Faculty of Manufacturing Engineering

DEVELOPMENT AND EVALUATION OF CUSTOMIZED PES PLANUS ORTHOTIC INSOLE USING ADDITIVE MANUFACTURING

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DECLARATION

I declare that this thesis entitles “Development and Evaluation of Customized Pes Planus Orthotic Insole Using Additive Manufacturing” is the result of my own research except as cited in the references. The thesis has not been accepted for any degree and is not concurrently submitted in candidature of any other degree.

Signature : ……..

Name : Azlinda binti Mohamad

Date : ……..

APPROVAL

I hereby declare that I have read this thesis and in my opinion this thesis is sufficient in terms of scope and quality for the award of Master of Manufacturing Engineering (Mafacturing System Engineering).

Signature : ……..

Name : Dr. Zulkeflee bin Abdullah

Date : ……..

DEDICATION

To my beloved husband

Mohammad Aizrulshah bin Kamaruddin

To my parents and parents in law

Rufiah binti Jaafar & Abu Bakar bin Awang

Hj. Kamaruddin bin Idris & Hjh. Aisah binti Abu Bakar

To my lovely kids

Muhammad Izzu Syahmi, Maryam Kayyisah & Azra Sufiyyah

To my siblings and Al-Fatihah for my late father

Allahyarham Mohamad bin Budin

ABSTRACT

Pes planus (also known as flat feet) orthotic insole designed to support, correct the deformities and improve the movement of joints or limbs. The custom orthotic insole can fit the patient's body and perform better than off-the-shelf insoles. Due to the large range of dimensions characteristic for each individual, a mass production is not suitable for the custom insole productions. For this reason, it is necessary to consider another approach, such as additive manufacturing. The purpose of this study is to develop a personal orthotic Pes Planus insole using Fused Deposition Modeling (FDM). Customized fabrication of orthotic insole using FDM has been through six main steps: Pes Planus feet screening, 3D scanning of the anatomic surface, feet 3D surface reconstruction and modification, insole 3D modeling and converting to STL format and finally fabricating using FDM machine. Evaluation by a medical practitioner was conducted at the end of the study for the purpose of obtaining feedback from the expert and ensuring the insole's ability to correct Pes Planus feet. The most suitable material in the insole production is TPU. This technique will contribute to better orthotic planus insole in terms of reducing manufacturing time, economic and personal at the patient's foot, rather than conventional methods that need to go through the mold manufacturing process in advance.

ABSTRAK

Pelapik kaki ortotik bagi Pes Planus (juga kenali sebagai kaki rata) direkabentuk untuk menyokong, membetulkan serta menambahbaik pergerakan anggota kaki. Pelapik kaki ortotik peribadi mampu disesuaikan pada kaki pesakit berbanding insole yang dijual di pasaran. Oleh kerana setiap individu berbeza dari segi tubuh, pengeluaran insole secara besar-besaran adalah tidak sesuai. Oleh ini, pendekatan lain seperti 'Additive Manufacturing' perlu mempertimbangkan. Tujuan kajian ini adalah untuk membangunkan pelapik kaki Pes Planus orthotik peribadi menggunakan Fused Deposition Modeling (FDM). Pembangunan pelapik kaki Pes Planus orthotik peribadi akan melalui enam langkah utama iaitu saringan kaki Pes Planus, imbasan 3D ke atas bahagian anggota kaki, pembinaan semula dan modifikasi model 3D kaki, pembinaan model CAD bagi insole dan menukar kepada format STL dan akhirnya fabrikasi menggunakan mesin FDM. Penilaian oleh pengamal perubatan dilaksanakan di akhir kajian ini bagi tujuan mendapatkan maklumbalas daripada pakar dan memastikan pelapik kaki berupaya membetulkan struktur kaki Pes Planus kepada kedudukan yang neutral. Bahan yang paling sesuai untuk menghasilkan pelapik kaki ini ialah TPU. Penyelidikan ini bakal menyumbang kepada penghasilan pelapik kaki Pes Planus orthotik yang lebih baik untuk pembuatan pantas, ekonomik dan disesuaikan khas pada kaki individu pesakit, berbanding kaedah konvensional yang memerlukan proses pembuatan acuan dilaksanakan terlebih dahulu.

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LIST OF ABBEREVIATIONS

.AMF	-	Additive Manufacturing File Format
.STL	-	Stereolithography Format
3D	-	3 Dimension
ABS	-	Acrylonitrile Butadiene Styrene
AFO	-	Ankle and Foot Orthotic
AM	-	Additive Manufacturing
CAD	-	Computer Aided Design
CNC	-	Computer Numerical Control
EVA	-	Ethylene-Vinyl Acetate
FDM	-	Fused Deposition Modeling
FO	-	Foot Orthotic
IR	-	Infrared
KAFO	-	Knee, Ankle and Foot Orthotic
PE	-	Polyethylene
PLA	-	Polylactic Acid
PP	-	Polypropylene
RGB	-	Red, Green and Blue
SLS	-	Selective Laser Sintering
TPU	-	Thermoplastic Polyurethane

LIST OF SYMBOLS

%	-	Percentage
®	-	Registered trademark
°	-	Degree
°C	-	Degree Celcius
fps	-	Frames per second
g	-	gram
mm	-	Milimeter
mm/s	-	Milimeter per second
™	-	Trademark
α	-	Raster angle

CHAPTER 1

INTRODUCTION

1.1 Background

Foot orthotic devices designed to support, correct the deformities and improve the movement of joints or limbs. Normally, foot orthotic device such as corrective insole gets the demand from flat foot patients. Pes Planus also known as Flat Foot is the condition in which the arch of the foot collapses, with the entire foot in contact with the ground (Moorthy and Siti Fatimah Sulaiman, 2015). Figure 1.1 shows the difference between normal foot and flat foot.

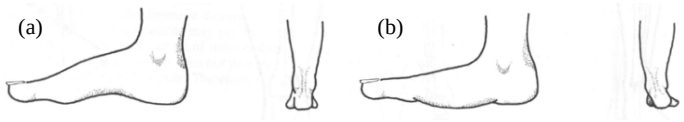

Figure 1.1: (a) Normal foot (b) Pes Planus (Flat Foot)

Insoles help to achieve the perfect support of the foot while walking and standing. According to Jin et al. (2015), there are two types of foot orthotic which are custom and off-the-shelf. Custom orthoses can fit the patient's body and perform better than off-the-shelf orthoses. Due to the large range of dimensions' characteristic for each individual, a mass production is not suitable for the custom insole productions. For this reason, it is necessary to consider another approach, such as rapid prototyping technology. According to Cotoros and Baritz (2012), 8.8% of the rapid prototyping technologies and additive manufacturing

are used for medical industry. The rapid prototyping technologies and additive manufacturing could provide benefits in terms of production time and patient satisfaction. This report will cover the development of flat foot insole, possibility and benefit of using additive manufacturing, focusing in fused deposition modeling in producing flat foot insole.

1.2 Problem Statement

The use of leg orthotic devices such as corrective insole is one of the rehabilitation methods proposed by orthopedist or podiatrist. The insoles will hold the foot in a better position so that it can work more effectively and may help reduce some of the symptoms (Association of Pediatric Chartered Physiotherapists 2018). Banwell (2016) believe that the best insole designed based on anthropometry and personalized on the patient's foot. Footwear like insole ideally needs to be personalized to provide optimum fit, comfort, performance and injury prevention.

Since off-the-shelf insoles are marketed based on shoe size, many people who do not have standard-size or symmetrical feet have encounter problems. Because these products are designed for people with differing foot conditions but the same shoe size, specific corrections can't be expected (Christensen, 2000). Patients, whose feet have unique form or size, or who have left or right asymmetry, will need customization for a proper fit. If there are biomechanical dysfunctions or structural imbalances, specific corrective support is definitely necessary.

Cotoros and Baritz (2012) proving the fact that in many situation the personalization of some medical devices like corrective insole should be the deciding factor when choosing a manufacturing technology type. The most common process involves vacuum forming (Telfer *et al.*, 2012) and CNC carving machine (Jin *et al.*, 2015) . Vacuum forming involved

handmade process and requires experience and high skills by orthopedist (Davia et al. 2018). Other than the limitation on the traditional manufacturing process, the higher production cost, higher labor cost and long manufacturing time-consuming are the weaknesses of existing insole manufacturing processes.

Therefore, it is necessary to consider another approach, such as Additive Manufacturing (AM) process. The insoles that are designed by employing CAD software could be produced by Fused Deposition Modeling (FDM). FDM is one of the AM process. FDM enables printing 3D models of any real objects specifically for customized products and prototypes. This process, which is time, labor, cost and source saving, is performed using different kinds of polymer such as Polylactic Acid (PLA) and Acrylonitrile Butadiene Styrene (ABS). According to Davia-aracil et al. (2018), Thermoplastic Polyurethane (TPU) is used due to its flexible nature and is more suitable for the human body.

From the recent studies, most of the research papers focus on medical and biomechanical aspects (Ozkan 2005; Bonanno et al. 2018; Fried 2016; Davia et al. 2018). There are lacks of studies on FDM process in the corrective insoles production. Therefore, it is important to determine the right method, tools, material and process parameters of the FDM machine in order to produce insoles.

1.3 Objectives

Based from the problems highlighted above, the objectives of this study are:

i. To understand Pes Planus problem and current foot orthotics solution.
ii. To develop customized Pes Planus orthotic insole using Fused Deposition Modelling.
iii. To evaluate the corrective ability of customized Pes Planus orthotic insole.

1.4 Scope of Study

This study includes AM applications in customize pes planus orthotic insole manufacturing, using FDM. The material used in producing the customize pes planus orthotic insole is Acrylonitrile Butadiene Styrene (ABS) and Thermoplastic polyurethane (TPU).

1.5 Significant of Study

Beside AM for prototyping and manufacturing, AM for medical application can be a valuable method. It is estimated that, with the advanced FDM technique and sparse structure, the printing time can be reduced. Consequently, this research should contribute to the better foot orthotic devices (shoe soles) for patient/user with Pes Planus problem. The results of the study will then highlight the effective tools and method to produce customized orthotic insole and the best material either ABS or TPU.

1.6 Research of Planning

Project planning is very important when making a project. The right planning ensure of the work completed within the time period. Project planning which is implemented at the initial stage of beginning a project. The Gantt chart will present every stage of the project from beginning until the completion of the project. It refers to possible period of time needed to run the project. Gantt charts for Master Project 1 and Master Project 2 are show in Table 1.1 and Table 1.2.

Table 1.1: Gantt chart (Master Project 1)

ACTIVITIES		Master Project 1 - 3rd semester (weeks)														
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Selecting a topic and research planning	P															
	A															
Understanding Topic - Background - Problem Statement - Objectives - Scopes	P															
	A															
Literature Review - Orthotic Insole - Insole design - Additive Manufacturing - FDM Process - Material	P															
	A															
Research Methodology	P															
	A															
Obtain preliminary result	P															
	A															
Proposal report writing	P															
	A															
Report submission	P															
	A															
Presentation	P															
	A															

P – Planning A – Actual

Table 1.2: Gantt chart (Master Project 2)

ACTIVITIES		Master Project 2 (Weeks)																	
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
Planning	P																		
	A																		
Feet Screening	P																		
	A																		
Development of Orthotic Insole	P																		
	A																		
Insole Testing	P																		
	A																		
Result & Discussion	P																		
	A																		
Report Writing	P																		
	A																		
Progress Report 1, 2 & 3	P																		
	A																		
Report Submission	P																		
	A																		
Presentation	P																		
	A																		

P – Planning A – Actual

CHAPTER 2

LITERATURE REVIEW

2.1 Orthotic

Kahle and Bauer (2003) define the orthotic also known as orthosis as an artificial device, added to the body to stabilize or immobilize a body part, prevent deformity, protect against injury, or assist with function. The orthosis is classified as static or dynamic. The static orthosis is designed to prevent or limit motion and have no moveable parts. The dynamic orthosis is designed to facilitate movement and have one or more movable parts. Mogan et al. (2016) divide the orthosis into three types (Figure 2.1) which are Foot Orthotic (FO), Ankle and Foot Orthotic (AFO) and Knee, Ankle and Foot Orthotic (KAFO).

Figure 2.1: (a) Foot Orthotic (b) Ankle and Foot Orthotic (c) Knee, Ankle and Foot Orthotic (Mogan et al. 2016)