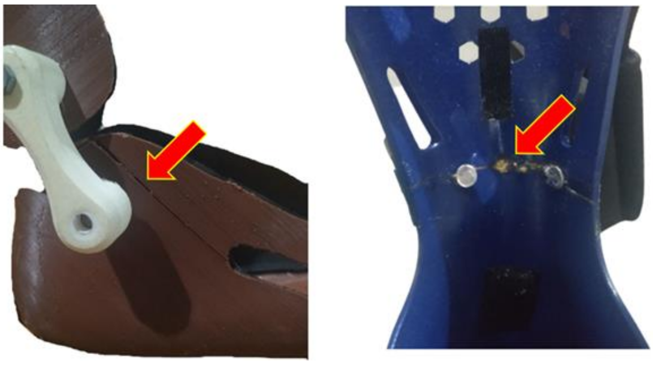

Figure 2-8: Defect and crack found on the design.

However, on further investigation, we have found some problems relating to both of these designs as all printed AFO will crack and break at some point due to some weaknesses in the design structure and/or printing parameters as shown in Figure 2-8. Thus, further improvement is needed in the AFO design and fabrication to ensure that the AFO could fulfill the best quality in the market.

CHAPTER 3

RESEARCH METHODOLOGY

3.1 Introduction

Chapter 3 summarises the design and development method of an AFO. The AFO is designed and analysed by using MediaAce3D while the fabrication process is done by using Creality Ender 5 Pro 3D printer. The assembly process is done when all the parts are ready. Lastly, pilot clinical testing which includes gait testing and analysis is carried out using Kinovea software with a real patient from Hospital USM.

3.2 AFO Development Flow Chart

In this project, the design and development of the AFO include 3D scanning, Pre-processing, CAD design, Post-design process, Additive Manufacturing (3D Printing), and Post-Processing. The design and development workflow is illustrated in Figure 3-1. This design method is the modern approach to fabricating an AFO as compared to the traditional approach which uses the cast moulding method.

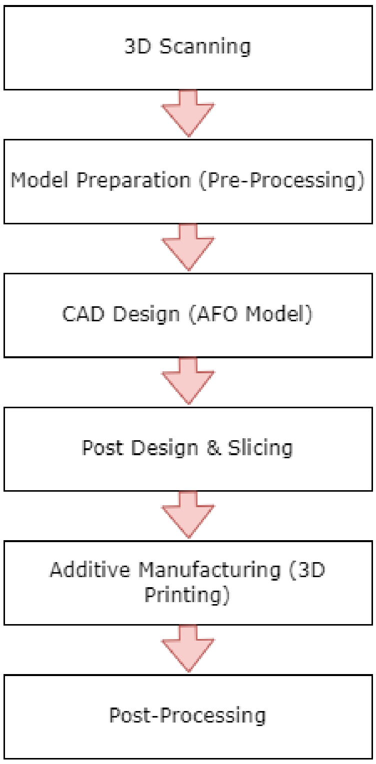

Figure 3-1: Design and development process of an AFO.

3.2.1 3D Scanning Process

This project utilises the use of 3D scanning technology to acquire patient foot models which to be corrected. Custom foot dimension measurements are crucial in AFO designing, fitting assessment and clinical evaluation. In this project, the 3D scanning process is accomplished by exploiting *Structure Sensor* by *Occipital Inc*. 3D scanning process exploit advanced optoelectronic technologies to obtain anthropometric data which can be used to model patient-specific foot [49].

Figure 3-2: 3D scanner structure sensor and its procedure. [50]

As illustrated in Figure 3-2, 3D scanning equipment consists of two components which are an iPad and a structure sensor attached to its camera. A structure sensor is a depth sensor that uses frequency-infrared light which allows the device to calculate the distance accurately. Frequency-Infrared light of the *Structure sensor* is projected to the surrounding via diffraction grating to capture depth data of the foot contour before being mapped with an accelerometer and gyroscope in the *iPad*. The Structure system provides a portable and convenient 3D scanning system. However, it is not suitable for patients with severe foot deformity as they have limited movement which makes the process inconvenient.

In this project, the depth data is processed in an open-source software; *Structure SDK* to generate the foot mesh which is useful in AFO designing in CAD software. The scanning procedure starts with the equipment setup as shown in Figure 3-2, structure sensor is connected to the iPad by using a cable and bracket. By utilising the *Structure Scanner* app, the iPad is panned around the patient foot to capture enough foot depth data to obtain foot mesh. A high-quality scan requires the foot to be scanned at consistent speed with 360° coverage around the foot before being processed, meshed, and exported to .obj format.

3.2.2 Model Preparation (Pre-Processing)

Pre-processing involves raw model preparation which contains meshing noises that need to be eliminated prior to proceeding with CAD design. Pre-processing removes noises, fills gaps, smoothes and refines model surfaces to obtain high-quality foot model which is necessary for AFO designing. In this project, *MediAce 3D* made by *RealDimension* is used as major CAD software for designing, pre-processing and post-processing.

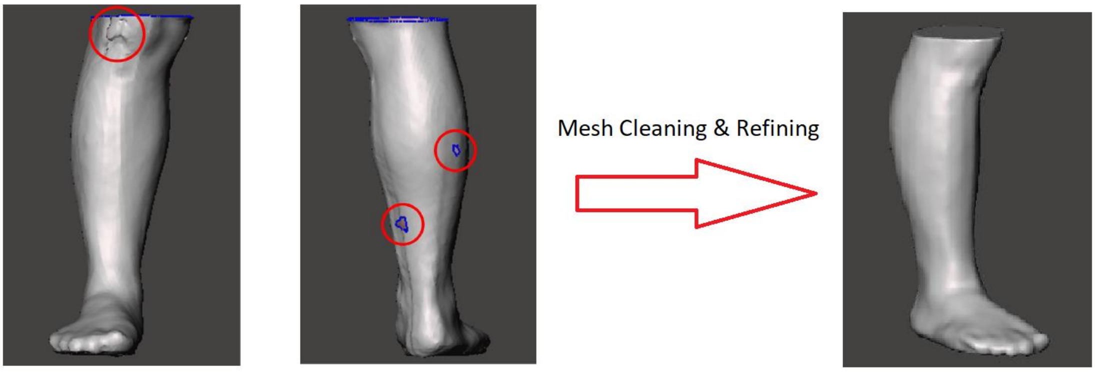

Figure 3-3: Model Preparation (Pre-processing) of the foot model. [22]

As illustrated in Figure 3-3, raw data obtained from the scanning process possess mesh noises and imperfections such as holes that need to be refined. Then, the defect regions are identified carefully to remove the noises by using Refine function in MediAce 3D. The foot model is then smoothed and refined a few times to obtain a high-quality model. Then, the model is converted into a solid body in .stl format for the design process. Figure 3-3 shows the refined meshed model after going through the post-processing procedure in the software.

3.2.3 CAD Design (AFO Development)

In this project, CAD design utilises the use of medical CAD software; *MediAce 3D* made by *RealDimension* which is specifically used for the development of custom-made orthosis which includes hand and foot orthosis [51]. Several processes involved with CAD design by using MediaAce 3D software are illustrated in Figure 3-4.

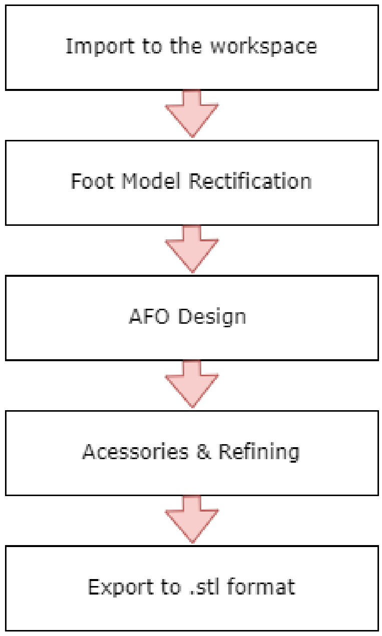

Figure 3-4: CAD design procedure in MediAce 3D.

The procedure for the CAD design of the AFO begins with the refined 3D model data imported into the MediAce3D workspace. Then, fifteen-foot index markers are selected and marked according to their designated position to ensure the accuracy of the correction as illustrated in Figure 3-5. The correction is done gradually especially for severe patients to ensure the efficacy of the AFO device. Figure 3-5 (b) shows the possible correction in foot drop patients which need to be corrected gradually until the condition is improving.

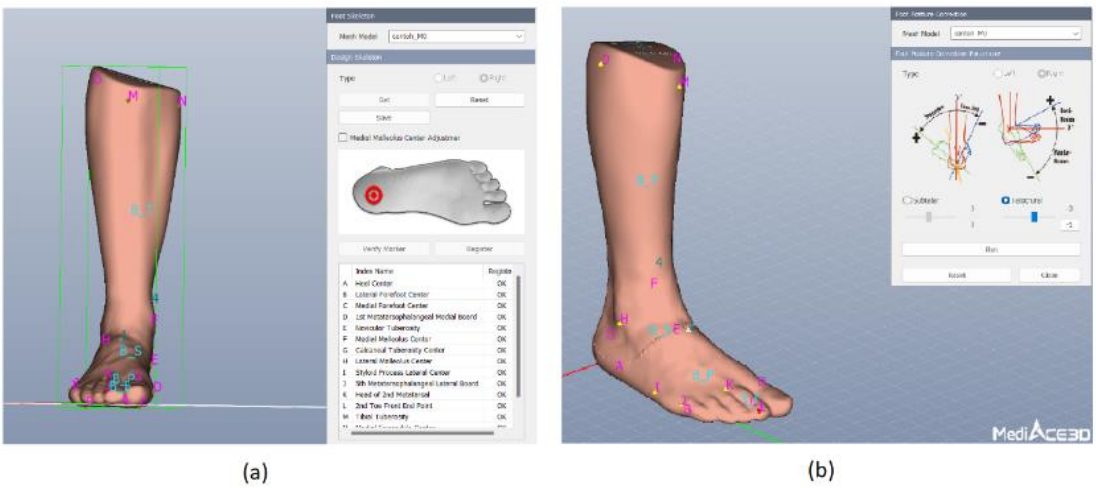

Figure 3-5: (a) Foot Skeleton and (b) Foot Posture Correction function in MediAce 3D software.

The foot correction in this stage is rectified according to their specific patient deformity by modifying the flexion and eversion angle at the subtalar and talocrural foot joint. This step is the most crucial in the AFO development as it will determine the rehabilitation effectiveness and require specific knowledge in orthotics and human bone. This step should be conducted by medical experts to ensure patient safety and device efficacy during the rehabilitation process. The report generated contains crucial patient information such as the medial malleolus height, lateral malleolus height, foot breadth instep height and foot length.

Then, the AFO model is designed according to the rectified foot model by using either a custom design or using the available template with minor modifications to suit the patient's needs. As shown in Figure 3-6, AFO CAD modelling starts with creation of inflating area around the foot model to compensate for knee bone and prepare a room for AFO padding. The model size may also be rescaled up to about 10% to compensate for the padding. Then, design the AFO structure by using the Model function around the foot model. The design can be also selected from available templates in the software with minor modifications to suit the patient's needs. Then, accessories and patterns are used to add AFO accessories such as structure joints and ventilation holes.

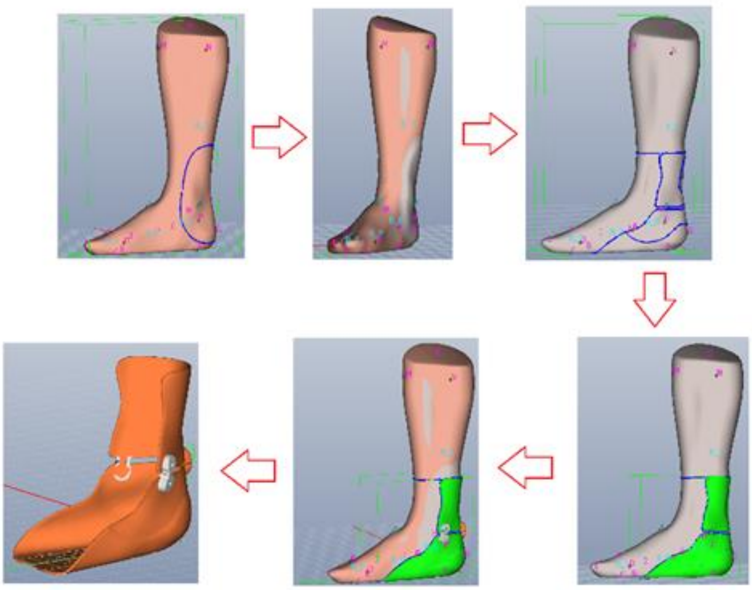

Figure 3-6: CAD modelling procedure in MediAce 3D.

3.2.4 3D Model Slicing Process

The 3D slicing process is another vital component in 3D printing technology that can deliver an optimised printing result. The slicing software is a tool to determine the route planning for calculating 3D layers and acts as an intermediate driver between